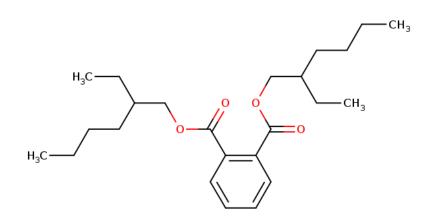


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# Draft Risk Evaluation for Diethylhexyl Phthalate (DEHP)

# CASRN 117-81-7



May 2025

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#### 407 Docket

Supporting information can be found in the public docket, Docket ID EPA-HQ-OPPT-2018-0433. 408

# 409

#### 410 Disclaimer

411 Reference to any specific commercial products, process, or service by trade name, trademark,

412 manufacturer, or otherwise does not constitute or imply its endorsement, recommendation, or favoring

- 413 by the United States Government.
- 414

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- 431
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# 434 EXECUTIVE SUMMARY

# 435 Background

COUs.

436 The U.S. Environmental Protection Agency (EPA or the Agency) has evaluated the health and

437 environmental risks of the chemical diethylhexyl phthalate (DEHP) under section 6 of the Toxic

- 438 Substances Control Act (TSCA). In this draft risk evaluation, EPA is preliminarily determining that
- 439 DEHP presents an unreasonable risk of injury to human health based on identified risks to workers from
- 13 conditions of use (COUs) and that DEHP presents an unreasonable risk to the environment from 20
- 441 COUs. After this draft risk evaluation is informed by public comment and independent, expert peer
- review, EPA will issue a final risk evaluation that includes its determination as to whether DEHP COUs present unreasonable risk to human health or the environment based on identified risk of injury from
- 444
- 445

446 DEHP is primarily used as a plasticizer for polyvinyl chloride (PVC) in consumer, commercial, and 447 industrial applications; it is also used in adhesives, sealants, paints, coatings, rubber products, and non-448 PVC plastics as well as other applications. Workers may be exposed to DEHP when making these 449 products or otherwise using DEHP in the workplace (Section 4.1.1). When it is manufactured or used to make products, DEHP can be released into water, where because of its properties, most will end up in 450 451 the sediment at the bottom of lakes and rivers (Sections 3.2 and 3.3.1.1). If released into the air (Section 452 3.3.1.2), DEHP will attach to dust particles and be deposited on land or into water. Indoors, DEHP has 453 the potential over time to be released from products and adhere to dust particles (Section 4.1.2). If it does, people could inhale or ingest dust that contains DEHP. 454

455

Laboratory animal studies have been conducted to study DEHP to determine whether it causes a range of non-cancer and cancer health effects in people. After reviewing the reasonably available studies, the Agency preliminarily concludes that there is robust evidence that DEHP exposure can cause developmental and reproductive toxicity (non-cancer human health hazards; Section 4.2). The most sensitive adverse developmental effects include adverse effects on the developing male reproductive system consistent with a disruption of androgen action—what is known as *phthalate syndrome*, which results from decreased fetal testicular testosterone.

463

464 EPA has also authored a draft cumulative risk analysis technical support document including DEHP and 465 five other phthalate chemicals that all cause the same health effect: phthalate syndrome (Section 4.4) 466 (U.S. EPA, 2025x). The CRA takes into consideration differences in the ability of each phthalate to 467 cause effects on the developing male reproductive system. Use of this "relative potency" across all the 468 phthalates EPA is reviewing that cause phthalate syndrome provides a common basis for adding risk 469 across the six phthalates included in the cumulative assessment. Notably, assessments by Health Canada, 470 U.S. Consumer Product Safety Commission (U.S. CPSC), European Chemicals Agency (ECHA), and the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) have 471 472 reached similar conclusions regarding the developmental effects of DEHP. They have also conducted CRAs of phthalates based on these chemicals' shared ability to cause phthalate syndrome. Further, 473 474 independent, expert peer reviewers endorsed EPA's proposal to conduct a CRA of phthalates under 475 TSCA during the May 2023 meeting of the Science Advisory Committee on Chemicals (SACC) because 476 doing so represents the best available science because humans are co-exposed to multiple 477 toxicologically similar phthalates that cause effects on the developing male reproductive system 478 consistent with a disruption of androgen action and phthalate syndrome (U.S. EPA, 2023f). In this draft 479 risk evaluation, the Agency has evaluated cumulative exposure to phthalates using human urinary 480 biomonitoring data obtained through the Center for Disease Control's (CDC) National Health and 481 Nutrition Examination Survey (NHANES), which provides relevant information to understand 482 exposures to chemical substances. Note that these cumulative phthalate exposures cannot be attributed to

specific COUs or other sources. This non-attributable cumulative exposure and risk, representing the
national population, was taken into consideration by EPA in its draft risk evaluation for DEHP. By
taking into account cumulative exposure and risk as other authoritative bodies have done, EPA is
confident that it is not underestimating the risk of DEHP and is reflecting the best available science.

- 487 488 In December 2019, EPA designated DEHP as a high-priority substance for TSCA risk evaluation and in 489 August 2020 released the Final Scope of the Risk Evaluation for Di-ethylhexyl phthalate (DEHP), 490 CASRN 117-81-7 (U.S. EPA, 2020c). This draft risk evaluation assesses human health risk to workers, 491 including occupational non-users (ONUs), consumers, including bystanders, and the general population 492 exposed to environmental releases. It also assesses risk to the environment, including risk to aquatic and 493 terrestrial species. Manufacturers report DEHP production volumes through the Chemical Data 494 Reporting (CDR) rule under the associated CAS Registry Number (CASRN) 117-81-7. The production 495 volume for DEHP between 2016 and 2019 was between 10 to 50 million pounds (lb) based on the latest 496 2020 CDR data (U.S. EPA, 2020b). EPA describes production volumes as a range to protect confidential 497 business information. The Agency has evaluated DEHP across its COUs, ranging from manufacture to 498 disposal.
- 499

Past assessments of DEHP from other government agencies that addressed a broad range of uses, which may have included some COUs assessed in this risk evaluation and have concluded that DEHP can pose

risk to human health based on its concentration in products and the environment. Notably, both the U.S.
 CPSC's and Health Canada's risk assessments included consideration of exposure from children's

503 CPSC's and Health Canada's risk assessments included consideration of exposure from children's 504 products as well as from other sources such as personal care products, diet, consumer products, and the 505 environment. However, these past assessments did not specifically consider exposure to workers. In the 506 United States, Canada, and the European Union, the use of DEHP in children's toys and childcare 507 products is restricted, with weight fraction limits on how much DEHP can be present in these articles

508 (see Appendix B for an overview of existing regulations on DEHP). Limits on DEHP concentrations in 509 the air in the workplace exist in the United States, Canada, the European Union, Australia, and

elsewhere (Appendix B). Additional international restrictions and labeling requirements for the use of
 DEHP exist.

512

513 In this draft risk evaluation, EPA evaluated whether manufacturing, processing, distribution in 514 commerce, use, or disposal of DEHP presents unreasonable risk to human health or the environment 515 under COUs subject to TSCA. Human or environmental exposure to DEHP through uses that are not 516 subject to TSCA (*e.g.*, use in cosmetics, medical devices, food additives) were not evaluated by the 517 Agency in reaching its preliminary determination of unreasonable risk of injury to human health. This is 518 because these uses are excluded from TSCA's definition of a chemical substance under TSCA section 519 3(2)(B). Thus, information in this risk evaluation cannot be extrapolated to form conclusions about uses

- 520 of DEHP that are not subject to TSCA and that EPA did not evaluate.
- 521

# 522 Determining Unreasonable Risk to Human Health

523 In TSCA existing chemical risk evaluations, EPA must determine whether a chemical substance presents 524 unreasonable risk of injury to health or the environment, under the COUs. The Agency must use the best

available science in making this determination. The Agency, in determining whether DEHP presents

unreasonable risk to human health, considers risk-related factors as described in its <u>risk evaluation</u>
 framework rule preamble 89 Fed. Reg. 37028, 37037 (May 3, 2024); see TSCA section 6(b)(4)(F)(iv).

528 Risk-related factors beyond the exceedance of benchmark levels of DEHP that EPA has identified

528 Risk-related factors beyond the exceedance of benchmark levels of DEHP that EPA has identified 529 include but are not limited to: the type of health effect under consideration, the reversibility of the health

- 530 effect being evaluated, exposure-related considerations (*e.g.*, duration, magnitude, frequency of
- 531 exposure), population exposed (including any potentially exposed or susceptible subpopulations), and

- 532 EPA's confidence in the information used to inform the hazard and exposure values. These
- 533 considerations are included as part of a pragmatic and holistic evaluation of hazard and exposure to
- 534 DEHP. If an estimate of risk for a specific COU indicate risk relative to the standard risk benchmarks
- 535 (Sections 4.3.1 and 5.3.1), then the formal determination of whether those risks present unreasonable
- risk under TSCA must be both case-by-case and context-driven.
- 537

EPA evaluated the risks to people from being exposed to DEHP at work, indoors, and outdoors. Risks were characterized for occupational and consumer exposures to DBP alone as well as in combination with the measured cumulative phthalate exposure that is experienced by the U.S. population and that cannot be attributed to a specific use. In its human health evaluation, the Agency used a tiered approach to assess how people might be exposed to DEHP through breathing or ingesting dust or other particulates, as well as through skin contact.

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545 In determining whether DEHP presents an unreasonable risk of injury to human health, EPA considered 546 the following potentially exposed and susceptible subpopulations (PESS) in its assessment: females of 547 reproductive age, pregnant women, infants, children and adolescents, people who frequently use 548 consumer products and/or articles containing high concentrations of DEHP, people exposed to DEHP in 549 the workplace, people in close proximity to releasing facilities (fenceline communities), and Tribes and 550 subsistence fishers whose diets include large amounts of fish. These subpopulations are PESS because 551 some have greater exposure to DEHP per body weight (*e.g.*, infants, children, adolescents) while others 552 may experience exposure from multiple sources or experience higher exposures than others.

553

# 554 Determining Unreasonable Risk to The Environment

555 In determining whether DEHP presents an unreasonable risk of injury to the environment, EPA 556 considered the following groups of organisms in its assessment: aquatic vertebrates, aquatic 557 invertebrates, benthic invertebrates, aquatic plants and algae, terrestrial mammals, soil invertebrates, and 558 terrestrial plants.

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# 560 Summary, Considerations, and Next Steps

561 EPA has preliminarily determined that of the 30 occupational COUs, 13 may significantly contribute to 562 an unreasonable risk to human health due to inhalation exposure to DEHP. For consumers and for the 563 general population, EPA has preliminarily determined that no COUs present unreasonable risk. EPA has 564 preliminarily determined that the following 13 COUs present an unreasonable risk of DEHP to workers 565 due to inhalation exposure:

- Manufacturing importing;
- Processing incorporation into formulation, mixture, or reaction product plasticizer in plastic material and resin manufacturing; synthetic rubber manufacturing; basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; basic inorganic chemical manufacturing;
   wholesale and retail trade; services; and ink, toner, and colorant manufacturing;
- Processing incorporation into article plasticizer in basic organic chemical manufacturing;
   plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing;
   and PVC extruding;
  - Processing repackaging repackaging in wholesale and retail trade and in paint and coating manufacturing;
- Recycling;
- Industrial use construction, paint, electrical, and metal products paints and coatings;
- Industrial use construction, paint, electrical, and metal products adhesives and sealants;

- Industrial use other uses solid rocket motor insulation and other aerospace applications;
- Industrial use other uses automotive articles;
- Commercial use construction, paint, electrical, and metal products adhesives and sealants;
- Commercial use construction, paint, electrical, and metal products paints and coatings;
- Commercial use furnishing, cleaning, treatment care products all-purpose waxes and polishes;
- Commercial use packaging, paper, plastic, toys, hobby products ink, toner, and colorants

587 EPA has preliminarily determined that the following 18 COUs may significantly contribute to
588 unreasonable risk to both aquatic vertebrates and benthic invertebrates through surface water and pore
589 water, respectively:

- Manufacturing manufacturing;
- Manufacturing importing;

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- Processing incorporation into formulation, mixture, or reaction product plasticizer in plastic material and resin manufacturing; synthetic rubber manufacturing; basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; basic inorganic chemical manufacturing; 596
- Processing incorporation into article plasticizer in basic organic chemical manufacturing;
   plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing;
   and PVC extruding;
- Processing repackaging repackaging in wholesale and retail trade and in paint and coating manufacturing;
- Processing other uses miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing);
- Industrial use construction, paint, electrical, and metal products paints and coatings;
- Industrial use construction, paint, electrical, and metal products adhesives and sealants;
- Industrial use other uses hydraulic fracturing;
- Commercial use construction, paint, electrical, and metal products adhesives and sealants;
- Commercial use construction, paint, electrical, and metal products paints and coatings;
- Commercial use furnishing, cleaning, treatment care products all-purpose waxes and polishes;
- Commercial use furnishing, cleaning, treatment care products fabric enhancer;
- Commercial use furnishing, cleaning, treatment care products fabric, textile, and leather products; furniture and furnishings;
- Commercial use packaging, paper, plastic, toys, hobby products ink, toner, and colorants;
- Commercial use other uses laboratory chemicals;
- Commercial use other uses automotive articles;
- Disposal

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- Further, EPA has preliminarily determined that the following 2 COUs may significantly contribute tounreasonable risk to aquatic vertebrates only through surface water:
  - Industrial use other uses solid rocket motor insulation and other aerospace applications;
  - Industrial use other uses automotive articles
- EPA did not preliminarily identify an unreasonable risk of injury to human health or the environmentfrom the following 23 COUs:
- Distribution in commerce;

- Commercial use automotive, fuel, agriculture, outdoor use products lawn and garden care products;
- Commercial use construction, paint, electrical, and metal products batteries and capacitors;
- Commercial use construction, paint, electrical, and metal products construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles;
  - Commercial use construction, paint, electrical, and metal products machinery, mechanical appliances, electrical/electronic articles;
- Commercial use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel;
- Commercial use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging) and other articles with routine direct contact during normal Use, including rubber articles; plastic articles (hard); plastic articles (soft);
- Commercial use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including paper articles;
- Commercial use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment;
- Consumer use automotive, fuel, agriculture, outdoor use products lawn and garden care products;
- Consumer use construction, paint, electrical, and metal products adhesives and sealants;
- Consumer use construction, paint, electrical, and metal products batteries;
- Consumer use construction, paint, electrical, and metal products construction, and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles;
- Consumer use construction, paint, electrical, and metal products machinery, mechanical appliances, electrical/electronic articles;
- Consumer use construction, paint, electrical, and metal products paints and coatings;
  - Consumer use furnishing, cleaning, treatment care products fabric, textile, and leather products; furniture and furnishings;
- Consumer use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel;
  - Consumer use packaging, paper, plastic, toys, hobby products ink, toner, and colorants;
- Consumer use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft);
- Consumer use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including paper articles;
- Consumer use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment;
  - Consumer use other uses novelty articles;

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• Consumer use – other uses – automotive articles;

This draft risk evaluation has been released for public comment and will undergo independent, expert
 scientific peer review. In addition to the charge questions that will be provided for the peer review, EPA
 seeks public comment on all aspects of this draft risk evaluation. In particular, the Agency seeks

671 comment on: (1) whether and how exposure controls and personal protective equipment (PPE) are used

672 for each of the COUs; (2) the use of surrogate data from one OES to estimate exposure in other OES

- 673 (*e.g.*, non-spray application of paints, coatings, adhesives, and sealants OES used rubber product 674 manufacturing data as a surrogate): and (3) the weight of scientific evidence and confidence conc
- 674 manufacturing data as a surrogate); and (3) the weight of scientific evidence and confidence conclusions 675 throughout the draft risk evaluation. EPA also seeks information that could be used to replace upper-
- bound or screening level assumptions, particularly for COUs that significantly contribute to the
- 677 unreasonable risk for DEHP.
- 678

EPA intends to publish an update to the draft risk evaluation for DEHP, which will be available prior to
peer review. This update to the draft risk evaluation will include information on the number of workers
and ONUs for each COU and will provide additional information on the data sets used to inform
exposures, including the number of non-detects (ND) in the exposure data for each COU and how these

- 683 data were incorporated into the exposure assessment.
- 684

EPA will issue a final DEHP risk evaluation after considering input from the public and peer reviewers.

- 686 If in the final risk evaluation the Agency determines that DEHP presents unreasonable risk to human 687 health or the environment, EPA will initiate regulatory action under TSCA section 6(a) to the extent
- 688 necessary so that DEHP no longer presents such risk.

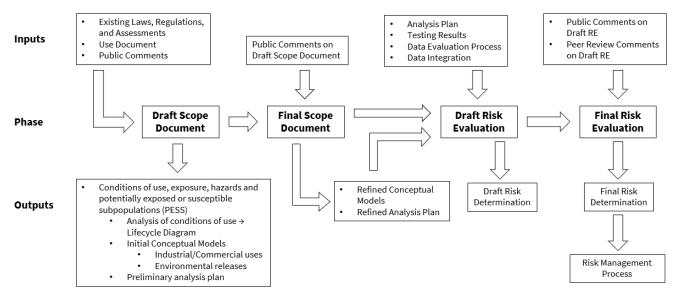
# 689 1 INTRODUCTION

EPA has evaluated di-ethylhexyl phthalate (DEHP) pursuant to section 6(b) of the Toxic Substances Control Act (TSCA). DEHP is a colorless, oily liquid that is used primarily as a plasticizer in polyvinyl chloride (PVC) plastics—although it is also used in adhesives, sealants, paints, coatings, rubbers, and non-PVC plastics, as well as for other applications. Section 1.1 summarizes the scope of the draft DEHP risk evaluation and provides information on production volume, a life cycle diagram (LCD), TSCA conditions of use (COUs), and conceptual models used for DEHP. Section 1.2 presents the organization of this draft risk evaluation.

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Figure 1-1 describes the major inputs, phases, and outputs/components of the TSCA risk evaluationprocess, from scoping to releasing the final risk evaluation.

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701

702 Figure 1-1. TSCA Existing Chemical Risk Evaluation Process

# 703 **1.1 Scope of the Risk Evaluation**

EPA evaluated risk to human and environmental populations for DEHP. Specifically for human 704 populations, the Agency evaluated risk to workers including occupational non-users (ONUs) via 705 inhalation and dermal routes; risk to consumers via inhalation, dermal, and oral routes; and risk to 706 707 bystanders via the inhalation route. Additionally, EPA incorporated the following potentially exposed 708 and susceptible populations (PESS) into its assessment—females of reproductive age, pregnant women, 709 infants, children and adolescents, people who frequently use consumer products and/or articles containing high-concentrations of DEHP, people exposed to DEHP in the workplace, and Tribes whose 710 diets include large amounts of fish. As described further in Section 4.1.3, using a screening level 711 analysis, EPA assessed risks to the general population, which considered risk from exposure to DEHP 712 713 via inhalation, dermal, and oral routes. For environmental populations, EPA evaluated risk to aquatic 714 species via water, sediment, and air as well as risk to terrestrial species via air, soil, sediment, and water. 715

716 Consistent with EPA's Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High-

717 Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act

718 (U.S. EPA, 2023d), EPA has also authored a draft cumulative risk technical support document (TSD) of

719 DEHP and five other toxicologically similar phthalates (*i.e.*, butyl benzyl phthalate [BBP], dibutyl

phthalate [DBP], diisobutyl phthalate [DIBP], dicyclohexyl phthalate [DCHP], and diisononyl phthalate

721 [DINP]) that are also being evaluated under TSCA based on a common toxicological endpoint (*i.e.*, 722 *phthalate syndrome*, which results from decreased fetal testicular testosterone) (U.S. EPA, 2025x). The 723 cumulative analysis takes into consideration differences in phthalate potency to cause effects on the developing male reproductive system. Use of relative potency across the phthalates provides a common 724 725 basis for adding risk across the cumulative chemicals. Numerous other regulatory agencies-Health 726 Canada, U.S. Consumer Product Safety Commission (U.S. CPSC), European Chemicals Agency 727 (ECHA), and the Australian National Industrial Chemicals Notification and Assessment Scheme 728 (NICNAS)—have assessed phthalates for cumulative risk, and EPA's 2023 proposal to conduct a CRA 729 of phthalates under TSCA was endorsed by the Science Advisory Committee on Chemicals (SACC) 730 because humans are co-exposed to multiple toxicologically similar phthalates that cause effects on the 731 developing male reproductive system consistent with a disruption of androgen action and phthalate syndrome. As described further in Sections 4.4.4 and 4.4.5, cumulative risk considerations focus on 732 733 acute duration exposures to the most susceptible subpopulations: female workers and consumers of 734 reproductive age (16–49 years of age) as well as male infants and male children (3–15 years of age) 735 exposed to consumer products and articles. 736

The draft DEHP risk evaluation comprises a series of technical support documents. Each TSD contains sub-assessments that inform adjacent, "downstream" TSDs. A basic diagram showing the layout and relationship of these draft assessments is provided below in Figure 1-2. High-level summaries of each relevant technical support document are presented in this risk evaluation. Detailed information for each TSD can be found in the corresponding documents. Appendix B incudes a list and citations for all technical support documents and supplemental files included in the draft risk evaluation for DEHP.

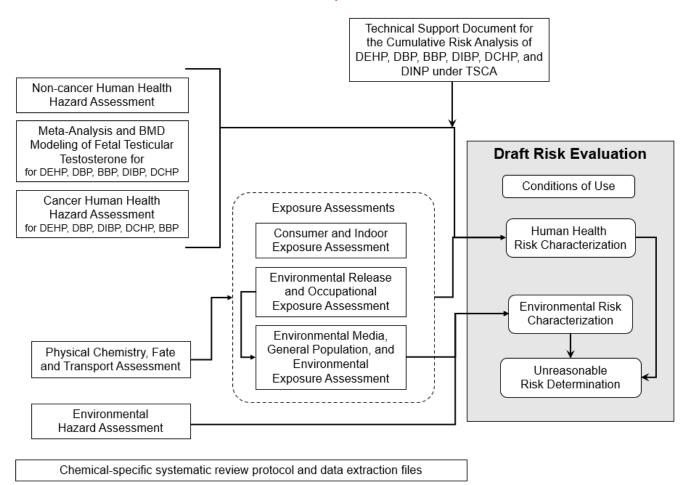
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These TSDs leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Di-ethylhexyl phthalate (DEHP); CASRN 117-81-7* (also called the "final scope
document") (U.S. EPA, 2020c). OPPT conducted a comprehensive search for reasonably available
information to identify relevant DEHP data for use in the risk evaluation as required by the TSCA

statute. The approach used to identify specific relevant risk assessment information was discipline-

specific and is detailed in the *Draft Systematic Review Protocol for Diethylhexyl*) *Phthalate (DEHP)* 

750 (U.S. EPA, 2025v), or as otherwise noted in the relevant technical support documents.



# 752 Figure 1-2. Draft Risk Evaluation Document Summary Map

# 1.1.1 Life Cycle and Production Volume

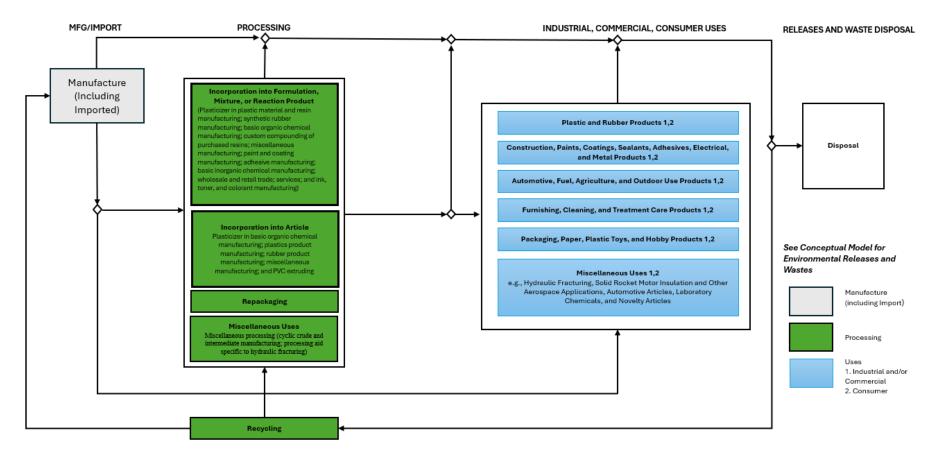
The LCD shown in Figure 1-3 depicts the COUs assessed in this draft the risk evaluation during various 754 life cycle stages, including manufacturing, processing, distribution, use (industrial, commercial, 755 756 consumer), and disposal. The LCD has been updated since its original inclusion in the final scope document, with consolidated and/or expanded processing and use steps. A complete list of updates and 757 758 explanations of the updates made to COUs for DEHP from the final scope document to this draft risk 759 evaluation is provided in Appendix D. The information in the LCD is grouped according to the Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes 760 761 for industrial uses and product categories for industrial and commercial uses). The CDR Rule under 762 TSCA section 8(a) (see 40 CFR Part 711) requires U.S. manufacturers (including importers) to provide 763 EPA with information on the chemicals they manufacture or import into the United States. EPA collects 764 CDR data approximately every 4 years with the latest collections occurring in 2006, 2012, 2016, and 765 2020.

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- 767 EPA included descriptions of the industrial, commercial, and consumer use categories identified from
- the 2020 CDR in the LCD (Figure 1-3) (U.S. EPA, 2020b). The descriptions provide a brief overview of
- the use category; the Draft Environmental Release and Occupational Exposure Assessment for
- 770 *Diethylhexyl Phthalate* (U.S. EPA, 2025r) contains more detailed descriptions (*e.g.*, process
- descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacturing,
- processing, use, and disposal category.



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# 774 Figure 1-3. DEHP Life Cycle Diagram

775 See Table 1-1 for categories and subcategories of conditions of use. Activities related to distribution (*e.g.*, loading, unloading) will be considered

throughout the DEHP life cycle, as well as qualitatively through a single distribution scenario.

- 777 The manufacture of DEHP has decreased significantly in the past 2 decades. The production volume for
- 778 CASRN 117-81-7 in 2015 and 2019 was between 10 to 50 million pounds (lb) based on the 2016 and
- 2020 CDR data cycles (U.S. EPA, 2020a, 2019b). EPA presents production volumes as a range to
- protect data claimed as confidential business information (CBI). For the 2016 and 2020 CDR cycles,
- collected data included the company name, volume of each chemical manufactured/
- imported, the number of workers at each site, and information on whether the chemical was used in the
- 783 commercial, industrial, and/or consumer sector(s). The U.S. EPA Chemical Data Access Tool (CDAT)
- reports that the 2012 national production volume was 10 to 50 million lb/year and shows at least 15
- 785 companies listed as importing or manufacturing.

786

# **1.1.2** Conditions of Use Included in the Risk Evaluation

- The final scope document (U.S. EPA, 2020c) identified and described the life cycle stages, categories,
  and subcategories that comprise COUs that EPA planned to consider in the risk evaluation. All COUs
  for DEHP included in this draft disk evaluation are reflected in the LCD (Figure 1-3) and conceptual
  models (Section 1.1.2.1). Table 1-1 below presents all COUs for DEHP.
- 791 792 In this draft risk evaluation, EPA made updates to the COUs listed in the final scope document (U.S. 793 EPA, 2020c). These updates reflect EPA's improved understanding of the COUs based on further 794 outreach, public comments, and updated industry code names under the CDR for 2020. Updates 795 included (1) additions and clarification of COUs based on new reporting in CDR for 2020 or 796 information received from stakeholders, (2) consolidation of redundant COUs from the processing 797 lifestage based on inconsistencies found in CDR reporting for DEHP processing and uses as well as 798 communications with stakeholders about the use of DEHP in industry, and (3) correction of typos or 799 edits for consistency. A complete list of updates and explanations of the updates made to COUs for 800 DEHP from the final scope document to this draft risk evaluation is provided in Appendix D. EPA may 801 further refine the COU descriptions for DEHP included in the draft risk evaluation when the final risk 802 evaluation for DEHP is published, based upon further outreach, peer-review comments, and public 803 comments. Table 1-1 presents the revised COUs that were included and evaluated in this draft risk
- 804 evaluation for DEHP. Appendix E contains descriptions of each COU.

# 805 Table 1-1. Categories and Subcategories of Use and Corresponding Exposure Scenario in the Risk Evaluation for DEHP

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	References
Manufacturing	Domestic manufacturing	Domestic manufacturing	( <u>U.S. EPA, 2020a, 2019b</u> )
Wanutacturing	Importing	Importing	( <u>U.S. EPA, 2020a</u> , <u>2019b</u> )
	Incorporation into formulation, mixture, or reaction product	Plasticizer in plastic material and resin manufacturing; synthetic rubber manufacturing; basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; basic inorganic chemical manufacturing; wholesale and retail trade; services; and ink, toner, and colorant manufacturing	(U.S. EPA, 2020a, 2019b; Just In Time Chemical, 2015)
Processing	Incorporation into article	Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; and PVC extruding	( <u>U.S. EPA, 2020a, 2019a, b; Just In Time</u> <u>Chemical, 2015</u> )
	Repackaging	Repackaging in wholesale and retail trade and in paint and coating manufacturing	( <u>U.S. EPA, 2020a, 2019b</u> )
	Other uses	Miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)	( <u>U.S. EPA, 2019b</u> ); EPA-600-R-16-236Fb
	Recycling	Recycling	(U.S. EPA, 2020a, 2019b)
Distribution in Commerce	Distribution in commerce	Distribution in commerce	
	Construction, paint, electrical, and metal products	Paints and coatings	(Wasser Corporation, 2021; Wasser Technologies, 2021; 3M Company, 2019) EPA- HQ-OPPT-2019-0501-0043; EPA-HQ-OPPT- 2018-0433-0004
Industrial Use		Adhesives and sealants	(Morgan Advanced Materials Wesgo Metals, 2016a, b); EPA-HQ-OPPT-2019-0501-0043; EPA-HQ-OPPT-2018-0433-0004
	Other uses	Hydraulic fracturing	EPA-HQ-OPPT-2019-0131-0054; EPA-600-R- 16-236Fb
		Solid rocket motor insulation and other aerospace applications	EPA-HQ-OPPT-2019-0501-0043; EPA-HQ- OPPT-2018-0433-0004

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	References
		Automotive articles	EPA-HQ-OPPT-2018-0433-0004
	Automotive, fuel, agriculture, outdoor use products	Lawn and garden care products	( <u>U.S. EPA, 2020a</u> )
Commercial	Construction, paint, electrical, and metal products	Adhesives and sealants	(U.S. Chemical & Plastics, 2020; U.S. EPA, 2020a; 3M, 2019, 2017; Morgan Advanced Materials Wesgo Metals, 2016a, b; Tremco, 2015); EPA-HQ-OPPT-2018-0433-0004
		Batteries and capacitors	(Kastar, 2024; Spypoint, 2024; Thumper Massager Inc, 2024; Just In Time Chemical, 2015)
		Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	(U.S. EPA, 2020a, 2019b; Hsu et al., 2017; Rockwool, 2017; Valero, 2014)
Use		Machinery, mechanical appliances, electrical/electronic articles	(ESAB, 2024; QuickCable Corporation, 2024; U.S. EPA, 2020a, 2019b; Just In Time Chemical, 2015)
		Paints and coatings	(Axalta Coating Systems LLC, 2024; Axalta Coating Systems, 2023; Wasser Corporation, 2021; U.S. EPA, 2020a; The Sherwin-Williams Company, 2019; U.S. EPA, 2019b; Eagle I.F.P. Company, 2015a, b)
	Furnishing, cleaning, treatment care products	All-purpose waxes and polishes	( <u>U.S. EPA, 2020a</u> )
		Fabric enhancer	( <u>U.S. EPA, 2020a</u> )
		Fabric, textile, and leather products; furniture and furnishings	(Kinco, 2024; U.S. EPA, 2019b)
		Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	(Duro Dyne Corporation, 2024; U.S. EPA, 2020a; WE Cork, 2001)
	Packaging, paper, plastic,	Ink, toner, and colorants	( <u>Identity Group, 2016</u> ); <u>EPA-HQ-OPPT-2018-</u> 0433-0004

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	References
	toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal Use, including rubber articles; plastic articles (hard); plastic articles (soft)	(Quad City Safety Inc, 2024a, b; Washington Department of Ecology, 2021; U.S. EPA, 2020a, 2019b; BriteLine, 2018); EPA-HQ-OPPT-2018- 0433-0004
		Packaging (excluding food packaging), including paper articles	( <u>U.S. EPA, 2020a</u> )
		Toys, playground, and sporting equipment	(Armada et al., 2022; U.S. EPA, 2020a, 2019b, <u>e</u> )
		Laboratory chemicals	(Chem Service Inc, 2018; Phenova, 2018); EPA- HQ-OPPT- 2019-0501-0043
Commercial Use	Other uses	Automotive articles	(Westin Automotive Products Inc, 2024; Reddam and Volz, 2021; U.S. EPA, 2019e); EPA-HQ-OPPT-2019-0131
Consumer Use	Automotive, fuel, agriculture, outdoor use products	Lawn and garden care products	( <u>U.S. EPA, 2020a</u> )
consumer ose	Construction, paint, electrical, and metal products	Adhesives and sealants	(U.S. Chemical & Plastics, 2020; U.S. EPA, 2020a)
		Batteries	(Kastar, 2024; Spypoint, 2024; Thumper Massager Inc, 2024)
		Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	( <u>U.S. EPA, 2020a; Hsu et al., 2017</u> )
		Machinery, mechanical appliances, electrical/electronic articles	(U.S. EPA, 2019b; Just In Time Chemical, 2015)
		Paints and coatings	(U.S. EPA, 2020a; <u>The Sherwin-Williams</u> <u>Company, 2019; U.S. EPA, 2019b; Eagle I.F.P.</u> <u>Company, 2015a, b</u> )
	Furnishing, cleaning,	Fabric, textile, and leather products; furniture and furnishings	(Equifit, 2024; Kinco, 2024; Mandal et al., 2022; U.S. EPA, 2019b)

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	References
	treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	(U.S. EPA, 2020a; WE Cork, 2001)
Consumer Use	Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorants	(Identity Group, 2016)
		Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)	(Quad City Safety Inc, 2024a, b; Washington Department of Ecology, 2021; U.S. EPA, 2020a, 2019b; BriteLine, 2018); EPA-HQ-OPPT-2018- 0433-0004
		Packaging (excluding food packaging), including paper articles	( <u>U.S. EPA, 2020a</u> )
		Toys, playground, and sporting equipment	(Armada et al., 2022; U.S. EPA, 2019e)
		Novelty articles	( <u>Stabile, 2013</u> )
	Other uses	Automotive articles	(Westin Automotive Products Inc, 2024; Armada et al., 2022; Reddam and Volz, 2021; U.S. EPA, 2019e); EPA-HQ-OPPT-2019-0131
Disposal	Disposal	Disposal	

<sup>*a*</sup> Life Cycle Stage Use Definitions (40 CFR 711.3)

- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.

- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.

- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.

- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.

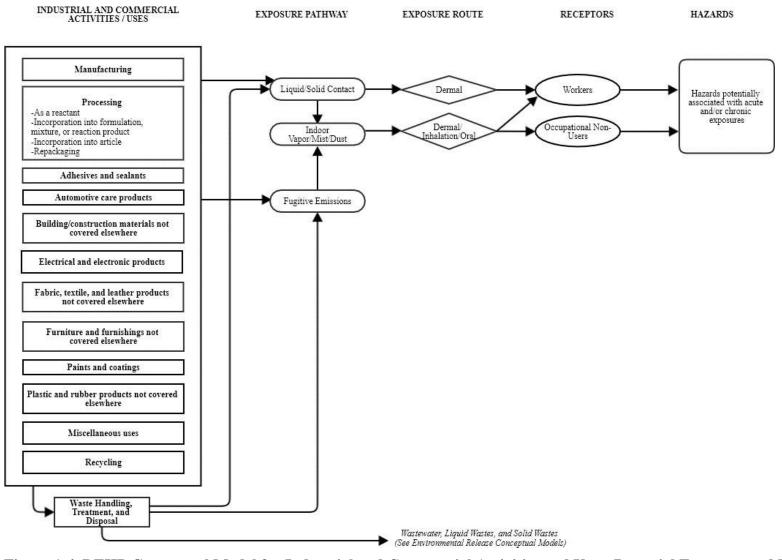
These categories of COUs appear in the LCD reflect CDR codes, and broadly represent COUs of DBP in industrial and/or commercial settings.

<sup>b</sup> These subcategories reflect more specific COUs of DBP.

<sup>c</sup> In the final scope document, EPA added the COU for DBP for processing, incorporation into formulation, mixture, or reaction product solid rocket motor insulation based on consultation with industry (EPA-HQ-OPPT-2018-0433-0038).

# 806 **1.1.2.1 Conceptual Models**

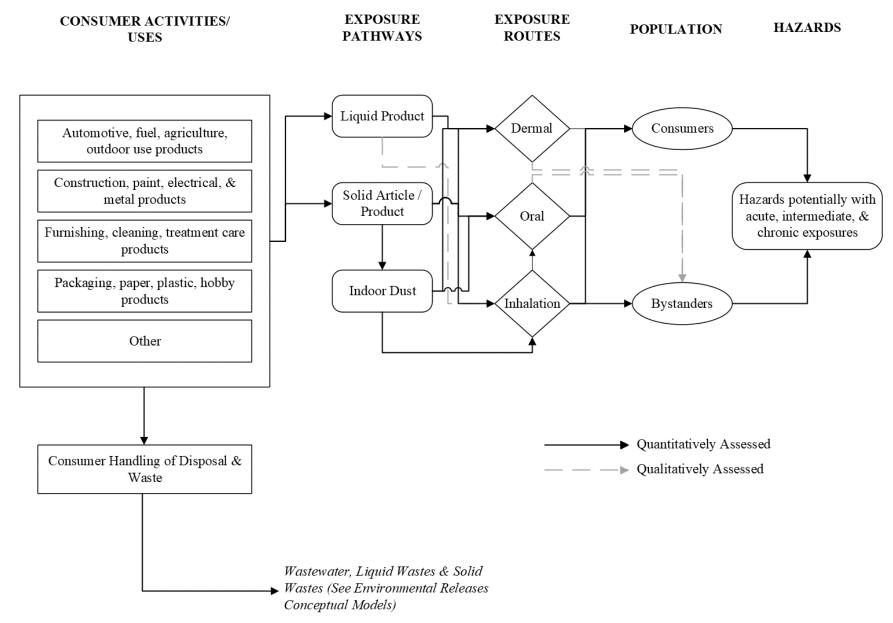
- 807 The conceptual model in Figure 1-4 presents the exposure pathways, exposure routes, and hazards to
- 808 human populations from industrial and commercial activities and uses of DEHP. There is potential for
- 809 exposures to workers and/or ONUs via inhalation and via dermal contact. The conceptual model also
- 810 includes potential ONU dermal exposure to DEHP in mists and dusts deposited on surfaces. EPA
- 811 evaluated activities resulting in exposures associated with distribution in commerce (*e.g.*, loading,
- 812 unloading) throughout the various life cycle stages and COUs (*e.g.*, manufacturing, processing,
- industrial use, commercial use, and disposal), as well as qualitatively through a single distributionscenario.
- 814 815
- Figure 1-5 presents the conceptual model for consumer activities and uses, Figure 1-6 presents general
- 817 population exposure pathways and hazards for environmental releases and wastes, and Figure 1-7
- 818 presents the conceptual model for ecological exposures and hazards from environmental releases and
- 819 wastes.



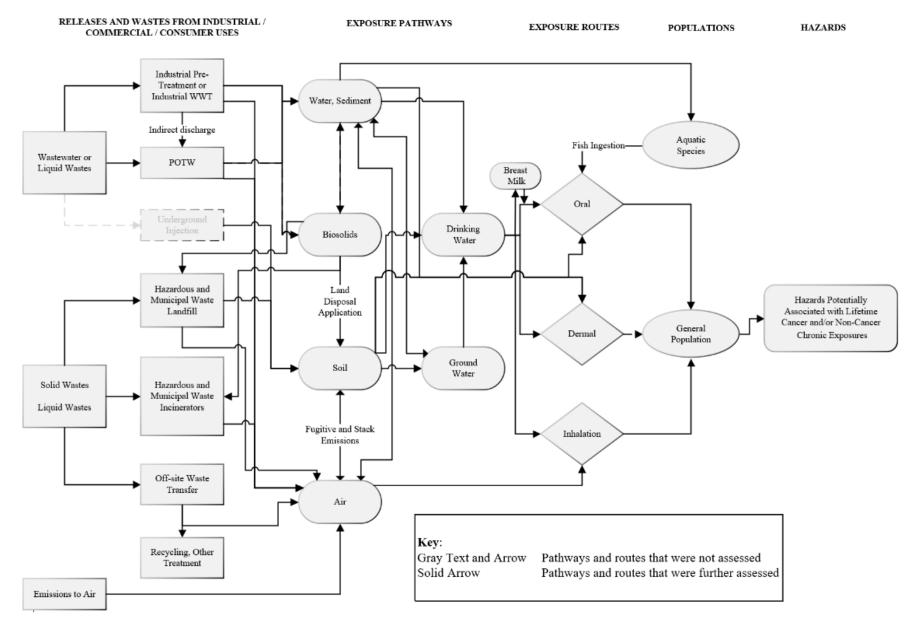
# 821 Figure 1-4. DEHP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

- <sup>a</sup> Some products are used in both commercial and consumer applications. See Table 1-1 for categories and subcategories of conditions of use.
- <sup>b</sup> Fugitive air emissions are emissions that are not routed through a stack and include fugitive equipment leaks from valves, pump seals, flanges,
- 824 compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation
- 825 systems.

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- 826 Figure 1-5. DEHP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards
- 827 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from consumer activities and uses of DEHP.

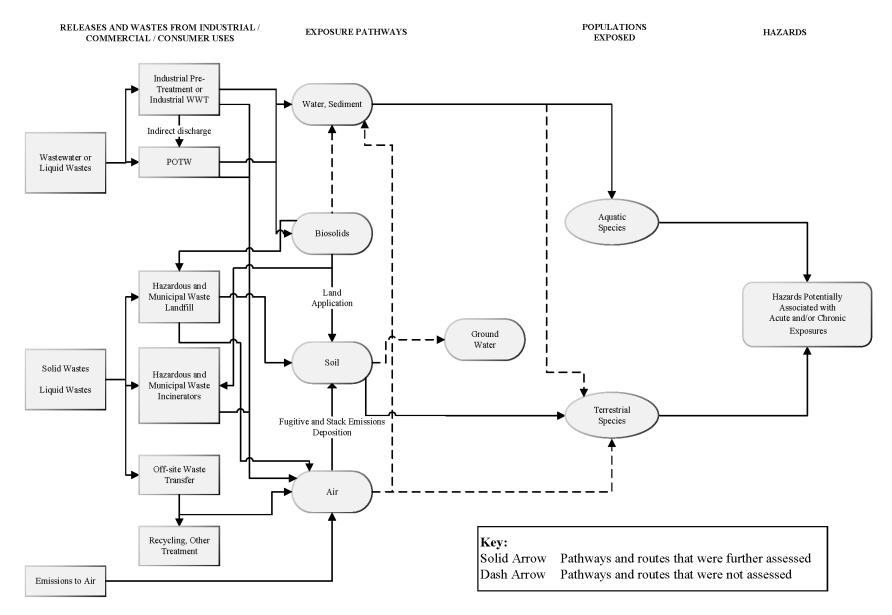


# 829 Figure 1-6. DEHP Conceptual Model for Environmental Releases and Wastes: General Population Hazards

830 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from releases and wastes from industrial,

831 commercial, and/or consumer uses of DEHP.

828



832

# 833 Figure 1-7. DEHP Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards

834 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from releases and wastes from industrial, 835 commercial, and/or consumer uses of DEHP.

# 836 **1.1.3 Populations and Durations of Exposure Assessed**

Based on the conceptual models presented in Section 1.1.2.1, EPA evaluated risk to environmental and
human populations. Environmental risks were evaluated for acute and chronic exposure scenarios for
aquatic and terrestrial species, as appropriate. Human health risks were evaluated for acute,
intermediate, and chronic exposure scenarios, as applicable based on reasonably available exposure and
hazard data, as well as the relevant populations for each. Human populations assessed include the
following:

- Workers, including average adults and females of reproductive age;
- ONUs, including average adults;
- Consumers, including infants (<1 year), toddlers (1–2 years), children (3–5 and 6–10 years), young teens (11–15 years), teenagers (16–20 years), and adults (21 years and above);</li>
- Bystanders, including infants (<1 year), toddlers (1–2 years), children (3–5 and 6–10 years), young teens (11–15 years), teenagers (16–20 years), and adults (21+ years);</li>
- General population, including infants (<1 year), toddlers (1–5 years), children (6–10 years), youth (11–15 and 16–20 years), and adults (21+ years).</li>

851 The age groups for consumers, bystanders, and general population are different because each life stage 852 used unique exposure factors (e.g., mouthing, drinking water ingestion, fish consumption rates). These 853 exposure factors are provided in EPA's Exposure Factors Handbook: 2011 Edition (U.S. EPA, 2011b). In general, factors such as exposure duration and frequency and product and article use patterns have a 854 855 greater impact on exposure or dose compared to sex-specific differences in body weight and body 856 surface area. Therefore, with the exception of workers, EPA characterized risk to average adults, and 857 considered all populations, including females of reproductive age, pregnant women, and other PESS to 858 be included in the resulting distribution of exposures examined.

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860 Consistent with its Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High-Priority 861 Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act (U.S. EPA, 2023d), EPA is focusing its relative potency factor (RPF) analysis and phthalate CRA on 862 populations most relevant to the common hazard endpoint (i.e., reduced fetal testicular testosterone)-863 864 specifically females of reproductive age and male infants and male children. This approach emphasizes 865 a common health effect for sensitive subpopulations; however, additional health endpoints are identified 866 for broader populations and described in the individual non-cancer human health hazard assessments for 867 DEHP (U.S. EPA, 2024f), DIBP (U.S. EPA, 2024g), DCHP (U.S. EPA, 2024e), DBP (U.S. EPA, 868 2024d), BBP (U.S. EPA, 2024c), and DINP (U.S. EPA, 2025w). Additionally, EPA is focusing its RPF and CRA on acute duration exposures. This is because—as described further in the Revised Draft 869 870 Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate 871 (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control 872 Act (TSCA) (U.S. EPA, 2025x)—there is evidence that effects on the developing male reproductive 873 874 system consistent with a disruption of androgen action can result from a single exposure during the critical window of development. 875

# 1.1.3.1 Potentially Exposed and Susceptible Subpopulations

TSCA section 6(b)(4)(A) requires that risk evaluations "determine whether a chemical substance
presents an unreasonable risk of injury to health or the environment, without consideration of costs or
other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible
subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of

use." TSCA section 3(12) states that "the term 'potentially exposed or susceptible subpopulation'
[PESS] means a group of individuals within the general population identified by the Administrator who,
due to either greater susceptibility or greater exposure, may be at greater risk than the general population
of adverse health effects from exposure to a chemical substance or mixture, such as infants, children,
pregnant women, workers, or the elderly."

886

887 This draft risk evaluation considers PESS throughout the human health risk assessment (Section 4), 888 including throughout the exposure assessment, hazard identification, and dose-response analysis 889 supporting this assessment. EPA incorporated the following PESS into its assessment: females of 890 reproductive age, pregnant women, infants, children and adolescents, people who frequently use consumer products and/or articles containing high concentrations of DEHP, people exposed to DEHP in 891 892 the workplace, people in close proximity to releasing facilities (including fenceline communities), and 893 Tribes and subsistence fishers whose diets include large amounts of fish. These subpopulations are 894 PESS because some have greater exposure to DEHP per body weight (e.g., infants, children, 895 adolescents) or due to age-specific behaviors (e.g., mouthing of toys, insulated cords, and erasers by 896 infants and children, assessed in the consumer exposure scenarios), while some experience aggregate or 897 sentinel exposures. EPA also evaluated non-attributable exposures and cumulative risk to phthalates 898 (*i.e.*, DEHP, DBP, BBP, DIBP, and DINP) using NHANES biomonitoring data. This non-attributable 899 cumulative risk from exposure to DEHP, DBP, BBP, DIBP, and DINP was taken into consideration as 900 part of EPA's cumulative risk calculations for DEHP, presented below in Sections 4.4.4 and 4.4.5 and 901 around exposures to DEHP from both occupational and consumer COUs/OES.

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Section 4.3.5 summarizes how PESS were incorporated into the risk evaluation through consideration of
 potentially higher exposures and/or potentially increased biological susceptibility and summarizes
 additional sources of uncertainty related to consideration of PESS.

# 906 **1.2 Organization of the Risk Evaluation**

This draft risk evaluation for DEHP includes five additional major sections, and several appendices,including:

- Section 2 summarizes basic physical and chemical characteristics as well as the fate and transport of DEHP.
  - Section 3 includes an overview of releases and concentrations of DEHP in the environment.
- Section 4 presents the human health risk assessment, including the exposure, hazard, and risk characterization based on the COUs. It includes a discussion of PESS based on both greater exposure and/or susceptibility, as well as a description of aggregate and sentinel exposures.
   Finally, Section 4 presents cumulative risk estimates from exposure to BBP, DEHP, DBP, DIBP, DCHP, and DINP (Section 4.4), as well as a comparison of the individual BBP risk assessment and the draft CRA (Section 4.5).
- Section 5 provides a discussion and analysis of the environmental risk assessment, including the environmental exposure, hazard, and risk characterization based on the COUs for DEHP. It also discusses assumptions and uncertainties and how they impact EPA's overall confidence in risk estimates.
  - Section 6 presents EPA's proposed determination of whether the chemical presents an unreasonable risk to human health or the environment under the assessed COUs.
- Appendix A provides a list of key abbreviations and acronyms used throughout this draft risk evaluation.

- Appendix B provides a brief summary of the federal, state, and international regulatory history of DEHP.
- Appendix B incudes a list and citations for all TSDs and supplemental files included in the draft risk evaluation for DEHP.
- Appendix D provides a summary of updates made to COUs for DEHP from the final scope document to this draft risk evaluation.
- Appendix E provides descriptions of the DEHP COUs evaluated by EPA.
- Appendix F provides the draft occupational exposure value for DEHP that was derived by EPA.

# 934 2 CHEMISTRY AND FATE AND TRANSPORT OF DEHP

- 935 Physical and chemical properties determine the behavior and characteristics of a chemical that inform its
- 936 conditions of use, environmental fate and transport, potential toxicity, exposure pathways, routes, and
- 937 hazards. Environmental fate and transport includes environmental partitioning, accumulation,
- degradation, and transformation processes. Environmental transport is the movement of the chemical
- within and between environmental media, such as air, water, soil, and sediment. Thus, understanding the
- 940 environmental fate of DEHP informs the specific exposure pathways, and potential human and 941 environmental exposed populations that EPA considered in this draft rick evaluation
- 941 environmental exposed populations that EPA considered in this draft risk evaluation.
- 942
- In general, under normal environmental conditions DEHP is a hydrophobic liquid that (1) is not
- 944 expected to volatilize from water, (2) has low bioaccumulation potential in aquatic and terrestrial
- organisms, (3) has no apparent biomagnification across trophic levels in aquatic food webs, and (4) is
- 946 considered readily biodegradable under most aquatic and terrestrial environmental conditions. Sections
- 2.1 and 2.2 summarize the physical and chemical properties, and environmental fate and transport of
- 948 DEHP, respectively. See the *Draft Physical and Chemical Property Assessment and Fate and Transport*
- 949 Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024h) for further details.

# 950 **2.1 Summary of Physical and Chemical Properties**

951 EPA gathered and evaluated physical and chemical property data and information according to the 952 process described in the Draft Systematic Review Protocol for Diethylhexyl Phthalate (DEHP) (U.S. 953 EPA, 2025v). The Agency considered both measured and estimated physical and chemical property 954 data/information as described in the Draft Physical Chemistry, Fate, and Transport Assessment for 955 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024h). The selected values are summarized in Table 2-1, 956 as applicable. Information on the full, extracted dataset is available in the Draft Data Quality Evaluation 957 and Data Extraction Information for Environmental Fate and Transport for Diethylhexyl Phthalate 958 (DEHP) (U.S. EPA, 2025j).

959

# 960 **Table 2-1. Physical and Chemical Properties of DEHP**

Property	Selected Value(s)	Reference(s)	Data Quality Rating
Molecular formula	C <sub>24</sub> H <sub>38</sub> O <sub>4</sub>	—	_
Molecular weight	390.56 g/mol	—	_
Physical form	Liquid	<u>Rumble (2018)</u>	High
Melting point	−55 °C	<u>Rumble (2018)</u>	High
Boiling point	384 °C	<u>Rumble (2018)</u>	High
Density	0.981 g/cm <sup>3</sup>	<u>Rumble (2018)</u>	High
Vapor pressure	1.42E–07 mmHg	<u>NLM (2015)</u>	High
Vapor density	16	<u>NLM (2015)</u>	High
Water solubility	0.003 mg/L	EC/HC (2017)	High
Octanol:water partition coefficient (log Kow)	7.60	<u>NLM (2015)</u>	High
Octanol:air partition coefficient (log KOA)	10.76 (EPI Suite <sup>™</sup> )	<u>NLM (2015)</u>	High
Henry's Law constant	9.87E–06 atm $\cdot$ m <sup>3</sup> /mol at 25 °C	Cousins and Mackay (2000)	High
Flash point	206 °C	<u>O'Neil (2013)</u>	High

Property	Selected Value(s)	Reference(s)	Data Quality Rating
Autoflammability	390 °C	NIOSH (1988)	High
Viscosity	57.94 cP at 25 °C	Mylona et al. (2013)	High

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# 962 **2.2 Summary of Environmental Fate and Transport**

963 Reasonably available environmental fate data—including biotic and abiotic biodegradation rates, 964 removal during wastewater treatment, volatilization from water sources, and organic carbon:water 965 partition coefficient (log  $K_{OC}$ )—are parameters used in the current risk evaluation. In assessing the 966 environmental fate and transport of DEHP, EPA considered the full range of results from the available 967 high quality data sources obtained during the Agency's systematic review of the relevant literatures. 968 Information on the full extracted dataset is available in the Draft Data Quality Evaluation and Data 969 *Extraction Information for Environmental Fate and Transport for Diethylberyl Phthalate (DEHP)* (U.S. 970 EPA, 2025j). Other fate estimates were based on modeling results from EPI Suite<sup>™</sup> (U.S. EPA, 2012a), 971 a predictive tool for physical and chemical properties and environmental fate estimation. Information 972 regarding the model inputs is available in the Draft Physical and Chemical Property Assessment and 973 Fate and Transport Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024h). 974

EPA evaluated the reasonably available information to characterize the environmental fate and transport
of DEHP. The key points of the fate assessment for DEHP (U.S. EPA, 2024h) are summarized below
and listed in Table 2-2.

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- Given the consistent results from numerous high-quality studies, there is a robust confidence of thefollowing:
- DEHP is expected to undergo significant direct photolysis;
- DEHP will partition to organic carbon and particulate matter in air;
  - DEHP will biodegrade in aerobic surface water, soil, and wastewater treatment processes;
- DEHP does not biodegrade in anaerobic environments;
- DEHP will be removed after undergoing wastewater treatment primarily via sorption to sludge at high fractions, with a small fraction being present in effluent;
  - DEHP is not bioaccumulative;
  - DEHP is not expected to biodegrade under anoxic conditions and may have high persistence in anaerobic soils and sediments; and
- DEHP may show persistence in surface water and sediment proximal to continuous points of release.
- As a result of limited studies identified, there is a moderate confidence that DEHP:
- Showed no significant degradation via hydrolysis under standard environmental conditions, but hydrolysis rate was seen to increase with increasing pH and temperature in deep-landfill environments; and
- is expected to be removed in conventional drinking water treatment systems by standard
- treatment processes, and via reduction by chlorination and chlorination byproducts in post treatment storage and drinking water conveyance.

999 Findings that were found to have a robust weight of evidence had one or more high-quality studies that1000 were largely in agreement with each other. Findings that were said to have a moderate weight of

1001 evidence were based on a mix of high- and medium-quality studies that were largely in agreement but

1002 varied in sample size and consistency of findings.

1003

# 1004 **Table 2-2. Summary of Environmental Fate Information for DEHP**<sup>a</sup>

Parameter	Value	Source(s)	Overall Quality Determination
Octanol:water (Log Kow)	7.60	<u>NLM (2015)</u>	High
Organic carbon:water (Log K <sub>OC</sub> )	5.41-5.95	Williams et al. (1995)	High
Octanol:air (Log KOA)	10.76 (EPI Suite estimate)	U.S. EPA (2017)	High
Air:water (Log KAW)	-2.12 (estimated)	Riederer (1990)	Medium
Aerobic primary biodegradation in water	70–78% in 24 hours (AS) >99%/28 days $t_{1/2} = <5$ days (AS) $t_{1/2} = <7$ days (river water)	Saeger and Tucker (1976) SRC (1983) Fujita et al. (2005)	High
Aerobic ready biodegradation in water	58.7–81% in 28 days $t_{1/2} = 6.9$ days (AS)	<u>NCBI (2020)</u> <u>Stasinakis et al. (2008)</u> <u>Scholz et al. (1997)</u>	High
Aerobic primary biodegradation in sediment	5.9–19.79% in 28 days $t_{1/2} = 7.3-27.5$ days	Johnson et al. (1984) Yuan et al. (2002)	High
Anaerobic primary biodegradation in sediment	13% in 30 days $t_{1/2} = 22.8 - 39.1$ days	<u>Kao et al. (2005)</u> <u>Yuan et al. (2002)</u>	High
	8.2% in 7 days	Schmitzer et al. (1988)	Medium
	10% in 10 days	Cartwright et al. (2000)	High
A 1 · 1 · 1 · 1 /· ·	7–43% in 35 days	Zhu et al. (2018)	High
Aerobic biodegradation in soil	31-38% in 42 days	Zhu et al. (2019)	High
5011	98.8% in 49 days	Carrara et al. (2011)	High
	8.5-21.8% in 60 days	Gejlsbjerg et al. (2001)	High
	55.5–90.47% in 112 days	<u>He et al. (2018)</u>	High
Hydrolysis	t <sub>1/2</sub> at pH 7: 5.36 years at 25 °C (estimated); t <sub>1/2</sub> at pH 8: 195 days at 25 °C (estimated)	<u>U.S. EPA (2017)</u>	High
Photolysis	Direct: expected to be susceptible to direct photolysis by sunlight; contains chromophores that absorb at wavelengths >290 nm Indirect: $t_{1/2} = 5.58$ hours (estimated; based on a 12-	<u>U.S. EPA (2017)</u>	High

Parameter	Value	Source(s)	Overall Quality Determination
	hour day with 21.96E–12 $\cdot$ OH/cm <sup>3</sup> and $\cdot$ OH rate constant of 2.39E–11 $\cdot$ OH/cm <sup>3</sup> and $\cdot$ OH cm <sup>3</sup> /molecule-sec)		
Wastewater treatment plant (WWTP) removal	>64% (median)	<u>U.S. EPA (1982)</u>	High
Aquatic bioconcentration factor (BCF)	Tilapia: 0.17–15.18 Catfish: 0.09–4.31 Rainbow trout: 1.6–51.5	Adeogun et al. (2015a) Adeogun et al. (2015b) Hayton et al. (1990)	High
Aquatic bioaccumulation factor (BAF)	Bluegill: 63.1 Bass: 316.2 Carp: 1,259	Lee et al. (2019)	High
Aquatic food web magnification factor (FWMF)	0.34–0.4	Burkhard et al. (2012) Mackintosh et al. (2004)	High
Terrestrial bioconcentration factor (BCF)	Earthworm: 0.2	ECJRC (2003)	High
Terrestrial biota-sediment accumulation factor (BSAF)	Earthworms: 0.073–0.244	Hu et al. (2005)	High
	value selection can be found in th Phthalate (DEHP) (U.S. EPA, 20		ate, and Transport

# 1006 3 RELEASES AND CONCENTRATIONS OF DEHP IN THE 1007 ENVIRONMENT

EPA estimated environmental releases and concentrations of DEHP. Section 3.1 describes the approach and methodology for estimating releases. Section 3.2 presents estimates of environmental releases, and Section 3.3 presents the approach and methodology for estimating environmental concentrations as well as a summary of concentrations of DEHP in the environment.

## 1012 **3.1 Approach and Methodology**

1013 This section provides an overview of the approach and methodology for assessing releases to the 1014 environment from industrial, commercial, and consumer uses. Specifically, Section 3.1.1 through 1015 Section 3.1.3 describe the approach and methodology for estimating releases to the environment from 1016 industrial and commercial uses, and Section 3.1.4 describes the approach and methodology for assessing 1017 down-the-drain releases from consumer uses.

#### 1018 **3.1.1 Manufacturing, Processing, Industrial and Commercial**

1019 This subsection describes the grouping of manufacturing, processing, industrial and commercial COUs 1020 into OESs as well as the use of DEHP within each OES. Specifically, Section 3.1.1.1 provides a 1021 crosswalk of COUs to OESs, and Section 3.1.1.2 provides descriptions for the use of DEHP within each 1022 OES.

1023 3.1.1.1 Crosswalk of Conditions of Use to Occupational Exposure Scenarios 1024 EPA categorized the COUs listed in Table 1-1 into OESs. Table 3-1 provides a crosswalk between the 1025 COUs and OESs whereas Table 3-2 provides the reverse: a crosswalk of OESs to COUs. Each OES is 1026 developed based on a set of occupational activities and conditions such that similar occupational 1027 exposures and environmental releases are expected from the use(s) covered under that OES. For each 1028 OES, EPA provided occupational exposure and environmental release results, which are expected to be 1029 representative of the entire population of workers and sites for the given OES in the United States. In 1030 some cases, EPA defined only a single OES for multiple COUs, while in other cases EPA developed 1031 multiple OESs for a single COU. EPA made this determination by considering variability in release and 1032 use conditions and whether the variability required discrete scenarios or could be captured as a 1033 distribution of exposures. The Draft Environmental Release and Occupational Exposure Assessment for 1034 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025r) provides further information on specific OESs. 1035

	OES		
Life Cycle Stage	Category	Subcategory	OES
Manufacture	Domestic manufacturing	Domestic manufacturing	Manufacture
	Importing Incorporation into article	Importing Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	
Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Rubber manufacturing
Processing	Incorporation into article	Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	Plastic converting
Industrial Use	Other uses	Solid Rocket Motor Insulation and other aerospace applications Automotive articles	
Processing Incorporation into formulation, mixture action product		Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Plastic compounding
Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic	Incorporation into formulation, mixture, o reaction product

## 1036 Table 3-1. Crosswalk of Conditions of Use to Assessed Occupational Exposure Scenarios

	OFS			
Life Cycle Stage	Category	Subcategory	OES	
		inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Incorporation into	
Processing	Other uses	Miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)	formulation, mixture, o reaction product	
Manufacture	Importing	Importing		
Processing	Repackaging	Repackaging in wholesale and retail trade and in paint and coating manufacturing	Import and repackaging	
Industrial Use	Construction, paint, electrical, and metal products	Paints and coatings		
commercial Use	Construction, paint,	Adhesives and sealants	Application of paints, coatings, adhesives, and	
Commercial Use	electrical, and metal products	Paints and coatings	sealants	
	Furnishing, cleaning, and treatment care products	All-purpose waxes and polishes		
C	Furnishing, cleaning, and treatment care products	Fabric, textile, and leather products; furniture and furnishings		
Commercial Use	Furnishing, cleaning, and treatment care products	inorganic chemical manufacturing;         wholesale and retail trade; services;         ink, toner and colorant         manufacturing         Miscellaneous processing (cyclic         crude and intermediate         manufacturing; processing aid         specific to hydraulic fracturing)         Importing         Repackaging in wholesale and retait         trade and in paint and coating         manufacturing         Paints and coatings         Adhesives and sealants         Paints and coatings         d         All-purpose waxes and polishes         furniture and furnishings         d         Batteries and capacitors         Construction and building materials         covering large surface areas,         including paper articles; metal         articles; stone, plaster, cement, glas         and ceramic articles         Machinery, mechanical appliances,         electrical/electronic articles         Lawn and garden care products         Packaging (excluding food         packaging) and other articles; rubber         articles; plastic articles (hard);         plastic articles (soft)         Packaging (excluding food         packaging (excluding	Textile finishing	
		Batteries and capacitors		
	Construction, paint, electrical, and metal products	including paper articles; metal articles; stone, plaster, cement, glass		
		Machinery, mechanical appliances, electrical/electronic articles		
Commercial Use	Automotive, fuel, agriculture, and outdoor use products	Lawn and garden care products	Fabrication or use of	
	Packaging, paper, plastic, toys, hobby products	packaging) and other articles with routine direct contact during normal use, including paper articles; rubber articles; plastic articles (hard); plastic articles (soft)	final product or articles	
		packaging), including paper articles		

	COU		OES	
Life Cycle Stage	Category	Subcategory	UES	
		Toys, playground, and sporting equipment		
Commercial Use	Furnishing, cleaning, and treatment care products	Floor coverings; Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and apparel	Fabrication or use of final product or articles	
Commercial Use	Packaging, paper, plastic, toys, hobby products	Ink, toner and colorants	Use of dyes and pigments, and fixing agents	
Industrial Use	Construction, paint, electrical, and metal products	Adhesives and Sealants	Application of paints, coatings, adhesives, and sealants (formulations for diffusion bonding)	
Commercial Use	Other uses	Laboratory chemicals	Use of laboratory chemicals	
Commercial Use	Other uses	Automotive articles	Use of automotive care products	
Industrial Use	Other uses	Hydraulic fracturing	Use in hydraulic fracturing	
Processing	Recycling	Recycling	Recycling	
Disposal	Disposal	Disposal	Waste handling, treatment, and disposal	
Distribution in Commerce	Distribution in Commerce		Distribution in Commerce	

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## 1039 **Table 3-2. Crosswalk of Assessed Occupational Exposure Scenarios to Conditions of Use**

OES			COU
ULS	Life Cycle Stage Category		Subcategory
Manufacturing	Manufacturing	Domestic manufacturing	Domestic manufacturing
		Importing	Importing
	Manufacture	Importing	Importing
Repackaging	Processing	Repackaging	Repackaging in wholesale and retail trade and in paint and coating manufacturing
Plastic converting	Processing	Incorporation into article	Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding
	Industrial Use	Other uses	Solid Rocket Motor Insulation and other aerospace applications Automotive articles

OFS			COU
OES	Life Cycle Stage	Category	Subcategory
		Incorporation into article	Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding
Rubber manufacturing	Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing
Plastic compounding	Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing
Incorporation into formulation, mixture, or reaction product	Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing
		Other uses	Miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)
Recycling	Processing	Recycling	Recycling
Use in hydraulic fracturing	Industrial Use	Other uses	Hydraulic fracturing
	Industrial Use	Construction, paint, electrical, and metal products	Paints and coatings
Application of paints, coatings,		Construction, paint, electrical, and	Adhesives and sealants
adhesives, and sealants	Commential	metal products	Paints and coatings
scalants	Commercial Use	Furnishing, cleaning, and treatment care products	All-purpose waxes and polishes
Use of automotive care products	Commercial Use	Other uses	Automotive articles

OFS			COU		
OES	Life Cycle Stage	Category	Subcategory		
		Construction, paint, electrical, and metal products	Batteries and capacitors Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles Machinery, mechanical appliances, electrical/electronic		
Fabrication or use		Automotive, fuel, agriculture, and outdoor use products	articles Lawn and garden care products		
of final product or articles	Commercial Use	Packaging, paper, plastic, toys, hobby	nt,       Batteries and capacitors         Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles         Machinery, mechanical appliances, electrical/electronic articles         Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including paper articles (soft)         Packaging (excluding food packaging), including paper articles         Toys, playground, and sporting equipment         Floor coverings; Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and apparel         Machinery       Ink, toner and colorants         Patric, textile, and l		
		products			
		Toys, playground, and sporting e	Toys, playground, and sporting equipment		
		Furnishing, cleaning, and treatment care products	covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and		
Use of dyes and pigments, and fixing agents	Commercial Use	Packaging, paper, plastic, toys, hobby products	Ink, toner and colorants		
	Textile finishing Commercial Use				
Textile finishing			Fabric enhancer		
Formulations for diffusion bonding	Industrial Use	Construction, paint, electrical, and metal products	Adhesives and Sealants		
Use of laboratory chemicals	Commercial Use	Other uses	Laboratory chemicals		
Waste handling, treatment, and disposal	Disposal	Disposal	Disposal		

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#### 3.1.1.2 Description of DEHP Use for Each OES

After EPA characterized the OESs for the occupational exposure assessment of DEHP, the occupational uses of DEHP for all OESs were summarized. Brief summaries of the uses of DEHP for all OESs are

1044 presented in Table 3-3.

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#### 1046 **Table 3-3. Description of the Function of DEHP for Each OES**

OES	Role/Function of DEHP
Manufacturing	DEHP is typically produced through the reaction of phthalic anhydride with 2-ethylhexanol using either an acid or metal catalyst or at a high temperature.
Repackaging	DEHP is imported domestically for use and/or may be repackaged before shipment to formulation sites.
Plastic converting	DEHP is used in PVC plastics to increase flexibility.
Rubber manufacturing	DEHP is used as a plasticizer in non-PVC polymers, such as resins, rubber tires, and synthetic rubbers.
Plastic compounding	DEHP is used in PVC plastics to increase flexibility.
Incorporation into formulation, mixture, or reaction product	DEHP is incorporated into products, such as paint, adhesives, synthetic dyes, and solid rocket motor insulation.
Recycling	Some PVC plastics that contain DEHP are recycled either in-house or at PVC recycling facilities for continuous compounding of new PVC material.
Use in hydraulic fracturing	DEHP is used as an additive in hydraulic fracturing fluids and has been identified in flowback water from hydraulic fracturing operations.
Application of paints, coatings, adhesives, and sealants	DEHP is a plasticizer in adhesives and sealants and in paint and coating products for industrial and commercial use.
Use of automotive care products	DEHP is used as a plasticizer in liquid automotive care products such as glass cleaners, fabric water proofing products, and rust converters.
Fabrication or use of final product or articles	DEHP is found in a wide array of different final articles not found in other OES including asphalt, banners, cork soundproofing, electrical tape, putty, pipe wrap, and rollers.
Use of dyes and pigments, and fixing agents	DEHP may be found in coloring agents, inks, or dyes as an additive or as a contaminant from plastic.
Textile finishing	DEHP is used in textile finishing as a fabric coating to impart fluidity to the coating formulation.
Formulations for diffusion bonding	DEHP is found in formulations for diffusion bonding, which are applied to metal surfaces to protect against the equipment and extreme temperatures of diffusion bonding equipment.
Use of laboratory chemicals	DEHP is a laboratory chemical used for laboratory analyses in liquid and solid forms.
Waste handling, treatment, and disposal	Upon fabrication or use of DEHP-containing products, residual chemical is disposed and released to air, wastewater, or disposal facilities.

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#### 3.1.2 Estimating the Number of Release Days per Year for Facilities in Each OES

1049 For many scenarios, EPA has limited data on the number of release days. Additionally, EPA may

1050 develop generic estimates of the number of operating days (days/year) for facilities in each OES (Table

3-4) through generic scenarios (GSs) or emission scenario documents (ESDs). Subsequently, EPA can
estimate the average daily releases for facilities by using the operating assumption that the number of
release days is equal to the number of operating days. For OES where there is no corresponding GS or
ESD, the basis for the operating days, unless otherwise stated, may be limited facility data from sites
within that OES. The operating assumptions for this approach are discussed in Section 2.3.3 and 3.0 of
the *Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate*(DEHP) (U.S. EPA, 2025r).

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#### Table 3-4. Generic Estimates of Number of Operating Days per Year for Each OES

Occupational Exposure Scenario (OES)	Operating Days (days/yr)	Basis
Manufacturing	350	EPA assumed 7 days/week, year-round site operation, considering a 2-week downtime, totaling 350 days/year.
Repackaging	260	EPA assumed 260 days/year as per the Revised Draft GS on Chemical Repackaging (U.S. EPA, 2022a).
Plastic converting	253	EPA assumed 253 days/year of operation according to the Revised Draft GS on Plastic Converting ( <u>U.S. EPA, 2014b</u> ).
Rubber manufacturing	250	EPA assumed 5 days/week, year-round site operation, considering a 2-week downtime, totaling 250 days/year.
Plastic compounding	246	EPA assumed 246 days/year of operation per the Revised Draft GS on the Use of Additives in Plastic Compounding (U.S. EPA, 2021e)
Incorporation into formulation, mixtures and reaction product	300	EPA assumed 300 days/year operation based on the assumption that DEHP is a commodity chemical with a large production volume.
Recycling	246	EPA assumed 246 release days per year per the Revised Draft GS on the Use of Additives in Plastic Compounding (U.S. EPA, 2021e).
Use in hydraulic fracturing	1–3	EPA modeled releases using a triangular distribution with a range of 1–3 days/year and mode of 1 day/year based on 2022 data from FracFocus ( <u>GWPC and IOGCC, 2022</u> ).
Application of paints, coatings, adhesives, and sealants	250	EPA assumed 250 days/year of operation per the ESD on Radiation Curable Coatings, Inks, and Adhesives (OECD, 2010). The ESD on the Use of Adhesives (OECD, 2015) provides an average of 171 working days for general assembly, but provides 250 days for use in specific industries such as motor and non-motor vehicle, vehicle parts, and tire manufacturing (except retreading), and labels and tapes manufacturing.
Use of automotive care products	235–258	EPA modeled releases using a range of 235–258 days/year based on the Methodology Review Draft on Use of Automotive Detailing Products (U.S. EPA, 2022b).
Fabrication or use of final product or articles	131–350	EPA identified operating days ranging from 131–350 with an average of 238 days, based on National Emissions Inventory (NEI) air release data.
Use of dyes and pigments, and fixing agents	157	EPA assumes 157 days/year of operation per the ESD on Use of Textile Dyes ( <u>OECD, 2017</u> ).
Textile finishing	225	EPA assumed 225 days/year of operation per the ESD on

Occupational Exposure Scenario (OES)	Operating Days (days/yr)	Basis
		Textile Finishing ( <u>OECD, 2004</u> ).
Formulations for diffusion bonding	250	EPA assumed 5 days/week, year-round site operation, considering a 2-week downtime, totaling 250 days/year.
Use of laboratory chemicals	235–258	The 2023 Use of Laboratory Chemicals GS estimated the total number of operating days based on the shift lengths of operators over the course of a full year as 174–260 days/year (U.S. EPA, 2023g). Shift lengths include 8, 10, or 12 hour/day shifts. Release estimates that EPA assessed using Monte Carlo modeling ( <i>Draft Environmental Release and Occupational</i> <i>Exposure Assessment for Diethylhexyl Phthalate (DEHP)</i> (U.S. EPA, 2025r)) used a 50th to 95th percentile range of 235 to 258 days/year
Waste handling, treatment, and disposal	365	EPA assumed 365 days/year based on NEI air release data and the assumption that waste management sites continuously operate 365 days/year.

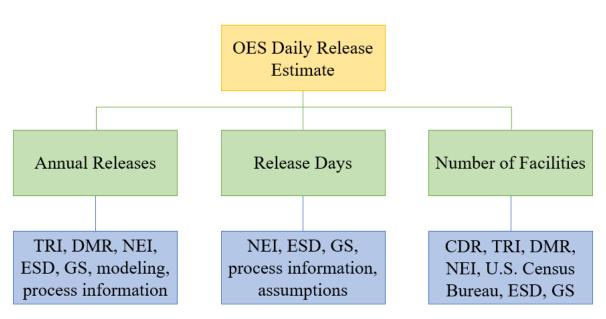
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#### 3.1.3 Daily Release Estimation

For each OES, EPA estimated releases to each media of release using Toxics Release Inventory (TRI) 1062 1063 Program data (years 2017–2022), Discharge Monitoring Report (DMR) data (years 2017–2022), and National Emissions Inventory (NEI) data (years 2017 and 2020) or modeling as shown in Figure 3-1. 1064 1065 Where available, EPA used NEI, GSs, or ESDs to estimate number of release days, which the Agency 1066 used to convert between annual release estimates and daily release estimates. EPA used 2020 CDR, TRI, 1067 DMR, NEI, and Monte Carlo modeling data to estimate the number of sites using DEHP within an OES. 1068 The Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate 1069 (DEHP) (U.S. EPA, 2025r) describes EPA's approach and methodology for estimating daily releases and provides detailed facility level results for each OES. 1070 1071

For each OES, EPA estimated DEHP releases per facility to each release media applicable to that OES.
For DEHP, EPA assessed releases to water, air, or land (*i.e.*, disposal to land).



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Figure 3-1. Overview of EPA's Approach to Estimate Daily Releases for Each OES

1077TRI = Toxics Release Inventory; DMR = Discharge Monitoring Report; NEI =National Emissions1078Inventory; CDR = Chemical Data Reporting; ESD = Emission Scenario Document; GS = Generic1079Scenario

#### 1080 **3.1.4 Consumer Disposal Down-the-Drain and Landfills**

1081 Environmental releases may occur from consumer products and articles containing DEHP via the end-1082 of-life disposal and demolition of consumer products and articles in the built environment, as well as 1083 from the associated down-the-drain release of DEHP. It is difficult for EPA to quantify these end-of-life 1084 and down-the-drain exposures due to limited information on source attribution of the consumer COUs. 1085 In previous assessments, EPA has considered down-the-drain analysis for consumer product scenarios 1086 where it can be reasonably foreseen that at least a portion of some consumer product (*e.g.*, paints, 1087 sealants, oils) may be discarded directly down-the-drain. Adhesives, sealants, paints, lacquers, and 1088 coatings can be disposed down-the-drain while users wash their hands, brushes, sponges, and other 1089 product applying tools. Although EPA acknowledges that there may be DEHP releases to the 1090 environment via the cleaning and disposal of adhesives, sealants, paints, lacquers, and coatings, the 1091 Agency did not quantitatively assess these scenarios due to limited information, monitoring data, or 1092 modeling tools. In addition, these products can be disposed of when users no longer have use for them, 1093 or they have reached the product shelf life and are taken to landfills.

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1095 All other solid products and articles included in Table 4-5 can be removed and disposed of in landfills or 1096 other waste handling locations that properly manage the disposal of products like adhesives, sealants, 1097 paints, lacquers, and coatings. EPA did not identify data for DEHP in drinking water in the United 1098 States. Based on the low water solubility and log K<sub>OW</sub>, DEHP in water is expected to mainly partition to 1099 suspended solids present in water. The available information suggest that the use of flocculants and 1100 filtering media could potentially help remove DEHP during drinking water treatment by sorption into 1101 suspended organic matter, settling, and physical removal. Although there is limited measured data on 1102 DEHP in landfill leachates, the data suggest that DEHP is unlikely to be present in landfill leachates. 1103 Further, the small amounts of DEHP that could potentially be in landfill leachates will have limited 1104 mobility and are unlikely to infiltrate groundwater due to high affinity of DEHP for organic compounds

1105 that would be present in receiving soil and sediment (U.S. EPA, 2025q).

### 1106 **3.2 Summary of Environmental Releases**

#### 1107 **3.2.1 Manufacturing, Processing, Industrial and Commercial**

1108 EPA combined its estimates for annual releases, release days, number of facilities, and hours of release

per day to estimate a range of daily releases for each OES. Table 3-5 presents a summary of these ranges

across facilities, and Table 3-6 provides a summary of the weight of scientific evidence supporting the

1111 overall confidence in environmental release estimates by OES. The complete data (from TRI, DMR,

and/or NEI) for each facility, including zero releases, are presented in Section 3 of the *Draft* 

1113 Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (1,2-

1114 Benzenedicarboxylic acid, 1,2-bis(2-ehtylhexyl) ester) (DEHP) (U.S. EPA, 2025r). Additional detail on

deriving the overall confidence score for each OES is also presented in this technical support document.

- 1116 EPA was not able to estimate site-specific releases for the final use of products or articles OES. Disposal 1117 sites handling post-consumer end-use DEHP were not quantifiable due to the wide and dispersed use of
- 1117 Sites handling post-consumer end-use DEHP were not quantifiable due to the wide and dispersed use of 1118 DEHP in PVC and other products. Pre-consumer waste handling, treatment, and disposal are assumed to
- 1119 be captured in upstream OES.

OES	Estimated Annual Release Across Sites <sup>a</sup> (kg/site-year)		Type of Discharge, <sup>b</sup> Air Emission, <sup>c</sup> or Transfer	Estimated Release Frequency Across	Number of Facilities <sup>f</sup>		Weight of Scientific	Source(s) <sup>j</sup>
	Central Tendency	High-End	for Disposal <sup>d</sup>	Sites (days) <sup>e</sup>	Central Tendency	High- End	Evidence Rating <sup>g</sup>	
	26	149	Fugitive Air	264				
M	28	141	Stack Air	364	2	Madausta	TRI, NEI,	
Manufacturing	38	204	Land	250	3		Moderate	DMR
	150	442	Water	350				
	0.22	145	Fugitive Air	100, 265				
Rubber	5.7	145	Stack Air	120–365		Moderate to	TRI, NEI,	
	862	6,060	Land	364	85		Robust	DMR
	227	227	Water 250					
	2.3	285	Fugitive Air			Moderate to	TRI, NEI,	
Plastic	9.7	1,342	Stack Air	365	(2)			
compounding	919	6,678	Land	67		Robust	DMR	
	13.5	227	Water	246				
	3.2	335	Fugitive Air	172 265			Moderate to Robust	TRI, NEI, DMR
	2.7	915	Stack Air	172–365	71			
Plastic converting	767	1.2E04	Land	296	71			
	15	227	Water	253				
T	0.19	227	Fugitive Air	200, 255			1	
formulation, or 1 reaction product	1.0	227	Stack Air	309–365		Moderate to	TRI, NEI,	
	113	1,406	Land	300	127		Robust	DMR
	4.2	227	Water	300				

OES	Estimated Annual Release Across Sites <sup>a</sup> (kg/site-year)		Type of Discharge, <sup>b</sup> Air Emission, <sup>c</sup> or Transfer	Estimated Release Frequency Across	Number of Facilities <sup>f</sup>		Weight of Scientific	Source(s) <sup>j</sup>
	Central Tendency	High-End	for Disposal <sup>d</sup>	Sites (days) <sup>e</sup>	Central Tendency	High- End	Evidence Rating <sup>g</sup>	
	72	227	Fugitive Air	250 265				
Danaskasina	227	227	Stack Air	350–365	47		Moderate to	TRI, NEI,
Repackaging	325	325	Land	364	47		Robust	DMR
	227	227	Water	260	-			
Annlingtion of	0	13	Fugitive Air	153–365				TRI, NEI,
Application of paints, coatings,	0.27	491	Stack Air		1.40	,	Moderate to	
adhesives, and	274	274	Land	364	- 140		Robust	DMR
sealants	1.2	1,057	Water	250				
	0.23	0.43	Fugitive Air	15.064	11		Slight	TRI, NEI, DMR
	0.45	80	Stack Air	15–364				
Textile finishing	Not reported		Land	No land release				
	390	738	Water	215				
	0.65	194	Fugitive Air			<b>a</b> 1. 1.		
Fabrication of	0	3.8	Stack Air	131–350	16		Slight	TRI, NEI
final products from articles	Not re	eported	Land	No land release				
	Not reported		Water	No water release				
Use of dyes,	Not re	eported	Fugitive Air	157	_			DMD
	Not re	eported	Stack Air	157	5		Slight	DMR
pigments, and fixing agents	1.1	22	Water					
	Not re	eported	Land					

OES	Estimated Annual Release Across Sites <sup>a</sup> (kg/site-year)		Type of Discharge, <sup>b</sup> Air Emission, <sup>c</sup> or Transfer	Estimated Release Frequency Across	Number of Facilities <sup>f</sup>		Weight of Scientific	Source(s) <sup>j</sup>
	Central Tendency	High-End	for Disposal <sup>d</sup>	Sites (days) <sup>e</sup>	Central Tendency	High- End	Evidence Rating <sup>g</sup>	
	4.2E-02	31	Fugitive Air		14	Slight	TRI, NEI,	
Formulations for	9.2	399	Stack Air				Slight	DMR
diffusion bonding	Not re	eported	Land					
	9.2E	E-02 <sup>h</sup>	Surface Water	-				
Use of laboratory	6.3E-09	2.1E-08	Fugitive or Stack Air					
chemicals (liquid)	26	96	Wastewater, Incineration, or Landfill		1,996	36,873		
	3.5	3.5	Water, Incineration, or Landfill	235 as central tendency and 258 as high-end	36,873		Moderate	Model, peer- reviewed literature (GS/ESD)
Use of laboratory chemicals (solid)	1.8E-02	1.8E-02	Air, Water, Incineration, or Landfill					
chemieus (sond)	1.7E-02	1.8E-02	Stack Air					
	1.7E-02	1.8E-02	Incineration or Landfill					
	4.6E-11	3.4E-10	Fugitive Air	235 as Central				Model, peer-
Use of automotive care products	5.2	23	POTW or Landfill	Tendency and 258 as High-End	25,170	147,152	Moderate	reviewed literature (GS/ESD)
	1.7E-11	1.8E-10	Fugitive Air	-				
Use in hydraulic fracturing	9.7E-02	2	Water, Incineration, or Landfill					
	0.37	6.5	Surface Water					Model, peer- reviewed
	0.12	2.1	Soil	1 as central tendency	44	L	Moderate	
	0	6.6E-04	Incineration or Landfill	and 3 as high end			Woderate	literature (GS/ESD)
	2.9	45	Deep Well Injection					
	9.6E-02	1.7	Recycle					
	3.6	56	Total	1				

OES	Estimated Annual Release Across Sites <sup>a</sup> (kg/site-year)		Type of Discharge, <sup>b</sup> Air Emission, <sup>c</sup> or Transfer	Estimated Release Frequency Across	Number of Facilities <sup>f</sup>		Weight of Scientific	Source(s) <sup>j</sup>	
	Central Tendency	High-End	for Disposal <sup>d</sup>	Sites (days) <sup>e</sup>	Central Tendency	High- End	Evidence Rating <sup>g</sup>		
	3.3E	$-02^{h}$	Fugitive Air	240					
Deerveling	1.2E-02 <sup>h</sup>		Stack Air	248	1		Slight	TRI	
Recycling	Not reported		Land	No land release	1				
	Not reported		Water	No water release	1				
	4.2E-02	224	Fugitive Air	- 15-365 365	15.065	15.005			
Waste handling, treatment, and disposal	13	224	Stack Air			Moderate to	TRI, NEI,		
	2.3	6,481	Land		477 Robus		Robust	DMR	
	7.9	1,451	Water 25	250					

<sup>*a*</sup> For programmatic data (TRI, NEI, DMR), central tendency and high-end values represent the 50th and 95th percentiles, respectively, of the available maximum values reported for all sites mapped to each OES. The specific central tendency and high-end values presented depends on the number of sites with programmatic data. For databases with six or more reporting facilities, EPA estimated central tendency and high-end releases using the 50th and 95th percentile values, respectively. For 3–5 facilities, EPA estimated the central tendency and high-end releases using the 50th percentile values, respectively. For 2 sites, EPA presented the midpoint and the maximum value. Finally, EPA presented sites with only 1 data point as-is from the programmatic database. It is important to note that when the reported maximum value for a given facility indicates zero releases, these values are included in the calculation of 50th and 95th percentile for each OES. For data from DMR: in instances where a facility reports a period's monitoring results as below the limit of detection (LOD), also referred to as a non-detect or ND for a pollutant, the Loading Tool applies a hybrid method to estimate the wastewater discharge for the period. The hybrid method sets the ND values to half of the LOD if there was at least 1 detected value in the facility's DMRs in a calendar year. If all values less than the LOD in a calendar year, the annual load is set to 0.

<sup>b</sup> Direct discharge to surface water; indirect discharge to non-POTW; indirect discharge to POTW

 $^{c}$  Emissions via fugitive air or stack air, or treatment via incineration.

<sup>d</sup> Transfer to surface impoundment, land application, or landfills.

<sup>e</sup> Where available, EPA used industry provided information, ESDs, or GSs to estimate the number of release days for each condition of use.

<sup>*f*</sup> Where available, EPA used 2020 CDR (U.S. EPA, 2020a), 2020 U.S. County Business Practices (U.S. Census Bureau, 2022), and Monte Carlo models to estimate the number of sites that use DEHP for each condition of use. Some modeled OES calculated the number of facilities/sites, presented as 50th and 95th percentiles. Other modeled OES set the number of facilities deterministically, presented as one value.

<sup>*g*</sup> See Section 3.2.2 for details on EPA's determination of the weight of scientific evidence rating

<sup>h</sup> Insufficient data to calculate central tendency and high-end values

<sup>*i*</sup>There are different release days for the different media for some OES, and they have been listed separately

<sup>j</sup>Data Quality Score – Release Sources: TRI (medium), DMR (medium), NEI (high)

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## **3.2.2** Weight of Scientific Evidence Conclusions for Environmental Releases from Industrial and Commercial Sources

For each OES, EPA considered the assessment approach, the quality of the data and models, and the uncertainties in the assessment results to determine a level of confidence for the environmental release estimates. Table 3-6 provides the Agency's weight of scientific evidence rating for each OES.

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1127 EPA integrated numerous evidence streams across systematic review sources to develop environmental 1128 releases for DEHP. The Agency made judgments on the weight of scientific evidence supporting the 1129 release estimates based on the strengths, limitations, and uncertainties associated with the release 1130 estimates. These judgements are characterized through the statement of weight of scientific evidence 1131 conclusions which express the plausibility of the estimate(s). Plausibility is determined through 1132 sufficient consideration of the representativeness of integrated underlying sources and assessment 1133 methods. EPA described these conclusions using the following descriptors: robust, moderate, slight, or 1134 indeterminate.

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1136 In determining the strength of the overall weight of scientific evidence, EPA considered factors that 1137 increase or decrease the strength of the evidence supporting the release estimate (whether measured or 1138 estimated), including quality of the data/information, relevance of the data to the release scenario 1139 (including considerations of temporal and spatial relevance), and the use of surrogate data when 1140 appropriate. In general, higher rated studies (as determined through data evaluation) increase the weight 1141 of scientific evidence when compared to lower rated studies, and EPA gave preference to chemical- and 1142 scenario-specific data over surrogate data (e.g., data from a similar chemical or scenario). For example, 1143 a conclusion of moderate weight of scientific evidence is appropriate where there is measured release 1144 data from a limited number of sources, such that there is a limited number of data points that may not 1145 cover most or all the sites within the OES. A conclusion of slight weight of scientific evidence is 1146 appropriate where there is limited information that does not sufficiently cover all sites within the COU. and the assumptions and uncertainties are not fully known or documented. See EPA's Draft Systematic 1147 1148 Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances, Version 1.0: A Generic 1149 TSCA Systematic Review Protocol with Chemical-Specific Methodologies (also called the "Draft 1150 Systematic Review Protocol") (U.S. EPA, 2021a) for additional information on weight of scientific 1151 evidence conclusions.

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1153 Table 3-6 summarizes EPA's overall weight of scientific evidence conclusions for its release estimates 1154 for each OES. TRI and DMR databases had data quality ratings of medium whereas NEI had a high data 1155 quality rating. In general, modeled data had data quality ratings of medium. As a result, for releases that used GSs/ESDs, the weight of scientific conclusion was moderate when used in tandem with Monte 1156 1157 Carlo modeling. In general, there is inherent uncertainty in the accuracy of any programmatic database 1158 with respect to the self-reported data elements. Additionally, representativeness of the releases for any COU with respect to the full distribution of releasing sites is unknown. However, the number of 1159 1160 facilities reporting and the variability of facilities within a COU may address some of the uncertainty.

#### 1161 **Table 3-6. Summary of Overall Confidence in Environmental Release Estimates by OES**

<b>OES</b> <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g), and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data set includes 2 reporting sites under TRI and 2 reporting sites under NEI, which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. Based on other reporting databases (CDR), there is 1 additional manufacturing site that is not accounted for in this assessment.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 1 reporting site, with the other TRI site reporting 0 land releases. EPA did not have additional sources to estimate land releases from this OES. Based on other reporting databases (CDR, DMR, NEI, etc.), there are 2 additional manufacturing sites that are not accounted for in this assessment.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. The primary limitation is that the water release assessment is based on 2 reporting sites for this OES, with 1 site reporting releases from which the maximum was used for the high-end, and the other TRI site reporting 0 water releases; therefore, EPA used the midpoint between the 0 release and the maximum (high-end) as an estimate for central tendency. EPA did not have additional sources to estimate water releases from this OES. Based on other reporting databases (CDR, NEI, etc.), there are 2 additional manufacturing sites that are not accounted for in this assessment.
	The release information sources are EPA programmatic data from the last 10 years and cover all media of primary concern. Although there are limited reporting sites, significant variability in the manufacture of DEHP and the associated releases from the manufacture are not expected. Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data. Note that facilities that do not report any data because releases were below the reporting threshold do not inform the concentrations calculated in these media (air, land, water) determined from the range of reported releases.
Rubber manufacturing	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g) and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data set includes 58 NEI reporting sites and 29 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases are assessed using reported releases from 2017–2022 TRI. The land release assessment is based on 19 reporting sites under TRI, which are used to estimate releases, with the remainder of TRI sites mapped to this OES reporting 0 land releases. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate

<b>OES</b> <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 TRI. The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. The primary limitation is that the water release assessment is based on 8 reporting sites, and EPA did not have additional sources to estimate water releases from this OES. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate water releases from this OES.
	Based on the availability of programmatic data from multiple sites across all media of primary concern, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robust confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Plastics compounding	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g) and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 14 NEI reporting sites and 22 TRI reporting sites, and this variability in data sources with different levels of granularity in reporting generally increases the representativeness of the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 9 reporting sites, which inform the release estimate to land for this OES, with the remainder of TRI sites mapped to this OES reporting 0 land releases which are not included in the release statistics. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. An additional strength is that the data set includes 28 DMR reporting sites and 13 TRI reporting sites that inform the release estimate to water for this OES, and the extensive reporting across these databases adds variability to the assessment. The remaining TRI sites mapped within this OES reported 0 water releases and are not included in the release statistics. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and DMR may not capture all relevant sites.
	Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robust confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Plastics converting	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g) and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An

OES <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	additional strength is that the data includes 23 NEI reporting sites and 48 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases are assessed using reported releases from 2017–2022 TRI. The land release assessment is based on 30 reporting sites under TRI with the remainder of TRI sites mapped to this OES reporting 0 land releases. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. An additional strength is that the data set includes 2 DMR reporting sites and 13 TRI reporting sites which adds variability to the assessment. The remaining TRI sites mapped within this OES reported 0 water releases. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and DMR may not capture all relevant sites.
	Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robust confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Incorporation into formulation, mixture, or reaction product	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g), and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 71 NEI reporting sites and 19 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 3 reporting sites, with the remainder of TRI sites mapped to this OES reporting 0 land releases. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. An additional strength is that the data set includes 38 DMR reporting sites and 8 TRI reporting sites which adds variability to the assessment. The remaining TRI sites mapped within this OES reported 0 water releases. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and DMR may not capture all relevant sites.

<b>OES</b> <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robust confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Repackaging	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g), and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 16 NEI reporting sites and 24 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land release assessment is based on 1 reporting site, with the remainder of TRI sites mapped to this OES reporting 0 land releases. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. An additional strength is that the data set includes 8 DMR reporting sites and 19 TRI reporting sites which adds variability to the assessment. The remaining TRI sites mapped within this OES reported 0 water releases. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and DMR may not capture all relevant sites.
	In summary, some media (land) had few reporting sites, while for others (air, water), there are a significantly more reporting sites. The release weight of scientific evidence is an integration across media that must consider the number of sites for each medium along with other factors. The only limiting medium is land, the others have release information from multiple sources (TRI/DMR, TRI/NEI). The fact that the release estimates were based on an integration of actual release data from programmatic databases with a data quality score of medium for TRI and DMR and a data quality score of high for NEI increase EPA's confidence in the release estimates. Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robust confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Application of paints, coatings, adhesives and sealants	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g) and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 117 NEI reporting sites and 2 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 1 reporting site, with the remainder of TRI sites mapped to this OES reporting 0 land releases. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness

<b>OES</b> <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. An additional strength is that the data set includes 21 DMR reporting sites and 1 TRI reporting site which adds variability to the assessment. The remaining TRI sites mapped within this OES reported 0 water releases. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and DMR may not capture all relevant sites.
	Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robust confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Textile finishing	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g) and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 9 NEI reporting sites and 2 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	All TRI sites within this OES reported 0 land releases. EPA did not have additional sources to estimate land releases from this OES. There is uncertainty if all sites within this OES that are not captured by TRI have 0 land releases. While some facilities report 0 releases, others do not report if below the reporting threshold. EPA's procedure for calculating central tendency and high end release estimates, including the treatment of reporting of 0 releases, are described in the note below this table.
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. The primary limitation is that the water release assessment is based on 1 reporting site under DMR and 1 reporting site under TRI. The remaining TRI sites mapped within this OES reported 0 water releases. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the limitations in representativeness to all sites because TRI and DMR may not capture all relevant sites.
	Due to the low number of reporting facilities across all media, EPA has concluded that the weight of scientific evidence for this assessment provides slight confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
Fabrication and final use of products or	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g) and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 13 NEI reporting sites and 3 TRI reporting sites which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases and the

<b>OES</b> <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
articles	limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	All TRI sites within this OES reported 0 land releases. EPA did not have additional sources to estimate land releases from this OES. There is uncertainty if all sites within this OES that are not captured by TRI have 0 land releases.
	All TRI sites reported 0 water releases, and no DMR facilities were mapped to this OES. EPA did not have additional sources to estimate water releases from this OES. There is uncertainty if all sites within this OES that are not captured by TRI have 0 water releases.
	Based on the limited release information for 1 medium (land) combined with the inherent uncertainty that the programmatic data for land and water releases is sufficiently representative of all facilities covered by this COU, EPA has concluded that the weight of scientific evidence for this assessment is slight.
Use of dyes, pigments, and fixing agents	No TRI and NEI facilities were mapped within this OES. EPA did not have additional sources to estimate air or land releases from this OES.
	Water releases are assessed using reported releases from 2017–2022 DMR (U.S. EPA, 2022c). The primary strength of DMR data is that DMR compiles the best readily available water release data for all reporting facilities. The primary limitation is that the water release assessment is based on 5 reporting sites under DMR. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because DMR may not capture all relevant sites, and EPA did not have additional sources to estimate water releases from this OES.
	Based on the limited programmatic release information for 1 medium (DMR data for water releases) combined with the lack of programmatic release data for land and air ( <i>i.e.</i> , no TRI or NEI facilities were mapped within this OES), EPA has concluded that the weight of scientific evidence provides slight confidence in the estimate of releases for this OES.
Formulations for diffusion bonding	Air releases are assessed using reported releases from 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in other databases due to reporting thresholds. The primary limitation is that the air release assessment is based on 13 reporting sites under NEI. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because NEI may not capture all relevant sites, and EPA did not have additional sources to estimate air releases from this OES.
	All TRI sites within this OES reported 0 land releases. EPA did not have additional sources to estimate land releases from this OES. There is uncertainty if all sites within this OES that are not captured by TRI have 0 land releases.
	Water releases are assessed using reported releases from 2017–2022 DMR (U.S. EPA, 2022c). The primary strength of DMR data is that DMR compiles the best readily available water release data for all reporting facilities. The primary limitation is that the water release assessment is based on 1 reporting site under DMR. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because DMR may not capture all

<b>OES</b> <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	relevant sites, and EPA did not have additional sources to estimate water releases from this OES.
	Based on a limited number of reporting sites for water (1 DMR site reporting) and the lack of reporting sites for land, EPA has concluded that the weight of scientific evidence provides slight confidence in the estimate of releases for this OES.
Use of laboratory chemicals	EPA identified 2 DMR facilities reporting water releases and 4 NEI facilities reporting air releases of DEHP; however, EPA determined this data is not sufficient to capture the entirety of environmental releases for this scenario. Therefore, EPA assessed releases to the environment using the Draft GS on the Use of Laboratory Chemicals, which has a high data quality rating based on systematic review (U.S. EPA, 2023g). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment and media of release using assumptions from the GS and EPA/OPPT models for solid and liquid DEHP lab materials. EPA believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA used SDSs from identified laboratory DEHP products to inform product concentration and material states.
	EPA believes the primary limitation to be the uncertainty in the representativeness of values toward the true distribution of potential releases. In addition, EPA lacks data on DEHP laboratory chemical throughput and number of laboratories; therefore, EPA based the number of laboratories and throughput estimates on stock solution throughputs from the Draft GS on the Use of Laboratory Chemicals and on CDR reporting thresholds. Additionally, because no entries in CDR indicate a laboratory use case and there were no other sources to estimate the volume of DEHP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold, which is expected to result in a release estimate that likely exceeds highest release in the full distribution of facilities covered by this OES.
	Due to the high-end bounding estimate, EPA concludes that the weight of scientific evidence provides moderate confidence in the accuracy of the release estimate for this OES. However, EPA has confidence that the estimates encompass the entire OES due to the high-end bounding release estimates.
Use of automotive care products	EPA identified 1 DMR facility reporting water releases of DEHP; however, EPA determined this data is not sufficient to capture the entirety of environmental releases for this scenario. Therefore, EPA assessed releases to the environment using the Automotive Detailing Methodology Review Draft (MRD), which has a high data quality rating based on systematic review (U.S. EPA, 2022b). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment, and media of release using assumptions from the MRD and EPA/OPPT models for paste/liquid DEHP automotive care product materials. EPA believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA used SDSs from identified automotive detailing products to inform product concentration and material states.
	EPA believes the primary limitation to be the uncertainty in the representativeness of values toward the true distribution of potential releases. In addition, EPA lacks data on DEHP automotive detailing throughput and number of sites; therefore, EPA based the

OES <sup>a</sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	number of sites and throughput estimates on total number of automotive detailing sites known to operate and use rate of product used per car provided by the Automotive Detailing MRD. Additionally, because no entries in CDR indicate an automotive detailing case and there were no other sources to estimate the volume of DEHP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold, which is expected to result in a release estimate that likely exceeds highest release in the full distribution of facilities covered by this OES.
	Due to the high-end bounding estimate, EPA concludes that the weight of scientific evidence provides moderate confidence in the accuracy of the release estimate for this OES. The accuracy is based on EPA's incorporation of the number of use sites, product use rate, and SDS for automotive detailing products from the Automotive Detailing MRD, which was rated high quality, and EPA used these empirical data as inputs for Monte Carlo modeling to generate a full distribution of release estimates. No data were available in CDR to estimate the volume of DEHP used in this OES, so we used the CDR reporting threshold for this parameter, which is the only factor that contributes to the estimate representing an upper bound. However, EPA has confidence that the estimates encompass the entire OES due to the high-end bounding release estimates.
Use in hydraulic fracturing	EPA found limited chemical specific data for the use in hydraulic fracturing OES and assessed releases to the environment using the Draft ESD on Chemicals Used in Hydraulic Fracturing and FracFocus 3.0, which has a high data quality rating based on systematic review (U.S. EPA, 2023g; GWPC and IOGCC, 2022). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment, and media of release using assumptions from the ESD and EPA/OPPT models for liquid DEHP formulations. EPA believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA used FracFocus distributions from identified DEHP products to inform product concentration and material states.
	EPA believes the primary limitation to be the uncertainty in the representativeness of values toward the true distribution of potential releases. Additionally, the Agency lacks data on DEHP hydraulic fracturing throughput and number of sites; therefore, EPA based the number of sites and throughput estimates on FracFocus Data.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of releases, considering the strengths and limitations of reasonably available data.
Recycling	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. The primary limitation is that the air release assessment is based on 1 reporting site under TRI. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate air releases from this OES.
	The singular TRI site within this OES reported 0 land and water releases. No DMR and NEI facilities were mapped within this OES. EPA did not have additional sources to estimate water or land releases from this OES.

<b>OES</b> <sup><i>a</i></sup>	Weight of Scientific Evidence Conclusion in Release Estimates
	Based on this information, EPA has concluded that the weight of scientific evidence for this assessment is slight yet provides a plausible estimate of releases in consideration of the strengths and limitations of reasonably available data.
Waste handling, treatment, and disposal	<i>General Waste Handling, Treatment, and Disposal</i> Air releases for non-POTW sites are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2022g), and 2017 and 2020 NEI (U.S. EPA, 2023a). A strength of NEI data is that NEI captures additional sources that are not included in TRI due to reporting thresholds. An additional strength is that the data includes 514 NEI reporting sites and 21 TRI reporting sites which adds variability to the assessment. Factors that decrease the confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites.
	Land releases for non-POTW are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 7 reporting sites, with the remainder of TRI sites mapped to this OES reporting 0 land releases. Oth factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate land releases from this OES.
	Water releases for non-POTW sites are assessed using reported releases from 2017–2022 TRI and DMR (U.S. EPA, 2014a). The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. For non-POTW sites, the primary limitation is that the water release assessment is based on 1 reporting site under TRI and 1 reporting site under DMR. The remaining TRI sites mapped within this OES reported 0 water releases. Other factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites becaus TRI and DMR may not capture all relevant sites.
	Based on this information, EPA has concluded that the weight of scientific evidence for this assessment provides moderate to robus confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.
	<i>Waste Handling, Treatment, and Disposal (POTW and Remediation)</i> Water releases for POTW and remediation sites are assessed using reported releases from 2017–2022 DMR (U.S. EPA, 2022c), which has a medium overall data quality determination from the systematic review process. A strength of using DMR data and the Pollutant Loading Tool used to pull the DMR data is that the tool calculates an annual pollutant load by integrating monitoring period release reports provided to the EPA and extrapolating over the course of the year. However, this approach assumes average quantities, concentrations, and hydrologic flows for a given period are representative of other times of the year. Based on this information, for POTW releases, EPA has concluded that the weight of scientific evidence provides moderate confidence in the estimate of releases in consideration of the strengths and limitations of reasonably available data.

with programmatic data. For databases with 6 or more reporting facilities, EPA estimated central tendency and high-end releases using the 50th and 95th

## OES<sup>a</sup> Weight of Scientific Evidence Conclusion in Release Estimates

percentile values, respectively. For 3–5 facilities, EPA estimated the central tendency and high-end releases using the 50th percentile and maximum values, respectively. For 2 sites, EPA presented the midpoint and the maximum value. Finally, EPA presented sites with only 1 data point as-is from the programmatic database. It is important to note that when the reported maximum value for a given facility indicates 0 releases, these values are included in the calculation of 50th and 95th percentile for each OES.

## 11633.2.3Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the1164Environmental Release Assessment

#### 1165 Strengths

1166 EPA compiled release information using reported releases from the 2017 through 2022 TRI (U.S. EPA, 1167 2022g), 2017 through 2022 DMR (U.S. EPA, 2022c), and 2017 through 2020 NEI (U.S. EPA, 2022e). 1168 TRI, DMR, and NEI data were determined to have a high data quality rating through EPA's systematic 1169 review process. Furthermore, TRI-reporting facilities are required to submit their "best available data" to 1170 EPA for TRI reporting purposes. Some facilities are required to measure or monitor emission or other 1171 waste management quantities due to regulations unrelated to the TRI Program (e.g., permitting 1172 requirements), or due to company policies. These existing, reasonably available data are often used 1173 by facilities for TRI reporting purposes, as they represent the best available data (e.g., stack releases can be directly measured by stack testing using EPA reference methods, providing a directly measured 1174 1175 emission rate which can then be used to calculate annual emissions). 1176

- NEI does not require stack testing or continuous emissions monitoring, and reporting agencies may use different emission estimation methods. These reasonable estimates may be obtained through various release estimation techniques, including continuous emissions monitoring, stack testing, mass-balance calculations, the use of emission factors, and engineering calculations.
- 1181

#### 1182 Limitations

1183 When monitoring or direct measurement data are not reasonably available or are known to be non-1184 representative for TRI reporting purposes, the TRI regulations require that facilities determine release and other waste management quantities of TRI-listed chemicals by making reasonable estimates. For 1185 1186 each release quantity reported, TRI facilities select a "Basis of estimate" code indicating the principal 1187 method used to determine the amount of the release. TRI provides six basis of estimate codes to choose 1188 from: continuous monitoring, periodic monitoring, mass balance, published emissions factors, site-1189 specific emissions factors, or engineering calculations/best engineering judgment. In facilities where a 1190 chemical is used in multiple operations, the facility may use a combination of methods to calculate the 1191 release reported. In such cases, TRI instructs the facility to enter the basis of estimate code of the 1192 method that applies to the largest portion of the release quantity. Additional details on the basis of 1193 estimate, such as any calculations and underlying assumptions, are not reported.

1193

1195 Facilities are only required to report to TRI if the facility has 10 or more full-time employees, is 1196 included in an applicable NAICS code, and manufactures, processes, or uses the chemical in quantities 1197 greater than a certain threshold (25,000 lb for manufacturers and processors and 10,000 lb for users). For 1198 NEI, the Air Emissions Reporting Requirements (AERR) only requires Criteria Air Pollutants and 1199 Precursors (CAP) data reporting, Hazardous Air Pollutant (HAP) data reporting is voluntary. As a result, 1200 EPA augments State/Local/Tribal (SLT)-provided HAP data with other information to better estimate 1201 point, nonpoint, and mobile source HAP emissions. For point sources, HAP augmentation is performed 1202 on each emissions source using the WebFIRE database or data from TRI. DMR data are submitted by 1203 National Pollutant Discharge Elimination System (NPDES) permit holders to states or directly to the 1204 EPA according to the monitoring requirements of the facility's permit. States are only required to load 1205 major discharger data into DMR and may or may not load minor discharger data. The definition of 1206 major vs. minor discharger is set by each state and could be based on discharge volume or facility size. 1207 Due to these limitations across programs, some sites may release DEHP but are not included in TRI, 1208 NEI, or DMR. It is uncertain the extent to which sites not captured in these databases release DEHP into 1209 the environment, or whether releases are to water, air, or landfill.

1211 Manufacturers and importers of DEHP submit CDR data to EPA if they meet reporting threshold

requirements. Sites are only required to load production data into CDR if their yearly production volume exceeds 25,000 lb. Sites can claim their production volume as CBI, further limiting the production

1214 volume information in CDR. As a result, some sites that produce or use DEHP may not be included in

1215 the CDR dataset and the total production volume for a given OES may be under or overestimated due to

- 1216 the absence of these sites in the universe of CDR reporters. The extent to which sites that are not
- 1217 captured in the CDR report releases of DEHP into the environment is unknown. The media of release for
- 1218 these sites is also unknown.
- 1219

### 1220 Assumptions and Uncertainties

1221 There is some uncertainty in the DMR data pulled using the ECHO Pollutant Loading Tool Advanced 1222 Search option. The average measurements may be reported as a quantity (kg/day) or a concentration 1223 (mg/L). Calculating annual loads from concentrations requires adding wastewater flow to the equation, 1224 which increases the uncertainty of the calculated annual load. In addition, for facilities that reported 1225 having zero pollutant loads to DMR, the EZ Search Load Module uses a combination of setting non-1226 detects equal to zero and as one-half the detection limit to calculate the annual pollutant loadings; if all 1227 values reported for a facility are non-detects, the loading tool sets the value to zero; and for facilities 1228 reporting some values above zero, the non-detects are set to one-half the detection limit. A strength of 1229 using DMR data and the Pollutant Loading Tool is that the tool calculates an annual pollutant load by 1230 integrating monitoring period release reports provided to the EPA and extrapolating over the course of 1231 the year. However, this approach assumes average quantities, concentrations, and hydrologic flows for a 1232 given period are representative of other times of the year.

1232

There is additional uncertainty in daily release estimates for air emissions. Facilities reporting to TRI and NEI report annual air emissions; to assess daily air emissions, EPA assumed a continuous value of S65 release days, 24/7 and averaged the annual releases over these days. Some sites do not operate yearround; therefore, the actual average daily releases may be higher if sites operate for fewer days than 365.

1238

For the characterization of releases per COU, EPA developed an approach to streamline analysis using the facility's primary NAICS code. The primary NAICS code corresponds to the primary economic activity at that facility. This approach does not rely on the TRI use codes or NEI SCC codes, which EPA views as a higher tier characterization. For TRI, a facility can also provide additional NAICS codes. Some sites are multi-use complexes where the activity of DEHP may not be best represented by the primary NAICS code. There is some uncertainty if a site's primary NAICS code will assign it to the appropriate COU.

1246

1247 CDR information on the downstream use of DEHP at facilities is also limited; therefore, there is some 1248 uncertainty as to the production volume attributed to a given OES. For OES with limited CDR data, 1249 EPA developed potential production volumes given reported CDR data and known reporting thresholds 1250 for DEHP in 2020. To handle an OES without programmatic data, EPA used the potential production 1251 volume ranges as uniform distributions in Monte Carlo modeling when assessing releases for each OES. 1252 Due to the wide range of potential production volumes attributable to certain OES, the overall releases 1253 may be over or underestimated. DEHP releases at each site may vary from day to day, such that on any 1254 given day the actual daily release rate may be higher or lower than the estimated average daily release 1255 rate.

1256

The EPA has further identified the following additional uncertainties that contribute to the overalluncertainty in the environmental release assessment:

- Use of Census Bureau for Number of Facilities: In some cases, EPA estimated the maximum number of facilities for a given OES using data from the U.S. Census. In such cases, EPA determined the maximum number of sites for use in Monte Carlo modeling from industry data from the U.S. Census Bureau, County and Business Patterns dataset (U.S. Census Bureau, 2022).
- Uncertainties Associated with Facility Throughputs: EPA estimated facility throughputs of DEHP or DEHP-containing products using various methods, including using generic industry data presented in the relevant GS or ESD or by calculation based on estimated number of facilities and overall production volume of DEHP from CDR for the given OES. In either case, the values used for facility throughputs may encompass a wide range of possible values. Due to these uncertainties, the facility throughputs may be under or overestimated.
- Uncertainties Associated with Number of Release Days Estimate: For most OES, EPA
   estimated the number of release days using programmatic data where available, or from GSs,
   ESDs, or SpERC factsheets when no programmatic data are found. In such cases, EPA used
   applicable sources to estimate a range of release days over the course of an operating year. Due
   to uncertainty in DEHP-specific facility operations, release days may be under or overestimated.
- Uncertainties Associated with DEHP-Containing Product Concentrations: In most cases, the number of identified products for a given OES were limited. In such cases, EPA estimated a range of possible DEHP concentrations for products in the OES. However, the extent to which these products represent all DEHP-containing products within the OES is uncertain. For OES with little-to-no product data, EPA estimated DEHP concentrations from GSs or ESDs. Due to these uncertainties, the average product concentrations may be under or overestimated.

## **3.3 Summary of Concentrations of DEHP in the Environment**

1282 Based off the environmental release assessment summarized in Section 3.2 and detailed in EPA's Draft 1283 Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (U.S. EPA, 1284 2025r), DEHP is expected to be released to the environment via air, water, biosolids, and disposal to landfills. Environmental media concentrations were quantified in ambient air, soil from ambient air 1285 deposition, sediment, and surface water. Additional analysis of surface water used as drinking water was 1286 1287 conducted for the Human Health Risk Assessment (Section 4). Given limited available information on 1288 DEHP in soil and groundwater from releases to biosolids and landfills, along with the availability of 1289 high-quality physical and chemical and fate data (Section 2), concentrations of DEHP in soil and 1290 groundwater from releases to biosolids and landfills were not quantified (discussed further below). 1291

EPA relied on its fate assessment to determine which environmental pathways to consider for its screening level analysis of environmental exposure and general population exposure to environmental releases. Details on the environmental partitioning and media assessment can be found in *Draft Physical Chemistry Assessment and Fate and Transport for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2024h).

- Briefly, based on DEHP's fate parameters (*e.g.*, Henry's Law constant, log K<sub>OC</sub>, water solubility, fugacity modeling), EPA anticipated DEHP to be predominantly in water, soil, and sediment though
- 1297 DEHP may also exist in air since it is released to air. Therefore, the Agency quantitatively assessed
- 1299 concentrations of DEHP in surface water, sediment, ambient air, and soil from air to soil deposition. Soil
- 1300 concentrations of DEHP from land applications were not quantitatively assessed in the screening level
- 1301 analysis as DEHP was expected to have limited persistence potential and mobility in soils receiving
- 1302 biosolids. To contrast, EPA has greater confidence in quantifying DEHP concentrations in soil resulting
- 1303 from air to soil deposition because it is direct deposition into soil rather than mobility from air to soil (as

with biosolids). Therefore, EPA quantified air to soil deposition with a screening level approach for thepurpose of the environmental exposure assessment.

1306

1307 Further detail on the screening-level assessment of each environmental pathway can be found in EPA's

1308 Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl

- 1309 *Phthalate (DEHP)* (U.S. EPA, 2025q). EPA began its environmental and general population exposure
- assessment with a screening-level approach using high-end environmental media concentrations for the environmental pathways expected to be of greatest concern. The high-end environmental media
- 1311 environmental pathways expected to be of greatest concern. The high-end environmental media 1312 concentrations were estimated using the release estimates for an OES that, when combined with
- 1313 conservative assumptions of environmental conditions, resulted in the greatest modeled concentration of
- 1314 DEHP in a given environmental media. Therefore, EPA did not estimate environmental concentrations
- 1315 of DEHP resulting from all OES presented in Table 3-1. The OESs resulting in the highest
- 1316 environmental concentration of DEHP varied by environmental media as shown in Table 3-7.
- 1317
- 1318 Details on the use of screening-level analyses in exposure assessment can be found in EPA's *Guidelines*
- 1319 *for Human Exposure Assessment* (U.S. EPA, 2019c). The summary table (Table 3-7) also indicates
- 1320 whether the highest estimate was used for environmental exposure assessment or general population
- 1321 exposure assessment.
- 1322

For the water pathway, different hydrological flow rates were used for the different screening level 1323 1324 exposure scenarios. The 30Q5<sup>1</sup> flows (lowest 30-day average flow that occurs in a 5-year period) are used to estimate acute, incidental human exposure through swimming or recreational contact. The 1325 harmonic mean<sup>2</sup> flows provide a more conservative estimate as compared to annual average flows and 1326 1327 are therefore preferred for assessing potential chronic human exposure via drinking water. The harmonic 1328 mean is also used for estimating human exposure through fish ingestion because it takes time for 1329 chemical concentrations to accumulate in fish. Lastly, for aquatic or ecological exposure, a  $7Q10^3$  flow 1330 (lowest 7-day average flow that occurs in a 10-year period) is used to estimate exceedances of

1331 concentrations of concern for aquatic life (U.S. EPA, 2007b).

1332

1333 For the screening level assessment, EPA identified the Plastic compounding OES as yielding the highest water concentrations using a 7Q10 flow, and 30Q5 flow, and the Use of laboratory chemicals OES as 1334 1335 yielding the highest water concentrations using a harmonic mean (Table 3-7). As described in further 1336 detail in the Draft Environmental Media and General Population and Environmental Exposure for 1337 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q) and in Section 3.3.1.1, EPA estimated the surface 1338 water concentration for Plastic compounding OES using TRI annual release reports. EPA selected a 1339 single facility reporting the highest release value for the Plastic compounding OES for the purpose of 1340 screening. The Use of laboratory chemicals OES relied on modeled release estimates (generic scenarios) 1341 due to a lack of reporting of releases to the TRI and DMR systems. The highest end of the estimated

 $<sup>^{1}</sup>$  30Q5 is defined as 30 consecutive days of lowest flow over a 5-year period. These flows are used to determine acute human exposures via drinking water and incidental surface water exposure via swimming .

<sup>&</sup>lt;sup>2</sup> Harmonic mean is defined as the inverse mean of reciprocal daily arithmetic mean flow values. These flows represent a long-term average and are used to generate estimates of chronic human exposures via drinking water and fish ingestion.

 $<sup>^{3}</sup>$  7Q10 is defined as 7 consecutive days of lowest flow over a 10-year period. These flows are used to calculate estimates of chronic surface water concentrations to compare with the COCs for aquatic life .

release concentrations from the generic scenario distribution were used for the purpose of screening for the harmonic mean flow scenarios (*e.g.*, chronic drinking water and fish ingestion).

1344

1345 The maximum daily release value for fugitive releases for DEHP used to model ambient air

1346 concentrations was 8.85 kg/site-day. This value was reported to the 2020 NEI dataset and categorized

1347 under the Plastic converting OES as fugitive releases. The maximum daily release value for stack

1348 releases for DEHP used to model ambient concentrations was 36.23 kg/site-day. This value was reported

- to the 2017 NEI dataset and categorized under the Application of paints, coatings, adhesives, and
- sealants OES as stack releases. Although the maximum releases for each release type are from different
- facilities in different locations and different OES, for this assessment EPA assumes the releases occurred from the same location at the same time under the same OES to determine a "total exposure" to DEHP
- from the same location at the same time under the same OES to determine a "total exposure" to DEHP from both release types. This approach may overestimate ambient concentrations of DEHP at the
- 1354 distances evaluate since exposures to each release type at the distances evaluated cannot occur at a
- 1355 single location at the same time.
- 1356

1357 For the surface water and ambient air pathways, only the OESs resulting in the highest estimated water 1358 column or ambient air concentrations were carried forward to the environmental and human health risk 1359 assessment (*i.e.*, plastic compounding for water and application of paints, coatings, adhesives, and 1360 sealants for ambient air). For the screening level analysis, if the highest environmental media 1361 concentrations did not result in potential environmental or human health risk, no further OESs were 1362 assessed, and no further refinements were pursued. Section 4.1.3 and Section 5.1 discusses the use of the various environmental media concentration presented in Table 3-7 for general population exposure and 1363 1364 environmental exposure, respectively. No refinements were needed for general population risk as 1365 described in Section 4.1.3, but additional refinements were needed for environmental risk that are 1366 discussed in Section 5.3.

1368	Table 3-7. Summary of Highest DEHP Concentrations in Various Environmental Media from
1369	Environmental Releases

OES <sup>a</sup>	Release Media	Environmental Media	<b>DEHP</b> <b>Concentration</b> <sup>b</sup>	Environmental or General Population
Plastic		Total water column (7Q10) <sup><i>c</i></sup>	16 µg/L	Environmental
compounding	Water	Benthic pore water (7Q10) <sup>c</sup>	7.98 µg/L	Environmental
		Benthic sediment (7Q10) <sup>c</sup>	83,800 µg/kg	Environmental
Plastic compounding	Water	Surface water (30Q5) <sup>d</sup>	10.3 μg/L	General Population
Use of laboratory chemicals <sup>f</sup>	Water	Surface water (harmonic mean) <sup>e</sup>	5.92 μg/L	General Population
Plastic converting (fugitive)		Total daily-average concentration (Sum: fugitive and stack, 100 m)	23.23 μg/m <sup>3</sup>	Canonal Demulation
Application of paints, coatings, adhesives, and sealants (stack) Ambient air		Total annual-average concentration (Sum: fugitive and stack, 100 m)	18.50 µg/m <sup>3</sup>	General Population

OES <sup>a</sup>	Release Media	Environmental Media	<b>DEHP</b> <b>Concentration</b> <sup>b</sup>	Environmental or General Population
Plastic Converting (fugitive)		Total annual deposition rate (Sum: fugitive and stack, 100m)	10	Environmental and General Population
Application of Paints, coatings, adhesives, and sealants (stack)	Ambient Air			

<sup>*a*</sup> Table 3-1 provides the crosswalk of OES to COUs.

<sup>b</sup> DEHP concentrations in environmental media were modeled using data on actual releases determined from programmatic databases (TRI, DMR, and NEI) when available.

 $^{c}$  7Q10 is the 7 consecutive days of lowest flow over a 10-year period.

<sup>d</sup> 30Q5 is defined as 30 consecutive days of lowest flow over a 5-year period.

<sup>e</sup> Harmonic mean is defined as the inverse mean of reciprocal daily arithmetic mean flow values. These flows represent a long-term average.

<sup>f</sup>Surface water concentration associated with Use of laboratory chemicals was modeled using release estimates from generic scenarios.

#### 1370 **3.3.1 Weight of Scientific Evidence Conclusions**

Detailed discussion of the strengths, limitations, and sources of uncertainty for modeled environmental
 media concentration leading to a weight of scientific evidence conclusion can be found in EPA's *Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate* (*DEHP*) (U.S. EPA, 2025q). However, the weight of scientific evidence conclusion is summarized
 below for the modeled concentrations for surface water and ambient air.

1376

For the screening level assessment, EPA used the release estimates presented in Table 3-5 to model
DEHP concentrations in different environmental media. The Agency considers additional variables
when considering the weight of scientific evidence for its estimation of environmental media
concentrations. Some additional considerations include the use of an additional model using the release
as an input, the applicability of the release data to the environmental media being considered, likelihood
of an occurrence of a release to the specific environmental compartment, and available monitoring data.

These considerations are largely discussed for surface water and ambient air within the proceeding
sections 3.3.1.1 and 3.3.1.2, respectively. Additional information is provided within the EPA's *Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate*

1386 (DEHP) (<u>U.S. EPA, 2025q</u>).

#### 1387 **3.3.1.1 Surface Water**

For the screening level assessment, EPA utilized releases associated with the Plastic compounding OES and the Use of laboratory chemicals OES, as these resulted in the highest modeled surface water concentrations. EPA determined the surface water concentration associated with these OESs represented conservative high-end exposure scenarios and were appropriate to use in its screening level assessment to assess all other OESs and their associated COUs.

1393

1394 EPA utilized daily release information to estimate surface water concentrations for use in general

1395 population and environmental exposure assessment. As mentioned in Section 3.2, EPA estimated a

1396 range for daily releases for each OES when possible. The Agency was not able to estimate site-specific

releases for the final use of products or articles OES. Disposal sites handling post-consumer end-use

1398 DEHP were not quantifiable due to the wide and dispersed use of DEHP in PVC and other products.

1399 Pre-consumer waste handling, treatment, and disposal are assumed to be captured in upstream OES.

1400 Many OES had releases estimated using programmatic data. EPA compiled programmatic release 1401 information using reported releases from TRI, DMR, and NEI, which were determined to have a high

- 1402 data quality rating through EPA's systematic review process and a weight of scientific evidence
- 1403 conclusion of moderate to robust across releases for the various OESs as shown in Table 3-6. One
- 1404 limitation noted was that it is uncertain the extent to which sites not captured in these databases release
- 1405 DEHP into the environment. Additionally, not all OESs are represented in these databases.
- 1406

1407 Table 3-8 below identifies the data available for use in modeling surface water concentrations for each 1408 OES and EPA's confidence in the estimated surface water concentrations used for exposure assessment. 1409 For the screening level assessment, EPA identified the OES (Plastic compounding) that resulted in the 1410 highest surface water concentrations, highlighted in the table below, to assess exposure. EPA prioritized 1411 use of programmatic data with actual release data from reporting facilities, where overall confidence in 1412 the estimates would be higher. For estimating concentrations from releases, EPA also prioritized the use 1413 of TRI annual release reports over DMR monitoring data, reviewing DMR period data as supporting 1414 information for the releases reported to TRI. Releases from facilities reporting via TRI Form A, which 1415 represents undefined releases to unspecified media types, less than 500 lb per year, were not directly 1416 modeled. For the purpose of the tiered approach taken for the general population analysis, environmental 1417 concentrations from potential releases to surface water from facilities reporting via TRI Form A were 1418 expected to be lower than the high-end concentrations applied for screening.

1419

For facilities reporting releases to TRI, relevant flow data from the associated receiving waterbody were collected by querying multiple EPA databases and permit IDs under the National Pollutant Discharge Elimination System (NPDES). The flow data include self-reported hydrologic reach codes on NPDES permits and the best available flow estimates from EPA and USGS databases. Other model inputs were derived from reasonably available literature collected and evaluated through EPA's systematic review process for TSCA risk evaluations. All monitoring and experimental data included in this analysis were from articles rated "medium" or "high" quality from this process.

1427

1428 For OESs that did not have reported release data, releases were estimated using GSs/ESDs. For releases 1429 that use GSs/ESDs, EPA concluded the weight of scientific evidence conclusion was moderate. Three 1430 OESs (Use of laboratory chemicals, Use of automotive care products, and Use in hydraulic fracturing) 1431 had modeled releases from generic scenarios for the following types of discharge: surface water; water, 1432 incineration, or landfill; and POTW or landfill. For the releases categorized as releasing to multiple 1433 media types, EPA could not differentiate the proportion of DEHP released only to surface water. For 1434 these generic scenario OESs, there was insufficient data precision to quantify estimated releases specifically to surface water. Therefore, EPA performed quantitative estimation of conservative high-1435 1436 end surface water concentrations and exposures for the Use of laboratory chemicals and Use of 1437 automotive care products OESs, applying the assumption that the entirety of the estimated multimedia 1438 release is directed to surface water. Due to the low confidence and high uncertainty inherent in assuming 1439 what portion of a release may be discharged to surface water, EPA would have slight confidence in risks 1440 identified through this method, but greater confidence in a finding that these conservative estimates did 1441 not show risk in excess of a benchmark and the Agency is confident that the screening analysis 1442 overestimates risk. For the Use in hydraulic fracturing OES, where releases were estimated based on 1443 generic scenario specifically to surface water, the surface water concentrations were lower than the 1444 highest water concentration associated with the Plastic compounding used in the screening level 1445 assessment.

1446

1447 Based on the weight of scientific evidence conclusions regarding confidence in the release estimates 1448 from facilities and the associated receiving waterbody and hydrologic flow information described in the

preceding paragraphs, EPA proceeded with the use of TRI data for modeling surface water
 concentrations. In considering the various OESs for use in a screening assessment, EPA identified the

- 1451 Plastic compounding OES as most appropriate as it resulted in the highest surface water concentration
- based on reporting data for actual facilities. Additionally, release concentrations were estimated at the point of release in the receiving waterbody, as a conservative assumption to evaluate the upper end of
- point of release in the receiving waterbody, as a conservative assumption to evaluate the upper end potential exposure concentrations for a given release. Overall, EPA has robust confidence that the
- 1455 highest estimated surface water concentration modeled using the Plastic compounding OES is
- 1456 appropriate to use in its screening level assessment of the general population surface water exposure
- 1457 pathway, as the releases from all other OESs and their associated COUs (including OESs and COUs
- 1458 with releases that could not be quantified and those with releases modeled from generic scenarios) are
- expected to result in lower environmental concentrations in surface water. General population and environmental risk from surface water can be found in Sections 4.3.4 and 5.3.2, respectively.
- 1460 1461

OES <sup>a</sup>	Water Release Data Type(s)	Weight of Scientific Evidence
Manufacture	TRI	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DEHP. PSC inputs include physical and chemical properties of DEHP which received a high confidence rating and a reported DEHP release from TRI which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Rubber manufacturing	TRI	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DEHP. PSC inputs include physical and chemical properties of DEHP which received a high confidence rating and a reported DEHP release from TRI which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Plastic converting	TRI	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DEHP. PSC inputs include physical and chemical properties of DEHP which received a high confidence rating and a reported DEHP release from TRI which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Plastic compounding <sup>b</sup>	TRI	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DEHP. PSC inputs include physical and chemical properties of DEHP which received a high confidence rating and reported DEHP releases from TRI which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust. This OES resulted in the highest surface water concentration used for screening purposes.
Incorporation into formulation, mixture, or reaction product	TRI	All reported releases to TRI within this OES were via Form A. Due to EPA's high confidence that such releases to surface water, if present, would not exceed the highest releases applied for screening, no quantitative estimate of surface water release concentrations was calculated for this OES.

#### 1462 Table 3-8. Summary of Weight of Scientific Evidence Associated with Each OES

OES <sup>a</sup>	Water Release Data Type(s)	Weight of Scientific Evidence
Repackaging	TRI	All reported releases to TRI within this OES were via Form A. Due to EPA's high confidence that such releases to surface water, if present, would not exceed the highest releases applied for screening, no quantitative estimate of surface water release concentrations was calculated for this OES.
Application of paints, coatings, adhesives, and sealants	DMR	No reported releases to TRI, and review of DMR period data demonstrated lower release concentrations than highest releases applied for screening. Due to limited annual data and low reported concentrations in effluent, no quantitative estimate of surface water release concentrations was calculated for this OES.
Textile finishing	TRI/DMR	One TRI facility reported no surface water discharge, and review of DMR period data demonstrated lower release concentrations than highest releases applied for screening. Due to limited annual data and low reported concentrations in effluent, no quantitative estimate of surface water release concentrations was calculated for this OES.
Use of dyes and pigments, and fixing agents	DMR	No reported releases to TRI, and review of DMR period data demonstrated lower release concentrations than highest releases applied for screening. Due to limited annual data and low reported concentrations in effluent, no quantitative estimate of surface water release concentrations was calculated for this OES.
Application of paints, coatings, adhesives, and sealants (formulations for diffusion bonding)	DMR	No reported releases to TRI, and review of DMR period data demonstrated lower release concentrations than highest releases applied for screening. Due to limited annual data and low reported concentrations in effluent, no quantitative estimate of surface water release concentrations was calculated for this OES.
Use of laboratory chemicals <sup>c</sup>	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because EPA was unable to model releases to just surface water, EPA performed a conservative analysis in which the total estimated multimedia release amount was assumed to be discharged to surface water. For this scenario, EPA included the resulting concentrations in the high-end screening analysis, with slight confidence in any subsequent risk identified, but robust confidence in the value being representative of an upper bound of potential exposure from these releases.
Use of automotive care products	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because EPA was unable to model releases to just surface water, EPA performed a conservative analysis in which the total estimated multimedia release amount was assumed to be discharged to surface water. For this scenario, the modeled release concentrations were less than the highest releases applied for screening.
Use in hydraulic fracturing	Generic Scenario (water-specific)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Sufficient release data were available to model a surface water-specific release, and the resulting range of estimated concentrations were below the highest releases applied for screening.
Recycling	TRI	Within this OES, only one facility reported to TRI, claiming zero release to surface water. No quantitative estimate of surface water

OES <sup>a</sup>	Water Release Data Type(s)	Weight of Scientific Evidence
		release concentrations was calculated for this OES.
Waste handling, treatment, and disposal	DMR	No reported releases to TRI, and review of DMR period data demonstrated lower release concentrations than highest releases applied for screening. Due to limited annual data and low reported concentrations in effluent, no quantitative estimate of surface water release concentrations was calculated for this OES.

DMR = Discharge Monitoring Report; OES = occupational exposure scenario; PSC = point source calculator (tool); TRI = Toxics Release Inventory

<sup>*a*</sup> Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

<sup>b</sup> Plastic compounding OES chosen as OES most appropriate for screening level assessment based on high surface water concentrations resulting from facility release

<sup>c</sup> Use of laboratory chemicals OES was chosen as OES most appropriate for screening level assessment for exposure scenarios utilizing harmonic mean concentration.

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1464

# 3.3.1.2 Ambient Air

1465 EPA used the Integrated Indoor-/Outdoor Air Calculator (IIOAC) Model, previously peer-reviewed 1466 methodology for fenceline communities (U.S. EPA, 2022d) and integrated recommendations from that 1467 and other peer reviews to evaluate exposures and deposition rates via the ambient air pathway for this 1468 assessment. The IIOAC Model was developed based on a series of pre-run scenarios within AERMOD 1469 (the Agency's regulatory model) which gives EPA greater confidence in the IIOAC results. However, 1470 since results from IIOAC are based on the pre-run AERMOD scenarios, IIOAC modeling is limited to 1471 the parameters s (e.g., stack parameters, meteorological data, and other factors) used as inputs to those 1472 pre-run AERMOD scenarios, thus limiting the flexibility of the IIOAC results for highly site-specific, or 1473 date specific modeling needs (e.g., if refined analyses are needed). The screening level analyses 1474 presented in this assessment, IIOAC provides reliable and reproduceable results which can be used to 1475 characterize upper-bound exposures and derive screening level risk estimates, giving EPA moderate 1476 confidence in the results and findings.

1477

1478 The Agency considered three different datasets for DEHP releases for this assessment. Those datasets 1479 include EPA estimated releases based on production volumes of DEHP from facilities that manufacture, 1480 process, repackage, or dispose of DEHP (U.S. EPA, 2025r), releases reported to TRI by industry (2017– 1481 2022 reporting years), and releases reported to NEI (U.S. EPA, 2025r) (2017 and 2020 reporting years). 1482 This gives the Agency moderate confidence that release data utilized is representative and high-end 1483 releases are not missed. EPA uses the maximum daily releases of DEHP across all OES/COUs as direct 1484 inputs to the IIOAC Model, giving EPA high confidence that the releases used are health protective for a 1485 screening level analysis. However, the use of estimated or reported annual release data and number of 1486 operating days to calculate daily average releases assumes operations are continuous and releases are the 1487 same for each day of operation. This can underestimate short-term or daily exposure and deposition rates 1488 because results may miss actual peak releases (and associated exposures) if higher and lower releases 1489 occur on different days. The uncertainties associated with the release data are detailed in the Draft 1490 Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (U.S. EPA, 1491 2025r).

1492

1493 The maximum daily fugitive and stack release values used for this ambient air assessment are from NEI 1494 reported datasets (fugitive from 2020 and stack from 2017). Additionally, these releases were reported

by two different facilities in two different locations. Therefore, these two releases do not align either spatially or temporally. For this screening level ambient air assessment EPA modeled these two releases

- 1497 assuming they occurred from the same location, at the same time, during the same reporting year, and 1498 under the same OES to determine a "total exposure" to DEHP from both release types. These 1499 assumptions provide a conservative estimate of "total exposure," ensures possible exposure from either 1500 release type are not missed, and retains health protective estimates of exposure and associated risk 1501 estimates. The lack of spatial or temporal alignment gives the Agency low confidence in the exposure 1502 scenario modeled (cannot occur at same time under assumptions modeled) and overestimates ambient 1503 concentrations and deposition rates at the evaluated distances. Due to the conservative assumptions 1504 made along with the use of the highest release estimates, EPA has robust confidence the modeled 1505 ambient air concentrations and deposition rates are highly conservative estimates appropriate for a 1506 screening level analysis for all OES and associated COUs. Based on the risk findings described in 1507 Section 4.1.3.1. Even with the conservative assumptions and exposure scenario modeled, results indicate the total exposure or deposition rate under this scenario still does not indicate an exposure or risk 1508 1509 concern. Therefore, EPA has robust confidence that exposure to and deposition rates of DEHP via the 1510 ambient air pathway do not pose an exposure or risk concern and no further, refined analysis is pursued. 1511 If new information becomes available and after the Agency's consideration of such information and 1512 results, under the same scenario and assumptions, indicate an exposure or risk concern, then EPA would 1513 have low confidence in the results and refine the analysis to be more representative of a real exposure 1514 scenario (e.g., only determine exposures and derive risk estimates based on a single facility reporting
- 1515 both release types).

# 1516 4 HUMAN HEALTH RISK ASSESSMENT

### DEHP – Human Health Risk Assessment (Section 4): Key Points

EPA evaluated all reasonably available information to support the human health risk characterization of DEHP for workers, ONUs, consumers, bystanders, and the general population. Exposures to workers, ONUs, consumers, bystanders, and the general population are described in Section 4.1. Human health hazards are described in Section 4.2. Human health risk characterization is described in Section 4.3. The following bullets summarize the key points.

### Exposure Key Points

- EPA assessed inhalation and dermal exposures for workers and ONUs, as appropriate, for each OES (Section 4.1.1). Both dermal and inhalation were primary routes of exposure, depending on the OES.
- EPA assessed inhalation, dermal, and oral exposures for consumers and bystanders, as appropriate, for each COU (Section 4.1.2) in scenarios that represent a range of use patterns and behaviors. The primary routes of exposure were ingestion and inhalation for most products, followed by dermal.
- EPA assessed inhalation, oral, and dermal exposures for the general population via ambient air, surface water, drinking water, and fish ingestion for Tribal populations (Sections 4.1.3).
- EPA assessed non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP for the U.S. civilian population using NHANES urinary biomonitoring data and reverse dosimetry (Section 4.4.2).

# Hazard Key Points

- EPA identified effects on the developing male reproductive system as the most sensitive and robust non-cancer hazard associated with oral exposure to DEHP in experimental animal models (Section 4.2).
- A non-cancer point of departure (POD) of 1.1 mg/kg-day was selected to characterize non-cancer risks for acute, intermediate, and chronic durations of exposure. A total uncertainty factor (UF) of 30 was selected for use as the benchmark margin of exposure (MOE).
- DEHP has been shown to cause liver, pancreatic, and testicular cancer in experimental studies of rats or mice; however, these cancers in rodents occurred at higher doses than observed for other non-cancer effects on the developing male reproductive system. Therefore, evaluating and protecting human health from non-cancer risks associated with exposure to DEHP is expected to be protective of cancer effects.
- EPA derived draft relative potency factors (RPFs) based on a common hazard endpoint (*i.e.*, reduced fetal testicular testosterone). Draft RPFs were derived via meta-analysis and benchmark dose (BMD) modeling (Section 4.4.1).

# Risk Assessment Key Points

- Inhalation exposures drive acute non-cancer risks to workers in occupational settings (Section 4.3.2).
- Ingestion and inhalation exposures drive acute non-cancer risks to consumers (Section 4.3.3).
- No potential non-cancer risk was identified for the general population for the land, surface water, fish ingestion, and ambient air pathways. (Section 4.3.4).
- EPA considered PESS throughout the exposure assessment, hazard identification, and dose-response analysis supporting this draft risk evaluation (Section 4.3.5).
- EPA considered cumulative risk to workers and consumers through exposure to DEHP from individual COUs in combination with cumulative non-attributable national exposure to DEHP, DBP, BBP, DIBP, and DINP as estimated from NHANES biomonitoring data (Sections 4.4.4 and 4.4.5).

# 1517 4.1 Summary of Human Exposures

# 1518 4.1.1 Occupational Exposures

The following subsections briefly describe EPA's approach to assessing occupational exposures and 1519 1520 provide exposure assessment results for each OES. As stated in the final scope document (U.S. EPA, 1521 2020c), EPA evaluated exposures to workers and ONUs via the inhalation route, including incidental 1522 ingestion of inhaled dust, and exposures to workers via the dermal route associated with the 1523 manufacturing, processing, use, and disposal of DEHP. Also, EPA assessed dermal exposure to workers 1524 and ONUs in scenarios where there is potential exposure to mist and dust on deposited surfaces. 1525 Determinants of exposure such as, but not limited to, worker activities, physical form, conditions of an application, and type of operation may be considered when determining whether the potential for ONU 1526 exposure exists. The Draft Environmental Release and Occupational Exposure Assessment for 1527 1528 Diethylhexyl Phthalate (U.S. EPA, 2025r) provides additional details on the development of approaches 1529 and the exposure assessment results.

# 4.1.1.1 Approach and Methodology

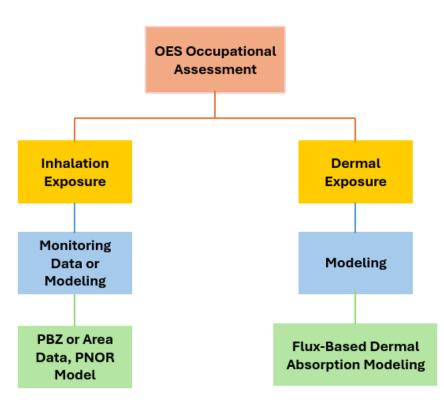
As described in the final scope document (U.S. EPA, 2020c), EPA distinguished exposure levels among potentially exposed employees for workers and ONUs. In general, the primary difference between workers and ONUs is that workers may handle DEHP and have direct contact with the DEHP, while ONUs work in the general vicinity of DEHP but do not handle DEHP. Where possible, for each condition of use, EPA identified job types and categories for workers and ONUs.

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1530

1537 As discussed in Section 3.1.1.1, EPA established OESs to assess the exposure scenarios more 1538 specifically within each COU, and Table 3-1 provides a crosswalk between COUs and OESs. EPA 1539 identified relevant inhalation exposure monitoring data for some of the OESs. EPA evaluated the quality 1540 of this monitoring data using the data quality review evaluation metrics and the rating criteria described 1541 in the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021a). EPA assigned an overall quality level 1542 of high, medium, or low to the relevant data. In addition, the Agency established an overall confidence 1543 level for the data when integrated into the occupational exposure assessment. EPA considered the 1544 assessment approach, the quality of the data and models, as well as uncertainties in assessment results to 1545 assign an overall confidence level of robust, moderate, or slight. 1546

1547 Where monitoring data were reasonably available, the Agency used these data to characterize central 1548 tendency and high-end inhalation exposures (see also Table 4-1). EPA may also use monitoring data 1549 from a similar condition of use as a surrogate. Where no inhalation monitoring data were available, but 1550 inhalation exposure models were reasonably available, the Agency estimated central tendency and high-1551 end exposures using only modeling approaches. If both inhalation monitoring data and exposure models 1552 were reasonably available, EPA presented central tendency and high-end exposures using both. For 1553 inhalation exposure to dust in occupational settings, EPA used the Generic Model for Central Tendency 1554 and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated 1555 (PNOR) (also called the "PNOR Model") (U.S. EPA, 2021d). In all cases of occupational dermal 1556 exposure to DEHP, EPA used flux-limited dermal absorption to estimate both high-end and central 1557 tendency dermal exposures for workers in each OES, as described in the Draft Environmental Release 1558 and Occupational Exposure Assessment for Diethylhexyl Phthalate (U.S. EPA, 2025r).



1561

Figure 4-1. Approaches Used for Each Component of the Occupational Assessment for Each OES
 PBZ = personal breathing zone; PNOR = particulates not otherwise regulated

1564

1565 For inhalation and dermal exposure routes, EPA provided occupational exposure results representative of central tendency and high-end exposure conditions. The central tendency is expected to represent 1566 1567 occupational exposures in the center of the distribution for a given COU. For risk evaluation, EPA used the 50th percentile (median), mean (arithmetic or geometric), mode, or midpoint value of a distribution 1568 1569 to represent the central tendency scenario. EPA preferred to provide the 50th percentile of the 1570 distribution. However, if the full distribution was unknown, the Agency used either the mean, mode, or 1571 midpoint of the distribution to represent the central tendency depending on the statistics available for the 1572 distribution. The high-end exposure is expected to represent occupational exposures that occur at probabilities above the 90th percentile, but below the highest exposure for any individual (U.S. EPA, 1573 1992a). For risk evaluation, EPA provided high-end results at the 95th percentile. If the 95th percentile 1574 1575 was not reasonably available, the Agency used a different percentile greater than or equal to the 90th 1576 percentile but less than or equal to the 99th percentile, depending on the statistics available for the 1577 distribution. If the full distribution is not known and the preferred statistics are not reasonably available, 1578 EPA estimated a maximum or bounding estimate in lieu of the high-end. Table 4-1 provides a summary 1579 of whether monitoring data were reasonably available for each OES, and if data were available, the 1580 number of data points and quality of that data. Table 4-1 also provides EPA's overall confidence rating 1581 and whether EPA used modeling to estimate inhalation and dermal exposures for workers.

### 1582 Table 4-1. Summary of Exposure Monitoring and Modeling Data for Occupational Exposure Scenarios

				0	In	halation ]	Exposur	e					Der	rmal Expo	sure <sup>d</sup>
OES		DEH	P Moni	itoring			Surrog	ate Moi	nitoring		Mode	ling	Emp	irical	Modeling
OES	Worker	# Data Points	<b>ONU</b> <sup>b</sup>	# Data Points	Data Quality Rating <sup>c</sup>	Worker	# Data Points	<b>ONU</b> <sup>b</sup>	# Data Points	Data Quality Rating <sup>c</sup>	Worker	<b>ONU</b> <sup>b</sup>	Worker	Data Quality Rating <sup>c</sup>	Worker
Manufacturing	$\checkmark$	45	×	N/A	M/H	×	N/A	×	N/A	Н	×	×	×	N/A	$\checkmark$
Rubber manufacturing	$\checkmark$	7	×	N/A	Н	×	N/A	×	N/A	N/A	×	×	×	N/A	$\checkmark$
Plastic compounding	✓	6	$\checkmark$	1	Н	×	N/A	×	N/A	N/A	×	×	×	N/A	~
Plastic converting	$\checkmark$	13	×	N/A	Н	×	N/A	×	N/A	N/A	×	×	×	N/A	$\checkmark$
Incorporation into formulation, mixture, or reaction product	×	N/A	×	N/A	N/A	~	45	×	N/A	N/A	×	×	×	N/A	$\checkmark$
Repackaging	$\checkmark$	1	×	N/A	Н	×	N/A	×	N/A	М	×	×	×	N/A	$\checkmark$
Application of paints, coatings, adhesives, and sealants	~	1	×	N/A	Н	×	N/A	×	N/A	N/A	$\checkmark$	×	×	N/A	$\checkmark$
Textile finishing	×	N/A	×	N/A	N/A	×	N/A	×	N/A	N/A	$\checkmark$	×	×	N/A	$\checkmark$
Fabrication or use of final product or articles	~	7	~	1	Н	×	N/A	×	N/A	N/A	×	×	×	N/A	$\checkmark$
Use of dyes, pigments, and fixing agents	x	N/A	×	N/A	N/A	~	1	×	N/A	Н	×	×	×	N/A	$\checkmark$
Formulations for diffusion bonding	×	N/A	×	N/A	N/A	×	N/A	×	N/A	N/A	~	×	×	N/A	$\checkmark$
Use of laboratory chemicals	~	1	×	N/A	M/H	×	N/A	×	N/A	N/A	×	×	×	N/A	$\checkmark$
Use of automotive care products	~	1	~	1	Н	×	N/A	×	N/A	N/A	×	×	×	N/A	$\checkmark$
Use in hydraulic fracturing	×	N/A	×	N/A	N/A	~	45	×	N/A	M/H		×	×	N/A	$\checkmark$
Recycling	×	N/A	×	N/A	N/A	✓	13	×	N/A	Н	×	×	×	N/A	$\checkmark$
Waste handling, treatment, and disposal	×	N/A	×	N/A	N/A	×	N/A	×	N/A	N/A	$\checkmark$	×	×	N/A	$\checkmark$

<sup>*b*</sup> ONU = occupational non-user

Where EPA was not able to estimate ONU inhalation exposure from monitoring data or models (indicated by an "x"), this was assumed equivalent to the central tendency experienced by workers for the corresponding OES.

<sup>c</sup> Data quality ratings for reported data are based on EPA systematic review and include ratings Low (L), Medium (M), and High (H). Data quality evaluation criteria are described in the Draft Systematic Review Protocol (U.S. EPA, 2021a) and include evaluation of the representativeness or applicability of the data to the OES.

		Inhalation Exposure											<b>Dermal Exposure</b> <sup>d</sup>		
OES		DEHP Monitoring				Surrogate Monitoring					Modeling		Empirical		
UES	Worker	Worker # Data Points 0		# Data Points	Data Quality Rating <sup>c</sup>	Worker	# Data Points	<b>ONU</b> <sup>b</sup>	# Data Points	Data Quality Rating <sup>c</sup>	Worker ONU <sup>b</sup>		Worker	Data Quality Rating <sup>c</sup>	Worker
<sup>d</sup> Dermal modeling incorpor	rated expe	rimental	dermal	loading da	ata for liqu	id DEHP f	from ( <u>U.S</u>	S. EPA,	<u>1992b</u> ) aı	nd solid D	EHP from	(Lansir	nk et al., 19	9 <u>96</u> ). These	data were
determined to have a data q	uality ratii	ng of mee	lium.												
× No data available															
✓ Data available															

1584 1585 1586 1587 1588 1589 1590 1591 1592 1593 1594	<b>4.1.1.2 Summary of Inhalation Exposure Assessment</b> Table 4-2 presents a summary of inhalation exposure results based on monitoring data and exposure modeling for each OES. This tables provides a summary of the 8-hour time weighted average (TWA) inhalation exposure estimates, as well as the acute dose (AD), the intermediate average daily dose (IADD), and the chronic average daily dose (ADD). The <i>Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate</i> (U.S. EPA, 2025r) provides exposure results for females of reproductive age and ONUs. The <i>Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate</i> (U.S. EPA, 2025r) also provides additional details regarding AD, IADD, and ADD calculations along with EPA's approach and methodology for estimating inhalation exposures. EPA applied the following hierarchy in selecting data and approaches for assessing occupational exposures:
1595 1596 1597 1598 1599 1600 1601 1602 1603 1604 1605 1606 1607 1608 1609 1610 1611 1612 1613	<ol> <li>Monitoring data:         <ul> <li>Personal and directly applicable to the OES</li> <li>Area and directly applicable to the OES</li> <li>Personal and potentially applicable or similar to the OES</li> <li>Personal and potentially applicable or similar to the OES</li> <li>Area and potentially applicable or similar to the OES</li> </ul> </li> <li>Modeling approaches:         <ul> <li>Surrogate monitoring data</li> <li>Fundamental modeling approaches</li> <li>Statistical regression modeling approaches</li> <li>Statistical regression modeling approaches</li> </ul> </li> <li>Occupational exposure limits:         <ul> <li>Company-specific occupational exposure limits (OELs) (for site-specific exposure assessments, <i>e.g.</i>, there is only one manufacturer who provides their internal OEL to EPA, but the manufacturer does not provide monitoring data)</li> <li>Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PEL)</li> <li>Voluntary limits (<i>i.e.</i>, American Conference of Governmental Industrial Hygienists [ACGIH] Threshold Limit Values [TLV], National Institute for Occupational Safety and Health [NIOSH] Recommended Exposure Limits [REL], Occupational Alliance for Risk Science (OARS) workplace environmental exposure level (WEEL) [formerly by AIHA])</li> </ul> </li> </ol>
1614 1615	Due to the lack of reasonably available exposure data for some OESs, surrogate assessment approaches were used for the following:
1616 1617 1618 1619 1620 1621 1622 1623 1624 1625 1626 1627 1628 1629 1630	<ul> <li>Incorporation into formulation, mixture, or reaction product (Manufacturing as surrogate: OES is expected to have comparable exposure potential based on the similarity of worker activities (<i>e.g.</i>, unloading transport containers, packaging final products, cleaning transport containers, product sampling, cleaning reaction vessels or other equipment, and during filter media change out) and physical form).</li> <li>Non-spray application of paints, coatings, adhesives, and sealants (rubber product manufacturing as surrogate: OES is expected to have comparable exposure potential based on the similarity of worker activities (<i>e.g.</i>, product unloading into application equipment, container and application equipment cleaning, and curing or drying or applied product) and physical form.</li> <li>Use of dyes, pigments, and fixing agents (Rubber product manufacturing as surrogate: OES is expected to have comparable exposure potential based on the similarity of worker activities (<i>e.g.</i>, during unloading of liquid dyes, container cleaning, and machine operation) and physical form.</li> <li>Hydraulic fracturing (Manufacturing as surrogate: OES is expected to have comparable exposure potential based on the similarity of morker activities (<i>e.g.</i>, transport containers, and during equipment/storage tank cleaning) and physical form.</li> </ul>

- Recycling (Plastic converting as surrogate: OES is expected to have comparable exposure 1631
- potential based on the similarity of worker activities (e.g., unloading of baled plastics or rubber, 1632 loading of processed DEHP-containing plastics or rubber onto compounding or converting lines 1633 1634 or into transport containers, processing of recycled plastics or rubber, and equipment cleaning).
- 1635

1636 Where available, EPA used inhalation monitoring data from the OSHA Chemical Exposure Health Data

(CEHD) database. The chemical exposure information in the CEHD represents samples for airborne 1637 1638 contaminants as collected by industrial hygienists as part of a compliance monitoring program. When

- 1639 the compliance officers collect these data, it is key to emphasize that they do not
- 1640 routinely visit every business that uses chemicals known to be toxic;
- 1641 • take representative samples of every employee and every activity on every day; and
- always obtain a sample for an entire 8-hour period or shift. 1642 •
- 1643 Additionally, it should be noted that historically slightly more than half of all inspections are
- unprogrammed (complaints, injuries/fatalities, and referrals). The remainder are programmed 1644
- inspections as part of national, regional, or local emphasis programs monitoring for known hazards (e.g., 1645

chemical processing, respirable silica, combustible dusts, ship-breaking, heat, falls in construction). The 1646

prevalence of bias in exposure monitoring across the dataset due to unprogrammed inspections is 1647

1648 uncertain.

# 1649 Table 4-2. Summary of Worker Inhalation Exposure Results for Each OES<sup>a</sup>

OES	Population	8-Hou Exposure Expo	r TWA es – Total osure /m <sup>3</sup> )	8-Hou Expos Partic Exposu	r TWA sures – culate re Only (m <sup>3</sup> )		e Dose g/day)	Non- Exp	liate, ADD, Cancer osures (g/day)	Cancer I	ADD, Non- Exposures g/day)
		СТ	HE	СТ	HE	СТ	HE	СТ	HE	СТ	HE
	Avg. Worker	1.20E-02	2.20E-02	_	_	1.50E-03	2.75E-03	1.10E-03	2.02E-03	1.03E-03	1.88E-03
Manufacturing	Female WORA	1.20E-02	2.20E-02	_	-	1.66E-03	3.04E-03	1.22E-03	2.23E-03	1.13E-03	2.08E-03
	ONU <sup>g</sup>	1.20E-02	1.20E-02	-	-	1.50E-03	1.50E-03	1.10E-03	1.10E-03	1.03E-03	1.03E-03
	Avg. Worker	1.40E-01	5.20E-01	_	-	1.75E-02	6.50E-02	1.28E-02	4.77E-02	1.20E-02	4.45E-02
Import and repackaging	Female WORA	1.40E-01	5.20E-01	-	-	1.93E-02	7.18E-02	1.42E-02	5.27E-02	1.32E-02	4.92E-02
	ONU <sup>g</sup>	1.40E-01	1.40E-01	_	_	1.75E-02	1.75E-02	1.28E-02	1.28E-02	1.20E-02	1.20E-02
	Avg. Worker	1.20E-02	2.20E-02	_	_	1.50E-03	2.75E-03	1.10E-03	2.02E-03	1.03E-03	1.88E-03
Incorporation into formulation, mixture, or reaction product <sup>b</sup>	Female WORA	1.20E-02	2.20E-02	-	-	1.66E-03	3.04E-03	1.22E-03	2.23E-03	1.13E-03	2.08E-03
reaction product	ONU <sup>g</sup>	1.20E-02	1.20E-02	-	-	1.50E-03	1.50E-03	1.10E-03	1.10E-03	1.03E-03	1.03E-03
	Avg. Worker	3.00E-01	2.76	-	-	3.75E-02	3.45E-01	2.75E-02	2.53E-01	2.57E-02	2.36E-01
Plastic compounding	Female WORA	3.00E-01	2.76	-	-	4.14E-02	3.81E-01	3.04E-02	2.79E-01	2.84E-02	2.61E-01
	ONU <sup>g</sup>	8.00E-03	8.00E-03	-	-	1.00E-03	1.00E-03	7.33E-04	7.33E-04	6.85E-04	6.85E-04
	Avg. Worker	3.40E-01	5.30E-01	-	-	4.25E-02	6.63E-02	3.12E-02	4.86E-02	2.91E-02	4.54E-02
Plastic converting	Female WORA	3.40E-01	5.30E-01	-	_	4.69E-02	7.32E-02	3.44E-02	5.37E-02	3.22E-02	5.01E-02
	ONU <sup>g</sup>	3.40E-01	3.40E-01	-	-	4.25E-02	4.25E-02	3.12E-02	3.12E-02	2.91E-02	2.91E-02
	Avg. Worker	1.67	8.13	_	-	2.09E-01	1.02	1.53E-01	7.45E-01	1.43E-01	6.96E-01
Rubber product manufacturing	Female WORA	1.67	8.13	_	_	2.31E-01	1.12	1.69E-01	8.23E-01	1.58E-01	7.69E-01
2	ONU <sup>g</sup>	1.67	1.67	-	—	2.09E-01	2.09E-01	1.53E-01	1.53E-01	1.43E-01	1.43E-01
	Avg. Worker	3.0E-01	2.2E01	_	-	3.80E-02	2.76	2.78E-02	2.03	2.60E-02	1.89
Spray application of paints, coatings, adhesives, and sealants	Female WORA	3.0E-01	2.2E01	_	_	4.19E-02	3.05	3.08E-02	2.24	2.87E-02	2.09
scarants	ONU <sup>g</sup>	3.0E-01	3.0E-01	-	-	3.80E-02	3.80E-02	2.78E-02	2.78E-02	2.60E-02	2.60E-02

OES	Population	8-Hour Exposure Expo (mg	es – Total osure	8-Hour Expos Partic Exposu (mg	ures – culate re Only		e Dose g/day)	Non- Exp	liate, ADD, Cancer osures (g/day)	Cancer l	ADD, Non- Exposures (g/day)
		СТ	HE	СТ	HE	СТ	HE	СТ	HE	СТ	HE
New York Construction of	Avg. Worker	1.67	8.13	-	_	2.09E-01	1.02	1.53E-01	7.45E-01	1.43E-01	6.96E-01
Non-spray application of paints, coatings, adhesives, and sealants $c$	Female WORA	1.67	8.13	-	_	2.31E-01	1.12	1.69E-01	8.23E-01	1.58E-01	7.69E-01
and solitants	ONU <sup>g</sup>	1.67	1.67	_	_	2.09E-01	2.09E-01	1.53E-01	1.53E-01	1.43E-01	1.43E-01
	Avg. Worker	1.67	8.13	-	-	2.09E-01	1.02	1.53E-01	7.45E-01	1.43E-01	6.96E-01
Use of dyes, pigments, and fixing agents $d$	Female WORA	1.67	8.13	_	_	2.31E-01	1.12	1.69E-01	8.23E-01	1.58E-01	7.69E-01
	ONU <sup>g</sup>	1.67	1.67	_	_	2.09E-01	2.09E-01	1.53E-01	1.53E-01	1.43E-01	1.43E-01
	Avg. Worker	5.50E-02	1.10E-01	_	-	6.88E-03	1.38E-02	5.04E-03	1.01E-02	4.43E-03	9.42E-03
Use of automotive care products	Female WORA	5.50E-02	1.10E-01	_	-	7.59E-03	1.52E-02	5.57E-03	1.11E-02	4.89E-03	1.04E-02
	ONU	5.00E-02	6.00E-02	-	-	6.25E-03	7.50E-03	4.58E-03	5.50E-03	4.02E-03	5.14E-03
	Avg. Worker	0	0	3.10E-06	4.30E-05	3.88E-07	5.38E-06	2.84E-07	3.94E-06	2.28E-07	3.17E-06
Textile finishing	Female WORA	0	0	3.10E-06	4.30E-05	4.28E-07	5.94E-06	3.14E-07	4.35E-06	2.52E-07	3.50E-06
	ONU <sup>g</sup>	0	0	3.10E-06	3.10E-06	3.88E-07	3.88E-07	2.84E-07	2.84E-07	2.28E-07	2.28E-07
	Avg. Worker	0.34	7.96	_	_	4.25E-02	9.95E-01	3.12E-02	7.30E-01	2.91E-02	6.82E-01
Formulation for diffusion bonding	Female WORA	0.34	7.96	-	-	4.69E-02	1.10	3.44E-02	8.06E-01	3.22E-02	7.53E-01
	ONU <sup>g</sup>	0.34	0.34	-	-	4.25E-02	4.25E-02	3.12E-02	3.12E-02	2.91E-02	2.91E-02
	Avg. Worker	1.20E-02	2.20E-02	-	-	1.50E-03	2.75E-03	5.00E-05	2.75E-04	4.11E-06	2.26E-05
Use in hydraulic fracturing <sup>e</sup>	Female WORA	1.20E-02	2.20E-02	_	_	1.66E-03	3.04E-03	5.52E-05	3.04E-04	4.54E-06	2.50E-05
	ONU	1.20E-02	1.20E-02	_	_	1.50E-03	1.50E-03	5.00E-05	1.50E-04	4.11E-06	1.23E-05
	Avg. Worker	1.00E-02	1.00E-01	_	-	1.25E-03	1.25E-02	9.17E-04	9.17E-03	8.05E-04	8.56E-03
Use of laboratory chemicals	Female WORA	1.00E-02	1.00E-01	_	_	1.38E-03	1.38E-02	1.01E-03	1.01E-02	8.89E-04	9.46E-03
	ONU	1.00E-02	1.00E-02	_	-	1.25E-03	1.25E-03	9.17E-04	9.17E-04	8.05E-04	8.56E-04

OES Population		8-Hour TWA Exposures – Total Exposure (mg/m <sup>3</sup> )		Expos Partic Exposu	8-Hour TWA Exposures – Particulate Exposure Only (mg/m <sup>3</sup> )		Acute Dose (mg/kg/day)		Intermediate, ADD, Non-Cancer Exposures (mg/kg/day)		Chronic ADD, Non- Cancer Exposures (mg/kg/day)	
		СТ	HE	СТ	HE	СТ	HE	СТ	HE	СТ	HE	
	Avg. Worker	0.34	0.53	_	_	4.25E-02	6.63E-02	3.12E-02	4.86E-02	2.91E-02	4.54E-02	
Recycling <sup><i>f</i></sup>	Female WORA	0.34	0.53	_	_	4.69E-02	7.32E-02	3.44E-02	5.37E-02	3.22E-02	5.01E-02	
	ONU <sup>g</sup>	3.40E-01	3.40E-01	-	_	4.25E-02	4.25E-02	3.12E-02	3.12E-02	2.91E-02	2.91E-02	
	Avg. Worker	4.00E-02	1.10E-01	_	_	5.00E-03	1.38E-02	3.67E-03	1.01E-02	3.26E-03	8.97E-03	
Fabrication or use of final products and articles	Female WORA	4.00E-02	1.10E-01	_	_	5.52E-03	1.52E-02	4.05E-03	1.11E-02	3.60E-03	9.90E-03	
	ONU <sup>g</sup>	4.00E-02	4.00E-02	-	_	5.00E-03	5.00E-03	3.67E-03	3.67E-03	3.26E-03	3.26E-03	
	Avg. Worker	0	0	1.06E-01	1.54	1.33E-02	1.93E-01	9.72E-03	1.41E-01	9.08E-03	1.32E-01	
Waste handling, treatment, and disposal	Female WORA	0	0	1.06E-01	1.54	1.46E-02	2.13E-01	1.07E-02	1.56E-01	1.00E-02	1.46E-01	
	ONU <sup>g</sup>	0	0	1.06E-01	1.06E-01	1.33E-02	1.33E-02	9.72E-03	9.72E-03	9.08E-03	9.08E-03	

Abbreviations: - = not assessed; ADD = average daily dose; CT = central tendency; HE = high-end; ONU = occupational non-user; TWA = time-weighted average; WORA = female workers of reproductive age.

Note that female workers of reproductive age have lower body weight than adult workers expressed as an average of males and females; therefore, although the exposure concentration in the air is the same, the dose (in mg per kg body weight) is higher for WORA compared to average adult workers.

<sup>*a*</sup> The source of the exposure data (*e.g.*, monitoring vs. modeling), number of data points used for each exposure estimate, and data quality rating are depicted in Table 4-1.

<sup>b</sup> Incorporation into formulation, mixture, or reaction product OES used data from Manufacturing OES as a surrogate.

<sup>c</sup> Non-spray application of paints, coatings, adhesives, and sealants OES used data from Rubber product manufacturing as a surrogate.

<sup>d</sup>Use of dyes, pigments, and fixing agents OES used data from Rubber product manufacturing as a surrogate.

<sup>e</sup> Hydraulic Fracturing OES used data from Manufacturing OES as a surrogate.

Recycling OES used data from Plastic Converting OES as a surrogate.

<sup>8</sup> Data were not available to estimate exposure of ONUs to DEHP; therefore, EPA used the central tendency of worker exposure for this OES as a surrogate for ONU exposure specific to this OES.

1650

### 16514.1.1.3 Summary of Dermal Exposure Assessment

- 1652 Table 4-3 presents a summary of dermal exposure results, which are based on both empirical dermal
- absorption data and dermal absorption modeling estimation efforts. Included is the summary of the
- 1654 Acute Potential Dose Rate (APDR) for occupational dermal exposure estimates, as well as the AD,
- 1655 IADD, and Chronic ADD. The Draft Environmental Release and Occupational Exposure Assessment
- 1656 for Diethylhexyl Phthalate (U.S. EPA, 2025r) provides exposure results for females of reproductive age
- and ONUs. The Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl
- 1658 *Phthalate* also provides additional details regarding AD, IADD, and ADD calculations along with
- 1659 EPA's approach and methodology for estimating dermal exposures.

## 1660 Table 4-3. Summary of Average Adult Worker Modeled Dermal Exposure Results for Each OES

				<b>Dermal Es</b>	stimates (A	Average A	dult Work	ker)		
OES	Expo			<b>DR</b> <sup>a</sup>		D		DD		DD
	Ту		· · · ·	/day)	, U	(mg/kg/day)		g/day)	(mg/kg/day)	
	Liquid	Solid	СТ	HE	СТ	HE	СТ	HE	СТ	HE
Manufacturing	$\checkmark$	×	5.6E-03	1.1E-02	7.0E-05	1.4E-04	5.1E-05	1.0E-04	4.8E-05	9.5E-05
Import and repackaging	$\checkmark$	×	5.6E-03	1.1E-02	7.0E-05	1.4E-04	5.1E-05	1.0E-04	4.8E-05	9.5E-05
Incorporation into formulation, mixture, or reaction product	$\checkmark$	×	5.6E-03	1.1E-02	7.0E-05	1.4E-04	5.1E-05	1.0E-04	4.8E-05	9.5E-05
Plastic compounding	~	~	5.6E-03 (0.21)	1.1E-02 <sup>b</sup> (0.41)	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.8E-03	3.5E-03
Plastic converting	×	$\checkmark$	2.1E-01	0.41	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.8E-03	3.5E-03
Rubber product manufacturing	~	~	5.6E-03 (0.21)	1.1E-02 (0.41)	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.8E-03	3.5E-03
Application of paints, coatings, adhesives, and sealants	~	×	1.1E-01	0.21	1.3E-03	2.7E-03	9.8E-04	2.0E-03	9.2E-04	1.8E-03
Use of dyes, pigments, and fixing agents	$\checkmark$	×	1.1E-01	0.21	1.3E-03	2.7E-03	9.8E-04	2.0E-03	9.2E-04	1.8E-03
Use of automotive care products	$\checkmark$	×	1.1E-01	0.21	1.3E-03	2.7E-03	9.8E-04	2.0E-03	8.6E-04	1.8E-03
Textile finishing	~	$\checkmark$	0.11 (0.21)	0.21 (0.41)	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.5E-03	3.0E-03
Formulation for diffusion bonding	$\checkmark$	×	1.1E-01	0.21	1.3E-03	2.7E-03	9.8E-04	2.0E-03	9.2E-04	1.8E-03
Use in hydraulic fracturing	$\checkmark$	×	1.1E-01	0.21	1.3E-03	2.7E-03	4.5E-05	2.7E-04	3.7E-06	2.2E-05
Use of laboratory chemicals	~	~	0.11 (0.21)	0.21 (0.41)	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.7E-03	3.5E-03
Recycling	×	$\checkmark$	2.1E-01	0.41	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.8E-03	3.5E-03
Fabrication or use of final products and articles	×	$\checkmark$	2.1E-01	0.41	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.7E-03	3.3E-03
Waste handling, treatment, and disposal	×	$\checkmark$	2.1E-01	0.41	2.6E-03	5.1E-03	1.9E-03	3.8E-03	1.8E-03	3.5E-03

APDR = acute potential dose rate; acute dose = ; IADD = intermediate average daily dose; ADD = average daily dose; HE = high-end; CT = central tendency.

<sup>a</sup> APDR values are reported for either liquid or solid exposure types as indicated by the Exposure Type column.

<sup>b</sup> For OESs with both liquid and solid exposure, the APDR value for liquids is presented first, and the APDR value for solids is presented in parentheses below.

1661

1662	4.1.1.4 Weight of Scientific Evidence Conclusions for Occupational Exposure
1663	Judgment on the weight of scientific evidence is based on the strengths, limitations, and uncertainties
1664	associated with the release estimates. The Agency considers factors that increase or decrease the
1665	strength of the evidence supporting the exposure estimate—including quality of the data/information,
1666	applicability of the exposure data to the COU (including considerations of temporal and locational
1667	relevance) and the representativeness of the estimate for the whole industry. The best professional
1668	judgment is summarized using the descriptors of robust, moderate, slight, or indeterminate, in
1669	accordance with the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021a). For example, a
1670	conclusion of moderate weight of scientific evidence is appropriate where there is measured exposure
1671	data from a limited number of sources, such that there is a limited number of data points that may not be
1672	representative of worker activities or potential exposures. A conclusion of slight weight of scientific
1673	evidence is appropriate where there is limited information that does not sufficiently cover all potential
1674	exposures within the COU, and the assumptions and uncertainties are not fully known or documented.
1675	
1676	As a general matter, for all COUs there is uncertainty regarding the representativeness of supporting
1677	data with respect to the full distribution of exposures. This uncertainty is due to the variability in the full
1678	distribution for each COU and how well the exposure estimates reflect that variability. Although each
1679	exposure assessment is intended to present a set of conditions from which an understanding of
1680	occupational risks may be constructed, the variability in the determinants of exposure (e.g., frequency,
1681	duration, etc.) from facility to facility within the full distribution of any COU is unknown. As a result,
1682	the worker exposure estimates uncertainties, as part of the integrated evidence streams, may impact the
1683	weight of scientific evidence conclusion for any particular COU. Unless otherwise stated, each scenario
1684	represents a worker with 8 exposure hours per day and 250 exposure days per year with continuous
1685	DEHP exposure each working day. With the exception of plastics compounding OES, no monitoring
1686	data specific to ONUs were identified; therefore, EPA used the central tendency estimates of worker
1687	exposure for each OES as a surrogate for ONU exposure. See the 2021 Draft Systematic Review
1688	Protocol (U.S. EPA, 2021a) for additional information on weight of scientific evidence conclusions.
1689	Table 4-4 provides a summary of EPA's overall confidence in its occupational exposure estimates for
1690	each of the OESs assessed.

# 1691 Table 4-4. Summary of Assumptions, Uncertainty, and Overall Confidence in Exposure Estimates by OES

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
Manufacturing	EPA used PBZ air concentration data to assess inhalation exposures, with the data sources having a medium and high data quality rating from the systematic review process (Liss and Hartel, 1983; Nuodex Inc., 1983). Data from these sources were DEHP-specific from 2 separate DEHP manufacturing facilities. The high-end and central tendency worker inhalation exposure results for this OES are based on the 95th and 50th percentile exposure values from full-shift samples. Several references were not included in the analysis as they did not provide discrete sample data (Kim, 2016; ECB, 2008; ECJRC, 2003; Modigh et al., 2002; Liss et al., 1985). The estimated central tendency from EPA's analysis generally aligns with these additional studies and is within an order of magnitude of the median presented in each study. No data with full-shift samples for ONUs was identified for this OES through systematic review. For this reason, worker central tendency exposures were used for ONU exposures.
	The primary strength is the use of directly applicable monitoring data, which are preferrable to other assessment approaches such as modeling or assumption of air concentrations at an OEL (occupational exposure limits).
	The primary limitations of these data include the uncertainty of the representativeness of these data toward the true distribution of inhalation concentrations in this scenario because: (1) the data only comprise 2 DEHP manufacturing facilities, and (2) no ONU exposure data were available; therefore, EPA used central tendency worker data as surrogate data for ONUs.
	Based on the direct relevance of exposure scenario to the OES, the use of monitoring data with a high number of data points and high data quality, and in consideration of limited number sites, EPA has concluded that the weight of scientific evidence for this assessment is provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.
Rubber manufacturing	EPA used monitoring data from a single rubber calendering site to estimate worker inhalation exposures to vapor, which had a data quality rating of high. This source provided TWA exposures from 6 samples, one of which was an area sample, and these 6 samples had unknown worker classifications (ECJRC, 2003). The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or the assumption of air concentrations at an OEL.
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which EPA used central tendency of worker data as a surrogate. Additionally, the monitoring dataset consisted of datapoints for unknown worker classifications, which correspond to job types providing an indication as to the worker activities. Finally, the sample type (PBZ vs. area) was not known for 5 of the 6 samples.
	Based on the direct relevance of the exposure scenario to OES, relevant monitoring data of high quality and in consideration of

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	the limited number of samples and unknown worker classification ( <i>i.e.</i> , activities), EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.
Plastics compounding	EPA used monitoring data from 2 PVC sites, one that manufactures floor sheeting and one that manufactures vinyl sheeting and wall coverings, to estimate high-end worker inhalation exposures to vapor, with the data sources having a medium and high data quality rating from the systematic review process. These sources provided twenty maximum TWA personal breathing zone exposures and 6 discrete TWA personal breathing zone exposures respectively (Modigh et al., 2002; Salisbury, 1984). For ONU exposures, a single PBZ TWA sample taken from a PVC pellet manufacturing plant was used for 8-hour TWA concentration, which had a rating of high (Huang et al., 2011). The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or assuming air concentration at an OEL.
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES; The use of a single full-shift PBZ sample for ONU exposures; and that all samples from ( <u>Salisbury, 1984</u> ) used for worker 8-hour TWAs were non-detects. It should be noted that several references were not included in the analysis as they did not provide discrete sample data ( <u>Huang et al., 2011</u> ; <u>Modigh et al., 2002</u> ). EPA's high-end exposure estimates align with these additional data and are generally within an order of magnitude of the maximums presented in the assessment.
	Based on the direct relevance of the exposure scenario to the OES, PBZ data, data of medium-high quality and in consideration of the limited number of data points, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides an upper bound estimates of exposures.
Plastics converting	EPA used the monitoring data from a single source that encompasses one PVC floor sheeting site using DEHP as a plasticizer, as well as OSHA CEHD data to calculate a central tendency exposure concentration, with the data sources having a medium and high data quality rating from the systematic review process ( <u>OSHA, 2019</u> ; <u>Modigh et al., 2002</u> ). EPA used the 95th percentile exposure values from full-shift, PBZ samples collected from OSHA CEHD as the high-end exposure concentration ( <u>OSHA, 2019</u> ). The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or assuming air concentrations at an OEL.
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate data.
	Based on the direct relevance of the exposure scenario, a moderate number of data points, and in consideration of the limited number of sites, use of weighted averages to determine the central tendency, EPA has concluded that the weight of scientific

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.
Incorporation into formulation, mixture, or reaction product	EPA used monitoring data from Manufacturing OES, comprised of 2 DEHP manufacturing facilities to estimate worker inhalation exposures due to limited data available for incorporation into formulation, mixture, or reaction product inhalation exposures. EPA used PBZ air concentration data to assess inhalation exposures, with the data sources having medium and high data quality ratings from the systematic review process (Liss and Hartel, 1983; Nuodex Inc., 1983). Data from these sources were DEHP-specific from 2 separate DEHP manufacturing facilities. The high-end and central tendency worker inhalation exposure results for this OES are based on the 95th and 50th percentile exposure values from full-shift samples. Several references were not included in the analysis as they did not provide discrete sample data (Kim, 2016; ECB, 2008; ECJRC, 2003; Modigh et al., 2002; Liss et al., 1985). The estimated central tendency from EPA's analysis generally aligns with these additional studies and is within an order of magnitude of the median presented in each study. No data with full-shift samples for ONUs was identified for this OES through systematic review. For this reason, worker central tendency exposures were used for both the ONU high-end and central tendency exposures.
	The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate; and that the data come from only 2 DEHP manufacturing facilities. Based on use of a surrogate scenario for this OES, uncertainty in the representativeness of the use patterns and practices to this OES, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposure in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates at central tendency as a surrogate for ONU exposure.
Repackaging	EPA used monitoring data from 2 studies that sampled drumming activities to estimate worker inhalation exposures to vapor, with the data sources both having a high data quality rating from the systematic review process (ECB, 2008; ECJRC, 2003). The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or assuming air concentration at an OEL. The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate. Additionally, the vapor monitoring dataset consisted of an unknown number of datapoints with unknown sample durations.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
	Based on the relevance of the exposure scenario to this OES, the high data quality and in consideration of the limited number of sites and exposure data (mean concentrations of area samples), EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Spray application of paints, coatings, adhesives, and sealants	EPA used surrogate mist monitoring data from the ESD on Coating Applications via Spray-Painting in the Automotive Refinishing Industry, which the systematic review process rated high for data quality, to estimate inhalation exposures (OECD, 2011). The primary strength of this approach is that it uses surrogate monitoring data, which is preferable to other assessment approaches, such as the assumption of air concentrations at an OEL. EPA used SDSs and product data sheets from identified DEHP-containing products to identify product concentrations, which were then applied to the surrogate mist data to estimate DEHP-specific exposures.					
	The primary limitation is the lack of DEHP-specific monitoring data, with the ESD serving as a surrogate source of monitoring data representing the level of exposure that could be expected at a typical work site for the given spray application method. EPA only assessed mist exposures to DEHP over a full 8-hour work shift to estimate the level of exposure, though other activities may result in vapor exposures other than mist and application duration may be variable depending on the job site. Additionally, the lack of ONU exposure data requires the use of central tendency worker data as surrogate data, which may not be fully representative of ONU exposures. EPA assessed 250 days of exposure per year based on continuous DEHP exposure each working day for a typical worker schedule; however, application sites may use DEHP-containing paints, coatings, adhesives, or sealant formulations at much lower or variable frequencies.					
	Based on the relevance of the scenario to the OES, use of monitoring data for mist concentration, and in consideration of the lack of DEHP-specific exposure data, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures, and this conclusion is supported by the detailed description and scientific rigor of the estimation approach, and the fact that the uncertainties/assumptions for the Exposure Scenario Factors and the estimation methodology are well documented. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Non-spray application of paints, coatings, adhesives, and sealants	EPA used PBZ and area monitoring data from a rubber calendering plant to estimate worker inhalation exposures to vapor, which had a data quality rating of high from the systematic review process (ECJRC, 2003). The primary strength of this approach is that it uses monitoring data which is preferrable to other assessment approaches such as modeling or assuming an air concentration at an OEL.					
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate.					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
	Based on the high data quality and in consideration of the uncertainty in the representativeness of the exposure data source to the OES, exposure data from mixed operations (worker activities), lack of knowledge in the relevance of the worker practices to the OES, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Textile finishing	EPA PNOR Model (U.S. EPA, 2021d) to estimate worker inhalation exposure to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the textile manufacturing industry and the resulting dataset contains 71 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DEHP in particulate using industry provided data on DEHP concentration in fabric finishing products. These data were also rated high for data quality in the systematic review process.					
	The primary limitations are the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures and the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate. EPA assumed 8 exposure hours per day and 215 exposure days per year based on continuous DEHP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. The exposure days were based on the release days for the OES.					
	Based on high data quality, the number of data points from the OSHA CEHD and in consideration of the lack of OES-specific or DEHP-specific exposure data, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data . EPA considers this exposure estimate for high end to represent an upper bound, given the assumption that the industry-specific dust level is comprised of DEHP at the highest concentration reflected in a SDS specific to this OES.					
	EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Fabrication of final products from articles	EPA used monitoring data from OSHA CEHD to estimate worker and ONU inhalation exposures ( <u>OSHA</u> , 2020). The systematic review process rated the source high for data quality ( <u>OSHA</u> , 2020). The primary strength is this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches such as modeling or assuming air concentration at an OEL.					
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES. Additionally, due to the lack of discrete TWA data, samples from the OSHA CEHD were combined by inspection number, establishment name, and sample number to calculate an 8-hour TWA in cases where the sum of sampling time was greater than 3 hours. This method represents workers that are exposed to DEHP for 3 hours during their shift, which may underestimate exposures if they were to be exposed for the full shift duration. Due to the					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
	lack of data for ONUs, EPA used central tendency worker data as a surrogate.					
	Based on the high data quality, relevance of the monitoring data to this OES, and in consideration of the low number of data points, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Use of dyes, pigments, and fixing agents	Due to limited data available for use of dyes, pigments, and fixing agents, EPA used surrogate monitoring data from a site that performs spray or spread coating on automobiles to estimate worker inhalation exposures, which had a data quality rating of high from the systematic review process (ECJRC, 2003). The primary strength is the use of monitoring data, which are preferrable to other assessment approaches such as modeling or assuming air concentration at an OELs. EPA used PBZ monitoring data from a single spray or spread coating automobile site to estimate worker inhalation exposures. Data from this source are DEHP-specific and from a facility that uses DEHP-containing products.					
	The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate; and that the data come from a single DEHP automobile coating facility.					
	Based on the use of a surrogate OES and high data quality, and in consideration of uncertainty regarding the representativeness of the surrogate OES to Use of Dyes, Pigments, and Fixing Agents, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Formulations for diffusion bonding	EPA used surrogate mist monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry, which the systematic review process rated high for data quality, to estimate inhalation exposures (OECD, 2011). The primary strength of this approach is that it uses surrogate monitoring data, which is preferrable to other assessment approaches, such the assumption of air concentrations at an OEL. EPA used SDSs and product data sheets from identified DEHP-containing products to identify product concentrations, which were then applied to the surrogate mist data to estimate DEHP-specific exposures.					
	The primary limitation is the lack of DEHP-specific monitoring data, with the ESD serving as a surrogate source of monitoring data representing the level of exposure that could be expected at a typical work site for the given spray application method. The inhalation monitoring data used were specific to the spray application of coating materials, so the estimates may not be representative of exposure during other application methods. Additionally, it is uncertain whether the substrates coated, and products used to generate the surrogate data are representative of those associated with DEHP-containing diffusion bonding formulations. EPA only assessed mist exposures to DEHP over a full 8-hour work shift to estimate the level of					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
	exposure, though other activities may result in vapor exposures other than mist, and application duration may be variable depending on the job site. Additionally, the lack of ONU exposure data requires the use of central tendency worker data as surrogate data, which may not be fully representative of ONU exposures. EPA assessed 250 days of exposure per year based on workers using diffusion bonding formulations on every working day, however, application sites may use DEHP-containing diffusion bonding formulations at much lower or variable frequencies.					
	Based on modeling, and in consideration of the uncertainty in representativeness of the underlying monitoring data (in the model) and lack of relevant worker activity knowledge, EPA has concluded that the weight of scientific evidence for this assessment provides moderate e confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Use of laboratory chemicals	EPA used monitoring data from 2 studies that sampled laboratories to estimate worker inhalation exposures to vapor. These data had data quality ratings ranging from medium to high (ECB, 2008; Modigh et al., 2002). EPA used the maximum of three full-shift area samples for the high-end worker exposures and the minimum of 2 full-shift PBZ samples, which was below the limit of detection, for the central tendency worker exposures. The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or the assumption of air concentrations at an OEL.					
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which EPA used central tendency worker exposure data as surrogate. Finally, EPA assumed 8 exposure hours per day and the 95th percentile and 50th percentile operating days from the release assessment, 238 and 250 days respectively, as the exposure days per year based on continuous DEHP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.					
	Based on the relevance of the exposure scenario to the OES, directly relevant monitoring data, medium-high data quality, and in consideration of the limited characterization of the monitoring data (minimum, maximum), and limited number composite samples (3 area, 2 PBZ), EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Use of automotive care products	EPA used monitoring data from one study that sampled a site which applies car sealings and under coatings to estimate worker inhalation exposures. This data had a data quality rating of high (ECB, 2008). EPA used the maximum full shift concentration from an unknown number of samples and unknown worker classification for the high-end worker exposures and the midpoint between the maximum and limit of detection, due to the minimum being below the limit of detection, for the central tendency worker exposure. The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or the assumption of air concentrations at an OEL.					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates			
	The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate.			
	Based on the relevance of the exposure data to the OES, high data quality, and in consideration of the uncertainty in the representativeness of the exposure data worker activities to the worker activities for this OES, and the limited number of sites, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.			
Use in hydraulic fracturing	EPA used surrogate monitoring data from 2 DEHP manufacturing facilities to estimate worker inhalation exposures due to limited data available for use in hydraulic fracturing inhalation exposures. EPA used PBZ air concentration data to assess inhalation exposures, with the data sources having medium and high data quality ratings from the systematic review process (Liss and Hartel, 1983; Nuodex Inc., 1983). Data from these sources were DEHP-specific from 2 separate DEHP manufacturing facilities. The primary strength is the use of monitoring data, which are preferrable to other assessment approaches such as modeling or the assumption of air concentrations at an OEL.			
	The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; the lack of ONU exposure data, for which EPA used central tendency worker data as surrogate; and that the data come from only 2 DEHP manufacturing facilities. EPA also assumed 8 exposure hours per day and 1 to 3 exposure days per year based on data obtained from Frac Focus ( <u>GWPC and IOGCC, 2022</u> ); it is uncertain whether this captures actual worker schedules and exposures.			
	Based on use of a surrogate OES, and in consideration of the uncertainty in the representativeness of the surrogate to this OES, EPA has concluded that the weight of scientific evidence for this assessment provides slight confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.			
Recycling	EPA used surrogate monitoring data from a PVC floor sheet manufacturer to estimate worker inhalation exposures due to limited data available for recycling inhalation exposures. EPA used the monitoring data from one source that encompasses one PVC floor sheeting site using DEHP as a plasticizer, as well as OSHA CEHD data to calculate a central tendency exposure concentration, which had data quality ratings of medium and high from the systematic review process (OSHA, 2019; Modigh et al., 2002). EPA used the 95th percentile exposure values from full-shift, PBZ samples collected from OSHA CEHD as the high-end exposure concentration (OSHA, 2019). Data from these sources were DEHP-specific. The primary strength is the use of monitoring data, which are preferrable to other assessment approaches such as modeling or the assumption of air concentrations at an OEL.			

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
	The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; the lack of ONU exposure data, for which EPA used central tendency of worker data as surrogate; and that the data come from a single PVC floor sheet manufacturer.					
	Based on use of DEHP-specific monitoring data and in consideration of the use of surrogate OES monitoring data and uncertainty in the representativeness of surrogate worker activities to this OES, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Waste handling, disposal, and treatment	EPA utilized the PNOR Model (U.S. EPA, 2021d) to estimate worker inhalation exposure to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the waste handling industry and the resulting dataset contains 130 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DEHP in waste that is handled using industry provided data on DEHP concentration in plastic products. These data were also rated high for data quality in the systematic review process.					
	The primary limitations are the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures and the lack of ONU exposure data, for which EPA used central tendency of worker data as surrogate. Additionally, the representativeness of the CEHD dataset and the identified DEHP maximum concentration in plastics for this specific OES is uncertain. EPA lacks facility and DEHP-containing waste handling, treatment, and disposal rates, methods, and operating times and EPA assumed 8 exposure hours per day and 250 exposure days per year based on continuous DEHP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. The exposure days were based on working 5 days per week and 50 weeks per year.					
	Based on high data quality, the number of data points from the OSHA CEHD and in consideration of the lack of OES-specific or DEHP-specific exposure data, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of exposures in consideration of the strengths and limitations of reasonably available data. EPA has lower confidence in the exposure estimates for ONUs because there are no specific ONU monitoring data, and EPA relied on worker exposure estimates at central tendency as a surrogate for ONU exposure.					
Dermal – liquids	EPA used dermal absorption data for dilute DEHP to estimate occupational dermal exposures to workers since the absorptive flux of dilute DEHP is greater than the absorptive flux of neat DEHP ( <u>Hopf et al., 2014</u> ). Because the absorptive flux of dilute DEHP is greater than the neat absorptive flux, EPA expects using the dilute absorptive flux for anything less than 90 percent DEHP to be a protective approach for assessing dermal exposures. Also, it is acknowledged that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. However, it is assumed that absorption of the dilute chemical serves as a reasonable upper bound across chemical compositions and the data received a medium rating					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	through EPA's systematic review process.
	For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and that the chemical is contacted at least once per day. Because DEHP has low volatility and low absorption, it is possible that the chemical remains on the surface of the skin after a dermal contact until the skin is washed. Therefore, absorption of DEHP from occupational dermal contact with materials containing DEHP may extend up to 8 hours per day (U.S. EPA, 1991). This could be a conservative estimate in the event of handwashing throughout the shift. For average adult workers, the surface area of contact was assumed equal to the area of 1 hand ( <i>i.e.</i> , 535 cm <sup>2</sup> ), or 2 hands ( <i>i.e.</i> , 1,070 cm <sup>2</sup> ), for central tendency exposures, or high-end exposures, respectively (U.S. EPA, 2011a). The standard sources for exposure duration and area of contact received high ratings through EPA's systematic review process. These estimates cover dermal contact for several potential worker activities including, but not limited to, equipment cleaning, sampling, activities related to liquid processing, etc. The representativeness of these estimates to actual worker exposure will be dependent on the worker activity.
	The occupational dermal exposure assessment for contact with liquid materials containing DEHP was based on dermal absorption data for the dilute material, as well as standard occupational inputs for exposure duration and area of contact, as described above. Based on the strengths and limitations of these inputs, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the upper bound estimate of occupational dermal exposures in consideration of the strengths and limitations of reasonably available data and the variable inputs for exposure duration, surface area, and concentration of the formulation.
Dermal – solids	EPA used dermal absorption data from an <i>in vivo</i> absorption study using male F344 rats and DEHP contained within PVC film (Chemical Manufacturers Association, 1991) to estimate occupational dermal exposures of workers and ONUs to solid materials as described in The <i>Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate</i> (U.S. EPA, 2025r). In general, rodent skin has a higher dermal absorption than human skin, therefore this model likely provides a conservative estimate of dermal absorption of DEHP in humans from solid matrices. This data had a data quality rating of medium from systematic review. It is acknowledged that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. In a typical occupational exposure setting, the duration of exposure is not expected to exceed the shift time (typically, 8 to 12 hours). Therefore, EPA used the 24-hour steady-state absorptive flux from the Chemical Manufacturers Association to estimate occupational exposures (Chemical Manufacturers Association, 1991). Because this duration exceeds the occupational exposure duration and because the Chemical Manufacturers Association show that the absorptive flux increased with longer test durations, EPA expects the use of the steady-state absorptive flux data from Chemical Manufacturers Association to be protective of the duration of dermal exposures in occupational settings (Chemical Manufacturers Association to be protective of the duration of dermal exposures in occupational settings (Chemical Manufacturers Association, 1991).
	For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and that the chemical is contacted at least once per day. Because DEHP has low volatility and low absorption, it is possible that the chemical remains on the surface of the skin after a dermal contact until the skin is washed. Therefore, absorption of DEHP from occupational dermal contact with materials containing DEHP may extend up to 8 hours per day (U.S. EPA, 1991). This could be a conservative estimate in

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates	
	the event of handwashing throughout the shift. For average adult workers, the surface area of contact was assumed equal to the area of 1 hand ( <i>i.e.</i> , 535 cm <sup>2</sup> ), or 2 hands ( <i>i.e.</i> , 1,070 cm <sup>2</sup> ), for central tendency exposures, or high-end exposures, respectively (U.S. EPA, 2011a). The standard sources for exposure duration and area of contact received high ratings through EPA's systematic review process. These estimates cover dermal contact for several potential worker activities including, but not limited to, equipment cleaning, sampling, activities related to solids processing, etc. The representativeness of these estimates to actual worker exposures will be dependent on the worker activity.	
	The occupational dermal exposure assessment for contact with solid materials containing DEHP was based on <i>in vivo</i> dermal absorption data using male F344 rats, as well as standard occupational inputs for exposure duration and area of contact, as described above. Based on the strengths and limitations of these inputs, EPA has concluded that the weight of scientific evidence for this assessment provides moderate confidence in the estimate of occupational dermal exposures in consideration of the strengths and limitations of reasonably available data.	
ESD = Emission Scenario Document; OEL = occupational exposure limit; OES = occupational exposure scenario; ONU = occupational non-user; OSHA CEHD = Occupational Safety and Health Administration Chemical Exposure Health Data; PBZ = personal breathing zone; PVC = polyvinylchloride; SDS = safety data sheet; TWA = time-weighted average		

1693	4.1.1.4.1 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for
1694	the Occupational Exposure Assessment
1695	EPA assigned overall confidence descriptions of high, medium, or low to the exposure assessments,
1696	based on the strength of the underlying scientific evidence. When the assessment is supported by robust
1697	evidence, EPA's overall confidence in the exposure assessment is high; when supported by moderate
1698	evidence, EPA's overall confidence is medium; when supported by slight evidence, EPA's overall
1699	confidence is low.
1700	
1701	Strengths
1702	The exposure scenarios and exposure factors underlying the inhalation and dermal assessment are
1703	supported by slight to robust evidence.
1704 1705	A strength of the modeling assessment includes the consideration of variable model input perspectors as
1705	A strength of the modeling assessment includes the consideration of variable model input parameters as opposed to using a single static value. Parameter distributions increase the variability of modeled
1700	exposures and the likelihood that the exposure estimates are more representative of the true distribution.
1707	An additional strength is that all data that EPA used to inform the modeling parameter distributions have
1708	overall data quality ratings of either high or medium from EPA's systematic review process. Strengths
1710	associated with dermal exposure assessment are described in Table 4-4.
1711	associated with definite exposure assessment are described in Table 4 4.
1712	Limitations
1713	The principal limitation of the inhalation monitoring data is uncertainty in the representativeness of the
1714	data, as there is limited exposure monitoring data in the literature from systematic review. Additionally,
1715	differences in work practices and engineering controls across sites can introduce variability and limit the
1716	representativeness of the monitoring data. The age of the monitoring data may introduce uncertainty, in
1717	scenarios where workplaces and equipment used when the monitoring data were collected may not
1718	reflect current practice. A limitation of the modeling methodologies is that most of the model input data
1719	from GSs/ESDs, such as air speed or loss factors, are generic for the OESs and not specific to the use of
1720	DEHP within the OESs. Additionally, the selected generic models and data may not be representative of
1721	all chemical- or site-specific work practices and engineering controls.
1722	
1723	For datasets that included exposure data reported as below the limit of detection (LOD), EPA estimated
1724	exposure concentrations following guidance in EPA's Guidelines for Statistical Analysis of
1725	Occupational Exposure Data (U.S. EPA, 1994a). That report recommends using the $\frac{LOD}{\sqrt{2}}$ if the geometric
1726	standard deviation of the data is less than 3.0 and $\frac{LOD}{2}$ if the geometric standard deviation is 3.0 or
1727	greater. Use of this substitution method may impact the calculation of the exposure estimate statistics.
1728	
1729	Additionally, bulk samples included in inhalation monitoring studies may be used to confirm the
1730	presence of DEHP which supports the inclusion of non-detect samples in the final statistics.
1731	
1732	Limitations associated with dermal exposure assessment are described in Table 4-4.
1733	
1734	Assumptions
1735	When determining the appropriate model for assessing exposures to DEHP, EPA considered the
1736	physical form of DEHP during different OESs. DEHP may be present in different physical forms such
1737	as a powder, mist, paste, or in solution during the various OESs. EPA assessed each respective OES
1738	based on the physical form information from available product data, CDR data, and information from

applicable GSs/ESDs. The physical form of DEHP can influence exposures substantially. Generally,
EPA used the most prevalent physical form for the given OES when assessing exposures.

- EPA calculated ADD values assuming workers and ONUs are routinely exposed during their entire
  working lifetime, which may result in an overestimate. Individuals may change jobs during their career
  which could result in DEHP exposures that are lower than estimated.
- 1745
- 1746 Assumptions associated with dermal exposure assessment are described in Table 4-4.
- 1747
- 1748 Uncertainties
- 1749 EPA addressed variability in inhalation models by identifying key model parameters and applying
- statistical distributions that mathematically represent the parameter's variability. The Agency definedstatistical distributions for parameters using documented statistical sources where available. Where the
- 1751 statistical distributions for parameters using documented statistical sources where available, where the 1752 statistical variability was unknown, EPA made assumptions to estimate the parameter distribution using
- available literature data, such as GSs and ESDs. However, there is uncertainty as to the
- 1754 representativeness of the parameter distributions because these data are often not specific to sites that
- 1755 use DEHP. In general, the effects of these uncertainties on the exposure estimates are unknown as the
- 1756 uncertainties may result in either overestimation or underestimation of exposures, depending on the true 1757 distribution of each of the model input parameters.
- 1758

Surrogate approaches may be used in cases where no reasonably available exposure data exists for an
OES. In these situations, EPA may use surrogate (analogous) monitoring/modeling data (same chemical
but a different/similar OES). Additionally, the Agency may use surrogate monitoring/modeling where
the different chemical but the same (or similar) OES.

1763

Due to lack of ONU exposure data, EPA used the worker central tendency estimate as a surrogate for
ONUs. How well the worker central tendency exposure estimate represents true ONU exposure is
unknown. Therefore, EPA has lower confidence in the ONU exposure estimates compared to worker
central tendency exposure estimates.

1768

Generic Scenarios and Emission Scenario Documents are industry-specific guidance documents that
 provide estimation methods for occupational exposures and environmental releases. Although these
 documents are industry-specific, they are generally not chemical-specific.

1772

1773 These approaches are used to fill data gaps but have inherent uncertainty in how well they represent the1774 populations and activities they are used to assess.

1775

1777

1776 Uncertainties associated with dermal exposure assessment are described in Table 4-4.

# 4.1.2 Consumer Exposures

The following subsections briefly describe EPA's approach to assessing consumer exposures and provide exposure assessment results for each COU. The *Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e) provides additional details on the development of approaches and the exposure assessment results. The consumer exposure assessment evaluated exposures from individual COUs, while the indoor dust assessment uses a subset of consumer articles with large surface area and presence in indoor environments to garner COU specific

1784 contributions to the total exposures from dust.

1785 1786	4.1.2.1 Summary of Consumer and Indoor Dust Exposure Scenarios and Modeling Approach and Methodology
1787	The main steps in performing a consumer exposure assessment are summarized below:
1788 1789 1790	<ul> <li>Identification and mapping of product and article examples following the consumer COU table (Table 4-5), product and article identification;</li> <li>Compilation of products' and articles' manufacturing use instructions to determine patterns of</li> </ul>
1791 1792 1793	<ul> <li>use;</li> <li>Selection of exposure routes and exposed populations according to product/article use descriptions;</li> <li>Identification of data gaps and further search to fill gaps with studies, shemical surrogates or</li> </ul>
1794 1795 1796	<ul> <li>Identification of data gaps and further search to fill gaps with studies, chemical surrogates or product and article proxies, or professional judgement;</li> <li>Selection of appropriate modeling tools based on available information and chemical properties;</li> </ul>
1797 1798	<ul><li>Gathering of input parameters per exposure scenario; and</li><li>Parameterization of selected modeling tools.</li></ul>
1799 1800 1801 1802 1803 1804 1805 1806	Consumer products or articles containing DEHP were matched with the identified consumer COUs. Table 4-5 summarizes the consumer exposure scenarios by COU for each product example(s), the exposure routes, which scenarios are also used in the indoor dust assessment, and whether the analysis was conducted qualitatively or quantitatively. The indoor dust assessment uses consumer product and article information for selected items with the goal of recreating the indoor environment. The subset of consumer products and articles that are used in the indoor dust assessment are selected for their potential to have large surface area for dust collection, roughly larger than one square meter.
1806 1807 1808	When a quantitative analysis of reasonably available information was conducted, exposure from the consumer COUs was estimated by modeling. Exposure via inhalation and ingestion routes were modeled
1809 1810 1811	using EPA's Consumer Exposure Model (CEM), Version 3.2 ( <u>U.S. EPA, 2023c</u> ). Dermal exposures were estimated using a computational framework implemented within a spreadsheet environment using a flux-limited dermal absorption approach for liquid and solid products. Where possible, for each
1812 1813 1814 1815	exposure route, EPA used the 10th percentile, average, and 95th percentile deemed to characterize a high level of uncertainty and/or variability ( <i>e.g.</i> , DEHP weight fraction, article surface area, mass of product used, etc.) to characterize low, medium, and high exposure for a given condition of use. If only a range was reported, EPA used the minimum and maximum of the range as the low and high values,
1816 1817 1818 1819 1820	respectively. The average of the reported low and high values from the reported range was used for the medium exposure scenario. See the <i>Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP)</i> (U.S. EPA, 2025e) for details about the consumer modeling approaches, sources of data, model parameterization, and assumptions.
1821 1822 1823 1824	Exposure via the inhalation route occurs from inhalation of DEHP gas-phase emissions or when DEHP partitions to suspended particulate from direct use or application of products. However, DEHP's low volatility is expected to result in negligible gas-phase inhalation exposures. Sorption to suspended and settled dust is likely to occur based on monitoring data (see indoor dust monitoring data in Section
1824 1825 1826 1827 1828 1829 1830 1831 1832	4.1.2.1) and its affinity for organic matter which is typically present in household dust. Thus, inhalation and ingestion of suspended and settled dust is considered in this assessment. Exposure via the dermal route can occur from direct contact with products and articles. Exposure via ingestion depends on the product or article use patterns. Exposure can occur via direct mouthing ( <i>i.e.</i> , directly putting article in mouth) in which the person can ingest settled dust containing DEHP, or directly ingesting DEHP from migration out of the article to saliva. Additionally, ingestion of suspended dust can occur when DEHP migrates from product to dust or partitions from gas-phase to suspended dust.

- 1833 EPA made some adjustments to match CEM's lifestages to those listed in the U.S. Centers for Disease
- 1834 Control and Prevention (CDC) guidelines (<u>CDC, 2021</u>) and EPA's *A Framework for Assessing Health*
- 1835 *Risks of Exposures to Children* (U.S. EPA, 2006). CEM lifestages are re-labeled from this point forward as follows:
- 1837 Adult  $(21 + years) \rightarrow Adult$
- 1838 Youth 2 (16–20 years)  $\rightarrow$  Teenager
- 1839 Youth 1 (11–15 years)  $\rightarrow$  Young teen
- 1840 Child 2 (6–10 years)  $\rightarrow$  Middle childhood
- Child 1 (3–5 years)  $\rightarrow$  Preschooler
- Infant 2 (1–2 years)  $\rightarrow$  Toddler
- 1843 Infant 1 (<1 year)  $\rightarrow$  Infant
- 1844 EPA assessed acute, intermediate, and chronic exposures to DEHP from consumer COUs. For the acute 1845 dose rate calculations, an averaging time of 1 day is used representing the maximum time-integrated
- 1845 dose rate calculations, an averaging time of 1 day is used representing the maximum time-integrated 1846 dose over a 24-hour period during the exposure event. The chronic dose rate is calculated iteratively at
- 1847 30-second intervals during the first 24 hours and every subsequent hour for 60 days and averaged over 1
- 1848 year. Intermediate dose is the exposure to continuous or intermittent (depending on product) use during
- a 30-day period, which is roughly 1 month. See Sections 2.2.1 and 2.2.2 and Appendix A in (U.S. EPA,
- 1850 2025e) for details about acute, chronic, and intermediate dose calculations. Professional judgment and
- 1851 product use descriptions were used to estimate events per day and per month/year for the calculation of
- 1852 the intermediate/chronic dose.
- 1853

# 1854 Table 4-5. Summary of Consumer COUs, Exposure Scenarios, and Exposure Routes

·				<b>Evaluated Routes</b>					
Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Inhalation <sup>a</sup>	Dermal	Suspended Dust	Settled Dust	Mouthing	
Automotive, fuel, agriculture, outdoor use products	Lawn and garden care products	Small articles with the potential for semi-routine contact: hose	Direct contact during use	×	~	×	×	×	
Construction, paint, electrical, and metal products	Adhesives and sealants	Adhesive/sealant for home DIY, large indoors	Use of product in DIY large-scale home repair activities. Direct contact during use; inhalation of emissions during use	~	~	×	×	×	
Construction, paint, electrical, and metal products	Adhesives and sealants	Adhesive/sealant for home DIY, small outdoors	Direct contact during application.	×	~	×	×	×	
Construction, paint, electrical, and metal products	Adhesives and sealants	Automotive filler/putty	Use of product in DIY small-scale auto repair. Direct contact during use; inhalation of emissions	×	~	×	×	×	
Construction, paint, electrical, and metal products	Batteries	Batteries	Contact is expected to be infrequent	~	~	×	×	×	
Construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Vinyl flooring	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	✓ b	~	✓ b	✓ b	*	
Construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Wallpaper	Two scenarios, installation, and in- place. Direct contact during installation (teenagers and adults) and while in place; inhalation of emissions / ingestion of dust adsorbed chemical	✓ b	~	✓ b	✓ b	×	

					Evalua	ted Routes		
				a		Ing	gestio	n
Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Inhalation '	Dermal	Suspended Dust	Settled Dust	Mouthing
Construction, paint, electrical, and metal products	Machinery, mechanical appliances, electrical/electronic articles	Small articles with the potential for semi-routine contact: phone charge, wireless earbuds, electrical tape	Direct contact during use	×	~	×	×	×
Construction, paint, electrical, and metal products	Machinery, mechanical appliances, electrical/electronic articles	Insulated cords	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical, mouthing by children	✓ b	~	✓ b	✓ b	×
Construction, paint, electrical, and metal products	Paints and coatings	Coating for home DIY, large outdoors	Direct contact during application.	×	~	×	×	x
Construction, paint, electrical, and metal products	Paints and coatings	Automotive coating	Use of product in DIY small-scale auto repair. Direct contact during use; inhalation of emissions	~	~	×	×	x
Furnishing, cleaning, treatment care products	Fabric, textile, and leather products; furniture and furnishings	Synthetic leather furniture	Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	✓ b	$\checkmark$	✓ b	✓ b	~
Furnishing, cleaning, treatment care products	Fabric, textile, and leather products; furniture and furnishings	Synthetic leather clothing	Direct contact during use	×	$\checkmark$	×	×	×
Furnishing, cleaning, treatment care products	Fabric, textile, and leather products; furniture and furnishings	Small articles with the potential for semi-routine contact: outdoor furniture, children's bags, wallets, footwear, interior and exterior components of jackets, handbags	Direct contact during use	<b>X</b> b	~	×	×	×
Furnishing, cleaning, treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	Vinyl flooring	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	✓ b	✓	✓ b	✓ b	×

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route		Evalua	Evaluated Route			
						Ingestion			
				Inhalation <sup>a</sup>	Dermal	Suspended Dust	Settled Dust	Mouthing	
Furnishing, cleaning, treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	Wallpaper	Two scenarios, installation, and in- place. Direct contact during installation (teenagers and adults) and while in place; inhalation of emissions / ingestion of dust adsorbed chemical	√ b	~	√ b	✓ b	×	
Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorants	Stamp ink	Direct contact during use	×	$\checkmark$	×	×	×	
Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)	Air mattresses and sleeping mats	Direct contact during use; inhalation of emissions / ingestion of dust adsorbed chemical	✓ b	~	✓ b	✓ b	×	
Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)	Rubber eraser	Direct contact during use; rubber particles may be inadvertently ingested during use. Eraser may be mouthed by children	×	~	×	×	~	
Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)	Mobile phone covers	Direct contact during use	×	~	×	×	×	
Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during	Shower curtain	Direct contact during use. See routine contact scenario inhalation of emissions / ingestion of dust adsorbed	✓ b	~	✓ b	✓ b	×	

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route		Evalua	ted Routes			
				Inhalation <sup>a</sup>	Dermal	Ingestion			
						Suspended Dust	Settled Dust	Mouthing	
	normal use, including rubber articles; plastic articles (hard); plastic articles (soft)		chemical while hanging in place						
Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)	Small articles with the potential for semi-routine contact: packaging, paper, plastic, toys, hobby products: cutting board, pencils, pouches, bags, hose, labels, covers, chewy toys, jewelry, gloves, packaging, mats, lampshade, vinyl floor runner, diving goggles, silly straws, stickers, diving goggles	Direct contact during use	×	✓	×	×	×	
Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging), including paper articles	Small articles with the potential for semi-routine contact: packaging, paper, hobby products: pencils, labels, covers, lampshade, stickers	Direct contact during use	×	<b>√</b>	×	×	×	
Packaging, paper, plastic, toys, hobby products	Toys, playground, and sporting equipment	Children's toys (legacy) produced before CPSIA statutory and regulatory limitations, 0.1%.	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	✓ b	~	✓ b	✓ b	~	
Packaging, paper, plastic, toys, hobby products	Toys, playground, and sporting equipment	Children's toys (new) produced after CPSIA statutory and regulatory limitations, 0.1%.	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne PM; ingestion by mouthing	✓ b	$\checkmark$	√ b	✓ b	✓	
Packaging, paper, plastic, toys, hobby products	Toys, playground, and sporting equipment	Tire crumb, artificial turf	Direct contact during use (particle ingestion via hand-to-mouth)	$\checkmark$	$\checkmark$		✓ <sub>c</sub>		
Packaging, paper, plastic, toys, hobby products	Toys, playground, and sporting equipment	Small articles with the potential for semi-routine	Direct contact during use	×	~	×	×	×	

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	<b>Evaluated Routes</b>					
				Inhalation <sup>a</sup>	Dermal	Ingestion			
						Suspended Dust	Settled Dust	Mouthing	
		contact: fitness balls, jump rope, yoga mat, football, and diving goggles							
Other	Novelty articles	Adult toys	Direct contact during use, ingestion by mouthing	×	$\checkmark$	×	×	✓	
Other	Automotive articles	Car mats	Direct contact during use. See routine contact scenario inhalation of emissions / ingestion of dust adsorbed chemical	✓ b	~	<b>√</b> b	✓ b	×	
Other	Automotive articles	Tire replacement	Direct contact during use	×	$\checkmark$	×	×	×	
Disposal	Disposal	Down the drain products and articles	Down the drain and releases to environmental media	×	×	×	×	×	
Disposal	Disposal	Residential end-of-life disposal, product demolition for disposal	Product and article end-of-life disposal and product demolition for disposal	×	×	×	×	×	

DIY = do-it-yourself

CPSIA – Consumer Product Safety Improvement Act of 2008 (CPSIA section 108(a), 15 U.S.C. § 2057c(a);16 CFR 1307.3(a)), Congress permanently prohibited the sale of children's toys or childcare articles containing concentrations of >0.1% DEHP.

<sup>a</sup> Inhalation scenarios consider suspended dust and gas-phase emissions.

<sup>b</sup> Scenario used in Indoor Dust Exposure Assessment in Section 4 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate* (*DEHP*) (U.S. EPA, 2025e). These indoor dust articles scenarios consider the surface area from multiple articles such as toys, while furniture and flooring already have large surface areas. For these articles dust can deposit and contribute to significantly larger concentration of dust than single small articles

<sup>c</sup> The tire crumb and artificial turf ingestion route assessment considers all three types of ingestions, settled dust, suspended dust, and mouthing altogether, but results cannot be provided separately as it was done for all other articles and products.

✓ Quantitative assessment

× Qualitative assessment; See Section 2 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e) for qualitative assessments (*i.e.*, batteries, stamp ink, disposal qualitative assessments) and Section 3.1.4 of this document for a detailed qualitative discussion of disposal exposures. Note that exposures resulting from disposing of down the drain are primarily expected to affect the environmental organisms and the general population who are downstream from wastewater releases. Note that exposures from disposal in general could not be estimated due to key uncertainties discussed in Section 2 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e) and Section 3.1.4 of this draft risk evaluation.

## 1856 Inhalation and Ingestion Exposure Routes Modeling Approaches

- 1857 Key parameters for articles modeled in CEM 3.2 are summarized in detail in Section 2 in *Draft*
- 1858 Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA,
- 1859 <u>2025e</u>). Calculations, sources, input parameters and results are also available in *Draft Consumer*
- 1860 *Exposure Analysis for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025f). Generally, and when
- 1861 possible, model parameters were determined based on specific articles identified in this assessment and
- 1862 CEM defaults were only used where specific information was not available. A list of some of the most
- 1863 important input parameters for exposure from articles and products is included below:
- weight fraction (articles and products);
- density (articles and products);
- duration of use (products);
- frequency of use for chronic, acute, and intermediate (products);
- 1868 product mass used (products);
- article surface area (articles);
- chemical migration rate to saliva (articles);
- area mouthed (articles); and
- use environment volume (articles and products).

1873 Of these, the chemical migration rate from articles to saliva and area mouthed are most important to 1874 mouthing exposure scenarios while duration, frequency and amount used have been determined to be 1875 key determinants of estimated exposure concentrations according to a sensitivity analysis conducted for 1876 CEM input parameters (U.S. EPA, 2023c).

1877

For each scenario, high-, medium-, and low-intensity use exposure scenarios were developed in which values for duration of use, frequency of use, and surface area were determined based on reasonably available information or professional judgment. Each input parameter listed above was parameterized according to the article-specific data found via systematic review. If article-specific data were not available, CEM default parameters were used, or if CEM default parameters were not applicable an assumption based on article use descriptions by manufacturers was used always leaning on the health protective values.

1885

1886 For all scenarios, the near-field modeling option was selected to account for a small personal breathing zone around the user during product use in which concentrations are higher, rather than employing a 1887 1888 single well-mixed room. This is because when the consumer product or article is being used, the near-1889 field/far-field modeling allows EPA to more accurately predict a consumer's exposure by assuming a 1890 volume of air (*i.e.*, 1 m<sup>3</sup>) around the individual as they move throughout the room and/or use a product 1891 during the time of use and otherwise follow their prescribed activity pattern (*i.e.*, applying sealant to the 1892 baseboard around a living room for a total of 30 minutes). On the other hand, bystanders follow their 1893 prescribed activity pattern and inhale far-field concentrations when they are in the room of use. For 1894 instance, by standers may be children playing on the living room floor as the active consumer product 1895 user (typically a parent or other adult), applies the sealant on the baseboard that surrounds the room 1896 during a 30-minute time frame. In this example, the parent is exposed to a higher concentration of 1897 DEHP compared to the children because the parent is closer to the DEHP being released from the 1898 sealant. Sometime later, as the sealant dries, through ventilation and as the fumes and particle matter 1899 disperse in the room, the parent and the children would be both exposed to a relatively more 1900 homogenous air concentration of DEHP that would be reflected in the modeling results for the well-1901 mixed room. The prior is a consumer application scenario best represented by the near-field/far-field 1902 modeling, and the latter is an indoor air exposure scenario best represented by the well-mixed room 1903 modeling. The well-mixed room modeling should be applied when estimating overall indoor air

1904 chemicals exposures occuring in the long-term, once peak concentrations (via emissions or

- abrasion/resuspension) have dissipated towards a background level of the chemical. This may take days weeks or months after use or installation—depending on the chemical, product/article, room of use,
- 1907 ventilation rate, and room volume. As appropriate, EPA uses the near-field/far-field model because it
- 1908 captures the highest potential chemical concentration that occurs during the consumer condition of use,
- 1909 while the well-mixed room scenario would not capture the short-term (*i.e.*, acute) exposure in the
- immediate space (volume of air) where the product is been used. See Section 2.1 for weight fraction
- selection and Section 2.2.3 for parameterization details in the *Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e).
- 1912 1913

## 1914 Dermal Exposure Routes Modeling Approaches

1915 Dermal modeling was done outside of CEM. The use of the CEM model for dermal absorption, which 1916 relies on total concentration rather than aqueous saturation concentration, would greatly overestimate 1917 exposure to DEHP in liquid and solid products and articles. See U.S. EPA (2025e) for more details. The 1918 dermal dose of DEHP associated with use of both liquid products and solid articles was calculated in a 1919 spreadsheet outside of CEM. All CEM and dermal spreadsheet inputs, sources of information, 1920 assumptions, and exposure scenario descriptions are available in the Draft Risk Evaluation for Di(2-1921 ethylhexyl) Phthalate (DEHP) - Supplemental Information File: Consumer Exposure Analysis (U.S. 1922 EPA, 2025a) and Draft DEHP Consumer Risk Calculator (U.S. EPA, 2025g). EPA used a screening 1923 approach with a range of conservative, yet plausible, input parameters for contact surface area, and 1924 duration and frequency of contact. The flux-limited, screening dermal absorption approaches for liquid and solid products and articles assumes an excess of DEHP in contact with the skin independent of 1925 1926 concentration in the article/product. Dermal flux value for liquid products was from Hopf et al. (2014) 1927 and solid products was from Chemical Manufacturers Association (1991). The flux-limited screening 1928 approach provides an upper bound of dermal absorption of DEHP and likely results in some 1929 overestimations, see Section 4.1.2.4 discussion on limitations, strengths, and confidence. For each 1930 product or article, high-, medium-, and low-intensity use exposure scenarios were developed. Values for 1931 duration of dermal contact and area of exposed skin were determined based on the reasonably expected 1932 use for each item. Key parameters for the dermal model are shown in Section 2.3 in (U.S. EPA, 2025e). 1933

1934 The screening dermal exposure risk assessment for air beds resulted in potential risks for the high-,

1935 medium-, and low-intensity use exposure scenarios, see Appendix B in U.S. EPA (2025e). EPA refined

the screening approach used for dermal exposures to air beds as described in this section for all

1937 lifestages. Specifically, the Agency moved from a screening approach of assuming flux limited dermal 1938 absorption to a more refined approach, which models dermal absorption using DEHP concentration in 1939 the article, material-, and DEHP-specific partition coefficients as well as a barrier bedsheet between the 1940 air bed and skin.

air bec

## 4.1.2.2 Modeling Dose Results by COU for Consumer

This section summarizes the dose estimates from inhalation, ingestion, and dermal exposure to DEHP in
consumer products and articles. Detailed tables of the dose results for acute, intermediate, and chronic
exposures are available in the *Draft Consumer Risk Calculator for Diethylhexyl Phthalate (DEHP)* (U.S.
EPA, 2025g). Modeling dose results for acute, intermediate, and chronic exposures and data patterns are
described in Section 3 in the *Draft Consumer and Indoor Exposure Assessment for Diethylhexyl*Phthalate (DEHP) (U.S. EPA, 2025e).

1948

1941

For teens and young adults (11–20 years old), and adults, dermal contact was a strong driver of exposure to DEHP, with the dose received being generally higher than or similar to the dose received from

1951 exposure via inhalation or ingestion. This is likely due to the dermal modeling assumption, per <u>Kissel</u>

1952 (2011), that the supply of the DEHP material added to the skin is in excess and not significantly depleted 1953 over the course of the product or article's use. This results in a potential overestimation of dose and 1954 subsequent risk. The largest dose estimated is for acute and chronic dermal exposure to synthetic leather 1955 furniture for all lifestages. Among the younger lifestages (infant to 11 years old), the pattern was less 1956 clear as these ages were designated as bystanders rather than product users, therefore dermal exposure 1957 was not modeled for any of the liquid products assessed. Key differences in exposures among lifestages 1958 include designation as a product user or bystander; behavioral differences such as hand to mouth contact 1959 times and time spent on the floor; and dermal contact expected from touching specific articles, which 1960 may not be appropriate for some lifestages.

## 19614.1.2.3 Indoor Dust Assessment

1962 Because PVC products are ubiquitous in modern indoor environments, and since DEHP is not 1963 chemically-bound to many consumer products and articles in which it is incorporated, it can leach, 1964 migrate or evaporate into indoor air and concentrate in household dust. See Section 2.2.3.1.9 of the Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 1965 2025e) for a detailed presentation of product and article DEHP migration rates observed in the literature. 1966 1967 Exposure to DEHP through dust ingestion, dust inhalation, and dermal absorption is a particular concern 1968 for young children between the ages of 6 months and 2 years. This is because crawling on the ground 1969 and pulling up on ledges increases hand-to-dust contact as does placing their hands and objects in their 1970 mouths. Exposure to DEHP via ingestion of dust was assessed for all articles expected to contribute 1971 significantly to dust concentrations due to high surface area (exceeding  $\sim 1 \text{ m}^2$ ) for either a single article 1972 or collection of like articles as appropriate. In a screening assessment, EPA considered the aggregation 1973 of chronic dust ingestion doses, see Section 4.3 in the Draft Consumer and Indoor Exposure 1974 Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e). The highest dose was for 1975 preschoolers, aged 3 to 5 years.

1976

1982

1983

1984

1985

1977 Articles included in the indoor assessment included the following:

- 1978 car mats;
- vinyl flooring;
- wallpaper in-place;
- 1981 insulated cords;
  - furniture components (textiles);
  - air beds;
  - shower curtains; and
  - children's toys, new and legacy.

1986 Regarding the mechanism through which exposures or risks to indoor dust may occur (*i.e.*, via migration 1987 of DEHP from consumer materials to indoor dust), abraded particles are generally assumed to be 1988 initially emitted to the air and thereafter may deposit and resuspend from the surfaces. Abraded 1989 particles, like suspended and settled particulate, are subject to cleaning and ventilation losses. Abraded particles, both in the suspended and settled phases, are not assumed to be in equilibrium with the air 1990 1991 phase. EPA could not predict how much DEHP originally in an article would become available in 1992 household dust where it may be ingested by infants via hand-to-mouth. Hence, the chemical transfer 1993 between particulates and the air phase was kinetically modeled in terms of two-phase mass transfer 1994 theory. EPA also assessed indoor dust ingestion from the monitoring literature. EPA compared these 1995 values in Section 4.3 of the Draft Consumer and Indoor Exposure Assessment for Diethylhexyl 1996 *Phthalate (DEHP)* (U.S. EPA, 2025e). Modeling and monitoring results were within the same order or 1997 magnitude. With an age group-specific margin of error ranging from 0.6 to 9 depending on the age 1998 group. For a detailed discussion of COU-specific uncertainties, see Sections 2 and 5 of the Draft

1999 Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e).

2000

## 4.1.2.4 Weight of Scientific Evidence Conclusions for Consumer Exposure

2001 Key sources of uncertainty for evaluating exposure to DEHP in consumer goods and strategies to 2002 address those uncertainties are described in detail in Section 5.1 of the Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e). Generally, designation of 2003 2004 robust confidence suggests that the supporting scientific evidence weighed against the uncertainties is 2005 adequate to characterize exposure assessments. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on 2006 2007 the exposure estimate. The designation of moderate confidence suggests that the supporting scientific 2008 evidence weighed against the uncertainties is reasonably adequate to characterize exposure assessments. 2009 The designation of slight confidence is assigned when the weight of scientific evidence may not be 2010 adequate to characterize the scenario, and when the assessor is making the best scientific assessment 2011 possible in the absence of complete information and there are additional uncertainties that may need to 2012 be considered. The DEHP consumer exposure overall confidence to use the results for risk characterization ranges from moderate to robust, depending on COU scenario. The basis for the 2013 2014 moderate to robust confidence in the overall exposure estimates is a balance between using parameters 2015 that will represent various populations' use patterns and leaning on conservative assumptions that are 2016 not excessive or unreasonable.

2017 2018

# 4.1.2.5 Strength, Limitations, Assumptions, and Key Sources of Uncertainty for the Consumer Exposure Assessment

2019 The exposure assessment of chemicals from consumer products and articles has inherent challenges due 2020 to many sources of uncertainty in the analysis, including variations in product formulation, patterns of consumer use, frequency, duration, and application methods. Variability in environmental conditions 2021 2022 may also alter physical and/or chemical behavior of the product or article. Table 4-6 summarizes the 2023 overall confidence per COU, and a discussion of rationale used to assign the overall confidence. The 2024 subsections preceding Table 4-6 describe sources of uncertainty for several parameters used in consumer 2025 exposure modeling that apply across COUs and provide an in depth understanding of sources of 2026 uncertainty and limitations and strengths within the analysis. The confidence to use the results for risk 2027 characterization ranges from moderate to robust.

2028

## 2029 **Product Formulation and Composition**

2030 Variability in the formulation of consumer products, including changes in ingredients, concentrations, 2031 and chemical forms, can introduce uncertainty in exposure assessments. In addition, data were 2032 sometimes limited for weight fractions of DEHP in consumer goods. EPA obtained DEHP weight 2033 fractions in various products and articles from material safety data sheets, data bases, and existing 2034 literature see Section 2.1 in U.S. EPA (2025e). Where possible, the Agency obtained multiple values for 2035 weight fractions for similar products or articles. The lowest value was used in the low exposure scenario, 2036 the highest value in the high exposure scenario, and the average of all values in the medium exposure 2037 scenario. The screening assessment for dermal exposure largely did not depend on weight fractions as a 2038 modeling input. Instead, it was highly dependent on the DEHP experimental dermal load applied from 2039 literature for liquid products and solid articles. On the other hand, the refined dermal exposure 2040 assessment for airbeds did utilize weight fraction as a key input parameter. EPA decreased uncertainty in exposure and subsequent risk estimates in the high-, medium-, and low-intensity use scenarios by 2041 capturing the weight fraction variability and obtaining a better characterization of the varying 2042 2043 composition of products and articles within one COU. Overall weight fraction confidence is moderate 2044 for products/articles with multiple sources but insufficient description on how the concentrations were

2045 obtained, *robust* for products/articles with more than one source, and *slight* for articles with only one 2046 source with unconfirmed content or little understanding on how the information was produced.

## 2048 **Product Use Patterns**

2047

2049 Consumer use patterns such as frequency of use, duration of use, method of application, and skin contact 2050 area are expected to differ. Where possible, low, medium, and high default values from CEM 3.2's 2051 prepopulated scenarios were selected for mass of product used, duration of use, and frequency of use. In 2052 instances where no prepopulated scenario was appropriate for a specific product, low, medium, and high values for each of these parameters were estimated based on the manufacturers' product descriptions. 2053 2054 EPA decreased uncertainty by selecting use pattern inputs that represent product and article use 2055 descriptions and furthermore capture the range of possible use patterns in the high- to low-intensity use 2056 scenarios. Exposure and risk estimates are considered representative of product use patterns and are well characterized. The overall confidence for most use patterns is rated *robust*. 2057 2058

## 2059 Article Use Patterns

2060 To calculate inhalation and ingestion exposures from articles, the high-, medium-, and low-intensity use 2061 scenarios default values from CEM 3.2's prepopulated scenarios were selected for indoor use 2062 environment/room volume, interzone ventilation, and surface layer thickness. To calculate dermal 2063 exposures from articles, use patterns such as frequency of use and skin contact area are expected to have 2064 a range of low to high use intensities. For articles, which do not use duration of use as an input in CEM, 2065 professional judgment was used to select the duration of use/article contact duration for the low, 2066 medium, and high exposure scenario levels for most articles except for vinyl flooring. Vinyl flooring 2067 contact duration values were taken from EPA's Standard Operating Procedures for Residential Pesticide 2068 Exposure Assessment for the high exposure level (2 hours; time spent on floor surfaces) (U.S. EPA, 2069 2012b), ConsExpo (U.S. EPA, 2012b) for the medium exposure level (1 hour; time a child spends 2070 crawling on treated floor), and professional judgment for the low exposure level (0.5 hour). There are 2071 more uncertainties in the assumptions and professional judgment for contact duration inputs for articles; 2072 thus, EPA has *moderate* confidence in those inputs.

## 2074 Article Surface Area

2075 The surface area of an article directly affects the potential for DEHP emissions to the environment. For 2076 each article modeled for inhalation exposure, low, medium, and high estimates for surface area were 2077 calculated see Section 2.2.3 in U.S. EPA (2025e). This approach relied on manufacturer-provided 2078 dimensions where possible, or values from EPA's *Exposure Factors Handbook* for floor and wall 2079 coverings. For small items that might be expected to be present in a home in significant quantities, such 2080 as insulated wires and children's toys, aggregate values were calculated for the cumulative surface area 2081 for each type of article in the indoor environment. Overall confidence in surface area is *moderate* for 2082 articles like wires because there is less understanding of the number of wires exposed to collect dust, and 2083 the great variability that is expected may not be well represented. Overall confidence in surface area is 2084 robust for articles like furniture, wall coverings, flooring, toys, and shower curtains because there is a 2085 good understanding of the presence and dimensions of these articles in indoor environments.

## 2087 Human Behavior

2088 CEM 3.2 has three different activity patterns: stay-at-home, part-time out-of-the home (daycare, school,

2089 or work), and full-time out-of-the-home. The activity patterns were developed based on the

- 2090 Consolidated Human Activity Database (CHAD). For all products and articles modeled, the stay-at-
- 2091 home activity pattern was chosen as it is the most protective assumption.
- 2092

2086

2073

- 2093 Mouthing durations are a source of uncertainty in human behavior. The data used in this assessment are 2094 based on a study in which parents observed children (n = 236) ages 1 month to 5 years of age for 15 2095 minutes each session and 20 sessions in total (Smith and Norris, 2003). There was considerable 2096 variability in the data due to behavioral differences among children of the same lifestage. For instance, 2097 while children aged 6 to 9 months had the highest average mouthing duration for toys at 39 minutes per 2098 day, the minimum duration was 0 minutes, and the maximum was 227 minutes per day. The observers 2099 noted that the items mouthed were made of plastic roughly 50 percent of the mouthing time, but this was 2100 not limited to soft plastic items likely to contain significant plasticizer content. In another study, 169 2101 children aged 3 months to 3 years were monitored by trained observers for 12 sessions at 12 minutes 2102 each session (Greene, 2002). They reported mean mouthing durations ranging from 0.8 to 1.3 minutes 2103 per day for soft plastic toys and 3.8 to 4.4 minutes per day for other soft plastic objects (except 2104 pacifiers). Thus, it is likely that the mouthing durations used in this assessment provide a health 2105 protective estimate for mouthing of soft plastic items likely to contain DBP. EPA assigned a *moderate* 2106 confidence associated with the duration of activity for mouthing because the magnitude of the 2107 overestimation is not well characterized. All other human behavior parameters are well understood or 2108 the ranges used capture use patterns representative of various lifestages, which results in a *robust* 2109 confidence in use patterns.
- 2110

## 2111 Inhalation and Ingestion Modeling Tool

2112 Confidence in the model used considers whether the model has been peer reviewed, as well as whether it 2113 is being applied in a manner appropriate to its design and objective. For example, the model used (CEM 2114 3.2) has been peer reviewed, is publicly available, and has been applied in a manner intended by 2115 estimating exposures associated with uses of household products and/or articles. This also considers the 2116 default values data source(s) such as building and room volumes, interzonal ventilation rates, and air 2117 exchange rates. Overall confidence in the proper use of CEM for consumer exposure modeling is *robust*. 2118

2119 Dermal Modeling of DEHP

Experimental dermal data was identified via the systematic review process to characterize consumer
dermal exposures to liquids or mixtures and formulations containing DEHP; see Section 2.3.1 in U.S.
EPA (2025e). The confidence in dermal exposure to liquid and solid products model used in this
assessment is *moderate*.

2124

EPA identified nine experimental studies directly related to the dermal absorption of DEHP. Of the nine
 available studies, EPA identified two studies that are most reflective of DEHP exposure from consumer
 products and articles: one for liquid products (Hopf et al., 2014) and one for solid products (Chemical
 Manufacturers Association, 1991). Section 2.3.1 in U.S. EPA (2025e) summarized the criteria applied to
 select these two studies. When available dermal absorption empirical data that is specific to the exposure

- 2130 scenarios of interest is preferrable over modeling approaches.
- 2131

2132The Chemical Manufacturers Association (1991)dermal absorption study was conducted in vivo using2133male F344 rats. There have been additional studies conducted to determine the difference in dermal

absorption between rat skin and human skin. Specifically, Scott (<u>1987</u>) examined the difference in

dermal absorption between rat skin and human skin for four different phthalates (*i.e.*, DMP, DEP, DBP, and DEUD) using in vitro dermal absorption testing. Peoples from the in vitro dermal absorption

- and DEHP) using *in vitro* dermal absorption testing. Results from the *in vitro* dermal absorption
   experiments showed that rat skin was more permeable than human skin for all four phthalates examined.
- 2137 Experiments showed that fat skin was more permeable than human skin for DEP, and rat skin was up to 30 times more permeable than human skin for DEP, and rat skin was up
- 2130 to 4 times more permeable than human skin for DEHP. Although there is uncertainty regarding the
- 2140 magnitude of difference between dermal absorption through rat skin vs. human skin for DEHP, EPA is
- 2141 confident that the *in vivo* dermal absorption data using male F344 rats may lead to an overestimation of

dermal absorption of DEHP based on the findings of <u>Scott et al. (1987)</u>. The <u>Chemical Manufacturers</u>
<u>Association (1991)</u> dermal absorption study provides the best available data for solid articles and met
most of the criteria for selection as highlighted in Section 2.3.1 in the *Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e). In fact, this study was the
only study identified that measured dermal absorption of DEHP from solid articles and accounted for

- both the low migration rate out of DEHP out of the PVC film (0.13%) and the low dermal absorption of that migrated DEHP available for absorption (3.4%).
- 2149

2150 EPA identified a study of dermal absorption to liquids for DEHP, Hopf et al. (2014), which reported dermal absorption based on metabolically active excised human skin, within just a few hours after 2151 2152 excision; therefore, this study was used for determining exposure of humans to liquids containing 2153 DEHP. It should be noted that the Agency identified an error with the reported applied dose whereby the units were incorrectly reported in  $mg/cm^2$  instead of  $\mu g/cm^2$ . Based on supporting information reported 2154 2155 within the study's report (*i.e.*, concentration of DEHP, application amount, and skin surface area), the 2156 Agency was able to recalculate the correct applied dose in  $\mu g/cm^2$ . As was the case with dermal contact with solid articles, the flux resulting from dermal contact with liquid formulations of DEHP was low, 2157 2158  $0.0013 \,\mu\text{g/cm}^2$ /hour for the neat material and  $0.025 \,\mu\text{g/cm}^2$ /h for aqueous solutions of DEHP.

2159

2160 EPA used a screening flux-limited approach to assess dermal exposures to air beds. Upon examination 2161 of the dermal exposure results for air beds using the screening flux-limited approach, EPA identified the 2162 concentration of DEHP in the article, direct surface contact area between skin and air bed, and duration 2163 of contact, to be key drivers of risk estimates resulting in a MOE under the benchmark of 30 (see 2164 Section 2.3.2 in U.S. EPA (2025e)). Moreover, the screening flux-limited approach was independent of concentration of DEHP in the air bed, due to an assumption of excess of DEHP available for exposure. 2165 2166 This conservative screening assumption did not result in evidence of potential for risk for any products 2167 or articles other than air beds. Generally, the screening approach is assumed to represent conservative 2168 potential dermal exposure scenarios. To refine its assessment of dermal exposures to air beds, EPA 2169 considered the concentration of DEHP in air beds instead of the flux-limited approach and included a 2170 barrier bedsheet between air bed and skin to better estimate typical dermal exposures to air beds, based 2171 on a wide range of possible usage patterns. This refinement was based on the application of DEHP 2172 partitioning coefficients among the air bed, bedsheet, and skin, which were all sourced from peer-2173 reviewed literature (see Section 2.3.2 in U.S. EPA (2025e)). This refinement increased EPA's 2174 confidence in the dermal exposure assessment of DEHP in air beds as it considers realistic exposure 2175 scenarios based on a wide range of possible usage patterns that consider long and shorter contact 2176 durations.

2177

2178 A key source of uncertainty regarding the dermal absorption of DEHP from products or formulations 2179 stems from the varying concentrations and co-formulants that exist in products or formulations 2180 containing DEHP. Dermal contact with products or formulations that have lower concentrations of 2181 DEHP may exhibit lower rates of flux because there is less material available for absorption. 2182 Conversely, co-formulants or materials within the products or formulations may lead to enhanced 2183 dermal absorption-even at lower concentrations. Therefore, it is uncertain whether the products or 2184 formulations containing DEHP would result in decreased or increased dermal absorption. Based on the 2185 available dermal absorption data for DEHP, EPA has made assumptions that result in exposure 2186 assessments that are the most human health protective in nature.

2187

Experimental dermal data were identified via the systematic review process to estimate dermal
exposures to solid products or articles containing DEHP, and a modeling approach was used to estimate
exposures; see Appendix A.4 in U.S. EPA (2025e). Because this study is accounting for the low

migration rate of DEHP out of the PVC film and the low dermal absorption of that migrated DEHP available for absorption to determine the flux of 0.048  $\mu$ g/cm<sup>2</sup>/hour, this test system provides the most

relevant estimate of dermal absorption from contact with solid articles. However, the study is in rats,

2194 whose skin is more permeable than human skin. Additionally, flux is concentration-dependent, and the

- study used a high percentage of DEHP in the film (40%). Therefore, the flux may provide a conservative
- estimate of dermal absorption in humans exposed to DEHP in solid articles. EPA has a *moderate* 
  - confidence in the dermal exposure to solid products or articles modeling approach.

## 2199 Ingestion Via Mouthing

2200 For chemical migration rates to saliva, existing data were highly variable both within and between 2201 studies. This indicates the significant level of uncertainty for the chemical migration rate, as it may also 2202 differ even among similar items due to variations in chemical makeup and polymer structure. As such, 2203 an effort was made to choose DEHP migration rates likely to be representative of broad classes of items 2204 that make up consumer COUs produced with different manufacturing processes and material 2205 formulations. There is no consensus on the correct value to use for this parameter in past assessments of 2206 DEHP. The 2003 EU Risk Assessment for DEHP used a migration rate of  $53.4 \,\mu g/cm^2/h$  selected from the highest individual estimate from a 1998 study by the Netherlands National Institute for Public Health 2207 2208 and the Environment (RIVM) (ECJRC, 2003; RIVM, 1998). The RIVM study measured DEHP in saliva of 20 adult volunteers biting and sucking four PVC disks with a surface of 10 cm<sup>2</sup>. Average migration to 2209 2210 saliva from the samples tested were 8.4, 14, 4, and 9.6  $\mu$ g/cm<sup>2</sup>/h, and there was considerable variability 2211 in the results. The reported standard deviations were very broad, up to twice the mean, for the 3 2212 mouthing approaches (*i.e.*, mild, medium, and harsh mouthing scenarios), which highlights a lack of 2213 specificity in the associated data.

2214

2215 In a somewhat more recent report, the European Chemicals Agency (ECHA) compiled and evaluated 2216 new evidence on human exposure to DEHP, including chemical migration rates (ECHA, 2013). They 2217 concluded that a chemical migration rate of 14  $\mu$ g/cm<sup>2</sup>/h was likely to be representative of a "typical" 2218 mouthing scenario" and a migration rate of 45  $\mu$ g/cm<sup>2</sup>/h was a reasonable worst-case estimate of this parameter. The "typical" value was determined by compiling in vivo migration rate data from existing 2219 2220 studies (Niino et al., 2003; Sugita et al., 2003; Fiala et al., 2000; Meuling et al., 2000; Chen, 1998; 2221 RIVM, 1998). The "worst case" value was midway between the two highest individual measurements 2222 among all the studies (the higher of which was used in the 2003 EU risk assessment). As such, based on 2223 available data for chemical migration rates of DEHP to saliva, the range of values used in this 2224 assessment (1.6, 13.3, and 44.8  $\mu$ g/cm<sup>2</sup>/h) are considered likely to capture the true value of the 2225 parameter depending on article expected uses. EPA assumes children's mouthing behavior can be harsh, 2226 medium, and mild for children's toys. Mouthing behavior for adults using adult toys is not expected to 2227 be harsh. Harsh mouthing of adult toys would likely result in the breakage or destruction of the article, and adults tend to control the harshness of their mouthing better than infants and toddlers. EPA 2228 2229 calculated a high-intensity use of adult toys using harsh mouthing approaches as part of the screening 2230 approach and recognized that this highly conservative result is very unlikely behavior and decided that it 2231 should not be further used in risk assessment approaches. The Agency did not identify use pattern 2232 information regarding adult toys, and most inputs are based on professional judgment assumptions. 2233

For other items that are not adult toys and were assumed to be mouthed by children, EPA used mouthing duration inputs from <u>Smith and Norris (2003)</u>. <u>Smith and Norris (2003)</u> conducted a study on mouthing behaviors in 236 children, using parental observation through a standardized diary form. Each child was observed for a total of 5 hours, divided into 20 15-minute sessions over 2 weeks. Daily mouthing durations were then extrapolated to total daily estimates based on recorded waking hours when the child was not eating. To assess the validity and reliability of the observation method, a subset of 25 children

2240 was re-evaluated using parental observations, trained observers, and video recordings. While this study 2241 provides robust data on total mouthing time, directly using these values would likely overestimate 2242 phthalate exposure since not all mouthed objects contain phthalates. The authors reported that a wide 2243 variety of objects were mouthed and provided an age-stratified analysis of material composition for 2244 "toys" and "other objects." However, the study does not specify whether these percentages reflect the 2245 fraction of total mouthing time spent on plastic items, nor does it distinguish between different types of 2246 plastic—including soft plastics more likely to contain phthalates.

2247

Another major limitation of all existing data is that DEHP weight fractions for products tested in mouthing studies skew heavily towards relatively high weight fractions (30–60%), and measurements for weight fractions less than 15 percent are very rarely represented in the data set. Thus, it is unclear whether these migration rate values are applicable to consumer goods with low (<15%) weight fractions of DEHP, where rates might be lower than represented by typical or worst-case values determined by existing data sets.

2254

2255 EPA has a *moderate* confidence in mouthing estimates mainly due to uncertainties with professional

- 2256 judgment inputs used in the absence of use pattern information, as previously mentioned. . In general,
- the chemical migration rate input parameter has a moderate confidence due to the large variability in the
- 2258 empirical data used in this assessment and unknown correlation between chemical migration rate and
- 2259 DEHP concentration in articles.
- 2260

Consumer COU Category and Subcategory	Weight of Scientific Evidence				
Automotive, fuel, agriculture, outdoor use product; Lawn and garden care products Other uses; Automotive articles	Three indoor scenarios were assessed for these COUs including car mats, tire replacements, and hose. These scenarios capture variability in product formulation in the low-, medium-, and high-intensity use estimates. The overall confidence in this indoor COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters generally represent actual products on the market, relevant use patterns and location of use. See Section 2.1.1 in U.S. (2025e) for number of products, product examples, and weight fraction data. For solid articles dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DEHP <i>in vivo</i> dermal absorption in rats. The flux-limited approach likely results in overestimations due to the assumption about excess DEHP in contact with skin. The overall confidence in this dermal	Inhalation and Ingestion – Robust Dermal – Moderate			
	exposure estimate is moderate for article exposures. There is some uncertainty regarding the magnitude of difference between dermal absorption through rat skin vs. human skin for DEHP. Due to increased permeability of rat skin as compared to human skin, dermal absorption estimates likely overestimate exposures.				
Construction, paint, electrical, and metal products; Adhesives and sealants; batteries; construction and building materials covering large surface areas, including	Ten different scenarios were assessed for these COUs for products and articles with differing use patterns for which each scenario had varying number of identified product and article examples: adhesive/sealant for home DIY (large indoors, small outdoors), automotive filler/putty, batteries, vinyl flooring, wallpaper, small articles with the potential for semi-routine contact (phone charge, wireless earbuds, electrical tape), insulated cords, coating for home DIY (large outdoors), automotive coating.	Inhalation – Robust Dermal – Moderate			
paper articles, metal articles, stone, plaster, cement, glass and ceramic articles; machinery, mechanical appliances,	These scenarios capture variability in product formulation weight fractions in the low-, medium-, and high-intensity use estimates. The overall confidence in this indoor COU inhalation and dust ingestion (articles only) exposure estimate is robust because the CEM default parameters are representative of typical use				

## 2261 Table 4-6. Weight of Scientific Evidence Summary Per Consumer COU

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
electrical/electronic articles; paints and coatings	patterns and location of use. The stay-at-home activity use input parameter is considered a conservative input that, although representative of actual uses for some populations, is also believed to result in an upper bound exposure. See Sections 2.1.1 and 2.1.2 in U.S. (2025e) for article examples and weight fraction data.	
	For solid articles dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DEHP <i>in vivo</i> dermal absorption in rats. The flux-limited approach likely results in overestimations due to the assumption about excess DEHP in contact with skin. The overall confidence in this dermal exposure estimate is moderate for article exposures. There is some uncertainty regarding the magnitude of difference between dermal absorption through rat skin vs. human skin for DEHP. Due to increased permeability of rat skin as compared to human skin, dermal absorption estimates likely overestimate exposures.	
	The overall confidence in this dermal exposure estimate is moderate for liquid product exposures. While <u>Hopf et al. (2014)</u> reported dermal absorption based on metabolically active excised human skin within just a few hours after excision, it should be noted that there may have been a unit error with the reported applied dose. Based on supporting information reported in the study ( <i>i.e.</i> , concentration of DEHP, application amount, and skin surface area), EPA was able to recalculate the correct applied dose. Although the default parameters applied for dermal absorption estimates generally represent actual products on the market and relevant use patterns due to the reported uncertainty in other modeling inputs, the overall confidence was moderate.	
Furnishing, cleaning, treatment care products; Fabric, textile, and leather products; furniture and furnishings; floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles, fabrics, textiles, and apparel	Five different scenarios were assessed for these COUs for articles with differing use patterns for which each scenario had varying number of identified article examples: synthetic leather furniture, synthetic leather clothing, small articles with the potential for semi-routine contact (outdoor furniture, children's bags, wallets, footwear, interior and exterior components of jackets, handbags), vinyl flooring, wallpaper. These scenarios capture variability in product formulation weight fractions in the low-, medium-, and high-intensity use estimates. The overall confidence in this indoor COU inhalation and dust ingestion (articles only) exposure estimate is robust because the CEM default parameters generally represent actual products on the market, relevant use patterns and location of use because the CEM default parameters are representative of typical use patterns and location of use. The stay-at-home activity use input parameter is considered a conservative input that, although representative of actual uses for some populations, is also believed to result in an upper bound exposure. See Sections 2.1.1 and 2.1.2 in U.S. (2025e) for article examples and weight fraction data.	Inhalation and Dust Ingestion – Robust Mouthing – Moderate Dermal – Moderate
	Ingestion via mouthing exposure estimate overall confidence is moderate due to uncertainties in the parameters used for chemical migration to saliva, such as large variability in empirical migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are uncertainties from the unknown correlation between chemical concentration in articles and chemical migration rates, and no data were reasonably available to compare and confirm selected rate parameters to better understand uncertainties. There are uncertainties in the duration of mouthing inputs, however EPA is confident that the selected inputs from <u>Smith and Norris (2003)</u> likely overestimate phthalate exposure since not all mouthed objects in the study contained phthalates.	
	For solid articles dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DEHP <i>in vivo</i> dermal absorption in rats. The	

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	flux-limited approach likely results in overestimations due to the assumption about excess DEHP in contact with skin. The overall confidence in this dermal exposure estimate is moderate for article exposures. There is some uncertainty regarding the magnitude of difference between dermal absorption through rat skin vs. human skin for DEHP. Due to increased permeability of rat skin as compared to human skin, dermal absorption estimates likely overestimate exposures.	
Packaging, paper, plastic, toys, hobby products; Ink, toner, and colorants; packaging (excluding food packaging) and other articles with routine direct contact during normal use, including paper articles, rubber articles, plastic articles (hard), plastic articles (soft); toys, playground, and sporting equipment	Ten different scenarios were assessed for these COUs for products and articles with differing use patterns for which each scenario had varying number of identified product and article examples: stamp ink, air mattresses and sleeping mats, rubber eraser, mobile phone covers, shower curtain, small articles with the potential for semi-routine contact (packaging, paper, plastic, toys, hobby products: cutting board, pencils, pouches, bags, hose, labels, covers, chewy toys, jewelry, gloves, packaging, mats, lampshade, vinyl floor runner, silly straws, stickers, diving goggles), children's toys (legacy, new), tire crumb, artificial turf, small articles with the potential for semi-routine contact (fitness balls, jump rope, yoga mat, football, and diving goggles). These scenarios capture variability in product formulation weight fraction in the low-, medium-, and high-intensity use estimates. The overall confidence in this indoor COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters generally represent actual products on the market, relevant use patterns and location of use. The stay-at-home activity use input parameter is considered a conservative input that although representative of actual uses for some populations is also believed to result in an upper bound exposure. See Sections 2.1.1 and 2.1.2 in U.S. (2025e) for article examples and weight fraction data.	Inhalation and Dust Ingestion – Robust Mouthing – Moderate Dermal – Moderate
	Ingestion via mouthing exposure estimate overall confidence is moderate due to uncertainties in the parameters used for chemical migration to saliva such as large variability in empirical migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are uncertainties from the unknown correlation between chemical concentration in articles and chemical migration rates, and no data were reasonably available to compare and confirm selected rate parameters to better understand uncertainties. There are uncertainties in the duration of mouthing inputs, however EPA is confident that the selected inputs from <u>Smith and Norris (2003)</u> likely overestimate phthalate exposure since not all mouthed objects in the study contained phthalates.	
	For solid articles dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DEHP <i>in vivo</i> dermal absorption in rats. The flux-limited approach likely results in overestimations due to the assumption about excess DEHP in contact with skin. The overall confidence in this dermal exposure estimate is moderate for article exposures. There is some uncertainty regarding the magnitude of difference between dermal absorption through rat skin vs. human skin for DEHP. Due to increased permeability of rat skin as compared to human skin, dermal absorption estimates likely overestimate exposures.	
	The overall confidence in this dermal exposure estimate is moderate for liquid product exposures. While <u>Hopf et al. (2014)</u> reported dermal absorption based on metabolically active excised human skin within just a few hours after excision, it should be noted that there may have been a unit error with the reported applied dose. Based on supporting information reported in the study ( <i>i.e.</i> , concentration of DEHP, application amount, and skin surface area), EPA was able to recalculate the correct applied dose. Though the default parameters applied for dermal absorption estimates generally represent actual products on	

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	the market and relevant use patterns, due to the reported uncertainty the overall confidence was moderate.	
Other uses; Novelty articles	One indoor scenario was assessed for this COU: adult toys. This scenario captures variability in article formulation in the low-, medium-, and high-intensity use estimates. The overall confidence in this indoor COU dust ingestion exposure estimate is robust because the CEM default parameters	Inhalation – Robust Mouthing –
	generally represent an actual article on the market, relevant use patterns and location of use.	Moderate
	The adult toys ingestion exposure estimate overall confidence is moderate due to uncertainties in the parameters used for chemical migration to saliva such as large variability in empirical migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are uncertainties from the unknown correlation between chemical concentration in articles and chemical migration rates, and no data were reasonably available to compare and confirm selected rate parameters to better understand uncertainties. In addition, there are unknown uncertainties in the use duration input parameters which were assumed based on professional judgment. EPA calculated a high-intensity use of adult toys using harsh mouthing approaches as part of the screening approach, however recognizing that this highly conservative use pattern is very unlikely behavior, it is not to be used to estimate risk. EPA did not identify use pattern information regarding adult toys. For solid articles dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DEHP <i>in vivo</i> dermal absorption in rats. The flux-limited approach likely results in overestimations due to the assumption about excess DEHP in contact with skin. The overall confidence in this dermal exposure estimate is moderate for article exposures. There is some uncertainty regarding the magnitude of difference between dermal absorption through rat skin vs. human skin for DEHP. Due to increased permeability of rat skin as compared to human skin, dermal absorption estimates likely overestimate exposures.	Dermal – Moderate

## **4.1.3 General Population Exposures to Environmental Releases**

General population exposures occur when DEHP is released into the environment and the environmental
 media is then a pathway for exposure. As described in the *Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate* (U.S. EPA, 2025r), releases of DEHP are
 expected in air, water, and land. Figure 4-2 provides a graphic representation of where and in which
 media DEHP is estimated to be found due to environmental releases and the corresponding route of
 exposure for the general population.

2270 EPA began its DEHP exposure assessment using a screening level approach that relies on conservative 2271 assumptions. Conservative assumptions, including default input parameters for modeling environmental 2272 media concentrations, help to characterize exposure resulting from the high-end of the expected 2273 distribution. Most of the OESs presented in Table 1-1 report facility location data and releases in the 2274 TRI, NEI, and DMR databases. When facility location- or where scenario-specific information is 2275 unavailable, the Agency used generic EPA models and default input parameter values as described in the 2276 Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate 2277 (DEHP) (U.S. EPA, 2025r). Details on the use of screening level analyses in exposure assessment can 2278 be found in EPA's Guidelines for Human Exposure Assessment (U.S. EPA, 2019c).

2279 2280 EPA evaluated the reasonably available information for releases of DEHP from facilities that use, 2281 manufacture, or process DEHP under industrial and/or commercial COUs detailed in the Draft 2282 Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (U.S. EPA, 2283 2025r). As described in Section 3.3 using the release data, EPA modeled predicted concentrations of 2284 DEHP in surface water, sediment, drinking water, ambient air, and soil due to deposition from ambient 2285 air in the United States. Table 3-7 summarizes the highest DEHP concentrations in environmental media 2286 from environmental releases. The reasoning for assessing different pathways qualitatively or 2287 quantitatively is discussed briefly below, and additional detail can be found in *Draft Environmental* 2288 *Media and General Population and Environmental Exposure for Diethylberyl Phthalate (DEHP)* (U.S. 2289 EPA, 2025q).

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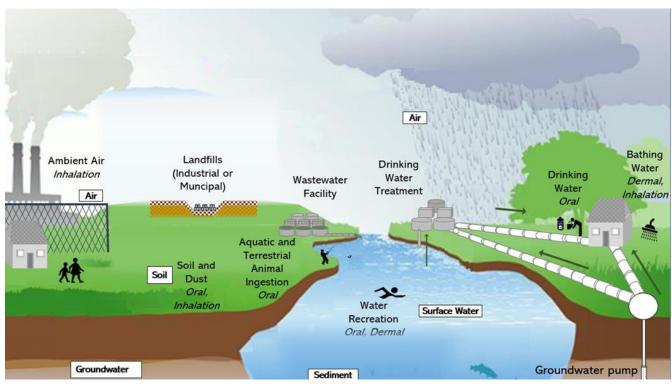


Figure 4-2. Potential Human Exposure Pathways to DEHP for the General Population
 Potential routes of exposure are shown in italics under each potential pathway of exposure.

2295 High-end estimates of DEHP concentration in the various environmental media presented in Table 3-7 2296 and in the Draft Environmental Media and General Population and Environmental Exposure for 2297 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q) were used for screening level purposes in the 2298 general population exposure assessment. EPA's Guidelines for Human Exposure Assessment (U.S. EPA, 2299 2019c) defines high-end exposure estimates as a "plausible estimate of individual exposure for those 2300 individuals at the upper end of an exposure distribution, the intent of which is to convey an estimate of 2301 exposure in the upper range of the distribution while avoiding estimates that are beyond the true 2302 distribution." If risk is not found for these individuals with high-end exposure, no risk is anticipated for 2303 central tendency exposures, which is defined as "an estimate of individuals in the middle of the 2304 distribution." Plainly, if there was no risk for an individual identified as having the potential for the 2305 highest exposure associated with a COU for a given pathway of exposure, then that pathway was 2306 determined not to be a pathway of concern and not pursued further. If any pathways were identified as a 2307 pathway of concern for the general population, further exposure assessments for that pathway would be 2308 conducted to include higher tiers of modeling when available, refinement of exposure estimates, and 2309 exposure estimates for additional subpopulations and OES/COUs.

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2311 Identifying individuals at the upper end of an exposure distribution included consideration of high-end 2312 exposure scenarios defined as those associated with the industrial and commercial releases from a COU 2313 and OES that resulted in the highest environmental media concentrations. As described in Section 3.3, 2314 EPA focused on estimating high-end concentrations of DEHP from the largest estimated releases for the 2315 purpose of its screening level assessment for environmental and general population exposures. This 2316 means that EPA considered the environmental concentration of DEHP in a given environmental media 2317 resulting from the OES that had the highest release compared to any other OES for the same releasing 2318 media. Release estimates from OES resulting in lower environmental media concentrations were not 2319 considered for this screening level assessment. Additionally, individuals with the greatest intake rate of 2320 DEHP per body weight were considered to be those at the upper end of the exposure.

2321 Table 4-7 summarizes the high-end exposure scenarios that were considered in the screening level 2322 analysis, including the lifestage assessed as the most potentially exposed population based on intake rate 2323 and body weight. Table 4-7 also indicates which pathways were evaluated quantitatively or 2324 qualitatively. Exposure was assessed quantitatively only when environmental media concentrations were 2325 quantified for the appropriate exposure scenario. For example, exposure from groundwater resulting 2326 from DEHP release to the environment via biosolids or landfills was not quantitatively assessed because

2327 environmental releases from biosolids and landfills were not quantified. Due to the high confidence in

- 2328 the biodegradation rates and physical and chemical data, there is robust confidence that DEHP in soils
- 2329 receiving DEHP will not be mobile and will have low persistence potential. There is robust confidence

2330 that DEHP is unlikely to be present in landfill leachates. However, exposure was still assessed 2331 qualitatively for exposures potentially resulting from biosolids and landfills. Further details on the 2332 screening level approach and exposure scenarios evaluated by EPA for the general population are 2333 provided in the Draft Environmental Media and General Population and Environmental Exposure for 2334 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q). Selected OESs represent those resulting in the highest modeled environmental media concentrations for the purpose of a screening level analysis.

- 2335
- 2336

OES	Exposure Pathway	Exposure Route	- Hyposure Scenario – Litestage		Analysis (Quantitative or Qualitative)
All	Biosolids		All considered qualitatively	-	Qualitative
All	Landfills		All considered qualitatively		Qualitative
Plastic	Surface	Dermal	Dermal exposure to DEHP in surface water during swimming	Adult, youth, and children	Quantitative
compounding	water	Oral	Incidental ingestion of DEHP in surface water during swimming	Adult, youth, and children	Quantitative
Plastic compounding	Drinking water	Oral	Ingestion of drinking water	Adult, youth, and children	Quantitative
	Fish ingestion		Ingestion of fish for general population	Adult and children	Quantitative
Use of laboratory chemicals		Oral	Ingestion of fish for subsistence fishers	Adult	Quantitative
			Ingestion of fish for Tribal populations	Adult	Quantitative
Application of paints, coatings, adhesives, and sealants (stack)	ngs, nd		Inhalation of DEHP in ambient air resulting from industrial	All	Quantitative
Plastic converting (fugitive)			releases		

2337 Table 4-7. Exposure Scenarios Assessed in General Population Screening Level Analysis

- 2338
- 2339 EPA also considered biomonitoring data, specifically urinary biomonitoring data from the CDC's

2340 NHANES, to estimate exposure using reverse dosimetry (see Section 11 of EPA's Draft Environmental

2341 *Media and General Population and Environmental Exposure for Diethylberyl Phthalate (DEHP)* (U.S.

2342 EPA, 2025q). Reverse dosimetry is a powerful tool for estimating exposure, but reverse dosimetry

2343 modeling does not distinguish between routes or pathways of exposure and does not allow for source

2344 apportionment (*i.e.*, exposure from COUs cannot be isolated from uses that are not subject to TSCA).

2345 Instead, reverse dosimetry provides an estimate of the total dose (or aggregate exposure) responsible for

the measured biomarker. Therefore, intake doses estimated using reverse dosimetry are not directly
comparable to the exposure estimates from the various environmental media presented in this document.
However, the total intake dose estimated from reverse dosimetry can help contextualize the exposure
estimates from exposure pathways outlined in Table 4-7 as being potentially underestimated or
overestimated.

## 2351

## 4.1.3.1 General Population Screening Level Exposure Assessment Results

## 2352 Land Pathway

2353 EPA evaluated general population exposures via the land pathway (*i.e.*, application of biosolids, 2354 landfills) qualitatively. DEHP is unlikely to migrate to groundwater via runoff after land application of 2355 biosolids due largely to its low water solubility (0.003 mg/L) and high affinity for sorption to soil (log 2356  $K_{OC} = 5.4$ ; log  $K_{OW} = 7.6$ ). DEHP will have low persistence potential in the aerobic environments 2357 associated with freshly applied biosolids with a typical half-life of 8.1 to 16.8 days in aerobic soils (U.S. 2358 EPA, 2025q). EPA did not model groundwater concentrations resulting from land application of 2359 biosolids, with the physical and chemical properties indicating that DEHP is unlikely to migrate from 2360 land applied biosolids to groundwater via infiltration.

2361

While there are no measured data on DEHP in landfill leachates, the potential to leach from landfills into nearby groundwater or surface water systems is limited. DEHP's high affinity to particulate (log Koc = 5.4) and organic media (log Kow = 7.6) will limit leaching to groundwater and result in high retardation and limited mobility in the subsurface. Similarly, DEHP is not expected to migrate from landfills via groundwater infiltration or surface runoff. EPA concludes that further assessment of DEHP in landfill leachate is not needed.

2368

## 2369 Surface Water Pathway – Incidental Ingestion and Dermal Contact from Swimming

2370 EPA conducted modeling of releases to surface water at the point of release (*i.e.*, in the immediate 2371 receiving waterbody receiving the effluent) to estimate the resulting environmental media concentrations 2372 from COUs. EPA conducted modeling with the U.S. EPA's Variable Volume Water Model (VVWM) 2373 with Point Source Calculator (PSC) tool to estimate concentrations of DEHP within surface water and to 2374 estimate settled sediment in the benthic region of streams. Releases associated with the Plastic 2375 compounding OES resulted in the highest total water column concentrations, with 30Q5 water 2376 concentrations of  $10.3 \,\mu$ g/L (Table 4-8). Because of relevance to the exposure route, acute incidental 2377 general population surface water exposures were derived from the 30Q5 flow concentrations. COUs 2378 mapped to this OES are shown in Table 3-1. As described in Section 3.3.1.1, plastic compounding OES 2379 was chosen as the most appropriate OES for a screening level assessment based on it having the highest 2380 surface water concentration based on actual facility release data paired with flow data for the receiving 2381 waterbody associated with the release as reported by the NPDES permit. When modeling this OES with 2382 PSC, EPA calculated the exposure concentration at the point of release in the receiving waterbody, 2383 applying the reported facility loading that includes any onsite treatment, and immediate dilution from 2384 mixing in the receiving waterbody.

2385

These water column concentrations were used in a screening level analysis to estimate the ADR from dermal exposure and incidental ingestion of DEHP while swimming for adults (21+ years), youths (11– 15 years), and children (6–10 years). Detailed results for all exposures can be found in EPA's *Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate* (*DEHP*) (U.S. EPA, 2025q). Exposure scenarios leading to the highest modeled ADR are shown in Table 4-8. The most exposed lifestage for incidental ingestion from swimming was youth with an ADR of  $5.51 \times 10^{-5}$  mg/kg-day. The most exposed lifestage for incidental dermal contact from swimming was

2393 adults with an ADR of  $7.0 \times 10^{-5}$  mg/kg-day.

- For the purpose of a screening level assessment, EPA used an MOE approach using high-end exposure estimates to determine if exposure pathways were pathways of concern for potential non-cancer risks.
- 2396 MOEs for general population exposure through dermal exposure and incidental ingestion during
- swimming in untreated surface water for the most exposed lifestage was 16,000 and 20,000, respectively
- (compared to a benchmark of 30) (Table 4-8). This is a conservative assumption that results in no
   removal of DEHP prior to release to surface water. Based on a screening level assessment, risks for non-
- 2400 cancer health effects are not expected for the surface water pathway; therefore, the surface water
- pathway is not considered to be a pathway of concern to DEHP for the general population for the Plastic
- 2402 compounding OES. Because MOEs were not below the benchmark for the Plastic compounding OES,
- which resulted in the highest exposure scenario, no other OES and their corresponding COUs (Table
- 2404 3-1) are expected to result in risk estimates below the benchmark.

#### 2405 2406 S

## 2406 Surface Water Pathway – Drinking Water

- 2407 For the drinking water pathway, modeled surface water concentrations were used to estimate drinking 2408 water exposures. For screening level purposes, only the OES scenario resulting in the highest modeled 2409 surface water concentrations, Plastic compounding, which had the highest 30Q5 flow concentration, was 2410 included in the drinking water exposure analysis. Because of relevance to the exposure route, drinking 2411 water exposures were derived from the 30Q5 flow concentrations for acute drinking water exposure. 2412 Chronic drinking water was also considered in COUs mapped to this OES are shown in Table 3-1. EPA 2413 evaluated drinking water scenarios assuming no wastewater treatment, no dilution beyond the point of 2414 discharge (*i.e.*, the surface water outfall is located very close to the drinking water location), and no 2415 further drinking water treatment (Table 4-8). ADR from drinking water for non-cancer effects was also 2416 calculated using the 95th percentile ingestion rate for drinking water. ADR values from drinking water 2417 exposure to DEHP were calculated for various age groups. Additionally, EPA assessed chronic drinking 2418 water exposure using the highest harmonic mean concentration. Detailed results for all exposures 2419 including chronic exposure and those for multiple lifestages can be found in EPA's Draft Environmental 2420 *Media and General Population and Environmental Exposure for Diethylberyl Phthalate (DEHP)* (U.S. EPA, 2025q), but the most exposed lifestage, infants (birth to <1 year), with the exposure duration 2421 2422 leading to the highest exposure, is shown in Table 4-8. The most exposed lifestage for drinking water 2423 was infants with an ADR of 1.5E-03 mg/kg-day. 2424
- The MOE for general population exposure through drinking water exposure for the highest exposed lifestage was 756 (compared to a benchmark of 30) (Table 4-8). Based on screening level analysis, risk for non-cancer health effects are not expected for the drinking water pathway; therefore, the drinking water pathway is not considered to be a pathway of concern to DEHP for the general population for the Plastic compounding OES. Because MOEs were not below the benchmark for the Plastic compounding OES, which resulted in the highest exposure scenario, no other OES and their corresponding COUs
- 2431 (Table 3-1) are expected to result in risk estimates below the benchmark.
- 2432

#### 2433 Table 4-8. Summary of the Highest Exposure and Risk in the General Population through Surface and Drinking Water Exposure 2434

Occupational	Water Column Concentrations	Incidental Dermal Surface Water <sup>b</sup>		Incidental Ingestion Surface Water cDrinking Wate		g Water <sup>d</sup>	
Exposure Scenario <sup>a</sup>	30Q5 Conc. (µg/L)	ADR (mg/kg-day)	Acute MOE (Benchmark MOE = 30)	ADR (mg/kg-day)	Acute MOE (Benchmark MOE = 30)	ADR (mg/kg-day)	Acute MOE (Benchmark MOE = 30)
Plastic compounding	10.3	7.0E–05	16,000	5.51E–05	20,000	1.5E-03	756

ADR = acute dose rate; MOE = margin of exposure; 30Q5 = 30 consecutive days of lowest flow over a 5-year period<sup>a</sup> Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

<sup>b</sup> Most exposed age group: Adults (21+ years).

<sup>c</sup> Most exposed age group: Youth (11–15 years).

<sup>d</sup> Most exposed age group: Infant (birth to <1 year).

## 2435

#### 2436 Fish Ingestion

2437 The key parameters to estimate human exposure to DEHP via fish ingestion are the surface water

2438 concentration, bioaccumulation factor (BAF), and fish ingestion rate. Surface water concentrations for

2439 DEHP associated with a particular COU were modeled using VVWM-PSC as described in Section 3.3.

2440 The harmonic mean flow and resulting estimated concentrations in surface water and fish tissue were

2441 applied to calculate exposure via fish ingestion because the harmonic mean flow is considered

2442 representative of long-term DEHP concentrations that would enter fish tissue over time. The details on

2443 the BAF, which considers the animal's uptake of a chemical from both diet and the water column, can

2444 be found in the Draft Environmental Media and General Population and Environmental Exposure for

2445 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q).

2446

2447 EPA evaluated exposure and potential risk to DEHP through fish ingestion for populations and age 2448 groups that had the highest fish ingestion rate per kg of body weight—including for adults and young

2449 toddlers in the general population, adult subsistence fishers, and adult Tribal populations. Children were

2450 not considered for all populations for reasons explained in Sections 7.2 and 7.3 of the Draft

2451 Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate

2452 (DEHP) (U.S. EPA, 2025q). Only the fish ingestion rate changes for these different populations; the 2453 surface water concentration and BAF remain the same. ADR and ADD values from fish ingestion

2454 exposure to DEHP were calculated for all populations and multiple age groups and can be found in

2455 Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl

2456 *Phthalate (DEHP)* (U.S. EPA, 2025q), but Table 4-9 shows only the scenarios for Tribal populations as 2457 they represent the highest exposure because of their elevated fish ingestion rates compared to the general

- 2458 population and subsistence fisher population.
- 2459

2460 Exposure to Tribal populations were estimated based on a current mean (U.S. EPA, 2011a) and current 2461 95th percentile (Polissar et al., 2016) fish ingestion rate. Current ingestion rate refers to the present-day

2462 consumption levels that are suppressed by contamination, degradation, or loss of access. Heritage rates

2463 existed prior to non-indigenous settlement on Tribal fishers' resources and changes to culture and 2464

lifeways. Therefore, current ingestion rates are considered more representative of contemporary rates of

2465 fish consumption and are presented below. Heritage rates are discussed in further detail Draft

2466 Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate 2467 (*DEHP*) (U.S. EPA, 2025q)

2468

2469 For the screening level analysis, EPA used DEHP's water solubility as an upper limit of DEHP

concentration in surface water to estimate DEHP concentration in fish tissue. The Agency also
incorporated the highest modeled surface water concentrations based on releases by the Use of
laboratory chemical OES because it exceeded the water solubility limit. Possible reasons for exceeding

- the water solubility limit include modeled concentrations corresponding to the total water column
- concentrations (*i.e.*, DEHP suspended in the water and sorbed to suspended sediment) as well as
   DEHP's tendency to form colloidal suspensions in water. Exposure estimates calculated with the water
- solubility limit and the highest modeled surface water concentration are within the same order of
   magnitude, as shown in Table 4-9.
- 2478

2479 Screening level risk estimates were calculated for all populations and multiple age groups. They 2480 exceeded the benchmark for the general population and subsistence fisher based on conservative 2481 exposure estimates (see Section 7 of (U.S. EPA, 2025q)). Table 4-9 shows only results for the Tribal 2482 populations exposed through the Use of laboratory chemicals OES because it led to the highest 2483 exposure. No risk estimates were below the benchmark for Tribal populations based on current mean 2484 and high-end (*i.e.*, 95th percentile) fish ingestion rate. Therefore, EPA concludes exposure to DEHP via 2485 fish ingestion is not a concern for the general population or Tribal populations for Use of laboratory 2486 chemicals. Because MOEs were not below the benchmark for the Use of laboratory chemicals OES, 2487 which resulted in the highest exposure scenario, no other OES and their corresponding COUs (Table 2488 3-1) are expected to result in risk estimates below the benchmark.

2489

Calculation Method <sup>c</sup>		Ingestion Rate <sup>b</sup> k MOE = 30)	Current 95th Percentile Ingestion Rate		
	ADR/ADD (mg/kg-day)	Chronic and Acute MOE <sup>a</sup>	ADR/ADD (mg/kg-day)	Chronic and Acute MOE <sup>a</sup>	
Water solubility limit (3.0E–03 mg/L)	3.87E-03	280	1.56E-02	70	
Use of laboratory chemicals (5.92E–03 mg/L) <sup>a</sup>	7.64E–03	140	3.09E-02	36	

## 2490 **Table 4-9. Fish Ingestion for Adults in Tribal Populations Summary**

ADR = acute dose rate; ADD = average daily dose; MOE = margin of exposure

<sup>*a*</sup> The acute and chronic MOEs are identical because the exposure estimates and the POD do not change between acute and chronic exposure scenarios.

<sup>b</sup> Current ingestion rate (mean at 2.7 g/kg-day and 95th percentile at 10.9 g/kg-day used in this assessment) refers to the present-day consumption levels that are suppressed by contamination, degradation, or loss of access.

## 2491

## 2492 Ambient Air Pathway

2022d).

The ambient air exposure assessment utilized a previously peer-reviewed screening level analysis to evaluate exposures to the general population in proximity to releasing facilities, including fenceline communities. The approach used is described in EPA's *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Version 1.0)* (U.S. EPA,

- 2497
- 2498

EPA used the IIOAC Model to estimate the high-end (95th percentile) and mean (50th percentile) dailyand annual average concentrations across the modeled distribution of DEHP concentrations in ambient

- air to assess general population exposures at three distances from the release point (100, 100–1,000, and
- 2502 1,000 m). The daily average concentration is the average of 24 consecutive hourly modeled
- 2503 concentrations within each day modeled in IIOAC across 5 years of meteorological data modeled within
- 2504 IIOAC as described in the IIOAC users guide (U.S. EPA, 2019f). The annual average is a rolling 365-
- 2505 day average of all daily average concentrations across 5 years of meteorological data modeled within

IIOAC. EPA also modeled the high-end (95th percentile) and mean (50th percentile) rolling annual
average wet, dry, and total deposition rates of DEHP from the ambient air at three distances from the
releasing facility (100; 100–1,000, and 1,000 m).

- 2510 EPA used the highest daily releases (stack and fugitive) across all COUs from the Draft Environmental 2511 Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025r) 2512 as direct inputs to the IIOAC Model to estimate concentrations and deposition rates. The highest daily 2513 estimated releases were used to represent a high-end release value for acute, short-term exposures and 2514 risk estimates. EPA used the maximum 95th percentile modeled concentrations and deposition rates 2515 across a series of exposure scenarios considering particle size and urban/rural topography to characterize 2516 exposures and derive risk estimates. The 95th percentile values were used to capture the high-end 2517 exposure scenario to better represent a peak concentration rather than a central tendency average 2518 concentration for acute exposures.
- 2519

2509

Calculations for general population exposure to ambient air via inhalation and ingestion from air to soil
 deposition for lifestages expected to be highly exposed based on exposure factors can be found in *Draft Ambient Air Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025c). Inhalation
 exposure to DEHP from ambient air is expected to be much higher than exposure to DEHP via soil
 ingestion resulting from air to soil deposition and is, therefore, presented below for the screening level
 analysis.

2526

2527 The maximum daily release value for fugitive releases for DEHP was 8.85 kg/site-day. This value was 2528 reported to the 2020 NEI dataset and categorized under the Plastic converting OES as fugitive releases. 2529 The maximum daily release value for stack releases for DEHP was 36.23 kg/site-day. This value was 2530 reported to the 2017 NEI dataset and categorized under the Application of paints, coatings, adhesives, 2531 and sealants OES as stack releases. COUs mapped to this OES are shown in Table 3-1. Although the maximum releases for each release type are from different facilities in different locations and different 2532 2533 OESs, for this assessment EPA assumes the releases occurred from the same location at the same time 2534 under the same OES to determine a "total exposure" to DEHP from both release types. This approach 2535 may overestimate ambient concentrations of DEHP at the distances evaluated since exposures to each 2536 release type at the distances evaluated cannot occur at a single location at the same time. 2537

The highest 95th percentile modeled daily average concentration used to derive acute non-cancer risk estimates for fugitive releases was 16.31  $\mu$ g/m<sup>3</sup> and for stack releases was 6.92  $\mu$ g/m<sup>3</sup>. These concentrations occurred at 100 m from the releasing facility, and together result in a total exposure from facility releases of 23.23  $\mu$ g/m<sup>3</sup>.

The highest 95th percentile modeled annual average concentration used to derive chronic risk estimates for fugitive releases was  $15.86 \,\mu$ g/m<sup>3</sup> and for stack releases was  $2.64 \,\mu$ g/m<sup>3</sup>. These concentrations occurred at 100 m from the releasing facility and together result in a total exposure from facility releases of  $18.50 \,\mu$ g/m<sup>3</sup>.

Table 4-10 summarizes the total exposures and the associated MOE calculated using the inhalation human equivalent concentration (HEC) described in Section 4.2. The HEC is derived in the *Draft Noncancer Human Health Hazard Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2024f) and is based on an 80 kg adult. Based on the 95th percentile air concentrations, MOEs for general population exposure through inhalation of ambient air are 267 for acute and 335 for chronic (both compared to a benchmark of 30) for an adult. Because the HEC was derived for adults, MOEs for other lifestages were not calculated. However, considering similar or smaller inhalation rates for younger lifestages and

greatest body weight difference of a factor of 16.7 between an adult (80 kg) and newborn (4.8 kg) based
on EPA's *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011b), MOEs for all lifestages will
still exceed the benchmark based on the estimates for adults.

- 2559 The risk estimates described in the preceding paragraph are derived from a highly conservative exposure 2560 scenario where such exposures to both fugitive and stack releases cannot physically occur at the same 2561 time based on assumptions made around the releases and total exposure. Even under this highly 2562 conservative exposure scenario, the derived risk estimates are well above relative benchmarks for non-2563 cancer health effects (greater than an order of magnitude). Therefore, EPA concludes exposure to DEHP 2564 via the ambient air pathway, inhalation route is not a concern for the general population for Plastic 2565 converting and Application of paints, coatings, adhesives, and sealants OESs. Because MOEs were not below the benchmark for the Plastic converting and Application of paints, coatings, adhesives, and 2566 2567 sealants OESs, which resulted in the highest exposure scenario, no other OES and their corresponding 2568 COUs (Table 3-1) are expected to result in risk estimates below the benchmark.
- 2569

2558

## 2570 **Table 4-10. General Population Ambient Air Exposure and Risk Summary**

	Acute (Daily-Aver	raged) <sup>b</sup>	Chronic (Annual-Averaged) <sup>b</sup>		
$OES^a$	Air Concentration <sup>c</sup> (µg/m <sup>3</sup> )	MOE	Air Concentration <sup>c</sup> (µg/m <sup>3</sup> )	MOE	
Plastic converting [Fugitive releases]	16.31	N/A	15.86	N/A	
Application of paints, coatings, adhesives, and sealants [Stack releases]	6.92	N/A	2.64	N/A	
Total exposure	23.23	267	18.50	335	

MOE = margin of exposure; OES = occupational exposure scenario;

<sup>a</sup> Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

<sup>b</sup> EPA assumes the general population is continuously exposed (*i.e.*, 24 hours per day, 365 days per year) to outdoor ambient air concentrations.

 $^{c}$  Air concentrations are reported for the high-end (95th percentile) modeled value at 100 m from the emitting facility and stack plus fugitive releases combined.

2571

Based on the 95th percentile total annual particle deposition rate for DEHP, the MOE for the oral HED is 11,559,812. Again, even under this highly conservative exposure scenario, the derived risk estimate is six orders of magnitude greater than the benchmark MOE of 30. Therefore, EPA concludes that soil

2575 ingestion resulting from air to soil deposition is not a pathway of concern for the general population.

2576 2577

# 4.1.3.2 Daily Intake Estimates for the U.S. Population Using NHANES Urinary Biomonitoring Data

2578 EPA used a screening level approach to calculate sentinel exposures to the general population from 2579 TSCA releases. EPA also analyzed urinary biomonitoring data from the CDC's NHANES dataset to 2580 provide context for aggregate exposures in the U.S. non-institutionalized civilian population. The 2581 NHANES dataset reports urinary concentrations for fifteen phthalate metabolites specific to individual 2582 phthalate diesters. Reverse dosimetry was used to calculate estimated daily intake of DEHP using NHANES reported urinary concentrations from 2017 to 2018 for four metabolites of DEHP: mono(2-2583 2584 ethylhexyl) phthalate (MEHP), mono(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP), mono(2-ethyl-5-2585 carboxypentyl) phthalate (MECPP), mono(2-ethyl-5-oxohexyl) phthalate (MEOHP). Urinary MEHP, 2586 MEHHP, MECPP, and MEOHP levels were used to calculate daily intake values for various

2587 demographic groups reported within NHANES (Table 4-11). Median daily intake estimates across

demographic groups ranged from 0.53 to 2.11  $\mu$ g/kg-day, while 95th percentile daily intake estimates ranged from 1.48 to 6.44  $\mu$ g/kg-day. The highest daily intake value estimated was for male toddlers (3 to <6 years old) and was 6.44  $\mu$ g/kg-day at the 95th exposure percentile. Detailed results of the NHANES analysis can be found in Section 11 of EPA's *Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025q).

2594 General population exposure estimates calculated from exposure to ambient air, surface water, fish 2595 ingestion, and soil from TSCA releases are not directly analogous to daily intake values estimated via 2596 reverse dosimetry from NHANES. While NHANES may be used to provide context for aggregate 2597 exposures in the U.S. population, NHANES is not expected to capture exposures from specific COUs 2598 that may result in high-dose exposure scenarios (*e.g.*, occupational exposures to workers), as compared 2599 to EPA's general population exposure assessment which evaluates sentinel exposures for specific 2600 exposure scenarios corresponding to TSCA releases. However, as a screening level analysis, media 2601 specific general population exposure estimates calculated were compared to daily intake values 2602 calculated using reverse dosimetry of NHANES biomonitoring data. Comparison of the values shows 2603 that the exposure estimates resulting from incidental dermal contact or ingestion of surface water 2604 (assuming no wastewater treatment) (Table 4-8) and fish ingestion (Table 4-9 are lower than median and 2605 95th percentile daily intake values estimated using NHANES (Table 4-11).

2606

Exposure estimates for the general population via ambient air, surface water, and drinking water releases quantified in this document may be overestimates. This is because exposure estimates from some of the individual pathways exceed (*i.e.*, drinking water, ambient air) the total intake values calculated from NHANES measured even at the 95th percentile of the U.S. population for all ages. Further, this is consistent with the U.S. CPSC's conclusion that DEHP exposure comes primarily from diet for women, infants, toddlers, and children and that the outdoor environment is not a major source of exposure to DEHP (U.S. CPSC, 2014).

2614

# Table 4-11. Daily Intake Values for DEHP Based on Urinary Biomonitoring from the 2017–2018 NHANES Cycle

Demographic	50th Percentile Daily Intake (95% CI) (μg/kg-day)	95th Percentile Daily Intake (95% CI) (µg/kg-day)
All	1.07 (0.96–1.18)	4.5 (3.86–5.15)
Females	1.1 (0.98–1.23)	4.22 (3.54–4.91)
Males	1.07 (0.91–1.23)	4.62 (3.71–5.53)
White non-Hispanic	1.11 (0.94–1.28)	3.74 (2.89–4.59)
Black non-Hispanic	0.84 (0.65–1.03)	4.1 (3.52–4.67)
Mexican-American	0.91 (0.75–1.07)	5.45 (3.67–7.23)
Other race	1.18 (1.01–1.36)	5.34 (3.25–7.43)
Above poverty level	1.29 (1.06–1.51)	5.89 (4.34–7.43)
Below poverty level	1.04 (0.91–1.16)	3.79 (3.17–4.42)
Toddlers (3 to <6 years old)	2.11 (1.86–2.35)	6.41 (5.13–7.69)
Children (6 to <11 years old)	1.32 (1.12–1.52)	4.62 (3.55–5.69)
Adolescents (12 to <16 years old)	0.69 (0.52–0.85)	2.05 (-5.34 to 9.43)
Adults (16+ years old)	0.54 (0.4–0.68)	1.78 (-0.23 to 3.79)
Male toddlers (3 to <6 years old)	2.11 (1.85–2.38)	6.44 (4.68–8.2)

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Demographic	50th Percentile Daily Intake (95% CI) (µg/kg-day)	95th Percentile Daily Intake (95% CI) (µg/kg-day)
Male children (6 to <11 years old)	1.24 (0.98–1.51)	4.68 (3.32–6.04)
Male adolescent (12 to <16 years old)	0.66 (0.56–0.76)	2.51 <sup><i>a</i></sup>
Male adults (16+ years old)	0.54 (0.29–0.79)	2.17 <sup><i>a</i></sup>
Female toddlers (3 to <6 years old)	2 (1.68–2.31)	6.17 (3.81–8.52)
Female children (6 to <11 years old)	1.38 (1.11–1.65)	4.35 (2.46–6.23)
Female adolescents (12 to <16 years old)	0.74 (0.5–0.98)	1.58 <sup><i>a</i></sup>
Females of reproductive age (16–49 years old)	0.53 (0.36–0.71)	1.48 (-1.55 to 4.52)
Female adults (16+ years old)	0.53 (0.36–0.71)	1.48 (-1.55 to 4.52)
<sup>a</sup> 95% confidence intervals (CI) could not be a	calculated due to small sample size o	r a standard error of zero.

2617 2618

## 4.1.3.3 Overall Confidence in General Population Screening Level Exposure Assessment

2619 The weight of scientific evidence supporting the general population exposure estimate is based on the strengths, limitations, and uncertainties associated with the exposure estimates, which are discussed in 2620 detail for ambient air, surface water, drinking water, and fish ingestion in the Draft Environmental 2621 2622 *Media and General Population and Environmental Exposure for Diethylberyl Phthalate (DEHP)* (U.S. 2623 EPA, 2025q). EPA summarized its weight of scientific evidence using confidence descriptors: robust, 2624 moderate, slight, or indeterminate. EPA used general considerations (*i.e.*, relevance, data quality, 2625 representativeness, consistency, variability, uncertainties) as well as chemical-specific considerations for 2626 its weight of scientific evidence conclusions. 2627

2628 EPA determined robust confidence in its qualitative assessment of biosolids and landfills. For its 2629 quantitative assessment for surface water, ambient air, and fish ingestion, EPA modeled exposure due to 2630 various general population and environmental release exposure scenarios resulting from different 2631 pathways of exposure. Exposure estimates used high-end inputs for the purpose of a screening level 2632 analysis. When available, monitoring data were compared to modeled estimates to evaluate overlap, 2633 magnitude, and trends. EPA has robust confidence that modeled releases used are appropriately 2634 conservative for a screening level analysis. Therefore, EPA has robust confidence that no exposure 2635 scenarios will lead to greater doses than presented in this evaluation. Despite moderate confidence in the 2636 estimated values themselves, confidence in exposure estimates capturing high-end exposure scenarios 2637 was robust given the conservative assumptions used for the estimates.

## 4.1.4 Human Milk Exposures

Infants are a potentially susceptible subpopulation for various reasons including their higher exposure
per body weight, immature metabolic systems, and the potential for chemical toxicants to disrupt
sensitive developmental processes. Reasonably available information from studies of experimental
animal models also indicates that DEHP is a developmental and reproductive toxicant (U.S. EPA,
2024a). EPA considered exposure and hazard information, as well as pharmacokinetic models, to
determine the most scientifically appropriate approach to evaluate infant exposure to DEHP from human
milk ingestion (U.S. EPA, 2025q).

2646

2638

EPA identified 13 biomonitoring studies—two from the U.S. and one from Canada—which measured
 concentrations of DEHP or its metabolites in human milk. None characterized if any of the study
 participants may be occupationally exposed to DEHP. DEHP or its metabolites were consistently

2650 detected in human milk across all 13 studies; the minimum and maximum measured concentrations

- varied by up to four orders of magnitude. However, one of the U.S. studies by Hines et al. (2009) that detected concentrations at less than 0.4 µg/L was given the most weight because its study design
- 2653 minimized potential contamination from food consumption or medical devices. A full description of the
- strengths and limitations of the studies and their reported concentrations are in Section 10 of the Draft
- 2655 Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate
- 2656 (*DEHP*) (<u>U.S. EPA, 2025q</u>). It is important to note that biomonitoring data do not distinguish between
- 2657 exposure routes or pathways and does not allow for source apportionment. In other words,
   2658 biomonitoring data reflect total infant exposure through human milk ingestion and the contribution of
- biomonitoring data reflect total infant exposure through human milk ingestion and the contribution of specific COUs to overall exposure cannot be determined.
- 2660

2661 Furthermore, no human health studies have evaluated only lactational exposure from quantified levels of 2662 DEHP or its metabolites in human milk. Although EPA explored the potential to model milk 2663 concentrations and concluded that there is insufficient information (e.g., sensitive and specific half-life 2664 data) available to support modeling of the milk pathway, EPA also concluded that modeling is not 2665 needed to adequately evaluate risks associated with exposure through milk. This conclusion is because 2666 the POD used in this assessment is based on male reproductive effects resulting from maternal dosing 2667 throughout sensitive phases of development in multigenerational studies encompassing both gestation 2668 and lactation. EPA has robust confidence in the assessment without quantifying the direct exposure to a 2669 nursing infant because the calculated MOE is based on the ratio of quantified (1) maternal dose resulting 2670 in hazard to offspring via exposure during gestation and lactation in studies in rodents and (2) maternal 2671 exposure to humans who may be pregnant and nursing. In other words, it is most scientifically 2672 defensible to use maternal exposure in humans to compare to hazard values expressed in terms of 2673 maternal dose from studies in animals. The uncertainty in this approach is limited to the toxicokinetic 2674 differences between rats and humans regarding the absorption, distribution, metabolism, and excretion 2675 (ADME) of phthalates from maternal oral exposure into milk, and this uncertainty is accounted for with 2676 the UF<sub>A</sub> in the benchmark MOE. Therefore, EPA has confidence that the risk estimates calculated based on adult (maternal) exposure throughout this assessment are protective of a nursing infant. Further 2677 2678 discussion of the human milk pathway is provided in Section 10 of the Draft Environmental Media and 2679 General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2680 2025q).

2681

## 4.1.5 Aggregate and Sentinel Exposure

TSCA section 6(b)(4)(F)(ii) (15 U.S.C. 2605(b)(4)(F)(ii)) requires EPA, in conducting a risk evaluation, to describe whether aggregate and sentinel exposures under the COUs were considered and the basis for their consideration.

2685

EPA defines aggregate exposure as "the combined exposures to an individual from a chemical substance
across multiple routes and across multiple pathways (40 CFR 702.33)." For the draft DEHP risk
evaluation, the Agency considered aggregate risk across all routes of exposure for each individual
consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations.
EPA did not consider aggregate exposure for the general population exposed to environmental releases.
As described in Section 4.1.3, the Agency employed a risk screen approach for the general population
exposure assessment.

2693

EPA did not consider aggregate exposure scenarios across COUs because the Agency did not find any
 evidence to support such an aggregate analysis, such as statistics of populations using certain products
 represented across COUs or workers performing tasks across COUs. However, EPA considered

2697 combined exposure across all routes of exposure for each individual occupational and consumer COU to2698 calculate aggregate risks (Sections 4.3.2 and 4.3.3).

2699

2700 EPA defines sentinel exposure as "the exposure to a chemical substance that represents the plausible 2701 upper bound of exposure relative to all other exposures within a broad category of similar or related 2702 exposures (40 CFR 702.33)." In terms of this draft risk evaluation, EPA considered sentinel exposures 2703 by considering risks to populations who may have upper-bound exposures; for example, workers and 2704 ONUs who perform activities with higher exposure potential, or consumers who have higher exposure 2705 potential or certain physical factors like body weight or skin surface area exposed. The Agency 2706 characterized high-end exposures in evaluating exposure using both monitoring data and modeling 2707 approaches. Where statistical data are available, EPA typically uses the 95th percentile value of the 2708 available data set to characterize high-end exposure for a given COU. The 95th percentile is defined as 2709 an estimate of individual exposure or dose for those persons at the upper end of an exposure or dose 2710 distribution, conceptually above the 90th percentile, but not higher than the individual in the population 2711 who has the highest exposure or dose (e.g., 99.9th percentile) (U.S. EPA, 1994a) (U.S. EPA, 2011a). As 2712 the midpoint of that range, the 95th percentile was selected to be representative of occupational 2713 exposures in the upper tail of the distribution. For general population and consumer exposures, the 2714 Agency occasionally characterized sentinel exposure through a "high-intensity use" category based on

2715 elevated consumption rates, breathing rates, or user-specific factors.

## **4.2 Summary of Human Health Hazard**

## 4.2.1 Background

This section briefly summarizes the non-cancer and cancer human health hazards of DEHP (Sections
4.2.2 and 4.2.30, respectively). Additional information on the non-cancer and cancer human health
hazards of DEHP are provided in the *Draft Non-cancer Human Health Hazard Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2024f) and the *Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate*(BBP), *Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2025d).

2724

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## 4.2.2 Non-Cancer Human Health Hazards of DEHP

2725 EPA identified developmental/reproductive toxicity as the most appropriate non-cancer hazard 2726 associated with oral exposure to DEHP in experimental animal models for use in human health risk assessment. Existing assessments of DEHP-including by the Agency for Toxic Substances and Disease 2727 2728 Registry (ATSDR, 2022), the U.S. Consumer Product Safety Commission (U.S. CPSC, 2014), 2729 Environment and Climate Change Canada/Health Canada (ECCC/HC, 2020), the European Chemicals Agency (ECHA, 2017a), and the Australian National Industrial Chemicals Notification and Assessment 2730 2731 Scheme (NICNAS, 2010)—also consistently identified developmental/reproductive toxicity as a 2732 sensitive and robust non-cancer effect following oral exposure to DEHP. In 2022, ATSDR also 2733 identified effects on the developing female reproductive tract and effects on glucose homeostasis 2734 following oral exposure, along with developmental/reproductive toxicity following inhalation exposure 2735 in experimental animal models.

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EPA is proposing a point of departure (POD) of 4.8 mg/kg-day (human equivalent dose [HED] of 1.1

2738 mg/kg-day) to estimate non-cancer risks from oral exposure to DEHP for acute, intermediate, and

chronic durations of exposure in the draft risk evaluation of DEHP. The proposed POD is a no-

- observed-adverse-effect level (NOAEL) associated with effects on the developing male reproductive
- system at the LOAEL of 14 or 15 mg/kg-day from a three-generation reproduction study (<u>Blystone et</u>
   al., 2010; TherImmune Research Corporation, 2004) and a co-critical study presented in publications by

Andrade and Grande (2006b; 2006a; 2006) which established a NOAEL of 5 mg/kg-day, along with 13
additional studies reporting effects on the developing male reproductive system consistent with
disrupted androgen action and phthalate syndrome at lowest-observed-adverse-effect levels (LOAELs)
in a narrow range of 10 to 15 mg/kg-day.

2748 The Agency has performed <sup>3</sup>/<sub>4</sub>-body weight scaling to yield the HED and is applying the animal to 2749 human uncertainty factor (*i.e.*, interspecies uncertainty factor; UF<sub>A</sub>) of  $3\times$  and the within human 2750 variability uncertainty factor an (*i.e.*, intraspecies uncertainty factor; UF<sub>H</sub>) of 10×. Thus, a total UF of 2751  $30 \times$  is applied for use as the benchmark MOE. Overall, based on the strengths, limitations, and 2752 uncertainties discussed in the Draft Non-cancer Human Health Hazard Assessment for DEHP (U.S. 2753 EPA, 2024f), EPA has robust overall confidence in the proposed POD based on effects on the 2754 developing male reproductive system consistent with a disruption of androgen action and phthalate 2755 syndrome, specifically increased male reproductive tract malformations observed in the principal study. 2756 This POD will be used to characterize risk from exposure to DEHP for acute, intermediate, and chronic 2757 exposure scenarios.

2759 The applicability and relevance of this POD for all exposure durations (acute, intermediate, and chronic) 2760 is described in the Draft Non-cancer Human Health Hazard Assessment for Diethylhexyl Phthalate 2761 (DEHP) (U.S. EPA, 2024f). Risk estimates based on the selected POD are relevant for females of reproductive age and males at any lifestage. Additionally, there is epidemiological evidence that DEHP 2762 2763 exposure can adversely affect the developing male reproductive system consistent with phthalate syndrome in males of any age, with effects including decreases in anogenital distance (AGD) and 2764 2765 testosterone and effects on sperm parameters in humans, and that DEHP exposure at higher 2766 concentrations can cause other health effects in females as well (see the Draft Non-cancer Human 2767 Health Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024f). Therefore, EPA 2768 considers the proposed POD to be relevant across sexes, lifestages, and exposure durations.

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2770 No reasonably available data were available for the dermal route that were suitable for deriving route-2771 specific PODs. Therefore, EPA used the acute/intermediate/chronic oral POD to evaluate risks from 2772 dermal exposure to DEHP. Differences between oral and dermal absorption will be accounted for in 2773 dermal exposure estimates in the draft risk evaluation for DEHP. Although inhalation studies were 2774 available, EPA did not consider any of these studies to be suitable for quantitative derivation of a route-2775 specific POD. For the inhalation route, EPA extrapolated the oral HED to an inhalation human 2776 equivalent concentration (HEC) per EPA's Methods for Derivation of Inhalation Reference 2777 Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994b) using the updated human 2778 body weight and breathing rate relevant to continuous exposure of an individual at rest provided in 2779 EPA's *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011b). The oral HED and inhalation 2780 HEC values selected by EPA to estimate non-cancer risk from acute/intermediate/chronic exposure to 2781 DEHP in the draft risk evaluation of DEHP are summarized in Table 4-12.

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EPA has robust overall confidence in the selected POD for acute, intermediate and chronic durations
based on the following weight of scientific evidence (see Section 4.3 of the *Draft Non-Cancer Human Health Hazard Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2024f) for further discussion
of the weight of scientific evidence):

DEHP exposure resulted in treatment-related effects on the developing male reproductive system consistent with a disruption of androgen action during the critical window of development in numerous oral exposure studies in rodents, of which 15 studies (comprising 19 publications) were well-conducted and provided robust evidence of a refined threshold, with effects occurring in a narrow dose range of 10 to 15 mg/kg-day, with the NOAEL of 4.8 mg/kg-day.

- Available epidemiology studies provide further evidence of male reproductive effects and underscore the human relevance of these endpoints, indicating moderate to robust evidence of effects on the developing male reproductive system in humans, including decreases in AGD and testosterone and effects on sperm parameters.
- Similar to EPA, five regulatory bodies (ECCC/HC, 2020; EFSA, 2019; ECHA, 2017a; U.S.
   CPSC, 2014; NICNAS, 2010) identified the developing male reproductive tract as the most sensitive and robust outcome to use for human health risk assessment and have consistently selected the same set of co-critical studies indicating a NOAEL of approximately 5 mg/kg-day and a LOAEL of approximately 15 mg/kg-day.

### 2801 Table 4-12. Non-Cancer HECs and HEDs Used to Estimate Risks

Target Organ System	Species	Duration	POD (mg/kg-day)	Effect	HED <sup>a</sup> (mg/kg-day)	HEC (mg/m <sup>3</sup> ) [ppm]	Benchmark MOE	Reference (TSCA Study Quality Rating)
Development /Reproductive	Rat	Continuous exposure for 3 generations	NOAEL = 4.8	↑total reproductive tract malformations in F1 and F2 males at 14 mg/kg-d	1.1	6.2 [0.39]	UF <sub>A</sub> = 3 UF <sub>H</sub> =10 <i>Total UF=30</i>	( <u>Blystone et al.,</u> 2010; <u>TherImmune</u> <u>Research</u> <u>Corporation, 2004</u> ) (High)
HEC = human equ	uivalent cond	centration; HED	= human equival	ent dose; MOE = margi	n of exposure; N	OAEL = no-obs	served-adverse-e	effect level; POD =

HEC = human equivalent concentration; HED = human equivalent dose; MOE = margin of exposure; NOAEL = no-observed-adverse-effect level; POD = point of departure; UF = uncertainty factor.

<sup>*a*</sup> EPA used allometric body weight scaling to the <sup>3</sup>/<sub>4</sub>-power to derive the HED. Consistent with EPA Guidance (U.S. EPA, 2011c), the interspecies uncertainty factor (UF<sub>A</sub>), was reduced from 10 to 3 to account for the remaining uncertainty associated with interspecies differences in toxicodynamics. EPA used a default intraspecies (UF<sub>H</sub>) of 10 to account for variation in sensitivity within human populations.

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## 4.2.3 Cancer Human Health Hazards of DEHP

Information pertaining to the genotoxicity and carcinogenicity of DEHP is summarized in the Draft 2804 *Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate* 2805 2806 (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate 2807 (DCHP) (U.S. EPA, 2025d). DEHP has been evaluated for genotoxicity in a number of in vitro and in *vivo* test systems. Overall, available data support the conclusion that DEHP and its metabolites are not 2808 2809 mutagenic, but that there is some limited evidence that DEHP may be weakly genotoxic, inducing 2810 effects such as deoxyribonucleic acid (DNA) damage and/or chromosomal aberrations. As noted by 2811 ATSDR (2022), these effects may be secondary to oxidative stress.

2812 2813 DEHP has been evaluated extensively for carcinogenicity in experimental rodent models, including 2814 seven chronic dietary studies of rats, two chronic dietary studies of mice, five chronic dietary studies of transgenic mice, one chronic inhalation study of hamsters, and one chronic intraperitoneal injection 2815 2816 study of hamsters. Across available studies, dose-related increases in hepatocellular adenomas and/or 2817 carcinomas have been observed in rats and mice of both sexes, while dose-related increases in pancreatic 2818 acinar cell tumors (PACTs) and Leydig cell tumors have been observed in male rats. EPA has 2819 preliminarily concluded that these tumor types, sometimes referred to as the "tumor triad," are related to 2820 PPAR $\alpha$  activation. This conclusion is in part informed by inferences from hypolipidemic drugs that 2821 lower lipid-levels in humans by activating PPARa, and also induce the tumor triad in rats, but not 2822 humans.

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2824 EPA has preliminarily concluded that DEHP is *Not Likely to be Carcinogenic to Humans* at doses below 2825 levels that do not result in PPARα activation. For DEHP, the non-cancer POD based on effects on the 2826 developing male reproductive system consistent with phthalate syndrome and a disruption of androgen 2827 action for DEHP is lower than the hazard values for PPARα activation identified by EPA. Therefore, 2828 EPA has concluded that the non-cancer POD for DEHP is expected to adequately account for all chronic 2829 toxicity, including carcinogenicity, and cancer risk was not further quantified.

## 2830 **4.3 Human Health Risk Characterization**

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## 4.3.1 Risk Assessment Approach

The exposure scenarios, populations of interest, and toxicological endpoints used for evaluating risks
 from acute, short-term/intermediate, and chronic/lifetime exposures are summarized in Table 4-13.

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## Table 4-13. Exposure Scenarios, Populations of Interest, and Hazard Values

1	
Population of Intere and Exposure Scena	
	Occupational Non-Users Male and female adolescents and adults (16+ years old) indirectly exposed to DEHP within the same work area as workers (breathing rate of 1.25 m <sup>3</sup> /h) (for further details see ( <u>U.S. EPA</u> , <u>2025r</u> )) Exposure Durations and Frequencies

• Acute, Intermediate, and Chronic – same as workers
<ul> <li>Exposure Routes</li> <li>Inhalation, dermal (mist and dust deposited on surfaces)</li> </ul>
<ul> <li>Inhalation, dermal (mist and dust deposited on surfaces)</li> <li>Consumers <u>"</u></li> <li>Male and female infants (&lt;1 year), toddlers (1–2 years), children (3–5 years and 6–10 years), young teens (11–15 years), teenagers (16–20 years) and adults (21+ years) exposed to DEHP through product or articles use (for further details see (U.S. EPA, 2025r))</li> <li>Exposure Frequencies <u>"</u></li> <li>Acute – 1 day exposure</li> <li>Intermediate – 30 days per year</li> <li>Chronic – 365 days per year</li> <li>Exposure Routes</li> <li>Inhalation, dermal, and oral</li> <li>Bystanders <u>"</u></li> <li>Male and female infants (&lt;1 year), toddlers (1–2 years), and children (3–5 years and 6–10 years) incidentally exposed to DEHP through product use (for further details see (U.S. EPA, 2025r))</li> <li>Exposure Frequencies</li> <li>Acute – 1 day exposure</li> <li>Intermediate – 30 days per year</li> <li>Exposure Frequencies</li> <li>Acute – 1 day exposure</li> <li>Intermediate – 30 days per year</li> <li>Chronic – 365 days per year</li> <li>Chronic – 365 days per year</li> <li>Chronic – 365 days per year</li> <li>Intermediate – 30 days per year</li> <li>Chronic – 365 days per year</li> <li>Exposure Routes</li> <li>Inhalation</li> <li>General Population</li> <li>Male and female infants, children, youth, and adults exposed to DEHP through drinking water, surface water, soil from air to soil deposition, and fish ingestion (for further details see (U.S. EPA, 2025q))</li> <li>Exposure Durations and Frequencies</li> <li>Acute – Exposed to DEHP continuously for a 24-hour period</li> <li>Chronic – Exposed to DEHP continuously up to 78 years (depending on lifestage)</li> <li>Exposure Routes – Inhalation, dermal, and oral (depending on exposure scenario)</li> <li>Cumulative Exposure Based on NHANES Biomonitoring</li> <li>Children aged 3–5, 6–11 years, and 11 to &lt;16 years; male and female adults 16+ years; and</li> </ul>
<ul> <li>females of reproductive age (16–49 years of age) exposed to DEHP, DBP, BBP, DIBP, and DINP through all exposure pathways and routes as measured through urinary biomonitoring (<i>i.e.</i>, NHANES) (for further details see (U.S. EPA, 2025x))</li> <li><u>Exposure Durations</u></li> <li>Durations not easily characterized in urinary biomonitoring studies</li> <li>Likely between acute and intermediate as phthalates have elimination half-lives on the order of several hours and are quickly excreted from the body in urine. Spot urine samples, as collected through NHANES, are representative of relatively recent exposures.</li> <li><u>Exposure Routes</u></li> <li>NHANES urinary biomonitoring data provides an estimate of aggregate exposure (<i>i.e.</i>, exposure through oral, inhalation, and dermal routes)</li> </ul>
<b>Non-Cancer Acute/Intermediate/Chronic Value</b> Sensitive health effect: Developmental toxicity ( <i>i.e.</i> , $\uparrow$ incidence of male reproductive tract malformations) (for further details see (U.S. EPA, 2024f)) HEC Daily, continuous = 6.2 mg/m <sup>3</sup> (0.39 ppm)
HED Daily = 1.1 mg/kg-day; dermal and oral Total UF (benchmark MOE) = 30 (UF <sub>A</sub> = 3; UF <sub>H</sub> = 10)
Hazard Relative Potency (Cumulative Risk) Relative potency factors for DEHP, DBP, BBP, DIBP, DCHP, and DINP were derived based on reduced fetal testicular testosterone. DBP was selected as the index chemical (for further details see (U.S. EPA, 2025x)). $RPF_{DEHP} = 0.84$ $RPF_{DBP} = 1$ (index chemical)

Concentration and Time Duration	$\begin{aligned} & \text{RPF}_{\text{BBP}} = 0.52 \\ & \text{RPF}_{\text{DIBP}} = 053 \\ & \text{RPF}_{\text{DCHP}} = 1.66 \\ & \text{RPF}_{\text{DINP}} = 0.21 \\ & \text{Index chemical (DBP) POD} = \text{HED Daily} = 2.1 \text{ mg/kg-day} \end{aligned}$				
	Total UF (benchmark MOE) = 30 (UF <sub>A</sub> = 3; UF <sub>H</sub> = 10)				
<sup><i>a</i></sup> Durations of use are not presented in this table as they varied according to products and articles used. For a summary of all					

<sup>a</sup> Durations of use are not presented in this table as they varied according to products and articles used. For a summary of all durations of exposure modeled for consumers and bystanders, see the *Draft Consumer Exposure Analysis for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025f).

### 2836

## 4.3.1.1 Estimation of Non-Cancer Risks

EPA used a margin of exposure (MOE) approach to identify potential non-cancer risks for individual exposure routes (*i.e.*, oral, dermal, inhalation). The MOE is the ratio of the non-cancer POD divided by a human exposure dose. Acute, short-term, and chronic MOEs for non-cancer inhalation and dermal risks were calculated using Equation 4-1.

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## 2842 Equation 4-1. Margin of Exposure Calculation

$$MOE = \frac{Non - cancer Hazard Value (POD)}{Human Exposure}$$

2845 2846 Where:

2040	where.		
2847	MOE	=	Margin of exposure for acute, short-term, or chronic
2848			risk comparison (unitless)
2849	Non-cancer Hazard Value (POD)	=	HEC (mg/m <sup>3</sup> ) or HED (mg/kg-day)
2850	Human Exposure	=	Exposure estimate (mg/m <sup>3</sup> or mg/kg-day)

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2852 MOE risk estimates may be interpreted in relation to benchmark MOEs. Benchmark MOEs are typically 2853 the total UF for each non-cancer POD. The MOE estimate is interpreted as a human health risk of 2854 concern if the MOE estimate is less than the benchmark MOE (*i.e.*, the total UF). On the other hand, if 2855 the MOE estimate is equal to or exceeds the benchmark MOE, the risk is not considered to be of concern, and mitigation is not needed. Typically, the larger the MOE, the more unlikely it is that a 2856 non-cancer adverse effect occurs relative to the benchmark. When determining whether a chemical 2857 2858 substance presents unreasonable risk to human health or the environment, calculated risk estimates are 2859 not "bright-line" indicators of unreasonable risk, and EPA has the discretion to consider other risk-2860 related factors in addition to risks identified in the risk characterization.

## 4.3.1.2 Estimation of Non-Cancer Aggregate Risks

As described in Section 4.1.5, EPA considered aggregate risk across all routes of exposure for each individual consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations. To identify potential non-cancer risks for aggregate exposure scenarios for workers (Section 4.3.2) and consumers (Section 4.3.3), EPA used the total MOE approach (U.S. EPA, 2001). For the total MOE approach, MOEs for each exposure route of interest in the aggregate scenario must first be calculated. The total MOE for the aggregate scenario can then be calculated using Equation 4-2.

(unitless)

2869 2870	Equation 4-2. Total	Margir	of Exposure Calculation
2871		Total	$MOE = \frac{1}{\frac{1}{100000000000000000000000000000$
2872			$\overline{MOE_{Oral}} + \overline{MOE_{Dermal}} + \overline{MOE_{Inhalation}}$
2873	Where:		
2874	Total MOE	=	Margin of exposure for aggregate scenario (unitless
2875	MOEoral	=	Margin of exposure for oral route (unitless)
2876	MOE <sub>Dermal</sub>	=	Margin of exposure for dermal route (unitless)
2877	<b>MOE</b> Inhalation	=	Margin of exposure for inhalation route (unitless)

2879 Total MOE risk estimates may be interpreted in relation to benchmark MOEs, similarly, as to described 2880 in the preceding Section 4.3.1.1.

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#### 4.3.2 **Risk Estimates for Workers**

2882 This section provides discussion and characterization of risk estimates for workers from inhalation and 2883 dermal exposures across all routes. In this section, risks are calculated for all exposed workers based on 2884 DEHP-derived PODs described in Section 4.2.2. This section provides discussion and characterization 2885 of risk estimates for workers, including females of reproductive age (WORA) and ONUs, for the various OESs and COUs. For OESs where no reasonably available ONU exposure data were found, the worker 2886 central tendency value was presented. Therefore, the MOEs for these ONUs, will be comparable to the 2887 2888 worker central tendency MOEs, although there is lower confidence in the exposure values for ONUs. 2889 given that EPA relied on central tendency exposure estimates for workers as surrogate data to estimate 2890 exposure to ONUs. For occupational risk estimates, females of reproductive age are the most sensitive 2891 exposed population with the lowest worker MOEs below the benchmark MOEs. The lower MOEs for female workers of reproductive age is a function of the lower body weight (72.4 kg) for this population 2892 2893 compared to the average adult worker (80 kg), which includes both male and female workers.

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2895 Furthermore, the acute exposure duration results in the lowest worker MOEs for this population. This 2896 means that PPE that raises the MOE above the benchmark for a female worker of reproductive age in the 2897 acute exposure duration will also raise the MOE above the benchmark for all other workers and 2898 exposure durations. Table 4-14 presents acute exposure occupational risk estimates for females of 2899 reproductive age and the corresponding PPE that would result in a worker MOE above the benchmark MOE. Risk estimates for other populations of workers, durations, and health effects for all the 2900 2901 COUs/OES, as well as aggregate exposures, are shown in Table 4-17, the Draft Environmental Release 2902 and Occupational Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025r), and the 2903 Draft Occupational Risk Calculator for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025t). 2904 Additionally, the risk calculator contains MOE calculations and PPE information for all the OES.

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2906 Table 4-14 includes three main sections according to the route of exposure: inhalation, dermal, and 2907 aggregate exposure. For inhalation, typical respirator Applied Protection Factor (APF) values of 10, 25, 2908 50, 1,000 and 10,000 were compared to the calculated MOE and the benchmark MOE to determine the 2909 level of APF that could be used to bring MOEs above the benchmark MOE. Table 4-14 shows that using 2910 PPE for inhalation scenarios when the MOEs are below the benchmark MOE, reduces the exposures to 2911 above benchmark MOE. Similarly, for dermal exposures, typical dermal Protection Factor (PF) values 2912 of 5, 10, and 20 could be compared to the calculated MOE and the benchmark MOE to determine the 2913 level of PF that would be required, based on the exposure assumptions, to bring MOEs above the

2914 benchmark MOE. However, for DEHP, no calculation of glove protection factors was used because no

2915 OES resulting in risk estimates below the benchmark from dermal exposure were identified. Given that 2916 risk estimates to workers from aggregate exposure are driven exclusively by inhalation, EPA did not 2917 present the APF and/or PF that could be used to bring MOEs above the benchmark for aggregate 2918 exposure, but instead rely on the effect of PPE for inhalation to depict that information. Descriptions of 2919 the different APFs are included in the notes below the table. The appropriateness of any protection 2920 factor that demonstrates exposures resulting in a worker MOE above the benchmark MOE may require 2921 additional consideration. The presented protection factors simply represent a value by which 2922 corresponding PPE may theoretically increase the estimated worker MOE above the benchmark MOE. 2923 The practicality and feasibility of implementing any PPE corresponding to a protection factor is part of a 2924 larger evaluation of effective occupational exposure control strategies and will be further discussed in 2925 any forthcoming risk management actions. 2926

2927 As a general matter, for all COUs there is uncertainty regarding the representativeness of these data with 2928 respect to the full distribution of exposures. This uncertainty is due to the inherent variability in the full 2929 distribution for each COU and how well the exposure estimates reflect that variability. Although each 2930 exposure assessment is intended to present a set of conditions from which an understanding of 2931 occupational risks may be constructed, the variability in the determinants of exposure (e.g., frequency, 2932 duration, etc.) from facility to facility within the full distribution of any COU is unknown. As a result, 2933 the worker exposure estimates presented for any particular COU may not be characteristic of all 2934 exposure scenarios. The central tendency represents a plausible estimate of exposure for those workers 2935 at or near the middle of the exposure estimate distribution. Similarly, the high-end represents a plausible 2936 estimate (or range) of exposure for those workers at the upper end of the exposure estimate distribution. 2937 Workers in this part of the distribution may represent a special population of workers or exposure group 2938 who are highly exposed due to the nature of their specific activities (e.g., higher concentration, 2939 frequency, duration, and/or surface area of exposure). Worker exposure monitoring data often does not 2940 distinguish between these subpopulations and their differing exposures that stem from their normal 2941 activities. As a result, worker exposure distributions, in some cases, (absent of subpopulation 2942 distinction) can appear to show exposure values at the upper end of the distribution which may seem to 2943 be unlikely or implausible but may be routine and expected due to the normal occupational activities of 2944 those subpopulations. 2945

The worker MOEs presented in the "Overview of Risk Estimates" subsections below calculated without the use of PPE. Table 4-14 along with Table 4-17 provide more information on PPE that may be used to increase the worker MOEs above the benchmark MOE.

## 2949 Table 4-14. Acute Exposure Occupational Risk Estimates for Female Workers of Reproductive Age (WORA)<sup>*a*</sup>

	Exposure Level	(Bench	Inhalation mark MOE = 30	<b>)</b> ) <sup>b</sup>	Dermal (Benchmark MOE = 30)		
Occupational Scenario		Worker MOE with No PPE	Worker MOE with PPE	APF <sup>c</sup>	Worker MOE No PPE	Worker MOE with PPE	PF
Manufacturing	High-End	362	_	N/A	8,607	_	N/A
	Central Tendency	664	_	N/A	17,214	-	N/A
Import and Danaskasing	High-End	15	153	APF 10	8,607	—	N/A
Import and Repackaging	Central Tendency	57	_	N/A	17,214	—	N/A
Incorporation into Formulations,	High-End	362	_	N/A	8,607	—	N/A
Mixtures, or Reaction Product	Central Tendency	664	_	N/A	17,214	_	N/A
Plastic compounding	High-End	2.9	72	APF 25	233	—	N/A
1 C	Central Tendency	27	266	APF 10	466	_	N/A
	High-End	15	150	APF 10	233	_	N/A
Plastic converting	Central Tendency	23	234	APF 10	466	_	N/A
	High-End	1	49	APF 50	233	_	N/A
Rubber product manufacturing	Central Tendency	4.8	48	APF 10	466	_	N/A
Spray application of paints,	High-End	0.4	360	APF 1,000	448	_	N/A
coatings, adhesives, and sealants	Central Tendency	26	262	APF 10	895	—	N/A
Non-spray application of paints,	High-End	1	49	APF 50	448	_	N/A
coatings, adhesives, and sealants	Central Tendency	4.8	48	APF 10	895	_	N/A
Use of dyes, pigments, and fixing	High-End	1	49	APF 50	448	_	N/A
agents	Central Tendency	4.8	48	APF 10	895	—	N/A
	High-End	72	_	N/A	448	_	N/A
Use of automotive care products	Central Tendency	145	_	N/A	895	-	N/A
Textile finishing	High-End	185,273	_	N/A	233	_	N/A
	Central Tendency	2,569,919	_	N/A	466	_	N/A
Formulation for diffusion	High-End	1	50	APF 50	448	—	N/A
bonding	Central Tendency	23	234	APF 10	895	—	N/A

Occupational Scenario	Exposure Level	(Bench	Inhalation mark MOE = 30	<b>)</b> ) <sup>b</sup>	Dermal (Benchmark MOE = 30)		
		Worker MOE with No PPE	Worker MOE with PPE	APF <sup>c</sup>	Worker MOE No PPE	Worker MOE with PPE	PF
Use in hydraulic fracturing	High-End	362	_	N/A	448	—	N/A
	Central Tendency	664	_	N/A	895	_	N/A
Liss of laboratory showing la	High-End	80	—	N/A	233	_	N/A
Use of laboratory chemicals	Central Tendency	797	—	N/A	466	_	N/A
	High-End	15	150	APF 10	233	_	N/A
Recycling	Central Tendency	23	234	APF 10	466	_	N/A
Fabrication or use of final	High-End	72	_	N/A	233	_	N/A
products and articles	Central Tendency	199	_	N/A	466	_	N/A
Waste handling, treatment, and	High-End	5.2	52	APF 10	233	—	N/A
disposal	Central Tendency	75	_	N/A	466	_	N/A

<sup>*a*</sup> APF = assigned protection factor

<sup>b</sup> Note: the lower inhalation MOEs for female workers of reproductive age (WORA) is a function of the lower body weight (72.4 kg) for this population compared to the average adult worker (80 kg), which includes both male and female workers per Chapter 8 of the *Exposure Factors Handbook* (U.S. EPA, 2011a), given that the air concentration and the respiration rate are the same between the populations. Risk estimates for other populations of workers and durations for all the COUs/OES are shown in Table 4-17 and in the *Draft Occupational Risk Calculator for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025t). Additionally, the risk calculator contains MOE calculations and PPE information for all the OES.

<sup>*c*</sup> Assigned protection factors (APFs) for respirators and assigned glove protection factors for gloves is discussed further in Section 4.3.2.20. The APF associated with different types of respirators based on function (air-purifying, powered air purifying, supplied air) and fit (half-mask, full-face piece, helmet/hood, loose-fitting facepiece) is depicted in matrix in Table 4-15.

## **4.3.2.1 Manufacturing**

2951 4.3.2.1.1 Overview of Risk Estimates 2952 For the manufacture of DEHP, inhalation exposure from vapors is expected to be the dominant route of 2953 exposure. Margins of Exposure (MOEs) for high-end acute, intermediate, and chronic inhalation 2954 exposure ranged from 362 to 584 for average adult workers and females of reproductive age, while high-2955 end dermal MOEs for the same populations and exposure scenarios ranged from 7,908 to 12,566 2956 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged 2957 from 664 to 1,071 for inhalation exposure and 15,816 to 25,133 for dermal exposure. Aggregation of 2958 inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates 2959 from inhalation exposure alone.

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## 4.3.2.1.2 Overview of Exposure Data

The high-end and central tendency worker inhalation exposure results for this OES are based on the 95th and 50th percentile exposure values from 45 full-shift samples collected from two DEHP manufacturing plants (Liss and Hartel, 1983; Nuodex Inc., 1983). These data had data quality ratings ranging from medium to high. EPA determined that all data were of acceptable quality without notable deficiencies and integrated all the data into the final exposure assessment.

### 2966

## 4.3.2.1.3 Risk Characterization of COUs

There is uncertainty about how well these data represent the true distribution of inhalation 2967 2968 concentrations in this scenario, the lack of ONU exposure data, for which EPA used central tendency 2969 worker data as surrogate data (resulting in lower confidence in the ONU exposure data relative to 2970 worker exposure data), and that the data come from two DEHP manufacturing facilities. This scenario 2971 represents a worker with 8 exposure hours per day and 250 exposure days per year with continuous 2972 DEHP exposure each working day. The representativeness of this scenario is influenced by the 2973 variability in worker activities, schedules, and facility operations across the full distribution of facilities 2974 covered by this COU. Given that worker inhalation exposure for this OES was based data from 45 full-2975 shift samples collected from two DEHP manufacturing plants (Liss and Hartel, 1983; Nuodex Inc., 2976 1983) determined to be medium to high quality data, the central tendency (50th percentile) and the high-2977 end (95th percentile) are expected to be plausible estimates of worker exposures within the COUs 2978 covered under the Manufacturing OES (*i.e.*, Manufacturing COU: Domestic manufacturing; Importing).

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## 4.3.2.2 Rubber Manufacturing

### 2981

## 4.3.2.2.1 Overview of Risk Estimates

For rubber manufacturing, inhalation exposure from dust generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 0.98 to 1.6 for average adult workers and female workers of reproductive age, while high-end dermal MOEs ranged from 214 to 340 (benchmark = 30). For central tendency, MOEs for the same population and exposure scenarios ranged from 4.8 to 7.7 for inhalation exposure and 428 to 681 for dermal exposures. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone.

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## 4.3.2.2.2 Overview of Exposure Data

2990 EPA did not identify any references with discrete, full-shift samples for this OES through systematic 2991 review; however, the European Commission document provided maximum concentrations based on

time-weighted average personal and area samples from a plant performing rubber calendaring (ECJRC, 2003). EPA assessed high-end worker inhalation exposures for this OES using the 95th percentile of the maximum concentrations and central tendency worker inhalation exposures using the 50th percentile of the maximum concentrations from the European Commission document (ECJRC, 2003). These data had a quality rating of high, meaning they are of acceptable quality.

## 4.3.2.2.3 Risk Characterization of COUs

2998 There is uncertainty about how well these data represent the monitoring data in capturing the true 2999 distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which 3000 EPA used central tendency worker data as surrogate data (resulting in lower confidence in the ONU 3001 exposure data relative to worker exposure data). Additionally, the monitoring dataset consisted of 3002 datapoints for unknown worker classifications and the sample type (PBZ vs. area) was not known for six 3003 of the seven samples. This scenario represents a worker with 8 exposure hours per day and 250 exposure 3004 days per year with continuous DEHP exposure each working day. The representativeness of this scenario is influenced by the relevance of the worker classifications to this COU as well as the 3005 3006 variability in worker activities, schedules, and facility operations across the full distribution of facilities 3007 covered by this OES. Given the fact that the worker inhalation exposures for this OES were based on 3008 high quality monitoring data (PBZ and/or area sampling) from the European Commission document 3009 (ECJRC, 2003), EPA considers central tendency (50th percentile of the maximum concentration) and 3010 high end (95th percentile of the maximum concentration) to be plausible estimates of worker exposures 3011 within the COUs covered under the Rubber manufacturing OES (*i.e.*, Processing – Incorporation into 3012 article COU: [Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; 3013 rubber product manufacturing; miscellaneous manufacturing; PVC extruding]; Processing – 3014 Incorporation into formulation, mixture, or reaction product COU: [Plasticizer in basic organic chemical 3015 manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and 3016 coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic 3017 rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; 3018 services; ink, toner and colorant manufacturing]).

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## 4.3.2.3 Plastics Compounding

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## 4.3.2.3.1 Overview of Risk Estimates

For plastics compounding, inhalation exposure from dust generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 2.9 to 4.7 for average adult workers and female workers of reproductive age, while high-end dermal MOEs ranged from 214 to 340 (benchmark = 30). For central tendency, MOEs for the same population and exposure scenarios ranged from 27 to 43 for inhalation exposure and 428 to 681 for dermal exposures. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone.

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## 4.3.2.3.2 Overview of Exposure Data

The high-end and central tendency worker inhalation exposure results for this OES are based on the 95th and 50th percentile exposure values from full-shift samples collected from a PVC production plant that manufactures vinyl wall coverings and vinyl sheeting (<u>Salisbury, 1984</u>). These data had a data quality rating of high and included workers across a variety of departments and facility operations. EPA determined that all data were of acceptable quality without notable deficiencies and integrated all the data in the final exposure assessment.

## 3036 4.3.2.3.3 Risk Characterization of COUs

3037 There is uncertainty about how well these data represent the monitoring data in capturing the true 3038 distribution of inhalation concentrations for this OES. This scenario represents a worker with 8 exposure 3039 hours per day and 250 exposure days per year with continuous DEHP exposure each working day. The 3040 representativeness of this scenario is influenced by the variability in worker activities, schedules, and 3041 facility operations across the full distribution of facilities covered by this OES. It is important to note 3042 that a single full-shift PBZ sample was used for exposure for ONUs (resulting in lower confidence in the 3043 ONU exposure data relative to worker exposure data). However, given that the worker exposure was 3044 based on high quality data comprising full-shift samples collected from a PVC production plant that 3045 manufactures vinyl wall coverings and vinyl sheeting (Salisbury, 1984) and included workers across a 3046 variety of departments and facility operations, the central tendency (50th percentile) and high-end (95th 3047 percentile) are considered plausible estimates of worker exposure within the COUs covered under the 3048 Plastics compounding OES (i.e., Processing COUs: Incorporation into formulation, mixture, or reaction 3049 product [Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic 3050 3051 material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical 3052 manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing]).

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#### 4.3.2.4 Plastics Converting

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#### 4.3.2.4.1 Overview of Risk Estimates

For PVC plastics converting, inhalation exposure from dust generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 15 to 24 for average adult workers and female workers of reproductive age, while high-end dermal MOEs ranged from 214 to 340 (benchmark = 30). For central tendency, MOEs for the same population and exposure scenarios ranged from 23 to 38 for inhalation exposure and 428 to 681 for dermal exposures. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone.

#### 3062

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## 4.3.2.4.2 Overview of Exposure Data

3063 The high-end worker inhalation exposure results for this OES are based on the 95th percentile exposure 3064 values from full-shift samples collected from (OSHA, 2019). These data had a data quality rating of 3065 high. The central tendency worker inhalation exposure results for this OES are based on a weighted 3066 average of mean values from full-shift samples collected from a facility which manufactures PVC floor sheeting using DEHP as a plasticizer and a mean sample calculated from the discrete samples given in 3067 3068 the 2019 OSHA CEHD data (OSHA, 2019; Modigh et al., 2002). These data both had a data quality rating of high. EPA determined that all data were of acceptable quality without notable deficiencies and 3069 3070 integrated all the data in the final exposure assessment.

## 4.3.2.4.3 Risk Characterization of COUs

3072 There is uncertainty about how well these data represent the monitoring data in capturing the true 3073 distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which 3074 EPA used central tendency worker data as surrogate data (resulting in lower confidence in the ONU 3075 exposure data relative to worker exposure data). This scenario represents a worker with 8 exposure 3076 hours per day and 250 exposure days per year with continuous DEHP exposure each working day. The representativeness of this scenario depends on the variability in worker activities, schedules, and facility 3077 3078 operations across the full distribution of facilities covered by this OES. Given that the worker exposure 3079 was based on high quality data from OSHA (OSHA, 2019; Modigh et al., 2002) comprising full-shift 3080 samples collected from a facility which manufactures PVC floor sheeting using DEHP as a plasticizer,

the central tendency (weighted average of mean values) and high-end (95th percentile) are considered
plausible estimates of worker exposure for this OES of worker exposures within the COUs covered
under the Plastics converting OES (*i.e.*, Processing COUs: Incorporation into article [Plasticizer in basic
organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing;
miscellaneous manufacturing; PVC extruding] and Industrial Use – Other Uses COU: [Solid rocket
motor insulation and other aerospace applications; automotive articles]).

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#### 4.3.2.5 Incorporation into Other Formulations, Mixtures, or Reaction Products Not Otherwise Specified

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## 4.3.2.5.1 Overview of Risk Estimates

3091 For the incorporation of DEHP into other formulations, mixtures, or reaction products not otherwise 3092 specified, inhalation exposure from vapor generation is expected to be the dominant route of exposure. 3093 In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 3094 362 to 584 for average adult workers and female workers of reproductive age, while high-end dermal 3095 MOEs for the same populations and exposure scenarios ranged from 7,908 to 12,566 (benchmark = 30). 3096 The central tendency MOEs for the same populations and exposure scenarios ranged from 664 to 1.071 3097 for inhalation exposure and 15,816 to 25,133 for dermal exposure. Aggregation of inhalation and dermal 3098 exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure 3099 alone.

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# 4.3.2.5.2 Overview of Exposure Data

No references with full-shift samples were identified for this OES through systematic review; however,
data were available for a similar OES (Manufacturing). These OES are expected to have similar
exposure potential based on the similarity of worker activities and chemical physical form in each OES.
Therefore, EPA assessed worker and ONU exposures using monitoring data for the Manufacturing OES
as a surrogate for this OES. These data had data quality ratings ranging from medium to high, meaning
they are of acceptable quality.

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# 4.3.2.5.3 Risk Characterization of COUs

3108 There is uncertainty about how well these data represent this OES and the true distribution of inhalation 3109 concentrations in this scenario, given the lack of ONU exposure data, for which EPA used central 3110 tendency worker data as surrogate (resulting in lower confidence in the ONU exposure data relative to worker exposure data), and the fact that the data come from two DEHP manufacturing facilities. as a 3111 3112 surrogate OES. This scenario represents a worker with 8 exposure hours per day and 250 exposure days 3113 per year with continuous DEHP exposure each working day. The representativeness of this scenario is 3114 influenced by the variability in worker activities, schedules, and facility operations across the full 3115 distribution of facilities covered by this OES. However, the manufacturing OES used as a surrogate is expected to have similar exposure potential based on the similarity of worker activities and chemical 3116 3117 physical form in each OES. Given that worker inhalation exposure for the manufacturing OES was 3118 based data from 45 full-shift samples collected from two DEHP manufacturing plants (Liss and Hartel, 3119 1983; Nuodex Inc., 1983) determined to be medium to high quality data, the central tendency (50th 3120 percentile) and the high-end (95th percentile) are expected to be plausible estimates of the worker 3121 exposures within the COUs covered under the Incorporation into formulations, mixtures, or reaction 3122 products OES (*i.e.*, Processing COU: Incorporation into formulation, mixture, or reaction 3123 product: [Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; 3124 miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic 3125 material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical

3126 manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing]; and

Processing COU: Other uses [Miscellaneous processing (cyclic crude and intermediate manufacturing;
 processing aid specific to hydraulic fracturing)].

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## 3130 4.3.2.6 Import and Repackaging

## 4.3.2.6.1 Overview of Risk Estimates

3132 For the repackaging of DEHP, inhalation exposure from vapor is expected to be the dominant route of 3133 exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure 3134 ranged from 15 to 25 for average adult workers and female workers of reproductive age, while high-end 3135 dermal MOEs for the same populations and exposure scenarios ranged from 7,908 to 12,566 (benchmark 3136 = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 57 to 92 for inhalation exposure and 15,816 to 25,133 for dermal exposure. Aggregation of inhalation and 3137 3138 dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone. 3139

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## 4.3.2.6.2 Overview of Exposure Data

3141 No references with discrete full-shift samples were identified for this OES through systematic review; 3142 however, the European Union Risk Assessment Report on DEHP provided a minimum, maximum, and 3143 mean based on area samples collected from a DEHP manufacturing facility and the European Union 3144 Risk Assessment Report on DINP provided a mean concentration for DEHP based on personal samples 3145 collected from a phthalate ester producer (ECB, 2008; ECJRC, 2003). EPA assessed the high-end worker inhalation exposure result for this OES using the maximum concentration from the European 3146 3147 Union Risk Assessment on DEHP and the central tendency worker inhalation exposure result for this 3148 OES using the mean concentration from the European Union Risk Assessment on DINP (ECB, 2008; 3149 ECJRC, 2003). These data had data quality ratings of high, meaning they are of acceptable quality.

#### 3150

## 4.3.2.6.3 Risk Characterization of COUs

3151 There is uncertainty about how well these data represent the monitoring data in capturing the true 3152 distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which 3153 EPA used central tendency worker data as surrogate (resulting in lower confidence in the ONU exposure 3154 data relative to worker exposure data). Additionally, the vapor monitoring dataset consisted of an unknown number of datapoints with unknown sample durations. This scenario represents a worker with 3155 3156 8 exposure hours per day and 250 exposure days per year with continuous DEHP exposure each working 3157 day. The representativeness of this scenario is influenced by the variability in worker activities, 3158 schedules, and facility operations across the full distribution of facilities covered by this OES. The European Union Risk Assessment Report on DINP provided a mean concentration for DEHP based on 3159 3160 personal samples collected from a phthalate ester producer (ECB, 2008; ECJRC, 2003), and EPA 3161 determined that this study was of high quality and considers this mean concentration to be a plausible estimate of central tendency for worker exposure for this OES. Given the limited reporting of sample 3162 3163 data from the European Union Risk Assessment on DEHP, EPA used the maximum concentration of the 3164 area sample data to determine high-end worker inhalation exposure for this OES. However, even though 3165 this high-end value is based on the maximum area sample concentration instead of a 95th percentile of 3166 the distribution, this value was based on a high-quality study specific to DEHP and considered to be a 3167 plausible estimate of high-end worker exposure within the COUs covered under the Import and 3168 repackaging OES (*i.e.*, Manufacture COU: Importing; and Processing COU: Repackaging [Repackaging 3169 in wholesale and retail trade and in paint and coating manufacturing]). 3170

- 3171 4.3.2.7 Spray Application of Paints, Coatings, Adhesives, and Sealants
  - 4.3.2.7.1 Overview of Risk Estimates

For the spray applications of paints, coatings, adhesives, and sealants containing DEHP, inhalation 3173 3174 exposure from mist generation is expected to be the dominant route of exposure. In support of this, 3175 MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 0.4 to 0.6 for 3176 average adult workers and female workers of reproductive age, while high-end dermal MOEs for the 3177 same populations and exposure scenarios ranged from 411 to 653 (benchmark = 30). The central 3178 tendency MOEs for the same populations and exposure scenarios ranged from 26 to 42 for inhalation 3179 exposure and 822 to 1,307 for dermal exposure. Aggregation of inhalation and dermal exposures led to 3180 negligible differences in risk when compared to risk estimates from inhalation exposure alone.

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## 4.3.2.7.2 Overview of Exposure Data

EPA did not identify inhalation monitoring data specific to DEHP for the spray applications of paints, 3182 3183 coatings, adhesives, and sealants OES during systematic review of literature sources. EPA assessed 3184 exposures from spray application using the Automotive Refinishing Spray Coating Mist Inhalation 3185 Model which estimates worker inhalation exposure based on the concentration of the chemical of 3186 interest in the nonvolatile portion of the sprayed product and the concentration of over-sprayed 3187 mist/particles (OECD, 2011). The model is based on PBZ monitoring data for mists during automotive 3188 refinishing. EPA used the 50th and 95th percentile mist concentrations along with the maximum and 3189 central tendency concentration of DEHP identified in diffusion bonding formulations to estimate the 3190 central tendency and high-end inhalation exposures, respectively. Engineering controls (e.g., spray booth 3191 type) have greater impact on the inhalation exposures than the spray equipment type, with down-draft 3192 ventilation being more effective in reducing mist exposures compared to cross-draft ventilation. While 3193 the applicability of engineering controls for this ESD to other exposure scenarios (non-automotive spray 3194 applications) covered by this COU is uncertain, it is expected that any scenarios in this COU which do 3195 not employ the ventilation engineering controls characteristic of the automotive refinishing spray industry may have higher air concentrations. 3196

#### 3197

## 4.3.2.7.3 Risk Characterization of COUs

3198 The primary uncertainty comes from the lack of DEHP-specific monitoring data, with the ESD serving 3199 as a surrogate source of monitoring data representing the level of exposure that could be expected at a 3200 typical work site for the given spray application method. Additionally, it is uncertain whether the 3201 substrates coated, and products used to generate the surrogate data are representative of those associated 3202 with DEHP-containing paints, coatings, adhesives, or sealant formulations. EPA only assessed mist 3203 exposures to DEHP over a full 8-hour work shift to estimate the level of exposure, though other 3204 activities may result in vapor exposures other than mist, and application duration may be variable 3205 depending on the job site. Additionally, the lack of ONU exposure data requires the use of central 3206 tendency worker data as surrogate data (resulting in lower confidence in the ONU exposure data relative 3207 to worker exposure data), which may not be fully representative of ONU exposures. EPA assessed 250 3208 days of exposure per year based on workers using paints, coatings, adhesives, or sealant formulations on 3209 every working day, however, application sites may use DEHP-containing paints, coatings, adhesives, or 3210 sealant formulations at much lower or variable frequencies. The ESD on which this assessment is based, 3211 presents several primary factors which may impact worker exposure estimates and the expected 3212 representativeness of any range of exposures. Two of the factors are spray gun type (conventional or 3213 high volume low pressure [HVLP]) and spray booth type (cross-draft, downdraft, semi-downdraft). 3214 There is more overspray and mist generation with the conventional spray guns than the HVLP spray 3215 guns which results in higher potential exposures. Additionally, there are higher exposures associated 3216 with the cross-draft booths than downdraft booths. However, as stated in the ESD, downdraft booths

3217 only account for 50 percent or fewer of spray booths. Furthermore, the booth type has a greater impact 3218 on the PBZ concentrations than the spray gun type. This OES is not limited to automotive spray 3219 applications where the ESD information on the prevalence of these booths or certain booth types may be 3220 more relevant. This OES assesses exposures to spray application for all substrate sizes and types where 3221 paints, coatings, adhesives, and sealants may be applied. Therefore, the central tendency exposure values 3222 may be representative of downdraft/HVLP applications for automotive scenarios whereas conventional 3223 spray gun/cross-draft booth (or a simple curtain booth) may be more representative of smaller substrates 3224 (e.g., playground equipment, recreational boat applications, etc.). It is for these reasons, that the full 3225 range of exposures, including central tendency and high-end, are expected to be plausible estimates of 3226 worker exposures for spray scenarios within the COUs covered under the Application of paints, 3227 coatings, adhesives, and sealants OES (i.e., Industrial use COU: Construction, paint, electrical, and metal products [paints and coatings] and Commercial use COUs: Construction, paint, electrical, and 3228 3229 metal products [adhesives and sealants; paints and coatings] and Furnishing, cleaning, and treatment 3230 care products [all-purpose waxes and polishes]).

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#### 4.3.2.8 Non-Spray Application of Paints, Coatings, Adhesives, and Sealants

#### 3232

#### 4.3.2.8.1 Overview of Risk Estimates

3233 For the non-spray applications of paints, coatings, adhesives, and sealants containing DEHP, inhalation 3234 exposure from vapor generation is expected to be the dominant route of exposure. In support of this, 3235 MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 1.0 to 1.6 for 3236 average adult workers and female workers of reproductive age, while high-end dermal MOEs for the 3237 same populations and exposure scenarios ranged from 411 to 653 (benchmark = 30). The central 3238 tendency MOEs for the same populations and exposure scenarios ranged from 4.8 to 7.7 for inhalation 3239 exposure and 822 to 1,307 for dermal exposure. Aggregation of inhalation and dermal exposures led to 3240 negligible differences in risk when compared to risk estimates from inhalation exposure alone.

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## 4.3.2.8.2 Overview of Exposure Data

3242 No references with discrete full-shift samples were identified for this OES through systematic review; 3243 however, a European Union Risk Assessment on phthalic esters (including DEHP) provided a maximum 3244 concentration based on personal samples collected during mixed operations at a rubber manufacturing 3245 facility (ECJRC, 2003). EPA assessed the high-end worker inhalation exposure result for this OES using 3246 the maximum concentration and central tendency worker inhalation exposure result for this OES by 3247 calculating the 95th and 50th percentile based on discrete mean samples with six unknown sample types 3248 and one area sample. These data had a data quality rating of high, meaning they are of acceptable 3249 quality. EPA acknowledges that the central tendency for the non-spray application results in an MOE 3250 lower than the spray application. It is important to note that the spray application scenario comprises 3251 modeling that includes monitoring data from the automotive spray paints/coatings industry which 3252 includes a variety of engineering controls, spray booth configurations, spray gun pressures, etc.; whereas 3253 the non-spray application is based on modeling without engineering controls, which may, in part, 3254 explain this difference.

#### 3255 4.3.2.8.3 Risk Characterization of COUs

3256 There is uncertainty about how well these data represent the monitoring data in capturing the true 3257 distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which 3258 EPA used central tendency worker data as surrogate (resulting in lower confidence in the ONU exposure 3259 data relative to worker exposure data). Additionally, the monitoring dataset consisted of six unknown 3260 sample types and a mixed composition of phthalate esters. This scenario represents a worker with 8 3261 exposure hours per day and 250 exposure days per year based on continuous DEHP exposure each 3262 working day for a typical worker schedule. The representativeness of this scenario is influenced by the 3263 variability in worker activities, schedules, and facility operations across the full distribution of facilities. There is uncertainty in how well the industrial operations in the monitoring study reflect the non-spray 3264 3265 applications covered by this OES; however, these data were determined to be of high quality and 3266 represent time-weighted average personal and area samples from a plant performing rubber calendaring (ECJRC, 2003), a surrogate OES expected to be similar to non-spray application of paints, coatings, 3267 3268 adhesives, and sealants. Therefore, the central tendency (50th percentile of the maximum 3269 concentrations) and high-end (95th percentile of the maximum concentrations) are considered to be 3270 plausible estimates of worker exposures for non-spray scenarios within the COUs covered under the 3271 Application of paints, coatings, adhesives, and sealants OES (*i.e.*, Industrial use COU: Construction, 3272 paint, electrical, and metal products [paints and coatings] and Commercial use COUs: Construction, 3273 paint, electrical, and metal products [adhesives and sealants; paints and coatings] and Furnishing, 3274 cleaning, and treatment care products [all-purpose waxes and polishes]. Again, non-spray application is 3275 based on modeling without engineering controls, so this may represent a conservative estimate of 3276 exposure.

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## 4.3.2.9 Textile Finishing

#### 3278

## 4.3.2.9.1 Overview of Risk Estimates

3279 For textile finishing using products containing DEHP, dermal exposure from liquid is expected to be the 3280 dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic 3281 inhalation exposure ranged from 185,273 to 347,431 for average adult workers and female workers of 3282 reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged 3283 from 214 to 396 (benchmark = 30). The central tendency MOEs for the same populations and exposure 3284 scenarios ranged from 2,569,919 to 4,819,205 for inhalation exposure and 428 to 791 for dermal 3285 exposure. Aggregation of inhalation and dermal exposures led to negligible differences in risk when 3286 compared to risk estimates from dermal exposure alone.

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## 4.3.2.9.2 Overview of Exposure Data

During textile finishing using DEHP-containing products, worker inhalation and dermal exposures to 3288 3289 liquids containing DEHP may occur while transferring products to finishing and coating equipment, 3290 cleaning of transport containers, finishing and coating operations, and cleaning of process vessels. EPA 3291 did not identify inhalation monitoring data for the textile finishing OES during systematic review. Based 3292 on the presence of DEHP in textile fabrics (Laursen et al., 2003), EPA assessed worker inhalation 3293 exposures to DEHP as an exposure to particulates of textile fabrics. Therefore, EPA estimated worker 3294 inhalation exposures during disposal using the Generic Model for Central Tendency and High-End 3295 Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) (also 3296 referred to as the "PNOR Model") (U.S. EPA, 2021d). To estimate fabric particulate concentrations in 3297 the air, EPA used a subset of the PNOR (U.S. EPA, 2021d) data that came from facilities with the 3298 NAICS code starting with 313 to 314 (Textile Manufacturing). EPA multiplied these dust concentrations 3299 by the maximum product concentrations to estimate DEHP particulate concentrations in the air. This 3300 dataset consisted of 71 measurements. EPA used the highest expected concentration of DEHP in textile

3301 products to estimate the concentration of DEHP present in particulates. For this OES, EPA selected

- 3302  $8.6 \times 10^{-6}$  percent by mass as the highest expected DEHP concentration based on the reported
- 3303 concentrations for several fabrics (<u>Laursen et al., 2003</u>). The estimated exposures are based on the
- operating assumption that DEHP is present in particulates of the fabrics at this fixed concentration
   throughout the working shift. Given the assumptions of DEHP present in dust at the concentration in the
- 3306 fabric products containing DEHP, EPA considers the exposure estimate to represent an upper bound for
- 3307 worker exposure. The model (U.S. EPA, 2021d) estimates an 8-hour TWA for particulate concentrations
- 3308 by assuming exposures outside the sample duration are zero. The model does not determine exposures
- 3309 during individual worker activities.

# **4.3.2.9.3 Ris**

# 4.3.2.9.3 Risk Characterization of COUs

3311 The PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker 3312 may experience in the textile industry. However, the variability in composition of workplace dust is 3313 uncertain. The exposure and risk estimates represent an air composition where the concentration of 3314 DEHP in workplace dust is equivalent to the maximum concentration of DEHP in the textile finishing 3315 product. The representativeness of the concentration of DEHP in the workplace dust is influenced by the 3316 variability in the true distribution of air compositions across all facilities and textile operations covered 3317 under this OES. The likelihood of the maximum DEHP concentration in dust and the PBZ air to be 3318 comprised entirely by DEHP-containing particles is unknown. EPA considers central tendency values of 3319 exposure to be most representative of worker exposures within the COUs covered under the Textile 3320 finishing OES (*i.e.*, Commercial Use – Furnishing, cleaning, and treatment care products COU: [Fabric, 3321 textile, and leather products; furniture and furnishings; and Fabric enhancer]), given the fact that: the air 3322 concentrations were modeled assuming that the: dust present during textile finishing is at the level in the 3323 subset of the PNOR (U.S. EPA, 2021d) data from facilities associated with the NAICS code for textile 3324 manufacturing; the dust is comprised entirely of abraded textile products containing DEHP; and the 3325 concentration of DEHP in those textile products in at the highest concentration reported in fabrics 3326 (Laursen et al., 2003). The high-end estimates are more likely to occur under the more conservative 3327 combination of these parameters, and even under these conditions that comprise high-end, the resulting 3328 MOEs for inhalation risk were four orders of magnitude above the benchmark.

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# 4.3.2.10 Fabrication and Final Use of Products or Articles

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# 4.3.2.10.1 Overview of Risk Estimates

3331 For fabrication and final use of products or articles, inhalation exposure from vapor generation is 3332 expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, 3333 intermediate, and chronic inhalation exposure ranged from 72 to 123 for average adult workers and 3334 female workers of reproductive age, while high-end dermal MOEs for the same populations and 3335 exposure scenarios ranged from 214 to 357 (benchmark = 30). For central tendency, MOEs for the same 3336 population and exposure scenarios ranged from 199 to 337 for inhalation exposure and 428 to 715 for 3337 dermal exposures. Aggregation of inhalation and dermal exposures led to negligible differences in risk 3338 when compared to risk estimates from inhalation exposure alone.

4.3.2.10.2 Overview of Exposure Data

The worker inhalation exposure results for this OES were calculated from personal samples collected from the 2019 OSHA CEHD data (OSHA, 2019). The time-weighted averages were calculated based on samples that shared the same Inspection, Establishment, and Sampling number and had a sum of sampling time greater than three hours. EPA calculated 8-hour TWAs by assuming exposures outside the sampling time were zero. These data had a data quality rating of high. As all data were deemed of acceptable quality without notable deficiencies, EPA elected to integrate all the data in the final

exposure assessment. EPA considered the 50th percentile of the TWA to represent central tendency, andthe 95th percentile of the TWA to represent the high-end exposure of workers.

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## 4.3.2.10.3 Risk Characterization of COUs

3349 There is uncertainty about how well these data represent the monitoring data in capturing the true distribution of inhalation concentrations for this OES. Additionally, due to the lack of discrete TWA 3350 3351 data, samples from the OSHA CEHD were combined by inspection number, establishment name, and 3352 sample number to calculate an 8-hour TWA in cases where the sum of sampling time was greater than 3 3353 hours. This method represents workers that are exposed to DEHP for 3 hours during their shift, which 3354 may underestimate exposures if they were to be exposed for the full shift duration. Due to the lack of 3355 data for ONUs, EPA used a discrete TWA area sample for both the high-end and central tendency 3356 exposures. Finally, this scenario represents a worker with 8 exposure hours per day and 250 exposure 3357 days per year with continuous DEHP exposure each working day; The representativeness of this 3358 scenario is influenced by the variability in worker activities, schedules, and facility operations across the 3359 full distribution of facilities covered by this OES. Given the possibility of underestimation of exposure, EPA considers the high-end (95th percentile of the TWA) to be most representative of worker exposures 3360 3361 within the COUs covered under the Fabrication or final use of products or articles OES (*i.e.*, 3362 Commercial use COU: Construction, paint, electrical, and metal products [batteries and capacitors; 3363 construction and building materials covering large surface areas, including paper articles; metal articles; 3364 stone, plaster, cement, glass and ceramic articles; machinery, mechanical appliances, electrical/electronic articles]; automotive, fuel, agriculture, and outdoor use products [lawn and garden 3365 care products]; packaging, paper, plastic, toys, hobby products [packaging (excluding food packaging) 3366 and other articles with routine direct contact during normal use, including paper articles; rubber articles; 3367 plastic articles (hard); plastic articles (soft); packaging (excluding food packaging), including paper 3368 3369 articles; toys, playground, and sporting equipment]; furnishing, cleaning, and treatment care products 3370 [floor coverings; construction and building materials covering large surface areas including stone, 3371 plaster, cement, glass and ceramic articles fabrics, textiles, and apparel].

3372
3373 To determine the potential impact of any underestimation of exposure on risk characterization for this
3374 OES, EPA reviewed the resulting MOEs (72–337) and determined that, even if you assumed that the
a375 exposure data reflected a 3-hour exposure and the exposure was actually for a full shift, the MOEs
3376 would still be above benchmark.

- 3377
- 3378

## 4.3.2.11 Use of Dyes, Pigments, and Fixing Agents

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## 4.3.2.11.1 Overview of Risk Estimates

3380 For the use of dyes, pigments, and fixing agents containing DEHP, inhalation exposure from vapor 3381 generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end 3382 acute, intermediate, and chronic inhalation exposure ranged from 1.0 to 1.6 for average adult workers 3383 and female workers of reproductive age, while high-end dermal MOEs for the same populations and 3384 exposure scenarios ranged from 411 to 653 (benchmark = 30). The central tendency MOEs for the same 3385 populations and exposure scenarios ranged from 4.8 to 7.7 for inhalation exposure and 822 to 1,307 for 3386 dermal exposure. Aggregation of inhalation and dermal exposures led to negligible differences in risk 3387 when compared to risk estimates from inhalation exposure alone.

- 3388 4.3.2.11.2 Overview of Exposure Data
  - No references with full-shift samples were identified for this OES through systematic review; however, data were available for a similar OES (non-spray application of paints, coatings, adhesives, and

sealants). The primary exposure from the use of dyes, pigments, and fixing agents is expected to come
 from unloading materials from transport containers. The monitoring data (rubber manufacturing) from
 the non-spray application of paints, coatings, sealants, and adhesives is expected to provide comparable

- exposure estimates for this OES since it includes monitoring data from some worker activities involving unloading. Therefore, EPA assessed worker and ONU exposures using monitoring data for the non-
- spray application of paints, coatings, adhesives, and sealants OES as a surrogate for this OES. These
- data had a data quality rating of high, meaning they are of acceptable quality. EPA assessed the high-end
- worker inhalation exposure result for this OES using the maximum concentration and central tendency
- worker inhalation exposure result for this OES by calculating the 95th and 50th percentile based on
- 3400 discrete mean samples with six unknown sample types and one area sample.

# 3401

# 4.3.2.11.3 Risk Characterization of COUs

3402 This scenario represents a worker with 8 exposure hours per day and 250 exposure days per year with continuous DEHP exposure each working day. The representativeness of this scenario is influenced by 3403 the variability in worker activities, schedules, and facility operations across the full distribution of 3404 3405 facilities covered by this OES. EPA did not identify any data on exposure to ONUs, therefore central 3406 tendency worker data was used as a surrogate (resulting in lower confidence in the ONU exposure data 3407 relative to worker exposure data). There is uncertainty about how well the data from the surrogate OES 3408 (non-spray application of paints, coatings, adhesives, and sealants) represent the true distribution of 3409 inhalation concentrations in the use of dyes, pigments, and fixing agents OES. However, these OES are 3410 expected to have similar exposure potential based on the similarity of worker activities and chemical 3411 physical form in each OES, and the data were determined to be high quality. Therefore, EPA considers 3412 the central tendency and high end to be plausible estimates of worker exposures within the COUs 3413 covered by under the Use of dyes and pigments, and fixing agents OES (*i.e.*, Commercial use COU: 3414 Packaging, paper, plastic, toys, hobby products [ink, toner and colorants]).

3415

# 4.3.2.12 Formulation for Diffusion Bonding

3416

# 4.3.2.12.1 Overview of Risk Estimates

3417 For use of formulations for diffusion bonding containing DEHP, inhalation exposure from vapor 3418 generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end 3419 acute, intermediate, and chronic inhalation exposure ranged from 1.0 to 1.6 for average adult workers 3420 and female workers of reproductive age, while high-end dermal MOEs for the same populations and 3421 exposure scenarios ranged from 411 to 653 (benchmark = 30). The central tendency MOEs for the same 3422 populations and exposure scenarios ranged from 23 to 38 for inhalation exposure and 822 to 1,307 for 3423 dermal exposure. Aggregation of inhalation and dermal exposures led to negligible differences in risk 3424 when compared to risk estimates from inhalation exposure alone.

3425

# 4.3.2.12.2 Overview of Exposure Data

3426 EPA did not identify inhalation monitoring data specific to DEHP for the Formulations for diffusion 3427 bonding OES during systematic review of literature sources. EPA assessed exposures from spray 3428 application using the Automotive Refinishing Spray Coating Mist Inhalation Model which estimates 3429 worker inhalation exposure based on the concentration of the chemical of interest in the nonvolatile 3430 portion of the sprayed product and the concentration of over sprayed mist/particles (OECD, 2011). The 3431 model is based on PBZ monitoring data for mists during automotive refinishing. EPA used the 50th and 3432 95th percentile mist concentrations along with the maximum and central tendency concentration of 3433 DEHP identified in diffusion bonding formulations to estimate the central tendency and high-end 3434 inhalation exposures, respectively.

#### 3435 **4.3.2.12.3 Risk Characterization of COUs**

3436 The primary uncertainty comes from the lack of DEHP-specific monitoring data, with the ESD serving 3437 as a surrogate source of monitoring data representing the level of exposure that could be expected at a 3438 typical work site for the given spray application method. The inhalation monitoring data used were 3439 specific to the spray application of coating materials, so the estimates may not be representative of 3440 exposure during other application methods. Additionally, it is uncertain whether the substrates coated, 3441 and products used to generate the surrogate data are representative of those associated with DEHP-3442 containing diffusion bonding formulations. EPA only assessed mist exposures to DEHP over a full 8-3443 hour work shift to estimate the level of exposure, though other activities may result in exposures other 3444 than mist and application duration may be variable depending on the job site. This scenario represents a 3445 worker with 8 exposure hours per day and 250 exposure days per year with continuous DEHP exposure 3446 based on workers using diffusion bonding formulations on every working day. However, application 3447 sites may use DEHP-containing diffusion bonding formulations at lower or variable frequencies.

3448

3449 The representativeness of this scenario is influenced by the variability in worker activities, schedules,

and facility operations across the full distribution of facilities covered by this OES. Additionally, the
lack of ONU exposure data requires the use of central tendency worker data as surrogate data, which
may not be fully representative of ONU exposures (resulting in lower confidence in the ONU exposure
data relative to worker exposure data). Although no inhalation monitoring data was identified that was
specific to DEHP use in formulations for diffusion bonding, EPA used the Automotive Refinishing

3455 Spray Coating Mist Inhalation Model, which estimates worker inhalation exposure based on the 3456 concentration of the chemical of interest in the nonvolatile portion of the sprayed product and the 3457 concentration of over sprayed mist/particles (OECD, 2011). The model is based on PBZ monitoring data

for mists during automotive refinishing, which is considered a relevant surrogate scenario. EPA used the

50th and 95th percentile mist concentrations along with the central tendency and maximum
 concentration of DEHP identified in diffusion bonding formulations to estimate the central tendency and

high-end inhalation exposures, respectively. As described in Section 4.3.2.7, EPA considers the central
tendency and high-end exposure from this model to be a plausible estimate of worker exposures within
the COUs covered under the Formulations for diffusion bonding OES (*i.e.*, Industrial Use: Construction,
paint, electrical, and metal products [Adhesives and Sealants]), emphasizing the fact that the
concentrations of DEHP used are specific to diffusion bonding products, along with the more generic
mist concentrations derived from a relevant surrogate OES.

3467

## 4.3.2.13 Use of Laboratory Chemicals

3468

## 4.3.2.13.1 Overview of Risk Estimates

3469 For the use of laboratory chemicals containing DEHP, inhalation exposure from dust or vapor 3470 generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end 3471 acute, intermediate, and chronic inhalation exposure ranged from 80 to 128 for average adult workers 3472 and female workers of reproductive age, while high-end dermal MOEs for the same populations and 3473 exposure scenarios ranged from 214 to 340 (benchmark = 30). The central tendency MOEs for the same 3474 populations and exposure scenarios ranged from 797 to 1,367 for inhalation exposure and 428 to 724 for 3475 dermal exposure. Aggregation of inhalation and dermal exposures led to slightly lower MOE values. 3476 MOEs for high-end acute, intermediate, and chronic aggregated exposure ranged from 59 to 91 for 3477 average adult workers and female workers of reproductive age, while high-end aggregated MOEs for the 3478 same populations and exposure scenarios ranged from 288 to 456.

**n** .

3479	4.3.2.13.2 Overview of Exposure Data
3480	No references with discrete full-shift samples were identified for this OES through systematic review;
3481	however, the European Union Risk Assessment for DEHP provided a minimum and maximum based on
3482	their collected full-shift area samples from a laboratory used during DEHP production (ECB, 2008). A
3483	report from Modigh et al. provided full-shift, personal sampling data statistics for two non-detected
3484	samples for laboratory staff at a plant producing DEHP (Modigh et al., 2002). EPA assessed the high-
3485	end worker inhalation exposure result for this OES using the maximum from the European Union Risk
3486	Assessment for DEHP and central tendency worker inhalation exposure result for this OES using the
3487	limit of detection result from the Modigh et al. study (ECB, 2008; Modigh et al., 2002). These data had
3488	data quality ratings ranging from medium to high, meaning they are of acceptable quality.

#### 3489

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#### 4.3.2.13.3 Risk Characterization of COUs

3490 There is uncertainty regarding how well these data represent the monitoring data in capturing the true 3491 distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which 3492 EPA used central tendency worker data as surrogate (resulting in lower confidence in the ONU exposure 3493 data relative to worker exposure data). This scenario represents a worker with 8 exposure hours per day 3494 and 250 exposure days per year with continuous DEHP exposure each working day. The 3495 representativeness of this scenario is influenced by the variability in worker activities, schedules, and facility operations across the full distribution of facilities covered by this OES. Although no studies were 3496 3497 identified that included discrete full-shift samples for this OES, EPA used monitoring data from two 3498 studies that sampled laboratories to estimate worker inhalation exposures to vapor (ECB, 2008; Modigh 3499 et al., 2002). EPA used the maximum of three full-shift area samples for the high-end worker exposures and the minimum of two full-shift PBZ samples, which was below the limit of detection, for the central 3500 3501 tendency worker exposures. The primary strength of this approach is that it uses monitoring data specific 3502 to this OES from studies that were rated medium to high quality. Therefore, EPA considers the central tendency and high-end exposures to be plausible estimates of worker exposures within the COUs 3503 3504 covered under the Use of laboratory chemicals OES (i.e., Commercial Use: Other uses [laboratory 3505 chemicals]).

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## 4.3.2.14 Use of Automotive Care Products

3507

## 4.3.2.14.1 Overview of Risk Estimates

For the use of automotive care products containing DEHP, inhalation exposure from vapor generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 72 to 117 for average adult workers and female workers of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 411 to 653 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 145 to 249 for inhalation exposure and 822 to 1,390. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to

- 3515 risk estimates from inhalation exposure alone.
- 3516

#### 4.3.2.14.2 Overview of Exposure Data

No references with discrete worker full-shift samples were identified for this OES through systematic
 review; however, the European Union Risk Assessment on DEHP provided a minimum (below limit of
 detection) concentration and maximum concentration based on their collected full-shift samples during
 the application of car sealings and under-coatings (ECB, 2008). EPA assessed the high-end worker

3521 inhalation exposure result for this OES using the maximum concentration and central tendency worker

- inhalation exposure result for this OES using the midpoint between zero and the maximum
- 3523 concentration from the European Union Risk Assessment on DEHP as the minimum given in the sample

3524 was below the limit of detection (ECB, 2008). These data had a data quality rating of high, meaning they 3525 are of acceptable quality.

## 4.3.2.14.3 Risk Characterization of COUs

3527 There is uncertainty about how well these data represent the vapor monitoring data in capturing the true distribution of inhalation concentrations for this OES and the lack of ONU exposure data, for which 3528 3529 EPA used central tendency worker data as surrogate (resulting in lower confidence in the ONU exposure 3530 data relative to worker exposure data). This scenario represents a worker with 8 exposure hours per day 3531 and 250 exposure days per year with continuous DEHP exposure each working day. The 3532 representativeness of this scenario is influenced by the variability in worker activities, schedules, and 3533 facility operations across the full distribution of facilities covered by this OES. Although EPA did not 3534 identify studies reporting discrete worker full-shift samples, EPA used the maximum concentration 3535 resulting from full-shift samples during the application of car sealings and under-coatings provided in 3536 the European Union Risk Assessment on DEHP (ECB, 2008) to represent high-end exposure, and the midpoint between zero and the maximum concentration to represent central tendency. These data had a 3537 data quality rating of high and were considered plausible estimates of worker exposures within COUs 3538 3539 covered under the Use of automotive care products OES (*i.e.*, Commercial Use: Other uses [automotive 3540 articles]).

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## 4.3.2.15 Use in Hydraulic Fracturing

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#### 4.3.2.15.1 Overview of Risk Estimates

3543 For the use in hydraulic fracturing, vapor inhalation and dermal exposure to liquids containing DEHP 3544 are both considered to be significant routes of exposure. In support of this, MOEs for high-end acute, 3545 intermediate, and chronic inhalation exposure ranged from 362 to 48,667 for average adult workers and 3546 female workers of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 411 to 54,454 (benchmark = 30). The central tendency MOEs for the 3547 3548 same populations and exposure scenarios ranged from 664 to 267,667 for inhalation exposure and 822 to 326,726 for dermal exposure. Aggregation of inhalation and dermal exposures led to lower MOEs 3549 compared to either individual route; MOEs for high-end acute, intermediate, and chronic aggregated 3550 exposure ranged from 118 to 24,354 for average adult workers and female workers of reproductive age, 3551 3552 while the central tendency MOEs for the same populations and exposure scenarios ranged from 226 to 3553 139,132 for aggregated exposure.

#### 4.3.2.15.2 Overview of Exposure Data

No references with full-shift samples were identified for this OES through systematic review; however,
data were available for a similar OES (Manufacturing). These OES are expected to have similar
exposure potential. However, while acknowledging the differences in worker activities in each OES.
EPA assessed worker and ONU exposures using monitoring data for the Manufacturing OES as a
surrogate for this OES. These data had data quality ratings ranging from medium to high, meaning they
are of acceptable quality.

#### 4.3.2.15.3 Risk Characterization of COUs

3562 There is uncertainty about how well these data represent this OES and the true distribution of inhalation 3563 concentrations in this scenario, given the lack of ONU exposure data, for which EPA used central 3564 tendency worker data as surrogate (resulting in lower confidence in the ONU exposure data relative to 3565 worker exposure data), and the fact that the data come from two DEHP manufacturing facilities as a 3566 surrogate for hydraulic fracturing exposures. This scenario represents a worker with 8 exposure hours 3567 per day and 1 to 3 exposure days per year based on data obtained from Frac Focus (GWPC and IOGCC, 3568 2022). The manufacturing OES used as a surrogate is expected to have similar exposure potential based 3569 on the similarity of worker activities and chemical physical form in each OES. Given that worker 3570 inhalation exposure for the manufacturing OES was based data from 45 full-shift samples collected from two DEHP manufacturing plants (Liss and Hartel, 1983; Nuodex Inc., 1983) determined to be medium 3571 3572 to high quality data, the central tendency (50th percentile) and the high-end (95th percentile) are expected to be plausible estimates of worker exposure within the COUs covered under the Use in 3573 3574 hydraulic fracturing OES (*i.e.*, Industrial Use: Other uses [hydraulic fracturing]).

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3561

#### **4.3.2.16 Recycling**

3577

## 4.3.2.16.1 Overview of Risk Estimates

For recycling of products containing DEHP, inhalation exposure from dust or vapor generation is 3578 3579 expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 15 to 24 for average adult workers and 3580 3581 female workers of reproductive age, while high-end dermal MOEs for the same populations and 3582 exposure scenarios ranged from 214 to 340 (benchmark = 30). The central tendency MOEs for the same 3583 populations and exposure scenarios ranged from 75 to 121 for inhalation exposure and 428 to 681 for 3584 dermal exposure. Aggregation of inhalation and dermal exposures led to negligible differences in risk 3585 when compared to risk estimates from inhalation exposure alone.

3586

## 4.3.2.16.2 Overview of Exposure Data

EPA did not identify inhalation monitoring data for the recycling OES during systematic review. Based 3587 3588 on plastic recyclers relying heavily on the plastic converting processes, EPA used plastic converting 3589 inhalation monitoring data as surrogate data. The high-end worker inhalation exposure results for this 3590 OES are based on the 95th percentile exposure values from full-shift samples collected from (OSHA, 3591 2019). These data had a data quality rating of High. The central tendency worker inhalation exposure 3592 results for this OES are based on a weighted average of mean values from full-shift samples collected 3593 from (Modigh et al., 2002) and a mean sample calculated from the discrete samples given in (OSHA, 3594 2019). These data had a data quality rating of high. As all data were deemed of acceptable quality 3595 without notable deficiencies, EPA elected to integrate all the data in the final exposure assessment.

#### 3596 4.3.2.16.3 Risk Characterization of COUs

3597 There is uncertainty about how well these data represent this OES and the true distribution of inhalation 3598 concentrations in this scenario; the lack of ONU exposure data, for which EPA used central tendency 3599 worker data as surrogate (resulting in lower confidence in the ONU exposure data relative to worker 3600 exposure data); and that the data come from a sole PVC floor sheet manufacturer. This scenario 3601 represents a worker with 8 exposure hours per day and 250 exposure days per year based on continuous 3602 DEHP exposure each working day for a typical worker schedule. There is uncertainty in the 3603 representativeness of this assessment for the recycling OES due to the use of a surrogate (plastic 3604 converting) exposure scenario. However, because plastic recyclers relying heavily on the plastic 3605 converting processes, EPA considers this surrogate data to be a reasonable representation of exposures

to workers from plastics recycling. Further, the high-end worker inhalation exposure results for this OES
 are based on the 95th percentile exposure values from full-shift samples collected from (OSHA, 2019),
 and the central tendency worker inhalation exposure results for this OES are based on a weighted

average of mean values from full-shift samples collected from (Modigh et al., 2002) and a mean sample

- 3610 calculated from the discrete samples provided in the OSHA data (2019). These data had a data quality
- 3611 rating of high, and the central tendency and high-end exposures are considered to be plausible estimates
- of worker exposures within the COUs covered under the Recycling OES (*i.e.*, Processing COU:
   Recycling).
- 3613 F 3614
- 3014
- 3615

3616

## 4.3.2.17 Waste Handling, Treatment and Disposal

# 4.3.2.17.1 Overview of Risk Estimates

For waste handling, treatment and disposal, the inhalation exposure from dust generation is expected to 3617 be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and 3618 3619 chronic inhalation exposure ranged from 5.2 to 8.3 for average adult workers and female workers of 3620 reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged 3621 from 214 to 340 (benchmark = 30) for both OES. The central tendency MOEs for the same populations 3622 and exposure scenarios ranged from 75 to 121 for inhalation exposure and 428 to 681 for dermal 3623 exposure for both OES. Aggregation of inhalation and dermal exposures led to negligible differences in 3624 risk when compared to risk estimates from inhalation exposure alone.

3625

# 4.3.2.17.2 Overview of Exposure Data

3626 EPA did not identify inhalation monitoring data for the Waste handling, treatment, and disposal OES 3627 during systematic review. Based on the presence of DEHP as an additive in plastics (U.S. CPSC, 2015), 3628 EPA assessed worker inhalation exposures to DEHP as an exposure to particulates of discarded plastic 3629 materials. Therefore, EPA estimated worker inhalation exposures during disposal using the PNOR 3630 Model (U.S. EPA, 2021d). To estimate plastic particulate concentrations in the air, EPA used a subset of 3631 the PNOR (U.S. EPA, 2021d) data that came from facilities with the NAICS code starting with 56 3632 (Administrative and Support and Waste Management and Remediation Services). This dataset consisted 3633 of 130 measurements. EPA used the highest expected concentration of DEHP in plastic products to 3634 estimate the concentration of DEHP present in particulates. For this OES, EPA selected 44 percent by 3635 mass as the highest expected DEHP concentration based on the product SDS for Vinoprene 647 (HB 3636 Chemical, 2015). The estimated exposures are based on the operating assumption that DEHP is present 3637 in particulates of the plastic at this fixed concentration throughout the working shift. The model (U.S. 3638 EPA, 2021d) estimates an 8-hour TWA for particulate concentrations by assuming exposures outside the 3639 sample duration are zero. The model does not determine exposures during individual worker activities. 3640 Given the assumptions of DEHP present in dust at the concentration in the plastic product representing 3641 the highest concentration of DEHP identified in SDS for relevant products for this OES, EPA considers 3642 the exposure estimate to represent an upper bound for worker exposure

3643

## 4.3.2.17.3 Risk Characterization of COUs

Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may experience in the disposal industry, the composition of workplace dust is uncertain. The exposure and risk estimates represent an air composition where the concentration of DEHP in workplace dust is equivalent to the maximum concentration of DEHP in PVC plastics. The representativeness of the concentration of DEHP in the workplace dust will be influenced by the variability in the true distribution of air compositions across all facilities and disposed products or articles covered under this OES. EPA considers central tendency values of exposure to be most representative of worker exposures

3651 within the COUs covered under the Waste handling, treatment, and disposal OES (*i.e.*, Disposal COU), 3652 given the fact that the air concentrations were modeled assuming that: the dust present during waste 3653 handling, treatment, and disposal is at the level in the subset of the PNOR data from facilities associated

- 3654 with the NAICS code for Administrative and Support and Waste Management and Remediation
- 3655 Services (U.S. EPA, 2021d); the dust is comprised entirely of abraded plastic products containing
- 3656 DEHP; and the concentration of DEHP in the abraded plastic is the highest concentration reported in
- 3657 SDS (*i.e.*, 44% DEHP in Vinoprene 647 (HB Chemical, 2015)). The high-end estimates are more likely to occur under the more conservative combination of these parameters.
  - 3658 3659

#### 3660 4.3.2.18 Distribution in Commerce

For purposes of assessment, distribution in commerce consists of the activities associated with the 3661 transportation of DEHP or DEHP-containing products and/or articles between sites that manufacture, 3662 3663 process, and use DEHP. Additionally, this OES includes the transportation of DEHP-containing wastes to recycling sites or for final disposal. EPA expects all the DEHP or DEHP-containing products and/or 3664 articles to be transported in a closed system or otherwise to be transported in a form (e.g., articles 3665 3666 containing DEHP) such that there is negligible potential for releases except during an incident. 3667 Therefore, no occupational exposures are reasonably expected to occur, and no separate assessment was performed for estimating releases and exposures from the COUs covered under the OES Distribution in 3668 3669 commerce (e.g., Distribution in commerce COU).

3670

# 4.3.2.19 Overall Confidence in Worker Risks

3671 As described in Section 4.1.1.4 and the Draft Environmental Release and Occupational Exposure 3672 3673 Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025r), EPA has slight to moderate 3674 confidence in the assessed inhalation and dermal OESs (Table 4-4), and robust confidence in the noncancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to 3675 3676 DEHP (see Section 4.2 and (U.S. EPA, 2024j)). Overall, EPA has moderate to robust confidence in the 3677 risk estimates calculated for worker and ONU inhalation and dermal exposure scenarios. Sources of 3678 uncertainty associated with these occupational COUs are discussed above in Section 4.3.2. 3679

3680

# 4.3.2.20 Consideration of Personal Protective Equipment (PPE)

OSHA and NIOSH recommend employers utilize the hierarchy of controls<sup>4</sup> to address hazardous 3681 exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, 3682 the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. The 3683 3684 hierarchy of controls prioritizes the most effective measures, which eliminate or substitute the harmful 3685 chemical (e.g., use a different process, substitute with a less hazardous material), thereby preventing or 3686 reducing exposure potential. Following elimination and substitution, the hierarchy recommends 3687 engineering controls to isolate employees from the hazard, followed by administrative controls or 3688 changes in work practices to reduce exposure potential (e.g., source enclosure, local exhaust ventilation)3689 systems). Administrative controls are policies and procedures instituted and overseen by the employer to 3690 protect worker exposures. OSHA and NIOSH recommend the use of PPE (e.g., respirators, gloves) as

<sup>&</sup>lt;sup>4</sup> See https://www.osha.gov/sites/default/files/Hierarchy\_of\_Controls\_02.01.23\_form\_508\_2.pdf.

the last means of control, when the other control measures cannot reduce workplace exposure to an acceptable level.

## 3693 4.3.2.20.1 Respiratory Protection

OSHA's Respiratory Protection Standard (29 CFR 1910.134) requires employers in certain industries to 3694 address workplace hazards by implementing engineering control measures and, if these are not feasible, 3695 3696 providing respirators that are applicable and suitable for the purpose intended. Respirator selection 3697 provisions are provided in section 1910.134(d) and require that appropriate respirators be selected based 3698 on the respiratory hazard(s) to which the worker will be exposed, in addition to workplace and user 3699 factors that affect respirator performance and reliability. APFs are provided in Table 1 under section 3700 1910.134(d)(3)(i)(A) (see below in Table 4-15) and refer to the level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a 3701 3702 respiratory protection program according to the requirements of OSHA's Respiratory Protection 3703 Standard.

3704

Workers are required to use respirators that meet or exceed the required level of protection listed in Table 4-15. Based on the APF, inhalation exposures may be reduced by a factor of 5 to 10,000, if respirators are properly worn and fitted.

3708

Type of Respirator	Quarter Mask	Half Mask	Full Facepiece	Helmet/ Hood	Loose- Fitting Facepiece
1. Air-Purifying Respirator	5	10	50	_	_
2. Power Air-Purifying Respirator (PAPR)	_	50	1,000	25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline l	Respirator				
Demand mode	—	10	50	_	—
Continuous flow mode	_	50	1,000	25/1,000	25
Pressure-demand or other positive- pressure mode	_	50	1,000	_	_
4. Self-Contained Breathing Apparatus (SCB	A)				
Demand mode	_	10	50	50	—
• Pressure-demand or other positive- pressure mode ( <i>e.g.</i> , open/closed circuit)	_	—	10,000	10,000	_
Source: 29 CFR 1910.134(d)(3)(i)(A)					

#### 3709 Table 4-15. Assigned Protection Factors for Respirators in OSHA Standard 29 CFR 1910.134

#### 3710

## 4.3.2.20.2 Glove Protection

Gloves are selected in industrial settings based on characteristics (permeability, durability, required task etc). Data on the frequency of glove use (*i.e.*, the proper use of effective gloves) in industrial settings is very limited. An initial literature review suggests that there is unlikely to be sufficient data to justify a specific probability distribution for effective glove use for handling of DEHP specifically, for a given industry. Instead, EPA explored the impact of effective glove use by considering different percentages of effectiveness (*e.g.*, 25% vs. 50% effectiveness).

3717

3718 Gloves only offer barrier protection until the chemical breaks through the glove material. Using a 3719 conceptual model, Cherrie (Cherrie et al., 2004) proposed a glove workplace protection factor, defined

as the ratio of estimated uptake through the hands without gloves to the estimated uptake though the

hands while wearing gloves. This protection factor is driven by flux, and thus the protection factor varies
with time. The ECETOC TRA model v.3.2 represents the glove protection factor as a fixed, assigned
value equal to 5, 10, or 20 (Marquart et al., 2017). Like the APR for respiratory protection, the inverse
of the protection factor is the fraction of the chemical that penetrates the glove. Table 4-16 presents
dermal doses without glove use, with the potential impacts of these protection factors presented as whatif scenarios in the dermal exposure summary.

# Table 4-16. Assigned Protection Glove Protection Factors for Different Dermal Protection Strategies

Dermal Protection Characteristics	Setting	Protection Factor, PF
a. No gloves used, or any glove/gauntlet without permeation data and without employee training	In ductrial and	1
b. Gloves with available permeation data indicating that the material of construction offers good protection for the substance	Industrial and Commercial Uses	5
c. Chemically resistant gloves ( <i>i.e.</i> , as <i>b</i> above) with "basic" employee training	Uses	10
d. Chemically resistant gloves in combination with specific activity training ( <i>e.g.</i> , procedure for glove removal and disposal) for tasks where dermal exposure can be expected to occur	Industrial Uses Only	20
Source: ( <u>Marquart et al., 2017</u> )	•	

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#### 3731 **Table 4-17. Overall Worker Risk Summary Table**

Life Cycle	COU	OES	Worker	Exposure		ion Risk E ımark MO			al Risk E mark M	stimates OE = 30)			Estimates IOE = 30
Stage – Category	Subcategory		Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
			Average Adult	СТ	733	1,000	1,071	15,816	21,567	23,091	701	956	1,023
Manufacturing			Worker	HE	400	545	584	7,908	10,784	11,546	381	519	556
– Domestic	Domestic manufacturing	Manufacturing	Female of	СТ	664	905	969	17,214	23,474	25,133	639	872	933
Manufacturing			Reproductive Age	HE	362	494	529	8,607	11,737	12,566	348	474	507
			ONU	СТ	733	1,000	1,071	_	-	-	—	_	-
Manufacturing	Importing		Average Adult	СТ	63	86	92	15,816	21,567	23,091	63	85	91
<ul> <li>Importing</li> </ul>			Worker	HE	17	23	25	7,908	10,784	11,546	17	23	25
Processing –	Repackaging in wholesale	Import and	Female of	СТ	57	78	83	17,214	23,474	25,133	57	77	83
Repacking	and retail trade and in paint and coating manufacturing	repackaging	Reproductive Age	HE	15	21	22	8,607	11,737	12,566	15	21	22
			ONU	СТ	63	86	92	_	_	-	_		-
Processing –	Plasticizer in basic organic			СТ	5.3	7.2	7.7	428	584	625	5.2	7.1	7.6
Incorporation into article	chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding		Average Adult Worker	HE	1.1	1.5	1.6	214	292	313	1.1	1.5	1.6
Processing –	Plasticizer in basic organic	_	Female of	СТ	4.8	6.5	7.0	466	636	681	4.7	6.4	6.9
Incorporation into	chemical manufacturing; custom compounding of		Reproductive Age	HE	1.0	1.3	1.4	233	318	340	1.0	1.3	1.4
formulation, mixture, or reaction product	purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Rubber manufacturing	ONU	СТ	5.3	7.2	7.7	428	584	625	5.2	7.1	7.6

Life Cycle	COU	OES	Worker	Exposure		ion Risk E mark MO			al Risk E mark M	stimates OE = 30)			Estimates IOE = 30
Stage – Category	Subcategory	OLS	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Processing –	Plasticizer in basic organic		Average Adult	СТ	29	40	43	428	584	625	27	37	40
Incorporation into	chemical manufacturing; custom compounding of		Worker	HE	3.2	4.3	4.7	214	292	313	3.1	4.3	4.6
formulation,	purchased resins;		Female of	СТ	27	36	39	466	636	681	25	34	37
mixture, or	miscellaneous		Reproductive	HE	2.9	3.9	4.2	233	318	340	2.9	3.9	4.2
reaction product	<i>U</i> ,	Plastic compounding	Age ONU	СТ	1,100	1,500	1,606	428	584	625	308	420	450
Processing –	Plasticizer in basic organic		Average Adult	СТ	733	1,000	1,071	15,816	21,567	23,091	701	956	1,023
Incorporation	chemical manufacturing;		Worker	HE	400	545	584	7,908	10,784	11,546	381	519	556
into formulation, mixture, or reaction product	manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Incorporation into formulation, mixture, or reaction product	Female of Reproductive Age	СТ	664	905	969	17,214	23,474	25,133	639	872	933
Processing –	Miscellaneous processing			HE	362	494	529	8,607	11,737	12,566	348	474	507
Other uses	(cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)		ONU	СТ	733	1,000	1,071			_		_	-

Life Cycle	COU	OFS	Worker	Exposure		ion Risk E mark MO			al Risk Ea mark M	stimates OE = 30)			Estimates OE = 30
Stage – Category	Subcategory	OES	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Processing – Incorporation into article	manufacturing, r vC	Plastic converting	Average Adult Worker		26 17	35 23	38 24	428 214	584 292		24 15		36 22
Industrial Use – Other uses	Solid rocket motor insulation and other aerospace applications		Female of Reproductive Age	CT HE	23 15	32 20	34 22	466 233	636 318		22 14	30 19	33 21
	Automotive Articles		ONU	СТ	26	35	38	428	584	625	24	33	36
Industrial Use – Other uses Industrial Use – Construction, paint, electrical,	Paints and coatings Paints and coatings		Average Adult	СТ	29	40	42	822	1,121	1,201	28	38	41
and metal products Commercial	Adhesives and sealants	Spray application of	Worker										
Use – Construction,		paints,		HE	0.4	0.5	0.6	411	561	600	0.4	0.5	0.6
paint, electrical, and metal products	Paints and coatings	coatings, adhesives, and sealants	Female of Reproductive Age		26 0.4	36 <b>0.5</b>	38 <b>0.5</b>	895 448	1,221 610	,	25 0.4	35 0.5	37 0.5
Commercial Use – Furnishing, cleaning, and treatment care products	All-purpose waxes and polishes		ONU	СТ	29	40	42	822	1,121	1,201	28	38	41

	COU					on Risk Es	stimates	Derma	al Risk E	stimates			Estimates
Life Cycle	Subastagawy	OES	Worker Population	Exposure Level	(Bench	mark MO	E = <b>30</b> )	(Bench	mark M	$\mathbf{OE}=30)$	(Bench	mark M	OE = 30
Stage – Category	Subcategory		ropulation	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
	Paints and coatings			СТ	5.3	7.2	7.7	822	1,121	1,201	5.2	7.1	7.6
Other uses Industrial Use – Construction, paint, electrical, and metal products	Paints and coatings	Non-spray application of paints, coatings,	Average Adult Worker	HE	1.1	1.5	1.6	411	561	600	1.1	1.5	1.6
Commercial	Adhesives and sealants	adhesives, and	Female of	СТ	4.8	6.5	7.0	895	1,221	1,307	4.7	6.5	6.9
Use – Construction,		sealants	Reproductive Age	HE	1.0	1.3	1.4	448	610	653	1.0	1.3	1.4
paint, electrical, and metal products			ONU	СТ	5.3	7.2	7.7	_	_	_	_	_	-
Commercial Use – Furnishing,	Fabric, textile, and leather products; furniture and furnishings		Average Adult Worker	СТ	2,838,710	3,870,968	4,819,205	428	584	727	428	584	727
cleaning, and	Fabric enhancer	Textile		HE	204,651	279,070	347,431	214	292	364	214	292	363
treatment care products		finishing	Female of	СТ	2,569,919	3,504,435	4,362,886	466	636	791	466	636	791
L			Reproductive Age	HE	185,273	252,645	314,534	233	318	396	233	317	395
			ONU	СТ	2,838,710	3,870,968	4,819,205	428	584	727	428	584	727

Life Cycle	COU	OES	Worker	Exposure		ion Risk E mark MO			al Risk E mark M	stimates OE = 30)		ate Risk I mark M	Estimates OE = 30
Stage – Category	Subcategory	OES	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	``		Chronic
Commercial	Batteries and capacitors			СТ	220	300	337	428	584	657	145	198	223
Use – Construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles		Average Adult Worker	HE	80	109	123	214	292	328	58	79	89
	Machinery, mechanical appliances, electrical/electronic articles			СТ	199	272	305	466	636	715	140	190	214
Commercial Use – Automotive, fuel, agriculture, and outdoor use products	Lawn and garden care products	Fabrication or	Female of Reproductive Age	HE	72	99	111	233	318	357	55	75	85
Commercial Use – Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including paper articles; rubber articles; plastic articles (hard); plastic articles (soft) Packaging (excluding food packaging), including paper articles Toys, playground, and sporting equipment	use of final products and articles	ONU	СТ	220	300	337	428	584	657	145	198	223
Commercial Use – Furnishing, Cleaning, and Treatment care products	Floor coverings; Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and apparel												

Life Cycle	COU	OES	Worker	Exposure		ion Risk E mark MO			al Risk E mark M	stimates OE = 30)	00 0		Estimates OE = 30
Stage – Category	Subcategory	OLS	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Commercial			Average Adult	СТ	5.3	7.2	7.7	822	1,121	1,201	5.2	7.1	7.6
Use –		Use of Dyes,	Worker	HE	1.1	1.5	1.6	411	561	600	1.1	1.5	1.6
Packaging, paper, plastic,	Ink, toner and colorants	Pigments, and	Female of	СТ	4.8	6.5	7.0	895	1,221	1,307	4.7	6.5	6.9
toys, hobby		Fixing Agents	Reproductive Age		1.0	1.3	1.4	448	610	653	1.0	1.3	1.4
products			ONU		5.3	7.2	7.7	-	_	_	_	-	_
			Average Adult	СТ	26	35	38	822	1,121	,	25	34	37
Industrial Use – Construction,		Formulation for	Worker	HE	1.1	1.5	1.6	411	561	600	1.1	1.5	1.6
	Adhesives and Sealants	Diffusion	Female of Reproductive		23	32	34	895	1,221	1,307	23	31	33
and metal products		Bonding	Age		1.0	1.4	1.5	448	610	653	1.0	1.4	1.5
*			ONU	СТ	26	35	38	—	_	_	_	_	_
			Average Adult		880	1,200	1,367	428	584	665	288	393	447
			Worker	HE	88	120	128	214	292	313	62	85	91
Commercial	<b>.</b>	Use of	Female of	СТ	797	1,086	1,237	466	636	724	294	401	457
Use – Other uses	Laboratory chemicals	Laboratory Chemicals	Reproductive Age	HE	80	109	116	233	318	340	59	81	87
				СТ	880	1,200	1,367	428	584	665	288	393	447
			ONU	HE	880	1,200	1,285	428	584	625	288	393	421
			Average Adult	СТ	160	218	249	822	1,121	1,277	134	183	208
			Worker	HE	80	109	117	411	561	600	67	91	98
Commercial		Use of	Female of	СТ	145	198	225	895	1,221	1,390	125	170	194
Use – Other uses	Automotive articles	Automotive Care Products	Reproductive Age	HE	72	99	106	448	610	653	62	85	91
			ONU	СТ	176	240	273	_	_	_	-	_	_
			ONU	HE	147	200	214	_	_	_	-	_	_
			Average Adult	СТ	733	22,000	267,667	822	24,673	300,187	388	11,630	141,498
			Worker	HE	400	4,000	48,667	411	4,112	50,031	203	2,028	24,670
Industrial Use –	Undersellin for the	Use in	Female of	СТ	664	19,917	242,322	895	26,854		381	11,436	139,132
Other uses	Hydraulic fracturing	Hydraulic Fracturing	Reproductive Age	HE	362	3,621	44,059	448	4,476	54,454	200	2,002	24,354
			ONU	СТ	733	22,000	267,667	_	_	-	_	_	_
			UNU	HE	733	7,333	89,222	_	_	_		_	_

	COU	-	Worker	Exposure		on Risk E		Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30		
Life Cycle Stage – Category	Subcategory	OES	Population	Level	Acute	mark MO	E = 50) Chronic	Acute	Inter.	Chronic	,		Chronic
Processing –	Recycling	Recycling	Average Adult	СТ	26	35	38	428	584	625	24	33	36
Recycling			Worker	HE	17	23	24	214	292	313	15	21	22
			Domas du stive	СТ	23	32	34	466	636	681	22	30	33
			Damma durativea	HE	15	20	22	233	318	340	14	19	21
				СТ	26	35	38	428	584	625	24	33	36
			Average Adult	СТ	83	113	121	428	584	625	70	95	102
		Waste	Worker	HE	5.7	7.8	8.3	214	292	313	5.6	7.6	8.1
Disposal:	Disposal	-	Female of C Reproductive H Age	СТ	75	102	110	466	636	681	65	88	94
Disposal		treatment and disposal		HE	5.2	7.1	7.6	233	318	340	5.1	6.9	74
				СТ	83	113	121	428	584	625	70	95	102

3732

#### 3733 4.3.3 Risk Estimates for Consumers

3734 Table 4-18 summarizes the dermal, inhalation, ingestion, and aggregate MOEs used to characterize non-3735 cancer risk for acute, intermediate, and chronic exposure to DEHP, and presents these values for all 3736 lifestages for each COU. A screening level assessment for consumers considers high-intensity exposure 3737 scenarios risk estimates and relies on conservative assumptions to assess exposures that would be 3738 expected to be on the high end of the expected exposure distribution. For instance, as described in 3739 4.1.2.5, for ingestion via mouthing EPA used a migration rate of 45  $\mu$ g/cm<sup>2</sup>/h from article mouthing 3740 experiments among children as a reasonable worst-case estimate, per (ECHA, 2013). MOEs for high-3741 intensity exposure scenarios are shown for all consumer COUs, while MOEs for medium-intensity 3742 exposure scenarios are shown only for COUs with high-intensity MOEs at, below, or under the 3743 benchmark of 30. Further, Table 4-18 provides MOEs for the modeling indoor exposure assessment. 3744 The main objective in reconstructing the indoor environment using consumer products and articles 3745 commonly present in indoor spaces is to calculate exposure and risk estimates by COU, and by product 3746 and article, from indoor dust ingestion and inhalation.

3747

3748 EPA identified article-specific information by COU to construct relevant and representative exposure

3749 scenarios. Exposure to DEHP via ingestion of dust was assessed for all articles expected to contribute 3750 significantly to dust concentrations due to high surface area (exceeding  $\sim 1 \text{ m}^2$ ) for either a single article

3750 significantly to dust concentrations due to high surface died (exceeding 14 hi ) for entire a single difference
 3751 or collection of like articles as appropriate. See Section 4.1.2.3 for a brief discussion of the assumptions
 3752 associated with DEHP migration from articles indoor dust. Articles included in the indoor environment

3753 assessment included: car mats, vinyl flooring, in-place wallpaper, insulated cords, furniture components 3754 (textiles), air beds, shower curtains, tire crumb, and children's toys (new and legacy). COUs associated

3755 with articles included in the indoor environment assessment are indicated with footnote d in Table 4-18.

3756 For a detailed discussion of COU-specific uncertainties, see Section 2 and 5 of the *Draft Consumer and* 

3757 Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e).

#### 3758 **Table 4-18. Consumer Risk Summary Table**

								estage (years mark MOE			
Consumer Condition of Use Category: Subcategory	Product or Article	Exposure Duration	Exposure Route	Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Dermal	High	-	-	-	-	1.7E04	1.9E04	1.8E04
		Acute	Ingestion	-	-	-	-	-	_	-	-
			Inhalation	-	-	-	-	-	_	-	-
	Auto repair putty		Dermal	High	_	-	_	_	2.6E05	2.8E05	2.7E05
		Intermediate	Ingestion	-	_	_	_	_	_	-	-
			Inhalation	-	-	-	-	-	-	-	-
		Chronic	-	-	_	-	-	-	_	-	-
			Dermal	High	-	-	-	-	4,300	4,700	4,400
			Ingestion	-	_	-	_	_	_	-	-
		Acute	Inhalation	High	1700 <sup>b</sup>	1800 <sup>b</sup>	2200 <sup>b</sup>	2700 <sup>b</sup>	3600 <sup>b</sup>	4600 <sup>b</sup>	5300 <sup>b</sup>
Construction, paint, electrical,			Aggregate	High	1,700	1,800	2,200	2,700	2,000	2,300	2,400
and metal products: Adhesives	Flooring adhesive		Dermal	High	_	-	-	-	6.5E04	7.1E04	6.7E04
and sealants			Ingestion	-	—	-	-	_	-	-	-
		Intermediate	Inhalation	High	4.1E04 <sup>b</sup>	5.4E04 <sup>b</sup>	6.9E04 <sup>b</sup>	8.0E04 <sup>b</sup>	4.1E04 <sup>b</sup>	5.4E04 <sup>b</sup>	6.9E04 <sup>b</sup>
			Aggregate	High	4.1E04	3.0E04	3.5E04	3.6E04	4.1E04	3.0E04	3.5E04
		Chronic	-	-	-	-	-	-	_	-	-
			Dermal	High	_	-	_	_	870	950	890
		Acute	Ingestion	-	_	-	-	-	-	-	-
			Inhalation	-	_	-	-	_	-	-	-
	Inductance loop sealant	Intermediate	-	-	-	-	-	-	-	-	-
	scalalit		Dermal	High	-	-	-	_	1.6E05	1.7E05	1.6E05
		Chronic	Ingestion	-	-	-	-	-	_	-	-
			Inhalation	-	-	-	_	_	_	-	-
Construction, paint, electrical, and metal products: Batteries	Batteries	interior ( <i>e.g.</i> , is in the exter batteries and	polymer elect ior of the batter because batter	rolytes), there ery, inhalatior ies are comm	is little po and inges only encas	ossibility of co stion exposure ed and not ex	batteries. If DE onsumer exposi- s are expected posed to indoo otential for sen	ure via inhala to be negligit r dust. Derma	tion, ingesti ble due to th l exposures	ion, or derma ne small surfa to DEHP us	d. If DEHP ace area of

								estage (years) mark MOE			
Consumer Condition of Use Category: Subcategory	Product or Article	Exposure Duration	Exposure Route	Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Dermal	High	-	-	-	-	1.8E04	2.0E04	1.8E04
		Acute	Ingestion <sup>c</sup>	High	5.1E04	4.3E04	4.0E04	1.0E05	1.7E05	2.1E05	3.9E05
		Acute	Inhalation <sup>c</sup>	High	2,400	2,600	3,200	4,600	6,500	7,600	9,400
			Aggregate	High	2,300	2,400	3,000	4,400	4,600	5,300	6,100
	Car mats	Intermediate	—	—	_	_	-	_	_	_	—
			Dermal	High	-	-	-	-	1.3E05	1.4E05	1.3E05
		Character	Ingestion <sup>c</sup>	High	5.5E04	4.7E04	4.4E04	1.1E05	1.9E05	2.3E05	4.3E05
		Chronic	Inhalation <sup>c</sup>	High	2,600	2,800	3,400	4,900	7,000	8,200	1.0E04
Other: Automotive articles			Aggregate	High	2,500	2,600	3,200	4,700	6,400	7,500	9,200
			Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700
		Acute	Ingestion	-	_	-	-	_	-	-	-
			Inhalation	-	-	-	-	_	-	-	-
	Tire replacement	Intermediate	-	-	-	-	-	_	-	-	-
			Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700
		Chronic	Ingestion	-	-	-	-	-	-	-	-
			Inhalation	-	-	-	-	-	-	-	-
			Dermal	High <sup>d</sup>	-	-	-	-	-	-	-
		•		Medium	_	-	-	-	350	380	360
		Acute	Ingestion	-	-	-	-	-	-	-	-
			Inhalation	-	-	-	-	-	-	-	-
	Clothing	Intermediate	-	-	-	-	-	-	-	-	-
			Dermal	High <sup>d</sup>	-	-	-	-	-	-	-
Furnishing, cleaning, treatment		a .		Medium	—	-	-	—	2,500	2,700	2,600
care products: Fabric, textile, and leather products; furniture		Chronic	Ingestion	—	—	-	-	—	—	-	-
and furnishings			Inhalation	—	—	-	-	—	-	-	-
				High <sup>d</sup>	—	-	-	—	-	-	-
		Acute	Dermal	Medium	—	_	210	270	350	380	360

		Exposure Duration	Exposure Route					estage (years mark MOE			
Consumer Condition of Use Category: Subcategory	Product or Article			Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
				Low	_	1,000	1,200	1,400	1,800	2,000	1,800
	Furniture components (textile)	Ingestion <sup>c</sup>	High	86	130	190	2,100	3,700	4,600	1.0E04	
				Medium	680	860	1,200	9,400	1.7E04	2.1E04	4.7E04
				Low	8.9E04	6.2E04	1.1E05	8.4E07	1.5E08	1.9E08	4.2E08
			Inhalation <sup>c</sup>	High	46	48	60	86	120	140	180
				Medium	210	220	270	390	560	650	810
				Low	1.9E06	2.0E06	2.5E06	3.6E06	5.1E06	6.0E06	7.4E06
			Aggregate	High	30	36	45	82	120	140	170
				Medium	160	180	110	160	210	240	250
				Low	8.50E04	980	1,140	1,400	1,800	2,000	1,800
		Intermediate	_	_	_	-	-	_	-	-	-
Furnishing, cleaning, treatment care products: Fabric, textile,	Furniture components			High <sup>d</sup>	_	-	-	_	-	-	-
and leather products; furniture			Dermal	Medium	_	-	210	270	350	380	360
and furnishings	(textile)			Low	_	1,000	1,200	1,400	1,800	2,000	1,800
			Ingestion <sup>c</sup>	High	86	130	190	2,100	3,700	4,600	1.0E04
				Medium	680	860	1,200	9,400	1.7E04	2.1E04	4.7E04
				Low	8.9E04	6.2E04	1.1E05	8.4E07	1.5E08	1.9E08	4.2E08
		Chronic		High	48	51	62	90	130	150	180
			Inhalation <sup>c</sup>	Medium	220	230	290	410	580	680	850
				Low	2.0E06	2.1E06	2.6E06	3.8E06	5.3E06	6.2E06	7.8E06
				High <sup>d</sup>	31	37	47	86	120	140	180
			Aggregate	Med	170	180	110	160	220	240	250
				Low	8.40E04	980	1,100	1,400	1,800	2,000	1,800
	Small articles with		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700
Furnishing, cleaning, treatment care products: Fabric, textile,	the potential for	Acute	Ingestion	-	-	-	-	_	-	-	-
and leather products; furniture	semi-routine contact: outdoor furniture,		Inhalation	—	—	-	-	_	—	-	-
and furnishings	outdoor furniture, children's bags,	Intermediate	-	-	—	_	_	_	_	_	—

		Exposure Duration			Lifestage (years) (Benchmark MOE = 30)								
Consumer Condition of Use Category: Subcategory	Product or Article		Exposure Route	Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)		
	wallets, footwear,		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
	interior and exterior components of	Chronic	Ingestion	—		_	-	-	_	_	_		
	jackets, handbags		Inhalation	—		_	-	-	_	_	_		
			Dermal	High	430	500	580	710	900	990	920		
		A auto	Ingestion <sup>c</sup>	High	2,900	2,300	2,100	5,900	1.0E04	1.3E04	3.0E04		
		Acute	Inhalation <sup>c</sup>	High	260	280	340	490	700	820	1,000		
			Aggregate	High	150	170	200	280	380	430	480		
	Vinyl flooring	Intermediate	-	-	_	-	-	_	-	-	_		
Construction, paint, electrical, and metal products: Floor		Chronic	Dermal	High	430	500	580	710	900	990	920		
coverings; construction and			Ingestion <sup>c</sup>	High	3,200	2,600	2,300	6,500	1.2E04	1.5E04	3.2E04		
building materials covering large surface areas including			Inhalation <sup>c</sup>	High	280	290	360	520	730	850	1,100		
stone, plaster, cement, glass and			Aggregate	High	160	170	200	290	390	440	490		
ceramic articles; Fabrics, textiles, and apparel		Acute	Dermal	High	3,400	4,000	4,600	5,700	7,200	7,900	_		
			Ingestion c	High	2.0E06	1.6E06	1.5E06	4.2E06	7.4E06	9.3E06	2.1E07		
And			Inhalation <sup>c</sup>	High	1.9E05	2.0E05	2.4E05	3.5E05	5.0E05	5.8E05	7.2E05		
Furnishing, cleaning, treatment			Aggregate	High	3,300	3,900	4,500	5,600	7,100	7,800	7.0E05		
care products: Floor coverings; construction and building	Wallpaper (In Place)	Intermediate	-	_	-	-	-	-	_	-	-		
materials covering large surface			Dermal	High	3,400	4,000	4,600	5,700	7,200	7,900	-		
areas including stone, plaster, cement, glass and ceramic		cı ·	Ingestion <sup>c</sup>	High	2.2E06	1.8E06	1.6E06	4.6E06	8.1E06	1.0E07	2.3E07		
articles; Fabrics, textiles, and		Chronic	Inhalation <sup>c</sup>	High	1.9E05	2.1E05	2.5E05	3.7E05	5.2E05	6.0E05	7.5E05		
apparel			Aggregate	High	3,300	3,900	4,500	5,600	7,100	7,800	7.3E05		
			Dermal	High	_	-	-	_	450	490	460		
		Acute	Ingestion	—	_	-	-	_	_	-	-		
	Wallpaper (Installation)		Inhalation	-	_	-	-	_	_	-	-		
	(instantation)	Intermediate	-	—	_	-	-	_	_	-	-		
		Chronic	-	-	_	_	-	_	_	_	_		

		Exposure Duration	Exposure Route		Lifestage (years) (Benchmark MOE = 30)								
Consumer Condition of Use Category: Subcategory	Product or Article			Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)		
			Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
Automotive fuel agriculture		Acute	Ingestion	—	_	_	_	_	_	_	-		
	Small articles with		Inhalation	-	_	_	_	_	_	_	-		
outdoor use products: Lawn and	the potential for semi-routine contact:	Intermediate	-	-	_	-	-	-	_	-	-		
garden care products	garden hose		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
		Chronic	Ingestion	-	_	-	-	-	_	-	-		
			Inhalation	-	_	-	-	-	-	-	-		
			Dermal	High	8,500	1.0E04	1.2E04	1.4E04	1.8E04	2.0E04	1.8E04		
	Insulated cords	Acute	Ingestion <sup>c</sup>	High	93	160	250	4.9E04	8.7E04	1.1E05	2.5E05		
			Inhalation <sup>c</sup>	High	2,900	3,100	3,800	5,400	7,600	8,900	1.1E04		
			Aggregate	High	90	150	230	3,600	5,100	5,800	6,800		
		Intermediate	-	-	-	-	-	_	-	-	_		
		Chronic	Dermal	High	8,500	1.0E04	1.2E04	1.4E04	1.8E04	2.0E04	1.8E04		
			Ingestion <sup>c</sup>	High	94	160	250	4.9E04	8.7E04	1.1E05	2.4E05		
Construction, paint, electrical, and metal products: Machinery,			Inhalation <sup>c</sup>	High	3,000	3,200	3,900	5,600	8,000	9,300	1.2E04		
mechanical appliances,			Aggregate	High	90	150	230	3,700	5,200	6,000	6,900		
electrical/electronic articles			Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
	Small articles with	Acute	Ingestion	-	_	-	-	-	-	-	-		
	the potential for		Inhalation	-	-	-	-	—	-	-	_		
	semi-routine contact: phone charge,	Intermediate	-	-	-	-	-	-	-	-	-		
	wireless earbuds,		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
	electrical tape	Chronic	Ingestion	-	-	-	-	-	-	-	-		
			Inhalation	—	—	-	-	-	-	-	-		
			Dermal	High	—	-	-	-	-	4,000	3,700		
				Medium	-	-	-	-	-	7,900	7,400		
Other: Novelty articles	Adult toys	Acute	Ingestion	High <sup>d</sup>	-	-	-	-	-	-	-		
				Medium	-	_	_	_	_	220	250		

		Exposure Duration	Exposure Route		Lifestage (years) (Benchmark MOE = 30)								
Consumer Condition of Use Category: Subcategory	Product or Article			Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)		
			Inhalation	_	-	-	-	_	_	-	_		
			Aggregate	High <sup>d</sup>	_	_	-	_	_	_	_		
				Medium	_	-	-	_	-	220	240		
		Intermediate	-	—	_	_	-	_	_	_	_		
			Dermal	High	-	_	-	_	-	4,000	3,700		
				Medium	-	-	-	-	-	7,900	7,400		
			Ingestion	High <sup>d</sup>	-	-	-	-	-	-	-		
		Chronic		Medium	-	-	-	-	-	220	250		
			Inhalation	-	-	-	-	-	-	-	-		
			Aggregate	High <sup>d</sup>	-	-	-	-	-	-	-		
				Medium	-	-	-	-	-	220	240		
Packaging, paper, plastic, toys, hobby products: Ink, toner, and colorants	Stamp ink		rinting on porc				nufacturing of ooard. Therefor						
		Acute	Dermal	High	57	130	170	220	290	310	300		
			Ingestion c	High	6,200	5,000	4,500	1.3E04	2.3E04	2.9E04	6.4E04		
			Inhalation <sup>c</sup>	High	690	730	900	1,300	1,800	2,100	2,700		
	Air beds (article		Aggregate	High	52	110	140	190	240	270	270		
	concentration and	Intermediate	-	-	-	-	-	-	-	-	-		
	barrier refinement)	Chronic	Dermal	High	580	1,400	1,700	2,300	2,900	3,200	3,000		
			Ingestion c	High	6,800	5,500	4,800	1.4E04	2.5E04	3.1E04	6.9E04		
			Inhalation <sup>c</sup>	High	720	760	940	1,400	1,900	2,200	2,800		
			Aggregate	High	310	450	540	800	1,100	1,300	1,400		
			Dermal	High	570	660	770	950	1,200	1,300	1,200		
		Acute	Ingestion	-	-	-	-	_	—	-	-		
	Mobile phone covers		Inhalation	-	—	_	-	_	-	-	-		
Packaging, paper, plastic, toys, hobby products: Packaging		Intermediate	-	-	-	-	-	-	-	-	-		
(excluding food packaging) and		Chronic	Dermal	High	570	660	770	950	1,200	1,300	1,200		

		Exposure Duration	Exposure Route					estage (years mark MOE			
Consumer Condition of Use Category: Subcategory	Product or Article			Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
other articles with routine direct			Ingestion	-	_	-	-	_	-	-	-
contact during normal use, including rubber articles; plastic			Inhalation	-	_	-	-	_	-	-	-
articles (hard); plastic articles (soft)			Dermal	High	8,500	1.0E04	1.2E04	1.4E04	1.8E04	2.0E04	1.8E04
		Acute	Ingestion	-	_	_	250	430	-	-	—
			Inhalation	-	_	-	-	-	-	-	—
	Eraser	Intermediate	-	-	_	-	-	-	-	-	—
			Dermal	High	8,500	1.0E04	1.2E04	1.4E04	1.8E04	2.0E04	1.8E04
		Chronic	Ingestion	-	-	-	250	430	-	-	-
			Inhalation	-	_	-	-	_	-	-	-
	Shower curtains	Acute	Dermal	High	3,400	4,000	4,600	5,700	7,200	7,900	7,400
			Ingestion <sup>c</sup>	High	1,900	1,500	1,300	3,800	6,800	8,500	1.9E04
			Inhalation <sup>c</sup>	High	62	66	81	120	170	190	240
			Aggregate	High	59	62	75	110	160	180	230
		Intermediate	-	-	_	-	-	-	-	-	-
			Dermal	High	3,400	4,000	4,600	5,700	7,200	7,900	7,400
			Ingestion <sup>c</sup>	High	2,000	1,600	1,500	4,200	7,400	9,300	2.1E04
	Shower curtains	Chronic	Inhalation <sup>c</sup>	High	65	69	85	120	170	200	250
			Aggregate	High	62	65	79	120	160	190	240
Packaging, paper, plastic, toys,	Small articles with		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700
hobby products: Packaging	the potential for semi-routine contact:	Acute	Ingestion	—	_	-	-	-	—	-	_
(excluding food packaging) and other articles with routine direct	packaging, paper,		Inhalation	—	_	-	-	-	—	-	-
contact during normal use,	plastic, toys, hobby products: cutting	Intermediate	-	-	-	-	-	-	-	-	-
including rubber articles; plastic articles (hard); plastic articles	board, pencils,		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700
(soft)	pouches, bags, hose,		Ingestion	-	-	-	-	_	-	-	-
	labels, covers, chewy toys, jewelry, gloves, packaging, mats, lampshade, vinyl floor runner, diving goggles, silly straws,	Chronic	Inhalation	_	_	_	_	_	_	-	_

		Exposure Duration			Lifestage (years) (Benchmark MOE = 30)									
Consumer Condition of Use Category: Subcategory	Product or Article		Exposure Route	Exposure Scenario <sup><i>a</i></sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)			
	stickers, diving goggles													
			Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700			
	Small articles with the potential for	Acute	Ingestion	-	_	-	-	_	-	-	_			
Packaging, paper, plastic, toys,	semi-routine contact:		Inhalation	-	_	-	-	-	-	-	_			
hobby products: Packaging (Excluding Food Packaging),	Packaging, paper, hobby products:	Intermediate	-	-	_	-	-	_	-	-	_			
Including Paper Articles	pencils, labels,		Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700			
	covers, lampshade, stickers	Chronic	Ingestion	-	_	-	-	-	-	-	_			
	SUCKETS		Inhalation	-	_	-	-	-	-	-	_			
	Auto coatings		Dermal	High	_	-	-	-	1.7E04	1.9E04	1.8E04			
		Acute	Ingestion	_	_	_	-	-	_	_	_			
			Inhalation	High	2000 <sup>b</sup>	2100 <sup>b</sup>	2500 <sup>b</sup>	3500 <sup>b</sup>	4500 <sup>b</sup>	5500 <sup>b</sup>	6600 <sup>b</sup>			
Construction, paint, electrical,			Aggregate	High	2,000	2,100	2,500	3,500	3,600	4,200	4,800			
and metal products: Paints and		Intermediate	-	-	-	-	-	_	-	-	-			
coatings		Chronic	Dermal	High	-	-	-	-	1.2E05	1.3E05	1.2E05			
			Ingestion	-	-	-	-	-	-	-	-			
			Inhalation	High	170 <sup>b</sup>	180 <sup>b</sup>	220 <sup>b</sup>	300 <sup>b</sup>	370 <sup>b</sup>	450 <sup>b</sup>	540 <sup>b</sup>			
	Auto coatings		Aggregate	High	170	180	220	300	370	450	540			
			Dermal	High	_	-	-	-	870	950	890			
			Ingestion	-	_	-	-	-	-	-	_			
		Acute	Inhalation	High	9700 <sup>b</sup>	1.0E04 <sup>b</sup>	1.3E04 <sup>b</sup>	1.6E04 <sup>b</sup>	5200 <sup>b</sup>	7000 <sup>b</sup>	7700 <sup><i>b</i></sup>			
Construction, paint, electrical, and metal products: Paints and			Aggregate	High	9,700	1.0E04	1.3E04	1.6E04	740	840	800			
coatings	Concrete sealant	Intermediate	Dermal	High	_	_	_	_	2.6E04	2.8E04	2.7E04			
			Ingestion	_	_	-	_	_	_	_	_			
			Inhalation	High	2.9E05 <sup>b</sup>	3.1E05 <sup>b</sup>	3.8E05 <sup>b</sup>	4.7E05 <sup>b</sup>	1.6E05 <sup>b</sup>	2.1E05 <sup>b</sup>	2.3E05 <sup>b</sup>			
			Aggregate	High	2.9E05	3.1E05	3.8E05	4.7E05	2.2E04	2.5E04	2.4E04			
		Chronic	-	-	—	-	-	-	—	-	—			
	Children's toys	Acute	Dermal	High	750	870	1,000	1,300	1,600	1,700	-			

								estage (years mark MOE :	·		
Consumer Condition of Use Category: Subcategory	Product or Article	Exposure Duration	Exposure Route	Exposure Scenario <sup>a</sup>	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
	(legacy)		Ingestion <sup>c</sup>	High	57	200	340	4,100	7,300	9,200	2.0E04
			Inhalation <sup>c</sup>	High	83	88	110	150	220	260	320
			Aggregate	High	32	57	76	130	190	220	310
		Intermediate	_	-	_	-	-	-	_	-	-
			Dermal	High	750	870	1,000	1,300	1,600	1,700	-
		<b>CI</b> .	Ingestion <sup>c</sup>	High	57	200	340	4,100	7,300	9,200	2.0E04
		Chronic	Inhalation <sup>c</sup>	High	86	92	110	160	230	270	330
Packaging, paper, plastic, toys,			Aggregate	High	33	58	78	140	200	230	330
hobby products: Toys,		Acute	Dermal	High	750	870	1,000	1,300	1,600	1,700	-
playground, and sporting			Ingestion <sup>c</sup>	High	59	220	440	1.3E07	2.4E07	3.0E07	6.8E07
equipment	Children's toys (new)		Inhalation <sup>c</sup>	High	2.7E05	2.9E05	3.6E05	5.1E05	7.2E05	8.5E05	1.1E06
			Aggregate	High	54	180	310	1,200	1,600	1,700	1.0E06
		Intermediate	-	-	-	-	-	-	-	-	-
		Chronic	Dermal	High	750	870	1,000	1,300	1,600	1,700	-
			Ingestion c	High	59	220	440	1.3E07	2.4E07	3.0E07	6.7E07
			Inhalation <sup>c</sup>	High	2.9E05	3.0E05	3.7E05	5.3E05	7.6E05	8.9E05	1.1E06
			Aggregate	High	53	160	250	960	1,300	1,500	2.0E04
			Dermal	High	-	-	1.7E04	1.8E04	2.4E04	2.7E04	2.6E04
			Ingestion	High	_	-	5.1E06	1.2E07	2.1E07	5.3E07	5.9E07
		Acute	Inhalation	High	_	-	1.7E08	2.6E08	1.3E08	2.5E08	2.7E08
			Aggregate	High	-	-	1.7E04	1.8E04	2.4E04	2.7E04	2.6E04
	Tire crumb, artificial turf	Intermediate	-	-	-	-	-	-	-	-	-
Packaging, paper, plastic, toys, hobby products: Toys, playground, and sporting	lull		Dermal	High	-	-	8.1E04	8.6E04	6.2E04	7.1E04	1.2E05
		a ·	Ingestion	High	-	-	2.4E07	5.5E07	5.5E07	1.4E08	2.7E08
		Chronic	Inhalation	High	-	-	8.0E08	1.2E09	3.5E08	6.6E08	1.3E09
equipment			Aggregate	High	-	_	8.1E04	8.6E04	6.2E04	7.1E04	1.2E05

Consumer Condition of Use Category: Subcategory	Product or Article	Exposure Duration	Exposure Route	Exposure Scenario <sup>a</sup>	Lifestage (years) (Benchmark MOE = 30)								
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)		
	Small articles with the potential for semi-routine contact:	Acute	Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
	Fitness balls, jump		Ingestion	-	-	-	-	-	-	-	-		
	rope, yoga mat, football, and diving		Inhalation	-	-	-	-	-	-	-	-		
	goggles	Intermediate	-	_	_	_	-	_	-	-	-		
			Dermal	High	1,700	2,000	2,300	2,900	3,600	4,000	3,700		
		Chronic	Ingestion	—	_	—	-	—	-	-	-		
			Inhalation	_	_	_	_	_	_	-	_		

<sup>a</sup> Exposure scenario intensities include high, medium, and low.

<sup>b</sup> MOE for bystander scenario. These individuals may inhale DEHP away (*i.e.*, in far-field within the room or outside room of use) from where the product or article is being used or emitted. Therefore, bystander exposures are lower than that of an active user or a do-it-your-self/hobbyist who may use or install a product or an article (*i.e.*, flooring adhesive application).

<sup>c</sup> Exposure routes evaluated for indoor environments in which dust containing DEHP may be inhaled via indoor air or ingested from suspended dust, mouthing of articles, or settled dust on various residential surfaces. For a detailed description of the sources, routes and pathways of consumer and bystander exposures to DEHP, see the *Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e).

<sup>d</sup> Scenario was deemed to be unlikely either due to a lack of adequate input parameters, input parameters may not reflect actual use scenarios, or calculated estimates may not effectively represent actual exposures and risks, see *Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e).

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Of note, the risk summary below is based on the most sensitive non-cancer endpoint for all relevant duration scenarios (*i.e.*, effects on the developing male reproductive system for acute, intermediate, and chronic durations). MOEs for all high-, medium- and low-intensity exposure scenarios for all COUs are described in the *Draft Consumer Risk Calculator for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025g).

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## 3766 COUs with MOEs for High-Intensity Use Exposure Scenarios Above Benchmark

The screening level assessment for consumers considers high-intensity exposure scenario risk estimates (MOEs) and relies on conservative assumptions to assess exposures that would be expected to be on the high end of the expected exposure distribution. If MOEs are above the benchmark of 30 for the highintensity use scenario then any exposures with lower intensity use inputs would result in larger MOEs. Consumer COUs that resulted in MOEs for high-intensity exposure scenarios above the benchmark of

- 3772 30 for acute, chronic and intermediate exposures are summarized in Table 4-18 and in the following list:
  - Automotive, fuel, agriculture, outdoor use products: Lawn and garden care products
- Construction, paint, electrical, and metal products: Adhesives and sealants
- Construction, paint, electrical, and metal products: floor coverings; construction and building
   materials covering large surface areas including stone, plaster, cement, glass and ceramic
   articles; fabrics, textiles, and apparel
- Construction, paint, electrical, and metal products: machinery, mechanical appliances,
   electrical/electronic articles
- Construction, paint, electrical, and metal products: paints and coatings
- Other uses: automotive articles
- Other uses: novelty articles
- Packaging, paper, plastic, toys, hobby products: packaging (excluding food packaging),
   including paper articles
- Packaging, paper, plastic, toys, hobby products; packaging (excluding food packaging) and other
   articles with routine direct contact during normal use, including rubber articles; plastic articles
   (hard); plastic articles (soft)
  - Packaging, paper, plastic, toys, hobby products; Toys, playground, and sporting equipment

3789 Variability in MOEs for these high-intensity exposure scenarios results from use of different exposure 3790 factors for each COU and product/article examples that led to different estimates of exposure to DEHP. 3791 As described in the Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate 3792 (DEHP) (U.S. EPA, 2025e) and Draft Non-cancer Human Health Hazard Assessment for Diethylhexyl 3793 Phthalate (DEHP) (U.S. EPA, 2024f), EPA has moderate to robust confidence in the exposure estimates 3794 and robust confidence in the non-cancer hazard value used to estimate non-cancer risk for these COUs. EPA is confident that the high-intensity use scenarios used in the screening approach represent a 3795 3796 plausible upper bound estimate and provide a health protective estimate for consumer exposures.

3797

3788

## 3798 COUs with MOEs for High-Intensity Exposure Scenarios Below Benchmark

3799 The screening level assessment for consumers considered high-intensity exposure scenario risk 3800 estimates (MOEs) and relied on conservative assumptions to assess exposures that would be expected to 3801 be on the high end of the expected exposure distribution. If MOEs were below the benchmark of 30 for 3802 the high-intensity use scenario, EPA reevaluated the approaches and inputs used and determined if 3803 refinement of those was needed. In addition, EPA considered the medium-intensity use scenario as 3804 either a possible upper bound estimate by reevaluating inputs and approaches or endeavors in the 3805 refinement of approaches by using other modeling tools or other input parameters within the same 3806 modeling tools. See Section 2 in Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e) for details about the consumer modeling approaches, sources of 3807

data, model parameterization, and assumptions. After reevaluating approaches and input parameters for
 each consumer COU with MOEs below the benchmark EPA concluded that further refinement of input
 parameters was not possible or would not result in different MOEs for those already presented in Table

3810 parameters was not possible of would not result in different works for mose aneady presented in T 3811 4-18. The consumer COU that resulted in MOEs for high-intensity exposure scenarios below the

- benchmark of 30 for acute, chronic, and intermediate exposures is summarized in Table 4-18 and in the
- 3813 following:
- Furnishing, Cleaning, Treatment Care Products: Fabric, Textile, and Leather Products; Furniture and Furnishings
- The consumer COU that resulted in MOEs for high-intensity exposure scenarios below the benchmark of 30 for acute, chronic and intermediate exposures is discussed in further detail in the subsection below which expands on the aspects driving the MOEs below the benchmark.
- 3819 3820 Europishing Cla

# Furnishing, Cleaning, Treatment Care Products: Fabric, Textile, and Leather Products; Furniture and Furnishings

3822 This section summarizes the risk estimates (MOEs) below the benchmark of 30 for the titled COU. Two 3823 different scenarios were assessed under this COU for articles with differing use patterns: synthetic leather clothing and synthetic leather furniture. The two scenarios capture the variability from 3824 3825 manufacturing formulation in the high, medium, and low-intensity use estimates and the weight fraction 3826 ranges reported. Indoor synthetic furniture articles were assessed for all exposure routes as part of the 3827 indoor exposure assessment (i.e., inhalation, ingestion (suspended and settled dust, and mouthing), and 3828 dermal), while synthetic clothing was only assessed for dermal contact since the articles were too small 3829 to result in significant inhalation and ingestion exposures.

3830

3831 Aggregate risk estimates across all evaluated exposure routes (dermal, ingestion, and inhalation) for 3832 synthetic leather furniture were considered, with the exception of the high-intensity use scenario. The 3833 aggregate high-intensity use scenario only considered inhalation and ingestion because the high-3834 intensity use dermal scenario was found to have high uncertainties for the skin contact area input. While 3835 dermal contact with synthetic leather furniture may be possible for infants and toddlers, it is expected to 3836 be minimal. Infants are not likely to be set on furniture for extended periods of time (*i.e.*, 2-8 hours) for safety reasons, and toddlers are unlikely to stay seated for the 4-hour exposure duration used in the 3837 3838 medium-intensity use dermal assessment. The acute high-intensity use aggregate exposure scenario 3839 MOE for infants was 29.8 (usually rounded to 30). Inhalation and ingestion MOEs have similar 3840 contributions to the overall aggregate MOE value (MOE = 86 for ingestion and MOE = 46 for 3841 inhalation). EPA has robust confidence in the inhalation and ingestion estimates for this COU. 3842

## 3843 Indoor Dust

3844 Exposure to DEHP via ingestion of dust was assessed for all articles expected to contribute significantly 3845 to dust concentrations. See Section 4.1.2.3 for a brief discussion of the assumptions associated with 3846 DEHP migration from articles indoor dust. Articles evaluated were those with a surface area exceeding 3847  $\sim 1 \text{ m}^2$  for a single article, or a collection of like articles with aggregate surface area exceeding  $\sim 1 \text{ m}^2$ . 3848 Collections of like articles satisfying these conditions include car mats, vinyl flooring, wallpaper in-3849 place, insulated cords, furniture components (textiles), air beds, shower curtains, and children's toys 3850 (legacy and new). In a screening assessment for indoor dust ingestion, EPA considered the aggregation 3851 of chronic dust ingestion doses (Section 4.1.2.3). However, the indoor assessment was further refined to 3852 only consider articles assumed to be present in residential indoor environments, such as vinyl flooring, 3853 wallpaper in-place, insulated cords, furniture components (textiles), shower curtains, and children's toys 3854 (new and legacy). Car mats and air beds were considered not to be continuously available in residential 3855 indoor environments, as car mats are present in vehicles, and air beds are often kept in storage as they're

expected to be used sporadically for overnight trips or camping a few nights per month throughout the

- year. The highest aggregated dose from indoor scenario chronic ingestion of settled dust was for
  preschoolers, aged 3 to 5 years and resulted in an MOE of 306. See *Draft Consumer Risk Calculator for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025g). All other doses were lower and would have resulted
- 3860 in even larger MOEs.
- 3861

## 3862 Overall Confidence in Consumer Risks

3863 As described in Section 4.1.2 and in more detail in the Draft Consumer and Indoor Exposure 3864 Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e), EPA has moderate to robust 3865 confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios, and robust 3866 confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to DEHP (see Section 4.2 and (U.S. EPA, 2024f)). The exposure doses used to 3867 estimate risk relied on conservative inputs and parameters that are considered representative of a wide 3868 3869 selection of use patterns. Dermal risks estimates may be conservative for consumer exposure to articles, 3870 especially given that the dermal flux used to determine exposure was based on a study in rats, which 3871 have higher dermal absorption than humans. However, dermal exposure to liquid products was based on 3872 studies using metabolically active human skin and likely did not overestimate exposure. For inhalation 3873 and ingestion, EPA's overall confidence is based on consideration of multiple factors including strength 3874 in applied methods, refinements to best represent real-world scenarios, support from and consistency 3875 with literature data, and uncertainties on a scenario-by-scenario basis, as presented in Section 4.1.2.4. 3876 Overall, EPA has moderate to robust confidence in the risk estimates calculated for inhalation, ingestion, and dermal exposure scenarios for consumers. Sources of uncertainty associated with consumer COUs 3877 which had MOEs less than 30 are discussed above in Section 4.3.3. 3878

38794.3.4Risk Estimates for General Population Exposed to DEHP through Environmental<br/>Releases

EPA utilized previously peer reviewed methodologies to conduct screening level analyses of general
population exposures to DEHP associated with TSCA COUs via the ambient air, ambient water, ambient
land, and fish ingestion pathways/routes as described in the *Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025q) and
Section 4.1.3. This assessment focuses on subsets of the general population in proximity to releasing
facilities, including fenceline communities.

3887 3888 EPA evaluated surface water, drinking water, fish ingestion, ambient air, and soil via deposition from ambient air pathways quantitatively. Land pathways (*i.e.*, landfills and application of biosolids) were 3889 3890 assessed qualitatively, and were inclusive of down-the-drain disposal of consumer products and landfill 3891 disposal of consumer articles (see Section 3.1.4 for details on the qualitative assessment of consumer 3892 disposal of DEHP-containing products and articles). For pathways assessed quantitatively, EPA used 3893 high-end estimates of DEHP concentration in the various environmental media for screening level 3894 purposes. EPA used an MOE approach using high-end exposure estimates with the human health POD 3895 to determine whether an exposure pathway had potential non-cancer risks. High-end exposure estimates 3896 were defined as those associated with the industrial and commercial releases from a COU and OES that 3897 resulted in the highest environmental media concentrations. If there is no risk for an individual identified 3898 as having the potential for the highest exposure for a COU and given pathway of exposure, then EPA 3899 determined that the pathway was not a pathway of concern, and the pathway was not evaluated further. 3900 If any pathways were identified as a pathway of concern for the general population, further exposure 3901 assessments for that pathway would be conducted to include higher tiers of modeling if available, 3902 additional subpopulations and COUs. Risk estimates for the screening analysis for the various pathways 3903 assessed quantitatively are shown below. No MOEs were below the benchmark of 30 for the highest

exposure scenario. Therefore, using a screening level approach described for all pathways in Section
4.1.3, exposure to DEHP through biosolids, landfills, surface water, drinking water, fish ingestion, and
ambient air were not determined to be pathways of concern for any COU listed in Table 3-1.

4.3.4.1 Overall Confidence in General Population Risk

3908 As described in Section 3.3.1 and 4.1.3.3 and in more technical details in the Draft Environmental 3909 *Media and General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP)* (U.S. 3910 EPA, 2025q), EPA has robust confidence that modeled releases used are appropriately conservative for a 3911 screening level analysis. Therefore, EPA has robust confidence that no general population exposure 3912 scenarios via the air, land, or surface water pathways will lead to greater exposures than presented in this 3913 evaluation. Despite moderate confidence in the estimated values themselves, confidence in exposure 3914 estimates capturing high-end exposure scenarios was robust given the conservative assumptions used for 3915 the estimates. Along with EPA's robust confidence in the non-cancer POD selected to characterize risk 3916 from acute, intermediate, and chronic duration exposures to DEHP (see Section 4.2 and (U.S. EPA, 3917 2024f)), EPA has robust confidence that the risk estimates calculated for the general population were 3918 conservative and appropriate for a screening level analysis.

3919

3907

## 4.3.5 Risk Estimates for Potentially Exposed or Susceptible Subpopulations

3920 EPA considered PESS throughout the exposure assessment and throughout the hazard identification and
 3921 dose-response analysis supporting the draft DEHP risk evaluation.
 3922

3923 Some population group lifestages may be more susceptible to the health effects of DEHP exposure. As 3924 discussed in Section 4.2 and in EPA's Draft Non-cancer Human Health Hazard Assessment for 3925 Diethylhexyll Phthalate (DEHP) (U.S. EPA, 2024f) and Revised Draft Technical Support Document for 3926 the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 3927 2025x), exposure to DEHP causes adverse effects on the developing male reproductive system 3928 consistent with a disruption of androgen action and phthalate syndrome in experimental animal models. 3929 Therefore, females of reproductive age, pregnant women, male infants, male children, and male 3930 adolescents are considered to be susceptible subpopulations. These susceptible lifestages were 3931 considered throughout the draft risk evaluation. For example, females of reproductive age were 3932 evaluated for occupational exposures to DEHP for each COU (Section 4.3.2). Additionally, infants (<1 3933 year), toddlers (1–2 years), preschoolers (3–5 years), middle school children (6–10 years), young teens 3934 (11–15 years), and teenagers (16–20 years) were evaluated for exposure to DEHP through consumer 3935 products and articles (Section 4.3.3). EPA also considered cumulative phthalate exposure and risk for 3936 female workers of reproductive age, as well as male children and female consumers of reproductive age. 3937 Additionally, the Agency used a value of 10 for the  $UF_{H}$  to account for human variability. The Risk 3938 Assessment Forum, in A Review of the Reference Dose and Reference Concentration Processes, 3939 discusses some of the evidence for choosing the default factor of 10 when data are lacking—including 3940 toxicokinetic and toxicodynamic factors as well as greater susceptibility of children and elderly 3941 populations (U.S. EPA, 2002b).

3942

The available data suggest that some groups or lifestages have greater exposure to DEHP. This includes people exposed to DEHP at work, those who frequently use consumer products and/or articles containing high concentrations of DEHP, and those who may have a greater intake of DEHP per body weight (*e.g.*, infants, children, adolescents) leading to greater exposure. EPA accounted for these populations with greater exposure in the draft DEHP risk evaluation as follows:

EPA evaluated a range of OESs for workers and ONUs, including high-end exposure scenarios
 for females of reproductive age (a susceptible subpopulation) and average adult workers.

- EPA evaluated a range of consumer exposure scenarios, including high-intensity exposure scenarios for infants and children (susceptible subpopulations). These populations had greater intake per body weight and exposure due to age-specific behaviors (*e.g.*, mouthing of toys, wires, and erasers by infants and children).
- EPA evaluated a range of general population exposure scenarios, including high-end exposure scenarios for infants and children (susceptible subpopulations). These populations had greater intake per body weight.
- EPA evaluated exposure of children to DEHP through use of legacy and new toys.
- EPA evaluated exposure to DEHP through fish ingestion for subsistence fishers and Tribal
   populations.
- EPA aggregated occupational inhalation and dermal exposures for each COU for females of reproductive age (a susceptible subpopulation) and average adult workers.
  - EPA aggregated consumer inhalation, dermal, and oral exposures for each COU for infants and children (susceptible subpopulations).
- EPA evaluated cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP for the U.S. civilian population using NHANES urinary biomonitoring data and reverse dosimetry for females of reproductive age (16–49 years) and male children (3–5, 6–11, and 12–15 years of age).
- For females of reproductive age, black non-Hispanic women had slightly higher 95th percentile cumulative exposures to DEHP, DBP, BBP, DIBP, and DINP compared to women of other races (*e.g.*, white non-Hispanic, Mexican America). The 95th percentile cumulative exposure estimate for black non-Hispanic women served as the non-attributable national cumulative exposure estimate used by EPA to evaluate cumulative risk to workers and consumers.

## 3972 **4.4 Cumulative Risk Considerations**

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3963

3973 EPA developed a Revised Draft Technical Support Document for the Cumulative Risk Analysis of 3974 DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2025x) (draft CRA TSD) for the 3975 CRA of six toxicologically similar phthalates being evaluated under section 6 of the Toxic Substances 3976 Control Act (TSCA): di(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl 3977 phthalate (DBP), dicyclohexyl phthalate (DCHP), diisobutyl phthalate (DIBP), and diisononyl phthalate 3978 (DINP). EPA previously issued a Draft Proposed Approach for Cumulative Risk Assessment of High-3979 Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act 3980 (draft 2023 approach), which outlined an approach for this assessment (U.S. EPA, 2023d). EPA's 3981 proposal was subsequently peer-reviewed by the Science Advisory Committee on Chemicals (SACC) in 3982 May 2023 (U.S. EPA, 2023f). In the 2023 draft approach, EPA identified a cumulative chemical group 3983 and PESS [15 U.S.C. section 2605(b)(4)]. Based on toxicological similarity and induced effects on the 3984 developing male reproductive system consistent with a disruption of androgen action and phthalate 3985 syndrome, EPA proposed a cumulative chemical group of DEHP, BBP, DBP, DCHP, DIBP, and DINP, 3986 but not diisodecyl phthalate (DIDP). This approach emphasizes a uniform measure of hazard for 3987 sensitive subpopulations, namely females of reproductive age and/or male infants and children, however 3988 additional health endpoints are known for broader populations and described in the individual non-3989 cancer human health hazard assessments for DEHP (U.S. EPA, 2024f), DBP (U.S. EPA, 2024d), DIBP 3990 (U.S. EPA, 2024g), BBP (U.S. EPA, 2024c), DCHP (U.S. EPA, 2024e), and DINP (U.S. EPA, 2025w), 3991 including hepatic, kidney, and other developmental and reproductive toxicity. 3992

EPA's approach for assessing cumulative risk is described in detail in the draft revised CRA TSD (U.S.
 EPA, 2025x) and incorporates feedback from the SACC (U.S. EPA, 2023f) on EPA's 2023 draft
 proposal (U.S. EPA, 2023d). EPA is focusing its CRA on acute duration exposures of females of
 reproductive age, male infants, and male children to six toxicologically similar phthalates (*i.e.*, DEHP,

3997 DBP, BBP, DIBP, DCHP, DINP) that induce effects on the developing male reproductive system 3998 consistent with a disruption of androgen action and phthalate syndrome. The Agency is further focusing 3999 its CRA on acute duration exposures because there is evidence that effects on the developing male 4000 reproductive system consistent with a disruption of androgen action can result from a single exposure 4001 during the critical window of development (see Section 1.5 of (U.S. EPA, 2025x) for further details). To 4002 evaluate cumulative risk, EPA is using a relative potency factor (RPF) approach. RPFs for DEHP, DBP, 4003 BBP, DIBP, DCHP, and DINP were developed using a meta-analysis and benchmark dose (BMD) 4004 modeling approach based on a uniform measure (*i.e.*, reduced fetal testicular testosterone). EPA is also 4005 using NHANES data to supplement, not substitute, evaluations for exposure scenarios for COUs to 4006 provide non-attributable, total exposure for addition to the relevant scenarios presented in the individual 4007 risk evaluations.

4008

4009 The analogy of a "risk cup" is used throughout Section 4.4 of this document to describe cumulative 4010 exposure estimates. The risk cup term is used to help conceptualize the contribution of various phthalate 4011 exposure routes and pathways to overall cumulative risk estimates and serves primarily as a

- 4012 communication tool. The term/concept describes exposure estimates where the full cup represents the
- 4013 total exposure that leads to risk (cumulative MOE) and each chemical contributes a specific amount of
- 4014 exposure that adds a finite amount of risk to the cup. A full risk cup indicates that the cumulative MOE
- 4015 has dropped below the benchmark MOE (*i.e.*, total UF), whereas cumulative MOEs above the
- 4016 benchmark indicate that only a percentage of the risk cup is full.
- 4017
- 4018 The remainder of this human health CRA section is organized as follows:
- Section 4.4.1 Describes the approach used by EPA to derive draft relative potency factors for DEHP, DBP, BBP, DIBP, DCHP, and DINP based on reduced fetal testicular testosterone, which are used by EPA as part of the current CRA and to assess exposures to individual phthalates by scaling to an index chemical (RPF analysis). Section 2 of EPA's draft revised CRA TSD (U.S. EPA, 2025x) provides more details.
- Section 4.4.2 Briefly describes the approach used by EPA to calculate cumulative nonattributable phthalate exposure for the U.S. population using NHANES urinary biomonitoring and reverse dosimetry. Section 4 of EPA's draft revised CRA TSD (U.S. EPA, 2025x) provides additional details.
- Section 4.4.3 Describes how EPA combined exposures to DEHP from individual consumer and occupational COUs/OES with cumulative non-attributable phthalate exposures from NHANES to estimate cumulative risk. An empirical example is also provided. Section 5 of EPA's draft revised CRA TSD (U.S. EPA, 2025x) provides additional details.
- Sections 4.4.4 through 4.4.6 Summarizes risk estimates for workers, consumers, and the general population based on relative potency assumptions.
- 4034 For additional details regarding EPA's draft CRA, readers are directed to the following TSDs:
- Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
   Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
   Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the
   Toxic Substances Control Act (TSCA) (U.S. EPA, 2025x);
- Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024b);

- 4042
   Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a 4043
   Manufacturer-Requested Phthalate under the Toxic Substances Control Act (U.S. EPA, 2023d);
- 4044
   Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act (U.S. EPA, 2023e); and
- Science Advisory Committee on Chemicals meeting minutes and final report, No. 2023-01 A set of scientific issues being considered by the Environmental Protection Agency regarding: Draft Proposed Principles of Cumulative Risk Assessment (CRA) under the Toxic Substances Control Act and a Draft Proposed Approach for CRA of High-Priority Phthalates and a Manufacturer-Requested Phthalate (U.S. EPA, 2023f).

4051 4.4.1 Hazard Relative Potency

This section briefly summarizes the RPF approach used by EPA to evaluate phthalates for cumulative
risk. Section 4.4.1.1 provides a brief overview and background for the RPF approach methodology,
while Section 4.4.1.2 provides a brief overview of the draft RPFs derived by EPA for DEHP, DBP,
BBP, DIBP, DCHP, and DINP based on decreased fetal testicular testosterone. Further details regarding
the draft relative potency analysis conducted by EPA are provided in the following two TSDs:

- Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
   Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
   Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the
   Toxic Substances Control Act (TSCA) (U.S. EPA, 2025x); and
- 4061
   Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2-4062
   4063
   Disobutyl Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024b).
  - 4.4.1.1 Relative Potency Factor Approach Overview

For the RPF approach, chemicals being evaluated require data that support toxicologic similarity (e.g., 4065 components of a mixture share a known or suspected common MOA or share a common apical 4066 4067 endpoint/effect) and have dose-response data for the effect of concern over similar exposure ranges (U.S. EPA, 2023b, 2000, 1986). RPF values account for potency differences among chemicals in a 4068 mixture and scale the dose of one chemical to an equitoxic dose of another chemical (i.e., the index 4069 4070 chemical). The chemical selected as the index chemical is often among the best characterized 4071 toxicologically and considered to be representative of the type of toxicity elicited by other components of the mixture. Implementing an RPF approach requires a quantitative dose-response assessment for the 4072 4073 index chemical and pertinent data that allow the potency of the mixture components to be meaningfully 4074 compared to that of the index chemical. In the RPF approach, RPFs are calculated as the ratio of the 4075 potency of the individual component to that of the index chemical using either (1) the response at a fixed 4076 dose, or (2) the dose at a fixed response (Equation 4-3).

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4064

## 4078 Equation 4-3. Calculating RPFs

4079

$$RPF_i = \frac{BMD_{R-IC}}{BMD_{R-i}}$$

4080 Where: 4081 BMD =Benchmark dose (mg/kg/day) 4082 R Magnitude of response (*i.e.*, benchmark response) = i<sup>th</sup> chemical 4083 Ι = IC Index chemical 4084 =

4085 After scaling the chemical component doses to the potency of the index chemical, the scaled doses are
4086 summed and expressed as index chemical equivalents for the mixture (Equation 4-4).
4087

## 4088 Equation 4-4. Calculating Index Chemical Equivalents

4089

Index Chemical Equivalents<sub>MIX</sub> = 
$$\sum_{i=1}^{n} d_i \times RPF_i$$

4090 Where:

4091 4092	Index chemical equivalents	=	Dose of the mixture in index chemical equivalents (mg/kg/day)
4093 4094 4095	di RPFi	=	Dose of the $i^{th}$ chemical in the mixture (mg/kg/day) Relative potency factor of the $i^{th}$ chemical in the mixture (unitless)

4096 Non-cancer risk associated with exposure to an individual chemical or a mixture can then be assessed by
4097 calculating an MOE, which in this case is the ratio of the index chemical's non-cancer hazard value
4098 (*e.g.*, the BMDL) to an estimate of exposure expressed in terms of index chemical equivalents. The
4099 MOE is then compared to the benchmark MOE (*i.e.*, the total uncertainty factor associated with the
4100 assessment) to characterize risk.

4101 4.4.1.2 Relative Potency Factors

## 4102 Derivation of Draft RPFs

To derive RPFs for DEHP, DBP, BBP, DIBP, DCHP, and DINP, EPA utilized a meta-analysis and
BMD modeling approach similar to that used by NASEM (2017) to model decreased fetal testicular
testosterone. As described further in EPA's *Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for DEHP, DBP, BBP, DIBP, and DCHP* (U.S. EPA, 2024b), the Agency

- 4107 evaluated benchmark responses (BMRs) of 5, 10, and 40 percent. For input into the CRA of phthalates,
- 4108 EPA has derived draft RPFs using BMD<sub>40</sub> estimates (Table 4-19). For further details regarding RPFs
- 4109 derivation, see Section 2 of EPA's *Revised Draft Technical Support Document for the Cumulative Risk*
- 4110 Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2025x).
- 4111

## 4112 Selection of the Index Chemical

4113 As described further in Section 2 of EPA's *Revised Draft Technical Support Document for the* 

4114 Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA (U.S. EPA,

4115 <u>2025x</u>), *EPA has preliminarily selected DBP as the index chemical*. DBP has a high-quality

4116 toxicological database of studies demonstrating effects on the developing male reproductive system

4117 consistent with a disruption of androgen action and phthalate syndrome. Furthermore, studies of DBP

4118 demonstrate toxicity representative of all phthalates in the cumulative chemical group and DBP is well

4119 characterized for the MOA associated with phthalate syndrome. Finally, compared to other phthalates,

4120 including well-studied phthalates such as DEHP, DBP has the most dose-response data available in the

low-end range of the dose-response curve where the BMD5 and BMDL5 are derived, which provides a
robust and scientifically sound foundation of BMD and BMDL estimates on which the RPF approach is

- 4123 based.
- 4124
- 4125
- 4126

4127 4128

Phthalate	BMD40 (mg/kg-day)	RPF Based on BMD <sub>40</sub>
DBP (Index chemical)	149	1
DEHP	178	0.84
DIBP	279	0.53
BBP	284	0.52
DCHP	90	1.66
DINP	699	0.21

# Table 4-19. Draft Relative Potency Factors Based on Decreased Fetal Testicular Testosterone

4129

## 4130 Index Chemical POD

4131 As with any risk assessment that relies on BMD analysis, the POD is the lower confidence limit used to

4132 mark the beginning of extrapolation to determine risk associated with human exposures. As described

4133 further in the draft non-cancer human health hazard assessments of DEHP (U.S. EPA, 2024f), DBP

4134 (U.S. EPA, 2024d), BBP (U.S. EPA, 2024c), DIBP (U.S. EPA, 2024g), DCHP (U.S. EPA, 2024e), and

- 4135 DINP (U.S. EPA, 2025w) (see Appendices titled "Considerations for Benchmark Response (BMR)
- 4136 Selection for Reduced Fetal Testicular Testosterone" in each hazard assessment), EPA has reached the
- 4137 conclusion that a BMR of 5 percent is the most appropriate and health protective response level for

4138 evaluating decreased fetal testicular testosterone. This is because, for some phthalates (*e.g.*, DEHP), a

4139 BMR of 10 percent is not protective of downstream apical outcomes on the developing male

reproductive system consistent with phthalate syndrome. For the index chemical, DBP, the BMDL<sub>5</sub> for the best fitting linear-quadratic model is 9 mg/kg-day for reduced fetal testicular. Using allometric body

4142 weight scaling to the three-quarters power (U.S. EPA, 2011c), EPA extrapolated an HED of 2.1 mg/kg-

4143 day to use as the POD for the index chemical in the CRA.

## 4144

## 4145 Selection of the Benchmark MOE

4146 Consistent with Agency guidance (U.S. EPA, 2022f, 2002b), EPA selected an intraspecies uncertainty factor (UF<sub>H</sub>) of 10, which accounts for variation in susceptibility across the human population and the 4147 4148 possibility that the available data might not be representative of individuals who are most susceptible to 4149 the effect. EPA used allometric body weight scaling to the three-quarters power to derive an HED of 2.1 mg/kg-day DBP, which accounts for species differences in toxicokinetics. Consistent with EPA 4150 4151 Guidance (U.S. EPA, 2011c), the interspecies uncertainty factor (UF<sub>A</sub>), was reduced from 10 to 3 to account for remaining uncertainty associated with interspecies differences in toxicodynamics. Overall, a 4152 total uncertainty factor of 30 was selected for use as the benchmark margin of exposure for the CRA 4153 4154 (based on an interspecies uncertainty factor [UFA] of 3 and an intraspecies uncertainty factor [UFH] of

4155 10). 4156

## 4157 Weight of Scientific Evidence

EPA has preliminary selected an HED of 2.1 mg/kg-day (BMDL<sub>5</sub> of 9 mg/kg-day) as the index chemical
(DBP) POD. This POD is based on a meta-analysis and BMD modeling of decreased fetal testicular
testosterone from eight studies of rats gestationally exposed to DBP. EPA has also derived draft RPFs of

4161 1, 0.84, 0.53, 0.52, 1.66, and 0.21 for DBP (index chemical), DEHP, DIBP, BBP, DCHP, and DINP,

4162 respectively, based on a common toxicological outcome (*i.e.*, reduced fetal testicular testosterone). EPA

4163 has robust overall confidence in the proposed POD for the index chemical (*i.e.*, DBP) and the derived

4164 draft RPFs.

4165	4.4.2 Cumulative Phthalate Exposure: Non-Attributable Cumulative Exposure to DEHP,
4166	DBP, BBP, DIBP, and DINP Using NHANES Urinary Biomonitoring and Reverse
4167	Dosimetry
4168	This section briefly summarizes EPA's approach and results for estimating non-attributable cumulative
4169	exposure to phthalates using NHANES urinary biomonitoring data and reverse dosimetry. Readers are
4170	directed to Section 4 of EPA's Revised Draft Technical Support Document for the Cumulative Risk
4171	Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2025x) for additional
4172	details.
4173	
4174	NHANES is an ongoing exposure assessment of the U.S. population's exposure to environmental
4175	chemicals using biomonitoring. The NHANES biomonitoring data set is a national, statistical
4176	representation of the general, non-institutionalized, civilian U.S. population. CDC's NHANES data set
4177	provides an estimate of average aggregate exposure to individual phthalates for the U.S. population.
4178	However, exposures measured via NHANES cannot be attributed to specific sources, such as COUs or
4179	other sources. Given the short half-lives of phthalates, NHANES also cannot capture acute, low
4180	frequency exposures. Instead, as concluded by the SACC review of the draft 2023 approach, NHANES
4181	provides a "snapshot" or estimate of total, non-attributable phthalate exposure for the U.S. population
4182	and relevant subpopulations (U.S. EPA, 2023f). These estimates of total non-attributable exposure can
4183	supplement assessments of scenario-specific acute risk in individual risk evaluations.
4184	
4185	Monoester metabolites of BBP, DBP, DEHP, DIBP, and DINP in human urine are regularly measured
4186	as part of the NHANES biomonitoring program and are generally detectable in human urine at a high
4187	frequency, including during the most recent NHANES survey period (i.e., 2017-2018). One urinary
4188	metabolite (i.e., monocyclohexyl phthalate [MCHP]) of DCHP was included in NHANES from 1999
4189	through 2010, but was excluded from NHANES after 2010 due to low detection levels and a low
4190	frequency of detection in human urine (detected in <10% of samples in 2009–2010 NHANES survey)
4191	(CDC, 2013). Therefore, EPA did not use NHANES urinary biomonitoring data to estimate a daily
4192	aggregate intake value for DCHP through reverse dosimetry.
4193	
4194	EPA used urinary phthalate metabolite concentrations for DEHP, DBP, BBP, DIBP, and DINP
4195	measured in the most recently available NHANES survey (2017–2018) to estimate the average daily
4196	aggregate intake of each phthalate through reverse dosimetry for
4197	• Females of reproductive age (16-49 years);
4198	• Male children (4 to <6 years, used as a proxy for male infants and toddlers);
4199	• Male children (6–11 years); and
4200	<ul> <li>Male children (12 to &lt;16 years).</li> </ul>
00	

4201 Since NHANES does not include urinary biomonitoring for infants or toddlers, and other national data 4202 sets are not available, EPA used biomonitoring data from male children 3 to less than 6 years of age as a 4203 proxy for male infants (<1 year) and male toddlers (1–2 years). See Section 4 of (U.S. EPA, 2025x) for 4204 further details regarding the reverse dosimetry approach. Aggregate daily intake estimates for these 4205 populations are presented in Table 4-20.<sup>5</sup> Aggregate daily intake values were also calculated for females

<sup>&</sup>lt;sup>5</sup> EPA defines *aggregate exposure* as the "combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways" (<u>40 CFR section 702.33</u>).

4206 of reproductive age stratified by race and socioeconomic status (Table 4-21). A similar analysis by race
4207 was not done for male children because the NHANES sample size is smaller for this population.

4208

4209 Aggregate daily intake values for each phthalate were then scaled by relative potency using the RPFs in

- Table 4-19, expressed in terms of index chemical (DBP) equivalents, and summed to estimate
  cumulative daily intake in terms of index chemical (DBP) equivalents using the approach outlined in
- 4212 Sections 4.4.1 and 4.4.3.
- 4213

Since EPA is focusing its CRA on acute exposure durations, EPA selected 95th percentile exposure
estimates from NHANES to serve as the non-attributable nationally representative exposure estimate for
use in its CRA. For females of reproductive age, EPA's analysis indicates that black, non-Hispanic
women have slightly higher 95th percentile cumulative phthalate exposure compared to other racial
groups; thus, 95th percentile cumulative estimates for black non-Hispanic females of
reproductive age was selected for use in the CRA of DEHP (Table 4-21).

- 4220
- The 95th percentile of national cumulative exposure serves as the estimate of non-attributable phthalateexposure for its CRA of DEHP as follows:
- Females of reproductive age (16-49 years, black Non-Hispanic): 5.16 μg/kg-day index chemical (DBP) equivalents. This serves as the non-attributable contribution to worker and consumer females of reproductive age in Section 4.4.4 and Section 4.4.5.
- Males (3–5 years): 10.8 µg/kg-day index chemical (DBP) equivalents. This serves as the non-attributable contribution to consumer male infants (<1 year), toddlers (1–2 years), and preschoolers (3–5 years) in Section 4.4.5. Since NHANES does not include urinary biomonitoring for infants (<1 year) or toddlers (1–2 years), and other national data sets are not available, EPA used biomonitoring data from male children (3 to <6 years) as a proxy for male infants and toddlers.</li>
- Males (6–11 years): 7.35 μg/kg-day index chemical (DBP) equivalents This serves as the non-attributable contribution to consumer male children (6–10 years) in Section 4.4.5.
- Males (12–15 years): 4.36 µg/kg-day index chemical (DBP) equivalents. This serves as the non-attributable contribution to consumer male teenagers (11–15 years) in Section 4.4.5.
- 4236 4237

# 4.4.2.1 Weight of Scientific Evidence: Non-Attributable Cumulative Exposure to Phthalates

Overall, EPA has robust confidence in the derived estimates of non-attributable cumulative exposure 4238 4239 from NHANES urinary biomonitoring using reverse dosimetry. EPA used urinary biomonitoring data 4240 from the CDC's national NHANES dataset, which provides a statistical representation of the general, 4241 non-institutionalized, civilian U.S. population. To estimate daily intake values from urinary 4242 biomonitoring for each phthalate, EPA used reverse dosimetry. The reverse dosimetry approach used by 4243 EPA has been used extensively in the literature and has been used by U.S. CPSC (2014) and Health 4244 Canada (ECCC/HC, 2020) to estimate phthalate daily intake values from urinary biomonitoring data. 4245 However, given the short half-lives of phthalates, NHANES biomonitoring data is not expected to 4246 capture low frequency exposures and may be an underestimate of acute phthalate exposure.

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Table 4-20. Cumulative Phthalate Daily Intake (µg/kg-day) Estimates for Females of Reproductive Age, Male Children, and Male
 Teenagers from the 2017–2018 NHANES Cycle

Population	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) <sup>a</sup>
		DBP	0.21	1	0.210	22.1			
		DEHP	0.53	0.84	0.445	46.9			
	50	BBP	0.08	0.52	0.042	4.38	0.950	2,211	1.4%
Females		DIBP	0.2	0.53	0.106	11.2			
(16–49		DINP	0.7	0.21	0.147	15.5			
years; n =		DBP	0.61	1	0.610	17.2			
1,620)		DEHP	1.48	0.84	1.24	35.0		592	5.1%
	95	BBP	0.42	0.52	0.218	6.15	3.55		
		DIBP	0.57	0.53	0.302	8.51			
		DINP	5.6	0.21	1.18	33.1			
		DBP	0.56	1	0.560	18.4	3.04		
		DEHP	2.11	0.84	1.77	58.2			
	50	BBP	0.22	0.52	0.114	3.76		690	4.3%
		DIBP	0.57	0.53	0.302	9.93			
Males		DINP	1.4	0.21	0.294	9.66			
(3-5  years; n = 267)		DBP	2.02	1	2.02	18.6			15.5%
n 207)		DEHP	6.44	0.84	5.41	49.9			
	95	BBP	2.46	0.52	1.28	11.8	10.8	194	
		DIBP	2.12	0.53	1.12	10.4			
		DINP	4.8	0.21	1.01	9.30			
		DBP	0.38	1	0.380	20.1			
Males		DEHP	1.24	0.84	1.04	55.1			
(6–11 years;	50	BBP	0.16	0.52	0.083	4.40	1.89	1,111	2.7%
n = 553)		DIBP	0.33	0.53	0.175	9.26			
		DINP	1	0.21	0.210	11.1			

Population	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) <sup>a</sup>
		DBP	1.41	1	1.41	19.2	_		
		DEHP	4.68	0.84	3.93	53.5			
	95	BBP	0.84	0.52	0.437	5.94	7.35	286	10.5%
		DIBP	1.62	0.53	0.859	11.7	-		
		DINP	3.4	0.21	0.714	9.71			
		DBP	0.33	1	0.330	27.6	1.19	1,758	1.7%
		DEHP	0.66	0.84	0.554	46.4			
	50	BBP	0.14	0.52	0.073	6.09			
Males		DIBP	0.21	0.53	0.111	9.32			
(12–15		DINP	0.6	0.21	0.126	10.5			
years; n =		DBP	0.62	1	0.620	14.2			
308)		DEHP	2.51	0.84	2.11	48.3			
	95	BBP	0.64	0.52	0.333	7.63	4.36	482	6.2%
		DIBP	0.59	0.53	0.313	7.17			
		DINP	4.7	0.21	0.987	22.6			

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<sup>*a*</sup> A cumulative exposure of 70  $\mu$ g DBP equivalents/kg-day would result in a cumulative MOE of 30 (*i.e.*, 2,100  $\mu$ g DBP-equivalents/kg-day  $\div$  70  $\mu$ g DBP equivalents/kg-day  $\pm$  30), which is equivalent to the benchmark of 30, indicating that the exposure is at the threshold for risk. Therefore, to estimate the percent contribution to the risk cup, the cumulative exposure expressed in DBP equivalents is divided by 70  $\mu$ g DBP equivalents/kg-day to estimate percent contribution to the risk cup.

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Table 4-21. Cumulative Phthalate Daily Intake (μg/kg-day) Estimates for Females of Reproductive Age (16–49 years old) by Race and
 Socioeconomic Status from the 2017–2018 NHANES Cycle

Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (μg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) <sup><i>a</i></sup>
		DBP	0.22	1	0.22	21.6			
		DEHP	0.59	0.84	0.50	48.6	1		
	50	BBP	0.10	0.52	0.05	5.1	1.02	2,058	1.5%
		DIBP	0.20	0.53	0.11	10.4			
Race: white non- Hispanic		DINP	0.70	0.21	0.15	14.4			
(n = 494)		DBP	0.58	1	0.58	17.6			4.7%
	95	DEHP	1.44	0.84	1.21	36.6	3.30	636	
		BBP	0.29	0.52	0.15	4.6			
		DIBP	0.55	0.53	0.29	8.8			
		DINP	5.10	0.21	1.07	32.4			
		DBP	0.10	1	0.10	15.0			
		DEHP	0.38	0.84	0.32	47.9		3,151	1.0%
	50	BBP	0.04	0.52	0.02	3.1	0.667		
Race: black non-		DIBP	0.15	0.53	0.08	11.9			
Hispanic		DINP	0.70	0.21	0.15	22.1			
(n = 371)		DBP	0.48	1	0.48	9.3			
	05	DEHP	4.28	0.84	3.60	69.7	5.16	407	7.40
	95	BBP	0.30	0.52	0.16	3.0		407	7.4%
		DIBP	0.40	0.53	0.21	4.1			

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Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) <sup>a</sup>
		DINP	3.40	0.21	0.71	13.8			
		DBP	0.19	1	0.19	22.4			
		DEHP	0.49	0.84	0.41	48.5			
	50	BBP	0.06	0.52	0.03	3.7	0.849	2,474	1.2%
		DIBP	0.17	0.53	0.09	10.6			
Race: Mexican American		DINP	0.60	0.21	0.13	14.8			
(n = 259)		DBP	0.42	1	0.42	11.6			5.2%
		DEHP	1.24	0.84	1.04	28.9	3.61		
	95	BBP	0.39	0.52	0.20	5.6		582	
		DIBP	0.46	0.53	0.24	6.8			
		DINP	8.10	0.21	1.70	47.1			
		DBP	0.26	1	0.26	25.3		2041	1.5%
		DEHP	0.64	0.84	0.54	52.2			
	50	BBP	0.07	0.52	0.04	3.5	1.03		
		DIBP	0.15	0.46	0.07	6.7			
Race: Other		DINP	0.60	0.21	0.13	12.2			
(n = 496)		DBP	0.84	1	0.84	20.7			
		DEHP	1.37	0.84	1.15	28.3			
	95	BBP	0.41	0.52	0.21	5.2	4.06	517	5.8%
		DIBP	0.46	0.53	0.24	6.0			
		DINP	7.70	0.21	1.62	39.8			

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Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	0/	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) <sup>a</sup>
		DBP	0.21	1	0.21	22.0			
		DEHP	0.53	0.84	0.45	46.6			
	50	BBP	0.09	0.52	0.05	4.9	0.955	2,199	1.4%
		DIBP	0.20	0.53	0.11	11.1			
SES: Below poverty level		DINP	0.70	0.21	0.15	15.4			
(n = 1,056)	95	DBP	0.82	1	0.82	18.2			
		DEHP	1.75	0.84	1.47	32.7	4.50	467	6.4%
		BBP	0.34	0.52	0.18	3.9			
		DIBP	0.51	0.53	0.27	6.0			
		DINP	8.40	0.21	1.76	39.2			
		DBP	0.20	1.00	0.20	27.9	0.718	2,924	1.0%
		DEHP	0.31	0.84	0.26	36.3			
	50	BBP	0.06	0.52	0.03	4.3			
		DIBP	0.15	0.53	0.08	11.1			
SES: At or above poverty		DINP	0.70	0.21	0.15	20.5			
level		DBP	0.48	1.00	0.48	16.3			
(n = 354)		DEHP	1.07	0.84	0.90	30.5			
	95	BBP	0.45	0.52	0.23	7.9	2.94	713	4.2%
		DIBP	0.65	0.53	0.34	11.7			
		DINP	4.70	0.21	0.99	33.5			
SES: Unknown	50	DBP	0.26	1.00	0.26	23.2	1.12	1,870	1.6%

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Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) <sup>a</sup>
(n = 210)		DEHP	0.67	0.84	0.56	50.1			
		BBP	0.06	0.52	0.03	2.8			
		DIBP	0.23	0.53	0.12	10.9			
		DINP	0.70	0.21	0.15	13.1			
		DBP	0.60	1.00	0.60	25.5			
		DEHP	0.86	0.84	0.72	30.7			
	95	BBP	0.21	0.52	0.11	4.6	2.35	893	3.4%
		DIBP	0.35	0.53	0.19	7.9			
		DINP	3.50	0.21	0.74	31.2			

a A cumulative exposure of 70 µg DBP equivalents/kg-day would result in a cumulative MOE of 30 (*i.e.*, 2,100 µg DBP-equivalents/kg-day  $\div$  70 µg DBP equivalents/kg-day  $\div$  70 µg DBP equivalents/kg-day to estimate the percent contribution to the risk cup, the cumulative exposure expressed in DBP equivalents is divided by 70 µg DBP equivalents/kg-day to estimate percent contribution to the risk cup.

4251

#### 4252 4.4.3 Estimation of Risk Based on Relative Potency

4253 As described in the Revised Draft Technical Support Document for the Cumulative Risk Analysis of 4254 DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA (U.S. EPA, 2025x), EPA is focusing its 4255 exposure assessment for the CRA for DEHP on evaluation of exposures through individual TSCA 4256 consumer and occupational DEHP COUs as well as non-attributable cumulative exposure to DEHP, 4257 DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data and reverse dosimetry.

4258

4259 As described in the Revised Draft Technical Support Document for the Cumulative Risk Analysis of 4260 DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA (U.S. EPA, 2025x), EPA is considering two 4261 options for characterizing cumulative risk. EPA uses the first option to estimate cumulative risk in which 4262 all phthalate exposures are scaled by relative potency using the RPFs presented in Table 4-19 to express 4263 phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual DEHP 4264 consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative risk was 4265 estimated using the four-step process outlined below, along with one empirical example of how EPA 4266 calculated cumulative risk for one occupational OES for DEHP (*i.e.*, Plastic converting). In the second 4267 option, which is presented in Section 5.2 of (U.S. EPA, 2025x), individual phthalate exposures for 4268 consumer and occupational COUs are not scaled by relative potency factors but use the individual 4269 phthalate hazard values and are combined with non-attributable cumulative exposures estimated using 4270 NHANES. Both options are compared in Section 5.4 of (U.S. EPA, 2025x). Both options for calculating 4271 cumulative risk will be peer-reviewed by the SACC in 2025. Following peer-review and public 4272 comment, EPA will select one option for characterizing cumulative risk in the final DEHP risk 4273 evaluation.

4274

4285

#### 4275 Step 1: Convert DEHP Exposure Estimates from Each Individual Consumer and Occupational COU 4276 to Index Chemical Equivalents (i.e., Occupational and Consumer Exposure from Sections 4.1.1 and 4277 4.1.2, Respectively)

4278 In this step, DEHP acute duration exposure estimates from each consumer and occupational COU/OES 4279 are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using 4280 Equation 4-5. This step is repeated for all individual exposure estimates for each route of exposure being 4281 assessed for each COU (*i.e.*, inhalation and dermal exposures for occupational COUs; inhalation, ingestion, and dermal exposure for consumer COUs). 4282 4283

#### 4284 **Equation 4-5. Scaling DEHP Exposures by Relative Potency**

DEHP Exposure (in DBP equivalents) =  $AD_{Route \ 1}x \ RPF_{DEHP}$ 

4286	Where:	•	
4287	DEHP exposure	=	Acute exposure for a given route of exposure from a single
4288			occupational or consumer COU expressed in terms of $\mu g/kg$ index
4289			chemical (DBP) equivalents
4290	AD <sub>Route 1</sub>	=	Acute dose in $\mu$ g/kg from a given route of exposure from a single
4291			occupational or consumer COU/OES
4292	RPFDEHP	=	The relative potency factor (unitless) for DEHP, which is 0.84
4293			(Table 4-19).
4294			

4295 *Example:* 50th percentile inhalation and dermal DEHP exposures for female workers of reproductive 4296 age are 46.9 and 2.36 µg/kg for the Plastic converting OES (U.S. EPA, 2025t). Using Equation 4-5, 4297 inhalation, dermal, and aggregate DEHP exposures for this OES can be scaled by relative potency to 4298 39.4, 1.98, and 41.4 µg/kg DBP equivalents, respectively.

4299

4300	$DEHP_{Inhalation-COU} = 39.4 \mu\text{g/kg}  DBP  equivalents = 46.9 \mu\text{g/kg}  DEHP  x  0.84$
4301	
4302	$DEHP_{Dermal-COU} = 1.98  \mu g/kg  DBP  equivalents = 2.36  \mu g/kg  DEHP  x  0.84$
4303	
4304	$DEHP_{Aggregate-COU} = 41.4  \mu g/kg  DBP  equivalents$
4305	$= (46.9 \mu\text{g/kg}  DEHP + 2.36 \mu\text{g/kg}  DEHP)  x  0.84$
4306	
4307	
4308	Step 2: Estimate Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and DINP
4309	Using NHANES Urinary Biomonitoring Data and Reverse Dosimetry (see Section 4.4.2 for Further
4310	Details)
4311	Non-attributable exposure for a national population to DEHP, DBP, BBP, DIBP, and DINP was
4312	estimated using Equation 4-6, where individual phthalate daily intake values estimated from NHANES
4313	biomonitoring data and reverse dosimetry were scaled by relative potency, expressed in terms of index
4314	chemical (DBP) equivalents, and summed to estimate non-attributable cumulative exposure in terms of
4315	DBP equivalents. Equation 4-6 was used to calculate the cumulative exposure estimates provided in
4316	Table 4-20 and Table 4-21.
4317	
4318	Equation 4-6. Estimating Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and
4319	DINP
4320	
4321	Cumulative Exposure (Non – attributable)
4322	$= (DI_{DEHP} x RPF_{DEHP}) + (DI_{DBP} x RPF_{DBP}) + (DI_{BBP} x RPF_{BBP})$
4323	$+ (DI_{DIBP} x RPF_{DIBP}) + (DI_{DINP} x RPF_{DINP})$
4324	Where:
4325	Cumulative exposure (non-attributable) is expressed in index chemical (DBP) equivalents
4326	(µg/kg-day).
4327	$DI$ is the daily intake value ( $\mu$ g/kg-day) for each phthalate that was calculated using NHANES
4328	urinary biomonitoring data and reverse dosimetry. DI values for each phthalate for each assessed
4329	population are provided in Table 4-20 and Table 4-21).
4330	<i>RPF</i> is the relative potency factor (unitless) for each phthalate from Table 4-19.
4331	
4332	<i>Example:</i> The 95th percentile cumulative exposure estimate of 5.16 µg/kg-day DBP equivalents for
4333	black, non-Hispanic females of reproductive age (Table 4-21) is calculated using Equation 4-6 as
4334	follows:
4335	
4336	5.16 µg/kg DBP equivalents
4337	$= (4.28 \mu\text{g/kg}  DEHP  x  0.84) + (0.48 \mu\text{g/kg}  DBP  x  1) + (0.30 \mu\text{g/kg}  BBP  x  0.52)$
4338	+ $(0.40 \ \mu g/kg \ DIBP \ x \ 0.53)$ + $(3.40 \ \mu g/kg \ DINP \ x \ 0.21)$
4339	
4340	
4341	Step 3: Calculate MOEs for DEHP Exposures and for Each Phthalate Exposure Included in the
4342	Cumulative Scenario
4343	Next, MOEs are calculated for each exposure of interest that is included in the cumulative scenario
4344	using Equation 4-7. For example, this step involves calculating MOEs for inhalation and dermal DEHP
4345	exposures expressed in index chemical equivalents for each individual COU/OES in Step 1, and an
4346	MOE for non-attributable cumulative phthalate exposure from Step 2 above.
4347	

4348 4349	Equation 4-7. Calculating MOEs for Exposures of Interest for Use in the RPF and Cumulative Approaches
4350	$MOE_{1} = \frac{Index \ Chemical \ (DBP) \ POD}{Exposure_{1} \ in \ DBP \ Equivalents}$
4351	Where:
4352 4353 4354 4355 4256	$MOE_1$ (unitless)=The MOE calculated for each exposure of interest included in the cumulative scenario. $Index chemical (DBP) POD$ =The POD selected for the index chemical, DBP. The index chemical POD is 2,100 µg/kg (Section 4.4.1).Emergence=The approximate in DBB equivalents for the nethway
4356 4357 4358 4359	Exposure1=The exposure estimate in DBP equivalents for the pathway of interest ( <i>i.e.</i> , from Step 1 or 2 above).Example: Using Equation 4-7, the MOEs for inhalation and dermal DEHP exposure estimates for the
4360 4361 4362	Plastic converting OES in DBP equivalents from Step 1 and the MOE for the non-attributable cumulative exposure estimate in DBP equivalents from Step 2 are 53, 1,060, and 407, respectively. 2,100 $\mu q/kq$
4363 4364	$MOE_{Cumulative Non-attributable} = 407 = \frac{2,100  \mu g/kg}{5.16  \mu g/kg}$
4365	$MOE_{COU-Inhalation} = 53 = \frac{2,100 \mu g/kg}{39.4 \mu g/kg}$
4366	
4367	$MOE_{COU-Dermal} = 1,060 = \frac{2,100 \ \mu g/kg}{1.98 \ \mu g/kg}$
4368 4369 4370 4371 4372 4373 4374 4375 4376	<i>Step 4: Calculate the Cumulative MOE</i> For the cumulative MOE approach, MOEs for each exposure of interest in the cumulative scenario are first calculated (Step 3). The cumulative MOE for the cumulative scenario can then be calculated using Equation 4-8, which shows the addition of MOEs for the inhalation and dermal exposures routes from an individual DIBP COU as well as the MOE for non-attributable cumulative exposure to phthalates from NHANES urinary biomonitoring and reverse dosimetry. Additional MOEs can be added to the equation as necessary ( <i>e.g.</i> , for the ingestion route for consumer scenarios).
4377	Equation 4-8. Cumulative Margin of Exposure Calculation
4378	$Cumulative MOE = \frac{1}{\frac{1}{MOE_{COU-Inhalation}} + \frac{1}{MOE_{COU-Dermal}} + \frac{1}{MOE_{Cumulative-Non-attributable}} \dots}$
4379 4380 4381 4382	<i>Example:</i> The cumulative MOE for the Plastic converting OES is 45 and is calculated by summing the MOEs for each exposure of interest from Step 3 as follows:
4383	Cumulative MOE = $45 = \frac{1}{\frac{1}{53} + \frac{1}{1,060} + \frac{1}{407}}$
4384 4385 4386	

## 4387 4.4.4 Risk Estimates for Workers Based on Relative Potency

This section summarizes RPF analysis risk estimates for female workers of reproductive age from acute duration exposures to DEHP. In the RPF analysis, EPA focused its occupational risk assessment on this population and exposure duration because as described in Section 4.4 and (U.S. EPA, 2025x), this population and exposure duration is considered most directly applicable to the common hazard outcome that serves as the basis for the RPF analysis (*i.e.*, reduced fetal testicular testosterone).

- 4393 4394 To evaluate cumulative risk to female workers of reproductive age, EPA combined inhalation and 4395 dermal exposures to DEHP from each individual occupational COU/OES with non-attributable 4396 cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP (estimated from NHANES urinary 4397 biomonitoring using reverse dosimetry). As described in Section 4.4.3, each individual phthalate 4398 exposure was scaled by relative potency per chemical, expressed in terms of index chemical (DBP) 4399 equivalents, and summed to estimate cumulative exposure and cumulative risk for each COU. MOEs in 4400 Table 4-22 are shown both with (cumulative MOE) and without (MOEs for individual DEHP COU 4401 derived using the RPF analysis) the addition of non-attributable cumulative exposure (estimated from 4402 NHANES using reverse dosimetry) so that MOEs scaled by relative potency can be compared.
- 4403 4404 After scaling high-end and central-tendency DEHP acute exposure estimates from individual 4405 COUs/OESs by relative potency and adding non-attributable cumulative exposure (calculated from 4406 NHANES) from DEHP, DBP, BBP, DIBP, and DINP, high-end and/or central tendency cumulative 4407 MOEs ranged from 0.8 to 11 (benchmark MOE = 30) for 6 of the 16 OES evaluated for DEHP (Table 4408 4-22), while the remaining 10 OES have high-end cumulative MOEs ranging from 30 to 318. However, 4409 all 6 of the OES with cumulative MOEs less than 30 also had MOEs below the benchmark in the 4410 individual DEHP worker risk assessment (Table 4-14). Additionally, and as will be discussed further in 4411 Section 4.5, the individual DEHP assessment provided more sensitive risk estimates compared to the 4412 cumulative assessment. This is primarily due to the lower (more sensitive) POD used to calculate MOEs 4413 in the individual DEHP risk evaluation (POD = 1.1 mg/kg-day) vs. the cumulative risk assessment (POD 4414 = 2.1 mg/kg-day).
- 4415

## 4.4.4.1 Overall Confidence in Cumulative Worker Risk Estimates

4416 As described in Section 4.1.1.4 and the Draft Environmental Release and Occupational Exposure 4417 Assessment for Diethylhexyl Phthalate (U.S. EPA, 2025r), EPA has slight to robust confidence in the 4418 assessed inhalation and dermal OESs. EPA has robust confidence in the RPFs and index chemical POD 4419 used to calculate the RPF analysis and cumulative MOEs (Section 4.4.1.2). To derive RPFs and the 4420 index chemical POD, the Agency integrated data from multiple studies evaluating fetal testicular 4421 testosterone using a meta-analysis approach and conducted BMD modeling. Finally, the Agency has 4422 robust confidence in the non-attributable cumulative exposure estimates for DEHP, DBP, BBP, DIBP, 4423 and DINP derived from NHANES urinary biomonitoring data using reverse dosimetry (Section 4.4.2.1). 4424 Overall, EPA has moderate to robust confidence in the cumulative risk estimates calculated for worker 4425 exposure scenarios.

## 4426 Table 4-22. Risk Summary Table for Female Workers of Reproductive Age Using the RPF Analysis

				Acute M		Workers of Reprod mark = 30)	uctive Age
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DEHP COU; Exposure in DBP Equivalents)	Dermal MOE (DEHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DEHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DEHP MOE + Cumulative Non- Attributable) <sup><i>a</i></sup>
Manufacturing –			HE	823	19,562	790	269
Domestic manufacturing	Domestic manufacturing	Manufacturing	СТ	1,509	39,123	1,453	318
Manufacturing – Importing	Importing	<b>T</b> ( <b>1</b>	HE	35	19,562	35	32
Processing – Repacking	Repackaging in wholesale and retail trade and in paint and coating manufacturing	Import and repackaging	СТ	129	39,123	129	98
Processing – Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Incorporation into formulation, mixture, or reaction product	HE	823	19,562	790	269
Processing – Other uses	Miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)		СТ	1,509	39,123	1,453	318

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DEHP COU; Exposure in DBP Equivalents)	Dermal MOE (DEHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DEHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DEHP MOE + Cumulative Non- Attributable) <sup>a</sup>		
	Plasticizer in basic organic chemical manufacturing; custom compounding of		HE	6.6	530	6.5	6.4		
Processing – incorporation into formulation, mixture, or reaction product	purchased resins; miscellaneous manufacturing; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Plastic compounding	СТ	60	1,060	57	50		
Processing – Incorporation into article	Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	Plastic converting	HE	34	530	32	30		
Industrial Use – Other uses	Solid rocket motor insulation and other aerospace applications Automotive articles, other than fluids		СТ	53	1,060	51	45		
Processing – Incorporation into article	Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding		не	2.2	530	2.2	2.2		
Processing – Incorporation into formulation, mixture, or reaction product	Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Rubber product manufacturing	СТ	11	1,060	11	10		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DEHP COU; Exposure in DBP Equivalents)	Dermal MOE (DEHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DEHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DEHP MOE + Cumulative Non- Attributable) <sup>a</sup>		
Industrial Use – Other uses	Paints and coatings		HE	0.8	1,017	0.8	0.8		
Industrial Use – Construction, paint, electrical, and metal products	Paints and coatings	Spray application of paints, coatings, adhesives, and sealants		60	2,034	58	51		
Commercial Use – Construction, paint, electrical, and metal products	Adhesives and sealants		СТ						
Commercial Use – Furnishing, cleaning, and treatment care products	All-purpose waxes and polishes								
Industrial Use – Other uses	Paints and coatings		HE	2.2	1,017	2.2	2.2		
Industrial Use – Construction, paint, electrical, and metal products	Paints and coatings	Non-spray application of paints, coatings,	СТ	11	2,034	11	11		
Commercial Use – Construction, paint, electrical, and metal products	Adhesives and sealants	adhesives, and sealants							
Commercial Use – Packaging, paper,	Ink, toner and colorants	Use of dyes,	HE	2.2	1,017	2.2	2.2		
plastic, toys, hobby products		pigments, and fixing agents	СТ	11	2,034	11	11		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DEHP COU; Exposure in DBP Equivalents)	Dermal MOE (DEHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DEHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DEHP MOE + Cumulative Non- Attributable) <sup><i>a</i></sup>		
Commercial Use – Other uses	Automotive articles	Use of automotive	HE	165	1,017	142	105		
other uses			СТ	329	2,034	283	167		
Commercial Use – Furnishing, cleaning,	Fabric, textile, and leather products; furniture and furnishings	Textile finishing	HE	421,076	530	529	230		
and treatment care ] products	Fabric enhancer		СТ	5,840,726	1,060	1059	294		
Industrial Use – Construction, paint,	Adhesives and sealants	Formulation for	HE	2.3	1,017	2.3	2.3		
electrical, and metal products		diffusion bonding	СТ	53	2,034	52	46		
Industrial Use – Other uses	Hydraulic fracturing	Use in Hydraulic	HE	823	1,017	455	215		
uses		fracturing	СТ	1,509	2,034	866	277		
Commercial Use –	Laboratory chemicals	Use of laboratory	HE	181	530	135	101		
Other uses		chemicals	СТ	1,811	1,060	668	253		
Processing –	Recycling		HE	34	530	32	30		
Recycling		Recycling	СТ	53	1,060	51	45		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DEHP COU; Exposure in DBP Equivalents)	Dermal MOE (DEHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DEHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DEHP MOE + Cumulative Non- Attributable) <sup><i>a</i></sup>		
Commercial Use – Construction, paint,	Batteries and capacitors		HE	165	530	126	96		
electrical, and metal products	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles Machinery, mechanical appliances,	Fabrication or use of final products and articles	СТ	453	1,060	317	178		
	electrical/electronic articles								
Commercial Use – Automotive, fuel, agriculture, and outdoor use products	Lawn and garden care products								
Commercial Use – Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including paper articles; rubber articles; plastic articles (hard); plastic articles (soft)								
	Packaging (excluding food packaging), including paper articles								
	Toys, playground, and sporting equipment								
Commercial Use – Furnishing, cleaning, and treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and apparel								
Disposal – Disposal	Disposal	Waste handling,	HE	12	530	12	11		
		treatment and disposal	CT	171	1,060	147	108		

<sup>*a*</sup> The acute cumulative MOE is derived by summing inhalation exposure from each individual DEHP COU with dermal exposure from the same DEHP COU and the cumulative non-attributable exposure to DEHP, DBP, BBP, DIBP, and DINP. Non-attributable cumulative exposure was estimated from NHANES urinary biomonitoring data using reverse dosimetry. All exposure estimates were (1) scaled by relative potency, (2) expressed in index chemical equivalents (*i.e.*, DBP equivalents), (3) summed to calculate cumulative exposure in index chemical equivalents, and then (4) compared to the index chemical POD (*i.e.*, HED of 2.1 mg/kg-day) to calculate the cumulative MOE.

## 4428 4.4.5 Risk Estimates for Consumers Based on Relative Potency

4429 This section summarizes cumulative risk estimates for consumers from acute duration exposures to 4430 DEHP. EPA focused its CRA on females of reproductive age and male infants and children. EPA 4431 focused its consumer CRA on these populations for the acute exposure duration because, as described in Section 4.4 and (U.S. EPA, 2025x), these populations and exposure duration are considered most 4432 4433 directly applicable to the common hazard outcome that serves as the basis for the cumulative assessment 4434 (*i.e.*, reduced fetal testicular testosterone). For consumers, EPA did not specifically evaluate females of 4435 reproductive age or male infants and children; however, consumer exposures of teenagers (16–20 years) 4436 and adults (21+ years) were considered to be a proxy for females of reproductive age, while infants (<1 4437 year), toddlers (1–2 years), children (3–5 and 6–10 years), and young teens (11–15 years) were 4438 considered a proxy for male infants and children. 4439

4440 After scaling high-intensity DEHP acute exposure estimates from individual COUs by relative potency 4441 and adding non-attributable cumulative exposure (calculated from NHANES) from DEHP, DBP, BBP, 4442 DIBP, and DINP, all high-intensity consumer product and article examples had cumulative MOEs 4443 ranging from 50 to 476 (benchmark = 30) (Table 4-23). Additionally, and as will be discussed further in 4444 Section 4.5, the individual DEHP assessment provided more sensitive risk estimates compared to the 4445 cumulative assessment. This is primarily due to the lower (more sensitive) POD used to calculate MOEs 4446 in the individual DEHP risk evaluation (POD = 1.1 mg/kg-day) vs. the cumulative risk assessment (POD 4447 = 2.1 mg/kg-day).

4448

## 4.4.5.1 Overall Confidence in Cumulative Consumer Risks

4449 As described in Section 4.1.2 and in more technical details in the Draft Consumer and Indoor Exposure 4450 Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e), EPA has moderate or robust 4451 confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios. The Agency has robust confidence in the RPFs and index chemical POD used to calculate the cumulative MOEs 4452 4453 (Section 4.4.1). To derive RPFs and the index chemical POD, EPA integrated data from multiple studies 4454 evaluating fetal testicular testosterone using a meta-analysis approach and conducted BMD modeling. 4455 Finally, EPA has robust confidence in the non-attributable cumulative exposure estimates since they 4456 were calculated from CDC's NHANES biomonitoring data set, which provides a statistically 4457 representative sampling of the U.S. civilian population (Section 4.4.2.1). Furthermore, the Agency used a well-established reverse dosimetry approach to calculate phthalate daily intake values from urinary 4458 4459 biomonitoring data. Overall, EPA has moderate to robust confidence in the cumulative risk estimates 4460 calculated for consumer exposure scenarios.

## 4461 Table 4-23. Consumer Cumulative Risk Summary Table

Life Crock Stears COU		Exposure		Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article	Scenario (H, M, L) <sup><i>a</i></sup>	Exposure Scenario	Exposure ScenarioInfant (<1 Year)	l Equivaler Teenager 	Adult (21+ years)					
	Auto repair putty	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)		_	_	-	476	403	403	
Construction, paint, electrical, and metal products: Adhesives and sealants	Flooring adhesive	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	273	435	378	379	
	Inductance loop sealant	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	-	-	—	-	387	342	339	
Other Automotive Articles	Car mats	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	188	188	189	278	461	394	395	
	Tire replacement	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	274	455	389	388	
Furnishing, cleaning, treatment		Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	-	—	_	-	_ <i>b</i>	_ <i>b</i>	_ <i>b</i>	
care products: Fabric, textile, and leather products; furniture	Clothing	М	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	-	-	_	-	300	278	273	
and furnishings	Furniture components (textile)	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	50 <sup>c</sup>	57 <sup>c</sup>	67 <sup>c</sup>	113 <sup>c</sup>	172 <sup>c</sup>	177 <sup>c</sup>	200 <sup>c</sup>	
Furnishing, cleaning, treatment care products: Fabric, textile, and leather products; furniture and furnishings	Small articles with the potential for semi- routine contact: Outdoor furniture, children's bags, wallets, footwear, interior and exterior components of jackets, handbags	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	274	455	389	388	

Life Cycle Stage: COU:		Exposure		Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article	Scenario (H, M, L) <sup><i>a</i></sup>	Exposure Scenario Infant (<1 Year) Toddler (1-2 Years) Preschooler (3-5 years) Middle Childhoo (6-10 years)	(6–10	Young Teen (11–15 years)	l Equivale Teenager (16–20 years) 288 398 299 398 398 389 389 389 389	Adult (21+ years)				
Construction, paint, electrical, and metal products: Floor	Vinyl flooring	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	125	128	135	197	309	288	296	
coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; Fabrics, textiles, and apparel	Wallpaper (in place)	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	190	190	191	279	468	398	407	
	Wallpaper (installation)	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	_	_	_	-	328	299	293	
Furnishing, cleaning, treatment care products: Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; Fabrics, textiles, and apparel											
Automotive, fuel, agriculture, outdoor use products: Lawn and garden care products	Small articles with the potential for semi- routine contact: garden hose	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	274	455	389	388	
Construction point electrical	Insulated cords	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	99	124	141	276	462	395	396	
Construction, paint, electrical, and metal products: Machinery, mechanical appliances, electrical/electronic articles	Small articles with the potential for semi- routine contact: phone charge, wireless earbuds, electrical tape	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	274	455	Teenager (16-20 years)           288           398           299           389           389           395           389	388	
Other: Novelty Products	Adult toys	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	_	_	_	_	—	389	388	

		Exposure		Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article	Scenario (H, M, L) <sup><i>a</i></sup>	Exposure Scenario	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenager (16-20 years)         245         403         358         206         389         389         389         391         335	Adult (21+ years)	
	Air beds (article concentration and barrier refinement)	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	74	110	120	171	258	245	243	
	Erasers	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	193	193	144	220	476	403	403	
	Mobile phone covers	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	169	172	175	252	410	358	355	
Packaging, paper, plastic, toys, hobby products: Packaging (excluding food packaging) and	Shower curtains	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	79	82	91	134	206	206	229	
(excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; Plastic articles (hard); plastic articles (soft)	routine contact:	Η	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	274	455	389	388	
Packaging, paper, plastic, toys, hobby products: Packaging (Excluding Food Packaging), Including Paper Articles	Small articles with the potential for semi- routine contact: packaging, paper, hobby products: pencils, labels, covers, lampshade, stickers	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	185	186	187	274	455	389	388	
Construction, paint, electrical, and metal products: Paints and	Auto Coatings	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	186	187	188	276	455	391	392	
coatings	Concrete sealant	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	193	193	193	283	375	335	332	

Life Cuele Stores COU	Exposure			Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article	Scenario (H, M, L) <sup>a</sup>	Exposure Scenario	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenager (16–20 years)	Adult (21+ years)	
playground, and sporting equipment	Children's toys (legacy)	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	53	78	91	147	226	224	259	
	Children's toys (new)	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	76	131	152	260	425	369	407	
	Tire crumb, artificial turf	Н	Cumulative (Aggregate DEHP COU + Cumulative Non-attributable)	_	_	193	284	477	404	404	

<sup>*a*</sup> Exposure scenario intensities include high (H), medium (M), and low (L).

<sup>b</sup> High-intensity dermal scenario was deemed to be unlikely due to high uncertainties, see *Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e).

<sup>*c*</sup> High-intensity aggregate scenario includes ingestion and inhalation exposure routes, while the medium-intensity aggregate scenario includes dermal, ingestion, and inhalation exposure routes for all populations except infants, which does not include the dermal route. The high-intensity dermal scenario was deemed to be unlikely due to high uncertainties, see *Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025e).

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#### 4463 4.4.6 **Cumulative Risk Estimates for the General Population**

4464 For DEHP, EPA did not evaluate cumulative risk for the general population from environmental releases. As discussed in Section 4.1.3, the Agency employed a screening level approach to assess risk 4465 4466 from exposure to DEHP for the general population from environmental releases. Using this conservative screening level approach, EPA did not identify any pathways of concern, indicating that refinement was 4467 4468 not necessary. However, as discussed in Section 4.4.2, EPA did evaluate cumulative exposure and risk 4469 from exposure to DEHP, DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data. The 4470 NHANES biomonitoring data set is a national, statistical representation of the general, non-4471 institutionalized, civilian U.S. population and provides estimates of average aggregate exposure to 4472 individual phthalates for the U.S. population. As can be seen from Table 4-20, and as discussed in more 4473 detail in the Revised Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, 4474 DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2025x), 95th percentile cumulative 4475 MOEs ranged from 194 to 592 (cumulative benchmark = 30) for females of reproductive age and male 4476 children. These MOEs indicate that the risk cup is 6.2 to 15.5 percent full and indicate that cumulative 4477 exposure to DEHP, DBP, DIBP, BBP, and DINP, based on the most recent NHANES survey data (2017 4478 to 2018), does not currently pose a risk to most male children or pregnant women within the U.S. 4479 civilian population.

#### 4.5 Comparison of Single Chemical and Cumulative Risk Assessments 4480

4481 In support of the developed CRA, EPA has relied substantially on existing CRA-related work by the Agency's Risk Assessment Forum (RAF), EPA Office of Pesticide Programs (OPP), the Organisation 4482 4483 for Economic Co-operation and Development (OECD), the European Commission, and the World 4484 Health Organization (WHO) and International Programme on Chemical Safety (IPCS), including

- 4485 Guidelines for the Health Risk Assessment of Chemical Mixtures (U.S. EPA, 1986); •
  - Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common *Mechanism of Toxicity* (U.S. EPA, 1999);
- 4488 • Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. 4489 EPA, 2000);
- 4490 • General Principles for Performing Aggregate Exposure and Risk Assessments (U.S. EPA, 2001);
- 4491 Guidance on Cumulative Risk Assessment of Pesticide Chemicals that Have a Common 4492 Mechanism of Toxicity (U.S. EPA, 2002a); 4493
  - Framework for Cumulative Risk Assessment (U.S. EPA, 2003);

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- 4494 Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple • 4495 Chemicals, Exposures, and Effects: A Resource Document (U.S. EPA, 2007a);
- 4496 Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose (U.S. EPA, • 4497 2016b);
- 4498 Advances in Dose Addition For Chemical Mixtures: A White Paper (U.S. EPA, 2023b). •
- 4499 Phthalates and Cumulative Risk Assessment: The Tasks Ahead (NRC, 2008); •
- 4500 State of the Art Report on Mixture Toxicity (European Commission, 2009); •
- 4501 Risk Assessment of Combined Exposure to Multiple Chemicals: A WHO/IPCS Framework (Meek • 4502 et al., 2011); and
- 4503 • Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals (OECD, 4504 2018).
- 4505 EPA has evaluated risks for workers (Section 4.3.2), consumers (Section 4.3.3), and the general
- 4506 population (Section 4.3.4) from exposure to DEHP alone, as well as cumulative risks for workers
- 4507 (Section 4.4.4) and consumers (Section 4.4.5) that take into account differences in relative potency and

4508 cumulative non-attributable exposure to DEHP, DBP, BBP, DIBP, and DINP from NHANES4509 biomonitoring and reverse dosimetry.

4510

4511 There are several notable differences between the individual DEHP assessment (Section 4.3) and the 4512 CRA (Section 4.4). As part of the individual DEHP assessment (Section 4.3), EPA considered all human 4513 health hazards of DEHP and selected a POD based on a NOAEL for phthalate syndrome-related effects 4514 to characterize risk from exposure to DEHP. As part of its exposure assessment in the individual DEHP 4515 assessment, EPA considered acute, intermediate, and chronic exposure durations for a broad range of 4516 populations—including female workers of reproductive age, average adult workers, ONUs, the general 4517 population, and consumers of various lifestages (e.g., infants, toddlers, children, adults). Furthermore, in 4518 the individual DEHP assessment, EPA evaluated inhalation and dermal exposures to workers, as well as 4519 consumer exposure to DEHP via the inhalation, dermal, and ingestion exposure routes. In contrast, the 4520 CRA is more focused in scope (Section 4.4). First, the CRA is based on a uniform measure of hazard 4521 (*i.e.*, reduced fetal testicular testosterone) that serves as the basis for deriving RPFs and the index 4522 chemical (DBP) POD, which were derived via meta-analysis and BMD modeling (Section 4.4.1). 4523 Second, the CRA is focused on acute duration exposures and the most sensitive populations (*i.e.*, 4524 females of reproductive age, male infants, male children) (Section 4.4). Finally, for the CRA, DEHP 4525 exposures from individual consumer and worker COUs were (1) scaled by relative potency; (2)

4526 expressed in index chemical (DBP) equivalents; and (3) combined with non-attributable cumulative4527 exposure to DEHP, DBP, BBP, DIBP, and DINP from NHANES.

4528

As discussed briefly above in Section 4.4.4 and Section 4.4.5, risk estimates derived from the CRA
(Section 4.4) are less sensitive than risk estimates derived via the individual DEHP assessment (*i.e.*,
cumulative MOEs are larger than MOEs from the individual DEHP assessment for each individual
COU) (Section 4.3). Overall, there are three primary factors that influenced differences in risk estimates
between the individual DEHP assessment (Section 4.3) and the RPF analysis (Section 4.4), which are
described below:

4535

## 4536 Scaling by Relative Potency

4537 DEHP inhalation, dermal, and ingestion exposures from individual COUs/OES were scaled by relative 4538 potency to the index chemical. The RPF for DEHP is 0.84 (Table 4-19), which means DEHP exposures 4539 when multiplied by the RPF and expressed in terms of index chemical (DBP) equivalents, decreased by 4540 16 percent, contributing to lower cumulative risk estimates compared to the individual DEHP 4541 assessment. RPFs used to scale for relative potency were calculated based on a common hazard endpoint 4542 (*i.e.*, reduced fetal testicular testosterone) from data from multiple studies evaluating effects of 4543 phthalates on fetal testicular testosterone using a meta-analysis and BMD modeling approach for each of 4544 the six phthalates included in the cumulative chemical group (see (U.S. EPA, 2025x) for further details). 4545 This analysis provides a robust basis for assessing the dose-response for the common hazard endpoint 4546 (*i.e.*, reduced fetal testicular testosterone) across the six toxicologically similar phthalates included in the 4547 cumulative assessment. Overall, EPA has robust confidence in the draft RPFs used in this CRA (Section 4548 4.4.1.2).

4549

# 4550 Index Chemical POD

4551 As described previously in Sections 4.4.1 and 4.4.3, cumulative MOEs are calculated by dividing the

4552 cumulative exposure estimate expressed in terms of index chemical (DBP) equivalents by the index

- 4553 chemical POD. The POD for the index chemical (DBP) used to calculate cumulative risk is 2.1 mg/kg
- 4554 (based on a BMDL<sub>5</sub> for reduced fetal testicular testosterone). Comparatively, the DEHP POD used to
- 4555 calculate MOEs for individual DEHP COUs in Section 4.3 is 1.1 mg/kg (based on a NOAEL for
- 4556 phthalate syndrome-related effects). The DEHP POD is approximately two-fold lower (i.e., more

*sensitive) than the index chemical (DBP), which is the primary factor leading to lower cumulative MOEs.* Overall, EPA has robust confidence in the index chemical (DBP) POD used in this CRA. This is
because the POD is based on fetal testicular testosterone data from eight publications that was integrated
via meta-analysis and BMD modeling. Notably, several of the available studies evaluated effects on fetal
testicular testosterone at dose levels in the low-end range of the dose response curve (*i.e.*, 1, 10, 33, and
50 mg/kg-day) where the BMD<sub>5</sub> (14 mg/kg-day) and BMDL<sub>5</sub> (9 mg/kg-day) were derived (see (U.S.
EPA, 2025x) for further details).

4564

## 4565 Addition of Non-Attributable Cumulative Exposure

4566 As part of its CRA, EPA calculated non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, 4567 and DINP using NHANES urinary biomonitoring data from the 2017 to 2018 survey (most recent data set available) and reverse dosimetry (see Section 4.4.2 and (U.S. EPA, 2025x) for further details), 4568 4569 representing exposure to a national population. DCHP was not included as part of the cumulative non-4570 attributable national exposure estimate because DCHP has not been included in NHANES analyses 4571 since 2011 due to low frequencies of detection and low detection levels in urine (Section 4.4.2). Non-4572 attributable cumulative exposure estimates were scaled by relative potency and expressed in index 4573 chemical (DBP) equivalents. Non-attributable cumulative exposure was then combined with DEHP 4574 exposures from each individual worker and consumer COU scaled by relative potency. Depending upon 4575 the population and age group, EPA added a non-attributable cumulative exposure of  $4.36 \,\mu g/kg$  to 10.8 4576  $\mu$ g/kg index chemical (DBP) equivalents to calculate the cumulative MOE (Section 4.4.2). This non-4577 attributable cumulative exposure contributes approximately 6.2 to 15.5 percent to the risk cup with a benchmark MOE of 30. Overall, EPA has robust confidence in the non-attributable cumulative exposure 4578 4579 estimate since it was calculated from CDC's NHANES biomonitoring data set, which provides a 4580 statistically representative sampling of the U.S. civilian population. Furthermore, the Agency used a 4581 well-established reverse dosimetry approach to calculate phthalate daily intake values from urinary 4582 biomonitoring data.

4583

Ultimately, the impact of scaling by relative potency and use of the index chemical POD has a
significant impact on the risk estimates for exposure to DEHP alone. There is little additional cumulative
risk by adding the simultaneous exposure of other phthalates to the single chemical risk estimates for
DCHP (*i.e.*, non-attributable cumulative exposure from NHANES adds 6.2–15.5% to the risk cup).

4588
4589 EPA has robust confidence in its CRA and moderate to robust confidence in its individual assessment of
4590 DEHP for workers (Section 4.3.2.19), consumers (Section 4.3.3), and the general population (Section
4591 4.3.4). RPFs used to scale for relative potency were calculated based on a common hazard endpoint (*i.e.*,
reduced fetal testicular testosterone) from data from multiple studies evaluating effects of phthalates on
4593 fetal testicular testosterone using a meta-analysis and BMD modeling approach for each of the six

- 4594 phthalates included in the cumulative chemical group (U.S. EPA, 2025x). This analysis provides a 4595 robust basis for assessing the dose-response for the common hazard endpoint (*i.e.*, reduced fetal
- 4596 testicular testosterone) across the six toxicologically similar phthalates included in the CRA.
- 4597

# 4598 **5 ENVIRONMENTAL RISK ASSESSMENT**

#### DEHP – Environmental Risk Assessment (Section 5): Key Points

EPA evaluated the reasonably available information for environmental exposures and hazard to ecological receptors following releases of DEHP to surface water, sediment, air deposition of DEHP to soil, and agricultural application of municipal biosolids. The following bullets summarize the key points.

#### Environmental Exposure Key Points

- Using TRI data, the highest surface water concentration resulted from the Plastic compounding (upper bound) OES with a 7Q10 value of 17.6  $\mu$ g/L, and the lowest surface water concentration resulted from plastic converting (lower-bound) OES 30Q5 value of 0.023  $\mu$ g/L, which represent a bounding for this risk characterization.
- Fugitive/stack deposition to soil was calculated from the maximum single release out of all OES's resulting in a daily soil concentration of 8.29×10<sup>-6</sup> mg/kg.

## Hazard Key Points

- The chronic aquatic COC of  $0.0032 \ \mu g/L$  was derived from a chronic value (ChV) of  $0.032 \ \mu g/L$  divided by an assessment factor (AF) of 10.
- The sediment dwelling organism COC was 0.03  $\mu$ g/L, derived from an unbounded LOAEC of 0.3  $\mu$ g/L divided by an AF of 10 in pore water.
- The hazard value for terrestrial mammals was 80.79 mg/kg-day, based on the geometric mean of a NOAEL of 46.58 mg/kg-day and LOAEL of 140.15 mg/kg-day via ingestion
- The avian threshold was based on a hazard LOAEL of 100 mg/kg-day via egg injection
- The terrestrial plant hazard threshold was 10 mg/kg soil, based on the geometric mean of a NOAEC of 5.0 mg/kg soil and LOAEC of 20 mg/kg soil.
- No effects were observed in aquatic organisms on an acute exposure basis, or in aquatic plants and algae, or terrestrial invertebrates, thus hazard thresholds were not established for these organisms.

## Risk Assessment Key Points

- Aquatic species
  - The COUs representing the highest (Plastic compounding) and lowest (Plastic converting) surface water concentrations from TRI releasers resulted in RQs greater than 1 for chronic exposure to aquatic vertebrates.
  - DEHP is unlikely to pose risk to aquatic vertebrates and invertebrates on an acute exposure basis and unlikely to pose risk to aquatic plants and algae.
- Benthic species
  - The COUs representing the highest (Plastic compounding) and second lowest (Manufacturing) pore water concentrations from TRI releasers resulted in RQs greater than 1 for chronic exposure to benthic invertebrates.
  - RQs were less than 1 for chronic exposures to DEHP for benthic invertebrates in the plastic converting (lower-bound) OES.
- Terrestrial species
  - RQs were less than 1 for terrestrial plants exposed via air deposition (fugitive or stack release) or biosolid land application.
  - DEHP is unlikely to pose risk to mammals, birds, and terrestrial invertebrates.
  - Risk from DEHP exposure through trophic transfer is not expected.
- EPA has robust and moderate confidence in the risk characterization for the chronic aquatic and chronic benthic assessments, respectively, and robust and moderate confidence in the terrestrial plant assessments through air deposition to soil and biosolid land application, respectively.

## 4599 **5.1 Summary of Environmental Exposures**

DEHP is expected to be released to the environment via air, water, and biosolids and landfills as detailed
within the environmental release assessment presented in the *Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate* (U.S. EPA, 2025r). Environmental media
concentrations were estimated in ambient air, soil from ambient air deposition, biosolids, surface water,
and sediment. Further details on the environmental partitioning and media assessment can be found in
the *Draft Chemistry, Fate, and Transport Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA,
2024h).

- 4608 EPA estimated environmental releases and concentrations of DEHP. Section 3.1 describes the approach 4609 and methodology for estimating releases. Section 3.2 presents estimates of environmental releases, and 4610 Section 3.3 presents the approach and methodology for estimating environmental concentrations as well 4611 as a summary of concentrations of DEHP in the environment.
- 4612

4607

- 4613 For the water pathway, the EPA's VVWM-PSC tool (PSC) (U.S. EPA, 2019d) was used to estimate 4614 surface water and sediment concentrations of DEHP resulting from COU releases. Industrial releases of 4615 DEHP to surface waters were reported to EPA via TRI and DMR databases or estimated using generic 4616 scenarios (U.S. EPA, 2025r). PSC inputs include physical and chemical properties of DEHP (*i.e.*, Kow, 4617 Koc, water column half-life, photolysis half-life, hydrolysis half-life, and benthic half-life) and 4618 estimated DEHP releases to water (U.S. EPA, 2025r), which are used to predict receiving water column 4619 concentrations. PSC was also used to estimate DEHP concentrations in settled sediment in the benthic 4620 region of streams. Site-specific parameters including the concentration of suspended sediments, water depth, and weather patterns influence how partitioning occurs over time. However, physical and 4621 4622 chemical properties of the chemical have a major influence on partitioning and half-lives in aqueous 4623 environments. DEHP has a log Koc of 5.4 indicating a high potential to sorb to suspended particles in the water column and settled sediment in the benthic environment (U.S. EPA, 2017). Physical and 4624 4625 chemical, and environmental fate properties selected by EPA for this assessment were used as inputs to 4626 the PSC model described in detail in the Draft Chemistry, Fate, and Transport Assessment for 4627 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024h) and Draft Environmental Media and General 4628 Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP), (U.S. EPA, 2025q). 4629 Measured concentrations of DEHP ranged less than 280 ng/L to 940 µg/L in surface waters while 4630 ranging less than 165 to 699,000 µg/kg in the sediment (Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (U.S. EPA, 2025r)). Monitored surface water 4631 concentrations of DEHP (U.S. EPA, 2025q) fall within these ranges of reported TRI data as presented 4632 4633 within Table 5-3. 4634
- Although there is the possibility of environmental releases from consumer uses containing DEHP, EPA
  was unable to quantify the environmental releases for the following COUs:
- 4637
   Consumer use automotive, fuel, agriculture, outdoor use products lawn and garden care products
- Consumer use construction, paint, electrical, and metal products batteries
- Consumer use construction, paint, electrical, and metal products construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
- 4643
   Consumer use construction, paint, electrical, and metal products machinery, mechanical appliances, electrical/electronic articles
- Consumer use construction, paint, electrical, and metal products paints and coatings

- Consumer use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Consumer use packaging, paper, plastic, toys, hobby products ink, toner, and colorants
- Consumer use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)
- Consumer use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including paper articles
- Consumer use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment

4657 It is difficult for EPA to quantify these end-of-life and down-the-drain exposures due to limited 4658 information on source attribution of the consumer COUs. Section 3.1.4 further details on the qualitative 4659 assessment of consumer disposal of DEHP-containing products and articles. Although EPA 4660 acknowledges that there may be DEHP releases to the environment, the Agency did not quantitatively assess these scenarios due to limited information, monitoring data, or modeling tools. Consumer releases 4661 to the environment are anticipated to be more dispersed and less direct than DEHP releases from 4662 COUs/OESs quantified for risk estimates for aquatic and terrestrial receptors detailed within Table 5-10. 4663 4664 DEHP from down-the-drain disposal of consumer products or landfill disposal of consumer articles is 4665 not likely lead to environmental concentrations that exceed hazard values for aquatic and terrestrial 4666 organisms.

4667

4668 For the land pathway, there are uncertainties in the relevance of limited monitoring data for biosolids 4669 and landfill leachate to the COUs considered. However, based on high-quality physical and chemical 4670 property data, EPA determined that DEHP will have low persistence potential and mobility in soils. 4671 Therefore, groundwater concentrations resulting from releases to the landfill or to agricultural lands via 4672 biosolids applications were not quantified but are discussed qualitatively. Modeled soil DEHP concentrations from air deposition to soil and modeled DEHP in biosolids-amended soils from OESs 4673 4674 with the resulting highest concentrations to soil were assessed quantitatively with hazard thresholds (U.S. EPA, 2024a) for relevant soil dwelling organisms and plants within the Draft Environmental 4675 4676 Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024a). The complete review of 4677 exposure pathways can be found in the Draft Environmental Media and General Population and 4678 Environmental Exposure for Diethylhexyl Phthalate (DEHP), (U.S. EPA, 2025q). DEHP concentrations 4679 in topsoil were estimated to range from 0.003 to 6.25 mg/kg (U.S. EPA, 2025q).

4680

EPA conducted qualitative assessments of DEHP trophic transfer as the physical properties, fate, and
exposure of the chemical preliminarily determined that it does not biomagnify and is characterized as
demonstrating trophic dilution. The Agency has robust confidence that DEHP has limited
bioaccumulation and bioconcentration potential based on physical and chemical and fate properties,
biotransformation, and empirical metrics of bioaccumulation metrics presented in Section 2. A summary
of relevant exposure pathways to receptors and resulting risk characterization summaries are presented
in Table 5-1.

4688

4689 DEHP releases to water are represented with data from TRI releases. Environmental releases were 4690 characterized with TRI, NEI, DMR data for thirteen OESs, while three OESs were modeled with generic 4691 scenarios because TRI, NEI, DMR data for these releases were not available (Table 3-5). Direct releases 4692 to surface water reported via TRI and DMR were applied as the actual loading to surface water, 4693 including any onsite treatment prior to discharge. Specifically for TRI-reported COU/OES, reported

4694 surface water releases are based on monitoring at the outfall to surface water and already reflect any 4695 applicable pretreatment and wastewater treatment, and no additional wastewater treatment removal was 4696 applied (See Section 2.3.3.1 of the Draft Environmental Release and Occupational Exposure 4697 Assessment for DEHP (U.S. EPA, 2025r)). As described within Section 3.3, the TRI release with the highest resulting environmental concentrations for surface and pore water indicated that ROs were 4698 4699 above one for these aquatic compartments. As a refinement from this initial approach, TRI data from the 4700 COU/OESs with the highest and lowest resulting concentrations within surface water and pore water 4701 were used to represent bounds with water releases of DEHP. For the COU/OESs with TRI release 4702 information, the highest surface water concentration was from the plastic compounding (upper bound) OES with a 7Q10 value of 17.6 µg/L, and the lowest surface water concentration was from plastic 4703 4704 converting (lower bound) 30Q5 value of 0.023 µg/L. As a result, DEHP concentrations from TRI data 4705 represent both the highest and lowest in stream concentrations as bounds for this risk characterization. 4706 Risk estimates from calculated hazard thresholds and TRI data representing the COU/OES with the 4707 highest and lowest surface and pore water concentrations can be found in Table 5-3 and Table 5-4.

4708

4709	Table 5-1. Relevant Exposure Pathway to Receptors and Corresponding Risk Assessment for the
4710	DEHP Environmental Risk Characterization

Exposu	re Pathway	Receptor	Risk Assessment
	Surface water	Acute exposure to aquatic vertebrates or invertebrates <sup><i>a</i></sup>	Qualitative; Unlikely to result in risk
Aquatic	Surface water	Chronic exposure to aquatic vertebrates, Reduced growth/development of Japanese medaka ( <i>Oryzias latipes</i> )	RQs >1 Risk identified <sup>₫</sup>
environment	Sediment	Chronic exposure to invertebrates, Reduced growth of the midge ( <i>Chironomus</i> <i>riparius</i> ) <sup>b</sup>	RQs >1 Risk identified <sup>d</sup>
	Surface water	Aquatic plants and algae <sup>a</sup>	Qualitative; Unlikely to result in risk
	Soil	Terrestrial invertebrates <sup><i>a,c</i></sup>	Qualitative; Unlikely to result in risk
Terrestrial	Soil (air to soil) Soil (biosolids)	Terrestrial plants	No RQs >1
environment	Atmospheric deposition	Birds	Qualitative; Unlikely to result in risk
	Trophic transfer	Terrestrial mammal	Qualitative; Unlikely to result in risk

<sup>*a*</sup> No hazard threshold identified up to the limit of solubility.

<sup>b</sup> No hazard threshold identified from chronic DEHP exposure for aquatic invertebrates in the water column as no studies below the limit of water solubility were available (see Section 5.3.6).

<sup>c</sup> No hazard threshold identified up to and exceeding 5,000 mg/kg after 50 days (Jensen et al., 2001).

 $\frac{d}{d}$  Table 5-3 and Table 5-4 details the risk estimates calculated from hazard thresholds and TRI data representing the COU/OESs with the highest and lowest resulting concentrations within surface water and pore water.

4711

## 4712 **5.2 Summary of Environmental Hazards**

4713 EPA evaluated the reasonably available information for environmental hazard endpoints associated with 4714 DEHP exposure to ecological receptors in aquatic and terrestrial ecosystems. EPA reviewed a total of 82

4715 high/medium quality ranked aquatic studies with 103 endpoints for toxicity to aquatic organisms. Of the

4716 82 aquatic studies, 73 demonstrated no acute or chronic effects up to or exceeding the highest

- 4717 concentration tested, exceeded the limit of solubility  $(3.0 \,\mu g/L)$ , or both (U.S. EPA, 2024h). In the 4718 terrestrial environment, EPA reviewed a total of 44 studies with 43 endpoints for toxicity to terrestrial
- 4718 receptors. Although low and uninformative studies were not used, they were reviewed for differences
- 4720 within the landscape/trends of the data. For an overview of the studies considered and environmental
- 4721 hazards refer to the *Draft Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP)* (U.S.
  4722 EPA, 2024a).
- 4723

4724 EPA has robust confidence that DEHP poses low hazard potential to aquatic vertebrates and 4725 invertebrates from acute exposure durations. This is supported by reasonably available data which 4726 consistently found that acute DEHP exposure poses no hazard up to and exceeding the limit of water 4727 solubility. Conversely, EPA has confidence that DEHP does pose potential hazard to aquatic vertebrates 4728 from chronic exposure durations below the limit of water solubility. This is supported by two studies in 4729 which effects on mortality, growth, and development were observed in Japanese medaka exposed to 0.1 4730 ug/L DEHP for 21d and followed for an additional 5 months. These studies reported effects from less 4731 than 0.01 to 10  $\mu$ g/L on mortality, growth, reproduction, and development. The COC of 0.0032  $\mu$ g/L 4732 was calculated from the chronic value (ChV) of  $0.032 \mu g/L$ , which is the geometric mean of the NOAEC of 0.01 µg/L and the LOAEC of 0.1 µg/L divided by an assessment factor (AF) of 10 (Chikae et al., 4733 4734 2004a; Chikae et al., 2004b). There is uncertainty, however, in the chronic aquatic invertebrate data 4735 since most studies only use DEHP concentrations above the limit of water solubility; these studies were not included in the development of the RQ. 4736 4737

4738 EPA has moderate confidence that DEHP has effects on growth and development to benthic dwelling 4739 invertebrate species below the limit of water solubility. This moderate confidence is supported by one 4740 study in which effects on growth were observed in the midge (*Chironomus riparius*). The COC of 0.03 4741  $\mu$ g/L was derived from an unbounded LOAEC of 0.3  $\mu$ g/L based on significant effects in body volume 4742 in C. riparius at every concentration tested divided by an AF of 10 (Kwak and Lee, 2005). There is 4743 uncertainty, however, regarding the hazard threshold for this species since an unbounded LOAEC was 4744 used to derive the COC because the study authors did not test lower concentrations where a NOAEC 4745 could be established. A pelagic invertebrate study with the marine copepod (Parvocalanus crassirostris) 4746 also showed effects around a similar threshold of less than 0.3 µg/L. This study was not considered for 4747 COC calculations due to analytical measurement concerns and potential background concentrations of 4748 DEHP.

4749

4750 EPA has robust confidence that DEHP poses low hazard potential to aquatic plants and algae. This
4751 robust confidence is supported by reasonably available data indicating DEHP poses no hazard to aquatic
4752 plants and algae below the limit of water solubility. EPA acknowledges the aquatic hazard conclusions
4753 are limited by studies that assessed hazard above the solubility limit or by the low number of studies
4754 available to assess hazard to aquatic plants and algae.

4755 4756 In the terrestrial environment, EPA has robust confidence that DEHP poses potential hazard to mammals 4757 and terrestrial plants, and slight confidence that DEHP poses potential hazard to birds. The conclusion 4758 that DEHP poses hazard to terrestrial mammals is supported by evidence obtained from 26 laboratory 4759 rodent studies conducted for use as human health models. EPA acknowledges that human health rodent 4760 models may not be fully representative of effects in a more diverse array of wild animal populations; 4761 however, it is important to note that hazard value was derived from the most sensitive ecologically-4762 relevant endpoint from the data set. The terrestrial mammalian hazard threshold of 80.79 mg/kg-day is 4763 the geometric mean of the NOAEL of 48.58 mg/kg-day and LOAEL of 140.15 mg/kg-day based on a

decrease in pup survival during lactation (<u>Tanaka, 2002</u>). Nearly all other rodent studies considered for
 hazard threshold determination were within an order of magnitude of the selected value.

4766

The conclusion that DEHP poses hazard to terrestrial plants is supported by two terrestrial plant studies that identified effects of DEHP on plant growth in six plant species (U.S. EPA, 2024a). The terrestrial plant hazard threshold was 10 mg/kg soil derived from a geometric mean of a NOAEC/LOAEC of 5.0/20 mg/kg soil for the growth of perennial ryegrass (*Lolium perenne*).

4771

The avian threshold was 100 mg/kg, derived from a single-dose pre-hatch egg injection study that
resulted in behavioral abnormalities (decreased imprinting preference scores). For avian taxa, EPA has
more uncertainty and less confidence in the hazard characterization, given (1) the number and quality of
the studies in the database; (1); (2) the study design, not allowing for dose-response effects to be
detected for mechanistic endpoints; and (3) uncertainty that the dose reached by the embryo is
representative of concentrations that would be depurated to the embryo in the egg development process.

4778

No studies were available to quantitatively assess the hazard of DEHP to terrestrial invertebrates as the
studies identified through systematic review showed no effects of DEHP. Other studies administered
DEHP as an aqueous test solution that exceeded the limit of solubility, or the amount of DEHP

4782 administered to test organisms was unclear. Therefore, a hazard threshold could not be established for

4783 terrestrial invertebrates. Based on the absence of studies with measurable effects in studies that have

4784 been reviewed, EPA has determined that DEHP is not hazardous to terrestrial invertebrates up to the 4785 exposures tested.

4786

# **5.3 Environmental Risk Characterization**

4787

## 5.3.1 Risk Assessment Approach

4788 EPA characterized the environmental risk of DEHP using risk quotients (RQs) (U.S. EPA, 1998;
4789 Barnthouse et al., 1982). The RQ is defined in Equation 5-1. Risk was also characterized qualitatively
4790 using a weight of evidence approach to support conclusions (Table 5-9).

4791

4794

#### 4792 **Equation 5-1. Calculating the Risk Quotient** 4793 *RO = Predicted Environmen*

RQ = Predicted Environmental Concentration/Hazard Threshold

4795 Environmental exposure concentrations for each compartment (*i.e.*, surface water, pore water, sediment, 4796 and soil) were based on measured (*i.e.*, monitored data and/or available literature) and/or modeled (*i.e.*, 4797 E-FAST 2014, VVMW-PSC, AERMOD, IIOAC) concentrations of DEHP from Section 3. EPA 4798 calculates hazard thresholds to identify potential concerns to aquatic and terrestrial species. These terms 4799 describe how the values are derived and can encompass multiple taxa or ecologically relevant groups of 4800 taxa as the environmental risk characterization serves populations of organisms within a wide diversity 4801 of environments. For hazard thresholds, EPA used the COCs calculated for aquatic organisms, and the 4802 hazard values calculated for terrestrial organisms as detailed within the Draft Environmental Hazard 4803 Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024a).

4804

4805 RQs equal to 1 indicate that environmental exposures are the same as the hazard threshold. If the RQ is 4806 above 1, the exposure is greater than the hazard threshold. If the RO is below 1, the exposure is less than

4807 the hazard threshold. Risk is indicated when the RQ greater than or equal to 1. RQs derived from

4808 modeled data for DEHP are described in Section 5.3.2 for aquatic organisms and Section 5.3.3 for

4809 terrestrial organisms. RQs derived from measured data for DEHP are presented within the *Draft* 

4810 Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024a), see Table 3-

- 4811 1 for aquatic organisms and Table 4-1 for terrestrial organisms. For aquatic species, acute risk is
- 4812 indicated when the RQ is greater than or equal to 1 for acute exposures. The chronic COC was derived
- 4813 from a 21-day exposure; therefore, the days of exceedance to demonstrate risk reflects the exposure
- 4814 period for that hazard value. For terrestrial species, RQ values are calculated from the hazard value for
- 4815 mammals, avian species, and plants.
- 4816

4820

- 4817 Monitoring data and published literature, when available, were used for comparison if modeled
- 4818 concentrations in the ambient environment exceeded the identified hazard benchmarks for aquatic and 4819 terrestrial receptors while also providing support for or in concurrence with modeled concentrations.
- 4819 terrestrial receptors while also providing support for or in concurrence with modeled concentrations.

## 5.3.2 Risk Characterization for Aquatic Receptors

4821 Fish and Aquatic Invertebrates (Acute Exposure)

4822 EPA did not identify any reasonably available data for the derivation of a hazard threshold for acute 4823 aquatic species, including sediment-dwelling organisms, therefore, RQs were not calculated for acute 4824 aquatic exposures. The data suggest that DEHP has low acute toxicity as no definitive effects were 4825 observed below the limit of water solubility and thus EPA has determined that DEHP is unlikely to 4826 result in risk for acute exposure to aquatic species. 4827

## 4828 Aquatic Plants and Algae

4829 No studies with definitive values below the limit of solubility were available to assess the hazard of
4830 DEHP to aquatic plants or algae. Therefore, a hazard threshold could not be established and RQs were
4831 not calculated. EPA has determined that DEHP is unlikely to result in risk for aquatic plants or algae.

4832

## 4833 Fish and Benthic Dwelling Organisms (Chronic Exposure)

4834 Releases of DEHP to surface water and sediment were identified for 31 COUs (Life cycle 4835 stage/Category/ Sub-category) represented by 16 OESs. The OESs with the highest and lowest DEHP 4836 surface water releases and corresponding flow rates were Plastic compounding (upper-bound) and 4837 Plastic converting (lower-bound), respectively (Table 5-2). Calculated RQs for chronic aquatic 4838 vertebrates and chronic aquatic benthic invertebrates can be found in Table 5-3 and Table 5-4, 4839 respectively, and were represented by the concentrations from TRI release data and hazard thresholds 4840 for aquatic organisms. The maximum daily average value for surface water and sediment pore water (in 4841 µg/L) was based on 21- and 32-day average release scenario for calculating RQs, respectively, modeled 4842 by VVWM-PSC. The release scenario duration was selected based on the study duration for those 4843 receptors. All days of exceedance were greater than the hazard threshold value study duration for each 4844 release scenario. Based on model estimates, release for the Plastic compounding OES's for surface water 4845 exceeded the EPA-determined DEHP limit of solubility (3.0 µg/L). Therefore, EPA used the DEHP 4846 limit of solubility 3.0 µg/L in calculations for quantitative risk assessment for surface water and 4847 sediment pore water.

4848

4849 Because this analysis is using TRI site data and not modeled data (*i.e.*, P50, P75, P90), only one release 4850 value is reported for each 7Q10, 30Q5, and harmonic mean flow scenario. Inputs for the TRI OES's are 4851 in Table 5-2. The flow data were represented by self-reported hydrologic reach codes on NPDES 4852 permits and represents the best available flow estimation from Enhanced Run Off Method (EROM) flow 4853 data. Surface water and benthic pore water RQs can be found in Table 5-3 and Table 5-4, respectively. 4854 Three different flow rates were considered to further refine risk under varying flow scenarios. 7Q10 is 4855 defined as seven consecutive days of lowest flow over a 10-year period used to calculate estimates of 4856 chronic surface water concentrations to compare with the COCs for aquatic life (Versar, 2014). The 4857 30Q5 is defined as 30 consecutive days of lowest flow over a 5-year period. Harmonic mean is defined as the inverse mean of reciprocal daily arithmetic mean flow values. The presented low end for an OES 4858

is calculated from the median reported release amounts whereas high-end is reported from maximum
release amounts. The specific high-end and low-end values presented depend on the number of sites
with programmatic data. Direct releases to surface water reported via TRI and DMR were applied as the
actual loading to surface water, including any onsite treatment prior to discharge.

4863

# Table 5-2. Releases to Water Based on Data from TRI and Resulting Water Concentrations Modeled Using PSC and Different Flow Conditions

OES (Release Distribution)	Annual Release (kg/year)	Maximum Number of Release Days <sup>a</sup>	Daily Release (kg/site-day)	Flow Rate 7Q10 <sup>b</sup> (m <sup>3</sup> /day)	Flow Rate HM <sup>c</sup> (m <sup>3</sup> /day)	Flow Rate 30Q5 <sup>d</sup> (m <sup>3</sup> /day)
Plastic compounding (upper-bound)	3.63	246	0.015	558.48	3,171.51	1,046.46
Plastic converting (lower-bound)	0.0045	253	1.79E-5	131.7	499.9	259.17

<sup>a</sup> Max days of release based on total number of operating days

 $^{b}$  7Q10 is defined as 7 consecutive days of lowest flow over a 10-year period. These flows are used to calculate estimates of chronic surface water concentrations to compare with the COCs for aquatic life (Versar, 2014).

<sup>c</sup> Harmonic mean (HM) is defined as the inverse mean of reciprocal daily arithmetic mean flow values. These flows represent a long-term average and are used to generate estimates of chronic human exposures via drinking water and fish ingestion.

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## 4867 Plastic Compounding – Upper Bound

4868 *Surface Water:* Surface water chronic RQ values for the plastic compounding OES all exceed 1 (Table 4869 5-3). Surface water concentrations were 17.6, 4.31, and 11.2  $\mu$ g/L for the 7Q10, harmonic mean, and 4870 30Q5 flow scenarios, respectively. Since the limit of solubility for DEHP is 3.0  $\mu$ g/L, the value used for 4871 surface water concentration in the calculation of RQs was 3.0  $\mu$ g/L.

4872

*Benthic Pore Water:* Benthic pore water chronic RQ values for the Plastic compounding OES all
exceeded 1 (Table 5-4). Pore water concentrations were 9.0, 2.25, and 5.74 μg/L for the 7Q10, harmonic
mean, and 30Q5 flow scenarios, respectively. Because the limit of solubility for DEHP is 3.0 μg/L, the
value used in the calculation of RQs was 3.0 μg/L for the 7Q10 and 30Q5 release scenarios.

4877

## 4878 Plastic Converting – Lower Bound

4879 *Surface Water:* Surface water chronic RQ values for the plastic converting OES all exceeded 1 (Table 4880 5-3). Pore water concentrations were 0.045, 0.023, and 0.034  $\mu$ g/L for the 7Q10, harmonic mean, and 4881 30Q5 flow scenarios, respectively.

4881 4882

4883 *Benthic Pore Water:* Benthic pore water chronic RQ values for the plastic converting OES were less 4884 than 1 for the 7Q10, 30Q5, and harmonic mean release scenarios (Table 5-4). Pore water concentrations 4885 were 0.023, 0.012, and 0.017  $\mu$ g/L for the 7Q10, harmonic mean, and 30Q5 flow scenarios, respectively. 4886 The second lowest resulting pore water concentration from a known TRI release represents the 4887 manufacturing OES with a pore water concentration of 0.391  $\mu$ g/L for the 7Q10 flow scenario. This 4888 results in a RQ of 13 when using the COC for sediment invertebrates of 0.03  $\mu$ g/L.

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- 4890

# Table 5-3. Chronic Aquatic Environmental Risk Quotients (RQs) by DEHP TRI Release Surface Water Concentrations (µg/L) Modeled by VVWM-PSC

COU (Life Cycle Stage: Category: Subcategory)	OES <sup>a</sup>	Flow Scenario (Flow Rate)	Surface Water Concentration (µg/L) (Limit of Water Solubility) <sup>b</sup>	Risk Quotient (RQ) <sup>c</sup>
Processing; Incorporation into formulation, mixture, or reaction product; Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing Processing; Incorporation into formulation, mixture, or reaction product;	Plastic	7Q10	17.6 [3.0]	>937.5
Adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing Processing; Incorporation into formulation, mixture, or reaction product; All other basic inorganic chemical manufacturing	compounding (upper bound)	Harmonic mean	4.31 [3.0]	>937.5
Processing; Incorporation into formulation, mixture, or reaction product; Wholesale and retail trade; services; ink, toner and colorant manufacturing		30Q5	11.2 [3.0]	>937.5
Processing; Incorporation into article; Plasticizer in basic organic chemical		7Q10	0.045	14.1
manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	Plastic converting	Harmonic mean	0.023	7.2
Industrial use; Other uses; Solid rocket motor insulation and other aerospace applications; Automotive articles	(lower bound)	30Q5	0.034	10.6
<sup><i>a</i></sup> The OESs with the highest and lowest DEHP surface water releases were plasti bound and lower bound, respectively. <sup><i>b</i></sup> The limit of solubility for DEHP is 3 µg/L. For cases in which the calculated su		-	•	

<sup>*b*</sup> The limit of solubility for DEHP is 3  $\mu$ g/L. For cases in which the calculated surface water concentration exceeded the limit of water solubility, EPA used the water solubility limit of 3  $\mu$ g/L as the exposure concentration and denoted the RQ as greater than the calculated value.

<sup>c</sup> RQ = exposure water concentration for each OES divided by the chronic COC of 0.0032 µg/L derived from a study in Japanese medaka O. latipes.

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# Table 5-4. Chronic Environmental Risk Quotients (RQs) by DEHP TRI Release Sediment Pore Water Concentrations (µg/L) Modeled by VVWM-PSC

COU (Life Cycle Stage/Category/Subcategory)	OES <sup>a</sup>	Flow Scenario (Flow Rate)	Sediment Pore Water Concentration (µg/L) (limit of water solubility)] <sup>b</sup>	Risk Quotient (RQ) <sup>c</sup>	
Processing; Incorporation into formulation, mixture, or reaction product; Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing		7Q10	9.0 [3.0]	>100	
<ul> <li>Processing; Incorporation into formulation, mixture, or reaction product;</li> <li>Adhesive manufacturing; plastic material and resin manufacturing;</li> <li>synthetic rubber manufacturing</li> <li>Processing; Incorporation into formulation, mixture, or reaction product;</li> <li>All other basic inorganic chemical manufacturing</li> </ul>	Plastic compounding (upper bound)	Harmonic mean	2.25	75	
Processing; Incorporation into formulation, mixture, or reaction product; Wholesale and retail trade; services; ink, toner and colorant manufacturing		30Q5	5.74 [3.0]	>100	
Processing; Incorporation into article; Plasticizer in basic organic		7Q10	0.023	0.77	
chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	Plastic converting	Harmonic mean	0.012	0.4	
Industrial use; Other uses; Solid rocket motor insulation and other aerospace applications; Automotive articles	(lower bound)	30Q5	0.017	0.57	
<sup><i>a</i></sup> The OESs with the highest and lowest DEHP surface water releases were plastic compounding (upper bound) and plastic converting (lower bound), respectively. <sup><i>b</i></sup> The limited of solubility for DEHP is 3 ug/L. The risk quotient presented represents the limit of solubility for DEHP. <sup><i>c</i></sup> Based on midge ( <i>C. riparius</i> ) 32-d hazard data exposed to DEHP resulting in a COC of 0.03 μg/L.					

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#### 4898 Modeled Generic Scenarios

4899 For OESs for which TRI data are not available, EPA used generic release scenarios and assumes that 4900 these modeled release scenarios would result in similar, or possibly more conservative, surface water 4901 concentrations, especially for untreated, low-flow aquatic releases. The use of hydraulic fracturing OES 4902 is a generic scenario with a surface water release, while two other OESs (use of laboratory chemicals 4903 [liquid], and use of automative care products) detail environmental releases that discharge to a 4904 combination of surface water, incineration, and/or landfill. Although OESs modeled from generic 4905 scenarios result in lower confidence in exposure estimates compared to those using release data from 4906 TRI, the chronic COCs for aquatic species indicate a high degree of hazard potential. Surface and pore 4907 water concentration of a DEHP modeled for these three OESs result in concentrations within the bounds 4908 of the lowest and highest DEHP concentrations from TRI releases and also result in RQs greater than 1 4909 under several flow conditions and release distributions (Table 5-5). The robust confidence in aquatic hazard thresholds and resulting risk estimates from for OES based on data from TRI releases increases 4910 4911 confidence in the risk characterization for these three OESs based on generic scenarios. These OESs 4912 based on generic scenarios would also result in deleterious effects to aquatic organisms, despite the 4913 relatively lower confidence in the exposure level, given the sensitive hazard values for aquatic 4914 organisms.

4915

# Table 5-5. Chronic Environmental Risk Quotients (RQs) by DEHP GS Releases for Surface and Pore Water Modeled by VVWM-PSC

COU (Life Cycle Stage; Category; Subcategory)	Days of Release	Media	DEHP Concentration	7Q10 Flow Rate <sup>a</sup>	СОС Туре	RQ <sup>b</sup>
	-	OES: I	Laboratory Chemi	cals	<u> </u>	
		Surface	0.178 µg/L	P75 CT	Chronic	55.6
Commercial use; Other uses;	260	water	0.038 µg/L	P90 HE	Chronic	12
Laboratory chemicals	260	Pore	0.088 µg/L	P75 CT	Chronic Benthic	2.94
		water	0.019 µg/L	P90 HE	Chronic Benthic	0.64
	OE	S: Use of	Automotive Care	Products <sup>c</sup>	·	
	260	Surface water	0.036 µg/L	P75 CT	Chronic	3.5
Commercial use;			0.009 µg/L	P90 HE	Chronic	0.92
Automotive; Automotive articles		Pore water	0.019 µg/L	P75 CT	Chronic Benthic	0.20
			0.005 µg/L	P90 HE	Chronic Benthic	0.05
		OES: Use	e in Hydraulic Fra	cturing		
		Surface	0.019 µg/L	P75 CT	Chronic	5.9
Industrial use; Other uses;	4	water	0.02 µg/L	P90 HE	Chronic	6.3
Hydraulic fracturing	4	Pore	0.0008 µg/L	P75 CT	Chronic Benthic	0.02
		water	0.0008 µg/L	P90 HE	Chronic Benthic	0.02
<sup><i>a</i></sup> 7Q10 flow rate and release di concentrations are presented w distribution, respectively.	ith the P75	and P90	of the 7Q10 flow f	or the centr	al tendency and high er	nd release

<sup>b</sup>Risk quotient for surface water is based on a chronic COC of  $0.0032 \,\mu$ g/L derived from a study in Japanese medaka.

COU (Life Cycle Stage; Category; Subcategory)	Days of Release	Media	DEHP Concentration	7Q10 Flow Rate <sup>a</sup>	СОС Туре	RQ <sup>b</sup>
Risk quotient for pore water is based on midge 32-d hazard data exposed to DEHP resulting in a COC of 0.03 $\mu$ g/L. <sup><i>c</i></sup> Use of Automotive Care Products is represented with a treatment removal due to environmental release to POTW. WWTP efficiency is represented with a 62% removal from a comprehensive USPOTW survey (U.S. EPA, 1982).						

## 5.3.3 Risk Characterization for Terrestrial Receptors

4919 EPA conducted an assessment for DEHP release to the terrestrial environment by preforming 4920 quantitative risk characterization using the OES/COU with the highest values of fugitive release or stack 4921 atmospheric deposition to soil. The OES with the highest fugitive and stack air release, selected using all 4922 TRI, NEI and/or generic scenario data, was application of paints, coatings, adhesives, and sealants 4923 (Section 8.1 of the Draft Environmental Media and General Population and Environmental Exposure 4924 for Diethylhexyl Phthalate (DEHP), (U.S. EPA, 2025q)). Soil concentrations were calculated from 4925 estimated soil catchment concentrations that could be in soil via maximum daily air deposition (95th 4926 percentile) of DEHP at a distance of 100m from a facility based on releases reported to TRI, resulting in a daily soil concentration of  $8.29 \times 10^{-6}$  mg/kg. RQs were less than 1 for exposure scenarios using the 4927 4928 highest IIOAC predictions for annual air deposition to soil at 100 m with an annual soil concentration of 4929  $3.0 \times 10^{-3}$  mg/kg.

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4931 Concentrations of DEHP in soil following agricultural application of municipal biosolids were not

4931 Concentrations of DEFR in son following agricultural application of municipal biosonds were not
 4932 identified nor were any monitoring studies identified during systematic review. Therefore, DEHP
 4933 concentrations in soil were estimated using the concentrations identified in sludge (*Draft Environmental* 4934 *Media and General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP)*, (U.S.
 4935 EPA, 2025q)). Annual application rates of biosolids ranged per application and frequency. Abiotic and

biodegradation were assumed to be negligible following biosolids applications. The surface loading rate
for spray or near surface injection applications range from 0.33 to 8,616 mg/m<sup>2</sup> while mixing
applications ranged from 0.0013 to 6.15 mg/m<sup>3</sup> depending on the application rate, frequency, and

- 4939 applied biosolids concentration.
- 4940

## 4941 Terrestrial Vertebrates (Mammals)

4942 Based on environmental monitoring and measured DEHP concentrations in soil, achieving a dose rate 4943 representative of the mammalian hazard threshold would be unlikely. Specifically, EPA conducted an 4944 assessment of risk to short-tailed shrew consuming earthworms from soil following biosolids application. Using the highest calculated topsoil concentration of 6.15 mg/kg following an agricultural 4945 4946 application of biosolids on soybeans, EPA assumed 100 percent uptake by a worm, so that the 4947 concentration of DEHP in the earthworm is equivalent to the soil concentration. Comparing the resulting 4948 dose to a shrew with a food intake rate of 55 percent earthworms, to the hazard threshold of 80.79 4949 mg/kg-day from a study of mice, the resulting RQ is less than 1 ( $4.32 \times 10^{-2}$ ). Furthermore, mean whole body earthworm samples from havfields and pastures with a history of biosolid amendment ranged from 4950 4951 approximately 0.15 to 0.29 mg/kg dw (Kinney et al., 2010), which is an order of magnitude lower than 4952 the calculated maximum of 6.15 mg/kg. Therefore, based on conservative assumptions of environmental topsoil concentrations and food consumption, EPA has determined that DEHP is unlikely to result in 4953 4954 risk for terrestrial mammals.

4955

## 4956 *Terrestrial Invertebrates*

Available invertebrate studies identified through systematic review showed no effects of DEHP. Since
no studies were available to quantitatively assess the hazard of DEHP to terrestrial invertebrates, a COC
could not be calculated. Other studies administered DEHP as an aqueous test solution that exceeded the

limit of solubility, or the amount of DEHP administered to test organisms was unclear. Therefore, a
 hazard threshold could not be established for terrestrial invertebrates because of the uncertainty

- 4962 regarding exposure concentrations.
- 4963

Mean whole body earthworm samples from hayfields and pastures with a history of biosolid amendment
samples ranged from approximately 0.15 to 0.29 mg/kg dw (Kinney et al., 2010). Studies that assessed
DEHP in invertebrates did not see effects up to and exceeding 5,000 mg/kg after 50 days (Jensen et al.,
2001). Based on the absence of measurable effects in studies of terrestrial invertebrates exposed to soil
concentrations approximately five orders of magnitude higher than soil concentrations from monitoring
studies of soils with a history of biosoilds application., EPA has determined that DEHP is unlikely to
result in risk for terrestrial invertebrates.

#### 4971 4972 *Birds*

4973 The avian hazard threshold was derived from pre-hatch DEHP egg injections in the chicken (Gallus 4974 gallus domesticus), which resulted in a LOAEL of 100 mg/kg-day based on effects on chick imprinting 4975 behavior (Abdul-Ghani et al., 2012), and a NOAEL was not established. The study authors indicated 4976 that doses resulting in effects were extremely high, and the elevated levels of alkaline phosphatase noted 4977 during the biochemical evaluation reflected non-specific toxicity resulting from the high dose of DEHP. 4978 No other effects on apical outcomes were observed in avian taxa even at high doses, and the effects 4979 observed at these doses are not expected in the environment. Two other studies from literature reported 4980 effects from DEHP, including a 45-day oral gavage study in quail (*Coturnix coturnix*), which 4981 demonstrated alterations in kidneys at 250 mg/kg-bw/day and in cardiac tissue at 500 mg/kg-day (Wang et al., 2020; Wang et al., 2019). However, these histological changes are not considered relevant to 4982 4983 species survival, growth, or reproduction. Furthermore, these doses are much higher than would be 4984 expected to occur from environmentally relevant concentrations.

4985

4986 Biota monitoring values of DEHP reported concentrations orders of magnitude lower than 4987 concentrations used in the hazard studies. Collected samples from failed peregrine falcon (Falco 4988 peregrinus) eggs within Germany as part of a large survey of pollutants reported "traces of DEHP" with 4989 no concentration reported within the study (LOD = 0.001 mg/kg dw; (Schwarz et al., 2016)). In another 4990 study, DEHP concentrations within liver tissue of a marine avian species, surf scooter (Melanitta 4991 perspicillata), were reported at a mean of 0.005 mg/kg wet weight (Mackintosh et al., 2004). A 4992 comprehensive study on environmental pollutants within egg samples was conducted on seabird species 4993 within coastal Norway (Huber et al., 2015). Concentrations of DEHP recorded within pooled eggs of the 4994 European herring gull (Larus argentatus) were between 0.011 to 0.024 mg/kg ww and 0.003 to 0.042 4995 mg/kg ww in European shag eggs (Phalacrocorax aristotelis aristotelis) (Huber et al., 2015). These 4996 measured phthalate concentrations found in eggs of wild bird populations are four orders of magnitude 4997 lower than that used in the laboratory administered injection treatment of 100 mg/kg DEHP in species 4998 chicken eggs by Abdul-Ghani et al. (2012). Therefore, EPA has determined that exposure to DEHP is 4999 unlikely to result in risk for birds. 5000

## 5001 Terrestrial Plants

5002 Two studies in terrestrial plant species were identified by EPA as relevant for quantitative assessment

5003 for the highest DEHP OES release to air (application of paints, coatings, adhesives, and sealants). The

terrestrial plant hazard threshold of 10 mg/kg soil was the geometric mean of the NOAEC of 5.0 mg/kg

- soil and the LOAEC of 20 mg/kg soil based on effects on the growth of perennial ryegrass (*Lolium*
- 5006 *perenne*) after 72-hour exposure (<u>Ma et al., 2015</u>) (Table 5-6). The RQ was less than 1 for terrestrial
- 5007 plants exposed via air deposition (fugitive or stack release). Therefore, EPA has determined that DEHP
- 5008 is unlikely to result in risk for terrestrial plants.

5009

### 5010 Biosolids

- 5011 Soil surface concentrations for biosolids were calculated from the minimum and maximum
- 5012 recommended application rates for each agricultural crop cover (in the Draft Environmental Media and
- 5013 General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP) (U.S. EPA,
- 5014 <u>2025q</u>)). Concentrations of DEHP in biosolids were selected from the observed concentrations in
- 5015 biosolids measured during the 2008 EPA National Sewage Survey (U.S. EPA, 2009). Using the generic
- application scenarios and biosolids concentrations collected from the national survey, the maximum
- 5017 concentration of DEHP within topsoil resulted in an RQ of 0.62 for terrestrial plants (Table 5-7).
  5018 Therefore, EPA has determined that DEHP is unlikely to result in risk for terrestrial plants.
- 5010

# Table 5-6. Risk Quotients (RQs) For Terrestrial Plants Based on Modeled Air Deposition of DEHP to Soil from Reported or Modeled Fugitive Emissions.

COU (Life Cycle Stage; Category; Subcategory)	OES	Annual Soil Concentration (mg/kg)	Hazard Value (mg/kg)	RQ
Commercial use; Furnishing, cleaning, and treatment care products; All-purpose waxes and polishes				
Industrial Use; construction, paint, electrical, and metal products; Paints and coatings				
Commercial use; Construction, paint, electrical, and metal products; Adhesives and sealants	Application of paints, coatings, adhesives, and sealants	3.0E-03	10	3.0E-04
Commercial use; Construction, paint, electrical, and metal products; Paints and coatings	scalants			
Commercial use; Furnishing, cleaning, and treatment care products; All-purpose waxes and polishes				

5022

## 5023

# 5024Table 5-7. Risk Quotients (RQs) For Terrestrial Plants Based on Biosolids Calculated Using5025Modeled Biosolid Land Application Data

Maximum Monitored Biosolid Concentration (mg/kg) from the 2008 EPA National Sewage Survey	Topsoil Concentration (mg/kg)	Hazard Value (mg/kg)	RQ
310	6.15	10	0.62

#### 5026

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## 5.3.4 Risk Characterization Based on Trophic Transfer

5028 DEHP is not expected to be persistent in the environment, as it is expected to degrade rapidly under 5029 most environmental conditions, with delayed biodegradation in low-oxygen media. In the atmosphere,

5030 DEHP is unlikely to remain for long periods of time as it is expected to undergo photolytic degradation

5031 through reaction with atmospheric hydroxyl radicals, with estimated half-lives of 5.5 hours. DEHP is

5032 predicted to hydrolyze slowly at ambient temperature but is not expected to persist in aquatic media as it

5033 undergoes rapid aerobic biodegradation (see Section 2.2). DEHP has the potential to remain for longer 5034 periods of time in soil and sediments, but due to the inherent hydrophobicity (log Kow = 7.60) and 5035 sorption potential (log Koc = 5.51) DEHP is not expected to be bioavailable for uptake. Using the Level 5036 III Fugacity model in EPI Suite<sup>TM</sup> (LEV3EPI<sup>TM</sup>) (see Section 2), DEHP's overall environmental half-life 5037 was estimated to be on the order of days to weeks (U.S. EPA, 2017). Therefore, DEHP is not expected 5038 to be persistent in the atmosphere, aquatic or terrestrial environments.

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5040 EPA did not conduct a quantitative analysis of DEHP food chain trophic transfer. Due to the physical 5041 and chemical properties, environmental fate, and exposure parameters of the chemical, DEHP is not 5042 expected to persist in surface water, groundwater, or air. Based on the low water solubility of 0.003 5043 mg/L, log Koc of 5.41 to 5.95, and low reported BCF values of 0.05 to 114, DEHP is expected to have low bioaccumulation potential, no apparent biomagnification potential, and low potential for uptake 5044 5045 overall. DEHP is expected to degrade rapidly via direct and indirect photolysis and has an environmental 5046 biodegradation half-life in aerobic environments on the order of days to weeks. Further, DEHP is not 5047 subject to long range transport and transforms in the environment via biotic and abiotic processes to 5048 form monoisononyl phthalate, isononanol, and phthalic acid. DEHP shows strong affinity and sorption 5049 potential for organic carbon in soil and sediment. Approximately 64 percent of the DEHP present in 5050 wastewater is expected to be accumulated in sewage sludge and released with biosolids disposal or 5051 application, and the remaining fraction is sorbed to suspended solids in wastewater treatment effluent 5052 and discharged with surface water (U.S. EPA, 1982). DEHP may persist in sediment, soil, biosolids, or 5053 landfills after release to these environments, but bioavailability is expected to be limited. The estimated 5054 BCF/BAF suggest DEHP does not meet the criteria to be considered bioaccumulative (BCF/BAF > 5055 1,000), and bioaccumulation and bioconcentration in aquatic and terrestrial organisms are not expected 5056 to be important environmental processes (U.S. EPA, 2012c). 5057

5058 Concentrations of DEHP in soil following agricultural application of municipal biosolids were not 5059 identified from TRI or the NEI release data nor were any monitoring studies identified during systematic 5060 review. As such, DEHP concentrations in soil were estimated using the concentrations identified in 5061 sludge, ranging from 0.657 to 0.31 mg/kg (U.S. EPA, 2009). The maximum biosolid topsoil 5062 concentration was estimated at 6.15 mg/kg based on application to soybeans (Draft Environmental 5063 *Media and General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP)*, (U.S. 5064 EPA, 2025q)). The mammalian hazard threshold was 80.79 mg/kg-day in the *Draft Environmental* 5065 Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024a). Terrestrial organisms, such 5066 as mammals, would need to consume a considerable over 13 kg of DEHP-tainted soil or prey items to 5067 reach the threshold for toxicity.

5068 Given the reasonably available data, EPA has robust confidence that that DEHP is not readily found or if 5069 5070 found is in relatively low concentrations in organism tissues, and that DEHP has low bioaccumulation 5071 and biomagnification potential in aquatic and terrestrial organisms, and thus low potential for trophic 5072 transfer through food webs. The conclusion that DEHP does not biomagnify is supported by the 5073 estimated BCF, BAF, BSAF, and TMF values and studies specifically centered on the characteristics of 5074 trophic transfer of DEHP and other phthalates. This conclusion is consistent with observations made for 5075 other phthalates with measured BCF/BAFs such as DIDP, DINP, DBP, DIBP, and DCHP. 5076

# 50775.3.5Overall Confidence and Remaining Uncertainties in Environmental Risk5078Characterization

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## 5.3.5.1 Risk Characterization Confidence

5080 The overall confidence in the risk characterization combines the confidence from the environmental 5081 exposure, hazard threshold, and trophic transfer sections. This approach aligns with *Draft Systematic* 5082 Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances (U.S. EPA, 2021a) and 5083 Draft Systematic Review Protocol for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025v). Confidence 5084 was evaluated from environmental exposures and environmental hazards. Hazard confidence was 5085 represented by evidence type as reported previously in the *Draft Environmental Hazard Assessment for* Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024a). Exposure confidence has been synthesized from 5086 5087 Section 3 and is further detailed within Section 5.1. All studies that factored into the environmental 5088 hazard and environmental media and general populations section received an overall quality 5089 determination of high or medium. Synthesis of confidence for exposure and hazard resulted in the 5090 following confidence ranks for risk characterization RQ inputs: robust for chronic aquatic evidence, 5091 moderate for chronic benthic evidence, moderate for terrestrial plant evidence based on air deposition, and moderate for terrestrial plant evidence based on biosolid land application (Table 5-8). 5092

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## 5094 RQ Inputs for Aquatic and Benthic Assessments

5095 Combining the robust confidence for the TRI-modeled surface water and benthic pore water sediment 5096 DEHP concentrations with robust hazard confidences for aquatic and benthic assessments (robust and 5097 robust, respectively) resulted in overall confidences of robust in the RQ inputs for chronic aquatic and 5098 benthic assessments, respectively (see Table 5-3 and Table 5-4).

5099

5100 EPA has robust confidence that DEHP poses hazard to aquatic vertebrates on a chronic basis below the 5101 limit of water solubility. This robust confidence is supported by two studies in which effects on 5102 mortality growth, and development were observed in Japanese medaka exposed to 0.1 µg/L DEHP for 5103 21-d (Chikae et al., 2004a; Chikae et al., 2004b) and further supported with chronic hazard studies 5104 conducted by Golshan et al. (2015), Corradetti et al. (2013), and Zanotelli et al. (2010). These studies 5105 reported effects on mortality, growth, reproduction, and development at concentrations ranging from 5106 0.01 to 10  $\mu$ g/L and exposure durations ranging from 21 to 91 days. For benthic dwelling invertebrates, 5107 EPA has moderate confidence based on effects observed on growth and development. This confidence is 5108 supported by one study in which effects on growth were observed in midge exposed to 0.3 µg/L DEHP 5109 (Kwak and Lee, 2005). However, since a LOAEC was used in the COC, there is uncertainty regarding 5110 the actual hazard value for this group. Although not used for COC determination, a pelagic invertebrate 5111 study with the marine copepod (Parvocalanus crassirostris) also showed effects around a similar 5112 threshold of less than 0.3  $\mu$ g/L (Heindler et al., 2017). This study was not considered for COC 5113 calculations due to analytical measurement concerns and background concentrations of DEHP.

5114

5115 The different PSC release scenarios (described in Section 5.3.2) were used to estimate and quantify 5116 concentrations of DEHP within surface water and sediment. PSC considers model inputs of physical and 5117 chemical properties of DEHP (*i.e.*, K<sub>OW</sub>, K<sub>OC</sub>, water column half-life, photolysis half-life, hydrolysis 5118 half-life, and benthic half-life) and allows EPA to estimate sediment concentrations. The use of vetted 5119 physical and chemical properties of DEHP increases confidence in the application of the PSC model. 5120 Only the chemical release amount, days-on of chemical release, and the receiving water body hydrologic 5121 flow were changed for each COU/OES. As presented in Section 3.3.1.1, the application of TRI-reported 5122 release data from actual facilities provides high confidence in the annual release estimates. Facility 5123 releases are paired with receiving waterbodies reported through NPDES permits, and flow statistics are

5124 calculated from the NHDPlus V2.1 EROM flow database, based on gage-adjusted modeled hydrologic

5125 flows. TRI-reported releases are based on releases to surface water at the external outfall of a releasing

- 5126 facility, and therefore include any treatment or removal from onsite wastewater processes. Overall
- 5127 confidence in the estimated environmental concentrations modeled from these releases is moderate to 5128 robust.
- 5128

5130 Concentrations of DEHP within the surface and pore water were estimated using the highest 2015 to 5131 2020 annual releases and estimates of 7Q10 hydrologic flow data for the receiving water body that were 5132 derived from NHD-modeled EROM flow data. The 7Q10 flow represents the lowest 7-day flow in a 10-5133 year period and is a conservative approach for examining a condition where a potential contaminate may

- 5134 be predicted to be elevated due to periodic low-flow conditions. A tiered approach was applied,
- 5135 examining the highest environmental media concentrations resulting from a releasing facility, and
- 5136 progressively stepping through the next lower release estimates. The finding of an RQ value greater than
- 5137 one for even the lowest environmental concentration from a modeled release derived from TRI-reported 5138 and facility-specific data provides robust confidence in this assessment for the ecological risk presented.
- 5139

## 5140 RQ Inputs for Terrestrial Plant Assessments

5141 EPA has robust confidence in the terrestrial plants hazard value due to the number of terrestrial plant 5142 endpoints with ecologically relevant endpoints and well-represented terrestrial plant data (two terrestrial 5143 plant studies that identified effects of DEHP on plant growth in six plant species; (Gao et al., 2018; Ma 5144 et al., 2015)). In perennial ryegrass, root elongation and seedling growth significantly decreased by 9 5145 and 22 percent, respectively, at 20 mg/kg DEHP resulting in 72-hour NOAEC/LOAEC of 5.0/20 mg/kg 5146 soil (dry weight). However, both root elongation and seedling growth increased at higher concentrations 5147 of DEHP (100 and 500 mg/kg DEHP). In the radish, root elongation and seedling growth were found to 5148 be significantly increased, compared to controls, at all tested concentrations. In alfalfa, root elongation 5149 and seedling growth were both significantly decreased at all treated concentrations (5 mg/kg soil and 5150 above). In wheat, root elongation was decreased in all treated groups (5 mg/kg soil and above), but 5151 seedling growth was only decreased at the low concentration (5 mg/kg soil). At 5.0 mg/kg soil DEHP, 5152 alfalfa root length and seedling growth decreased by 25 and 7 percent, respectively, and by 10 and 6 5153 percent, respectively, in bread wheat (Ma et al., 2014).

5154

5155 EPA has moderate confidence in the IIOAC-modeled results used to characterize exposures and 5156 deposition rotes. Conservative inputs (a.g., maximum estimated embient air release) and assumptions

- 5156 deposition rates. Conservative inputs (*e.g.*, maximum estimated ambient air release) and assumptions 5157 (*e.g.*, 100 m from a facility with no annual degradation) were included in modeling parameters. Soil
- 5158 concentrations of DEHP from land application of biosolids were not quantitatively assessed as DEHP
- 5150 was expected to have limited persistence potential and mobility in soils receiving biosolids.
- 5160 Concentrations of DEHP in soil following agricultural application of municipal biosolids were not
- 5161 identified from TRI or NEI release data nor were any monitoring studies identified during systematic
- 5162 review. As such, DEHP concentrations in soil were estimated using the concentrations identified in
- 5163 sludge concentrations in accordance with 40 CFC Part 503, *Standards for the Use of Disposal of Sewage*
- 5164 *Sludge*. Uncertainties in the soil resulting from land application of biosolids containing DEHP result in
- 5165 slight confidence for DEHP.
- 5166
- 5167 Combining the moderate exposure confidence for the calculated soil based on IIOAC modeling of
- 5168 DEHP air deposition from TRI-reported fugitive emissions with the robust hazard confidence for
- terrestrial plants resulted in overall confidences of robust and moderate in the RQ inputs for the
- 5170 terrestrial plant exposed via air deposition and biosolid application, respectively (Table 5-6 and Table
- 5171 5-7). Confidence and uncertainties in environmental hazard and environmental exposure estimates from 5172 PSC have been described in Section 5 of the Durft Environment (11)
- 5172 PSC have been described in Section 5 of the *Draft Environmental Hazard Assessment for Diethylhexyl* 5173 Phthalata (DEHP) (U.S. EPA, 2024a) and Section 4.2.1 of the Dwaft Environmental Madi
- 5173 *Phthalate (DEHP)* (U.S. EPA, 2024a) and Section 4.3.1 of the *Draft Environmental Media and General*

- 5174 Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q),
- 5175 respectively.
- 5176

# 5177 Table 5-8. Evidence Table Summarizing Overall Confidence for Environmental Risk 5178 Characterization

Types of Evidence	Exposure	Hazard	Trophic Transfer	Risk Characterization RQ Inputs		
Aquatic						
Chronic aquatic assessment	+++	+++	N/A	Robust		
Chronic benthic assessment	+++	++	N/A	Moderate		
		Terrestrial				
Terrestrial plant assessment, air deposition	++	+++	N/A	Robust		
Terrestrial plant assessment, biosolid land application	+	+++	N/A	Moderate		

+ + + Robust confidence suggests thorough understanding of the scientific evidence and uncertainties. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the risk estimate.

+ + Moderate confidence suggests some understanding of the scientific evidence and uncertainties. The supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize risk estimates.

+ Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the scenario, and when the assessor is making the best scientific assessment possible in the absence of complete information. There are additional uncertainties that may need to be considered.

5179

5180 Table 5-9 represents receptors for which qualitative risk characterization was performed. Within the

aquatic environment a qualitative assessment was performed with the exposure pathway for surface

5182 water including receptors for acute exposure to aquatic organisms, aquatic plants, and algae. A

qualitative assessment of soil includes terrestrial invertebrates for which exposure studies did not
 determine a hazard value for these taxa within a soil medium. Risk to avian and mammals was assessed

5185 qualitatively.

5186	Table 5-9. Evidence Table for Q	Qualitative Risk Characterization to S	pecific Receptor Groups
			r · · · · · · · · · · · · · · · · · · ·

Receptors	Exposure	Hazard <sup>a</sup>	Trophic Transfer <sup>b</sup>	Qualitative Assessment
Acute aquatic assessment	EPA has high confidence in quantifying a high-end estimated concentration at the point of release as reporting data for actual facilities were used and many conservative assumptions, such as the assumption that there is no removal of DEHP prior to release in surface water, was applied to the modeling.	EPA has robust confidence that acute DEHP exposure poses no hazard up to and exceeding the limit of water solubility.	Investigations on DEHP consistently present evidence that DEHP has low bioaccumulation potential and exhibits trophic dilution within aquatic ecosystems (Burkhard et al., 2012). The case study presented within Burkhart et al. (2012) further supports the weight of evidence that DEHP does not biomagnify, partially due to the crucial role of biotransformation	Hazard thresholds from acute DEHP exposures were not identified within invertebrates or vertebrates nor were hazard thresholds identified for aquatic plants or algae. EPA has robust confidence in the acute aquatic assessment and moderate confidence in the Algal and aquatic plants assessment. DEHP is unlikely to pose risk to aquatic
Algal and aquatic plants assessment	TRI data from the COU/OESs with the highest and lowest resulting concentrations within surface water and pore water were used to represent upper and lower bounds with water releases of DEHP.	EPA has robust confidence that DEHP exhibits low hazard potential to aquatic plants and algae. Available aquatic plant and algae hazard studies were not able to identify acute hazard thresholds for DEHP below the limit of solubility.	resulting in trophic dilution across trophic levels. EPA has robust confidence that DEHP has limited bioaccumulation and bioconcentration potential based on its physical, chemical, and fate	vertebrates and invertebrates on an acute exposure basis and aquatic plants and algae.
Terrestrial invertebrate assessment	EPA has moderate confidence in the IIOAC-modeled results used to characterize exposures and deposition rates. DEHP present in soil through the application of biosolids or otherwise introduced to topsoil has limited mobility within the soil column. High-quality biodegradation rates and physical and chemical properties suggest that DEHP will have limited persistence potential and mobility in soils receiving biosolids.	Studies that assessed DEHP in soil invertebrates (springtails) did not see effects up to and exceeding 5000 mg/kg after 50 days (Jensen et al., 2001). Other studies performed on nematodes administered DEHP as an aqueous test solution that exceeded the limit of solubility, or the amount of DEHP administered to test organisms was unclear.	properties, biotransformation, and biomonitoring data. Investigations on DEHP consistently present evidence that DEHP has low bioaccumulation potential and exhibits trophic dilution within aquatic ecosystems ( <u>Burkhard et al.</u> , <u>2012</u> ). The case study presented within Burkhart et al. ( <u>2012</u> ) further supports the weight of evidence that DEHP does not biomagnify, partially due to the	EPA has moderate confidence that reasonably available information on DEHP in soil concentrations from air deposition and environmental monitoring; in combination with the absence of hazard studies with measurable effects from chronic DEHP exposure provide evidence that DEHP is unlikely to pose risk to terrestrial invertebrates.
Avian assessment	DEHP concentrations found in eggs of wild bird populations are four	The avian hazard threshold was derived from pre-hatch DEHP	crucial role of biotransformation resulting in trophic dilution	EPA has moderate confidence that the qualitative assessment

Receptors	Exposure	Hazard <sup>a</sup>	Trophic Transfer <sup>b</sup>	Qualitative Assessment
	orders of magnitude lower than that used in the laboratory administered injection treatment of 100 mg/kg DEHP in species chicken eggs by Abdul-Ghani (2012). Due to the high confidence in the biodegradation rates and physical and chemical data, there is robust confidence that DEHP in soils will not be mobile and will have low persistence potential. The existing literature suggests that DEHP present in biosolid amended soils will likely not be absorbed by any plants or crops growing in the soil.	egg injections, which resulted in a less than 100/100 mg/kg/day NOAEL/LOAEL for chick imprinting behavior in the chicken ( <i>Gallus gallus</i> <i>domesticus</i> ) ( <u>Abdul-Ghani et al.,</u> <u>2012</u> ). Two oral studies in quail have indicated hazards to cardiac and kidney tissue at higher DEHP concentrations of 500 mg/kg- bd/day and 250 mg/kg-bw/day, respectively.	across trophic levels. EPA has robust confidence that DEHP has limited bioaccumulation and bioconcentration potential based on its physical, chemical, and fate properties, biotransformation, and biomonitoring data.	
Mammalian assessment	Oral intake of DEHP would be the expected route of exposure for mammals. Using the highest estimated topsoil concentration of 6.15 mg/kg following an agricultural application of biosolids on soybeans, assuming a 100% uptake by a worm (food source) then ingested by a short-tailed shrew with a food intake rate of 55%, and a TRV of 80.79 mg/kg-bw/d, the resulting RQ is less than 1 (4.32E–02).	Twenty-six laboratory rat and mouse studies were assessed with the most sensitive (lowest LOAEL) ecologically-relevant endpoint chosen to represent the terrestrial mammalian hazard threshold. The terrestrial mammalian COC that was determined was 80.79 mg/kg- bw/d based on decreased pup survival during lactation (Tanaka, 2002).		EPA has robust confidence that reasonably available information indicates that DEHP would not be present within biota, prey, or environmental media at concentrations that produce hazard within mammals and is unlikely to pose risk to mammals.

<sup>*a*</sup> Overall confidence for each receptor as presented within Apx B-2 from the *Draft Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2024a).

<sup>b</sup> Robust overall confidence that DEHP has limited bioaccumulation and bioconcentration potential as presented within Section 12 of the *Draft Environmental Media and General Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025q).

5187	5.3.6 Summary of Environmental Risk Characterization
5188	Aquatic Organisms
5189	TRI data from the COU/OESs with the highest and lowest resulting concentrations within surface water
5190	and pore water were used to represent bounds that encompass all COU/OESs with water releases of
5191	DEHP. Direct releases to surface water reported via TRI and DMR were applied as the actual loading to
5192	surface water, including any onsite treatment prior to discharge. The higher bound release included the
5193	OES of Plastic compounding and resulted in the highest environmental concentration for the aquatic
5194	environment (Table 3-7). The OES of Plastic converting resulted in the lowest environmental
5195	concentration for the aquatic environment and thus served as a lower bound of the assessment for TRI
5196	based releases (Table 5-3).
5197	
5198	Risk quotients were calculated for chronic aquatic exposures based on COCs for aquatic organisms
5199	described within Section 5.2. For the aquatic assessment, all RQs calculated from TRI surface water
5200	releases previously detailed as resulting in the highest and lowest DEHP concentrations were greater
5201	than one (Table 5-3). For the benthic assessment, the OES resulting in the highest concentrations of
5202	DEHP in pore water (Plastic compounding) resulted in RQs greater than one, while the OES resulting in
5202	the lowest concentration of DEHP in pore water resulted in an RQ of 0.77 when using the 7Q10 flow
5203 5204	rate (Table 5-4). Furthermore, for the benthic assessment all other facilities reporting releases results in
5201	pore water concentrations above the COC for sediment invertebrates, thus resulting in RQs greater than
5206	1.
5207	
5208	EPA has robust and moderate confidence in the risk characterization RQ inputs for the chronic aquatic
5200 5209	and chronic benthic assessment, respectively. Hazard thresholds from acute DEHP exposures were not
5210	identified within aquatic invertebrates or vertebrates nor were hazard thresholds identified for aquatic
5210	plants or algae. EPA has robust confidence in the acute aquatic assessment and moderate confidence in
5211	the algal and aquatic plants assessment. DEHP is unlikely to pose risk to aquatic vertebrates and
5212	invertebrates on an acute exposure basis, and aquatic plants and algae.
5215 5214	invercestates on an acute exposure basis, and aquate plants and argue.
5215	Although there was no hazard threshold identified from chronic DEHP exposure for aquatic
5215	invertebrates in the water column, the results of quantified risk estimates using COCs representing
5210	chronic DEHP exposures to fish and sediment invertebrates adds to the weight of scientific evidence
5217	supporting the identification of risk to the aquatic environment for this chemical. Based on surface water
5210	concentrations of DEHP and COCs for hazard to aquatic organisms, EPA expects that all COUs
5220	represented by analysis would result in DEHP concentrations that produce harm to fish and benthic
5220	invertebrates (Table 5-10).
5221	
5223	DEHP concentrations modeled with generic scenarios or for discharges to multiple media in the same
5223 5224	OES ( <i>i.e.</i> , surface water, non-POTW, indirect discharge to POTW, emissions via fugitive or stack air,
5224	treatment via incinerations) were assessed qualitatively. The use of hydraulic fracturing OES is a generic
5225 5226	scenario with a surface water release while two other OESs (use of laboratory chemicals [liquid], use of
5220 5227	laboratory chemicals [solid], and use of automative care products) detail environmental releases that
5227	discharge to a combination of surface water, incineration, or landfill. Although OESs modeled from
5228 5229	generic scenarios may result in reduced confidence compared to TRI releases. Surface and pore water
5230	concentration of a DEHP modeled for these three OESs result in concentrations within the bounds of the
5230 5231	lowest and highest DEHP concentrations from TRI releases and also result in RQs greater than 1 under
5231 5232	several flow conditions and release distributions (Table 5-5). The robust confidence in aquatic hazard
5232 5233	thresholds and resulting risk estimates from TRI releasing OESs increases confidence in a qualitative
5233 5234	assessment for these three OESs. The chronic COCs for aquatic species indicate a high degree of hazard
5434	assessment for these times of the chrome coes for aquatic species indicate a high degree of hazard

- 5235 potential and EPA believes that under low flow conditions, these OESs would result in deleterious
- 5236 effects to aquatic organisms from chronic aquatic DEHP exposures.
- 5237

## 5238 Terrestrial Plants

A assessment to examine air releases and subsequent air to soil deposition was employed to produce quantified risk estimates for terrestrial plants. The OES with the highest fugitive or stack air release, was application of paints, coatings, adhesives, and sealants and was used in the determination of risk of DEHP air deposition to soil. The RQ value from this assessment was less than one (Table 5-6). Using the generic application scenarios and biosolids concentrations collected from the national survey, the maximum concentration of DEHP within topsoil resulted in an RQ of 0.62 for terrestrial plants (Table 5-7). DEHP is expected to have limited persistence potential and mobility in soils receiving biosolids.

- EPA has robust and moderate confidence in the risk characterization RQ inputs for the terrestrial plant
  assessment for air deposition to soil and biosolid land application, respectively. EPA expects DEHP
  would not produce hazards within terrestrial plants from air to soil deposition or the application of
  biosolids.
- 5249 bioso 5250

## 5251 Mammals

Risk to terrestrial mammals from DEHP exposure through ingestion of terrestrial invertebrates is

5253 expected to be limited and not approach the hazard threshold of 80.79 mg/kg-bw/d. Using the highest 5254 estimated topsoil concentration of 6.15 mg/kg following an agricultural application of biosolids on 5255 soybeans, assuming a 100 percent uptake by a worm (food source) then ingested by a short-tailed shrew 5256 with a food intake rate of 55 percent, and a TRV of 80.79 mg/kg-day, the resulting RQ is less than 1  $(4.32 \times 10^{-2})$ . EPA has robust confidence that DEHP has limited bioaccumulation and bioconcentration 5257 5258 potential based on its physical, chemical, and fate properties, biotransformation, and the empirical 5259 metrics of bioaccumulation metrics. EPA has robust confidence that reasonably available information 5260 indicates that DEHP would not be present within biota, prey, or environmental media approaching

5261 concentrations that produce hazard within mammals and is unlikely to pose risk to mammals.

#### 5262 5263 **Birds**

5264 The avian hazard threshold was derived from pre-hatch DEHP egg injections, which resulted in a LOAEL of 100 mg/kg-day, with no NOAEL established. However, this dosage exceeds environmentally 5265 5266 relevant concentrations. The measured phthalate concentrations found in eggs of wild bird populations 5267 in monitoring studies are four orders of magnitude lower than that used in the laboratory administered 5268 injection treatment. Furthermore, EPA has robust confidence that DEHP has limited bioaccumulation 5269 and bioconcentration potential based on empirical bioaccumulation data and on its biotransformation 5270 and physical, chemical, and fate properties. EPA has moderate confidence in the qualitative assessment 5271 presented within Section 5.3.3 of the current environmental risk characterization. Reasonably available 5272 information indicates that DEHP is unlikely to pose risk to birds based on biomonitoring, limited trophic 5273 transfer, and measured DEHP concentrations in the environment.

5274

## 5275 *Terrestrial Invertebrates*

5276 No studies were available to quantitatively assess the hazard of DEHP to terrestrial invertebrates.

5277 Available invertebrate studies identified through systematic review showed no effects from DEHP

5278 exposure up to 5,000 mg/kg (Section 5.3.3), four orders of magnitude higher than concentrations

detected in earthworms from soils amended with biosolids. EPA has moderate confidence that

5280 reasonably available information on DEHP in soil concentrations from air deposition and environmental

- 5281 monitoring; in combination with the absence of hazard studies with measurable effects from chronic
- 5282 DEHP exposure provide evidence that DEHP is unlikely to pose risk to terrestrial invertebrates.

### 5283 Table 5-10. Environmental Risk Summary and Basis for Quantified Risk Characterization

COU (Life Cycle Stage; Category; Subcategory)	Occupational Exposure Scenario (OES)	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Manufacture; Domestic manufacturing; Domestic manufacturing	Manufacture	Concentration is within the highest and lowest bounded values from TRI releasers	Included in screening level assessment
Processing; Incorporation into article; Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding		Concentration is within the highest and lowest bounded values from TRI releasers	
Processing; Incorporation into formulation, mixture, or reaction product; Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Rubber manufacturing		Included in screening level assessment
Processing; Incorporation into article; Plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	Plastic converting	COU resulting in the lowest concentrations and serves as the lowest bound for this assessment <sup>a</sup> ; RQ >1	Included in screening level assessment
Industrial use; Other uses; Solid rocket motor insulation and other aerospace applications; Automotive articles			
Processing; Incorporation into formulation, mixture, or reaction product; Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	Plastic compounding	COU resulting in the highest environmental concentration and serves as the highest bound for this assessment <sup><i>a</i></sup> ; RQ >1	Included in screening level assessment
Processing; Incorporation into formulation, mixture, or reaction product; Plasticizer in basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner	Incorporation into formulation, mixture, or reaction product	Concentration is within the highest and lowest bounded values from TRI releasers	Included in screening level assessment

COU (Life Cycle Stage; Category; Subcategory)	Occupational Exposure Scenario (OES)	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
and colorant manufacturing			
Processing; Other uses; Miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)			
Manufacture; Importing; Importing		Concentration is within the highest and lowest bounded values from TRI releasers	Included in screening level assessment
Processing; Repackaging; Repackaging in wholesale and retail trade and in paint and coating manufacturing	Repackaging		
Commercial use; Furnishing, cleaning, and treatment care products ; All- purpose waxes and polishes	Application of	Concentration is within the highest and lowest bounded values from TRI releasers	COU resulting in highest environmental concentration for air to soil deposition and serving as a screening level assessment <sup>b</sup> ; RQ < 1
Industrial Use; Construction, Paint, Electrical, and Metal products; Paints and Coatings			
Commercial use; Construction, paint, electrical, and metal products; Adhesives and sealants	paints, coatings, adhesives, and		
Commercial use; Construction, paint, electrical, and metal products; Paints and coatings	sealants		
Commercial use; Furnishing, cleaning, and treatment care products; All- purpose waxes and polishes			
Commercial use; Furnishing, cleaning, and treatment care products; Fabric, textile, and leather products; furniture and furnishings		Concentration is within the highest and lowest bounded values from TRI releasers	Included in screening level assessment
Commercial use; Furnishing, cleaning, and treatment care products; Fabric enhancer	Textile finishing		
Commercial use; Construction, paint, electrical, and metal products; Batteries and capacitors		e No water releases	Included in screening level assessment
Commercial use; Construction, paint, electrical, and metal products; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Fabrication or use of final product		
Commercial use; Construction, paint, electrical, and metal products; Machinery, mechanical appliances, electrical; electronic articles	or articles		
Commercial use; Automotive, fuel, agriculture, and outdoor use products; Lawn and garden care products			

COU (Life Cycle Stage; Category; Subcategory)	Occupational Exposure Scenario (OES)	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Commercial use; Packaging, paper, plastic, toys, hobby products; Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including paper articles; rubber articles; plastic articles (hard); plastic articles (soft); Packaging (excluding food packaging), including paper articles Commercial use; Packaging, paper, plastic, toys, hobby products; Toys, playground, and sporting equipment Commercial use; Furnishing, cleaning, and treatment care products; Floor	Fabrication or use of final product or articles	No water releases	Included in screening level assessment
coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and apparel			
Commercial use; Packaging, paper, plastic, toys, hobby products; Ink, toner, and colorants	Use of dyes and pigments, and fixing agents	Concentration is within the highest and lowest bounded values from TRI releasers	No air releases
Industrial use; Packaging, paper, plastic, toys, hobby products; Adhesives and sealants	Application of paints, coatings, adhesives, and sealants (formulations for diffusion bonding)	Concentration is within the highest and lowest bounded values from TRI releasers	Included in screening level assessment
Commercial use; Other uses; Laboratory chemicals	Use of laboratory chemicals (solid and liquid) <sup>c</sup>	Qualitatively assessed <sup>d</sup>	Included in screening level assessment
Commercial use; Automotive; Automotive articles	Use of automotive care products <sup>c</sup>	Qualitatively assessed <sup>d</sup>	Included in screening level assessment
Industrial use; Other uses; Hydraulic fracturing	Use in hydraulic fracturing <sup>c</sup>	Qualitatively assessed <sup>d</sup>	Included in screening level assessment
Processing; Recycling; Recycling	Recycling	No water releases	Included in screening level assessment
Disposal; Disposal; Disposal	Waste handling,	Concentration is within the	Included in screening

COU (Life Cycle Stage; Category; Subcategory)	Occupational Exposure Scenario (OES)	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
	treatment, and disposal	highest and lowest bounded values from TRI releasers	level assessment

<sup>a</sup> See Section 5.3.2; The COUs resulting in the highest and lowest environmental concentration of DEHP for the aquatic environment served the bounding for quantified risk estimates

<sup>b</sup> See Section 5.3.3; The COU resulting in the highest environmental concentration for air to soil deposition served as the bounding for quantified risk estimates

<sup>c</sup> Table 3-5 provides details on these COUs represented with generic scenario releases <sup>d</sup> Section 5.3.2 provides details on qualitative assessment of these COU

# 5284 6 UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether a chemical
substance presents an unreasonable risk of injury to health or the environment, without consideration of
costs or other nonrisk factors, including an unreasonable risk to a PESS identified by EPA as relevant to
this risk evaluation, under the COUs.

- 5289 5290 EPA is preliminarily determining that DEHP presents unreasonable risk of injury to human health and 5291 the environment based on (1) identified risk to workers from 13 COUs, (2) identified risk to aquatic 5292 vertebrates from 20 COUs, and (3) identified risk to benthic organisms from 18 COUs. The 5293 unreasonable risk results from risk identified for 21 out of 44 total COUs for DEHP. Of the 21 5294 occupational COUs, 13 have risk due to inhalation exposure. Of the 44 COUs, 20 COUs have 5295 environmental risk to aquatic vertebrates due to chronic exposure to DEHP based on releases to surface 5296 water, and of those 20 COUs, 18 COUs also have environmental risk to benthic organisms due to 5297 chronic exposure to DEHP based on releases to sediment pore water. This preliminary unreasonable risk 5298 determination is based on the information in previous sections of this draft risk evaluation, the 5299 appendices and technical support documents of this draft risk evaluation in accordance with TSCA 5300 section 6(b). This preliminary unreasonable risk determination and the underlying evaluation are 5301 consistent with the best available science (TSCA section 26(h)) and based on the weight of scientific 5302 evidence (TSCA section 26(i)).
- 5303

As noted in the EXECUTIVE SUMMARY, DEHP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications—although it is also used in adhesives, sealants, paints, coatings, rubbers, and non-PVC plastics as well as for other applications. 5307

EPA notes that human or environmental exposure to DEHP through non-TSCA uses (*e.g.*, cosmetics, medical devices, use of shells and cartridges as identified in 26 U.S.C. § 4181, and food additives such as food contact materials) were not evaluated by the Agency because these uses are explicitly excluded from TSCA's definition of chemical substance. Thus, it is not appropriate to extrapolate from this preliminary risk determination to form conclusions about uses of DEHP that are not subject to TSCA and that EPA did not evaluate.

5314 5315 Additionally, where relevant, the Agency analyzed aggregate exposures and cumulative risk. Aggregate 5316 exposure analyses consider effects on populations that are exposed to DEHP via multiple routes (i.e., 5317 dermal contact, ingestion, and inhalation). Cumulative risk refers to human health risks related to 5318 exposures to multiple chemicals. EPA included DEHP in its draft cumulative risk analysis TSD along 5319 with five other toxicologically similar phthalate chemicals (*i.e.*, DBP, BBP, DIBP, DCHP, and DINP) 5320 that are also being evaluated under TSCA (U.S. EPA, 2025x). Based on the Revised Draft Technical 5321 Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl 5322 Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate 5323 (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA) (U.S. EPA, 5324 2025x), the Agency has considered the draft cumulative risk (*i.e.*, human health risks related to exposures to multiple phthalates), which is inclusive of the NHANES biomonitoring data, in this 5325 5326 preliminary DEHP unreasonable risk determination and concluded that the analysis indicates decreased 5327 risk or no additional risk for all COUs compared to the individual chemical analysis for DEHP, since 5328 DEHP's relative potency factor is less than the index chemical (DBP). Additionally, DEHP's POD is 5329 approximately two-fold lower (*i.e.*, more sensitive) than the index chemical, which is the primary factor 5330 leading to higher MOEs after scaling based on the relative potency factor approach in the cumulative 5331 risk analysis compared to MOEs in the individual chemical analysis for DEHP. More information on the 5332 cumulative risk considerations is provided in Section 4.4.

5333 EPA has preliminarily determined that the following 12 COUs may significantly contribute to 5334 unreasonable risk to human health, due to inhalation exposure for workers, and to the environment:

- Manufacturing importing (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Processing incorporation into formulation, mixture, or reaction product plasticizer in plastic material and resin manufacturing; synthetic rubber manufacturing; basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; basic inorganic chemical manufacturing; wholesale and retail trade; services; and ink, toner, and colorant manufacturing (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Processing incorporation into article plasticizer in basic organic chemical manufacturing;
   plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing;
   and PVC extruding (inhalation exposure for workers and aquatic vertebrates and benthic
   invertebrates through surface water and pore water)
- Processing repackaging repackaging in wholesale and retail trade and in paint and coating
   manufacturing (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates
   through surface water and pore water)
- Industrial use construction, paint, electrical, and metal products paints and coatings
   (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through
   surface water and pore water)
  - Industrial use construction, paint, electrical, and metal products adhesives and sealants (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Industrial use other uses solid rocket motor insulation and other aerospace applications
   (inhalation exposure for workers and aquatic vertebrates only through surface water)
  - Industrial use other uses automotive articles (inhalation exposure for workers and aquatic vertebrates only through surface water)
- Commercial use construction, paint, electrical, and metal products adhesives and sealants
   (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through
   surface water and pore water)
- Commercial use construction, paint, electrical, and metal products paints and coatings
   (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through
   surface water and pore water)
- Commercial use furnishing, cleaning, treatment care products all-purpose waxes and polishes
   (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through
   surface water and pore water)
- Commercial use packaging, paper, plastic, toys, hobby products ink, toner, and colorants (inhalation exposure for workers and aquatic vertebrates and benthic invertebrates through surface water and pore water)
- 5373 EPA has preliminarily determined that the following COU may significantly contribute to unreasonable 5374 risk to human health, due to inhalation exposure for workers:
- Processing recycling

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5376 EPA has preliminarily determined that the following eight COUs may significantly contribute to 5377 unreasonable risk to the environment:

- Manufacturing domestic manufacturing (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Processing other uses miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing) (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Industrial use other uses hydraulic fracturing (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Commercial use furnishing, cleaning, treatment care products fabric enhancer (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Commercial use furnishing, cleaning, treatment care products fabric, textile, and leather
   products; furniture and furnishings (aquatic vertebrates and benthic invertebrates through surface
   water and pore water)
- Commercial use other uses laboratory chemicals (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Commercial use other uses automotive articles (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- Disposal (aquatic vertebrates and benthic invertebrates through surface water and pore water)
- 5395 EPA did not preliminarily identify unreasonable risk of injury to human health or the environment from 5396 the following 23 COUs:
- Distribution in commerce
- Commercial use automotive, fuel, agriculture, outdoor use products lawn and garden care products
- Commercial use construction, paint, electrical, and metal products batteries and capacitors
- Commercial use construction, paint, electrical, and metal products construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
- Commercial use construction, paint, electrical, and metal products machinery, mechanical appliances, electrical/electronic articles
- Commercial use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Commercial use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging) and other articles with routine direct contact during normal Use, including rubber articles; plastic articles (hard); plastic articles (soft)
- 5412 Commercial use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including paper articles
- 5414
   Commercial use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment
- 5416 Consumer use automotive, fuel, agriculture, outdoor use products lawn and garden care products
- Consumer use construction, paint, electrical, and metal products adhesives and sealants
- Consumer use construction, paint, electrical, and metal products batteries
- Consumer use construction, paint, electrical, and metal products construction, and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
- Consumer use construction, paint, electrical, and metal products machinery, mechanical appliances, electrical/electronic articles

- Consumer use construction, paint, electrical, and metal products paints and coatings
- Consumer use furnishing, cleaning, treatment care products fabric, textile, and leather products; furniture and furnishings
- Consumer use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Consumer use packaging, paper, plastic, toys, hobby products ink, toner, and colorants
- Consumer use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)
  - Consumer use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including paper articles
  - Consumer use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment
  - Consumer use other uses novelty articles
    - Consumer use other uses automotive articles

For some COUs, the Agency has limited information to derive risk estimates (such as MOEs or RQs) to support a determination of whether the COU contributes to unreasonable risk of injury to human health or the environment. In such cases, EPA integrates reasonably available information *e.g.*, physical and chemistry properties, available monitoring data in a risk characterization using a weight of evidence approach and professional judgment to support conclusions. The risk characterizations of COUs without risk estimates are a best estimate of what EPA expects given the weight of scientific evidence without overstating the science.

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5449 The unreasonable risk determination must be informed by science and in making a finding of "presents" 5450 unreasonable risk," EPA considers risk-related factors beyond exceedance of benchmarks. Risk-related 5451 factors include the type and severity of health effect under consideration, the reversibility of the health 5452 effects being evaluated, exposure-related considerations (e.g., duration, magnitude, frequency of 5453 exposure), or population exposed—particularly populations with greater exposure or greater 5454 susceptibility (PESS), and the confidence in the information used to inform the hazard and exposure 5455 values. EPA also considers, where relevant and appropriate, the Agency's analyses on aggregate 5456 exposures and cumulative risk. For COUs evaluated quantitatively, as described in the risk 5457 characterization, EPA based the preliminary unreasonable risk determination on the risk estimate that 5458 best represented the COU. Additionally, in the draft risk evaluation, the Agency describes the strength of 5459 the scientific evidence supporting the human health and environmental assessments as robust, moderate, 5460 slight, or indeterminate.

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5462 Robust confidence suggests thorough understanding of the scientific evidence and uncertainties, and the 5463 supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that 5464 the uncertainties could have a significant effect on the risk estimates. Moderate confidence suggests 5465 some understanding of the scientific evidence and uncertainties, and the supporting scientific evidence 5466 weighed against the uncertainties is reasonably adequate to characterize risk. Slight confidence is 5467 assigned when the weight of scientific evidence may not be adequate to characterize the risk, and when 5468 the Agency is making the best scientific assessment possible in the absence of complete information. In 5469 cases where EPA lacked reasonably available data, the Agency's confidence in risk is indeterminate. In 5470 general, EPA makes an unreasonable risk determination based on risk estimates that have an overall 5471 confidence rating of moderate or robust because those confidence ratings indicate the scientific evidence 5472 is adequate to characterize risk estimates despite uncertainties or is such that it is unlikely the

5473 uncertainties could have a significant effect on the risk estimates. This draft risk evaluation discusses

important assumptions and key sources of uncertainty in the risk characterization, and these are
 described in more detail in the respective weight of scientific evidence conclusions sections for fate and

5476 transport (Section 2.2); environmental release (Sections 3.2.2 and 3.2.3); environmental concentrations

5477 (Section 3.3.1); environmental exposures and hazards (Section 5.3.5); and human health exposures and

hazards (Sections 4.1.1.4, 4.1.2.4, and 4.1.3.3). The draft risk evaluation also includes overall

5479 confidence and remaining uncertainties sections for human health (Sections 4.3.2, 4.3.3, and 4.3.4.1) and 5480 environmental risk characterizations (Section 5.3.5).

## 5481 6.1 Human Health

Calculated non-cancer risk estimates (MOEs<sup>6</sup>) can provide a risk profile of DEHP by presenting a range 5482 5483 of estimates for different health effects for different COUs. When characterizing the risk to human 5484 health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline 5485 assessments of risk and makes its determination of unreasonable risk in a manner that takes in 5486 consideration reasonably available information (e.g., test order information, site visits) regarding the use of respiratory protection or other PPE.<sup>7</sup> This allows EPA to make unreasonable risk determinations 5487 5488 based on the available information regarding workers. In addition, the risk estimates may be based on 5489 exposure scenarios with monitoring data that reflect existing requirements, such as those established by 5490 OSHA (*i.e.*, permissible exposure limit [PEL]), or industry or sector best practices. In this draft risk 5491 evaluation, some of the risk estimates calculated do not reflect use of PPE; however, section 4.3.2.20 5492 and Table 4-14 provide more information on PPE, including risk estimates calculated with PPE, that 5493 could be used to reduce exposures so that the risk estimates are above the benchmark MOE. Because 5494 EPA does not currently have information regarding use of PPE under the COUs, the preliminary 5495 unreasonable risk determination is based on the risk estimates that do not reflect use of PPE. 5496

5497 To characterize risk from non-cancer endpoints, the estimated MOEs are compared to their respective 5498 benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD. The benchmark 5499 MOE is the total of several individual uncertainty factors relevant to a given POD with values usually of 5500 1, 3 or 10. For DEHP, two uncertainty factors were used to derive a benchmark MOE, (1) UFA of 3 for 5501 the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability) and (2)  $UF_H$  of 10 5502 for the variation in sensitivity among the members of the human population (*i.e.*, intrahuman/ 5503 intraspecies variability). Therefore, the benchmark MOE for DEHP is 30, and is based on effects on the 5504 developing male reproductive system, consistent with a disruption of androgen action and phthalate 5505 syndrome, specifically the increased incidence of reproductive tract malformations, and was used to 5506 characterize risk from exposure to DEHP for acute, intermediate, and chronic exposure scenarios. A 5507 lower benchmark MOE (e.g., 30) indicates greater certainty in the data (because the total uncertainty 5508 factor (UF) for the relevant POD is low). A higher benchmark MOE (e.g., 100) would indicate more extrapolation uncertainty for specific hazard endpoints and scenarios. Additional information regarding 5509 5510 the non-cancer hazard identification and the benchmark MOE is in Section 4.2 of this draft risk evaluation. An MOE that is less than the benchmark MOE indicates risk and is a starting point for 5511

<sup>&</sup>lt;sup>6</sup> EPA derives non-cancer MOEs by dividing the non-cancer POD (HEC [mg/m<sup>3</sup>] or HED [mg/kg-day]) by the exposure estimate (mg/m<sup>3</sup> or mg/kg-day). Section 4.3.1 has additional information on the risk assessment approach for human health. <sup>7</sup> It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

informing a determination of unreasonable risk of injury to health, based on non-cancer effects. EPA
also considers the conservative assumptions to assess exposures in this preliminary unreasonable risk
determination. It is important to emphasize that these calculated risk estimates and benchmarks alone are
not "bright-line" indicators of unreasonable risk.

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## 6.1.1 Populations and Exposures EPA Assessed for Human Health

5517 EPA has evaluated risk to workers (16+ years old) including ONUs and females of reproductive age 5518 directly working with DEHP; consumers and bystanders (adults and children), and the general 5519 population (including fenceline communities), using reasonably available monitoring and modeling data 5520 for inhalation, dermal, and ingestion exposures, as applicable. EPA has evaluated risk from inhalation, 5521 incidental ingestion of inhaled dust, and dermal exposure of DEHP to workers, including dermal 5522 exposures to ONUs from mist and dust deposited on surfaces. The Agency also has evaluated risk from 5523 inhalation, dermal, and ingestion exposures for consumers. For the general population, EPA has 5524 evaluated risk from (1) ingestion exposures via drinking water, incidental surface water ingestion during 5525 swimming, fish ingestion (including subsistence and Tribal fishers), and soil ingestion; (2) dermal 5526 exposure to surface water during swimming; (3) acute and chronic inhalation exposure; and (4) 5527 exposures measured through urinary biomonitoring (*i.e.*, NHANES). EPA concluded it is not necessary 5528 to separately model risks to infants consuming the human milk of exposed individuals because the POD 5529 used in the assessment is based on male reproductive tract malformations resulting from maternal 5530 exposures in multigenerational studies and co-critical studies with effects on developing male offspring 5531 consistent with phthalate syndrome following maternal dosing throughout the gestation and lactation 5532 periods. 5533

5534 Although no studies have evaluated only lactational exposure from quantified levels of DEHP in milk, 5535 the human health hazard values are based on studies that cover the lactational period. Because these 5536 values designed to be protective of infants are expressed in terms of maternal exposure levels and hazard 5537 values to assess direct exposures to infants are unavailable, EPA concluded that further characterization 5538 of infant exposure through human milk ingestion would be uninformative. Descriptions of the data used 5539 for human health exposure are in Section 4.1. Uncertainties for overall exposures are presented in the 5540 respective occupational, consumer, and general population exposure sections of this draft risk evaluation 5541 and are considered in the preliminary unreasonable risk determination.

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## 6.1.2 Summary of Human Health Effects

EPA has preliminarily determined that DEHP presents unreasonable risk to human health because of
non-cancer effects in workers, including ONUs and female workers of reproductive age, from acute,
intermediate, and chronic inhalation exposures under 13 occupational COUs.

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5547 With respect to the health endpoint upon which EPA has based this preliminary unreasonable risk 5548 determination, the non-cancer effects on the developing male reproductive system are consistent with a 5549 disruption of androgen action and phthalate syndrome and increased overall incidence of reproductive 5550 tract malformations observed in both generations in a multi-generation reproduction study, following 5551 continuous dietary exposure (e.g., gestational and lactational exposure). The proposed POD to estimate 5552 non-cancer risks from oral exposure to DEHP is a NOAEL associated with effects on the developing 5553 male reproductive system at the LOAEL of 14 or 15 mg/kg-day from a three-generation reproduction 5554 study (Blystone et al., 2010; TherImmune Research Corporation, 2004) and a supporting study presented 5555 in publications by Andrade and Grande (2006b; 2006a; 2006) which established a NOAEL of 5 mg/kg-5556 day, along with 13 additional studies reporting effects on the developing male reproductive system 5557 consistent with disrupted androgen action and phthalate syndrome at lowest-observed-adverse-effect 5558 levels (LOAELs) in a narrow range of 10 to 15 mg/kg-day. Risk estimates based on the developmental

toxicity POD are relevant for females of reproductive age and males at any lifestage. Additionally, there 5559 5560 is epidemiological evidence that DEHP exposure can adversely affect the developing male reproductive 5561 system consistent with phthalate syndrome in males of any age, with effects including decreases in 5562 anogenital distance (AGD) and testosterone and effects on sperm parameters in humans, and that DEHP 5563 exposure at higher concentrations can cause other health effects in females as well (see the Draft Non-5564 cancer Human Health Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024f)). 5565 Therefore, EPA considers the proposed POD to be relevant across sex, lifestage, and durations. The 5566 Agency has robust overall confidence in the proposed developmental toxicity POD. The confidence in 5567 the POD and descriptions of the data used to determine the human health effects from DEHP are 5568 explained in Section 4.2.2. 5569

With respect to carcinogenicity, EPA has preliminarily concluded that DEHP is *Not Likely to be Carcinogenic to Humans* at doses below levels that do not result in PPARα activation. For DEHP, the
non-cancer POD based on effects on the developing male reproductive system consistent with phthalate
syndrome and a disruption of androgen action for DEHP is lower than the hazard values for PPARα
activation identified by EPA. Therefore, EPA has concluded that the non-cancer POD for DEHP is
expected to adequately account for all chronic toxicity, including carcinogenicity, and cancer risk was
not further quantified (Section 4.2.1).

5578 The health risk estimates for consumers and bystanders are presented in Table 4-15 and in the *Draft* 5579 DEHP Consumer Risk Calculator (U.S. EPA, 2025g) and are characterized in Section 4.3. Health risk estimates for the general population are presented in the Draft Environmental Media and General 5580 Population and Environmental Exposure for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q) and 5581 5582 characterized in Section 4.3. Health risk estimates for workers including ONUs are presented in Table 5583 4-14 and characterized in Section 4.3. The benchmarks are not "bright-lines," and EPA has discretion to 5584 consider other risk-related factors when concluding whether a COU significantly contributes to the 5585 unreasonable risk of the chemical substance, including the type of health effect under consideration, the 5586 reversibility of the health effect being evaluated, exposure-related considerations (e.g., duration, magnitude, frequency of exposure), or population exposed—particularly populations with greater 5587 5588 exposure or greater susceptibility (PESS)), and the confidence in the information used to inform the 5589 hazard and exposure values.

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## 6.1.3 Basis for Unreasonable Risk to Human Health

5591 In developing the exposure and hazard assessments for DEHP, EPA has analyzed reasonably available 5592 information to ascertain whether some human populations may have greater exposure and/or 5593 susceptibility than the general population to the hazard posed by DEHP. For the DEHP draft risk 5594 evaluation, EPA has accounted for the following PESS: high-end exposures to workers, including ONUs 5595 and females of reproductive age (WORA), and considering aggregated occupational inhalation and dermal exposures; infants and children exposed through consumer uses, general population exposures, 5596 5597 use of legacy and new toys, including aggregate inhalation, dermal and oral exposures; cumulative 5598 exposures to DEHP and other phthalates for the general population and for females of reproductive age, 5599 black non-Hispanic women with higher cumulative exposures; and exposures to subsistence fishers and 5600 Tribal populations through fish ingestion. Section 4.3.5 summarizes how PESS were incorporated into 5601 the risk evaluation through consideration of potentially increased exposures and/or potentially increased 5602 biological susceptibility and summarizes additional sources of uncertainty related to consideration of 5603 PESS.

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5605 Because EPA was able to calculate risk estimates for PESS groups in this assessment (*e.g.*, female 5606 workers of reproductive age, and infants and children), EPA did not always use risk estimates based on

5607 high-end exposure levels as the basis of the preliminary unreasonable risk determination for DEHP. 5608 Additionally, EPA considered whether high-end risk estimates represented sentinel exposure levels 5609 accurately. As explained in the human health risk characterization, for occupational uses, both central 5610 tendency and high-end risk estimates were expected to be representative of worker exposures for all but 5611 11 COUs because the available data to evaluate the COUs may not be characteristic of exposures under 5612 all tasks and facilities within a COU, which is explained further in Section 6.1.4. Similarly, for 5613 consumer uses, high-intensity risk estimates were used to preliminarily determine unreasonable risk 5614 except for the consumer use of fabric, textile and leather products; furniture and furnishings; and novelty 5615 articles. The  $UF_H$  of 10 for human variability that EPA has applied to MOEs accounts for increased 5616 susceptibility of populations. The non-cancer POD for DEHP selected by EPA for use in risk 5617 characterization is based on the most sensitive developmental effects observed following exposure during the most sensitive lifestage (*i.e.*, gestation) and is therefore expected to be based on the most 5618 5619 sensitive population. More information on how EPA characterized PESS risks is provided in Section 5620 4.3.4.

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5622 Additionally, EPA did not consider aggregate exposure scenarios across COUs because the Agency did 5623 not find any evidence to support such an aggregate analysis, such as statistics of populations using 5624 certain products represented across COUs, or workers performing tasks across COUs. However, EPA 5625 considered combined exposure across all routes of exposure for each occupational and consumer COU 5626 to calculate aggregate risk estimates (Section 4.3.5). The Agency aggregated exposures across routes for 5627 workers, including ONUs, and consumers for COUs with quantitative risk estimates. EPA did not 5628 consider aggregate exposure for the general population. As described in Section 4.1.3, EPA employed a 5629 risk screening approach for the general population exposure assessment. More information on how EPA 5630 characterized sentinel and aggregate risks is provided in Section 4.1.5. 5631

5632 In addition to the analysis done for DEHP alone (referred to as "individual analysis"), EPA applied both 5633 the methods and principles of CRA (Revised Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances 5634 5635 Control Act (U.S. EPA, 2023c), as well as the Revised Draft Technical Support Document for the 5636 Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl 5637 Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl 5638 Phthalate (DINP) Under the Toxic Substances Control Act (TSCA) (U.S. EPA, 2025, 12335232)), to 5639 derive non-cancer risk estimates for occupational and consumer exposures. EPA's draft CRA includes 5640 cumulative exposure to other toxicologically similar phthalates being evaluated under TSCA (*i.e.*, 5641 DEHP, DBP, BBP, DIBP, DCHP, and DINP) and uses a "Relative Potency Factor (RPF) analysis" to 5642 characterize risk. DBP was used as the index chemical for the meta-analysis and BMD modeling 5643 approach to model decreased fetal testicular testosterone as the POD for the CRA. In contrast, for the 5644 individual DEHP assessment (Section 4.3), EPA considered all human health hazards of DEHP and 5645 selected a POD based on a NOAEL for phthalate syndrome-related effects (*i.e.*, increased incidence of 5646 reproductive tract malformations). Because DEHP's RPF is less than 1 compared to the index chemical, 5647 scaling by relative potency decreases the DEHP exposure estimates used to derive DEHP cumulative 5648 risk estimates and DEHP's POD is approximately 2-fold lower (i.e., more sensitive) than the index 5649 chemical, resulting cumulative MOEs do not indicate additional risk after considering the MOEs from 5650 the individual chemical analysis for DEHP. More information on how EPA characterized the risk from the cumulative exposure to the phthalates is provided in Section 4.4.1. 5651

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5653 The revised draft CRA TSD also includes the addition of cumulative exposure to DEHP, DBP, BBP, 5654 DIBP, and DINP as estimated from NHANES urinary biomonitoring data using reverse dosimetry.

5655 (Note: DCHP was not included as part of this exposure assessment, because DCHP was excluded from

5656 NHANES after the 2009/10 cycle due to low and infrequent detection in human urine). The NHANES 5657 exposure cannot be attributed to specific COUs or other sources that may result in high-dose exposure 5658 scenarios (e.g., occupational exposures to workers), but likely includes exposures from both COUs assessed under TSCA and other non-TSCA sources (e.g., cosmetics, medical devices, and food additives 5659 5660 such as food contact materials). EPA has determined that there is little additional cumulative risk by 5661 adding the simultaneous exposure of other phthalates to the single chemical risk estimates for DEHP 5662 (*i.e.*, non-attributable cumulative exposure from NHANES adds 6.2 to 15.5 percent to the risk cup, 5663 depending upon the population under consideration).

### **6.1.4 Workers**

5665 Based on the occupational risk estimates and related risk factors, EPA is preliminarily determining that DEHP presents unreasonable risk due to non-cancer risks from acute, intermediate, and chronic 5666 5667 inhalation exposure to workers, including ONUs and females of reproductive age for 13 COUs (see Table 6-1 for specific COUs and associated unreasonable risk by route of exposure). Although the 5668 5669 aggregate exposures MOEs indicate risk (see Table 4-1 for risk estimates including aggregate 5670 exposures), EPA is preliminarily determining that DEHP does not present unreasonable risk from the 5671 dermal exposure route since the aggregate MOEs are equal or slightly less than the inhalation MOEs, indicating that the risk is driven by the inhalation exposure. More information on occupational risk 5672 5673 estimates is in Section 4.3.2.

Scaling high-end and central-tendency DEHP acute exposure estimates from individual COUs by
relative potency and adding cumulative exposure (estimated from NHANES urinary biomonitoring
using reverse dosimetry) did not impact the results of the occupational risk assessment. More
information and discussion can be found in Section 4.4.4. EPA's confidence in the cumulative MOEs for
workers is moderate to robust (Section 4.4.4.1).

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5681 EPA is preliminarily determining that 13 COUs may significantly contribute to unreasonable risk of 5682 injury to human health for workers, including ONUs. For OES where no reasonably available ONU 5683 exposure data were found, the worker central tendency value was presented. Therefore, the MOEs for 5684 these ONUs, will be comparable to the worker central tendency MOEs, although there is lower 5685 confidence in the exposure values for ONUs, given that EPA relied on central tendency exposure 5686 estimates for workers as surrogate data to estimate exposure to ONUs. For datasets that included 5687 exposure data reported as below the limit of detection (LOD), EPA estimated exposure concentrations 5688 following guidance in EPA's Guidelines for Statistical Analysis of Occupational Exposure Data (U.S. EPA, 1994a). 5689

5690 5691 Where monitoring data were reasonably available, EPA used these data to characterize central tendency 5692 and high-end inhalation exposures (see also Table 4-1). The Agency may also use monitoring data from 5693 a similar condition of use as a surrogate, which is described in further detail in Section 4.1.1.2. Five 5694 OESs used data from other OESs as a surrogate: (1) Incorporation into formulation, mixture or reaction 5695 product (manufacturing as surrogate); (2) Non-spray application of paints, coatings, adhesives, and 5696 sealants (rubber product manufacturing as surrogate); (3) Use of dyes pigments, and fixing agents 5697 (rubber product manufacturing as surrogate); (4) Hydraulic fracturing (manufacturing as surrogate); and 5698 (5) Recycling (plastic converting as surrogate). Where no inhalation monitoring data were available, but 5699 inhalation exposure models were reasonably available, the Agency estimated central tendency and high-5700 end exposures using only modeling approaches. If both inhalation monitoring data and exposure models 5701 were reasonably available, EPA presented central tendency and high-end exposures using both. For 5702 inhalation exposure to dust in occupational settings, the Agency used the PNOR Model (U.S. EPA,

5703 <u>2021d</u>). Where EPA was not able to estimate ONU inhalation exposure from monitoring data or models, 5704 this was assumed equivalent to the central tendency experienced by workers for the corresponding OES.

- 5705 5706 In all cases of occupational dermal exposure to DEHP, EPA used a flux-limited dermal absorption 5707 model to estimate both high-end and central tendency dermal exposures for workers in each OES, as 5708 described in the Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl 5709 *Phthalate* (U.S. EPA, 2025r). Using the flux-limited dermal absorption model, EPA used two 5710 approaches to estimate dermal exposure to liquid and solid DEHP in occupational settings. For cases 5711 where occupational dermal exposure to liquid DEHP was assessed, EPA used dermal absorption data for 5712 dilute DEHP to estimate occupational dermal exposures to workers since the absorptive flux of dilute 5713 DEHP is greater than the absorptive flux of neat DEHP (Hopf et al., 2014). For occupational dermal 5714 exposure to solid DEHP. EPA used dermal absorption data from an *in vivo* absorption study using male 5715 F344 rats and DEHP contained within PVC film (Chemical Manufacturers Association, 1991). As noted 5716 in Section 4.1.1.4, in general, rodent skin has a higher dermal absorption than human skin; therefore, this 5717 model likely provides a conservative estimate of dermal absorption of DEHP in humans from solid 5718 matrices. Both approaches are described in the Draft Environmental Release and Occupational 5719 *Exposure Assessment for Diethylhexyl Phthalate (DEHP)* (U.S. EPA, 2025r). Dermal exposure for 5720 ONUs was assessed for COUs where contact with DEHP-containing mist or dust on surfaces was 5721 expected. EPA has considered the weight of scientific evidence for dermal risk estimates to be sufficient 5722 for determining whether a COU presents unreasonable risk. However, EPA is preliminarily determining 5723 that unreasonable risk of DEHP is not driven by occupational dermal exposures to DEHP. All risk estimates are below the benchmark of 30, which indicates no risk due to dermal exposure for all of 5724 DEHP's occupational COUs. More information on EPA's confidence in these risk estimates and the 5725 5726 uncertainties associated with them can be found in Section 4.1.1.4.
- 5727

5728 As described in Section 4.3.2, EPA expects both high-end and central tendency exposure estimates to be 5729 representative of worker exposures for all COUs except those evaluated using the Textile finishing, 5730 Fabrication or use of final product or articles, and Waste handling, treatment, and disposal OESs. For the 5731 two COUs evaluated with the Textile finishing OES (Commercial use – furnishing, cleaning, and 5732 treatment care products – fabric, textile, and leather products; furniture and furnishings; Commercial use 5733 - furnishing, cleaning, and treatment care products - fabric enhancer) and the one COU evaluated with 5734 the Waste handling, treatment, and disposal OES (Disposal), EPA has determined central tendency values to be most representative of worker exposures within these COUs since the air concentrations 5735 5736 were modeled assuming that: the dust present during textile finishing is at the level in the subset of the 5737 PNOR (U.S. EPA, 2021d) data from facilities associated with the NAICS code for textile 5738 manufacturing; the dust is comprised entirely of abraded textile products containing DEHP; and the 5739 concentration of DEHP in those textile products in at the highest concentration reported in fabrics 5740 (Laursen et al., 2003). The high-end estimates are more likely to occur under the more conservative 5741 combination of these parameters, and even under these conditions that comprise high-end, the resulting 5742 MOEs for inhalation risk were four orders of magnitude above the benchmark (see Section 4.3.2.9.3). 5743 For the COU evaluated with the waste handling, treatment, and disposal OES, this is due to the fact that 5744 the air concentrations were modeled assuming that: the dust present during waste handling, treatment, 5745 and disposal is at the level in the subset of the PNOR data from facilities associated with the NAICS 5746 code for Administrative and Support and Waste Management and Remediation Services (U.S. EPA, 5747 2021d); the dust is comprised entirely of abraded plastic products containing DEHP; and the 5748 concentration of DEHP in the abraded plastic is the highest concentration reported in SDS (*i.e.*, 44% 5749 DEHP in Vinoprene 647 (HB Chemical, 2015)). The high-end estimates are more likely to occur under 5750 the more conservative combination of these parameters per Section 4.3.2.17.3. Risk was not indicated at 5751 either high-end or central tendency exposure level for these COUs. For the eight COUs evaluated with

the Fabrication or use of final product or articles OES, because of the possibility of underestimation of
exposure per Section 4.3.2.10.3, EPA considered the high-end exposure values to be a reasonable
estimate of worker exposures in these COUs. Risk was not indicated at either high-end or central
tendency exposure level for these COUs.

5756

5757 For situations where COUs were evaluated using multiple OESs, EPA considered MOEs from all 5758 associated OESs for the purposes of making an unreasonable risk determination (see Table 3-1 and 5759 Table 3-2). For example, three OESs, Incorporation into formulation, mixture, or reaction product, Plastic compounding, and Rubber manufacturing, were used to evaluate the COU Processing -5760 5761 incorporation into formulation, mixture, or reaction product – plasticizer in basic organic chemical 5762 manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and 5763 coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic 5764 rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; 5765 services; ink, toner and colorant manufacturing. The Incorporation into formulation, mixture, or reaction 5766 product OES had MOEs above the benchmark for all populations and durations assessed, for both 5767 central tendency and high-end inhalation exposure. The Plastic compounding OES has MOEs below the 5768 benchmark (ranging from 25–29) for central tendency exposure inhalation for both average adult 5769 workers and female workers of reproductive age for acute duration, as well as central tendency 5770 aggregate exposure estimates for average adult workers for acute exposure duration. The Rubber 5771 manufacturing OES indicated risk for more populations than the Plastic compounding OES and has a 5772 greater number of MOEs that fall below the benchmark MOE. The Rubber manufacturing OES MOEs 5773 are below the benchmark across all evaluated populations, exposure levels, and durations, for inhalation 5774 and aggregate risk estimates (ranging from 1-7). Both the Plastic compounding and Rubber 5775 manufacturing OESs used monitoring data specific to the respective OES, whereas the incorporation 5776 into formulation, mixture, or reaction product OES used surrogate monitoring data, and EPA concluded 5777 that the weight of scientific evidence for each OES was moderate.

5778

5788

5779 The monitoring data used to estimate worker exposures within the Rubber manufacturing OES had a 5780 data quality rating of high, whereas the monitoring data used to estimate worker exposures within the 5781 Plastics compounding OES as well as the Incorporation into formulation, mixture, or reaction product 5782 OES were derived from two data sources each, with medium and high data quality ratings. Furthermore, 5783 EPA has robust confidence in the hazard, given that the POD is derived from a robust set of 5784 approximately 15 studies indicating no effects at 5 mg/kg-day and a suite of effects on the developing 5785 male reproductive system consistent with phthalate syndrome in a very narrow dose range of 10 to 15 5786 mg/kg-day. Therefore, EPA is preliminarily determining that this COU may significantly contribute to 5787 unreasonable risk of injury to health for workers, including ONUs.

5789 Two COUs, Importing and processing – repackaging – repackaging in wholesale and retail trade and in 5790 Paint and coating manufacturing, have MOEs indicating risk only for high-end inhalation exposure, for 5791 workers (except for ONUs) and for all durations (with MOEs ranging from 15-25). Both COUs are 5792 associated with the Import and repackaging OES. Given the limited reporting of sample data from the 5793 data source, EPA used the maximum concentration of the area sample data to determine high-end worker inhalation exposure for this OES. However, even though this high-end value is based on the 5794 5795 maximum area sample concentration instead of a 95th percentile of the distribution, this value was based 5796 on a high-quality study specific to DEHP and considered to be a reasonable estimate of high-end worker 5797 exposure for this OES. Therefore, EPA is preliminarily determining that these COUs may significantly 5798 contribute to unreasonable risk of injury to human health for workers, including ONUs.

5799

5800 For Processing – recycling; Industrial uses – other uses – solid rocket motor insulation and other 5801 aerospace applications; and Industrial uses – other uses – automotive articles, high-end MOEs for 5802 chronic inhalation exposure indicate risk for average adult workers (MOE = 24). Additionally, for these 5803 COUs, central tendency and high-end acute inhalation and acute aggregate MOEs for ONUs ranged 5804 between 24 and 26. As discussed in Section 4.3, the central tendency and high-end exposures are 5805 considered to be estimates of worker exposures covered by these COUs. Because high-end acute and 5806 intermediate inhalation MOEs for these COUs were below the benchmark MOE for average adult 5807 workers, and because all high-end inhalation MOEs (ranging between 14–22) were below the 5808 benchmark MOE for females of reproductive age, EPA is preliminarily determining that these COUs 5809 may significantly contribute to unreasonable risk of injury to human health for workers based on all 5810 inhalation exposure durations as well as for ONUs based on acute inhalation and acute aggregate 5811 exposure durations.

5812

5830

5813 EPA has assessed one (the following) occupational COU without deriving risk estimates:

• Distribution in commerce: For purposes of assessment, EPA determined distribution in

commerce consists of the activities associated with the transportation of DEHP or DEHP-5815 5816 containing products and/or articles between sites that manufacture, process, and use DEHP. Additionally, this COU includes the transportation of DEHP containing wastes to recycling sites 5817 5818 or for final disposal. EPA expects all the DEHP or DEHP-containing products and/or articles to 5819 be transported in a closed system or otherwise to be transported in a form (e.g., articles 5820 containing DEHP) such that there is negligible potential for releases except during an accident. 5821 Therefore, no occupational exposures are reasonably expected to occur, no separate assessment 5822 was performed for estimating releases and exposures from distribution in commerce, and distribution in commerce would not result in unreasonable risk. 5823

5824 Overall, EPA has moderate to robust confidence in the risk estimates calculated for workers, including
5825 ONUs, inhalation and dermal exposure scenarios. EPA's overall risk characterization confidence for
5826 workers is summarized in Section 4.3.2.18.

## **5827 6.1.5 Consumers**

Based on the consumer risk estimates and related risk factors, EPA is preliminarily determining that
DEHP does not present unreasonable risk of injury to human health for consumers.

5831 EPA reviewed the parameters for the exposure scenarios analyzed under each COU and preliminarily 5832 determined risk based on the most representative intensity assessed. The high-intensity was chosen for 5833 all COUs, except for Consumer use – furnishing, cleaning, treatment/care products – fabric, textile, and 5834 leather products; furniture and furnishings. For this COU, although dermal contact with synthetic leather 5835 furniture may be possible for infants and toddlers, it is expected to be minimal. Infants are not likely to 5836 be set on furniture for extended periods of time (*i.e.*, 2–8 hours) for safety reasons, and toddlers are 5837 unlikely to stay seated for the 4-hour exposure duration used in the medium-intensity use dermal 5838 assessment. See Section 4.3.2.19 and Draft Consumer and Indoor Dust Exposure Assessment for 5839 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e) for additional discussion and characterization. 5840

5841 For the COU, Consumer use – furnishing, cleaning, treatment/care products – fabric, textile, and leather 5842 products, high-intensity aggregate acute and aggregate chronic MOEs ranged from 30 to 36 for infants 5843 and preschoolers and only considered inhalation and ingestion because the high-intensity dermal 5844 scenario was found to have high uncertainties for the skin contact area input. One other COU, Consumer 5845 use – packaging, paper, plastic, toys, hobby products – toys, playground, and sporting equipment had 5846 high-intensity aggregate acute and chronic MOEs of 32 and 33, respectively, for infants. However, the

draft cumulative risk analysis does not indicate increased risk for consumers compared to the individual
chemical assessment when factoring in the relative potency factor (RPF) and NHANES cumulative risk
assessment data, increasing EPA's confidence in preliminarily determining these two COUs may not
contribute to unreasonable risk on the basis of the individual analysis. More information on the
cumulative risk considerations is provided in Section 4.4.

5852

5853 One COU, Consumer use – packaging, paper, plastic, toys and hobby products – packaging (excluding 5854 food packaging) and other articles with routine direct contact during normal use, including rubber 5855 articles; plastic articles (hard); plastic articles (soft) had potential risks for the high-, medium-, and low-5856 intensity use exposure scenarios in a screening dermal exposure risk assessment for air beds. Because 5857 risk was indicated, EPA refined the screening approach used for dermal exposures to air beds and, 5858 instead of using a flux-limited dermal absorption model, used a more refined approach which models 5859 dermal absorption using DEHP concentration in the article, material and DEHP specific partition 5860 coefficients, and a barrier bedsheet between the air bed and skin (Section 4.1.2.1). The lowest MOE 5861 resulting from the refinements was 57 for infants sleeping 8 hours on a bedsheet and considering a body 5862 surface area of 50 percent contact (e.g., without clothing). However, the screening approach that 5863 indicated risk for all life stages without refinements may best represent select populations who may use 5864 air beds without sheets (see Section 2.3.2 of Draft Consumer and Indoor Dust Exposure Assessment for 5865 Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e)), since some families may still allow for infants to use airbeds due to the lower cost, easier access, and versatility of airbeds (Section 2.2.3.1.4 of Draft 5866 5867 Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025e)). It is important to note that, even in the screening level assessment, only high-end exposure 5868 assumptions for surface area (*i.e.*, 50% body surface area in contact with the air bed (*i.e.*, without 5869 5870 clothing or bedsheet) for a duration of 14 hours resulted in risk estimates with MOEs below the 5871 benchmark. The refinement with inclusion of a bedsheet and consideration of an 8-hour duration did not 5872 result in a risk estimate below the benchmark, even without clothing (e.g., 50% body surface). Based on 5873 the analysis conducted, EPA is preliminarily determining this COU may not contribute to unreasonable 5874 risk.

5875

Three COUs were assessed qualitatively for consumers: Consumer use – packaging, paper, plastic, toys
hobby products – ink, toner and colorants; Consumer use – construction, paint, electrical, and metal
products – batteries; and Disposal. The qualitative assessments for these COUs are summarized in Table
4-18 and did not indicate risk.

5880

EPA's overall confidence in the acute, intermediate, and chronic consumer inhalation, ingestion, and
dermal exposure risk estimates ranges from moderate to robust. EPA has moderate to robust confidence
in the risk estimates calculated for consumers inhalation, ingestion, and dermal exposure scenarios
(Section 4.3.3). EPA's confidence in the cumulative consumer MOEs is moderate to robust (Section
4.4.5.1).

#### 5886 6.1.6 General Population

5887 Based on the risk estimates, EPA did not identify risk to the general population from the following 5888 exposure routes and pathways for DEHP:

- soil ingestion exposure from air deposition to soil;
- dermal and oral exposure to surface water (incidental ingestion and dermal contact from swimming, and ingestion of drinking water);
- acute and chronic ingestion exposure from fish consumption; and
- acute and chronic inhalation exposure to ambient air.

5894 EPA employed a screening method assessing high-end exposure scenarios with data that reflects 5895 exposure expected to occur in proximity to releasing facilities, including to fenceline communities. The 5896 Agency evaluated surface water, drinking water, fish ingestion, and ambient air pathways quantitatively. 5897 EPA used an MOE approach using high-end exposure estimates to determine whether an exposure 5898 pathway had potential non-cancer risks. High-end exposure estimates were defined as those associated 5899 with the industrial and commercial releases from a COU and OES that resulted in the highest 5900 environmental media concentrations. If there is no risk for an individual identified as having the 5901 potential for the highest exposure associated with a COU for a given pathway of exposure, then that 5902 pathway was determined not to be a pathway of concern and not pursued further. The results for the 5903 quantitatively assessed pathways are as follows:

- MOEs for general population exposure through dermal exposure and incidental ingestion during swimming in untreated surface water for the most exposed lifestage was 16,000 and 20,000, respectively (compared to a benchmark of 30) (Table 4-8). This is a conservative assumption that results in no removal of DEHP prior to release to surface water. Based on a screening level assessment, risks for non-cancer health effects are not expected for the surface water pathway.
- The MOE for general population exposure through drinking water exposure for the highest
   exposed lifestage was 756 (compared to a benchmark of 30) (Table 4-8). Based on screening
   level analysis, risk for non-cancer health effects are not expected for the drinking water pathway.
- 5912 • The MOEs for fish ingestion, including subsistence fisher based on conservative exposure 5913 estimates exceeded the benchmark (see Section 7 of (U.S. EPA, 2025q)). Table 4-9 shows only results for the Tribal populations exposed through the Use of laboratory chemicals OES because 5914 5915 it led to the highest exposure. Current ingestion rate refers to the present-day consumption levels 5916 that are suppressed by contamination, degradation, or loss of access. Heritage rates existed prior to non-indigenous settlement on Tribal fishers' resources and changes to culture and lifeways. 5917 5918 Therefore, current ingestion rates are considered more representative of contemporary rates of 5919 fish consumption and are presented below. Heritage rates are discussed in further detail in Draft 5920 Environmental Media and General Population and Environmental Exposure for Diethylhexyl 5921 Phthalate (DEHP) (U.S. EPA, 2025q). No risk estimates were below the benchmark for Tribal 5922 populations based on current mean and high-end (*i.e.*, 95th percentile) fish ingestion rate. 5923 Therefore, EPA concludes exposure to DEHP via fish ingestion does not indicate risk for the 5924 general population or Tribal populations.
- For screening level assessment of the ambient air pathway, EPA utilized the highest modelled
   95th percentile ambient air concentration across all release scenarios used to derive acute risk
   estimates for fugitive releases for the Application of Paints, Coatings, Adhesives, and Sealants
   OES. COUs mapped to this OES are shown in Table 3-1. Based on the 95th percentile air
   concentrations, MOEs for general population exposure through inhalation of ambient air are 267
   for acute and 335 for chronic (both compared to a benchmark of 30) for an adult (Table 4-18),
   and MOEs for all lifestages also exceed the benchmark based on the estimates for adults. The

- risk estimates are derived from a highly conservative exposure scenario, and even under this
  highly conservative exposure scenario, the derived risk estimates are well above relative
  benchmarks for non-cancer health effects (greater than an order of magnitude). Therefore, EPA
- concludes exposure to DEHP via the ambient air pathway, inhalation route does not indicate risk
  for the general population

5937 EPA has qualitatively evaluated the land pathway (*i.e.*, landfills and application of biosolids), including 5938 down-the-drain releases of consumer products and landfill disposal of consumer articles. Exposure 5939 potential was based on physical and chemical properties, and/or available relevant data. DEHP can leach 5940 from landfill material but is expected to have limited mobility beyond the landfill. DEHP in leachate is 5941 unlikely to infiltrate groundwater due to the high affinity to organic matter and sediment. Interpretation 5942 of the physical and chemical property data also suggest that DEHP is unlikely to infiltrate groundwater 5943 or surface runoff from landfills and is also unlikely to migrate to groundwater via runoff after land 5944 application of biosolids due to its low water solubility and high affinity for sorption to soil. Considering 5945 this, EPA is preliminarily determining that the COUs may not contribute to unreasonable risk of DEHP 5946 due to the general population exposure to soil and water contaminated with DEHP migrating from 5947 biosolids and landfills, including down-the-drain releases and disposal of consumer products. Sections 5948 4.1.3 and 4.3.4 provide more detail about the general population assessment.

5949

5950 With respect to the overall confidence in the assessment, EPA has robust confidence that the high-end 5951 estimated surface water concentration modelled using the Plastic compounding OES is appropriate to 5952 use in its screening level assessment to assess all other OESs and their associated COUs, including 5953 OESs and COUs with releases that could not be quantified and those with releases modeled from generic 5954 scenarios (Section 3.3.1.1). EPA has robust confidence that the ambient air concentration modeled from 5955 releases from the Application of paints, coatings, adhesives, and sealants OES are appropriately 5956 conservative to use for a screening level analysis for all OES and associated COUs (Section 3.3.1.2). 5957 Additionally, EPA determined robust confidence in its qualitative assessment of biosolids and landfills.

5958

5959 Sections 4.1.3 and 4.3.4 provide more detail about the general population assessment.

## **5960 6.2 Environment**

Based on the environmental risk assessment, EPA is preliminarily determining that DEHP presents
unreasonable risk of injury to the environment due to chronic exposure for aquatic vertebrates and
chronic exposure for benthic invertebrates under 20 COUs from releases to water based on a bounding
assessment that represents the highest and lowest possible exposures from water releases.

- 5965 5966 EPA characterized the environmental risk of DEHP using risk quotients (RQs), which compare the 5967 predicted environmental concentration with hazard threshold values. Environmental exposure 5968 concentrations for each compartment (*i.e.*, surface water, pore water, sediment, and soil) were based on 5969 measured (i.e., monitored data and/or available literature) and/or modeled (i.e., E-FAST 2014, VVMW-PSC, AERMOD, IIOAC) concentrations of DEHP as described in Section 3. EPA calculates hazard 5970 thresholds to identify potential concerns to aquatic and terrestrial species. EPA used the COCs 5971 5972 calculated for aquatic organisms, and the hazard values calculated for terrestrial organisms as detailed 5973 within the Draft Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 5974 2024a).
- 5975

5976 Calculated RQs can provide a risk profile by presenting a range of estimates for different environmental 5977 hazard effects for different COUs. An RQ equal to 1 indicates that the exposures are the same as the 5978 concentration that causes effects. An RQ less than 1, when the exposure is less than the effect

5979 concentration, generally indicates that there is not risk of injury to the environment that would support a 5980 determination of unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure 5981 is greater than the effect concentration, generally indicates that, there is risk of injury to the 5982 environment, and EPA considers the assumptions, uncertainties, and conservatisms that support the RQ, 5983 to determine if the chemical substance would present unreasonable risk. Additionally, if a chronic RO is 5984 1 or greater, the Agency evaluates whether the chronic RQ is 1 or greater for 21 days or more for aquatic 5985 species, or 31 days or more for benthic species, based on the exposure period of the hazard toxicity tests 5986 before making a determination of unreasonable risk. Risk was also characterized qualitatively for 5987 specific receptor groups to support conclusions (Table 5-9).

5989 Based on the assessment, EPA is preliminary determining that 20 COUs may significantly contribute to 5990 unreasonable risk to the environment. Of these 20 COUs, 17 COUs were addressed quantitatively using 5991 a bounding assessment based on 2 OESs representing the highest/upper bound and the lowest bound of 5992 possible exposures from water releases (see Table 5-3 and Table 5-4 for RQ values for surface water and 5993 sediment, respectively). EPA identified two OESs, one with the highest and a second with the lowest 5994 surface water releases, capturing releases from all COUs included within the screening level assessment. 5995 Therefore, while EPA did not calculate RO values for all of the COUs; however, the RO values for all 5996 COUs should be captured between the highest and lowest releases. For the surface water risk estimates 5997 (Table 5-3), even the lowest-releasing OES has RQs showing risk (RQ = 7.2 at the harmonic mean), 5998 therefore all COUs in this bounding assessment indicate risk to the environment (see Section 5.3.2 for 5999 additional characterization). For the sediment pore water risk estimates (Table 5-4), the lowest-releasing 6000 OES is not indicating risk, however as explained in Section 5.3.2, all other facilities reporting releases resulted in pore water concentrations with RQs greater than 1; therefore, with exception of the two 6001 6002 COUs mapped to the lower bound OES, which, as previously stated, is not indicating risk, all other 6003 COUs within this bounding assessment indicate risk to the environment.

6004

5988

6005 Three COUs (Industrial use – other uses – hydraulic fracturing; Commercial use – other uses – 6006 laboratory chemicals; Commercial use – other uses – automotive articles) were assessed using modeled 6007 generic scenarios. One of those three COUs assessed with a generic scenario, the Industrial use – other 6008 uses – hydraulic fracturing COU, was assessed using a generic scenario with a surface water release, 6009 while the scenarios for the remaining two COUs encompass environmental releases that discharge to a 6010 combination of surface water, incineration, or landfill. Due to the lack of specificity regarding the media 6011 of release, EPA is unable to quantify the release to water for this COU. However, the fact that the 6012 chronic COCs for aquatic species are so low, indicating a high degree of hazard potential, EPA's 6013 confidence in risk identified by the generic scenarios is robust due to the confidence in aquatic hazard 6014 thresholds and the RQs from the COUs with release data and evaluated with the bounding assessment. 6015 Surface and pore water concentration of DEHP modeled for these three COUs result in concentrations 6016 within the bounds of the lowest and highest DEHP concentrations from TRI releases and result in RQs 6017 greater than 1 under several flow conditions and release distributions (Table 5-5). These COUs based on 6018 generic scenarios would also result in deleterious effects to aquatic organisms-despite the relatively 6019 lower confidence in the exposure level, given the sensitive hazard values for aquatic organisms. See 6020 Section 5.3.2 for more information regarding the aquatic assessment. Table 5-10 summarizes how each 6021 COU was assessed.

6022

EPA is preliminarily determining that 10 COUs may not contribute to unreasonable risk to theenvironment. These 10 COUs result in no releases to the surface water pathway, based on all TRI sites

6025 associated with these COUs reporting 0 water releases, in addition to resulting in no risk through the air 6026 deposition to soil or biosolid application pathways. More information regarding environmental release

6027 estimates and the associated weight of scientific evidence conclusions is in Section 3.2.2 of this draft

6028 risk evaluation. Additionally, in previous assessments, EPA has considered down-the-drain analysis for 6029 consumer product scenarios where it can be reasonably foreseen that the consumer product (e.g., paints, 6030 sealants, oils) will be discarded directly down-the-drain. It is difficult for the Agency to quantify these 6031 end-of-life and down-the-drain exposures for DEHP due to limited information on source attribution of 6032 the consumer COUs, and EPA did not quantitatively assess these scenarios due to limited information, 6033 monitoring data, or modeling tools. Section 3.1.4 discusses the challenges associated with identifying 6034 down-the-drain exposures of DEHP, although EPA acknowledges that there may be DEHP releases to 6035 the environment. Consumer releases to the environment are anticipated to be more dispersed and less 6036 direct than DEHP releases from occupational COUs/OESs quantified for risk estimates for aquatic and 6037 terrestrial receptors. See Section 5.1 and Table 5-10 for additional information.

6038

#### 6.2.1 Populations and Exposures EPA Assessed for the Environment

EPA evaluated risk for aquatic receptors and terrestrial receptors. For aquatic and terrestrial species, the
Agency expects the main environmental exposure pathways for DEHP to be releases to surface water
and subsequent deposition to sediment, and limited dispersal from fugitive and stack air release
deposition to soil, respectively.

6043

6044 For aquatic organisms, EPA has evaluated exposures via surface water and subsequent deposition to 6045 sediment quantitatively. For aquatic plants and algae, the Agency has evaluated exposures qualitatively 6046 since a hazard threshold could not be established below the limit of solubility. Therefore, EPA is 6047 preliminary determining that DEHP is unlikely to present unreasonable risk to aquatic plants or algae. 6048 Similarly, for fish and aquatic invertebrates, the data suggests that DEHP has low acute toxicity and no 6049 definitive effects were observed below the limit of water solubility. Therefore, EPA is preliminary 6050 determining that DEHP is unlikely to present unreasonable risk from acute exposure to aquatic species. 6051 For fish and benthic organisms, the Agency has quantitatively evaluated chronic exposures via surface water and sediment concentrations resulting from COU releases. As previously explained, EPA is 6052 preliminarily determining that those COUs may significantly contribute to unreasonable risk of DEHP 6053 from chronic exposures to fish and benthic organisms. 6054

6055

For terrestrial plants, the Agency has evaluated exposures via air deposition to soil and biosolids application quantitatively using a screening level risk assessment using the OES with the highest air release or considering if air releases were no reported. The assessment results do not indicate risk through the air deposition to soil pathway. Soil surface concentrations for biosolids were calculated from the minimum and maximum recommended application rates for each agricultural crop cover and the maximum concentration of DEHP within topsoil resulted in and RQ of 0.62 for terrestrial plants (Table 5-7), indicating no unreasonable risk through biosolids biosolid application.

- 6064 For terrestrial vertebrates (*i.e.*, mammals), terrestrial invertebrates, and birds, the Agency evaluated 6065 exposures qualitatively, with assessment results not indicating risk.
- 6066

6063

Additionally, EPA evaluated exposures to all environmental receptors from trophic transfer, biosolids (other than terrestrial plants, for which a quantitative biosolids assessment was conducted), landfills, and down the drain disposal associated with consumer use qualitatively.

6070

6071 EPA's confidence in the aquatic exposure assessment is robust for COUs with TRI and DMR release 6072 data and evaluated with a bounding assessment. Although aquatic exposures from COUs with modeled

6072 data and evaluated with a bounding assessment. Although aquatic exposures from COUs with modeled 6073 generic scenarios result in lower confidence compared to aquatic exposures from COUs with TRI and

6074 DMR releases, the Agency's robust confidence in aquatic hazard thresholds and resulting risk estimates

from the TRI and DMR-releasing COUs increases confidence in EPA's assessment of the COUs with

modeled generic scenarios. More information about the Agency's confidence in and the evidence 6076

6077 available about the aquatic, terrestrial, and trophic transfer exposure assessments is in Table 5-8 and 6078 Table 5-9 of this draft risk evaluation.

6079

#### 6.2.2 Summary of Environmental Effects

6080 EPA is preliminarily determining that 17 COUs assessed quantitatively and 3 COUs assessed with a modeled generic scenario may significantly contribute to unreasonable risk to the environment presented 6081 6082 by DEHP because of the following chronic effects:

- 6083 reduced growth and development for aquatic vertebrates; and
- reduced growth and development for benthic-dwelling invertebrates. 6084 •

6085 Although there was no hazard threshold identified from chronic DEHP exposure for aquatic 6086 invertebrates in the water column, because no studies below the limit of water solubility were available 6087 to establish the threshold, the results of quantified risk estimates using COCs representing chronic DEHP exposures to fish (*i.e.*, aquatic vertebrates) and sediment invertebrates adds to the weight of 6088 scientific evidence supporting the identification of risk to the aquatic environment for this chemical 6089 6090 (Section 5.3.6).

6091

6092 EPA is preliminarily determining that DEHP is unlikely to present unreasonable risk from acute 6093 exposures to aquatic vertebrates and aquatic invertebrates. The data suggests that DEHP has low acute 6094 toxicity as no definitive effects were observed below the limit of water solubility and thus EPA has 6095 determined that DEHP is unlikely to result in risk for acute exposure to aquatic species, including 6096 sediment-dwelling organisms (Section 5.3.2).

6097

6098 EPA has determined that DEHP is unlikely to present unreasonable risk for terrestrial plants through air 6099 deposition to soil or biosolid application to soil, as the screening level RQ was less than 1 for terrestrial plants exposed via air deposition (fugitive or stack release), and the RQ derived from the generic 6100 application scenarios and biosolid concentrations collected from the national survey was less than 1 for 6101 6102 terrestrial plants exposed via biosolid application.

6103

6104 EPA has robust confidence that DEHP has chronic effects on aquatic vertebrates in the environment. 6105 The Agency has moderate confidence that DEHP has chronic effects on benthic-dwelling invertebrates 6106 in the environment. EPA has robust confidence that DEHP poses hazard to aquatic vertebrates on a

6107 chronic basis below the limit of water solubility. This robust confidence is supported by two studies in which effects on mortality growth, and development were observed in Japanese medaka fish exposed to 6108

6109 DEHP. For benthic dwelling invertebrates, EPA has moderate confidence based on effects seen on

6110 growth and development. This confidence is supported by one study in which effects on growth were

6111 observed in midge exposed to DEHP. More information about EPA's confidence in the aquatic,

- 6112 terrestrial, and trophic transfer hazard assessments is provided in Table 5-8 and Table 5-9 of this draft
- 6113 risk evaluation.

#### 6114

### 6.2.3 Basis for Unreasonable Risk to the Environment

6115 Based on the risk evaluation for DEHP-including the risk estimates, the environmental effects of

6116 DEHP, the exposures, physical and chemical properties of DEHP, and consideration of uncertainties— 6117 EPA has preliminarily identified unreasonable risk to the environment from DEHP.

6118

- 6119 Consistent with EPA's determination of unreasonable risk to human health, the RQ is not treated as a
- 6120 "bright-line" and other risk-based factors may be considered (e.g., confidence in the hazard and
- exposure characterization, duration, magnitude, uncertainty) for purposes of making an unreasonable 6121

6122 risk determination. EPA is preliminary determining that 20 COUs may significantly contribute to 6123 unreasonable risk based on risk estimates from chronic exposures to aquatic organisms (aquatic 6124 vertebrates and benthic invertebrates) quantitatively estimated through a bounding assessment, using 6125 release data and modeled generic scenarios. Combining the robust confidence for the modeled surface 6126 water and benthic pore water sediment DEHP concentrations based on released data, with robust hazard 6127 confidences for aquatic and benthic assessments (robust and robust, respectively) resulted in overall 6128 confidences of robust in the RO inputs for chronic aquatic and benthic assessments, respectively (Table 6129 5-3 and Table 5-4). Discussion of the bounding approach and the modeled generic scenarios can be

found in Sections 5.1 and Section 5.3.2, respectively.

6130

6131 6132 Three COUs (Industrial use – other uses – hydraulic fracturing; Commercial use – other uses – 6133 laboratory chemicals; and Commercial use – other uses – automotive articles) were assessed using 6134 modeled, generic release scenarios. The Industrial use – other uses – hydraulic fracturing COU was 6135 assessed using a generic scenario with a surface water release, while the scenarios for the other two 6136 COUs detail environmental releases that discharge to a combination of surface water, incineration, or 6137 landfill. EPA acknowledges that although COUs associated with OESs modeled from generic scenarios 6138 result in lower confidence compared to TRI releases, the chronic COCs for aquatic species indicate a 6139 high degree of hazard potential. Surface and pore water concentration of DEHP modeled for these three 6140 OESs result in concentrations within the bounds of the lowest and highest DEHP concentrations from 6141 TRI releases and also result in RQs greater than 1 under several flow conditions and release distributions 6142 (Table 5-5). The robust confidence in aquatic hazard thresholds and resulting risk estimates from TRI 6143 and DMR-releasing COUs increases confidence in the assessment for these three COUs. These COUs 6144 based on generic scenarios would also result in deleterious effects to aquatic organisms, despite the 6145 relatively lower confidence in the exposure level, given the sensitive hazard values for aquatic 6146 organisms.

6147

6148 Although EPA acknowledges that there may be DEHP releases to the environment via the cleaning and 6149 disposal of adhesives, sealants, paints, lacquers, and coatings, the Agency did not quantitatively assess 6150 these scenarios due to limited information, monitoring data, or modeling tools. In addition, these 6151 products can be disposed of when users no longer have use for them, or they have reached the product shelf life and are taken to landfills. EPA did not identify data for DEHP in drinking water in the United 6152 6153 States. Based on the low water solubility and log Kow, DEHP in water is expected to mainly partition to 6154 suspended solids present in water. More information on the consideration of down-the-drain release of 6155 DEHP is in Section 3.1.4 of this draft risk evaluation.

6156

EPA is preliminarily determining that 10 COUs do not appear to contribute to unreasonable risk. EPA is
concluding that these 10 COUs result in no releases to the surface water pathway, based on all TRI sites
associated with these COUs reporting 0 water releases. Additionally, these COUs result in no risk
through the air deposition to soil or biosolid application pathways. More information regarding
environmental release estimates and the associated weight of scientific evidence conclusions is in
Section 3.2.2 of this draft risk evaluation.

6163

6164 In addition, releases to the environment from the 14 consumer COUs are anticipated to be more 6165 dispersed and less direct than DEHP releases from the COUs with quantified risk estimates.

6166

Although there is limited measured data on DEHP in landfill leachates, the data suggest that DEHP is
unlikely to be present in landfill leachates. Further, the small amounts of DEHP that could potentially be
in landfill leachates will have limited mobility and are unlikely to infiltrate groundwater due to high

- 6170 affinity of DEHP for organic compounds that would be present in receiving soil and sediment (U.S. 6171 EPA, 2025q).
- 6172

EPA has determined that DEHP is unlikely to present unreasonable risk to terrestrial plants through air
deposition to soil or biosolid application to soil, as the screening level RQ was less than 1 for terrestrial
plants exposed via air deposition (fugitive or stack release), and the RQ derived from the generic
application scenarios and biosolid concentrations collected from the national survey was less than 1 for
terrestrial plants exposed via biosolid application. Therefore, EPA is preliminary determining that DEHP
is unlikely to present unreasonable risk to terrestrial plants via biosolid application.

6179

Based on conservative assumptions of environmental topsoil concentrations and food consumption,
absence of effects studies with measurable effects for terrestrial invertebrates, and biota monitoring
values orders of magnitude less than concentrations used in bird studies, EPA is preliminary determining
that DEHP is unlikely to present unreasonable risk to terrestrial mammals, terrestrial invertebrates, and
birds.

6184 6185

6186 EPA qualitatively assessed the potential for trophic transfer of DEHP through food webs to wildlife

- 6187 using the available environmental monitoring information and physical and chemical properties. DEHP
- 6188 is not expected to be persistent in the environment as it is expected to degrade rapidly under most
- 6189 environmental conditions (though there is delayed biodegradation in low-oxygen media); and DEHP's
  6190 bioavailability is expected to be limited (see Section 5.3.4). With respect to trophic transfer,
- 6190 bioavariability is expected to be initial (see Section 5.5.4). With respect to tropinc transfer, 6191 concentrations of DEHP in soil (biosolids, landfills, air deposition) and air is limited or is not expected
- 6192 to be bioavailable. Therefore, EPA is preliminarily determining that DEHP does not present
- 6193 unreasonable risk to the environment via trophic transfer. The Agency has robust confidence that that
- 6194 DEHP is not readily found or if found is in relatively low concentrations in organism tissues, and that
- 6195 DEHP has low bioaccumulation and biomagnification potential in aquatic and terrestrial organisms, and 6196 thus low potential for trophic transfer through food webs. Therefore, EPA is preliminarily determining
- 6197 that DEHP does not present unreasonable risk to the environment via trophic transfer.
- 6198

6199 EPA evaluated activities resulting in exposures associated with distribution in commerce throughout the 6200 various life cycle stages and COUs (e.g., manufacturing, processing, industrial use, commercial use, 6201 transportation) rather than a single distribution scenario. The Agency expects that environmental 6202 releases from distribution in commerce will be similar or less than the exposure estimates from the 6203 COUs evaluated that did not exceed hazard to ecological receptors. EPA further expects all the DEHP or 6204 DEHP-containing products and/or articles to be transported in closed system or otherwise to be 6205 transported in a form (e.g., articles containing DEHP) such that there is negligible potential for releases 6206 except during an incident. Therefore, no separate assessment was performed for estimating releases and 6207 exposures from distribution in commerce.

6208

6209 EPA's overall environmental risk characterization confidence levels ranged from moderate to robust for 6210 all quantitative assessments. More information about EPA's confidence in and the evidence available 6211 about the environmental risk assessment is provided in Table 5-8 and Table 5-9 of this draft risk 6212 and the environmental risk assessment is provided in Table 5-8 and Table 5-9 of this draft risk

6212 evaluation.

# 6.3 Additional Information Regarding the Basis for the Risk 6214 Determination

Table 6-1 summarizes the basis for this preliminary unreasonable risk determination of injury to human health presented in this DEHP risk evaluation. In this table, bold text indicates that an MOE is below the

6217 benchmark value. This table identifies the duration of exposure (*e.g.*, acute, intermediate, or chronic

- 6218 duration) and the exposure route to the population. As explained in Section 6.2, for this preliminary
- 6219 unreasonable risk determination, EPA has considered the effects of DEHP to human health, including
- 6220 PESS, as well as a range of risk estimates as appropriate, risk related factors and the confidence in the
- analysis. See Sections 4.3 and 5.3 for a summary of risk estimates.

6222

#### 6223 Table 6-1. Overall Worker Risk Summary Table

	COU			Exposure		ion Risk H 1mark M(		Dermal Risk Estimates (Benchmark MOE = 30)			
Life Cycle Stage – Category	Subcategory	OES	OES Worker Exposu Population Level		Acute	Inter.	Chronic	Acute	Inter.	Chronic	
			Average Adult	СТ	733	1,000	1,071	15,816	21,567	23,091	
Manufacturing –			Worker	HE	400	545	584	7,908	10,784	11,546	
Domestic	Domestic manufacturing	Manufacturin	Female of	СТ	664	905	969	17,214	23,474	25,133	
Manufacturing		g	Reproductive Age	HE	362	494	529	8,607	11,737	12,566	
			ONU	СТ	733	1,000	1,071	-	-	_	
Manufacturing –	Importing		Average Adult	СТ	63	86	92	15,816	21,567	23,091	
Importing			Worker	HE	17	23	25	7,908	10,784	11,546	
Processing –	Repackaging in wholesale and retail trade	Import and repackaging	Female of	CT	57	78	83	17,214	23,474	25,133	
Repacking	and in paint and coating manufacturing	repackaging	Reproductive Age	HE	15	21	22	8,607	11,737	12,566	
			ONU	СТ	63	86	92	_	-	—	
Processing –	Plasticizer in basic organic chemical	Rubber manufacturin g		СТ	5.3	7.2	7.7	428	584	625	
Incorporation into article	manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding		Average Adult Worker	HE	1.1	1.5	1.6	214	292	313	
Processing –	purchased resins; miscellaneous		Female of Reproductive Age	СТ	4.8	6.5	7.0	466	636	681	
Incorporation into formulation,				HE	1.0	1.3	1.4	233	318	340	
mixture, or reaction product			ONU	СТ	5.3	7.2	7.7	428	584	625	
Processing –	Plasticizer in basic organic chemical		Average Adult	СТ	29	40	43	428	584	625	
Incorporation into formulation,	manufacturing; custom compounding of purchased resins; miscellaneous		Worker	HE	3.2	4.3	4.7	214	292	313	
mixture, or reaction	manufacturing; paint and coating		Female of	СТ	27	36	39	466	636	681	
product	manufacturing; adhesive manufacturing; plastic material and resin manufacturing;	Plastic compounding	Reproductive Age	HE	2.9	3.9	4.2	233	318	340	
	synthetic rubber manufacturing; basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	compounding	ONU	СТ	1,100	1,500	1,606	428	584	625	

Life Carela Sterra	COU	11 A B B B B B B B B B B B B B B B B B B	Exposure		ion Risk E 1mark MC		Dermal Risk Estimates (Benchmark MOE = 30)			
Life Cycle Stage – Category	Subcategory	OLS	OES Worker Exposi Population Leve		Acute	Inter.	Chronic	Acute	Inter.	Chronic
Processing –	Plasticizer in basic organic chemical		Average Adult	СТ	733	1,000	1,071	15,816	21,567	23,091
Incorporation into	manufacturing; custom compounding of purchased resins; miscellaneous		Worker	HE	400	545	584	7,908	10,784	11,546
formulation, mixture, or reaction product	purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; all other basic inorganic chemical manufacturing; wholesale and retail trade; services; ink, toner and colorant manufacturing	mixture or	Female of Reproductive Age	СТ	664	905	969	17,214	23,474	25,133
Processing – Other	Miscellaneous processing (cyclic crude and	-		HE	362	494	529	8,607	11,737	12,566
uses	intermediate manufacturing; processing aid specific to hydraulic fracturing)		ONU	СТ	733	1,000	1,071	_	-	_
Processing –	Plasticizer in basic organic chemical			СТ	26	35	38	428	584	625
Incorporation into article	manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; PVC extruding	Plastic	Average Adult Worker	HE	17	23	24	214	292	313
Industrial Use –	Solid rocket motor insulation and other	converting	Female of	СТ	23	32	34	466	636	681
Other uses	aerospace applications		Reproductive Age	HE	15	20	22	233	318	340
	Automotive Articles		ONU	СТ	26	35	38	428	584	625
Industrial Use – Other uses Industrial Use – Construction, paint, electrical, and metal	Paints and coatings Paints and coatings	-	Average Adult Worker	СТ	29	40	42	822	1,121	1,201
products		Spray								
Commercial Use – Construction, paint,	Adhesives and sealants	application of paints,		HE	0.4	0.5	0.6	411	561	600
electrical, and meta	Deinte and coefings	-coatings,		HE CT	0.4 26	36	38	411 895	1,221	1,307
products	Paints and coatings	adhesives, and sealants	Female of	HE	0.4	0.5	0.5	448	610	653
Commercial Use – Furnishing, cleaning, and treatment care products	All-purpose waxes and polishes		Reproductive Age	СТ	29	40	42	822	1,121	1,201

	COU	XX/ 1			Inhalati	ion Risk E	stimates	Dermal Risk Estimates				
Life Cycle Stage –	Subcategory	OES	ORS		Worker Exposure Population Level	Exposure Level	(Benchmark MOE = 30)			(Benchmark MOE = 30)		
Category	~~~~gj		_		Acute	Inter.	Chronic	Acute	Inter.	Chronic		
Industrial Use –	Paints and coatings			CT	5.3	7.2	7.7	822	1,121	1,201		
Other uses				HE	1.1	1.5	1.6	411	561	600		
Industrial Use – Construction, paint, electrical, and metal products		i on oping	Average Adult Worker									
Commercial Use –		adhesives, and sealants	ealants Female of	СТ	4.8	6.5	7.0	895	1,221	1,307		
Construction, paint, electrical, and metal				HE	1.0	1.3	1.4	448	610	653		
products			ONU	СТ	5.3	7.2	7.7	_	_	_		
Commercial Use – Furnishing,	Fabric, textile, and leather products; furniture and furnishings		Average Adult	СТ	2,838,710	3,870,968	4,819,205	428	584	727		
	Fabric enhancer	Textile	Worker	HE	204,651	279,070	347,431	214	292	364		
treatment care products			Female of	СТ	2,569,919	3,504,435	4,362,886	466	636	791		
Products		Reproductive Age	HE	185,273	252,645	314,534	233	318	396			
			ONU	СТ	2,838,710	3,870,968	4,819,205	428	584	727		

Life Cycle Steere	COU			Exposure		ion Risk E ımark MC		Dermal Risk Estimates (Benchmark MOE = 30)			
Life Cycle Stage – Category	Subcategory	OLD	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	
Commercial Use –	Batteries and capacitors			СТ	220	300	337	428	584	657	
Construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	-	Average Adult Worker	HE	80	109	123	214	292	328	
	Machinery, mechanical appliances, electrical/electronic articles			СТ	199	272	305	466	636	715	
Commercial Use – Automotive, fuel, agriculture, and outdoor use products	Lawn and garden care products	Fabrication or	Female of Reproductive Age	HE	72	99	111	233	318	357	
Commercial Use – Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging) and other articles with routine direct contact during normal use, including paper articles; rubber articles; plastic articles (hard); plastic articles (soft)	use of final products and articles	ONU	СТ	220	300	337	428	584	657	
	Packaging (excluding food packaging), including paper articles										
	Toys, playground, and sporting equipment										
Commercial Use – Furnishing, cleaning, and treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles fabrics, textiles, and apparel										
			Average Adult	СТ	5.3	7.2	7.7	822	1,121	1,201	
Commercial Use –		Use of dyes,	Worker	HE	1.1	1.5	1.6	411	561	600	
Packaging, paper, plastic, toys, hobby	Ink, toner and colorants		I emaie of	СТ	4.8	6.5	7.0	895	1,221	1,307	
products		fixing agents	Reproductive Age	HE	1.0	1.3	1.4	448	610	653	
			ONU	СТ	5.3	7.2	7.7	-	-	-	
			Average Adult	СТ	26	35	38	822	1,121	1,201	
Industrial Use – Construction, paint,		Formulation	Worker	HE	1.1	1.5	1.6	411	561	600	
electrical, and metal	Adhesives and Sealants	for diffusion	Female of	СТ	23	32	34	895	1,221	1,307	
products		bonding	Reproductive Age	HE	1.0	1.4	1.5	448	610	653	
			ONU	СТ	26	35	38	-	-	-	

	COU	-	Exposure		ion Risk E mark MO		Dermal Risk Estimates (Benchmark MOE = 30)			
Life Cycle Stage – Category	Subcategory	OES	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic
			Average Adult	СТ	880	1,200	1,367	428	584	665
			Worker	HE	88	120	128	214	292	313
Commercial Use –		Use of	Female of	СТ	797	1,086	1,237	466	636	724
Other uses	Laboratory chemicals	laboratory chemicals	Reproductive Age	HE	80	109	116	233	318	340
		chemicals	0) W I	СТ	880	1,200	1,367	428	584	665
			ONU	HE	880	1,200	1,285	428	584	625
			Average Adult	СТ	160	218	249	822	1,121	1,277
			Worker	HE	80	109	117	411	561	600
Commercial Use –	Automotive articles	Use of	Female of	СТ	145	198	225	895	1,221	1,390
Other uses		automotive care products		HE	72	99	106	448	610	653
			ONU	СТ	176	240	273	-	-	_
				HE	147	200	214	_	_	-
	Hydraulic fracturing	Use in hydraulic fracturing	Female of Reproductive Age	СТ	733	22,000	267,667	822	24,673	300,187
				HE	400	4,000	48,667	411	4,112	50,031
Industrial Use –				СТ	664	19,917	242,322	895	26,854	326,726
Other uses				HE	362	3,621	44,059	448	4,476	54,454
				СТ	733	22,000	267,667	<b>—</b>	—	-
				HE	733	7,333	89,222	-	_	_
			Average Adult	СТ	26	35	38	428	584	625
			Worker	HE	17	23	24	214	292	313
Processing – Recycling	Recycling	Recycling	Female of	СТ	23	32	34	466	636	681
Recyching			Reproductive Age	HE	15	20	22	233	318	340
			ONU	СТ	26	35	38	428	584	625
			Average Adult	СТ	83	113	121	428	584	625
		Waste handling,	Worker	HE	5.7	7.8	8.3	214	292	313
Disposal: Disposal	Disposal	treatment and	Female of	СТ	75	102	110	466	636	681
		disposal		HE	5.2	7.1	7.6	233	318	340
			ONU	СТ	83	113	121	428	584	625

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## 6225 **REFERENCES**

6226	<u>3M. (2017)</u> . 3M One-Step Rust Converter, PN 3513.
6227	https://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSuUn_zu8l00xM8teoxtvmv70k1
6228	7zHvu9lxtD7SSSSSS
6229	<u>3M. (2019)</u> . 3M Temflex Corrosion Protection Tapes 1100, 1100P and 1200.
6230	https://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8100xmxtvMYt15v70k
6231	17zHvu9lxtD7xtBevSSSSS-
6232	<u>3M Company. (2019)</u> . 3M <sup>™</sup> Finesse-It Polish - Finishing Material, 13084, 28792, 81235, 83058.
6233	http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8100xm8tZP8_91v70k17
6234	zHvu9lxtD7xt1evSSSSSS-
6235	Abdul-Ghani, S; Yanai, J; Abdul-Ghani, R; Pinkas, A; Abdeen, Z. (2012). The teratogenicity and
6236	behavioral teratogenicity of di(2-ethylhexyl) phthalate (DEHP) and di-butyl Phthalate (DBP) in a
6237	chick model. Neurotoxicol Teratol 34: 56-62. http://dx.doi.org/10.1016/j.ntt.2011.10.001
6238	ACC HPP. (2019). Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP). American
6239	Chemistry Council High Phthalates Panel.
6240	Adeogun, AO; Ibor, OR; Omiwole, RA; Hassan, T; Adegbola, RA; Adewuyi, GO; Arukwe, A. (2015a).
6241	Occurrence, species, and organ differences in bioaccumulation patterns of phthalate esters in
6242	municipal domestic water supply lakes in Ibadan, Nigeria. J Toxicol Environ Health A 78: 761-
6243	777. http://dx.doi.org/10.1080/15287394.2015.1030487
6244	Adeogun, AO; Ibor, OR; Omogbemi, ED; Chukwuka, AV; Adegbola, RA; Adewuyi, GA; Arukwe, A.
6245	(2015b). Environmental occurrence and biota concentration of phthalate esters in Epe and Lagos
6246	Lagoons, Nigeria. Mar Environ Res 108: 24-32.
6247	http://dx.doi.org/10.1016/j.marenvres.2015.04.002
6248	AIA. (2019). Comment submitted by David Hyde, Director, Environmental Policy, Aerospace Industries
6249	Association (AIA) on Di-2-ethylhexyl phthalate uses for EPA high priority candidates.
6250	Arlington, VA. https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0433-0004
6251	Andrade, AJ; Grande, SW; Talsness, CE; Gericke, C; Grote, K; Golombiewski, A; Sterner-Kock, A;
6252	Chahoud, I. (2006a). A dose response study following in utero and lactational exposure to di-(2-
6253	ethylhexyl) phthalate (DEHP): Reproductive effects on adult male offspring rats. Toxicology
6254	228: 85-97. http://dx.doi.org/10.1016/j.tox.2006.08.020
6255	Andrade, AJ; Grande, SW; Talsness, CE; Grote, K; Golombiewski, A; Sterner-Kock, A; Chahoud, I.
6256	(2006b). A dose-response study following in utero and lactational exposure to di-(2-ethylhexyl)
6257	phthalate (DEHP): Effects on androgenic status, developmental landmarks and testicular
6258	histology in male offspring rats. Toxicology 225: 64-74.
6259	http://dx.doi.org/10.1016/j.tox.2006.05.007
6260	Armada, D; Llompart, M; Celeiro, M; Garcia-Castro, P; Ratola, N; Dagnac, T; de Boer, J. (2022).
6261	Global evaluation of the chemical hazard of recycled tire crumb rubber employed on worldwide
6262	synthetic turf football pitches. Sci Total Environ 812: 152542.
6263	http://dx.doi.org/10.1016/j.scitotenv.2021.152542
6264	ATSDR. (1993). Toxicological profile for di(2-ethylhexyl)phthalate [ATSDR Tox Profile]. (TP-92/05).
6265	Atlanta, GA.
6266	ATSDR. (2002). Toxicological profile for di(2-ethylhexyl) phthalate [ATSDR Tox Profile]. Atlanta,
6267	GA: U.S. Department of Health and Human Services, Public Health Service.
6268	http://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=684&tid=65
6269	ATSDR. (2019). Toxicological profile for di(2-ethylhexyl)phthalate (DEHP): draft for public comment.
6270	ATSDR. (2022). Toxicological profile for di(2-ethylhexyl)phthalate (DEHP) [ATSDR Tox Profile].
6271	(CS274127-A). Atlanta, GA. <u>https://www.atsdr.cdc.gov/ToxProfiles/tp9.pdf</u>

6272	Axalta Coating Systems. (2023). Safety Data Sheet (SDS): Undercoat Primer Surfacer. Glen Mills, PA.
6273	https://www.axalta.com/content/dam/NA/US/Public/Challenger/English_SDS_NR/CH2030-
6274	<u>SDS-EN.pdf</u>
6275	Axalta Coating Systems LLC. (2024). Safety Data Sheet (SDS): Rapid Dry Multi-Surface Gray Primer.
6276	Glen Mills, PA. https://www.axalta.com/content/dam/NA/HQ/Public/PCL/Documents/sds-
6277	english/633-SDS-EN.pdf
6278	Barnthouse, LW; DeAngelis, DL; Gardner, RH; O'Neill, RV; Suter, GW; Vaughan, DS. (1982).
6279	Methodology for Environmental Risk Analysis. (ORNL/TM-8167). Oak Ridge, TN: Oak Ridge
6280	National Laboratory.
6281	Blystone, CR; Kissling, GE; Bishop, JB; Chapin, RE; Wolfe, GW; Foster, PM. (2010). Determination of
6282	the di-(2-ethylhexyl) phthalate NOAEL for reproductive development in the rat: importance of
6283	the retention of extra animals to adulthood. Toxicol Sci 116: 640-646.
6284	http://dx.doi.org/10.1093/toxsci/kfq147
6285	BriteLine. (2018). Material Safety Data Sheet (MSDS): BriteLine Banner. Riverview, FL.
6286	https://www.briteline.com/cmss_files/attachmentlibrary/BriteLine-Product-Sheet-
6287	PDFs/BriteLine-Banner-MSDS.pdf
6288	Burkhard, LP; Arnot, JA; Embry, MR; Farley, KJ; Hoke, RA; Kitano, M; Leslie, HA; Lotufo, GR;
6289	Parkerton, TF; Sappington, KG; Tomy, GT; Woodburn, KB. (2012). Comparing laboratory and
6290	field measured bioaccumulation endpoints. Integr Environ Assess Manag 8: 17-31.
6291 6292	http://dx.doi.org/10.1002/ieam.260
6292 6293	Carrara, SM; Morita, DM; Boscov, ME. (2011). Biodegradation of di(2-ethylhexyl)phthalate in a typical tropical soil. J Hazard Mater 197: 40-48. http://dx.doi.org/10.1016/j.jhazmat.2011.09.058
6293 6294	<u>Cartwright, CD; Thompson, IP; Burns, RG. (2000)</u> . Degradation and impact of phthalate plasticizers on
6294 6295	soil microbial communities. Environ Toxicol Chem 19: 1253-1261.
6296	http://dx.doi.org/10.1002/etc.5620190506
6297	<u>CDC. (2013)</u> . Fourth national report on human exposure to environmental chemicals, updated tables,
6298	September 2013. (CS244702-A). Atlanta, GA.
6299	http://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Sep2013.pdf
6300	CDC. (2021). Child development: Positive parenting tips [Website].
6301	https://www.cdc.gov/ncbddd/childdevelopment/positiveparenting/index.html
6302	Chem Service Inc. (2018). Safety Data Sheet (SDS): EPA Method 625 Base Neutrals Mixture - 1. West
6303	Chester, PA. http://cdn.chemservice.com/product/msdsnew/External/English/M-
6304	EPA625BN1X3%20English%20SDS%20US.pdf
6305	Chemical Manufacturers Association. (1991). Chloride film in male Fischer 344 rats (final report) with
6306	attachments and cover sheet dated 042491 [TSCA Submission]. (EPA/OTS Doc #86-
6307	910000794). https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/OTS0529426.xhtml
6308	Chen, SB. (1998). Migration of diisononyl phthalate from a Danish polyvinyl chloride teether. Bethesda,
6309	MD: U.S. Consumer Product Safety Commission.
6310	Cherrie, JW; Semple, S; Brouwer, D. (2004). Gloves and Dermal Exposure to Chemicals: Proposals for
6311	Evaluating Workplace Effectiveness. Ann Occup Hyg 48: 607-615.
6312	http://dx.doi.org/10.1093/annhyg/meh060
6313	Chikae, M; Hatano, Y; Ikeda, R; Morita, Y; Hasan, Q; Tamiya, E. (2004a). Effects of bis(2-ethylhexyl)
6314	phthalate and benzo[a]pyrene on the embryos of Japanese medaka (Oryzias latipes). Environ
6315	Toxicol Pharmacol 16: 141-145. <u>http://dx.doi.org/10.1016/j.etap.2003.11.007</u>
6316	Chikae, M; Ikeda, R; Hatano, Y; Hasan, Q; Morita, Y; Tamiya, E. (2004b). Effects of bis(2-ethylhexyl)
6317	phthalate, $\gamma$ -hexachlorocyclohexane, and 17 $\beta$ -estradiol on the fry stage of medaka (Oryzias
6318	latipes). Environ Toxicol Pharmacol 18: 9-12. <u>http://dx.doi.org/10.1016/j.etap.2004.04.004</u>

6319	Corradetti, B; Stronati, A; Tosti, L; Manicardi, G; Carnevali, O; Bizzaro, D. (2013). Bis-(2-ethylexhyl)
6320	phthalate impairs spermatogenesis in zebrafish (Danio rerio). Reprod Biol 13: 195-202.
6321	http://dx.doi.org/10.1016/j.repbio.2013.07.003
6322	Cousins, I; Mackay, D. (2000). Correlating the physical-chemical properties of phthalate esters using
6323	the `three solubility' approach. Chemosphere 41: 1389-1399. http://dx.doi.org/10.1016/S0045-
6324	<u>6535(00)00005-9</u>
6325	Duro Dyne Corporation. (2024). Safety Data Sheet (SDS): DURO DYNE DUROLON FABRIC. Bay
6326	Shore, NY. https://www.durodyne.com/msds/DFD-Durolon_SDS.pdf
6327	Eagle I.F.P. Company. (2015a). Safety Data Sheet (SDS): Eagle Paver Sealer. Nashville, TN.
6328	https://docs.wixstatic.com/ugd/51c53a_b9d365d033d0406eb1fcc6754dc5c707.pdf
6329	Eagle I.F.P. Company. (2015b). Safety Data Sheet (SDS): Eagle Supreme Seal. Nashville, TN.
6330	https://docs.wixstatic.com/ugd/51c53a_4f73c7f584f2420bb44d933c74ef7cf6.pdf
6331	EC/HC. (1994). Canadian Environmental Protection Act: Priority substances list assessment report:
6332	Bis(2-ethylhexyl) phthalate. Ottawa, Ontario.
6333	EC/HC. (2015). State of the science report: Phthalate substance grouping: Medium-chain phthalate
6334	esters: Chemical Abstracts Service Registry Numbers: 84-61-7; 84-64-0; 84-69-5; 523-31-9;
6335	5334-09-8;16883-83-3; 27215-22-1; 27987-25-3; 68515-40-2; 71888-89-6. Gatineau, Quebec:
6336	Environment Canada, Health Canada. https://www.ec.gc.ca/ese-ees/4D845198-761D-428B-
6337	A519-75481B25B3E5/SoS_Phthalates%20%28Medium-chain%29_EN.pdf
6338	EC/HC. (2017). Draft screening assessment: Phthalate substance grouping. Ottawa, Ontario:
6339	Government of Canada, Environment Canada, Health Canada. http://www.ec.gc.ca/ese-
6340	ees/default.asp?lang=En&n=516A504A-1
6341	ECB. (2008). European Union risk assessment report: Bis(2-ethylhexyl)phthalate (DEHP) [Standard]. In
6342	2nd Priority List. (EUR 23384 EN). Luxembourg: Office for Official Publications of the
6343	European Communities. https://op.europa.eu/en/publication-detail/-/publication/80eaeafa-5985-
6344	<u>4481-9b83-7b5d39241d52</u>
6345	ECCC/HC. (2020). Screening assessment - Phthalate substance grouping. (En14-393/2019E-PDF).
6346	Environment and Climate Change Canada, Health Canada.
6347	https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-
6348	substances/screening-assessment-phthalate-substance-grouping.html
6349	ECHA. (2008). Member state committee support document for identification of bis(2-
6350	ethylhexyl)phthalate (DEHP) as a substance of very high concern. Helsinki, Finland.
6351	https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/10410580
6352	ECHA. (2011). Annex XV restriction report: Proposal for a restriction, version 2. Substance name:
6353	bis(2-ehtylhexyl)phthlate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP),
6354	diisobutyl phthalate (DIBP). Copenhagen, Denmark: Danish Environmental Protection Agency ::
6355	Danish EPA. https://echa.europa.eu/documents/10162/c6781e1e-1128-45c2-bf48-8890876fa719
6356	ECHA. (2013). Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52
6357	of Annex XVII to REACH Regulation (EC) No 1907/2006. Helsinki, Finland.
6358	http://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715
6359	ECHA. (2014). Member state committee support document for identification of bis(2-ethylhexyl)
6360	phthalate (DEHP) as a substance of very high concern because of its endocrine disrupting
6361	properties which cause probable serious effects to the environment which give rise to an
6362	equivalent level of concern to those of CMR and PBT/vPvB substances. Helsinki, Finland.
6363	https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/10410581
6364	ECHA. (2017a). Annex to the Background document to the Opinion on the Annex XV dossier
6365	proposing restrictions on four phthalates (DEHP, BBP, DBP, DIBP). (ECHA/RAC/RES-O-
6366	0000001412-86-140/F; ECHA/SEAC/RES-O-0000001412-86-154/F).
6367	https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/10328892

(2(0	
6368	ECHA. (2017b). Opinion on an Annex XV dossier proposing restrictions on four phthalates (DEHP,
6369	BBP, DBP, DIBP). (ECHA/RAC/RES-O-0000001412-86-140/F). Helsinki, Finland.
6370	https://echa.europa.eu/documents/10162/e39983ad-1bf6-f402-7992-8a032b5b82aa
6371	ECJRC. (2003). European Union risk assessment report: 1,2-Benzenedicarboxylic acid, di-C8-10-
6372	branched alkyl esters, C9-rich - and di-"isononyl" phthalate (DINP). In European Union Risk
6373	Assessment Report, Vol 35. (EUR 20784 EN). Luxembourg, Belgium: Office for Official
6374	Publications of the European Communities. http://bookshop.europa.eu/en/european-union-risk-
6375	assessment-report-pbEUNA20784/
6376	EFSA. (2005). Opinion of the Scientific Panel on food additives, flavourings, processing aids and
6377	materials in contact with food (AFC) related to Bis(2-ethylhexyl)phthalate (DEHP) for use in
6378	food contact materials. EFSA J 3: 243. http://dx.doi.org/10.2903/j.efsa.2005.243
6379	EFSA. (2019). Update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP),
6380	bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate
6381	(DIDP) for use in food contact materials. EFSA J 17: ee05838.
6382	http://dx.doi.org/10.2903/j.efsa.2019.5838
6383	EPA, US. (2025). Draft Occupational and Consumer Cumulative Risk Calculator for Di(2-ethylhexyl)
6384	Phthalate (DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6385	Equifit. (2024). EquiFit® Rain Jacket [Website]. <u>https://equifit.net/products/equifit-rain-jacket</u>
6386	ESAB. (2024). Safety Data Sheet (SDS): Arcair Sea-Jet Electrode. Denton, TX.
6387	https://www.stoodyind.com/Safety/MSDS/Arcair%20SeaJet%20Electrode.pdf
6388	European Commission. (2009). State of the art report on mixture toxicity - Final report. Brussels,
6389	Belgium: European Commission.
6390	https://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf
6391	Fiala, F; Steiner, I; Kubesch, K. (2000). Migration of di-(2-ethylhexyl)phthalate (DEHP) and diisononyl
6392	phthalate (DINP) from PVC articles. Dtsch Lebensm-Rundsch 96: 51-57.
6393	Fujita, M; Ike, M; Ishigaki, T; Sei, K; Jeong, JS; Makihira, N; Lertsirisopon, R. (2005). Biodegradation
6394	of Three Phthalic Acid Esters by Microorganisms from Aquatic Environment. Nihon Mizushori
6395	Seibutsu Gakkaishi 41: 193-201. http://dx.doi.org/10.2521/jswtb.41.193
6396	Gao, M; Dong, Y; Liu, Y; Song, Z. (2018). Photosynthetic and antioxidant response of wheat to di(2-
6397	ethylhexyl) phthalate (DEHP) contamination in the soil. Chemosphere 209: 258-267.
6398	http://dx.doi.org/10.1016/j.chemosphere.2018.06.090
6399	Garberg, P; Högberg, J; Lundberg, I; Lundberg, P. (1989). NIOH and NIOSH basis for an occupational
6400	health standard. Di(2-ethylhexyl)phthalate (DEHP). Arbete och Hälsa 25.
6401	Gejlsbjerg, B; Klinge, C; Madsen, T. (2001). Mineralization of organic contaminants in sludge-soil
6402	mixtures. Environ Toxicol Chem 20: 698-705. http://dx.doi.org/10.1002/etc.5620200402
6403	Golshan, M; Hatef, A; Socha, M; Milla, S; Butts, IA; Carnevali, O; Rodina, M; Sokołowska-
6404	Mikołajczyk, M; Fontaine, P; Linhart, O; Alavi, SM. (2015). Di-(2-ethylhexyl)-phthalate
6405	disrupts pituitary and testicular hormonal functions to reduce sperm quality in mature goldfish.
6406	Aquat Toxicol 163: 16-26. http://dx.doi.org/10.1016/j.aquatox.2015.03.017
6407	Grande, SW; Andrade, AJ; Talsness, CE; Grote, K; Chahoud, I. (2006). A dose-response study
6408	following in utero and lactational exposure to di(2-ethylhexyl)phthalate: effects on female rat
6409	reproductive development. Toxicol Sci 91: 247-254. <u>http://dx.doi.org/10.1093/toxsci/kfj128</u>
6410	<u>Greene, MA. (2002)</u> . Mouthing times among young children from observational data. Bethesda, MD:
6411	U.S. Consumer Product Safety Commission.
6412	<u>GWPC and IOGCC. (2022)</u> . FracFocus: Chemical disclosure registry [Database].
6413	https://fracfocus.org/data-download
6414	Hayton, WL; Barron, MG; Tarr, BD. (1990). Effect of Body Size on the Uptake and Bioconcentration of
6415	Di-2-Ethylhexyl Phthalate in Rainbow Trout. Environ Toxicol Chem 9: 989-996.

6416	HB Chemical. (2015). Safety Data Sheet (SDS): VINOPRENE 647. Twinsburg, OH.
6417	https://web.archive.org/web/20210506161832/https://www.hbchemical.com/wp-
6418	content/uploads/2014/04/VINOPRENE-647-SDS.pdf
6419	He, L; Fan, S; Müller, K; Wang, H; Che, L; Xu, S; Song, Z; Yuan, G; Rinklebe, J; Tsang, DCW; Ok,
6420	YS; Bolan, NS. (2018). Comparative analysis biochar and compost-induced degradation of di-(2-
6421	ethylhexyl) phthalate in soils. Sci Total Environ 625: 987-993.
6422	http://dx.doi.org/10.1016/j.scitotenv.2018.01.002
6423	Health Canada. (2015). Supporting documentation: Carcinogenicity of phthalates - mode of action and
6424	human relevance. In Supporting documentation for Phthalate Substance Grouping. Ottawa, ON.
6425	Heindler, FM; Alajmi, F; Huerlimann, R; Zeng, C; Newman, SJ; Vamvounis, G; van Herwerden, L.
6426	(2017). Toxic effects of polyethylene terephthalate microparticles and Di(2-ethylhexyl)phthalate
6427	on the calanoid copepod, Parvocalanus crassirostris. Ecotoxicol Environ Saf 141: 298-305.
6428	http://dx.doi.org/10.1016/j.ecoenv.2017.03.029
6429	Hines, EP; Calafat, AM; Silva, MJ; Mendola, P; Fenton, SE. (2009). Concentrations of phthalate
6430	metabolites in milk, urine, saliva, and serum of lactating North Carolina women. Environ Health
6431	Perspect 117: 86-92. http://dx.doi.org/10.1289/ehp.11610
6432	Hopf, NB; Berthet, A; Vernez, D; Langard, E; Spring, P; Gaudin, R. (2014). Skin permeation and
6433	metabolism of di(2-ethylhexyl) phthalate (DEHP). Toxicol Lett 224: 47-53.
6434	http://dx.doi.org/10.1016/j.toxlet.2013.10.004
6435	Hsu, NY; Liu, YC; Lee, CW; Lee, CC; Su, HJ. (2017). Higher moisture content is associated with
6436	greater emissions of DEHP from PVC wallpaper. Environ Res 152: 1-6.
6437	http://dx.doi.org/10.1016/j.envres.2016.09.027
6438	Hu, XY; Wen, B; Zhang, S; Shan, XQ. (2005). Bioavailability of phthalate congeners to earthworms
6439	(Eisenia fetida) in artificially contaminated soils. Ecotoxicol Environ Saf 62: 26-34.
6440	http://dx.doi.org/10.1016/j.ecoenv.2005.02.012
6441	Huang, LP; Lee, CC; Hsu, PC; Shih, TS. (2011). The association between semen quality in workers and
6442	the concentration of di(2-ethylhexyl) phthalate in polyvinyl chloride pellet plant air. Fertil Steril
6443	96: 90-94. http://dx.doi.org/10.1016/j.fertnstert.2011.04.093
6444	Huber, S; Warner, NA; Nygård, T; Remberger, M; Harju, M; Uggerud, HT; Kaj, L; Hanssen, L. (2015).
6445	A broad cocktail of environmental pollutants found in eggs of three seabird species from remote
6446	colonies in Norway. Environ Toxicol Chem 34: 1296-1308. http://dx.doi.org/10.1002/etc.2956
6447	IARC. (2013). Di(2-ethylhexyl)phthalate [IARC Monograph]. In IARC Monographs on the Evaluation
6448	of Carcinogenic Risks to Humans, vol 101 (pp. 149-284). Lyon, France.
6449	Identity Group. (2016). Blue Stamp-Ever stamp. Identity Group.
6450	https://content.oppictures.com/Master_Images/Master_PDF_Files/USSIB61_SDS.PDF
6451	Jensen, J; van Langevelde, J; Pritzl, G; Krogh, PH. (2001). Effects of di(2-ethylhexyl) phthalate and
6452	dibutyl phthalate on the collembolan Folsomia fimetaria. Environ Toxicol Chem 20: 1085-1091.
6453	http://dx.doi.org/10.1002/etc.5620200520
6454	Johnson, BT; Heitkamp, MA; Jones, JR. (1984). Environmental and chemical factors influencing the
6455	biodegradation of phthalic-acid esters in freshwater sediments. Environ Pollut Ser B 8: 101-118.
6456	http://dx.doi.org/10.1016/0143-148X(84)90021-1
6457	Just In Time Chemical. (2015). Safety Data Sheet (SDS): DOP Plasticizer. Linden, NJ.
6458	https://www.recarroll.com/cw3/Assets/product_files/DOP%20(JIT).pdf
6459	Kao, PH; Lee, FY; Hseu, ZY. (2005). Sorption and biodegradation of phthalic acid esters in freshwater
6460	sediments. J Environ Sci Health A Tox Hazard Subst Environ Eng 40: 103-115.
6461	http://dx.doi.org/10.1081/ESE-200033605
6462	Kastar. (2024). Kastar 1-Pack Battery and AC Wall Charger Replacement [Website].
6463	https://www.walmart.com/ip/Kastar-1-Pack-Battery-AC-Wall-Charger-Replacement-Olympus-

6464	Li-10B-Li-12B-Battery-Li-10C-Li-10CN-Charger-Camedia-X-2-X-3-X-500-IR-500-FE-200-
6465	<u>Camera/947567954</u>
6466	Kim, HY. (2016). Risk assessment of di(2-ethylhexyl) phthalate in the workplace. Environmental Health
6467	and Toxicology 31: e2016011. http://dx.doi.org/10.5620/eht.e2016011
6468	Kinco. (2024). KINCO: 10 Oz Canvas with PVC Dots [Website]. https://www.kinco.com/862-3pk-1
6469	Kinney, CA; Furlong, ET; Kolpin, DW; Zaugg, SD; Burkhardt, MR; Bossio, JP; Werner, SL. (2010).
6470	Earthworms: Diagnostic indicators of wastewater derived anthropogenic organic contaminants in
6471	terrestrial environments. In RU Halden (Ed.), ACS Symposium Series Volume 1048 (pp. 297-
6472	317). Washington, DC: American Chemical Society. <u>http://dx.doi.org/10.1021/bk-2010-</u>
6473	$\frac{1048.ch014}{1000}$
6474 6475	Kissel, JC. (2011). The mismeasure of dermal absorption. J Expo Sci Environ Epidemiol 21: 302-309. http://dx.doi.org/10.1038/jes.2010.22
6476	Kwak, IS; Lee, W. (2005). Endpoint for DEHP exposure assessment in Chironomus riparius. Bull
6470 6477	Environ Contam Toxicol 74: 1179-1185. http://dx.doi.org/10.1007/s00128-005-0705-0
6478	Lansink, CJM; Breelen, MSC; Marquart, J; van Hemmen, JJ. (1996). Skin exposure to calcium
6479	carbonate in the paint industry. Preliminary modelling of skin exposure levels to powders based
6480	on field data. (V96.064). Rijswijk, The Netherlands: TNO Nutrition and Food Research Institute.
6481	Laursen, SE; Hansen, J; Drøjdahl, A; Hansen, OC; Pommer, K; Pedersen, E; Bernth, N. (2003). Survey
6482	of chemical compounds in textile fabrics. (Survey of chemicals in consumer products No. 23).
6483	Odense, Denmark: Danish Environmental Protection Agency.
6484	https://eng.mst.dk/media/mst/69105/23.pdf
6485	Lee, YM; Lee, JE; Choe, W; Kim, T; Lee, JY; Kho, Y; Choi, K; Zoh, KD. (2019). Distribution of
6486	phthalate esters in air, water, sediments, and fish in the Asan Lake of Korea. Environ Int 126:
6487	635-643. http://dx.doi.org/10.1016/j.envint.2019.02.059
6488	Liss, GM; Albro, PW; Hartle, RW; Stringer, WT. (1985). Urine phthalate determinations as an index of
6489	occupational exposure to phthalic anhydride and di(2-ethylhexyl)phthalate. Scand J Work
6490	Environ Health 11: 381-387. http://dx.doi.org/10.5271/sjweh.2209
6491	Liss, GM; Hartel, RW. (1983). Health Hazard Evaluation Report No. HETA-82-032-1384, Badische
6492	Corporation, Kearny, New Jersey (pp. 82-032). (NIOSH/00178915). Liss, GM; Hartel, RW.
6493	Ma, T; Teng, Y; Christie, P; Luo, Y. (2015). Phytotoxicity in seven higher plant species exposed to di-n-
6494	butyl phthalate or bis (2-ethylhexyl) phthalate. Front Env Sci Eng 9: 259-268.
6495	http://dx.doi.org/10.1007/s11783-014-0652-2
6496	Ma, TT; Christie, P; Luo, YM; Teng, Y. (2014). Physiological and antioxidant responses of germinating
6497	mung bean seedlings to phthalate esters in soil. Pedosphere 24: 107-115.
6498	http://dx.doi.org/10.1016/S1002-0160(13)60085-5
6499	Mackintosh, CE; Maldonado, J; Hongwu, J; Hoover, N; Chong, A; Ikonomou, MG; Gobas, FA. (2004).
6500	Distribution of phthalate esters in a marine aquatic food web: Comparison to polychlorinated
6501	biphenyls. Environ Sci Technol 38: 2011-2020. http://dx.doi.org/10.1021/es034745r
6502	Mandal, S; Suresh, S; Priya, N; Banothu, R; Mohan, R; Sreeram, KJ. (2022). Phthalate migration and its
6503	effects on poly(vinyl chloride)-based footwear: Pathways, influence of environmental conditions,
6504	and the possibility of human exposure. Environ Sci Process Impacts 24: 1844-1854.
6505	http://dx.doi.org/10.1039/d2em00059h
6506	Marquart, H; Franken, R; Goede, H; Fransman, W; Schinkel, J. (2017). Validation of the dermal
6507 6508	exposure model in ECETOC TRA. Ann Work Expo Health 61: 854-871.
6508 6500	http://dx.doi.org/10.1093/annweh/wxx059 Maak ME: Paabia AB: Crofton KM: Hainamayar C: Paaii MV: Viakara C (2011) Bisk assessment
6509 6510	Meek, ME; Boobis, AR; Crofton, KM; Heinemeyer, G; Raaij, MV; Vickers, C. (2011). Risk assessment
6510 6511	of combined exposure to multiple chemicals: A WHO/IPCS framework. Regul Toxicol
6511	Pharmacol 60. http://dx.doi.org/10.1016/j.yrtph.2011.03.010

Meuling, WJA; Rijk, MAH; Vink, AA. (2000). Study to investigate the phthalate release into saliva
from plasticized PVC during sucking and biting by human volunteers. Meuling, WJA; Rijk,
MAH; Vink, AA.
Modigh, CM; Bodin, SLV; Lillienberg, L; Dahlman-Höglund, A; Akesson, B; Axelsson, G. (2002).
Time to pregnancy among partners of men exposed to di(2-ethylhexyl)phthalate. Scand J Work
Environ Health 28: 418-428. <u>http://dx.doi.org/10.5271/sjweh.694</u>
Morgan Advanced Materials Wesgo Metals. (2016a). Safety Data Sheet (SDS): Stopyt Product 62A.
Hayward, CA. http://www.morganadvancedmaterials.com/media/5354/sds-stopyt-62a-rr-15-apr-
<u>2016.pdf</u>
Morgan Advanced Materials Wesgo Metals. (2016b). Safety Data Sheet (SDS): Stopyt product: Regular.
Hayward, CA. http://www.morgantechnicalceramics.com/media/5356/sds-stopyt-regular-05-
<u>2016.pdf</u>
Mylona, SK; Assael, MJ; Antoniadis, KD; Polymatidou, SK; Karagiannidis, L. (2013). Measurements of
the Viscosity of Bis(2-ethylhexyl) Sebacate, Squalane, and Bis(2-ethylhexyl) Phthalate between
(283 and 363) K at 0.1 MPa. Journal of Chemical and Engineering Data 58: 2805-2808.
http://dx.doi.org/10.1021/je4005245
NASEM. (2017). Application of systematic review methods in an overall strategy for evaluating low-
dose toxicity from endocrine active chemicals. In Consensus Study Report. Washington, D.C.:
The National Academies Press. http://dx.doi.org/10.17226/24758
NCBI. (2020). PubChem Compound Summary for CID 8343, Bis(2-ethylhexyl) phthalate.
https://pubchem.ncbi.nlm.nih.gov/compound/8343
NICNAS. (2010). Priority existing chemical draft assessment report: Diethylhexyl phthalate. (PEC32).
Sydney, Australia: Australian Department of Health and Ageing.
https://www.industrialchemicals.gov.au/sites/default/files/PEC32-Diethylhexyl-phthalate-
DEHP.pdf
NICNAS. (2013). 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester: Human health tier II
assessment. Sydney, Australia: Australian Department of Health, National Industrial Chemicals
Notification and Assessment Scheme.
https://www.industrialchemicals.gov.au/sites/default/files/1%2C2-
Benzenedicarboxylic%20acid%2C%20bis%282-
ethylhexyl%29%20ester_Human%20health%20tier%20II%20assessment.pdf
NICNAS. (2019). Phthalate esters: Environment tier II assessment. Sydney, Australia: Australian
Department of Health, National Industrial Chemicals Notification and Assessment Scheme.
https://www.industrialchemicals.gov.au/sites/default/files/Phthalate%20esters_%20Environment
<u>%20tier%20II%20assessment.pdf</u>
Niino, T; Asakura, T; Ishibashi, T; Itoh, T; Sakai, S; Ishiwata, H; Yamada, T; Onodera, S. (2003). A
simple and reproducible testing method for dialkyl phthalate migration from polyvinyl chloride
products into saliva simulant. Shokuhin Eiseigaku Zasshi 44: 13-18.
http://dx.doi.org/10.3358/shokueishi.44.13
NIOSH. (1988). Occupational safety and health guideline for di-2-ethylhexyl phthalate (DEHP)
potential human carcinogen. U.S. Department of Health and Human Services, Public Health
Service, Centers for Disease Control, National Institute for Occupational Safety and Health.
NLM. (2015). PubChem: Hazardous Substance Data Bank: Bis(2-ethylhexyl) phthalate, 117-81-7
[Website].
NRC. (2008). Phthalates and cumulative risk assessment: The task ahead. Washington, DC: National
Academies Press. http://dx.doi.org/10.17226/12528
NTP-CERHR. (2006). NTP-CERHR monograph on the potential human reproductive and
developmental effects of di(2-ethylhexyl) phthalate (DEHP) [NTP]. (NIH Publication No. 06-

6560	4476). Research Triangle Park, NC. http://cerhr.niehs.nih.gov/evals/phthalates/dehp/DEHP-
6561	Monograph.pdf
6562	NTP. (1982). Carcinogenesis bioassay of di(2-ethylhexyl)phthalate (CAS No. 117-81-7) in F344 rats
6563	and B6C3F1 mice (feed studies) [NTP]. In National Toxicology Program Technical Report (pp.
6564	1-127). (NTP-80-37). Research Triangle Park, NC.
6565	http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr217.pdf
6566	NTP. (2021a). Di(2-ethylhexyl) Phthalate: CAS No. 117-81-7 [NTP] (15th ed.). Research Triangle Park,
6567	NC: U.S. Department of Health and Human Services.
6568	https://ntp.niehs.nih.gov/ntp/roc/content/profiles/diethylhexylphthalate.pdf
6569	NTP. (2021b). NTP technical report on the toxicology and carcinogenesis studies of di(2-ethylhexyl)
6570	phthalate (CASRN 117-81-7) administered in feed to Sprague Dawley (Hsd:Sprague Dawley®
6571	SD®) rats [NTP]. (TR 601). U.S. Department of Health and Human Services.
6572	https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr601_508.pdf
6573	Nuodex Inc. (1983). Di-(2-ethylhexyl) phthalate monitoring - Chestertown memo CHMD-83-002
6574	[TSCA Submission]. (OTS0206260. 878211174. TSCATS/018070).
6575	https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/OTS0206260.xhtml
6576	O'Neil, MJ. (2013). DEHP. 117-81-7. [Bis(2-ethylhexyl) ester] [Encyclopedia]. In MJ O'Neill; PE
6577	Heckelman; PH Dobbelaar; KJ Roman; CM Kenney; LS Karaffa (Eds.), (15th ed., pp. 517).
6578	Cambridge, UK: The Royal Society of Chemistry.
6579	OECD. (2004). Emission scenario document on textile finishing industry. In OECD Series on Emission
6580	Scenario Documents. (OECD SESD No. 7; JT00166691). Paris, France.
6581	https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env
6582	/jm/mono(2004)12
6583	OECD. (2009). Emission scenario document on adhesive formulation. (ENV/JM/MONO(2009)3;
6584	JT03263583). Paris, France.
6585	http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)3&
6586	<u>doclanguage=en</u>
6587	OECD. (2010). Emission scenario document on the formulation of radiation curable coatings, inks and
6588	adhesives.
6589	http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)2&
6590	<u>doclanguage=en</u>
6591	OECD. (2011). Emission scenario document on coating application via spray-painting in the automotive
6592	refinishing industry. In OECD Series on Emission Scenario Documents No 11.
6593	(ENV/JM/MONO(2004)22/REV1). Paris, France: Organization for Economic Co-operation and
6594	Development.
6595	http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2004)22/
6596	rev1&doclanguage=en
6597	OECD. (2015). Emission scenario document on use of adhesives. In Series on Emission Scenario
6598	Documents No 34. (Number 34). Paris, France.
6599	http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2015
6600	)4&doclanguage=en
6601	OECD. (2017). Emission scenario document (ESD) on the use of textile dyes. In Emission Scenario
6602	Document, Series No 36. (ENV/JM/MONO(2015)50). Paris, France: OECD, Inter-Organization
6603	Programme for the Sound Management of Chemicals (IOMC).
6604	http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm
6605	OECD. (2018). Considerations for assessing the risks of combined exposure to multiple chemicals (No.
6606	296). In Series on Testing and Assessment No 296. Paris, France.
6607	http://dx.doi.org/10.1787/ceca15a9-en

6608	OEHHA. (2002). No Significant Risk Level (NSRL) for the Proposition 65 carcinogen di(2-
6609	ethylhexyl)phthalate. California: California Environmental Protection Agency, Office of
6610	Environmental Health Hazard Assessment, Reproductive and Cancer Hazard Assessment
6611	Section. https://oehha.ca.gov/media/downloads/crnr/dehpnsrlfinal.pdf
6612	OEHHA. (2005). Proposition 65 Maximum Allowable Dose Level (MADL) for reproductive toxicity for
6613	di(2-ethylhexyl)phthalate (DEHP) by oral exposure. Okland, California: California
6614	Environmental Protection Agency, Office of Environmental Health Hazard Assessment,
6615	Reproductive and Cancer Hazard Assessment Section.
6616	https://oehha.ca.gov/media/downloads/proposition-65/chemicals/dehporalmadl062405.pdf
6617	OSHA. (1994). Method 104. Dimethyl Phthalate (DMP), diethyl phthalate (DEP), dibutyl phthalate
6618	(DBP), di-2-ethylhexyl phthalate (DEHP), di-n-octyl phthalate (DNOP). Sampling and analytical
6619	methods. Washington, DC: Occupational Safety and Health Administration.
6620	OSHA. (2019). Chemical exposure health data (CEHD) sampling results: CASRNs 75-34-3, 85-68-7,
6621	84-74-2, 78-87-5, 117-81-7, 106-93-4, 50-00-0, 95-50-1, 85-44-9, 106-46-7, 79-00-5, and 115-
6622	86-6. Washington, DC: U.S. Department of Labor.
6623	https://www.osha.gov/opengov/healthsamples.html
6624	OSHA. (2020). Chemical Exposure Health Data (CEHD). Washington, DC.
6625	https://www.osha.gov/opengov/healthsamples.html
6626	Phenova. (2018). Safety Data Sheet (SDS): Custom 8270 Cal Mix 1. Golden, CO.
6627	https://phenomenex.blob.core.windows.net/documents/31013f05-5fd0-489e-b2b0-
6628	<u>f687f596910c.pdf</u>
6629	Polissar, NL; Salisbury, A; Ridolfi, C; Callahan, K; Neradilek, M; Hippe, D; Beckley, WH. (2016). A
6630	fish consumption survey of the Shoshone-Bannock Tribes: Vols. I-III. Polissar, NL; Salisbury,
6631	A; Ridolfi, C; Callahan, K; Neradilek, M; Hippe, D; Beckley, WH.
6632	https://www.epa.gov/sites/production/files/2017-01/documents/fish-consumption-survey-
6633	shoshone-bannock-dec2016.pdf
6634	Quad City Safety Inc. (2024a). Cordova Duo Safety <sup>TM</sup> Cap-Style Helmets [Website].
6635	https://www.quadcitysafety.com/duo-safety-cap-style-helmets11
6636	Quad City Safety Inc. (2024b). Cordova Vinyl Aprons and Sleeves [Website].
6637	https://www.quadcitysafety.com/vinyl-aprons-and-sleeves10
6638	QuickCable Corporation. (2024). QuickCable: 230101 [Website].
6639	https://www.quickcable.com/product/230101/
6640	Reddam, A; Volz, DC. (2021). Inhalation of two Prop 65-listed chemicals within vehicles may be
6641	associated with increased cancer risk. Environ Int 149: 106402.
6642	http://dx.doi.org/10.1016/j.envint.2021.106402
6643	<u>Riederer, M. (1990)</u> . Estimating partitioning and transport of organic chemicals in the
6644	foliage/atmosphere system: Discussion of a fugacity-based model. Environ Sci Technol 24: 829-
6645	837. <u>http://dx.doi.org/10.1021/es00076a006</u>
6646	<u>RIVM. (1998)</u> . Phthalate release from soft PVC baby toy : Report from the Dutch Consensus Group.
6647	(RIVM report 613320 002). Bilthoven, the Netherlands: National Institute for Public Health and
6648	the Environment (Netherlands) :: RIVM.
6649	http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/1998/september/Phthalat
6650	e_release_from_soft_PVC_baby_toys_Report_from_the_Dutch_Consensus_Group?sp=cml2bX
6651	E9ZmFsc2U7c2VhcmNoYmFzZT0zNDQ4MDtyaXZtcT1mYWxzZTs=&pagenr=3449
6652	<u>Rockwool. (2017)</u> . Material Safety Data Sheet (MSDS): ROCKWOOL Intumescent Pipe Wraps.
6653	https://www.rockwool.com/siteassets/rw-uk/downloads/msds/intumescent-pipe-wraps-msds.pdf
6654 6655	Rumble, JR. (2018). CRC handbook of chemistry and physics Big(2 athylhayyd) rhtholata (00 ad). Base Baten, EL, CRC Press, Taylor & Francis Crown
6655	Bis(2-ethylhexyl) phthalate (99 ed.). Boca Raton, FL: CRC Press. Taylor & Francis Group.

6656	Saeger, VW; Tucker, ES. (1976). Biodegradation of phthalic acid esters in river water and activated
6657	sludge. Appl Environ Microbiol 31: 29-34. http://dx.doi.org/10.1128/AEM.31.1.29-34.1976
6658	Salisbury, S. (1984). Health hazard evalution report, No. HETA-79-034-1440, Intex Plastics, Corinth,
6659	Mississippi. Salisbury, S. https://www.cdc.gov/niosh/hhe/reports/pdfs/79-34-1440.pdf
6660	Schmitzer, JL; Scheunert, I; Korte, F. (1988). Fate of bis(2-ethylhexyl) ( super(14)C)phthalate in
6661	laboratory and outdoor soil-plant systems. J Agric Food Chem 36: 210-215.
6662	http://dx.doi.org/10.1021/jf00079a053
6663	Scholz, N; Diefenbach, R; Rademacher, I; Linnemann, D. (1997). Biodegradation of DEHP, DBP, and
6664	DINP: poorly water soluble and widely used phthalate plasticizers. Bull Environ Contam Toxicol
6665	58: 527-534. http://dx.doi.org/10.1007/s001289900367
6666	Schwarz, S; Rackstraw, A; Behnisch, PA; Brouwer, A; Koehler, HR; Kotz, A; Kuballa, T; Malisch, R;
6667	Neugebauer, F; Schilling, F; Schmidt, D; von Der Trenck, KT. (2016). Peregrine falcon egg
6668	pollutants Mirror Stockholm POPs list including methylmercury. Toxicol Environ Chem 98:
6669	886-923. http://dx.doi.org/10.1080/02772248.2015.1126717
6670	Scott, RC; Dugard, PH; Ramsey, JD; Rhodes, C. (1987). In vitro absorption of some o-phthalate diesters
6671	through human and rat skin. Environ Health Perspect 74: 223-227.
6672	http://dx.doi.org/10.2307/3430452
6673	Smith, SA; Norris, B. (2003). Reducing the risk of choking hazards: Mouthing behaviour of children
6674	aged 1 month to 5 years. Inj Contr Saf Promot 10: 145-154.
6675	http://dx.doi.org/10.1076/icsp.10.3.145.14562
6676	Spypoint. (2024). SPYPOINT LIT-10 3.7V Rechargeable Lithium Battery [Website].
6677	https://www.amazon.com/SPYPOINT-LIT-10-LIT-10-SPP/dp/B086TYQQBG
6678	SRC. (1983). Exhibit I shake flask biodegradation of 14 commercial phthalate esters [TSCA
6679	Submission]. (SRC L1543-05. OTS0508481. 42005 G5-2. 40-8326129. TSCATS/038111).
6680	Chemical Manufacturers Association.
6681	https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/OTS0508481.xhtml
6682	Stabile, E. (2013). Commentary - Getting the government in bed: How to regulate the sex-toy industry.
6683	BGLJ 28: 161-184.
6684	Stasinakis, A; Petalas, A; Mamais, D; Thomaidis, N. (2008). Application of the OECD 301F
6685	respirometric test for the biodegradability assessment of various potential endocrine disrupting
6686	chemicals. Bioresour Technol 99: 3458-3467. http://dx.doi.org/10.1016/j.biortech.2007.08.002
6687	Sugita, T; Kawamura, Y; Tanimura, M; Matsuda, R; Niino, T; Ishibashi, T; Hirabahashi, N; Matsuki, Y;
6688	Yamada, T; Maitani, T. (2003). [Estimation of daily oral exposure to phthalates derived from
6689	soft polyvinyl chloride baby toys]. Shokuhin Eiseigaku Zasshi 44: 96-102.
6690	http://dx.doi.org/10.3358/shokueishi.44.96
6691	Tanaka, T. (2002). Reproductive and neurobehavioural toxicity study of bis(2-ethylhexyl) phthalate
6692	(DEHP) administered to mice in the diet. Food Chem Toxicol 40: 1499-1506.
6693	http://dx.doi.org/10.1016/S0278-6915(02)00073-X
6694	The Sherwin-Williams Company. (2019). Safety Data Sheet (SDS): PLANET COLOR™ FX Rubber
6695	Black. Warrensville Heights, OH: Sherwin-Williams Company.
6696	https://www.paintdocs.com/docs/webPDF.jsp?SITEID=AUTOESTORE&doctype=SDS⟨=
6697	2&prodno=PCFX10
6698	TherImmune Research Corporation. (2004). Diethylhexylphthalate: Multigenerational reproductive
6699	assessment by continuous breeding when administered to Sprague-Dawley rats in the diet - Final
6700	report. (TRC Study No7244-200; NTP-RACB-98-004). Research Triangle Park, NC: National
6701	Toxicology Program, National Institute of Environmental Health Sciences.
6702	Thumper Massager Inc. (2024). Thumper lithium replacement battery [Website].
6703	https://thumpermassager.com/products/thumper-lithium-replacement-battery
0705	maps.//mampermassager.com/products/mamper-manan-replacement-battery

6704	Tremco. (2015). Safety Data Sheet (SDS): Vulkem 45 SSL White. Toronto, ON, Canada.
6705	http://www.tremcosealants.com/fileshare/msds/445806_333_C.pdf
6706	U.S. Census Bureau. (2022). County Business Patterns: 2020. Suitland, MD.
6707	https://www.census.gov/data/datasets/2020/econ/cbp/2020-cbp.html
6708	U.S. Chemical & Plastics. (2020). Safety Data Sheet (SDS): Pronto Kombi Spot Putty. Massillon, OH.
6709	https://s3.amazonaws.com/cdn.autobodytoolmart.com/downloads/tech-sheets/USC-32046-
6710	<u>SDS.pdf</u>
6711	U.S. CPSC. (2010). Toxicity review of Di(2-ethylhexyl) Phthalate (DEHP). Bethesda, MD.
6712	http://www.cpsc.gov//PageFiles/126533/toxicityDEHP.pdf
6713	U.S. CPSC. (2014). Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (with
6714	appendices). Bethesda, MD: U.S. Consumer Product Safety Commission, Directorate for Health
6715	Sciences. https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf
6716	U.S. CPSC. (2015). Exposure assessment: Composition, production, and use of phthalates. Cincinnati,
6717	OH: Prepared by: Toxicology Excellence for Risk Assessment Center at the University of
6718	Cincinnati. https://web.archive.org/web/20190320060357/https://www.cpsc.gov/s3fs-
6719	public/pdfs/TERAReportPhthalates.pdf
6720	U.S. EPA. (1982). Fate of priority pollutants in publicly owned treatment works, Volume i. (EPA 440/1-
6721	82/303). Washington, DC: Effluent Guidelines Division.
6722	http://nepis.epa.gov/exe/ZyPURL.cgi?Dockey=000012HL.txt
6723	U.S. EPA. (1986). Guidelines for the health risk assessment of chemical mixtures. Fed Reg 51: 34014-
6724	34025.
6725	U.S. EPA. (1988). Integrated Risk Information System (IRIS), chemical assessment summary, di(2-
6726	ethylhexyl)phthalate (DEHP); CASRN 117-81-7. Washington, DC: U.S. Environmental
6727	Protection Agency, National Center for Environmental Assessment.
6728	https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/5113322
6729	<u>U.S. EPA. (1991)</u> . Chemical engineering branch manual for the preparation of engineering assessments.
6730	(68-D8-0112). Cincinnati, OH: US Environmental Protection Agency, Office of Toxic
6731	Substances.
6732	https://nepis.epa.gov/Exe/ZyNET.exe/P10000VS.txt?ZyActionD=ZyDocument&Client=EPA&I
6733	ndex=1991%20Thru%201994&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRe
6734	strict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField
6735	=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5CZYFILES%5CINDEX%20
6736	DATA%5C91THRU94%5CTXT%5C00000019%5CP10000VS.txt&User=ANONYMOUS&Pas
6737	sword=anonymous&SortMethod=h%7C-
6738	&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&D
6739	isplay=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results
6740	<u>%20page&amp;MaximumPages=233&amp;ZyEntry=1</u>
6741	U.S. EPA. (1992a). Guidelines for exposure assessment. Federal Register 57(104):22888-22938 [EPA
6742	Report]. (EPA/600/Z-92/001). Washington, DC.
6743	http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=15263
6744	<u>U.S. EPA. (1992b)</u> . A laboratory method to determine the retention of liquids on the surface of hands
6745	[EPA Report]. (EPA/747/R-92/003). Washington, DC.
6746	U.S. EPA. (1994a). Guidelines for Statistical Analysis of Occupational Exposure Data: Final. United
6747	States Environmental Protection Agency :: U.S. EPA.
6748	U.S. EPA. (1994b). Methods for derivation of inhalation reference concentrations and application of
6749	inhalation dosimetry [EPA Report]. (EPA600890066F). Research Triangle Park, NC.
(750	
6750 6751	https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=71993&CFID=51174829&CFTOKEN=2 5006317

6752	U.S. EPA. (1998). Guidelines for ecological risk assessment [EPA Report]. (EPA/630/R-95/002F).
6753	Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum.
6754	https://www.epa.gov/risk/guidelines-ecological-risk-assessment
6755	U.S. EPA. (1999). Guidance for identifying pesticide chemicals and other substances that have a
6756	common mechanism of toxicity. Washington, DC. https://www.epa.gov/sites/default/files/2015-
6757	07/documents/guide-2-identify-pest-chem_0.pdf
6758	U.S. EPA. (2000). Supplementary guidance for conducting health risk assessment of chemical mixtures
6759	(pp. 1-209). (EPA/630/R-00/002). Washington, DC: U.S. Environmental Protection Agency,
6760	Risk Assessment Forum. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20533
6761	U.S. EPA. (2001). General principles for performing aggregate exposure and risk assessments [EPA
6762	Report]. Washington, DC. https://www.epa.gov/pesticide-science-and-assessing-pesticide-
6763	risks/general-principles-performing-aggregate-exposure
6764	U.S. EPA. (2002a). Guidance on cumulative risk assessment of pesticide chemicals that have a common
6765	mechanism of toxicity [EPA Report]. Washington, D.C.
6766	U.S. EPA. (2002b). A review of the reference dose and reference concentration processes.
6767	(EPA630P02002F). Washington, DC. https://www.epa.gov/sites/production/files/2014-
6768	<u>12/documents/rfd-final.pdf</u>
6769	U.S. EPA. (2003). Framework for cumulative risk assessment [EPA Report]. (EPA/630/P-02/001F).
6770	Washington, DC. https://www.epa.gov/sites/production/files/2014-
6771	<u>11/documents/frmwrk_cum_risk_assmnt.pdf</u>
6772	U.S. EPA. (2006). A framework for assessing health risk of environmental exposures to children.
6773	(EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of
6774	Research and Development, National Center for Environmental Assessment.
6775	http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363
6776	U.S. EPA. (2007a). Concepts, methods, and data sources for cumulative health risk assessment of
6777	multiple chemicals, exposures, and effects: A resource document [EPA Report]. (EPA/600/R-
6778	06/013F). Cincinnati, OH. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190187
6779	U.S. EPA. (2007b). Exposure and Fate Assessment Screening Tool (E-FAST), Version 2.0 [Computer
6780	Program]. Washington, DC.
6781	U.S. EPA. (2009). Targeted national sewage sludge survey sampling and analysis technical report [EPA
6782	Report]. (EPA-822-R-08-016). Washington, DC: U.S. Environmental Protection Agency, Office
6783	of Water. http://nepis.epa.gov/exe/ZyPURL.cgi?Dockey=P1003RL8.txt
6784	U.S. EPA. (2011a). Exposure factors handbook: 2011 edition [EPA Report]. (EPA/600/R-090/052F).
6785	Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development,
6786	National Center for Environmental Assessment.
6787	https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100F2OS.txt
6788	U.S. EPA. (2011b). Exposure factors handbook: 2011 edition (final) (EPA/600/R-090/052F).
6789	Washington, DC. <u>http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252</u>
6790	U.S. EPA. (2011c). Recommended use of body weight 3/4 as the default method in derivation of the oral
6791	reference dose. (EPA100R110001). Washington, DC.
6792	https://www.epa.gov/sites/production/files/2013-09/documents/recommended-use-of-bw34.pdf
6793	U.S. EPA. (2012a). Estimation Programs Interface Suite <sup>TM</sup> for Microsoft® Windows, v 4.11 [Computer
6794	Program]. Washington, DC. https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-
6795	program-interface
6796	<u>U.S. EPA. (2012b)</u> . Standard operating procedures for residential pesticide exposure assessment.
6797	Washington, DC: U.S. Environmental Protection Agency, Office of Pesticide Programs.
6798	https://www.epa.gov/sites/default/files/2015-08/documents/usepa-opp-
6799	hed_residential_sops_oct2012.pdf

6800	U.S. EPA. (2012c). Sustainable futures: P2 framework manual [EPA Report]. (EPA/748/B-12/001).
6801	Washington DC. http://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-
6802	manual
6803	U.S. EPA. (2014a). Discharge monitoring report (DMR) pollutant loading tool. Washington, DC.
6804	https://cfpub.epa.gov/dmr/index.cfm
6805	U.S. EPA. (2014b). Use of additives in the thermoplastic converting industry - generic scenario for
6806	estimating occupational exposures and environmental releases. Washington, DC.
6807	https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-
6808	under-tsca
6809	U.S. EPA. (2016a). Hydraulic fracturing for oil and gas: Impacts from the hydraulic fracturing water
6810	cycle on drinking water resources in the United States [EPA Report]. (EPA/600/R-16/236F).
6811	Washington, DC. https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990
6812	U.S. EPA. (2016b). Pesticide cumulative risk assessment: Framework for screening analysis.
6813	Washington, DC: Office of Pesticide Programs. https://www.epa.gov/pesticide-science-and-
6814	assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework
6815	U.S. EPA. (2017). Estimation Programs Interface Suite <sup>TM</sup> v.4.11. Washington, DC: U.S. Environmental
6816	Protection Agency, Office of Pollution Prevention Toxics. https://www.epa.gov/tsca-screening-
6817	tools/download-epi-suitetm-estimation-program-interface-v411
6818	U.S. EPA. (2019a). 40 CFR 1307: Prohibition of children's toys and child care articles containing
6819	specified phthalates. (Code of Federal Regulations Title 16 Part 1307).
6820	U.S. EPA. (2019b). Chemical data reporting (2012 and 2016 public CDR database). Washington, DC:
6821	U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics.
6822	https://www.epa.gov/chemical-data-reporting
6823	U.S. EPA. (2019c). Guidelines for human exposure assessment [EPA Report]. (EPA/100/B-19/001).
6824	Washington, DC: Risk Assessment Forum. https://www.epa.gov/sites/production/files/2020-
6825	01/documents/guidelines_for_human_exposure_assessment_final2019.pdf
6826	U.S. EPA. (2019d). Point Source Calculator: A Model for Estimating Chemical Concentration in Water
6827	Bodies. Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and
6828	Pollution Prevention.
6829	U.S. EPA. (2019e). Synthetic turf field recycled tire crumb rubber research under the Federal Research
6830	Action Plan, Final report part 1: Tire crumb rubber characterization, volume 1. (EPA/600/R-
6831	19/051.1). Washington, DC: U.S. Environmental Protection Agency, ATSDR, CDC.
6832	https://www.epa.gov/sites/default/files/2019-
6833	08/documents/synthetic_turf_field_recycled_tire_crumb_rubber_research_under_the_federal_res
6834	earch action plan final report part 1 volume 1.pdf
6835	U.S. EPA. (2019f). User's Guide: Integrated Indoor-Outdoor Air Calculator (IIOAC). Washington, DC:
6836	U.S. EPA.
6837	U.S. EPA. (2020a). 2020 CDR data [Database]. Washington, DC: U.S. Environmental Protection
6838	Agency, Office of Pollution Prevention and Toxics. https://www.epa.gov/chemical-data-
6839	reporting/access-cdr-data
6840	U.S. EPA. (2020b). 2020 CDR: Commercial and consumer use. Washington, DC.
6841	U.S. EPA. (2020c). Final scope of the risk evaluation for di-ethylhexyl phthalate (1,2-
6842	benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester); CASRN 117-81-7 [EPA Report]. (EPA-
6843	740-R-20-017). Washington, DC: Office of Chemical Safety and Pollution Prevention.
6844	https://www.epa.gov/sites/default/files/2020-09/documents/casrn_117-81-7_di-
6845	ethylhexyl_phthalate_final_scope.pdf
6846	U.S. EPA. (2021a). Draft systematic review protocol supporting TSCA risk evaluations for chemical
6847	substances, Version 1.0: A generic TSCA systematic review protocol with chemical-specific
6848	methodologies. (EPA Document #EPA-D-20-031). Washington, DC: Office of Chemical Safety

6849	and Pollution Prevention. <u>https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-</u>
6850	
6851	U.S. EPA. (2021b). Final scope of the risk evaluation for di-isodecyl phthalate (DIDP) (1,2-
6852	benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-benzenedicarboxylic acid, di-C9-11-
6853	branched alkyl esters, C10-rich); CASRN 26761-40-0 and 68515-49-1 [EPA Report]. (EPA-740-
6854	R-21-001). Washington, DC: Office of Chemical Safety and Pollution Prevention.
6855	https://www.epa.gov/system/files/documents/2021-08/casrn-26761-40-0-di-isodecyl-phthalate-
6856	<u>final-scope.pdf</u> U.S. ERA (2021a) Final scope of the risk evaluation for di isonervi atthelate (DINB) (1.2 herrore
6857 6858	<u>U.S. EPA. (2021c)</u> . Final scope of the risk evaluation for di-isononyl phthalate (DINP) (1,2-benzene-
6859	dicarboxylic acid, 1,2-diisononyl ester, and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich); CASRNs 28553-12-0 and 68515-48-0 [EPA Report]. (EPA-740-R-21-
6860	002). Washington, DC: Office of Chemical Safety and Pollution Prevention.
6861	https://www.epa.gov/system/files/documents/2021-08/casrn-28553-12-0-di-isononyl-phthalate-
6862	final-scope.pdf
6863	<u>U.S. EPA. (2021d)</u> . Generic model for central tendency and high-end inhalation exposure to total and
6864	respirable Particulates Not Otherwise Regulated (PNOR). Washington, DC: Office of Pollution
6865	Prevention and Toxics, Chemical Engineering Branch.
6866	U.S. EPA. (2021e). Use of additives in plastic compounding – Generic scenario for estimating
6867	occupational exposures and environmental releases (Revised draft) [EPA Report]. Washington,
6868	DC: Office of Pollution Prevention and Toxics, Risk Assessment Division.
6869	U.S. EPA. (2022a). Chemical repackaging - Generic scenario for estimating occupational exposures and
6870	environmental releases (revised draft) [EPA Report]. Washington, DC.
6871	U.S. EPA. (2022b). Commercial use of automotive detailing products - Generic scenario for estimating
6872	occupational exposures and environmental releases (Methodology review draft) [EPA Report].
6873	Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and
6874	Toxics, Risk Assessment Division.
6875	U.S. EPA. (2022c). Discharge Monitoring Report (DMR) data: Di (2-ethylhexyl)phthalate (CASRN
6876	117-81-7), 2017-2022 [Database]. Washington, DC. https://echo.epa.gov/trends/loading-
6877	tool/water-pollution-search
6878	U.S. EPA. (2022d). Draft TSCA screening level approach for assessing ambient air and water exposures
6879	to fenceline communities (version 1.0) [EPA Report]. (EPA-744-D-22-001). Washington, DC:
6880	Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency.
6881	https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/10555664
6882	U.S. EPA. (2022e). National emissions inventory (NEI) [Website]. <u>https://www.epa.gov/air-emissions-</u>
6883	inventories/national-emissions-inventory
6884	U.S. EPA. (2022f). ORD staff handbook for developing IRIS assessments [EPA Report]. (EPA 600/R-
6885	22/268). Washington, DC: U.S. Environmental Protection Agency, Office of Research and
6886 6897	Development, Center for Public Health and Environmental Assessment.
6887 6888	<u>https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370</u> U.S. EPA. (2022g). Toxics Release Inventory (TRI) data: Di (2-ethylhexyl)phthalate (CASRN 117-81-
6889	7), 2017-2022 [Database]. Washington, DC. https://www.epa.gov/toxics-release-inventory-tri-
6890	program/tri-data-and-tools
6891	U.S. EPA. (2023a). 2020 National Emissions Inventory (NEI) Data (August 2023 version) (August 2023
6892	ed.). Washington, DC: US Environmental Protection Agency. https://www.epa.gov/air-
6893	emissions-inventories/2020-national-emissions-inventory-nei-data
6894	<u>U.S. EPA. (2023b)</u> . Advances in dose addition for chemical mixtures: A white paper. (EPA/100/R-
6895	23/001). Washington, DC. <u>https://assessments.epa.gov/risk/document/&amp;deid=359745</u>

6896	U.S. EPA. (2023c). Consumer Exposure Model (CEM) Version 3.2 User's Guide. Washington, DC.
6897	https://www.epa.gov/tsca-screening-tools/consumer-exposure-model-cem-version-32-users-
6898	guide
6899	U.S. EPA. (2023d). Draft Proposed Approach for Cumulative Risk Assessment of High-Priority
6900	Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act.
6901	(EPA-740-P-23-002). Washington, DC: U.S. Environmental Protection Agency, Office of
6902	Chemical Safety and Pollution Prevention. https://www.regulations.gov/document/EPA-HQ-
6903	OPPT-2022-0918-0009
6904	U.S. EPA. (2023e). Draft Proposed Principles of Cumulative Risk Assessment under the Toxic
6905	Substances Control Act. (EPA-740-P-23-001). Washington, DC: U.S. Environmental Protection
6906	Agency, Office of Chemical Safety and Pollution Prevention.
6907	https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0008
6908	U.S. EPA. (2023f). Science Advisory Committee on Chemicals meeting minutes and final report, No.
6909	2023-01 - A set of scientific issues being considered by the Environmental Protection Agency
6910	regarding: Draft Proposed Principles of Cumulative Risk Assessment (CRA) under the Toxic
6911	Substances Control Act and a Draft Proposed Approach for CRA of High-Priority Phthalates and
6912	a Manufacturer-Requested Phthalate. (EPA-HQ-OPPT-2022-0918). Washington, DC: U.S.
6913	Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
6914	https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0067
6915	U.S. EPA. (2023g). Use of laboratory chemicals - Generic scenario for estimating occupational
6916	exposures and environmental releases (Revised draft generic scenario) [EPA Report].
6917	Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and
6918	Toxics, Existing Chemicals Risk Assessment Division.
6919	U.S. EPA. (2024a). Draft Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP).
6920	Washington, DC: Office of Pollution Prevention and Toxics.
6921	U.S. EPA. (2024b). Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular
6922	Testosterone for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl
6923	Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP).
6924	Washington, DC: Office of Pollution Prevention and Toxics.
6925	U.S. EPA. (2024c). Draft Non-cancer Human Health Hazard Assessment for Butyl benzyl phthalate
6926	(BBP). Washington, DC: Office of Pollution Prevention and Toxics.
6927	U.S. EPA. (2024d). Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate (DBP).
6928	Washington, DC: Office of Pollution Prevention and Toxics.
6929	U.S. EPA. (2024e). Draft Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate
6930	(DCHP). Washington, DC: Office of Pollution Prevention and Toxics.
6931	U.S. EPA. (2024f). Draft Non-cancer Human Health Hazard Assessment for Diethylhexyl Phthalate
6932	(DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6933	U.S. EPA. (2024g). Draft Non-cancer Human Health Hazard Assessment for Diisobutyl phthalate
6934	(DIBP). Washington, DC: Office of Pollution Prevention and Toxics.
6935	U.S. EPA. (2024h). Draft Physical and Chemical Property Assessment and Fate and Transport
6936	Assessment for Di-ethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution
6937	Prevention and Toxics.
6938	U.S. EPA. (2024i). Draft Summary of Facility Release Data for Di(2-ethylhexyl) Phthalate (DEHP),
6939	Dibutyl Phthalate (DBP), and Butyl Benzyl Phthalate (BBP). Washington, DC: Office of
6940	Pollution Prevention and Toxics.
6941	U.S. EPA. (2024j). Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP). Washington,
6942	DC: Office of Pollution Prevention and Toxics.
6943	U.S. EPA. (2025a). Consumer Exposure Analysis for Diisononyl Phthalate (DINP) Washington, DC:
6944	Office of Pollution Prevention and Toxics.

6945	U.S. EPA. (2025b). Discussion with Di(2-ethylhexyl) phthalate (DEHP) stakeholder - ChemSpec North
6946	America. Washington, DC: Office of Chemical Safety and Pollution Prevention.
6947	U.S. EPA. (2025c). Draft Ambient Air Exposure Assessment for Diethylhexyl Phthalate (DEHP).
6948	Washington, DC: Office of Pollution Prevention and Toxics.
6949	U.S. EPA. (2025d). Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate
6950	(DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP),
6951	and Dicyclohexyl Phthalate (DCHP). Washington, DC: Office of Pollution Prevention and
6952	Toxics.
6953	U.S. EPA. (2025e). Draft Consumer and Indoor Exposure Assessment for Diethylhexyl Phthalate
6954	(DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6955	U.S. EPA. (2025f). Draft Consumer Exposure Analysis for Diethylhexyl Phthalate (DEHP).
6956	Washington, DC: Office of Pollution Prevention and Toxics.
6957	U.S. EPA. (2025g). Draft Consumer Risk Calculator for Diethylhexyl Phthalate (DEHP). Washington,
6958	DC: Office of Pollution Prevention and Toxics.
6959	U.S. EPA. (2025h). Draft Data Extraction Information for Environmental Hazard and Human Health
6960	Hazard Animal Toxicology and Epidemiology for Diethylhexyl Phthalate (DEHP). Washington,
6961	DC: Office of Pollution Prevention and Toxics.
6962	U.S. EPA. (2025i). Draft Data Extraction Information for General Population, Consumer, and
6963	Environmental Exposure for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of
6964	Pollution Prevention and Toxics.
6965	<u>U.S. EPA. (2025j)</u> . Draft Data Quality Evaluation and Data Extraction Information for Environmental
6966	Fate and Transport for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution
6967	Prevention and Toxics.
6968	U.S. EPA. (2025k). Draft Data Quality Evaluation and Data Extraction Information for Environmental
6969	Release and Occupational Exposure for Diethylhexyl Phthalate (DEHP). Washington, DC:
6970	Office of Pollution Prevention and Toxics.
6971	<u>U.S. EPA. (20251)</u> . Draft Data Quality Evaluation and Data Extraction Information for Physical and
6972	Chemical Properties for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution
6973	Prevention and Toxics.
6974	U.S. EPA. (2025m). Draft Data Quality Evaluation Information for Environmental Hazard for
6975	Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6976	U.S. EPA. (2025n). Draft Data Quality Evaluation Information for General Population, Consumer, and
6977	Environmental Exposure for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of
6978	Pollution Prevention and Toxics.
6979	<u>U.S. EPA. (20250)</u> . Draft Data Quality Evaluation Information for Human Health Hazard Animal
6980	Toxicology for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution Prevention
	and Toxics.
6981	
6982	U.S. EPA. (2025p). Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology
6983	for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6984	U.S. EPA. (2025q). Draft Environmental Media and General Population and Environmental Exposure
6985	for Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6986	U.S. EPA. (2025r). Draft Environmental Release and Occupational Exposure Assessment for
6987	Diethylhexyl Phthalate (DEHP). Washington, DC: Office of Pollution Prevention and Toxics.
6988	U.S. EPA. (2025s). Draft Fish Ingestion Risk Calculator for Diethylhexyl Phthalate (DEHP).
6989	Washington, DC: Office of Pollution Prevention and Toxics.
6990	U.S. EPA. (2025t). Draft Occupational Risk Calculator for Diethylhexyl Phthalate (DEHP).
6991	Washington, DC: Office of Pollution Prevention and Toxics.
6992	U.S. EPA. (2025u). Draft Surface Water Human Exposure Risk Calculator for Diethylhexyl Phthalate
6993	(DEHP). Washington, DC: Office of Pollution Prevention and Toxics.

6994	U.S. EPA. (2025v). Draft Systematic Review Protocol for Diethylhexyl Phthalate (DEHP). Washington,
6995	DC: Office of Pollution Prevention and Toxics.
6996	U.S. EPA. (2025w). Non-Cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)
6997	Washington, DC: Office of Pollution Prevention and Toxics.
6998	U.S. EPA. (2025x). Revised Draft Technical Support Document for the Cumulative Risk Analysis of
6999	Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP),
7000	Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP)
7001	Under the Toxic Substances Control Act (TSCA). Washington, DC: Office of Pollution
7002	Prevention and Toxics.
7003	Valero. (2014). Safety Data Sheet (SDS): Modified asphalt. San Antonio, TX.
7004	https://www.valero.com/sites/default/files/2019-12/sds_us212-
7005	<u>ghs_modified_asphalt_rev1_0.pdf</u>
7006	Versar. (2014). Exposure and Fate Assessment Screening Tool (E-FAST 2014) - Documentation
7007	manual. Washington, DC: U.S. Environmental Protection Agency. https://www.epa.gov/tsca-
7008	screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014
7009	Wang, H; Guan, TQ; Sun, JX; Talukder, M; Huang, YQ; Li, YH; Li, JL. (2020). Di-(2-ethylhexyl)
7010	phthalate induced nephrotoxicity in quail (Coturnix japonica) by triggering nuclear xenobiotic
7011	receptors and modulating the cytochrome P450 system. Environ Pollut 261: 114162.
7012	http://dx.doi.org/10.1016/j.envpol.2020.114162
7013	Wang, H; Li, XN; Li, PC; Liu, W; Du, ZH; Li, JL. (2019). Modulation of heat-shock response is
7014	associated with di (2-ethylhexyl) phthalate (DEHP)-induced cardiotoxicity in quail (Coturnix
7015	japonica). Chemosphere 214: 812-820. http://dx.doi.org/10.1016/j.chemosphere.2018.10.002
7016	Washington Department of Ecology. (2021). Phthalates in children's products and consumer and
7017	children's packaging. Olympia, WA.
7018	https://apps.ecology.wa.gov/publications/documents/1404017.pdf
7019	Wasser Corporation. (2021). Safety Data Sheet (SDS): MC-Shieldcoat 100. Auburn, WA.
7020	http://www.wassercoatings.com/docs/ProductSpecs/Data/MC-Shieldcoat100_w511.7_004.pdf
7021	Wasser Technologies. (2021). Material Safety Data Sheet (MSDS): Polyflex 411A Iso-Catalyst. Auburn,
7022	WA. https://wassercoatings.com/wp-content/uploads/2021/02/Polyflex-411-AB.pdf
7023	WE Cork. (2001). Agglomerate cork composition MSDS: WECU Soundless / WECU Soundless+.
7024	Exeter, NH. https://www.wecork.com/wp-content/forms/Soundless_Soundless+MSDS.pdf
7025	Westin Automotive Products Inc. (2024). Westin Floor and Cargo Liners [Website].
7026	https://www.westinautomotive.com/sure-fit-floor-liners
7027	Williams, MD; Adams, WJ; Parkerton, TF; Biddinger, GR; Robillard, KA. (1995). Sediment sorption
7028	coefficient measurements for four phthalate esters: Experimental results and model theory.
7029	Environ Toxicol Chem 14: 1477-1486. http://dx.doi.org/10.1002/etc.5620140906
7030	Yuan, SY; Liu, C; Liao, CS; Chang, BV. (2002). Occurrence and microbial degradation of phthalate
7031	esters in Taiwan river sediments. Chemosphere 49: 1295-1299. <u>http://dx.doi.org/10.1016/s0045-</u>
7032	<u>6535(02)00495-2</u>
7033	Zanotelli, V; Neuhauss, S; Ehrengruber, M. (2010). Long-term exposure to bis(2-ethylhexyl)phthalate
7034	(DEHP) inhibits growth of guppy fish (Poecilia reticulata). J Appl Toxicol 30: 29-33.
7035	$\frac{\text{http://dx.doi.org/10.1002/jat.1468}}{\text{T}}$
7036	Zhu, F; Zhu, C; Doyle, E; Liu, H; Zhou, D; Gao, J. (2018). Fate of di (2-ethylhexyl) phthalate in
7037	different soils and associated bacterial community changes. Sci Total Environ 637-638: 460-469.
7038	http://dx.doi.org/10.1016/j.scitotenv.2018.05.055
7039 7040	Zhu, F; Zhu, C; Zhou, D; Gao, J. (2019). Fate of di (2-ethylhexyl) phthalate and its impact on soil bacterial community under aerobic and anaerobic conditions. Chemosphere 216: 84-93.
7040	http://dx.doi.org/10.1016/j.chemosphere.2018.10.078
7041	$\frac{100}{100} \frac{1000}{1000} $
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## 7043 APPENDICES

7044

## 7045 Appendix A KEY ABBREVIATIONS AND ACRONYMS

1010			
7046	AD	Acute Dose	
7047	ADC	Average daily concentration	
7048	ADD	Average daily dose	
7049	ADR	Acute dose rate	
7050	AERMOD	American Meteorological Society/EPA Regulatory Model	
7051	AERR	Air Emissions Reporting Requirements	
7052	AGD	Anogenital distance	
7053	APDR	Acute Potential Dose Rate	
7054	BLS	Bureau of Labor Statistics	
7055	CASRN	Chemical Abstracts Service Registry Number	
7056	CAP	Criteria Air Pollutants and PreCursors	
7057	CBI	Confidential business information	
7058	CDR	Chemical Data Reporting	
7059	CEHD	Chemical Exposure Health Data	
7060	CEM	Consumer Exposure Model	
7061	CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act	
7062	CFR	Code of Federal Regulations	
7063	COU	Condition(s) of Use	
7064	CPSC	Consumer Product Safety Commission	
7065	CWA	Clean Water Act	
7066	DEHP	Diethylhexyl phthalate	
7067	DIDP	Diisodecyl phthalate	
7068	DINP	Diisononyl phthalate	
7069	DIY	Do-it-yourself	
7070	DMR	Discharge Monitoring Report	
7071	ECHO	Enforcement and Compliance History Online	
7072	EPA	Environmental Protection Agency (or the Agency)	
7073	EPCRA	Emergency Planning and Community Right-to-Know Act	
7074	ESD	Emission scenario document	
7075	EU	European Union	
7076	FDA	Food and Drug Administration	
7077	FFDCA	Federal Food, Drug, and Cosmetic Act	
7078	GWPC	Ground Water Protection Council	
7079	GS	Generic scenario	
7080	HAP	Hazardous air pollutant	
7081	HEC	Human equivalent concentration	
7082	HED	Human equivalent dose	
7083	IADD	Intermediate average daily dose	
7084	IIOAC	Integrated Indoor-/Outdoor Air Calculator (Model)	
7085	IOGCC	Interstate Oil and Gas Compact Commission	
7086	IR	Ingestion rate	
7087	Koc	Soil organic carbon: water partitioning coefficient	
7088	Kow	Octanol: water partition coefficient	
7089	LCD	Life cycle diagram	
7090	LOD	Limit of detection	

7091	LOEC	Lowest-observed-effect concentration
7092	Log Koc	Logarithmic organic carbon: water partition coefficient
7093	Log Kow	Logarithmic octanol: water partition coefficient
7094	MOE	Margin of exposure
7095	MRD	Methodology Review Draft
7096	NAICS	North American Industry Classification System
7097	NEI	National Emissions Inventory
7098	NHANES	National Health and Nutrition Examination Survey
7099	NICNAS	National Industrial Chemicals Notification and Assessment Scheme
7100	NOAEL	No-observed-adverse-effect level
7101	NOEC	No-observed-effect concentration
7102	NPDES	National Pollutant Discharge Elimination System
7103	NTP	National Toxicology Program
7104	OCSPP	Office of Chemical Safety and Pollution Prevention
7105	OECD	Organisation for Economic Co-operation and Development
7106	OEL	Occupational exposure limit
7107	OES	Occupational exposure scenario
7108	ONU	Occupational non-user
7109	OPPT	Office of Pollution Prevention and Toxics
7110	OSHA	Occupational Safety and Health Administration
7111	PBZ	Personal breathing zone
7112	PECO	Population, exposure, comparator, and outcome
7113	PEL	Permissible exposure limit (OSHA)
7114	PESS	Potentially exposed or susceptible subpopulations
7115	PND	Postnatal day
7116	PNOR	Particulates not otherwise regulated
7117	POD	Point of departure
7118	POTW	Publicly owned treatment works
7119	PPARα	Peroxisome proliferator activated receptor alpha
7120	PSC	Point Source Calculator (tool)
7121	PVC	Polyvinyl chloride
7122	REL	Recommended Exposure Limit
7123	SACC	Science Advisory Committee on Chemicals
7124	SCC	Source Classification Code
7125	SDS	Safety data sheet
7126	SLT	State/Local/Tribal
7127	SOC	Standard Occupational Classification
7128	SpERC	Specific Emission Release Category
7129	SUSB	Statistics of U.S. Businesses (U.S. Census)
7130	TRI	Toxic Release Inventory
7131	TRV	Toxicity reference value
7132	TSCA	Toxic Substances Control Act
7132	TSD	Technical support document
7134	TWA	Time-weighted average
7135	UF	Uncertainty factor
7135	U.S.	United States
7130	VVWM	Variable Volume Water Model
7137	WebFIRE	Web Factor Information Retrieval (FIRE) Data System
7138	WORA	Women of reproductive age
1107		

- 7140 WWTP Wastewater treatment plant
- 7141 7Q10 The lowest 7-day average flow that occurs (on average) once every 10 years
- The lowest 30-day average flow that occurs (on average) once every 5 years

## 7143 Appendix B REGULATORY AND ASSESSMENT HISTORY

## 7144 **B.1 Federal Laws and Regulations**

#### 7145 7146

# Table Apx B-1. Federal Laws and Regulations

Statutes/Regulations	<b>Description of Authority/Regulation</b>	Description of Regulation
	EPA Statutes/Regulati	ons
Toxic Substances Control Act (TSCA) section 4	Provides EPA with authority to issue rules, orders, or consent agreements requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	25 chemical data submissions from test rules received for diethylhexyl phthalate: Ecotoxicity Acute aquatic plant toxicity (1) Acute aquatic toxicity (8) Chronic aquatic toxicity (1) Environmental fate Persistence (3) Biodegradation (3) Transport Between Environmental Compartments (Fugacity) (1) Sorption to Soil and Sediments (1) Human health Metabolism and Pharmacokinetics (3) Mutagenicity/Genetic toxicity (6) Physical and chemical properties Vapor pressure (1) Water solubility (1) (1982–1985) (U.S. EPA, ChemView. Accessed April 9, 2019).
Toxic Substances Control Act (TSCA) – section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Diethylhexyl phthalate is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA ( <u>84 FR 71924</u> , December 30, 2019). Designation of di-ethylhexyl phthalate as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure- related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Diethylhexyl phthalate manufacturing (including importing), processing and use information is reported under the CDR rule ( <u>76 FR 50816</u> , August 16, 2011).
Toxic Substances Control Act (TSCA) – section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Diethylhexyl phthalate was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 ( <u>60 FR 16309</u> , March 29, 1995).
Toxic Substances Control Act (TSCA) – section 8(d)	Provides EPA with authority to issue rules requiring producers, importers, and (if specified) processors of a chemical	No health and safety studies were received for diethylhexyl phthalate (1982-1992). (U.S. EPA, ChemView. Accessed April 24, 2019).

Statutes/Regulations	<b>Description of Authority/Regulation</b>	Description of Regulation
	substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies.	Diethylhexyl phthalate is listed under the category "Alkyl phthalates — all alkyl esters of 1, 2-benzenedicarboxylic acid (ortho -phthalic acid)" ( <u>40 CFR</u> <u>716.120</u> ).
Toxic Substances Control Act (TSCA) section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	14 risk reports received for diethylhexyl phthalate (1992-2009) (U.S. EPA, ChemView. Accessed (April 9, 2019)).
Emergency Planning and Community Right- To-Know Act (EPCRA) – section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management ( <i>e.g.</i> , quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data ( <i>i.e.</i> , air, land and water).	Diethylhexyl phthalate is a listed substance subject to reporting requirements <u>under 40</u> <u>CFR 372.65</u> effective as of January 1, 1987.
Clean Air Act (CAA) – section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA Section 112(d). CAA Section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	Diethylhexyl phthalate is listed as a HAP ( <u>42</u> <u>U.S.C. 7412</u> ).
Clean Air Act (CAA) – section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA	EPA has established NESHAPs for a number of source categories that emit diethylhexyl phthalate to air (See <u>https://www.epa.gov/stationary-sources-air- pollution/national-emission-standards- hazardous-air-pollutants-neshap-9</u> ).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	
Clean Water Act (CWA) – section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for diethylhexyl phthalate, including recommendations for "water + organism" and "organism only" human health criteria for states and authorized Tribes to consider when adopting criteria into their water quality standards. Human Health for the consumption of Water + Organism( $\mu$ g/L): 0.32 Human Health for the consumption of Organism Only ( $\mu$ g/L): 0.37 Human Health WQC is based on carcinogenicity of 10 <sup>-6</sup> risk.
Clean Water Act (CWA) – sections 301, 304, 306, 307, and 402	Clean Water Act section 307(a) established a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	<ul> <li>Diethylhexyl phthalate is designated as a toxic pollutant under Section 307(a)(1) of the CWA and as such is subject to effluent limitations (40 CFR 401.15).</li> <li>Under CWA Section 304, di-ethylhexyl phthalate is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).</li> <li>Appendix A to 40 CFR, part 423-126 Priority Pollutants</li> <li>Aluminum Forming Point Source Category 40 CFR part 467</li> <li>The Centralized Waste Treatment Point Source Category 40 CFR part 467</li> <li>Coil Coating Point Source Category 40 CFR part 465</li> <li>Electrical and Electronic Components Point Source Category 40 CFR part 469</li> <li>Electroplating Point Source Category 40 CFR part 413</li> <li>Metal Finishing Point Source Category 40 CFR part 413</li> <li>Metal Molding and Casting Point Source Category 40 CFR part 464</li> <li>Organic Chemicals, Plastics, And Synthetic Fibers 40 CFR part 414</li> <li>Plastics Molding And Forming Point Source</li> </ul>

Statutes/Regulations	<b>Description of Authority/Regulation</b>	Description of Regulation
		Category <u>40 CFR part 463</u> Steam Electric Power Generating Point Source Category <u>40 CFR part 423</u>
Safe Drinking Water Act (SDWA) – section 1412	Requires EPA to publish a non- enforceable maximum contaminant level goal (MCLG) for a contaminant for which EPA makes the determination that the contaminant: 1. may have an adverse effect on the health of persons; 2. is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	Diethylhexyl phthalate is subject to NPDWR under the SDWA with an MCLG of zero and an enforceable MCL of .006 mg/L (40 CFR 141.24).
Resource Conservation and Recovery Act (RCRA) – section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Diethylhexyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U028 ( <u>40</u> <u>CFR 261.33</u> ). (Appendix VIII to Part 261—Hazardous Constituents).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity	Diethylhexyl phthalate is a hazardous substance under CERCLA. Releases of di- ethylhexyl phthalate in excess of 100 lb must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation	
	threshold.		
Superfund Amendments and Reauthorization Act (SARA)	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	Diethylhexyl phthalate is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health. ATSDR ranked #77.	
-	Other federal statutes/regu	lations	
Consumer Product Safety Improvement Act of 2008 (CPSIA)	Under section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC prohibits the manufacture for sale, offer for sale, distribution in commerce or importation of 8 phthalates in toys and child care articles at concentrations greater than 0.1 percent: DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP and DCHP.	The use of diethylhexyl phthalate at concentrations greater than 0.1 percent is banned in toys and child care articles ( <u>16</u> <u>CFR part 1307</u> ).	
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or that the nature of the hazard is such that labeling is not adequate to protect consumers.	Use of diethylhexyl phthalate was banned by the CPSC in 2008 in any children's toy or child care article that contains concentrations of more than 0.1 percent of di-ethylhexyl phthalate ( <u>16 CFR part 1307</u> )	
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Diethylhexyl phthalate is an optional substance that can be used in: the base sheet and coating of cellophane, alone or in combination with other phthalates where total phthalates do not exceed 5 percent (21 CFR § 177.1200) Non-regulatory Warning FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP (medical).	
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure	OSHA established a PEL for diethylhexyl phthalate of 5 mg/m <sup>3</sup> as an 8-hour, TWA ( <u>29</u> <u>CFR 1910.1000</u> ). OSHA established a Sampling and Analytical Method for DEHP.	

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation	
	monitoring, engineering and administrative control measures, and respiratory protection.		
Federal Hazardous Materials Transportation Act (HMTA)	<ul> <li>Section 5103 of the Act directs the Secretary of Transportation to:</li> <li>Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property.</li> <li>Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.</li> </ul>	Diethylhexyl phthalate is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials Reportable Quantity 100 lb. (45.4 kg) ( <u>49 CFR 172.1</u> , Appendix A, Table 1).	

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# 7148 **B.2 State Laws and Regulations**

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### 7150 **Table\_Apx B-2. State Laws and Regulations**

State Actions	Description of Action	
State Air Regulations	<ul> <li>New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants)</li> <li>Toxicity Class I, 24-hour AAL 18 (µg/m<sup>3</sup>), Annual AALB 12 (µg/m<sup>3</sup>), 24-hour De Minimis 0.21 (lb/day), Annual De Minimis 78 (lb/year)</li> <li>Rhode Island (<u>Air Pollution Regulation No. 22</u>)</li> <li>Acceptable Ambient Levels (AALs) (mg/m3)</li> <li>24 Hour 70, Annual 0.4</li> </ul>	
State Drinking Water	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008)	
Standards and	MCL .0006 mg/L MCLG 0 mg/L Discharge from rubber and chemical factories	
Guidelines	California ( <u>Cal Code Regs. Title 26, § 22-64444</u> )	
	Table 64444-A Maximum Contaminant Levels Organic Chemicals 0.004 mg/L	
	Connecticut (Conn. Agencies Regs. § 19-13-B102)	
	Maximum Contaminant Level (mg/l) 0.006	
	Delaware (Del. Admin. Code Title 16, § 4462)	
	Synthetic organic contaminants including pesticides and herbicides:	
	Traditional MCL 0.006 mg/L To convert for CCR, multiply by 1,000 MCL in CCR units 6, MCLG 0	
	Florida (Fla. Admin. Code R. Chap. 62-550), 6 µg/L MCL	
	Maine ( <u>10 144 Me. Code R. Chap. 231</u> ), 0.006 mg/L	
	Massachusetts (310 Code Mass. Regs. § 22.00), 0.006 mg/L	
	Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017)	
	Minnesota (Minn R. Chap. 4720)	
	Maximum Contaminant Level (MCL) for di-ethylhexyl phthalate of 6 ppb	
	New Jersey (7:10 N.J Admin. Code § 5.2), Standard 6 µg/L	
	Pennsylvania ( <u>25 Pa. Code § 109.202</u> )	

State Actions	Description of Action		
	Synthetic Organic Chemicals (SOCs): 0.006 mg/L Rhode Island ( <u>Rules and Regulations Pertaining to Public Drinking Water R46-13-DWQ</u> ) MCLG 0 mg/L MCL 0.006 mg/L		
State PELs	California (PEL of 5 mg/m <sup>3</sup> ( <u>Cal Code Regs. Title 8, § 5155</u> ) Hawaii PEL TWA 5 mg/m <sup>3</sup> and PEL STEL 10 mg/m3 ( <u>Hawaii Administrative Rules</u> Section 12-60-50)		
State Right-to-Know Acts	Massachusetts ( <u>105 Code Mass. Regs. § 670.000 Appendix A</u> ) New Jersey ( <u>8:59 N.J. Admin. Code § 9.1</u> ) Carcinogen, Teratogen Pennsylvania ( <u>P.L. 734</u> , No. 159 and 34 Pa. Code § 323)		
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing di-ethylhexyl phthalate including: Maine ( <u>38 MRSA Chapter 16-D</u> ) Minnesota ( <u>Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407</u> ) Oregon ( <u>Toxic-Free Kids Act, Senate Bill 478, 2015</u> ) Vermont ( <u>18 V.S.A § 1776</u> ) Washington State ( <u>Wash. Admin. Code 173-334-130</u> )		
Other	<ul> <li>California listed di-ethylhexyl phthalate on Proposition 65 in 1988 due cancer and in 2003 due to developmental male cancer. (Cal Code Regs. Title 27, § 27001).</li> <li>California issued a Health Hazard Alert for DEHP (Hazard Evaluation System and Information Service, 2016).</li> <li>California lists di-ethylhexyl phthalate as a designated priority chemical for biomonitoring (California SB 1379).</li> <li>Di-ethylhexyl phthalate is on the MA Toxic Use Reduction Act (TURA) list MGL, Chapter 21I, Section 1 to Section 23</li> <li>Maine 2019 ME H 1043</li> <li>Prohibition of sale of food package containing phthalates.</li> </ul>		

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# 7152 **B.3 International Laws and Regulations**

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# Table\_Apx B-3. International Laws and Regulations

Country/ Organization	Requirements and Restrictions	
Canada	<ul> <li>Di-ethylhexyl phthlate is on the Canadian List of Toxic Substances (Government of Canada. Managing substances in the environment. Substances search. Database accessed April 30, 2020).</li> <li>Other Canadian regulations include:</li> </ul>	
	<ul> <li>Canada's National Pollutant Release Inventory (NPRI).</li> <li>For soft vinyl children's toys and child-care articles, compliance and enforcement of the existing regulation of di-ethylhexyl phthalate (and 5 other phthalates) will continue as part of the regular enforcement of the <u>Phthalates Regulations under the Canada Consumer Product Safety Act.</u></li> </ul>	
	<ul> <li>Compliance and enforcement of the existing requirements for medical devices containing di-ethylhexyl phthalate will continue as part of the regular enforcement of the <u>Medical Devices Regulations under the Food and Drugs Act</u>.</li> <li>Diethylhexyl phthlate, which was previously concluded to be harmful to human health, was added to the <u>Cosmetic Ingredient Hotlist</u> in 2009. The listing indicates</li> </ul>	

Country/ Organization	<b>Requirements and Restrictions</b>		
	<ul> <li>that the use of di-ethylhexyl phthalate is prohibited and must not be present in cosmetic products.</li> <li>Risk Management Scope for 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester [DEHP] Chemical Abstracts Service Registry Number (CAS RN): 117-81-7.</li> </ul>		
European Union	Di-ethylhexyl phthlate is registered for use in the EU ( <u>European Chemicals Agency</u> ( <u>ECHA</u> ) database. Accessed February 3, 2020).		
	Restriction <u>Annex XVII TO REACH</u> – Conditions of restriction Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.		
	<b>Candidate Substance</b> In 2008, di-ethylhexyl phthalate was listed on the Candidate list as a Substance of Very High Concern (SVHC) under <u>Article 59 regulation (EC) No 1907/2006 - REACH</u> (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 1B). Reason for inclusion: Toxic for reproduction (Article 57c), Endocrine disrupting properties (Article 57(f) - environment), Endocrine disrupting properties (Article 57(f) - human health.		
	Authorisation In August 2013, di-ethylhexyl phthalate was added to Annex XIV of REACH (Authorisation List) with a sunset date of February 21, 2015. After the sunset date, only persons with approved authorization applications may continue to use the chemical (European Chemicals Agency (ECHA) database. Accessed April 24, 2019). Commission Delegated Directive//EU of 31.3.2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.		
	<b>Restriction of Hazardous Substances Directive (RoHS), EU/2015/863</b> Di-ethylhexyl phthlate is subject to the <u>Restriction of Hazardous Substances Directive</u> ( <u>RoHS</u> ), <u>EU/2015/863</u> , which restricts the use of hazardous substances at more than 0.1% by weight at the 'homogeneous material' level in electrical and electronic equipment, beginning July 22, 2019. (European Commission RoHS).		
Australia	Diethylhexyl phthlate was assessed under Human Health Tier II of the Inventory Multi- Tiered Assessment and Prioritisation (IMAP).		
	The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 10,000 and 99,000 tonnes per annum.		
	Diethylhexyl phthlate is used in the production of plastic products. Plastic products that contain more than 1 percent of di-ethylhexyl phthalate are permanently banned from sale.		
	(1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester: Human health tier II assessment (2013). Accessed April 24, 2019).		
Japan	<ul> <li>Diethylhexyl phthlate is regulated in Japan under the following legislation:</li> <li>Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)</li> </ul>		

Country/ **Requirements and Restrictions** Organization Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in • the Environment and Promotion of Improvements to the Management Thereof Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law • World Health Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 1989 Organization (WHO) The Committee previously concluded that di-ethylhexyl phthalate is a peroxisomeproliferator and carcinogen in the livers of both rats and mice and induces age-dependent testicular atrophy in rats. The use of food-contact materials from which bis(2-ethylhexyl) phthalate may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable. **Tolerable Intake: NONE ESTABLISHED** 1999 Monograph Australia, Austria, Occupational exposure limits for DEHP (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 24, 2019). Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Japan, New Zealand, Poland, South Korea, Spain. Sweden Switzerland, United Kingdom

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# **B.4** Assessment History

#### 7157 7158 **Table Apx B-4. Assessment History of DEHP**

Authoring Organization	Publication			
	U.S. EPA publications			
EPA Integrated Risk Information System	Integrated Risk Information System (IRIS), chemical assessment summary, di(2-ethylhexyl)phthalate (DEHP); CASRN 117-81-7 (U.S. EPA, 1988)			
	Other U.Sbased organizations			
Agency for Toxic Substances and Disease Registry (ATSDR)	<i>Toxicological profile for di</i> (2 <i>-ethylhexyl</i> ) <i>phthalate</i> ( <i>DEHP</i> ) ( <u>ATSDR</u> , <u>2022</u> )			
	<i>Toxicological profile for di</i> (2 <i>-ethylhexyl</i> ) <i>phthalate (DEHP): draft for public comment</i> ( <u>ATSDR, 2019</u> )			
	Toxicological profile for di(2-ethylhexyl) phthalate (ATSDR, 2002)			
	Toxicological profile for di(2-ethylhexyl)phthalate (ATSDR, 1993)			
	Toxicological profile for di(2-ethylhexyl)phthalate (ATSDR, 1989)			

Authoring Organization	Publication	
California Office of Environmental Health Hazard Assessment (OEHHA)	Proposition 65 Maximum Allowable Dose Level (MADL) for reproductive toxicity for di(2-ethylhexyl)phthalate (DEHP) by intravenous injection (OEHHA, 2006)	
	Proposition 65 Maximum Allowable Dose Level (MADL) for reproductive toxicity for di(2-ethylhexyl)phthalate (DEHP) by oral exposure (OEHHA, 2005)	
	No Significant Risk Level (NSRL) for the Proposition 65 carcinogen di(2-ethylhexyl)phthalate (OEHHA, 2002)	
Consumer Product Safety Commission (CPSC)	<i>Chronic Hazard Advisory Panel on Phthalates and Phthalate</i> <i>Alternatives (with Appendices)</i> (U.S. CPSC, 2014)	
	<i>Toxicity review of Di</i> (2- <i>ethylhexyl</i> ) <i>Phthalate (DEHP)</i> (U.S. CPSC, 2010)	
National Academies of Sciences, Engineering, and Medicine (NASEM)	Application of systematic review methods in an overall strategy for evaluating low-dose toxicity from endocrine active chemicals (NASEM, 2017)	
	Phthalates and cumulative risk assessment: The task ahead (NRC, $2008$ )	
National Institute for Occupational Safety and Health (NIOSH)	NIOH and NIOSH basis for an occupational health standard. Di(2- ethylhexyl)phthalate (DEHP) (Garberg et al., 1989)	
National Toxicology Program (NTP)	Report on Carcinogens, Fifteenth Edition – Di(2-ethylhexyl) Phthalate ( <u>NTP, 2021a</u> )	
	Toxicology and Carcinogenesis Studies of Di(2-ethylhexyl) Phthalate (CASRN 117-81-7) Administered in Feed to Sprague Dawley (Hsd:Sprague Dawley SD) Rats ( <u>NTP, 2021b</u> )	
	Carcinogenesis bioassay of di(2-ethylhexyl)phthalate (CAS No. 117- 81-7) in F344 rats and B6C3F1 mice (feed studies) ( <u>NTP, 1982</u> )	
National Toxicology Program Center for Evaluation of Risks to Human Reproduction (NTP-CERHR)	NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of di(2-ethylhexyl) phthalate (DEHP) ( <u>NTP-</u> <u>CERHR, 2006</u> )	
International		
Australia National Industrial Chemicals Notification and Assessment Scheme	Phthalate esters: Environment tier II assessment (NICNAS, 2019)	
(NICNAS)	1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester: Human health tier II assessment ( <u>NICNAS, 2013</u> )	
	<i>Priority existing chemical draft assessment report: Diethylhexyl phthalate</i> (NICNAS, 2010)	
European Chemicals Agency (ECHA)	Annex to the Background document to the Opinion on the Annex XV Dossier Proposing 588 Restrictions on Four Phthalates (DEHP, BBP, DBP, DIBP) (ECHA, 2017a)	
	Opinion on an Annex XV Dossier Proposing Restrictions on Four	

Authoring Organization	Publication
	Phthalates (DEHP, BBP, 590 DBP, DIBP) (ECHA, 2017b)
	Member state committee support document for identification of bis(2- ethylhexyl) phthalate (DEHP) as a substance of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances (ECHA, 2014)
	Annex XV restriction report: Proposal for a restriction, version 2. Substance name: bis(2-ehtylhexyl)phthlate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP) (ECHA, 2011)
	Member state committee support document for identification of bis(2- ethylhexyl)phthalate (DEHP) as a substance of very high concern (ECHA, 2008)
	European Union risk Assessment Report: Bis(2-ethylhexyl)phthalate (DEHP) (ECB, 2008)
Environment Canada and Health Canada	Screening assessment - Phthalate substance grouping (ECCC/HC, 2020)
	State of the science report: Phthalate substance grouping: Medium- chain phthalate esters: Chemical Abstracts Service Registry Numbers: 84-61-7; 84-64-0; 84-69-5; 523-31-9; 5334-09-8;16883-83-3; 27215- 22-1; 27987-25-3; 68515-40-2; 71888-89-6 (EC/HC, 2015)
	Supporting documentation: Carcinogenicity of phthalates - mode of action and human relevance (Health Canada, 2015)
	Canadian Environmental Protection Act: Priority substances list assessment report: Bis(2-ethylhexyl) phthalate (EC/HC, 1994)
European Food Safety Authority (EFSA)	Update of the risk assessment of di-butylphthalate (DBP), butyl- benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di- isononylphthalate (DINP) and di-isodecylphthalate (DIDP) for use in food contact materials (EFSA, 2019)
	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to Bis(2-ethylhexyl)phthalate (DEHP) for use in food contact materials (EFSA, 2005)
International Agency for Research on Cancer (IARC)	Some chemicals present in industrial and consumer products, food and drinking-water – Di(2-ethylhexyl) phthalate (IARC, 2013)

# 7159 Appendix C LIST OF TECHNICAL SUPPORT DOCUMENTS

Appendix C includes a list and citations for all supplemental documents included in the Draft Risk
Evaluation for DEHP.

7163 Associated Systematic Review Protocol and Data Quality Evaluation and Data Extraction

7164 Documents – Provide additional detail and information on systematic review methodologies used as
 7165 well as the data quality evaluations and extractions criteria and results.

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7167 Draft Systematic Review Protocol for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025v) – In lieu 7168 of an update to the Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances, also referred to as the "2021 Draft Systematic Review Protocol" (U.S. EPA, 7169 7170 2021a), this systematic review protocol for the Draft Risk Evaluation for DEHP describes some 7171 clarifications and different approaches that were implemented than those described in the 2021 Draft 7172 Systematic Review Protocol in response to (1) SACC comments, (2) public comments, or (3) to reflect chemical-specific risk evaluation needs. This supplemental file may also be referred to as the 7173 "DEHP Systematic Review Protocol." 7174

Draft Data Quality Evaluation and Data Extraction Information for Physical and Chemical
Properties for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 20251) – Provides a compilation of tables
for the data extraction and data quality evaluation information for DEHP. Each table shows the data
point, set, or information element that was extracted and evaluated from a data source that has
information relevant for the evaluation of physical and chemical properties. This supplemental file
may also be referred to as the "DEHP Data Quality Evaluation and Data Extraction Information for
Physical and Chemical Properties."

Draft Data Quality Evaluation and Data Extraction Information for Environmental Fate and
Transport for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025j)– Provides a compilation of tables
for the data extraction and data quality evaluation information for DEHP. Each table shows the data
point, set, or information element that was extracted and evaluated from a data source that has
information relevant for the evaluation for Environmental Fate and Transport. This supplemental file
may also be referred to as the "DEHP Data Quality Evaluation and Data Extraction Information for
Environmental Fate and Transport."

Draft Data Quality Evaluation and Data Extraction Information for Environmental Release and
Occupational Exposure for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025k)– Provides a
compilation of tables for the data extraction and data quality evaluation information for DCHP. Each
table shows the data point, set, or information element that was extracted and evaluated from a data
source that has information relevant for the evaluation of environmental release and occupational
exposure. This supplemental file may also be referred to as the "DEHP Data Quality Evaluation and
Data Extraction Information for Environmental Release and Occupational Exposure."

Draft Data Quality Evaluation Information for General Population, Consumer, and Environmental
Exposure for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025n)– Provides a compilation of tables
for the data quality evaluation information for DEHP. Each table shows the data point, set, or
information element that was evaluated from a data source that has information relevant for the
evaluation of general population, consumer, and environmental exposure. This supplemental file
may also be referred to as the "DEHP Data Quality Evaluation Information for General Population,
Consumer, and Environmental Exposure."

Draft Data Extraction Information for General Population, Consumer, and Environmental Exposure
for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025i) – Provides a compilation of tables for the data
extraction for DEHP. Each table shows the data point, set, or information element that was extracted
from a data source that has information relevant for the evaluation of general population, consumer,
and environmental exposure. This supplemental file may also be referred to as the "DEHP Data
Extraction Information for General Population, Consumer, and Environmental Exposure."

Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology for
Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025p) – Provides a compilation of tables for the data
quality evaluation information for DEHP. Each table shows the data point, set, or information
element that was evaluated from a data source that has information relevant for the evaluation of
epidemiological information. This supplemental file may also be referred to as the "DEHP Data
Quality Evaluation Information for Human Health Hazard Epidemiology."

Draft Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for
Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025o) – Provides a compilation of tables for the data
quality evaluation information for DEHP. Each table shows the data point, set, or information
element that was evaluated from a data source that has information relevant for the evaluation of
human health hazard animal toxicity information. This supplemental file may also be referred to as
the "DEHP Data Quality Evaluation Information for Human Health Hazard Animal Toxicology."

Draft Data Quality Evaluation Information for Environmental Hazard for Diethylhexyl Phthalate
(DEHP) (U.S. EPA, 2025m) – Provides a compilation of tables for the data quality evaluation
information for DEHP. Each table shows the data point, set, or information element that was
evaluated from a data source that has information relevant for the evaluation of environmental
hazard toxicity information. This supplemental file may also be referred to as the "DEHP Data
Quality Evaluation Information for Environmental Hazard."

7235 Draft Data Extraction Information for Environmental Hazard and Human Health Hazard Animal 7236 Toxicology and Epidemiology for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025h) – Provides a 7237 compilation of tables for the data extraction for DEHP. Each table shows the data point, set, or 7238 information element that was extracted from a data source that has information relevant for the 7239 evaluation of environmental hazard and human health hazard animal toxicology and epidemiology 7240 information. This supplemental file may also be referred to as the "DEHP Data Extraction 7241 Information for Environmental Hazard and Human Health Hazard Animal Toxicology and 7242 Epidemiology."

Associated Technical Support Documents (TSDs) – Provide additional details and information on
 exposure, hazard, and risk assessments.

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7247 Draft Physical Chemistry and Fate and Transport Assessment for Diethylhexyl Phthalate (DEHP)
 7248 (U.S. EPA, 2024h).
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7250 Draft Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate
 7251 (DEHP) (U.S. EPA, 2025r).

Draft Consumer and Indoor Dust Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S.
 EPA, 2025e).

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- Draft Environmental Media and General Population and Environmental Exposure Assessment for
   Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025q).
- 7259 Draft Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2024a).
- 7261 Draft Non-Cancer Human Health Hazard Assessment for Diethylhexyl Phthalate (DEHP) (U.S.
   7262 EPA, 2024f).

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Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl
Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl
Phthalate (DCHP) (U.S. EPA, 2025d).

- 7268 Draft Occupational Risk Calculator for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025t).
- 7270 Draft Fish Ingestion Risk Calculator for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025s).
- 7272 Draft Ambient Air Exposure Assessment for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025c).
- 7274 Draft Consumer Risk Calculator for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025g).
- 7276 Draft Consumer Exposure Analysis for Diethylhexyl Phthalate (DEHP) (U.S. EPA, 2025f).
- 7278 Draft Surface Water Human Exposure Risk Calculator for Diethylhexyl Phthalate (DEHP) (U.S.
   7279 EPA, 2025u).
- Draft Occupational and Consumer Cumulative Risk Calculator for Diethylhexyl Phthalate (DEHP)
   (EPA, 2025).
- Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
  Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024b).

Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate
(DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic
Substances Control Act (TSCA) (U.S. EPA, 2025x).

Draft Summary of Facility Release Data for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate
(DBP), and Butyl Benzyl Phthalate (BBP) (U.S. EPA, 2024i).

# Appendix D UPDATES TO THE DEHP CONDITIONS OF USE TABLE

After the final scope document (U.S. EPA, 2020c) was released, EPA received updated submissions 7297 7298 from the 2020 CDR cycle (U.S. EPA, 2020a). In addition to new submissions received under the 2020 7299 CDR cycle, the use and processing codes changed for the 2020 CDR cycle. Therefore, EPA amended 7300 the description of certain DEHP COUs based on those new submissions and new use and processing 7301 codes. Also, EPA received information from stakeholders about uses of DEHP. For cases where COUs 7302 were consolidated under a category, if the category was not present in the scope, the nomenclature was 7303 taken directly from the 2020 CDR cycle codes and categories. Table\_Apx D-1 summarizes the changes 7304 to the COUs based on the new codes in the 2020 CDR and any other additional information reasonably available to EPA since the publication of the final scope document. 7305

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7307	Table_Apx D-1. Changes to Categories and Subcategories of COUs Based on CDR and
7308	Stakeholder Engagement

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
	Plasticizer in plastic material and resin manufacturing, rubber product manufacturing, and synthetic manufacturing And	Consolidated under "Processing - incorporation into article," and "Processing - incorporation into formulation, mixture, or reaction product" categories based on stakeholder feedback (U.S. EPA, 2025b).	Processing – incorporation into article - plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; and PVC extruding And
Processing – as a reactant	Adhesive and sealant chemical in adhesive manufacturing		Processing – incorporation into formulation, mixture, or reaction product - plasticizer in plastic material and resin manufacturing; synthetic rubber manufacturing; basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; basic inorganic chemical manufacturing; wholesale and retail trade; services; and ink, toner, and colorant manufacturing
Processing - incorporation into article	Plasticizer in all other basic organic chemical manufacturing, plastics product manufacturing	Added sectors "miscellaneous manufacturing" and "PVC extruding" based on 2020 CDR reports. Recategorized "plastics product manufacturing" and "rubber product manufacturing" which were previously categorized under the "Incorporation into formulation, mixture, or reaction product" category to more accurately reflect use of DEHP.	Processing – incorporation into article - plasticizer in basic organic chemical manufacturing; plastics product manufacturing; rubber product manufacturing; miscellaneous manufacturing; and PVC extruding

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Processing - incorporation into formulation, mixture, or reaction product	compounding of purchased resins; miscellaneous	Consolidated subcategories and added sector "synthetic rubber manufacturing, wholesale and retail trade, and ink, toner, and colorant manufacturing (including pigment)" based on 2020 CDR cycle data and identified products based on reasonably available information.	Processing – incorporation into formulation, mixture, or reaction product - plasticizer in plastic material and resin manufacturing; synthetic rubber manufacturing; basic organic chemical manufacturing; custom compounding of purchased resins; miscellaneous manufacturing; paint and coating manufacturing; adhesive manufacturing; basic inorganic chemical manufacturing; wholesale and retail trade; services; and ink, toner, and colorant manufacturing (including pigment)
Processing – intermediate	Intermediate in plastic products manufacturing	Consolidated COU; see below table for further explanation.	N/A
Processing - Repackaging – other repackaging functional use in wholesale and retail trade		Added "paint and coating manufacturing" sector based on 2020 CDR cycle data.	Processing – repackaging - repackaging in wholesale and retail trade and in paint and coating manufacturing
N/A	N/A	Added category and subcategory to reflect updates from 2020 CDR cycle.	Processing - other uses - miscellaneous processing (cyclic crude and intermediate manufacturing; processing aid specific to hydraulic fracturing)
Processing - incorporation into formulation, mixture, or reaction product	Solid rocket motor insulation	Redesignated category to Industrial use and added additional aerospace applications based on public comment ( <u>AIA</u> , <u>2019</u> ).	Industrial use - other uses - solid rocket motor insulation and other aerospace applications
Distribution	Distribution	Revised to align with "Distribution in commerce" in TSCA statute	Distribution in commerce
Industrial use - processing aid, specific to petroleum production	Hydraulic fracturing	Consolidated this subcategory under new "Other uses" category for Industrial use to better reflect DEHP use.	Industrial use - other uses - hydraulic fracturing

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Industrial use - reference material and/or laboratory reagent	Laboratory chemicals	Redesignated this subcategory as a Commercial use within the "other uses" category.	Commercial use - other uses - laboratory chemicals
Industrial use – transportation equipment manufacturing	( <i>e.g.</i> , formulations for diffusion bonding and manufacture of aero engine fan blades)	Consolidated under "Industrial use – construction, paint, electrical, and metal products - adhesives and sealants" and "Commercial use – construction, paint, electrical, and metal	Industrial use – construction, paint, electrical, and metal products - adhesives and sealants
		products - adhesives and sealants" to avoid redundancy and better reference products ( <u>Morgan Advanced Materials</u> <u>Wesgo Metals, 2016a, b</u> ).	And Commercial use – construction, paint, electrical, and metal products - adhesives and sealants
Industrial use - paints and coatings	Paints and coatings ( <i>e.g.</i> , industrial polish)	Consolidated under "Construction, paint, electrical, and metal products" category within Industrial use life cycle and removed "( <i>e.g.</i> , Industrial Polish)" sector from subcategory name reflect updates from 2020 CDR cycle.	Industrial use - construction, paint, electrical, and metal products - paints and coatings
N/A	N/A	Added Industrial use – construction, paint, electrical, and metal products - adhesives and sealants to account for products used in an industrial setting identified through further investigation for ongoing use, as well as products categorized under previous "Industrial use - transportation equipment manufacturing - ( <i>e.g.</i> , formulations for diffusion bonding and manufacture of aero engine fan blades)" COU.	Industrial use – construction, paint, electrical, and metal products - adhesives and sealants
N/A	N/A	Added "Automotive articles" subcategory to "Other uses" category within Industrial use life cycle due to public comment (AIA, 2019).	Industrial use – other uses - automotive articles
Commercial use - adhesives and sealants	Adhesives and sealants	Consolidated under "Construction, paint, electrical, and metal products" category to be consistent with 2020 CDR codes.	Commercial use - construction, paint, electrical, and metal products - adhesives and sealants
Commercial use – arts, crafts, and hobby materials	Arts, crafts, and hobby materials	Removed category and subcategory because it was not reported in CDR data in 2016, or 2020, and no products with	N/A

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		ongoing use were identified.	
Commercial use - batteries	Batteries ( <i>e.g.</i> , digital camera)	Consolidated under "Construction, paint, electrical, and metal products" category and removed " <i>e.g.</i> , digital camera" to be consistent with 2020 CDR codes. Added "and capacitors" to account for additional products	Commercial use - construction, paint, electrical, and metal products - batteries and capacitors
		identified ( <u>Just In Time</u> Chemical, 2015).	
Commercial use - building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Consolidated under "Construction, paint, electrical, and metal products" category	Commercial use - construction, paint, electrical, and metal products - construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Commercial use - dyes, pigments, and fixing agents	Dyes, pigments, and fixing agents	Consolidated under "Packaging, paper, plastic, toys, hobby products" category and updated subcategory name to be consistent with 2020 CDR codes.	Commercial use - packaging, paper, plastic, toys, hobby products - ink, toner, and colorants
Commercial use - Electrical and electronic products	Electrical and electronic products	Consolidated under "Construction, paint, electrical, and metal products" category and updated subcategory name to be consistent with 2020 CDR codes and identified products (ESAB, 2024; QuickCable Corporation, 2024; Just In Time Chemical, 2015).	Commercial use - construction, paint, electrical, and metal products - machinery, mechanical appliances, electrical/electronic articles
Commercial use - fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	Consolidated under "Furnishing, cleaning, treatment care products" category and updated subcategory name to be consistent with 2020 CDR codes.	cleaning, treatment care products - fabric, textile, and leather products; furniture and furnishings
		Added "furniture and furnishings" (previously "Furniture and furnishings not covered elsewhere" subcategory) because products identified for the previously two separate subcategories appeared to be the same or similar.	
Commercial use - lawn and garden care products	Lawn and garden care products	Consolidated under "Automotive, fuel, agriculture, outdoor use products" category to be consistent with 2020 CDR codes.	Commercial use - automotive, fuel, agriculture, outdoor use products - lawn and garden care products

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Commercial use - paints and coatings	Paints and coatings ( <i>e.g.</i> , sealer for decorative concrete as waterproof polyurethane)	Consolidated under "Construction, paint, electrical, and metal products" category and removed "( <i>e.g.</i> , sealer for decorative concrete as waterproof polyurethane)" to be consistent with 2020 CDR codes.	Commercial use - construction, paint, electrical, and metal products - paints and coatings
Commercial use - plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	Consolidated under "Packaging, paper, plastic, toys, hobby products" category and updated subcategory name to be consistent with 2020 CDR codes.	Commercial use - packaging, paper, plastic, toys, hobby products - packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)
Commercial use - toys, playground, and sporting equipment	Toys, playground, and sporting equipment	Consolidated under "Packaging, paper, plastic, toys, hobby products" category to be consistent with 2020 CDR codes.	Commercial use - packaging, paper, plastic, toys, hobby products - toys, playground, and sporting equipment
N/A	N/A	Added subcategory "All-purpose waxes and polishes" to be consistent with 2020 CDR codes.	cleaning, treatment care products - all-
N/A	N/A	Added subcategory "Fabric enhancer" to be consistent with 2020 CDR codes.	Commercial use - furnishing, cleaning, treatment care products - fabric enhancer
N/A	N/A	surface areas including stone, plaster, cement, glass and	Commercial use - furnishing, cleaning, treatment care products - floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
N/A	N/A	Added subcategory "Packaging (excluding food packaging), including paper articles" to be consistent with 2020 CDR codes.	Commercial use - packaging, paper, plastic, toys, hobby products - packaging (excluding food packaging), including paper articles
N/A	N/A	Added subcategory "Automotive articles" due to public comment (EPA-HQ-OPPT-2019-0131- 0022).	Commercial use - other uses - automotive articles
Consumer use - adhesives and sealants	Adhesives and sealants	Consolidated under "Construction, paint, electrical, and metal products" category to be consistent with 2020 CDR codes.	Consumer use - construction, paint, electrical, and metal products - adhesives and sealants
Consumer use – Arts, crafts, and hobby materials	Arts, crafts, and hobby materials	Removed category and subcategory because it was not reported in CDR data in 2016, or 2020, and no products with ongoing use were identified.	N/A

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Consumer use - batteries	Batteries ( <i>e.g.</i> , digital camera)	Consolidated under "Construction, paint, electrical, and metal products" category and removed " <i>e.g.</i> , digital camera" to be consistent with 2020 CDR codes.	Consumer use - construction, paint, electrical, and metal products - batteries
Consumer use - building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Consolidated under "Construction, paint, electrical, and metal products" category to be consistent with 2020 CDR codes.	Consumer use - construction, paint, electrical, and metal products - construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Consumer use - dyes, pigments, and fixing agents	Dyes, pigments, and fixing agents	Consolidated under "Packaging, paper, plastic, toys, hobby products" category to be consistent with 2020 CDR codes.	Consumer use - packaging, paper, plastic, toys, hobby products - ink, toner, and colorants
Consumer use - electrical and electronic products	Electrical and electronic products	Consolidated under "Construction, paint, electrical, and metal products" category to be consistent with 2020 CDR codes.	Consumer use - construction, paint, electrical, and metal products - machinery, mechanical appliances, electrical/electronic articles
Consumer use - fabric, textile, and leather products not covered elsewhere	Fabric, textile, and leather products not covered elsewhere	Consolidated under "Furnishing, cleaning, treatment care products" category to be consistent with 2020 CDR codes. Added "furniture and furnishings" (previously "Furniture and furnishings not covered elsewhere" subcategory) as the reported products referred to the same or similar products.	Consumer use - furnishing, cleaning, treatment care products - fabric, textile, and leather products; furniture and furnishings
Consumer use - lawn and garden care products	Lawn and garden care products	Consolidated under "Automotive, fuel, agriculture, outdoor use products" category to be consistent with 2020 CDR codes.	Consumer use - automotive, fuel, agriculture, outdoor use products - lawn and garden care products
Consumer use - paints and coatings	Paints and coatings ( <i>e.g.</i> , sealer for decorative concrete as waterproof polyurethane)	Consolidated under "Construction, paint, electrical, and metal products" category and removed "( <i>e.g.</i> , sealer for decorative concrete as waterproof polyurethane)" to be consistent with 2020 CDR codes.	Consumer use - construction, paint, electrical, and metal products - paints and coatings
Consumer use - plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	Consolidated under "Packaging, paper, plastic, toys, hobby products" category and updated subcategory name to be consistent with 2020 CDR codes.	Consumer use - packaging, paper, plastic, toys, hobby products - packaging (excluding food packaging) and other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard); plastic articles (soft)

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Consumer use - toys, playground, and sporting equipment	Toys, playground, and sporting equipment	Consolidated under "Packaging, paper, plastic, toys, hobby products" category to be consistent with 2020 CDR codes.	Consumer use - packaging, paper, plastic, toys, hobby products - toys, playground, and sporting equipment
N/A	N/A	surface areas including stone, plaster, cement, glass and	Consumer use - furnishing, cleaning, treatment care products - floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
N/A	N/A	Added subcategory "Packaging (excluding food packaging), including paper articles" to reflect 2020 CDR cycle data.	Consumer use - packaging, paper, plastic, toys, hobby products - packaging (excluding food packaging), including paper articles
N/A	N/A	Added subcategory "Automotive articles" due to public comment (EPA-HQ-OPPT-2019-0131- 0022).	Consumer use - other uses - automotive articles
N/A	N/A	Added subcategory "novelty articles" based on additional information ( <u>Stabile, 2013</u> ).	Consumer use - other uses - novelty articles

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In addition, EPA is including further detail about edits to the following COUs, which are alreadypresented in Table\_Apx D-1:

- Processing, incorporation into a formulation, mixture, or reaction product, "Plastic product manufacturing" was consolidated under Processing incorporation into articles to better
   represent incorporation of DEHP into plastic articles, as opposed to incorporation into plastic material or resin.
- Processing, incorporation into a formulation, mixture, or reaction product, "Rubber product
   manufacturing" was consolidated under the Processing, incorporation into articles category to
   better represent incorporation of DEHP into rubber articles, as opposed to rubber material.
- Processing as a reactant, and its associated subcategories, "Plasticizer in plastic material and resin manufacturing, rubber product manufacturing, and synthetic rubber manufacturing" and "Adhesive and sealant chemical in adhesive manufacturing" were consolidated under either Processing incorporation into article or Processing, incorporation into formulation, mixture, or reaction products, based on EPA's understanding of DEHP's use in processing following further consultations with industry (U.S. EPA, 2025b).
- Processing intermediate, and its associated subcategory, "Intermediate in plastics product manufacturing" were consolidated under Processing, incorporation into formulation, mixture, or reaction products - plasticizer because upon further investigation, the Agency determined that the two COUs were redundant. The term "intermediate" is used here to describe the intermediate step in plastic product/article production where a PVC plastic or non-PVC resin is formed prior to conversion to the final article.

The subcategory "automotive care products" in the COUs, Commercial use - automotive care products - automotive care products and Consumer use - automotive care products - automotive care products and Consumer use - automotive care products - automotive care products was revised to "automotive articles" based on further investigation revealing a lack of ongoing use for referenced automotive care products and to clarify DEHP's use in automotive applications. This subcategory was additionally added to the "Industrial use" life cycle stage within the "other uses" category, to reflect DEHP's use in industrial settings for automotive applications.

# 7338 Appendix E CONDITIONS OF USE DESCRIPTIONS

7339 The following descriptions are intended to include examples of uses, so as not to exclude other activities 7340 that may also be included in the COUs of the chemical substance. To better describe the COU, EPA 7341 considered CDR submissions from the last two CDR cycles for DEHP (CASRN 117-81-7) and the COU 7342 descriptions reflect what EPA identified as the best fit for that submission. Examples of articles, 7343 products, or activities are included in the following descriptions to help describe the COU but are not exhaustive. EPA uses the terms "articles" and "products" or "product mixtures" in the following 7344 7345 descriptions and is generally referring to articles and products as defined by 40 CFR Part 751. There 7346 may be instances where the terms are used interchangeably by a company or commenters, or by the 7347 Agency in reference to a code from the CDR reports which are referenced; for example, "plastic 7348 products manufacturing," or "fabric, textile, and leather products." EPA will clarify as needed when 7349 these references are included throughout the COU descriptions below.

# E.1 Manufacturing – Domestic Manufacturing

Domestic manufacturing means to manufacture or produce DEHP within the Unites States. For purposes
of the DEHP risk evaluation, this includes the extraction of DEHP from a previously existing chemical
substance or complex combination of chemical substances and loading and repackaging (but not
transport) associated with the manufacturing or production of DEHP.

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DEHP is typically manufactured through catalytic esterification of phthalic anhydride with 2-ethylhexyl
alcohol in the presence of an acid catalyst. A typical manufacturing operation takes place in closed
systems either via batch or more automated continuous operations and will involve the purification of
diethylhexyl phthalate product streams via either vacuum distillation or by passing over activated
charcoal as a means of recovering unreacted alcohols (U.S. EPA, 2021c). This condition of use includes
the typical manufacturing process and any other similar manufacturing of DEHP.

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# 7363 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported domestic manufacture of DEHP, and in 2020, another
 company reported domestic manufacture of DEHP (U.S. EPA, 2020a, 2019b).

# 7366 E.2 Manufacturing – Importing

Import refers to the import of DEHP into the customs territory of the United States. This condition of
use includes loading/unloading and repackaging (but not transport) associated with the import of DEHP.
In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal
shipments. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and
intermodal tank containers. Imported DEHP is shipped in liquid or solid pellet form (U.S. EPA, 2019b).

### 7373 Examples of CDR Submissions

In the 2016 and 2020 CDR cycles, several companies reported import of DEHP (<u>U.S. EPA, 2020a</u>, 2019b).

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E.3 Processing – Incorporation into a Formulation, Mixture, or Reaction 7377 **Product – Plasticizer in Plastic Material and Resin Manufacturing:** 7378 Synthetic Rubber Manufacturing; Basic Organic Chemical 7379 Manufacturing; Custom Compounding of Purchased Resins; 7380 Miscellaneous Manufacturing; Paint and Coating Manufacturing; 7381 Adhesive Manufacturing: Basic Inorganic Chemical Manufacturing: 7382 Wholesale and Retail Trade; Services; and Ink, Toner, and Colorant 7383 Manufacturing 7384

This COU refers to the preparation of a product; that is, the incorporation of DEHP into formulation, 7385 7386 mixture, or a reaction product which occurs when a chemical substance is added to a product (or product mixture), after its manufacture, for distribution in commerce-in this case, processing of DEHP as a 7387 7388 plasticizer into several different products for use in multiple sectors, such as basic organic chemical 7389 manufacturing, wholesale and retail trade, and services. DEHP is also blended with other volatile and 7390 nonvolatile chemical components to produce hydraulic fluid and capacitor fluid, plastic material and 7391 resin, synthetic rubber, compounded resin, paints and coatings, ink, toner, and colorants, and adhesives 7392 and sealants (ACC HPP, 2019; Just In Time Chemical, 2015; OECD, 2009).

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7394 A plasticizer provides flexibility to non-PVC and PVC plastic materials. In manufacturing of plastic 7395 material and resin through non-PVC and PVC compounding, DEHP is blended into polymers. 7396 compounding involves the mixing of the polymer with the plasticizer and other chemicals such as fillers 7397 and heat stabilizers. The plasticizer needs to be absorbed into the particle to impart flexibility to the 7398 polymer. For PVC compounding, compounding occurs through mixing of ingredients to produce a 7399 powder (dry blending) or a liquid (Plastisol blending). The most common process for dry blending 7400 involves heating the ingredients in a high-intensity mixer and transferring to a cold mixer. The Plastisol blending is done at ambient temperature using specific mixers that allow for the breakdown of the PVC 7401 7402 agglomerates and the absorption of the plasticizer into the resin particle. DEHP is also added to produce 7403 a mixture of chemical substances used as a reference standard in analytical methods monitoring 7404 chemical substances in aqueous and solid samples (Chem Service Inc, 2018; Phenova, 2018).

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### 7406 Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported use of DEHP as a plasticizer in all other basic organic
chemical manufacturing; one company reported use of DEHP as a plasticizer in custom compounding of
purchased resin; another company reported use of DEHP as a plasticizer in miscellaneous
manufacturing; two other companies reported use of DEHP as a plasticizer in paint and coating
manufacturing; five other companies reported using DEHP as a plasticizer in plastics material and resin
manufacturing; two companies reported use of DEHP as a plasticizer in synthetic rubber manufacturing;
one company reported using DEHP in adhesive manufacturing for all other basic inorganic chemical

- manufacturing, this same company reported using DEHP as a plasticizer and as a plasticizer in services
   (U.S. EPA, 2019b).
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7417 In the 2020 CDR cycle, one company reported use of DEHP as a plasticizer in all other basic organic

7418 chemical manufacturing; two companies reported using DEHP as a plasticizer in custom compounding

of purchased resin; another company reported using DEHP as a plasticizer in miscellaneous

manufacturing; three other companies reported the use of DEHP as a plasticizer in plastics material and

resin manufacturing; one company reported use of DEHP as a plasticizer in synthetic rubber

manufacturing; and another company reported use of DEHP as a plasticizer for processing in wholesale

and retail trade (U.S. EPA, 2020a).

# 7424 E.4 Processing – Incorporation into Article – Plasticizer in Basic Organic 7425 Chemical Manufacturing; Plastics Product Manufacturing; Rubber 7426 Product Manufacturing; Miscellaneous Manufacturing; PVC 7427 Extruding

7428 This COU refers to the preparation of an article; that is, the incorporation of DEHP into articles, 7429 meaning DEHP becomes a component of the article, after its manufacture, for distribution in commerce. 7430 In this case, DEHP is present in a raw material such as rubber or plastic that contains a mixture of 7431 plasticizers and other additives, and this COU refers to the manufacturing of PVC and non-PVC articles. 7432 including rubber, plastic, and miscellaneous articles using those raw materials. The raw material is converted by processes such as calendaring, extrusion, injection molding, and plastisol spread coating. 7433 7434 This COU encompasses the step that occurs immediately after PVC compounding, where the 7435 compounded resin is sent to an extruder that shapes and sizes the plastic into an article or pellet to be 7436 used in downstream processing at PVC or non-PVC conversion sites (U.S. EPA, 2021e). This COU also 7437 includes the forming, shaping, or cutting articles containing DEHP and the incorporation of the rubber 7438 or plastic and other articles into finished articles, such as electrical and electronic articles, machinery, 7439 mechanical appliances, fabric, textiles and leather articles, or furniture and furnishings.

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DEHP is additionally incorporated as a plasticizer into articles used for food contact materials like food
additives, and into medical devices; Food additives and medical devices are exempt from TSCA's
definition of chemical substance.

DEHP may be incorporated into machinery or machinery parts as part of a hydraulic fluid mixture, as
well as a dielectric fluid in capacitors (Just In Time Chemical, 2015).

In toy manufacturing, toys could contain up to 0.1 percent of DEHP. (The CPSC has a regulatory limit
of no more than 0.1 percent for DEHP concentration in toys.) Additionally, it is possible that DEHP
could be incorporated into playground equipment manufacturing due to its use as a plasticizer in PVC
and non-PVC articles that may be components of playground equipment (U.S. EPA, 2019a).

7453 Examples of CDR Submissions

In the 2016 CDR cycle, five companies reported use of DEHP as a plasticizer in plastic product
manufacturing. One company reported using DEHP as a plasticizer in medical devices, as well as food,
beverage, and tobacco product manufacturing. As noted above, the use in food additives and medical
devices are exempt from the TSCA definition of chemical substance and the processing into food
additives and medical devices are not subject to evaluation under TSCA. Another company used DEHP
as a plasticizer in basic organic chemical manufacturing. Three companies reported using DEHP as a
plasticizer in rubber product manufacturing (U.S. EPA, 2019b).

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In the 2020 CDR cycle, four companies reported using DEHP as a plasticizer in plastic product
manufacturing. One company also reported use of DEHP as a plasticizer in food, beverage, and tobacco
product manufacturing, as well as miscellaneous manufacturing. Three companies reported use of DEHP
as a plasticizer in rubber product manufacturing. Another company reported use of DEHP as a
plasticizer in PVC extruding (U.S. EPA, 2020a).

# 7467 E.5 Processing – Repackaging – Repackaging in Wholesale and Retail 7468 Trade and in Paint and Coating Manufacturing

Repackaging refers to the preparation of DEHP for distribution in commerce in a different form, state, or
 quantity than originally received or stored by various industrial sectors, including the repackaging of

7471 DEHP for adhesion/cohesion promoter applications in wholesale and retail trade, as well as the paint and

- coating manufacturing sector. This COU includes the transferring of DEHP from a bulk storage
  container into smaller containers. This COU would not apply to the relabeling or redistribution of a
  chemical substance without removing the chemical substance from the original container it was supplied
  in.
- 7476

# 7477 Examples of CDR Submissions

7478 In the 2016 CDR cycle, three companies all reported use of DEHP in repackaging for wholesale and
 7479 retail trade (U.S. EPA, 2019b).

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7481 In the 2020 CDR cycle, one company reporting use in repackaging for wholesale and retail trade and
7482 repacking for adhesion/cohesion promoter in wholesale and retail trade, another company reporting use
7483 in repackaging for paint and coating manufacturing (U.S. EPA, 2020a).

# E.6 Processing – Other uses – Miscellaneous Processing (Cyclic Crude and Intermediate Manufacturing; Processing Aid Specific to Hydraulic Fracturing)

7487 This COU refers to the preparation of a product, that is, the incorporation of DEHP into formulation, 7488 mixture, or a reaction product which occurs when DEHP is added to a product (or product mixture) after 7489 its manufacture, for distribution in commerce. In this case, DEHP is incorporated into products that then 7490 are used as a processing aid for hydraulic fracturing and the exploration and/or extraction of natural gas 7491 through horizontal drilling, particularly in shale formations, as well as cyclic crude and intermediate 7492 manufacturing, or distilling coal tars and/or manufacturing cyclic crudes or cyclic intermediates (i.e., 7493 hydrocarbons, except aromatic petrochemicals) from refined petroleum or natural gas. DEHP has been 7494 identified in EPA's Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water 7495 Cycle on Drinking Water Resources in the United States (EPA-600-R-16-236Fb), December 2016 7496 document to be a known constituent of hydraulic fracturing fluid. 7497

# 7498 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported use of DEHP in cyclic crude and intermediate
 manufacturing (U.S. EPA, 2019b).

# E.7 Processing – Recycling

This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be disposed of as waste), containing DEHP, that are collected, either on-site or at a third-party site, for commercial purpose.

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# 7506 *Examples of CDR Submissions*

The 2016 and 2020 CDR cycles indicate DEHP is recycled (U.S. EPA, 2020a, 2019b).

# 7508 **E.8 Distribution in Commerce**

7509 For purposes of assessment in this risk evaluation, distribution in commerce consists of the

transportation associated with the moving of DEHP or DEHP-containing products and/or articles

between sites manufacturing, processing or recycling DEHP or DEHP-containing products and/or

articles, or to final use sites, or for final disposal of DEHP or DEHP-containing products and/or articles.

7513 More broadly under TSCA, "distribution in commerce" and "distribute in commerce" are defined under

7514 TSCA section 3(5).

# 7515 E.9 Industrial Use – Construction, Paint, Electrical, and Metal Products – 7516 Paint and Coatings

This COU refers to the use of DEHP in various industrial sectors as a component of paints and coatings.
This is a use of DEHP after it has already been incorporated into a paint or coating or mixture, as
opposed to when it is used upstream (*e.g.*, when DEHP is processed into the paint or coating
formulation).

7521

7522 EPA has identified off the shelf paints and sealants in the industrial use of paint and coating materials 7523 (EPA-HQ-OPPT-2019-0501-0043). An example of a type of coating product that contains DEHP indicates that the product is used for "part of a comprehensive bridge waterproofing system typically 7524 7525 used on heavy highway projects" but the supplier also noted it has many industrial applications. As 7526 noted in the product SDS: "In order to obtain the optimum results, a system must be capable of applying at pressures greater than 2,500 psi and at temperatures of 140 - 160°F" (Wasser Technologies, 2021). 7527 7528 Another example of a type of coating product that contains DEHP is used to protect metals and concrete 7529 from UV, weathering, and abrasion. It can be applied by brush, roller, mitt or spray methods (Wasser 7530 Corporation, 2021). EPA also identified products that used to contain DEHP but have been 7531 reformulated. The typical industrial application of these paints and coatings would take place on metal 7532 alloys (e.g., steel), metals, or concrete during fabrication of structural components that would later be 7533 installed by commercial contractors. The coatings can be used to protect components from water, UV 7534 light, and abrasion. This COU includes these typical paint and coating uses, and any similar paint and 7535 coating use of DEHP.

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Additionally, this COU encompasses DEHP-containing coatings and lacquers are used in the aerospace
industry, including for very specific applications such as aluminum pigmented coatings on fasteners,
strippable coatings, and maskants (EPA-HQ-OPPT-2018-0433-0004).

7540

In the *Final Scope of the Risk Evaluation for Diethylhexyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester) (CASRN 117-81-7)* EPA identified a product used in wood, automotive original
equipment manufacturing, marine, and aerospace applications as a paint and coating. This product seems
to have been reformulated without DEHP as of 2023; however, the product formulated with DEHP is
likely still in use(<u>3M Company, 2019</u>).

7546

# 7547 Examples of CDR Submissions

The industrial use of DEHP in paints and coatings was not reported in the 2016 or 2020 CDR cycles.
However, one company reported Processing – incorporation into formulation, mixture, or reaction
product – paints and coatings – plasticizer in the 2016 CDR cycle. One company reported the use of
DEHP in paints and coatings, but the life stage and category were reported as NKRA (U.S. EPA,
2019b). In the 2020 CDR cycle, one company reported the processing-repackaging of DEHP for use in

the paints and coatings industry (U.S. EPA, 2020a).

# 7554 E.10 Industrial Use – Construction, Paint, Electrical, and Metal Products 7555 Adhesives and Sealants

This COU refers to DEHP as it is used in various industrial sectors as a component of adhesive or sealant mixtures, meaning the use of DINP after it has already been incorporated into an adhesive and/or sealant product or mixture, as opposed to when it is used upstream, (*e.g.*, when DEHP is processed into the adhesive and sealant formulation). EPA identified a product used as a barrier to the flow of molten metal alloys during soldering processes to protect holes and non-braze areas from coverage and clogging (Morgan Advanced Materials Wesgo Metals, 2016a, b). In the *Final Scope of the Risk Evaluation for* 

Di-ethylhexyl phthalate (DEHP), CASRN 117-81-7 (U.S. EPA, 2020c) EPA included this product under
the "Transportation Equipment Manufacturing" COU; however, the "Transportation Equipment
Manufacturing" COU was consolidated under this adhesives and sealants COU to avoid redundancy, as
this product was better categorized as a sealant. Additionally, this COU encompasses DEHP-containing
adhesives and tapes are used in the aerospace industry (EPA-HQ-OPPT-2018-0433-0004), and DEHP
used as a component of adhesives and sealants used for sealing vacuum system connection points.
NASA considered this use as mission critical (EPA-HQ-OPPT-2018-0501-0043).

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The industrial use of DEHP in adhesives and sealants was not reported during the 2016 and 2020 CDRcycles.

# E.11 Industrial Use – Other Uses – Hydraulic Fracturing

7573 This COU refers to the use of DEHP as a processing aid for hydraulic fracturing and the exploration 7574 and/or extraction of natural gas through horizontal drilling, particularly in shale formations (EPA-HQ-7575 OPPT-2019-0131-0054). DEHP has been identified in EPA's Hydraulic Fracturing for Oil and Gas: 7576 Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States 7577 (EPA-600-R-16-236Fb), December 2016 document to be a known constituent of hydraulic fracturing 7578 fluid. This COU is associated with the actual use of DEHP as a component of the hydraulic fracturing 7579 fluid or other products, as opposed to when DEHP is used upstream (e.g., when DEHP is processed into 7580 the hydraulic fluid or other products). 7581

The industrial use of DEHP as a processing aid specific to petroleum (hydraulic fracturing) was notreported during the 2016 and 2020 CDR cycles.

# E.12 Industrial Use – Other Uses - Solid Rocket Motor Insulation and Other Aerospace Applications

This COU refers to the use of DEHP as a component of solid rocket motor insulation for human-related
space vehicles (EPA-HQ-OPPT-2018-0501-0043). The use was described by NASA as a mission
critical use. Additionally, this COU encompasses DEHP-containing materials are used in aerospace
applications such as tubing and pressure pads in composite processing (EPA-HQ-OPPT-2018-04330004).

The industrial use of DEHP in solid rocket motor insulation and other aerospace applications does nothave data reported for the 2016 and 2020 CDR cycles.

# 7594 E.13 Industrial Use – Other Uses - Automotive Articles

This COU refers to the use of DEHP in the automobile manufacturing sector as a component in various automotive articles. This is a use of DEHP after it has already been incorporated into a plastic article, as opposed to when it is used upstream (*e.g.*, when DEHP is processed into an article).

This COU includes DEHP used in a number of automotive parts, both in current production and replacement parts, including electrical system wiring, seat assemblies, radiator assemblies, hoses in

chassis assembly, and hardware modules in the automobile doors (EPA-HQ-OPPT-2019-0131).

Based on DEHP found downstream in tire crumb applications for playgrounds and turf (<u>Armada et al.</u>,
 2022; <u>U.S. EPA</u>, 2019e), users may be handling DEHP in tires for automobiles in industrial settings.

The industrial use of DEHP in automotive articles does not have CDR data reported for the 2016 and 2020 cycles.

# E.14 Commercial Use – Automotive, Fuel, Agriculture, Outdoor Use Products - Lawn and Garden Care Products

This COU refers to the use of DEHP in lawn and garden care products. This is a use of DEHP after it has already been incorporated into a lawn and garden care product or mixture, as opposed to when it is used upstream (*e.g.*, when DEHP is processed into a product).

7612

Examples of typical lawn and garden care products included in the CDR description for the processing
and use code, "lawn and garden care products," are fertilizers and nutrient mixtures, soil amendments,
mulches, pH adjustors, water retention beads, vermiculite, and perlite. Use of lawn and garden care
products containing DEHP in commercial settings would typically be handled by landscapers or
maintenance technicians for properties or facilities. EPA was unable to identify any products in the

- 7618 marketplace containing DEHP.
- 7619

### 7620 Example of CDR Submissions

In the 2020 CDR cycle, one company reported both the commercial and consumer use of DEHP for use
 in lawn and garden care products (U.S. EPA, 2020a).

# 7623 E.15 Commercial Use – Construction, Paint, Electrical, and Metal 7624 Products – Adhesives and Sealants

This COU refers to the commercial use of DEHP in adhesives and sealants. This COU includes onecomponent caulks, fillers and putties, as well as sealant barrier items. This is a use of DEHP-containing adhesives and sealants in a commercial setting, such as a business or at a job site, as opposed to upstream use of DEHP (*e.g.*, when DEHP-containing products are used in the manufacturing of the construction products) or use in an industrial setting.

7630 7631 EPA identified several examples of products under this COU. DEHP is present in a glazing product used 7632 to repair scratches and other imperfections on the exterior of the automotive body (U.S. Chemical & 7633 Plastics, 2020). This COU would include the commercial use in automotive shops that focus on 7634 automobile repair and maintenance post-original manufacture. This product may be used for consumer use and included in a different COU. Another example is a DEHP-containing product that acts as a 7635 7636 barrier to the flow of molten metal alloys during brazing processes (Morgan Advanced Materials Wesgo 7637 Metals, 2016a, b). DEHP is contained within a one-step rust converter, used primarily for rust on 7638 automotives (3M, 2017). A sealant product used on floor and sidewalk joints contains DEHP (Tremco, 7639 2015). Also, DEHP is used in adhesives tapes to protect electrical equipment and pipes from corrosion 7640 and temperature change, such as conduits, pipes, and metal-clad cables (3M, 2019). The description of 7641 the tape indicates that it is used in commercial construction, industrial construction, irrigation, 7642 maintenance and repair operations, mining, residential construction, solar, utility, and wind power. The 7643 tape is not intended for consumer use.

7644

Additionally, this COU includes DEHP-containing construction materials used in the aerospace
 industry, such as epoxy adhesives, self-leveling compounds, and stop-off materials (EPA-HQ-OPPT 2018-0433-0004).

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### 7649 *Example of CDR Submissions*

7650 In the 2020 CDR cycle, one company reported both commercial and consumer use of DEHP in one-

7651 component caulks (<u>U.S. EPA, 2020a</u>).

# 7652 E.16 Commercial Use – Construction, Paint, Electrical, and Metal Products 7653 – Batteries and Capacitors

This COU refers to the commercial use of DEHP in batteries for articles such as digital cameras, as well as capacitors containing DEHP.

O In the *Final Scope of the Risk Evaluation for Diethylhexyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester) (CASRN 117-81-7)* EPA identified DEHP in a replacement digital camera
battery, which was available for purchase on Amazon at some point in 2023 but appears to be no longer
available for purchase. EPA has identified battery products listing California Proposition 65 warnings
for DEHP content, including battery replacements for trail cameras, and digital camera batteries (Kastar,
2024; Spypoint, 2024; Thumper Massager Inc, 2024).

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Capacitors may include DEHP as a dielectric fluid (Just In Time Chemical, 2015). These capacitors may
 also be used in industrial settings.

The commercial use of DEHP in batteries and capacitors was not reported during the 2016 and 2020CDR cycles.

# E.17 Commercial Use – Construction, Paint, Electrical, and Metal Products – Construction and Building Materials Covering Large Surface Areas, Including Paper Articles; Metal Articles; Stone, Plaster, Cement, Glass and Ceramic Articles

This COU refers to the commercial installation of building and construction materials that already have
DEHP incorporated (*e.g.*, asphalt, pipe wraps),maintenance and repair of construction and building
materials that have already been installed with DEHP-containing materials.

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DEHP is found in modified asphalt used for many waterproofing and sealing applications such as in
roads and highways (Valero, 2014). DEHP is found in wraps that are used for fire protection of plastic
pipes in walls and floors (Rockwool, 2017). EPA identified references indicating DEHP may be used in
wallpaper (Hsu et al., 2017).

7682 Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported commercial use of DEHP in building/construction
 materials not covered elsewhere (U.S. EPA, 2019b).

In the 2020 CDR cycle, one company reported commercial use and consumer use of DEHP in
construction and building materials covering large surface areas, including paper articles; metal articles;
stone, plaster, cement, glass and ceramic articles (U.S. EPA, 2020a).

E.18 Commercial Use – Construction, Paint, Electrical, and Metal Products
 – Machinery, Mechanical Appliances, Electrical/Electronic Articles

This COU refers to the commercial use of DEHP already incorporated as a plasticizer in machinery, mechanical appliances, and electrical and electronic articles. This is a use of DEHP in such articles, as opposed to upstream use of DEHP (*e.g.*, when DEHP is processed into the articles).

7694 EPA identified the use of DEHP in PVC formulations for wire and cable insulation (<u>QuickCable</u>

Corporation, 2024). The Danish EPA identifies use of DEHP in electrical and electronic articles in
 Denmark. EPA was not able to verify if DEHP is still used in these articles in the U.S.

- 7697 DEHP is part of a plastic electrode used in underwater cutting processes (ESAB, 2024).
- 7698 DEHP may be used as a hydraulic fluid in machinery or machinery parts (Just In Time Chemical, 2015).
- 7700 **Examples of CDR Submissions**
- 7701 In the 2016 CDR cycle, one company reported commercial use and consumer use of DEHP in electrical 7702 and electronic products (U.S. EPA, 2019b).
- 7704 In the 2020 CDR cycle, one company reported the commercial use of DEHP as a plasticizer in 7705 machinery, mechanical appliances, and electrical/electronic articles (U.S. EPA, 2020a).

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#### E.19 Commercial Use – Construction, Paint, Electrical, and Metal Products 7707 – Paints and Coatings

7708 This COU refers to the commercial use of paints and coatings with DEHP already incorporated. EPA 7709 also expects that some of these products could be used for industrial applications; however, they would 7710 be available and used in smaller scale commercial settings for similar purposes (e.g., corrosion 7711 protection on structural components, residential construction, etc.). This COU encompasses solvent and 7712 water-based paints.

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7714 DEHP is found in pigments used in the field to color coatings and sealants. EPA identified examples of 7715 pigments that contains DEHP and could be used for commercial/consumer applications and colorants 7716 used to color products used in building/roofing maintenance and traffic applications (The Sherwin-7717 Williams Company, 2019). The colorants that have been incorporated into the coating/sealant would be 7718 applied to the building material. Another example of a type of coating product that contains DEHP is 7719 used to protect metals and concrete from UV, weathering, and abrasion. It can be applied by brush, 7720 roller, mitt or spray methods (Wasser Corporation, 2021). EPA expects that such products would be 7721 purchased by commercial operations and applied by professional contractors in various commercial 7722 settings to protect concrete from weathering and abrasion.

7723 7724

In addition, EPA identified a sealant containing DEHP, used to prevent vegetation growth as well as 7725 create a stain and water-resistant barrier to prevent weathering of concrete (Eagle I.F.P. Company, 7726 2015a, b). EPA identified undercoat primer and multi-surface gray primer products containing DEHP 7727 (Axalta Coating Systems LLC, 2024; Axalta Coating Systems, 2023). 7728

7729 **Examples of CDR Submissions** 

7730 The commercial use of DEHP in paints and coatings was reported by two companies in the 2016 CDR 7731 cycle (U.S. EPA, 2019b).

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7733 One company reported the use of DEHP in solvent-based paint as Not Known or Reasonably

7734 Ascertainable (NKRA), and another reported the commercial and consumer use of DEHP in solvent-7735 based paint in the 2020 CDR cycle. One company reported the commercial and consumer use of DEHP 7736 in water-based paint in the 2020 CDR cycle (U.S. EPA, 2020a).

#### E.20 Commercial Use – Furnishing, Cleaning, Treatment Care Products – 7737 **All-Purpose Waxes and Polishes** 7738

7739 This COU refers to the commercial use of DEHP of in waxes and polishes that incorporated DEHP into 7740 the formulation (as a binder).

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- All-purpose waxes and polishes are typically waxes and other semi-solids and are applied to surfaces,
- such as furniture (generally wooden furniture), to improve shine and/or impart stain resistance. EPA
- would expect that commercial users of these products would apply them via hand or mechanical
- equipment without aerosolization or spray as they are semi-solid and/or wax in nature. EPA recognizes
  that these products may be used in a similar way in an industrial setting and are included in a different
  COU.
- 7747 7748

### 7749 Example of CDR Submissions

In the 2020 CDR cycle, one company reported the commercial use of DEHP as a binder in waxes and
 polishes (U.S. EPA, 2020a).

# 7752 E.21 Commercial Use – Furnishing, Cleaning, Treatment Care Products – 7753 Fabric Enhancer

This COU refers to the commercial use of DEHP already incorporated into fabric enhancers. EPA notes
that the CDR use code for "fabric enhancers" includes the following examples: liquid products added to
washing machines or sheets added to driers, bleach, film, lime and rust removers.

### 7758 Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the commercial use of fabric enhancers containing DEHP
 as a plasticizer (U.S. EPA, 2020a).

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# E.22 Commercial Use – Furnishing, Cleaning, Treatment Care Products – Fabric, Textile, and Leather Products; Furniture and Furnishings

This COU refers to the commercial use of DEHP already incorporated as a plasticizer in fabric, textile,
and synthetic leather materials and articles. This COU includes workers cutting and shaping of textiles
and workers who wear DEHP-containing textiles. This COU is also referring to the commercial use of
DEHP already incorporated into furniture and furnishings. EPA expects this COU to include use of
DEHP in furniture upholstery or in plastic materials used to make furniture.

7768

DEHP is used as a plasticizer in the PVC dots that are incorporated into canvas gloves for workers
performing tasks related to farming, ranching, oil, or gas. The PVC dots are used to improve grip
(Kinco, 2024). EPA recognizes that gloves can be included in the "Other articles with routine direct
contact during normal use including rubber articles; plastic articles (hard)" COU; however, EPA
believes this glove to be better captured within this COU, as the glove is not a plastic glove.

### 7775 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP in fabric,
textile, and leather products not covered elsewhere (U.S. EPA, 2019b). In the 2016 CDR cycle, one
company reported the commercial and consumer use of DEHP in furniture and furnishings not covered
elsewhere in the CDR (U.S. EPA, 2019b).

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The commercial use of fabric, textile, and leather products or furniture and furnishings were not reportedin the 2020 CDR cycle.

# E.23 Commercial Use – Furnishing, Cleaning, Treatment Care Products – Floor Coverings; Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass and Ceramic Articles; Fabrics, Textiles, and Apparel

This COU refers to the commercial installation of floor covering containing DEHP as construction and
building materials covering large surface areas including stone, plaster, cement, glass and ceramic
articles; fabrics, textiles, and apparel. DEHP is expected to be already incorporated into the floor
covering, and the COU describes the workers handling and installing the construction materials, tiles,
carpeting, etc.

7793 DEHP is present in the polyurethane binder attached to cork that is laid under tile, marble, and 7794 hardwood floors for sound control (WE Cork, 2001). DEHP may also be found in vinyl tile, planks, and 7795 accessories (DEHP Use Report). DEHP is also present in a waterproof and weather resistant fabric used 7796 to make connections between outdoor air handers and ducts and air conditioning and heating systems, 7797 and the fabric is used in industrial/commercial settings and is not for consumer use. EPA notes that in 7798 the newest revision of the safety data sheet for this product, it seems to be no longer formulated with 7799 DEHP. However, DEHP can still be found within conditioning and heating systems that have already 7800 been installed with the DEHP-containing fabric. (Duro Dyne Corporation, 2024).

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### 7802 Examples of CDR Submissions

Two companies reported the commercial use of DEHP, including one company reporting it as a
plasticizer, in construction and building materials covering large surface areas including stone, plaster,
cement, glass and ceramic articles; fabrics, textiles, and apparel in the 2020 CDR cycle (U.S. EPA,
<u>2020a</u>).

# 7807 E.24 Commercial Use – Packaging, Paper, Plastic, Toys, Hobby Products – 7808 Ink, Toner, and Colorants

This COU refers to the commercial use of DEHP in inks (including those used for stamps), pigments,
toner, and colorants, that can be used in packaging, paper, plastic, toys, hobby products and articles.

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7812 EPA identified a DEHP-containing product which is "intended for use in the manufacturing of pre-inked
7813 handstamps for the purpose of marking/printing on porous substrates such as paper or paper board."
7814 (Identity Group, 2016). Workers could be exposed to DEHP during the use of the stamp that contains
7815 DEHP. It is assumed that the stamps could be used for commercial and consumer purposes.

Additionally, this COU includes DEHP found within the color cartridge used in inkjet printing of markers and placards for use in proprietary specifications within federal, military, industry and company settings (EPA-HQ-OPPT-2018-0433-0004).

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The commercial use of DEHP in ink, toner, and colorants (including pigment) was not reported during
the 2016 and 2020 CDR cycles.

# E.25 Commercial Use – Packaging, Paper, Plastic, Toys, Hobby Products – Packaging (Excluding Food Packaging) and Other Articles with Routine Direct Contact During Normal Use, Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft)

This COU refers to the commercial use of DEHP as a plasticizer in various packaging, plastic, and
hobby articles. EPA notes that the CDR use code for "packaging (excluding food packaging), including

- rubber articles; plastic articles (hard); plastic articles (soft)" includes examples such as phone covers,
- personal tablets covers, styrofoam packaging, and bubble wrap. In addition, the CDR use code for "other
  articles with routine direct contact during normal use including rubber articles; plastic articles (hard)" in
  the 2020 CDR cycle includes examples such as gloves, boots, clothing, rubber handles, gear lever,
- 7832 steering wheels, handles, pencils, and handheld device casing.
- 7833
- An example of a commercial use covered by this COU is use of DEHP-containing packaging during the final stages of assembly, such as putting art supplies or tennis balls in DEHP-containing packaging material for sale (Washington Department of Ecology, 2021). . Examples of rubber articles and soft and hard plastic articles included in this COU that EPA identified are a DEHP-containing vinyl banner used in digital printing (BriteLine, 2018); helmets and vinyl aprons with sleeves listed for sale with Proposition 65 warnings for DEHP content (Quad City Safety Inc, 2024a, b); and DEHP-containing
- 7840 Tygon® tubing (EPA-HQ-OPPT-2018-0433-0004). 7841
- 7842 Examples of CDR Submissions
- In the 2016 CDR cycle, multiple companies reported the commercial use of DEHP in plastic and rubber
   products not covered elsewhere (U.S. EPA, 2019b).
- 7845

In the 2020 CDR cycle, one company reported the use of DEHP as a plasticizer in packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft) (U.S. EPA,
2020a). Multiple companies reported commercial as well as consumer use of DEHP as a plasticizer in packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (hard); plastic articles (soft). One company reported use of DEHP as a plasticizer in other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) (U.S. EPA, 2020a).

# 7852 E.26 Commercial Use – Packaging, Paper, Plastic, Toys, Hobby Products – 7853 Packaging (Excluding Food Packaging), Including Paper Articles

This COU refers to the commercial use of DEHP as a plasticizer in paper packaging, excluding food
packaging. The expected users of articles under this category would be during completion of the final
packaging of the article for commercial and consumer applications. EPA expects that the workers could
be exposed to DEHP through the handling of DEHP-containing packaging during the final stages of
product completion.

7860 Examples of CDR Submissions

In the 2020 CDR, one company reported both the commercial and consumer use of DEHP as a
 plasticizer in packaging (excluding food packaging), including paper articles (U.S. EPA, 2020a).

# E.27 Commercial Use – Packaging, Paper, Plastic, Toys, Hobby Products – Toys, Playground, and Sporting Equipment

This COU refers to the commercial use of DEHP in toys, playground, and sporting equipment. The 7865 COU includes the commercial installation, use, and maintenance of toys, playgrounds, and sporting 7866 7867 equipment that contain DEHP (such as in daycare or school environments by workers, e.g., teachers or 7868 providers). Exposure to DEHP could occur during the final product manufacture such as when workers 7869 would be anticipated to mold or otherwise fabricate the products for commercial and consumer 7870 applications, as well as during installation of sporting or playground equipment. DEHP is reported to be 7871 found downstream in tire crumb applications for playgrounds and turf (Armada et al., 2022; U.S. EPA, 7872 2019e). 7873

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7874 The use of DEHP in playground and sporting equipment would be as a general-purpose plasticizer for

- 7875 PVC in various applications under this subcategory, including tires with incorporated DEHP being used
- for tire crumb in playground settings. (U.S. EPA, 2019e)
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7882

DEHP can be used as a plasticizer to provide flexibility to toys. The Consumer Product Safety
Improvement Act (CPSIA) of 2008 limited manufacturers' use of DEHP in children's toys to 0.1 percent
(16 CFR Part 1307). Toys containing higher concentrations of DEHP that were manufactured and/or
processed prior to the CPSIA restriction in 2008 may still be in use.

### 7883 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial use of DEHP in toys, playground, and sporting equipment (U.S. EPA, 2019b).

7886

In the 2020 CDR cycle, another company reported the commercial and consumer use of DEHP in toys,
playground, and sporting equipment (U.S. EPA, 2020a).

# 7889 E.28 Commercial Use – Other – Laboratory Chemicals

7890 This COU refers to the commercial use of DEHP as a laboratory chemical.

7891

7892 DEHP can be used as a laboratory chemical, such as a chemical standard or reference material during 7893 analyses. Commercial use of laboratory chemicals may involve handling DEHP by hand-pouring or 7894 pipette and either adding to the appropriate labware in its pure form to be diluted later or added to dilute 7895 other chemicals already in the laborate. EPA expects that laboratory DEHP products are pure DEHP in 7896 neat liquid form or DIDP present as an impurity in other products. The Agency notes that the same 7897 applications and methods used for quality control can be applied in industrial and commercial settings. 7898 DEHP is also used as a laboratory chemical in applications such as analytical standards, research, 7899 equipment calibration, sample preparation (EPA-HO-OPPT-2018-0501-0043). EPA identified laboratory chemicals including DEHP used as reference materials (Chem Service Inc, 2018; Phenova, 7900 7901 2018).

7902

The commercial use of DEHP as a laboratory chemical does not have CDR data reported during the2016 and 2020 CDR cycles.

# 7905 E.29 Commercial Use – Other Uses - Automotive Articles

This COU refers to the commercial use of DEHP in automotive articles, which already have DEHP incorporated into them. This is a use of DEHP-containing automotive articles in a commercial setting, such as an automotive parts business or a worker driving a vehicle, as opposed to upstream use of DEHP (*e.g.*, when DEHP-containing products are used in the manufacturing of the automobile) or use in an industrial setting.

- 7911
- 7912 EPA identified references indicating automotive upholstery may contain DEHP (<u>Reddam and Volz</u>,
- 7913 <u>2021</u>). EPA identified insertable floor liners for automobiles listed for sale with a Proposition 65
- 7914 warning for DEHP content (Westin Automotive Products Inc, 2024). Additionally, this COU includes
- 7915 DEHP used in a number of automotive parts, both in current production and replacement parts,
- including electrical system wiring, seat assemblies, radiator assemblies, hoses in chassis assembly, and
- hardware modules in the automobile doors (EPA-HQ-OPPT-2019-0131).
- 7918

7919 DEHP is reported to be found downstream in tire crumb applications for playgrounds and turf (<u>Armada</u>

7920 <u>et al., 2022; U.S. EPA, 2019e</u>). Commercial users may be exposed to tires when handling tires for 7921 replacement on automobiles, or when performing maintenance and repair on automobiles.

7921

### 7923 Examples of CDR Submissions

7924 This specific COU was not reported in the 2016 and 2020 CDR cycles. However, in the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP in fabric, textile, and leather

- products not covered elsewhere (U.S. EPA, 2019b). EPA recognizes that use in fabric, textile, and
- 1927 leather products not covered elsewhere may be in reference to fabric or leather products used in 1928 sutemptive interiors
- automotive interiors.

# 7929 E.30 Consumer Use – Automotive, Fuel, Agriculture, Outdoor Use Products 7930 – Lawn and Garden Care Products

- 7931 This COU refers to the consumer use of DEHP in lawn and garden care products which contain DEHP.
- 7932

Examples included in the CDR description for the use code "lawn and garden care products" are

fertilizers and nutrient mixtures, soil amendments, mulches, pH adjustors, water retention beads,

vermiculite, and perlite. Use of lawn and garden care products containing DEHP in consumer settings would typically be handled by consumers EPA was unable to identify any products in the marketplace

- 7937 containing DEHP.
  - 7938

### 7939 Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the consumer use of DEHP for use in lawn and garden
 care products (U.S. EPA, 2020a).

# 7942 E.31 Consumer Use – Construction, Paint, Electrical, and Metal Products – 7943 Adhesives and Sealants

This COU refers to the consumer use of DEHP in adhesives and sealants. This COU includes onecomponent caulks, as well as fillers and putties.

DEHP is present in "lazing putty red," which is used to repair scratches and other imperfections on the
exterior of the automotive body (<u>U.S. Chemical & Plastics, 2020</u>).

- 7950 Examples of CDR Submissions
- In the 2020 CDR cycle, one company reported the consumer use of DEHP in one-component caulks
   (U.S. EPA, 2020a).

# 7953 E.32 Consumer Use – Construction, Paint, Electrical, and Metal Products – 7954 Batteries

- This COU refers to the consumer use of batteries with DEHP already included in them, for articles suchas digital cameras.
- 7957

7958In the Final Scope of the Risk Evaluation for Diethylhexyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-

*bis*(2-*ethylhexyl*) *ester*) (*CASRN* 117-81-7) EPA identified DEHP in a replacement digital camera

battery, which was available for purchase on Amazon at some point in 2023 but appears to be no longer

available for purchase. EPA has identified battery products listing California Proposition 65 warnings

for DEHP content, including battery replacements for trail cameras, and digital camera batteries (Kastar,
 2024; Spypoint, 2024; Thumper Massager Inc, 2024).

7964 7965 The co

The consumer use of DEHP in batteries was not reported during the 2016 or 2020 CDR cycles.

# E.33 Consumer Use – Construction, Paint, Electrical, and Metal Products – Construction and Building Materials Covering Large Surface Areas, Including Paper Articles; Metal Articles; Stone, Plaster, Cement, Glass and Ceramic Articles

The COU refers to the consumer use of DEHP in household use of solid flooring, including vinyl and vinyl-backed flooring, and other building materials, such as cement and ceramic tiles. EPA identified references indicating DEHP may be used in wallpaper (Hsu et al., 2017).

### 7974 Example of CDR Submissions

In the 2020 CDR cycle, one company reported use of DEHP as Not Known or Reasonably Ascertainable
under this COU, and another company reported use of DEHP as a plasticizer under this COU (U.S.
EPA, 2020a).

# E.34 Consumer Use – Construction, Paint, Electrical, and Metal Products – Machinery, Mechanical Appliances, Electrical/Electronic Articles

This COU refers to the consumer use of DEHP already incorporated as a plasticizer in machinery,
mechanical appliances, and electrical and electronic articles.

EPA identified the use of DHEP in PVC formulations for wire and cable insulation. The Danish EPA
identifies use of DEHP in electrical and electronic articles in Denmark. EPA was not able to verify if
DEHP is still used in these articles in the U.S.

7987 DEHP may be used as a hydraulic fluid in machinery or machinery parts (Just In Time Chemical, 2015).

7988

7986

7973

### 7989 *Example of CDR Submissions*

In the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP as a
 plasticizer in electrical and electronic products (U.S. EPA, 2019b).

# 7992 E.35 Consumer Use – Construction, Paint, Electrical, and Metal Products – 7993 Paints and Coatings

This COU refers to the consumer use of DINP in paints and coatings. This COU includes the consumer
DIY and bystander exposure to the paint and coating products during the application of paints and
coatings. This COU includes solvent and water-based paints.

7997
7998 DEHP is found in pigments used in the field to color coatings and sealants, EPA identified examples of pigments that contain DEHP and could be used for consumer applications (<u>The Sherwin-Williams</u>
8000 <u>Company, 2019</u>). The colorants that have been incorporated into the coating/sealant would be applied to the building material.
8002

In addition, EPA identified a sealant containing DEHP, used to prevent vegetation growth as well as
create a stain and water-resistant barrier to prevent weathering of concrete (Eagle I.F.P. Company,
2015a, b).

8006

- 8007 Consumers could be exposed to DEHP during the DIY application to decorative concrete at their 8008 residential home(s).
- 8009

### 8010 Examples of CDR Submissions

- 8011 In the 2016 CDR cycle, one company reported the use of DEHP in paints and coatings, for both commercial and consumer use (U.S. EPA, 2019b).
- 8013
- 8014 In the 2020 CDR cycle, one company reported the use of DEHP in solvent-based paint as NKRA, but
- another company reported the commercial and consumer use of DEHP as a plasticizer in solvent-based
- 8016 paint, and a third company reported the commercial and consumer use of DEHP as a plasticizer in
- 8017 water-based paint (<u>U.S. EPA, 2020a</u>).

# 8018 E.36 Consumer Use – Furnishing, Cleaning, Treatment Care Products – 8019 Fabric, Textile, and Leather Products; Furniture and Furnishings

8020 This COU refers to the consumer use of DEHP already incorporated as a plasticizer in fabric, textile, and synthetic leather materials and articles, as well as DEHP already incorporated into furniture and 8021 8022 furnishings. Consumers may be exposed during the wearing of the clothing or use of the product. DEHP 8023 can be found in the soles of shoes (Mandal et al., 2022). DEHP is used as the plasticizer in the PVC dots 8024 that are incorporated into canvas gloves for workers performing tasks related to farming, ranching, oil, 8025 or gas. The PVC dots are used to improve grip (Kinco, 2024). EPA recognizes that gloves can be 8026 included in the "Other articles with routine direct contact during normal use including rubber articles: 8027 plastic articles (hard)" COU; however, EPA believes this glove product to be better captured within this COU, as the glove is not a plastic glove. Additionally, EPA identified a rain jacket listed for sale with a 8028 8029 Proposition 65 warning for DEHP content (Equifit, 2024).

8030

# 8031 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP in fabric, textile, and leather products not covered elsewhere (U.S. EPA, 2019b). In the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP in fabric, textile, and leather products not covered elsewhere (U.S. EPA, 2019b).

- 8036
- 8037 This COU was not reported in the 2020 CDR cycle.

# E.37 Consumer Use – Furnishing, Cleaning, Treatment Care Products – Floor Coverings; Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass and

- 8040 8041
  - **Ceramic Articles; Fabrics, Textiles, and Apparel**

This COU refers to the consumer use of DEHP in floor coverings and construction and building
materials including various types of flooring. The COU includes consumers using flooring containing
DEHP in an indoor environment and DIYers handling the construction materials, tiles, carpeting, etc.
that have DEHP incorporated into the products and may involve cutting and shaping the products for
installation.

8047

DEHP is present in the polyurethane binder attached to cork that is laid under tile, marble, and
hardwood floors for sound control (<u>WE Cork, 2001</u>). DEHP may also be found in vinyl tile, planks, and
accessories (DEHP Use Report).

- 8051
- 8052 Example of CDR Submissions

In the 2020 CDR cycle, one company reported both commercial and consumer use of DEHP as a
plasticizer in Construction and building materials covering large surface areas including stone, plaster,
cement, glass and ceramic articles; fabrics, textiles, and apparel, as a plasticizer (U.S. EPA, 2020a).

# 8056 E.38 Consumer Use – Packaging, Paper, Plastic, Toys, Hobby Products – 8057 Inks, Toner, and Colorants

- 8058 This COU refers to the consumer use of DEHP in inks (including those used for stamps), pigment, 8059 toners, and colorants, that can be used in packaging, paper, plastic, toys, and hobby products and 8060 articles.
- 8061

8066

EPA identified a DEHP-containing product, which is "intended for use in the manufacturing of preinked handstamps for the purpose of marking/printing on porous substrates such as paper or paper board." (<u>Identity Group, 2016</u>). Workers could be exposed to DEHP during the use of the stamp that contains DEHP. It is assumed that the stamps could be used for commercial and consumer purposes.

The consumer use of DEHP in inks, toner, pigments, and colorants was not reported during the 2016 or2020 CDR cycles.

# 8069 E.39 Consumer Use – Packaging, Paper, Plastic, Toys, Hobby Products – 8070 Packaging (Excluding Food Packaging) and Other Articles with 8071 Routine Direct Contact During Normal Use, Including Rubber 8072 Articles; Plastic Articles (Hard); Plastic Articles (Soft)

# 8073 This COU refers to the consumer use of DEHP in various packaging, plastic, and hobby articles. 8074

EPA notes that the CDR use code for "packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)" in the 2020 CDR cycle includes examples such as phone covers, personal tablets covers, styrofoam packaging, and bubble wrap. In addition, the use code for "other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)" in the 2020 CDR cycle includes examples such as gloves, boots, clothing, rubber handles, gear lever, steering wheels, handles, pencils, handheld device casing.

8081

8082 The type of articles being reported under this code could be both commercial and consumer in nature. 8083 EPA expects that the consumers could be exposed to DEHP through the handling of DEHP-containing 8084 packaging during use. DEHP is used in packaging for toys and other articles, which consumers may be 8085 exposed to during handling (Washington Department of Ecology, 2021). EPA identified a DEHPcontaining vinyl banner used in digital printing (BriteLine, 2018). EPA also identified helmets and vinyl 8086 8087 aprons with sleeves listed for sale with Proposition 65 warnings for DEHP content (Quad City Safety 8088 Inc, 2024a, b). Additionally, DEHP was identified in Tygon® tubing (EPA-HQ-OPPT-2018-0433-8089 0004).

8090

# 8091 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP in plastic
 and rubber products not covered elsewhere (U.S. EPA, 2019b).

8094

In the 2020 CDR cycle, one company reported the use of DEHP as a plasticizer in packaging (excluding
food packaging), including rubber articles; plastic articles (hard); plastic articles (soft). They reported
the use as NKRA (U.S. EPA, 2020a). Another company reported the consumer and commercial use of

8098 DEHP as a plasticizer in packaging (excluding food packaging), including rubber articles; plastic articles

8099 (hard); plastic articles (soft) (U.S. EPA, 2020a). A third company reported the NKRA use of DEHP as a

plastic articles (soft) (<u>0.5. EFA, 2020a</u>). A time company reported the reference use of DEFFF as a plasticizer in other articles with routine direct contact during normal use including rubber articles;
 plastic articles (hard) (U.S. EPA, 2020a).

# 8102 E.40 Consumer Use – Packaging, Paper, Plastic, Toys, Hobby Products – 8103 Packaging (Excluding Food Packaging) Including Paper Articles

8104 This COU refers to the consumer use of DEHP in paper packaging, excluding food packaging. The 8105 expected users of products under this category would be consumers handling products with paper 8106 packaging.

8107

# 8108 Example of CDR Submissions

8109 In the 2020 CDR, one company reported both the commercial and consumer use of DEHP as a 8110 plasticizer in Packaging (excluding food packaging), including paper articles (U.S. EPA, 2020a).

# 8111 E.41 Consumer Use – Packaging, Paper, Plastic, Toys, Hobby Products – 8112 Toys, Playground, and Sporting Equipment

8113 This COU refers to the consumer use of DEHP in toys, playgrounds, and sporting equipment that
8114 contain DEHP. The use also refers to the do-it-yourself building of home playground equipment.
8115 In addition, a plastisol coating is commonly used on sporting equipment, such as fitness balls and hand

8116 weights. EPA recognizes tires with incorporated DEHP are used for tire crumb in playground and

8117 athletic field settings (<u>Armada et al., 2022</u>; <u>U.S. EPA, 2019e</u>). Consumers are expected to use 8118 playgrounds and athletic fields.

8119

8120 DEHP can be used as a plasticizer to provide flexibility to toys. The Consumer Product Safety

8121 Improvement Act (CPSIA) of 2008 limited manufacturers' use of DEHP in children's toys to 0.1 percent

8122 (16 CFR Part 1307). Toys containing higher concentrations of DEHP that were manufactured and/or

8123 processed prior to the CPSIA restriction in 2008 may still be in use.

8124

The consumer use of DEHP in toys, playground and sporting equipment was not reported to EPA during
the 2016 and 2020 CDR cycles.

# 8127 **E.42 Consumer Use – Other Uses – Novelty Articles**

This COU refers to the consumer use of DEHP in adult novelty articles. This COU is describing adult sex toys that are available for consumer use in the United States. Although the U.S. Food and Drug Administration (FDA) classifies certain sex toys (such as vibrators) as obstetrical and gynecological

therapeutic medical devices, many manufacturers label these products "for novelty use only" and are not

8132 subject to FDA regulations (<u>Stabile, 2013</u>). This same study indicated tested concentrations of phthalates

between 24 and 49 percent of the tested sex toys for creating a softer, more flexible plastic (<u>Stabile</u>, 2013). The Agency would expect the concentration of DEUD to be explored to the curve of the second second

8134 <u>2013</u>). The Agency would expect the concentration of DEHP to be analogous to the overall content of 8135 the mix of phthalates tested and found in this study for these articles.

8136

8137 The consumer use of DEHP in novelty articles was not reported to EPA during the 2016 CDR and 20208138 CDR cycles.

# 8139 **E.43 Consumer Use – Other uses – Automotive Articles**

8140 This COU refers to the consumer use of DEHP in automotive articles. This COU includes the use of

8141 DEHP-containing automotive articles in a consumer DIY setting or by consumers driving a

8142 vehicle. EPA identified references indicating automotive upholstery products may contain DEHP

- 8143 (Reddam and Volz, 2021). EPA identified insertable floor liners for automotives listed for sale with a
- 8144 Proposition 65 warning for DEHP content (Westin Automotive Products Inc, 2024). Additionally, this
- 8145 COU includes DEHP used in a number of automotive parts, both in current production and replacement
- parts, including electrical system wiring, seat assemblies, radiator assemblies, hoses in chassis assembly,
- and hardware modules in the automobile doors (EPA-HQ-OPPT-2019-0131).
- 8148
- 8149 DEHP is reported to be found downstream in tire crumb applications for playgrounds and turf (<u>Armada</u>
- 8150 <u>et al., 2022; U.S. EPA, 2019e</u>). Consumers use tires containing DEHP when handling tires for 8151 replacement on automobiles.
- 8152

## 8153 Examples of CDR Submissions

- This specific COU was not reported during the 2016 and 2020 CDR cycles. However, in the 2016 CDR cycle, one company reported the commercial and consumer use of DEHP in fabric, textile, and leather products not covered elsewhere (U.S. EPA, 2019b). EPA recognizes that use in fabric, textile, and
- 8157 leather products not covered elsewhere may be in reference to fabric or leather products used in
- 8158 automotive interiors.

# 8159 E.44 Disposal

For purposes of the DEHP risk evaluation, this COU refers to the DEHP in a waste stream that is 8160 8161 collected from facilities and households and are unloaded at and treated or disposed at third-party sites. 8162 Each of the COUs of DEHP may generate waste streams of the chemical. This COU also encompasses 8163 DEHP contained in wastewater discharged by consumers or occupational users to POTW or other, non-POTW for treatment, as well as other wastes. DEHP is expected to be released to other environmental 8164 8165 media, such as introductions of biosolids to soil or migration to water sources, through waste disposal 8166 (e.g., disposal of formulations containing DEHP, plastic and rubber products, textiles, and transport 8167 containers). Disposal may also include destruction and removal by incineration (U.S. EPA, 2021b). Additionally, DEHP has been identified in EPA's Hydraulic Fracturing for Oil and Gas: Impacts from 8168 8169 the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States, December 8170 2016 document to be a chemical reported to be detected in produced water, which is subsequently disposed (U.S. EPA, 2016a). Recycling of DEHP and DEHP-containing products is considered a 8171 8172 different COU. Environmental releases from industrial sites are assessed in each condition of use and are 8173 not considered as part of the disposal COU.

# 8174 Appendix F 8175 DRAFT OCCUPATIONAL EXPOSURE VALUE B175 DERIVATION

8176 EPA has calculated a draft 8-hour existing chemical occupational exposure value to summarize the 8177 occupational exposure scenario and sensitive health endpoints into a single value. This calculated draft value may be used to support risk management efforts for DEHP under TSCA section 6(a), 15 U.S.C. 8178 8179 §2605. EPA calculated the draft value rounded to 0.31 mg/m<sup>3</sup> for inhalation exposures to DEHP as an 8hour time-weighted average (TWA) and for consideration in workplace settings (see Appendix F.1) 8180 8181 based on the acute non-cancer human equivalent concentration (HEC) for adverse effects on the 8182 developing male reproductive system consistent with phthalate syndrome. 8183 8184 TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk 8185 factors; thus, this draft occupational exposure value represents a risk-only number. If risk management 8186 for DEHP follows the final risk evaluation, EPA may consider costs and other non-risk factors, such as 8187 technological feasibility, the availability of alternatives, and the potential for critical or essential uses. 8188 Any existing chemical exposure limit used for occupational safety risk management purposes could 8189 differ from the draft occupational exposure value presented in this appendix based on additional 8190 consideration of exposures and non-risk factors consistent with TSCA section 6(c). 8191 8192 This calculated draft value for DEHP represents the exposure concentration below which exposed 8193 workers and ONUs are not expected to exhibit any appreciable risk of adverse toxicological outcomes, 8194 accounting for potentially exposed and susceptible populations (PESS). It is derived based on the most 8195 sensitive human health effect (*i.e.*, developing male reproductive system) and exposure duration (*i.e.*, 8196 acute) relative to benchmarks and a standard occupational scenario assumptions of an 8-hour workday. 8197 8198 EPA expects that at the draft occupational exposure value of 0.019 ppm (0.31 mg/m<sup>3</sup>), a worker or ONU 8199 also would be protected against developmental and reproductive toxicity from intermediate and chronic 8200 duration occupational exposures if ambient exposures are kept below this draft occupational exposure 8201 value. EPA has not separately calculated a draft short-term (*i.e.*, 15-minute) occupational exposure value 8202 because the Agency did not identify hazards for DEHP associated with this very short duration. 8203 8204 The Occupational Safety and Health Administration (OSHA) has set a permissible exposure limit (PEL) 8205 of 5 mg/m<sup>3</sup> as an 8-hour TWA for DEHP (https://www.osha.gov/annotated-pels), which was established 8206 in August 1994. Similarly, in 1996 ACGIH also set an 8-hour TWA threshold limit value (TLV) of 5 8207 mg/m<sup>3</sup>; however, ACGIH has subsequently issued a notice of intended change, with 8-hour TWA TLV 8208 being updated to 0.1 mg/m<sup>3</sup> (https://www.acgih.org/di2-ethylhexyl-phthalate-notice-of-intendedchange/). EPA located several occupational exposure limits for DEHP (CASRN 117-81-7) in other 8209 8210 countries (https://ilv.ifa.dguv.de/limitvalues/18036). Identified 8-hour TWA values range from 0.8  $mg/m^3$  in Poland to 10  $mg/m^3$  in South Africa. Additionally, EPA found that New Zealand and the 8211 United Kingdom have an established occupational exposure limit of 2 and 5 mg/m<sup>3</sup> (8-hour TWA) in 8212 8213 each country's code of regulation that is enforced by each country's worker safety and health agency. 8214 8215 Validated air monitoring methods are available for DEHP, including OSHA Method 104 (OSHA, 1994), and NIOSH Method 5020, which is partially validated for DEHP 8216

8217 (https://www.cdc.gov/niosh/docs/2003-154/pdfs/5020HEX.pdf).

# 8218 F.1 Draft Occupational Exposure Value Calculations

8219 This appendix presents the calculations used to estimate draft occupational exposure values using inputs 8220 derived in this draft risk evaluation. Multiple values are presented below for hazard endpoints based on

different exposure durations. For DEHP, the most sensitive occupational exposure value is based on non-cancer developmental effects and the resulting 8-hour TWA is rounded to  $0.31 \text{ mg/m}^3$ .

#### 8223

#### 8224 Draft Acute Non-Cancer Occupational Exposure Value

The draft acute occupational exposure value (EV<sub>acute</sub>) was calculated as the concentration at which the
acute MOE would equal the benchmark MOE for acute occupational exposures using Equation\_Apx
F-1:

#### 8228 8229 Equation Apx F-1.

8230

8231 
$$EV_{acute} = \frac{HEC_{acute}}{Benchmark MOE_{acute}} * \frac{AT_{HECacute}}{ED} * \frac{IR_{resting}}{IR_{workers}} = 8232$$

8233 
$$\frac{0.39 \text{ ppm}}{30} * \frac{\frac{24h}{d}}{\frac{8h}{d}} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.019 \text{ ppm}$$

8234

8235 
$$EV_{acute} \left(\frac{\text{mg}}{\text{m}^{3}}\right) = \frac{EV \, ppm \, * MW}{Molar \, Volume} = \frac{0.019 \, \text{ppm} \, * \, 390.56 \frac{g}{mol}}{24.45 \, \frac{L}{mol}} = 0.31 \, \frac{\text{mg}}{\text{m}^{3}}$$

8236

### 8237 Draft Intermediate Non-Cancer Occupational Exposure Value

The draft intermediate occupational exposure value (EV<sub>intermediate</sub>) was calculated as the concentration at
which the intermediate MOE would equal the benchmark MOE for intermediate occupational exposures
using Equation\_Apx F-2:

#### 8242 Equation\_Apx F-2.

8243

# 8244 $EV_{intermediate} = \frac{HEC_{intermediate}}{Benchmark MOE_{intermediate}} * \frac{AT_{HEC intermediate}}{ED * EF} * \frac{IR_{resting}}{IR_{workers}}$

8245

$$= \frac{0.39 \text{ ppm}}{30} * \frac{\frac{24h}{d} * 30d}{\frac{8h}{d} * 22d} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.026 \text{ ppm} = 0.42 \frac{\text{mg}}{\text{m}^3}$$

8247

8246

### 8248 Draft Chronic Non-Cancer Exposure Value

The draft chronic occupational exposure value (EV<sub>chronic</sub>) was calculated as the concentration at which
the chronic MOE would equal the benchmark MOE for chronic occupational exposures using
Equation\_Apx F-3:

### 8253 Equation\_Apx F-3.

8254

8252

8255 
$$EV_{chronic} = \frac{HEC_{chronic}}{Benchmark MOE_{chronic}} * \frac{AT_{HEC chronic}}{ED * EF * WY} * \frac{IR_{resting}}{IR_{workers}}$$

8256

8257		$=\frac{0.39\mathrm{ppm}}{30}*\frac{2}{30}$	$\frac{\frac{24h}{d} * \frac{365d}{y} * 40 \ y * 0.6125 \frac{\text{m}^3}{hr}}{\frac{8h}{d} * \frac{250d}{y} * 40 \ y * 1.25 \frac{\text{m}^3}{hr}} = 0.028 \text{ ppm} = 0.45 \frac{\text{mg}}{\text{m}^3}$
8258	Where:		
8259	AThecate	=	Averaging time for the POD/HEC used for evaluating non-cancer
8260			acute occupational risk based on study conditions and HEC
8261			adjustments (24 h/day).
8262	$AT_{HEC}$ intermediate	=	Averaging time for the POD/HEC used for evaluating non-cancer
8263			intermediate occupational risk based on study conditions and/or
8264			any HEC adjustments (24 h/day for 30 days).

8264			any HEC adjustments (24 n/day for 30 days).
8265	<b>AT</b> HECchronic	=	Averaging time for the POD/HEC used for evaluating non-cancer
8266			chronic occupational risk based on study conditions and/or HEC
8267			adjustments (24 h/day for 365 days/year) and assuming the same
8268			number of years as the high-end working years (WY, 40 years) for
8269			a worker.
8270	Benchmark MOEacute	=	Acute non-cancer benchmark margin of exposure, based on the
8271			total uncertainty factor of 30
8272	Benchmark MOE intermedia	$_{te} =$	Intermediate non-cancer benchmark margin of exposure, based on
8273			the total uncertainty factor of 30
8274	Benchmark MOEchronic	=	Chronic non-cancer benchmark margin of exposure, based on the
8275			total uncertainty factor of 30
8276	$EV_{acute}$	=	Acute Occupational exposure value
8277	EVintermediate	=	Intermediate Occupational exposure value
8278	EVchronic	=	Chronic Occupational exposure value
8279	ED	=	Exposure duration (8 h/day)
8280	EF	=	Exposure frequency (1 day for acute, 22 days for intermediate, and
8281			250 days/year for chronic and lifetime)
8282	HEC	=	Human equivalent concentration for acute, intermediate, or chronic
8283			non-cancer occupational exposure scenarios
8284	IR	=	Inhalation rate (default is 1.25 m <sup>3</sup> /h for workers and 0.6125 m <sup>3</sup> /h
8285			assumed from "resting" animals from toxicity studies)
8286	Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 $^{\circ}$ C
8287	MW	=	Molecular weight of DEHP (390.56 g/mole)
8288	WY	=	Working years per lifetime at the 95th percentile (40 years).
8289			
8290	Unit conversion:		

8290 Unit conversion:

8291 1 ppm = 15.97 mg/m<sup>3</sup> (see equation associated with the  $EV_{acute}$  calculation

8292