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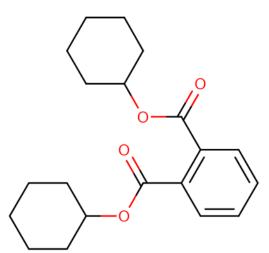
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Draft Risk Evaluation for Dicyclohexyl Phthalate (DCHP)

CASRN 84-61-7



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- 294
- 295 This draft risk evaluation was reviewed and cleared for release by OPPT and OCSPP leadership.

296 EXECUTIVE SUMMARY

297 Background

298 EPA has evaluated the health and environmental risks of the chemical dicyclohexyl phthalate (DCHP)

299 under the Toxic Substances Control Act (TSCA). In this draft risk evaluation, EPA has preliminarily determined that DCHP presents an unreasonable risk of injury to human health under the 300 301 conditions of use (COUs). Of the 24 COUs that the Agency evaluated, 9 COUs have risk estimates that 302 raise concerns for workers' exposure to DCHP; no COUs raise such concerns for consumers or the 303 general population. In this draft evaluation, EPA's protective, screening-level approaches demonstrated 304 that DCHP does not pose an unreasonable risk of injury to the environment. After this draft risk 305 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 DCHP presents unreasonable risk to human 306 307 health or the environment under the TSCA COUs.

308

309 DCHP is used primarily as a plasticizer in manufacturing adhesives, paints and coatings, plastic 310 products, rubber products, and plastic resins. It is also used as a stabilizing agent in the manufacturing of 311 adhesives, paint and coatings, plastic products, printing ink, rubber products, as well as plastic material 312 and resin. Other uses of DCHP include industrial use in transportation equipment, computer, and 313 electronic product manufacturing and commercial use in building/construction materials and laboratory chemicals—all of which are COUs. Workers may be exposed to DCHP when making these products or 314 otherwise using DCHP in the workplace. When it is manufactured or used to make products, DCHP can 315 316 be released into water, where because of its properties, most will end up in the sediment at the bottom of 317 lakes and rivers. If released into the air, DCHP will attach to dust particles and be deposited on land or 318 into water. Indoors, DCHP has the potential over time to be released from products and adhere to dust particles. If it does, people could inhale or ingest dust that contains DCHP.

319 320

Laboratory animal studies have been conducted to study DCHP to determine whether it causes a range of non-cancer health effects on people. After reviewing the available studies, the Agency concludes that there is strong evidence that DCHP causes developmental toxicity (a non-cancer human health hazard). The most sensitive adverse developmental effects include 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.

- 328 EPA is including DCHP for cumulative risk assessment (CRA) along with five other phthalate 329 chemicals that also cause effects on laboratory animals consistent with phthalate syndrome (U.S. EPA, 330 <u>2023c</u>). Notably, assessments by Health Canada, U.S. Consumer Product Safety Commission (U.S. CPSC), European Chemicals Agency (ECHA), and the Australian National Industrial Chemicals 331 332 Notification and Assessment Scheme (NICNAS) have reached similar conclusions regarding the 333 developmental effects of DCHP. They have also conducted CRAs of phthalates based on these 334 chemicals' shared ability to cause phthalate syndrome. Further, independent, expert peer reviewers 335 endorsed EPA's proposal to conduct a CRA of phthalates under TSCA during the May 2023 meeting of 336 the Science Advisory Committee on Chemicals (SACC) because doing so represents the best available science. In this draft risk evaluation, the Agency has evaluated cumulative exposure to phthalates for the 337 338 U.S. civilian population using human biomonitoring data. Note that these phthalate exposures to the 339 general civilian population cannot be attributed to specific TSCA COUs or other sources. This non-340 attributable cumulative exposure and risk, representing the national population, was taken into 341 consideration by EPA in reaching its preliminary determination of unreasonable risk of injury of human 342 health for DCHP. Had EPA not taken this into consideration, it could have understated the unreasonable 343 risk of injury to human health for DCHP.
- 344

- In December 2019, EPA designated DCHP as a high-priority substance for TSCA risk evaluation and in
 August 2020 released the final scope of the risk evaluation (U.S. EPA, 2020b). This draft risk evaluation
 assesses human health risk to workers, including occupational non-users (ONUs), consumers, and the
- 348 general population exposed to environmental releases. It also assesses risk to the environment.
- 349 Manufacturers report DCHP production volumes through the Chemical Data Reporting (CDR) rule
- 350 under the associated CAS Registry Number (CASRN) 84-61-7. The production volume for DCHP was
- between 500,000 and 1,000,000 lb in 2019 based on the latest 2020 CDR data (EPA describes
- 352 production volumes as a range to protect confidential business information). The Agency has evaluated
- 353 DCHP across its TSCA COUs, ranging from manufacture to disposal.
- 354

355 Past assessments of DCHP from other government agencies that addressed a broad range of uses, which may have included TSCA and non-TSCA uses, have concluded that DCHP does not pose risk to human 356 357 health or the environment 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 358 359 products as well as from other sources such as personal care products, diet, consumer products, and the 360 environment. However, these past assessments did not specifically consider exposure to workers. In this draft assessment, EPA comes to the same general conclusions of those assessments with regard to risk to 361 362 consumers and the general population—with the exception of where it evaluated and has identified risks 363 to workers with some manufacturing and processing uses of DCHP.

364

365 In this draft risk evaluation, EPA evaluated risks resulting from exposure to DCHP from facilities that use, manufacture, or process DCHP under industrial and/or commercial COUs subject to TSCA and the 366 products resulting from such manufacture and processing. Human or environmental exposure to DCHP 367 368 through uses that are not subject to TSCA (e.g., use in cosmetics, medical devices, food contact 369 materials) were not specifically evaluated by the Agency in reaching its preliminary determination of 370 unreasonable risk to injury of human health. This is because these uses are excluded from TSCA's 371 definition of chemical substance. Thus, although EPA is preliminarily determining in this draft risk 372 evaluation that nine specific TSCA COUs significantly contribute to its draft unreasonable risk finding 373 for DCHP, this determination cannot be extrapolated to form conclusions about uses of DCHP that are 374 not subject to TSCA and that EPA did not evaluate. 375

376 Determining Unreasonable Risk to Human Health

377 EPA's TSCA existing chemical risk evaluations must determine whether a chemical substance does or 378 does not present unreasonable risk to human health or the environment under its TSCA COUs. The 379 unreasonable risk must be informed by the best available science. The Agency, in making the finding of 380 presents unreasonable risk to human health, considers risk-related factors as described in its risk evaluation framework rule. Risk-related factors beyond the levels of DCHP that can cause specific 381 382 health effects include but are not limited to the type of health effect under consideration, the reversibility 383 of the health effect being evaluated, exposure-related considerations (e.g., duration, magnitude, 384 frequency of exposure), population exposed (including any potentially exposed or susceptible 385 subpopulations), and EPA's confidence in the information used to inform the hazard and exposure 386 values. These considerations must be included as part of a pragmatic and holistic evaluation of hazard 387 and exposure to DCHP. If an estimate of risk for a specific scenario exceeds the standard risk 388 benchmarks, then the formal determination of whether those risks significantly contribute to the 389 unreasonable risk of DCHP under TSCA must be both case-by-case and context-driven.

390

391 EPA evaluated the risks to people from being exposed to DCHP at work, indoors, and outdoors. In its 392 human health evaluation, the Agency used a combination of screening-level and more refined

approaches to assess how people might be exposed to DCHP through breathing or ingesting dust or

394 other particulates, as well as through skin contact. EPA has also authored a draft cumulative risk 395 technical support document including DCHP and five other phthalate chemicals that all cause the same 396 health effect—phthalate syndrome. The CRA takes into consideration differences in the ability of each 397 phthalate to cause effects on the developing male reproductive system. Use of this "relative potency" 398 across all the phthalates EPA is reviewing that cause phthalate syndrome provides a more robust risk 399 assessment of DCHP as well as a common basis for adding risk across the six phthalates included in the 400 cumulative assessment. Thus, risks are characterized for occupational and consumer exposures to 401 DCHP, alone as well as in combination with the measured cumulative phthalate exposure that is

- 402 experienced by the U.S. population and that cannot be attributed to a specific use.
- 403

In determining whether DCHP presents an unreasonable risk of injury to human health, EPA considered
 the following potentially exposed and susceptible subpopulations (PESS) in its assessment: women of
 reproductive age, pregnant women, infants, children and adolescents, people who frequently use
 consumer products and/or articles containing high concentrations of DCHP, people exposed to DCHP in

408 the workplace, people in proximity to releasing facilities, including fenceline communities, and Tribes 409 and subsistence fishers whose diets include large amounts of fish. These subpopulations are PESS

- 409 and subsistence fishers whose diets include large amounts of fish. These subpopulations are FESS 410 because some have greater exposure to DCHP per body weight (*e.g.*, infants, children, adolescents)
- 411 while others may experience exposure from multiple sources or higher exposures than others. EPA's
- 412 robust screening analysis preliminarily finds that exposure of consumers and of the general population to
- 413 DCHP does not contribute to unreasonable risk of injury to human health. However, the Agency
- 414 preliminarily identified nine COUs where occupational exposure for workers significantly contributes to
- 415 the unreasonable risk of injury to human health.
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417 Summary, Considerations, and Next Steps

418 EPA is preliminarily determining the following COUs, based on the DCHP individual analysis and the 419 relative potency factor analysis, significantly contribute to the unreasonable risk to workers:

- Manufacturing domestic manufacturing;
- Processing incorporation into formulation, mixture, or reaction product adhesive and sealant chemicals in adhesive manufacturing;
 - Processing incorporation into formulation, mixture, or reaction product plasticizer (adhesive manufacturing; paint and coating manufacturing; and printing ink manufacturing);
 - Processing incorporation into formulation, mixture, or reaction product stabilizing agent (adhesive manufacturing; asphalt paving, roofing, and coating materials manufacturing; and paints and coating manufacturing);
- Industrial use finishing agent cellulose film production;
- Industrial use inks, toner, and colorant products (*e.g.*, screen printing ink);
- Industrial use paints and coatings;
- Commercial use inks, toner, and colorant products (*e.g.*, screen printing ink); and
 - Commercial use paints and coatings.
- 433 EPA is preliminarily determining that the following COUs do *not* significantly contribute to the 434 unreasonable risk:
- Manufacturing importing;
- Processing incorporation into article plasticizer in plastics product manufacturing and rubber
 product manufacturing;
- Processing repackaging (*e.g.*, laboratory chemicals);
- Processing recycling;
- Distribution in commerce;

- Industrial use adhesives and sealants (*e.g.*, computer and electronic product manufacturing;
 transportation equipment manufacturing);
- Industrial use other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) (*e.g.*, transportation equipment manufacturing);
- Commercial use adhesives and sealants;
- Commercial use building/construction materials not covered elsewhere;
- Commercial use laboratory chemicals;
- Commercial use other articles with routine direct contact during normal use including rubber articles; plastic articles (hard);
- Consumer use adhesives and sealants;
 - Consumer use other articles with routine direct contact during normal use including rubber articles; plastic articles (hard);
 - Consumer use other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (*e.g.*, paper products, textiles, products using cellulose film, etc.); and
 - Disposal.

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- 457 This risk evaluation has been released for public comment and will undergo independent, expert
- 458 scientific peer review. EPA will issue a final DCHP risk evaluation after considering input from the
- 459 public and peer reviewers. If in the final risk evaluation the Agency determines that DCHP presents
- 460 unreasonable risk to human health or the environment, EPA will initiate regulatory action so that DCHP
- 461 no longer presents such risk.

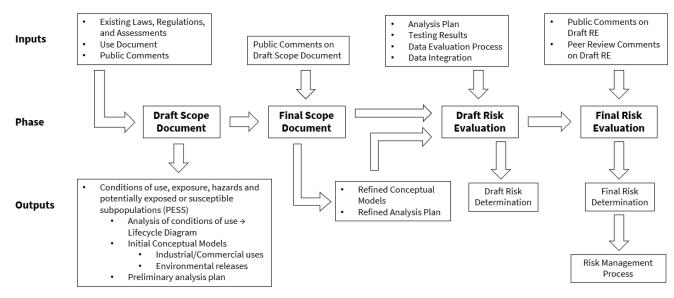
462 **1 INTRODUCTION**

463 EPA has evaluated dicyclohexyl phthalate (DCHP) under the Toxic Substances Control Act (TSCA)
464 section 6(b). DCHP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer,
465 commercial, and industrial applications—although it is also used in adhesives, sealants, paints, coatings,
466 rubbers, and non-PVC plastics as well as for other applications. Section 1.1 summarizes the scope of the
467 draft DCHP risk evaluation and provides information on production volume, a life cycle diagram (LCD),
468 conditions of use (COUs), and conceptual models used for DCHP. Section 1.2 presents the organization
469 of this draft risk evaluation.

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471 Figure 1-1 describes the major inputs, phases, and outputs/components of the <u>TSCA risk evaluation</u>
 472 process, from scoping to releasing the final risk evaluation.

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

476 **1.1 Scope of the Risk Evaluation**

477 EPA evaluated risk to humans and the environment for DCHP. Specifically for human populations, the 478 Agency evaluated risk to workers and occupational non-users (ONUs) via inhalation routes; risk to 479 workers via dermal routes; risk to ONUs via dermal routes for occupational exposure scenarios (OESs) 480 in mists and dusts; risk to consumers via inhalation, dermal, and oral routes; and risk to bystanders via 481 the inhalation route. Additionally, EPA considered the following potentially exposed and susceptible 482 populations (PESS) in its assessment—women of reproductive age, pregnant women, infants, children and adolescents, people who frequently use consumer products and/or articles containing high-483 concentrations of DCHP, people exposed to DCHP in the workplace, and Tribes and subsistence fishers 484 whose diets include large amounts of fish. As described further in Section 4.1.3, EPA assessed risks to 485 486 the general population, including considerations for fenceline populations, from environmental releases 487 using a screening-level analysis, which considered risk from exposure to DCHP via oral ingestion of 488 surface water, drinking water, fish, and soil from air to soil deposition. For environmental populations, 489 EPA evaluated risk to aquatic species via water, sediment, and air as well as risk to terrestrial species via 490 air, soil, sediment, and water.

491

492 Consistent with EPA's Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High 493 Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act

494 (U.S. EPA, 2023c), EPA has also authored a draft cumulative risk technical support document of DCHP 495 and five other toxicologically similar phthalates (*i.e.*, diethylhexyl phthalate [DEHP], dibutyl phthalate 496 [DBP], diisobutyl phthalate [DIBP], butyl benzyl phthalate [BBP], and diisononyl phthalate [DINP]) 497 that are also being evaluated under TSCA based on a common toxicological endpoint (*i.e.*, *phthalate* 498 syndrome, which results from decreased fetal testicular testosterone). The cumulative analysis takes into 499 consideration differences in phthalate potency to cause effects on the developing male reproductive 500 system. Use of relative potency across the phthalates provides a more robust risk assessment of DCHP 501 and a common basis for adding risk across the cumulative chemicals. Numerous other regulatory 502 agencies—Health Canada, U.S. Consumer Product Safety Commission (U.S. CPSC), European 503 Chemicals Agency (ECHA), and the Australian National Industrial Chemicals Notification and 504 Assessment Scheme (NICNAS)—have assessed phthalates for cumulative risk, and EPA's proposal to 505 conduct a CRA of phthalates under TSCA was endorsed by the Science Advisory Committee on 506 Chemicals (SACC) as the best available science. As described further in Sections 4.4.4 and 4.4.5, 507 cumulative risk considerations focus on acute duration exposures to the most susceptible 508 subpopulations: female workers and consumers of reproductive age (16–49 years of age) as well as male 509 infants and male children (3–15 years of age) exposed to consumer products and articles.

510

511 The draft DCHP risk evaluation includes a series of technical support documents (TSD). Each TSDI

512 support document contains sub-assessments that inform adjacent, "downstream" technical support

513 documents. A basic diagram showing the layout and relationship of these assessments is provided below

514 in Figure 1-2. High-level summaries of each relevant technical support document are presented in this

515 risk evaluation. Detailed information for each technical support document can be found in the 516 corresponding documents. Appendix C incudes a list and citations for all technical support documents

and supplemental files included in the draft risk evaluation for DCHP.

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519 These technical support documents leveraged the data and information sources already identified in the

520 Final Scope of the Risk Evaluation for Dicyclohexyl Phthalate (1,2-Benzenedicarboxylic acid, 1,2-

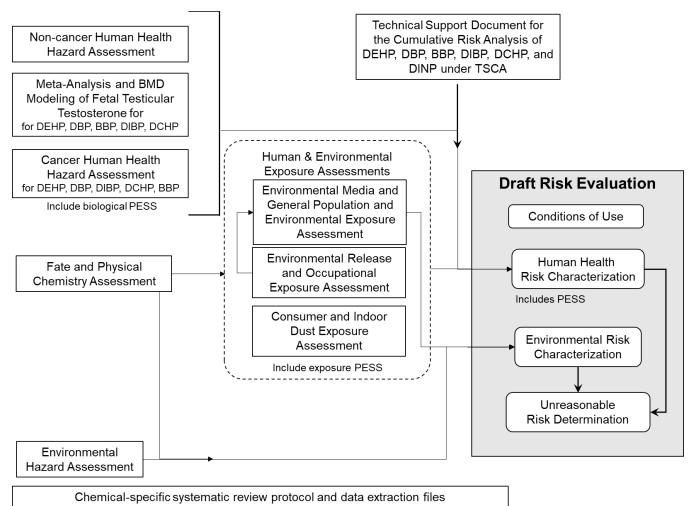
dicyclohexyl ester); *CASRN* 84-61-7 (also referred to as "final scope document") (U.S. EPA, 2020b).
 OPPT conducted a comprehensive search for "reasonably available information" to identify relevant

523 DCHP data for use in the draft risk evaluation. The approach used to identify specific relevant risk

assessment information was discipline-specific and is detailed in *Draft Systematic Review Protocol for*

525 Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024ag), or as otherwise noted in the relevant TSDs.

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527

528 Figure 1-2. Draft Risk Evaluation Document Summary Map

529

1.1.1 Life Cycle and Production Volume

The LCD shown in Figure 1-3 depicts the COUs that are within the scope of the risk evaluation, during 530 various life cycle stages, including manufacturing, processing, distribution, use (industrial, commercial, 531 532 consumer), and disposal. The LCD has been updated since its inclusion in the final scope document, 533 with consolidated and/or expanded processing and use steps. A complete list of updates and 534 explanations of the updates made to COUs for DCHP from the final scope document to this draft risk 535 evaluation is provided in Appendix D. The information in the LCD is grouped according to the 536 Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes 537 for industrial uses and product categories for industrial and commercial uses). The CDR Rule under TSCA section 8(a) (see 40 CFR part 711) requires certain U.S. manufacturers (including importers) to 538 539 provide EPA with information on the chemicals they manufacture or import into the United States. EPA 540 collects CDR data approximately every four years with the latest collections occurring in 2006, 2012, 541 2016, and 2020.

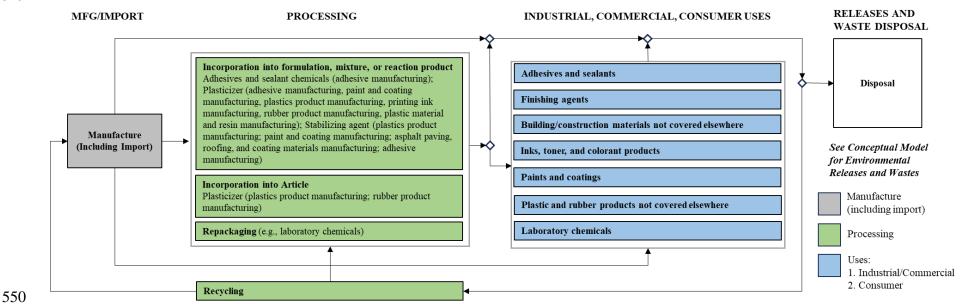
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543 EPA included descriptions of the industrial, commercial, and consumer use categories identified from

the 2020 CDR in the LCD (Figure 1-3) (U.S. EPA, 2020a). The descriptions provide a brief overview of

- 545 the use category; the *Draft Environmental Release and Occupational Exposure Assessment for*
- 546 Dicyclohexyl Phthalate (U.S. EPA, 2024q) contains more detailed descriptions (e.g., process

- 547 descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacturing,
- 548 processing, use, and disposal category.



551 Figure 1-3. DCHP Life Cycle Diagram

- 552 See Table 1-1 for categories and subcategories of COUs. Activities related to distribution (*e.g.*, loading, unloading) will be considered throughout the
- 553 DCHP life cycle, as well as qualitatively through a single distribution scenario.

549

The production volume for CASRN 84-61-7 in 2019 was between 500,000 and 1,000,000 pounds (lb) in

- 555 2019 based on the latest 2020 CDR data. EPA describes production volumes as a range to protect
- 556 production volume data claimed as confidential business information (CBI). For the 2020 CDR cycle,
- 557 collected data included the company name, volume of each chemical manufactured/imported, the 558 number of workers at each site, and information on whether the chemical was used in the commercial,
- 559 industrial, and/or consumer sector(s).
- 560

561 In the 2020 CDR, two sites reported production of DCHP. LANXESS reported a production volume of 562 17,290 lb for the 2019 CDR reporting year. The remaining site, Vertellus LLC, reported their production volumes as CBI but also reported an export volume of 410,849 lb for 2019 and that 10 percent of their 563 564 PV was used as a plasticizer in adhesive manufacturing. EPA assumed that this site had no uses of DCHP that are included under the reporting threshold and that 410,849 lb represented 90 percent of their 565 566 total PV. Therefore, EPA calculated the total manufactured PV from the site as 456,499 lb ($410,849 \div$ 0.9 = 456,499 lb or 207,064 kg). EPA was able to use this data and the number of reporting import sites 567 568 to estimate an average import volume per site.

1.1.2 Conditions of Use Included in the Risk Evaluation

570 The final scope document (U.S. EPA, 2020b) identified and described the life cycle stages, categories, 571 and subcategories that comprise TSCA COUs that EPA planned to consider in the risk evaluation. All 572 COUs for DCHP included in this draft risk evaluation are reflected in the LCD (Figure 1-3) and 573 conceptual models (Section 1.1.2.1). Table 1-1 below presents all COUs for DCHP. 574

In this draft risk evaluation, EPA made updates to the COUs listed in the final scope document (U.S.
 <u>EPA, 2020b</u>). A complete list of updates and explanations of the updates made to COUs for DCHP from
 the final scope document to this draft risk evaluation is provided in Appendix D.

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
	Domestic manufacturing	Domestic manufacturing	(<u>U.S. EPA, 2020a, 2019a</u>)
Manufacturing	Importing	Importing	(<u>U.S. EPA, 2020a, 2019a</u>)
		Adhesive and sealant chemicals in: – Adhesive manufacturing	(<u>U.S. EPA, 2019a</u>)
Processing	Processing – incorporation into formulation, mixture, or reaction product	 Plasticizer in: Adhesive manufacturing Paint and coating manufacturing Plastic material and resin manufacturing Plastics product manufacturing Printing ink manufacturing Rubber product manufacturing 	(<u>U.S. EPA, 2020a; ACA, 2019; AIA, 2019;</u> Carboline, 2019a, b; <u>MEMA, 2019; U.S. EPA, 2019a, d</u>)
		Stabilizing agent in: – Adhesive manufacturing – Asphalt paving, roofing, and coating materials manufacturing – Paint and coating manufacturing – Plastics product manufacturing	(U.S. EPA, 2024aj; Nouryon Chemicals LLC, 2020; U.S. EPA, 2020a; AIA, 2019; U.S. EPA, 2019c)

579Table 1-1. Categories and Subcategories of Use and Corresponding Exposure Scenario in the580Draft Risk Evaluation for DCHP

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
	Processing – incorporation into article	Plasticizer in: – Plastics product manufacturing – Rubber product manufacturing	(<u>AIA, 2019; MEMA, 2019;</u> <u>U.S. EPA, 2019a</u>)
	Repackaging	Repackaging (<i>e.g.</i> , laboratory chemical)	(<u>U.S. EPA, 2020d</u>)
	Recycling	Recycling	(<u>U.S. CPSC, 2015</u>)
Distribution in Commerce	Distribution in commerce	Distribution in commerce	
	Adhesives and sealants	Adhesives and sealants (<i>e.g.</i> , computer and electronic product manufacturing; transportation equipment manufacturing)	(<u>Henkel, 2024; AIA, 2019;</u> <u>Henkel, 2019; MEMA,</u> <u>2019; Henkel, 2017</u>)
	Finishing agent	Cellulose film production	(<u>U.S. EPA, 2020c;</u> Earthjustice, 2019)
Industrial Use	Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)	(<u>LANXESS, 2021; U.S.</u> <u>EPA, 2021c, 2019e; Gans</u> <u>Ink and Supply, 2018</u>)
	Paints and coatings	Paints and coatings	(<u>Carboline, 2019a, b; U.S.</u> <u>EPA, 2019d</u>)
	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) (<i>e.g.</i> , transportation equipment manufacturing)	(<u>AIA, 2019; MEMA,</u> <u>2019</u>)
	Adhesives and sealants	Adhesives and sealants	
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	(<u>LANXESS, 2021;</u> <u>U.S.</u> <u>EPA, 2019a</u>)
Commercial Use	Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)	(LANXESS, 2021; U.S. EPA, 2021c, 2019e; Gans Ink and Supply, 2018)
	Laboratory chemicals	Laboratory chemicals	(Restek Corporation, 2024; Sigma-Aldrich, 2024a, b; NASA, 2020; U.S. EPA, 2020d; SPEX CertiPrep, 2019)
Commercial Use	Paints and coatings	Paints and coatings	
	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	(<u>U.S. EPA, 2020a; AIA,</u> 2019; <u>MEMA, 2019; U.S.</u> <u>EPA, 2019a</u>)
Consumer Use	Adhesives and sealants	Adhesives and sealants	(DeWalt, 2024a; ITW Permatex, 2024; Lord Corporation, 2024; Midwest Technology

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
			<u>Products, 2024; MKT,</u> 2024; <u>ITW Permatex,</u> 2021; <u>DeWalt, 2020;</u> <u>MKT, 2018; Lord</u> <u>Corporation, 2017</u>)
	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	(<u>U.S. EPA, 2020a; AIA,</u> 2019; <u>MEMA, 2019; U.S.</u> <u>EPA, 2019a</u>)
	Other	Other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	(<u>Hydro-Gard, 2024;</u> <u>Hallstar, 2022; LANXESS,</u> <u>2021; U.S. EPA, 2020c;</u> <u>Earthjustice, 2019;</u> <u>MEMA, 2019; U.S. EPA,</u> <u>2019e; Gans Ink and</u> <u>Supply, 2018; Hydro-Gard,</u> <u>2017a, b; U.S. CPSC,</u> <u>2015</u>)
Disposal	Disposal	Disposal	

^{*a*} 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.

^b These categories of COUs appear in the LCD and broadly represent COUs of DCHP in industrial and/or commercial settings.

^c These subcategories reflect more specific COUs of DCHP.

^d The consumer COU of "Toys, playground, and sporting equipment" was removed and not included in DCHP's final scoping document. The U.S. CPSC Chronic Hazard Advisory Panel (CHAP) report from 2014 (U.S. CPSC, 2014) that states, "DCHP is currently not found in children's toys or child care articles, and it is not widely found in the environment" (page 117); the preamble of the 2017 CPSC final rule titled "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates," which explains that ". . . the CPSC staff has not detected DCHP in toys and child care articles during routine compliance testing thus far. . ." (U.S. CPSC, 2017); As a result, EPA has no reasonably available information demonstrating that the consumer use of DCHP in toys is intended, known, or reasonably foreseen, and has not included it in the analysis for this draft risk evaluation of DCHP.

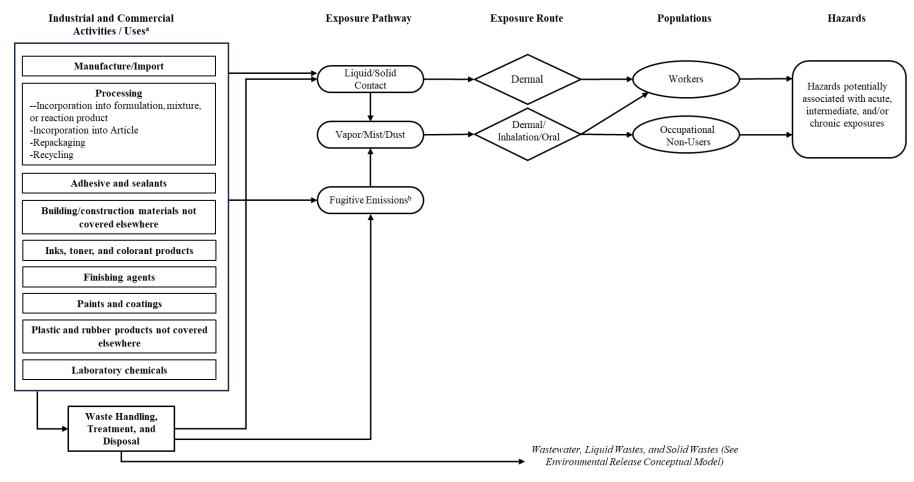
1.1.2.1 Conceptual Models

The conceptual model in Figure 1-4 presents the exposure pathways, exposure routes, and hazards to human populations from industrial and commercial activities and uses of DCHP. There is potential for exposure to workers and/or ONUs via inhalation and via dermal contact. The conceptual model also includes potential ONU dermal exposure to DCHP in mists and dusts deposited on surfaces. EPA evaluated activities resulting in exposures associated with distribution in commerce (*e.g.*, loading, unloading) throughout the various life cycle stages and COUs (*e.g.*, manufacturing, processing,

- 588 industrial use, commercial use, and disposal).
- 589

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- 590 Figure 1-5 presents the conceptual model for consumer activities and uses, Figure 1-6 presents general
- 591 population exposure pathways and hazards for environmental releases and wastes, and Figure 1-7
- presents the conceptual model for ecological exposures and hazards from environmental releases and 592
- 593 wastes.



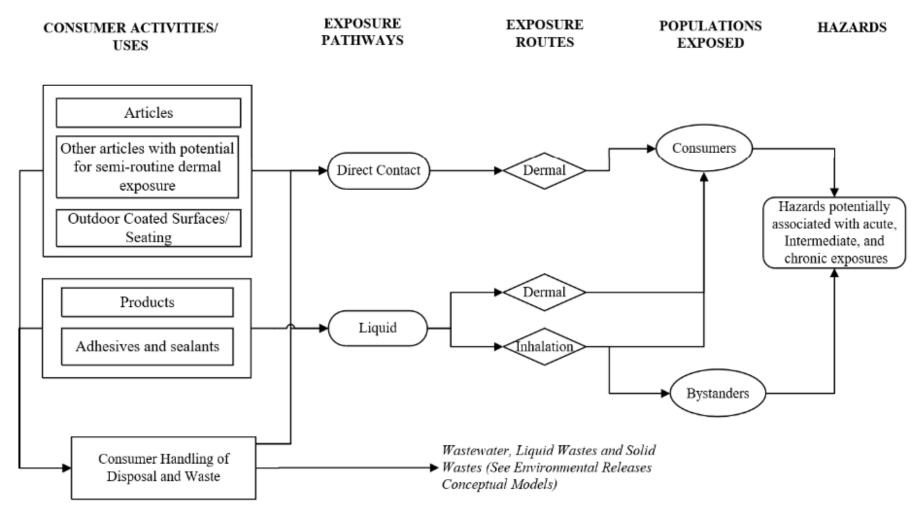
595 Figure 1-4. DCHP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

^a Some products are used in both commercial and consumer applications. See Table 1-1 for categories and subcategories of COUs.

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^b Fugitive air emissions are emissions that are not routed through a stack and include fugitive equipment leaks from valves, pump seals, flanges,

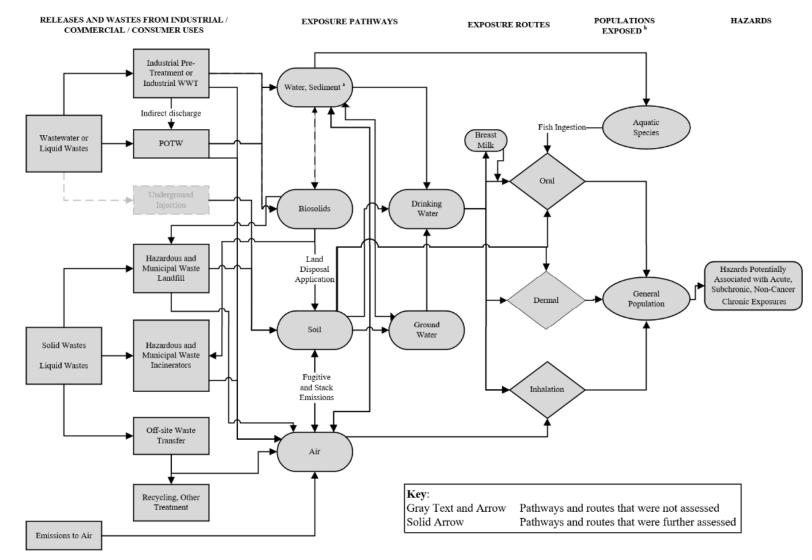
598 compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation 599 systems.



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601 Figure 1-5. DCHP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

602 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from consumer activities and uses of DCHP.



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604 Figure 1-6. DCHP Conceptual Model for Environmental Releases and Wastes: General Population Hazards

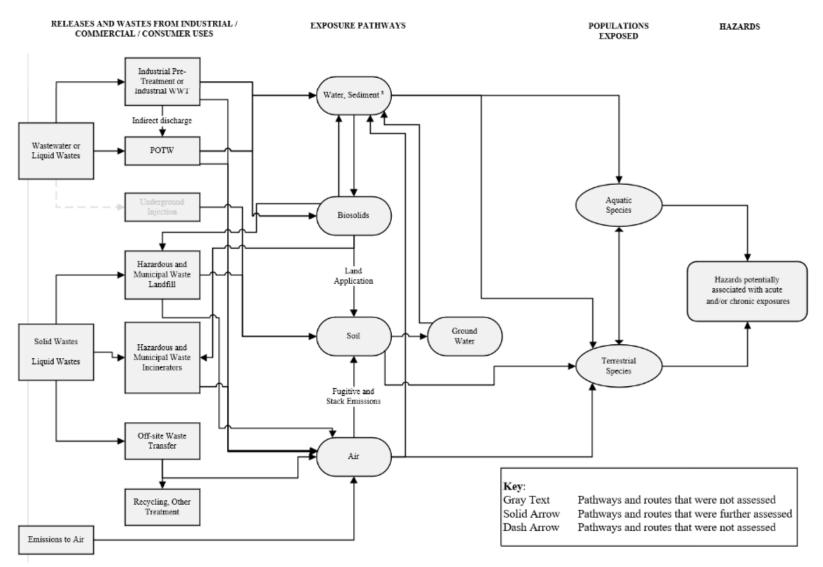
605 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from releases and wastes from industrial,

606 commercial, and/or consumer uses of DCHP.^{*a*} Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct

discharge), or pre-treated and released to publicly owned treatment works (POTWs) (indirect discharge). For consumer uses, such wastes may be released

608 directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Groundwater may also be a source of drinking water.

609 Inhalation from drinking water may occur via showering. ^b Populations assessed include PESS.



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611 Figure 1-7. DCHP Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards

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

613 commercial, and/or consumer uses of DCHP.^{*a*} Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct

614 discharge), or pre-treated and released to POTWs (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water

615 will undergo further treatment in drinking water treatment plant. Groundwater may also be a source of drinking water. Inhalation from drinking water may

616 occur via showering.

617 **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 humans and the environment. Environmental risks were evaluated for acute and chronic exposure scenarios for aquatic and terrestrial species, as appropriate. Human health risks associated with exposure to DCHP 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 women 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);
 - Bystanders, including infants (<1 year), toddlers (1–2 years), and children (3–5 and 6–10 years), young teens (11–15 years), teenagers (16–20 years), and adults (21+ years);
 - 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).
- The age groups for consumers, bystanders, and general population are different because each life
 stage used unique exposure factors (*e.g.*, mouthing, drinking water ingestion, fish consumption
 rates). These exposure factors are provided in EPA's *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011b).
- 636 Consistent with its Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High-Priority
- 637 *Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act* (U.S.
- 638 <u>EPA, 2023c</u>), EPA is focusing its relative potency factor (RPF) analysis and phthalate CRA on
- 639 populations most relevant to the common hazard endpoint (*i.e.*, reduced fetal testicular testosterone)—
- specifically women of reproductive age and male infants and male children. This approach emphasizes a
- 641 common health effect for sensitive subpopulations; however, additional health endpoints are identified 642 for broader populations and described in the individual non-concer burger bestte because for
- for broader populations and described in the individual non-cancer human health hazard assessments for
 DCHP (U.S. EPA, 2024v), DEHP (U.S. EPA, 2024w), DBP (U.S. EPA, 2024u), BBP (U.S. EPA,
- 643 DCHP (<u>U.S. EPA, 2024v</u>), DEHP (<u>U.S. EPA, 2024w</u>), DBP (<u>U.S. EPA, 2024u</u>), BBP (<u>U.S. EPA, 2024v</u>), BBP (<u>U.S. EPA, 2024v</u>), DIBP (<u>U.S. EPA, 2024x</u>), and DINP (<u>U.S. EPA, 2025b</u>). Additionally, EPA is focusing its RPF
- and CRA on acute duration exposures. This is because—as described further in the *Draft Technical*
- 646 Support Document for the CRA of DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA (U.S. EPA,
- 647 <u>2024ah</u>)—there is evidence that effects on the developing male reproductive system consistent with a
- 648 disruption of androgen action can result from a single exposure during the critical window of
- 649 development.

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1.1.3.1 Potentially Exposed and Susceptible Subpopulations

651 TSCA section 6(b)(4)(A) requires that risk evaluations "determine whether a chemical substance" 652 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 653 654 subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of 655 use." TSCA section 3(12) states that "the term 'potentially exposed or susceptible subpopulation' 656 [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 657 of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, 658 pregnant women, workers, or the elderly." 659 660

- 661 This draft risk evaluation considers PESS throughout the human health risk assessment (Section 4),
- 662 including throughout the exposure assessment, hazard identification, and dose-response analysis

663 supporting this assessment. EPA incorporated the following PESS into its assessment—women of 664 reproductive age; pregnant women, infants, children and adolescents; people who frequently use 665 consumer products and/or articles containing high-concentrations of DCHP; people exposed to DCHP in the workplace; and people who may be in proximity to releasing facilities, including fenceline 666 667 communities, and people whose diets include large amounts of fish (*i.e.*, subsistence fisher and Tribal populations). These subpopulations are PESS because some have greater exposure to DCHP per body 668 669 weight (*e.g.*, infants, children, adolescents), while some experience aggregate or sentinel exposures. 670 EPA also evaluated non-attributable exposures and cumulative risk to phthalates (*i.e.*, DEHP, DBP, BBP, DIBP, and DINP) for the U.S. civilian population using NHANES biomonitoring data. This non-671 672 attributable cumulative risk from exposure to DEHP, DBP, BBP, DIBP, and DINP was taken into 673 consideration as part of EPA's cumulative risk calculations for DCHP, presented below in Sections 4.4.4 and 4.4.5 and around exposures to DCHP from both occupational and consumer COUs/OES. 674

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

679 **1.2 Organization of the Risk Evaluation**

- This draft risk evaluation for DCHP includes five additional major sections, and several appendices, aslisted below:
- Section 2 summarizes basic physical and chemical characteristics as well as the fate and transport of DCHP.
 - Section 3 includes an overview of releases and concentrations of DCHP in the environment.
- Section 4 presents the human health risk assessment, including the exposure, hazard, and risk characterization based on the DCHP 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. Section 4 also includes EPA's CRA of DCHP, DEHP, DBP, BBP, DIBP, and DINP.
- 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 DCHP. 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 as a whole chemical approach and 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 DCHP.
- Appendix C incudes a list and citations for all TSDs and supplemental files included in the draft risk evaluation for DCHP.
 - Appendix D provides a summary of updates made to COUs for DCHP from the final scope document to this draft risk evaluation.
- Appendix E provides descriptions of the DCHP COUs evaluated by EPA.
- Appendix F provides the draft occupational exposure value for DCHP that was derived by EPA.

706 2 CHEMISTRY AND FATE AND TRANSPORT OF DCHP

- 707 Physical and chemical properties determine the behavior and characteristics of a chemical that inform its
- 708 COUs, environmental fate and transport, potential toxicity, exposure pathways, routes, and hazards.
- 709 Environmental fate and transport includes environmental partitioning, accumulation, degradation, and
- 710 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 environmental fate
- of DCHP informs the specific exposure pathways, and potential human and environmental exposed
- 713 populations that EPA considered in this draft risk evaluation.
- 714

715 Sections 2.1 and 2.2 summarize the physical and chemical properties, and environmental fate and

716 transport of DCHP, respectively. EPA's Draft Physical Chemistry and Fate and Transport Assessment

717 *for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024z) provides further details.

718 **2.1 Summary of Physical and Chemical Properties**

EPA gathered and evaluated physical and chemical property data and information according to the
 process described in the *Draft Systematic Review Protocol for Dicyclohexyl Phthalate (DCHP)* (U.S.

721 <u>EPA, 2024ag</u>). During the evaluation of DCHP, EPA considered both measured and estimated physical

and chemical property data/information summarized in Table 2-1, as applicable. Information on the full,

extracted data set is available in the *Data Quality Evaluation and Data Extraction Information for*

- 724 Physical and Chemical Properties for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024j).
- 725

706	
726	Table 2-1. Physical and Chemical Properties of DCHP

Property	Selected Value	Reference	Overall Quality Rating
Molecular Formula	C ₂₀ H ₂₆ O ₄		
Molecular Weight	330.43 g/mol		
Physical Form	Solid, prism	(<u>Haynes, 2014</u>)	High
Physical Properties	White granular solid	(<u>NLM, 2024</u>)	High
Melting Point	66 °C	(<u>Haynes, 2014</u>)	High
Boiling Point	225 °C at 4 mm Hg	(<u>Haynes, 2014</u>)	High
Density	1.383 g/cm^3	(<u>Haynes, 2014</u>)	High
Vapor Pressure	$8.69 \times 10^{-7} \text{ mmHg}$	(<u>NLM, 2024</u>)	High
Vapor Density	No data		
Water Solubility	0.030–1.48 mg/L ^a	(<u>U.S. EPA, 2017</u>)	Medium
Octanol:Water Partition coefficient (log KOW)	4.82	(<u>EC/HC, 2017</u>)	High
Octanol:Air Partition	10.23 ^{<i>a</i>}	(<u>U.S. EPA, 2017</u>)	Medium
Coefficient (log K _{OA})			
Henry's Law Constant	9.446×10 ⁻⁸ atm·m ³ /mol at 25 °C ^{<i>a</i>}	(<u>U.S. EPA, 2017</u>)	Medium
Flash Point	207 °C	(<u>RSC, 2019</u>)	Medium
Auto-Flammability	No data		
Viscosity	Solid, N/A	(<u>NLM, 2024</u>)	High
^{<i>a</i>} Modeled value using EPI Suite [™]			

727 **2.2 Summary of Environmental Fate and Transport**

- Reasonably available environmental fate data—including biotic and abiotic biodegradation rates,
- removal during wastewater treatment, volatilization from lakes and rivers, and organic carbon:water
- partition coefficient (log K_{OC})—are the parameters used in this draft risk evaluation. In assessing the
- environmental fate and transport of DCHP, EPA considered the full range of results from the available
- data sources with medium and high data quality ratings collected through systematic review.
- 733 Information on the full extracted data set is available in the *Data Quality Evaluation and Data*
- Extraction Information for Physical and Chemical Properties for Dicyclohexyl Phthalate (DCHP) (U.S.
 EPA, 2024j).
- 736
- 737 Other fate estimates were based on modeling results from EPI SuiteTM (U.S. EPA, 2012), a predictive 738 tool for physical and chemical properties and environmental fate estimation.
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- EPA evaluated the reasonably available information to characterize the physical and chemical propertiesand environmental fate and transport of DCHP. The key points are summarized below; DCHP
- Is a granular, crystalline solid under environmental conditions.
 - Has a tendency to partition to soil, sediment, and particulate over water or air.
 - Has limited solubility in water.
 - Has low volatility in water or soil.
- Given consistent results from numerous high-quality studies, there is robust evidence that when presentin the environment, DCHP
 - May degrade through hydrolysis, photolysis, aerobic or anaerobic biodegradation.
 - May transport through the air and be deposited to soil or water.
 - Will sorb to particulate in the atmosphere and in water.
- Is expected to be removed in wastewater treatment processes by sorbing to particulate, biosolids, and sludge.
- As a result of limited studies identified, there is moderate confidence that DCHP
 - Might be partially removed in conventional drinking water treatment.
- Might accumulate in individual fish and aquatic organisms, but is not expected to move up the food chain in aquatic environments.
- 757 The following bullets summarize the key points of the partitioning analysis; DCHP
- Will remain mostly in water but may sorb to sediment when released to aquatic environments.
- Will sorb to atmospheric particulate but may end up in small amounts in soil, water, and sediment when released to air.
- Will remain exclusively in soil when released to soil.
- Will sorb to particulate phases (soil, sediment, air particulate) with a small amount ending up in water when released to all three phases (air, water, and soil).

764 3 RELEASES AND CONCENTRATIONS OF DCHP IN THE 765 ENVIRONMENT

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

770 **3.1 Approach and Methodology**

At the time of this draft risk evaluation, releases of DCHP have not been reported to programmatic 771 772 databases, including the Toxics Release Inventory (TRI), Discharge Monitoring Report (DMR), or 773 National Emissions Inventory (NEI). Therefore, EPA utilized models to estimate environmental releases 774 for each OES. This section provides an overview of the approach and methodology for assessing 775 releases to the environment from industrial, commercial, and consumer uses. Specifically, Sections 3.1.1 776 through 3.1.3 describe the approach and methodology for estimating releases to the environment from 777 industrial and commercial uses, and Section 3.1.4 describes the approach and methodology for assessing 778 down-the-drain releases from consumer uses.

7793.1.1 Manufacturing, Processing, Industrial and Commercial Use

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

784 3.1.1.1 Crosswalk of Conditions of Use to Occupational Exposure Scenarios 785 EPA categorized the COUs listed in Table 1-1 into OESs. Table 3-1 provides a crosswalk between the 786 COUs and OESs. Each OES is developed based on a set of occupational activities and conditions such 787 that similar occupational exposures and environmental releases are expected from the use(s) covered 788 under that OES. For each OES, EPA provided occupational exposure and environmental release results, 789 which are expected to be representative of the entire population of workers and sites for the given OES 790 in the United States. In some cases, EPA defined only a single OES for multiple COUs, while in other cases the Agency developed multiple OESs for a single COU. EPA made this determination by 791 792 considering variability in release and use conditions and whether the variability required discrete 793 scenarios or could be captured as a distribution of exposures. The Draft Environmental Release and 794 Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q) provides 795 further information on specific OESs.

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Life Cycle Category Subcategory OES Stage Domestic manufacturing Domestic manufacturing Manufacturing Manufacturing Import and repackaging Importing Importing Repackaging Repackaging (e.g., laboratory Import and repackaging chemicals) Adhesive and sealant chemicals Incorporation into adhesives and sealants in: - Adhesive manufacturing Plasticizer in: - Adhesive manufacturing Incorporation into adhesives and - Paint and coating sealants: manufacturing Incorporation into paints and - Plastics product manufacturing coatings; - Printing ink manufacturing PVC plastics compounding: Processing -- Rubber product manufacturing non-PVC material compounding incorporation into - Plastic material and resin formulation, mixture, or manufacturing Processing reaction product Stabilizing agent in: Incorporation into adhesives and - Plastics product manufacturing sealants; - Paint and coating Incorporation into paints and manufacturing coatings; - Asphalt paving, roofing, and Incorporation into other coating materials manufacturing formulations, mixtures, or - Adhesive manufacturing reaction products: PVC plastics compounding; non-PVC material compounding PVC plastics converting; Plasticizer in: Processing incorporation into - Plastics product manufacturing non-PVC material converting article - Rubber product manufacturing Recycling Recycling Recycling Distribution in Distribution in commerce Distribution in commerce Distribution commerce Adhesives and sealants Adhesives and sealants in: Application of adhesives and - Transportation equipment sealants manufacturing - Computer and electronic product manufacturing Finishing agent Cellulose film production Application of paints and Industrial Use coatings Inks, toner, and colorant Application of paints and Inks, toner, and colorant products products (e.g., screen printing coatings ink) Paints and coatings Paints and coatings Application of paints and coatings

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

Life Cycle Stage	Category	Subcategory	OES
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere in: - Transportation equipment manufacturing	Fabrication or use of final products or articles
Commercial Use	Adhesives and sealants	Adhesives and sealants	Application of adhesives and sealants
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Fabrication or use of final products or articles
	Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)	Application of paints and coatings
	Laboratory chemical	Laboratory chemical	Use of laboratory chemicals
	Paints and coatings	Paints and coatings	Application of paints and coatings
	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Fabrication or use of final products or articles
Disposal	Disposal	Disposal	Waste handling, treatment, and disposal

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3.1.1.2 Description of DCHP Use for Each OES

After EPA characterized the OESs for the occupational exposure assessment of DCHP, the occupational uses of DCHP for all OESs were summarized. Brief summaries of the uses of DCHP for all OESs are presented in Table 3-2.

802 803

Table 3-2. Description of the Use of DCHP for Each OES

OES	Use of DCHP	
Manufacturing	DCHP is formed through the reaction of phthalic anhydride with cyclohexane ring alcohols (cyclohexanol).	
Import and repackaging	DCHP is imported domestically for use and/or may be repackaged before shipment to formulation sites.	
PVC plastics compounding		
PVC plastics converting	DCHP is used as an additive in PVC plastics to increase flexibility.	
Incorporation into adhesives and sealants	DCHP is a plasticizer and stabilizing agent in adhesive and sealant products for industrial and commercial use.	
Incorporation into paints and coatings	DCHP is a plasticizer and stabilizing agent in paint and coating products for industrial and commercial use.	
Incorporation into other formulations, mixtures, or reaction products, not covered elsewhere	DCHP is incorporated into products, such as laboratory chemicals and asphalt paving, roofing, and coating materials.	

OES	Use of DCHP	
Non-PVC material compounding	DCHP is used as an additive in non-PVC polymers, such as rubber and cellulose, to increase flexibility.	
Non-PVC material converting		
Application of adhesives and sealants	Industrial and commercial sites often apply DCHP in powdered form to serve as a hardener, thickener, or curing agent for adhesive and sealant materials. Liquid adhesive and sealant products containing DCHP are generally thick and paste-like, and these products are applied using roll or bead application methods. Products may also be applied using a syringe or caulk gun.	
Application of paints and coatings	Industrial and commercial sites apply DCHP-containing paints and coatings using roll, brush, trowel, and spray application methods.	
Use of laboratory chemicals	DCHP is a laboratory chemical used for laboratory analyses in solid and liquid forms.	
Recycling	A fraction of PVC plastics that contain DCHP are recycled either in-house or at PVC recycling facilities for continuous compounding of new PVC material.	
Fabrication or use of final products or articles	DCHP is found in a wide array of different final articles not found in other OES such as wall coverings or other solid plastic or rubber products.	
Waste handling, treatment, and disposal	DCHP-containing products or residuals are managed as waste to be treated and/or disposed.	

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

Based on the limited data on the number of release days for the majority of the OESs, EPA developed
generic estimates of the number of annual operating days (days/year) for facilities in each OES, as
presented in Table 3-3. Generally, EPA does not have information on the number of operating days for
facilities; however, the Agency used Generic Scenarios (GSs) or Emission Scenario Documents (ESDs)
to assess the number of operating days for a given OES. EPA estimated average daily releases for
facilities by assuming that the number of release days is equal to the number of operating days.

811

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

Occupational Exposure Scenario	Operating Days (days/yr)	Basis
Manufacturing	250	EPA assumed year-round site operation for 5 days each week, considering a 2-week downtime, totaling 250 days/year.
Import and repackaging	208–260	The 2022 Chemical Repackaging GS estimated the total number of operating days as one of three discrete values based on the typical shift lengths of operators over the course of a full year. Shift lengths include 8, 10, or 12 hour/day shifts, which resulted in operating day estimates of 174, 208, or 260 days/year. EPA assessed releases using Monte Carlo modeling (see <i>Draft Environmental Release</i> <i>and Occupational Exposure Assessment for Dicyclohexyl</i> <i>Phthalate (DCHP)</i> (U.S. EPA, 2024q)), which used a 50th to 95th percentile range of 208–260 days/year (U.S. EPA, 2022a).

Occupational Exposure Scenario	Operating Days (days/yr)	Basis
Incorporation into adhesives and sealants	250	EPA assumed year-round site operation for 5 days each week, considering a 2-week downtime, totaling 250 days/year.
Incorporation into paints and coatings	250	EPA assumed year-round site operation for 5 days each week, considering a 2-week downtime, totaling 250 days/year.
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	250	EPA assumed year-round site operation for 5 days each week, considering a 2-week downtime, totaling 250 days/year.
PVC plastics compounding	223–254	The 2021 <i>Revised Draft GS on the Use of Additives in</i> <i>Plastic Compounding</i> estimated the number of operating days as 148–264 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft</i> <i>Environmental Release and Occupational Exposure</i> <i>Assessment for Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021d, 2014c).
PVC plastics converting	219–251	The 2021 Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry estimated the number of operating days as 138–253 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft</i> <i>Environmental Release and Occupational Exposure</i> <i>Assessment for Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2021e).
Non-PVC material compounding	234–280	The 2021 Revised Draft GS on the Use of Additives in Plastic Compounding and the 2020 <i>SpERC Factsheet on</i> <i>Rubber Production and Processing</i> estimated the total number of operating days as 148–300 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational</i> <i>Exposure Assessment for Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 234–280 days/year (U.S. EPA, 2021d; ESIG, 2020b; U.S. EPA, 2014c)
Non-PVC material converting	219–251	The 2021 Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry estimated the number of operating days as 137–254 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2021e).
Application of adhesives and sealants	232–325	Based on several end use products categories, the 2015 ESD on the Use of Adhesives estimated the total number of operating days as 50–365 days/year. Release estimates that EPA assessed using Monte Carlo modeling (<i>Draft</i>

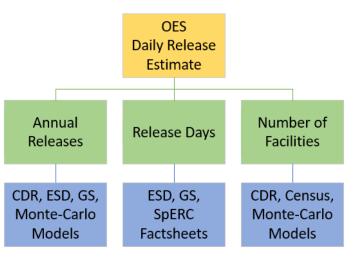
Occupational Exposure Scenario	Operating Days (days/yr)	Basis
		<i>Environmental Release and Occupational Exposure</i> <i>Assessment for Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, <u>2024q</u>)) used a 50th to 95th percentile range of 232–325 days/year (<u>OECD, 2015b</u>).
Application of paints and coatings	257–287	EPA assessed the total number of operating days based on the 2011 ESD on Radiation Curable Coatings, Inks and Adhesives, the 2011 ESD on Coating Application via Spray- Painting in the Automotive Finishing Industry, the 2004 GS on Spray Coatings in the Furniture Industry, and the <i>SpERC</i> <i>Factsheet for Industrial Application of Coatings and Inks by</i> <i>Spraying</i> . These sources estimated the total number of operating days as 225–300 days/year. Release estimates that EPA assessed using Monte Carlo modeling (<i>Draft</i> <i>Environmental Release and Occupational Exposure</i> <i>Assessment for Dicyclohexyl Phthalate</i> (<i>DCHP</i>) (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 257–287 days/year (ESIG, 2020a; OECD, 2011a, b; U.S. EPA, 2004c).
Use of laboratory chemicals	Solid and Liquid: 235– 258	The 2023 Use of Laboratory Chemicals GS estimated the total number of operating days with a discrete distribution based on the shift lengths of operators over the course of a full year. Shift lengths include 8, 10, or 12 hour/day shifts, which result in a range of 174–260 days/year for operating days. Release estimates that EPA assessed using Monte Carlo modeling (<i>Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 235–258 days/year (U.S. EPA, 2023g).
Fabrication or use of final products or articles	250	EPA assumed year-round site operation for 5 days each week, considering a 2-week downtime, totaling 250 days/year. However, EPA was not able to perform a quantitative release assessment for this OES because the release parameters were unknown and unquantifiable.
Recycling	223–254	The 2021 Revised Draft GS on the Use of Additives in Plastic Compounding estimated the number of operating days as 148–264 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft</i> <i>Environmental Release and Occupational Exposure</i> <i>Assessment for Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, 2024q)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021d, 2014c).
Waste handling, treatment, and disposal	250	EPA assumed year-round site operation for 5 days each week, considering a 2-week downtime, totaling 250 days/year.

813 **3.1.3 Daily Release Estimation**

For each OES, EPA estimated releases to each medium of release using 2020 CDR data (U.S. EPA,
 2020a), GSs and ESDs, and EPA published models as shown in Figure 3-1. Where available, EPA used

GSs or ESDs to estimate number of release days, which EPA used to convert between annual release

- 817 estimates and daily release estimates. EPA used 2020 CDR, 2020 U.S. County Business Practices, and
- 818 Monte Carlo modeling data to estimate the number of sites using DCHP within an OES. Generally,
- 819 information for reporting sites in CDR was sufficient to accurately characterize each reporting site's
- 820 OES. The Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl
- 821 *Phthalate (DCHP)* (U.S. EPA, 2024q) describes EPA's approach and methodology for estimating daily
- releases and provides detailed facility level results for each OES.
- 823824 For each OES, EPA estimated DCHP releases per facility to each release medium applicable to that
- 825 OES. For DCHP, EPA assessed releases to water, air, or land (*i.e.*, disposal to land).
- 826



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Figure 3-1. An Overview of How EPA Estimated Daily Releases for Each OES

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CDR = Chemical Data Reporting; ESD = Emission Scenario Document; GS =

Generic Scenario; SpERC = Specific Environmental Release Category

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3.1.4 Consumer Down-the-Drain and Landfills

832 EPA evaluated down-the-drain releases of DCHP for consumer COUs qualitatively. Although the 833 Agency acknowledges that there may be DCHP releases to the environment via the cleaning and 834 disposal of adhesives and sealants, the Agency did not quantitatively assess down-the-drain and disposal scenarios of consumer products due to limited information from monitoring data as well as limited 835 836 availability of modeling tools that can adequately quantify disposal. EPA provides a qualitative 837 assessment of down-the-drain releases of DCHP using physical and chemical properties in this section. 838 See EPA's Draft Consumer and Indoor Dust Exposure Assessment for Dicyclohexyl phthalate (DCHP) 839 (U.S. EPA, 2024c) for further details. For example, adhesives and sealants can be disposed down-the-840 drain when people using them wash their hands, brushes, sponges, and other product-applying tools. 841 Very limited information is available on wastewater treatment and the removal of DCHP in drinking 842 water treatment plants. As stated in the Draft Physical Chemistry and Fate And Transport Assessment 843 for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024z), no data was identified by the EPA for DCHP in 844 drinking water. Based on the low water solubility and log K_{OW}, DCHP in water is expected to mainly partition to suspended solids present in water. The available information suggest that the use of 845 flocculants and filtering media could potentially help remove DCHP during drinking water treatment by 846 847 sorption into suspended organic matter, settling, and physical removal. 848

In addition, adhesives and sealant products can be disposed of when users no longer have use for them or when the products have reached the product shelf life and are taken to landfills. All other solid products and articles listed in Table 4-6 can be removed and disposed of in landfills, or other waste

handling locations that properly manage the disposal of products like adhesives and sealants. DCHP is

expected to be persistent as it leaches from consumer products disposed of in landfills. Due to low water
solubility, DCHP is likely to be present in landfill leachate up to its aqueous limit of solubility (1.48
mg/L). However, due to its affinity for organic carbon, DCHP is expected to be immobile in
groundwater. Even in cases where landfill leachate containing DCHP were to migrate to groundwater,
DCHP would likely partition from groundwater to organic carbon present in the subsurface (U.S. EPA,
2024p).

3.2 Summary of Environmental Releases

860 **3.2.1 Manufacturing, Processing, Industrial and Commercial**

861 EPA combined its estimates for total production volume, release days, number of facilities, and hours of release per day to estimate a range of daily releases for each OES. Table 3-4 presents a summary of 862 863 these ranges across facilities. See the Draft Environmental Release and Occupational Exposure 864 Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q) for additional detail on deriving the 865 overall confidence score for each OES. EPA was not able to estimate site-specific releases for the fabrication or use of final products or articles OES. Disposal sites handling post-consumer, end-use 866 867 DCHP were not quantifiable due to the wide and disperse use of DCHP in PVC and other products. Pre-868 consumer waste handling, treatment, and disposal are assumed to be captured in upstream OESs.

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b orEstimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence	Sources				
	Central Tendency	High- End	Transfer for Disposal ^c	Central Tendency	High- End		Rating ^f				
	9.4E-02	0.42	Stack Air								
	0.12	0.55	Fugitive Air, Water, Incineration, or Landfill	250		1 – LANXESS Corporation,	Moderate	CDR, Peer- reviewed literatur			
	0.94		Water, Incineration, or Landfill	250		Pittsburgh, PA	Widderate	(GS/ESD)			
Manufacturing	0.15	0.57	Incineration or Landfill								
Wandracturing	2.5	11	Stack Air					CDR, Peer-			
	3.2	15	Fugitive Air, Water, Incineration, or Landfill	250		1 – Vertellus LLC,					
	12		Water, Incineration, or Landfill	- 250		Indianapolis, IN	Moderate	reviewed literature (GS/ESD)			
	4.0	15	Incineration or Landfill								
	1.5	9.3	Stack Air								
Import and repackaging	1.9	12	Fugitive Air, Water, Incineration, or Landfill	208	208 260	208	208	208 260	2 – United Initiators, Inc., Elyria, OH;	Moderate	CDR, Peer- reviewed literature
	4.0	8.2	Water, Incineration, or Landfill				Nouryon Chemicals LLC, Chicago, IL		(GS/ESD)		
	2.4	13	Incineration or Landfill								

869 Table 3-4. Summary of EPA's Daily Release Estimates for Each OES and EPA's Overall Confidence in these Estimates

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or	Estimated R Frequency acr (days) ^d	oss Sites	Number of Facilities ^e	Weight of Scientific	Sources
	Central Tendency	High- End	Transfer for Disposal ^c	Central Tendency	High- End		Evidence Rating ^f	
	0.11	0.70	Stack Air					
Incorporation into adhesives and	0.14	0.93	Fugitive Air, Water, Incineration, or Landfill	250		5. O generio sites	Moderate	CDR, Peer- reviewed literature
sealants	2.6	4.9	Water, Incineration, or Landfill	250		5–9 generic sites	Moderate	(GS/ESD)
	0.18	0.99	Incineration or Landfill					
	1.2E-02	0.10	Stack Air	250		20–34 generic sites	Moderate	CDR, Peer- reviewed literature (GS/ESD)
Incorporation into	1.6E-02	0.14	Fugitive Air, Water, Incineration, or Landfill					
paints and coatings	1.1	3.0	Water, Incineration, or Landfill					
	2.0E-02	0.15	Incineration or Landfill					
	8.3E-02	0.78	Stack Air					
Incorporation into other formulations, mixtures, and	0.11	1.0	Fugitive Air, Water, Incineration, or Landfill	250		11. 22	Madamata	CDR, Peer-
	0.13	1.2	Water, Incineration, or Landfill			11–22 generic sites	Moderate	reviewed literature (GS/ESD)
reaction products	0.13	1.2	Incineration or Landfill					

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence	Sources
	Central Tendency	High- End	Transfer for Disposal ^c	CentralHigh-TendencyEnd	Rating ^f			
	0.12	4.1	Fugitive or Stack Air					
PVC plastics	0.83	7.9	Fugitive Air, Water, Incineration, or Landfill		254			CDR, Peer-
compounding	3.5	18	Water, Incineration, or Landfill	223	254	5–9 generic sites	Moderate	reviewed literature (GS/ESD)
	1.1	6.1	Water					
	1.4	11	Incineration or Landfill	1				
	7.2E-03	0.19	Fugitive or Stack Air	219	251	42–67 generic sites	Moderate	CDR, Peer- reviewed literature (GS/ESD)
PVC plastics	4.7E-02	0.35	Fugitive Air, Water, Incineration, or Landfill					
converting	0.96	1.9	Water, Incineration, or Landfill					
	0.13	0.41	Water					
	0.43	1.4	Incineration or Landfill					
	3.1E-02	0.88	Fugitive or Stack Air				Moderate	CDR, Peer- reviewed literature (GS/ESD)
Non-PVC material compounding	0.25	1.6	Fugitive Air, Water, Incineration, or Landfill	- 234	280	2–4 generic sites		
	1.5	2.9	Water, Incineration, or Landfill		200			
	0.30	0.90	Water					
	0.41	2.1	Incineration or Landfill					

OES	Estimated Release acro (kg/site-	oss Sites	Type of Discharge, ^a Air Emission, ^b or	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High- End	Transfer for Disposal ^c	Tendency End				
	2.0E-02	0.47	Fugitive or Stack Air					
Non-PVC material	0.13	0.86	Fugitive Air, Water, Incineration, or Landfill	219	251	2–4 generic sites	Moderate	CDR, Peer- reviewed literature
converting	1.1	2.9	Water, Incineration, or Landfill	219	231	2–4 generic sites	Widderate	(GS/ESD)
	0.32	0.96	Water	-				
	1.1	3.3	Incineration or Landfill					
	5.8E–09 [5.8E–09]	1.3E–08 [1.3E– 08]	Fugitive Air	257	287	1–14 generic sites [1–14 generic sites]	Moderate	CDR, Peer- reviewed literature (GS/ESD)
Application of paints and coatings	1.4 [7.4E–02]	5.1 [0.63]	Stack Air					
with overspray controls (no overspray	9.4E–02 [13]	0.82 [47]	Fugitive Air, Water, Incineration, or Landfill					
controls)	1.3 [1.3]	3.3 [3.3]	Water, Incineration, or Landfill					
	11 [0.12]	42 [0.88]	Incineration or Landfill					
	5.7E-10	1.5E-09	Fugitive Air				Moderate	
	4.2E-02	0.46	Stack Air					CDR, Peer- reviewed literature (GS/ESD)
Application of adhesives and sealants	5.3E-02	0.61	Fugitive Air, Water, Incineration, or Landfill	232	325	6–80 generic sites		
	0.33	1.6	Water, Incineration, or Landfill					
	0.67	3.6	Incineration or Landfill					

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence	Sources
	Central Tendency	High- End	Transfer for Disposal ^c	Central Tendency	High- End		Rating ^f	
Use of laboratory	1.5E-12	2.6E-12	Fugitive or Stack Air	235	258	36,873 generic sites	Moderate	
chemicals – liquid	4.0E-03	5.0E-03	Water, Incineration, or Landfill	233	238	50,075 generie sites	Widderate	
	1.2E-04	1.0E-03	Stack Air					
Use of laboratory	2.3E-04	2.0E-03	Unknown Media (Air, Water, Incineration, or Landfill)	235	258	1,978–25,643 generic sites	Moderate	CDR, Peer- reviewed literature (GS/ESD)
chemicals – solid	6.6E–02	0.27	Water, Incineration, or Landfill			SICS		
	3.1E-04	3.0E-03	Incineration or Landfill					
	7.4E-04	4.3E-03	Stack Air		254	58 generic sites	Moderate	
Recycling	2.8E-03	9.2E-03	Fugitive Air, Water, Incineration, or Landfill	223				CDR, Peer- reviewed literature
	1.9E-03	3.9E-03	Water					(GS/ESD)
	1.3	1.8	Water, Incineration, or Landfill					
^b Emissions via fug ^c Transfer to surface ^d Where available, I	itive air or stack e impoundment, EPA used indust EPA used 2020	air, or trea land appli ry provide CDR (<u>U.S</u>	<u>EPA, 2020a</u>), 2020 U.	or GSs to estimate t	he number	Vs c of release days for each C s (<u>U.S. Census Bureau, 20</u> 2		Carlo models to

estimate the number of sites that use DCHP for each COU. ^f See Section 3.2.2 for details on EPA's determination of the weight of scientific evidence rating.

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 3-5 provides the Agency's weight of scientific evidence rating for each OES.

- 876
 877 EPA integrated numerous evidence streams across systematic review sources to develop environmental
 878 estimates for DCHP. The Agency made a judgment on the weight of scientific evidence supporting the
 879 release estimates based on the strengths, limitations, and uncertainties associated with the release
 880 estimates. EPA described this judgment using the following confidence descriptors: robust, moderate,
 881 slight, or indeterminate.
- 882

883 In determining the strength of the overall weight of scientific evidence, EPA considered factors that 884 increase or decrease the strength of the evidence supporting the release estimate (whether measured or estimated)—including quality of the data/information, relevance of the data to the release scenario 885 886 (including considerations of temporal and spatial relevance), and the use of surrogate data when 887 appropriate. In general, higher rated studies (as determined through data evaluation) increase the weight 888 of scientific evidence when compared to lower rated studies, and EPA gave preference to chemical- and 889 scenario-specific data over surrogate data (e.g., data from a similar chemical or scenario). For example, 890 a conclusion of moderate weight of scientific evidence is appropriate where there is measured release 891 data from a limited number of sources, such that there is a limited number of data points that may not 892 cover most or all the sites within the OES. A conclusion of slight weight of scientific evidence is 893 appropriate where there is limited information that does not sufficiently cover all sites within the COU, 894 and the assumptions and uncertainties are not fully known or documented. See EPA's Draft Systematic 895 Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances, Version 1.0: A Generic 896 TSCA Systematic Review Protocol with Chemical-Specific Methodologies (also called "Draft Systematic 897 Review Protocol") (U.S. EPA, 2021a) for additional information on weight of scientific evidence 898 conclusions. 899

Table 3-5 summarizes EPA's overall weight of scientific evidence conclusions for its release estimates for each OES. In general, modeled data had data quality ratings of medium. As a result, for releases that used GSs/ESDs, the weight of scientific evidence conclusion was moderate, when used in tandem with Monte Carlo modeling.

904 **Table 3-5. Summary of Overall Confidence in Environmental Release Estimates by Occupational Exposure Scenario**

OES	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	EPA found limited chemical specific data for the manufacturing OES and assessed environmental releases using models and model parameters derived from CDR, the 2023 Methodology for Estimating Environmental Releases from Sampling Wastes (U.S. EPA, 2023e), and sources identified through systematic review (including surrogates DINP and DIDP industry-supplied data). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment, with media of release assessed using assumptions from EPA/OPPT models and industry supplied data. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Additionally, Monte Carlo modeling uses a large number of data points (simulation runs) and considers the full distributions to CDR and non-DCHP-specific operating parameters derived using data from a current U.S. manufacturing site for DIDP and DINP that is assumed to operate using similar operating parameters as DCHP manufacturing. This information was used to provide more accurate estimates than the generic values provided by the EPA/OPPT models. These strengths increase the weight of evidence. The primary limitation of EPA's approach is the uncertainty in the representativeness of release estimates toward the true distribution of potential releases. In addition, one DCHP manufacturing site claimed their DCHP production volume as CBI for the purpose of CDR reporting; therefore, DCHP throughput estimates for this site are based on the site's reported export volume and their reported PV percentage for industrial use. Additional limitations include uncertainties in the representativeness of the surrogate industry-provided operating parameters for DIDP and DINP and the generic EPA/OPPT models for DCHP manufacturing sites. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases considering the strengths and limitations of the reasonably available data.
Import and repackaging	EPA found limited chemical specific data for the import and repackaging OES and assessed releases to the environment using the assumptions and values from the Chemical Repackaging Generic Scenario (U.S. EPA, 2022a), which the systematic review process rated high for data quality. EPA also referenced the 2023 Methodology for Estimating Environmental Releases from Sampling Wastes (U.S. EPA, 2023e). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment. EPA assessed the media of release using assumptions from the GS and EPA/OPPT models. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Additionally, Monte Carlo modeling uses a large number of data points (simulation runs) and the full distributions of input parameters. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, because the default values in the GS are generic, there is uncertainty in the representativeness of these generic site estimates in characterizing actual releases from real-world sites that import and repackage DCHP. In addition, EPA lacks DCHP facility import volume data for all CDR-reporting import and repackaging sites due to claims of CBI; therefore, throughput estimates for these sites are based on the CDR reporting threshold of 25,000 lb and an annual DCHP national aggregate production volume range from CDR. These limitations decrease the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Incorporation into adhesives and sealants	EPA found limited chemical specific data for the incorporation into adhesives and sealants OES and assessed releases to the environment using the ESD on the Formulation of Adhesives (OECD, 2009a), which has a high data quality rating based on the systematic review process. EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment and assessed the media of release using assumptions from the ESD and EPA/OPPT models. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DCHP-specific data on concentrations in adhesive and sealant products in the analysis to provide more accurate estimates than the generic values provided by the ESD. The safety and product data sheets that EPA obtained these values from have high and medium data quality ratings based on the systematic review process. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the default values in the ESD may not be representative of actual releases from real-world sites that incorporate DCHP into adhesives and sealants. In addition, EPA lacks data on DCHP-specific facility production volume and number of formulation sites, which are needed to estimate site throughput of DCHP. EPA based throughput on the CDR reporting threshold of 25,000 lb, an annual DCHP national aggregate production volume range, and ranges of downstream sites. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Incorporation into paints and coatings	EPA found limited chemical specific data for the incorporation into paints and coatings OES and assessed releases to the environment using the Draft GS for the Formulation of Waterborne Coatings (U.S. EPA, 2014a), which has a medium data quality rating based on systematic review. EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment and assessed the media of release using assumptions from the GS and EPA/OPPT models. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DCHP-specific data on concentrations in paint and coating products to provide more accurate estimates of DCHP concentrations than the generic values provided by the GS. The safety and product data sheets that EPA obtained these values from have medium to high data quality ratings based on the systematic review process. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the GS are specific to waterborne coatings and may not be representative of releases from real-world sites that incorporate DCHP into paints and coatings, particularly for

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	sites formulating other coating types (<i>e.g.</i> , solvent-borne coatings). In addition, EPA lacks data on DCHP-specific facility production volume and number of formulation sites; therefore, EPA based throughput and production volume estimates on CDR which has a reporting threshold of 25,000 lb, an annual DCHP production national aggregate production volume range, and ranges of downstream sites. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Incorporation into other formulations, mixtures, and reaction products	EPA found limited chemical specific data for the incorporation into other formulations, mixtures, and reaction products not covered elsewhere OES and assessed releases to the environment using the Draft GS for the Formulation of Waterborne Coatings (U.S. EPA, 2014a), which has a medium data quality rating based on systematic review process. 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. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DCHP-specific data on concentrations in other formulation, mixture, and reaction products in the analysis to provide more accurate estimates than the generic values provided by the GS. The safety and product data sheets that EPA obtained these values from have high and medium data quality ratings based on the systematic review process. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the GS are based on the formulation of paints and coatings and may not represent releases from real-world sites that incorporate DCHP into other formulations, mixtures, or reaction products. In addition, because no entries in CDR indicated a use relevant to this formulation OES, and there were no other sources to estimate the volume of DCHP used in this OES, EPA developed a high-end bounding estimate for production volume based on the CDR reporting threshold of 25,000 lb or 5% of total product volume for a given use, which by definition is expected to overestimate the average release case. For DCHP facility throughputs, EPA used a range of generic default values in the GS. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
PVC plastics compounding	EPA found limited chemical specific data for the plastics compounding OES and assessed releases to the environment using the Revised Draft GS for the Use of Additives in Plastic Compounding (U.S. EPA, 2021d), which has a medium data quality rating based on systematic review. 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. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. These strengths increase the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. The generic default concentration values in the GS consider all types of plastic compounding and may not represent releases from real-world sites that compound DCHP into specific types of plastic raw material. In addition, EPA lacks data on DCHP-specific facility production volume and number of compounding sites; therefore, EPA estimated throughput and production volume based on CDR which has a reporting threshold of 25,000 lb and an annual DCHP production national aggregate production volume range. These limitations decrease the weight of evidence.
	provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
PVC plastics converting	EPA found limited chemical specific data for the plastics converting OES and assessed releases to the environment using the Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry, which has a medium data quality rating based on systematic review (U.S. EPA, 2021e). 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. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo also considers a large number of data points (simulation runs) and the full distributions of input parameters. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the ESD are based on all types of thermoplastics converting sites and processes and may not represent actual releases from real-world sites that convert DCHP-containing raw material into plastic articles using a variety of methods, such as extrusion or calendering. In addition, EPA lacks data on DCHP-specific facility production volume and number of converting sites; therefore, EPA estimated throughput based on CDR which has a reporting threshold of 25,000 lb, an annual DCHP national aggregate production volume range, and ranges of downstream sites. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Non-PVC material compounding	EPA found limited chemical specific data for the non-PVC material compounding OES and assessed releases to the environment using the Revised Draft GS for the Use of Additives in Plastic Compounding and the ESD on Additives in the Rubber Industry (U.S. EPA, 2021d; OECD, 2004). Both sources have a medium data quality rating based on the systematic review process. 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, ESD, and EPA/OPPT models. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. These strengths increase the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, there was a lack of concentration data for specific products that contained DCHP; EPA relied on the GS and ESD to generate concentration estimates. These values may not be representative of actual values from real-world sites that compound DCHP into non-PVC material. In addition, because no entries in CDR indicated a use relevant to compounding or converting non-PVC material, and there were no other sources to estimate the volume of DCHP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold of 25,000 lb or 5% of total product volume for a given use, which by definition is expected to over-estimate the average release case. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Non-PVC material converting	EPA found limited chemical specific data for the non-PVC material converting OES and assessed releases to the environment using the Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry and the ESD on Additives in the Rubber Industry (U.S. EPA, 2021e; OECD, 2004). Both documents have a medium data quality rating based on systematic review. 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, ESD, and EPA/OPPT models. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, there was a lack of concentration data for specific products that contained DCHP; EPA relied on the GS and ESD to generate concentration estimates. These values may not be representative of actual values from real-world sites that convert DCHP into non-PVC articles. In addition, because no entries in CDR indicated a use relevant to compounding or converting non-PVC material, and there were no other sources to estimate the volume of DCHP or number of sites used in this OES, EPA developed a range of high-end bounding estimates based on the CDR reporting thresholds, or 25,000 lb of 5% of total product volume for a given use, which by definition is expected to over-estimate the average release case. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Application of adhesives and sealants	EPA found limited chemical specific data for the application of adhesives and sealants OES and assessed releases to the environment using the <i>esd on the use of adhesives</i> (OECD, 2015a), which has a medium data quality rating based on systematic review. 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. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	parameters. Additionally, EPA used DCHP-specific data on concentration and application methods for different DCHP-containing adhesives and sealant products in the analysis. These data provide more accurate estimates than the generic values provided by the ESD. The safety and product data sheets from which these values were obtained have high and medium data quality ratings from the systematic review process. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the ESD may not represent releases from real-world sites that incorporate DCHP into adhesives and sealants. The overall production volume of DCHP for this OES was based on CDR data using the same assumptions as the Incorporation into adhesives and sealants OES. EPA lacks data on DCHP-specific facility use volume and number of use sites; therefore, EPA based facility throughput estimates and number of sites on industry-specific default facility throughputs from the ESD, DCHP product concentrations, and the overall production volume range from CDR data which has a reporting threshold of 25,000 lb. EPA also had minimal data for solid additives in adhesives, and had to base the DCHP concentration range for solid additives on the SDS for one product. These limitations decrease the weight of evidence.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of reasonably available data.
Application of paints and coatings	EPA found limited chemical specific data for the application of paints and coatings OES and assessed releases to the environment using the ESD on the Application of Radiation Curable Coatings, Inks and Adhesives and the GS on Coating Application via Spray Painting in the Automotive Refinishing Industry (U.S. EPA, 2014b; OECD, 2011b). These documents have a medium data quality rating based on the systematic review process. EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment. EPA assessed media of release using assumptions from the ESD, GS, and EPA/OPPT models and a default assumption that all paints and coatings are applied via spray application. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DCHP-specific data on concentration for different DCHP-containing paints and coatings in the analysis. These data provide more accurate estimates than the generic values provided by the GS and ESD. The safety and product data sheets that EPA obtained these values from have high and medium data quality ratings based on the systematic review process.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the GS and ESD may not represent releases from real-world sites that incorporate DCHP into paints and coatings. Additionally, EPA assumes spray applications of the coatings, which may not be representative of other coating application methods. In addition, EPA lacks data on DCHP-specific facility use volume and number of use sites; therefore, EPA based throughput estimates on values from ESD, GS, and CDR data which has a reporting threshold of 25,000 lb and an annual DCHP production volume range. EPA also lacked data for ready-to-apply coatings, and consequently assumed a concentration range for liquid coatings based on the SDS for one product. These limitations decrease the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of reasonably available data.
Use of laboratory chemicals	EPA found limited chemical specific data for the use of laboratory chemicals OES and assessed releases to the environment using the Draft GS on the Use of Laboratory Chemicals (U.S. EPA, 2023g), which has a high data quality rating based on systematic review. 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 DCHP materials. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allows for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. 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 DCHP products to inform product concentration and material states. These strengths increase the weight of evidence.
	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 DCHP-specific laboratory chemical throughput and number of laboratories; therefore, EPA based the number of laboratories and throughput estimates on stock solution throughputs from the GS on the Use of Laboratory Chemicals (U.S. EPA, 2023c) and on CDR reporting thresholds. Additionally, because no entries in CDR indicate a laboratory use and there were no other sources to estimate the volume of DCHP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold of 25,000 lb or 5% of total product volume for a given use, which by definition is expected to overestimate the average release case. These limitations decrease the weight of evidence.
	provides a plausible estimate of releases, considering the strengths and limitations of reasonably available data.
Fabrication or use of final products or articles	No data were available to estimate releases for this OES and there were no suitable surrogate release data or models. This release is described qualitatively.
Recycling	EPA found limited chemical specific data for the recycling OES. EPA assessed releases to the environment from recycling activities using the Revised Draft GS for the Use of Additives in Plastic Compounding (U.S. EPA, 2021d) as surrogate for the recycling process. The GS has a medium data quality rating based on systematic review. EPA/OPPT models were combined with Monte Carlo modeling to estimate releases to the environment. 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 referenced the <i>Quantification and Evaluation of Plastic Waste in the United States</i> , which has a medium quality rating based on systematic review (Milbrandt et al., 2022), to estimate the rate of PVC recycling in the United States. EPA estimated the DCHP PVC market share (based on the surrogate market shares from DINP and DIDP) to define an approximate recycling volume of PVC containing DCHP. These strengths increase the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values and release points in the GS represent all types of plastic compounding sites and may not represent sites that recycle PVC products containing DCHP. In addition, EPA lacks DCHP-specific PVC recycling rates and facility production volume data; therefore, EPA based throughput estimates on PVC plastics compounding data and U.S. PVC recycling rates, which are not specific to DCHP, and may not accurately reflect current U.S. recycling volume. DCHP may also be present in non-PVC plastics that are recycled; however, EPA was unable to identify information on these recycling practices. These limitations decrease the weight of evidence.
	provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Waste handling, treatment, and disposal	No data were available to estimate releases for this OES and there were no suitable surrogate release data or models. This release is described qualitatively.
Distribution in commerce	These releases are assessed as part of individual OESs where the relevant activities occur.

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3.2.3 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the Environmental Release Assessment

Manufacturers and importers of DCHP 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 volume information in CDR. As a result, some sites that produce or use DCHP may not be included in the CDR data set and the total production volume for a given OES may be under or overestimated. The extent to which sites that are not captured in the CDR reports release DCHP into the environment is unknown. The media of release for these sites is also unknown.

- 915
- 916 CDR information on the downstream use of DCHP at facilities is also limited; therefore, there is some
- 917 uncertainty as to the production volume attributed to a given OES. For OES with limited CDR data,
- 918 EPA developed potential production volume ranges given reported CDR data, known reporting
- thresholds, and the national aggregate production volume of 500,000 to less than 1,000,000 lb for DCHP
- 920 in 2019. The Agency used the potential production volume ranges as uniform distributions in Monte
- 921 Carlo modeling when assessing releases for each OES. Due to the wide range of potential production 922 volumes attributable to certain OES, the overall releases may be over or underestimated. DCHP releases
- volumes attributable to certain OES, the overall releases may be over or underestimated. DCHP releasesat each site may vary from day to day, such that on any given day the actual daily release rate may be
- higher or lower than the estimated average daily release rate.
- 925
- The EPA has further identified the following additional uncertainties that contribute to the overalluncertainty in the environmental release assessment:
- Use of Census Bureau data for Number of Facilities In some cases, EPA determined the maximum number of facilities for a given OES (for use in Monte Carlo modeling) from industry data from the U.S. Census Bureau, County and Business Patterns data set (U.S. Census Bureau, 2022).
- Uncertainties Associated with Facility Throughputs EPA estimated facility throughputs of DCHP or DCHP-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 DCHP 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 For most OESs, EPA estimated the number of release days using data from GSs, ESDs, or SpERC factsheets. 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 DCHP-specific facility operations, release days may be under or overestimated.
- Uncertainties Associated with DCHP-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 DCHP concentrations for products in the OES. However, the extent to which these products represent all DCHP-containing products within the OES is uncertain. For OESs with little-to-no product data, EPA estimated DCHP concentrations from GSs or ESDs. Due to these uncertainties, the average product concentrations may be under or overestimated.

3.3 Summary of Concentrations of DCHP in the Environment

950 Based off the environmental release assessment summarized in Section 3.2 and detailed in EPA's Draft 951 Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) 952 (U.S. EPA, 2024q), DCHP is expected to be released to the environment via air, water, biosolids, and 953 disposal to landfills. Environmental media concentrations were quantified in ambient air, sediment, and 954 surface water. Additional analysis of surface water used as drinking water was conducted for the Human 955 Health Risk Assessment (see Section 4.1.3). EPA relied on its fate assessment to determine which 956 environmental pathways to consider for its screening level analysis of environmental exposure and 957 general population exposure to environmental releases. Details on the environmental partitioning and 958 media assessment can be found in Draft Physical Chemistry and Fate and Transport Assessment for 959 Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024z). Briefly, based on DCHP's fate parameters (e.g., Henry's Law constant, log Koc, water solubility, fugacity modeling), EPA anticipated DCHP to be 960 predominantly in water, soil, and sediment. Soil concentration of DCHP from land applications were not 961 962 quantitatively assessed in the screening level analysis as DCHP was expected to have limited persistence potential and mobility in soils receiving biosolids. 963

964

965 Further detail on the screening-level assessment of each environmental pathway can be found in EPA's Draft Environmental Media, General Population, and Environmental Exposure Assessment for 966 967 Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p). Because of limited environmental monitoring data and lack of location data for DCHP releases, EPA began its environmental and general population 968 969 exposure assessment with a screening-level approach using the highest modeled environmental media 970 concentrations for the environmental pathways expected to be of greatest concern. The highest 971 environmental media concentrations were estimated using the release estimates for an OES associated 972 with a COU that, paired with conservative assumption of environmental conditions, resulted in the 973 greatest modeled concentration of DCHP in a given environmental medium type. Therefore, EPA did 974 not estimate environmental concentrations of DCHP resulting from all OES presented in Table 3-1. 975

976 The OES resulting in the highest environmental concentration of DCHP varied by environmental media 977 as shown in Table 3-6. PVC plastics compounding with or without consideration of wastewater treatment efficiency yielded the highest water concentrations using a 7Q10 flow,¹ 30Q5 flow,² and 978 979 harmonic mean.³ The Application of paints, coatings, adhesives, and sealants OES yielded the highest 980 ambient air concentration. The summary table also indicates whether the high-end estimate was used for 981 environmental or general population exposure assessment. For the screening-level analysis, if the high-982 end environmental media concentrations did not result in potential environmental or human health risk, 983 no further OESs were assessed and no further refinements were pursued. For the surface water and 984 ambient air pathways, only the OESs resulting in the highest estimated water column or ambient air 985 concentrations were carried forward to the human health risk assessment (i.e., Plastic compounding for 986 water and Application of paints, coatings, adhesives, and sealants for ambient air).

¹ 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 (<u>Versar, 2014</u>).

 $^{^{2}}$ 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 (Versar, 2014).

³ 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.

OES ^{<i>a</i>}	Release Media	Environmental Media	DCHP Concentration	Environmental or General Population
		Total water column (7Q10, ^b median flow)	165 µg/L	Environmental
		Total water column (7Q10, p75 flow)	5.56 μg/L	Environmental
PVC plastics compounding without wastewater treatment	Watan	Total water column (7Q10, p90 flow)	0.57 μg/L	Environmental
	Water	Median 7Q10 (benthic pore water)	95.3 μg/L	Not carried forward to environmental risk assessment ^c
		Median 7Q10 (benthic sediment)	112,000 μg/kg	Not carried forward to environmental risk assessment ^c
PVC plastics compounding	Watan	Surface water (30Q5, ^{<i>d</i>} median flow)	126 µg/L	General population
without wastewater treatment	Water	Surface water (harmonic mean, ^e median flow)	87.7 μg/L	General Population
PVC plastics compounding	Watan	Surface water (30Q5, median flow)	39.6 μg/L	General population
with wastewater treatment	Water	Surface water (harmonic mean, median flow)	27.5 μg/L	General population
Application of	Engitive cir	Daily-averaged total (fugitive and stack, 100 m)	67.57 μg/m ³	General population
paints, and coatings	Fugitive air	Annual-averaged total (fugitive and stack, 100 m)	46.28 μg/m ³	General population

Table 3-6. Summary of High-End DCHP Concentrations in Various Environmental Media from Environmental Releases

^{*a*} Table 3-1 provides the crosswalk of OES to COUs.

^b7Q10 is the 7 consecutive days of lowest flow over a 10-year period.

^{*c*} See Section 4.4 for further details.

^d 30Q5 is defined as 30 consecutive days of lowest flow over a 5-year period

^{*e*} Harmonic mean is defined as the inverse mean of reciprocal daily arithmetic mean flow values. These flows represent a long-term average.

990

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, General Population, and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024p). However, the weight of scientific evidence conclusion is
 summarized below for the modeled DCHP concentrations in surface water, sediment, and ambient air.

996

3.3.1.1 Surface Water

997 Due to the lack of release data for facilities discharging DCHP to surface water, releases to water were

998 modeled as described in Section 3.2. The high-end estimate of releases to water for each COU was

applied for surface water modeling as part of a conservative screening-level assessment. Additionally,

- 1000 due to a lack of site-specific release information, a generic distribution of hydrologic flows was
- 1001 developed from facilities which had been classified under relevant North American Industry
- 1002 Classification System (NAICS) codes, and which had National Pollutant Discharge Elimination System

- 1003 (NPDES) permits. The flow rates were selected from the generated distributions and coupled with high-
- 1004 end (95th percentile) release scenarios. EPA assumed higher releases are generally correlated with 1005 higher receiving water body flows. EPA generally has moderate confidence in the modeled
- 1005 Inglief receiving water body nows. EFA generally has moderate confidence in the modeled 1006 concentrations as being representative of actual releases, with greater confidence in the modeled
- 1007 scenarios where high-end release amounts are paired with high-end flow rates. Additionally, EPA has
- 1008 robust confidence that no surface water release scenarios exceed the high-end concentrations presented
- 1009 *in this evaluation, which have been applied as screening values.* Other model inputs were derived from
- 1010 reasonably available literature collected and evaluated through EPA's systematic review process for
- 1011 TSCA risk evaluations. All monitoring and experimental data included in this analysis were from
- 1012 articles rated "medium" or "high" quality from this process.
- 1013
- 1014 The high-end modeled concentrations in the surface water and sediment identified through systematic
- 1015 review exceeded the highest values available from monitoring studies by more than three orders of
- 1016 magnitude. This confirms EPA's expectation that modeled concentrations presented here are biased
- 1017 toward overestimation, and thus appropriate to be applied as a screening-level evaluation in the
- 1018 environmental and general population exposure to environmental releases assessment.
- 1019 **3.3.1.2** Ambient Air

1020 Similar to the surface water analysis, due to the lack of release data, releases to ambient air were 1021 modeled using generic scenarios, and the high-end estimates of releases to ambient air for each COU 1022 were applied for ambient air modeling. The uncertainties associated with the release data are detailed in the Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate 1023 (DCHP) (U.S. EPA, 2024q). However, EPA has robust confidence in using the IIOAC (Integrated 1024 1025 Indoor-Outdoor Air Calculator) modeling in the ambient air exposure assessment because its approach 1026 and methodology were derived from peer-reviewed models and incorporate extensive feedback received 1027 from the Science Advisory Committee on Chemicals. Due to the conservative assumptions made with 1028 the use of high-end estimates, EPA has robust confidence that its modeled releases used for estimating 1029 ambient air concentrations are appropriately conservative for a screening-level analysis.

1030 4 HUMAN HEALTH RISK ASSESSMENT

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

EPA evaluated all reasonably available information to support human health risk characterization of DCHP for workers, ONUs, consumers, bystanders, and the general population, including PESS. 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.

Exposure Key Points

- EPA assessed inhalation and dermal exposures for workers and ONUs, as appropriate, for each OES (Section 4.1.1). The primary route of exposure was inhalation.
- EPA assessed inhalation, dermal, and oral exposures for consumers and bystanders, as appropriate, for each TSCA COU (Section 4.1.2) in scenarios that represent a range of use patterns and behaviors. The primary route of exposure was dermal for most products, followed by inhalation.
- EPA assessed inhalation, oral, and dermal exposures for the general population via ambient air, surface water, drinking water, and fish ingestion for Tribal populations and determined that all exposures assessed for the general population were not of concern (Sections 4.1.3 and 4.3.4).
- 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 consistent with a disruption of androgen action, leading to phthalate syndrome, as the most sensitive and robust non-cancer hazard associated with oral exposure to DCHP in experimental animal models (Section 4.2).
- A non-cancer POD of 2.4 mg/kg-day was selected to characterize non-cancer risks for acute, intermediate, and chronic durations of exposure. A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure.
- 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). Given its limited toxicological data set, scaling by the RPF and application of the index chemical POD provides a more sensitive and robust dose-response assessment than the DCHP-specific POD.

Risk Assessment Key Points

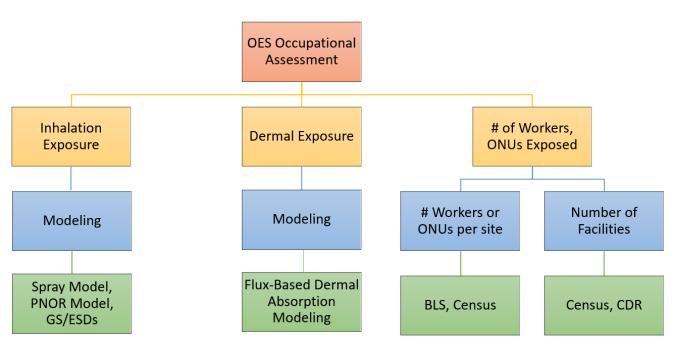
- Dermal and ingestion exposures were not a risk driver for any duration of exposure or population.
- Inhalation exposures drive acute non-cancer risks to workers in occupational settings (Section 4.3.2).
- No potential non-cancer risk was identified for consumers (Section 4.3.3).
- No potential non-cancer risk was identified for the general population.
- EPA considered combined exposure across all routes of exposure for each individual occupational and consumer COU to calculate aggregate risks (Sections 4.3.2 and 4.3.3). No potential aggregate risk was identified for consumer COUs.
- EPA considered cumulative risk to workers and consumers through exposure to DCHP 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).
- EPA considered PESS throughout the exposure assessment, hazard identification, and dose-response analysis supporting this draft risk evaluation (Section 4.3.5).

1031 **4.1 Summary of Human Exposures**

1032 **Occupational Exposures** 4.1.1 The following subsections briefly describe EPA's approach to assessing occupational exposures and 1033 1034 provide exposure assessment results for each OES. As stated in the final scope document (U.S. EPA, 1035 2020b), the Agency evaluated exposures to workers and ONUs via the inhalation route—including 1036 incidental ingestion of inhaled dust and exposures to workers via the dermal route from direct contact 1037 with DCHP. Also, EPA accounted for dermal exposure to workers and ONUs from mist and dust 1038 deposited on surfaces. The Draft Environmental Release and Occupational Exposure Assessment for 1039 Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q) provides additional details on the development of 1040 approaches and the exposure assessment results. 1041 1042 4.1.1.1 Approach and Methodology 1043 As described in the final scope document for DCHP (U.S. EPA, 2020b), EPA distinguished exposure 1044 levels among potentially exposed employees for workers and ONUs. In general, the primary difference between workers and ONUs is that workers may handle DCHP and have direct contact with DCHP, 1045 1046 while ONUs work in the general vicinity of DCHP but do not handle DCHP. Where possible, for each 1047 COU, EPA identified job types and categories for workers and ONUs. 1048 1049 As discussed in Section 3.1.1.1, EPA established OESs to assess the exposure scenarios within each 1050 COU. Table 3-1 provides a crosswalk between COUs and OESs. EPA did not identify relevant 1051 chemical-specific inhalation exposure monitoring data for the OESs. In the absence of inhalation 1052 monitoring data, EPA used inhalation exposure models to estimate both central tendency and high-end exposures. For inhalation exposure to dust in occupational settings, EPA used the data and approaches 1053 1054 from the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) (U.S. EPA, 2021b). In all cases of 1055 1056 occupational dermal exposure to DCHP, EPA used a flux-limited dermal absorption model to estimate 1057 high-end and central tendency dermal exposures for workers in each OES, as described in the Draft 1058 Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) 1059 (U.S. EPA, 2024q). 1060 1061 EPA evaluated the quality of the models and data sources using the data quality review evaluation 1062 metrics and the rating criteria described in the Draft Systematic Review Protocol (U.S. EPA, 2021a). 1063

1063 The Agency assigned an overall quality level of high, medium, or low to the relevant data. In addition, 1064 EPA established an overall confidence level for the data when integrated into the occupational exposure 1065 assessment. The Agency considered the assessment approach, the quality of the data and models, and 1066 uncertainties in assessment results to assign an overall weight of scientific evidence rating of robust,

1067 moderate, or slight.



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Figure 4-1. Approaches Used for Each Component of the Occupational Assessment for Each OES
 CDR = Chemical Data Reporting; GS = Generic Scenario; ESD = Emission Scenario Document; BLS = Bureau
 of Labor Statistics; PNOR = Particulates not Otherwise Regulated.

1073

1074 For inhalation and dermal exposure routes, EPA provides occupational exposure results representative of both central tendency and high-end exposure conditions. The central tendency is expected to 1075 1076 represent occupational exposures in the center of the distribution for a given COU. For this risk 1077 evaluation, EPA used the 50th percentile (median), mean (arithmetic or geometric), mode, or midpoint 1078 value of a distribution to represent the central tendency scenario. Although the Agency preferred to 1079 report the 50th percentile of the distribution, if the full distribution was unknown, EPA used either the 1080 mean, mode, or midpoint of the distribution to represent the central tendency depending on the statistics available for the distribution. The high-end exposure is expected to represent occupational exposures 1081 that occur at probabilities above the 90th percentile, but below the highest exposure for any individual 1082 1083 (U.S. EPA, 1992). For this draft risk evaluation, EPA reported high-end results at the 95th percentile. If 1084 the 95th percentile was not reasonably available, the Agency used a different percentile greater than or 1085 equal to the 90th percentile but less than or equal to the 99th percentile-depending on the data that was 1086 available for the distribution. If the full distribution is not known and the preferred statistics were not 1087 reasonably available, EPA estimated a maximum or bounding estimate in lieu of the high-end. Table 4-1 1088 provides a summary of the approach used to assess worker and ONU exposures and the Agency's 1089 weight of scientific evidence rating for the given exposure assessments.

1090 Table 4-1. Summary of Exposure Monitoring and Modeling Data for Occupational Exposure Scenarios

				0	Inhalatio	n Exposure	•	•	-		Der	mal Exposure	
OES		Mo	onitorin	g		Modeling		Weight of Scientific Evidence Conclusion		Modeling		Weight of Scientific Evidence Conclusion	
015	Worker	# Data Points	ONU	# Data Points	Data Quality Ratings	Worker	ONU	Worker	ONU	Worker	ONU	Worker	ONU
Manufacturing	×	N/A	×	N/A	N/A	✓	√	Moderate	Moderate	✓	\checkmark	Moderate	Moderate
Import and repackaging	×	N/A	×	N/A	N/A	~	1	Moderate	Moderate	~	~	Moderate	Moderate
Incorporation into adhesives and sealants	×	N/A	×	N/A	N/A	~	~	Moderate	Moderate	~	1	Moderate	Moderate
Incorporation into paints and coatings	×	N/A	×	N/A	N/A	•	1	Moderate	Moderate	~	1	Moderate	Moderate
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	×	N/A	×	N/A	N/A	~	~	Moderate	Moderate	~	√	Moderate	Moderate
PVC plastics compounding	×	N/A	×	N/A	N/A	~	1	Moderate	Moderate	~	~	Moderate	Moderate
PVC plastics converting	×	N/A	×	N/A	N/A	~	~	Moderate	Moderate	~	~	Moderate	Moderate
Non-PVC material compounding	×	N/A	×	N/A	N/A	√	1	Moderate	Moderate	~	\checkmark	Moderate	Moderate
Non-PVC material converting	×	N/A	×	N/A	N/A	~	1	Moderate	Moderate	~	~	Moderate	Moderate
Application of adhesives and sealants	×	N/A	×	N/A	N/A	~	√	Moderate	Moderate	~	1	Moderate	Moderate
Application of paints and coatings	×	N/A	×	N/A	N/A	•	√	Moderate	Moderate	~	1	Moderate	Moderate
Use of laboratory chemicals	×	N/A	×	N/A	N/A	~	1	Moderate	Moderate	~	1	Moderate	Moderate

						Dermal Exposure							
OES	Monitoring			Mod	Modeling Weight of Scientific Evidence Conclusion			Mode	eling	Weight of Scientific Evidence Conclusion			
	Worker	# Data Points	ONU	# Data Points	Data Quality Ratings	Worker ONU		Worker	ONU	Worker	ONU	Worker	ONU
Fabrication or use of final products or articles	×	N/A	×	N/A	N/A	~	~	Moderate	Moderate	~	~	Moderate	Moderate
Recycling	×	N/A	×	N/A	N/A	~	√	Moderate	Moderate	✓	1	Moderate	Moderate
Waste handling, treatment, and disposal	×	N/A	×	N/A	N/A	~	√	Moderate	Moderate	✓	~	Moderate	Moderate
Distribution in Commerce ^{<i>a</i>}	×	N/A	×	N/A	N/A	×	×	N/A	N/A	×	×	N/A	N/A
^a Activities related	to distribut	ion (<i>e.g.</i> , loa	ading, u	nloading)	are consid	lered throug	ghout the D	OCHP life cycle	e, as well as qu	ualitatively	through a	a single distribu	tion scenario.

4.1.1.2 Summary of Number of Workers and ONUs

1093 The Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate 1094 (DCHP) (U.S. EPA, 2024q) provides a summary of the estimates of the number of exposed workers and ONUs for each OES. To prepare these estimates, EPA first identified relevant NAICS Codes for each 1095 1096 OES. For these NAICS codes, the Standard Occupational Classification (SOC) codes from the Bureau of 1097 Labor Statistics (BLS) were used to classify SOC codes as either workers or ONUs. The Agency assumed that all other SOC codes represent occupations where exposure is unlikely. EPA also estimated 1098 the total number of facilities associated with the relevant NAICS Codes based on data from the U.S. 1099 Census Bureau. To estimate the average number of potentially exposed workers and ONUs per site, the 1100 total number of workers and ONUs were divided by the total number of facilities. The Draft 1101 Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) 1102 1103 (U.S. EPA, 2024q) provides additional details on the approach and methodology for estimating the number of facilities using DCHP as well as the number of potentially exposed workers and ONUs. 1104 1105 1106 Table 4-2 summarizes the number of facilities and total number of exposed workers for all OESs. For

- 1106 Table 4-2 summarizes the number of facilities and total number of exposed workers for all OESs. For 1107 scenarios in which the results are expressed as a range, the low end of the range is based on the 50th 1108 percentile estimate of the number of sites and the upper end of the range is based on the 95th percentile 1109 estimate of the number of sites.
- 1110

1092

1111 Table 4-2. Summary of Total Number of Workers and ONUs Potentially Exposed to DCHP for 1112 Each OES

OES	Total Exposed Workers ^{a b}	Total Exposed ONUs ^{a b}	Number of Facilities ^{a b}	Notes
Manufacturing	77	36	2	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Import and repackaging	40	18	2	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>). Averaged for two NAICS codes identified.
Incorporation into adhesives and sealants	90–162	35–126	5–9	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Incorporation into paints and coatings	280–476	70–170	20–34	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>).
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	561–1,122	264–528	11–21	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau,

OES	Total Exposed Workers ^{<i>a b</i>}	Total Exposed ONUs ^{a b}	Number of Facilities ^{a b}	Notes
				2015). Averaged for two NAICS codes identified.
PVC plastics compounding	135–243	60–108	5–9	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>).
PVC plastics converting	756–1,206	210–335	42–67	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>).
Non-PVC material compounding	46–92	12–24	2-4	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016</u> ; <u>U.S. Census Bureau</u> , <u>2015</u>). Averaged for three NAICS codes identified.
Non-PVC material converting	46–92	12–24	2-4	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015). Averaged for three NAICS codes identified.
Application of adhesives and sealants	336–4,480	108–1,440	6–80	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015). Averaged for 18 NAICS codes identified.
Application of paints and coatings	12–168	6-84	1–14	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015). Averaged for 10 NAICS codes identified.
Use of laboratory chemicals (liquid)	36,873	331,857	36,873	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>). Averaged for two NAICS codes identified.
Use of laboratory chemicals (solid)	1,978–25,643	17,802– 230,787	1,978–25,643	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>). Averaged for two NAICS codes identified.

OES	Total Exposed Workers ^{a b}	Total Exposed ONUs ^{a b}	Number of Facilities ^{a b}	Notes
Fabrication or use of final products or articles		N/A		Number of sites data was unavailable for this OES. Based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015), the average exposed workers per site was 9, and the average exposed ONUs per site was 3.
Recycling	754	432	58	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>). Averaged for three NAICS codes identified.
Waste handling, treatment, and disposal	754	432	58	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S.</u> <u>BLS, 2016; U.S. Census Bureau,</u> <u>2015</u>). Averaged for three NAICS codes identified.
				g DCHP and the number of workers tal Release and Occupational

Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q). ^b When there is a range, the low end of the range is based on the 50th percentile estimate of the number of sites and the upper end is based on the 95th percentile estimate of the number of sites.

1113 1114

4.1.1.3 Summary of Inhalation Exposure Assessment

1115 Table 4-3 presents a summary of inhalation exposure results based on exposure modeling for each OES. 1116 This tables provides a summary of the 8-hour time weighted average (8-hour TWA) inhalation exposure 1117 estimates for the average adult worker, as well as the Acute Dose (AD), the Intermediate Average Daily 1118 Dose (IADD), and the Chronic Average Daily Dose (ADD). The Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q) provides 1119 exposure results specific to women of reproductive age and ONUs. The Draft Environmental Release 1120 and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) also provides additional 1121 1122 details regarding AD, IADD, and ADD calculations along with EPA's approach and methodology for

1123 estimating inhalation exposures.

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1124 Table 4-3. Summary of Average Adult Worker Inhalation Exposure Results for Each Occupational Exposure Scenario

			I	nhalation Es	stimates	(Average A	dult Worl	ker)		
OES		B-h TWA g/m ³)	PNOR 8-h TWA (mg/m ³)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	HE	СТ	HE	СТ	HE	СТ	HE	СТ	HE	СТ
Manufacturing	N/A	N/A	5.0	0.48	0.63	6.0E-02	0.46	4.4E-02	0.43	4.1E-02
Import and repackaging	N/A	N/A	3.0	0.13	0.38	1.6E-02	0.28	1.2E-02	0.26	9.3E-03
Incorporation into adhesives and sealants	N/A	N/A	5.0	0.48	0.63	6.0E-02	0.46	4.4E-02	0.43	4.1E-02
Incorporation into paints and coatings	N/A	N/A	5.0	0.48	0.63	6.0E-02	0.46	4.4E-02	0.43	4.1E-02
Incorporation into other formulations, mixtures, or reaction products	N/A	N/A	5.0	0.48	0.63	6.0E-02	0.46	4.4E-02	0.43	4.1E-02
PVC plastics compounding	N/A	N/A	4.7	0.23	0.59	2.9E-02	0.43	2.1E-02	0.40	1.8E-02
PVC plastics converting	N/A	N/A	2.1	0.10	0.26	1.3E-02	0.19	9.5E-03	0.18	7.8E-03
Non-PVC materials compounding	N/A	N/A	2.8	0.14	0.35	1.7E-02	0.26	1.3E-02	0.24	1.1E-02
Non-PVC materials converting	N/A	N/A	0.94	4.6E-02	0.12	5.8E-03	8.6E-02	4.2E-03	8.0E-02	3.5E-03
Application of paints and coatings (liquids)	8.84	0.422	N/A	N/A	1.11	5.3E-02	0.81	3.9E-02	0.76	3.6E-02
Application of paints and coatings (solids)	N/A	N/A	4.9	0.28	0.61	3.5E-02	0.45	2.6E-02	0.42	2.4E-02
Application of adhesives and sealants (liquids)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Application of adhesives and sealants (solids)	N/A	N/A	2.7	0.15	0.34	1.9E-02	0.25	1.4E-02	0.23	1.2E-02
Use of laboratory chemicals (liquids)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Use of laboratory chemicals (solids)	N/A	N/A	2.7	0.19	0.34	2.4E-02	0.25	1.7E-02	0.23	1.5E-02
Recycling	N/A	N/A	1.6	0.11	0.20	1.4E-02	0.14	9.9E-03	0.13	8.2E-03
Fabrication or use of final products or articles	N/A	N/A	0.81	0.09	0.10	1.1E-02	7.4E-02	8.3E-03	6.9E-02	7.7E-03
Waste handling, treatment, and disposal	N/A	N/A	1.6	0.11	0.20	1.4E-02	0.14	9.9E-03	0.13	8.2E-03

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4.1.1.4 Summary of Dermal Exposure Assessment

- 1127 Table 4-4 presents a summary of dermal exposure results for the average adult worker, which are based 1128 on both empirical dermal absorption data and dermal absorption modeling. The table includes the Acute
- on both empirical dermal absorption data and dermal absorption modeling. The table includes the Acute
 Potential Dose Rate (APDR) for occupational dermal exposure estimates, as well as the AD, IADD, and
- 1129 Potential Dose Rate (APDR) for occupational definal exposure estimates, as well as the AD, IADD, a 1130 Chronic ADD for the average adult worker. The *Draft Environmental Release and Occupational*
- 1131 *Exposure Assessment for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024q) provides exposure results
- 1132 for women of reproductive age and ONUs. The *Draft Environmental Release and Occupational*
- 1133 Exposure Assessment for Dicyclohexyl Phthalate (DCHP) provides additional details regarding AD,
- 1134 IADD, and ADD calculations along with EPA's approach and methodology for estimating dermal
- 1135 exposures.

1136 Table 4-4. Summary of Average Adult Worker Dermal Exposure Results for Each OES

	Dermal Estimates (Average Adult Worker)											
OES	Exposure Type		APDR (mg/day)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)			
	Liquid	Solid	HE	СТ	HE	СТ	HE	СТ	HE	СТ		
Manufacturing; Incorporation into adhesives and sealants; Incorporation into paints and coatings; Incorporation into other formulations, mixtures, or reaction products; Application of paints and coatings (solids); Use of laboratory chemicals (solids); Fabrication or use of final products or articles		Х	0.36	0.18	4.5E-03	2.3E-03	3.3E-03	1.7E-03	3.1E-03	1.5E-03		
Import and repackaging		Х	0.36	0.18	4.5E-03	2.3E-03	3.3E-03	1.7E-03	3.1E-03	1.3E-03		
PVC plastics compounding; PVC plastics converting; non-PVC materials compounding; non-PVC materials converting; Application of adhesives and sealants (solids); Recycling; Waste handling, treatment, and disposal		Х	0.36	0.18	4.5E-03	2.3E-03	3.3E-03	1.7E-03	3.1E-03	1.4E-03		
Application of paints and coatings (liquids); Use of laboratory chemicals (liquids)	Х		0.36	0.18	4.5E-03	2.3E-03	3.3E-03	1.7E-03	3.1E-03	1.5E-03		
Application of adhesives and sealants (liquids)	Х		0.36	0.18	4.5E-03	2.3E-03	3.3E-03	1.7E-03	3.1E-03	1.4E-03		
Abbreviations: AD = acute dose; ADD = average dai average daily dose	Abbreviations: $AD = acute dose; ADD = average daily dose; APDR = Acute Potential Dose Rate; CT = central tendency; HE = high-end; IADD = intermediate$											

1138	4.1.1.5 Weight of Scientific Evidence Conclusions for Occupational Exposure
1139	Judgment on the weight of scientific evidence is based on the strengths, limitations, and uncertainties
1140	associated with the exposure estimates. The Agency considers factors that increase or decrease the
1141	strength of the evidence supporting the exposure estimate—including quality of the data/information,
1142	applicability of the exposure data to the COU (including considerations of temporal and locational
1143	relevance) and the representativeness of the estimate for the whole industry. The best professional
1144	judgment is summarized using the descriptors of robust, moderate, slight, or indeterminant, in
1145	accordance with the Draft Systematic Review Protocol (U.S. EPA, 2021a). For example, a conclusion of
1146	moderate is appropriate where exposure data is generated from a generic model with high quality data
1147	and some chemical-specific or industry-specific inputs, such that the exposure estimate is a reasonable
1148	representation of potential sites within the OES. A conclusion of slight weight of scientific evidence is
1149	appropriate where there is limited information that does not sufficiently cover all potential exposures
1150	within the COU, and the assumptions and uncertainties are not fully known or documented. See the
1151	Draft Systematic Review Protocol for additional information on weight of scientific evidence
1152	conclusions. Table 4-5 provides a summary of EPA's overall confidence in its occupational exposure
1153	estimates for each of the OESs assessed.

1154 Table 4-5. Summary of Assumptions, Uncertainty, and Overall Confidence in Exposure Estimates by OES

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
Manufacturing	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the manufacturing OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Chemical Manufacturing NAICS code (NAICS code 325) to assess this OES, which EPA expects to be the most representative subset of the particulate data in the absence of chemical-specific data. EPA estimated the highest expected concentration of DCHP in particulates during manufacturing using DCHP concentration information from CDR reporters, which wa also rated high for data quality in the systematic review process (U.S. EPA, 2020a). These strengths increase the weight of scientific evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day and 250 exposure days per year based on continuous DCHP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure when compared to particulate exposures. This is based on DCHP's vapor pressure, and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Import and repackaging	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the import and repackaging OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Wholesale and Retail Trade NAICS codes (NAICS codes 42 through 45) to assess this OES, which EPA expects to be the most representative subset of the particulate data in the absence of chemical-specific data. EPA estimated the highest expected concentration of DCHP in particulates during import and repackaging using DCHP concentration information from CDR reporters, which was also rated high for data quality in the systematic review process (U.S. EPA, 2020a). These strengths increase the weight of evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day and 208 to 250 exposure days per year based on continuous DCHP exposure each working

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into adhesives and sealants	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the incorporation into adhesives and sealants OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Chemical Manufacturing NAICS code (NAICS code 325) to assess this OES, which EPA expects to be the most representative subset of the particulate data for chemical product manufacturing in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during adhesive and sealant manufacturing using DCHP concentration information from CDR reporters, which was also rated high for data quality in the systematic review process (U.S. EPA, 2020a). These strengths increase the weight of evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day and 250 exposure days per year based on continuous DCHP particulate exposure while unpacking DCHP received on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into paints and coatings	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the incorporation into paints and coatings OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Chemical Manufacturing NAICS code (NAICS code 325) to assess this OES, which EPA expects to be the most representative subset of the particulate data for chemical product manufacturing in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during paint and coating manufacturing using DCHP

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	concentration information from CDR reporters, which was also rated high for data quality in the systematic review process (U.S. <u>EPA, 2020a</u>). These strengths increase the weight of evidence. The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day and 250 exposure days per year based on continuous DCHP particulate exposure while unpacking DCHP received on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the incorporation into other formulations, mixtures, and reaction products not covered elsewhere OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Chemical Manufacturing NAICS code (NAICS code 325) to assess this OES, which EPA expects to be the most representative subset of the particulate data for chemical product manufacturing in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during formulation, mixture or other chemical product manufacturing using DCHP concentration information from CDR reporters, which was also rated high for data quality in the systematic review process (U.S. EPA, 2020a). These strengths increase the weight of evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day and 250 exposure days per year based on continuous DCHP particulate exposure while unpacking DCHP received on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
PVC plastics compounding	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for PVC plastics compounding OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Plastics and Rubber Manufacturing NAICS code (NAICS code 326) to assess this OES, which EPA expects to be the most representative subset of the particulate data for PVC plastic manufacturing in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during PVC plastic compounding using DCHP concentration information from CDR reporters, which was also rated high for data quality in the systematic review process (U.S. EPA, 2020a). These strengths increase the weight of evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while unpacking DCHP received on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year. The central tendency exposures use 223 days per year as the exposure, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
PVC plastics converting	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for PVC plastics converting OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Plastics and Rubber Manufacturing NAICS code (NAICS code 326) to assess this OES, which EPA expects to be the most representative subset of the particulate data for PVC plastic converting using plasticizer additive concentration information from the Use of Additives in Plastic Converting Generic Scenario that was rated medium for data quality in the systematic review process (U.S. EPA, 2004a). These strengths increase the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while handling DCHP-containing plastics on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year. The central tendency exposures use 219 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Non-PVC material compounding	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for non-PVC material compounding OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Plastics and Rubber Manufacturing NAICS code (NAICS code 326) to assess this OES, which EPA expects to be the most representative subset of the particulate data for non-PVC plastic or rubber manufacturing in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during non-PVC material compounding using DCHP concentration from CDR reporters, which was also rated high for data quality in the systematic review process (U.S. EPA, 2020a). These strengths increase the weight of evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while unpacking DCHP received on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year. The central tendency exposures use 227 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							
Non-PVC material converting	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for non-PVC material converting OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Plastics and Rubber Manufacturing NAICS code (NAICS code 326) to assess this OES, which EPA expects to be the most representative subset of the particulate data for non-PVC plastic and rubber product manufacturing in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during non-PVC material converting using rubber plasticizer concentration information from the Emission Scenario Document on Additives in Rubber Industry which has a medium rating for data quality in the systematic review process (OECD, 2004). These strengths increase the weight of evidence.							
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while handling DCHP-containing plastics or rubbers on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposures use 219 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							
Application of adhesives and sealants	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the application of adhesives and sealants OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used the entire respirable particulate data set from the generic model to assess this OES, since adhesives and sealants containing DCHP may be used in a variety of end-use industries. EPA estimated the highest expected concentration of DCHP in particulates during application of adhesives and sealants using SDSs and product data sheets from identified DCHP-containing adhesives and sealant products in solid form. These strengths increase the weight of evidence.							

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates							
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while handling DCHP-containing products on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposure suce 232 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment exceeded 250 days per year. The central tendency exposures use 232 days per year as the exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							
Application of paints and coatings	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. EPA used surrogate 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 exposure to DCHP in the liquid form (OECD, 2011a). EPA also used the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate, since DCHP may be received on site in solid form. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used the entire respirable particulate data set from the generic model to assess this OES, since paints and coatings containing DCHP may be used in a variety of end-use industries. EPA used SDSs and product data sheets from identified DCHP-containing products to identify product concentrations for the liquid spray and the solid particulate assessments. A strength of this approach is that both models (for solid particulate and for mist exposure) resulted in exposure estimates within an order of magnitude of each other. These strengths increase the weight of evidence.							
	The primary limitation is the lack of DCHP-specific monitoring data. Specifically, the ESD serves 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, and the generic model data represents particulate concentrations in air for solids handling exposures. EPA assumes spray applications of the coatings, so the estimates may not be representative of exposure during other coating application methods. Additionally, it is uncertain whether the substrates coated, and products used to generate the surrogate data are representative of those associated with DCHP-containing coatings. EPA only assessed mist or solid exposures to DCHP over a full 8-hour work shift to estimate the level of exposure, though other activities may result in exposures other than mist or solid particulate and application duration may be variable depending on the job site. EPA assessed 250 days of exposure per year based on workers applying coatings on every working day, however, application sites may use DCHP-containing coatings at much lower or variable frequencies. These limitations decrease the weight of evidence.							

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							
Use of laboratory chemicals	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for use of laboratory chemicals OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Professional, Scientific, and Technical Services NAICS code (NAICS code 54) to assess this OES, which EPA expects to be the most representative subset of the particulate data for use of laboratory chemicals in the absence of DCHP-specific data. EPA estimated the highest expected concentration of DCHP in particulates during laboratory use using SDSs and product data sheets from identified lab-grade chemicals. These strengths increase the weight of evidence.							
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while handling DCHP-containing products on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year. The central tendency exposures use 232 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment. EPA did not account for vapor inhalation exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP's vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							
Fabrication or use of final products or articles	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the fabrication or use of final products or articles OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Furniture and Related Product Manufacturing NAICS code (NAICS code 337) to assess this OES, which EPA expects to be the most representative subset of the particulate data for this OES. EPA estimated the highest expected concentration of DCHP in particulates during product fabrication using plasticizer additive concentration information from the Use of Additives in Plastic Converting Generic Scenario that has a medium rating for data quality from the systematic review process (U.S. EPA, 2004a). These strengths increase the weight of evidence.							

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates							
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. EPA also assumed eight exposure hours per day based on continuous DCHP particulate exposure while handling DCHP-containing products on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. EPA set the number of exposure days based on Monte Carlo modeling of the operating days from the release assessment, with a maximum number of working days capped at 250 days per year based on EPA default assumptions. The high-end exposures are based on 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year. The central tendency exposures use 232 days per year as the exposures, but vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures based on DCHP vapor pressure and the solid physical form assessed for this OES. These limitations decrease the weight of evidence.							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							
Recycling	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the recycling OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Administrative and Support and Waste Management and Remediation Services NAICS code (NAICS code 56) to assess this OES, which EPA expects to be the most representative subset of the particulate data for this OES. EPA estimated the highest expected concentration of DCHP in plastic using plasticizer additive concentration information from the Use of Additives in Plastic Converting Generic Scenario that has a medium rating for data quality from the systematic review process (U.S. EPA, 2004a). These strengths increase the weight of evidence.							
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. The high-end exposures use 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year, which is the expected maximum number of working days. The central tendency exposures use 223 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment. Also, it was assumed that each worker is potentially exposed for 8 hours per workday; however, it is uncertain whether this captures actual worker schedules and exposures. These limitations decrease the weight of evidence.							
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.							

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
Waste handling, treatment, and disposal	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the waste handling, treatment, and disposal OES. EPA utilized the PNOR Model (U.S. EPA, 2021b) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model were rated high for data quality from the systematic review process, and the model was built using OSHA CEHD data (OSHA, 2020). EPA used a subset of the respirable particulate data from the generic model identified with the Administrative and Support and Waste Management and Remediation Services NAICS code (NAICS code 56) to assess this OES, which EPA expects to be the most representative subset of the particulate data for this OES. EPA estimated the highest expected concentration of DCHP in plastic using plasticizer additive concentration information from the Use of Additives in Plastic Converting Generic Scenario that has a medium rating for data quality from the systematic review process (U.S. EPA, 2004a). These strengths increase the weight of evidence.
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DCHP is uncertain. Further, the model lacks metadata on worker activities. The high-end exposures use 250 days per year as the exposure frequency since the 95th percentile of operating days in the release assessment exceeded 250 days per year, which is the expected maximum number of working days. The central tendency exposures use 223 days per year as the exposure frequency based on the 50th percentile of operating days from the release assessment. Also, it was assumed that each worker is potentially exposed for 8 hours per workday; however, it is uncertain whether this captures actual worker schedules and exposures. These limitations decrease the weight of evidence.
Distribution in	and provides a plausible estimate of exposures.These exposures are assessed as part of individual OESs where the relevant activities occur.
commerce Dermal	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of
	scientific evidence conclusion for the dermal exposure estimates. EPA used dermal modeling of aqueous materials (U.S. EPA, 2023b, 2004b) to estimate occupational dermal exposures of DCHP to workers and ONUs. The modeling approach for determining the aqueous permeability coefficient was within the range of applicability given the physical and chemical parameters of DCHP, and the modeling approach received a medium rating through EPA's systematic review process. Additionally, the neat form of DCHP is a solid, the concentrated formulations are paste-like, and any liquid containing DCHP has very low concentrations; therefore, it is reasonable to assume that flux-limited absorption of aqueous DCHP serves as a reasonable upper bound for the dermal absorption of DCHP from occupational scenarios. Additionally, EPA assumed a standard 8-hour workday and that the chemical is contacted at least once per day. Because DCHP 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 DCHP from occupational dermal contact with materials containing DCHP may extend up to 8 hours per day (U.S. EPA, 1991). For average adult workers, the surface area of contact was assumed equal to the area of one hand (<i>i.e.</i> , 535 cm ²) for central tendency, or two hands (<i>i.e.</i> , 1,070 cm ²) for high-end

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	exposures (U.S. EPA, 2011a). The standard sources for exposure duration and area of contact received high ratings through EPA's systematic review process. These strengths increase the weight of evidence.
	EPA acknowledges that variations in chemical concentration and co-formulant components affect the rate of dermal absorption, and that these variations were not considered in the occupational dermal exposure assessment in favor of an upper bound dermal absorption estimate from flux-limited absorption of aqueous DCHP. Additionally, worker activity metadata used in the model, such as surface area of skin contact and exposure duration, are not facility or industry-specific and are meant to address generic dermal exposures in all OESs assessed. These limitations decrease the weight of evidence.
	The occupational dermal exposure assessment for contact with materials containing DCHP was based on dermal absorption modeling of aqueous DCHP, 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 is moderate and provides a plausible estimate of occupational dermal exposures.

4.1.1.5.1	Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for
	the Occupational Exposure Assessment

- 1158 EPA assigned overall confidence descriptions of high, medium, or low to the exposure assessments,
- based on the strength of the underlying scientific evidence. When the assessment is supported by robust evidence, the Agency's overall confidence in the exposure assessment is high; when supported by
- 1161 moderate evidence, EPA's overall confidence is medium; when supported by slight evidence, the
- 1162 Agency's overall confidence is low.
- 1163

1156 1157

1164 Strengths

The exposure scenarios and exposure factors underlying the inhalation and dermal assessment are supported by moderate to robust evidence. Occupational inhalation exposure scenarios were informed by moderate or robust sources of surrogate monitoring data or GSs/ESDs used to model the inhalation exposure concentration. Exposure factors for occupational inhalation exposure include duration of exposure, body weight, and breathing rate, which were informed by moderate to robust data sources.

- 1170
- 1171 A strength of the modeling assessment includes the consideration of variable model input parameters as
- 1172 opposed to using a single static value. Parameter variation increases the likelihood that the true
- 1173 occupational inhalation exposures fall within the range of modeled estimates. An additional strength is
- that all data that EPA used to inform the modeling parameter distributions have overall data quality
- 1175 ratings of either high or medium from EPA's systematic review process. Strengths associated with
- dermal exposure assessment are described in Table 4-5.

1178 Limitations

- 1179 The principal limitation of the exposure assessments is uncertainty in the representativeness of the data
- and models used, as there is no direct exposure monitoring data for DCHP in the literature from
- 1181 systematic review. A limitation of the modeling methodologies is that most of the model input data from
- 1182 GSs/ESDs, such as air speed or loss factors, are generic for the OESs and not specific to the use of
- 1183 DCHP within the OESs. Additionally, the selected generic models and data may not be representative of
- all chemical- or site-specific work practices and engineering controls. Limitations associated with
- 1185 dermal exposure assessment are described in Table 4-5.
- 1186

1187 Assumptions

- 1188 When determining the appropriate model for assessing exposures to DCHP, EPA considered the 1189 physical form of DCHP during different OESs. DCHP may be present in various physical forms such as
- 1190 a powder, mist, paste, or in solution during the various OESs. EPA assessed each respective OES
- 1191 assuming the physical form of DCHP based on available product data, CDR data, and information from
- applicable GSs/ESDs. The physical form of DCHP can influence exposures substantially, so EPA
- assumed DCHP is present in the physical form that is most prevalent and/or most protective for the
- 1194 given OES when assessing the exposures.
- 1195
- 1196 EPA calculated ADD values assuming workers and ONUs are regularly exposed during their entire
- 1197 working lifetime, which likely results in an overestimate. Individuals may change jobs during the course
- of their career such that they are no longer exposed to DCHP, and the actual ADD values become lower
- than the estimates presented. Assumptions associated with dermal exposure assessment are described in
- 1200 Table 4-5.
- 1201

1202 **Uncertainties**

- 1203 EPA addressed variability in inhalation models by identifying key model parameters and applying 1204 statistical distributions that mathematically define the parameter's variability. The Agency defined 1205 statistical distributions for parameters using documented statistical variations where available. Where 1206 the statistical variation was unknown, EPA made assumptions to estimate the parameter distribution
- 1207 using available literature data, such as GSs and ESDs. However, there is uncertainty as to the
- 1208 representativeness of the parameter distributions because these data are often not specific to sites that
- 1209 use DCHP. In general, the effects of these uncertainties on the exposure estimates are unknown as the
- 1210 uncertainties may result in either overestimation or underestimation of exposures depending on the
- 1211 actual distributions of each of the model input parameters. Uncertainties associated with dermal 1212 exposure assessment are described in Table 4-5.
- 1213

1214 There are several uncertainties surrounding the estimated number of workers potentially exposed to 1215 DCHP. First, BLS' OES employment data for each industry/occupation combination are only available

- 1216 at the 3-, 4-, or 5-digit NAICS level, rather than the full 6-digit NAICS level. This lack of granularity
- 1217 could result in an overestimate of the number of exposed workers if some 6-digit NAICS are included in
- 1218 the less granular BLS estimates but are not likely to use DCHP for the assessed applications. EPA
- 1219 addressed this issue by refining the OES estimates using total employment data from the U.S. Census'
- 1220 Statistics of U.S. Businesses (SUSB). However, this approach assumes that the distribution of
- 1221 occupation types (SOC codes) in each 6-digit NAICS is equal to the distribution of occupation types at 1222 the parent 5-digit NAICS level. If the distribution of workers in occupations with DCHP exposure
- 1223 differs from the overall distribution of workers in each NAICS, then this approach will result in
- 1224 inaccuracy.

1225

Consumer Exposures 4.1.2

1226 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 1227 Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c) provides additional details on the 1228 1229 development of approaches and the exposure assessment results. The consumer exposure assessment 1230 evaluated exposures from individual COUs while the indoor dust assessment uses a subset of consumer 1231 articles with large surface area and presence in indoor environments to garner COU specific 1232 contributions to the total exposures from dust.

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4.1.2.1 Summary of Consumer and Indoor Dust Exposure Scenarios and Modeling **Approach and Methodology**

1235 The main steps in performing a consumer exposure assessment are summarized below: 1236

- Identification and mapping of product and article examples following the consumer COU table • (Table 1-1), product, and article identification.
- Compilation of products and articles manufacturing use instructions to determine patterns of use.
- Selection of exposure routes and exposed populations according to product/article use descriptions.
 - Identification of data gaps and further search to fill gaps with studies, chemical surrogates or • product and article proxies, or professional judgement.
- 1244 Selection of appropriate modeling tools based on available information and chemical properties. •
- 1245 • Gathering of input parameters per exposure scenario.
- 1246 • Parameterization of selected modeling tools.

1247 Consumer products or articles containing DCHP were matched with the identified consumer COUs.

- Table 4-6 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
- 1249 exposure routes, which scenarios are also used in the indoor dust assessment, and whether the analysis 1250 was conducted qualitatively or quantitatively. The indoor dust assessment uses consumer products and
- 1251 articles information for selected items with the goal of recreating the indoor environment. The subset of
- 1252 consumer products and articles that can be used in the indoor dust assessment are selected for their
- 1253 potential to have large surface area for dust collection, roughly larger than one square meter. Using these 1254 criteria, EPA did not identify articles in the modeling exposure estimates to include in the indoor
- 1255

assessment.

1256

1257 When a quantitative analysis was conducted, exposure from the consumer COUs was estimated by 1258 modeling. Exposure via inhalation and ingestion routes were modeled using EPA's Consumer Exposure 1259 Model (CEM), Version 3.2 (U.S. EPA, 2023b). Dermal exposures were estimated using a computational framework implemented within a spreadsheet environment. For each exposure route, EPA used the 10th 1260 1261 percentile, average, and 95th percentile value of an input parameter (*e.g.*, weight fraction, surface area) 1262 where possible to characterize low, medium, and high exposure scenarios for a given COU. If only a 1263 range was reported, EPA used the minimum and maximum of the range as the low and high values, 1264 respectively. The average of the reported low and high values from the reported range was used for the 1265 medium exposure scenario. See Draft Consumer and Indoor Dust Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c) for details about the consumer modeling 1266

approaches, sources of data, model parameterization, and assumptions.

- 1269 Exposure via the inhalation route occurs from inhalation of DCHP gas-phase emissions or when DCHP 1270 partitions to suspended particulate from direct use or application of products. However, DCHP's low 1271 volatility is expected to result in negligible gas-phase inhalation exposures. Sorption to suspended and 1272 settled dust is likely to occur based on monitoring data (see indoor dust monitoring data in Section 4.1.2.1) and its affinity for organic matter which is typically present in household dust. Thus, inhalation 1273 1274 and ingestion of suspended and settled dust is considered in this assessment. Exposure via the dermal 1275 route can occur from direct contact with products and articles. Exposure via ingestion depends on the 1276 product or article use patterns. Exposure can occur via direct mouthing (*i.e.*, directly putting product in 1277 mouth) in which the person can ingest settled dust with DCHP, or directly ingesting DCHP from 1278 migration to saliva. Additionally, ingestion of suspended dust can occur when DCHP migrates from 1279 product to dust or partitions from gas-phase to suspended dust.
- EPA labeled CEM lifestages to match those listed in the U.S. Centers for Disease Control and
 Prevention (CDC) guidelines (CDC, 2021) and the Agency's A Framework for Assessing Health Risks
 of Exposures to Children (U.S. EPA, 2006). CEM lifestages were re-labeled as follows:
- 1284 Adult (21+ years) \rightarrow Adult
- 1285 Youth 2 (16–20 years) \rightarrow Teenager
- 1286 Youth 1 (11–15 years) \rightarrow Young teen
- 1287 Child 2 (6–10 years) \rightarrow Middle childhood
- 1288 Child 1 (3–5 years) \rightarrow Preschooler
- 1289 Infant 2 (1–2 years) \rightarrow Toddler
- 1290 Infant 1 (<1 year) \rightarrow Infant

EPA assessed acute, intermediate, and chronic exposures to DCHP from consumer COUs. For the acute dose rate calculations, an averaging time of 1 day is used representing the maximum time-integrated dose over a 24-hour period during the exposure event. The chronic dose rate is calculated iteratively at a 30-second interval during the first 24 hours and every hour after that for 60 days. Intermediate dose is

- 1295 the exposure to continuous or intermittent (depending on product) use during a 30-day period, which is
- 1296 roughly a month. Professional judgment and product use descriptions were used to estimate events per
- 1297 day and per month/year for the calculation of the intermediate/chronic dose.

1298 Table 4-6. Summary of Consumer COUs, Exposure Scenarios, and Exposure Routes

	Consumer COU Subcategory	Product/Article		Evaluated Routes						
Consumer COU Category				8 -		Ingestion				
			Exposure Scenario and Route	Suspended Dust & Vapor Inhalation	Dermal	Suspended Dust	Settled Dust	Mouthing	Qualitative / Quantitative ^d	
Adhesives and sealants	Adhesives and sealants	Auto or construction bonding adhesive	Use of product in DIY ^{<i>a</i>} large-scale home repair activities. Direct contact during use; inhalation of emissions during use	~	~	×	*	×	Quantitative	
Adhesives and sealants	Adhesives and sealants	Adhesives for small repairs	Use of product in DIY ^{<i>a</i>} small-scale home repair activities. Direct contact during use	×	~	×	×	×	Quantitative	
Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Small articles with the potential for semi-routine contact: labels, nitrocellulose; ethylcellulose; chlorinated rubber; PVAc; PVC	Direct contact during use	X b	~	×	*	×	Quantitative	
Other	Other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	Outdoor coated surfaces/seating	Direct contact during use	x c	√	×	×	×	Quantitative	

				Evaluated Routes						
Consumer COU Category	Consumer COU Subcategory	Product/Article		8		Ingestion				
			Exposure Scenario and Route	Suspended Dust & Vapor Inhalation	Dermal	Suspended Dust	Settled Dust	Mouthing	Qualitative / Quantitative ^d	
Other	Other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	Small articles with the potential for semi-routine contact: labels, and packaging adhesives, foil and cellophane lacquers, and printing inks	Direct contact during use	X b	~	X	×	×	Quantitative	
Other	Other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	Electronics containing dye adhesive	No exposures expected	×	×	×	×	×	Qualitative	
Disposal	Disposal	Down the drain products and articles	Down the drain and releases to environmental media	×	×	×	×	×	Qualitative	
Disposal	Disposal	Residential end-of-life disposal, product demolition for disposal	Product and article end- of-life disposal and product demolition for disposal	×	×	×	×	×	Qualitative	

DIY^a – Do-it-Yourself

 \checkmark Scenario is considered either qualitatively or quantitatively in this assessment.

* Scenario was deemed unlikely based on low volatility and small surface area, likely negligible gas and particle phase concentration for inhalation, low possibility of mouthing based on product use patterns and targeted population age groups, and/or low possibility of dust on surface due to barriers or low surface area for dust ingestion.

x^{*b*} Scenario was deemed unlikely based on low volatility and small surface area and likely negligible gas and suspended particle phase concentration.

 \mathbf{x}^{c} Outdoor use with significantly higher ventilation minimizes inhalation.

^d Quantitative applies to green check marks and qualitative applies to red "x" marks for the routes that were deemed unlikely.

1300 Inhalation and Ingestion Exposure Routes Modeling Approaches

- 1301 Key parameters for articles modeled in CEM 3.2 are summarized in detail in Section 2 in the *Draft*
- 1302 Consumer and Indoor Dust Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA,
- 1303 <u>2024c</u>). Calculations, information and data sources, input parameters, and results are available in the
- 1304 Draft Consumer Exposure Analysis for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024d). Generally,
- and when possible, model parameters were determined based on specific articles identified in this
- 1306 assessment and CEM defaults were only used where specific information was not available. A list of 1307 some of the most sensitive input parameters for exposure from articles and products are listed below:
- weight fraction (articles and products);
- density (articles and products);
- duration of use (products);
- frequency of use for chronic, acute, and intermediate (products);
- product mass used (products);
- article surface area (articles);
- chemical migration rate to saliva (articles);
- 1315 area mouthed (articles); and
- use environment volume (articles and products).

1317 Low, medium, and high intensity use exposure scenarios correspond to the use of reported statistics, or 1318 single values. When different values are reported for low, medium, and high, the corresponding statistics 1319 are the reported minimum for the low intensity use scenarios, calculated average from maximum and 1320 minimum for the medium intensity use scenarios and reported maximum for the high intensity use 1321 scenarios. Each input parameter listed above was parameterized according to the article-specific data 1322 found via systematic review. If article-specific data were not available, CEM default parameters were 1323 used, or an assumption based on article use descriptions by manufactures always leaning on the health 1324 protective values. For example, for all scenarios, the near-field modeling option was selected to account 1325 for a small personal breathing zone around the user during product use in which concentrations are 1326 higher, rather than employing a single well-mixed room. A near-field volume of 1 m³ was selected. See 1327 Section 2.1 for weight fraction selection and Section 2.2.3 for parameterization details in the Draft 1328 Consumer and Indoor Dust Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 1329 2024c).

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1331 Dermal Exposure Routes Modeling Approaches

1332 Dermal modeling was done outside of CEM. The use of the CEM model for dermal absorption, which relies on total concentration rather than aqueous saturation concentration, would greatly overestimate 1333 1334 exposure to DCHP in liquid and solid products and articles. See (U.S. EPA, 2024c) for more details. The 1335 dermal dose of DCHP associated with use of both liquid products and solid articles was calculated in a spreadsheet outside of CEM. See the Draft Consumer Exposure Analysis for Dicyclohexyl Phthalate 1336 1337 (DCHP) (U.S. EPA, 2024d) for details. For each product or article, high, medium, and low exposure 1338 scenarios were developed. Values for duration of dermal contact and area of exposed skin were 1339 determined based on the reasonably expected use for each item. In addition, high, medium, and low 1340 estimates for dermal exposures using a flux-limited approach were calculated and applied in the 1341 corresponding exposure scenario. Key parameters for the dermal model are shown in Section 2.3 in 1342 (U.S. EPA, 2024c).

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4.1.2.2 Modeling Dose Results by COU for Consumer and Indoor Dust

1344 This section summarizes the dose estimates from inhalation, ingestion, and dermal exposure to DCHP in 1345 consumer products and articles. Detailed tables of the dose results for acute, intermediate, and chronic 1346 exposures are available in *Draft Consumer Risk Calculator for Dicyclohexyl Phthalate (DCHP)* (U.S.

1347 EPA, 2024e). Modeling dose results for acute, intermediate, and chronic exposures and data patterns are 1348 described in Section 3 in the Draft Consumer and Indoor Dust Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c). Generally, dermal exposures were overall highest followed by 1349 1350 inhalation across scenarios, COUs and lifestages. The range of inhalation doses for each scenario and 1351 lifestage covered several orders of magnitude due to the wide range of DCHP content (weight fractions) 1352 for adhesives, wide range of article exposure durations, and various skin contact surface area options for 1353 the low, medium, and high scenarios. The dermal dose range was smaller for all scenarios driven 1354 primarily by exposure durations and frequencies.

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1356 The spread of values estimated for each product or article reflects the aggregate effects of variability and 1357 uncertainty in key modeling parameters for each item; acute dose rate for some products and articles 1358 covers a larger range than others primarily due to a wider distribution of DCHP weight fraction values 1359 and behavioral factors such as duration of use or contact time and mass of product used as described in 1360 Section 2 in (U.S. EPA, 2024c). Key differences in exposures among lifestages include designation as a 1361 product user or bystander; behavioral differences such as hand to mouth contact times, and time spent on 1362 the floor; and dermal contact expected from touching specific articles which may not be appropriate for 1363 some lifestages.

4.1.2.3 Weight of Scientific Evidence Conclusions for Consumer Exposure

1365 Key sources of uncertainty for evaluating exposure to DCHP in consumer goods and strategies to address those uncertainties are described in detail in Section 5.1 of Draft Consumer and Indoor Dust 1366 Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c). Generally, designation of 1367 1368 robust confidence suggests thorough understanding of the scientific evidence and uncertainties. The 1369 supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that 1370 the uncertainties could have a significant effect on the exposure estimate. The designation of moderate 1371 confidence suggests some understanding of the scientific evidence and uncertainties. More specifically, 1372 the supporting scientific evidence weighed against the uncertainties is reasonably adequate to 1373 characterize exposure estimates. The designation of slight confidence is assigned when the weight of 1374 scientific evidence may not be adequate to characterize the scenario, and when the assessor is making 1375 the best scientific assessment possible in the absence of complete information and there are additional 1376 uncertainties that may need to be considered. While the uncertainty for some of the scenarios and parameters ranges from slight to robust the overall confidence to use the results for risk characterization 1377 1378 ranges from moderate to robust, depending on COU scenario. The basis for the moderate to robust 1379 confidence in the overall exposure estimates is a balance between using parameters that will represent 1380 various populations use patterns and lean on protective assumptions that are not excessive or 1381 unreasonable.

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

1384 The exposure assessment of chemicals from consumer products and articles has inherent challenges due 1385 to many sources of uncertainty in the analysis, including variations in product formulation, patterns of 1386 consumer use, frequency, duration, and application methods. Variability in environmental conditions 1387 may also alter physical and/or chemical behavior of the product or article. Table 4-7 summarizes the 1388 overall uncertainty per COU and provides a discussion of rationale used to assign the overall 1389 uncertainty. The subsections ahead of the table describe sources of uncertainty for several parameters 1390 used in consumer exposure modeling that apply across COUs and provide an in depth understanding of 1391 sources of uncertainty and limitations and strengths within the analysis. The confidence to use the results 1392 for risk characterization ranges from moderate to robust (Table 4-7).

1394 **Product Formulation and Composition**

1395 Variability in the formulation of consumer products-including changes in ingredients, concentrations, 1396 and chemical forms—can introduce uncertainty in exposure assessments. In addition, data were limited 1397 for weight fractions of DCHP in consumer goods. EPA obtained DCHP weight fractions in various 1398 products and articles from material safety sheets, databases, and existing literature. Where possible, the 1399 Agency obtained multiple values for weight fractions for similar products or articles. The lowest value 1400 was used in the low exposure scenario, the highest value in the high exposure scenario, and the average 1401 of all values in the medium exposure scenario. EPA decreased uncertainty in exposure and subsequent 1402 risk estimates in the high, medium, and low intensity use scenarios by capturing the weight fraction variability and obtaining a better characterization of the products' and articles' varying composition 1403 1404 within one COU. Overall weight fraction confidence is *moderate* for products/articles with only one 1405 source with descriptions on chemical testing, *robust* for products/articles with more than one source, and 1406 *slight* for articles with only one source with unconfirmed content or little understanding on how the 1407 information was produced. For example, when a source does not provide a description of the analysis or 1408 the concentrations are derived from product production approaches rather than product testing.

1409

1410 **Product Use Patterns**

- 1411 Consumer use patterns like frequency of use, duration of use, and methods of application are expected to
- 1412 differ. Where possible, high, medium, and low default values from CEM 3.2's prepopulated scenarios
- were selected for mass of product used, duration of use, and frequency of use. In instances where no 1413
- 1414 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. EPA decreased 1415 1416
- uncertainty by selecting use pattern inputs that represent product and article use descriptions and 1417 furthermore capture the range of possible use patterns in the high to low intensity use scenarios.
- 1418 Exposure and risk estimates are considered representative of product use patterns and well characterized.
- 1419 Most use patterns' overall confidence is rated robust.
- 1420

1421 Article Surface Area

1422 The surface area of an article directly affects the potential for DCHP emissions to the environment. For 1423 each article modeled for inhalation exposure, low, medium, and high estimates for surface area were 1424 calculated (see Section 2 in (U.S. EPA, 2024c)). Overall, confidence in surface area is robust for articles 1425 because there is a good understanding of the dimensions of articles and their presence in indoor environments.

1426

1427

- 1428 Human Behavior
- 1429 CEM 3.2 has three different human activity patterns: stay-at-home, part-time out-of-the home (daycare,
- 1430 school, or work), and full-time out-of-the-home. The activity patterns were developed based on the
- 1431 Consolidated Human Activity Database (CHAD). For all products and articles modeled, the stay-at-
- 1432 home activity pattern was selected as it is the most protective assumption.
- 1433

1434 Modeling Tool

- 1435 Confidence in the model used considers whether the model has been peer-reviewed, as well as whether
- 1436 it is being applied in a manner appropriate to its design and objective. The model used, CEM 3.2, has
- 1437 been peer-reviewed (ERG, 2016), is publicly available, and has been applied in the manner intended by
- 1438 estimating exposures associated with uses of household products and/or articles. This also considers the
- 1439 default values data source(s) such as building and room volumes, interzonal ventilation rates, and air
- 1440 exchange rates. Overall confidence in the proper use of CEM and the consumer exposure estimates
- 1441 results modeled is *robust*.
- 1442

1443 Dermal Modeling for DCHP

- Experimental dermal data was identified via the systematic review process to characterize consumer dermal exposures to liquids or mixtures and formulations containing DCHP (see Section 2.3.1 in (U.S. <u>EPA, 2024c</u>). EPA has moderate understanding of the scientific evidence and the uncertainties. The identification of uncertainties within the dermal approach is reasonably adequate to characterize exposure estimates. The Agency has a *moderate* confidence in the dermal exposure to liquid and solid products or articles modeling approach.
- 1450

1451 A source of uncertainty regarding the dermal absorption of DCHP from products or formulations stems 1452 from the varying concentrations and co-formulants that exist in products or formulations containing 1453 DCHP. For purposes of this draft risk evaluation, EPA assumes that the absorptive flux of DCHP serves 1454 as an upper bound of chemical into and through the skin for dermal contact with all liquid products or 1455 formulations and solid products/articles. Dermal contact with products or formulations that have lower 1456 concentrations of DCHP might exhibit lower rates of flux since there is less material available for 1457 absorption. Conversely, co-formulants or materials within the products or formulations may lead to 1458 enhanced dermal absorption, even at lower concentrations. Therefore, it is uncertain whether the 1459 products or formulations containing DCHP would result in decreased or increased dermal absorption. 1460 Based on the available dermal absorption data for DCHP, EPA has made assumptions that result in

- 1461 exposure assessments that are the most human health protective in nature.
- 1462

1463 Lastly, EPA notes that there is uncertainty with respect to the modeling of dermal absorption of DCHP from solid matrices or articles and liquid products and formulations. Because there were no available 1464 1465 data related to the dermal absorption of DCHP from solid matrices or articles and liquid products, EPA 1466 has assumed that dermal absorption of DCHP from solid objects would be limited by aqueous solubility 1467 of DCHP. Therefore, to determine the maximum steady-state aqueous flux of DCHP, EPA utilized CEM 1468 (U.S. EPA, 2023b) to first estimate the steady-state aqueous permeability coefficient of DCHP. The 1469 estimation of the steady-state aqueous permeability coefficient within CEM (U.S. EPA, 2023b) is based 1470 on a quantitative structure-activity relationship (QSAR) model presented by ten Berge (2009), which 1471 considers chemicals with $\log(K_{ow})$ ranging from -3.70 to 5.49 and molecular weights ranging from 18 to 1472 584.6. The molecular weight of DCHP falls within the range suggested by ten Berge (2009), as does the 1473 $\log(K_{ow})$ of DCHP. Therefore, there is a low to medium (due to assumptions used in migration of DCHP) 1474 from solid to aqueous media) uncertainty regarding the accuracy of the QSAR model used to predict the 1475 steady-state aqueous permeability coefficient for DCHP.

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
Adhesives and	Two different scenarios were assessed under this COU for products with	Inhalation –
sealants	differing use patterns for which each scenario had a varying number of identified product examples (in parentheses): adhesives for small repairs	Robust
	(2) and automotive adhesives (3). The two scenarios and the products	Dermal –
	within capture the variability in product formulation and are represented	Moderate
	in the high, medium, and low intensity use estimates. The overall	
	confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of	
	use.	
	For dermal exposure EPA used a dermal flux approach; moderate confidence was selected for this approach because uncertainty in the	

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	partitioning from product to skin and subsequent dermal absorption is not well characterized or confirmed with experimental results. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence in a health protective estimate moderate.	
Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	One scenario was assessed under this COU. The scenario considered multiple articles and routine dermal contact with similar use patterns. The scenario for small articles of routine dermal contact was assessed for dermal exposures only because inhalation and ingestion would have low exposure potential due to the small surface area of the articles. The articles with routine contact scenario considered multiple input parameters used in the high, medium, and low intensity use scenarios. The dermal absorption estimate assumes that dermal absorption of DCHP from solid objects would be limited by the aqueous solubility of DCHP. EPA has slight confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. However, other parameters, such as frequency and duration of use as well as surface area in contact, are well understood and representative, resulting in an overall confidence of moderate in a health protective estimate.	Dermal – Moderate
Other; Other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	Two different scenarios were assessed under this COU for articles with differing use patterns. The scenarios of outdoor seating (single article in use), and small articles with potential for routine contact (multiple articles) were evaluated. These two scenarios were assessed for dermal exposures. Dermal absorption estimates assumed that dermal absorption of DCHP from solid objects would be limited by the aqueous solubility of DCHP. EPA has slight confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. However, other parameters such as frequency and duration of use, and surface area in contact, are well understood and representative, resulting in an overall confidence of moderate in a health protective estimate.	Dermal – Moderate

1478

4.1.3 General Population Exposures to Environmental Releases

General population exposures occur when DCHP is released into the environment and the environmental media are then a pathway for exposure. As described in the *Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024q), releases of DCHP are expected in air, water, and disposal to landfills. Figure 4-2 provides a graphic representation of where and in which media DCHP is estimated to be found due to environmental releases and the corresponding route of exposure for the general population.

1485

EPA took a screening-level approach to assess DCHP exposure to environmental releases for the general
population. Screening level assessments are useful when there is little facility location- or scenariospecific information available. EPA began its DCHP general population exposure assessment using a

screening-level approach because of limited environmental monitoring data for DCHP and lack of

- 1490 location data for DCHP releases. A screening-level analysis relies on conservative assumptions,
- including default input parameters for modeling exposure, to assess exposures that would be expected tobe on the high end of the expected exposure distribution. Details on the use of screening-level analyses
- in exposure assessment can be found in EPA's *Guidelines for Human Exposure Assessment* (U.S. EPA,
- 1494 <u>2019b</u>).

EPA considered fenceline populations in proximity to releasing facilities as part of the ambient air
exposure assessment by utilizing pre-screening methodology 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, 2022b). For other exposure pathways, EPA's screening method assessing high-end
exposure scenarios used release data that reflect exposures expected to occur in proximity to releasing

- 1501 facilities, which would include fenceline populations.
- 1502

1503 EPA evaluated the reasonably available information for releases of DCHP from facilities that use,

1504 manufacture, or process DCHP under industrial and/or commercial COUs subject to TSCA regulations

detailed in the Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl

1506 *Phthalate (DCHP)* (U.S. EPA, 2024q). As described in Section 3.3, using the release data, EPA modeled

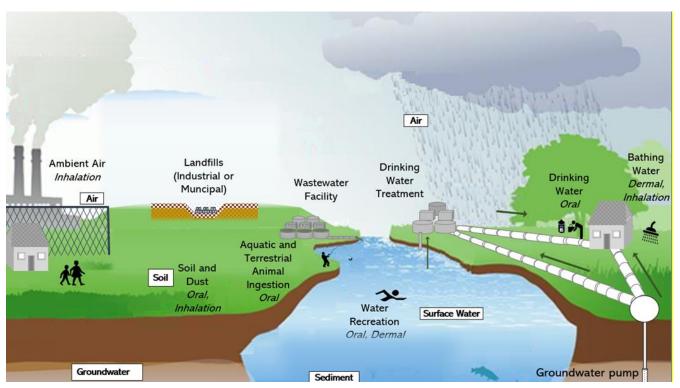
1507 predicted concentrations of DCHP in surface water, sediment, drinking water, and ambient air in the 1508 United States, Table 3.6 summarizes the high and DCHP concentrations in any improvemental media from

1508 United States. Table 3-6 summarizes the high-end DCHP concentrations in environmental media from

1509 environmental releases. The reason for assessing different pathways qualitatively or quantitatively is

discussed briefly in Section 3.3, and additional detail can be found in *Draft Environmental Media*,

- General Population, and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP)
 (U.S. EPA, 2024p).
- 1513



- 1515 Figure 4-2. Potential Human Exposure Pathways to DCHP Environmental Releases for the
- 1516 General Population
- 1517 Potential routes of exposure are shown in italics under each potential pathway of exposure.
- 1518

1519 High-end estimates of DCHP concentration in the various environmental media presented in Table 3-6 1520 and in the Draft Environmental Media, General Population, and Environmental Exposure Assessment 1521 for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p) were used for screening-level purposes in the 1522 general population exposure assessment. EPA's Guidelines for Human Exposure Assessment (U.S. EPA, 1523 2019b) defines high-end exposure estimates as a "plausible estimate of individual exposure for those 1524 individuals at the upper end of an exposure distribution, the intent of which is to convey an estimate of 1525 exposure in the upper range of the distribution while avoiding estimates that are beyond the true 1526 distribution." If risk is not found for these individuals with high-end exposure, no risk is anticipated for central tendency exposures, which is defined as "an estimate of individuals in the middle of the 1527 1528 distribution." Plainly, if there is no risk for an individual identified as having the potential for the highest 1529 exposure associated with a COU for a given pathway of exposure, then that pathway was determined not to be a pathway of concern and not pursued further. If any pathways were identified as a pathway of 1530 1531 concern for the general population, further exposure assessments for that pathway would be conducted 1532 to include higher tiers of modeling when available, refinement of exposure estimates, and exposure 1533 estimates for additional subpopulations and OES/COUs.

1534

1535 Identifying individuals at the upper end of an exposure distribution included consideration of high-end 1536 exposure scenarios defined as those associated with the industrial and commercial releases from a COU 1537 and OES that resulted in the highest environmental media concentrations. As described in Section 3.3, 1538 EPA focused on estimating high-end concentrations of DCHP from the largest estimated releases for the 1539 purpose of its screening level assessment for environmental and general population exposures. This 1540 means that the Agency considered the environmental concentration of DCHP in a given environmental 1541 medium resulting from the OES that had the highest release compared to any other OES for the same 1542 releasing media. Release estimates from OES resulting in lower environmental media concentrations 1543 were not considered for this screening-level assessment. Additionally, individuals with the greatest intake rate of DCHP per body weight were considered to be those at the upper end of the exposure. 1544

1545

1546 Table 4-8 summarizes the high-end exposure scenarios that were considered in the screening level 1547 analysis, including the lifestage assessed as the most potentially exposed population based on intake rate 1548 and body weight. It also indicates which pathways were evaluated quantitatively or qualitatively. 1549 Exposure was assessed quantitatively only when environmental media concentrations were quantified 1550 for the appropriate exposure scenario. For example, exposure from groundwater resulting from DCHP 1551 release to the environment via biosolids or landfills was not quantitatively assessed because 1552 environmental releases from biosolids and landfills were not quantified. Due to the high confidence in the biodegradation rates and physical and chemical data, there is robust confidence that DCHP in soils 1553 1554 will not be mobile and will have low persistence potential. There is robust confidence that DCHP is unlikely to be present in landfill leachates. However, exposure was still assessed qualitatively for 1555 1556 exposures potentially resulting from biosolids and landfills. Further details on the screening level 1557 approach and exposure scenarios evaluated by EPA for the general population are provided in the *Draft* Environmental Media, General Population, and Environmental Exposure Assessment for Dicyclohexyl 1558 1559 *Phthalate (DCHP)* (U.S. EPA, 2024p). Selected OESs represent those resulting in the highest modeled 1560 environmental media concentrations for the purpose of a screening-level analysis. A crosswalk between 1561 OESs and COUs is presented in Section 3.1.1.1.

OES Exposure Pathway		Exposure Route Exposure Scenario Lifestage			Analysis (Quantitative or Qualitative) ^{<i>a</i>}
All	Biosolids	No specific exposure scenarios were assessed for qualitative assessments			Qualitative Section 3.1
All	Landfills	No specific	exposure scenarios were qualitative assessments	assessed for	Qualitative Section 3.2
PVC plastics	Surface Water	Dermal	mal Dermal exposure to DCHP in surface water during swimming children		Quantitative Section 5.1.1
compounding		Oral	Incidental ingestion of DCHP in surface water during swimming	Adults, youths, and children	Quantitative Section 5.1.2
PVC plastics compounding	Drinking Water	Oral	8		Quantitative Section 6
All			Ingestion of fish for General Population	Adults and children	Quantitative Section 7.1
PVC plastics compounding	Fish Ingestion	Oral	Ingestion of fish for subsistence fishers	Adult	Quantitative Section 7.2
PVC plastics compounding			Ingestion of fish for Tribal populations	Adult	Quantitative Section 7.3
Application of paints, coatings, adhesives, and sealants	Ambient Air	Inhalation	Inhalation of DCHP in ambient air resulting from industrial releases	All	Quantitative Section 9

1563

Note the references are to sections in Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p) and not this document.

1564

EPA also considered urinary biomonitoring data, from CDC's National Health and Nutrition 1565

1566 Examination Survey (NHANES) (see Section 11 of EPA's Draft Environmental Media, General

1567 Population, and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA,

2024p)). The Agency analyzed urinary data for MCHP (mono-cyclohexyl phthalate, a metabolite of 1568

1569 DCHP) measured in the 1999 to 2010 NHANES cycle. Low detection rates and limited variability in

data precluded any meaningful statistical analyses. CDC stopped collecting urinary data for MCHP after 1570

1571 2010. Furthermore, EPA's systematic review process did not identify any suitable alternative sources of

1572 DCHP biomonitoring data fit for use in this risk evaluation Those studies were not considered because

1573 they used NHANES data, had very low (<30%) detection levels, evaluated very specific study

populations (e.g., a cohort examining specific health concerns), or were not measured in the United 1574

- 1575 States. Given the lack of recent urinary biomonitoring data, EPA did not conduct reverse dosimetry to
 - 1576 calculate daily intake values for DCHP.

1577

4.1.3.1 General Population Screening Level Exposure Assessment Results

1578 Land Pathway

1579 EPA evaluated general population exposures via the land pathway (*i.e.*, application of biosolids,

- 1580 landfills) qualitatively. Due to low water solubility (1.48 mg/L) and affinity for sorption to soil and
- 1581 organic constituents in soil (log Koc = 4.47), DCHP is unlikely to migrate to groundwater via runoff
- after land application of biosolids. Additionally, the half-life of 8.1 to 13.8 days in aerobic soils (U.S. 1582

1583 <u>EPA, 2024z</u>) indicates that DCHP will have low persistence potential in the aerobic environments

- associated with freshly applied biosolids. Because the physical and chemical properties of DCHP
 indicate that it is unlikely to migrate from land applied biosolids to groundwater via runoff, EPA did not
 model groundwater concentrations resulting from land application of biosolids.
- 1587

Although there are no measured data on DCHP in landfill leachates, the potential to leach from landfills into nearby groundwater or surface water systems is limited. Interpretation of the high-quality physical and chemical property data indicates that DCHP is expected to have a high affinity to particulate (log Koc = 4.47) and organic media (log Kow = 4.82). This will cause significant retardation in groundwater and limit leaching to groundwater. Because of its high hydrophobicity and high affinity for soil sorption,

1593 it is unlikely that DCHP will migrate from landfills via groundwater infiltration or surface runoff.

1594 Therefore, EPA concludes that further assessment of DCHP in landfill leachate is not needed.

1595

1596 Surface Water Pathway – Incidental Ingestion and Dermal Contact from Swimming

1597 EPA conducted modeling of releases to surface water at the point of release (*i.e.*, in the immediate water 1598 body receiving the effluent) to estimate the resulting environmental media concentrations from TSCA

1599 COUs. EPA conducted modeling with the U.S. EPA's Variable Volume Water Model with Point Source

- 1600 Calculator tool (PSC) to estimate concentrations of DCHP within surface water and to estimate settled
 - 1601 sediment in the benthic region of streams. Releases associated with the PVC plastics compounding OES
- 1602 resulted in the highest total water column concentrations, with 30Q5 water concentrations of 126 μ g/L
- 1603 without wastewater treatment and $39.6 \,\mu$ g/L when run under an assumption of 68.6 percent wastewater 1604 treatment removal efficiency (Table 4-9). Both treated and untreated scenarios were assessed due to
- uncertainty about the prevalence of wastewater treatment from discharging facilities and to demonstratethe hypothetical disparity in exposures between treated and untreated effluent in the generic release
- scenarios. COUs mapped to this OES are shown in Table 3-1. These water column concentrations were used to estimate the ADR from dermal exposure and incidental ingestion of DCHP while swimming for adults (2+ years), youths (11–15 years), and children (6–10 years). Exposure scenarios leading to the highest modeled ADR are shown in Table 4-9.
- 1611

1612 Surface Water Pathway – Drinking Water

For the drinking water pathway, modeled surface water concentrations were used to estimate drinking water exposures. For screening-level purposes, only the OES scenario resulting in the highest modeled

1615 surface water concentrations, PVC plastics compounding, was included in the drinking water exposure

- analysis. COUs mapped to this OES are shown in Table 3-1. EPA evaluated drinking water scenarios
- 1617 that assumed a wastewater treatment removal efficiency of 68.6 percent and no further drinking water
- 1618 treatment (Table 4-9). ADR and ADD values from drinking water exposure to DCHP were calculated
- 1619 for various age groups but the most exposed lifestage, infants (birth to <1 year), is shown below.
 1620 Exposure scenarios leading to the highest ADR and ADD are shown in Table 4-9.
- 1621

1622 Table 4-9. Summary of the Highest Doses in the General Population through Surface and Drinking Water Exposure

1623

OES^a	Water Column Concentrations	Incidental Dermal Surface Water ^b	Incidental Ingestion ^c	Drinking Water ^d	
	30Q5 Conc. (µg/L)	ADR _{POT} (mg/kg- day)	ADR _{POT} (mg/kg-day)	ADR _{POT} (mg/kg- day)	
PVC plastics compounding without wastewater treatment	126	1.1E-03	6.7E-04	1.8E-02	
PVC plastics compounding With Wastewater Treatment	39.6	3.50E-04	2.1E-04	5.6E-03	

^a Only this OES was used in the screening assessment because it resulted in the highest surface water concentrations. Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

^b Most exposed age group: Adults (21+ years)

^c Most exposed age group: Youth (11–15 years)

Most exposed age group: Infant (birth to <1 year)

1624

1625 Fish Ingestion

1626 The key parameters to estimate human exposure to DCHP via fish ingestion are the surface water

1627 concentration, bioaccumulation factor (BAF), and fish ingestion rate. Surface water concentrations for

1628 DCHP associated with a particular COU were modeled using VVWM-PSC as described in Section

1629 3.3.1.1. EPA used the PVC plastics compounding OES that resulted in the highest modeled DCHP

1630 concentrations in surface water, as well as various flow rates, in its screening-level analysis. The details

on the BAF, which considers the animal's uptake of a chemical from both diet and the water column, 1631

1632 can be found in Section 8 of the Draft Environmental Media, General Population, and Environmental

1633 *Exposure Assessment for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024p).

1634

1635 EPA evaluated exposure to DCHP through fish ingestion for populations and age groups that had the 1636 highest fish ingestion rate per kg of body weight—including for adults and young toddlers in the general

1637 population, adult subsistence fishers, and adult Tribal populations. Only the fish ingestion rate changes 1638 for across the different populations; the surface water concentration and BAF remain the same. ADR

1639 and ADD values from fish ingestion exposure to DCHP were calculated for various populations and age

1640 groups and can be found in Draft Environmental Media, General Population, and Environmental

Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p), but Table 4-10 shows 1641

1642 only the scenarios leading to the highest exposure.

Colordation Mathed	Current Mean Ingestion Rate ^b	Heritage Ingestion Rate ^b	
Calculation Method	ADR/ADD (mg/kg-day) ^a	ADR/ADD (mg/kg-day) ^a	
Water solubility limit (1.48 mg/L)	2.68E-01	2.04	
Modeled SWC for PVC plastics compounding, P50 flow (0.087 mg/L)	1.59E-02	1.21E-01	
Modeled SWC for PVC plastics compounding, P75 flow (3.48E–03 mg/L)	6.30E-04	4.80E-03	
Modeled SWC for PVC plastics compounding, P90 flow (2.4E–04 mg/L)	4.40E-05	3.35E-04	
Highest monitored SWC (1.0E-05 mg/L)	2.53E-06	1.93E-05	

. 1. 1 1644

SWC = surface water concentration

^a Current ingestion rate refers to the present-day consumption levels that are suppressed by contamination, degradation, or loss of access. Heritage rates existed prior to non-indigenous settlement on Tribal fisheries resources and changes to culture and lifeway.

^b The ADR and ADDs are identical because the inputs to estimating both exposure scenarios are identical.

1645

1646 Ambient Air Pathway

1647 As part of the ambient air exposure assessment, EPA considered exposures to the general population in proximity to releasing facilities, including fenceline communities, by utilizing pre-screening 1648

methodology described in EPA's Draft TSCA Screening Level Approach for Assessing Ambient Air and 1649

- 1650 Water Exposures to Fenceline Communities (Version 1.0) (U.S. EPA, 2022b). EPA used the IIOAC to
- estimate ambient air concentrations using pre-run results from a suite of dispersion scenarios in a variety 1651
- of meteorological and land-use settings within EPA's American Meteorological Society/EPA 1652
- Regulatory Model (AERMOD). The highest modeled 95th percentile annual ambient air concentration 1653
- across all release scenarios was $67.57 \,\mu g/m^3$ at 100 m from the releasing facility for the Application of 1654
- paints and coatings OES (Table 3-6). COUs mapped to this OES are shown in Table 3-1. This OES was 1655
- 1656 the only one assessed for the purpose of a screening-level assessment as it was associated with the
- 1657 highest ambient air concentration (see Section 13 of Draft Environmental Media, General Population,
- and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p) for 1658 1659 more details).
- 1660

Table 4-11. General Population Ambient Air Exposure Summary 1661

	Acute (Daily A	verage) ^b	Chronic (Annual Average) ^b		
OES ^a	Air Concentration ^c (µg/m ³)	AC (mg/kg-day)	Air Concentration ^c (µg/m ³)	ADC (mg/kg-day)	
Application of paints and coatings	67.57	67.57	46.28	46.28	

AC = acute concentration; ADC = average daily concentration

^a Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

^b EPA assumes the general population is continuously exposed (*i.e.*, 24 hours per day, 365 days per year) to outdoor ambient air concentrations. Therefore, daily average modeled ambient air concentrations are equivalent to acute exposure concentrations, and annual average modeled ambient air concentrations are equivalent to chronic exposure 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.

1662 1663

4.1.3.1 Overall Confidence in General Population Screening Level Exposure Assessment

1664 The weight of scientific evidence supporting the general population exposure to environmental releases 1665 estimate is decided based on the strengths, limitations, and uncertainties associated with the exposure estimates, which are discussed in detail for ambient air, surface water, drinking water, and fish ingestion 1666 1667 in the Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p). EPA summarized its weight of scientific evidence 1668 1669 using confidence descriptors: robust, moderate, slight, or indeterminate. The Agency used general 1670 considerations (*i.e.*, relevance, data quality, representativeness, consistency, variability, uncertainties) as 1671 well as chemical-specific considerations for its weight of scientific evidence conclusions.

1672

1673 EPA determined robust confidence in its qualitative assessment of biosolids and landfills. For its

quantitative assessment, the Agency modeled exposure due to various general population and
 environmental release exposure scenarios resulting from different pathways of exposure. Exposure

1676 estimates used high-end inputs for the purpose of risk screening. When available, monitoring data were

1677 compared to modeled estimates to evaluate overlap, magnitude, and trends. EPA has robust confidence

1678 that modeled releases used are appropriately conservative for a screening level-analysis. *Therefore, EPA*

1679 has robust confidence that no exposure scenarios will lead to greater doses than presented in this draft

1680 risk evaluation. Despite slight and moderate confidence in the estimated values themselves, confidence

1681 in exposure estimates capturing high-end exposure scenarios was robust given that many of the modeled

1682 *values exceeded those of monitored values.*

4.1.4 Human Milk Exposures

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

1691

1683

EPA identified two studies from Germany that measured DCHP concentrations in human milk. Neither
of the studies characterized the possibility of occupational exposure to DCHP. No U.S. biomonitoring
studies were identified. It is important to note that biomonitoring data do not distinguish between
exposure routes or pathways and do not allow for source apportionment. In other words, biomonitoring
data reflect total infant exposure through human milk ingestion and the contribution of specific TSCA
COUs to overall exposure cannot be determined.

1698

1699 Furthermore, no human health studies have evaluated only lactational exposure from quantified levels of 1700 DCHP in milk. Uncertainties in the toxic moiety for DCHP and the limited half-life data of its 1701 metabolites in the human body that are both sensitive and specific also precluded modeling human milk 1702 concentrations by COUs. However, EPA has robust confidence that not modeling human milk 1703 concentrations is still protective of a nursing infant because multigenerational studies were evaluated to 1704 derive the hazard values. The multigenerational studies observed the effects on offspring across at least 1705 three generations resulting from maternal exposure during lactation, gestation, and other exposure 1706 periods. The hazard values are thus expected to protect a nursing infant's greater susceptibility during 1707 this unique lifestage whether due to sensitivity or greater exposure per body weight. Further discussion

- 1708 of the human milk pathway is provided in the *Draft Environmental Media, General Population, and*
- 1709 Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p).

1710 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.

1714

1715 EPA defines aggregate exposure as "the combined exposures to an individual from a chemical substance 1716 across multiple routes and across multiple pathways (40 CFR 702.33)." For the draft DCHP risk

1717 evaluation, the Agency considered aggregate risk across all routes of exposure for each individual

1718 consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations.

1719 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. Based on results from the risk screen, no pathways of concern (*i.e.*, ambient air, surface water, drinking water, fish ingestion) to DCHP exposure were identified for the generation

- 1723 population.
- 1724

1725 EPA did not consider aggregate exposure scenarios across COUs because the Agency did not find any 1726 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

1728 combined exposure across all routes of exposure for each individual occupational and consumer COU to

1729 calculate aggregate risks (Sections 4.3.2 and 4.3.3).

1730

1750

1731 EPA defines sentinel exposure as "the exposure to a chemical substance that represents the plausible 1732 upper bound of exposure relative to all other exposures within a broad category of similar or related 1733 exposures (40 CFR 702.33)." In terms of this draft risk evaluation, EPA considered sentinel exposures 1734 by considering risks to populations who may have upper bound exposures; for example, workers and 1735 ONUs who perform activities with higher exposure potential, or consumers who have higher exposure 1736 potential or certain physical factors like body weight or skin surface area exposed. The Agency 1737 characterized high-end exposures in evaluating exposure using both monitoring data and modeling 1738 approaches. Where statistical data are available, EPA typically uses the 95th percentile value of the 1739 available data set to characterize high-end exposure for a given COU. For general population and 1740 consumer exposures, the Agency occasionally characterized sentinel exposure through a "high-intensity

1741 use" category based on elevated consumption rates, breathing rates, or user-specific factors.

1742 **4.2 Summary of Human Health Hazards**

1743 **4.2.1 Background**

This section briefly summarizes the non-cancer and cancer human health hazards of DCHP (Section
4.2.2 and 4.2.3). Additional information on the non-cancer and cancer human health hazards of DCHP
are provided in the *Draft Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate*(DCHP) (U.S. EPA, 2024v) and *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, 2025a).

4.2.2 Non-cancer Human Health Hazards of DCHP

1751 EPA identified effects on the developing male reproductive system as the most sensitive and robust non-1752 cancer hazard associated with oral exposure to DCHP in experimental animal models. Existing

1753 assessments of DCHP—including (<u>U.S. CPSC, 2014, 2010</u>), (<u>ECCC/HC, 2020</u>; <u>EC/HC, 2015</u>), (<u>ECHA</u>, 2014) and (<u>UCNAS</u>, 2016, 2008)

1754 <u>2014</u>), and (<u>NICNAS, 2016, 2008</u>)—also consistently identified effects on the developing male

reproductive system as a sensitive and robust non-cancer effect following oral exposure to DCHP. EPA

also considered epidemiologic evidence qualitatively as part of hazard identification and

characterization. However, epidemiologic evidence from the one DCHP study was not considered
 further for dose-response analysis due to limitations and uncertainties in exposure characterization that

are discussed further in the *Draft Non-cancer Human Health Hazard Assessment for Dicyclohexyl*

1760 *Phthalate (DCHP)* (U.S. EPA, 2024v). Use of epidemiologic evidence qualitatively is consistent with

- 1761 phthalates assessments by Health Canada and U.S. CPSC.
- 1762

1763 EPA is proposing a point of departure (POD) of 10 mg/kg-day (human equivalent dose [HED] of 2.4 mg/kg-day) based on phthalate syndrome-related effects on the developing male reproductive system 1764 (decreased fetal testicular testosterone; decreased AGD; Leydig cell effects; decreased mRNA and/or 1765 1766 protein expression of steroidogenic genes; decreased protein expression of INSL3) to estimate noncancer risks from oral exposure to DCHP for acute, intermediate, and chronic durations of exposure in 1767 1768 the draft risk evaluation of DCHP. The proposed POD is the most sensitive no-observed-adverse-effect 1769 level (NOAEL) and is further supported by one study reporting a NOAEL of 17 mg/kg-day (Hoshino et 1770 al., 2005) and four other studies reporting effects on the developing male reproductive system consistent 1771 with a disruption of androgen action and phthalate syndrome in rats at lowest-observed-adverse-effect 1772 (LOAELs) ranging from 20 to 33 mg/kg-day (Ahbab et al., 2017; Ahbab and Barlas, 2015; Furr et al., 1773 2014; Ahbab and Barlas, 2013). The Agency has performed ³/₄ body weight scaling to yield the HED and 1774 is applying the animal to human uncertainty factor (*i.e.*, interspecies uncertainty factor; UF_A) of 3 and 1775 the within human variability uncertainty factor an (*i.e.*, intraspecies uncertainty factor; UF_H) of 10. Thus, 1776 a total UF of 30 is applied for use as the benchmark MOE.

Overall, based on the strengths, limitations, and uncertainties discussed in the *Draft Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024v), EPA has robust *overall confidence in the proposed POD based on adverse effects on the developing male reproductive system (i.e., phthalate syndrome, which results from decreased fetal testicular testosterone). This POD will be used to characterize risk from exposure to DCHP for acute, intermediate, and chronic exposure scenarios.*

1784

1777

The applicability and relevance of this POD for all exposure durations (acute, intermediate, and chronic) is described in the *Draft Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate* (*DCHP*) (U.S. EPA, 2024v). For purposes of assessing non-cancer risks, the selected POD is considered most applicable to women of reproductive age, pregnant women, male infants, and male children. Use of this POD to assess risk for other age groups (*e.g.*, adult males, and the elderly) is considered to be conservative and appropriate for a screening-level assessment for these other age groups.

1791

No data are available for the dermal or inhalation routes that are suitable for deriving route-specific
PODs. Therefore, EPA is using the acute/intermediate/chronic oral POD to evaluate risks from dermal

exposure to DCHP. Differences between oral and dermal absorption are accounted for in dermal

exposure estimates in the draft risk evaluation for DCHP. For the inhalation route, EPA is extrapolating the oral HED to an inhalation human equivalent concentration (HEC) per EPA's *Methods for Derivation*

1796 the oral HED to an innalation numan equivalent concentration (HEC) per EPA's *Methods for Derivation* 1797 Of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994)

1798 using the updated human body weight and breathing rate relevant to continuous exposure of an

1799 individual at rest provided in EPA's *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011b). The

1800 oral HED and inhalation HEC values selected by EPA to estimate non-cancer risk from

1801 acute/intermediate/chronic exposure to DCHP in the draft risk evaluation of DCHP are summarized in

1802 Table 4-12.

Exposure Scenario	Target Organ System	Species	Duration	POD (mg/kg- day)	Effect at LOAEL	HED ^{<i>a</i>} (mg/ kg- day)	HEC ^a (mg/m ³) [ppm]	Benchmark MOE ^b	Reference
Acute,	Developing	Rat	10 days	NOAEL=	Phthalate	2.4	13	$UF_A = 3$	(<u>Li et al.,</u>
intermed.,	male		during	10 ^c	syndrome-related		[0.95]	$UF_{H}=10$	<u>2016</u>)
chronic	reproductive		gestation		effects (<i>e.g.</i> , \downarrow			Total	
	system				fetal testicular			UF=30	
					testosterone; \downarrow				
					AGD; Leydig				
					cell effects; ↓				
					mRNA and/or				
					protein				
					expression of				
					steroidogenic				
					genes; ↓INSL3)				

1804 **Table 4-12. Non-cancer HECs and HEDs Used to Estimate Risks**

HEC = human equivalent concentration; HED = human equivalent dose; MOE = margin of exposure; NOAEL = noobserved-adverse-effect level; LOAEL = lowest-observed-adverse-effect level; POD = point of departure; UF = uncertainty factor

^a HED and HEC values were calculated based on the most sensitive NOAEL of 10 mg/kg-day.

^{*b*} EPA used allometric body weight scaling to the ³/₄ power to derive the HED. Consistent with EPA Guidance (U.S. EPA, <u>2011c</u>), the interspecies uncertainty factor (UF_A), was reduced from 10 to 3 to account remaining uncertainty associated with interspecies differences in toxicodynamics. The Agency used a default intraspecies (UF_H) of 10 to account for variation in sensitivity within human populations.

^c Statistically significant effects at 10 mg/kg-day are limited to fetal Leydig cell effects, decreased expression of genes and proteins involved in steroidogenesis, and decreased protein expression of INSL3 (all of which are not considered adverse in isolation). The remaining effects listed reached statistical significance at higher doses.

1805 4.2.3 Cancer Human Health Hazards of DCHP

1806 DCHP has not been evaluated for carcinogenicity in any 2-year cancer bioassays. EPA therefore 1807 evaluated the relevance of read-across approaches to assess potential cancer hazards of DCHP based on 1808 cancer bioassays and MOA information available for other phthalates being evaluated under TSCA (*i.e.*, DEHP, DBP, BBP, DINP, DIDP) as discussed in the Draft Cancer Human Health Hazard Assessment 1809 for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), 1810 Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2025a). (Note: EPA 1811 plans to release the draft cancer assessment for peer review by the SACC and public comment in early 1812 1813 2025.)

1814

1815 EPA used elements of the Rethinking Chronic Toxicity and Carcinogenicity Assessment for

1816Agrochemicals Project (ReCAAP) weight of evidence framework (Hilton et al., 2022) to determine the1817need for carcinogenicity studies for DCHP. The framework takes into consideration multiple lines of

1818 evidence to support decision-making for the chemical(s) of interest—including information pertaining to

nomenclature, physical and chemical properties; exposure and use patterns; absorption, distribution,
metabolism, and excretion (ADME) properties; and toxicological data (*e.g.*, genetic toxicity, acute

1821 toxicity, subchronic toxicity, hormone perturbation, immunotoxicity, and mode of action [MOA]). The

1822 framework was developed by a workgroup comprising scientists from academia, government, non-

1823 governmental organizations, and industry stakeholders. Recently, the Organisation for Economic Co-

1824 operation and Development (OECD) developed several Integrated Approach to Testing and Assessment

1825 (IATA) case studies demonstrating applicability of the weight of evidence framework (OECD, 2024).

1826

1827 As part of this weight of evidence approach, human health hazard profiles for DCHP were evaluated and 1828 compared to profiles for five read-across chemicals, including DEHP, DBP, BBP, DINP, and DIDP

- (also referred to as "read-across phthalates" in this document). Overall, based on the weight of scientific
 evidence, EPA has preliminarily concluded that the non-cancer POD for DCHP based on effects on the
- 1831 developing male reproductive system consistent with a disruption of androgen action and phthalate
- 1832 syndrome that was selected for characterizing risk from acute, intermediate, and chronic exposure to
- 1833 DCHP is appropriate for use in human health risk assessment and is protective of human health,
- 1834 including for PESS. Furthermore, EPA preliminarily concludes that potential carcinogenicity of DCHP
- 1835 is not a significant remaining source of uncertainty in the quantitative and qualitative risk
- 1836 characterization, despite the lack of carcinogenicity bioassays for DCHP. Further, these preliminary
- 1837 conclusions are based on several key weight of scientific evidence considerations.
- 1838
- 1839 First, DCHP is toxicologically similar to DEHP, DBP, BBP, DINP, and DIBP and can induce
- 1840 antiandrogenic effects and disrupt fetal testicular testosterone biosynthesis in rats leading to a spectrum
- 1841 of effects on the developing male reproductive system consistent with phthalate syndrome. Second, for
- 1842 the five read-across phthalates, effects on the developing male reproductive system consistent with
- 1843 phthalate syndrome was the most sensitive and robust endpoint for deriving PODs for use in
- 1844 characterizing risk for acute, intermediate, and chronic exposure scenarios. The only exception to this
- 1845 was for DINP, in which chronic non-cancer liver effects were identified as a more sensitive outcome
- than developmental toxicity for deriving a chronic POD. Finally, although cancer classifications for the five read across phthelates very in polyces was concer found to be a rick driver.
- 1847 five read-across phthalates vary, in no case was cancer found to be a risk driver.

1848 4.3 Human Health Risk Characterization

1849

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.

1853 **Table 4-13. Exposure Scenarios, Populations of Interest, and Hazard Values**

- 4810 · 201 2	becharlos, i opulations of interest, and flazaru values			
	Workers			
	Male and female adolescents and adults (16+ years) and women of reproductive age directly			
	working with DCHP under light activity (breathing rate of 1.25 m ³ /h) (for further details see			
	(<u>U.S. EPA, 2024q</u>))			
	Exposure Durations			
	• Acute – 8 hours for a single workday			
	• Intermediate – 8 hours per workday for 22 days per 30-day period			
	• Chronic – 8 hours per workday for 250 days per year for 31 or 40 working years			
	Exposure Routes			
	Inhalation and dermal			
	Occupational Non-users			
	Male and female adolescents and adults (16+ years old) indirectly exposed to DCHP within the			
Population of Interest	same work area as workers (breathing rate of 1.25 m ³ /h) (for further details see (U.S. EPA,			
and Exposure Scenario	<u>2024q</u>))			
	Exposure Durations			
	• Acute, Intermediate, and Chronic – same as workers			
	Exposure Routes			
	• Inhalation, dermal (mist and dust deposited on surfaces)			
	Consumers			
	Male and female infants (<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 DCHP			
	through product or article use (for further details see (U.S. EPA, 2024c))			
	Exposure Durations			
	• Acute – 1 day exposure			
	• Intermediate – 30 days per year			

	• <i>Chronic</i> – 365 days per year
	Exposure Routes
	Inhalation, dermal, and oral
	Bystanders
	Male and female infants (<1 year), toddlers (1–2 years), and children (3–5 years and 6–10 years)
	incidentally exposed to DCHP through product use (for further details see (U.S. EPA, 2024c))
	Exposure Durations
	• <i>Acute</i> – 1 day exposure
	• Intermediate – 30 days per year
	• <i>Chronic</i> – 365 days per year
	Exposure Routes
	Inhalation
	General Population
	Male and female infants, children, youth, and adults exposed to DCHP through drinking water,
	surface water, ambient air, and fish ingestion (for further details see (U.S. EPA, 2024p))
Population of Interest	Exposure Durations
and Exposure Scenario	 Acute – Exposed to DCHP continuously for a 24-hour period Chronic – Exposed to DCHP continuously for up to 78 years
	Exposure Routes
	• Inhalation, dermal, and oral (depending on exposure scenario)
	National Population Children aged 3–5, 6–11 years, and 11 to <16 years; male and female adults 16+ years; and
	women 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>U.S. EPA, 2024ah</u>))
	Exposure Durations
	Durations not easily characterized in urinary biomonitoring studies
	• 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.
	Exposure Routes
	• NHANES urinary biomonitoring data provides an estimate of aggregate exposure (<i>i.e.</i> ,
	exposure through oral, inhalation, and dermal routes)
	Non-cancer Acute/Intermediate/Chronic Value
	Sensitive health effect: Developmental toxicity (i.e., effects on the developing male reproductive
	system including decreased fetal testicular testosterone; decreased AGD; Leydig cell effects;
	decreased mRNA and/or protein expression of steroidogenic genes; decreased protein expression
	of INSL3) (for further details see (U.S. EPA, $2024v$))
	HEC Daily, continuous = 13 mg/m^3 (0.95 ppm) HED Daily = 2.4 mg/kg-day ; dermal and oral
	Total UF (benchmark MOE) = $30 (UF_A = 3; UF_H = 10)$
	10 (defermine WOL) = 50 (01 A = 5, 01 H = 10)
Health Effects,	Hazard Relative Potency
Concentration and	Relative potency factors for DEHP, DBP, BBP, DIBP, DCHP, and DINP were derived based on
Time Duration	reduced fetal testicular testosterone. DBP was selected as the index chemical (for further details
	see (<u>U.S. EPA, 2024ah</u>)).
	$\text{RPF}_{\text{DEHP}} = 0.84$
	$RPF_{DBP} = 1$ (index chemical)
	$\operatorname{RPF}_{\operatorname{BBP}} = 0.52$
	$\operatorname{RPF}_{\operatorname{DIBP}} = 053$
	$RPF_{DCHP} = 1.66$ $PPE_{max} = 0.21$
	$RPF_{DINP} = 0.21$ Index chemical (DBP) POD = HED Daily = 2.1 mg/kg-day
	Total UF (benchmark MOE) = $30 (UF_A = 3; UF_H = 10)$
	10000 Or (00000000000000000000000000000000000

1854**4.3.1.1 Estimation of Non-cancer Risks from Exposure to DCHP**1855EPA used a margin of exposure (MOE) approach to identify potential non-cancer risks for individual1856exposure routes (*i.e.*, oral, dermal, inhalation). The MOE is the ratio of the non-cancer POD divided by a1857human exposure dose. Acute, short-term, and chronic MOEs for non-cancer inhalation and dermal risks1858were calculated using Equation 4-1.

1860 Equation 4-1. Margin of Exposure Calculation1861

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

1863

1862

1859

1864 Where:

1001	where.		
1865	MOE	=	Margin of exposure for acute, intermediate, or
1866			chronic risk comparison (unitless)
1867	Non-cancer Hazard Value (POD)	=	HEC (mg/m ³) or HED (mg/kg-day)
1868	Human Exposure	=	Exposure estimate (mg/m ³ or mg/kg-day)
1869			

1870 MOE risk estimates may be interpreted in relation to benchmark MOEs. Benchmark MOEs are typically the total UF for each non-cancer POD. The MOE estimate is interpreted as a human health risk of 1871 1872 concern if the MOE estimate is less than the benchmark MOE (*i.e.*, the total UF). On the other hand, if 1873 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 non-cancer 1874 1875 adverse effect occurs relative to the benchmark. When determining whether a chemical substance presents unreasonable risk to human health or the environment, calculated risk estimates are not "bright-1876 1877 line" indicators of unreasonable risk, and EPA has the discretion to consider other risk-related factors in addition to risks identified in the risk characterization. 1878

4.3.1.2 Estimation of Non-cancer Aggregate Risks from Exposure to DCHP

As described in Section 4.1.5, EPA considered aggregate risk from exposure to DCHP 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.

1888 Equation 4-2. Total Margin of Exposure Calculation

1889

1879

1890

$$Total MOE = \frac{1}{\frac{1}{MOE_{Oral}} + \frac{1}{MOE_{Dermal}} + \frac{1}{MOE_{Inhalation}} \dots}$$

1891 1892 Wh

1892	where:		
1893	Total MOE	=	Margin of exposure for aggregate scenario (unitless)
1894	MOE _{Oral}	=	Margin of exposure for oral route (unitless)
1895	MOE _{Dermal}	=	Margin of exposure for dermal route (unitless)
1896	MOE Inhalation	=	Margin of exposure for inhalation route (unitless)
1897			

1898 Total MOE risk estimates may be interpreted in relation to benchmark MOEs, as described in Section4.3.1.1.

1900 4.3.2 Risk Estimates for Workers

This section summarizes risk estimates for workers from inhalation and dermal exposures, as well as aggregated exposures to DCHP from individual DCHP COUs across routes. In this section, risks are calculated for all exposed workers based on the DCHP-derived PODs described in Section 4.2.2. Subsequently in Section 4.4.4, those same risks for female workers of reproductive age exposed to DCHP at the highest levels (acute durations) are calculated using the more robust RPFs described in Section 4.4.1 and added to estimates of national non-attributable exposure of five toxicologically similar phthalates for an estimate of cumulative risk.

- 1908
 1909 Risk estimates for workers from inhalation and dermal exposures, as well as aggregated exposures, are
 1910 shown in Table 4-14. This section provides discussion and characterization of risk estimates for worker
 - shown in Table 4-14. This section provides discussion and characterization of risk estimates for workers,
 including women of reproductive age and ONUs, for the various OESs and COUs.
 - 19121913 *Manufacturing*
 - For the manufacture of DCHP, inhalation exposure from dust generation is expected to be the dominant
 - 1915 route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from
 - 1916 3.5 to 5.6 for average adult workers and women of reproductive age, while high-end dermal MOEs for
 - 1917 the same populations and exposure scenarios ranged from 532 to 845 (Benchmark = 30). The central
 - tendency MOEs for the same populations and exposure scenarios ranged from 36 to 58 for inhalation
 - 1919 exposure and 1,064 to 1,689 for dermal exposure (Benchmark = 30). Aggregation of inhalation and
 1920 dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation
 - exposure alone. The variations between the central tendency and high-end estimates of worker
 inhalation exposures are described below.
 - 1923

1924 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-1925 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 1926 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 1927 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting 1928 with 325 (Chemical Manufacturing). EPA multiplied these dust concentrations by the industry provided 1929 maximum DCHP concentration manufactured (*i.e.*, 100%) to estimate DCHP particulate concentrations 1930 in the air. Therefore, the differences in the central tendency and high-end dust concentrations led to 1931 significant differences between the central tendency and high-end risk estimates.

1932

1933 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 1934 worker may experience in the chemicals industry, the composition of workplace dust is uncertain. The 1935 exposure and risk estimates are based on the assumption that the concentration of DCHP in workplace 1936 dust is the same as the concentration of DCHP manufactured. However, it is likely that workplace dust 1937 contains a variety of constituents that do not contain any DCHP in addition to particles from 1938 manufactured DCHP. The constituents that do not contain DCHP would dilute the overall concentration 1939 of DCHP in the dust, and the concentration of DCHP in workplace dust is likely less than the 1940 concentration of DCHP in the final product. Due to this uncertainty in DCHP concentration in 1941 workplace dust, central tendency values of exposure are expected to be most reflective of worker 1942 exposures within the COUs covered under the "Manufacturing" OES (i.e., Manufacturing COU:

1943 Domestic manufacturing).

1945 Import and Repackaging

For the import of DCHP, inhalation exposure from dust generation is expected to be the dominant route 1946 1947 of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 5.8 to 1948 9.3 for average adult workers and women of reproductive age, while high-end dermal MOEs for the 1949 same populations and exposure scenarios ranged from 532 to 845 (Benchmark = 30). The central 1950 tendency MOEs for the same populations and exposure scenarios ranged from 134 to 259 for inhalation 1951 exposure and 1,064 to 2,031 for dermal exposure (Benchmark = 30). Aggregation of inhalation and 1952 dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation 1953 exposure alone. The large variations between the central tendency and high-end estimates of worker

- 1954 inhalation exposures are described below.
- 1955

1956 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-1957 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 1958 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 1959 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting 1960 with 45 (Wholesale and Retail Trade). EPA multiplied these dust concentrations by the industry 1961 provided maximum DCHP concentration imported (i.e., 100%) to estimate DCHP particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust 1962 1963 concentrations led to significant differences between the central tendency and high-end risk estimates.

1964

1965 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may experience in the wholesale and retail trade industry, the composition of workplace dust is 1966 1967 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DCHP 1968 in workplace dust is the same as the concentration of imported DCHP. However, it is likely that 1969 workplace dust contains a variety of constituents that do not contain any DCHP in addition to particles 1970 from imported DCHP. The constituents that do not contain DCHP would dilute the overall concentration 1971 of DCHP in the dust, and the concentration of DCHP in workplace dust is likely less than the 1972 concentration of DCHP in the imported product. Due to this uncertainty in DCHP concentration in 1973 workplace dust, central tendency values of exposure are expected to be most reflective of worker 1974 exposures within the COUs covered under the "Import and repackaging" OES (i.e., Manufacture COU: Importing; Processing COU: Repackaging [e.g., laboratory chemicals]). 1975

1976

1977 Incorporation into Adhesives and Sealants

1978 For the incorporation of DCHP into adhesives and sealants, inhalation exposure from dust generation is 1979 expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic 1980 inhalation exposure ranged from 3.5 to 5.6 for average adult workers and women of reproductive age, 1981 while high-end dermal MOEs for the same populations and exposure scenarios ranged from 532 to 845 1982 (Benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged 1983 from 36 to 58 for inhalation exposure and 1,064 to 1,689 for dermal exposure (Benchmark = 30). 1984 Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to 1985 risk estimates from inhalation exposure alone. The variations between the central tendency and high-end 1986 estimates of worker inhalation exposures are described below.

1987

1988 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-

1989 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for

1990 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and

1991 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Ccodes starting

- 1992 with 325 (Chemical Manufacturing). EPA multiplied these dust concentrations by the industry provided
- 1993 maximum potential DCHP concentration in the raw material (*i.e.*, 100%) to estimate DCHP particulate

concentrations in the air. Therefore, the differences in the central tendency and high-end dustconcentrations led to significant differences between the central tendency and high-end risk estimates.

1996

1997 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 1998 worker may experience in the chemical manufacturing industry, the composition of workplace dust is 1999 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DCHP 2000 in workplace dust is the same as the concentration of DCHP in the raw material. However, it is likely 2001 that workplace dust contains a variety of constituents that do not contain any DCHP in addition to 2002 particles from DCHP-containing raw materials. The constituents that do not contain DCHP would dilute 2003 the overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is 2004 likely less than the concentration of DCHP in the raw material. Due to this uncertainty in DCHP 2005 concentration in workplace dust, central tendency values of exposure are expected to be most reflective 2006 of worker exposures within the COUs covered under the "Incorporation into adhesives and sealants" 2007 OES (*i.e.*, Processing COUs: Plasticizer in adhesive manufacturing; Adhesive and sealant chemicals in 2008 adhesive manufacturing; Stabilizing agent in adhesive manufacturing).

2010 Incorporation into Paints and Coatings

For the incorporation of DCHP into paints and coatings, inhalation exposure from dust generation is expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 3.5 to 5.6 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 532 to 845 (Benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 36 to 58 for inhalation exposure and 1,064 to 1,689 for dermal exposure (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to

- risk estimates from inhalation exposure alone. The variations between the central tendency and high-end
 estimates of worker inhalation exposures are described below.
- 2020

2009

2021 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-2022 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 2023 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 2024 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting 2025 with 325 (Chemical Manufacturing). EPA multiplied these dust concentrations by the industry provided 2026 maximum potential DCHP concentration in the raw material (*i.e.*, 100%) to estimate DCHP particulate 2027 concentrations in the air. Therefore, the differences in the central tendency and high-end dust 2028 concentrations led to significant differences between the central tendency and high-end risk estimates.

2029

Although the PNOR (i.e., dust) concentration data provides a reliable range of dust concentrations that a 2030 2031 worker may experience in the chemical manufacturing industry, the composition of workplace dust is 2032 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DCHP 2033 in workplace dust is the same as the concentration of DCHP in the raw material. However, it is likely 2034 that workplace dust contains a variety of constituents that do not contain any DCHP in addition to 2035 particles from DCHP-containing raw materials. The constituents that do not contain DCHP would dilute the overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is 2036 likely less than the concentration of DCHP in the raw material. Due to this uncertainty in DCHP 2037 2038 concentration in workplace dust, central tendency values of exposure are expected to be most reflective 2039 of worker exposures within the COUs covered under the "Incorporation into paints and coatings" OES 2040 (*i.e.*, Processing COUs: Plasticizer in paint and coating manufacturing; Stabilizing agent in paint and 2041 coating manufacturing).

- 2043 Incorporation into Other Formulations, Mixtures, or Reaction Products Not Otherwise Specified For the incorporation of DCHP into other formulations, mixtures, or reaction products not otherwise 2044 2045 specified, inhalation exposure from dust generation is expected to be the dominant route of exposure. 2046 MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 3.5 to 5.6 for 2047 average adult workers and women of reproductive age, while high-end dermal MOEs for the same 2048 populations and exposure scenarios ranged from 532 to 845 (Benchmark = 30). The central tendency 2049 MOEs for the same populations and exposure scenarios ranged from 36 to 58 for inhalation exposure 2050 and 1,064 to 1,689 for dermal exposure (Benchmark = 30). Aggregation of inhalation and dermal 2051 exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure 2052 alone. The variations between the central tendency and high-end estimates of worker inhalation 2053 exposures are described below.
- 2054

2055 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-2056 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 2057 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 2058 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS codes starting 2059 with 325 (Chemical Manufacturing). EPA multiplied these dust concentrations by the industry provided 2060 maximum potential DCHP concentration in the raw material (i.e., 100%) to estimate DCHP particulate 2061 concentrations in the air. Therefore, the differences in the central tendency and high-end dust 2062 concentrations led to significant differences between the central tendency and high-end risk estimates. 2063

2064 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2065 worker may experience in the chemical manufacturing industry, the composition of workplace dust is 2066 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DCHP 2067 in workplace dust is the same as the concentration of DCHP in the raw material. However, it is likely 2068 that workplace dust contains a variety of constituents that do not contain any DCHP in addition to 2069 particles from DCHP-containing raw materials. The constituents that do not contain DCHP would dilute 2070 the overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is 2071 likely less than the concentration of DCHP in the raw material. Due to this uncertainty in DCHP 2072 concentration in workplace dust, central tendency values of exposure are expected to be most reflective 2073 of worker exposures within the COUs covered under the "Incorporation into other formulations, 2074 mixtures, or reaction products not Covered Elsewhere" OES (i.e., Processing COU: Stabilizing agent in 2075 asphalt paving, roofing, and coating materials manufacturing).

2077 PVC Plastics Compounding

2078 For PVC plastics compounding, inhalation exposure from dust generation is expected to be the dominant 2079 route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 2080 3.7 to 6.0 for average adult workers and women of reproductive age, while high-end dermal MOEs 2081 ranged from 532 to 845 (Benchmark = 30). For central tendency, MOEs for the same population and 2082 exposure scenarios ranged from 76 to 137 for inhalation exposure and 1,064 to 1,894 for dermal 2083 exposures (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible 2084 differences in risk when compared to risk estimates from inhalation exposure alone. The reason for the 2085 variation between high-end and central tendency estimates of worker inhalation exposures is described 2086 below.

2087

2076

2088EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-2089End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for

2090 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and

2091 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting

with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry provided maximum potential DCHP concentration in the raw additive material (*i.e.*, 100%) to estimate DCHP particulate concentrations in the air. Therefore, the differences in the central tendency and highend dust concentrations led to significant differences between the central tendency and highestimates.

2097

2098 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2099 worker may experience in the compounding industry, the composition of workplace dust is uncertain. 2100 The exposure and risk estimates assume that the concentration of DCHP in workplace dust is the same 2101 as the concentration of DCHP in the raw material. However, it is likely that workplace dust contains a 2102 variety of constituents that do not contain any DCHP in addition to particles from DCHP-containing raw 2103 materials. The constituents that do not contain DCHP would dilute the overall concentration of DCHP in 2104 the dust, and the concentration of DCHP in workplace dust is likely less than the concentration of DCHP 2105 in the raw material. Due to the uncertainty of DCHP concentrations in workplace dust, central tendency 2106 values of exposure are expected to be most reflective of worker exposures within the COUs covered 2107 under the "PVC plastics compounding" OES (i.e., Processing COUs: Plasticizer in plastic material and 2108 resin manufacturing; Plastics product manufacturing; Stabilizing agent in plastics product 2109 manufacturing).

2110

2111 Non-PVC Material Compounding

2112 For non-PVC material compounding, inhalation exposure from dust generation is expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure 2113 2114 ranged from 6.2 to 9.9 for average adult workers and women of reproductive age, while high-end dermal 2115 MOEs ranged from 532 to 845 (Benchmark = 30). For central tendency, MOEs for the same population 2116 and exposure scenarios ranged from 126 to 217 for inhalation exposure and 1,064 to 1,805 for dermal 2117 exposures (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible 2118 differences in risk when compared to risk estimates from inhalation exposure alone. The reason for the 2119 variation between high-end and central tendency estimates of worker inhalation exposures is described 2120 below.

2121

2122 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-2123 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 2124 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 2125 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting 2126 with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry 2127 provided maximum potential DCHP concentration in the raw additive material (*i.e.*, 60%) to estimate 2128 DCHP particulate concentrations in the air. Therefore, the differences in the central tendency and high-2129 end dust concentrations led to significant differences between the central tendency and high-end risk 2130 estimates. 2131

2132 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2133 worker may experience in the compounding industry, the composition of workplace dust is uncertain. The exposure and risk estimates assume that the concentration of DCHP in workplace dust is the same 2134 2135 as the concentration of DCHP in the raw material. However, it is likely that workplace dust contains a 2136 variety of constituents that do not contain any DCHP in addition to particles from DCHP-containing raw 2137 materials. The constituents that do not contain DCHP would dilute the overall concentration of DCHP in 2138 the dust, and the concentration of DCHP in workplace dust is likely less than the concentration of DCHP 2139 in the raw material. Due to the uncertainty of DCHP concentrations in workplace dust, central tendency 2140 values of exposure are expected to be most reflective of worker exposures within the COUs covered

- 2141 under the "Non-PVC Material Compounding" OES (i.e., Processing COUs: Plasticizer in in plastic
- 2142 material and resin manufacturing; Plastics product manufacturing; Rubber product manufacturing;
- 2143 Stabilizing agent in plastics product manufacturing).
- 2144

2145 **PVC Plastics Converting**

- 2146 For PVC plastics converting, inhalation exposure from dust generation is expected to be the dominant 2147 route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 2148 8.2 to 13 for average adult workers and women of reproductive age, while high-end dermal MOEs 2149 ranged from 532 to 845 (Benchmark = 30). For central tendency, MOEs for the same population and 2150 exposure scenarios ranged from 168 to 309 for inhalation exposure and 1,064 to 1,929 for dermal 2151 exposures (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible 2152 differences in risk when compared to risk estimates from inhalation exposure alone. The reason for the 2153 variation between high-end and central tendency estimates of worker inhalation exposures is described 2154 below.
- 2154

2156 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-2157 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 2158 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 2159 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codesstarting 2160 with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry 2161 provided maximum potential DCHP concentration in PVC plastic (i.e., 45%) to estimate DCHP particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust 2162 2163 concentrations led to differences between the central tendency and high-end risk estimates.

2164

2165 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2166 worker may experience in the converting industry, the composition of workplace dust is uncertain. The 2167 exposure and risk estimates assume that the concentration of DCHP in workplace dust is the same as the 2168 concentration of DCHP in the PVC plastic. However, it is likely that workplace dust contains a variety 2169 of constituents that do not contain any DCHP in addition to particles from DCHP-containing PVC 2170 plastics. The constituents that do not contain DCHP would dilute the overall concentration of DCHP in 2171 the dust, and the concentration of DCHP in workplace dust is likely less than the concentration of DCHP 2172 in the PVC plastic. Due to the uncertainty of DCHP concentrations in workplace dust, central tendency 2173 values of exposure are expected to be most reflective of worker exposures within the COUs covered 2174 under the "PVC plastics converting" OES (i.e., Processing COU: Plasticizer in plastics product 2175 manufacturing).

2176

2177 Non-PVC Material Converting

2178 For non-PVC material converting, inhalation exposure from dust generation is expected to be the 2179 dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure 2180 ranged from 18 to 30 for average adult workers and women of reproductive age, while high-end dermal 2181 MOEs ranged from 532 to 845 (Benchmark = 30). For central tendency, MOEs for the same population 2182 and exposure scenarios ranged from 378 to 696 for inhalation exposure and 1,064 to 1,929 for dermal 2183 exposures (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible 2184 differences in risk when compared to risk estimates from inhalation exposure alone. The reason for the 2185 variation between high-end and central tendency estimates of worker inhalation exposures is described 2186 below.

2187

2188 EPA estimated worker inhalation exposures using the *Generic Model for Central Tendency and High-*2189 *End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR)* for

dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry provided maximum potential DCHP concentration in non-PVC material (*i.e.*, 20%) to estimate DCHP particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust concentrations led to differences between the central tendency and high-end risk estimates.

2196

2197 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2198 worker may experience in the converting industry, the composition of workplace dust is uncertain. The 2199 exposure and risk estimates assume that the concentration of DCHP in workplace dust is the same as the 2200 concentration of DCHP in the non-PVC material. However, it is likely that workplace dust contains a 2201 variety of constituents that do not contain any DCHP in addition to particles from DCHP-containing 2202 non-PVC materials. The constituents that do not contain DCHP would dilute the overall concentration of 2203 DCHP in the dust, and the concentration of DCHP in workplace dust is likely less than the concentration 2204 of DCHP in the non-PVC material. Due to the uncertainty of DCHP concentrations in workplace dust, 2205 central tendency values of exposure are expected to be most reflective of worker exposures within the 2206 COUs covered under the "Non-PVC Material Converting" OES (*i.e.*, Processing COUs: Plasticizer in 2207 plastics product manufacturing; Rubber product manufacturing).

2208

2209 Application of Adhesives and Sealants

The applications of adhesives and sealants were assessed for solid and liquid products containing 2210 DCHP. The majority of DCHP-containing adhesive and sealant products identified exist in solid form 2211 2212 and inhalation exposure from dust generation is expected to be the dominant route of exposure for solid 2213 adhesive and sealant products, though dermal exposures to solid adhesive and sealant products 2214 containing DCHP were also considered. There were a few liquid adhesive and sealant products 2215 containing DCHP identified; however, liquid adhesive and sealant products containing DCHP are 2216 extremely viscous and are better classified as "paste-like" materials. The literature and product data do 2217 not indicate the potential for spray coating of DCHP-containing adhesive and sealant products; 2218 therefore, inhalation exposures from the use of liquid adhesive and sealant chemicals containing DCHP 2219 are expected to be *de minimis* since there are no mists generated during use, and the vapor pressure of 2220 DCHP is very low. Consequently, EPA assumed negligible inhalation exposure from the use of liquid 2221 adhesive and sealant products containing DCHP and only assessed dermal exposures for liquid adhesive 2222 and sealant use. Risk values associated with the use of liquid adhesive and sealant products containing 2223 DCHP are covered under the "Application of adhesives and sealants – liquids" OES (i.e., Industrial COUs: Adhesives and sealants (transportation equipment manufacturing; computer and electronic 2224 2225 product manufacturing) and Commercial COUs: Adhesives and sealants). See Appendix F of the Draft 2226 Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate (DCHP) 2227 (U.S. EPA, 2024q) for product details.

2228

2229 MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 6.4 to 10 for 2230 average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 532 2231 to 845 (Benchmark = 30). For central tendency, MOEs for the same population and exposure scenarios ranged from 116 to 201 for inhalation exposure and 1,064 to 1,821 for dermal exposures (Benchmark = 2232 2233 30). For dust exposure from solid products, the aggregation of inhalation and dermal exposures led to 2234 negligible differences in risk when compared to risk estimates from inhalation exposure alone. The use 2235 of liquid adhesive and sealant products is not expected to produce an inhalation exposure and therefore 2236 dermal exposure to the liquid is expected to be the dominant route of exposure. For liquid adhesive and 2237 sealant products, the high-end and central tendency dermal MOEs ranged from 532 to 845 and 1,064 to 2238 1,821, respectively (Benchmark = 30). The reason for the variation between high-end and central

tendency estimates of inhalation exposure to dust and the rationale for not assessing inhalation data forliquids is described below.

2241

2242 EPA estimated worker inhalation exposures to dust from solid products using the Generic Model for 2243 Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not 2244 Otherwise Regulated (PNOR) for dust exposures (U.S. EPA, 2021b). The application of adhesives and 2245 sealants does not fall under a specific NAICS Code; therefore, EPA used the entire PNOR model data 2246 set to estimate DCHP particulate concentrations in the air during the use of solid DCHP-containing 2247 adhesive and sealant products. EPA determined the 50th and 95th percentiles of the surrogate dust 2248 monitoring data and multiplied these dust concentrations by the maximum potential DCHP 2249 concentration in solid adhesive and sealant products (*i.e.*, 55%) to estimate DCHP particulate 2250 concentrations in the air. Therefore, the differences in the central tendency and high-end dust 2251 concentrations led to differences between the central tendency and high-end risk estimates.

2252

2253 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2254 worker may experience in a variety of industries, the composition of workplace dust is uncertain. The 2255 exposure and risk estimates assume that the concentration of DCHP in workplace dust is the same as the 2256 concentration of DCHP in the adhesive or sealant material. However, it is likely that workplace dust 2257 contains a variety of constituents that do not contain any DCHP in addition to particles from solid DCHP-containing adhesive and sealant products. The constituents that do not contain DCHP would 2258 2259 dilute the overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is likely less than the concentration of DCHP in solid adhesive and sealant products. Due to the 2260 2261 uncertainty of DCHP concentrations in workplace dust, central tendency values of exposure are 2262 expected to be most reflective of worker exposures within the COUs covered under the "Application of 2263 adhesives and sealants – solids" OES (*i.e.*, Industrial COUs: Adhesives and sealants (Transportation 2264 equipment manufacturing; Computer and electronic product manufacturing) and Commercial COUs: 2265 Adhesives and sealants).

2266

2267 Application of Paints and Coatings

2268 The applications of paints and coatings were assessed for solid and liquid products containing DCHP. 2269 For the liquid and solid paint and coating products containing DCHP, inhalation exposure is expected to 2270 be the dominant route of exposure. For liquids, inhalation exposure is expected to occur primarily from 2271 mist during spray application of the product, and for solids, inhalation exposure is expected to primarily 2272 occur from dust release of the solid product prior to mixing with other components. Therefore, EPA 2273 distinguished exposure estimates between *liquid spray* and *solid dust* exposure from the application of 2274 paint and coating products containing DCHP. MOEs for high-end acute, intermediate, and chronic 2275 inhalation exposure from the *liquid spray application scenario* ranged from 2.0 to 3.2 for average adult 2276 workers and women of reproductive age, while high-end dermal MOEs ranged from 532 to 845 2277 (Benchmark = 30). For central tendency of the *liquid spray application scenario*, MOEs for the same 2278 populations and exposure scenarios ranged from 41 to 66 for inhalation exposures and 1,064 to 1,689 for 2279 dermal exposures (Benchmark = 30). MOEs for high-end acute, intermediate, and chronic inhalation 2280 exposure from the solid dust scenario ranged from 3.5 to 5.7 for average adult workers and women of 2281 reproductive age, while high-end dermal MOEs ranged from 532 to 845 (Benchmark = 30). For central 2282 tendency of the solid dust scenario, MOEs for the same populations and exposure scenarios ranged from 2283 62 to 100 for inhalation exposure and 1,064 to 1,689 for dermal exposure (Benchmark = 30). 2284 Aggregation of inhalation and dermal exposures led to small differences in MOEs when compared to 2285 MOE estimates from dominant exposure route alone.

2286

2287 For the "Application of paint and coatings – liquids" exposure scenario, EPA relied on mist monitoring 2288 data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry 2289 (OECD, 2011a), which showed that the central tendency (*i.e.*, 50th percentile) of mist concentrations 2290 from automotive refinishing was 3.38 mg/m³ and the high-end (*i.e.*, 95th percentile) was 22.1 mg/m³. 2291 These mist concentration data were derived from a variety of industrial and commercial automotive 2292 refinishing scenarios (e.g., different gun types and booth configurations), but all scenarios considered in 2293 the ESD commonly used the spray application of auto refinishing coatings. While the tasks evaluated for 2294 mist concentrations varied in time, with the 95th percentile of spray times among tasks being 141 2295 minutes, EPA assumed that these mist concentrations may be persistent in an environment where 2296 spraying occurs throughout all or most of the workday. The more highly pressurized spray guns 2297 generally lead to higher inhalation exposure levels, and less pressurized spray guns generally lead to 2298 lower inhalation exposure levels. The same trend is expected for dermal exposure. Specifically, high-2299 pressure spray applications are more likely to lead to higher levels of dermal exposure, and low-pressure 2300 spray guns are more likely to lead to lower levels of dermal exposure. However, there are a variety of 2301 factors other than spray equipment type that affect exposure levels, such as spray booth ventilation 2302 configuration, product concentration, and spray duration. High-end levels of exposure represent 2303 scenarios where one or more factors are contributing to unusually elevated exposure levels, whereas 2304 central tendency levels of exposure represent more typical levels of exposure for scenarios where there 2305 are few factors contributing to increased exposure. There is uncertainty regarding the particular 2306 combination of factors that would lead to high-end levels of exposure.

2308 The range of exposure estimates shown in Table 4-14 for "Application of paints and coatings – liquids" 2309 are potentially reflective of industrial or commercial operations where paints and coatings are applied 2310 using spray methods (i.e., Industrial COU: Paints and coatings; and Commercial COU: Paints and 2311 coatings). As described in the section above, EPA assumed that task-based mist concentrations may be 2312 persistent throughout the entirety of a workday, which is realistic but on the conservative end of 2313 expected exposure duration for spray coating scenarios. The central tendency estimates of the spray application scenario represent the midpoint of available product concentrations and the mist 2314 2315 concentration from the 50th percentile of the data presented in the ESD on Coating Application via 2316 Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), and these levels of exposure are 2317 expected to be typical for standard working conditions where workers are spray applying paint and 2318 coating products containing DCHP for up to 8 hours per day. However, it is noted that there are several 2319 factors that affect exposure levels related to the spray application of paint and coating chemicals 2320 including spray equipment type, spray booth ventilation configuration, product concentration, and spray 2321 duration.

2307

2322

2323 High-end levels of exposure may occur if one or more of these factors contribute to elevated levels of 2324 exposure; however, there is uncertainty regarding the conditions associated with high-end exposures. 2325 Because the high-end risk estimates are based on high-end mist concentration levels, high-end product 2326 concentration, and high-end exposure duration, the high-end risk values presented in Table 4-14 for 2327 "Application of paints and coatings – liquids" may overestimate exposures for typical working 2328 conditions. However, EPA does expect high-pressure spray application of paint and coating products 2329 containing DCHP based on the available product information. Specifically, EPA identified one product 2330 (Carboline, 2019b) that is intended for high-pressure spray application and the concentration of DCHP 2331 in the product is listed as up to 2.5 percent. For an 8-hour workday spent spraying with a paint/coating 2332 product containing 2.5 percent DCHP, mist levels exceeding 12.8 mg/m³ (*i.e.*, 91st percentile of the 2333 distribution of mist monitoring data) would result in risk values below the benchmark MOE. Although 2334 most worker exposures to DCHP through spray application of paints and coatings are expected to be 2335 closer to the central tendency exposure values for this COU, a confluence of a subset of variables (e.g., a)

low ventilation, high-pressure spray, *etc.*) would result in risk below the benchmark. While most
workers are not expected to experience elevated exposures (*i.e.*, greater than 90th percentile of mist
concentration data for an 8-hour period) on a daily basis, it is considered plausible and expected for such
exposures to occur in an acute one-day scenario.

2340

2341 For any liquid paint and coating products that are applied using non-spray methods (*i.e.*, Industrial 2342 COUs: Inks, toner, and colorant products [e.g., screen printing ink]; Cellulose film production; Paints 2343 and coatings; and Commercial COUs: Inks, toner, and colorant products [*e.g.*, screen printing ink]; 2344 Paints and coatings), inhalation exposures are expected to be *de minimis* because mists or dusts are not 2345 generated during application and the vapor pressure of DCHP is extremely low at room temperature. 2346 However, workers may be exposed through the dermal route under non-spray application scenarios. 2347 Therefore, exposures associated with the non-spray application of liquid paint and coating products 2348 containing DCHP are characterized by the range of dermal risk values only, which are shown in Table 2349 4-16 for "Application of paints and coatings – liquids."

2350

2351 For the "Application of paints and coatings – solids" exposure scenario, EPA estimated worker

2352 inhalation exposures to dust from solid products using the Generic Model for Central Tendency and 2353 High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) 2354 for dust exposures (U.S. EPA, 2021b). The application of paints and coatings does not fall under a 2355 specific NAICS Code; therefore, EPA used the entire PNOR model data set to estimate DCHP 2356 particulate concentrations in the air during the use of solid DCHP-containing paint and coating products. EPA determined the 50th and 95th percentiles of the surrogate dust monitoring data and multiplied these 2357 2358 dust concentrations by the maximum potential DCHP concentration in the solid paint and coating 2359 component (i.e., 100%) to estimate DCHP particulate concentrations in the air. Therefore, the 2360 differences in the central tendency and high-end dust concentrations led to differences between the 2361 central tendency and high-end risk estimates.

2362

2363 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2364 worker may experience in a variety of industries, the composition of workplace dust is uncertain. The 2365 exposure and risk estimates assume that the concentration of DCHP in workplace dust is the same as the concentration of DCHP in the solid paint and coating component. However, it is likely that workplace 2366 2367 dust contains a variety of constituents that do not contain any DCHP in addition to particles from solid 2368 DCHP-containing paint and coating products. The constituents that do not contain DCHP would dilute 2369 the overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is 2370 likely less than the concentration of DCHP in solid paint and coating products. Due to the uncertainty of 2371 DCHP concentrations in workplace dust, central tendency values of exposure are expected to be most 2372 reflective of worker exposures within the COUs covered under the "Application of paints and coatings -2373 solids" OES (*i.e.*, Industrial COUs: Inks, toner, and colorant products [*e.g.*, screen printing ink]; 2374 Cellulose film production; Paints and coatings; and Commercial COUs: Inks, toner, and colorant 2375 products [e.g., screen printing ink]; Paints and coatings).

2376

2377 Use of Laboratory Chemicals

2378 The use of laboratory chemicals was assessed for solid and liquid products containing DCHP. Inhalation

exposure from dust generation is expected to be the dominant route of exposure for solid laboratory

2380 chemicals. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 6.4 to

- 10 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from
- 532 to 845 (Benchmark = 30). For central tendency, MOEs for the same population and exposure
 scenarios ranged from 91 to 157 for inhalation exposure and 1,064 to 1,797 for dermal exposures
- (Benchmark = 30). For dust exposure, the aggregation of inhalation and dermal exposures led to

negligible differences in risk when compared to risk estimates from inhalation exposure alone. The use of liquid laboratory chemicals is not expected to produce an inhalation exposure and therefore dermal

- 2387 exposure to the liquid is expected to be the dominant route of exposure. For liquid laboratory chemicals,
- the high-end and central tendency dermal MOEs ranged from 532 to 845 and 1,064 to 1,797,
- 2389 respectively (Benchmark = 30). The reason for the variation between high-end and central tendency
- estimates of worker inhalation exposure to dust and the rational for not assessing inhalation data forliquids is described below.
- 2392

EPA assessed worker inhalation exposures to dust from solid laboratory chemicals. The literature and
product data do not indicate the potential for the generation of mists during the use of liquid lab
chemicals. Therefore, inhalation exposures from the use of liquid DCHP-containing lab chemicals
containing DCHP are expected to be *de minimis* because there are no mists generated during use and the
vapor pressure of DCHP is very low. Consequently, EPA assumed negligible inhalation exposure from
the use of liquid lab chemicals and only assessed dermal exposures for liquid laboratory chemical use.

2399

2400 EPA estimated worker inhalation exposures to dust from solid laboratory chemicals using the *Generic* 2401 Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates 2402 Not Otherwise Regulated (PNOR) for dust exposures (U.S. EPA, 2021b). For inhalation exposure to 2403 PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust monitoring data taken from 2404 facilities with NAICS Codes starting with 54 (Professional, Scientific, and Technical Services). EPA 2405 determined the 50th and 95th percentiles of the surrogate dust monitoring data and multiplied these dust 2406 concentrations by the industry provided maximum potential DCHP concentration in lab chemicals (*i.e.*, 2407 100%) to estimate DCHP particulate concentrations in the air. Therefore, the differences in the central 2408 tendency and high-end dust concentrations led to differences between the central tendency and high-end 2409 risk estimates.

2410

2411 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2412 worker may experience in the laboratory services industry, the composition of workplace dust is 2413 uncertain. The exposure and risk estimates assume that the concentration of DCHP in workplace dust is 2414 the same as the concentration of DCHP in the laboratory chemicals. However, it is likely that workplace 2415 dust contains a variety of constituents that do not contain any DCHP in addition to particles from solid 2416 DCHP-containing laboratory chemicals. The constituents that do not contain DCHP would dilute the 2417 overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is likely 2418 less than the concentration of DCHP in the solid laboratory chemicals. Due to the uncertainty of DCHP 2419 concentrations in workplace dust, central tendency values of exposure are expected to be most reflective 2420 of worker exposures within the COUs covered under the "Use of lab chemicals" OES (i.e., Commercial 2421 COU: Laboratory chemical).

2422

2423 Fabrication or Use of Final Products or Articles

For fabrication or use of final products or articles, inhalation exposure from dust generation is expected 2424 2425 to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation 2426 exposure ranged from 21 to 35 for average adult workers and women of reproductive age, whereas high-2427 end dermal MOEs for the same populations and exposure scenarios ranged from 532 to 845 (Benchmark 2428 = 30). For central tendency, MOEs for the same population and exposure scenarios ranged from 193 to 2429 311 for inhalation exposure and 1,064 to 1,689 for dermal exposures (Benchmark = 30). Aggregation of 2430 inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates 2431 from inhalation exposure alone. The variations between the central tendency and high-end estimates of 2432 worker inhalation exposures are described below. 2433

EPA estimated worker inhalation exposures using the *Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR)* for dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting with 337 (Furniture and Related Product Manufacturing). EPA multiplied these dust concentrations by the maximum DCHP concentration in PVC (*i.e.*, 45%) to estimate DCHP particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust concentrations led to

- significant differences between the central tendency and high-end risk estimates.
- 2442

2443 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a 2444 worker may experience in the end use and fabrication industries, the composition of workplace dust is 2445 uncertain. The exposure and risk estimates assume that the concentration of DCHP in workplace dust is 2446 the same as the concentration of DCHP in the PVC material. However, it is likely that workplace dust 2447 contains a variety of constituents that do not contain any DCHP in addition to particles from DCHP-2448 containing products or articles. The constituents that do not contain DCHP would dilute the overall 2449 concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is likely less than 2450 the concentration of DCHP in final products and articles. Due to the uncertainty of DCHP 2451 concentrations in workplace dust, central tendency values of exposure are expected to be most reflective 2452 of worker exposures within the COUs covered under the "Fabrication or use of final products or 2453 articles" OES (*i.e.*, Industrial COU: Plastic and rubber products not covered elsewhere in transportation equipment manufacturing; and Commercial COUs: Building/construction materials not covered 2454 elsewhere; Other articles with routine direct contact during normal use including rubber articles; Plastic 2455 2456 articles [hard]).

2457

2458 Recycling and Waste Handling, Treatment, and Disposal

2459 The approaches for the Recycling OES and the Waste handling, treatment and disposal OES are 2460 identical and therefore consolidated here. For both OESs, the inhalation exposure from dust generation is expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic 2461 2462 inhalation exposure ranged from 11 to 18 for average adult workers and women of reproductive age, 2463 while high-end dermal MOEs for the same populations and exposure scenarios ranged from 532 to 845 2464 (Benchmark = 30) for both OESs. The central tendency MOEs for the same populations and exposure 2465 scenarios ranged from 161 to 291 for inhalation exposure and 1,064 to 1,894 for dermal exposure for 2466 both OES (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone. The variations 2467 2468 between the central tendency and high-end estimates of worker inhalation exposures are described 2469 below.

2470

2471 EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-2472 End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for 2473 dust exposures (U.S. EPA, 2021b). For inhalation exposure to PNOR, EPA determined the 50th and 2474 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS Codes starting 2475 with 56 (Administrative and Support and Waste Management and Remediation Services). EPA 2476 multiplied these dust concentrations by the industry provided maximum DCHP concentration in PVC 2477 (i.e., 45%) to estimate DCHP particulate concentrations in the air. PVC concentration was used for this 2478 estimate because it is expected to be the predominant type of waste containing DCHP that is recycled or 2479 disposed of. Therefore, the differences in the central tendency and high-end dust concentrations led to 2480 significant differences between the central tendency and high-end risk estimates.

2481

2482 Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a

2483 worker may experience in the recycling and disposal industry, the composition of workplace dust is 2484 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DCHP 2485 in workplace dust is the same as the concentration of DCHP in PVC plastics. However, it is likely that 2486 workplace dust contains a variety of constituents that do not contain any DCHP in addition to particles 2487 from DCHP-containing products or articles. The constituents that do not contain DCHP would dilute the 2488 overall concentration of DCHP in the dust, and the concentration of DCHP in workplace dust is likely 2489 less than the concentration of DCHP in recycled or disposed products or articles. Therefore, central 2490 tendency values of exposure are expected to be more reflective of worker exposures within the COUs 2491 covered under the "Recycling" and the "Disposal" OESs (i.e., Processing COU: Recycling; and Disposal 2492 COU: Disposal).

2494 Distribution in Commerce

2495 Distribution in commerce includes transporting DCHP or DCHP-containing products between work 2496 sites or to final use sites as well as loading and unloading from transport vehicles. Individuals in 2497 occupations that transport DCHP-containing products (*e.g.*, truck drivers) or workers who load and 2498 unload transport trucks may encounter DCHP or DCHP-containing products.

Although some worker activities (*e.g.*, loading or unloading) associated with distribution in commerce are similar to COUs such as manufacturing or import, it is expected that workers involved in distribution in commerce spend less time exposed to DCHP than workers in manufacturing or import facilities since only part of the workday is spent in an area with potential exposure. Therefore, occupational exposures associated with the distribution in commerce COU are expected to be less than other COUs with similar worker activities (*i.e.*, manufacturing and import).

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4.3.2.1 Overall Confidence in Worker Risk Estimates for Individual DCHP COUs

As described in Section 4.1.1.5, EPA has moderate confidence in the assessed occupational inhalation

and dermal exposures (Table 4-5) and robust confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to DCHP (Section 4.2). Overall, the

Agency has moderate confidence in the risk estimates calculated for worker and ONU inhalation and

2510 Agency has moderate connected in the risk estimates calculated for worker and Ovo initiatation and 2511 dermal exposure scenarios. Sources of uncertainty associated with the occupational COUs are discussed

above in Section 4.3.2.

2513 Table 4-14. Occupational Aggregate Risk Summary Table for DCHP

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk E hmark MO			al Risk Est hmark MO			gate Risk Es hmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Average	High-End	3.8	5.2	5.6	532	725	776	3.8	5.2	5.6
			Adult Worker	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
Manufacturing –	Domestic		Women of	High-End	3.5 ª	4.7	5.1	579 ^a	789	845	3.5 ^a	4.7	5.0
Domestic	manufacturing	Manufacturing	Reproductive Age	Central Tendency	36 ^a	49	53	1,157ª	1,578	1,689	35 ^a	48	51
				High-End	40	55	58	1,064	1,451	1,553	39	53	56
			ONU	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
			Average	High-End	6.4	8.7	9.3	532	725	776	6.3	8.6	9.2
Manufacturing – Importing	Importing		Adult Worker	Central Tendency	148	201	259	1,064	1,451	1,867	130	177	228
		Import and	Women of	High-End	5.8 ^a	7.9	8.5	579 ^a	789	845	5.7 <i>ª</i>	7.8	8.4
	Repackaging	repackaging	Reproductive Age	Central Tendency	134 ^a	182	235	1,157ª	1,578	2,031	120 ^a	163	210
Processing =	(e.g., laboratory			High-End	148	201	216	1,064	1,451	1,553	130	177	189
Repackaging	chemicals)		ONU	Central Tendency	148	201	259	1,064	1,451	1,867	130	177	228

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk E hmark MO			al Risk Est hmark MO			gate Risk E chmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
	Plasticizer in: – adhesive manufacturing		Average	High-End	3.8	5.2	5.6	532	725	776	3.8	5.2	5.6
Processing – Processing – incorporation	Adhesive and sealant chemicals in: – adhesive manufacturing	Incorporation	Adult Worker	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
into formulation, mixture, or	Stabilizing	and sealants	women of	High-End	3.5 ^a	4.7	5.1	579 ^a	789	845	3.5 ^a	4.7	5.0
reaction product – adhesive			Reproductive Age	Central Tendency	36 ^a	49	53	1,157ª	1,578	1,689	35 ^a	48	51
				High-End	40	55	58	1,064	1,451	1,553	39	53	56
			ONU	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
Processing –	Plasticizer in: – paint and coating manufacturing – printing ink manufacturing		Average Adult Worker	High-End	3.8	5.2	5.6	532	725	776	3.8	5.2	5.6
Processing – mar Processing – incorporation		Incorporation into paints and		Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
into formulation, mixture, or	Stabilizing	coatings	Women of	High-End	3.5 ^a	4.7	5.1	579 ^a	789	845	3.5 ^a	4.7	5.0
reaction product	agent in: – Paint and coating		Reproductive Age	Central Tendency	36 ^a	49	53	1,157ª	1,578	1,689	35 ^a	48	51
	manufacturing			High-End	40	55	58	1,064	1,451	1,553	39	53	56
			ONU	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk Es hmark MO			al Risk Est hmark MO			gate Risk Es chmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Average	High-End	3.8	5.2	5.6	532	725	776	3.8	5.2	5.6
Processing –	Stabilizing agent in:	Incorporation into other	Adult Worker	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
Processing – incorporation	– asphalt	formulations,	women or	High-End	3.5 ^a	4.7	5.1	579 ^a	789	845	3.5 ^a	4.7	5.0
into formulation, mixture, or	ation nulation, or product product and coating materials covered	Reproductive Age	Central Tendency	36 ^a	49	53	1,157ª	1,578	1,689	35 ^a	48	51	
reaction product	materials covered			High-End	40	55	58	1,064	1,451	1,553	39	53	56
		elsewhere	ONU	Central Tendency	40	55	58	1,064	1,451	1,553	39	53	56
	Plasticizer in:			High-End	4.1	5.6	6.0	532	725	776	4.1	5.5	5.9
Processing – Processing – incorporation	 plastic material and resin manufacturing plastics product manufacturing 	PVC plastics	Average Adult Worker	Central Tendency	83	114	137	1,064	1,451	1,741	77	106	127
into formulation,		compounding	Women of	High-End	3.7ª	5.0	5.4	579 ^a	789	845	3.7ª	5.0	5.4
a	Stabilizing agent in:		Reproductive Age	Central Tendency	76 ^a	103	124	1,157ª	1,578	1,894	71 ^a	97	116
	 plastics product 			High-End	83	114	122	1,064	1,451	1,553	77	106	113
	manufacturing		ONU	Central Tendency	83	114	137	1,064	1,451	1,741	77	106	127

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk Es hmark MO			al Risk Est hmark MO			egate Risk E chmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Average	High-End	9.1	12	13	532	725	776	8.9	12	13
			Adult Worker	Central Tendency	186	253	309	1,064	1,451	1,773	158	215	263
U	Plasticizer in: – Plastics	PVC plastics	Women of	High-End	8.2 ^a	11	12	579 ^a	789	845	8.1 ^a	11	12
1	product manufacturing	converting	Reproductive Age	Central Tendency	168 ^a	229	280	1,157ª	1,578	1,929	147 ^a	200	244
				High-End	186	253	271	1,064	1,451	1,553	158	215	231
			ONU	Central Tendency	186	253	309	1,064	1,451	1,773	158	215	263
	Plasticizer in:			High-End	6.8	9.3	9.9	532	725	776	6.7	9.2	9.8
	– plastics product manufacturing – rubber		Average Adult Worker	Central Tendency	139	190	217	1,064	1,451	1,659	123	168	192
Processing – Processing – incorporation mixture, or reaction product	product manufacturing – plastic material and resin manufacturing	Non-PVC material compounding	Women of Reproductive Age	High-End	6.2 ^a	8.4	9.0	579 ^a	789	845	6.1 ^a	8.3	8.9
	Stabilizing			Central Tendency	126 ^a	172	196	1,157ª	1,578	1,805	114 ^a	155	177
	agent in: – Plastics			High-End	139	190	203	1,064	1,451	1,553	123	168	180
	product manufacturing		ONU	Central Tendency	139	190	217	1,064	1,451	1,659	123	168	198

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk Es chmark MO			al Risk Est hmark MO			gate Risk E hmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Average	High-End	20	28	30	532	725	776	20	27	29
	Plasticizer in: – plastics		Adult Worker	Central Tendency	417	569	696	1,064	1,451	1,773	300	409	500
Processing –	product	Non-PVC	Women of	High-End	18 ^a	25	27	579 ^a	789	845	18 ^a	24	26
Processing – incorporation into article	manufacturing – rubber	material converting	Reproductive Age	Central Tendency	378 ^a	515	630	1,157 ª	1,578	1,929	285 ^a	388	475
	product manufacturing			High-End	417	569	609	1,064	1,451	1,553	300	409	438
			ONU	Central Tendency	417	569	696	1,064	1,451	1,773	300	409	500
Industrial Use – Finishing agent	Cellulose film production		Average Adult	High-End	2.2	3.0	3.2	532	725	776	2.2	2.9	3.2
Industrial Use – Inks, toner, and	Inks, toner, and colorant		Worker	Central Tendency	45	62	66	1,064	1,451	1,553	44	59	64
colorant products	products (<i>e.g.</i> , screen printing ink)		Women of Reproductive	High-End	2.0 ^{<i>a</i>}	2.7	2.9	579 ^a	789	845	2.0 ª	2.7	2.9
Commercial Use – Inks, toner,	colorant	paints and	Age	Central Tendency	41 ^a	56	60	1,157 ª	1,578	1,689	40 ^a	54	58
and colorant products	products (<i>e.g.</i> , screen printing ink)	coatings – liquids		High-End	45	62	66	1,064	1,451	1,553	44	59	64
Industrial Use – Paints and coatings	Paints and coatings		ONU	Central Tendency	45	62	66	1,064	1,451	1,553	44	59	64
Commercial Use – Paints and coatings	Paints and coatings												

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk E hmark MO			al Risk Est hmark MO			gate Risk E chmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Industrial Use – Finishing agent	Cellulose film production			High-End	3.9	5.3	5.7	532	725	776	3.9	5.3	5.7
Industrial Use – Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)		Average Adult Worker	Central Tendency	69	94	100	1,064	1,451	1,553	64	88	94
Commercial Use				High-End	3.5 ^a	4.8	5.2	579 ^a	789	845	3.5 ^a	4.8	5.1
– Inks, toner, and colorant products	colorant products (<i>e.g.</i> , screen printing ink)	paints and coatings – solids	Women of Reproductive Age	Central Tendency	62 ^a	85	91	1,157ª	1,578	1,689	59 ^a	80	86
Industrial Use – Paints and coatings	Paints and coatings		ONU	High-End	69	94	100	1,064	1,451	1,553	64	88	94
Commercial Use – Paints and coatings	Paints and coatings		ONU	Central Tendency	69	94	100	1,064	1,451	1,553	64	88	94
	Adhesives and		Average	High-End	N/A	N/A	N/A	532	725	776	532	725	776
Industrial Uses –	sealants (<i>e.g.</i> , computer and electronic		Adult Worker	Central Tendency	N/A	N/A	N/A	1,064	1,451	1,674	1,064	1,451	1,674
Adhesives and sealants	product manufact.; transportation equipment manufact.)	Application of adhesives and sealants –	Women of Reproductive Age	High-End	N/A	N/A	N/A	579 ^a	789	845	579 ^a	789	845
Commercial		liquids	6	Central Tendency	N/A	N/A	N/A	1,157 ^a	1,578	1,821	1,157ª	1,578	1,821
uses – Adhesives and	Adhesives and sealants		ONU	High-End	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
sealants	isculants			Central Tendency	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk E hmark MO			al Risk Est hmark MO			gate Risk E hmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
	Adhesives and		Average	High-End	7.1	9.7	10	532	725	776	7.0	9.6	10
Industrial Uses –	sealants in – computer and electronic		Adult Worker	Central Tendency	128	175	201	1,064	1,451	1,674	114	156	180
Adhesives and sealants	product manufact.; transportation equipment manufact.	Application of adhesives and sealants –	Women of Reproductive Age	High-End	6.4 ^a	8.8	9.4	579 ^a	789	845	6.4 ^a	8.7	9.3
Commercial		solids		Central Tendency	116 ^a	158	182	1,157 ª	1,578	1,821	105 ^a	144	166
Uses – Adhesives and	Adhesives and sealants			High-End	128	175	187	1,064	1,451	1,553	114	156	167
sealants	scarants		ONU	Central Tendency	128	175	201	1,064	1,451	1,674	114	156	180
			Average	High-End	N/A	N/A	N/A	532	725	776	532	725	776
			Adult Worker	Central Tendency	N/A	N/A	N/A	1,064	1,451	1,652	1,064	1,451	1,652
Commercial Use	Laboratore	Use of	Women of	High-End	N/A	N/A	N/A	579 ^a	789	845	579 ^a	789	845
_ Laboratory	Laboratory chemicals	laboratory chemicals – liquid	Reproductive Age	Central Tendency	N/A	N/A	N/A	1,157 ª	1,578	1,797	1,157ª	1,578	1,797
				High-End	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ONU	Central Tendency	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk E hmark MO			al Risk Est hmark MO			gate Risk E hmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Average	High-End	7.1	9.7	10	532	725	776	7.0	9.6	10
			Adult Worker	Central Tendency	101	138	157	1,064	1,451	1,652	92	126	143
Commercial Use	Laboratory	Use of	Women of	High-End	6.4 ^a	8.8	9.4	579 ^a	789	845	6.4 ^a	8.7	9.3
 Laboratory chemicals 	chemicals	laboratory chemicals – solid	Reproductive Age	Central Tendency	91 ^a	125	142	1,157 ª	1,578	1,797	85 ^a	116	132
				High-End	101	138	148	1,064	1,451	1,553	92	126	135
			ONU	Central Tendency	101	138	157	1,064	1,451	1,652	92	126	143
Industrial Use –	Other articles		Average	High-End	24	32	35	532	725	776	23	31	33
Other articles with routine direct contact	with routine direct contact during normal		Adult Worker	Central Tendency	213	291	311	1,064	1,451	1,553	178	242	259
during normal use including rubber articles; plastic articles (hard)	use including rubber articles; plastic articles (hard) (<i>e.g.</i> , transportation equipment manufact.)		Women of Reproductive	High-End	21 ª	29	31	579 ª	789	845	21 ^a	28	30
Commercial Use – Building/ construction materials not covered elsewhere	Building/ construction materials not covered elsewhere	Fabrication or use of final products or articles	Age	Central Tendency	193 ^a	263	282	1,157 ª	1,578	1,689	166 ^a	226	242
		-		High-End	213	291	311	1,064	1,451	1,553	178	242	259
- Other articles with routine direct contact during normal use including rubber articles	articleswith routineutinedirect contactontactduring normalnormaluse includingudingrubber articles;	ONU	Central Tendency	213	291	311	1,064	1,451	1,553	178	242	259	

Life Cycle Stage/ Category	Subcategory	OES	Worker Population	Exposure Level		tion Risk E hmark MO		-	al Risk Est nmark MO		00	gate Risk Es hmark MO	
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Average	High-End	12	17	18	532	725	776	12	16	17
			Adult Worker	Central Tendency	178	242	291	1,064	1,451	1,741	152	208	249
Processing			Women of	High-End	11 ^a	15	16	579 ^a	789	845	11 ^a	15	16
Processing – Recycling	Recycling	Recycling	Reproductive Age	Central Tendency	161 ^a	219	263	1,157ª	1,578	1,894	141 ^a	193	231
				High-End	178	242	260	1,064	1,451	1,553	152	208	222
			ONU	Central Tendency	178	242	291	1,064	1,451	1,741	152	208	249
			Average	High-End	12	17	18	532	725	776	12	16	17
			Adult Worker	Central Tendency	178	242	291	1,064	1,451	1,741	152	208	249
Diamagal		Waste	Women of	High-End	11 ^a	15	16	579 ^a	789	845	11 ^a	15	16
Disposal – Di Disposal Di	Disposal	handling, treatment and disposal	Reproductive Age	Central Tendency	161 ^a	219	263	1,157ª	1,578	1,894	141 ^a	193	231
				High-End	178	242	260	1,064	1,451	1,553	152	208	222
			ONU	Central Tendency	178	242	291	1,064	1,451	1,741	152	208	249

^{*a*} Scaling by the RPF and application of the index chemical POD provides a more sensitive and robust hazard assessment than the DCHP-specific POD, given its more limited toxicological data set. Please see Table 4-22 for the RPF analysis values.

2514

2515 4.3.3 Risk Estimates for Consumers

2516 This section summarizes risk estimates for consumers from inhalation, ingestion, and dermal exposures, 2517 as well as aggregated exposures, to DCHP from individual DCHP COUs across routes. In this section, 2518 risks are calculated for all exposed populations based on the DCHP-derived PODs described in Section 4.2.2. Subsequently in Section 4.4.5, those same risks for consumers that are adults of reproductive age, 2519 2520 infants, children, and teenagers exposed to DCHP at the highest levels (acute durations) are calculated 2521 using the more robust RPFs described in Section 4.4.1 and added to estimates of national non-2522 attributable exposure of five toxicologically similar phthalates for an estimate of cumulative risk. 2523 Table 4-15 summarizes the dermal, inhalation, ingestion, and aggregate MOEs used to characterize non-2524 cancer risk for acute, intermediate, and chronic exposure to DCHP and presents these values for all 2525 lifestages for each COU. A screening-level assessment for consumers considers high-intensity exposure 2526 scenarios which rely on conservative assumptions to assess exposures that would be expected to be on 2527 the high end of the expected exposure distribution. The corresponding high-intensity exposure scenario 2528 risk estimates are used as a conservative and health protective screening approach. MOEs for high-2529 intensity exposure scenarios are shown for all consumer COUs, while MOEs for medium-intensity 2530 exposure scenarios are shown only for COUs with high-intensity MOEs close to the benchmark of 30 2531 (no scenarios were in exceedance or within 20% of the benchmark). Exposure risk estimates were 2532 calculated considering product and article user and bystander. Bystanders are people that are not in 2533 direct use or application of a product but can be exposed to DCHP by proximity to the use of the product 2534 via inhalation of gas-phase emissions or suspended dust. Some product scenarios were assessed for 2535 children under 10 years as bystanders and children older than 11 years as users, because the products 2536 were not targeted for direct use by young children (<10 years). In instances where a lifestage could 2537 reasonably be either a product user or bystander, the inputs for a user were selected because that 2538 scenario would result in larger exposure doses.

2539

Of note, the risk summary below is based on the most sensitive non-cancer endpoint for all relevant duration scenarios (*i.e.*, developmental toxicity for acute, intermediate, and chronic durations). MOEs for all high-, medium- and low-intensity exposure scenarios for all COUs are provided in the *Draft Consumer Risk Calculator for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024e).

2545 COUs with MOEs for High-Intensity Exposure Scenarios Ranging from 740 to 950,000

2546 All consumer COUs product and article examples resulted in MOEs for high-intensity exposure 2547 scenarios ranging from 740 for acute duration dermal exposure to DCHP from outdoor seating for 2548 infants (less than one year old) to 950,000 for intermediate duration inhalation of suspended dust from 2549 automotive adhesives for adults (21+ years) (Table 4-15). Variability in MOEs for these high-intensity 2550 exposure scenarios results from use of different exposure factors for each COU and product or article 2551 example that led to different estimates of exposure to DCHP. As described in the Draft Consumer and 2552 Indoor Dust Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c) and Draft 2553 Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024v), 2554 EPA has moderate to robust confidence in the exposure estimates and robust confidence in the non-2555 cancer hazard value used to estimate non-cancer risk for these COUs. 2556

2557 Adhesives and Sealants

Two different scenarios were assessed under this COU for products with differing use patterns for example, adhesives for small repairs (2 products) and automotive adhesives (2 products). The two scenarios capture the variability in product formulation and use patterns in the high, medium, and low intensity use estimates. The small repairs products are used in small amounts and have very short working times (<5 minutes), which limits the potential for inhalation exposure. However, if dermal

2563 exposure occurs during use it is possible that the product may not be washed off immediately, resulting 2564 in exposure. As such, both products were modeled for dermal exposure only. The automotive adhesives 2565 products may be used for large repairs to vehicle bodies and were assessed for both inhalation and 2566 dermal exposure. The overall confidence in the inhalation exposure estimates for this COU is robust 2567 because the CEM default parameters are representative and plausible use patterns and location of use. 2568 For dermal exposure, EPA used a dermal flux approach. The Agency has moderate confidence in dermal 2569 estimates because of the moderate uncertainty in the partitioning from product to skin. In addition, 2570 subsequent dermal absorption is not well characterized or confirmed with experimental results. 2571 However, other parameters such as frequency and duration of use, and surface area in contact, are well 2572 understood and representative, resulting in an overall confidence of moderate in a health protective 2573 estimate. Additionally, EPA has robust overall confidence in the underlying chronic POD based on 2574 developmental toxicity (Section 4.2). 2575

Aggregate risk from dermal, ingestion, and inhalation exposures to DCHP for the two scenarios was also
 considered. All three exposure routes are essentially negligible in their overall contribution to the
 aggregate since the individual MOE values were significantly higher than the benchmark of 30.

Other Articles with Routine Direct Contact During Normal Use Including Rubber Articles; Plastic Articles (Hard)

One scenario was assessed under this COU. It considered multiple articles and routine dermal contact with similar use patterns. The scenario for small articles of routine dermal contact was assessed for dermal exposures only because inhalation and ingestion would have low exposure potential due to the small surface area of the articles and limited time spent in an indoor environment before disposal and mouthing was not an expected behavior based on the generic article examples identified.

2588 The small articles with the potential for semi-routine contact scenario considers some generic example 2589 descriptions but not specific products, for example labels, nitrocellulose; ethylcellulose; chlorinated 2590 rubber; PVAc; PVC. These examples are expected to be used in smaller items and the primary exposure 2591 route is through dermal contact when handling the goods. Although DCHP content was not reported or 2592 measured in specific products, this scenario was included for dermal exposure calculations, which does 2593 not use weight fractions. Dermal contact events are likely short and/or infrequent, but an individual 2594 could have appreciable daily contact with multiple items. All acute and chronic MOE values were well 2595 above the benchmark of 30. The MOE values increase with increasing age due to changes in inhalation 2596 rate to body weight ratios, thus leading to decreasing exposure with increasing age. 2597

Dermal absorption estimates are based on the assumption that dermal absorption of DCHP from solid objects would be limited by aqueous solubility of DCHP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning from solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters such as frequency and duration of use, and surface area in contact, are well understood and representative, resulting in an overall confidence of moderate in a health protective estimate. Additionally, EPA has robust overall confidence in the underlying chronic POD based on developmental toxicity (Section 4.2).

2605

2579

Other; Consumer Articles that Contain Dicyclohexyl Phthalate from: Inks, Toner, and Colorant, Paints and Coatings, Adhesives, and Sealants (e.g., Paper Products, Textiles, Products Using

- 2608 Cellulose Film, etc.)
- 2609 Three different scenarios were assessed under this COU for articles with differing use patterns: Outdoor
- 2610 seating, small articles with potential for routine contact (multiple non-specific articles), and electronics
- 2611 containing dye adhesive (qualitative discussion). The outdoor seating and small articles scenarios were

2612 assessed for dermal exposures only. For the outside seating scenario, based on DCHP's waterproofing 2613 and weather resistant properties and the expected use case for outdoor seating, EPA anticipated use of 2614 this article occurs outdoors where air exchange rates are large; thus, inhalation exposure is expected to 2615 be negligible. Dermal exposures were modeled for a scenario where consumers sit on coated surfaces 2616 (e.g., on seats at a sporting event or directly on a terrace). The small articles with the potential for semi-2617 routine contact scenario considers generic examples but no specific items were identified (like labels for 2618 cleaning products or arts and crafts materials); instead, EPA used article descriptors like labels and 2619 packaging adhesives, foil and cellophane lacquers, and printing inks. These articles are expected to be used in small quantities and the primary exposure route is through dermal contact when handling the 2620 2621 goods. Although DCHP content was not reported or measured in specific articles, this scenario was 2622 included for dermal exposure calculations that do not use weight fractions. Dermal contact events are 2623 likely short and/or infrequent, but an individual could have appreciable daily contact with multiple 2624 items. The items are not expected to be mouthed and the likelihood of inhalation exposure is minimal 2625 due to their small surface area and limited time spent in an indoor environment before disposal. The 2626 electronics containing dye adhesive was qualitatively assessed because it is used in small quantities and 2627 contained within the electronic articles; thus, no exposures are expected during potential use of these 2628 items. An aggregate analysis for this COU was not performed because all scenarios were assessed for 2629 dermal exposures only.

2630

EPA has slight confidence in some aspects of the exposure estimate for solid articles because of the high
uncertainty in the assumption of partitioning from solid to liquid and because subsequent dermal
absorption is not well characterized. However, other parameters such as frequency and duration of use
and surface area in contact are well understood and representative, resulting in an overall confidence of
moderate in a health protective estimate. Additionally, EPA has robust overall confidence in the
underlying chronic POD based on developmental toxicity (Section 4.2).

2637

4.3.3.1 Overall Confidence in Consumer Risks

2638 As described in Section 4.1.2.3 and in more detail in the *Draft Consumer and Indoor Dust Exposure* 2639 Assessment Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c), EPA has moderate and robust 2640 confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios, and robust 2641 confidence in the acute, intermediate and chronic non-cancer PODs selected to characterize risk from 2642 acute, intermediate, and chronic duration exposures to DCHP (see Section 4.2 and (U.S. EPA, 2024c)). 2643 The exposure doses used to estimate risk relied on conservative, health protective inputs and parameters 2644 that are considered representative of a wide selection of use patterns. Sources of uncertainty associated with all consumer COUs are discussed above in Section 4.3.3. 2645

2646 **Table 4-15. Consumer Risk Summary Table**

Life Cruele Sterrer			F	Exposure				Lifestage (year nchmark MOE			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	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)	Adult (21+ years)
		Acute ^c	Dermal	Н	-	-	-	-	16,000	17,000	16,000
			Ingestion	Н	—	-	-	_	-	_	—
			Inhalation	Н	_	-	-	_	_	_	_
Consumer Uses: Adhesives and	A 11 · C 11		Aggregate	Н	—	-	-	-	16,000	17,000	16,000
	Adhesives for small repairs	Intermed.	—	-	-	_	-	_	_	_	—
and sealants	repairs	Chronic	Dermal	Н	-	_	-	_	110,000	120,000	110,000
			Ingestion	Н	-	-	-	-	-	-	—
			Inhalation	Н	-	-	-	-	-	-	—
			Aggregate	Н	-	_	-	_	110,000	120,000	110,000
		Acute ^c	Dermal	Н	-	-	-	-	11,000	12,000	11,000
			Ingestion	Н	-	-	-	-	-	-	—
	Automotive		Inhalation	Н	20,000 ^b	21,000 ^b	26,000 ^b	37,000 ^b	43,000	52,000	63,000
Consumer Uses:	adhesives		Aggregate	Н	20,000 ^b	21,000 ^b	26,000 ^b	37,000 ^b	8,800	9,800	9,600
Adhesives and sealants: Adhesives		Intermed.	Dermal	Н	—	-	-	_	170,000	180,000	170,000
and sealants	$(^{b} = MOE \text{ for})$		Ingestion	Н	_	_	_	-	_	_	—
	bystander scenario)		Inhalation	Н	300,000 ^b	310,000 ^b	390,000 ^b	560,000 ^b	650,000	780,000	950,000
			Aggregate	Н	300,000 ^b	310,000 ^b	390,000 ^b	560,000 ^b	130,000	150,000	140,000
		Chronic	—	-	—	-	-	_	_	_	—
		Acute ^c	Dermal	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500
Consumer Uses:	Small articles with		Ingestion	Н	_	_	_	_	_	_	—
Other articles with	potential for semi-		Inhalation	Н	_	_	_	_	_	_	—
routine direct contact	routine contact:		Aggregate	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500
during normal use	labels, nitrocellulose;	Intermed.	-	-	-	-	-	_	-	_	-
including rubber	ethylcellulose;	Chronic	Dermal	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500
articles; plastic	chlorinated rubber;		Ingestion	Н	-	-	_	-	-	_	-
articles (llaru)	PVAc; PVC		Inhalation	Н	-	-	_	-	-	_	-
			Aggregate	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500

Life Cycle Stages			Evnosuro	Exposure				Lifestage (year nchmark MOE					
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	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)	Adult (21+ years)		
Consumer Uses:		Acute ^c	Dermal	Н	740	870	1,000	1,200	1,600	1,700	1,600		
Consumer articles			Ingestion	Н	—	_	_	_	_	—	_		
that contain dicyclohexyl			Inhalation	Н	_	_	_	_	-	_	_		
phthalate from: Inks,			Aggregate	Н	740	870	1,000	1,200	1,600	1,700	1,600		
toner, and colorants;		Intermed.	_	-	—	_	_	_	_	—	_		
Paints and coatings;	Outdoor seating	Chronic	Dermal	Н	5,200	6,100	7,000	8,700	11,000	12,000	11,000		
Adhesives and			Ingestion	Н	_	—	_	—	_	_	_		
sealants (e.g., paper			Inhalation	Н	_	_	_	_	_	_	_		
products, textiles, products using cellulose film, etc.)			Aggregate	Н	5,200	6,100	7,000	8,700	11,000	12,000	11,000		
Consumer Uses:		Acute ^c	Dermal	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500		
Consumer articles			Ingestion	Н	_	_	_	_	_	_	_		
that contain	Small articles with		Inhalation	Н	_	_	_	_	=	_	_		
dicyclohexyl	the potential for		Aggregate	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500		
phthalate from: Inks, toner, and colorants;	semi-routine contact: labels, and	Intermed.	-	-	_	_	_	_	_	_	_		
Paints and coatings;	packaging	Chronic	Dermal	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500		
Adhesives and	adhesives, foil and		Ingestion	Н	_	_	_	_	_	_	_		
sealants (e.g., paper	cellophane lacquers,		Inhalation	Н	-	_	_	_	_	_	_		
products, textiles, products using cellulose film, etc.)	and printing inks		Aggregate	Н	2,100	2,400	2,800	3,500	4,400	4,900	4,500		
Consumer Uses: Consumer articles that contain dicyclohexyl phthalate from: Inks, toner, and colorants; Paints and coatings; Adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.) ^{<i>a</i>} Exposure scenario ir		ectronics ntaining dye Exposures not expected. Identified in dye attach adhesive used in wirebond packaging for semiconductor devices or in automotive cameras. As the adhesive is used in small quantities and contained within the electronic articles, no exposures are expected during potential use of these items											
^b Bystander scenarios ^c Scaling by the RPF a set. Please see Table 4	and application of the		cal POD provi	des a more se	nsitive and rob	oust hazard asses	ssment than the	DCHP-specific	POD, given its m	ore limited toxi	cological data		

26484.3.4Risk Estimates for General Population Exposed to DCHP through Environmental
Releases

2650 As described in the Draft Environmental Media, General Population, and Environmental Exposure 2651 Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p) and Section 4.1.3, EPA used a screening-level approach for general population exposures for DCHP releases associated with TSCA 2652 2653 COUs. Fenceline communities were considered as part of the general population in proximity to 2654 releasing facilities as part of the ambient air exposure assessment by utilizing pre-screening 2655 methodology 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, 2022b). For other exposure 2656 2657 pathways, the Agency's screening method assessing high-end exposure scenarios used release data that 2658 reflect exposures expected to occur in proximity to releasing facilities, which would include fenceline 2659 communities.

2660

2661 EPA evaluated surface water, drinking water, fish ingestion, and ambient air pathways quantitatively, in addition to the land pathway (*i.e.*, landfills and application of biosolids) qualitatively. For pathways 2662 2663 assessed quantitatively, high-end estimates of DCHP concentration in the various environmental media were used for screening-level purposes. EPA used an MOE approach using high-end exposure estimates 2664 2665 to determine whether an exposure pathway had potential non-cancer risks. High-end exposure estimates 2666 were defined as those associated with the industrial and commercial releases from a COU and OES that 2667 resulted in the highest environmental media concentrations. If there is no risk for an individual identified 2668 as having the potential for the highest exposure associated with a COU for a given pathway of exposure, 2669 then that pathway was determined to not be a pathway of concern and not pursued further. If any 2670 pathways were identified as a pathway of concern for the general population, further exposure assessments for that pathway would be conducted to include higher tiers of modeling when available 2671 2672 and exposure estimates developed for additional subpopulations and COUs. Using a screening-level approach described in Section 4.1.3, no pathways of exposure were identified to be of concern for the 2673 2674 general population exposed to environmental releases. 2675

2676 Land Pathway

DCHP has a low water solubility and high affinity for sorption to particulate and organic media. This
indicates that it is unlikely to migrate from land-applied biosolids to groundwater via runoff. DCHP's
potential to leach from landfills into nearby groundwater or surface water systems is also limited.
Therefore, EPA evaluated general population exposures via the land pathway (*i.e.*, application of
biosolids, landfills) qualitatively (Section 4.1.3.1).

2683 Surface Water Pathway

MOEs for general population exposure through incidental ingestion and dermal contact during swimming ranged from 2,171 to 6,310 for scenarios assuming no wastewater treatment and from 5,521 to 20,000 for scenarios assuming 68.6 percent wastewater treatment removal efficiency (Table 4-16). Therefore, *based on a screening-level assessment, risk for non-cancer health effects is not expected for the surface water pathway, and the pathway is not considered to be a pathway of concern for the general population.*

2690

Acute MOEs through drinking water ingestion were 135 and 430 without and with wastewater

treatment, respectively, for the lifestage (*i.e.*, infants) with the highest exposure (Table 4-16). Based on

2693 the screening-level analysis, risk for non-cancer health effects is not expected for the drinking water

2694 pathway, and the drinking water pathway is not considered to be a pathway of concern for the general

2695 *population*.

Table 4-16. Summary of the Highest Doses for General Population through Surface and Drinking Water Exposure

0.504	Water Column Concen.		tal Dermal æ Water ^b		tal Ingestion ce Water ^c	Drinki	ng Water ^d
OES ^a	30Q5 Conc. (μg/L)	ADR _{POT} (mg/kg- day)	Acute MOE (Benchmark MOE = 30)	ADR _{POT} (mg/kg- day)	Acute MOE (Benchmark MOE = 30)	ADR _{POT} (mg/kg- day)	Acute MOE (Benchmark MOE = 30)
PVC plastics compounding without wastewater treatment	126	1.1E-03	2,171	6.7E–04	3,559	1.8E-02	135
PVC plastics compounding with wastewater treatment	39.6	3.50E-04	6,913	2.1E-04	11,000	5.6E-03	430

N/A = not applicable

^{*a*} Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

^b Most exposed age group: Adults (21+ years)

Most exposed age group: Youth (11–15 years)

^d Most exposed age group: Infant (birth to <1 year)

2698

2699 Fish Ingestion

EPA evaluated potential exposure and subsequent risks to DCHP through fish ingestion for populations
and age groups that had the highest fish ingestion rate per kg of body weight—including adults and
young toddlers in the general population, adult subsistence fishers, and adult Tribal populations. Risks
were estimated for various populations and age groups; however, Table 4-17 show only results for the
Tribal populations because it led to the highest exposure.

2705

2706 For the screening-level analysis, EPA started with the water solubility limit as an upper limit of DCHP 2707 concentration in surface water for the general population, subsistence fisher, and Tribal populations. 2708 Screening-level risk estimates were above the benchmark for the general population based on 2709 conservative exposure estimates. Refinements were needed for the subsistence fisher and Tribal populations because screening-level risk estimates using the water solubility limit were below the 2710 2711 benchmark (see Section 8 of (U.S. EPA, 2024p)). Refinements included use of estimated water releases 2712 by OES, as well as incorporation of various hydrologic flow data for each OES, to model the surface 2713 water concentrations. Briefly, hydrologic flow data were categorized into median flow (P50), 75th 2714 percentile flow (P75), and 90th percentile flow (P90). EPA expects high-end releases to discharge to 2715 surface waters with higher flow conditions (e.g., P75 and P90).

2716

The PVC plastics compounding OES resulted in the highest surface water concentrations. Surface water 2717 2718 concentrations calculated based on the median flow rate led to risk estimates below benchmark for only 2719 Tribal populations ingesting fish at the heritage rate. Heritage rates are not suppressed by contamination, 2720 degradation, or loss of access and existed prior to non-indigenous settlement on Tribal fisheries resources (U.S. EPA, 2016a). As high-end releases are not expected to discharge to water bodies with 2721 2722 low flow conditions like P50, EPA incorporated higher flow rates and treatment efficiency into its analysis for Tribal populations. When treatment is considered, risk estimates were above benchmark 2723 2724 even at the P50 condition for all scenarios. Lastly, DCHP is expected to have low potential for 2725 bioaccumulation, biomagnification, and uptake by aquatic organisms because of its low water solubility 2726 and high hydrophobicity as described in Section 4.4. Therefore, fish ingestion is not a pathway of 2727 concern for DCHP for Tribal members, subsistence fishers, or the general population.

	Current Mean (Benchmark	0	Heritage Ingestion Rate ^b (Benchmark MOE = 30)		
Calculation Method	ADR/ADD (mg/kg-day)	Chronic and Acute MOE ^a	ADR/ADD (mg/kg-day)	Chronic and Acute MOE ^a	
Water solubility limit (1.48 mg/L)	2.68E-01	9	2.04	1	
Modeled SWC for PVC plastics compounding, P50 flow (0.087 mg/L)	1.59E-02	151	1.21E-01	20	
Modeled SWC for PVC plastics compounding, P75 flow (3.48E–03 mg/L)	6.30E-04	3,812	4.80E-03	500	
Modeled SWC for PVC plastics compounding, P90 flow (2.4E–04 mg/L)	4.40E-05	54,597	3.35E-04	7,163	
Modeled SWC for PVC plastics compounding, P50 flow, Treated (2.7E–02 mg/L)	4.97E-03	482	3.79E-02	63	
Highest monitored SWC (1.0E-05 mg/L)	2.53E-06	947,643	1.93E-05	124,326	

2728 Table 4-17. Fish Ingestion for Adults in Tribal Populations Summary

SWC = surface water concentration

^{*a*} The acute and chronic MOEs are identical because the exposure estimates and the POD do not change between acute and chronic.

^b Current ingestion rate refers to the present-day consumption levels 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 lifeway.

2729

2730 Ambient Air Pathway

2731 As part of the ambient air exposure assessment, EPA considered exposures to the general population in

2732 proximity to releasing facilities, including fenceline communities, by utilizing pre-screening

2733 methodology described in EPA's Draft TSCA Screening Level Approach for Assessing Ambient Air and

2734 Water Exposures to Fenceline Communities (Version 1.0) (U.S. EPA, 2022b). Using the highest

modeled 95th percentile air concentration, MOEs for general population exposure through inhalation are
for acute and 281 for chronic (Table 4-18) (compared to a benchmark of 30).

2737

Based on risk screening results, risk for non-cancer health effects is not expected for the ambient air
pathway; therefore, the ambient air pathway is not considered to be a pathway of concern to DCHP for
the general population, including fenceline communities.

2741

2742 **Table 4-18. General Population Ambient Air Exposure Summary**

	Acute (Dai	ily Average)		Chronic (Annual Average)			
OES ^a	Air Concentration ^b (µg/m ³)	AC (mg/kg-day)	MOE	Air Concentration ^b (µg/m ³)	ADC (mg/kg-day)	MOE	
Application of paints and coatings	67.57	67.57	192	46.28	46.28	281	

AC = acute concentration; ADC = average daily concentration; MOE = margin of exposure; OES = occupation exposure scenario

^a Table 1-1 provides a crosswalk of industrial and commercial COUs to OES.

^b 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.

2743

2745 Urinary Biomonitoring Data – NHANES

CDC stopped collected urinary data for MCHP after 2010. EPA analyzed biomonitoring data from the
1999–2010 NHANES cycle but the low detection rates and limited data variability precluded any
meaningful statistical analyses. Furthermore, EPA's systematic review process did not identify any
suitable alternative sources of DCHP biomonitoring data. Therefore, EPA did not conduct reverse
dosimetry to calculate daily intake values for DCHP (Section 4.1.3.1).

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2772 2773

4.3.4.1 Overall Confidence in General Population Screening Level Exposure Assessment

2753 The weight of scientific evidence supporting the general population exposure estimate is decided based 2754 on the strengths, limitations, and uncertainties associated with the exposure estimates, which are discussed in detail for ambient air, surface water, drinking water, and fish ingestion in the Draft 2755 2756 Environmental Media, General Population, and Environmental Exposure Assessment for Dicyclohexyl 2757 *Phthalate (DCHP)* (U.S. EPA, 2024p). EPA summarized its weight of scientific evidence using 2758 confidence descriptors: robust, moderate, slight, or indeterminate. EPA used general considerations (i.e., 2759 relevance, data quality, representativeness, consistency, variability, uncertainties) as well as chemical-2760 specific considerations for its weight of scientific evidence conclusions.

2762 EPA determined robust confidence in its qualitative assessment of biosolids and landfills. For its 2763 quantitative assessment, EPA modeled exposure due to various general population exposure scenarios resulting from different pathways of exposure. Exposure estimates used high-end inputs for the purpose 2764 of risk screening. When available, monitoring data was compared to modeled estimates to evaluate 2765 2766 overlap, magnitude, and trends, EPA has robust confidence that modeled releases used are appropriately 2767 conservative for a screening level analysis. Therefore, EPA has robust confidence that no exposure 2768 scenarios will lead to greater doses than presented in this evaluation. Despite slight and moderate 2769 confidence in the estimated values themselves, confidence in exposure estimates capturing high-end 2770 exposure scenarios was robust given that many of the modeled values exceeded those of monitored 2771 values.

4.3.5 Risk Estimates for Potentially Exposed or Susceptible Subpopulations

EPA considered PESS throughout the exposure assessment and throughout the hazard identification and
 dose-response analysis supporting the draft DCHP risk evaluation.

2777 Some population group lifestages may be more susceptible to the health effects of DCHP exposure. As 2778 discussed in Section 4.2 and in EPA's Draft Non-cancer Human Health Hazard Assessment for 2779 Dicyclohexyl Phthalate (U.S. EPA, 2024y) and Draft Technical Support Document for the Cumulative 2780 Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2024ah), 2781 exposure to DCHP causes adverse effects on the developing male reproductive system consistent with a 2782 disruption of androgen action and phthalate syndrome in experimental animal models. Therefore, 2783 women of reproductive age, pregnant women, male infants, male children, and male adolescents are considered to be susceptible subpopulations. These susceptible lifestages were considered throughout 2784 2785 the draft risk evaluation. For example, women of reproductive age were evaluated for occupational 2786 exposures to DCHP for each COU (Section 4.3.2). Additionally, infants (<1 year), toddlers (1–2 years), 2787 preschoolers (3–5 years), middle school children (6–10 years), young teens (11–15 years), and teenagers (16-20 years) were evaluated for exposure to DCHP through consumer products and articles (Section 2788 2789 4.3.3). EPA also considered cumulative phthalate exposure and risk for female workers of reproductive 2790 age, as well as male children and female consumers of reproductive age. Additionally, the Agency used 2791 a value of 10 for the UF_H to account for human variability. The Risk Assessment Forum, in A Review of 2792 the Reference Dose and Reference Concentration Processes, discusses some of the evidence for

choosing the default factor of 10 when data are lacking—including toxicokinetic and toxicodynamic
factors as well as greater susceptibility of children and elderly populations (U.S. EPA, 2002b).

- 2795
 2796 The available data suggest that some groups or lifestages have greater exposure to DCHP. This includes
 2797 people exposed to DCHP at work, those who frequently use consumer products and/or articles
- 2797 people exposed to DCH1 at work, those who nequently use consumer products and/or articles2798 containing high concentrations of DCHP, those who may have greater intake of DCHP per body weight
- 2799 (*e.g.*, infants, children, adolescents) leading to greater exposure. EPA accounted for these populations
- 2800 with greater exposure in the draft DCHP risk evaluation as follows:
- EPA evaluated a range of OESs for workers and ONUs, including high-end exposure scenarios
 for women 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.
- 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 to DCHP through fish ingestion for subsistence fishers and Tribal populations.
- EPA aggregated occupational inhalation and dermal exposures for each COU for women 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 women of reproductive age (16-49 years) and male children (3-5, 6-11, and 12-15 years of age).
- For women of reproductive age, black non-Hispanic women had higher, albeit not statistically significantly 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.

2824 4.4 Human Health Cumulative Risk Assessment and Characterization

2825 EPA developed a Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2024ah) (draft CRA TSD) for the CRA of six 2826 2827 toxicologically similar phthalates being evaluated under Section 6 of the Toxic Substances Control Act 2828 (TSCA): di(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), 2829 dicyclohexyl phthalate (DCHP), diisobutyl phthalate (DIBP), and diisononyl phthalate (DINP). EPA 2830 previously issued a Draft Proposed Approach for Cumulative Risk Assessment of High-Priority 2831 Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act (draft 2832 2023 approach), which outlined an approach for this assessment (U.S. EPA, 2023c). EPA's proposal 2833 was subsequently peer-reviewed by the Science Advisory Committee on Chemicals (SACC) in May 2834 2023 (U.S. EPA, 2023f). In the 2023 draft approach, EPA identified a cumulative chemical group and 2835 PESS [15 U.S.C. section 2605(b)(4)]. Based on toxicological similarity and induced effects on the 2836 developing male reproductive system consistent with a disruption of androgen action and phthalate 2837 syndrome, EPA proposed a cumulative chemical group of DEHP, BBP, DBP, DCHP, DIBP, and DINP, 2838 but not diisodecyl phthalate (DIDP). This approach emphasizes a uniform measure of hazard for 2839 sensitive subpopulations, namely women of reproductive age and/or male infants and children, however

additional health endpoints are known for broader populations and described in the individual noncancer human health hazard assessments for DEHP (<u>U.S. EPA, 2024w</u>), DBP (<u>U.S. EPA, 2024u</u>), DIBP
(<u>U.S. EPA, 2024x</u>), BBP (<u>U.S. EPA, 2024t</u>), DCHP (<u>U.S. EPA, 2024v</u>), and DINP (<u>U.S. EPA, 2025b</u>),
including hepatic, kidney, and other developmental and reproductive toxicity.

2845 EPA's approach for assessing cumulative risk is described in detail in the draft CRA TSD (U.S. EPA, 2846 2024ah) and incorporates feedback from the SACC (U.S. EPA, 2023f) on EPA's 2023 draft proposal 2847 (U.S. EPA, 2023c). EPA is focusing its CRA on acute duration exposures of women of reproductive 2848 age, male infants, and male children to six toxicologically similar phthalates (*i.e.*, DEHP, DBP, BBP, 2849 DIBP, DCHP, DINP) that induce effects on the developing male reproductive system consistent with a 2850 disruption of androgen action and phthalate syndrome. The Agency is further focusing its CRA on acute 2851 duration exposures because there is evidence that effects on the developing male reproductive system 2852 consistent with a disruption of androgen action can result from a single exposure during the critical 2853 window of development (see Section 1.5 of (U.S. EPA, 2024ah) for further details). To evaluate 2854 cumulative risk, EPA is using a relative potency factor (RPF) approach. RPFs for DEHP, DBP, BBP, 2855 DIBP, DCHP, and DINP were developed using a meta-analysis and benchmark dose (BMD) modeling 2856 approach based on a uniform measure (*i.e.*, reduced fetal testicular testosterone). EPA is also using 2857 NHANES data to supplement, not substitute, evaluations for exposure scenarios for TSCA COUs to 2858 provide non-attributable, total exposure for addition to the relevant scenarios presented in the individual 2859 risk evaluations. 2860

2861 The analogy of a "risk cup" is used throughout this document to describe cumulative exposure estimates. The risk cup term is used to help conceptualize the contribution of various phthalate exposure routes and 2862 2863 pathways to overall cumulative risk estimates and serves primarily as a communication tool. The term/ 2864 concept describes exposure estimates where the full cup represents the total exposure that leads to risk 2865 (cumulative MOE) and each chemical contributes a specific amount of exposure that adds a finite 2866 amount of risk to the cup. A full risk cup indicates that the cumulative MOE has dropped below the benchmark MOE (*i.e.*, total UF), whereas cumulative MOEs above the benchmark indicate that only a 2867 2868 percentage of the risk cup is full.

2869

2844

2870 The remainder of the human health CRA 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 CRA TSD (U.S. EPA, 2024ah) 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 CRA TSD (U.S. EPA, 2024ah) provides additional details.
- Section 4.4.3 Describes how EPA combined exposures to DCHP 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 CRA TSD (U.S. EPA, 2024ah) provides additional details.
- 2884 For additional details regarding EPA's draft CRA, readers are directed to the following TSDs:
- Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
 Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl

- 2887Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the2888Toxic Substances Control Act (TSCA) (U.S. EPA, 2024ah);
- 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, 2024s);
- Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act (U.S. EPA, 2023c);
- Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act (U.S. EPA, 2023d); 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).
- 2901 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:

- 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
- 2910 Toxic Substances Control Act (TSCA) (U.S. EPA, 2024ah); and
- 2911 Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2-
- 2912 *ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP),*
- 2913 Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024s).
- 2914

4.4.1.1 Relative Potency Factor Approach Overview

For the RPF approach, chemicals being evaluated require data that support toxicologic similarity (e.g., 2915 2916 components of a mixture share a known or suspected common MOA or share a common apical 2917 endpoint/effect) and have dose-response data for the effect of concern over similar exposure ranges 2918 (U.S. EPA, 2023a, 2000, 1986). RPF values account for potency differences among chemicals in a mixture and scale the dose of one chemical to an equitoxic dose of another chemical (i.e., the index 2919 2920 chemical). The chemical selected as the index chemical is often among the best characterized 2921 toxicologically and considered to be representative of the type of toxicity elicited by other components 2922 of the mixture. Implementing an RPF approach requires a quantitative dose-response assessment for the 2923 index chemical and pertinent data that allow the potency of the mixture components to be meaningfully 2924 compared to that of the index chemical. In the RPF approach, RPFs are calculated as the ratio of the 2925 potency of the individual component to that of the index chemical using either (1) the response at a fixed 2926 dose, or (2) the dose at a fixed response (Equation 4-3).

2927

2928 Equation 4-3. Calculating RPFs

2929

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

2930	Where:		
2931	BMD	=	Benchmark dose (mg/kg/day)
2932	R	=	Magnitude of response (<i>i.e.</i> , benchmark response)
2933	Ι	=	i th chemical
2934	IC	=	Index chemical

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

2938 Equation 4-4. Calculating Index Chemical Equivalents

2939

2937

Index Chemical Equivalents_{MIX} =
$$\sum_{i=1}^{n} d_i \times RPF_i$$

2940 Where:

2941	Index chemical equivalents	=	Dose of the mixture in index chemical equivalents
2942			(mg/kg/day)
2943	d_i	=	Dose of the i^{th} chemical in the mixture (mg/kg/day)
2944	RPF_i	=	Relative potency factor of the i^{th} chemical in the mixture
2945			(unitless)

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

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4.4.1.2 Relative Potency Factors

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2953

2954 Derivation of Draft RPFs

2955 To derive RPFs for DEHP, DBP, BBP, DIBP, DCHP, and DINP, EPA utilized a meta-analysis and 2956 BMD modeling approach similar to that used by NASEM (2017) to model decreased fetal testicular 2957 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, 2024s), the Agency 2958 evaluated benchmark responses (BMRs) of 5, 10, and 40 percent. For input into the CRA of phthalates, 2959 EPA has derived draft RPFs using BMD₄₀ estimates (Table 4-19). For further details regarding RPFs 2960 derivation, see Section 2 of EPA's Draft Technical Support Document for the Cumulative Risk Analysis 2961 2962 of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2024ah).

2963

2964 Selection of the Index Chemical

Of the six phthalates being evaluated for cumulative risk under TSCA (*i.e.*, DEHP, DBP, BBP, DIBP,
DCHP, and DINP), *EPA has preliminarily selected DBP as the index chemical.*

2967

As described further in Section 2 of EPA's *Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA* (U.S. EPA, 2024ah), EPA selected

2970 DBP as the index chemical DBP has a high-quality toxicological database of studies demonstrating

2971 effects on the developing male reproductive system consistent with a disruption of androgen action and

- 2972 phthalate syndrome. Furthermore, studies of DBP demonstrate toxicity representative of all phthalates in
- 2973 the cumulative chemical group and DBP is well characterized for the MOA associated with phthalate
- 2974 syndrome. Finally, compared to other phthalates, 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 based.

- 2978
- 2979
- 2980

Table 4-19. Draft Relative Potency Factors Based onDecreased Fetal Testicular Testosterone

Phthalate	BMD40 (mg/kg-day)	RPF Based on BMD40		
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		

2981

2982Index Chemical POD

2983 As with any risk assessment that relies on BMD analysis, the POD is the lower confidence limit used to 2984 mark the beginning of extrapolation to determine risk associated with human exposures. As described 2985 further in the non-cancer human health hazards of DEHP (U.S. EPA, 2024w), DBP (U.S. EPA, 2024u), 2986 BBP (U.S. EPA, 2024t), DIBP (U.S. EPA, 2024x), DCHP (U.S. EPA, 2024v), and DINP (U.S. EPA, 2987 2025b) (see Appendices titled "Considerations for Benchmark Response (BMR) Selection for Reduced 2988 Fetal Testicular Testosterone" in each hazard assessment). EPA has reached the conclusion that a BMR 2989 of 5 percent is the most appropriate and health protective response level for evaluating decreased fetal 2990 testicular testosterone. For the index chemical, DBP, the $BMDL_5$ for the best fitting linear-quadratic 2991 model is 9 mg/kg-day for reduced fetal testicular. Using allometric body weight scaling to the three-2992 quarters power (U.S. EPA, 2011c), EPA extrapolated an HED of 2.1 mg/kg-day to use as the POD for 2993 the index chemical in the CRA.

2995 Selection of the Benchmark MOE

2996 Consistent with Agency guidance (U.S. EPA, 2022c, 2002b), EPA selected an intraspecies uncertainty 2997 factor (UF_H) of 10, which accounts for variation in susceptibility across the human population and the 2998 possibility that the available data might not be representative of individuals who are most susceptible to 2999 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 3000 Guidance (U.S. EPA, 2011c), the interspecies uncertainty factor (UF_A), was reduced from 10 to 3 to 3001 3002 account remaining uncertainty associated with interspecies differences in toxicodynamics. Overall, a 3003 total uncertainty factor of 30 was selected for use as the benchmark margin of exposure for the CRA 3004 (based on a interspecies uncertainty factor $[UF_A]$ of 3 and a intraspecies uncertainty factor $[UF_H]$ of 10).

3005

2994

3006 Weight of Scientific Evidence

3007 EPA has preliminary selected an HED of 2.1 mg/kg-day (BMDL₅ of 9 mg/kg-day) as the index chemical

3008 (DBP) POD. This POD is based on a meta-analysis and BMD modeling of decreased fetal testicular

- 3009 testosterone from eight studies of rats gestationally exposed to DBP. The Agency EPA has also derived
- 3010 draft RPFs of 1, 0.84, 0.53, 0.52, 1.66, and 0.21 for DBP (index chemical), DEHP, DIBP, BBP, DCHP,
- and DINP, respectively, based on a common toxicological outcome (*i.e.*, reduced fetal testicular
- 3012 testosterone). EPA has robust overall confidence in the proposed POD for the index chemical (i.e.,
- 3013 *DBP*) and the derived draft RPFs.

3014

- 3015 Application of RPF provides a more robust basis for assessing the dose-response to the common hazard
- 3016 endpoint across all assessed phthalates. For DCHP and a subset of the phthalates with a more limited
- toxicological data set, scaling by the RPF and application of the index chemical POD provides a more
- 3018 sensitive and robust hazard assessment than the chemical-specific POD. Readers are directed to the
- 3019 Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, 2020 DCHP, and DINP Under TSCA (U.S. EPA, 2024ab) for a discussion of the weight of evidence
- 3020 *DCHP, and DINP Under TSCA* (U.S. EPA, 2024ah) for a discussion of the weight of evidence
- 3021 supporting EPA's preliminary conclusions.
- 3022
- 3023 3024

4.4.2 Cumulative Phthalate Exposure: Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and DINP Using NHANES Urinary Biomonitoring and Reverse Dosimetry

This section briefly summarizes EPA's approach and results for estimating non-attributable cumulative exposure to phthalates using NHANES urinary biomonitoring data and reverse dosimetry. Readers are directed to Section 4 of EPA's *Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA* (U.S. EPA, 2024ah) for additional details.

- 3030 NHANES is an ongoing exposure assessment of the U.S. population's exposure to environmental
- chemicals using biomonitoring. The NHANES biomonitoring data set is a national, statistical
 representation of the general, non-institutionalized, civilian U.S. population. CDC's NHANES data set
- provides an estimate of average aggregate exposure to individual phthalates for the U.S. population.
 However, exposures measured via NHANES cannot be attributed to specific sources, such as TSCA
- However, exposures measured via NHANES cannot be attributed to specific sources, such as TSCA
 COUs or other sources. Given the short half-lives of phthalates, neither can NHANES capture acute, low
- frequency exposures. Instead, as concluded by the SACC review of the draft 2023 approach, NHANES provides a "snapshot" or estimate of total, non-attributable phthalate exposure for the U.S. population and relevant subpopulations (U.S. EPA, 2023f). These estimates of total non-attributable exposure can supplement assessments of scenario-specific acute risk in individual risk evaluations.
- Monoester metabolites of BBP, DBP, DEHP, DIBP, and DINP in human urine are regularly measured 3040 3041 as part of the NHANES biomonitoring program and are generally detectable in human urine at a high 3042 frequency, including during the most recent NHANES survey period (*i.e.*, 2017–2018). One urinary 3043 metabolite (i.e., monocyclohexyl phthalate [MCHP]) of DCHP was included in NHANES from 1999 3044 through 2010, but was excluded from NHANES after 2010 due to low detection levels and a low 3045 frequency of detection in human urine (detected in <10% of samples in 2009–2010 NHANES survey) 3046 (CDC, 2013). Therefore, EPA did not use NHANES urinary biomonitoring data to estimate a daily 3047 aggregate intake value for DCHP through reverse dosimetry.
- 3048

EPA used urinary phthalate metabolite concentrations for DEHP, DBP, BBP, DIBP, and DINP
 measured in the most recently available NHANES survey (2017–2018) to estimate the average daily
 aggregate intake of each phthalate through reverse dosimetry for

- Women of reproductive age (16-49 years);
- Male children (4 to <6 years, used as a proxy for male infants and toddlers);
- Male children (6–11 years); and
- Male children (12 to <16 years).

Since NHANES does not include urinary biomonitoring for infants or toddlers, and other national data sets are not available, EPA used biomonitoring data from male children 3 to less than 6 years of age as a proxy for male infants (<1 year) and male toddlers (1–2 years). See Section 4 of (U.S. EPA, 2024ah) for further details regarding the reverse dosimetry approach. Aggregate daily intake estimates for these

populations are presented in Table 4-20.⁴ Aggregate daily intake values were also calculated for women
of reproductive age stratified by race and socioeconomic status (Table 4-21). A similar analysis by race
was not done for male children because the NHANES sample size is smaller for this population.

- 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
 Sections 4.4.1 and 4.4.3.
- 3069 Since EPA is focusing its CRA on acute exposure durations, EPA selected 95th percentile exposure 3070 estimates from NHANES to serve as the non-attributable nationally representative exposure estimate for 3071 use in its CRA. For women of reproductive age, EPA's analysis indicates that black, non-Hispanic 3072 women have slightly higher 95th percentile cumulative phthalate exposure compared to other racial 3073 groups; thus, 95th percentile cumulative estimates for black non-Hispanic women of 3074 reproductive age was selected for use in the CRA of DCHP (Table 4-20).
- 3075

3068

- 3076 The 95th percentile of national cumulative exposure serves as the estimate of non-attributable phthalate 3077 exposure for its CRA of DCHP as follows:
- Women 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 women 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.
- 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.
- 3091 3092

4.4.2.1.1 Weight of Scientific Evidence: Non-attributable Cumulative Exposure to Phthalates

3093 Overall, EPA has robust confidence in the derived estimates of non-attributable cumulative exposure 3094 from NHANES urinary biomonitoring using reverse dosimetry. The Agency EPA used urinary 3095 biomonitoring data from the CDC's national NHANES dataset, which provides a statistical 3096 representation of the general, non-institutionalized, civilian U.S. population. To estimate daily intake 3097 values from urinary biomonitoring for each phthalate, EPA used reverse dosimetry. The reverse 3098 dosimetry approach used by EPA has been used extensively in the literature and has been used by CPSC 3099 (2014) and Health Canada (ECCC/HC, 2020) to estimate phthalate daily intake values from urinary biomonitoring data. However, given the short half-lives of phthalates, NHANES biomonitoring data is 3100 not expected to capture low frequency exposures and may be an underestimate of acute phthalate 3101 3102 exposure.

⁴ 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>).

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

Population	Percentile		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) ^a
		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%
		DIBP	0.2	0.53	0.106	11.2			
Females (16–49 years;		DINP	0.7	0.21	0.147	15.5			
n = 1,620		DBP	0.61	1	0.610	17.2	3.55	592	5.1%
	95	DEHP	1.48	0.84	1.24	35.0			
		BBP	0.42	0.52	0.218	6.15			
		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	-	690	4.3%
		DEHP	2.11	0.84	1.77	58.2			
	50	BBP	0.22	0.52	0.114	3.76	3.04		
		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			
		DEHP	6.44	0.84	5.41	49.9			
	95	BBP	2.46	0.52	1.28	11.8	10.8	194	15.5%
		DIBP	2.12	0.53	1.12	10.4			
		DINP	4.8	0.21	1.01	9.30			

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) ^a
		DBP	0.38	1	0.380	20.1			
		DEHP	1.24	0.84	1.04	55.1			
	50	BBP	0.16	0.52	0.083	4.40	1.89	1,111	2.7%
		DIBP	0.33	0.53	0.175	9.26			
Males		DINP	1	0.21	0.210	11.1			
(6-11 years; n = 553)		DBP	1.41	1	1.41	19.2		286	10.5%
n <i>555)</i>	95	DEHP	4.68	0.84	3.93	53.5	7.35		
		BBP	0.84	0.52	0.437	5.94			
		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	-	1,758	1.7%
		DEHP	0.66	0.84	0.554	46.4			
	50	BBP	0.14	0.52	0.073	6.09	1.19		
		DIBP	0.21	0.53	0.111	9.32			
Males		DINP	0.6	0.21	0.126	10.5			
(12-15 years; n = 308)		DBP	0.62	1	0.620	14.2			
11 – 500)		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			

^{*a*} A cumulative exposure of 70 μ g DBP equivalents/kg-day would result in a cumulative MOE of 30 (*i.e.*, 2,100 μ g DBP-equivalents/kg-day \div 70 μ 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 μ 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 Women of Reproductive Age (16–49 years old) by Race and
 Socioeconomic Status from the 2017–2018 NHANES Cycle

Race/ Socioeconomic Status (SES)	Percentile		Aggregate Daily Intake (µg/kg-day)		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) ^a
		DBP	0.22	1	0.22	21.6			
		DEHP	0.59	0.84	0.50	48.6			
	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		636	4.7%
	95	DEHP	1.44	0.84	1.21	36.6			
		BBP	0.29	0.52	0.15	4.6	3.30		
		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		3,151	1.0%
		DEHP	0.38	0.84	0.32	47.9			
	50	BBP	0.04	0.52	0.02	3.1	0.667		
		DIBP	0.15	0.53	0.08	11.9			
Race: black non-		DINP	0.70	0.21	0.15	22.1			
Hispanic $(n = 371)$		DBP	0.48	1	0.48	9.3			
(DEHP	4.28	0.84	3.60	69.7			
	95	BBP	0.30	0.52	0.16	3.0	5.16	407	7.4%
		DIBP	0.40	0.53	0.21	4.1			
		DINP	3.40	0.21	0.71	13.8			

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) ^a
		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		582	5.2%
(95	DEHP	1.24	0.84	1.04	28.9	3.61		
		BBP	0.39	0.52	0.20	5.6			
		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			

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) ^{<i>a</i>}	
		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		DINP	0.70	0.21	0.15	15.4				
poverty level $(n = 1,056)$		DBP	0.82	1	0.82	18.2				
(DEHP	1.75	0.84	1.47	32.7	4.50			
	95	BBP	0.34	0.52	0.18	3.9		467	6.4%	
		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			1.0%	
		DEHP	0.31	0.84	0.26	36.3				
	50	BBP	0.06	0.52	0.03	4.3	0.718	2,924		
SES: At or		DIBP	0.15	0.53	0.08	11.1				
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				

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 Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) ^{<i>a</i>}
		DBP	0.26	1.00	0.26	23.2			
		DEHP	0.67	0.84	0.56	50.1			
	50	BBP	0.06	0.52	0.03	2.8	1.12	1,870	1.6%
	ES: Unknown	DIBP	0.23	0.53	0.12	10.9			
SES: Unknown		DINP	0.70	0.21	0.15	13.1			
(n = 210)		DBP	0.60	1.00	0.60	25.5	2.35	893	3.4%
		DEHP	0.86	0.84	0.72	30.7			
	95	BBP	0.21	0.52	0.11	4.6			
		DIBP	0.35	0.53	0.19	7.9			
		DINP	3.50	0.21	0.74	31.2			
^{<i>a</i>} A cumulative exp	posure of 70	ug DBP equiv	alents/kg-day w	yould resi	ult in a cumulati	ve MOE of 30 (i.e.	2,100 µg DBP-equiva	alents/kg-day ÷	70 ug DBP

^{*a*} A cumulative exposure of 70 μ g DBP equivalents/kg-day would result in a cumulative MOE of 30 (*i.e.*, 2,100 μ g DBP-equivalents/kg-day \div 70 μ 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 μ g DBP equivalents/kg-day to estimate percent contribution to the risk cup.

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3111As described in the Draft Technical Support Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA (U.S. EPA, 2024ab), EPA is focusing its exposure assessment for the CRA for DCHP on evaluation of exposures through individual TSCA consumer and occupational DCHP COUs as well as non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data and reverse dosimetry. To estimate cumulative isk, EPA first scaled all phthalate exposures by relative potency using the RPFs presented in Table 4-191117to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative risk was estimated using the four-step process outlined below, along with one empirical example of how EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and coatings [solids]).1123Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and 4.1.2, Respectively)112In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using Equation 4-5. Scaling DCHP Exposures by Relative Potency DCHP exposure for consumer COUs).113Equation 4-5. Scaling DCHP Exposures by Relative Potency DCHP exposure (in DBP equivalents) = $AD_{Route 1} x RPF_{DCHP}$ 114Chemical (DBP) equivalents occupational cous in haladion, ingestion, and dermal exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of µg
3113assessment for the CRA for DCHP on evaluation of exposures through individual TSCA consumer and occupational DCHP COUs as well as non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data and reverse dosimetry. To estimate cumulative risk, EPA first scaled all phthalate exposures by relative potency using the RPFs presented in Table 4-19 to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative risk was estimated using the four-step process outlined below, along with one empirical example of how EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and coating [solids]).3123Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and 4.1.2, Respectively)3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using Equation 4-5. Scaling DCHP Exposures by Relative Potency DCHP Exposure (<i>in DBP equivalents</i>) = $AD_{Route 1} x RPF_{DCHP}$ 3134BCHP exposure = Acute dose in µg/kg from a given route of exposure from a single occupational or consumer COU/OES3137CHP exposure = Acute dose in µg/kg from a given route of exposure from a single occupational or consumer COU/OES3140RPF _{DCHP} = The relative potency factor (unitless) for DCHP, which is 1.66 (Table 4-19).3143Example: 50th percentile inhalation and dermal DCHP exposures for female workers of reproductive
3114occupational DCHP COUs as well as non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP,3115and DINP using NHANES urinary biomonitoring data and reverse dosimery. To estimate cumulative3116risk, EPA first scaled all phthalate exposures by relative potency using the RPFs presented in Table 4-193117to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual3118DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative3119risk was estimated using the four-step process outlined below, along with one empirical example of how3121EXPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and3122coatings [solids]).3123Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU3124to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and3125A1.2, Respectively3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES3127are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using3128Equation 4-5. Scaling DCHP Exposure by Relative Potency3139DCHP Exposure in Consumer COUs).3131BCHP exposure =3132Acute exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of µg/kg index chemical (DBP) equivalents3138ADRoute 1=3139Acute exposure for a given route of exposure from a single occupational or
3114occupational DCHP COUs as well as non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data and reverse dosimetry. To estimate cumulative risk, EPA first scaled all phthalate exposures by relative potency using the RPFs presented in Table 4-19 to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative risk was estimated using the four-step process outlined below, along with one empirical example of how trisk was estimated using the four-step process outlined below, along with one empirical example of how trisk was estimated using the four-step process outlined below, along with one empirical example of how to aclutated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and coatings [solids]).3123Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and 4.1.2, Respectively)3124In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using Equation 4-5. This step is repeated for all individual exposure estimates for cach route of exposure being assessed for each COU (<i>i.e.</i> , inhalation and dermal exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of µg/kg index chemical (DBP) equivalents313Equation 4-5. Scaling DCHP Exposure 5 by Relative Potency DCHP Exposure = Acute exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of µg/kg index chemical (DBP) equivalent
3115and DINP using NHANES urinary biomonitoring data and reverse dosimetry. To estimate cumulative3116risk, EPA first scaled all phthalate exposures by relative potency using the RPFs presented in Table 4-193117to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual3118DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative3120risk was estimated using the four-step process outlined below, along with one empirical example of how3121EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and coatings [solids]).3122Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and 4.1.2, Respectively)3122In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using Equation 4-5. This step is repeated for all individual exposure estimates for acch route of exposure being assessed for each COU (<i>i.e.</i> , inhalation and dermal exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of $\mu g/kg$ index chemical (DBP) equivalents3133DCHP exposure = DCHP Exposure by Relative Potency3134DCHP Exposure (<i>in DBP equivalents</i>) = $AD_{Route 1}x RPF_{DCHP}$ 3135DCHP exposure = Acute exposure for a given route of exposure from a single occupational or consumer COU/OES3136DCHP exposure = Acute dose in $\mu g/kg$ from a given route of exposure from a single
3116risk, EPA first scaled all phthalate exposures by relative potency using the RPFs presented in Table 4-193117to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from individual3118DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative3119risk was estimated using the four-step process outlined below, along with one empirical example of how3120EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and3121coatings [solids]).3122Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU3124to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and3125A1.2, Respectively)3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES3127are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using3128Equation 4-5. This step is repeated for all individual exposure stimates for each route of exposure being3139assessed for each COU (<i>i.e.</i> , inhalation and dermal exposures for occupational COUs; inhalation,3131ingestion, and dermal exposure by Relative Potency3133DCHP exposure (in DBP equivalents) = AD _{Route 1} x RPF _{DCHP} 3134Where:3135DCHP exposure =3144Acute dose in µg/kg from a given route of exposure from a single occupational or consumer COU expressed in terms of µg/kg index chemical (DBP) equivalents3139Chemet 13140RPF _{DCHP} </td
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3118DCHP consumer or worker COUs/OES were then combined to estimate cumulative risk. Cumulative3119risk was estimated using the four-step process outlined below, along with one empirical example of how3120EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and3121coatings [solids]).3122Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU3124to Index Chemical Equivalents (i.e., Occupational and Consumer Exposure from Sections 4.1.1 and3125A.1.2, Respectively)3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES3127are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using3128Equation 4-5. This step is repeated for all individual exposure stimates for each route of exposure being3130ingestion, and dermal exposure for consumer COUs).3131BCHP Exposure (in DBP equivalents) = $AD_{Route 1}x RPF_{DCHP}$ 3134Where:3135DCHP exposure = Acute exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of μ_g/kg index chemical (DBP) equivalents3138AD _{Route 1} = Acute dose in μ_g/kg from a given route of exposure from a single occupational or consumer COU/OES3140RPF _{DCHP} = The relative potency factor (unitless) for DCHP, which is 1.66 (Table 4-19).3142Example: 50th percentile inhalation and dermal DCHP exposures for female workers of reproductive age as 8.7 and 2.07 μ_g/kg for the Application of paints and coating (solids) OES (U.S. EPA, 2024ab).
3119risk was estimated using the four-step process outlined below, along with one empirical example of how3120EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and3121coatings [solids]).3122Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU3124to Index Chemical Equivalents (i.e., Occupational and Consumer Exposure from Sections 4.1.1 and31254.1.2, Respectively)3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES3127are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using3128Equation 4-5. This step is repeated for all individual exposure estimates for each route of exposure being3139assessed for each COU (<i>i.e.</i> , inhalation and dermal exposures for occupational COUs; inhalation,3131ingestion, and dermal exposure for consumer COUs).3131BCHP Exposure (in DBP equivalents) = $AD_{Route 1} x RPF_{DCHP}$ 3138ADRoute 13140RPF_DCHP3140RPF _{DCHP} 3141The relative potency factor (unitless) for DCHP, which is 1.66 (Table 4-19).3142Example: 50th percentile inhalation and dermal DCHP exposures for female workers of reproductive age are 38.7 and 2.07 µg/kg for the Application of paints and coatings (solids) OES (U.S. EPA, 2024ab).3142Using Equation 4-5. inhalation, dermal, and aggregate DCHP exposures for this OES can be scaled by relative potency to 64.2, 3.44, and 67.68 µg/kg DBP equivalents, respectively.
3120EPA calculated cumulative risk for one occupational OES for DCHP (<i>i.e.</i> , Application of paints and coatings [solids]).3121Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU to Index Chemical Equivalents (<i>i.e.</i> , Occupational and Consumer Exposure from Sections 4.1.1 and 4.1.2, Respectively)3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using Equation 4-5. This step is repeated for all individual exposure estimates for each route of exposure being assessed for each COU (<i>i.e.</i> , inhalation and dermal exposures for occupational COUs; inhalation, ingestion, and dermal exposure for consumer COUs).3131Equation 4-5. Scaling DCHP Exposures by Relative Potency DCHP Exposure (in DBP equivalents) = $AD_{Route 1} x RPF_{DCHP}$ 3132Where: DCHP exposure = Acute exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of $\mu g/kg$ index chemical (DBP) equivalents3133AD _{Route 1} = Chemical (DBP) equivalents3134AD _{Route 1} = The relative potency factor (unitless) for DCHP, which is 1.66 (Table 4-19).3142Example: 50th percentile inhalation and dermal DCHP exposures for female workers of reproductive age are 38.7 and 2.07 $\mu g/kg$ for the Application of paints and coatings (solids) OES (U.S. EPA, 2024ab).3145Using Equation 4-5, inhalation, dermal, and aggregate DCHP exposures for this OES can be scaled by relative potency to 64.2, 3.44, and 67.68 $\mu/g/g$ DBP equivalents, respectively.
3121coatings [solids]).3122Step 1: Convert DCHP Exposure Estimates from Each Individual Consumer and Occupational COU3124to Index Chemical Equivalents (i.e., Occupational and Consumer Exposure from Sections 4.1.1 and31254.1.2, Respectively)3126In this step, DCHP acute duration exposure estimates from each consumer and occupational COU/OES3127are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using3128Equation 4-5. This step is repeated for all individual exposure stimates for each route of exposure being3139assessed for each COU (i.e., inhalation and dermal exposures for occupational COUs; inhalation,3130ingestion, and dermal exposure for consumer COUs).3131DCHP Exposure (in DBP equivalents) = $AD_{Route 1}x RPF_{DCHP}$ 3139Where:3136DCHP exposure =3137Acute exposure for a given route of exposure from a single occupational or consumer COU expressed in terms of $\mu g/kg$ index chemical (DBP) equivalents3139assessed in terms of index for a given route of exposure from a single occupational or consumer COU/OES3140RPF _{DCHP} =3141The relative potency factor (unitless) for DCHP, which is 1.66 (Table 4-19).3142Example: 50th percentile inhalation and dermal DCHP exposures for female workers of reproductive age are 38.7 and 2.07 $\mu g/kg$ for the Application of paints and coatings (solids) OES (U.S. EPA, 2024ab).3142Using Equation 4-5, inhalation, dermal, and aggregate DCHP exposures for this OES can be scaled by relative potency to 64.2, 3.44, and 67.68 $\mu g/kg$ DBP equivalent
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3148 $DCHP_{Inhalation-COU} = 64.2 \mu\text{g/kg} DBP equivalents = 38.7 \mu\text{g/kg} DCHP x 1.66$
$2150 \qquad \qquad$
3150 $DCHP_{Dermal-COU} = 3.44 \mu\text{g/kg} DBP equivalents = 2.07 \mu\text{g/kg} DCHP x 1.66$
$\frac{3151}{2152} = -(7.0) \times (127.0) \times (127.0)$
3152 $DCHP_{Aggregate-COU} = 67.68 \mu\text{g/kg} DBP equivalents$
$= (2.07 \mu\text{g/kg}DCHP + 38.7 \mu\text{g/kg}DCHP) x 1.66$
3154
21.55
3155
3155 3156 3157

3158 3159	Step 2: Estimate Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and DINP Using NHANES Urinary Biomonitoring Data and Reverse Dosimetry (see Section 4.4.2 for Further
3160	Details)
3161	Non-attributable exposure for a national population to DEHP, DBP, BBP, DIBP, and DINP was
3162	estimated using Equation 4-6, where individual phthalate daily intake values estimated from NHANES
3163	biomonitoring data and reverse dosimetry were scaled by relative potency, expressed in terms of index
3164	chemical (DBP) equivalents, and summed to estimate non-attributable cumulative exposure in terms of
3165	DBP equivalents. Equation 4-6 was used to calculate the cumulative exposure estimates provided in
3166	Table 4-20 and Table 4-21.
3167	
3168	Equation 4-6. Estimating Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and
3169	DINP
3170	
	Comulating Exposure (Non attributable)
3171	Cumulative Exposure (Non – attributable)
3172	$= (DI_{DEHP} x RPF_{DEHP}) + (DI_{DBP} x RPF_{DBP}) + (DI_{BBP} x RPF_{BBP})$
3173	$+ (DI_{DIBP} x RPF_{DIBP}) + (DI_{DINP} x RPF_{DINP})$
3174	Where:
3175	Cumulative exposure (non-attributable) is expressed in index chemical (DBP) equivalents
3176	$(\mu g/kg-day).$
3177	DI is The daily intake value (μ g/kg-day) for each phthalate that was calculated using NHANES
3178	urinary biomonitoring data and reverse dosimetry (DI) values for each phthalate for each
3179	assessed population are provided in Table 4-20 and Table 4-21).
3180	<i>RPF</i> is the relative potency factor (unitless) for each phthalate from Table 4-19.
3181	
3182	<i>Example:</i> The 95th percentile cumulative exposure estimate of 5.16 µg/kg-day DBP equivalents for
3182	black, non-Hispanic women of reproductive age (Table 4-21) is calculated using Equation 4-6 as
3183	follows:
3184	10110WS.
	F 16 ug/lag DDD againglanta
3186	5.16 μ g/kg DBP equivalents (4.20 μ g/kg DFUB μ 0.04) + (0.40 μ g/kg DFB μ 1) + (0.20 μ g/kg DFB μ 0.52)
3187	$= (4.28 \mu\text{g/kg}DEHPx0.84) + (0.48 \mu\text{g/kg}DBPx1) + (0.30 \mu\text{g/kg}BBPx0.52)$
3188	+ $(0.40 \ \mu g/kg \ DIBP \ x \ 0.53)$ + $(3.40 \ \mu g/kg \ DINP \ x \ 0.21)$
3189	
3190	Step 3: Calculate MOEs for DCHP Exposures and for Each Phthalate Exposure Included in the
3191	Cumulative Scenario
3192	Next, MOEs are calculated for each exposure of interest that is included in the cumulative scenario
3193	using Equation 4-7. For example, this step involves calculating MOEs for inhalation and dermal DCHP
3194	exposures expressed in index chemical equivalents for each individual COU/OES in Step 1, and an
3195	MOE for non-attributable cumulative phthalate exposure from Step 2 above.
3196	
3197	Equation 4-7. Calculating MOEs for Exposures of Interest for Use in the RPF and Cumulative
3198	Approaches
5170	
3199	$MOE_{1} = \frac{Index \ Chemical \ (DBP) \ POD}{Exposure_{1} \ in \ DBP \ Equivalents}$
2200	
3200	Where:
3201	MOE_1 (unitless) = The MOE calculated for each exposure of interest included
3202	in the cumulative scenario.
3203	Index chemical (DBP) $POD =$ The POD selected for the index chemical, DBP. The index
3204	chemical POD is 2,100 μ g/kg (Section 4.4.1).
3205	$Exposure_1$ = The exposure estimate in DBP equivalents for the pathway

of interest (*i.e.*, from Step 1 or 2 above).

Example: Using Equation 4-7, the MOEs for inhalation and dermal DCHP exposure estimates for the
Application of paints and coatings (solids) OES in DBP equivalents from Step 1 and the MOE for the
non-attributable cumulative exposure estimate in DBP equivalents from sSep 2 are 33, 610, and 407,
respectively.

3212
$$MOE_{Cumulative Non-attributable} = 407 = \frac{2,100 \ \mu g/kg}{5.16 \ \mu g/kg}$$

3214
$$MOE_{COU-Inhalation} = 32.7 = \frac{2,100 \ \mu g/kg}{64.2 \ \mu g/kg}$$

3213

3206

3216
$$MOE_{COU-Dermal} = 610 = \frac{2,100 \, \mu g/kg}{3.44 \, \mu g/kg}$$

3217

3218 Step 4: Calculate the Cumulative MOE

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 DCHP 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 (*e.g.*, for the ingestion route for consumer scenarios).

3226 Equation 4-8. Cumulative Margin of Exposure Calculation

3227 Cumulative
$$MOE = \frac{1}{\frac{1}{MOE_{COU-Inhalation}} + \frac{1}{MOE_{COU-Dermal}} + \frac{1}{MOE_{Cumulative-Non-attributable}} \dots}$$

3228

Example: The cumulative MOE for the Application of paints and coatings (solids) OES is 28.9 and is calculated by summing the MOEs for each exposure of interest from Step 3 as follows:

3225

Cumulative MOE =
$$28.9 = \frac{1}{\frac{1}{32.7} + \frac{1}{610} + \frac{1}{407}}$$

3233

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 DCHP. 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, 2024ah), 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).

3239

3240 To evaluate cumulative risk to female workers of reproductive age, EPA combined inhalation and

3241 dermal exposures to DCHP from each individual occupational COU/OES with non-attributable

3242 cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP (estimated from NHANES urinary

3243 biomonitoring using reverse dosimetry). As described in Section 4.4.3, for each individual phthalate

3244 exposures were scaled by relative potency per chemical, expressed in terms of index chemical (DBP)

3245 equivalents, and summed to estimate cumulative exposure and cumulative risk for each COU. MOEs in

Table 4-22 are shown both with (cumulative MOE) and without (MOEs for individual DCHP COU derived using the RPF analysis) the addition of non-attributable cumulative exposure (estimated from

NHANES using reverse dosimetry) so that MOEs scaled by relative potency can be compared.

3248 3249

3250 Table 4-22 summarizes the acute duration central tendency and high-end MOEs for female workers of 3251 reproductive age used to characterize cumulative risk from exposure to DCHP, DEHP, DBP, BBP, 3252 DIBP, and DINP, as well as DCHP MOEs scaled by relative potency without non-attributable 3253 cumulative exposure (*i.e.*, NHANES) included. MOE calculations are also provided in the *Draft* 3254 Occupational and Consumer Cumulative Risk Calculator for Dicyclohexyl Phthalate (DCHP) (U.S. 3255 EPA, 2024y). As discussed in Section 4.3.2, high-end acute MOEs for female workers of reproductive 3256 age were below the benchmark of 30 for all DCHP COUs/OES evaluated as part of the individual 3257 chemical assessment. Addition of non-attributable cumulative national exposure (from NHANES) 3258 would have no influence on high-end risk conclusions. Therefore, EPA focused its cumulative risk 3259 characterization on central tendency MOEs (none of which were <30 in the individual DCHP 3260 assessment in Section 4.3.2). For all COUs, the Agency presents MOEs for each individual exposure 3261 route. That is, MOEs resulting from inhalation and dermal DCHP exposures for each COU/OES scaled 3262 to index chemical (DBP) equivalents (*i.e.*, the RPF analysis) as well as cumulative occupational 3263 exposure (*i.e.*, aggregate exposure to DCHP from a single COU [in index chemical equivalents] 3264 combined with cumulative national exposure [in index chemical equivalents]), so that the contribution of 3265 each exposure to the cumulative MOE can be discerned.

3266

3278

3267 COUs/OES with Cumulative MOEs Ranging from 34 to 244

As can be seen from Table 4-22, cumulative acute central tendency MOEs ranged from 34 to 244 for COUs covered under 12 of the OESs evaluated for DCHP, including the following:

- Import and repackaging (cumulative MOE = 55);
- PVC plastics compounding (cumulative MOE = 34);
- PVC plastics converting (cumulative MOE = 65);
- Non-PVC materials compounding (cumulative MOE = 52);
- Non-PVC materials converting (cumulative MOE = 110);
- Application of adhesives and sealants (liquids) (cumulative MOE = 244);
- Application of adhesives and sealants (solids) (cumulative MOE = 49);
- Use of laboratory chemicals (liquids) (cumulative MOE = 244);
 - Use of laboratory chemicals (solids) (cumulative MOE = 40);
- Recycling (cumulative MOE = 63);
- Fabrication or use of final products and articles (cumulative MOE = 72); and
- Waste handling, treatment, and disposal (cumulative MOE = 63).

3282 COUs/OES with Cumulative MOEs Ranging from 18 to 29

As can be seen from Table 4-22, cumulative acute central tendency MOEs ranged from 18 to 29 for COUs covered under six OES, including:

- Manufacturing (cumulative MOE = 18);
- Incorporation into other formulations, mixtures, or reaction products (cumulative MOE = 18);
- Incorporation into adhesives and sealants (cumulative MOE = 18);
- Incorporation into paints and coatings (cumulative MOE = 18);
- Application of paints and coatings liquids (cumulative MOE = 20); and
- Application of paints and coatings solids (cumulative MOE = 29).

- 3291 EPA characterizes these preceding six OESs as part of the individual chemical assessment in Section 3292 4.3.2. The central tendency acute aggregate MOE from exposure to DCHP alone for female workers of 3293 reproductive age is 35 for four of the six OESs showing cumulative risk (*i.e.*, Manufacturing; 3294 Incorporation into other formulations, mixtures, or reaction products; Incorporation into adhesives and 3295 sealants; and Incorporation into paints and coatings) (Table 4-14), while the cumulative MOE for these 3296 four OES is 18 (Table 4-22). For one OES (Application of paints and coatings – liquids), the central 3297 tendency acute aggregate MOE from exposure to DCHP alone for female workers of reproductive age is 3298 40 (Table 4-14), while the cumulative MOE for this OES is 20 (Table 4-22). For the sixth OES 3299 (Application of paints and coatings – solids), the central tendency acute aggregate MOE from exposure 3300 to DCHP alone for female workers of reproductive age is 60 (Table 4-14), while the cumulative MOE 3301 for this OES is 29 (Table 4-22).
- 3302

For all of the evaluated OESs, including these six OESs, three factors contribute to the lower cumulative
 MOEs compared to the acute aggregate central tendency MOE for female workers of reproductive age:

- 3305 Scaling by Relative Potency: DCHP inhalation and dermal exposures for the six OESs were scaled by 3306 relative potency to the index chemical. The RPF for DCHP is 1.66, which means DCHP exposures when 3307 multiplied by the RPF and expressed in terms of index chemical (DBP) equivalents, increased by 66 3308 percent. This 66 percent increase in exposure expressed in terms of index chemical equivalents is the 3309 primary factor leading to lower cumulative MOEs. RPFs used to scale for relative potency were 3310 calculated based on a common hazard endpoint (*i.e.*, reduced fetal testicular testosterone) from data 3311 from multiple studies evaluating effects of phthalates on fetal testicular testosterone using a meta-3312 analysis and BMD modeling approach for each of the six phthalates included in the cumulative chemical 3313 group (see (U.S. EPA, 2024ah) for further details). This analysis provides a robust basis for assessing 3314 the dose-response for the common hazard endpoint (*i.e.*, reduced fetal testicular testosterone) across the 3315 six toxicologically similar phthalates included in the cumulative assessment. For example, use of meta-3316 analysis and BMD modeling allowed EPA to utilize more fetal testicular testosterone data in the low-3317 end range of the dose-response curve to gain a better understanding of the hazards of DCHP at the low-3318 end range of the dose-response curve compared to the index chemical, DBP. Overall, EPA has robust 3319 confidence in the draft RPFs used in this CRA (Section 4.4.4.1). 3320
- 3321 Index Chemical POD: As described previously in Sections 4.4.1 and 4.4.3, cumulative MOEs are 3322 calculated by dividing the cumulative exposure estimate expressed in terms of index chemical (DBP) 3323 equivalents by the index chemical POD. The POD for the index chemical (DBP) used to calculate 3324 cumulative risk is 2.1 mg/kg (based on a BMDL₅ for reduced fetal testicular testosterone). 3325 Comparatively, the DCHP POD used to calculate MOEs for individual DCHP COUs in Section 4.3.2 is 3326 2.4 mg/kg (based on a NOAEL for phthalate syndrome-related effects). The index chemical (DBP) POD 3327 is 12.5 percent lower (i.e., more sensitive) than the individual DCHP POD, which contributes to the 3328 lower cumulative MOEs. Overall, EPA has robust confidence in the index chemical (DBP) POD used in 3329 this CRA. This is because the POD is based on fetal testicular testosterone data from eight publications 3330 that was integrated via meta-analysis and BMD modeling. Notably, several of the available studies 3331 evaluated effects on fetal testicular testosterone at dose levels in the low-end range of the dose response 3332 curve (*i.e.*, 1, 10, 33, and 50 mg/kg-day) where the BMD₅ (14 mg/kg-day) and BMDL₅ (9 mg/kg-day) 3333 were derived (see (U.S. EPA, 2024ah) for further details). 3334
- Addition of Non-attributable Cumulative Exposure: As part of its CRA, EPA calculated non-attributable
 cumulative exposure to DEHP, DBP, BBP, DIBP, 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, 2024ah) for further details), representing exposure to a national population. DCHP
 was not included as part of the cumulative non-attributable national exposure estimate because DCHP

3340 has not been included in NHANES analyses since 2011 due to low frequencies of detection and low 3341 detection levels in urine (Section 4.4.2). Non-attributable cumulative exposure estimates were scaled by 3342 relative potency and expressed in index chemical (DBP) equivalents. Non-attributable cumulative 3343 exposure was then combined with acute inhalation and dermal DCHP exposures for each individual 3344 COU/OES scaled by relative potency. For female workers of reproductive age, EPA added a non-3345 attributable cumulative exposure of $5.16 \,\mu g/kg$ index chemical (DBP) equivalents to calculate the 3346 cumulative MOE. This non-attributable cumulative exposure estimate is the 95th percentile estimate for 3347 black non-Hispanic women of reproductive age (16 to 49 years). This non-attributable cumulative exposure contributes approximately 7.4 percent to the risk cup with a benchmark MOE of 30. 3348

3349

3350 Overall, EPA has robust confidence in the non-attributable cumulative exposure estimate since it was calculated from CDC's NHANES biomonitoring data set, which provides a statistically representative 3351 3352 sampling of the U.S. civilian population. Furthermore, the Agency used a well-established reverse 3353 dosimetry approach to calculate phthalate daily intake values from urinary biomonitoring data. 3354 For five out of the six OESs showing cumulative risk (*i.e.*, Manufacturing; Incorporation into other 3355 formulations, mixtures, or reaction products; Incorporation into adhesives and sealants; Incorporation 3356 into paints and coatings; and Application of paints and coatings – liquids), scaling acute inhalation exposures by relative potency alone led to acute inhalation MOEs below 30, ranging from 19 to 22, 3357 3358 whereas the acute cumulative MOE (DCHP OES + cumulative non-attributable) ranged from 18 to 20. 3359 For one OES showing cumulative risk (*i.e.*, Application of paints and coatings – solids), the acute 3360 aggregate MOE based on exposure to DCHP expressed in index chemical equivalents was 31 and 3361 adding non-attributable cumulative exposure resulted in a cumulative MOE of 29.

3362

4.4.4.1 Overall Confidence in Cumulative Worker Risk Estimates

3363 EPA has robust confidence in the RPFs and index chemical POD used to calculate the RPF analysis and 3364 cumulative MOEs. To derive RPFs and the index chemical POD, the Agency integrated data from 3365 multiple studies evaluating fetal testicular testosterone using a meta-analysis approach and conducted BMD modeling. This meta-analysis and BMD modeling approach represents a refinement of the 3366 3367 NOAEL/LOAEL approach used in the individual DCHP assessment and therefore increases EPA's 3368 confidence in risk estimates. Finally, the Agency has robust confidence in the non-attributable 3369 cumulative exposure estimates for DEHP, DBP, BBP, DIBP, and DINP derived from NHANES urinary 3370 biomonitoring data using reverse dosimetry.

3371 Table 4-22. Risk Summary Table for Female Workers of Reproductive Age Using the RPF Analysis

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category			Exposure Level	Inhalation MOE (DCHP COU; Exposure in DBP Equivalents)	Dermal MOE (DCHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DCHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DCHP MOE + Cumulative Non- attributable) ^{<i>a</i>}		
Manufacturing –	Domestic manufacturing	Manufacturing	СТ	19.1	610	18.5	17.7		
Domestic manufacturing		Manufacturing	HE	1.8	305	1.8	1.8		
Manufacturing – Importing	Importing	Import and	CT	70	610	63	55		
Processing – Repackaging	Repackaging (<i>e.g.</i> , laboratory chemicals)	Repackaging	HE	3.1	305	3.0	3.0		
	Plasticizer in: – Adhesive manufacturing		СТ	19.1	610	18.5	17.7		
Processing – Processing – incorporation into formulation, mixture, or reaction product	Adhesive and sealant chemicals in:	Incorporation into adhesives and							
	 Adhesive manufacturing 	sealants	HE	1.8	305	1.8	1.8		
Freedom Process	Stabilizing Agent in: – Adhesive manufacturing								
Plasticizer in: – Paint and coating Processing – Processing manufacturing		•	СТ	19.1	610	18.5	17.7		
formulation, mixture, or reaction product Stabi – Pair	– Printing ink manufacturing	Incorporation into paints and coatings	HE	1.8	305	1.8	1.8		
	Stabilizing agent in: – Paint and coating manufacturing								
Processing – Processing – incorporation into	Stabilizing agent in: Asphalt paving, roofing, and	Incorporation into other formulations, mixtures, and	СТ	19.1	610	18.5	17.7		
formulation, mixture, or reaction product	coating materials manufacturing	reaction products not covered elsewhere	HE	1.8	305	1.8	1.8		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category			Exposure Level	Inhalation MOE (DCHP COU; Exposure in DBP Equivalents)	Dermal MOE (DCHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DCHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DCHP MOE + Cumulative Non- attributable) ^{<i>a</i>}		
Processing – Processing – incorporation into formulation, mixture, or	Plasticizer in: – Plastic material and resin manufacturing – Plastics product manufacturing	PVC plastics compounding	CT HE	40	610 305	37	34 1.9		
reaction product	Stabilizing agent in: —Plastics product manufacturing								
Processing – Processing – incorporation into	Plasticizer in: – Plastics product	PVC plastics converting	СТ	89	610	77	65		
article	manufacturing		HE	4.3	305	4.3	4.2		
Processing – Processing – incorporation into formulation, mixture, or	Plasticizer in: – Plastics product manufacturing – Rubber product manufacturing – Plastic material and resin	Non-PVC material compounding	CT HE	66	610	60	52		
reaction product	manufacturing Stabilizing agent in:		HE	3.2	305	3.2	3.2		
	-Plastics product manufacturing		075	100	(10	1.50	110		
Processing – Processing	Plasticizer in: – Plastics product menufacturing	Non-PVC material	СТ	199	610	150	110		
 incorporation into article 	manufacturing – Rubber product manufacturing	converting	HE	9.7	305	9.4	9.2		

				Acute MO	Vorkers of Repro nark = 30)	roductive Age	
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DCHP COU; Exposure in DBP Equivalents)	Dermal MOE (DCHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DCHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DCHP MOE + Cumulative Non- attributable) ^{<i>a</i>}
Industrial Use – Finishing agent	Cellulose film production		СТ	21.7	610	21.0	19.9
Industrial Use – Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)	Application of points	HE	1.0	305	1.0	1.0
Commercial Use – Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)	Application of paints and coatings – liquids					
Industrial Use – Paints and coatings	Paints and coatings						
Commercial Use – Paints and coatings	Paints and coatings						
Industrial Use – Finishing agent	Cellulose film production		СТ	32.7	610	31.1	28.9
Industrial Use – Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)		HE	1.9	305	1.9	1.8
Commercial Use – Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)	Application of paints and coatings – solids					
Industrial Use – Paints and coatings	Paints and coatings						
Commercial Use – Paints and coatings	Paints and coatings						

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DCHP COU; Exposure in DBP Equivalents)	Dermal MOE (DCHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DCHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DCHP MOE + Cumulative Non- attributable) ^{<i>a</i>}		
Industrial Uses – Adhesives and sealants	Adhesives and sealants (<i>e.g.</i> , computer and electronic product manufacturing; transportation	Application of	СТ	_	610	_	244		
	equipment manufacturing)	adhesives and sealants – liquids	HE	_	305	_	174.3		
Commercial Uses – Adhesives and sealants	Adhesives and sealants								
	Adhesives and sealants in (<i>e.g.</i> ,	Application of	CT	61	610	56	49		
Industrial Uses – Adhesives and sealants	computer and electronic product manufacturing; transportation equipment manufacturing)	adhesives and sealants – solids	HE	3.4	305	3.4	3.3		
Commercial Use –	Laboratory chemicals	Use of laboratory	СТ	_	610	_	244		
Laboratory chemicals		chemicals – liquid	HE	-	305	—	174.3		
Commercial Use –	Laboratory chemicals	Use of laboratory	СТ	48	610	45	40		
Laboratory chemicals		chemicals – solid	HE	3.4	305	3.4	3.3		

				Acute MO	ductive Age		
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Inhalation MOE (DCHP COU; Exposure in DBP Equivalents)	Dermal MOE (DCHP COU; Exposure in DBP Equivalents)	Aggregate MOE (DCHP COU; Exposure in DBP Equivalents)	Cumulative MOE (Aggregate DCHP MOE + Cumulative Non- attributable) ^a
Industrial Use – Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) (<i>e.g.</i> , transportation equipment manufacturing)		СТ	102	610	87	72
Commercial Use – Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Fabrication or use of final products or articles	HE	11.3	305	10.9	10.6
Commercial Use – Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)						
			СТ	85	610	74	63
Processing – Recycling	Recycling	Recycling	HE	5.8	305	5.7	5.6
Diseased Diseased	Dispersel	Waste handling,	СТ	85	610	74	63
Disposal – Disposal	Disposal	treatment and disposal	HE	5.8	305	5.7	5.6

^{*a*} The acute cumulative MOE is derived by summing inhalation exposure from each individual DCHP COU with dermal exposure from the same DCHP 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.

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4.4.5 Risk Estimates for Consumers Based on Relative Potency

3374 This section summarizes cumulative risk estimates for consumers from acute duration exposures to 3375 DCHP. EPA focused its CRA on women of reproductive age and male infants and children. EPA 3376 focused its consumer CRA on these populations for the acute exposure duration because, as described in 3377 Section 4.2 and (U.S. EPA, 2024ah), these populations and exposure duration are considered most 3378 directly applicable to the common hazard outcome that serves as the basis for the cumulative assessment 3379 (*i.e.*, reduced fetal testicular testosterone). For consumers, EPA did not specifically evaluate women of 3380 reproductive age or male infants and children; however, consumer exposures of teenagers (16–20 years) 3381 and adults (21+ years) were considered a proxy for women of reproductive age, while infants (<1 year), 3382 toddlers (1–2 years), children (3–5 and 6–10 years), and young teens (11–15 years) were considered a 3383 proxy for male infants and children.

3384

3385 After scaling high-intensity DCHP acute exposure estimates from individual COUs by relative potency

and adding non-attributable cumulative exposure (calculated from NHANES) from DEHP, DBP, BBP,

3387 DIBP, and DINP, all high-intensity consumer COUs product and article examples had cumulative 3388 MOEs above the benchmark of 20 renging from 130 for courts infont exposure through outdoor section

3388 *MOEs above the benchmark of 30*, ranging from 130 for acute infant exposure through outdoor seating 3389 to 455 for acute exposure to adhesives for small repairs for young teens (11–15 years) (Table 4-23).

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4.4.5.1 Overall Confidence in Cumulative Consumer Risks

3391 As discussed in Section 4.3.3, EPA has moderate to robust confidence in all of the exposure estimates 3392 for the evaluated consumer product scenarios. The Agency has robust confidence in the RPFs and index 3393 chemical POD used to calculate the cumulative MOEs. To derive RPFs and the index chemical POD, 3394 EPA integrated data from multiple studies evaluating fetal testicular testosterone using a meta-analysis 3395 approach and conducted BMD modeling. This meta-analysis and BMD modeling approach represents a 3396 refinement of the NOAEL/LOAEL approach used in the individual DCHP assessment and therefore 3397 increases EPA's confidence in risk estimates. Finally, EPA has robust confidence in the non-attributable 3398 cumulative exposure estimates for DEHP, DBP, BBP, DIBP, and DINP derived from NHANES urinary 3399 biomonitoring data using reverse dosimetry.

3400 **Table 4-23. Consumer Cumulative Risk Summary Table**

			Exposure		Lifestage (Years) MOE (Based on All Exposures in Index Chemica (Benchmark MOE = 30)			l Equivalents)			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Scenario (H, M, L) ^{<i>a</i>}	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)
Consumer Uses: Adhesives and sealants: Adhesives and sealants	Adhesives for small repairs	Acute	Н	Cumulative (Aggregate DCHP COU + Cumulative Non-attributable)	_	_	_	_	455	389	388
Consumer Uses: Adhesives and sealants: Adhesives and sealants	Automotive adhesives	Acute	Н	Cumulative (Aggregate DCHP COU + Cumulative Non-attributable)	191	191	192	282	437	377	377
Consumer Uses: Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Small articles with potential for semi- routine contact: labels, nitrocellulose; ethylcellulose; chlorinated rubber; PVAc; PVC	Acute	Н	Cumulative (Aggregate DCHP COU + Cumulative Non-attributable)	165	169	172	248	400	351	348
Consumer Uses: Consumer articles that contain dicyclohexyl phthalate from: Inks, toner, and colorants; Paints and coatings; Adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	Outdoor seating	Acute	Н	Cumulative (Aggregate DCHP COU + Cumulative Non-attributable)	130	136	142	199	305	281	275
Consumer Uses: Consumer articles that contain dicyclohexyl phthalate from: Inks, toner, and colorants; Paints and coatings; Adhesives and sealants (<i>e.g.</i> , paper products, textiles, products using cellulose film, etc.)	Small articles with the potential for semi- routine contact: labels, and packaging adhesives, foil and cellophane lacquers, and printing inks	Acute	Н	Cumulative (Aggregate DCHP COU + Cumulative Non-attributable)	165	169	172	248	400	351	348
Consumer Uses: Consumer articles that contain dicyclohexyl phthalate from: Inks, toner, and colorants; Paints and coatings; Adhesives and sealants (<i>e.g.</i> , paper	Electronics containing dye adhesive	automotiv	e cameras. As	I. Identified in dye attach s the adhesive is used in ial use of these items.							

			Exposure		Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Scenario (H, M, L) ^{<i>a</i>}	nario Exposure Scenario		(1-2)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenager (16–20 years)	Adult (21+ years)	
products, textiles, products using cellulose film, etc.)												
^{<i>a</i>} Exposure scenario intensities in ^{<i>b</i>} Bystander scenarios ^{<i>c</i>} Indoor scenario	⁴ Exposure scenario intensities include high (H), medium (M), and low (L). ⁹ Bystander scenarios											

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3402 **4.4.6 Cumulative Risk Estimates for the General Population**

For DCHP, 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
from exposure to DCHP 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
not necessary.

3408 **4.5 Comparison of Single Chemical and Cumulative Risk Assessments**

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
for Economic Co-operation and Development (OECD), the European Commission, and the World
Health Organization (WHO) and International Programme on Chemical Safety (IPCS), including

- 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);
- Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. EPA, 2000);
- General Principles for Performing Aggregate Exposure and Risk Assessments (U.S. EPA, 2001);
- Guidance on Cumulative Risk Assessment of Pesticide Chemicals that Have a Common Mechanism of Toxicity (U.S. EPA, 2002a);
 - Framework for Cumulative Risk Assessment (U.S. EPA, 2003);
 - Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures, and Effects: A Resource Document (U.S. EPA, 2007);
- Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose (U.S. EPA, 2016b);
- Advances in Dose Addition For Chemical Mixtures: A White Paper (U.S. EPA, 2023a).
 - *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (NRC, 2008);
 - State of the Art Report on Mixture Toxicity (European Commission, 2009);
 - *Risk Assessment of Combined Exposure to Multiple Chemicals: A WHO/IPCS Framework* (Meek et al., 2011); and
- Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals (OECD, 2018).
- 3433 Herein, EPA has evaluated risks for workers (Section 4.3.2), consumers (Section 4.3.3), and the general
- 3434 population (Section 4.3.4) from exposure to DCHP alone, as well as cumulative risks for workers
- 3435 (Section 4.4.4) and consumers (Section 4.4.5) that take into account differences in relative potency and
- 3436 cumulative non-attributable exposure to DEHP, DBP, BBP, DIBP, and DINP from NHANES
- 3437 biomonitoring and reverse dosimetry.
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- 3439 There are several notable differences between the individual DCHP assessment (Section 4.3) and the
- 3440 CRA (Section 4.4). As part of the individual DCHP assessment (Section 4.3), EPA considered all human
- health hazards of DCHP and selected a POD based on a NOAEL for phthalate syndrome-related effects
- 3442 to characterize risk from exposure to DCHP. As part of its exposure assessment in the individual DCHP
- 3443 assessment, EPA considered acute, intermediate, and chronic exposures durations for a broad range of
- 3444 populations—including female workers of reproductive age, average adult workers, ONUs, the general
- 3445 population, and consumers of various lifestages (e.g., infants, toddlers, children, adults). Furthermore, in
- 3446 the individual DCHP assessment, EPA evaluated inhalation and dermal exposures to workers, as well as

- consumer exposure to DCHP via the inhalation, dermal, and ingestion exposure routes. In contrast, the
 CRA is more focused in scope (Section 4.4). First, the CRA is based on a uniform measure of hazard
 (*i.e.*, reduced fetal testicular testosterone) that serves as the basis for deriving RPFs and the index
 chemical (DBP) POD, which were derived via meta-analysis and BMD modeling (Section 4.4.1).
 Second, the CRA is focused on acute duration exposures and the most sensitive populations (*i.e.*, women
 cf reproductive account of the context and a children) (Section 4.4). Finally, for the CRA and the account of the context and the sensitive populations (*i.e.*, women
- of reproductive age, male infants, male children) (Section 4.4). Finally, for the CRA, DCHP exposures
 from individual consumer and worker COUs were (1) scaled by relative potency; (2) expressed in index
- 3454 chemical (DBP) equivalents; and (3) combined with non-attributable cumulative exposure to DEHP,
- 3455 DBP, BBP, DIBP, and DINP from NHANES.
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Both the individual DCHP assessment (Section 4.3) and the CRA (Section 4.4) led to similar
conclusions regarding risk estimates for consumers. As discussed in Section 4.3.3, high-intensity MOEs
for consumer scenarios ranged from 740 to 950,000 in the individual DCHP assessment (Benchmark =
30), while cumulative consumer MOEs ranged from 130 to 455 (cumulative Benchmark = 30) (Section
4.4.5).

- For workers, cumulative acute central tendency MOEs ranged from 18 to 29 for COUs covered under six OESs (Section 4.4.5). Comparatively, these same six OESs had aggregate acute MOEs that ranged from 35 to 60 in the individual DCHP assessment (Section 4.3.2). Overall, there are three primary factors that influenced differences in risk estimates between the individual DCHP assessment (Section 4.3) and the RPF analysis (Section 4.4), which are described below:
- Scaling by Relative Potency. DCHP inhalation, dermal, and ingestion exposures from individual COUs/OES were scaled by relative potency to the index chemical. The RPF for DCHP is 1.66, which means DCHP exposures when multiplied by the RPF and expressed in terms of index chemical (DBP) equivalents, increased by 66 percent. This increase in exposure expressed in terms of index chemical equivalents is the primary factor leading to lower cumulative MOEs.
- Index Chemical POD. Cumulative MOEs are calculated by dividing the index chemical POD by a cumulative exposure estimate expressed in terms of index chemical (DBP) equivalents. The POD for the index chemical (DBP) used to calculate cumulative risk is 2.1 mg/kg (based on a BMDL₅ for reduced fetal testicular testosterone). Comparatively, the DCHP POD used to calculate MOEs for individual DCHP COUs is 2.4 mg/kg (based on a NOAEL for phthalate syndrome-related effects). The index chemical (DBP) POD is 12.5 percent lower (*i.e.*, more sensitive) than the individual DCHP POD, which contributes to the lower cumulative MOEs.
- Addition of Non-attributable Cumulative Exposure. As part of its CRA, EPA calculated nonattributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data from the 2017 to 2018 survey reverse dosimetry (Section 4.4.2), representing exposure to a national population. Overall, this non-attributable cumulative exposure contributes approximately 7.4 to 15.5 percent to the risk cup, depending on the population and age group.
- Ultimately, the impact of scaling by relative potency has a significant impact on the risk estimates for
 exposure to DCHP 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 NAHNES adds 7.4–15.5% to the risk cup).
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EPA has robust confidence in its CRA and moderate to robust confidence in its individual assessment of
DCHP for workers (Section 4.3.2.1), consumers (Section 4.3.3.1), and the general population (Section
4.3.4.1). 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

3494 phthalates on fetal testicular testosterone using a meta-analysis and BMD modeling approach for each of 3495 the six phthalates included in the cumulative chemical group (U.S. EPA, 2024ah). This analysis provides 3496 a robust basis for assessing the dose-response for the common hazard endpoint (*i.e.*, reduced fetal 3497 testicular testosterone) across the six toxicologically similar phthalates included in the CRA. For 3498 example, use of meta-analysis and BMD modeling allowed EPA to utilize more fetal testicular 3499 testosterone data in the low-end range of the dose-response curve to gain a better understanding of the 3500 hazards of DCHP at the low-end range of the dose-response curve compared to the index chemical, 3501 DBP.

3502 **5 ENVIRONMENTAL RISK ASSESSMENT**

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DCHP - Environmental Risk Assessment (Section 5): Key Points

EPA evaluated the reasonably available information to support the environmental risk assessment of DCHP. The key points of the environmental risk assessment are summarized below:

- DCHP is expected to be released to the environment via air, water, biosolids, and disposal to landfills. Based on DCHP's fate parameters, concentrations of DCHP in soil and groundwater resulting from releases to the landfill or via biosolids were not quantified but discussed qualitatively because DCHP is not expected to be persistent or be mobile in soils (Section 2).
- High-end concentrations of DCHP in surface water were estimated for the purpose of risk assessment for environmental exposure. The only two OESs with estimated water releases were Plastic compounding and Recycling, with Plastic compounding being the highest release and subsequent environmental concentrations in surface water (Section 3 and (U.S. EPA, 2024p)).
- The physical and chemical properties of DCHP indicate that it has low bioaccumulation potential and is unlikely to biomagnify. Therefore, EPA did not analyze the trophic transfer of DCHP through dietary exposures to aquatic organisms (U.S. EPA, 2024p).
- EPA derived a concentration of concern (COC) for reproductive effects of chronic DCHP water exposure of 32 µg/L DCHP to an aquatic invertebrate, *Daphnia magna* (U.S. EPA, 2024o). Empirical toxicity data for laboratory rats were used to estimate a terrestrial mammal hazard threshold of 179.3 mg/kg bw/d DCHP (U.S. EPA, 2024o).
- EPA found no reasonably available definitive environmental hazard data for DCHP exposures to birds, reptiles, sediment-dwelling animals, terrestrial invertebrates, or plants (U.S. EPA, 2024o). Therefore, DCHP hazards to these organisms were not assessed.
- Based on qualitative risk characterization, EPA does not expect risk for any assessed pathways for exposure of DCHP to terrestrial organisms. Risk is not expected because exposure to terrestrial organisms in water, soil, air, and diet is expected to be low (Section 2) and no evidence of DCHP hazard to wild terrestrial organisms was reasonably available (Section 5.2). EPA considered DCHP hazard to laboratory rodents in lieu of reasonably available wild mammal hazard resulting in conservative dietary mammal exposures being at least an order of magnitude lower than the hazard threshold (Section 5.3). The Agency has robust confidence in the preliminary determination of no risk to terrestrial organisms.
- Based on qualitative risk characterization, EPA does not expect risk for acute durations of DCHP exposure to aquatic organisms because reasonably available data found no acute hazard effects up to and above the estimated upper bound of the range of probable water solubility limits (1,480 µg/L) (Section 5.3).
- Based on qualitative risk characterization, EPA does not expect risk of chronic DCHP exposure to aquatic animals. Considerable uncertainties exist about the limit of water solubility, water release estimates, and low flow surface water modeling estimates. No risk was indicated under scenarios of lower limits of water solubility, lower release estimates, more rapid stream flow, and available measured DCHP water concentrations from the literature.

5.1 Summary of Environmental Exposures

EPA assessed environmental concentrations of dicyclohexyl phthalate (DCHP) in air, water, and land (soil, biosolids, and groundwater) for use in environmental exposure. The environmental exposures are described in the *Draft Physical Chemistry and Fate and Transport Assessment for Dicyclohexyl*

3508 Phthalate (DCHP) (U.S. EPA, 2024z) and the Draft Environmental Media, General Population, and 3509 Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p). DCHP 3510 will preferentially sorb into sediments, soils, particulate matter in air, and in wastewater solids during 3511 wastewater treatment. High-quality studies of DCHP biodegradation rates and physical and chemical 3512 properties indicate that DCHP will have limited persistence and mobility in soils receiving biosolids 3513 (U.S. EPA, 2024z). Surface water, pore water, and sediment concentrations of DCHP were modeled 3514 using VVWM-PSC. The PVC plastics compounding COU resulted in the highest estimated release to water, followed by Recycling. DCHP concentrations in receiving waters were estimated for these COUs 3515 3516 and ranged from 0.057 μ g/L to 165 μ g/L DCHP in the water column in low flow (7Q10) conditions. For 3517 the land pathways, there are uncertainties in the relevance of limited monitoring data for biosolids and 3518 landfill leachate to the COUs considered. However, based on high-quality physical and chemical property data, EPA determined that DCHP will have low persistence potential and mobility in soils. 3519 3520 Therefore, groundwater concentrations resulting from releases to the landfill or to agricultural lands via 3521 biosolids applications were not quantified but were discussed qualitatively.

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3523 Limited measured data were reasonably available from the scientific literature on DCHP concentrations 3524 in soils, biosolids, soils receiving biosolids, and landfills. No monitoring data of DCHP in these 3525 environments were reasonably available. Limited reasonably available information was available related 3526 to the uptake and bioavailability of DCHP soils. Based on the range of estimates of water solubility (30-3527 1,480 μ g/L) and hydrophobicity (log Kow = 4.82; log Koc = 4.47), DCHP is expected to have low 3528 bioavailability in soil. DCHP has not readily measured or monitored in aquatic or terrestrial organisms and has low bioaccumulation and biomagnification potential. Therefore, DCHP has low potential for 3529 trophic transfer through food webs. DCHP is expected to have minimal air to soil deposition. 3530

5.2 Summary of Environmental Hazards

EPA evaluated the reasonably available information for environmental hazard endpoints associated with DCHP exposure to ecological receptors in aquatic and terrestrial ecosystems. The Agency reviewed two references from the peer-reviewed literature and four studies reported by the Japanese Ministry of the Environment that were subsequently summarized by EU ECHA. EPA determined all references had high or medium data quality. These hazards are described in the *Draft Environmental Hazard Assessment for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 20240).

EPA found limited definitive environmental hazard data for DCHP. The reasonably available studies found all acute exposure hazards to fish, invertebrates, and algae to be higher than the upper bound of the range of probable water solubility limits of 1,480 μ g/L DCHP. However, DCHP caused chronic reproductive effects to an aquatic invertebrate (*Daphnia magna*) and a fish species (*Danio rerio*) at concentrations below the water solubility limit. EPA derived a concentration of concern (COC) for reproductive effects of chronic DCHP water exposure of 32 μ g/L DCHP.

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In terrestrial habitats, the available data suggest that DCHP might cause hazard to terrestrial mammals
through dietary exposures. A hazard effects threshold was estimated based on laboratory rodent
experiments because wild organism hazard studies were not reasonable available. EPA determined a
terrestrial mammal hazard threshold leading to reduced body weight over two generations of dietary
exposure to 179.3 mg/kg bw/d DCHP.

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No hazard data were reasonably available for birds, reptiles, terrestrial invertebrates, and plants.

3553 Therefore, these taxa were not assessed.

3554 **5.3 Environmental Risk Characterization**

3555 5.3.1 Risk Assessment Approach

3556 The environmental risk characterization of DCHP was conducted to evaluate whether the potential releases and resultant exposures of DCHP in water, air, or soil will exceed the DCHP concentrations 3557 3558 observed to result in hazardous effects to aquatic or terrestrial organisms. In evaluating the DCHP 3559 exposure concentrations, monitored and modeled DCHP concentrations in surface water were used quantitatively. Concentrations of DCHP in soil (biosolids, landfills, air deposition) and air is limited or 3560 3561 is not expected to be bioavailable and were used qualitatively. In evaluating the environmental hazard of DCHP, a weight of evidence approach was used to select hazard threshold concentrations for the 3562 3563 derivation of risk quotients for aquatic organisms. A weight of evidence approach was also used to 3564 select hazard threshold concentrations for a description of risk for terrestrial organisms. 3565

Environmental risk was characterized by calculating risk quotients or RQs (U.S. EPA, 1998; Barnthouse
et al., 1982). The RQ is defined in Equation 5-1 below.

35683569 Equation 5-1. Calculating the Risk Quotient

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- 3571

$RQ = \frac{Predicted \ Environmental \ Concentration}{Hazard \ Threshold}$

3572 3573 For aquatic organisms, the "effect level" is a derived COC based on a hazard effects concentration. The COC used to calculate ROs for aquatic organisms was derived from hazard values resulting from 3574 3575 chronic exposures to DCHP. An RQ equal to 1 indicates that the exposures are the same as the concentration that causes effects. If the RQ exceeds 1, the exposure is greater than the effect 3576 3577 concentration and risk is indicated. If the RQ is less than 1, the exposure is less than the effect 3578 concentration and risk is not indicated. In this assessment, an initial RQ value was determined only for 3579 surface water exposure to aquatic organisms where the worst-case scenario of release, flow, water 3580 solubility and chronic invertebrate hazard were considered. After further consideration of realistic 3581 conditions and hazards, risk was assessed qualitatively for surface water exposures and all other 3582 pathways.

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3584 In addition to modeling, environmental monitoring and biomonitoring data were reviewed and screened 3585 to assess wildlife exposure to DCHP (U.S. EPA, 2024p). EPA qualitatively assessed the trophic transfer of DCHP through food webs to wildlife using a worst-case scenario and physical and chemical 3586 properties. DCHP is not expected to be persistent in the environment as it is expected to degrade rapidly 3587 3588 under most environmental conditions with delayed biodegradation in low-oxygen media and DCHP's 3589 bioavailability is expected to be limited (U.S. EPA, 2024z). Estimates of the DCHP limit of water 3590 solubility range from 30 to 1,480 µg/l, leading to uncertainty about DCHP dissolved in surface water. 3591 DCHP is expected to have low bioaccumulation potential, biomagnification potential, and low potential 3592 for uptake based on a log BCF (bioconcentration factor) of 2.85 and a log BAF (bioaccumulation factor) 3593 of 1.83 (U.S. EPA, 2024p, z).

5.3.2 Risk Estimates for Aquatic and Terrestrial Species

For DCHP, surface water exposure was the only scenario where modeled concentrations could be compared with a hazard threshold or a COC. Thus, EPA calculated an initial RQ for surface water DCHP concentration but did not calculate RQs for other scenarios of exposure to organisms. Instead, because either exposure or hazard effects estimates were not reasonably available for other scenarios,

- environmental risk of DCHP to other organisms was characterized by a qualitative description of risk(Table 5-1).
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Table 5-1. Relevant Exposure Pathway to Receptors and Corresponding Risk Assessment for the DCHP Environmental Risk Characterization

Exposure Pathway	Receptor	Risk Assessment
	Chronic exposure to aquatic species (reduced <i>Daphnia magna</i> reproduction >21 days)	Qualitative; No risk
Surface water	Acute exposure: no hazard up to and above 2,000 µg/L DCHP to fish (<i>Oryzias latipes</i>), <i>D. magna</i> , and algae (<i>Raphidocelis subcapitata</i>)	Qualitative; No risk
Trophic transfer	Terrestrial mammal	Qualitative; No risk
Biosolids	Terrestrial mammal	Qualitative; No risk
Landfills	Terrestrial mammal	Qualitative; No risk

3604

3605 Surface Water

3606 The COC was derived from a study of the hazard effects due to chronic (21-day) aqueous exposures to 3607 the freshwater invertebrate, *Daphnia magna* (NITE, 2000) and determined to be 32 μ g/L DCHP. The 3608 reasonably available studies on Japanese medaka (*Oryzias latipes*), *D. magna*, and the freshwater algae 3609 (*Raphidocelis subcapitata*) found no aquatic acute exposure hazards up to and above the water solubility 3610 limit of 1,480 μ g/L DCHP (U.S. EPA, 2024o).

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3612 EPA found no evidence from monitoring reports or the scientific literature that DCHP occurs in surface water at the COC of 32 µg/L. However, EPA modeled surface water release under the most conservative 3613 3614 and least likely scenario from the PVC plastics compounding COU. This conservative model included 3615 (1) the highest modeled release estimate, (2) the lowest 7-day average flow over 10 years from a generic 3616 stream, and (3) the highest modeled estimate of the limit of DCHP water solubility (1,480 µg/L). These conditions are unlikely for at least two reasons. First, it combined the highest release from a facility into 3617 3618 a low flow scenario indicative of a small stream. Without site-specific data, EPA does not have evidence 3619 that a high release, small stream combination exists in the Unites States. Second, experimental evidence 3620 suggests that the functional limit of DCHP water solubility may be near the lower EPA estimated range 3621 of 30 μ g/L rather than the upper bound of the estimated range of 1,480 μ g/L. Specifically, two studies 3622 that attempted to find hazard thresholds of DCHP to aquatic organisms report their inability to keep 3623 DCHP in solution above 30 to 50 µg/L even with the aid of cosolvents (Swedish Chemicals Agency, 3624 2023; Mathieu-Denoncourt et al., 2016). The VMM-PSC modeled concentrations were 165 µg/L DCHP 3625 in surface water and 95 µg/L in porewater over 21 days, which are below the upper bound estimate of 3626 the limit of water solubility of 1,480 µg/L (U.S. EPA, 2024aa), but over 3 times greater than the lower bound estimate of the limit of water solubility (30 μ g/L) and the water solubility limit (30 μ g/L) 3627 3628 proposed by the Swedish Chemicals Agency (Swedish Chemicals Agency, 2023). 3629

A first-tier screen computed RQs using the upper bound estimate of water solubility (1,480 μ g/L), the

highest release, and median low flow (7Q10) and the COC ($32 \mu g/L$) over 21 days resulting in a RQ greater than 1. However, RQs were less than 1 under all other scenarios that considered one or more of the following surface water scenarios, higher flow rates (*e.g.*, 75th percentile 7Q10), modeled central tendency release estimates (*e.g.*, 1.11 kg/day), or limits of water solubility at the lower bounded estimate

3636 from a Daphnia study that found a 12.9 percent reduction in offspring reproduction after two to three 3637 generations of exposure to 572 µg/L DCHP (NITE, 2000). The exposure concentrations in this 3638 experiment were enhance by the use of dimethylformamide as a cosolvent, which resulted in DCHP 3639 concentrations well above the lower bound estimate of water solubility (30 µg/L) (NITE, 2000). 3640 Therefore, EPA determined a low likelihood of DCHP persisting in surface waters for a long enough 3641 duration (21 days) to cause chronic hazard in aquatic invertebrates, and thus a preliminary indication of 3642 no risk.

3643

3644 In one available study, DCHP concentrations measured in the water column did not exceed $0.014 \,\mu g/L$ 3645 (Keil et al., 2011). Monitoring by the Washington State Department of Ecology resulted in no DCHP 3646 detection above the detection limit (0.05 µg/L) (WA DOE, 2022). No information is available on the potential continuous or persistent nature of DCHP in the water column of natural systems or from 3647 specific release sites. Modeled concentrations from the Processing/ PVC plastics compounding 3648 3649 COU/OES release scenarios coupled with low flow conditions predict unlikely conditions for exposure 3650 to exceed COCs. Risk of chronic DCHP exposure to aquatic invertebrates requires surface water 3651 concentrations to be three orders of magnitude greater than those reported in the literature as background 3652 concentration or at a point source (Keil et al., 2011). Modeled DCHP water concentrations from recycling release scenarios did not indicate risk even in similar low flow conditions. 3653

3654

3655 Sediment and Pore Water

3656 DCHP is expected to partition primarily to soil and sediment, regardless of the compartment of environmental release (U.S. EPA, 2024ai). DCHP is not expected to undergo long-range transport and is 3657 expected to be found predominantly in sediments near point sources, with a decreasing trend in sediment 3658 3659 concentrations downstream due to DCHP's strong affinity and sorption potential for organic carbon in 3660 sediment. EPA's maximum modeled concentrations under low flow conditions of 112 mg/kg/d (U.S. 3661 EPA, 2024p) reflect the physical and chemical properties of DCHP and its predicted affinity for 3662 sediment (U.S. EPA, 2024z), but may be overestimated due to conservative parameters and the Variable Volume Water Model - Point Source Calculator (VVM-PSC) three compartment model. Also, DCHP is 3663 3664 not expected to be persistent in the environment as it is expected to degrade rapidly under most 3665 environmental conditions with delayed biodegradation in low-oxygen media (U.S. EPA, 2024z). 3666

3667 EPA found no evidence from monitoring reports or the scientific literature that DCHP occurs in pore 3668 water at the COC of 32 µg/L. Porewater DCHP concentrations from VVM-PSC modeling resulted in a maximum of 93 µg/L, which exceeded the DCHP limit of solubility (30 µg/L). EPA found no 3669 reasonably available studies on the hazard effects of DCHP sediment exposures to aquatic organisms 3670 3671 (U.S. EPA, 2024o). Despite this, the Agency considered the COC of DCHP to Daphnia (32 µg/L) to 3672 indicate chronic exposure hazard effects to sediment dwelling animals. Because of the water solubility 3673 uncertainties described for surface risk to aquatic invertebrates, EPA determined a low likelihood of 3674 DCHP persisting in sediment and pore waters for a long enough duration (21 days) to cause chronic 3675 hazard in aquatic invertebrates, and thus a preliminary indication of no risk.

3677 Air

3676

3678 No studies on the hazardous effects of DCHP inhalation were reasonably available for EPA to review. 3679 Only a few studies that monitored ambient DCHP air concentrations were reasonably available for the 3680 Agency to review. DCHP in particulates averaged 0.01 ng/m³ in one study (Lee et al., 2019). Low to 3681 negligible air concentrations are expected from TSCA COUs and air to soil modeling was not

- 3682 conducted. Thus, EPA qualitatively assessed risk using low exposures via air pathways and a preliminary indication of no risk.
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3685 Landfill

EPA qualitatively assessed risk of landfill to groundwater and soil DCHP exposure to aquatic and
terrestrial organisms. No hazard data were reasonably available for groundwater-dwelling or soildwelling animals or plants. EPA considered the COC of DCHP to *Daphnia* (32 μg/L) to indicate chronic
exposure hazard effects to groundwater dwelling animals. Empirical toxicity data for rats and mice were
used to estimate a hazard threshold value for terrestrial mammals that may ingest soils at 179.3 mg/kgbw/day (U.S. EPA, 2024o).

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3693 DCHP may be deposited into landfills through various waste streams, including consumer waste, 3694 residential waste, and industrial waste, as well as through municipal waste like dewatered wastewater 3695 biosolids. No studies were identified which reported the concentration of DCHP in landfills or in the surrounding land. There is limited information regarding DCHP in dewatered biosolids, which may be 3696 3697 sent to landfills for disposal. DCHP is not expected to be persistent in the environment as it is expected 3698 to degrade rapidly under most environmental conditions with delayed biodegradation in low-oxygen 3699 media. DCHP is slightly soluble in water (range from 0.03-1,480 mg/L) and has limited potential to 3700 leach from landfills into nearby groundwater or surface water systems. However, DCHP is expected to 3701 have a high affinity to particulate (log Koc = 4.47) and organic media (log Kow = 4.82), which would cause significant retardation in groundwater and limit leaching to groundwater. Because of its high 3702 3703 hydrophobicity and high affinity for soil sorption, it is not expected to be bioavailable for uptake. As a 3704 result, the available evidence indicates that migration from landfills to surface water and sediment is 3705 limited, and EPA did not model DCHP leaching from landfills to groundwater or surface water systems. 3706 EPA determined a low likelihood of DCHP persisting in and being bioavailable in groundwater from 3707 landfills for a long enough duration to cause chronic hazard in animals, and thus a preliminary indication 3708 of no risk.

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3710 There is limited reasonably available information related to the uptake and bioavailability of DCHP in 3711 soils. DCHPs solubility and sorption coefficients suggest that bioaccumulation and biomagnification 3712 will not be of significant concern for soil-dwelling organisms adjacent to landfills. The combination of 3713 factors such as biodegradation (U.S. EPA, 2024z) and the weight of evidence supporting a lack of 3714 bioaccumulation and lack of biomagnification supports this qualitative assessment that potential DCHP 3715 concentrations in landfills do not present concentrations greater than the hazard thresholds to terrestrial 3716 organisms. EPA determined a low likelihood of DCHP persisting and being bioavailable to solid-3717 dwelling animals, plants, or in the diets of mammals for a long enough duration to cause chronic hazard, 3718 and thus a preliminary indication of no risk. 3719

3720 Biosolids

EPA qualitatively assessed risk of biosolids to soil DCHP exposure to terrestrial organisms. No hazard 3721 3722 data were reasonably available for soil-dwelling animals or plants. Empirical toxicity data for rats and 3723 mice were used to estimate a hazard threshold value for terrestrial mammals at 179.3 mg/kg-bw/day 3724 (U.S. EPA, 2024o). DCHP may be introduced to biosolids by the absorption or adsorption of DCHP to 3725 particulate or organic material during wastewater treatment. Wastewater treatment is expected to remove 3726 up to 98 percent of DCHP during wastewater treatment via sorption of DCHP to biosolids (Wu et al., 3727 2019). Modeling of DCHP removal in wastewater treatment predicts sorption to account for a total of 3728 71.2 percent removal of DCHP with 70.6 percent overall removal attributed to biosolid sorption and the 3729 remaining 0.6 percent removal attributed to biological treatment (U.S. EPA, 2017). There are currently 3730 no reasonably available U.S.-based studies reporting DCHP concentration in biosolids or in soil 3731 following land application.

3732

High-end release scenarios were considered not to be applicable to the evaluation of land application of
biosolids. More specifically, high-end releases of DCHP from industrial facilities are unlikely to be

- discharged directly to municipal wastewater treatment plants without pre-treatment, and biosolids from
 industrial facilities are unlikely to be directly land applied following on-site treatment.
- 3737

3748

3738 There is limited measured data on concentrations of DCHP in biosolids or soils receiving biosolids and 3739 there is uncertainty that concentrations used in this analysis are representative of all types of 3740 environmental releases. However, the high-quality biodegradation rates and physical and chemical 3741 properties show that DCHP will have limited persistence potential and mobility in soils receiving 3742 biosolids (U.S. EPA, 2024z). The combination of factors such as biodegradation and the weight of 3743 evidence supporting a lack of bioaccumulation and lack of biomagnification supports this qualitative 3744 assessment that potential DCHP concentrations in biosolids do not present concentrations greater than 3745 hazard threshold values to terrestrial organisms. Therefore, EPA determined a low likelihood of DCHP 3746 persisting and being bioavailable to soil-dwelling animals, plants, or in the diets of mammals for a long 3747 enough duration to cause chronic hazard, and thus a preliminary indication of no risk.

3749 Trophic Transfer

3750 EPA did not conduct a quantitative modeling analysis of the trophic transfer of DCHP through food 3751 webs because of the chemical properties and fate of DCHP indicate low potential for bioaccumulation or biomagnification. Specifically, the Agency does not expect DCHP to persist in surface water, 3752 3753 groundwater, or air. DCHP is not expected to be persistent in the environment as it is expected to degrade rapidly under most environmental conditions with delayed biodegradation in low-oxygen 3754 3755 media, and DCHP's bioavailability is expected to be limited (U.S. EPA, 2024z). Estimates of the DCHP 3756 limit of water solubility range from 30 to 1,480 µg/L, leading to uncertainty about DCHP dissolved in 3757 surface water. DCHP is expected to have low bioaccumulation potential, biomagnification potential, and 3758 low potential for uptake based on a log BCF of 2.85 and a log BAF of 1.83 (U.S. EPA, 2024p, z). For 3759 example, a worst-case scenario screening that uses the upper bound of water solubility as the water 3760 concentration (1,480 µg/L DCHP) and BAF of 67, results in 99 mg/kg-bw DCHP in fish. A similar 3761 calculation results in 11 mg/kg-bw DCHP in fish if the highest modeled concentration from EPA's 3762 VVM-PSC (164 µg/L) is used. These values are less than the terrestrial mammal threshold value of 3763 179.3 mg/kg-bw/day over 70 days. These values would only be lower in simulations that incorporate 3764 other release and exposure scenarios in a trophic transfer model. Finally, EPA also did not find 3765 reasonably available data sources that report the aquatic bioconcentration, aquatic bioaccumulation, 3766 aquatic food web magnification, terrestrial biota-sediment accumulation, or terrestrial bioconcentration of DCHP. Therefore, EPA determined a low likelihood of DCHP transferring through food webs to 3767 3768 reach the terrestrial mammal threshold value of 179.3 mg/kg-bw/day and thus a preliminary indication 3769 of no risk.

3770

3771 Distribution in Commerce

EPA evaluated activities resulting in exposures associated with distribution in commerce (*e.g.*, loading,
unloading) throughout the various life cycle stages and COUs (*e.g.*, manufacturing, processing,
industrial use, commercial use, disposal) rather than a single distribution scenario. The Agency lacks
data to assess risks to the environment from environmental releases and exposures related to distribution

- 3776 data to assess risks to the environment from environmental releases and exposures related to distri-3776 of DCHP in commerce as a single OES. However, most of the releases from this COU/OES are
- 3776 of DCHP in commerce as a single OES. However, most of the releases from this COU/OES are 3777 expected to be captured within the releases of other COU/OES because most of the activities (loading,
- 3778 unloading) generating releases from distribution of commerce are release points of other COU/OES.

3779	5.3.3 Overall Confidence and Remaining Uncertainties Confidence in Environmental
3780	Risk Characterization
3781	The environmental risk characterization of DCHP evaluated confidence from environmental exposures
3782	and environmental hazards. Exposure confidence is detailed within U.S. EPA (2024p), the TSD Draft
3783	Environmental Media and General Population and Environmental Exposure Assessment for
3784	Dicyclohexyl Phthalate (DCHP), represented by modeled and monitored data. Hazard confidence was
3785	represented by evidence as reported previously in the Draft Environmental Hazard Assessment for
3786	Dicyclohexyl Phthalate (DCHP) U.S. EPA (20240).
3787	
3788	The overall confidence in the preliminary risk characterization for the aquatic assessment is robust. EPA
3789	has indicated no risk to aquatic organisms under most realistic release, flow, and solubility scenarios
3790	except in a scenario with the most conservative assumptions. The Agency has robust confidence that the
3791	conservative scenario with worst-case assumptions is unlikely for several reasons. First, EPA has
3792	determined DCHP water releases to be low due to its chemical properties and predicted fate (U.S. EPA,
3793	<u>2024</u> z), making modeled exposure predictions greater than COCs unlikely. Also, DCHP is a solid at
3794	room temperature with considerable variation in the estimates of water solubility that ranges from 30
3795	µg/L to 1,480 µg/L. Under EPA's release of DCHP to water generic scenarios, the amount of DCHP that
3796	may be released to surface water as a solid and the amount that is dissolved in water critically depends
3797	on the functional or environmentally relevant solubility of DCHP in water bodies. Evidence from the
3798	only available U.S. monitoring study reported the maximum DCHP at 0.014 µg/L (Keil et al., 2011),
3799	plus two toxicity studies that reported DCHP leaving solution above 30 µg/L (Swedish Chemicals
3800	Agency, 2023; Mathieu-Denoncourt et al., 2016) suggest that EPA's modeled high-end release and low
3801	stream flow scenario resulting 165 µg/L DCHP is unlikely to occur in aquatic ecosystems. Thus, no
3802	reasonably available evidence reports dissolved water concentrations as high as 165 µg/L and the weight
3803	of evidence points to a low likelihood of DCHP concentrations reaching 165 µg/L.
3804	
3805	The environmental hazard to aquatic organisms is also not clear because only two peer-reviewed studies
3806	and a handful of reports are reasonably available for EPA to review. These studies have high data
3807	quality evaluation ratings, but corroborating results from additional studies would improve the accuracy
3808	and precision of the Agency's COC for chronic exposure while increasing the confidence for indications
3809	of low likelihood of risk. All but two of these studies did not find acute exposure effects at
3810	concentrations up to 2,000 μ g/L, indicating that short exposure durations pose little risk to aquatic
3811	organisms. Chronic exposure effects on reproductive endpoints were documented for an invertebrate and
3812	a fish at approximately 30 µg/L DCHP concentrations. All these studies used solvent carriers to keep
3813	DCHP in solution. Taken together, it remains unclear whether high concentrations of DCHP in the water
3814	column occur in ecosystems and whether these exposure concentrations can persist long enough to incur
3815	reproductive effects on aquatic organisms. Thus, the weight of evidence summarized in this document
3816	leads to the preliminary characterization of no risk to aquatic receptors.
3817	

3818 The overall confidence in the preliminary risk characterization for the terrestrial assessment is robust. EPA has robust confidence that DCHP is not likely to present environmental risk through most scenarios 3819 that may expose DCHP to terrestrial organisms. This confidence is due to the relatively low volumes of 3820 3821 release across COUs, the physical and chemical properties of DCHP, and the low number of studies that document DCHP in the environment. These result in low to negligible exposure concentrations in air, 3822 3823 landfills, biosolids and soils. Trophic transfer of DCHP through food webs is also unlikely due to DCHP's chemical and fate properties that indicate that it has low potential to bioaccumulate or 3824 3825 biomagnify in food webs. This weight of evidence of low potential for DCHP exposures in terrestrial 3826 ecosystems-coupled with no reasonably available studies of DCHP hazard effects to wildlife and a 3827 relatively high surrogate mammal hazard threshold from laboratory rodent data—indicate exposure

- 3828 above the hazard threshold is an unlikely risk to terrestrial organisms. Although the lack of reasonably
- 3829 available studies on the hazardous effects of DCHP on wildlife does not rule out hazard and subsequent
- 3830 risk, the weight of evidence summarized in this document leads to the preliminary indication that risk to
- 3831 terrestrial receptors is not expected.

3832 6 UNREASONABLE RISK DETERMINATION

3837

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 non-risk factors, including an unreasonable risk to a PESS identified by EPA as relevant to
the risk evaluation, under the TSCA COUs.

3838 EPA is preliminarily determining that DCHP presents an unreasonable risk of injury to human health 3839 under the COUs. The Agency is preliminary determining that DCHP does not present unreasonable risk 3840 of injury to the environment. This draft unreasonable risk determination is based on the information in previous sections of this draft risk evaluation, the appendices, and the TSDs of this draft risk evaluation 3841 3842 in accordance with TSCA section 6(b). It is also based on (1) the best available science (TSCA section 3843 26(h)); (2) weight of scientific evidence standards (TSCA section 26(i)); and (3) relevant implementing 3844 regulations in 40 CFR part 702, including, to the extent practicable, the amendments to the procedures 3845 for chemical risk evaluations under TSCA finalized in May 2024 (89 FR 37028; May 3, 2024).

3846 3847 If, in the final TSCA risk evaluation for DCHP, EPA determines that DCHP presents an unreasonable 3848 risk of injury to health or the environment under the COUs, the Agency will initiate risk management for 3849 DCHP by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that DCHP no longer presents such risk. The risk management requirements will likely focus on the 3850 3851 COUs significantly contributing to the unreasonable risk. However, under TSCA section 6(a), EPA is 3852 not limited to regulating the specific COUs found to significantly contribute to the unreasonable risk and 3853 may select from among a suite of risk management options related to manufacture, processing, 3854 distribution in commerce, commercial use, and disposal to address the unreasonable risk. For instance, 3855 EPA may regulate "upstream" COUs (e.g., processing, distribution in commerce) to address 3856 "downstream" COUs that significantly contribute to unreasonable risk (e.g., use)—even if the upstream activities are not significantly contributing to the unreasonable risk. The Agency would also consider 3857 3858 whether such risk may be prevented or reduced to a sufficient extent by action taken under another 3859 federal law, such as referral to another agency under TSCA section 9(a) or use of another EPA-3860 administered authority to protect against such risk pursuant to TSCA section 9(b), as appropriate. 3861

3862 As noted in the EXECUTIVE SUMMARY, DCHP is used primarily as a plasticizer to make flexible PVC. It is also used to make building and construction materials; automotive care and fuel products; and 3863 3864 other commercial and consumer products including adhesives and sealants, paints and coatings, 3865 electrical and electronic products. Workers may be exposed to DCHP when making these products or 3866 otherwise using DCHP in the workplace. When it is manufactured or used to make products, DCHP can be released into the water, where because of its properties, most of it will end up in the sediment at the 3867 3868 bottom of lakes and rivers. If it is released into the air, DCHP will attach to dust particles and then be 3869 deposited onto land or into water. Indoors, DCHP has the potential over time to be come out of products 3870 and adhere to dust particles. If it does, people could inhale or ingest dust that contains DCHP. In addition to DCHP, workers and consumers can be exposed to other phthalates that have the same 3871 3872 toxicological endpoint (i.e., decreased fetal testicular testosterone). EPA has authored a draft cumulative risk technical support document of DCHP and five other toxicologically similar phthalates (*i.e.*, DEHP, 3873 3874 DBP, DIBP, BBP, and DINP) that are also being evaluated under TSCA. This TSD will allow EPA to assess the combined risk to health from multiple chemicals with similar effects simultaneously, 3875 3876 recognizing that human exposure to phthalates is widespread and that multiple phthalates can disrupt 3877 development of the male reproductive system. The use of EPA's cumulative risk assessment (CRA) in 3878 the preliminary risk determination is discussed in more detail in Section 6.1.3 as well as the worker 3879 (Section 6.1.4) and consumer (Section 6.1.5) sections. 3880

3881 The COUs evaluated for DCHP are listed in Table 1-1. EPA is preliminarily determining the following

3882 COUs based on the DCHP individual analysis and the relative potency factor (RPF) analysis,

3883 significantly contribute to the unreasonable risk to workers:

- Manufacturing domestic manufacturing;
- Processing incorporation into formulation, mixture, or reaction product adhesive and sealant chemicals in adhesive manufacturing;
- Processing incorporation into formulation, mixture, or reaction product plasticizer (adhesive manufacturing; paint and coating manufacturing; and printing ink manufacturing);
- Processing incorporation into formulation, mixture, or reaction product stabilizing agent (adhesive manufacturing; asphalt paving, roofing, and coating materials manufacturing; and paints and coating manufacturing)
- Industrial use finishing agent cellulose film production;
- Industrial use inks, toner, and colorant products (*e.g.*, screen printing ink);
- Industrial use Paints and coatings;
- Commercial use inks, toner, and colorant products (*e.g.*, screen printing ink); and
- Commercial use paints and coatings.

3897 EPA is preliminarily determining that the following COUs do *not* significantly contribute to the3898 unreasonable risk:

- Manufacturing importing;
- Processing incorporation into article plasticizer (plastics product manufacturing and rubber product manufacturing);
- Processing repackaging (*e.g.*, laboratory chemicals);
- Processing recycling;
- Distribution in commerce;
- Industrial use adhesives and sealants (*e.g.*, computer and electronic product manufacturing;
 transportation equipment manufacturing);
- Industrial use other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) (*e.g.*, transportation equipment manufacturing);
- Commercial use adhesives and sealants;
- Commercial use building/construction materials not covered elsewhere;
- Commercial use laboratory chemicals;
- 3912 Commercial use other articles with routine direct contact during normal use including rubber articles; plastic articles (hard);
- Consumer use adhesives and sealants;
- 3915 Consumer use other articles with routine direct contact during normal use including rubber articles; plastic articles (hard);
- Consumer use other consumer articles that contain dicyclohexyl phthalate from: inks, toner, and colorants; paints and coatings; adhesives and sealants (*e.g.*, paper products, textiles, products using cellulose film, etc.); and
 - Disposal.

3920

3921 Whether EPA makes a determination of unreasonable risk for a particular chemical substance under

3922 TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under

- 3923 consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude,
- frequency of exposure, population exposed), how PESS groups were considered in the assessment, and
- the confidence in the information used to inform the hazard and exposure values. For COUs evaluated
- 3926 quantitatively, EPA also considers how central tendency or high-end risk estimates represented the risk

3927 related factors, and the Agency based the risk determination on the risk estimates that best represented 3928 the COUs. Additionally, in this draft risk evaluation, EPA describes the strength of the scientific 3929 evidence supporting the human health and environmental assessments as robust, moderate, or slight. 3930 Robust confidence suggests thorough understanding of the scientific evidence and uncertainties, as well 3931 as the supporting weight of scientific evidence, outweighs the uncertainties to the point where it is 3932 unlikely that the uncertainties could have a significant effect on the risk. Moderate confidence suggests 3933 some understanding of the scientific evidence and uncertainties, and the supporting scientific evidence 3934 weighed against the uncertainties is reasonably adequate to characterize the risk. Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the risk, and when 3935 3936 the Agency is making the best scientific assessment possible in the absence of complete information. 3937

3938 This draft risk evaluation discusses important assumptions and key sources of uncertainty in the risk 3939 characterization, and these are described in more detail in the respective weight of scientific evidence 3940 conclusions sections for fate and transport, environmental release, environmental exposures, 3941 environmental hazards, and human health hazards, respectively. It also includes overall confidence and 3942 remaining uncertainties sections for human health and environmental risk characterizations.

3943 3944 Additionally, EPA considered, where relevant, the Agency's analyses on aggregate exposures and 3945 cumulative risk. Aggregate exposure analyses consider effects on populations that are exposed to DCHP 3946 via multiple routes (e.g., dermal contact, ingestion, and inhalation). Cumulative risk refers to human 3947 health risks related to exposures to multiple chemicals-in this case the six phthalates considered in the 3948 CRA TSD. EPA has applied the methods and principles of CRA outlined in EPA's Draft Proposed 3949 Approach for Cumulative Risk Assessment (CRA) of High-Priority Phthalates and a Manufacturer-3950 Requested Phthalate under the Toxic Substances Control Act (U.S. EPA, 2023c) and EPA's Draft 3951 Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), 3952 Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl 3953 Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA) 3954 (U.S. EPA, 2024ah), to derive non-cancer risk estimates for occupational and consumer exposures. 3955 These cumulative, non-cancer risk estimates are considered in addition to the individual risk estimates 3956 for DCHP. Notably, other authoritative and regulatory agencies (i.e., CPSC, Health Canada, ECHA, 3957 NICNAS, EFSA) have evaluated phthalates, including DCHP, for cumulative risk. Further, independent, 3958 expert peer reviewers on the SACC endorsed EPA's proposal to conduct a CRA of phthalates under TSCA because it represents the best available science. The Agency's approach for assessing cumulative 3959 3960 risk, which is described in detail in the draft CRA TSD (U.S. EPA, 2024ah), incorporates feedback from 3961 the SACC (U.S. EPA, 2023f) who peer reviewed EPA's draft proposed approach in May 2023 (U.S. 3962 EPA, 2023f).

6.1 Human Health

Calculated non-cancer risk estimates (MOEs) can provide a risk profile of DCHP by presenting a range
of estimates for different health effects for different COUs. When characterizing the risk to human
health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline
assessments of risk and makes its determination of unreasonable risk from a baseline scenario that does
not assume use of respiratory protection or other personal protective equipment (PPE).⁵ A calculated
MOE that is less than the benchmark MOE is a starting point for informing a determination of

⁵ 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.

unreasonable risk of injury to health, based on non-cancer effects. It is important to emphasize that thesecalculated risk estimates alone are not bright-line indicators of unreasonable risk.

6.1.1 Populations and Exposures EPA Assessed for Human Health

3973 EPA has evaluated risk to adolescent and adult workers (including ONUs and female workers of 3974 reproductive age) 16 years of age and older; consumer users and bystanders, including infants and 3975 children; and the general population, including infants and children and people who consume fish. The 3976 Agency evaluated these risks using reasonably available monitoring and modeling data for inhalation 3977 and dermal exposures, as applicable. EPA has evaluated risk from inhalation and dermal exposure of 3978 DCHP to workers, including ONUs, as appropriate for each exposure scenario, but the primary route of 3979 exposure was inhalation. The Agency evaluated risk from inhalation, dermal, and oral-exposure to 3980 consumer users and inhalation exposures to bystanders. Finally, EPA also evaluated risk from exposures 3981 from surface water, drinking water, fish ingestion, ambient air, and land pathways (i.e., landfills and application of biosolids) to the general population. 3982

3983

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3984 Descriptions of the data used for human health exposure and human health hazards are provided in 3985 Sections 4.1 and 4.2, respectively, in this draft risk evaluation. Uncertainties for overall exposures and 3986 hazards are presented in this draft risk evaluation, the Draft Consumer and Indoor Dust Exposure 3987 Assessment for Dicyclohexyl phthalate (DCHP) (U.S. EPA, 2024c), the Draft Environmental Media and 3988 General Population and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. 3989 EPA, 2024p), the Draft Environmental Release and Occupational Exposure Assessment for 3990 Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024q), and the Draft Non-Cancer Human Health Hazard 3991 Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024v) and are considered in this 3992 preliminary unreasonable risk determination.

3993

3997

6.1.2 Summary of Human Health Effects

3994 EPA is preliminarily determining that the unreasonable risk presented by DCHP is due to

- non-cancer effects in workers from inhalation exposures;
- non-cancer effects in workers from aggregate exposures (*i.e.*, inhalation + dermal); and
 - non-cancer effects in workers from cumulative exposures (*i.e.*, DCHP + other phthalates).

3998 With respect to health endpoints upon which EPA is basing this preliminary unreasonable risk 3999 determination, the Agency has robust overall confidence in the proposed POD based on the developing 4000 male reproductive system for use in characterizing risk from exposure to DCHP for acute, intermediate, 4001 and chronic exposure scenarios. In addition, overall, EPA has robust confidence in the draft factors used 4002 in the RPF analysis and cumulative risk analysis. See Section 4.4 and EPA's Draft Technical Support 4003 Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate 4004 (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), 4005 and Diisononyl Phthalate (DINP) Under the Toxic Substances Control Act (TSCA) (U.S. EPA, 2024ah), 4006 for further description of the RPF analysis.

- 4007
- 4008 DCHP has not been evaluated for carcinogenicity in any two-year cancer bioassays. EPA therefore 4009 evaluated the relevance of read-across approaches to assess potential cancer hazards of DCHP based on
- 4009 evaluated the relevance of read-across approaches to assess potential cancer hazards of DCHP based on 4010 cancer bioassays and MOA information available for other phthalates being evaluated under TSCA (*i.e.*,
- 4010 cancer bloassays and MOA information available for other phthalates being evaluated under ISCA (*i.e.* 4011 DEHP, DBP, BBP, DINP, DIDP) as discussed in the *Draft Cancer Human Health Hazard Assessment*
- 4011 DEHP, DBP, BBP, DINP, DIDP) as discussed in the *Draft Cancer Human Health Hazard Assessment* 4012 *for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP),*
- 4013 Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2025a). Overall, based
- 4014 on the weight of scientific evidence, EPA preliminarily concludes that potential carcinogenicity of

- 4015 DCHP is not a significant remaining source of uncertainty in the quantitative and qualitative risk
- 4016 characterization, despite the lack of DCHP carcinogenicity bioassays.
- 4017

4024

- 4018 EPA's exposure and overall risk characterization PODs and MOEs are summarized in Section 4.3, with
- 4019 specific health risk estimates for workers (including ONUs), consumers, bystanders, and the general
- 4020 population presented in Section 4.3.2 (workers), Section 4.3.3 (consumers and bystanders), Section 4.3.4
- 4021 (general population), and Section 4.3.5 (PESS). Again, these MOEs and benchmarks are not bright-4022 lines, and EPA has discretion to consider other risk-related factors when determining if a COU
- 4022 lines, and EPA has discretion to consider other risk-related factors when determining if a COU
 4023 significantly contributes to the unreasonable risk determination of the chemical substance.
- 4025 significantly contributes to the unreasonable risk determination of the chemical substar

6.1.3 Basis for Unreasonable Risk to Human Health

4025 In developing the exposure and hazard assessments for DCHP, EPA analyzed reasonably available 4026 information to ascertain whether some human populations may have greater exposure and/or 4027 susceptibility than the general population to the hazard posed by DCHP. For this DCHP draft risk evaluation, EPA has accounted for the following PESS groups: people who are expected to have greater 4028 4029 exposure to DCHP, such as people exposed to DCHP at work; women of reproductive age; infants and 4030 children who frequently have contact with consumer products and/or articles containing high 4031 concentrations of DCHP; those who may have greater intake of DCHP per body weight (e.g., infants, 4032 children, adolescents); those exposed to DCHP through certain age-specific behaviors (e.g., mouthing by 4033 infants and children); and Tribes and subsistence fishers whose diets include large amounts of fish. 4034 Additionally, EPA identified population group lifestages that may have greater susceptibility to the health effects of DCHP as PESS, including women of reproductive age, pregnant women, infants, 4035 4036 children, and adolescents. A full PESS analysis is provided in Section 4.3.5 of this draft risk evaluation. 4037

- 4038 Risk estimates based on high-end exposure levels (e.g., 95th percentile, or high intensity scenarios) are 4039 generally intended to cover individuals with sentinel exposures, whereas risk estimates at the central 4040 tendency exposure are generally estimates of average or typical exposures. For DCHP, EPA was able to calculate risk estimates for PESS groups in this assessment (e.g., female workers of reproductive age, 4041 4042 infants and children). In addition, the non-cancer PODs are based on susceptible populations. The 4043 POD—which is used for acute, intermediate, and chronic exposure durations—is based on effects 4044 observed during pregnancy whereas the intermediate and chronic PODs are based on reproductive 4045 effects observed in adolescent males. The use of either central tendency or high-end risk estimates for 4046 female workers of reproductive age to make a determination of unreasonable risk was based on 4047 assumptions about the COU using reasonably available information about a typical scenario and process within the COU. In determining whether a COU significantly contributes to the unreasonable risk to 4048 4049 DCHP, EPA considered the central tendency for most of the occupational estimates. Central tendency 4050 values of exposure are often expected to be the most reflective of worker exposures within the DCHP 4051 COUs, as explained further in Section 6.1.3.
- 4052

To make an unreasonable risk determination for consumers, EPA considered risk estimates for consumers (*e.g.*, infants and children) representing high-intensity *exposure* levels, which are distinct from the occupational central-tendency or high-end risk estimates that represent a point within the modeled distribution. For example, high-intensity consumer indoor dust exposure scenarios assumed that people are in their homes for longer periods than the medium- or lower- intensity scenarios. Health parameters were also adjusted for each population, such as inhalation rates used per lifestage.

4059

EPA has also aggregated exposures across certain routes for workers, including ONUs, and consumers
 for COUs with quantitative risk estimates. For most occupational COUs, aggregation of inhalation and
 dermal exposures led to negligible differences in risk estimates when compared with risk estimates from

inhalation alone, because inhalation is the predominant route of exposure. For consumers, dermal, oral,
and inhalation routes were aggregated, which did not result in any risk estimates below the benchmark
MOE, similar to the consumer risks from individual exposure routes. The UF of 10 for human variability
that EPA applied to MOEs accounts for increased susceptibility of populations such as children and
elderly populations. Detailed information on how EPA characterized sentinel and aggregate risks is
provided in Section 4.1.5.

4069

In addition to the analysis done for DCHP alone (referred to as "individual analysis"), EPA applied both 4070 4071 the methods and principles of CRA (Draft Proposed Approach for Cumulative Risk Assessment (CRA) 4072 of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances 4073 Control Act (U.S. EPA, 2023c), as well as the Draft Technical Support Document for the Cumulative 4074 Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate 4075 (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate 4076 (DINP) Under the Toxic Substances Control Act (TSCA) (U.S. EPA, 2024ah)), to derive non-cancer risk 4077 estimates for occupational and consumer exposures. EPA's draft CRA includes cumulative exposure to 4078 other toxicologically similar phthalates being evaluated under TSCA (*i.e.*, DEHP, DBP, BBP, DIBP, and 4079 DINP) and uses an "RPF analysis" to characterize risk. Using a meta-analysis and BMD modeling 4080 approach to model decreased fetal testicular testosterone, EPA derived an RPF for DCHP of 1.66 based 4081 on BMD_{40} . This means DCHP exposures, when multiplied by the relative potency factor and expressed 4082 in terms of index chemical (*i.e.*, DBP) equivalents, increased by 66 percent. 4083

4084 The above approach accounts for potency differences among chemicals in a mixture and scales the dose 4085 of one chemical to an equitoxic dose of another chemical (*i.e.*, the index chemical). The chemical 4086 selected as the index chemical (*i.e.*, DBP) is the best characterized toxicologically and considered to be 4087 representative of the type of toxicity elicited by other components of the mixture, which allows EPA to 4088 utilize more fetal testicular testosterone data in the low-end range of the dose-response curve to gain a 4089 better understanding of the hazards of DCHP at the low-end range of the dose-response curve. 4090 Additionally, the index chemical (i.e., DBP) POD is 12.5 percent lower (i.e., more sensitive) than the 4091 individual DCHP POD, which also contributes to the lower RPF analysis MOEs as compared with the 4092 individual non-scaled DCHP risk estimates. Non-cancer risk associated with exposure to an individual 4093 phthalate or a mixture can then be assessed by calculating an MOE, which is then compared with the 4094 benchmark MOE. EPA has robust confidence in the proposed POD for the index chemical (*i.e.*, DBP) 4095 and the EPA-derived RPF for DCHP used to calculate the RPF analysis and cumulative MOEs.

4096 4097 The draft CRA TSD also includes the addition of a non-attributable cumulative exposure to DEHP, 4098 DBP, BBP, DIBP, and DINP as estimated from NHANES urinary biomonitoring data using reverse 4099 dosimetry. The NHANES exposure is non-attributable—meaning it cannot be attributed to specific 4100 COUs or other sources, but likely includes exposures attributable to both TSCA COUs and other sources 4101 (e.g., diet, food packaging cosmetics). However, as discussed in more detail below, DCHP's toxicity 4102 reflected in the previously discussed 66 percent increase in exposure expressed in terms of index 4103 chemical equivalents is the primary factor leading to lower RPF analysis MOEs and indications of 4104 unreasonable risk. Adding in the non-attributable cumulative exposure to other phthalates contributes approximately 7.1 percent to the risk cup for female workers of reproductive age, assuming a benchmark 4105 4106 MOE of 30 (see Section 4.4.4 for the cumulative worker risk estimates). EPA has robust confidence in 4107 the estimates of non-attributable cumulative exposure derived from NHANES urinary biomonitoring 4108 data using reverse dosimetry. Note that this draft risk evaluation has been released for public comment 4109 and will undergo independent, expert scientific peer review by the SACC. EPA will issue a final DCHP 4110 risk evaluation after considering input from the public and peer reviewers, which will include peer 4111 review of EPA's draft RPF analysis.

4112 **6.1.4 Workers**

- EPA took into consideration both the individual analysis and the draft RPF analysis; based on the
 occupational and cumulative risk estimates and related risk factors from the individual and draft RPF
 analyses, the Agency is preliminarily determining that the non-cancer effects from worker inhalation
 exposure to DCHP and worker aggregate exposures to DCHP from manufacturing and eight processing,
 industrial, and commercial COUs significantly contribute to the unreasonable risk.
- 4118

4119 Nearly all occupational COUs were quantitatively assessed in the individual analysis. EPA analyzed 4120 vapor/mist and/or particulate concentration inhalation exposure in the occupational scenarios, and 4121 separate estimates of central tendency and high-end exposures were made for adolescent and adult (16+ years) workers, female workers of reproductive age, and ONUs. Dermal exposure in the OESs in the 4122 4123 individual analysis was analyzed using the acute potential dose rate. For the COUs assessed, dermal 4124 exposure for ONUs was evaluated using the central tendency estimates for workers because the risk to 4125 ONUs are assumed to be equal to or less than risk to workers who handle materials containing DCHP as 4126 a part of their job. Risk was not indicated to workers, including ONUs, for any COU at the high-end or 4127 central tendency for dermal exposure estimates. More information on occupational risk estimates is in 4128 Section 4.3.2 of this risk evaluation.

4129

4130 Within the individual analysis, non-cancer risk estimates were calculated from acute, intermediate, and 4131 chronic inhalation and dermal exposures. However, the draft RPF analysis focused on non-cancer risk 4132 estimates from acute exposure as there is evidence that effects on the developing male reproductive 4133 system can result from a single exposure during the critical window of development. Additionally, because relative potency factors are based on reduced fetal testicular testosterone, EPA considers the 4134 4135 most directly applicable populations for the draft RPF analysis to be pregnant women, women of 4136 reproductive age, and male infants and male children. More information on the draft RPF analysis is 4137 provided in Section 4.4 of this risk evaluation.

4138

4139 In the absence of inhalation monitoring data, EPA used inhalation exposure models to estimate central 4140 tendency and high-end worker (including ONU) inhalation exposures using the Particulates Not 4141 Otherwise Regulated (PNOR) Model. In the individual analysis, there were multiple COUs where the 4142 exposure and risk estimates are based on the assumption that the concentration of DCHP in workplace 4143 dust is the same as the maximum concentration of DCHP manufactured or in the product. It is likely that 4144 workplace dusts contain a variety of constituents besides the final product, so the concentration of 4145 DCHP in workplace dust is likely less than the concentration of DCHP in the final product. Therefore, in 4146 those cases, central tendency values of exposure are expected to be the most reflective of worker 4147 exposures within the DCHP COUs, and EPA is relying on central tendency when considering estimates 4148 from the PNOR model (*i.e.*, dust) in this preliminary unreasonable risk determination.

4149

4150 There are notable differences in the risk estimates from the individual analysis and the RPF analysis for 4151 four OESs represented by four COUs: Domestic manufacturing; Processing – incorporation into 4152 formulation, mixture, or reaction product – adhesive and sealant chemicals in (adhesive manufacturing); 4153 Processing – incorporation into formulation, mixture, or reaction product – plasticizer in (adhesive 4154 manufacturing, paint and coating manufacturing, and printing ink manufacturing); and Processing – 4155 incorporation into formulation, mixture, or reaction product – stabilizing agent in (adhesive 4156 manufacturing, paint and coating manufacturing, and asphalt paving, roofing and coating materials manufacturing). All four COUs have the same risk estimates. At the central tendency in the individual 4157 4158 analysis, these COUs have acute inhalation and acute aggregate risk estimates for female workers of 4159 reproductive age that initially do not appear to significantly contribute to unreasonable risk because they

4160 are slightly above the benchmark of 30 (*i.e.*, MOEs of 36 for acute inhalation and 35 for acute aggregate

4161 exposure). However, at the central tendency using the draft RPF analysis, those same four COUs have

- acute inhalation and acute aggregate risk estimates for DCHP exposure expressed in index chemical
- 4163 equivalents that are well below the benchmark for female workers of reproductive age (*i.e.*, MOEs of
- 4164 19.1 for acute inhalation and 18.5 for aggregate exposure). Adding in the non-attributable cumulative
- 4165 phthalate exposure (*i.e.*, NHANES) to the aggregate exposure lowers the MOE only slightly from 18.5
- 4166 to 17.7. A COU example of the risk estimates is presented in Table 6-1.
- 4167

Table 6-1. Example of Occupational Risk Estimates for OES Manufacturing (Female Workers of Reproductive Age and Benchmark MOE = 30)

	Subcategory	OES	Exposure Level	Individual Analysis		RPF Analysis		
Life Cycle Stage/ Category				Acute Inhalation Risk Estimates	Acute Aggregate Risk Estimates	Acute Inhalation Risk Estimates	Acute Aggregate Risk Estimates	Cumulative (Acute Aggregate + Cumulative Non- attributable)
Manufacturing	Domestic	Manufacturing	High-End	3.5	3.5	1.8	1.8	1.8
 Domestic 			Central Tendency	36	35	19.1	18.5	17.7

4170

4171 Note that for DCHP, as explained in Section 6.1.3, most of the difference between the MOEs calculated
4172 using the individual analysis and the MOEs calculated using the draft RPF analysis is due to scaling

4173 DCHP to the index chemical and not to the additional, non-attributable cumulative risk from NHANES.

4174 As previously noted, the phthalate selected as the index chemical (*i.e.*, DBP) is the best characterized

4175 toxicologically and considered to be representative of the type of toxicity elicited by other components4176 of the mixture. This allows EPA to utilize more fetal testicular testosterone data in the low-end range of

4176 of the inixture. This anows EFA to utilize hore retaint estocutar testosterione data in the low-end range of 4177 the dose-response curve to gain a better understanding of the hazards of DCHP at the low-end range of 4178 the dose-response curve. This analysis provides a more robust basis for assessing the dose-response for

the common hazard endpoint (*i.e.*, reduced fetal testicular testosterone) across the six toxicologically
 similar phthalates included in the CRA, including DCHP.

4181

4182 Additionally, there are two COUs associated with PVC plastics compounding, PVC plastics converting, 4183 non-PVC material compounding, and non-PVC material converting (*i.e.*, Processing – incorporation into 4184 formulation, mixture, or reaction product – plasticizer and Processing – incorporation into formulation, 4185 mixture, or reaction product – stabilizing agent) that do not indicate risk in either the individual or the RPF analysis. These OESs have acute inhalation and acute aggregate risk estimates for female workers 4186 of reproductive age above the benchmark MOE of 30 in the individual analysis (i.e., MOEs range from 4187 4188 76–378 for acute inhalation and 71–285 for acute aggregate exposure) and for risk estimates based on 4189 the RPF analysis (*i.e.*, MOEs range from 40–199 for acute inhalation and 37–150 for acute aggregate 4190 DCHP exposure expressed in index chemical equivalents). The acute aggregate MOEs in the RPF 4191 analysis range from 34 to 110 when including non-attributable cumulative risk from NHANES.

4192

4193 As a result, EPA is preliminarily determining that those four COUs, with the exception of the activities 4194 associated with plastic and rubber manufacturing discussed in the previous paragraph, significantly 4195 contribute to the unreasonable risk to human health. This determination is based on the central tendency 4196 acute inhalation and aggregate (*i.e.*, inhalation plus dermal) exposure estimates for female workers of 4197 reproductive age from the individual analysis, and it takes into consideration the RPF analysis acute 4198 inhalation, aggregate and non-attributable cumulative (from NHANES) risk estimates. It is also 4199 important to note that while EPA is relying on the central tendency, as it is expected to be the most 4200 reflective of worker exposures, the high-end risk estimates for acute inhalation and aggregate risk

4201 estimates for female workers of reproductive age for these four COUs are also well below the MOE

- 4202 benchmark of 30 (*i.e.*, MOEs of 3.5 for acute inhalation and 3.5 for acute aggregate exposure in the 4203 individual analysis).
- Manufacturing domestic manufacturing;
- 4205
 Processing incorporation into formulation, mixture, or reaction product adhesive and sealant chemicals in adhesive manufacturing;
- 4207
 Processing incorporation into formulation, mixture, or reaction product plasticizer in adhesive manufacturing; paint and coating manufacturing; and printing ink manufacturing; and
- Processing incorporation into formulation, mixture, or reaction product stabilizing agent in adhesive manufacturing; asphalt paving, roofing, and coating materials manufacturing; and paints and coating manufacturing.

4212 At the central tendency in the individual analysis, there are five other COUs (represented by two OESs 4213 that were assessed as paints and coatings both as liquids and solids) that have acute inhalation and 4214 aggregate risk estimates for female workers of reproductive age that are above the benchmark MOE of 4215 30 (*i.e.*, MOEs of 41 for acute inhalation and 40 for aggregate exposure for liquids/spray application and 4216 MOEs of 62 for acute inhalation and 59 for aggregate exposure for solids) and risk estimates that are 4217 below the benchmark at the high-end estimates (*i.e.*, MOEs of 2 for acute inhalation and 2 for aggregate 4218 exposure for liquids/spray application and MOEs of 3.5 for acute inhalation and 3.5 for aggregate 4219 exposure for solids). As explained above, the central tendency values of exposure are expected to be the 4220 most reflective of worker exposures within the DCHP COUs when utilizing the PNOR model, such as 4221 for applications of paints and coatings *solids*—because the high-end assumption about the concentration 4222 of DCHP in workplace dust is extremely conservative and highly unlikely in actual workplaces. For 4223 paints and coatings *liquids*, in general, central tendency represents the typical exposure of most workers 4224 to DCHP through spray application; however, a confluence of a subset of variables (e.g., low ventilation, 4225 high-pressure spray, etc.) would result in risk below the benchmark (of which EPA assessed a DCHP 4226 product that resulted in such an example). While most workers are not expected to experience elevated 4227 exposures (*i.e.*, greater than 90th percentile of mist concentration data for an 8-hour period) on a daily 4228 basis, it is considered plausible and expected for such exposures to occur in an acute 1-day scenario. 4229 Therefore, for these COUs, EPA's preliminary risk determination is based on the estimates associated 4230 with the high-end scenario. This is consistent with EPA's approach to liquid spray applications in other 4231 phthalate risk evaluations.

4232

Additionally, at the high-end in the draft RPF analysis, those same five COUs, which are listed below,
have acute inhalation and aggregate risk estimates that are well below the benchmark for female workers
of reproductive age for liquids (*i.e.*, MOEs of 1 for acute inhalation and 1 for aggregate exposure for

- 4236 liquid application for high end). Adding in the non-attributable cumulative phthalate exposure (*i.e.*,
 4237 NHANES) to the aggregate exposure does not impact the high-end estimates at all. A COU example of
- 4238 the risk estimates for both liquids and solids is represented in
- Table 6-2; all five COUs (Industrial use of a finishing agent in cellulose film production, Industrial and commercial use of paints and coatings, and Industrial and commercial use of inks, toner, and colorant products [*e.g.*, screen printing ink]) have the same risk estimates for each scenario of liquids vs. solids.
- 4242 4243 Because risk estimates for liquids in the individual analysis, as well as the draft RPF analysis, are well
 - 4244 below the benchmark MOE, EPA is preliminarily determining that those five COUs significantly
 - 4245 contribute to the unreasonable risk of injury to human health based on the high-end acute inhalation and
 - 4246 aggregate exposure estimates for female workers of reproductive age. The Agency also considered the
 - 4247 RPF analysis acute inhalation, aggregate, and non-attributable cumulative (from NHANES) risk
 - 4248 estimates.

- Industrial use finishing agent cellulose film production;
- Industrial use inks, toner, and colorant products (*e.g.*, screen printing ink);
- Industrial use paints and coatings;
 - Commercial use inks, toner, and colorant products (*e.g.*, screen printing ink); and
 - Commercial use paints and coatings.
- 4254

4252

4253

Table 6-2. Example of Occupational Risk Estimates for OES Applications of Paints and Coatings (Female Workers of Reproductive Age and Benchmark MOE = 30)

				Individua	l Analysis		RPF Ana	alysis
Life Cycle Stage/ Category	Subcategory	OES	Exposure Level	Acute Inhalation Risk Estimates	Acute Aggregate Risk Estimates	Acute Inhalation Risk Estimates	Acute Aggregate Risk Estimates	Cumulative (Acute Aggregate + Cumulative Non- attributable)
Industrial Use –	Cellulose film	Application of paints and	High-End	2.0	2.0	1.0	1.0	1.0
Finishing agent	production	coatings – liquids	Central Tendency	41	40	21.7	21.0	19.9
Industrial Use –	Cellulose film	Application of paints and	High-End	3.5	3.5	1.9	1.9	1.8
Finishing agent	production	coatings – solids	Central Tendency	62	59	32.7	31.1	28.9

4257

4258 One COU, Distribution in commerce, did not have quantitative risk estimates for workers. For the

4259 purposes of the unreasonable risk determination and the individual analysis, distribution in commerce of 4260 DCHP includes transporting DCHP or DCHP-containing products between work sites or to final use sites, as well as loading and unloading from transport vehicles. Individuals in occupations that transport 4261 4262 DCHP-containing products (e.g., truck drivers) or workers who load and unload transport trucks may 4263 encounter DCHP or DCHP-containing products. EPA did not calculate risk estimates for the specific 4264 Distribution in commerce COU. The Agency evaluated activities resulting in exposures associated with 4265 distribution in commerce (e.g., loading, unloading) throughout the various life cycle stages and COUs 4266 (e.g., manufacturing, processing, industrial use, commercial use, disposal) rather than a single 4267 distribution scenario. Although some worker activities associated with distribution in commerce are 4268 similar to COUs such as manufacturing or import, it is expected that workers involved in distribution in 4269 commerce spend less time exposed to DCHP than workers in manufacturing or import facilities because 4270 only part of the workday is spent in an area with potential exposure. Therefore, occupational exposures 4271 associated with the distribution in commerce COU are expected to be less than other COUs with similar 4272 worker activities and the Agency preliminarily determines that distribution in commerce does not 4273 significantly contribute to DCHP's unreasonable risk to human health.

4274

4275 In the overall occupational assessment for the individual analysis, EPA has moderate confidence in the 4276 assessed occupational inhalation and dermal exposure scenarios (Table 4-5) and robust confidence in the 4277 non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures 4278 to DCHP. The Agency has moderate confidence in the risk estimates calculated for worker and ONU 4279 inhalation and dermal exposure scenarios. More information on EPA's confidence in these risk estimates 4280 and the uncertainties associated with them can be found in Section 4.3.2.

4281

4282 For the draft RPF analysis, EPA has robust confidence in the relative potency factors and index

4283 chemical POD used to calculate the MOEs. To derive RPFs and the index chemical POD, EPA

4284 integrated data from multiple studies evaluating fetal testicular testosterone using a meta-analysis

4285 approach and conducted BMD modeling. This meta-analysis and BMD modeling approach represents a 4286 refinement of the NOAEL/LOAEL approach used in the individual DCHP assessment and therefore 4287 increases EPA's confidence in the risk estimates (for further information, see Section 4.4). Finally, EPA 4288 has robust confidence in the non-attributable cumulative exposure estimates for DEHP, DBP, BBP, 4289 DIBP, and DINP derived from NHANES urinary biomonitoring data using reverse dosimetry. Given the 4290 fast elimination kinetics of phthalates, NHANES biomonitoring data is not expected to capture low-4291 frequency, high-intensity exposures and therefore is not intended to be an estimate of acute cumulative 4292 phthalate exposure. Overall, EPA has moderate confidence in the dermal and inhalation exposure 4293 assessments for all nine of the COUs showing risk at the central tendency in the RPF analysis.

6.1.5 Consumers

4295 Based on the consumer risk estimates and related risk factors, EPA's preliminarily determination is that 4296 consumer uses do not significantly contribute to the unreasonable risk of DCHP. The consumer and 4297 bystander exposure scenarios described in this draft risk evaluation represent a wide selection of 4298 consumer use patterns. EPA did not find MOEs that were below the benchmark for any consumer COU.

4299 4300 For DCHP, EPA assessed consumer risk from inhalation, ingestion, and dermal exposures, as well as 4301 aggregated exposure across consumer COUs. Consumer and bystander populations assessed were infant 4302 (<1 year), toddler (1–2 years), preschooler (3–5 years), middle childhood (6–10 years), young teen (11– 4303 15 years), teenager (16–20), and adult (21+ years). A screening-level assessment for consumers was 4304 conducted considering high-intensity exposure scenario risk estimates, which relies on conservative 4305 assumptions to assess exposures that would be expected to be on the high-end of the expected exposure 4306 distribution. All high-end MOEs were above the benchmark MOE for all consumer COUs. MOEs for 4307 high-intensity exposure scenarios ranged from 56 to 17,000,000. In addition, the highest levels (acute 4308 durations) were calculated using the more sensitive and robust relative potency factor analysis described 4309 in Section 4.4.5 and added to estimates of national non-attributable cumulative exposure of five 4310 toxicologically similar phthalates (i.e., DEHP, DBP, BBP, DIBP, and DINP) so that an estimate of 4311 cumulative risk could be considered. The cumulative risk estimates, listed in Table 4-23, also did not 4312 indicate risk to consumers and all MOEs were well above the benchmark for all COUs.

4313

4294

4314 EPA has moderate and robust confidence in the assessed inhalation, ingestion, and dermal consumer 4315 exposure scenarios, and robust confidence in the acute, intermediate, and chronic non-cancer PODs 4316 selected to characterize risk from acute, intermediate, and chronic duration exposures to DCHP. No 4317 intermediate duration was assessed for any consumer use outside of automobile adhesives. The exposure 4318 doses used to estimate risk relied on conservative, health-protective inputs and parameters that are 4319 considered representative of a wide selection of use patterns. In addition, EPA has robust confidence in 4320 the RPFs and index chemical POD used to calculate the RPF analysis and cumulative MOEs as well as 4321 in the derived estimates of non-attributable cumulative exposure from NHANES urinary biomonitoring 4322 using reverse dosimetry. More information on the Agency's confidence in these risk estimates and the 4323 uncertainties associated with them can be found in this draft risk evaluation and the Draft Consumer and 4324 Indoor Dust Exposure Assessment Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c).

4325

6.1.6 General Population

4326 EPA employed a screening-level approach for general population exposures for DCHP because of 4327 limited environmental monitoring data for DCHP and lack of location data for DCHP releases. If risks 4328 were not indicated for an individual (adult, infant, etc.) identified as having the potential for the highest 4329 exposure associated with a COU for a given pathway of exposure (i.e., at high-end or the 95th 4330 percentile), then that pathway was determined not to significantly contribute to the risk and was not 4331 further analyzed. Also, as a part of EPA's screening-level approach, the Agency considered the

4332 environmental concentration of DCHP in a given environmental medium resulting from the OES (e.g., 4222 DVG abatise segmentation) that he data bis best subsets are advected with a segmentation of DCHP in a given environmental medium resulting from the OES for the second seco

- PVC plastics compounding) that had the highest release compared with any other OES for the samereleasing media. Release estimates from OESs resulting in lower environmental media concentrations
- were not considered for this screening-level assessment. For DCHP, EPA did not evaluate cumulative
 risk for the general population from environmental releases because after using the previously described
- 4336 risk for the general population from environmental releases because after using the previously described 4337 conservative screening-level approach, the Agency did not identify any pathways of concern, indicating
- that refinement and further evaluation were not necessary. EPA evaluated surface water, sediment,
 drinking water, fish ingestion, and ambient air pathways quantitatively, and land pathways (*i.e.*, landfills
- 4340 and application of biosolids) qualitatively (see Section 4.1.3).
- 4341

4342 EPA is preliminarily determining that the COUs do not significantly contribute to the unreasonable risk 4343 of DCHP to the general population from the ambient air—including people living or working near 4344 facilities (fenceline populations)—based on analysis of non-cancer risk. Although EPA is preliminarily 4345 determining that nine COUs significantly contribute to unreasonable risk of DCHP due to occupational 4346 exposures (e.g., through dust that a worker may experience in the chemicals industry; see also Section 4347 6.1.4), the general population exposures from DCHP COUs, including those, are minimal and do not 4348 indicate unreasonable risk. This is due in part to the physical and chemical properties of DCHP; for 4349 example, it has low bioaccumulation potential, low water solubility (1.48 mg/L), low affinity for 4350 sorption to soil, and is unlikely to migrate. EPA's preliminary determination for each pathway (e.g.,4351 land, surface water, fish ingestion) is discussed below in more detail.

43524353 *Land Pathway*

Due to DCHP's low water solubility (1.48 mg/L) and low persistence under most conditions, DCHP is unlikely to migrate from land-applied biosolids to groundwater via runoff and is unlikely to be present in landfill leachate or be mobile in soils. For these reasons, biosolids and landfill were evaluated qualitatively. As such, EPA does not expect general population exposure to DCHP to occur via the land pathway. Therefore, the Agency is preliminarily determining that the land pathway does not significantly contribute to the unreasonable risk for DCHP. For further information, see Section 4.3.4.

4360

4361 Drinking Water and Incidental Surface Water Ingestion and Dermal Contact

4362 EPA used the highest possible DCHP concentration in surface water due to facility release (*i.e.*, in the 4363 immediate water body receiving the effluent) to quantitatively evaluate the risk to the general population 4364 from exposure to DCHP from drinking water or incidental ingestion and dermal contact during 4365 recreational swimming. The Agency took the high-end exposure estimates associated with the COU with 4366 the highest total water column concentration to calculate an MOE. Releases associated with the PVC 4367 plastics compounding OES (i.e., plasticizer in plastic material and resin manufacturing and plastics 4368 product manufacturing and stabilizing agent in plastics product manufacturing) resulted in the highest 4369 total water column concentrations, with the lowest 30-day average flow that occurs once every 5 years 4370 (*i.e.*, 30Q5 water concentration) of 126 µg/L without wastewater treatment and 39.6 µg/L when run 4371 under an assumption of 68.6 percent wastewater treatment removal efficiency. These water column 4372 concentrations were used to estimate dermal exposure and incidental ingestion of DCHP while 4373 swimming for adults (21+ years), youths (11–15 years), and children (6–10 years). MOEs for general 4374 population exposure through incidental ingestion and dermal contact during swimming were well above 4375 the benchmark MOE of 30 and ranged from 2,171 to 6,310 for scenarios assuming no wastewater 4376 treatment and from 5,521 to 20,000 for scenarios assuming 68.6 percent wastewater treatment removal 4377 efficiency (Table 4-16).

4378

4379 Based on this screening level assessment, risk for non-cancer health effects is not expected for the

- 4381 used to estimate drinking water exposures. Drinking water exposure to DCHP was calculated for various
- 4382 age groups—but even at the most susceptible lifestage, infants (birth to <1 year), risk is not expected.
- 4383 Acute MOEs through drinking water ingestion were 135 and 430 without and with wastewater
- 4384 treatment, respectively, for the lifestage (*i.e.*, infants) with the highest exposure (Table 4-16). Therefore,
 4385 the drinking water pathway is not considered to be a pathway of concern for DCHP exposure for the
- 4386 general population and EPA is preliminarily determining that the drinking water and surface water
- 4387 pathway do not significantly contribute to the unreasonable risk for DCHP for the general population.
- 4388 For further information, see Section 4.3.4.
- 4389

4390 Fish Ingestion

4391 EPA evaluated potential risk from exposure to DCHP through fish ingestion using a screening-level 4392 analysis based on conservative exposure estimates for adults in the general population, adult subsistence 4393 fishers, and adult Tribal populations. The Agency started with the water solubility limit as an upper limit 4394 of DCHP concentration in surface water and determined refinements were needed because the 4395 screening-level risk estimates were below the benchmark MOE of 30. Refinements using modeled 4396 concentrations at the 50th percentile (or P50 flow rate) were needed for the adult subsistence fisher and 4397 adult Tribal populations because the water solubility limit resulted in risk estimates below the benchmark. Because the P50 modeled concentrations still resulted in risk estimates below benchmarks 4398 4399 for Tribal populations, EPA further refined its analysis by incorporating higher flow rates and treatment 4400 efficiency. Hydrologic flow data were categorized into median flow (P50), 75th percentile flow (P75), 4401 and 90th percentile flow (P90). The Agency expects high-end releases to discharge to surface waters 4402 with higher flow conditions (e.g., P75 and P90). Exposure estimates based on the P50 flow rate resulted 4403 in risk estimates below the benchmark. Risk estimates for fish ingestion generated at concentrations of 4404 DCHP at the water solubility limit or at highest measured concentrations in surface water did not 4405 indicate risk to Tribal populations. MOEs based on conservative values, such as surface water concentration from a stormwater catchment area, still resulted in risk estimates that are above their 4406 4407 benchmarks. Therefore, EPA is preliminarily determining that fish ingestion does not significantly 4408 contribute to the unreasonable risk for DCHP for Tribal members, subsistence fishers, and the general 4409 population. For further information, see Section 4.3.4. 4410

4411 Inhalation

- 4412 EPA estimated ambient air concentrations using results from dispersion scenarios. The highest modeled 4413 95th percentile annual ambient air concentration across all release scenarios was 67.57 μ g/m³ at 100 m 4414 from the releasing facility for the Application of paints and coatings OES. This OES was the only one 4415 assessed for the purpose of a screening-level assessment as it was associated with the highest ambient air 4416 concentration. MOEs for general population exposure through inhalation were both well above the 4417 benchmark MOE of 30 (i.e., 192 for acute and 281 for chronic; see also Table 4-18). Therefore, based 4418 on this screening-level analysis, risk for non-cancer health effects is not expected for the ambient air 4419 pathway and EPA is preliminarily determining that the ambient air pathway does not significantly 4420 contribute to the unreasonable risk for DCHP for the general population. For further information, see 4421 Section 4.3.4.
- 4422
- 4423 EPA expects that general population inhalation exposures from distribution in commerce would be even
- 4424 lower than those for workers. Therefore, the Agency is preliminarily determining that distribution in 4425 commerce does not significantly contribute to the unreasonable risk of DCHP
- 4425 commerce does not significantly contribute to the unreasonable risk of DCHP.

4426 **6.2 Environment**

4427 EPA is preliminarily determining that DCHP does not present unreasonable risk of injury to the
4428 environment. DCHP is expected to be released to the environment via air, water, biosolids, and disposal

4429 to landfills. The physical and chemical properties of DCHP indicate that it is not expected to be 4430 persistent or be mobile in soils and that it has low bioaccumulation potential. Given these characteristics 4431 and the data available, the environmental risk characterization for DCHP involved qualitative analysis of 4432 risk to aquatic and terrestrial organisms via exposure pathways of surface water, trophic transfer, biosolids, and landfills. EPA has robust confidence in its preliminary determination that all assessed 4433 4434 pathways of exposure to terrestrial animals do not significantly contribute to the unreasonable risk of 4435 DCHP. The Agency also has robust confidence in its preliminary determination that there is no risk for 4436 acute durations of DCHP exposure to aquatic organisms because reasonably available data found no acute hazard effects up to and above the estimated upper bound of water solubility. EPA has 4437 4438 preliminarily determined that chronic exposure to aquatic animals does not significantly contribute to 4439 the unreasonable risk of DCHP. Considerable uncertainties exist about the limit of water solubility, 4440 water release estimates, and low-flow surface water modeling estimates. However, EPA has robust 4441 confidence in this preliminary unreasonable risk determination because no risk was indicated under 4442 realistic scenarios of lower water solubility, lower release estimates, more rapid stream flow, and 4443 available measured DCHP water concentrations from the literature.

4444

6.2.1 Populations and Exposures EPA Assessed for the Environment

4445 EPA assessed environmental concentrations of DCHP in air, water, and land (soil, biosolids, and 4446 groundwater) for use in environmental exposure. DCHP will preferentially sorb into sediments, soils, 4447 particulate matter in air, and in wastewater solids during wastewater treatment. High-quality studies of 4448 DCHP biodegradation rates and physical and chemical properties indicate that DCHP will have limited 4449 persistence and mobility in soils receiving biosolids (U.S. EPA, 2024z) and low bioavailability in soil. 4450 DCHP is not readily found in aquatic or terrestrial organisms and has low bioaccumulation and 4451 biomagnification potential. Therefore, DCHP has low potential for trophic transfer through food webs 4452 and DCHP is expected to have minimal air to soil deposition.

4453

4454 Surface water exposure was the only scenario where modeled concentrations could be compared with a 4455 COC. The reasonably available studies found all acute exposure hazards to fish, invertebrates, and algae 4456 to be higher than the water solubility limit of DCHP, so no unreasonable risk for acute exposures to 4457 DCHP in surface water was indicated. For chronic exposures, EPA derived a COC for reproductive 4458 effects of chronic DCHP water exposure to an aquatic invertebrate (*Daphnia magna*) (NITE, 2000). The 4459 Agency EPA found no evidence that DCHP occurs in surface water at the COC of 32 µg/L. EPA 4460 modeled surface water concentrations and under the most conservative and least likely scenario, 4461 estimated a high-end concentration of 165 µg/L DCHP and a RQ greater than 1. However, all other scenarios with more realistic release values, stream flow rates, or DCHP water solubility had RQs less 4462 4463 than 1. Therefore, EPA determined a low likelihood of DCHP persisting in surface waters for a long 4464 enough duration (21 days) to cause chronic hazard in aquatic invertebrates, and thus a preliminary 4465 determination that chronic exposure to aquatic animals does not significantly contribute to the 4466 unreasonable risk of DCHP.

4467

6.2.2 Summary of Environmental Effects

4468 EPA qualitatively assessed risk via release to surface water and subsequent deposition to sediment as
4469 well as the ambient air exposure pathway for its limited contribution via deposition to soil, water, and
4470 sediment and is preliminarily identifying

- No adverse effects to aquatic organisms;
- No adverse effects to aquatic dependent mammals; and
- No adverse effects to terrestrial mammals.

4474 EPA did not conduct a quantitative modeling analysis of the trophic transfer of DCHP through food 4475 webs because the chemical properties and fate of DCHP indicate low potential for bioaccumulation or 4476 biomagnification. Specifically, the Agency does not expect DCHP to persist in surface water, 4477 groundwater, or air. DCHP may persist in sediment, soil, biosolids, or landfills after release to these 4478 environments, but DCHP's bioavailability is expected to be limited. Finally, EPA also did not find 4479 reasonably available data sources that report the aquatic bioconcentration, aquatic bioaccumulation, 4480 aquatic food web magnification, terrestrial biota-sediment accumulation, or terrestrial bioconcentration 4481 of DCHP. Therefore, the Agency determined a low likelihood of DCHP transferring through food webs 4482 thus a preliminary indication of no risk. 4483

4484 As explained in Section 5.3.1, EPA used a screening level approach in this draft risk evaluation using 4485 conservative environmental release estimates for occupational COUs with the highest releases to 4486 determine whether there is risk to the environment and the general population. The Agency first 4487 characterized risk based upon the COU with the highest estimated concentrations for a given pathway, 4488 based on the OES and the associated environmental media assessed in the draft risk evaluation. If this 4489 exposure concentration did not exceed the hazard thresholds harmful to organisms, EPA based the draft 4490 risk determination on this maximum exposure scenario to be most inclusive and protective by 4491 encompassing the exposures from other COUs within the OES. The Agency determined that the hazard 4492 data for fish, aquatic invertebrates, sediment-dwelling organisms, algae, terrestrial invertebrates, and 4493 terrestrial mammals indicated no adverse effects from exposures up to and exceeding the limit of water 4494 solubility.

EPA expects that environmental releases from distribution in commerce will be similar or less than the
exposure estimates from the COUs evaluated qualitatively, which did not exceed hazard to ecological
receptors. Therefore, the Agency has preliminarily determined that distribution in commerce also would
not result in exposures that significantly contribute to the unreasonable risk of DCHP.

4500 4501 EPA evaluated down-the-drain releases of DCHP for consumer COUs qualitatively. Although the 4502 Agency acknowledges that there may be DCHP releases to the environment via the cleaning and 4503 disposal of adhesives, sealants, paints, and coatings, EPA did not quantitatively assess down-the drain 4504 and disposal scenarios of consumer products due to limited information from monitoring data and 4505 limited availability of modeling tools. However, modeling tools and consideration of the physical and 4506 chemical properties of DCHP allows the Agency to conduct a qualitative assessment. DCHP is expected 4507 to be persistent as it leaches from consumer products disposed of in landfills. Due to low water 4508 solubility, DCHP is likely to be present in landfill leachate up to its aqueous limit of solubility. 4509 However, due to its affinity for organic carbon, DCHP is expected to be immobile in groundwater, and 4510 even in cases where landfill leachate containing DCHP were to migrate to groundwater, DCHP would 4511 likely partition from groundwater to organic carbon present in the subsurface. Therefore, EPA is 4512 preliminarily determining that the consumer COUs do not significantly contribute to the unreasonable

- 4513 risk of DCHP due to down-the-drain releases.
- 4514

4495

6.2.3 Basis for No Unreasonable Risk of Injury to the Environment

Based on the draft risk evaluation for DCHP—including the risk estimates, the environmental effects of
DCHP, the exposures, physical and chemical properties of DCHP, and consideration of uncertainties—
EPA did not identify risk of injury to the environment that would significantly contribute to the
unreasonable risk determination for DCHP. For aquatic organisms, surface water was determined to be
the driver of exposure, but the Agency does not expect this pathway to significantly contribute to
unreasonable risk to the environment. EPA does not expect exposure to DCHP via water, land, or

dietary pathways to significantly contribute to unreasonable risk to the environment. The overall
 confidence in the preliminary risk characterizations for aquatic and terrestrial assessments is robust.

4523 **6.3 Additional Information Regarding the Basis for Unreasonable Risk**

4524 Table 6-3 summarizes the basis for this unreasonable risk determination of injury to human health 4525 presented in this draft DCHP risk evaluation. In these tables, a checkmark (\checkmark) indicates how the COU 4526 significantly contributes to the unreasonable risk by identifying the type of effect (e.g., non-cancer for 4527 human health) and the exposure route to the population that results in such significant contribution. As 4528 explained in Section 6.1, for this draft unreasonable risk determination, EPA has considered the effects 4529 of DCHP to human health at the central tendency and high-end, as well as effects of DCHP to human 4530 health and the environment from the exposures associated with the COU, risk estimates, and 4531 uncertainties in the analysis. In addition, certain exposure routes for some COUs were not assessed 4532 because it was determined that there was no viable exposure pathway. These COUs and their respective 4533 exposure routes are graved-out in Table 6-3. Checkmarks in Table 6-3 represent risk at the high-end and 4534 central tendency exposure level as discussed in Section 6.1. See Sections 4.3 and 5.3 for a summary of risk estimates. 4535

	4536	Table 6-3. Supporting Basis for the Draft Unreasonable Risk Determination for Human Health ^a (Occupational COUs)	
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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
	Domestic	Domestic manufacturing	Essel Westers	Dermal			
	manufacturing	Domestic manufacturing	Female Worker of Reproductive Age ^c	Inhalation	✓		
			.1	Aggregate	√		
			ONU	Dermal			
				Inhalation			
Manufacturing				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
	- ·			Dermal			
	Importing	Importing	Female Worker of Reproductive Age	Inhalation			
				Aggregate			
			0.111	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
		Adhesive and sealant chemicals in:		Dermal			
	Processing –	- Adhesive Manufacturing	Female Worker of Reproductive Age	Inhalation	✓		
	incorporation into formulation,		Reproductive rige	Aggregate	✓		
	mixture, or		ONU	Dermal			
	reaction product		ONU	Inhalation			
		Plasticizer in:		Dermal			
		Adhesive manufacturingPaint and coating manufacturing	Average Adult Worker	Inhalation			
		 Print and coating manufacturing Printing ink manufacturing 	WOIKEI	Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
				Dermal			
		Plasticizer in:	Female Worker of Reproductive Age	Inhalation	\checkmark		
		-Adhesive manufacturing		Aggregate	\checkmark		
		 Paint and coating manufacturing Printing ink manufacturing 	ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
		Plasticizer in: – Plastic material and resin manufacturing		Dermal			
		– Plastics product manufacturing	Female Worker of Reproductive Age	Inhalation			
		– Rubber product manufacturing	Reproductive Age	Aggregate			
				Dermal			
	Processing –		ONU	Inhalation			
	incorporation into			Dermal			
	formulation, mixture, or		Average Adult Worker	Inhalation			
	reaction product	Stabilizing agent in:	W OIKEI	Aggregate			
		– Adhesive manufacturing		Dermal			
		– Asphalt paving, roofing, and coating materials manufacturing	Female Worker of Reproductive Age	Inhalation	√		
		– Paint and coating manufacturing	Reproductive Age	Aggregate	√		
			ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
		Stabilizing agent in:		Aggregate			
		– Plastics product manufacturing		Dermal			
			Female Worker of Reproductive Age	Inhalation			
				Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
			ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
	Processing – incorporation into	Plasticizer in: – Plastics product manufacturing		Dermal			
	article	 – Plastics product manufacturing – Rubber product manufacturing 	Female Worker of Reproductive Age	Inhalation			
				Aggregate			
			ONU	Dermal			
			ONO	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
Deservations			Worker	Aggregate			
Processing				Dermal			
	Repackaging	Repackaging (<i>e.g.</i> , laboratory chemical)	Female Worker of Reproductive Age	Inhalation			
			itepioudetive rige	Aggregate			
				Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			WORKEI	Aggregate			
				Dermal			
	Recycling	Recycling	Female Worker of Reproductive Age	Inhalation			
			Reproductive Age	Aggregate			
				Dermal			
			ONU	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
			Worker	Dermal			
Distribution in	Distribution in	Distribution in commerce	WOIKEI	Inhalation			
Commerce	Commerce	Distribution in commerce	ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
	Adhesive and	Adhesives and sealants (<i>e.g.</i> , computer and electronic product manufacturing;		Dermal			
	sealants	transportation equipment manufacturing)	Female Worker of Reproductive Age	Inhalation			
			insproductive rige	Aggregate			
			ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			() officer	Aggregate			
Industrial Use	T 1 .			Dermal			
	Finishing agent	Cellulose film production	Female Worker of Reproductive Age	Inhalation	√		
			Reproductive Age	Aggregate	✓		
				Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			WORKE	Aggregate			
	Inks, toner, and colorant products	Inks, toner, and colorant products (<i>e.g.</i> , screen printing ink)		Dermal			
	colorant products	serven printing lik)	Female Worker of Reproductive Age	Inhalation	✓		
			Reproductive Age	Aggregate	✓		
			ONU	Dermal			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
				Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			W OIKCI	Aggregate			
				Dermal			
	Paints and coatings	Paints and coatings	Female Worker of Reproductive Age	Inhalation	✓		
			Reproductive Age	Aggregate	✓		
Industrial Use			0.111	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
	Other articles with routine direct		Worker	Aggregate			
	contact during	Other articles with routine direct contact during normal use including rubber		Dermal			
	normal use including rubber	articles; plastic articles (hard) (e.g.,	Female Worker of Reproductive Age	Inhalation			
	articles; plastic	transportation equipment manufacturing)	heproductive rige	Aggregate			
	articles (hard)		ONU	Dermal			
			UNU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
				Aggregate			
	Adhesives and	Adhesives and sealants		Dermal			
	sealants	Autorives and searants	Female Worker of Reproductive Age	Inhalation			
Commercial Use			·r ···································	Aggregate			
			ONU	Dermal			
				Inhalation			
		Building/construction materials not	Average Adult	Dermal			
		covered elsewhere	Worker	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
				Aggregate			
				Dermal			
	Building/constructi on materials not		Female Worker of Reproductive Age	Inhalation			
	covered elsewhere		in productive rige	Aggregate			
			ONU	Dermal			
			UNU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			Worker	Aggregate			
	Inks, toner, and	Inks, toner, and colorant products (<i>e.g.</i> ,		Dermal			
	colorant products	screen printing ink)	Female Worker of Reproductive Age	Inhalation	✓		
			Replotuetive Age	Aggregate	✓		
				Dermal			
Commercial Use			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			Worker	Aggregate			
	Laboratory			Dermal			
	chemicals	Laboratory chemicals	Female Worker of Reproductive Age	Inhalation			
			Replotuetive Age	Aggregate			
				Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
	Paints and coatings	Paints and coatings	WOIKCI	Aggregate			
			Female Worker of	Dermal			
			Reproductive Age	Inhalation	√		

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^b	Acute	Life Cycle Stage	Category
				Aggregate	✓		
			ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
Commercial Use	Other articles with routine direct			Aggregate			
	contact during	Other articles with routine direct contact		Dermal			
	normal use including rubber	during normal use including rubber articles; plastic articles (hard)	Female Worker of Reproductive Age	Inhalation			
	articles; plastic		heproductive rige	Aggregate			
	articles (hard)		ONU	Dermal			
			ONU	Inhalation			
				Dermal			
			Average Adult Worker	Inhalation			
			Worker	Aggregate			
D' 1	Discussion	Discul		Dermal			
Disposal	Disposal	Disposal	Female Worker of Reproductive Age	Inhalation			
			heproductive rige	Aggregate			
			ONU	Dermal			
			ONU	Inhalation			
^b Inhalation, derm determined that th	al, and aggregate rist nere was a viable exp	posure routes that were not assessed becaus k estimates were generated for each COU for posure pathway.	or workers (average a	dult and women	of reproduction	ve age) and ONU	

^c EPA analyzed and presented risk for female workers of reproductive age, which are a subset of the average adult worker population, separately due to the greater susceptibility of developing fetuses to adverse health effects from phthalate exposure.

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5050	U.S. EPA. (2024q). Draft Environmental Release and Occupational Exposure Assessment for				
5051	Dicyclohexyl Phthalate (DCHP). Washington, DC: Office of Pollution Prevention and Toxics.				
5052	U.S. EPA. (2024r). Draft Fish Ingestion Risk Calculator for Dicyclohexyl Phthalate (DCHP).				
5053	Washington, DC: Office of Pollution Prevention and Toxics.				
5054	U.S. EPA. (2024s). Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular				
5055	Testosterone for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl				
5056	Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP).				
5057	Washington, DC: Office of Pollution Prevention and Toxics.				
5058	U.S. EPA. (2024t). Draft Non-cancer Human Health Hazard Assessment for Butyl benzyl phthalate				
5059	(BBP). Washington, DC: Office of Pollution Prevention and Toxics.				
5060	U.S. EPA. (2024u). Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate (DBP).				
5061	Washington, DC: Office of Pollution Prevention and Toxics.				
5062	U.S. EPA. (2024v). Draft Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate				
5063	(DCHP). Washington, DC: Office of Pollution Prevention and Toxics.				
5064	U.S. EPA. (2024w). Draft Non-cancer Human Health Hazard Assessment for Diethylhexyl Phthalate				
5065	(DEHP). Washington, DC: Office of Pollution Prevention and Toxics.				
5066	U.S. EPA. (2024x). Draft Non-cancer Human Health Hazard Assessment for Diisobutyl phthalate				
5067	(DIBP). Washington, DC: Office of Pollution Prevention and Toxics.				

U.S. EPA. (2024y). Draft Occupational and Consumer Cumulative Risk Calculator for Dicyclohexyl 5068 5069 Phthalate (DCHP). Washington, DC: Office of Pollution Prevention and Toxics. 5070 U.S. EPA. (2024z). Draft physical chemistry and fate and transport assessment for dicyclohexyl 5071 phthalate (DCHP). Washington, DC: Office of Pollution Prevention and Toxics. 5072 U.S. EPA. (2024aa). Draft Physical Chemistry Assessment for Dicyclohexyl Phthalate (DCHP). 5073 Washington, DC: Office of Pollution Prevention and Toxics. 5074 U.S. EPA. (2024ab). Draft Risk Calculator for Occupational Exposures for Dicyclohexyl Phthalate 5075 (DCHP). Washington, DC: Office of Pollution Prevention and Toxics. 5076 U.S. EPA. (2024ac). Draft Summary of Facility Release Data for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), and Butyl Benzyl Phthalate (BBP). Washington, DC: Office of 5077 5078 Pollution Prevention and Toxics. 5079 U.S. EPA. (2024ad). Draft Surface Water Human Exposure Risk Calculator for Dicyclohexyl Phthalate 5080 (DCHP) for P50 Flow Rates. Washington, DC: Office of Pollution Prevention and Toxics. 5081 U.S. EPA. (2024ae). Draft Surface Water Human Exposure Risk Calculator for Dicyclohexyl Phthalate 5082 (DCHP) for P75 Flow Rates. Washington, DC: Office of Pollution Prevention and Toxics. 5083 U.S. EPA. (2024af). Draft Surface Water Human Exposure Risk Calculator for Dicyclohexyl Phthalate 5084 (DCHP) for P90 Flow Rates. Washington, DC: Office of Pollution Prevention and Toxics. U.S. EPA. (2024ag). Draft Systematic Review Protocol for Dicyclohexyl Phthalate (DCHP). 5085 Washington, DC: Office of Pollution Prevention and Toxics. 5086 U.S. EPA. (2024ah). Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-5087 5088 ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) 5089 5090 Under the Toxic Substances Control Act (TSCA). Washington, DC: Office of Chemical Safety 5091 and Pollution Prevention. 5092 U.S. EPA. (2024ai). Environmental Media and General Population Screening for Diisononyl Phthalate 5093 (DINP). Washington, DC: Office of Pollution Prevention and Toxics. https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0436 5094 5095 U.S. EPA. (2024aj). Meeting summary with Nouryon and EPA to discuss conditions of use for dicyclohexyl phthalate. Washington, DC. 5096 5097 U.S. EPA. (2025a). Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), 5098 5099 and Dicyclohexyl Phthalate (DCHP). Washington, DC: Office of Pollution Prevention and 5100 Toxics. 5101 U.S. EPA. (2025b). Non-Cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP) 5102 Washington, DC: Office of Pollution Prevention and Toxics. 5103 Versar. (2014). Exposure and Fate Assessment Screening Tool (E-FAST 2014) - Documentation 5104 manual. Washington, DC: U.S. Environmental Protection Agency. https://www.epa.gov/tsca-5105 screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014 5106 Vertellus LLC. (2020). Comment submitted by Misty L. Bogle, Global Director, Regulatory 5107 Management, Vertellus LLC regarding the Draft Scope of the Risk Evaluation for Dicyclohexyl Phthalate (1,2Benzenedicarboxylic acid, 1,2-dicyclohexyl ester). Indianapolis, IN: Vertellus 5108 5109 LLC. https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0504-0043 5110 WA DOE. (2022). Survey of phthalates in Washington State waterbodies, 2021. (Publication 22-03-5111 027). Olympia, WA. https://apps.ecology.wa.gov/publications/documents/2203027.pdf 5112 Wu, J; Ma, T; Zhou, Z; Yu, Na; He, Z; Li, B; Shi, Y; Ma, D. (2019). Occurrence and fate of phthalate 5113 esters in wastewater treatment plants in Qingdao, China. Hum Ecol Risk Assess 25: 1547-1563. 5114 http://dx.doi.org/10.1080/10807039.2018.1471341 5115

5116 APPENDICES

5117

5118 Appendix A KEY ABBREVIATIONS AND ACRONYMS

0110		
5119	ADD	Average daily dose
5120	ADC	Average daily concentration
5121	BBP	Butyl benzyl phthalate
5122	BLS	Bureau of Labor Statistics
5123	CASRN	Chemical Abstracts Service Registry Number
5124	CBI	Confidential business information
5125	CDR	Chemical Data Reporting
5126	CEHD	Chemical Exposure Health Data
5127	CEM	Consumer Exposure Model
5128	CFR	Code of Federal Regulations
5129	COC	Concentration of concern
5130	CPSC	Consumer Product Safety Commission
5131	CRA	Cumulative risk assessment
5132	DBP	Dibutyl phthalate
5133	DCHP	Dicyclohexyl phthalate
5134	DEHP	Diethylhexyl phthalate
5135	DIBP	Diisobutyl phthalate
5136	DIDP	Diisodecyl phthalate
5137	DINP	Dicyclohexyl phthalate
5138	DIY	Do-it-yourself
5139	EPA	Environmental Protection Agency
5140	ESD	Emission scenario document
5141	EU	European Union
5142	FDA	Food and Drug Administration
5143	GS	Generic scenario
5144	K _{OC}	Soil organic carbon: water partitioning coefficient
5145	K _{OW}	Octanol: water partition coefficient
5146	HEC	Human equivalent concentration
5147	HED	Human equivalent dose
5148	IADD	Intermediate average daily dose
5149	IR	Ingestion rate
5150	LCD	Life cycle diagram
5151	LOAEL	Lowest-observed-adverse-effect level
5152	Log K _{OC}	Logarithmic organic carbon: water partition coefficient
5153	Log K _{OW}	Logarithmic octanol: water partition coefficient
5154	MOA	Mode of action
5155	MOE	Margin of exposure
5156	NAICS	North American Industry Classification System
5157	NHANES	National Health and Nutrition Examination Survey
5158	NICNAS	National Industrial Chemicals Notification and Assessment Scheme
5159	NOAEL	No-observed-adverse-effect level
5160	NPDES	National Pollutant Discharge Elimination System
5161	OCSPP	Office of Chemical Safety and Pollution Prevention
5162	OECD	Organisation for Economic Co-operation and Development
5163	OES	Occupational exposure scenario

5164	OEV	Occupational exposure value
5165	ONU	Occupational non-user
5166	OPPT	Office of Pollution Prevention and Toxics
5167	OSHA	Occupational Safety and Health Administration
5168	PBZ	Personal breathing zone
5169	PESS	Potentially exposed or susceptible subpopulations
5170	PND	Postnatal day
5171	PNOR	Particulates not otherwise regulated
5172	POD	Point of departure
5173	PV	Production volume
5174	PVC	Polyvinyl chloride
5175	RPF	Relative potency factor
5176	RQ	Risk quotient
5177	SACC	Science Advisory Committee on Chemicals
5178	SDS	Safety data sheet
5179	SOC	Standard occupational classification
5180	SpERC	Specific emission release category
5181	TRI	Toxic Release Inventory
5182	TRV	Toxicity reference value
5183	TSCA	Toxic Substances Control Act
5184	TSD	Technical support document
5185	TWA	Time-weighted average
5186	UF	Uncertainty factor
5187	U.S.	United States
5188	WWTP	Wastewater treatment plant
5189	7Q10	The lowest 7-day average flow that occurs (on average) once every 10 years
5190	30Q5	The lowest 30-day average flow that occurs (on average) once every 5 years

5191 Appendix B REGULATORY AND ASSESSMENT HISTORY

5192 B.1 Federal Laws and Regulations

5193 5194

Table_Apx B-1. Federal Laws and Regulations

Description of Authority/Regulation	Description of Regulation		
EPA statutes/regulations			
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 3.5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	DCHP is one of the 20 chemicals EPA designated as a high-priority substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of DCHP as high-priority substance constitutes the initiation of the risk evaluation on the chemical.		
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.	DCHP manufacturing (including importing), processing and use information is reported under the CDR rule (<u>85 FR</u> <u>20122</u> , April 9, 2020).		
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.	DCHP 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).		
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 part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423 Appendix A. 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	As a phthalate ester, DCHP 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).		
	EPA statutes/regulations 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 3.5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. 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. 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. 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 part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423 Appendix A. 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		

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the Food and Drug Administration (FDA) with authority to oversee the safety of food, drugs, and cosmetics, except residues of pesticides in food are regulated by EPA under FFDCA section 408 (discussed above where applicable).	DCHP is listed as an optional substance to be used in: adhesives to be used as components of articles intended for use, in accordance with prescribed conditions, in packaging, transporting, or holding food (<u>21 CFR section 175.105</u>); the base sheet and coating of cellophane (<u>21 CFR section</u> <u>177.1200</u>); plasticizers in polymeric substances (<u>21 CFR section 178.3740</u>).
Consumer Product Safety Improvement Action 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 eight phthalates in toys and childcare articles at concentrations >0.1%: DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP and DCHP.	The use of DCHP at concentrations >0.1% is banned in toys and childcare articles (<u>16</u> <u>CFR part 1307</u>).

5195 B.2 State Laws and Regulations

5196

5197 **Table_Apx B-2. State Laws and Regulations**

State Actions	Description of Action
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing DCHP, including Maine (<u>38 MRSA Chapter 16-D</u>) and Washington State (<u>Wash. Admin. Code 173-334-130</u>).
Other	DCHP is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code section 25252 and 25253 (California, <u>Candidate Chemical List</u> . Accessed April 16, 2019). California lists DCHP as a designated priority chemical for biomonitoring under criteria established by California SB 1379 (<u>Biomonitoring California, Priority Chemicals</u> , February 2019). Oregon lists DCHP as a toxic air contaminant (<u>OAR 340-245-8020</u> <u>Table 2</u>).

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B.3 International Laws and Regulations

5199 5200

Table_Apx B-3. International Laws and Regulations

Country/ Organization	Requirements and Restrictions
European Union	On June 27, 2018, DCHP was listed on the Candidate List as a Substance of Very High
	Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration,
	Evaluation, Authorization and Restriction of Chemicals because it is toxic for
	reproduction (Article 57(c) and has endocrine disrupting properties (Article 57(f) -
	human health). DCHP was evaluated under the 2017 Community rolling action plan
	(CoRAP) under regulation (European Commission [EC]) No1907/2006 - REACH
	(Registration, Evaluation, Authorization and Restriction of Chemicals) (European
	Chemicals Agency (ECHA) database. Accessed April 16, 2019).

Country/ Organization	Requirements and Restrictions
Australia	DCHP was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritization (IMAP) as part of the C4-6 side chain transitional phthalates. Uses reported include in adhesives and printing inks (NICNAS, 2016, Human Health Tier II assessment for C4-6 side chain transitional phthalates). In addition, DCHP was assessed under Environment Tier II of IMAP as part of the phthalate esters. In 2015, DCHP was also assessed as a Priority Existing Chemical (Assessment Report No. 40) (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). <u>Chemical inventory</u> . Database accessed April 3, 2019).
Japan	 DCHP is regulated in Japan under the following legislation: Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof. (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. Accessed April 16, 2019).
Austria, Denmark, Ireland, New Zealand, United Kingdom	Occupational exposure limits for DCHP (<u>GESTIS International limit values for</u> <u>chemical agents (Occupational exposure limits, OELs) database</u> . Accessed April 18, 2017). Austria, Ireland, New Zealand and the United Kingdom have an eight-hours limit of 5 mg/m ³ . Denmark has an eight-hours limit of 3 mg/m ³ and a short-term limit of 6 mg/m ³ .

5201 B.4 Assessment History

5202

5203 Table_Apx B-4. Assessment History of DCHP

Authoring Organization	Publication	
U.S. EPA publications		
_	_	
Other U.Sbase	d organizations	
U.S. Consumer Product Safety Commission (CPSC)	Chronic Hazard Panel on Phthalates and Phthalate Alternatives Final Report (with Appendices) (<u>U.S.</u> <u>CPSC, 2014</u>) Toxicity Review of DCHP (<u>U.S. CPSC, 2010</u>)	
Interna	ational	
European Union, European Chemicals Agency (ECHA)	Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of DCHP, EC number: 201-545-9, CAS number: 84-61-7 (ECHA, 2014)	
Government of Canada, Environment Canada, 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)	

Authoring Organization	Publication
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	C4-6 side chain transitional phthalates: Human health tier II assessment (<u>NICNAS, 2016</u>)
	Phthalates hazard compendium: A summary of physicochemical and human health hazard data for 24 ortho-phthalate chemicals (NICNAS, 2008)

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5205 Appendix C LIST OF TECHNICAL SUPPORT DOCUMENTS

5206 Appendix C incudes a list and citations for all supplemental documents included in the Draft Risk
5207 Evaluation for DCHP.
5208

5209 Associated Systematic Review Protocol and Data Quality Evaluation and Data Extraction

5210 Documents – Provide additional detail and information on systematic review methodologies used as 5211 well as the data quality evaluations and extractions criteria and results.

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5213 Draft Systematic Review Protocol for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024ag) – In lieu 5214 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, 5215 5216 2021a), this systematic review protocol for the Draft Risk Evaluation for DCHP describes some clarifications and different approaches that were implemented than those described in the 2021 Draft 5217 5218 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 5219 "DCHP Systematic Review Protocol." 5220

5221
5222 Draft Data Quality Evaluation and Data Extraction Information for Physical and Chemical
5223 Properties for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024j) – Provides a compilation of tables
5224 for the data extraction and data quality evaluation information for DCHP. Each table shows the data
5225 point, set, or information element that was extracted and evaluated from a data source that has
5226 information relevant for the evaluation of physical and chemical properties. This supplemental file
5227 may also be referred to as the "DCHP Data Quality Evaluation and Data Extraction Information for
528 Properties."

5230 *Draft Data Quality Evaluation and Data Extraction Information for Environmental Fate and* 5231 *Transport for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024h) – Provides a compilation of tables 5232 for the data extraction and data quality evaluation information for DCHP. Each table shows the data 5233 point, set, or information element that was extracted and evaluated from a data source that has 5234 information relevant for the evaluation for Environmental Fate and Transport. This supplemental file 5235 may also be referred to as the "DCHP Data Quality Evaluation and Data Extraction Information for 5236 Environmental Fate and Transport."

5238 Draft Data Quality Evaluation and Data Extraction Information for Environmental Release and 5239 Occupational Exposure for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024i) – Provides a 5240 compilation of tables for the data extraction and data quality evaluation information for DCHP. Each 5241 table shows the data point, set, or information element that was extracted and evaluated from a data 5242 source that has information relevant for the evaluation of environmental release and occupational 5243 exposure. This supplemental file may also be referred to as the "DCHP Data Quality Evaluation and 5244 Data Extraction Information for Environmental Release and Occupational Exposure."

52455246Draft Data Quality Evaluation Information for General Population, Consumer, and Environmental5247Exposure for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 20241) – Provides a compilation of tables5248for the data quality evaluation information for DCHP. Each table shows the data point, set, or5249information element that was evaluated from a data source that has information relevant for the5250evaluation of general population, consumer, and environmental exposure. This supplemental file5251may also be referred to as the "DCHP Data Quality Evaluation Information for General Population,5252Consumer, and Environmental Exposure."

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5254 *Draft Data Extraction Information for General Population, Consumer, and Environmental Exposure* 5255 *for Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2024g) – Provides a compilation of tables for the 5256 data extraction for DCHP. Each table shows the data point, set, or information element that was 5257 extracted from a data source that has information relevant for the evaluation of general population, 5258 consumer, and environmental exposure. This supplemental file may also be referred to as the 5259 "DCHP Data Extraction Information for General Population, Consumer, and Environmental 5260 Exposure."

5262Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology for5263Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024n) – Provides a compilation of tables for the data5264quality evaluation information for DCHP. Each table shows the data point, set, or information5265element that was evaluated from a data source that has information relevant for the evaluation of5266epidemiological information. This supplemental file may also be referred to as the "DCHP Data5267Quality Evaluation Information for Human Health Hazard Epidemiology."

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Draft Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for
Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024m) – Provides a compilation of tables for the data
quality evaluation information for DCHP. 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 "DCHP Data Quality Evaluation Information for Human Health Hazard Animal Toxicology."

5276 *Draft Data Quality Evaluation Information for Environmental Hazard for Dicyclohexyl Phthalate* 5277 (*DCHP*) (U.S. EPA, 2024k) – Provides a compilation of tables for the data quality evaluation 5278 information for DCHP. Each table shows the data point, set, or information element that was 5279 evaluated from a data source that has information relevant for the evaluation of environmental 5280 hazard toxicity information. This supplemental file may also be referred to as the "DCHP Data 5281 Quality Evaluation Information for Environmental Hazard."

5283 Draft Data Extraction Information for Environmental Hazard and Human Health Hazard Animal 5284 Toxicology and Epidemiology for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024f) – Provides a 5285 compilation of tables for the data extraction for DCHP. Each table shows the data point, set, or 5286 information element that was extracted from a data source that has information relevant for the 5287 evaluation of environmental hazard and human health hazard animal toxicology and epidemiology 5288 information. This supplemental file may also be referred to as the "DCHP Data Extraction 5289 Information for Environmental Hazard and Human Health Hazard Animal Toxicology and 5290 Epidemiology."

Associated Technical Support Documents (TSDs) – Provide additional details and information on
 exposure, hazard, and risk assessments.

- 5295 Draft Physical Chemistry and Fate and Transport Assessment for Dicyclohexyl Phthalate (DCHP)
 5296 (DCHP) (U.S. EPA, 2024z).
 5297
- 5298Draft Environmental Release and Occupational Exposure Assessment for Dicyclohexyl Phthalate5299(DCHP) (U.S. EPA, 2024q).
- 5300
 5301 Draft Consumer and Indoor Dust Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024c).

5303 5304	Draft Environmental Media and General Population and Environmental Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024p).
5305	
5306	Draft Environmental Hazard Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 20240).
5307	.,
5308	Draft Non-Cancer Human Health Hazard Assessment for Dicyclohexyl Phthalate (DCHP) (U.S.
5309	EPA, 2024v).
5310	
5311	Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl
5312	Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl
5312	Phthalate (DCHP) (U.S. EPA, 2024b).
5314	$1 \text{ minimum (DCIII) (0.5. \text{LIR}, 20240).$
5315	Draft Consumer Risk Calculator for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024e).
5316	Draft Consumer Risk Calculator for Dicyclonexyl Thindiate (DCIII) (0.5. LIA, 20240).
5317	Draft Consumer Exposure Analysis for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024d).
5318	Druji Consumer Exposure Analysis for Dicyclonexyl I nindiale (DCIII) $(0.5. \text{ El } \text{A}, 20240)$.
5319	Draft Risk Calculator for Occupational Exposures for Dicyclohexyl Phthalate (DCHP) (U.S. EPA,
5320	2024ab).
5320 5321	2024a0).
5322	Draft Fish Ingestion Risk Calculator for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024r).
5323	Druji Fish Ingestion Risk Culculator for Dicyclonexyl Thinadale (DCIII) (<u>0.5. EFA, 20241</u>).
5323 5324	Draft Surface Water Human Exposure Risk Calculator for Dicyclohexyl Phthalate (DCHP) for P50
5325	Flow Rates (U.S. EPA, 2024ad).
5325 5326	<i>Pilow Rules</i> (<u>0.5. EI A, 2024ad</u>).
5320 5327	Draft Surface Water Human Exposure Risk Calculator for Dicyclohexyl Phthalate (DCHP) for P75
5328	Flow Rates (U.S. EPA, 2024ae).
5328 5329	<i>Flow Rales</i> (<u>0.5. EFA, 2024ae</u>).
5330	Draft Surface Water Human Exposure Risk Calculator for Dicyclohexyl Phthalate (DCHP) for P90
5330 5331	Flow Rates (U.S. EPA, 2024af).
5332	<i>Pilow Rules</i> (<u>0.5. EI A, 2024al</u>).
5333	Draft Ambient Air Exposure Assessment for Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024a).
5334	$Draji Ambieni An Exposure Assessment for Dicyclonexyl I ninulate (DCIII) (\underline{0.5. \text{ Li A}, 2024a}).$
5335	Draft Occupational and Consumer Cumulative Risk Calculator for Dicyclohexyl Phthalate (DCHP)
5336	(U.S. EPA, 2024y).
5337	(0.5. LIA, 2024 y).
5338	Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2-
5339	ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
5340	<i>Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP)</i> (U.S. EPA, 2024s).
5340 5341	Thindidle (DIDI), and Dicyclonexyl Thindidle (DCIII) (0.5 , ETA, 20245).
5342	Draft Tashniad Support Decument for the Cumulative Pick Analysis of Di(2 sthull and) Phthalate
	Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate
5343 5344	(DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic Substances
5345 5346	Control Act (TSCA) (U.S. EPA, 2024ah).
5346 5347	Draft Summary of Facility Pologgo Data for Di(2 other bary) Dith alate (DEUD) Ditected Did alate
5347 5348	Draft Summary of Facility Release Data for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DRP) and Putyl Pathalate (PRP) (U.S. EPA, 2024ac)
5348 5349	(DBP), and Butyl Benzyl Phthalate (BBP) (U.S. EPA, 2024ac).
JJ 4 7	

Appendix D UPDATES TO THE DCHP CONDITIONS OF USE TABLE

- After the final scope document (U.S. EPA, 2020b), EPA received updated submissions under the 2020 CDR reported data. In addition to new submissions received under the 2020 CDR, the reporting name codes changed for the 2020 CDR reporting cycle. Therefore, the Agency is amending the description of certain DCHP COUs based on those new submissions and new reporting name codes. Also, EPA received information from stakeholders on specific uses of DCHP. Table_Apx D-1 summarizes the changes to the COUs based on the new reporting codes in the 2020 CDR and any other new information since the publication of the final scope.
- 5359

Table_Apx D-1. Additions and Name Changes to Categories and Subcategories of Conditions of Use Based on CDR Reporting and Stakeholder Engagement

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing, Processing as a reactant	Processing aids not otherwise listed in: – Miscellaneous manufacturing	Consolidated into a category and associated subcategory under "processing, incorporation into formulation, mixture, or reaction product, stabilizing agent" based on further consultations with the submitters of the CDR data, review of their 2020 CDR cycle submissions, and given EPA's refined understanding of how DCHP is used (<u>U.S. EPA, 2024aj</u> , <u>2020a</u>).	Processing – Incorporation in formulation, mixture, or reaction product – Stabilizing agent (plastics product manufacturing)
Processing, Processing as a reactant	Process regulator in: – Paint and coating manufacturing – Plastic material and resin manufacturing – Plastics product manufacturing – Rubber product manufacturing	Consolidated category and associated subcategories under "processing, incorporation into formulation, mixture, or reaction products" based on further consultations with the submitters of the CDR data, review of their 2020 CDR cycle submissions, and given EPA's refined understanding of how DCHP is used (U.S. EPA, 2024aj, 2020a).	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizer (plastic material and resin manufacturing; rubber product manufacturing) And Processing – Incorporation in formulation, mixture, or reaction product – Stabilizing agent (paint and coating manufacturing; plastics product manufacturing)
Processing, Incorporation into formulation, mixture, or reaction product	Filler in: – Rubber product manufacturing	Removed COU based on further consultations with the submitters of the CDR data and review of their 2020 CDR cycle submissions (<u>U.S.</u> <u>EPA, 2024aj, 2020a</u>). DCHP is not used as a hardener, or the previously reported CDR code of "filler" (<u>Nouryon Chemicals LLC,</u> <u>2024</u>).	N/A
Processing, Incorporation into formulation,	Laboratory chemical	Consolidated category and associated subcategory under "repackaging" as an example based	Processing – Repackaging – Repackaging (<i>e.g.</i> , laboratory chemical)

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
mixture, or reaction product		on further review of the COUs. DCHP is not being reformulated or used in laboratory manufacturing, rather it is being used as a technical standard or reference reagent (U.S. EPA, 2020d).	
Processing, Incorporation into formulation, mixture, or reaction product	Paint additives and coating additives not described by other codes: – Printing ink manufacturing	Consolidated category and associated subcategory under a COU that was reported in a more recent CDR cycle.	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizer (printing ink manufacturing)
Processing, Incorporation into formulation, mixture, or reaction product	N/A	Updated the subcategory to reflect the 2020 CDR cycle.	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizer (plastic material and resin manufacturing)
Processing, Incorporation into formulation, mixture, or reaction product	Processing aids not otherwise listed: - Services - Paint and coating manufacturing - Asphalt paving, roofing, and coating materials manufacturing - Adhesive manufacturing	Consolidated category and associated subcategories as a "stabilizing agent" based on further consultations with the submitters of the CDR data and review of their 2020 CDR cycle submissions (U.S. EPA, 2024aj; Nouryon Chemicals LLC, 2020; U.S. EPA, 2020a, 2019c).	Processing – Incorporation in formulation, mixture, or reaction product – Stabilizing agent (adhesive manufacturing; asphalt paving, roofing, and coating materials manufacturing; paint and coating manufacturing)
Processing, Incorporation into formulation, mixture, or reaction product	Process regulator in: – Adhesive manufacturing	Consolidated category and associated subcategory under a COU that was both reported in a more recent CDR cycle and more appropriate given EPA's understanding of how DCHP is used.	Processing – Incorporation in formulation, mixture, or reaction product – Stabilizing agent (adhesive manufacturing)
Processing; Incorporation into formulation, mixture, or reaction product	N/A	Updated the subcategory to reflect the 2020 CDR cycle.	Processing – Incorporation in formulation, mixture, or reaction product – Stabilizing agent (paints and coating manufacturing)
Processing, Incorporation into formulation, mixture, or reaction product	N/A	Updated the subcategory to reflect the 2020 CDR cycle.	Processing – Incorporation in formulation, mixture, or reaction product – Stabilizing agent (plastics product manufacturing)
Industrial Use, Adhesives and sealants	Adhesives and sealants in: – Transportation equipment manufacturing – Computer and electronic product manufacturing	Updated the category and subcategory to add "computer and electronic product manufacturing" and "transportation equipment manufacturing" as examples to not preclude other industrial sectors.	Industrial Use – Adhesives and sealants (<i>e.g.</i> , computer and electronic product manufacturing; transportation equipment manufacturing)

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Industrial Use	N/A	Added the COU "paints and coatings" to the new life cycle stage of "industrial use" based on a new understanding of information from an SDS that explained the use could take place on an industrial scale (<u>Carboline, 2019b</u>).	Industrial Use – Paints and coatings
Industrial Use, Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere in: – Transportation equipment manufacturing	Updated the category and subcategory to better reflect 2020 CDR reporting codes and to add "transportation equipment manufacturing" as an example to not preclude other industrial sectors.	Industrial Use – Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) (<i>e.g.</i> , transportation equipment manufacturing)
Commercial Use, Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	Updated the category and subcategory to reflect the 2020 CDR cycle.	Commercial Use – Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)
Consumer Use, Arts, crafts, and hobby materials	Arts, crafts, and hobby materials (<i>e.g.</i> , modeling clay)	Removed this COU upon further review, concluding it was no longer reasonably foreseen.	N/A
Consumer Use, Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	Updated the category and subcategory to reflect the 2020 CDR cycle.	Consumer Use – Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)

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As indicated in Table_Apx D-1, the changes are based on close examination of the CDR reports, including the 2020 CDR reports that were received after the scope was completed, additional research on the COUs, additional comments from stakeholders, and overall systematic review of the use information.

5367

When developing this draft risk evaluation, EPA concluded that some subcategories of the COUs listed in the final scope document (U.S. EPA, 2020b) were redundant and consolidation was needed to avoid evaluation of the same COU multiple times. The Agency further concluded that there were some instances where subcategory information on the processing and uses of DCHP was misreported by CDR reporters based on outreach with stakeholders. For these instances, EPA recategorized the activity described in the COU listed in the scope to fit the description of the COU included in this draft risk evaluation.

5376 In addition, EPA did further analysis of the following COUs, which resulted in the changes presented on
5377 the table that warrant further explanation because these COUs were changed significantly between the
5378 final scope and this draft risk evaluation:

 Processing, Processing as a reactant, "processing aids not otherwise listed in miscellaneous manufacturing; process regulator in paint and coating manufacturing, plastic material and resin manufacturing, plastics product manufacturing, and rubber product manufacturing" were all removed from the COUs as it was determined (due in part to a refined understanding of how

- 5383 DCHP is used and stakeholder outreach) that DCHP is not used as a reactant and it is more 5384 appropriately characterized as "Processing – incorporated into a formula, mixture or reaction 5385 product." These uses are better captured under other processing COUs that more accurately 5386 reflect EPA's understanding of how DCHP is used.
- EPA has also included further information about any other COUs (reported in the 2020 CDR cycle (U.S.
 EPA, 2020a) or otherwise) that are not included in the draft DCHP risk evaluation:
- 5389 Processing, Processing as a reactant, "plasticizer in plastics product manufacturing; intermediate 5390 in all other basic organic chemical manufacturing; stabilizing agent in paint and coating 5391 manufacturing and plastics product manufacturing; and processing aids not otherwise specified in plastics product manufacturing" were reported in the 2020 CDR cycle and were not included 5392 5393 in the draft risk determination analysis as it was determined that DCHP is not used as a reactant 5394 and it is more appropriately characterized as "Processing - incorporated into a formula, mixture 5395 or reaction product." These uses are better captured under other processing COUs that more 5396 accurately reflect EPA's understanding of how DCHP is used.
- 5397 Processing, Processing as a reactant, "hardener in paint and coating manufacturing; and plastics • 5398 product manufacturing" were reported in the 2020 CDR cycle and were not included in the draft 5399 risk determination analysis as it was determined that DCHP is not used as a reactant and is more appropriately characterized as "Processing – incorporated into a formula, mixture or reaction 5400 product." Additionally, based on Agency research and communication with stakeholders it is 5401 5402 EPA's understanding that the use of "hardener" is better captured as a "stabilizing agent" for the 5403 draft DCHP risk evaluation (U.S. EPA, 2024aj). Ultimately, these uses are better captured under 5404 other processing COUs that more accurately reflect EPA's understanding of how DCHP is used.
- Processing, Processing incorporation into formulation, mixture, or reaction product, "processing aids not otherwise specified in plastics product manufacturing" was reported in the 2020 CDR cycle and was not included in the draft risk determination analysis after additional research and communication with stakeholders (U.S. EPA, 2024aj). It is EPA's understanding that this COU is more appropriately consolidated into Processing, Processing incorporation into formulation, mixture, or reaction product, "stabilizing agent."
- 5411 Note that in the final scope document for DCHP (U.S. EPA, 2020b), EPA removed the consumer 5412 use of dicyclohexyl phthalate in toys, playground, and sporting equipment as a COU for numerous reasons, which include: a public comment received on the draft DCHP scoping 5413 5414 document (Vertellus LLC, 2020); the Consumer Product Safety Commission's (CPSC) Chronic 5415 Hazard Advisory Panel (CHAP) report from 2014 (U.S. CPSC, 2014) that states, "DCHP is 5416 currently not found in children's toys or child care articles, and it is not widely found in the 5417 environment" (page 117); the preamble of the 2017 CPSC final rule titled "Prohibition of 5418 Children's Toys and Child Care Articles Containing Specified Phthalates," which explains that ". 5419 ... the CPSC staff has not detected DCHP in toys and child care articles during routine 5420 compliance testing thus far. ..." (U.S. CPSC, 2017); and CPSC's final rule, which prohibits 5421 manufacture for sale, offer for sale, distribution in commerce, and importation into the United 5422 States of any children's toy or child care article that contains more than 0.1 percent of 5423 dicyclohexyl phthalate as it "would prevent [DCHP's] use as a substitute for other banned 5424 phthalates" (82 FR 49982 (2017); 16 CFR 1307.3). As a result, EPA has no reasonably available 5425 information demonstrating that the consumer use of dicyclohexyl phthalate in toys, playground, 5426 and sporting equipment is intended, known, or reasonably foreseen, and therefore removed this 5427 COU from the final scope and has not included it in the analysis for this draft risk evaluation of DCHP. 5428

5429 Appendix E CONDITIONS OF USE DESCRIPTIONS

5430 The following descriptions are intended to include examples of uses, so as not to exclude other activities 5431 that may also be included in the COUs of the chemical substance. To better describe the COU, EPA 5432 considered CDR submissions from previous CDR cycles for DCHP (CASRN 84-61-7), and the COU 5433 descriptions reflect what the Agency identified as the best fit for those submissions. Examples of 5434 articles, products, or activities are included in the following descriptions to help describe the COU but 5435 are not exhaustive. EPA uses the terms "articles" and "products" or product mixtures in the following 5436 descriptions and is generally referring to articles and products as defined by 40 CFR part 751. There 5437 may be instances where the terms are used interchangeably by a company or commenters, or by EPA in 5438 reference to a code from CDR reports that are referenced (*e.g.*, "plastics products manufacturing," or 5439 "fabric, textile, and leather products"), EPA will clarify as needed when these references are included 5440 throughout the COU descriptions below.

5441 **5.1 Manufacturing – Domestic Manufacturing**

5442 Domestic manufacture means to manufacture or produce DCHP within the United States. For purposes 5443 of the DCHP risk evaluation, this includes the extraction of DCHP from a previously existing chemical 5444 substance or complex combination of chemical substances and loading and repackaging (but not 5445 transport) associated with the manufacturing or production of DCHP.

5446

5447 DCHP is typically manufactured in a closed system through catalytic esterification of phthalic anhydride 5448 and cyclohexanol in solvent at elevated temperatures (130 °C) (U.S. CPSC, 2010). After the reaction, 5449 excess alcohol is recovered and DCHP is purified through vacuum distillation or activated charcoal 5450 (U.S. EPA, 2020b). Based on manufacturing operations for similar phthalates, activities may also 5451 include filtrations and quality control sampling of the DCHP product. Additionally, manufacturing 5452 operations include equipment cleaning/reconditioning and product transport to other areas of the 5453 manufacturing facility or offsite shipment for downstream processing or use. Current manufacturing 5454 processes can achieve a DCHP purity of 99 percent or greater, with some impurities of water and 5455 phthalic acid (U.S. CPSC, 2010). This COU includes the typical manufacturing process and any other 5456 similar production of DCHP.

5457

5458 Examples of CDR Submissions.

5459 In the 2016 CDR cycle, one company reported domestic manufacturing of DCHP (CASRN 84-61-7) as 5460 large crystal pellets.

5461

5462 In the 2020 CDR cycle, two companies reported domestic manufacturing of DCHP (CASRN 84-61-7).

5463 One CDR company reported domestic manufacturing of DCHP as pellets or large crystals, while the 5464 second company reported domestic manufacturing of DCHP as a dry powder.

5465 E.2 Manufacturing – Importing

Import refers to the import of DCHP into the customs territory of the United States. In general,
chemicals may be imported into the United States in bulk via water, air, land, and intermodal shipments,
and loading and repackaging (but not transport) associated with the import of DCHP (Tomer and Kane,
2015). These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and
intermodal tank containers (U.S. EPA, 2020b).

5471

5472 Imported DCHP is shipped in either dry powder, liquid, water or solvent wet solid form (U.S. EPA,

5473 <u>2020a</u>). Import sites unload the import containers and transfer DCHP into smaller containers (bags or 5474 supersacks) for downstream processing, use within the facility, or offsite use. Operations may include

- 5475 quality control sampling of DCHP product and equipment cleaning. No changes to chemical
- 5476 composition occur during importation of this COU (U.S. EPA, 2022a).
- 5478 Examples of CDR Submissions.
- 5479 In the 2016 CDR cycle, one company reported importation of DCHP (CASRN 84-61-7) in a solid form.
- 5480

5477

- 5481 In the 2020 CDR cycle, two companies reported importation of DCHP (CASRN 84-61-7).
- 5482 One CDR company reported importation of DCHP as dry powder, liquid, while the second company 5483 reported importation of DCHP as water or a solvent wet solid.
- 5484 E.3 Processing Incorporation into Formulation, Mixture, or Reaction
 5485 Product Adhesive and Sealant Chemicals in Adhesive
 5486 Manufacturing

5487 This COU refers to the preparation of a product; that is, the incorporation of DCHP into formulation, 5488 mixture, or a reaction product that occurs when a chemical substance is added to a product (or product 5489 mixture), after its manufacture, for distribution in commerce. In this case, processing of DCHP into an 5490 adhesive and sealant in adhesive manufacturing.

5491

Based on the 2009 Emission Scenario Document (ESD) on the Manufacture of Adhesives, a typical
adhesive incorporation site receives and unloads DCHP into adhesive and sealant formulations in
industrial mixing vessels as a batch blending or mixing process, with no reactions or chemical changes
occurring to the plasticizer (*i.e.*, DCHP) during the mixing process (OECD, 2009a). Process operations
may also include quality control sampling. EPA expects that sites will load DCHP-containing adhesive
and sealant products into bottles, small containers, or drums depending on the product type. (OECD,
2009a).

5499

5500 Examples of CDR Submissions.

5501 In the 2016 cycle, one company reported the use of DCHP (CASRN 84-61-7) as adhesive and sealant 5502 chemicals in adhesive manufacturing.

E.4 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Plasticizer (Adhesive Manufacturing; Paint and Coating Manufacturing; Plastic Material and Resin Manufacturing; Plastics Product Manufacturing; Printing Ink Manufacturing; and Rubber Product Manufacturing)

- 5508 This COU refers to the preparation of a product; that is, the incorporation of DCHP into formulation, 5509 mixture, or a reaction product that occurs when a chemical substance is added to a product (or product 5510 mixture) after its manufacture, for distribution in commerce—in this case as a plasticizer in various 5511 industrial sectors and uses, specifically as an adhesive, paint and coating, plastic material and resin, 5512 plastic product, printing or PVC plastisol ink and as a rubber product.
- 5513

5514 The American Coatings Association explained that DCHP is a plasticizer, additive and impurity in

adhesives in amounts less than 1 percent (<u>ACA, 2019</u>) and according to information provided to EPA,

5516 DCHP is also used within products or formulations for the manufacture, operation and maintenance of

5517 aerospace products (<u>AIA, 2019</u>). More specifically, the Aerospace Industries Association explained that

5518 DCHP can be used as a plasticizer for nitrocellulose, chlorinated rubber polyvinyl chloride and other

5519 polymers and adhesives.

- 5520 In manufacturing of plastic material and resin through non-PVC and PVC compounding, DCHP is
- 5521 blended into polymers. Compounding involves the mixing of the polymer with the plasticizer and other 5522 chemical such as fillers and heat stabilizers. The plasticizer needs to be absorbed into the particle to
- 5522 chemical such as mers and heat stabilizers. The plasticizer needs to be absorbed into the particle to 5523 impart flexibility to the polymer. For PVC compounding, compounding occurs through mixing of
- 5524 ingredients to produce a powder (dry blending) or a liquid (plastisol blending). The most common
- 5525 process for dry blending involves heating the ingredients in a high intensity mixer and transfer to a cold
- 5526 mixer. The plastisol blending is done at ambient temperature using specific mixers that allow for the
- 5527 breakdown of the PVC agglomerates and the absorption of the plasticizer into the resin particle. EPA is
- also aware that DCHP may be incorporated into PVC plastisol inks and inks for screen printing
 (Hallstar, 2022; LANXESS, 2021; Gans Ink and Supply, 2018; U.S. CPSC, 2015).
- 5530

5531 Examples of CDR Submissions

5532 In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in 5533 plastics product manufacturing and one CDR company reported the use of DCHP as a plasticizer in 5534 printing ink manufacturing.

In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in plastics material and resin manufacturing and one CDR company reported the use of DCHP as a plasticizer in adhesive manufacturing.

E.5 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Stabilizing Agent (Adhesive Manufacturing; Asphalt Paving, Roofing, and Coating Materials Manufacturing; Paints and Coating Manufacturing; and Plastics Product Manufacturing)

5543 This COU refers to the preparation of a product; that is, the incorporation of DCHP into formulation, 5544 mixture, or a reaction product that occurs when a chemical substance is added to a product (or product 5545 mixture), after its manufacture, for distribution in commerce. In this case DCHP is used as a stabilizing 5546 agent, specifically as a phlegmatizer (a compound that minimizes the explosive tendency of another 5547 compound or material) for dibenzoyl peroxide (BPO) and peroxide-based formulations to improve the safety and handling properties and to prevent explosions (U.S. EPA, 2024aj; AIA, 2019). These BPO 5548 5549 mixtures (in which DCHP is present) are then used as a curing agent for unsaturated polyesters or 5550 methyl methacrylate (MMA) systems, which is used in various industrial sectors and uses including 5551 asphalt, roofing, and flooring systems, coatings, adhesives, and within the aerospace industry (U.S. EPA, 2024aj; Nouryon Chemicals LLC, 2020; AIA, 2019; U.S. EPA, 2019c). EPA has confirmed that 5552 5553 this COU has recently been discontinued with the CDR submitter. However, the use of DCHP as a 5554 stabilizing agent was only recently ceased (*i.e.*, in 2021) and the available information regarding DCHP 5555 suggests that this COU could occur. Therefore, it is included in EPA's evaluation.

5556

5557 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a process
regulator in paints and coating manufacturing, which has been recategorized in the COU table to
"stabilizing agent" after discussions with the company that purchased the previous 2016 reporting
company (U.S. EPA, 2024aj, 2019c). See Appendix D for more information on the changes from the
COU from the *Final Scope of the Risk Evaluation for Dicyclohexyl Phthalate (DCHP); CASRN 84-61-7*(U.S. EPA, 2020b).

5564

5565 In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a stabilizing agent 5566 in paints and coating manufacturing.

5567 E.6 Processing – Incorporation into Articles – Plasticizer (Plastics Product 5568 Manufacturing and Rubber Product Manufacturing)

5569 This COU refers to the preparation of an article; that is, the incorporation of DCHP into articles, 5570 meaning DCHP becomes an integral component of the article, after its manufacture, for distribution in commerce. In this case, DCHP is present in a raw material such as rubber or plastic that contains a 5571 5572 mixture of plasticizers and other additives, and this COU refers to the manufacturing of PVC and non-5573 PVC articles including rubber, plastic, and miscellaneous articles using those raw materials. According 5574 to information provided to EPA, DCHP is used as a plasticizer in plastic and rubber articles used in the 5575 aerospace industry (AIA, 2019), and a variety of articles in transportation equipment such as automotive 5576 vehicles (MEMA, 2019). Simple and complex plastic and rubber articles containing DCHP are also assumed to be used in electronics (U.S. CPSC, 2015), as well as a variety of other industrial and 5577 5578 commercial end uses. DCHP is also assumed to be used as a plasticizer in a variety of other simple and 5579 complex articles such those found in building and construction materials (LANXESS, 2021).

5580

5581 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in plastics products manufacturing, one company reported the commercial and consumer use of DCHP in plastic and rubber products not covered elsewhere.

- In the 2020 CDR cycle, one company reported the commercial and consumer use of DCHP (CASRN
 84-61-7) as a plasticizer in other articles with routine direct contact during normal use including rubber
 articles; plastic articles (hard), which is a further refined description compared with the 2016 CDR cycle
- 5589 code of "plastic and rubber products not covered elsewhere."

5590 E.7 Processing – Repackaging (e.g., Laboratory Chemical)

5591 Repackaging refers to the preparation of DCHP for distribution in commerce in a different form, state, 5592 or quantity than originally received or stored by various industrial sectors, including chemical product 5593 and preparation manufacturing, wholesale and retail trade, and laboratory chemicals manufacturing. This 5594 COU includes the transferring of DCHP from a bulk container into smaller containers. One company 5595 explained that DCHP and phthalates more generally are domestically repackaged for laboratory use 5596 (U.S. EPA, 2020d). This COU would not apply to the relabeling or redistribution of a chemical 5597 substance without removing the chemical substance from the original container it was supplied in. No 5598 changes to chemical composition occur during repackaging of this COU (U.S. EPA, 2022a).

- 5599
- 5600 This COU was not reported in the 2016 or 2020 CDR cycles.

5601 E.8 Processing – Recycling

5602 This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be 5603 disposed of as waste) containing DCHP that are collected, either on-site or at a third-party site, for 5604 commercial purpose. DCHP is primarily recycled industrially in the form of DCHP-containing 5605 PVC/plastic waste streams. New PVC can be manufactured from recycled and virgin materials at the 5606 same facility. Some (ENF Plastic, 2024) estimate a total of 228 plastics recyclers operating in the United 5607 States of which 58 accept PVC wastes for recycling. It is unclear if the total number of sites includes 5608 some or all circular recycling sites-facilities where new PVC can be manufactured from recycled and 5609 virgin materials on the same site. Articles containing DCHP from inks, coatings, etc., may also be 5610 recycled (U.S. EPA, 2020b). EPA notes that although DCHP was not reported for recycling in the 2016 5611 or 2020 CDR reporting periods, EPA is assuming that recycling waste streams could contain DCHP.

5612 E.9 Distribution in Commerce

- 5613 For purposes of assessment in this draft risk evaluation, distribution in commerce consists of the
- transportation associated with the moving of DCHP or DCHP-containing products between sites
- 5615 manufacturing, processing or recycling DCHP or DCHP-containing products, or to final use sites, or for
- final disposal of DCHP or DCHP-containing products. More broadly under TSCA, "distribution in
- 5617 commerce" and "distribute in commerce" are defined under TSCA section 3(5). No changes to chemical
- 5618 composition occur during transportation of DCHP (<u>U.S. EPA, 2022a</u>).

5619 E.10 Industrial Use – Adhesive and Sealants (*e.g.*, Computer and Electronic 5620 Product Manufacturing; Transportation Equipment Manufacturing)

5621 This COU refers to DCHP as it is used in various industrial sectors as a component of adhesive or 5622 sealant mixtures. Meaning the use of DCHP after it has already been incorporated into an adhesive 5623 and/or sealant product or mixture, as opposed to when it is used upstream (*e.g.*, when DCHP is 5624 processed into the adhesive and sealant formulation). The American Coatings Association explained that 5625 DCHP is a plasticizer, additive, and impurity in adhesives in amounts less than 1 percent (<u>ACA, 2019</u>).

5626

5627 According to information provided to EPA, DCHP is used as an adhesive within the aerospace industry

5628 (AIA, 2019) and as an adhesive sealant for body panel assemblies and parts by automobile

- manufacturers applications (MEMA, 2019). EPA has also identified several examples of specific
 products for this COU, such as a nonconductive die attach adhesive containing DCHP at concentrations
 of 0.1 to 1 percent. This adhesive has been formulated for use in high throughput die attach applications
 within the semi-conductor industry within various types of electronics (*e.g.*, automotive cameras)
 (Henkel, 2024, 2019, 2017).
- 5634

5635 Examples of CDR Submissions

5636 In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as adhesive and 5637 sealant chemicals in adhesive manufacturing.

5638

In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer inadhesive manufacturing.

5641 E.11 Industrial Use – Finishing Agent – Cellulose Film Production

This COU refers to the use of DCHP as a component of the finishing agent used in cellulose film production. Meaning the use of DCHP after it has already been incorporated into the finishing agent itself, as opposed to when it is used upstream (*e.g.*, when DCHP is processed into the finishing agent or paint and coating formulation).

5646

5647 CDR described a "finishing agent" as a chemical substance used to impart such functions as softening, 5648 static-proofing, wrinkle resistance, and water repellence. Substances may be applied to textiles, paper, 5649 and leather. In this case DCHP is used during the cellulose film production to bathe or coat the film, 5650 giving it barrier properties as well as promoting heat seal. This cellulose film is then used in a variety of 5651 labeling, and packaging end uses (U.S. EPA, 2020c; Earthjustice, 2019).

- 5652
- 5653 This COU was not reported in the 2016 or 2020 CDR reporting cycles.

5654 E.12 Industrial Use – Inks, Toner, and Colorant Products

5655 This COU refers to the use of DCHP in various industrial sectors as a component in ink, toner, and 5656 colorant products. Meaning the use of DCHP after it has already been incorporated into ink, toner,

and/or colorant products, or while it is being applied to various articles, as opposed to when it is used upstream (*e.g.*, when DCHP is processed into the ink, toner, and colorant product formulation).

- 5659 According to information provided to EPA in 2021, DCHP (referred to in this case as Uniplex 250) has 5660 5661 been used as an element of PVC inks/PVC plastisol formulations (Hallstar, 2022; LANXESS, 2021; 5662 U.S. EPA, 2021c, 2019e). Uniplex 250 is also marketed as being used as a polymer additive in labels 5663 and printing ink formulations (Hallstar, 2022) and DCHP has been used as part of the screen-printing 5664 process for textiles (Gans Ink and Supply, 2018). Printing inks are composed of colorants (e.g., pigments, dyes and toners) dispersed in a formulation to form a paste, liquid or solid, which can be 5665 applied to a substrate surface and dried (U.S. EPA, 2010). Screen printing requires a mesh screen to 5666 5667 transfer the ink to a substrate, whereas digital printing allows for the transfer of a digital image directly onto a substrate. Inkjet printing is the most common form of digital printing. It involves the application 5668 5669 of small drops of ink onto a substrate, with direct contact between the ink nozzle and the substrate (U.S. EPA, 2010). 5670
- 5670 5671

5680

5672 Examples of CDR Submissions

5673 In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in 5674 printing ink manufacturing.

5675 E.13 Industrial Use – Paints and Coatings

5676 This COU refers to the use of DCHP in various industrial sectors as a component in paints and coating 5677 mixtures. This is a use of DCHP after it has already been incorporated into paint and coating or BPO 5678 mixtures, or while it is being applied to various articles, as opposed to when it is used upstream (*e.g.*, 5679 when DCHP is processed into adhesive, sealant or BPO formulation).

EPA has identified an example of an industrial paint and coating product for this COU; a singlecomponent silicone acrylic finish that air dries and is suitable for high temperature exposures up to
500 °F with DCHP concentrations of 2.5 to less than 10 percent. This paint and coating is applied via
pressurized or conventional spray and can be used to protect various elements, equipment, etc. in an
industrial or manufacturing setting (Carboline, 2019a, b; U.S. EPA, 2019d).

5687 EPA expects that products under this COU would be applied in the industrial sector; however, note that 5688 it is possible for these products to be purchased by commercial users and applied in the commercial 5689 sector as well.

5691 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a process regulator in paints and coating manufacturing, which has been recategorized in the COU table to "stabilizing agent" after discussions with the company that purchased the previous 2016 reporting company (U.S. EPA, 2024aj). See Appendix D for more information on the changes from the COUs from the *Final Scope of the Risk Evaluation for Dicyclohexyl Phthalate (DCHP) CASRN 84-61-7* (U.S. EPA, 2020b).

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5699 In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a stabilizing agent 5700 in paints and coating manufacturing.

5701

5702 E.14 Industrial Use – Other Articles with Routine Direct Contact During 5703 Normal Use Including Rubber Articles; Plastic Articles (Hard) (*e.g.*, 5704 Transportation Equipment Manufacturing)

5705 This COU refers to the use of DCHP in rubber and plastic products in various industrial sectors, such as 5706 transportation equipment manufacturing. Meaning the use of DCHP after it has already been 5707 incorporated into a plastic or rubber product, as opposed to when it is used upstream (*e.g.*, when DCHP 5708 is processed into the plastic/rubber product).

- 5710 According to information provided to EPA, DCHP is used as a plasticizer in plastic and rubber products 5711 used in the aerospace industry (<u>AIA, 2019</u>) and a variety of transportation equipment such as both
- 5712 vehicles production parts and replacement parts (<u>MEMA, 2019</u>). The Alliance of Automobile
- 5713 Manufacturers and the Motor & Equipment Manufacturers Association did explain that "[t]he average
- 5714 scope of the relative mass of DCHP in the parts from the Alliance's data collection is 0.24 gram.
- 5715 Excluding body/exterior parts, that average drops below 0.01 gram" (MEMA, 2019). 5716
- 5717 As such, workers would be expected to handle or touch products covered by this COU with their hands 5718 and be exposed to DCHP through dermal contact.

57195720 Examples of CDR Submissions

- 5721 In the 2016 CDR cycle, one company reported the commercial use of DCHP (CASRN 84-61-7) in 5722 plastic and rubber products not covered elsewhere. 5723
- 5724 In the 2020 CDR cycle, the same company reported the commercial use of DCHP (CASRN 84-61-7) as 5725 a plasticizer in other articles with routine direct contact during normal use including rubber articles;
- 5726 plastic articles (hard), which is a further refined description compared to the 2016 CDR cycle code of 5727 "plastic and rubber products not covered elsewhere".

5728 E.15 Commercial Use – Adhesives and Sealants

- 5729 This COU is referring to the commercial use of DCHP in adhesives and sealants. Meaning the use of 5730 DCHP-containing adhesives and sealants in a commercial setting, such as a business or at a job site, as 5731 opposed to upstream use of DCHP (*e.g.*, when DCHP is processed into the adhesive and sealant 5732 formulation) or use in an industrial setting.
- 5733

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5734 Workers in a commercial setting generally apply adhesives and sealants that already have DCHP 5735 incorporated as a plasticizer or combine two-part adhesives where DCHP acts as a phlegmatizer with 5736 BPO in unsaturated polyesters or MMA systems (U.S. EPA, 2024aj). The American Coatings

5737 Association explained that DCHP is a plasticizer, additive and impurity in adhesives in amounts less

- 5738 than one percent (<u>ACA, 2019</u>). According to information provided to EPA, DCHP is used as an 3739 adhesive within the aerospace industry (<u>AIA, 2019</u>), and an adhesive sealant for body panel assemblies 3740 and parts by automobile manufacturers applications (<u>MEMA, 2019</u>).
- 5741

5742 Commercial adhesives and sealants that are used to fasten other materials together or to prevent the 5743 passage of liquid or gas are captured under this COU. For example, products under this COU can be 5744 two-part adhesives, glues or caulks, which are stored in separate parts, generally a base and an activator 5745 or a resin and a hardener that may undergo a reaction or cure once combined. EPA expects that some 5746 commercial applications of adhesives and sealants containing DCHP may occur using non-pressurized

- 5747 methods, but that most commonly, the products containing DCHP are more likely applied via a syringe
- or caulk gun. More specifically, EPA has identified several examples of products for this COU, such as

- 5749 a metal bonding adhesive used in variety of automotive care applications (*e.g.*, panel bonding, weld and 5750 rivet bonding of quarter panels, rear body panels, roof panels, door skins, van side panels and outer truck
- 5751 bed panels) that contain DCHP concentrations of one to five percent (Lord Corporation, 2021, 2020,
- 5752 <u>2017</u>) as well as a similar metal bonding product with DCHP concentrations from three to less than five 5753 percent (Ford Motor Company, 2015). EPA also identified various two-part adhesive anchoring systems,
- 5754 such as a two-part hammer-capsule system designed for use in the installation of a threaded rod into
- 5755 solid concrete and masonry materials that contained DCHP concentrations of 1 to 2.5 percent (DeWalt,
- 5756 $\underline{2024b}, \underline{2022}, \underline{2020}$), as well as another two-part polyester liquid system to be used once again in
- 5757 construction and building environments (<u>MKT, 2023a, b, 2018</u>).
- 5758

EPA expects that the use of these types of products would occur in commercial applications; however,
EPA notes that these products are likely to be sourced by DIY consumers through various online
vendors as well (DeWalt, 2024a; Lord Corporation, 2024; MKT, 2024).

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5766

5763 Examples of CDR Submissions

5764 In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as adhesive and 5765 sealant chemicals in adhesive manufacturing.

5767 In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in adhesive manufacturing.

5769 E.16 Commercial Use – Building/Construction Materials Not Covered 5770 Elsewhere

5771 This COU is referring to the commercial use of DCHP in building/construction materials not covered 5772 elsewhere. Meaning the use of DCHP-containing building/construction materials in a commercial 5773 setting, such as at a business or at a job site, as opposed to upstream use of DCHP (*e.g.*, when DCHP is 5774 processed into articles).

5775

According to information provided to EPA in 2021, DCHP (referred to in this case as Uniplex 250) has
been used as an article in a "range of construction products-boards" (LANXESS, 2021). These boards
are presumed to be used in a variety of commercial applications and settings.

5779

5780 Examples of CDR Submissions

5781 In the 2012 CDR cycle, one company reported the commercial use of DCHP (CASRN 84-61-7) as 5782 building/construction materials not covered elsewhere.

5783 E.17 Commercial Use – Ink, Toner, and Colorant Products

5784 This COU refers to the commercial use of DCHP in ink, toner, and colorant products. Meaning the use 5785 of DCHP-containing ink, toner, and/or colorant products in a commercial setting, such as a business or 5786 at a job site, as opposed to upstream use of DCHP (*e.g.*, when DCHP is processed into the ink, toner, 5787 and colorant product formulation) or use in an industrial setting.

5788

5789 According to information provided to EPA in 2021, DCHP (referred to in this case as Uniplex 250) has

5790 been used as an element of PVC inks/PVC plastisol formulations (LANXESS, 2021; U.S. EPA, 2021c,

- 5791 <u>2019e</u>). Uniplex 250 is also marketed as being used as a polymer additive in labels and printing ink
- 5792 formulations (<u>Hallstar, 2022</u>) and has been used as part of the screen-printing process for textiles (<u>Gans</u> 5793 Ink and Supply 2018). The expected users of these products would be specific to the printing.
- 5793 Ink and Supply, 2018). The expected users of these products would be specific to the printing

- 5794 community and these inks would likely be applied through mechanical methods or as part of the screen-5795 printing process.
- 5796
- 5797 Examples of CDR Submissions
- 5798 In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in
- 5799 printing ink manufacturing.

5800 E.18 Commercial Use – Laboratory Chemicals

This COU is referring to the commercial use of DCHP in laboratory chemicals. DCHP can be used as a 5801 5802 laboratory chemical, such as a chemical standard or reference material during analyses. Some laboratory 5803 chemical manufacturers identify use of DCHP as a certified reference material and research chemical 5804 (Restek Corporation, 2024; Sigma-Aldrich, 2024a, b; U.S. EPA, 2020d; SPEX CertiPrep, 2019). Users 5805 of the products under this category would be expected to apply these products through general 5806 laboratory use applications. According to information provided to EPA by NASA, the Agency indicated 5807 that DCHP is used as a laboratory chemical in applications such as analytical standards, research, 5808 equipment calibration and sample preparation (NASA, 2020).

- 5809
- 5810 DCHP has also been used as the powder in a two-part laboratory acrylic mounting system for laboratory 5811 specimens that are sensitive to high pressures and temperatures, as well as an embedding polymer resin
- 5812 kit intended for preparation for samples for high resolution light microscopy (<u>Ted Pella, 2024, 2017</u>).
- 5813 DCHP in this case is used as part of a BPO catalyst.
- 5814
- 5815 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

5816 E.19 Commercial Use – Paints and Coatings

5817 This COU is referring to the commercial use of DCHP as a plasticizer and stabilizer (*i.e.*, phlegmatizer) 5818 in paints and coating systems. Meaning the use of DCHP-containing paints and coatings in a commercial 5819 setting, such as at a business or at a job site, as opposed to upstream use of DCHP (*e.g.*, when DCHP is 5820 processed into the paint, coating, or BPO formulation) or use in an industrial setting.

5821
5822 Workers in a commercial setting generally apply paints and coatings that already have DCHP
5823 incorporated as a plasticizer or combine two (or even sometimes three) part paints and coatings where
5824 DCHP acts as a phlegmatizer with BPO in unsaturated polyesters or MMA systems (U.S. EPA, 2024ai).

5825 The solid DCHP/BPO product often acts as a catalyst or curing agent when mixed with a second, often 5826 liquid, component by workers at the end use site before application. This mixing begins the

polymerization reaction or process. Workers are expected to be potentially exposed when mixing components to form a liquid paint/coating, when transferring the liquid mixture to the application equipment if necessary, and/or when applying the coating or system itself to the substrate (U.S. EPA, 2014b; OECD, 2009b; U.S. EPA, 2004d). End use sites may also receive liquid paint and coating formulations already containing DCHP as a single component, making the need to mix two components obsolete. Application methods for DCHP-containing paints and coatings may include spray, brush, and/or trowel coating.

5834

Various paints and coatings that utilize DCHP are applied in commercial settings such as in roofing, construction, and in cement/protection for high traffic areas, etc. often to provide waterproofing, UV protection and/or chemical resistance. More specifically, EPA has identified several examples of products for this COU, such as a single-component silicone acrylic finish that air dries and is suitable for high temperature exposures up to 500 °F with DCHP concentrations of 2.5 to less than 10 percent. This paint and coating is applied via pressurized spray and can be used to protect various elements,

5841 equipment, and so on, in an industrial or manufacturing setting (<u>Carboline, 2019a</u>, <u>b</u>; <u>U.S. EPA, 2019d</u>).

- EPA also identified various two or even multi-part paints and coatings systems including: a vinyl ester
 silicone filled mortar; a three component, MMA-based grout; a poly methyl-methacrylate (PMMA) resin
 used in roofing and waterproofing applications; a polyurethane modified methyl methacrylate
 (PUMMA) vehicular and pedestrian traffic coating system; and a MMA resin used as a penetrating
 crack healer/sealer or to fortify extremely porous concrete substrates.
- 5847

5848 The vinyl ester silicone filled mortar contained concentrations of DCHP at less than 0.005 percent and 5849 when used with chemical-resistant masonry units and the proper membrane, it will protect concrete and steel substrates from chemical attack and physical abuse. The mortar is a two-part system including a 5850 5851 liquid and the powder (which contains DCHP), which must be mixed together (3.25 parts powder to 1 5852 part liquid) prior to trowel based application of an average one-eighth inch thick bed directly on top of 5853 membrane or preceding course of brickwork. According to the company, this product is used in the 5854 construction of floors, sumps, trenches, tanks, vessels and bleach towers in chemical processing; food 5855 and beverage plants; dairies; laboratories; and textile, steel and pulp and paper mills (Sauereisen, 2024, 5856 2022).

5857

5858 The three component MMA based grout is flowable, non-shrink, durable polymer grout that according 5859 to the company's website, can be used as the grouting of bearing plates on bridges and trestles, rehabilitation of bridge decks, airport runways, expansion joints and column grouting. DCHP can be 5860 5861 found in the catalyst or Part B in concentrations of 50 to 51 percent. Seven to 14 fluid ounces (oz) 5862 (depending on the ambient air temperature) of the catalyst/Part B, is mixed with 1 gallon of Part A resin, 5863 and 70 lb of Part C grout aggregate. Once mixed, the company directs workers to distribute the blended 5864 resin over the surface and brush in or prepare a form and pour the material into place (ChemMasters, 5865 2024, 2018, 2017a, b). 5866

- The PMMA resin is used in roofing and waterproofing applications through a two-part plus fleece/membrane self-flashing and self-adhering system, which according to the company is used in structural below-grade concrete surfaces, and protected roof and split-slab decks (<u>CETCO, 2024, 2018a</u>, <u>b</u>, <u>c</u>). DCHP has been identified in the catalyst powder at 50 percent which is then mixed with the resin at various ratios ranging from 2 to 6 percent depending on the weight of the resin used and temperature.
- The polyurethane modified methyl methacrylate (PUMMA) vehicular and pedestrian traffic coating
 system, is specifically designed for use in parking structures, balconies, stadium seating, walkways,
 plaza decks, etc. (Hydro-Gard, 2012a, b). This is a multi-component system, which uses a catalyst that
 contains DCHP in concentrations of 40 to 55 percent combined with a resin and a flashing or polyester
 fleece to create a liquid applied waterproofing membrane/coating (Hydro-Gard, 2024, 2017a, b).
- 5878
- 5879 Finally, the last product example for commercial paints and coatings is an MMA resin that is used as a 5880 penetrating crack healer/sealer or to fortify extremely porous concrete substrates, such as parking and bridge decks, loading docks and warehouses. DCHP can be found in the initiator component in 5881 5882 concentrations of 50 to less than 100 percent. To begin the hardening process the workers must add roughly 0.5 oz to a gallon of resin at around 32 to 39 degrees, increasing up to 2 oz at 90 to 105 degrees 5883 5884 Fahrenheit. The product is then recommended to be spread evenly on the surface as a flood coat with a 5885 squeegee or rollers and allowed to absorb completely into the concrete substrate (Euclid Chemical 5886 Company, 2019a, b, 2018).
- 5887

5888Note these listed examples are not all inclusive of every product under this COU, and that EPA expects5889that these types of products would be purchased by commercial operations and applied by professional

5890 contractors in various commercial settings. The Agency also expects that some of these products are 5891 likely to be used for industrial applications; however, they would be available and used in smaller scale 5892 commercial settings for similar purposes (*e.g.*, protection on structural components, construction).

5893

5894 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a process
regulator in paints and coating manufacturing, which has been recategorized in the COU table to
"stabilizing agent" after discussions with the company that purchased the previous 2016 reporting
company (U.S. EPA, 2024aj). See Appendix D for more information on the changes from the COUs
from the *Final Scope of the Risk Evaluation for Dicyclohexyl Phthalate (DCHP); CASRN 84-61-7* (U.S.
EPA, 2020b).

5901

In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a stabilizing agent
 in paints and coating manufacturing.

5904E.20 Commercial Use – Other Articles with Routine Direct Contact During5905Normal Use Including Rubber Articles; Plastic Articles (Hard)

5906 This COU is referring to the commercial use of DCHP in various rubber and plastic articles that are 5907 intended for routine direct contact. The 2020 CDR reporting category "other articles with routine direct 5908 contact during normal use including rubber articles; plastic articles (hard)" is intended to capture items 5909 such as gloves, boots, clothing, rubber handles, gear levers, steering wheels, handles, pencils, and 5910 handheld device casing. Given the use of DCHP as a general-purpose plasticizer for PVC and non-PVC 5911 applications, EPA expects that this use of DCHP has been identified in previous CDR reports as "plastic 5912 and rubber products not covered elsewhere."

5913

According to information provided to EPA, DCHP is used as a plasticizer in plastic and rubber products used in the aerospace industry (AIA, 2019) and a variety of transportation equipment such as both vehicles production parts and replacement parts (*e.g.*, brake calipers, fender shim, disc brake assembly) (MEMA, 2019). The Alliance of Automobile Manufacturers and the Motor & Equipment Manufacturers Association did explain that "[t]he average scope of the relative mass of DCHP in the parts from the Alliance's data collection is 0.24 gram. Excluding body/exterior parts, that average drops below 0.01 gram" (MEMA, 2019).

As such, workers would be expected to handle or touch products covered by this COU with their hands and be exposed to DCHP through dermal contact.

5924

5925 Examples of CDR Submissions

In 2016 one CDR company reported the commercial use of DCHP (CASRN 84-61-7) in plastic and
rubber products not covered elsewhere.

- 5928
- 5929 In 2020 the same CDR company reported the commercial use of DCHP (CASRN 84-61-7) as a
- 5930 plasticizer in other articles with routine direct contact during normal use including rubber articles;
- 5931 plastic articles (hard), which is a further refined description compared to the 2016 CDR cycle code of
- 5932 "plastic and rubber products not covered elsewhere."

5933 E.21 Consumer Use – Adhesives and Sealants

5934 This COU is referring to the consumer use of DCHP in adhesives and sealants. According to

5936 additive, and impurity in adhesives in amounts less than 1 percent (ACA, 2019). EPA has identified 5937 DCHP in a multi-purpose nitrocellulose household glue at one to five percent with suggested 5938 applications of china, vases, plastic, wood, metal, and crafts (ITW Permatex, 2024; Midwest 5939 Technology Products, 2024; ITW Permatex, 2021) as well as adhesives and sealants meant for the industrial and commercial automotive industry that are also available to consumer customers (Lord 5940 5941 Corporation, 2021, 2020, 2017). For example, the two-part metal bonding adhesive is meant for use in 5942 various elements of an automotive (e.g., panel bonding, weld and rivet bonding of quarter panels, rear 5943 body panels, roof panels, door skins, van side panels and outer truck bed panels) and has a DCHP 5944 concentration of one to five percent (Lord Corporation, 2017). EPA has also identified various two-part 5945 adhesive anchoring systems, such as a two-part hammer-capsule system designed for use in the 5946 installation of a threaded rod into solid concrete and masonry materials that contained DCHP 5947 concentrations of 1 to 2.5 percent (DeWalt, 2024b, 2022, 2020), as well as another two-part polyester 5948 liquid system to be used once again in construction and building environments (MKT, 2023a, b, 2018). 5949

Aside from the household glue, EPA expects that the primary use of several of these products is meant
to occur in industrial/commercial applications only; however, the Agency notes that several of these
products can be sourced by DIY consumers through various online vendors (DeWalt, 2024a; Lord
<u>Corporation, 2024; MKT, 2024</u>).

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5955 This COU was not reported in the 2016 or 2020 CDR cycles.

5956 5957

E.22 Consumer Use – Other Articles with Routine Direct Contact During Normal Use Including Rubber Articles; Plastic Articles (Hard)

5958 This COU is referring to the consumer use of DCHP in various rubber and plastic articles that are 5959 intended for consumer use through routine direct contact. The 2020 CDR reporting category "other 5960 articles with routine direct contact during normal use including rubber articles; plastic articles (hard)" is 5961 intended to capture items such as gloves, boots, clothing, rubber handles, gear levers, steering wheels, 5962 handles, pencils, and handheld device casing. Given the use of DCHP as a general-purpose plasticizer 5963 for PVC and non-PVC applications, EPA expects that this use of DCHP has been identified in previous 5964 CDR reports as "plastic and rubber products not covered elsewhere."

According to information provided to EPA, DCHP is used as a plasticizer in plastic and rubber products used in the aerospace industry (AIA, 2019) as well as a variety of transportation equipment such as both vehicles production parts and replacement parts (MEMA, 2019). The Alliance of Automobile Manufacturers and the Motor & Equipment Manufacturers Association did explain that "[t]he average scope of the relative mass of DCHP in the parts from the Alliance's data collection is 0.24 gram. Excluding body/exterior parts, that average drops below 0.01 gram" (MEMA, 2019).

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5965

According to additional information provided to EPA in 2021, DCHP (referred to in this case as Uniplex 250) has been used as an article in a "range of construction products-boards" (LANXESS, 2021). These boards are presumed to be used in a variety of commercial applications and settings; however, could still be a source of exposure for consumers.

5977

As such, consumers would be expected to handle or touch products covered by this COU with theirhands and be exposed to DCHP through dermal contact.

5980

5981 Examples of CDR Submissions

5982 In the 2016 CDR cycle, one company reported the consumer use of DCHP (CASRN 84-61-7) in plastic 5983 and rubber products not covered elsewhere.

5984 In the 2020 CDR cycle, the same company reported the consumer use of DCHP (CASRN 84-61-7) as a 5985 plasticizer in other articles with routine direct contact during normal use including rubber articles; 5986 plastic articles (hard), which is a further refined description compared to the 2016 CDR cycle code of 5987 "plastic and rubber products not covered elsewhere."

5988] 5989

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E.23 Consumer Use – Other Consumer Articles that Contain DCHP from: Inks, Toner, and Colorants; Paints and Coatings; and Adhesives and Sealants

5991 This COU is referring to the consumer use of articles that contain DCHP from inks, toner, and colorants, 5992 paints and coatings and adhesives and sealants.

According to information provided to EPA in 2021, DCHP (referred to in this case as Uniplex 250) has
been used as an element of PVC inks/PVC plastisol formulations (LANXESS, 2021; U.S. EPA, 2019e).
Uniplex 250 is also marketed as being used as a polymer additive in labels and printing ink formulations
(Hallstar Website) and has been used as part of the screen-printing process for textiles (Gans Ink and
Supply, 2018). EPA expects consumers to exposed to DCHP through various products, such as textiles,
labels, packaging, etc.

6000

6001 The Agency has also identified several examples of commercial paints and coatings that already have 6002 DCHP incorporated as a plasticizer or combine two (or even multiple) components where DCHP acts as 6003 a phlegmatizer with BPO in unsaturated polyesters or MMA systems (U.S. EPA, 2024aj). These paints 6004 and coatings that utilize DCHP, are often applied in commercial settings such as in roofing, 6005 construction, and in cement/protection for high traffic areas (etc.)-often to provide waterproofing, UV 6006 protection and/or chemical resistance. In particular, EPA identified a product that is used as a vehicular 6007 and pedestrian traffic coating system, specifically designed for use in parking structures, balconies, 6008 stadium seating, walkways, plaza decks, etc. (Hydro-Gard, 2024, 2017a, b, 2012a, b). EPA expects consumers to be exposed to DCHP through this coating in areas where consumer access is presumed, 6009 6010 such as balconies and stadium seating.

6011

Additionally, DCHP is used during the cellulose film production to bathe or coat the film, giving it
barrier properties as well as promoting heat seal. This cellulose film is then used in a variety of labeling,
and packaging end uses (U.S. EPA, 2020c; Earthjustice, 2019). Any packaging or cellulose film end
uses that are not subject to the U.S. Food and Drug Administration (FDA) regulations, would be
captured under this COU. EPA would expect dermal exposure to DCHP through handling cellulose film.

6017

6018 Finally, EPA has identified commercial or industrial adhesives and sealants that already have DCHP 6019 incorporated as a plasticizer or combine a two-part adhesive where DCHP acts as a phlegmatizer in 6020 unsaturated polyesters or MMA systems (U.S. EPA, 2024aj). The American Coatings Association explained that DCHP is a plasticizer, additive, and impurity in adhesives in amounts less than one 6021 6022 percent (ACA, 2019). According to information provided to EPA, DCHP is used as an adhesive within 6023 the aerospace industry (AIA, 2019), and an adhesive sealant for body panel assemblies and parts by 6024 automobile manufacturers applications (MEMA, 2019). EPA has also identified various industrial and 6025 commercial applications of adhesives and sealants in the construction industry, electronics etc. As a 6026 result, the Agency expects consumer to be exposed to DCHP through various complex articles that used 6027 an adhesive and sealant that contained DCHP, such as electronics, cars, airplanes, and 6028 building/construction materials.

6029

6030 Examples of CDR Submissions

- In the 2016 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a plasticizer in
- 6032 printing ink manufacturing. One company reported the use of DCHP as a process regulator in paints and
- 6033 coating manufacturing, which has been recategorized in the COU table to "stabilizing agent" after
- discussions with the company that purchased the previous 2016 reporting company (U.S. EPA, 2024aj).
- 6035 Another company reported the use of DCHP as an adhesive and sealant chemicals in adhesive 6036 manufacturing.
- 6036 manufactu 6037
- 6037 In the 2020 CDR cycle, one company reported the use of DCHP (CASRN 84-61-7) as a stabilizing agent
 - 6039 in paints and coating manufacturing and one company reported the use of DCHP (CASKN 84-01-7) as a stabilizing agent
 - 6040 adhesive manufacturing.

6041 **E.24 Disposal**

Each of the COUs of DCHP may generate waste streams of the chemical. For purposes of the DCHP

- risk evaluation, this COU refers to the DCHP in a waste stream that is collected from facilities and
- households and are unloaded at and treated or disposed at third-party sites. This COU also encompasses
- 6045 DCHP contained in wastewater discharged by consumers or occupational users to a POTW or other,
- 6046 non-POTW for treatment, as well as other wastes.
- 6047

6048 DCHP is expected to be released to other environmental media, such as introductions of biosolids to soil

or migration to water sources, through waste disposal (*e.g.*, disposal of formulations containing DCHP,

6050 plastic and rubber products, and transport containers). Disposal may also include destruction and

- 6051 removal by incineration. Recycling of DCHP and DCHP containing products is considered a different
- 6052 COU. Environmental releases from industrial sites are assessed in each COU.

6053Appendix FDRAFT OCCUPATIONAL EXPOSURE VALUE6054DERIVATION

6055 EPA has calculated a draft 8-hour existing chemical occupational exposure value to summarize the 6056 occupational exposure scenario and sensitive health endpoints into a single value. This calculated draft value may be used to support risk management efforts for DCHP under TSCA section 6(a), 15 U.S.C. 6057 6058 section 2605. EPA calculated the draft value rounded to 0.63 mg/m³ for inhalation exposures to DCHP as an 8-hour time-weighted average (TWA) and for consideration in workplace settings (see Appendix 6059 6060 F.1) based on the acute, non-cancer human equivalent concentration (HEC) for developmental toxicity 6061 (*i.e.*, phthalate syndrome-related effects on the developing male reproductive system). 6062 6063 TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk 6064 factors, and thus this draft occupational exposure value represents a risk-only number. If risk management for DCHP follows the finalized risk evaluation, EPA may consider costs and other non-risk 6065 factors, such as technological feasibility, the availability of alternatives, and the potential for critical or 6066 essential uses. Any existing chemical exposure limit used for occupational safety risk management 6067 6068 purposes could differ from the draft occupational exposure value presented in this appendix based on 6069 additional consideration of exposures and non-risk factors consistent with TSCA section 6(c). 6070 6071 This calculated draft value for DCHP represents the exposure concentration below which exposed 6072 workers and ONUs are not expected to exhibit any appreciable risk of adverse toxicological outcomes, accounting for PESS. It is derived based on the most sensitive human health effect (*i.e.*, effects on the 6073 6074 developing male reproductive system) and exposure duration (*i.e.*, acute) relative to benchmarks and a standard occupational scenario assumption of an 8-hour workday. 6075 6076 6077 EPA expects that at the draft occupational exposure value of 0.047 ppm (0.63 mg/m³), a worker or ONU 6078 also would be protected against developmental toxicity from intermediate and chronic duration

6079 occupational exposures if ambient exposures are kept below this draft occupational exposure value. The
 6080 Agency has not separately calculated a draft short-term (*i.e.*, 15-minute) occupational exposure value
 6081 because EPA did not identify hazards for DCHP associated with this very short duration.

6081 6082

6083 EPA did not identify a government-validated method for analyzing DCHP in air.

60846085 The Occupational Safety and Health Administration (OSHA) has not set a permissible exposure limit

(PEL) as an <u>8-hour TWA for DCHP</u>. EPA located several occupational exposure limits for DCHP
(CASRN 84-61-7) in other countries (<u>https://ilv.ifa.dguv.de/limitvalues/20258</u>). Identified 8-hour TWA
values range from 3 mg/m³ in Denmark to 5 mg/m³ in Austria, Ireland, New Zealand, South Africa, and
the United Kingdom. Additionally, EPA found that <u>New Zealand</u> and the <u>United Kingdom</u> have an
established occupational exposure limit of 5 mg/m³ (8-hour TWA) in each country's code of regulation
that is enforced by each country's worker safety and health agency.

6092 **F.1 Draft Occupational Exposure Value Calculations**

This appendix presents the calculations used to estimate draft occupational exposure values using inputs derived in this draft risk evaluation. Multiple values are presented below for hazard endpoints based on different exposure durations. For DCHP, the most sensitive occupational exposure value is based on non-cancer developmental effects and the resulting 8-hour TWA is rounded to 0.63 mg/m³.

6098 Draft Acute Non-cancer Occupational Exposure Value

6099The draft acute occupational exposure value (EV_{acute}) was calculated as the concentration at which the6100acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx6101F-1:

6102

6103 Equation_Apx F-1.

6105
$$EV_{acute} = \frac{HEC_{acute}}{Benchmark MOE_{acute}} * \frac{AT_{HECacute}}{ED} * \frac{IR_{resting}}{IR_{workers}} =$$

6

107
$$\frac{0.95 \text{ ppm}}{30} * \frac{\frac{24h}{d}}{\frac{8h}{d}} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.047 \text{ ppm}$$

6108

6109
$$EV_{acute} \left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{EV \, ppm \, * MW}{Molar \, Volume} = \frac{0.047 \, ppm \, * 330.4 \frac{g}{mol}}{24.45 \frac{L}{mol}} = 0.63 \frac{\text{mg}}{\text{m}^3}$$

6110

6111 Draft Intermediate Non-cancer Occupational Exposure Value

6112 The draft intermediate occupational exposure value (EV_{intermediate}) was calculated as the concentration at 6113 which the intermediate MOE would equal the benchmark MOE for intermediate occupational exposures 6114 using Equation_Apx F-2:

6116 Equation_Apx F-2.

6115

6118
$$EV_{intermediate} = \frac{HEC_{intermediate}}{Benchmark MOE_{intermediate}} * \frac{AT_{HEC intermediate}}{ED * EF} \frac{IR_{resting}}{IR_{workers}}$$

6119

6120
$$= \frac{0.95 \text{ ppm}}{30} * \frac{\frac{24h}{d} * 30d}{\frac{8h}{d} * 22d} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.063 \text{ ppm} = 0.86 \frac{\text{mg}}{\text{m}^3}$$

6121

6122 Draft Chronic Non-cancer Exposure Value

6123 The draft chronic occupational exposure value (EV_{chronic}) was calculated as the concentration at which

6124 the chronic MOE would equal the benchmark MOE for chronic occupational exposures using6125 Equation_Apx F-3:

6126

6127 Equation_Apx F-3.

6128

$$EV_{chronic} = \frac{HEC_{chronic}}{Benchmark MOE_{chronic}} * \frac{AT_{HEC \ chronic}}{ED * EF * WY} * \frac{IR_{resting}}{IR_{workers}}$$

6130

6129

6131
$$= \frac{0.95 \text{ ppm}}{30} * \frac{\frac{24h}{d} * \frac{365d}{y} * 40 \text{ } y * 0.6125 \frac{\text{m}^3}{hr}}{\frac{8h}{d} * \frac{250d}{y} * 40 \text{ } y * 1.25 \frac{\text{m}^3}{hr}} = 0.068 \text{ ppm} = 0.92 \frac{\text{mg}}{\text{m}^3}$$

6132 Where:

 $AT_{hecate} = \text{Averaging time for the POD/HEC used for evaluating non-cancer}$

6134			acute occupational risk based on study conditions and HEC
6135			adjustments (24 h/day).
6136	AT_{HEC} intermediate	=	Averaging time for the POD/HEC used for evaluating non-cancer
6137			intermediate occupational risk based on study conditions and/or
6138			any HEC adjustments (24 h/day for 30 days).
6139	AT_{HECchronic}	=	Averaging time for the POD/HEC used for evaluating non-cancer
6140			chronic occupational risk based on study conditions and/or HEC
6141			adjustments (24 h/day for 365 days/year) and assuming the
6142			same number of years as the high-end working years (WY, 40
6143			years) for a worker.
6144	Benchmark MOE _{acute}	=	Acute non-cancer benchmark margin of exposure, based on the
6145			total uncertainty factor of 30
6146	Benchmark MOE _{intermedia}	$_{te} =$	Intermediate non-cancer benchmark margin of exposure, based on
6147			the total uncertainty factor of 30
6148	Benchmark MOE _{chronic}	=	Chronic non-cancer benchmark margin of exposure, based on the
6149			total uncertainty factor of 30
6150	EV_{acute}	=	Acute occupational exposure value
6151	$EV_{intermediate}$	=	Intermediate occupational exposure value
6152	EV _{chronic}	=	Chronic occupational exposure value
6153	ED	=	Exposure duration (8 h/day)
6154	EF	=	Exposure frequency (1 day for acute, 22 days for intermediate, and
6155			250 days/year for chronic and lifetime)
6156	HEC	=	Human equivalent concentration for acute, intermediate, or chronic
6157			non-cancer occupational exposure scenarios
6158	IR	=	Inhalation rate (default is $1.25 \text{ m}^3/\text{h}$ for workers and $0.6125 \text{ m}^3/\text{h}$
6159			assumed from "resting" animals from toxicity studies)
6160	Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 $^{\circ}$ C
6161	MW	=	Molecular weight of DCHP (330.4 g/mole)
6162	WY	=	Working years per lifetime at the 95th percentile (40 years).
6163			
6164	Unit conversion:		
6165	$1 \text{ ppm} - 1351 \text{ mg/m}^3$ (se		u_{1} under the two states v_{1} and v_{2} and

6165 1 ppm = 13.51 mg/m^3 (see equation associated with the EV_{acute} calculation)