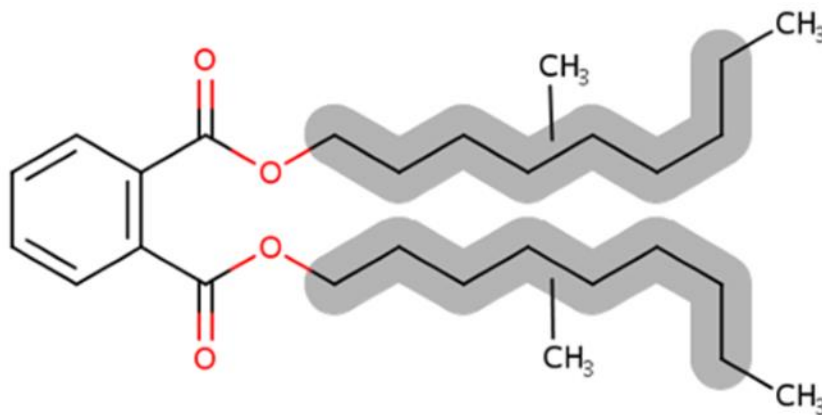




United States
Environmental Protection Agency

Draft Risk Evaluation for Diisodecyl Phthalate (DIDP)

CASRN: 26761-40-0 and 68515-49-1



(Representative Structure)

May 2024

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294 **ACKNOWLEDGEMENTS**

295 This report and associated technical support documents were developed by the United States
296 Environmental Protection Agency (U.S. EPA or the Agency), Office of Chemical Safety and Pollution
297 Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

298

299 **Acknowledgements**

300 The Assessment Team gratefully acknowledges the participation, input, and review comments on the
301 draft risk evaluation and associated technical support documents from OPPT and OCSPP senior
302 managers and science advisors and assistance from EPA contractors ICF (Contract No.
303 68HERC19D0003 and 68HERD22A0001), ERG (Contract No. 68HERD20A0002), and SRC, Inc.
304 (Contract No. 68HERH19D0022). Special acknowledgement is given for the contributions of technical
305 experts from EPA's Office of Research and Development (ORD), including Hisham El-Masri, Rogelio
306 Tornero-Velez, and Elaina Kenyon, for their support in evaluation and interpretation of oral absorption
307 data for DIDP.

308

309 As part of an intra-agency review, the draft DIDP risk evaluation and associated technical support
310 documents were provided to multiple EPA Program Offices for review. Comments were submitted by
311 EPA's Office of Air and Radiation (OAR), Office of Children's Health Protection (OCHP), Office of
312 General Counsel (OGC), Office of Land and Emergency Management (OLEM), ORD, and Office of
313 Water (OW).

314

315 **Docket**

316 Supporting information can be found in the public docket, Docket ID ([EPA-HQ-OPPT-2024-0073](#)).

317

318 **Disclaimer**

319 Reference herein to any specific commercial products, process, or service by trade name, trademark,
320 manufacturer, or otherwise does not constitute or imply its endorsement, recommendation, or favoring
321 by the United States Government.

322

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341 **Technical Support:** Mark Gibson and Hillary Hollinger

342

343 **This draft report and associated technical support documents were reviewed and cleared by**
344 **OPPT and OCSPP leadership.**

345 **EXECUTIVE SUMMARY**346 ***Background***

347 The U.S. Environmental Protection Agency (EPA or the Agency) has evaluated the health and
348 environmental risks of the chemical diisodecyl phthalate (DIDP) under the Toxic Substances Control
349 Act (TSCA). In its draft evaluation, EPA's protective, screening-level approaches demonstrated that
350 DIDP does not pose risk to the environment. Of the forty-seven conditions of use (COUs) that EPA
351 evaluated, only one has risk estimates that raise concerns for workers' exposure to DIDP, and none raise
352 such concerns for consumers or the general population. EPA preliminarily finds that DIDP presents an
353 unreasonable risk of injury to human health, but notes that there is some uncertainty around whether the
354 single COU of DIDP—the high-pressure spraying of it in the workplace—is currently conducted in
355 facilities that use DIDP. The Agency expects that public comments on this draft will help address this
356 uncertainty. Once this draft risk evaluation is informed by public comment and independent, expert peer
357 review advice, EPA will issue a final risk evaluation that includes its determination as to whether DIDP
358 presents unreasonable risk to health or the environment under the TSCA COUs.

359

360 EPA has evaluated DIDP because, as allowed under TSCA, EPA received a request from ExxonMobil
361 Chemical Company, through the American Chemistry Council's High Phthalates Panel, to conduct a
362 TSCA risk evaluation for DIDP. EPA determined that the request met the regulatory criteria and
363 requirements and in 2019 granted the request. DIDP production in the United States has increased
364 significantly over the past decade. In 2015 the production volume was between 100 and 250 million
365 pounds; in 2019 it had increased to between 100 million and 1 billion pounds. (EPA describes
366 production volumes as a range to protect confidential business information.)

367

368 DIDP is used primarily as a plasticizer to make flexible polyvinyl chloride (PVC). It is also used to
369 make building and construction materials; automotive care and fuel products; and other commercial and
370 consumer products including adhesives and sealants, paints and coatings, electrical and electronic
371 products, which are all considered TSCA uses. Workers may be exposed to DIDP when making these
372 products or otherwise using DIDP in the workplace. When it is manufactured or used to make products,
373 DIDP can be released into the water, where because of its properties, most of it will end up in the
374 sediment at the bottom of lakes and rivers. If it is released into the air, DIDP will attach to dust particles
375 and then be deposited onto land or into water. Indoors, DIDP has the potential over time to come out of
376 products and adhere to dust particles. If it does, people could inhale or ingest dust that contains DIDP.

377

378 Past assessments of DIDP from other regulatory agencies that addressed a broad range of DIDP uses
379 have concluded that DIDP did not pose risk to human health or the environment based on its
380 concentration in products and the environment. Notably, the U.S. Consumer Product Safety
381 Commission's (CPSC) risk assessment—which included consideration of exposure from children's
382 products as well as from other sources such as personal care products, diet, consumer products, and the
383 environment—concluded that DIDP exposure comes primarily from diet for women, infants, toddlers,
384 and children, which is a source of exposure that is not by law subject to TSCA.

385

386 In this draft risk evaluation, EPA only evaluated risks resulting from exposure to DIDP from facilities
387 that use, manufacture, or process DIDP under industrial and/or commercial COUs subject to TSCA and
388 the products resulting from such manufacture and processing. Human or environmental exposure to
389 DIDP through uses that are not subject to TSCA (*e.g.*, food, use in food packaging materials, dental
390 sealants and nail polish, fragrances, medical devices, and pharmaceuticals) were not evaluated by EPA
391 or taken into account in reaching its preliminary determination of unreasonable risk to injury of human
392 health, because these uses are explicitly not subject to TSCA. Further, although the production volume
393 of DIDP has increased over the past decade, it is unknown how TSCA versus non-TSCA sources have

394 contributed to this increase. Thus, while EPA is preliminarily concluding in this draft risk evaluation
395 that only one TSCA COU contributes to its draft unreasonable risk finding for DIDP, this conclusion
396 cannot be extrapolated to form conclusions about uses of DIDP that are not subject to TSCA and that
397 EPA did not evaluate.

398

399 ***Determining Unreasonable Risk to Human Health***

400 EPA's TSCA existing chemical risk evaluations must determine whether a chemical substance does or
401 does not present unreasonable risk under its TSCA COUs. The unreasonable risk must be informed by
402 science, but EPA, in making the finding of *presents unreasonable risk*, also considers risk-related
403 factors as described in its risk evaluation framework rule. Risk-related factors beyond the levels of DIDP
404 that can cause specific health effects include the type of health effect under consideration, the
405 reversibility of the health effect being evaluated, exposure-related considerations (*e.g.*, duration,
406 magnitude, or frequency of exposure), population exposed (including any susceptible subpopulations),
407 and the confidence in the information used to inform the hazard and exposure values. These
408 considerations must be included as part of a pragmatic and holistic evaluation of hazard and exposure to
409 DIDP. If an estimate of risk for a specific scenario exceeds the standard risk benchmarks, then the
410 formal determination of whether those risks contribute to the unreasonable risk of DIDP under TSCA
411 must be both case-by-case and context-driven.

412

413 Laboratory animal studies have been conducted to study DIDP for a range of cancer and non-cancer
414 effects on people. EPA reviewed the studies that investigated DIDP's potential to cause cancer and
415 determined that, following EPA's *Guidelines for Carcinogen Risk Assessment*, the evidence is not strong
416 enough to support an assessment of the risk of DIDP to cause cancer in people. The evidence also
417 suggests that DIDP does not cause effects on the developing male reproductive system consistent with a
418 disruption of androgen action—what is known as *phthalate syndrome*—and therefore EPA is not
419 including DIDP in its cumulative risk assessment for six other phthalate chemicals that do demonstrate
420 effects on laboratory animals consistent with phthalate syndrome. The human health hazard that EPA
421 identified as having the strongest evidence to support this draft risk evaluation is developmental toxicity,
422 which means that laboratory animals dosed with DIDP had litters where more rodent offspring died than
423 was the case with the litters of rodents that were not dosed with DIDP. Notably, assessments by Health
424 Canada, U.S. CPSC, European Chemicals Agency (ECHA), European Food Safety Authority (EFSA),
425 and the Australian National Industrial Chemicals Notification and Assessment Scheme have reached
426 similar conclusions regarding the effects of DIDP on development.

427

428 EPA evaluated the risks to people from being exposed to DIDP at work, indoors, and outdoors. In its
429 human health evaluation, the Agency used a combination of screening-level and more-refined
430 approaches to look at how people might be exposed to DIDP through breathing or ingesting dust or
431 other particulates, or through skin contact. In determining whether DIDP presents an unreasonable risk
432 of injury to human health, EPA incorporated the following potentially exposed and susceptible
433 subpopulations (PESS) into its assessment: women of reproductive age, pregnant women, infants,
434 children and adolescents, people who frequently use consumer products and/or articles containing high-
435 concentrations of DIDP, and people exposed to DIDP in the workplace. These subpopulations are PESS
436 because some have greater exposure to DIDP per body weight (*e.g.*, infants, children, adolescents) or
437 due to age-specific behaviors (*e.g.*, mouthing of toys, wires, and erasers by infants and children), while
438 some people may experience exposure from multiple sources or experience higher exposure than others.
439 EPA's robust scientific analysis preliminarily shows DIDP to not result in unreasonable risk to
440 consumers or the general population, including PESS, except for those exposed to DIDP at work for a
441 single COU.

442

443 The single COU that EPA identified as preliminarily presenting unreasonable risk was for a scenario in
444 which unprotected workers were to spray adhesives and sealants that contain DIDP with high-pressure
445 sprayers, because doing so could create high concentrations of DIDP in mist that an unprotected worker
446 could inhale. Because the health effects of concern relate to the developing fetus, the population to
447 which this risk determination is relevant is female workers of reproductive age.
448

449 ***Summary, Considerations, and Next Steps***

450 EPA evaluated a total of 47 TSCA COUs for DIDP. The Agency is preliminarily determining that only
451 the following COU, considered singularly or in combination with other exposures, contributes to the
452 unreasonable risk to unprotected female workers of reproductive age and average adult workers:

453 *Industrial use – adhesives and sealants, due to high-pressure spray applications.*
454

455 The remaining COUs, listed below, are not expected to contribute to the unreasonable risk:

- 456 • Domestic manufacturing (including import);
- 457 • Processing – repackaging;
- 458 • Processing – incorporation into a formulation, mixture, or reaction product – adhesives and
459 sealants manufacturing;
- 460 • Processing – incorporation into a formulation, mixture, or reaction product – laboratory
461 chemicals manufacturing;
- 462 • Processing – incorporation into a formulation, mixture, or reaction product – petroleum
463 lubricating oil manufacturing; lubricants and lubricant additives manufacturing
- 464 • Processing – incorporation into a formulation, mixture, or reaction product – surface modifier in
465 paint and coating manufacturing;
- 466 • Processing – incorporation into a formulation, mixture, or reaction product – plastic material and
467 resin manufacturing;
- 468 • Processing – incorporation into a formulation, mixture, or reaction product – plasticizers (paint
469 and coating manufacturing; pigments; rubber manufacturing);
- 470 • Processing – incorporation into a formulation, mixture, or reaction product – processing aids,
471 specific to petroleum production (oil and gas drilling, extraction, and support activities);
- 472 • Processing – incorporation into a formulation, mixture, or reaction product – other; (part of the
473 formulation for manufacturing synthetic leather);
- 474 • Processing – incorporation into an article – abrasives manufacturing;
- 475 • Processing – incorporation into an article – plasticizers (asphalt paving, roofing, and coating
476 materials manufacturing; construction; automotive products manufacturing, other than fluids;
477 electrical equipment, appliance, and component manufacturing; fabric, textile, and leather
478 products manufacturing; floor coverings manufacturing; furniture and related product
479 manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel,
480 and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant
481 (including pigment) products manufacturing; photographic supplies manufacturing; toys,
482 playground, and sporting equipment manufacturing);
- 483 • Processing – recycling;
- 484 • Distribution in commerce;
- 485 • Industrial use – abrasives (surface conditioning and finish discs; semi-finished and finished
486 goods);
- 487 • Industrial use – functional fluids (closed systems) (SBCA compressor oil);
- 488 • Industrial use – lubricant and lubricant additives;
- 489 • Industrial use – solvents (for cleaning and degreasing);

- 490 • Commercial use – automotive, fuel, agriculture, outdoor use products – automotive products
491 other than fluid;
- 492 • Commercial use – automotive, fuel, agriculture, outdoor use products – automotive, fuel,
493 agriculture, outdoor use products – lubricants;
- 494 • Commercial use – construction, paint, electrical, and metal products – adhesives and sealants
495 (including plasticizers in adhesives and sealants);
- 496 • Commercial use – construction, paint, electrical, and metal products – building/construction
497 materials (wire or wiring systems; joint treatment, fire-proof insulation);
- 498 • Commercial use – construction, paint, electrical, and metal products – electrical and electronic
499 products;
- 500 • Commercial use – construction, paint, electrical, and metal products – paints and coatings
501 (including surfactants in paints and coatings);
- 502 • Commercial use – construction, paint, electrical, and metal products – lacquers, stains, varnishes,
503 and floor finishes (as plasticizer);
- 504 • Commercial use – furnishing, cleaning, treatment/care products – furniture and furnishings;
- 505 • Commercial use – furnishing, cleaning, treatment/care products – construction and building
506 materials covering large surface areas including stone, plaster, cement, glass and ceramic
507 articles; fabrics, textiles, and apparel (as plasticizer) (floor coverings (vinyl tiles, PVC-backed
508 carpeting, scraper mats));
- 509 • Commercial use – furnishing, cleaning, treatment/care products – ink, toner, and colorant
510 products;
- 511 • Commercial use – furnishing, cleaning, treatment/care products – PVC film and sheet;
- 512 • Commercial use – furnishing, cleaning, treatment/care products – plastic and rubber products
513 (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)
- 514 • Commercial use – other uses – laboratory chemicals;
- 515 • Commercial use – other uses – inspection fluid/penetrant;
- 516 • Consumer use – automotive, fuel, agriculture, outdoor use products – automotive products other
517 than fluids;
- 518 • Consumer use – automotive, fuel, agriculture, outdoor use products – lubricants;
- 519 • Consumer use – construction, paint, electrical, and metal products – adhesives and sealants
520 (including plasticizers in adhesives and sealants);
- 521 • Consumer use – construction, paint, electrical, and metal products – building/construction
522 materials covering large surface areas including stone, plaster, cement, glass and ceramic articles
523 (wire or wiring systems; joint treatment)
- 524 • Consumer use – construction, paint, electrical, and metal products – electrical and electronic
525 products;
- 526 • Consumer use – construction, paint, electrical, and metal products – paints and coatings;
- 527 • Consumer use – Furnishing, cleaning, treatment/care products – fabrics, textiles, and apparel (as
528 plasticizer)
- 529 • Consumer use – packaging, paper, plastic, hobby products – arts, crafts, and hobby materials
530 (crafting paint applied to craft);
- 531 • Consumer use – packaging, paper, plastic, hobby products – ink, toner, and colorant products;
- 532 • Consumer use – packaging, paper, plastic, hobby products – PVC film and sheet;
- 533 • Consumer use – packaging, paper, plastic, hobby products – plastic and rubber products (textiles,
534 apparel, and leather; vinyl tape; flexible tubes; profiles; hoses);
- 535 • Consumer use – packaging, paper, plastic, hobby products – toys, playgrounds, and sporting
536 equipment;

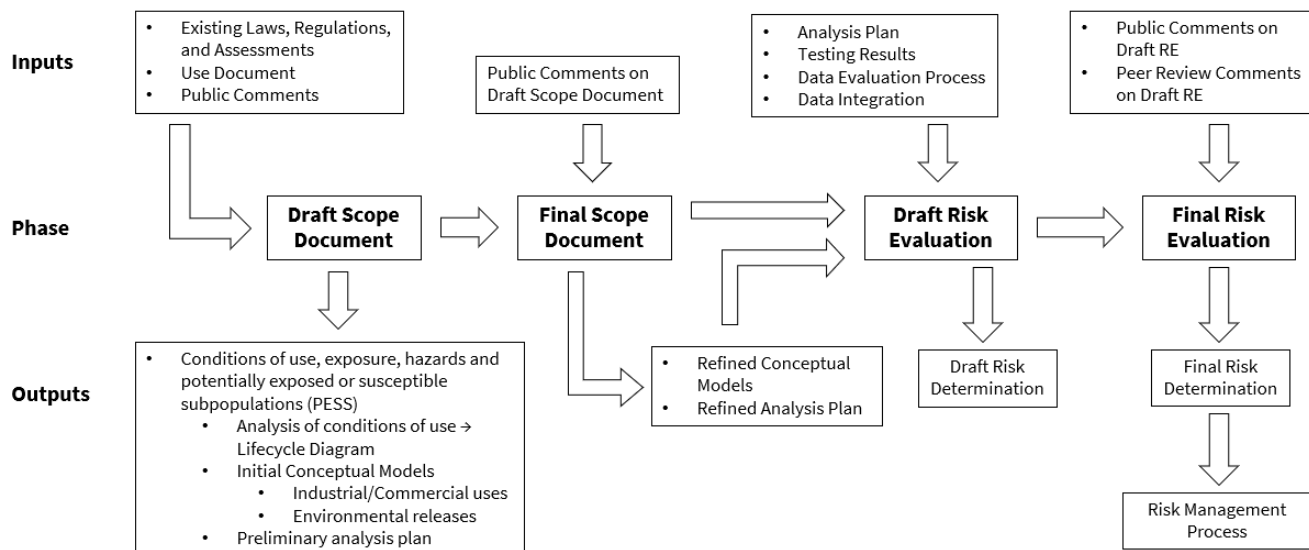
- 537 • Consumer use – other – novelty products, and
538 • Disposal.

539 This draft risk evaluation has been released for public comment and will undergo independent, expert
540 scientific peer review. EPA will issue a final DIDP risk evaluation after considering input from the
541 public and peer reviewers. If in the final risk evaluation the Agency determines that DIDP presents
542 unreasonable risk to human health or the environment, EPA will initiate regulatory action to mitigate
543 those risks.

544 **1 INTRODUCTION**

545 EPA has evaluated diisodecyl phthalate (DIDP) under the Toxic Substances Control Act (TSCA) section
 546 6(b). DIDP is a common chemical name for the category of chemical substances that includes the
 547 following substances: 1,2-benzenedicarboxylic acid, 1,2-diisodecyl ester (CASRN 26761-40-0) and 1,2-
 548 benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CASRN 68515-49-1). Both
 549 CASRNs contain mainly C10 dialkyl phthalate esters. DIDP is primarily used as a plasticizer in
 550 polyvinyl chloride (PVC) in consumer, commercial, and industrial applications. Section 1.1 summarizes
 551 the scope of the draft DIDP risk evaluation and provides information on production volume, a life cycle
 552 diagram (LCD), conditions of use (COUs), and conceptual models used for DIDP. Section 1.2 presents
 553 the organization of this draft risk evaluation. Figure 1-1 describes the major inputs, phases, and
 554 outputs/components of the [TSCA risk evaluation process](#), from scoping to releasing the final risk
 555 evaluation.

556



557

558 **Figure 1-1. TSCA Existing Chemical Risk Evaluation Process**

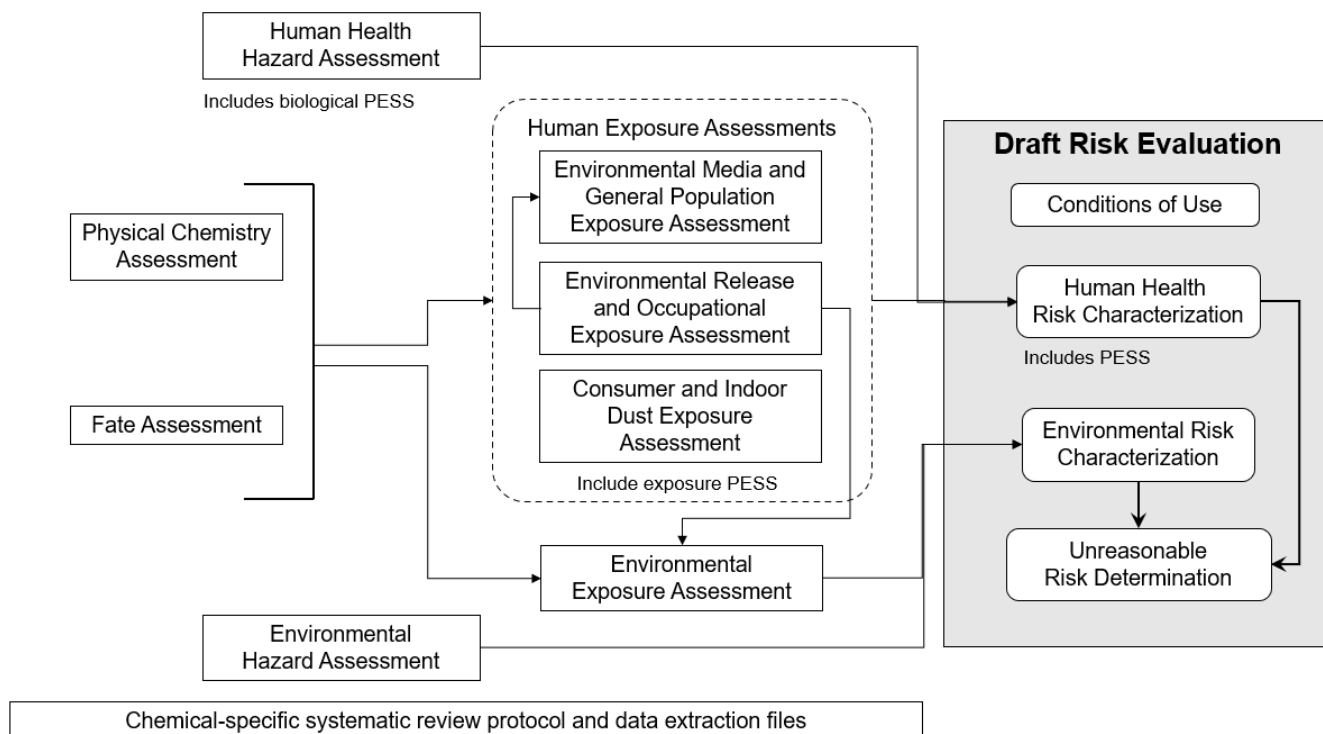
559 **1.1 Scope of the Risk Evaluation**

560 EPA evaluated risk to human and environmental populations for DIDP. Specifically for human
 561 populations, the Agency evaluated risk to workers and occupational non-users (ONUs) via inhalation
 562 routes; risk to workers via dermal routes; risk to ONUs via dermal routes for occupational exposure
 563 scenarios (OESs) in mists and dusts; risk to consumers via inhalation, dermal, and oral routes; and risks
 564 to bystanders via the inhalation route. As described further in Section 4.1.3, using a screening level
 565 analysis EPA assessed risks to the general population, which considered risk from exposure to DIDP via
 566 oral ingestion of surface water, drinking water, fish, and soil from air to soil deposition. For
 567 environmental populations, EPA evaluated risk to aquatic species via water, sediment, and air as well as
 568 risk to terrestrial species via air, soil, sediment, and water.

569 The draft DIDP risk evaluation comprises a series of technical support documents. Each technical
 570 support document contains sub-assessments that inform adjacent, “downstream” technical support
 571 documents. A basic diagram showing the layout and relationship of these assessments is provided below
 572 in Figure 1-2. High-level summaries of each relevant technical support document are presented in this
 573 risk evaluation. Detailed information for each technical support document can be found in the
 574

575 corresponding documents. Appendix C includes a list and citations for all technical support documents
576 and supplemental files included in the draft risk evaluation for DIDP.

577
578 These technical support documents leveraged the data and information sources already identified in the
579 *Final Scope of the Risk Evaluation for Di-isodecyl Phthalate (DIDP), CASRN 26761-40-0 and 68515-*
580 *49-1 (U.S. EPA, 2021b)*. OPPT conducted a comprehensive search for “reasonably available
581 information” to identify relevant DIDP data for use in the risk evaluation. The approach used to identify
582 specific relevant risk assessment information was discipline-specific and is detailed in *Draft Risk*
583 *Evaluation for Diisodecyl Phthalate (DIDP) – Systematic Review Protocol (U.S. EPA, 2024k)*, or as
584 otherwise noted in the relevant technical support documents.
585

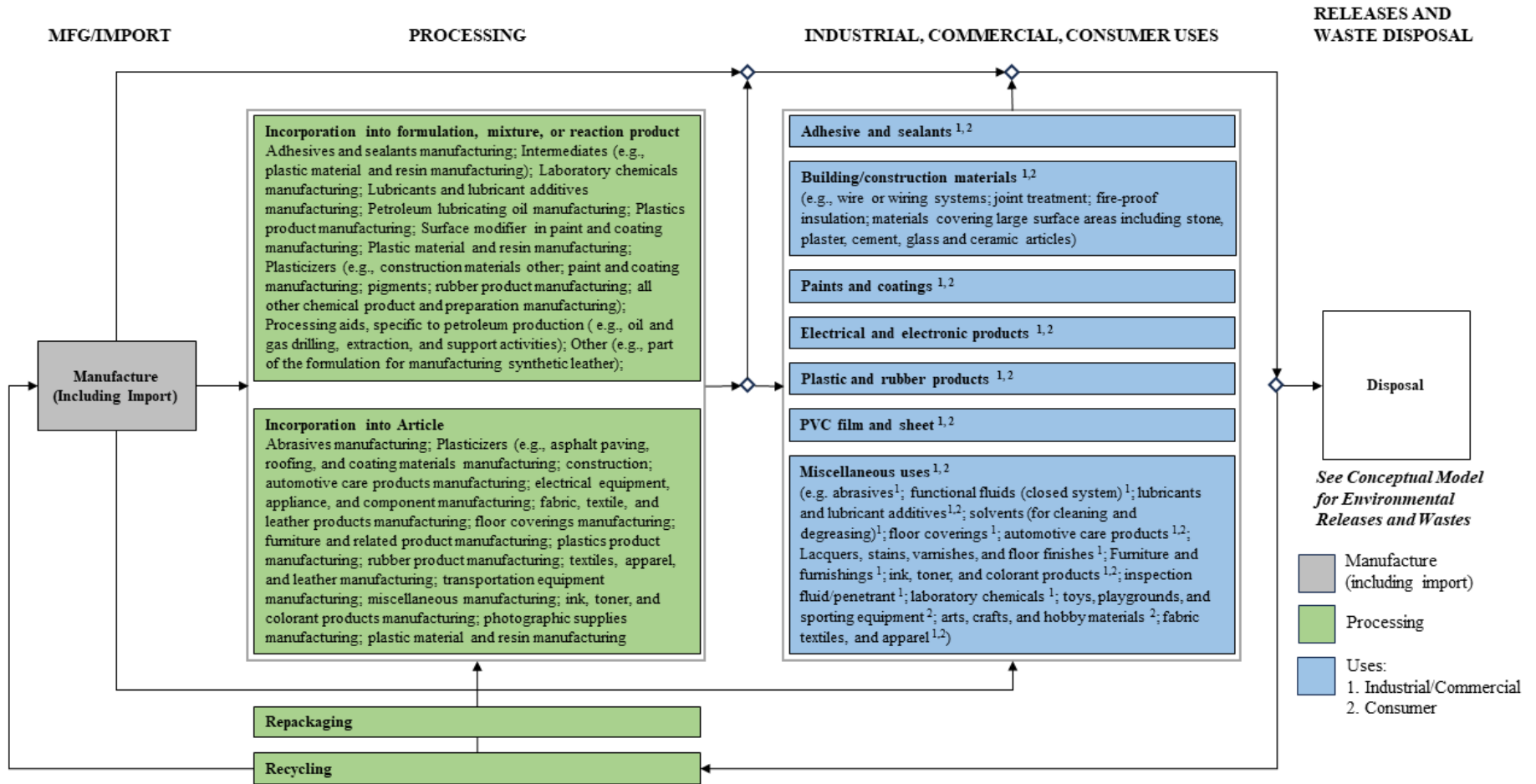


586
587 **Figure 1-2. Draft Risk Evaluation Document Summary Map**

588 1.1.1 Life Cycle and Production Volume

589 The LCD shown in Figure 1-3 depicts the COUs that are within the scope of the risk evaluation, during
590 various life cycle stages, including manufacturing, processing, distribution, use (industrial, commercial,
591 consumer), and disposal. The LCD has been updated since its original inclusion in the final scope
592 document, with consolidated and/or expanded processing and use steps. The key changes are the
593 removal of open system functional fluids and photographic supplies as COUs and refinements of other
594 COUs (e.g., building and construction materials now includes a more specific collection of uses). A
595 complete list of updates and explanations of the updates made to COUs for DIDP from the final scope
596 document to this draft risk evaluation is provided in Appendix D. The information in the LCD is
597 grouped according to the Chemical Data Reporting (CDR) processing codes and use categories
598 (including functional use codes for industrial uses and product categories for industrial and commercial
599 uses). The CDR Rule under TSCA Section 8(a) (see 40 CFR Part 711) requires U.S. manufacturers
600 (including importers) to provide EPA with information on the chemicals they manufacture or import into
601 the United States. EPA collects CDR data approximately every 4 years with the latest collections
602 occurring in 2006, 2012, 2016, and 2020.

603 Descriptions of the industrial, commercial, and consumer use categories identified from the 2019 CDR
604 are included in the LCD (Figure 1-3) ([U.S. EPA, 2020b](#)). The descriptions provide a brief overview of
605 the use category; the *Draft Environmental Release and Occupational Exposure Assessment for*
606 *Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) contains more detailed descriptions (*e.g.*, process
607 descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacturing,
608 processing, use, and disposal category.



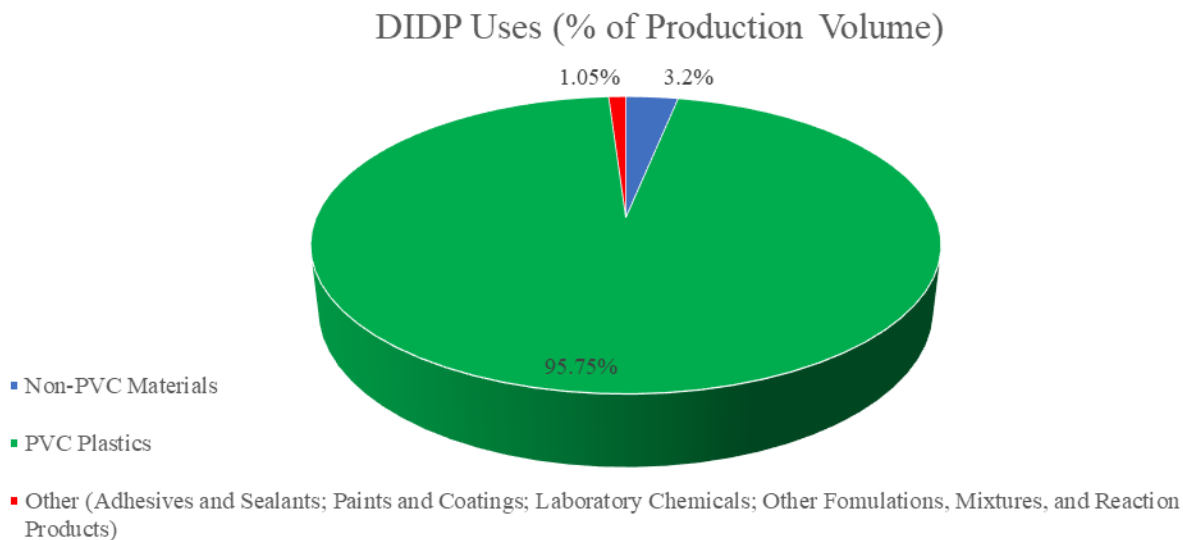
609

610 **Figure 1-3. DIDP Life Cycle Diagram**

611 See Table 1-1 for categories and subcategories of conditions of use. Activities related to distribution (e.g., loading, unloading) will be considered
612 throughout the DIDP life cycle, as well as qualitatively through a single distribution scenario.

613 The production volume for CASRN 26761-40-0 in 2015 was between 1 and 20 million lbs and
614 decreased to less than 1 million lbs in 2019 based on the latest 2020 CDR data. The production volume
615 for CASRN 68515-49-1 in 2015 was between 100 and 250 million lb and increased to between 100
616 million and 1 billion lb in 2019 based on the latest 2020 CDR data. EPA described production volumes
617 as a range to protect production volume data claimed as confidential business information (CBI). For the
618 2016 and 2020 CDR cycle, data collected per chemical included the company name, volume of each
619 chemical manufactured/imported, the number of workers at each site, and information on whether the
620 chemical is used in the commercial, industrial, and/or consumer sector(s).

621
622 The production volumes for the most recent reporting year available in CDR (2019) are split between
623 two CAS Registry Numbers (CASRN) based on the method of manufacture. Due to facility CBI claims
624 on manufacture and import volume, the known production volume of DIDP is presented as a range. For
625 CASRN 26761-40-0, the quantity of known sites with known production volume is sufficient to reduce
626 the uncertainty of production volume for sites reporting their production volume as CBI; there are three
627 sites with 63,646 lb of DIDP shared between them. For CASRN 68515-49-1, however, there is only one
628 site with a reported production volume and that volume accounts for only 0.045 percent to 0.00045
629 percent of the total estimated DIDP production volume as reported in CDR and does not provide any
630 clarity into the overall production volume of the remaining manufacturing and import sites. Due to
631 greater than 99 percent of the total manufacturing and import volume being indicated as CBI by
632 reporting sites, EPA did not have the ability specify the percent of production volume for each OES
633 based on CDR and instead relied on industry submitted data from the ACC and the EU Risk Assessment
634 to estimate relative percentages of use for DIDP. In Figure 1-4 the OES remaining in the “Other”
635 category is comprised of all smaller use case OES, including paints and coatings, adhesives and sealants,
636 laboratory chemicals, and other formulations, mixture, or reaction products. Due to the limitations in
637 reporting, these estimates may not fully reflect actual use and each OES may make up a smaller or larger
638 percentage of the overall production volume of DIDP.



639
640 **Figure 1-4. Percentage of DIDP Production Volume by Use**

641 **1.1.2 Conditions of Use Included in the Risk Evaluation**

642 The *Final Scope of the Risk Evaluation for Di-isodecyl Phthalate (DIDP), CASRN 26761-40-0 and*
643 *68515-49-1* ([U.S. EPA, 2021b](#)) identified and described the life cycle stages, categories, and
644 subcategories that comprise TSCA COUs that EPA planned to consider in the risk evaluation. All COUs

645 for DIDP included in this draft risk evaluation are reflected in the LCD (Figure 1-3) and conceptual
646 models (Section 1.1.2.1). Table 1-1 below presents all COUs for DIDP.

647

648 In this draft risk evaluation, EPA made updates to the COUs listed in the final scope document ([U.S.
649 EPA, 2021b](#)). These updates reflect EPA's improved understanding of the COUs based on further
650 outreach, public comments received, and updated industry code names under the CDR for 2020.
651 Updates included (1) additions and clarification of COUs based on new reporting in CDR for 2020 or
652 information received from stakeholders, (2) consolidation of redundant COUs from the processing
653 lifestage based on inconsistencies found in CDR reporting for DIDP processing and uses and
654 communications with stakeholders about the use of DIDP in industry, and (3) correcting typos or editing
655 for consistency. A complete list of updates and explanations of the updates made to COUs for DIDP
656 from the final scope document to this draft risk evaluation is provided in Appendix D. EPA may further
657 refine COU descriptions for DIDP included in the draft risk evaluation when the final risk evaluation for
658 DIDP is published based upon further outreach, peer-review, and public comment. Table 1-1 presents
659 the revised COUs that were included and evaluated in this Draft Risk Evaluation for DIDP.

660 **Table 1-1. Categories and Subcategories of Use in the Risk Evaluation for DIDP**

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
Manufacturing	Domestic manufacturing	Domestic manufacturing ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)
	Importing	Importing ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)
Processing	Incorporation into formulation, mixture, or reaction product	Adhesives and sealants manufacturing	(U.S. EPA, 2019a)	(U.S. EPA, 2019a)
		Laboratory chemicals manufacturing	EPA-HQ-OPPT-2018-0504-0019	
		Petroleum lubricating oil manufacturing; lubricants and lubricant additives manufacturing	(ACC HPP, 2023; U.S. EPA, 2019a)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)
		Surface modifier and plasticizer in paint and coating manufacturing		(U.S. EPA, 2020a)
		Plastic material and resin manufacturing		(U.S. EPA, 2019a)
		Plasticizers (paint and coating manufacturing; pigments; rubber manufacturing)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)
		Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities) ^e	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
		Other (part of the formulation for manufacturing synthetic leather)	(U.S. EPA, 2020a)	
	Incorporation into articles	Abrasives manufacturing	(U.S. EPA, 2019a)	
		Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive products manufacturing, other than fluids; electrical equipment, appliance, and	EPA-HQ-OPPT-2018-0435-0012 ; (ACC HPP, 2023; U.S. EPA, 2020a, 2019a)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
		component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; transportation equipment manufacturing; ink, toner, and colorant products manufacturing (including pigment); photographic supplies manufacturing; toys, playground, and sporting equipment manufacturing)		
	Repackaging	Repackaging	(U.S. EPA, 2019a)	(U.S. EPA, 2019a)
	Recycling	Recycling		
Distribution in Commerce	Distribution in commerce	Distribution in commerce		
Industrial Uses	Abrasives	Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)	EPA-HQ-OPPT-2018-0435-0012	
	Adhesive and sealants	Adhesives and sealants ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
	Functional fluids (closed systems)	Functional fluids (closed systems) (SCBA compressor oil)	EPA-HQ-OPPT-2018-0435-0012	
	Lubricant and lubricant additives	Lubricants and lubricant additives ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	(Duratherm, 2018; Quincy Compressor, 2012)	
Commercial Uses	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids ^d	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
		Lubricants	(ACC HPP, 2023; U.S. EPA, 2019a)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
Commercial Uses	Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants) ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)
		Building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation) ^d	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005
		Electrical and electronic products ^{df}	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
		Paints and coatings (including surfactants in paints and coatings) ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)
		Lacquers, stains, varnishes, and floor finishes (as plasticizer)		(U.S. EPA, 2020a)
	Furnishing, cleaning, treatment/care products	Furniture and furnishings	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
		Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer) (Floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats)) ^d	(ACC HPP, 2023); EPA-HQ-OPPT-2018-0435-0005	(ACC HPP, 2023); U.S. EPA, 2020a ; EPA-HQ-OPPT-2018-0435-0005
	Packaging, paper, plastic, hobby products	Ink, toner, and colorant products ^d	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0012	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0012
		PVC film and sheet	EPA-HQ-OPPT-2018-0435-0012	EPA-HQ-OPPT-2018-0435-0012
		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses) ^d	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0012 ; (ACC HPP, 2023)	EPA-HQ-OPPT-2018-0435-0005 ; (ACC HPP, 2023); U.S. EPA, 2019a

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
	Other uses	Laboratory chemicals	EPA-HQ-OPPT-2018-0435-0012	EPA-HQ-OPPT-2018-0435-0012
		Inspection fluid/penetrant	EPA-HQ-OPPT-2018-0435-0023	EPA-HQ-OPPT-2018-0435-0023
Consumer Uses	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids ^d	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0022	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0022
		Lubricants ^d	EPA-HQ-OPPT-2018-0435-0005 ; (ACC HPP, 2023 ; U.S. EPA, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (ACC HPP, 2023 ; U.S. EPA, 2019a)
	Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants) ^d	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2020a, 2019a)
		Building/construction materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles (wire or wiring systems; joint treatment) ^d	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005
		Electrical and electronic products ^{d,f}	EPA-HQ-OPPT-2018-0435-0005	EPA-HQ-OPPT-2018-0435-0005 ; (U.S. EPA, 2019a)
		Paints and coatings ^d	(U.S. EPA, 2019a)	(U.S. EPA, 2019a)
	Furnishing, cleaning, treatment/care products	Fabrics, textiles, and apparel (as plasticizer)	(ACC HPP, 2023)	(ACC HPP, 2023 ; U.S. EPA, 2020a)
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials (crafting paint applied to craft)		(U.S. EPA, 2020a, 2019a)
		Ink, toner, and colorant products ^d	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0022 ; (ACC HPP, 2023)	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0022 ; (ACC HPP, 2023)

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
Consumer Uses		PVC film and sheet	EPA-HQ-OPPT-2018-0435-0022	EPA-HQ-OPPT-2018-0435-0022
		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses) ^d	EPA-HQ-OPPT-2018-0435-0005 ; EPA-HQ-OPPT-2018-0435-0022 ; (ACC HPP, 2023)	EPA-HQ-OPPT-2018-0435-0005 ; (ACC HPP, 2023) ; U.S. EPA, 2019a)
		Toys, playgrounds, and sporting equipment ^d	EPA-HQ-OPPT-2018-0435-0005 ; (ACC HPP, 2023)	EPA-HQ-OPPT-2018-0435-0005 ; (ACC HPP, 2023) ; U.S. EPA, 2020a, 2019a)
	Other	Novelty Products	(Sipe et al., 2023) ; Stabile, 2013)	(Sipe et al., 2023) ; Stabile, 2013)
Disposal	Disposal	Disposal ^e		

^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 conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of DIDP in industrial and/or commercial settings.

^c These subcategories reflect more specific conditions of use of DIDP.

^d Circumstances on which ACC HPP is requesting that EPA conduct a risk evaluation. DIDP was limited in toys to less than 0.1% until 2018 by the CPSC. EPA will evaluate risk both from toys that are manufactured with less than .1% of DIDP as well as toys that remain in commerce that were manufactured prior to the CPSC ban and have DIDP in greater amounts than 0.1%. In addition, DIDP processing into sporting equipment is ongoing and evaluated in this draft risk evaluation.

^e Identified in EPA’s Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States (EPA-600-R-16-236Fb), December 2016 document to be a chemical reported to be detected in produced water.

^f New CDR reporting codes of machinery, mechanical appliances, electrical/electronic articles and other machinery, mechanical appliances, electronic/electronic articles are represented under the electrical and electronic articles reporting code, so for commercial and consumer uses these conditions of use are combined.

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1.1.2.1 Conceptual Models

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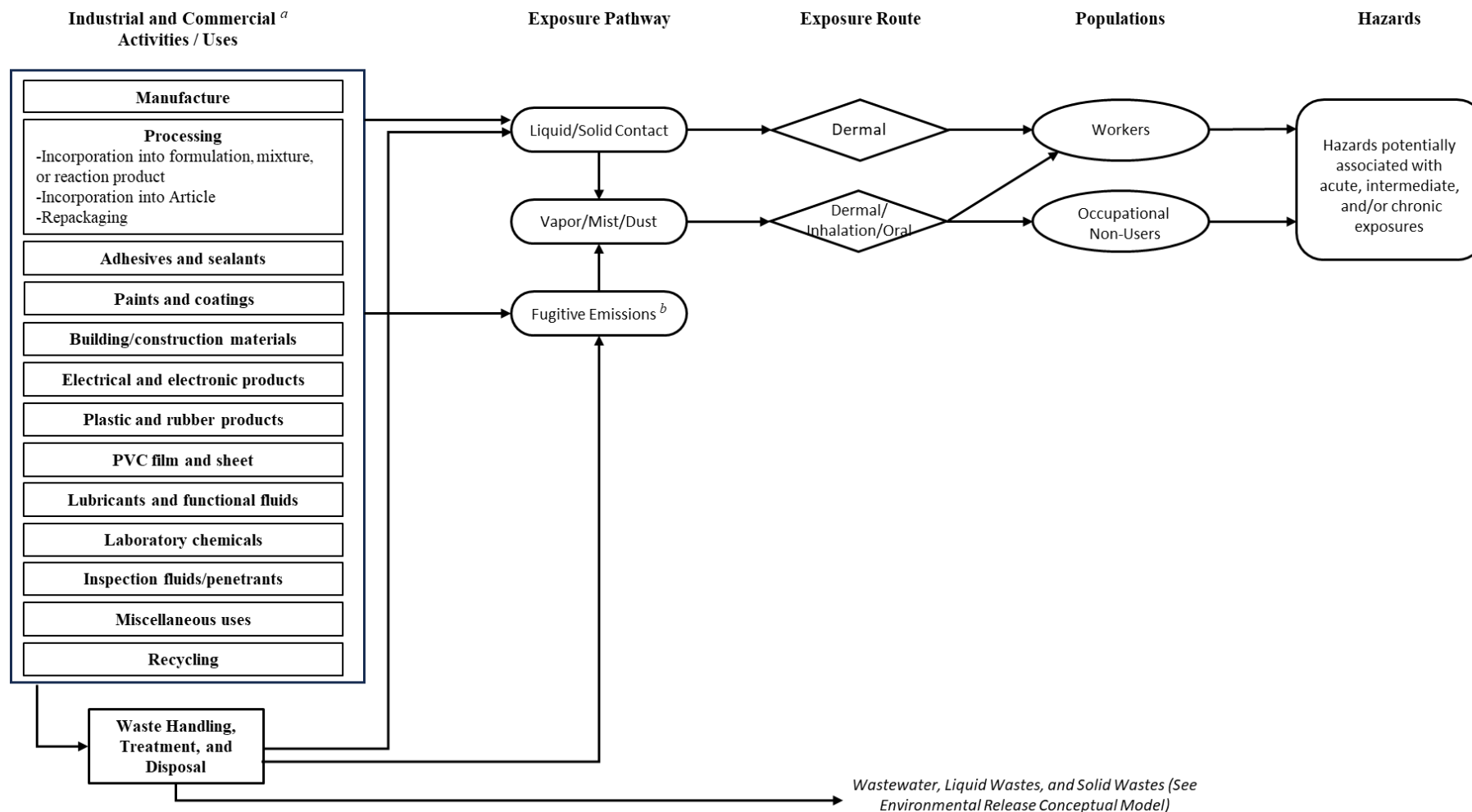
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The conceptual model in Figure 1-5 presents the exposure pathways, exposure routes, and hazards to human populations from industrial and commercial activities and uses of DIDP. There is potential for exposures to workers and/or ONUs via inhalation and dermal routes. The conceptual model also includes potential ONU dermal exposure to DIDP 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, industrial use, commercial use, and disposal), as well as qualitatively through a single distribution scenario.

Figure 1-6 presents the conceptual model for consumer activities and uses, Figure 1-7 presents general population exposure pathways and hazards for environmental releases and wastes, and Figure 1-8 presents the conceptual model for ecological exposures and hazards from environmental releases and wastes.

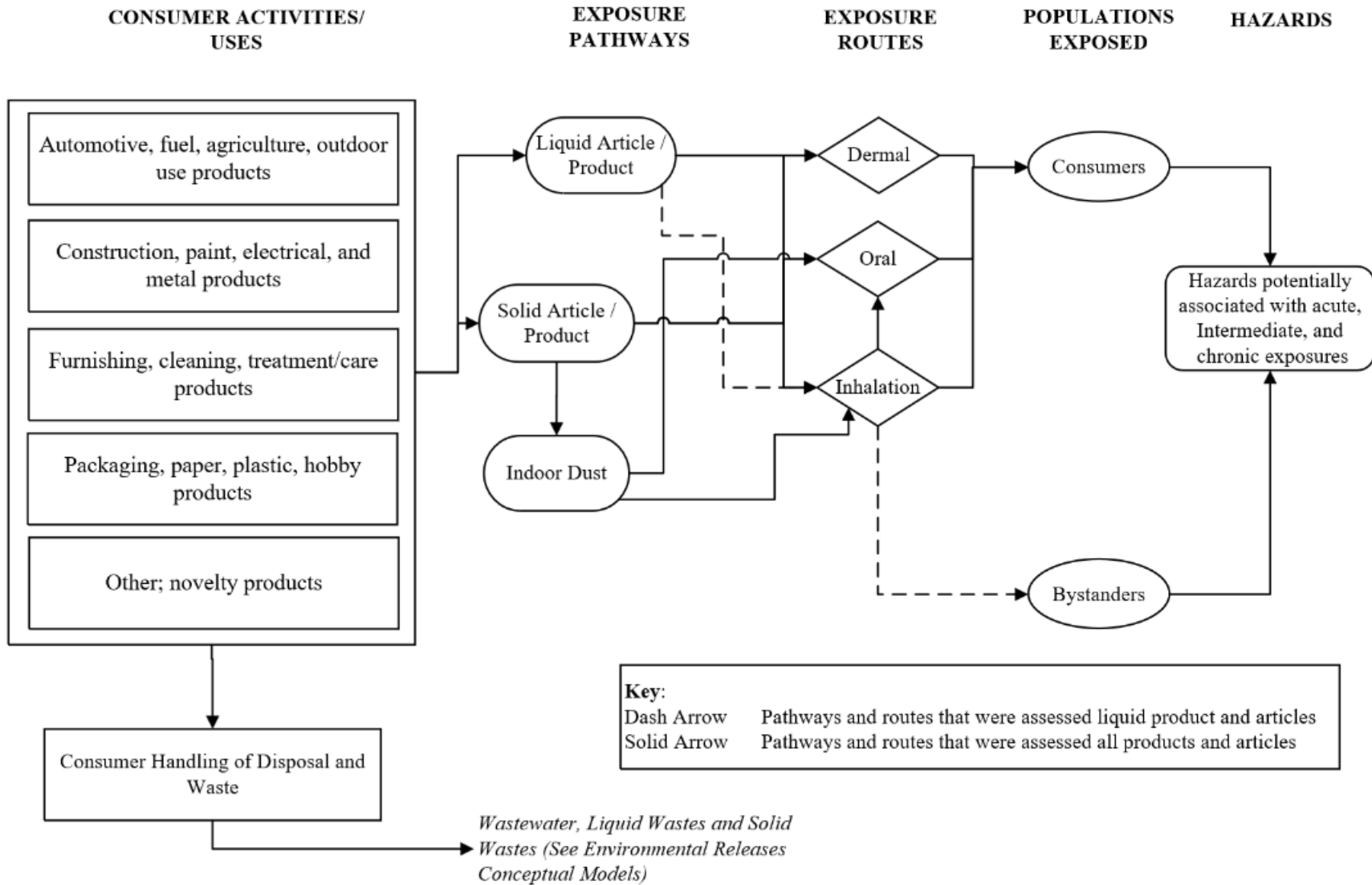


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677 **Figure 1-5. DIDP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards**

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

679 ^b Fugitive air emissions are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors,
680 sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.



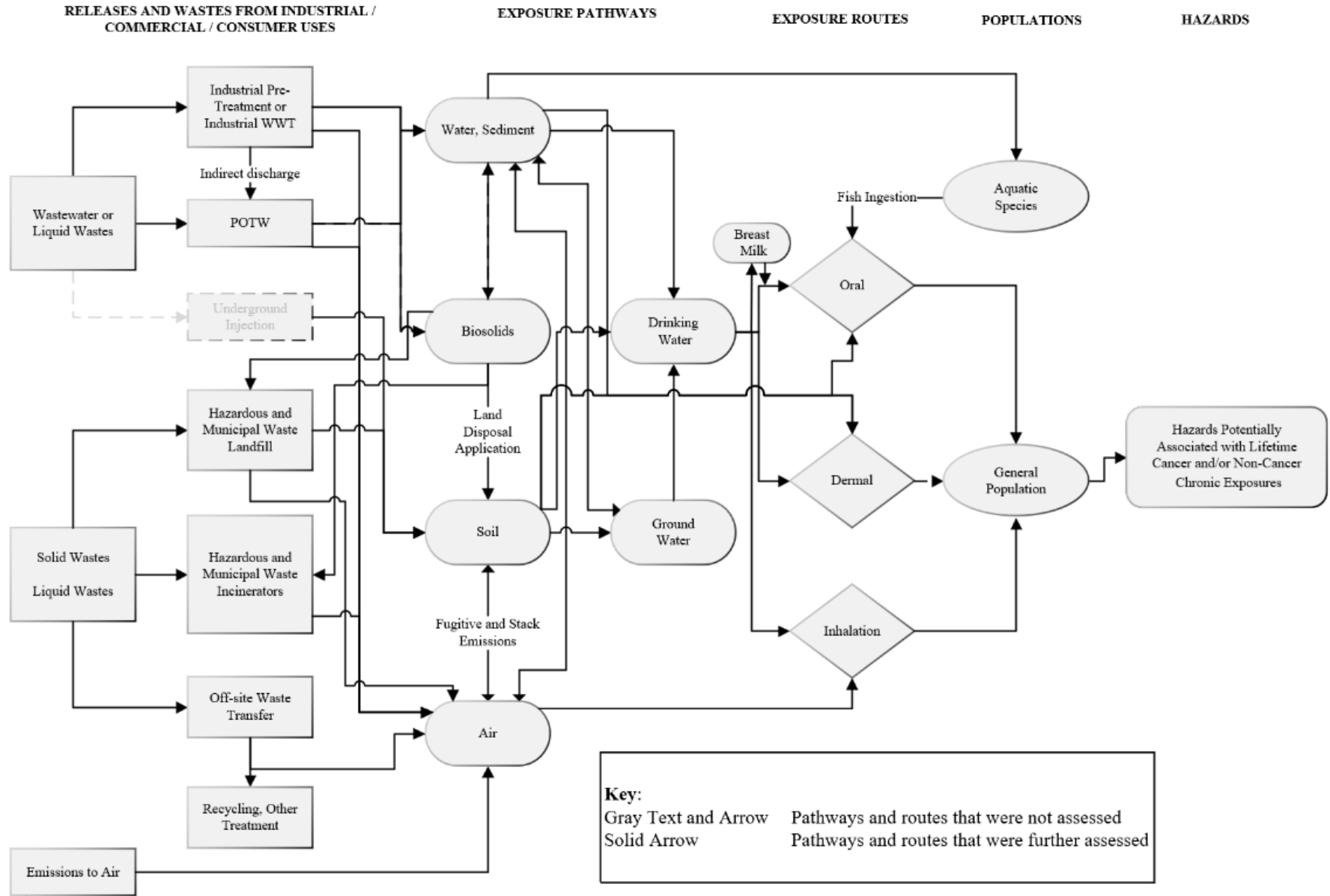
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Figure 1-6. DIDP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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



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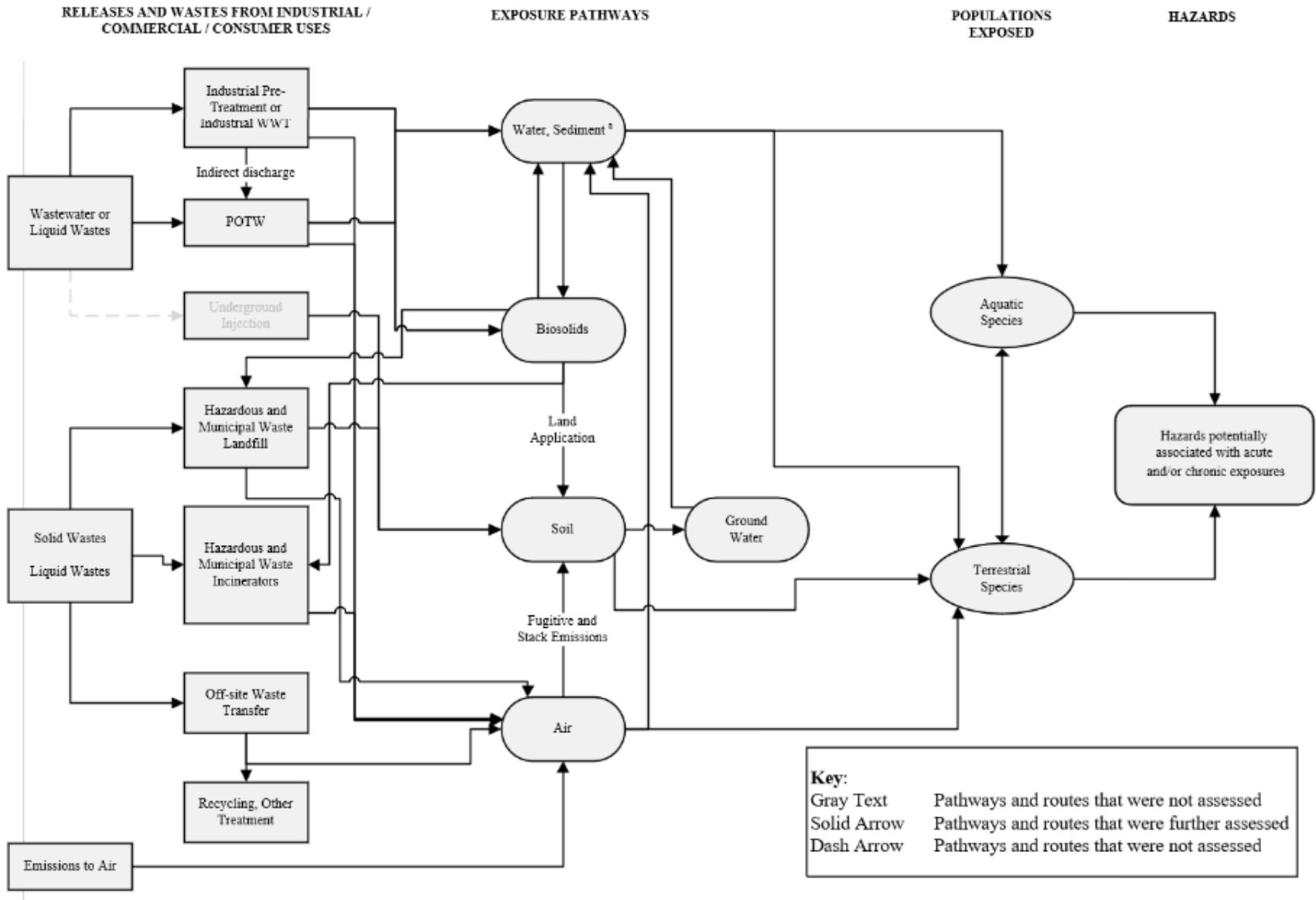
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Figure 1-7. DIDP Conceptual Model for Environmental Releases and Wastes: General Population Hazards

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



688

689 **Figure 1-8. DIDP Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards**

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

692 **1.1.3 Populations and Durations of Exposure Assessed**

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

- 698 • Workers, including average adults and women of reproductive age;
- 699 • ONUs, including average adults;
- 700 • Consumers, including infants (less than 1 year), toddlers (1 to 2 years), children (3 to 5 years and
701 6 to 10 years), young teens (11 to 15 years), teenagers (16 to 20 years) and adults (21 years and
702 above);
- 703 • Bystanders, including infants (less than 1 year), toddlers (1 to 2 years), and children (3 to 5 years
704 and 6 to 10 years); and
- 705 • General population, including infants, children, youth, and adults.

706
707 TSCA Section 6(b)(4)(A) requires that risk evaluations “determine whether a chemical substance
708 presents an unreasonable risk of injury to health or the environment, without consideration of costs or
709 other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible
710 subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of
711 use.” TSCA section 3(12) states that “the term ‘potentially exposed or susceptible subpopulation’
712 [PESS] means a group of individuals within the general population identified by the Administrator who,
713 due to either greater susceptibility or greater exposure, may be at greater risk than the general population
714 of adverse health effects from exposure to a chemical substance or mixture, such as infants, children,
715 pregnant women, workers, or the elderly.”

716
717 This risk evaluation considers PESS throughout the human health risk assessment (Section 4), including
718 throughout the exposure assessment, hazard identification, and dose-response analysis supporting this
719 assessment. EPA incorporated the following potentially exposed and susceptible populations (PESS)
720 into its assessment—women of reproductive age, pregnant women, infants, children and adolescents,
721 people who frequently use consumer products and/or articles containing high-concentrations of DIDP,
722 people exposed to DIDP in the workplace, and tribes whose diets include large amounts of fish. These
723 subpopulations are PESS because some have greater exposure to DIDP per body weight (*e.g.*, infants,
724 children, adolescents) or due to age-specific behaviors (*e.g.*, mouthing of toys, wires, and erasers by
725 infants and children, assessed in the consumer exposure scenarios), while some experience aggregate or
726 sentinel exposures.

727
728 Section 4.3.5 summarizes how PESS were incorporated into the risk evaluation through consideration of
729 potentially increased exposures and/or potentially increased biological susceptibility, and summarizes
730 additional sources of uncertainty related to consideration of PESS.

731 **1.2 Organization of the Risk Evaluation**

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

- 734 • Section 2 summarizes basic physical-chemical characteristics as well as the fate and transport of
735 DIDP.
- 736 • Section 3 includes an overview of releases and concentrations of DIDP in the environment.

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- Section 4 presents the human health risk assessment, including the exposure, hazard, and risk characterization based on the COUs. Section 4 also 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 discusses assumptions and uncertainties and how they potentially impact the strength of the evidence of draft risk evaluation.
 - 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 DIDP. Sections 5 also discusses assumptions and uncertainties and how they potentially impact the strength of the evidence of draft risk evaluation.
 - 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 abbreviations and acronyms used throughout this draft risk evaluation.
 - Appendix B provides a brief summary of the federal, state, and international regulatory history of DIDP.
 - Appendix C includes a list and citations for all technical support documents and supplemental files included in the draft risk evaluation for DIDP.
 - Appendix D provides a summary of updates made to COUs for DIDP from the final scope document to this draft risk evaluation.
 - Appendix E provides descriptions of the DIDP COUs evaluated by EPA.
 - Appendix F provides the draft occupational exposure value for DIDP that was derived by EPA.

759 **2 CHEMISTRY AND FATE AND TRANSPORT OF DIDP**

760 Physical and chemical properties determine the behavior and characteristics of a chemical that inform its
761 condition of use, environmental fate and transport, potential toxicity, exposure pathways, routes, and
762 hazards. Environmental fate and transport includes environmental partitioning, accumulation,
763 degradation, and transformation processes. Environmental transport is the movement of the chemical
764 within and between environmental media, such as air, water, soil, and sediment. Thus, understanding the
765 environmental fate of DIDP informs the specific exposure pathways, and potential human and
766 environmental exposed populations that EPA considered in this draft risk evaluation.

767
768 Sections 2.1 and 2.2 summarize the physical and chemical properties, and environmental fate and
769 transport of DIDP, respectively. EPA’s *Draft Physical Chemistry Assessment for Diisodecyl Phthalate*
770 ([U.S. EPA, 2024i](#)) and *Draft Fate Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024f](#)) provide
771 further details.

772 **2.1 Summary of Physical and Chemical Properties**

773 EPA gathered and evaluated physical and chemical property data and information according to process
774 described in the *Draft Risk Evaluation for Diisodecyl Phthalate (DIDP) – Systematic Review Protocol*
775 ([U.S. EPA, 2024k](#)). During the evaluation of DIDP, EPA considered both measured and estimated
776 physical and chemical property data/information summarized in Table 2-1, as applicable. Information on
777 the full, extracted dataset is available in the *Draft Risk Evaluation for Diisodecyl Phthalate (DIDP) –*
778 *Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for*
779 *Physical and Chemical Properties* ([U.S. EPA, 2024q](#)).

780
781 **Table 2-1. Physical and Chemical Properties of DIDP**

Property	Selected Value(s)	Reference(s)	Data Quality Rating
Molecular formula	C ₂₈ H ₄₆ O ₄		
Molecular weight	446.7 g/mol		
Physical form	Clear Liquid	(Haynes, 2014)	High
Melting point	-50 °C	(Haynes, 2014)	High
Boiling point	>400 °C	(Haynes, 2014)	High
Density	0.967 g/cm ³ at 25 °C	(Cadogan and Howick, 2000)	High
Vapor pressure	5.28E-07 mmHg at 25 °C	(NLM, 2020)	High
Vapor density	15.4 (air = 1)	(NLM, 2020)	High
Water solubility	0.00017 mg/L at 20 °C	(Letinski et al., 2002)	High
Octanol:water partition coefficient (log K _{OW})	10.21 (EPI Suite™)	(U.S. EPA, 2017)	High
Octanol:air partition coefficient (log K _{OA})	13.0 (EPI Suite™)	(U.S. EPA, 2017)	High
Henry’s Law constant	2.132E-04 atm·m ³ /mol at 25 °C	(Cousins and Mackay, 2000)	High
Flash point	>200 °C	(ECJRC, 2003a)	High
Autoflammability	402 °C	(NLM, 2020)	Medium
Viscosity	87.797 cP at 20 °C	(Caetano et al., 2005)	High

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 water sources, and organic carbon:water partition coefficient ($\log K_{OC}$)—are parameters used in the current draft risk evaluation. In assessing the environmental fate and transport of DIDP, EPA considered the full range of results from the available highest quality data sources obtained during systematic review. Information on the full extracted dataset is available in the *Draft Risk Evaluation for Diisodecyl Phthalate (DIDP) – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport* ([U.S. EPA, 2024o](#)). Other fate estimates were based on modeling results from EPI Suite™ ([U.S. EPA, 2012](#)), a predictive tool for physical and chemical properties and environmental fate estimation. Information regarding the model inputs is available in the *Draft Fate Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024f](#)).

EPA evaluated the reasonably available information to characterize the environmental fate and transport of DIDP, the key points of the *Draft Fate Assessment for DIDP* ([U.S. EPA, 2024f](#)) are summarized below and listed in Table 2-2.

Given the consistent results from numerous high-quality studies, there is robust evidence that DIDP

- Is expected to undergo significant direct photolysis and will rapidly degrade in the atmosphere ($t_{1/2} = 0.32$ days).
- Is expected to degrade rapidly via direct and indirect photolysis.
- Is not expected to appreciably hydrolyze under environmental conditions.
- Is expected to have environmental biodegradation half-life in aerobic environments on the order of days to weeks.
- Is not expected to be subject to long range transport.
- Is expected to transform in the environment and via biotic and abiotic processes to form monoisodecyl phthalate, isodecanol, and phthalic acid.
- Is expected to show strong affinity and sorption potential for organic carbon in soil and sediment.
- Will be removed at rates greater than 93 percent in conventional wastewater treatment systems.
- When released to air, will not likely exist in gaseous phase, but will show strong affinity for adsorption to particulate matter.
- Is likely to accumulate and be found in indoor dust.

As a result of limited studies identified, there is moderate confidence that DIDP

- Is not expected to biodegrade under anoxic conditions and may be persistent in anaerobic soils and sediments.
- Is not bioaccumulative in fish in the water column.
- Is expected to be partially removed in conventional drinking water treatment systems both in the treatment process, and via reduction by chlorination and chlorination byproducts in post treatment storage and drinking water conveyance.

822 **Table 2-2. Summary of Environmental Fate Information for DIDP**

Parameter	Value	Source(s)
Octanol:water (Log K _{OW})	10.21	(U.S. EPA, 2017)
Organic carbon:water (Log K _{OC})	5.04–5.78	(Analytical Bio-Chemistry Labs, 1991)
Adsorption coefficient (Log K _d)	2.22–3.60	(Mackay et al., 2006b; Williams et al., 1995)
Octanol:air (Log K _{OA})	13.034 (estimated)	(U.S. EPA, 2017)
Air:water (Log K _{AW})	–2.824 (estimated)	(U.S. EPA, 2017)
Aerobic primary biodegradation in water	39% at 9 days, 53% at 21 days >99% at 28 days	(ECJRC, 2003a)
Aerobic ready biodegradation in water	88% to >99% at 28 days	(ECJRC, 2003a; SRC, 1983)
Aerobic ultimate biodegradation in water	56.2% at 28 days	(SRC, 1983)
Anaerobic biodegradation in sediment	0% after 100 days by CH ₄	(Ejlertsson et al., 1996)
Hydrolysis	125 days at pH 8 and 25 °C, and 3.4 years at pH 7 and 25 °C	(U.S. EPA, 2017)
Photolysis	t _{1/2} (air) = 4.7 to 7.68 hours	(U.S. EPA, 2017)
Environmental degradation half-lives (selected values for modeling)	7.68 hours (air) 10 days (water) 20 days (soil) 90 days (sediment)	(U.S. EPA, 2017)
Wastewater treatment plant (WWTP) removal	>94%	(U.S. EPA, 2017)
Aquatic bioconcentration factor (BCF)	<14.4 L/kg wet weight (Experimental; fish, <i>Cyprinus carpio</i>) 1.3 L/kg wet weight (upper trophic Arnot-Gobas estimation)	(U.S. EPA, 2017; ECJRC, 2003b)
Aquatic bioaccumulation factor (BAF)	9.9 L/kg wet weight (upper trophic Arnot-Gobas estimation)	(U.S. EPA, 2017)
Aquatic food web magnification factor (FWMF)	0.44 (Experimental; 18 marine species)	(Mackintosh et al., 2004)
Terrestrial bioconcentration factor (BCF)	0.01–0.02 Experimental; earthworms (<i>Eisenia fetida</i>)	(ECJRC, 2003b)

823

824 **3 RELEASES AND CONCENTRATIONS OF DIDP IN THE**
825 **ENVIRONMENT**

826 EPA estimated environmental releases and concentrations of DIDP. Section 3.1 describes the approach
827 and methodology for estimating releases. Estimates of environmental releases are presented in Sections
828 3.2 and 3.3 present the approach, methodology, and summary of concentrations of DIDP in the
829 environment.

830 **3.1 Approach and Methodology**

831 This section provides an overview of the approach and methodology for assessing releases to the
832 environment from industrial, commercial, and consumer uses. Specifically, Section 3.1.1 through
833 Section 3.1.3 describe the approach and methodology for estimating releases to the environment from
834 industrial and commercial uses, and Section 3.1.4 describes the approach and methodology for assessing
835 down-the-drain releases from consumer uses.

836 **3.1.1 Manufacturing, Processing, Industrial and Commercial**

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

841 **3.1.1.1 Crosswalk of Conditions of Use to Occupational Exposure Scenarios**

842 EPA categorized the COUs listed in Table 1-1 into OESs. Table 3-1 provides a crosswalk between
843 COUs and OESs. Each OES is developed based on a set of occupational activities and conditions such
844 that similar occupational exposures and environmental releases are expected from the use(s) covered
845 under the OES. For each OES, EPA provided occupational exposure and environmental release results,
846 which are expected to be representative of the entire population of workers and sites for the given OES
847 in the United States. In some cases, EPA defined only a single OES for multiple COUs, while in other
848 cases the Agency developed multiple OESs for a single COU. EPA made this determination by
849 considering variability in release and use conditions and whether the variability required discrete
850 scenarios or could be captured as a distribution of exposures. The *Draft Environmental Release and*
851 *Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) provides
852 further information on each specific OES.

853

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

Life Cycle Stage	Category	Subcategory	OES
Manufacturing	Domestic manufacturing	Domestic manufacturing	Manufacturing
	Importing	Importing	Import and repackaging
Processing	Repackaging	Repackaging	Import and repackaging
	Incorporation into formulation, mixture, or reaction product	Adhesives and sealants manufacturing	Incorporation into adhesives and sealants
		Laboratory chemicals manufacturing	Incorporation into other formulations, mixtures, or reaction products
		Petroleum lubricating oil manufacturing; Lubricants and lubricant additives manufacturing	Incorporation into other formulations, mixtures, or reaction products
		Surface modifier in paint and coating manufacturing	Incorporation into paints and coatings
		Plastic material and resin manufacturing	PVC plastics compounding; non-PVC material compounding
		Plasticizers (paint and coating manufacturing; colorants (including pigments); rubber manufacturing)	Incorporation into paints and coatings; non-PVC material compounding
		Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities)	Incorporation into other formulations, mixtures, or reaction products
		Other (part of the formulation for manufacturing synthetic leather)	PVC plastics compounding; non-PVC material compounding
	Incorporation into articles	Abrasives manufacturing	Application of adhesives and sealants
		Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive products manufacturing, other than fluids; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant (including pigment) products manufacturing; photographic supplies manufacturing; toys, playground, and sporting equipment manufacturing)	PVC plastics converting non-PVC material converting
Processing	Recycling	Recycling	Recycling

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Life Cycle Stage	Category	Subcategory	OES	
Disposal	Disposal	Disposal	Disposal	
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial uses	Abrasives	Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)	Fabrication or use of final products or articles	
	Adhesive and sealants	Adhesives and sealants	Application of adhesives and sealants	
	Functional fluids (closed systems)	Functional fluids (closed systems) (SCBA compressor oil)	Use of lubricants and functional fluids	
	Lubricant and lubricant additives	Lubricants and lubricant additives	Use of lubricants and functional fluids	
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	Use of lubricants and functional fluids	
Commercial uses	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Fabrication or use of final products or articles	
		Lubricants	Use of lubricants and functional fluids	
	Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)		Application of adhesives and sealants
		Building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation)		Fabrication or use of final products or articles
		Electrical and electronic products		Fabrication or use of final products or articles
		Paints and coatings (including surfactants in paints and coatings)		Application of paints and coatings
		Lacquers, stains, varnishes, and floor finishes (as plasticizer)		Application of paints and coatings; application of adhesives and sealants
	Furnishing, cleaning, treatment/care products	Furniture and furnishings		Fabrication or use of final products or articles
		Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer) (floor coverings [vinyl tiles, PVC-backed carpeting, scraper mats])		Fabrication or use of final products or articles
		Ink, toner, and colorant products		Application of paints and coatings

Life Cycle Stage	Category	Subcategory	OES
Commercial uses		PVC film and sheet	Fabrication or use of final products or articles
		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Fabrication or use of final products or articles
	Other uses	Laboratory chemicals	Use of laboratory chemicals
		Inspection fluid/penetrant	Use of inspection fluid and penetrant

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3.1.1.2 Description of DIDP Use for Each OES

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

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

OES	Use of DIDP
Manufacturing	DIDP may be produced through the reaction of phthalic anhydride and isodecyl alcohol using an acid catalyst. The alkyl esters of DIDP are a mixture of branched hydrocarbon isomers in the C9 through C11 ranges, comprised primarily of C10 isomers of decyl esters.
Import and repackaging	DIDP is imported domestically for use and/or may be repackaged before shipment to formulation sites.
PVC plastics compounding	DIDP is used as a plasticizer in PVC and plastic resins manufacturing.
PVC plastics converting	DIDP is used as a plasticizer in PVC and plastic resins product manufacturing.
Incorporation into adhesives and sealants	DIDP is a plasticizer in adhesives and sealants for industrial and commercial use.
Incorporation into paints and coatings	DIDP is a plasticizer in paint, coating, ink, and colorant products for industrial and commercial use.
Incorporation into other formulations, mixtures, or reaction products, not covered elsewhere	DIDP is incorporated into products for asphalt applications, functional fluids, and other product uses.
Non-PVC material compounding	DIDP is used in non-PVC polymers, such as rubber, vinyl resins, cellulose ester plastics, and flexible fibers.
Non-PVC material converting	DIDP is used in non-PVC polymers, such as rubber, vinyl resins, cellulose ester plastics, and flexible fibers.
Application of adhesives and sealants	Industrial and commercial sites use DIDP-containing adhesives and sealants that are roll or bead applied. Products may also be applied using a syringe, caulk gun, or spray gun.
Application of paints and coatings	Industrial and commercial sites use DIDP-containing paints and coatings that are roll, brush, trowel, and spray applied.
Use of laboratory chemicals	DIDP is used for laboratory analyses in both solid and liquid forms.

OES	Use of DIDP
Use of lubricants and functional fluids	DIDP is incorporated into lubricants and functional fluids for air compressors and found in functional fluids for heat exchanger processes in both commercial and industrial processes.
Use of penetrants and inspection fluids	DIDP is found in inspection fluids or penetrants that are used to reveal surface defects on metal parts, including cracks, folds, or pitting.
Fabrication and final use of products or articles	DIDP is found in a wide array of different final articles not found in other OES including automotive care products, abrasives, heat-resistant electric cords, interior leather for cars, roofing sheets, synthetic leather, tool handles, and hoses.
Recycling and disposal	Upon manufacture or use of DIDP-containing products, residual chemical is disposed and released to air, wastewater, or disposal facilities. A fraction of PVC plastics is recycled either in-house or at PVC recycling facilities for continuous compounding of new PVC material.

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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 releases days for the majority of the OESs, EPA developed generic estimates of the number of 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, EPA used Generic Scenario (GSs) or Emission Scenario Document (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.

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

OES	Operating Days (days/year)	Basis
Manufacturing	180	EPA assumed the number of operating days and release days equals 180 days/per year, based on industry-provided information on operating days (ExxonMobil, 2022b).
Import and repackaging	208 to 260	The 2022 <i>Chemical Repackaging GS</i> estimated the total number of operating days based on the shift lengths of operators over the course of a full year, or 174–260 days/year. Shift lengths include 8, 10, or 12 hour/day shifts. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 208–260 days/year (U.S. EPA, 2022).
Incorporation into adhesives and sealants	250	EPA assumed year-round site operation, considering a 2-week downtime, totaling 250 days/year.
Incorporation into paints and coatings	250	EPA assumed year-round site operation, 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, considering a 2-week downtime, totaling 250 days/year.
PVC plastics compounding	223 to 254	The 2014 Plastic Compounding GS and 2021 Plastic Compounding Revised GS estimated the number of operating

OES	Operating Days (days/year)	Basis
		days as 148–264 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021e , 2014c).
PVC plastics converting	219 to 251	The 2004 Additives in Plastic Processing (Converting into Finished Products) GS estimated the number of operating days as 137 to 254 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2004a).
Non-PVC material compounding	234 to 280	The 2014 Plastic Compounding GS, 2021 Plastic Compounding Revised GS, and the 2020 <i>SpERC Factsheet on 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 Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 234–280 days/year (U.S. EPA, 2021e ; ESIG, 2020 ; U.S. EPA, 2014c).
Non-PVC material converting	219 to 251	The 2004 Additives in Plastic Processing (Converting into Finished Products) GS and the 2014 Use of Additives in the Thermoplastic Converting Industry GS estimated the number of operating days as 137 to 254 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2004a).
Application of adhesives and sealants	232 to 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 Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e) Appendix E.9.2) used a 50th to 95th percentile range of 232–325 days/year (OECD, 2015b).
Application of paints and coatings	257 to 287	EPA assessed the total number of operating days based on 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 Factsheet for Industrial Application of Coatings and Inks by 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 (see <i>Draft</i>

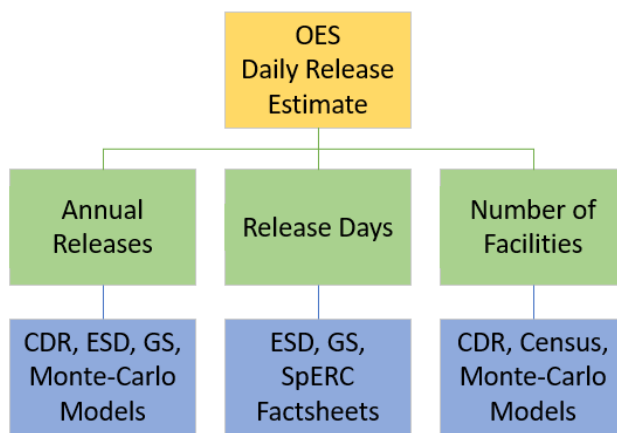
OES	Operating Days (days/year)	Basis
		<i>Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e) used a 50th to 95th percentile range of 257–287 days/year (CEPE, 2020 ; OECD, 2011a, b ; U.S. EPA, 2004c).
Use of laboratory chemicals	Liquid: 235 to 258 Solid: 260	The 2023 Use of Laboratory Chemicals GS estimated the total number of operating days based on the shift lengths of operators over the course of a full year as 174-260 days/year. Shift lengths include 8, 10, or 12 hour/day shifts. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 235-258 days/year (U.S. EPA, 2023e).
Use of lubricants and functional fluids	2 to 4	EPA assumed 1-4 changeouts per year based on identified product data for different types of hydraulic fluids and the ESD on the Lubricant and Lubricant Additives. EPA assumed each changeout occurs over 1 day. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 2–4 days/year (OECD, 2004b).
Use of penetrants and inspection fluids	247 to 249	The 2011 Use of Metalworking Fluids ESD estimated the total number of operating days based on general metal shaping activities as ranging from 246–249 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) estimated a 50th to 95th percentile range of 247–249 days/year (OECD, 2011c).
Recycling and disposal	223 to 254	EPA estimated Recycling and Disposal releases separately. For the PVC recycling OES, the 2014 Plastic Compounding GS and 2021 Plastic Compounding Revised GS estimated the number of operating days as 148–264 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021e, 2014c). EPA evaluated disposal releases within the assessments for each OES. EPA provided operating days for individual OES in this table.
Fabrication and final use of products or articles	N/A	EPA assumed year-round site operation, considering a two-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.

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3.1.3 Daily Release Estimation

For each OES, EPA estimated daily releases for each media of release using CDR, GSs and ESDs, EPA published models, and the previously published *European Union DIDP Risk Assessment*, as shown in Figure 3-1. Generally, EPA used 2020 CDR ([U.S. EPA, 2020a](#)) and 2004 *EU DIDP Risk Assessment* ([ECJRC, 2003a](#)) to estimate annual releases. Where available, EPA used GSs or ESDs for applicable OES to estimate the associated number of release days. Where available, EPA used 2020 CDR, 2020 U.S. County Business Practices, and Monte Carlo modeling data to estimate the number of sites using DIDP within an OES. Generally, information for reporting sites in CDR was sufficient to accurately characterize each reporting site's OES. The *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) describes EPA's approach and methodology for estimating daily releases, as well as detailed facility level results for each OES.

EPA estimated DIDP releases for each OES and release into media applicable to the OES. For DIDP, EPA assumed that releases occur to water, air, or disposal to land.



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Figure 3-1. An Overview of How EPA Estimated Daily Releases for Each OES
CDR = Chemical Data Reporting; ESD = Emission Scenario Document; GS = Generic Scenario

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3.1.4 Consumer Down-the-Drain and Disposal

EPA did not evaluate down-the-drain releases of DIDP for consumer COUs. Although EPA acknowledges that there may be DIDP releases to the environment via the cleaning and disposal of adhesives, sealants, lacquers, and coatings, the Agency did not quantitatively assess these scenarios due to limited information, monitoring data, or modeling tools but provides a qualitative assessment using physical and chemical properties in this section. See EPA's *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024a](#)) for further details. Adhesives, sealants, lacquers, and coatings can be disposed down-the-drain while consumer users wash their hands, brushes, sponges, and other product applying tools. In addition, these products can be disposed of when users no longer have use for them or have reached the product shelf life and taken to landfills. All other solid products and articles in Table 4-6 can be removed and disposed in landfills, or other waste handling locations that properly manage the disposal of products like adhesives, sealants, lacquers, and coatings. EPA did not identify monitoring data for DIDP in surface and drinking water in the United States, but some non-U.S. monitoring studies pointed at 98 percent DIDP removal efficiency and additional non-U.S. sediment data points at DIDP affinity to organic material in sediments ([U.S. EPA, 2024d](#)). Based on the low water solubility and log K_{ow} , DIDP in water is expected to mainly partition to suspended solids present in water. The available information suggest that the use of flocculants and filtering media could potentially help remove DIDP during drinking water treatment by sorption into suspended organic

906 matter, settling, and physical removal. Once products/articles are disposed in landfills there is potential
907 for migration to soils and water. Although there are limited measured data on DIDP in landfill leachates,
908 the data suggest that DIDP is unlikely to be present in landfill leachates. Further, the small amounts of
909 DIDP that could potentially be in landfill leachates will have limited mobility and are unlikely to
910 infiltrate groundwater due to high affinity of DIDP for organic compounds that would be present in
911 receiving soil and sediment ([U.S. EPA, 2024d](#)).

912 **3.2 Summary of Environmental Releases**

913 **3.2.1 Manufacturing, Processing, Industrial and Commercial**

914 EPA combined its estimates for total production volume, release days, number of facilities, and hours of
915 release per day to estimate a range for daily releases for each OES. A summary of these ranges across
916 facilities is presented in Table 3-4. See the *Draft Environmental Release and Occupational Exposure*
917 *Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) for additional detail on deriving the
918 overall confidence score for each OES. For the Fabrication and final use of products or articles OES
919 EPA was not able to estimate release.

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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 Transfer for Disposal ^c	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High-End		Central Tendency	High-End			
Manufacturing	2.56E-07	8.52E-07	Fugitive Air	180		1 - Troy Chemical Corp., Phoenix, AZ	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.14E-01		Stack Air					
	1.05E-01	1.89E-01	Wastewater to Onsite treatment or Discharge to POTW					
	2.70	2.84	Onsite Wastewater Treatment, Incineration, or Landfill					
	1.30	2.25	Landfill					
	4.24E-06	7.47E-06	Fugitive Air	180		3 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	2.31E02	4.01E02	Stack Air					
	1.93E02	5.06E02	Wastewater to Onsite Treatment or Discharge to POTW					
	4.69E03	8.14E03	Onsite Wastewater Treatment, Incineration, or Landfill					
	8.69E02		Landfill					

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OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or Transfer for Disposal ^c	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High-End		Central Tendency	High-End			
Import and Repackaging	4.71E-08	6.13E-08	Fugitive Air	208	260	1 - LG Hausys America, Adairsville, GA	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.57	1.81	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.00E-07	1.05E-07	Fugitive Air	208	260	1 - Harwick Standard Distribution Corp., Akron, OH	Moderate	
	2.31	2.86	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	2.17E-08	4.08E-08	Fugitive Air	208	260	1 - Tremco Inc., Beachwood, OH	Moderate	
	4.17E01	5.16E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	4.69E-08	6.10E-08	Fugitive Air	208	260	1 - Akrochem Corp., Stow, OH.	Moderate	
	1.09	1.50	Wastewater to Onsite Treatment, discharge to POTW, or Landfill.					
	1.01E-07	1.06E-07	Fugitive Air	208	260	1 - Chemspec, Ltd., Uniontown, OH	Moderate	
	2.82	3.51	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	7.38E-08	1.01E-07	Fugitive Air	208	260	3 generic sites CASRN 26761-40-0	Moderate	
	1.39	1.83	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
2.45E-06	6.99E-06	Fugitive Air	208	260	3 generic sites CASRN 68515-49-1	Moderate		
4.12E03	7.98E03	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill						

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OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or Transfer for Disposal ^c	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High-End		Central Tendency	High-End			
PVC plastics compounding	3.29E01	1.45E02	Fugitive or Stack Air	223	254	98–195 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	4.29E02	6.80E02	Wastewater, Incineration, or Landfill					
	1.09E02	1.64E02	Wastewater					
	8.29E01	2.73E02	Fugitive air, Wastewater, Incineration, or landfill					
	2.21E01	1.11E02	Incineration or Landfill					
PVC plastics converting	1.57	6.86	Fugitive or Stack Air	219	251	2,128–4,237 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.54E01	2.35E01	Wastewater, Incineration, or Landfill					
	5.14	7.84	Wastewater					
	3.94	1.30E01	Fugitive air, Wastewater, Incineration, or Landfill					
	1.43E01	2.28E01	Incineration or Landfill					
Non-PVC material compounding	4.39E01	1.44E02	Fugitive or Stack Air	234	280	4–9 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	9.07E02	1.66E03	Wastewater, Incineration, or Landfill					
	8.25E01	1.07E02	Wastewater					
	3.80	1.27E01	Fugitive Air, Wastewater, Incineration, or Landfill					
	6.35E01	1.87E02	Incineration or Landfill					

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OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or Transfer for Disposal ^c	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High-End		Central Tendency	High-End			
Non-PVC material converting	1.11	3.86	Fugitive or Stack Air	219	251	178–212 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	7.79	1.41E01	Wastewater, Incineration, or Landfill					
	2.05	3.31	Wastewater					
	1.08E-01	3.53E-01	Fugitive Air, Wastewater, Incineration, or Landfill					
	6.89	1.23E01	Incineration or Landfill					
Incorporation into adhesives and sealants	6.63E-09	3.35E-08	Fugitive Air	250		6–50 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	5.70E-09	8.04E-08	Stack Air					
	4.16E01	1.08E02	Wastewater, Incineration, or Landfill					
Incorporation into paints and coatings	4.46E-09	1.59E-08	Fugitive Air	250		6–38 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	5.27E-10	5.12E-09	Stack Air					
	3.35E01	1.08E02	Wastewater, Incineration, or Landfill					
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	4.13E-07	1.04E-06	Fugitive Air	250		1–2 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.06E-07	4.97E-07	Stack Air					
	7.39E02	1.29E03	Wastewater, Incineration, or Landfill					

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OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or Transfer for Disposal ^c	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High-End		Central Tendency	High-End			
Application of paints and coatings with overspray controls [No overspray controls]	2.62E-09 [2.62E-09]	6.90E-09 [6.87E-09]	Fugitive Air	257	287	222-1,242 generic sites [223-1,226 generic sites]	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	6.34E-01 [6.32]	2.04 [2.04E01]	Stack Air [Unknown]					
	6.29 [5.58E-01]	1.98E01 [1.55]	Wastewater, Incineration, or Landfill					
Application of adhesives and sealants	9.80E-09 2.61	3.24E-08 1.45E01	Fugitive or Stack Air Wastewater, Incineration, or Landfill	232	325	84-1,056 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
Use of laboratory chemicals – liquid	1.94E-09 1.83	3.31E-09 3.47	Fugitive or Stack Air Wastewater, Incineration, or Landfill	235	258	225-2,095 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
Use of laboratory chemicals – solid	1.08E-04 9.83E-03	2.37E-04 9.88E-03	Stack Air Wastewater, Incineration, or Landfill	260		36,873	Moderate	
Use of lubricants and functional fluids	7.29E01 3.21E01	2.69E02 1.30E02	Wastewater Landfill	2	4	2,596-18,387 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.19 2.64E01	6.31 1.40E02	Recycling Fuel Blending (Incineration)					
Use of penetrants and inspection fluids	3.68E-03 2.14E-02	4.80E-3 2.77E-02	Fugitive Air Wastewater, Incineration, or Landfill	247	249	15,315-21,892 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	2.46E-09 2.50E-02	4.57E-09 3.25E-02	Fugitive Air Wastewater, Incineration, or Landfill					

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OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, ^a Air Emission, ^b or Transfer for Disposal ^c	Estimated Release Frequency across Sites (days) ^d		Number of Facilities ^e	Weight of Scientific Evidence Rating ^f	Sources
	Central Tendency	High-End		Central Tendency	High-End			
Recycling	2.33E-02	4.68E-01	Stack Air	223	254	58 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.84	3.36	Fugitive Air, Wastewater, Incineration, or Landfill					CDR, Peer-reviewed literature (GS/ESD)
	7.80E-01	1.70	Wastewater					CDR, Peer-reviewed literature (GS/ESD)

^a Direct discharge to surface water; indirect discharge to non-POTW; indirect discharge to POTW
^b Emissions via fugitive air or stack air, or treatment via incineration
^c Transfer to surface impoundment, land application, or landfills
^d Where available, EPA used industry provided information, ESDs, or GSs to estimate the number of release days for each condition of use.
^e Where available, EPA used 2020 CDR ([U.S. EPA, 2020a](#)), 2020 U.S. County Business Practices ([U.S. Census Bureau, 2022](#)), and Monte Carlo models to estimate the number of sites that use DIDP for each condition of use.
^f See Section 3.2.2 for details on EPA’s determination of the weight of scientific evidence rating.

922 **3.2.2 Weight of Scientific Evidence Conclusions for Environmental Releases from**
923 **Manufacturing, Processing, Industrial and Commercial Sources**

924 For each OES, EPA considered the assessment approach, the quality of the data and models, and the
925 uncertainties in the assessment results to determine a level of confidence as presented in Table 3-4.

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927 Integration of the environmental release evidence streams across systematic review and non-systematic
928 review sources results in an environmental release estimate for the chemical of interest. EPA made a
929 judgment on the weight of scientific evidence supporting the environmental release estimate based on
930 the strengths, limitations, and uncertainties associated with the environmental release estimates. EPA
931 described this judgment using the following confidence descriptors: robust, moderate, slight, or
932 indeterminate.

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934 In determining the strength of the overall weight of scientific evidence, EPA considered factors that
935 increase or decrease the strength of the evidence supporting the exposure estimate (whether measured or
936 estimated), including quality of the data/information, relevance of the data to the exposure scenario
937 (including considerations of temporal relevance, spatial relevance), and the use of surrogate data when
938 appropriate. In general, higher rated studies (as determined through data evaluation) increase the weight
939 of scientific evidence when compared to lower rated studies, and EPA gave preference to chemical- and
940 scenario-specific data over surrogate data (similar chemical or scenario). For example, a conclusion of
941 moderate weight of scientific evidence is appropriate where there is measured release data from a
942 limited number of sources such that there is a limited number of data points that may not cover most or
943 all of the sites within the COU. A conclusion of slight weight of scientific evidence is appropriate where
944 there is limited information that does not sufficiently cover all sites within the COU, and the
945 assumptions and uncertainties are not fully known or documented. See EPA's *Draft systematic review*
946 *protocol supporting TSCA risk evaluations for chemical substances, Version 1.0: A generic TSCA*
947 *systematic review protocol with chemical-specific methodologies* ([U.S. EPA, 2021a](#)) for additional
948 information on weight of scientific evidence conclusions.

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

Table 3-5. Summary of Overall Confidence in Environmental Release Estimates by OES

OES	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	<p>EPA found limited chemical specific data for the manufacturing OES and assessed environmental releases using models and model parameters derived from CDR, the <i>2023 Methodology for Estimating Environmental Releases from Sampling Wastes</i> (U.S. EPA, 2023c), and sources identified through systematic review (including 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 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 a discrete value. Additionally, Monte Carlo modeling uses a large number of data points (simulation runs) and considers the full distributions of input parameters. EPA used facility-specific DIDP manufacturing volumes for all facilities that reported this information to CDR and DIDP-specific operating parameters derived using data with a high data quality ranking from a current U.S. manufacturing site to provide more accurate estimates than the generic values provided by the EPA/OPPT models.</p> <p>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, EPA lacks DIDP facility production volume data for some DIDP manufacturing sites that claim this information as CBI for the purposes of CDR reporting; therefore, throughput estimates for these sites are based on the CDR reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. Additional limitations include uncertainties in the representativeness of the industry-provided operating parameters and the generic EPA/OPPT models for all DIDP manufacturing sites.</p> <p>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.</p>
Import and repackaging	<p>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 <i>Chemical Repackaging GS</i>, which the systematic review process rated high for data quality (U.S. EPA, 2022). EPA also referenced the <i>2023 Methodology for Estimating Environmental Releases from Sampling Wastes</i> (U.S. EPA, 2023c) and 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 ESD and EPA/OPPT models. 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 at sites than discrete value. Additionally, Monte Carlo modeling uses a high number of data points (simulation runs) and the full distributions of input parameters. EPA used facility specific DIDP import volumes for all facilities that reported this information to CDR.</p> <p>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 ESD 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 DIDP. In addition, EPA lacks DIDP facility import volume data for some CDR-reporting import and repackaging sites that claim this information as CBI; therefore, throughput estimates for these sites are based on the CDR reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude.</p> <p>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.</p>

OES	Weight of Scientific Evidence Conclusion in Release Estimates
<p>Incorporation into adhesives and sealants</p>	<p>EPA found limited chemical specific data for the incorporation into adhesives and sealants OES and assessed releases to the environment using the <i>ESD on the Formulation of Adhesives</i>, which has a high data quality rating based on the systematic review process (OECD, 2009). 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 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 at sites 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 DIDP-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. EPA based the production volume for the OES on use rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 DIDP into adhesives and sealants. In addition, EPA lacks data on DIDP-specific facility production volume and number of formulation sites; therefore, EPA based throughput estimates on CDR which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. The respective share of DIDP use for each OES (as presented in the <i>EU Risk Assessment Report</i>) may differ from actual conditions adding additional uncertainty to estimated releases.</p> <p>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.</p>
<p>Incorporation into paints and coatings</p>	<p>EPA found limited chemical specific data for the incorporation into paints and coatings OES and assessed releases to the environment using the <i>Draft GS for the Formulation of Waterborne Coatings</i>, which has a medium data quality rating based on systematic review (U.S. EPA, 2014a). 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 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 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 DIDP-specific data on concentrations in paint and coating products to provide more accurate estimates of DIDP concentrations than the generic values provided by the GS. EPA based the production volume for the OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 DIDP into paints and coatings, particularly for sites formulating other coating types (<i>e.g.</i>, solvent-borne coatings). In addition, EPA lacks data on DIDP-specific facility production volume and number of formulation sites; therefore, EPA based throughput estimates on CDR which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. The share of DIDP use for each OES presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p>

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>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.</p>
<p>Incorporation into other formulations, mixtures, and reaction products not covered elsewhere</p>	<p>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 <i>Draft GS for the Formulation of Waterborne Coatings</i>, which has a medium data quality rating based on systematic review process (U.S. EPA, 2014a). 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 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. Additionally, EPA used DIDP-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 data quality ratings based on the systematic review process. EPA based the production volume for the OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 the formulation of paints and coatings and may not represent releases from real-world sites that incorporate DIDP into other formulations, mixtures, or reaction products. In addition, EPA lacks data on DIDP-specific facility production volume and number of formulation sites; therefore, EPA based the throughput estimates on CDR which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. Finally, the share of DIDP use for each OES presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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.</p>
<p>PVC plastics compounding</p>	<p>EPA found limited chemical specific data for the PVC plastics compounding OES and assessed releases to the environment using the <i>Revised Draft GS for the Use of Additives in Plastic Compounding</i>, 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 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. Additionally, EPA used DIDP-specific data on concentrations in different DIDP-containing PVC plastic products and PVC-specific additive throughputs in the analysis. These data 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 data quality ratings based on systematic review. EPA based production volumes for the OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 consider all types of plastic compounding and may not represent releases from real-world sites that compound DIDP into PVC plastic raw material. In addition, EPA lacks data on DIDP-</p>

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OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>specific facility production volume and number of compounding sites; therefore, EPA estimated throughput based on CDR which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. The respective share of DIDP use for each OES presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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.</p>
PVC plastics converting	<p>EPA found limited chemical specific data for the PVC plastics converting OES and assessed releases to the environment using the <i>Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry</i>, which has a medium data quality rating based on systematic review (U.S. EPA, 2021f). 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 the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values is more likely to capture actual releases than discrete values. Monte Carlo also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DIDP-specific data on concentrations in different DIDP-containing PVC plastic products and PVC-specific additive throughputs in the analysis. These data provide more accurate estimates than the generic values provided by the GS. The safety and product data sheets that EPA used to obtain these values have high data quality ratings based on systematic review. EPA based the production volume for the OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 DIDP-containing PVC raw material into PVC articles using a variety of methods, such as extrusion or calendaring. In addition, EPA lacks data on DIDP-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 (<i>i.e.</i>, not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. The respective share of DIDP use for each OES presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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.</p>
Non-PVC material compounding	<p>EPA found limited chemical specific data for the non-PVC material compounding OES and assessed releases to the environment using the <i>Revised Draft GS for the Use of Additives in Plastic Compounding</i> and the <i>ESD on Additives in the Rubber Industry</i>. Both sources have a medium data quality rating based on the systematic review process (U.S. EPA, 2021e; OECD, 2004a). 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 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.</p>

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>Additionally, EPA used DIDP-specific concentration data for different DIDP-containing rubber products 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 data quality ratings based on systematic review. EPA based the production volume for the OES on rates cited by the ACC (2020) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 are based on all types of plastic compounding and rubber manufacturing, and the DIDP-specific concentration data only consider rubber products. As a result, these values may not be representative of actual releases from real-world sites that compound DIDP into non-PVC material. In addition, EPA lacks data on DIDP-specific facility production volume and number of compounding sites; therefore, EPA estimated throughput based on CDR which has a reporting threshold of 25,000 lb (i.e., not all potential sites represented) and an annual DIDP production volume range that spans an order of magnitude. The respective share of DIDP use for each OES presented in the EU Risk Assessment Report may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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.</p>
Non-PVC material converting	<p>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. Both documents have a medium data quality rating based on systematic review (U.S. EPA, 2021f; OECD, 2004a). 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 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.</p> <p>Additionally, EPA used DIDP-specific data on concentrations in different DIDP-containing rubber products 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 data quality ratings based on the systematic review process. EPA based the production volume for the OES on rates cited by the ACC (2020) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 consider all types of plastic converting and rubber manufacturing sites, and the DIDP-specific concentration data only considers rubber products. As a result, these generic site estimates may not represent actual releases from real-world sites that convert DIDP containing non-PVC material into finished articles. In addition, EPA lacks data on DIDP-specific facility production volume and number of converting sites; therefore, EPA based throughput estimates on values from industry SpERC documents, CDR data (which has a reporting threshold of 25,000 lb (i.e., not all potential sites represented), and an annual DIDP production volume range that spans an order of magnitude. The share of DIDP use for each OES presented in the EU Risk Assessment Report may differ from actual conditions adding some uncertainty to estimated releases.</p>

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>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.</p>
Application of adhesives and sealants	<p>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>, which has a medium data quality rating based on systematic review (OECD, 2015a). 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 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. Additionally, EPA used DIDP-specific data on concentration and application methods for different DIDP-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 data quality ratings from the systematic review process. EPA based OES PV on rates cited by the ACC (2020), which references the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 DIDP into adhesives and sealants. In addition, EPA lacks data on DIDP-specific facility use volume and number of use sites; therefore, EPA based throughput estimates on values from industry SpERC documents, CDR data (which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented), and an annual DIDP production volume range that spans an order of magnitude. The respective share of DIDP use for each OES as presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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.</p>
Application of paints and coatings	<p>EPA found limited chemical specific data for the application of paints and coatings OES and assessed releases to the environment using the <i>ESD on the Application of Radiation Curable Coatings, Inks and Adhesives</i>, the <i>GS on Coating Application via Spray Painting in the Automotive Refinishing Industry</i>, the <i>GS on Spray Coatings in the Furniture Industry</i>. These documents have a medium data quality rating based on the systematic review process (U.S. EPA, 2014b; OECD, 2011b; U.S. EPA, 2004d). 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 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. Additionally, EPA used DIDP-specific data on concentration and application methods for different DIDP-containing paints and coatings in the analysis. These data provide more accurate estimates than the generic values provided by the GS and ESDs. The safety and product data sheets that EPA obtained these values from have high data quality ratings based on the systematic review process. EPA based production volumes for these OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 ESDs may not represent releases from real-</p>

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>world sites that incorporate DIDP 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 DIDP-specific facility use volume and number of use sites; therefore, EPA based throughput estimates on values from industry SpERC documents, CDR data (which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented), and an annual DIDP production volume range that spans an order of magnitude. The share of DIDP use for each OES presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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</p>
Use of laboratory chemicals	<p>EPA found limited chemical specific data for the use of laboratory chemicals OES and assessed releases to the environment using the <i>Draft GS on the Use of Laboratory Chemicals</i>, which has a high data quality rating based on systematic review (U.S. EPA, 2023e). 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 DIDP materials. EPA believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA used SDSs from identified laboratory DIDP products to inform product concentration and material states.</p> <p>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 DIDP laboratory chemical throughput and number of laboratories; therefore, EPA based the number of laboratories and throughput estimates on stock solution throughputs from the <i>Draft GS on the Use of Laboratory Chemicals</i> and on CDR reporting thresholds. Additionally, because no entries in CDR indicate a laboratory use case and there were no other sources to estimate the volume of DIDP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold, which by definition is expected to over-estimate the average release case.</p> <p>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.</p>
Use of lubricants and functional fluids	<p>EPA found limited chemical specific data for the use of lubricants and functional fluids OES and assessed releases to the environment using the <i>ESD on the Lubricant and Lubricant Additives</i>, which has a medium data quality rating based on systematic review (OECD, 2004b). 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 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. Additionally, EPA used DIDP-specific data on concentration and uses of different DIDP-containing lubricants and functional fluid products in the analysis. These data provide more accurate estimates than the generic values provided by the ESD. The safety and product data sheets that EPA used to obtain these values have high data quality ratings based on systematic review. EPA based production volumes for the OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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</p>

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OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>using DIDP-containing lubricants and functional fluids. In addition, EPA lacks information on the specific facility use rate of DIDP-containing products and number of use sites; therefore, EPA estimated the number of sites and throughputs based on CDR, which has a reporting threshold of 25,000 lb (<i>i.e.</i>, not all potential sites represented), and an annual DIDP production volume range that spans an order of magnitude. The respective share of DIDP use for each OES presented in the <i>EU Risk Assessment Report</i> may differ from actual conditions adding some uncertainty to estimated releases.</p> <p>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 in consideration of the strengths and limitations of reasonably available data.</p>
Use of penetrants and inspection fluids	<p>EPA found limited chemical specific data for the use of penetrants and inspection fluids OES and assessed releases to the environment using the <i>ESD on the Use of Metalworking Fluids</i>, which has a medium data quality rating based on systematic review (OECD, 2011c). 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 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 consider a large number of data points (simulation runs) and the full distributions of input parameters. Because there were no DIDP-containing penetrant products identified, EPA assessed an aerosol and non-aerosol application method based on surrogate DINP-specific penetrant data which also provided DINP concentration. The safety and product data sheets that EPA used to obtain these values have high data quality ratings based on systematic review and provide more accurate estimates than the generic values provided by the ESD. EPA based production volumes for the OES on rates cited by the ACC (2020) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.</p> <p>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 and the surrogate material parameters may not be representative of releases from real-world sites that use DIDP-containing inspection fluids and penetrants. Additionally, because no entries in CDR indicate this OES use case and there were no other sources to estimate the volume of DIDP used in this OES, EPA developed a high-end bounding estimate based on CDR reporting threshold, which by definition is expected to over-estimate the average release case.</p> <p>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.</p>
Fabrication and final use of products or articles	<p>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.</p>
Recycling and disposal	<p>EPA found limited chemical specific data for the recycling and disposal OES. EPA assessed releases to the environment from recycling activities using the <i>Revised Draft GS for the Use of Additives in Plastic Compounding</i> as surrogate for the recycling process. The GS 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 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. Additionally, EPA used DIDP-specific data on concentrations in different DIDP-containing PVC</p>

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	<p>plastic 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 used to obtain these values have high data quality ratings based on systematic review. 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 U.S. and applied it to DIDP PVC market share to define an approximate recycling volume of PVC containing DIDP.</p> <p>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 represent all types of plastic compounding sites and may not represent sites that recycle PVC products containing DIDP. In addition, EPA lacks DIDP-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 DIDP, and may not accurately reflect current U.S. recycling volume.</p> <p>Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, yet the assessment still provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.</p>

955

956 **3.2.3 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the**
957 **Environmental Release Assessment**

958 Manufacturers and importers of DIDP submit CDR data to EPA if they meet reporting threshold
959 requirements. Sites are only required to load production data into CDR if their yearly production volume
960 exceeds 25,000 lb. Sites can claim their production volume as CBI, thereby further limiting the
961 production volume information in CDR. As a result, some sites that produce or use DIDP may not be
962 included in the CDR dataset and the total production volume for a given OES may be under or
963 overestimated. The extent to which sites that are not captured in the CDR reports release DIDP into the
964 environment is unknown. The media of release for these sites is also unknown.

965
966 CDR information on the downstream use of DIDP at facilities is also limited; therefore, there is some
967 uncertainty as to the production volume attributed to a given OES. For OES with limited CDR data,
968 EPA used a 2004 DIDP Risk Assessment published by the European Union, Joint Research Centre and a
969 DIDP report presented by the American Chemistry Council (ACC) to determine approximate production
970 volumes ([ECJRC, 2003a](#)). The ACC report indicates that the use rate of DIDP in the United States is
971 similar to the production volume in the European Union ([ACC, 2020](#)). EPA calculated the production
972 volume for a given OES as the use rate percentage of the total production volume for the relevant OES
973 as defined in the EU Risk Assessment. Specifically, the EU Risk Assessment assumed that 1.1 percent
974 of the total DIDP production volume was used in non-polymer materials (*e.g.*, paints, coatings,
975 adhesives, sealants). EPA split this percentage equally between paint/coating, adhesive/sealant, and
976 other formulation use cases. Due to these uncertainties, the total production volume attributed to a given
977 OES may be under or overestimated.

978
979 Furthermore, DIDP releases at each site may vary from day-to-day such that on any given day the actual
980 daily release rate may be higher or lower than the estimated average daily release rate.

- 981
- 982 • **Use of Census Bureau for Number of Facilities** – In some cases, EPA estimated the maximum
983 number of facilities for a given OES using data from the U.S. Census. In such cases, the
984 maximum number of sites for use in Monte Carlo estimations were determined based on industry
985 data from the U.S. Census Bureau, County and Business Patterns dataset. ([U.S. Census Bureau, 2022](#)).
 - 986 • **Uncertainties Associated with Number of Release Days Estimate** – For most OES, EPA
987 estimated the number of release days using data from GSs, ESDs, or SpERC factsheets. In such
988 cases, EPA used applicable sources to estimate a range of release days over the course of an
989 operating year. Due to uncertainty in DIDP-specific facility operations, release days may be
990 under or overestimated.
 - 991 • **Uncertainties Associated with DIDP-Containing Product Concentrations** – In most cases,
992 the number of identified products for a given OES were limited. In such cases, EPA estimated a
993 range of possible concentrations for products in the OES. However, the extent to which these
994 products represent all DIDP-containing products within the OES is uncertain. For OES with
995 little-to-no product data, EPA estimated DIDP concentrations from GSs or ESDs. Due to these
996 uncertainties, the average product concentrations may be under or overestimated.

997 **3.3 Summary of Concentrations of DIDP in the Environment**

998 Based off the environmental release assessment summarized in Section 3.2 and presented in EPA's
999 *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)*
1000 ([U.S. EPA, 2024e](#)), DIDP is expected to be released to the environment via air, water, biosolids, and

1001 disposal to landfills. Environmental media concentrations were quantified in ambient air, soil from
1002 ambient air deposition, surface water, and sediment. Additional analysis of surface water used as
1003 drinking water was conducted for the Human Health Risk Assessment (Section 4.1.3). Given the
1004 physical chemical properties and fate parameters of DIDP (Section 2), concentrations of DIDP in soil
1005 and groundwater from releases to biosolids and landfills were not quantified. Instead, DIDP in soil and
1006 groundwater are discussed qualitatively. EPA relied on its fate assessment to determine which
1007 environmental pathways to consider for its screening level analysis of environmental exposure and
1008 general population exposure. Details on the environmental partitioning and media assessment can be
1009 found in *Draft Fate Assessment for DIDP* ([U.S. EPA, 2024f](#)) and its use for determining pathways to
1010 assess are detailed in *Draft Environmental Media and General Population Screening for Diisodecyl*
1011 *Phthalate (DIDP)* ([U.S. EPA, 2024d](#)). Briefly, based on DIDP's fate parameters, EPA anticipated DIDP
1012 to be expected predominantly in water, soil, and sediment, with DIDP in soils attributable to air to soil
1013 deposition and land application of biosolids. Therefore, EPA quantitatively assessed concentrations of
1014 DIDP in surface water, sediment, and soil from air to soil deposition. Ambient air concentrations were
1015 quantified for the purpose of estimating soil concentrations from air to soil deposition but was not used
1016 for the exposure assessment as DIDP was not assumed to be persistent in the air ($t_{1/2} = 7.6$ hours
1017 ([Mackay et al., 2006b](#))) and partitioning analysis showed DIDP partitions primarily to soil, compared to
1018 air, water, and sediment, even in air releases. Soil concentration of DIDP from land applications and
1019 resulting concentrations in groundwater were not quantitatively assessed in the screening level analysis
1020 as DIDP was expected to have limited persistence potential and mobility in soils receiving biosolids.

1021
1022 Further detail on the screening-level assessment of each environmental pathway can be found in EPA's
1023 *Draft Environmental Media and General Population Screening for Diisodecyl Phthalate (DIDP)* ([U.S.](#)
1024 [EPA, 2024d](#)). Screening level assessments are useful when there is little location- or scenario-specific
1025 information available. Because of limited environmental monitoring data and lack of location data for
1026 DIDP releases, EPA began its environmental and general population exposure assessment with a
1027 screening-level approach using the highest modeled environmental media concentrations for the
1028 environmental pathways expected to be of greatest concern. Details on the use of screening-level
1029 analyses in exposure assessment can be found in EPA's *Guidelines for Human Exposure Assessment*
1030 ([U.S. EPA, 2019b](#))

1031
1032 In addition to considering the most likely environmental pathways for DIDP exposure based on the fate
1033 properties of DIDP, EPA considered the highest potential environmental media concentrations for the
1034 purpose of a screening-level analysis. The highest environmental media concentrations were estimated
1035 using the release estimates for an OES associated with a COU that resulted in the greatest modeled
1036 concentration of DIDP in a given environmental media type. Therefore, EPA did not estimate
1037 environmental concentrations of DIDP resulting from all OES presented in Table 3-1. The OES
1038 resulting in the highest environmental concentration of DIDP varied by environmental media as shown
1039 in Table 3-6.

1040
1041 High-end concentration of DIDP in surface water and soil from air to soil deposition were estimated for
1042 the purpose of risk screening for environmental exposure described in EPA's *Draft Environmental*
1043 *Exposure Assessment for DIDP* ([U.S. EPA, 2024c](#)) and for general population exposure described in
1044 EPA's *Draft Environmental Media and General Population Screening for Diisodecyl Phthalate (DIDP)*
1045 ([U.S. EPA, 2024d](#)). Ambient air concentrations were quantified to estimate soil concentrations from air
1046 to soil deposition. However, ambient air concentrations themselves were not used for the environmental
1047 or general population exposure as it was not expected to be a major exposure pathway of concern. Table
1048 3-6 summarizes the highest concentrations of DIDP estimated in different environmental media based
1049 on releases to the environment from various OES associated with COUs. This means that the PVC

1050 Plastics Compounding OES yielded the highest water concentrations using a 7Q10 flow and highest soil
 1051 concentration compared to any other OES. The Use of Lubricants and Functional Fluids OES yielded
 1052 the highest water concentration using a 30Q5 flow compared to any other OES. The summary table also
 1053 indicates whether the high-end estimate was used for environmental exposure assessment or general
 1054 population exposure assessment. For the screening-level analysis, if the high-end environmental media
 1055 concentrations did not result in potential environmental or human health risk, no further OES were
 1056 assessed. For the surface water component of this screening analysis, only the OES resulting in the
 1057 highest estimated sediment concentrations was carried forward to the environmental risk assessment
 1058 (PVC plastics compounding), and only the OES resulting in the highest estimated water column
 1059 concentrations was carried forward to the human health risk assessment (Use of lubricants and
 1060 functional fluids).

1061
 1062 **Table 3-6. Summary of High-End DIDP Concentrations in Various Environmental Media from**
 1063 **Environmental Releases**

OES ^a	Release Media	Environmental Media	DIDP Concentration	Environmental or General Population
PVC plastics compounding	Water	Total Water Column (7Q10)	7,460 µg/L	Environmental
		Benthic Pore Water (7Q10)	4,760 µg/L	Environmental
		Benthic Sediment (7Q10)	27,600 mg/kg	Environmental
	Fugitive Air	Soil (Air to Soil Deposition 100 m)	1,850 µg/kg	General Population
		Soil (Air to Soil Deposition 1,000 m)	13 µg/kg	Environmental
Use of lubricants and functional fluids	Water	Surface Water (30Q5)	9,110 µg/L	General Population
		Surface Water (Harmonic Mean)	7,450 µg/L	General Population

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

1064 3.3.1 Weight of Scientific Evidence Conclusion

1065 Detailed discussion of the strengths, limitations, and sources of uncertainty for modeled environmental
 1066 media concentration leading to a weight of scientific evidence conclusion can be found in EPA's *Draft*
 1067 *Environmental Media and General Population Screening for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)).
 1068 However, the weight of scientific evidence conclusion is summarized below for the modeled
 1069 concentrations for surface water and of soil from ambient air to soil deposition.

1070 3.3.1.1 Surface Water

1071 Due to the lack of release data for facilities discharging DIDP to surface waters, releases were modeled,
 1072 and the high-end estimate for each COU was applied for surface water modeling. Additionally, due to
 1073 site-specific release information, a generic distribution of hydrologic flows was developed from
 1074 facilities which had been classified under relevant NAICS codes, and which had NPDES permits citing
 1075 NHDPlus V2.1 reach codes for receiving waterbodies. From the distributions of flow statistics reported,
 1076 the median receiving waterbody represented a stream with minimal flow, dominated by the effluent
 1077 from the facility, while the lower end of the distribution represented a stream with essentially no flow
 1078 beyond the facility effluent, as described in EPA's *Draft Environmental Media and General Population*
 1079 *Screening for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)). As there was little variation between the
 1080 minimum and median stream conditions, the median flow rates selected from the generated distributions
 1081 represented conservative low flow rates from the distributions of 7Q10, 30Q5, and harmonic mean
 1082 flows. When coupled with high-end release scenarios, these low flow rates result in high modeled
 1083 instream concentrations. EPA has slight confidence in the modeled concentrations as being

1084 representative of actual releases, but for the purpose of a screening level assessment, EPA has robust
1085 confidence that no surface water release scenarios result in instream concentrations that exceed the
1086 modeled concentrations presented in this evaluation. Other model inputs were derived from reasonably
1087 available literature collected and evaluated through EPA’s systematic review process for TSCA risk
1088 evaluations. All monitoring and experimental data included in this analysis were from articles rated
1089 “medium” or “high” quality from this process.

1090 **3.3.1.2 Ambient Air – Air to Soil Deposition**

1091 Similar to the surface water analysis, due to the lack of release data, releases were modeled using
1092 generic scenarios and the high-end estimates for each COU was applied for ambient air modeling. With
1093 moderate confidence in the release data detailed in *Draft Release and Occupational Exposure*
1094 *Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024e](#)) and conservative assumptions used for modeled
1095 air dispersion and particle distribution inputs, EPA has slight confidence in the air and deposition
1096 concentrations modeled based on EPA estimated releases being representative of actual releases, but for
1097 the purposed of a risk screening level assessment, EPA has robust confidence that it’s modeled releases
1098 used for estimating air to soil deposition is appropriately conservative for a screening level analysis.

4 HUMAN HEALTH RISK ASSESSMENT

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

EPA evaluated all reasonably available information to support human health risk characterization of DIDP for workers, ONUs, consumers, bystanders, and the general population. Exposures to workers, ONUs, consumers, bystanders, and the general population are described in Section 0. 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 condition of use (Section 4.1.1). However, the primary route of exposure was the inhalation route.
- EPA assessed inhalation, dermal, and oral exposures for consumers and bystanders, as appropriate, for each condition of use (Section 4.1.2) in scenarios that represent a range of use patterns and behaviors. The primary route of exposure was inhalation followed by ingestion.
- EPA assessed oral and dermal exposures for the general population, as appropriate, via surface water, drinking water, soil, and fish (Sections 4.1.3 and 4.3.4).

Hazard Key Points

- EPA identified liver and developmental toxicity as the most sensitive and robust non-cancer hazards associated with oral exposure to DIDP in experimental animal models (Section 4.2).
- A non-cancer POD of 9.0 mg/kg-day was selected to characterize non-cancer risks for acute, intermediate, and chronic durations of exposure. The POD is from a two-generation study of rats in which animals dosed with DIDP had litters where more infants died than was the case with the litters of rodents that were not dosed with DIDP. A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure (Section 4.2).
- For purposes of assessing non-cancer risks, the selected POD is considered most applicable to women of reproductive age, pregnant women, and infants. Use of this POD to assess risk for other lifestages (*e.g.*, toddlers, preschoolers, children of other ages, and adult males) is a conservative approach.
- EPA reviewed the weight of evidence for the carcinogenicity of DIDP and determined that there is *Suggestive Evidence of Carcinogenic Potential* of DIDP in rodents based on evidence of leukemia in rats and liver tumors in mice. EPA did not conduct a dose-response assessment or further evaluate DIDP for carcinogenic risk to humans.

Risk Assessment Key Points

- DIDP was evaluated for non-cancer risk.
- Inhalation exposures drive acute non-cancer risks to workers in occupational settings (Section 4.3.2).
- Inhalation exposures were found to drive acute non-cancer risks to 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).
- EPA considered potentially exposed or susceptible subpopulation(s) (PESS) throughout the exposure assessment and throughout the hazard identification and dose-response analysis supporting this draft risk evaluation (Section 4.3.5).

4.1 Summary of Human Exposures

4.1.1 Occupational Exposures

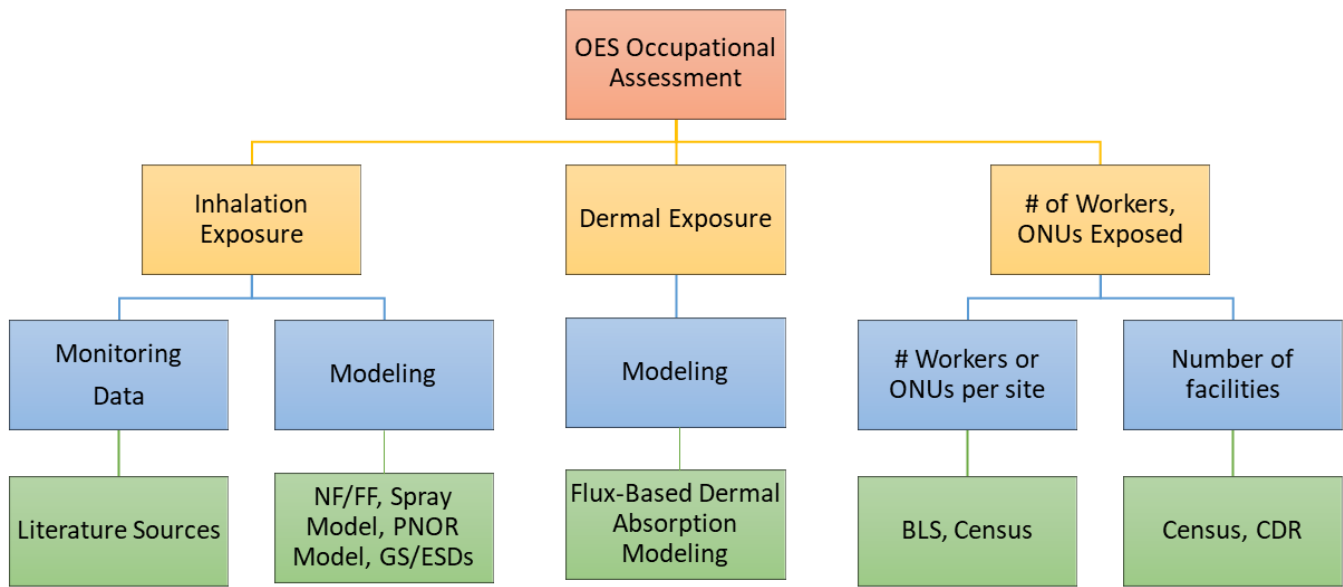
The following subsections briefly describe EPA's approach to assessing occupational exposures and provide exposure assessment results for each OES. As stated in the *Final Scope of the Risk Evaluation for Diisodecyl phthalate (DIDP)* ([U.S. EPA, 2021b](#)), EPA evaluated exposures to workers and ONUs via the inhalation route, including incidental ingestion of inhaled dust, and exposures to workers via the dermal route associated with the manufacturing, processing, use and disposal of DIDP. Also, EPA analyzed dermal exposure for workers and ONUs to mists and dust that deposit on surfaces. The *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) provides additional details on the development of approaches and the exposure assessment results.

4.1.1.1 Approach and Methodology

As described in the *Final Scope of the Risk Evaluation for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2021b](#)), EPA distinguishes exposure levels among potentially exposed employees for workers and ONUs. In general, the primary difference between workers and ONUs is that workers may handle DIDP and have direct contact with the DIDP, while ONUs work in the general vicinity of DIDP but do not handle DIDP. Where possible, for each condition of use, EPA identified job types and categories for workers and ONUs.

As discussed in Section 3.1.1.1, EPA established OESs to assess the exposure scenarios more specifically within each COU, and Table 3-1 provides a crosswalk between COUs and OESs. EPA identified relevant inhalation exposure monitoring data for some of the OESs. EPA evaluated the quality of this monitoring data using the data quality review evaluation metrics and the rating criteria described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances, Version 1.0: A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies* ([U.S. EPA, 2021a](#)). EPA assigned an overall quality level of high, medium, or low to the relevant data. In addition, EPA established an overall confidence level for the data when integrated into the occupational exposure assessment. EPA considered the assessment approach, the quality of the data and models, and uncertainties in assessment results to assign an overall confidence level of robust, moderate, or slight.

Where monitoring data were reasonably available, EPA used these data to characterize central tendency and high-end inhalation exposures. Where no inhalation monitoring data were available, but inhalation exposure models were reasonably available, EPA estimated central tendency and high-end exposures using only modeling approaches. If both inhalation monitoring data and exposure models were reasonably available, EPA presented central tendency and high-end exposures using both. For inhalation exposure to dust in occupational settings, EPA used the *Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR)* ([U.S. EPA, 2021d](#)). In all cases of occupational dermal exposure to DIDP, EPA used a flux-limited dermal absorption model to estimate high-end and central tendency dermal exposures for workers in each OES, as described in the *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)).



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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; NF/FF = near-field/far-field; PNOR = Particulates not Otherwise Regulated.

For inhalation and dermal exposure routes, EPA provided occupational exposure results representative of central tendency and high-end exposure conditions. The central tendency is expected to represent occupational exposures in the center of the distribution for a given COU. For risk evaluation, EPA used the 50th percentile (median), mean (arithmetic or geometric), mode, or midpoint values of a distribution as representative of the central tendency scenario. EPA preferred to provide the 50th percentile of the distribution. However, if the full distribution is unknown, EPA may assume that the mean, mode, or midpoint of the distribution represents the central tendency depending on the statistics available for the distribution. The high-end exposure is expected to be representative of occupational exposures that occur at probabilities above the 90th percentile, but below the highest exposure for any individual (U.S. EPA, 1992). For risk evaluation, EPA provided high-end results at the 95th percentile. If the 95th percentile is not reasonably available, EPA used a different percentile greater than or equal to the 90th percentile but less than or equal to the 99th percentile, depending on the statistics available for the distribution. If the full distribution is not known and the preferred statistics are not reasonably available, EPA estimated a maximum or bounding estimate in lieu of the high-end. Table 4-1 provides a summary of whether monitoring data were reasonably available for each OESs, and if data were available, the number of data points and quality of the data. Table 4-1 also provides EPA's overall confidence rating and whether EPA used modeling to estimate inhalation and dermal exposures for workers.

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

OES	Inhalation Exposure								Dermal Exposure				
	Monitoring					Modeling		Weight of Scientific Evidence Conclusion		Modeling		Weight of Scientific Evidence Conclusion	
	Worker	# Data Points	ONU	# Data Points	Data Quality Ratings	Worker	ONU	Worker	ONU	Worker	ONU	Worker	ONU
Manufacturing	✓	2	✓	2	Medium	✗	✗	Moderate to Robust	Moderate	✓	✗	Moderate	N/A
Import/ repackaging	✓	2 ^a	✓	2 ^a	Medium	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
Incorporation into adhesives and sealants	✓	2 ^a	✓	2 ^a	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
Incorporation into paints and coatings	✓	2 ^a	✓	2 ^a	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	✓	2 ^a	✓	2 ^a	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
PVC plastics compounding	✓	1 ^b	✓	1 ^b	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
PVC plastics converting	✓	1	✓	1	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Non-PVC material compounding	✓	1 ^b	✓	1 ^b	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Non-PVC material converting	✓	1 ^b	✓	1 ^b	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Application of adhesives and sealants	✗	N/A	✗	N/A	N/A	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Application of paints and coatings	✗	N/A	✗	N/A	N/A	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Use of laboratory chemicals	✓	2 ^a	✓	2 ^a	Medium	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Use of lubricants and functional fluids	✓	2 ^a	✓	2 ^a	Medium	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A

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OES	Inhalation Exposure								Dermal Exposure				
	Monitoring					Modeling		Weight of Scientific Evidence Conclusion		Modeling		Weight of Scientific Evidence Conclusion	
	Worker	# Data Points	ONU	# Data Points	Data Quality Ratings	Worker	ONU	Worker	ONU	Worker	ONU	Worker	ONU
Use of penetrants and inspection fluids	✘	N/A	✘	N/A	N/A	✔	✔	Moderate	Moderate	✔	✔	Moderate	Moderate
Fabrication and final use of products or articles	✘	N/A	✘	N/A	N/A	✔	✔	Moderate	Moderate	✔	✔	Moderate	Moderate
Recycling and disposal	✘	N/A	✘	N/A	N/A	✔	✔	Moderate	Moderate	✔	✔	Moderate	Moderate
<p>^a Inhalation monitoring data for exposure to vapors from the Manufacturing OES were used as surrogate data for OES where inhalation exposure comes from vapor generating-activities only.</p> <p>^b Inhalation monitoring data for exposure to vapors from the PVC Plastics Converting OES were used as surrogate data for OES where inhalation exposure to vapor occurs during the heating and cooling plastic and non-plastic polymer materials.</p>													

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4.1.1.2 Summary of Number of Workers and ONUs

The *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) provides a summary of the estimates for the total exposed workers and ONUs for each OES. To prepare these estimates, EPA first attempted to identify relevant North American Industrial Classification (NAICS) codes for each OES. For these NAICS codes, the Standard Occupational Classification (SOC) codes from the Bureau of Labor Statistics (BLS) were used to classify SOC codes as either workers or ONUs. EPA assumed that all other SOC codes represent occupations where exposure is unlikely. EPA also estimated the total number facilities associated with the relevant NAICS codes based on data from the U.S. Census Bureau. To estimate the average number of potentially exposed workers and ONUs per site, the total number of workers and ONUs were divided by the total number of facilities. Lastly, using estimates of the number of facilities using DIDP, the total number of workers and ONUs potentially exposed to DIDP for each OES were estimated. The *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) provides additional details on the approach and methodology for estimating the number of facilities using DIDP and the number of potentially exposed workers and ONUs.

Table 4-2 summarizes the number of facilities and total number of exposed workers for all OES. For scenarios in which the results are expressed as a range, the low end of the range represents the central tendency result, and the upper end of the range represents the high-end result.

Table 4-2. Summary of Total Number of Workers and ONUs Potentially Exposed to DIDP for Each OES^a

OES	Total Exposed Workers	Total Exposed ONUs	Number of Facilities	Notes
Manufacturing	155	71	4	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Import/Repackaging	151	41	11	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Incorporation into Adhesives and Sealants	108 to 903	41 to 338	6 to 50	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Incorporation into Paints and Coatings	91 to 576	27 to 170	6 to 38	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Incorporation into Other Formulations, Mixtures, and Reaction Products Not Covered Elsewhere	51 to 102	24 to 48	1 to 2	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
PVC Plastics Compounding	1,798 to 3,578	509 to 1,012	98 to 195	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)

OES	Total Exposed Workers	Total Exposed ONUs	Number of Facilities	Notes
PVC Plastics Converting	39,044 to 77,739	11,049 to 22,000	2,128 to 4,237	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Non-PVC Material Compounding	90 to 203	24 to 54	4 to 9	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Non-PVC Material Converting	4,016 to 4,783	1,068 to 1,272	178 to 212	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Application of Adhesives and Sealants	4,523 to 56,857	1,433 to 18,012	84 to 1,056	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Application of Paints and Coatings	2,615 to 14,631	1,140 to 6,375	222 to 1,242	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Use of Laboratory Chemicals (Liquid)	223 to 2,075	1,964 to 18,290	225 to 2,095	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Use of Laboratory Chemicals (Solid)	36,517	321,917	36,873	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Use of Lubricants and Functional Fluids	228,779 to 1,620,403	56,176 to 397,887	2,596 to 18,387	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Use of Penetrants and Inspection Fluids	203,772 to 291,282	85,651 to 122,433	15,315 to 21,892	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
Fabrication and Final Use of Products or Articles	N/A	N/A	N/A	Number of workers and sites data were unavailable for this OES.
Recycling and Disposal	754	432	58	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB (U.S. BLS, 2016 ; U.S. Census Bureau, 2015)
^a EPA's approach and methodology for estimating the number of facilities using DIDP and the number of workers and ONUs potentially exposed to DIDP can be found in <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e).				

4.1.1.3 Summary of Inhalation Exposure Assessment

Table 4-3 presents a summary of inhalation exposure results based on monitoring data and exposure modeling for the various OESs. This tables provides a summary of the 8-hour time weighted average (8-hour TWA) inhalation exposure estimates, as well as the Acute Dose (AD), the Intermediate Average Daily Dose (IADD), and the Average Daily Dose (ADD). The *Draft Environmental Release and*

1194 Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024e) provides
 1195 exposure results for females of reproductive age and ONUs. The Draft Environmental Release and
 1196 Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024e) also provides
 1197 additional details regarding AD, IADD, and ADD calculations along with EPA's approach and
 1198 methodology for estimating inhalation exposures.
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Table 4-3. Summary of Average Adult Worker Inhalation Exposure Results for Each OES

OES	Inhalation Estimates (Average Adult Worker)									
	Vapor/Mist 8-Hr TWA (mg/m ³)		PNOR 8-hr TWA (mg/m ³)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	HE	CT	HE	CT	HE	CT	HE	CT	HE	CT
Manufacturing	7.2E-02	3.6E-02	N/A	N/A	9.0E-03	4.5E-03	6.6E-03	3.3E-03	4.4E-03	2.2E-03
Import/ Repackaging	7.2E-02	3.6E-02	N/A	N/A	9.0E-03	4.5E-03	6.6E-03	3.3E-03	6.2E-03	2.6E-03
Incorporation into Adhesives and Sealants	3.0E-02	3.0E-02	N/A	N/A	3.8E-03	3.8E-03	2.8E-03	2.8E-03	2.6E-03	2.6E-03
Incorporation into Paints and Coatings	3.0E-02	3.0E-02	N/A	N/A	3.8E-03	3.8E-03	2.8E-03	2.8E-03	2.6E-03	2.6E-03
Incorporation into Other Formulations, Mixtures, and Reaction Products Not Covered Elsewhere	3.0E-02	3.0E-02	N/A	N/A	3.8E-03	3.8E-03	2.8E-03	2.8E-03	2.6E-03	2.6E-03
PVC Plastics Compounding	3.0E-02	3.0E-02	2.1	0.10	0.27	1.7E-02	0.20	1.2E-02	0.18	1.0E-02
PVC Plastics Converting	3.0E-02	3.0E-02	2.1	0.10	0.27	1.7E-02	0.20	1.2E-02	0.18	1.0E-02
Non-PVC Material Compounding	3.0E-02	3.0E-02	0.94	4.6E-02	0.12	9.5E-03	8.9E-02	7.0E-03	8.3E-02	6.10E-03
Non-PVC Material Converting	3.0E-02	3.0E-02	0.94	4.6E-02	0.12	9.5E-03	8.9E-02	7.0E-03	8.3E-02	5.7E-03
Application of Adhesives and Sealants	22	0.14	N/A	N/A	2.8	1.7E-02	2.0	1.2E-02	1.9	1.1E-02
Application of Paints and Coatings	2.2	0.14	N/A	N/A	0.28	1.7E-02	0.20	1.2E-02	0.19	1.2E-02
Use of Laboratory Chemicals - Liquid	7.2E-02	3.6E-02	N/A	N/A	9.0E-03	4.5E-03	6.6E-03	3.3E-03	6.2E-03	2.9E-03
Use of Laboratory Chemicals - Solid	N/A	N/A	8.1E-0 2	5.7E-03	1.0E-02	7.1E-04	7.4E-03	5.2E-04	6.9E-03	4.9E-04
Use of Lubricants and Functional Fluids	7.2E-02	3.6E-02	N/A	N/A	9.0E-03	4.5E-03	1.2E-03	3.0E-04	9.9E-05	2.5E-05
Use of Penetrants and Inspection Fluids	5.6	1.5	N/A	N/A	0.70	0.19	0.51	0.14	0.47	0.13
Fabrication and Final Use of Products or Articles	N/A	N/A	0.81	9.0E-02	0.10	1.1E-02	7.4E-02	8.3E-03	6.9E-02	7.7E-03

OES	Inhalation Estimates (Average Adult Worker)									
	Vapor/Mist 8-Hr TWA (mg/m ³)		PNOR 8-hr TWA (mg/m ³)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	HE	CT	HE	CT	HE	CT	HE	CT	HE	CT
Recycling 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

AD = acute dose; ADD = average daily dose; CT = central tendency; HE = high-end; IADD = intermediate average daily dose; PNOR = Particulates Not Otherwise Regulated; TWA = time-weighted average

4.1.1.4 Summary of Dermal Exposure Assessment

Table 4-4 presents a summary of dermal exposure results, which are based on both empirical dermal absorption data and dermal absorption modeling estimation efforts. This tables provides a summary of the Acute Potential Dose Rate (APDR) for occupational dermal exposure estimates, as well as the Acute Dose (AD), the Intermediate Average Daily Dose (IADD), and the Average Daily Dose (ADD). The *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024e) provides exposure results for females of reproductive age and ONUs. The *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024e) also provides additional details regarding AD, IADD, and ADD calculations along with EPA’s approach and methodology for estimating dermal exposures.

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

OES	Dermal Estimates (Average Adult Worker)									
	Exposure Type		APDR (mg/day)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	Liquid	Solid	HE	CT	HE	CT	HE	CT	HE	CT
Manufacturing	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	4.5E-02	2.3E-02
Import/ Repackaging	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	2.6E-02
Incorporation into Adhesives and Sealants	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02
Incorporation into Paints and Coatings	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02
Incorporation into Other Formulations, Mixtures, and Reaction Products Not Covered Elsewhere	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02
PVC Plastics Compounding	X	X	7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	2.8E-02
PVC Plastics Converting		X	7.7E-02	3.8E-02	9.6E-04	4.8E-04	7.1E-04	3.5E-04	6.6E-04	2.9E-04
Non-PVC Material Compounding	X	X	7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	2.9E-02
Non-PVC Material Converting		X	7.7E-02	3.8E-02	9.6E-04	4.8E-04	7.1E-04	3.5E-04	6.6E-04	2.9E-04
Application of Adhesives and Sealants	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	2.9E-02
Application of Paints and Coatings	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02

OES	Dermal Estimates (Average Adult Worker)									
	Exposure Type		APDR (mg/day)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	Liquid	Solid	HE	CT	HE	CT	HE	CT	HE	CT
Use of Laboratory Chemicals - Liquid	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.0E-02
Use of Laboratory Chemicals - Solid		X	7.7E-02	3.8E-02	9.6E-04	4.8E-04	7.1E-04	3.5E-04	6.6E-04	3.3E-04
Use of Lubricants and Functional Fluids	X		7.3	3.7	9.2E-02	4.6E-02	1.2E-02	3.1E-03	1.0E-03	2.5E-04
Use of Penetrants and Inspection Fluids	X		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02
Fabrication and Final Use of Products or Articles		X	7.7E-02	3.8E-02	9.6E-04	4.8E-04	7.1E-04	3.5E-04	6.6E-04	3.3E-04
Recycling and Disposal		X	7.7E-02	3.8E-02	9.6E-04	4.8E-04	7.1E-04	3.5E-04	6.6E-04	2.9E-04

Abbreviations: AD = acute dose; ADD = average daily dose; APDR = Acute Potential Dose Rate; CT = central tendency; HE = high-end; IADD = intermediate average daily dose

4.1.1.5 Weight of Scientific Evidence Conclusions for Occupational Exposure

Judgment on the weight of scientific evidence is based on the strengths, limitations, and uncertainties associated with the release estimates. The Agency considers factors that increase or decrease the strength of the evidence supporting the exposure estimate—including quality of the data/information, applicability of the exposure data to the COU (including considerations of temporal relevance, locational relevance) and the representativeness of the estimate for the whole industry. The best professional judgment is summarized using the descriptors of robust, moderate, slight, or indeterminant, in accordance with the *Draft systematic review protocol supporting TSCA risk evaluations for chemical substances, Version 1.0: A generic TSCA systematic review protocol with chemical-specific methodologies* (U.S. EPA, 2021a). For example, a conclusion of moderate weight of scientific evidence is appropriate where there is measured exposure data from a limited number of sources such that there is a limited number of data points that may not be representative of the worker activities or potential exposures. A conclusion of slight weight of scientific evidence is appropriate where there is limited information that does not sufficiently cover all potential exposures within the COU, and the assumptions and uncertainties are not fully known or documented. See the *Draft systematic review protocol supporting TSCA risk evaluations for chemical substances, Version 1.0: A generic TSCA systematic review protocol with chemical-specific methodologies* (U.S. EPA, 2021a) for additional information on weight of scientific evidence conclusions. Table 4-5 summarizes the overall weight of scientific evidence conclusions for exposure assessments for each OES.

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Table 4-5. Summary of Overall Confidence in Occupational Exposure Estimates by OES

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
Manufacturing	<p>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 full-shift TWA inhalation exposure estimates for the Manufacturing OES. The primary strength is the use of directly applicable monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data to assess inhalation exposures, with the data source having a high data quality rating from the systematic review process (ExxonMobil, 2022a). Data from these sources were DIDP-specific from a DIDP manufacturing facility, though it is uncertain whether the measured concentrations accurately represent the entire industry. A further strength of the data is that it was compared against an EPA developed Monte Carlo model and the data points from ExxonMobil were found to be more protective.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward the true distribution of inhalation concentrations in this scenario, that the data come from one industry-source, and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. EPA also assumed 8 exposure hours per day and 180 exposure days per year based on a manufacturing site reporting half-year DIDP campaign runs (ExxonMobil, 2022a); it is uncertain whether this captures actual worker schedules and exposures at that and other manufacturing sites.</p> <p>Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate to robust and provides a plausible estimate of exposures.</p>
Import and Repackaging	<p>EPA used surrogate manufacturing data to estimate worker inhalation exposures due to limited data. Import and repackaging inhalation exposures were estimated using the manufacturing inhalation exposure as a surrogate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data to assess inhalation exposures, with the data source having a high data quality rating from the systematic review process (ExxonMobil, 2022a). Data from these sources were DIDP-specific from a DIDP manufacturing facility, though it is uncertain whether the measured concentrations accurately represent the entire industry.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; that the data come from one industry-source; and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. 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, which is the expected maximum for working days. The central tendency exposures use 208 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.</p> <p>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.</p>
Incorporation into Adhesives and Sealants	<p>EPA used surrogate data to estimate worker inhalation exposures due to limited data. Incorporation into adhesives and sealants exposures were estimated using the PVC plastics converting OES inhalation exposure as a surrogate estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	<p>review process (Irwin, 2022; Porras et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward the true distribution of inhalation concentrations in this scenario, that the data come from one datapoint from each source, and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DIDP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.</p> <p>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.</p>
Incorporation into Paints and Coatings	<p>EPA used surrogate data to estimate worker inhalation exposures due to limited data. Incorporation into paints and coatings exposures were estimated using the PVC plastics converting OES inhalation exposure as a surrogate estimate. The primary strength is the use of monitoring data, which is preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic review process (Irwin, 2022; Porras et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward the true distribution of inhalation concentrations in this scenario, that the data come from one datapoint from each source, and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DIDP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.</p> <p>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.</p>
Incorporation into Other Formulations, Mixtures, and Reaction Products Not Covered Elsewhere	<p>EPA used surrogate data to estimate worker inhalation exposures due to limited data. Incorporation into other formulations, mixtures, and reaction products not covered elsewhere exposures were estimated using the PVC plastics converting OES inhalation exposure as a surrogate estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic review process (Irwin, 2022; Porras et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward the true distribution of inhalation concentrations in this scenario, that the data come from one datapoint from each source, and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	<p>continuous DIDP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.</p> <p>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.</p>
PVC Plastics Compounding	<p>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-hr TWA inhalation exposure estimates. EPA used surrogate data to estimate worker inhalation exposures due to limited data. PVC plastics compounding exposures were estimated using the PVC plastics converting OES inhalation exposure as a surrogate bounding estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate from for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic review process (Irwin, 2022; Porras et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry. Compounding activities are also expected to generate dust from the solid product; therefore, EPA incorporated the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) into the assessment to estimate worker inhalation exposure to solid particulate. The respirable PNOR range was refined using OSHA CEHD data sets, which the systematic review process rated high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DIDP in plastic using industry provided data on DIDP concentration in PVC, which were also rated high for data quality in the systematic review process.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of the monitoring data and PNOR model toward the true distribution of inhalation concentrations in this scenario, that the monitoring data come from one datapoint from each source, that 100% of the data for both workers and ONUs from the source were reported as below the LOD, and that the OSHA CEHD data are not specific to DIDP. 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, which is the expected maximum for 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.</p> <p>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.</p>
PVC Plastics Converting	<p>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 full-shift TWA inhalation exposure estimates for the PVC Plastics Converting OES. The primary strength is the use of directly applicable monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate from for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic review process (Irwin, 2022; Porras et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry. Converting activities are also expected to generate dust from the solid product; therefore, EPA incorporated the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) into the assessment to estimate worker inhalation exposure to solid particulate. The respirable PNOR range was refined using OSHA CEHD data sets, which the systematic review process rated</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	<p>high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DIDP in plastic using industry provided data on DIDP concentration in PVC, which were also rated high for data quality in the systematic review process.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of the monitoring data and PNOR model toward the true distribution of inhalation concentrations in this scenario, that the monitoring data come from one datapoint from each source, that 100% of the data for both workers and ONUs from the source were reported as below the LOD, and that the OSHA CEHD data are not specific to DIDP. 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, which is the expected maximum for working days. 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. 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.</p> <p>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.</p>
Non-PVC Material Compounding	<p>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-hr TWA inhalation exposure estimates. EPA used surrogate data to estimate worker inhalation exposures due to limited data. Non-PVC material compounding exposures were estimated using the PVC plastics converting OES inhalation exposure as a surrogate bounding estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate from for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic review process (Irwin, 2022; Porrás et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry. Compounding activities are also expected to generate dust from the solid product; therefore, EPA incorporated the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) into the assessment to estimate worker inhalation exposure to solid particulate. The respirable PNOR range was refined using OSHA CEHD data sets, which the systematic review process rated high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DIDP in plastic using industry provided data on DIDP concentration in PVC, which were also rated high for data quality in the systematic review process.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of the monitoring data and PNOR model toward the true distribution of inhalation concentrations in this scenario, that the monitoring data come from one datapoint from each source, that 100% of the data for both workers and ONUs from the source were reported as below the LOD, and that the OSHA CEHD data are not specific to DIDP. 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, which is the expected maximum for working days. The central tendency exposures use 234 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.</p> <p>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.</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
<p>Non-PVC Material Converting</p>	<p>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-hr TWA inhalation exposure estimates. EPA used surrogate data to estimate worker inhalation exposures due to limited data. Non-PVC material converting exposures were estimated using the PVC plastics converting OES inhalation exposure as a surrogate bounding estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and stationary air concentration data to assess inhalation exposures. The PBZ data are surrogate from for an ONU exposed to DINP and the area sample is a DPHP sample taken adjacent to two extruders in plastic cable manufacturing. Both data sources have a high data quality rating from the systematic review process (Irwin, 2022; Porras et al., 2020). Data from these sources are specific to a PVC plastic converting facility, though it is uncertain whether the measured concentrations accurately represent the entire industry. Converting activities are also expected to generate dust from the solid product; therefore, EPA incorporated the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) into the assessment to estimate worker inhalation exposure to solid particulate. The respirable PNOR range was refined using OSHA CEHD data sets, which the systematic review process rated high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DIDP in plastic using industry provided data on DIDP concentration in PVC, which were also rated high for data quality in the systematic review process.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of the monitoring data and PNOR model toward the true distribution of inhalation concentrations in this scenario, that the monitoring data come from one datapoint from each source, that 100% of the data for both workers and ONUs from the source were reported as below the LOD, and that the OSHA CEHD data are not specific to DIDP. 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, which is the expected maximum for working days. 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. 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.</p> <p>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.</p>
<p>Application of Adhesives and Sealants</p>	<p>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-hr TWA inhalation exposure estimates. EPA used surrogate monitoring data from the <i>ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry</i>, which the systematic review process rated high for data quality, to estimate inhalation exposures (OECD, 2011a). EPA used SDSs and product data sheets from identified DIDP-containing adhesives and sealant products to identify product concentrations.</p> <p>The primary limitation is the lack of DIDP-specific monitoring data, with the ESD serving as a surrogate source of monitoring data representing the level of exposure that could be expected at a typical work site for the given spray application method. EPA assumes spray applications of the adhesives and sealants, so the estimates may not be representative of exposure during other application methods. Additionally, it is uncertain whether the substrates bonded, and products used to generate the surrogate data are representative of those associated with DIDP-containing adhesives and sealants. EPA only assessed mist exposures to DIDP over a full 8-hour work shift to estimate the level of exposure, though other activities may result in vapor exposures other than mist and application duration may be variable depending on the job site. 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, which is the expected maximum for working days. The central tendency exposures use 232 days per</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	<p>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.</p> <p>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.</p>
Application of Paints and Coatings	<p>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-hr TWA inhalation exposure estimates. EPA used surrogate monitoring data from the <i>ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry</i>, which the systematic review process rated high for data quality, to estimate inhalation exposures (OECD, 2011a). EPA used SDSs and product data sheets from identified DIDP-containing products to identify product concentrations.</p> <p>The primary limitation is the lack of DIDP-specific monitoring data, with the ESD serving as a surrogate source of monitoring data representing the level of exposure that could be expected at a typical work site for the given spray application method. EPA 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 DIDP-containing coatings. EPA only assessed mist exposures to DIDP over a full 8-hour work shift to estimate the level of exposure, though other activities may result in vapor exposures other than mist and application duration may be variable depending on the job site. EPA assessed 250 days of exposure per year based on workers applying coatings on every working day, however, application sites may use DIDP-containing coatings at much lower or variable frequencies.</p> <p>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.</p>
Use of Laboratory Chemicals	<p>EPA used surrogate data to estimate worker vapor inhalation exposures due to limited data. Use of laboratory chemicals inhalation exposures were estimated using the manufacturing inhalation exposure as a surrogate bounding estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data to assess inhalation exposures, with the data source having a high data quality rating from the systematic review process (ExxonMobil, 2022a). Data from these sources were DIDP-specific from a DIDP manufacturing facility, though it is uncertain whether the measured concentrations accurately represent the entire industry.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; that the data come from one industry-source; and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. The high-end and central tendency exposures to solid laboratory chemicals use 250 days per year as the exposure frequency since the 95th and 50th percentiles of operating days in the release assessment exceeded 250 days per year, which is the expected maximum number of working days. The high-end and central tendency exposures to liquid laboratory chemicals use 235 days per year and 250 days per year, respectively, as the exposure frequencies. 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.</p> <p>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.</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
Use of Lubricants and Functional Fluids	<p>EPA used surrogate data to estimate worker inhalation exposures due to limited data. Use of lubricants and functional fluids inhalation exposures were estimated using the manufacturing inhalation exposure as a surrogate bounding estimate. The primary strength is the use of monitoring data, which are preferable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data to assess inhalation exposures, with the data source having a high data quality rating from the systematic review process (ExxonMobil, 2022a). Data from these sources were DIDP-specific from a DIDP manufacturing facility, though it is uncertain whether the measured concentrations accurately represent the entire industry.</p> <p>The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; that the data come from one industry-source; and that 100% of the data for both workers and ONUs from the source were reported as below the LOD. The high-end exposures use 4 days per year as the exposure frequency based on the 95th percentile of operating days from the release assessment. The central tendency exposures use 2 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.</p> <p>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.</p>
Use of Penetrants and Inspection Fluids	<p>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-hr TWA inhalation exposure estimates. EPA utilized a near-field/far-field approach (AIHA, 2009), and the inputs to the model were derived from references that received ratings of medium-to-high for data quality in the systematic review process. EPA combined this model with Monte Carlo modeling to estimate occupational exposures in the near-field (worker) and far-field (ONU) inhalation exposures. A strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential exposure values is more likely than a discrete value to capture actual exposure at sites, the high number of data points (simulation runs), and the full distributions of input parameters. EPA identified and used a DINP-containing penetrant/inspection fluid product as surrogate to estimate concentrations, application methods, and use rate.</p> <p>The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. EPA lacks facility and DIDP-specific product use rates, concentrations, and application methods, therefore, estimates are made based on surrogate DINP-containing product. EPA only found one product to represent this use scenario, however, and its representativeness of all DIDP-containing penetrants and inspection fluids is not known. The high-end exposures use 249 days per year as the exposure frequency based on the 95th percentile of operating days from the release assessment. The central tendency exposures use 247 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.</p> <p>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.</p>
Fabrication and Final Use of	<p>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-hr TWA inhalation exposure estimates. EPA utilized the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) to estimate worker inhalation exposure to solid particulate. The respirable PNOR range was refined using OSHA CEHD data sets, which the systematic review process rated high for data</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
Products or Articles	<p>quality (OSHA, 2020). EPA estimated the highest expected concentration of DIDP in plastic using industry provided data on DIDP concentration in PVC, which were also rated high for data quality in the systematic review process.</p> <p>The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Additionally, the representativeness of the CEHD data set and the identified DIDP concentrations in plastics for this specific fabrication and final use of products or articles is uncertain. EPA lacks facility and DIDP-containing product fabrication and use rates, methods, and operating times and EPA assumed eight exposure hours per day and 250 exposure days per year based on continuous DIDP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.</p> <p>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.</p>
Recycling and Disposal	<p>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-hr TWA inhalation exposure estimates. EPA utilized the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) to estimate worker inhalation exposure to solid particulate. The respirable PNOR range was refined using OSHA CEHD data sets, which the systematic review process rated high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DIDP in plastic using industry provided data on DIDP concentration in PVC, which were also rated high for data quality in the systematic review process.</p> <p>The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Additionally, the representativeness of the CEHD data set and the identified DIDP concentrations in plastics for this specific recycling end-use is uncertain. 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.</p> <p>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.</p>
Dermal – Liquids	<p>EPA used <i>in vivo</i> rat absorption data for neat DIDP (Elsisi et al., 1989) to estimate occupational dermal exposures to workers since exposures to the neat material or concentrated formulations are possible for occupational scenarios. Because rat skin generally has greater permeability than human skin (Scott et al., 1987), the use of <i>in vivo</i> rat absorption data is assumed to be a conservative assumption. Also, it is acknowledged that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. However, it is assumed that absorption of the neat chemical serves as a reasonable upper bound across chemical compositions and the data received a medium rating through EPA’s systematic review process.</p> <p>For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and that the chemical is contacted at least once per day. Because DIDP 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 DIDP from occupational dermal contact with materials containing DIDP may extend up to 8 hours per day (U.S. EPA, 1991a). For average adult workers, the surface area of contact was assumed equal to the area of one hand (<i>i.e.</i>,</p>

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	<p>535 cm²), or two hands (<i>i.e.</i>, 1,070cm²), for central tendency exposures, or high-end exposures, respectively (U.S. EPA, 2011b). The standard sources for exposure duration and area of contact received high ratings through EPA’s systematic review process.</p> <p>The occupational dermal exposure assessment for contact with liquid materials containing DIDP was based on dermal absorption data for the neat material, as well as standard occupational inputs for exposure duration and area of contact, as described above. Based on the strengths and limitations of these inputs, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of occupational dermal exposures.</p>
Dermal - Solids	<p>EPA used dermal modeling of aqueous materials (U.S. EPA, 2023a, 2004b) to estimate occupational dermal exposures of workers and ONUs to solid materials as described in Appendix D.2.1.2 of the <i>Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024e). However, the modeling approach for determining the aqueous permeability coefficient was used outside the range of applicability given the p-chem parameters of DIDP. Also, it is acknowledged that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. However, it is assumed that absorption of aqueous DIDP serves as a reasonable upper bound for the dermal absorption of DIDP from solid matrices, and the modeling approach received a medium rating through EPA’s systematic review process.</p> <p>For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and that the chemical is contacted at least once per day. Because DIDP 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 DIDP from occupational dermal contact with materials containing DIDP may extend up to 8 hours per day (U.S. EPA, 1991a). For average adult workers, the surface area of contact was assumed equal to the area of one hand (<i>i.e.</i>, 535 cm²), or two hands (<i>i.e.</i>, 1,070cm²), for central tendency exposures, or high-end exposures, respectively (U.S. EPA, 2011b). The standard sources for exposure duration and area of contact received high ratings through EPA’s systematic review process.</p> <p>The occupational dermal exposure assessment for contact with solid materials containing DIDP was based on dermal absorption modeling of aqueous DIDP, 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.</p>

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

EPA assigned overall confidence descriptions of robust, moderate, or slight to the exposure assessments for each OES, based on the strength of the underlying scientific evidence. When the assessment is supported by robust evidence, EPA's overall confidence in the exposure assessment is robust; when supported by moderate evidence, EPA's overall confidence is moderate; when supported by slight evidence, EPA's overall confidence is slight.

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 the 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.

A strength of the modeling assessment includes the consideration of variable model input parameters as opposed to using a single static value. Parameter variation increases the likelihood that the true 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 ratings of either high or medium from EPA's systematic review process. Strengths associated with dermal exposure assessment are described in Table 4-5.

Limitations

The principal limitation of the inhalation monitoring data is uncertainty in the representativeness of the data, as there is limited exposure monitoring data in the literature for several scenarios. Differences in work practices and engineering controls across sites can introduce variability and limit the representativeness of the monitoring data. Age of the monitoring data can also introduce uncertainty, due to differences in workplace practices and equipment used at the time the monitoring data were collected compared those currently in use. A limitation of the modeling methodologies is that model input data from GSs/ESDs are generic for the OESs and not specific to the use of DIDP within the OESs. Limitations associated with dermal exposure assessment are described in Table 4-5.

Assumptions

To analyze the inhalation monitoring data, EPA categorized each data point as either "worker" or "ONU." The categorizations are based on descriptions of worker job activity as provided in literature and EPA's judgment. Exposures for ONUs can vary substantially and exposure levels for the "ONU" category will have high variability depending on the specific work activity performed.

EPA calculated average daily concentration (ADC) values assuming that workers and ONUs are regularly exposed during their entire 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 DIDP, and the actual ADC values become lower than the estimates presented. Assumptions associated with dermal exposure assessment are described in Table 4-5.

Uncertainties

EPA addressed variability in inhalation models by identifying key model parameters to apply a statistical distribution that mathematically defines the parameter's variability. EPA defined statistical

distributions for parameters using documented statistical variations where available. Where the statistical variation was unknown, assumptions were made to estimate the parameter distribution using available literature data, such as GSs and ESDs. However, there is uncertainty as to the representativeness of the parameter distributions because these data are often not specific to sites that use DIDP. In general, the effects of these uncertainties on the exposure estimates are unknown, as the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distributions of each of the model input parameters. Uncertainties associated with dermal exposure assessment are described in Table 4-5.

There are several uncertainties surrounding the estimated number of workers potentially exposed to DIDP. First, BLS's OES employment data for each industry/occupation combination are only available at the 3-, 4-, or 5-digit NAICS level, rather than the full 6-digit NAICS level. This lack of granularity could result in an overestimate of the number of exposed workers if some 6-digit NAICS are included in the less granular BLS estimates but are not, in reality, likely to use DIDP for the assessed applications. EPA addressed this issue by refining the OES estimates using total employment data from the U.S. Census' Statistics of US Businesses (SUSB). However, this approach assumes that the distribution of occupation types (SOC codes) in each 6-digit NAICS is equal to the distribution of occupation types at the parent 5-digit NAICS level. If the distribution of workers in occupations with DIDP exposure differs from the overall distribution of workers in each NAICS, then this approach will result in inaccuracy.

4.1.2 Consumer Exposures

The following subsections briefly describe EPA's approach to assessing consumer exposures and provide exposure assessment results for each COU. The *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)) provides additional details on the development of approaches and the exposure assessment results. The consumer exposure assessment evaluated exposures from individual COUs while the indoor dust assessment uses a subset of consumer articles with large surface area and presence in indoor environments to garner COU specific contributions to the total exposures from dust.

4.1.2.1 Consumer and Indoor Dust Exposure Scenarios and Modeling Approach and Methodology

Consumer products or articles containing DIDP 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 was done qualitatively or quantitatively. The indoor dust assessment uses consumer products information for selected articles with the goal of recreating the indoor environment. The subset of consumer articles used in the indoor dust assessment were selected for their potential to have large surface area for dust collection.

When a quantitative analysis was conducted, exposure from the consumer COUs was estimated by modeling. Exposure via inhalation and ingestion routes were modeled using EPA's CEM Version 3.2 ([U.S. EPA, 2023a](#)) and dermal exposures were done using a computational framework implemented within a spreadsheet environment. For each exposure route, EPA used the 10th percentile, average, and 95th percentile value of an input parameter (e.g., weight fraction, surface area and others) where possible to characterize low, medium, and high exposure for a given condition of use. Should only a range be reported as the minimum, average, and maximum EPA used these for the low, medium, and high, respectively. See *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)) for details about the consumer modeling approaches, sources of data, model parameterization, and assumptions.

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1330 Exposure via the inhalation route occurs from inhalation of DIDP gas-phase emissions or when DIDP
1331 partitions to suspended particulate from direct use or application of products and articles. Exposure via
1332 the dermal route can occur from direct contact with products and articles. Exposure via ingestion
1333 depends on the product or article use patterns. It can occur via direct mouthing (*i.e.*, directly putting
1334 product in mouth) or ingestion of suspended dust when DIDP migrates from product to dust or partitions
1335 from gas-phase to dust.

1336

1337 EPA made some adjustments to match CEM's lifestages to those listed in the Center for Disease Control
1338 and Prevention (CDC) guidelines ([CDC, 2021](#)) and *EPA's A Framework for Assessing Health Risks of*
1339 *Exposures to Children* ([U.S. EPA, 2006](#)). CEM lifestages are re-labeled from this point forward as
1340 follows:

1341

- Adult (≥ 21 years) → Adult
- Youth 2 (16–20 years) → Teenager
- Youth 1 (11–15 years) → Young teen
- Child 2 (6–10 years) → Middle childhood
- Child 1 (3–5 years) → Preschooler
- Infant 2 (1–2 years) → Toddler
- Infant 1 (<1 year) → Infant

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1348 EPA assessed acute, chronic, and intermediate exposures to DIDP from consumer COUs. For the acute
1349 dose rate calculations, an averaging time of 1 day is used to represent the maximum time-integrated dose
1350 over a 24-hour period during the exposure event. The chronic dose rate is calculated iteratively at a 30-
1351 second interval during the first 24 hours and every hour after that for 60 days. Professional judgment and
1352 product use descriptions were used to estimate events per day and per month for the calculation of the
1353 intermediate dose.

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

Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					Qualitative/ Quantitative /None
				Inhalation	Dermal	Ingestion			
						Dust (Air)	Dust (Surface)	Mouthing	
Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Products are like synthetic leather fabrics in furniture	See synthetic leather furniture scenarios. Use patterns are for dermal exposure to automotive synthetic leather fabric is like the same considerations for furniture	✗	✓	✗	✗	✗	Quantitative
Automotive, fuel, agriculture, outdoor use products	Lubricants	Auto transmission conditioner	Direct contact during use; inhalation of emissions resulting from small spill of product	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)	Construction Adhesive for Small Scale Projects	Use of product in DIY ^c small-scale home repair and hobby activities. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)	Construction Sealant for Large Scale Projects	Use of product in DIY ^c small-scale home repair and hobby activities. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)	Epoxy Floor Patch	Use of product in DIY ^c home repair and hobby activities. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)	Lacquer Sealer (Non-Spray)	Application of product in house via roller or brush. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative

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Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					Qualitative/ Quantitative /None
				Inhalation	Dermal	Ingestion			
						Dust (Air)	Dust (Surface)	Mouthing	
Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)	Lacquer Sealer (Spray)	Application of product in house via spray. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Building/construction materials covering large surface areas including stone, plaster, cement, glass and ceramic articles (wire or wiring systems; joint treatment)	Solid flooring	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	✓ ^a	✓	✓ ^a	✓ ^a	✗	Quantitative
Construction, paint, electrical, and metal products	Electrical and Electronic Products	Wire Insulation	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical, mouthing by children	✓ ^a	✓	✓ ^a	✓ ^a	✓	Quantitative
Construction, paint, electrical, and metal products	Paints and coatings	Paint products/articles were not identified. For coatings, lacquers and sealants were used as their use patterns are similar	See lacquers and sealants	See lacquers and sealants					Quantitative
Furnishing, cleaning, treatment/care products	Fabrics, textiles, and apparel (as plasticizer)	See synthetic leather furniture and clothing	See synthetic leather furniture and clothing	See synthetic leather furniture and clothing					Quantitative
Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials (crafting paint applied to craft)	Rubber Eraser	Direct contact during use; rubber particles may be inadvertently ingested during use. Eraser may be mouthed by children	✗ ^b	✓	✗	✗	✓	Quantitative
Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials (crafting paint applied to craft)	Crafting paint applied to craft.	Current products were not identified. Foreseeable uses were matched with the lacquers, and sealants (small and large projects)	See lacquers and sealants (small and large projects)					Quantitative

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Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					Qualitative/ Quantitative /None
				Inhalation	Dermal	Ingestion			
						Dust (Air)	Dust (Surface)	Mouthing	
			because similar use patterns are expected.						
Packaging, paper, plastic, hobby products	Ink, toner, and colorant products	No consumer products identified	Current products were not identified. Foreseeable uses were matched with the lacquers, and sealants (small and large projects) because similar use patterns are expected.	See lacquers and sealants (small and large projects)					Quantitative
Packaging, paper, plastic, hobby products	PVC film and sheet	Miscellaneous coated textiles: truck awnings	Direct contact during use	✗ ^b	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Shower Curtain	Direct contact during use; inhalation of emissions / ingestion of dust adsorbed chemical while hanging in place	✓ ^a	✓	✓ ^a	✓ ^a	✗	Quantitative
Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Wallpaper	Direct contact during installation (teenagers and adults) and while in place; inhalation of emissions / ingestion of dust adsorbed chemical	✓ ^a	✓	✓ ^a	✓ ^a	✗	Quantitative
Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Foam Flip Flops	Direct contact during use	✗ ^b	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Synthetic Leather Furniture	Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	✓ ^a	✓	✓ ^a	✓ ^a	✓	Quantitative
Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Synthetic Leather Clothing	Direct contact during use	✗ ^b	✓	✗	✗	✗	Quantitative

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Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					Qualitative/ Quantitative /None
				Inhalation	Dermal	Ingestion			
						Dust (Air)	Dust (Surface)	Mouthing	
Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Bags	Direct contact during use	✗ ^b	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Toys, playgrounds, and sporting equipment	Fitness Ball	Direct contact during use	✗	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Toys, Playground, and Sporting Equipment	Children's Toys (new)	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne PM; ingestion by mouthing	✓ ^a	✓	✓ ^a	✓ ^a	✓	Quantitative
Packaging, paper, plastic, hobby products	Toys, Playground, and Sporting Equipment	Children's Toys (legacy)	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	✓ ^a	✓	✓ ^a	✓ ^a	✓	Quantitative
Other	Novelty Products	Adult Toys	Direct contact during use, ingestion by mouthing	✗ ^b	✓	✗	✗	✓	Quantitative
Disposal	Disposal	Down the drain products and articles	Down the drain and releases to environmental media	✗	✗	✗	✗	✗	None

✓ Scenario is considered either qualitatively or quantitatively in this assessment.
 ✓^a Scenario used in Indoor Dust Exposure Assessment in Section 4.1.2.3. These indoor dust articles scenarios consider the surface area from multiple articles such as toys and wire insulation, while furniture, curtains, flooring, and wallpaper already have large surface areas in which dust can deposit and contribute to significantly larger concentration of dust than single small articles and products.
 ✗ Scenario was deemed unlikely based 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 lifestyles, and low possibility of dust on surface due to barriers or low surface area for dust ingestion.
 ✗^b Scenario was deemed unlikely based low volatility and small surface area and likely negligible gas and suspended particle phase concentration.
 DIY^c – Do-it-Yourself

1356 ***Inhalation and Ingestion Exposure Routes Modeling Approaches***

1357 Key parameters for articles modeled in CEM 3.2 are summarized in detail in Section 2.1.2 in *Draft*
1358 *Consumer Exposure Analysis for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024v](#)). Calculations,
1359 sources, input parameters and results are also available in *Draft Consumer and Indoor Dust Exposure*
1360 *Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)). Generally, and when possible, model
1361 parameters were determined based on specific articles identified in this assessment and CEM defaults
1362 were only used where specific information was not available. A list of some of the most important input
1363 parameters for exposure from articles and products:

- 1364 • Weight fraction (articles and products),
- 1365 • Density (articles and products),
- 1366 • duration of use (products),
- 1367 • frequency of use for chronic, acute, and intermediate (products),
- 1368 • product mass used (products),
- 1369 • article surface area (articles),
- 1370 • chemical migration rate to saliva (articles),
- 1371 • area mouthed (articles), and
- 1372 • use environment volume (articles and products).

1373 Low, medium, and high scenarios correspond to the use of reported statistics, or single values usually an
1374 average, or range of maximum and minimum or when different values are reported for low, medium,
1375 and high, the corresponding statistics are maximum, calculated average from maximum and minimum,
1376 and minimum. Each input in the list was parameterized according to the article data found via systematic
1377 review, or provided by CEM if article specific parameters were not available, or an assumption based on
1378 article use descriptions by manufactures always leaning on the health protective values. For example, the
1379 chemical migration rate of DIDP was estimated based on data compiled in a review published by the
1380 Denmark Environmental Protection Agency in 2016 ([Danish EPA, 2016](#)). DINP chemical migration
1381 rates were used as surrogates since such data was not readily available for DIDP. The physical and
1382 chemical characteristics of DIDP and DINP that affect chemical migration rates are similar, but the
1383 larger size, higher molecular weight, and lower solubility of DIDP as compared to DINP can be
1384 expected to result in a slower rate of migration through the polymer matrix of the article and less
1385 partitioning to saliva for DIDP is expected in comparison to DINP. Thus, using chemical migration rates
1386 for DINP to calculate the DIDP dose received during mouthing will provide a health protective estimate,
1387 and it would still be a reasonable DIDP exposure estimate. For all scenarios, the near-field modeling
1388 option was selected to account for a small personal breathing zone around the user during product use in
1389 which concentrations are higher, rather than employing a single well-mixed room. A near-field volume
1390 of 1 m³ was selected.

1391

1392 ***Dermal Exposure Routes Modeling Approaches***

1393 Dermal modeling was done outside of CEM. The use of the CEM model for dermal absorption, which
1394 relies on total concentration rather than aqueous saturation concentration, would greatly overestimate
1395 exposure to DIDP in liquid and solid products and articles. See *Draft Consumer and Indoor Dust*
1396 *Exposure Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)) and ([U.S. EPA, 2024v](#)) for more
1397 details. The dermal dose of DIDP associated with use of both liquid products and solid articles was
1398 calculated in a spreadsheet outside of CEM. See *Draft Consumer Exposure Analysis for Diisodecyl*
1399 *Phthalate (DIDP)* ([U.S. EPA, 2024v](#)). For each product or article, high, medium, and low exposure
1400 scenarios were developed. Values for duration or dermal contact and area of exposed skin were
1401 determined based on reasonably expected use for each item. In addition, high, medium, and low
1402 estimates for dermal flux (liquid products) or absorption (solid products) were calculated and applied in

1403 the corresponding scenario. Key parameters for the dermal model are shown in Section 2.2 in ([U.S.](#)
1404 [EPA, 2024a](#)).

1405 **4.1.2.2 Modeling Dose Results by COU for Consumer and Indoor Dust**

1406 This section summarizes the dose estimates from inhalation, ingestion, and dermal exposure to DIDP in
1407 consumer products and articles. Detailed tables of the dose results for acute, intermediate, and chronic
1408 exposures are available in Section 4 of *Draft Consumer and Indoor Dust Exposure Assessment for*
1409 *Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)) and *Draft Consumer Risk Calculator for Diisodecyl Phthalate*
1410 (*DIDP*) ([U.S. EPA, 2024w](#)).

1411 ***Acute, Intermediate, and Chronic Dose Rate Results, Conclusions, and Data Patterns***

1412 Figure 4-2 summarizes the high, medium, and low acute dose rate results from modeling in CEM and
1413 outside of CEM (dermal only) for all exposure routes for infants, children, teenagers, and adults. The
1414 chronic average daily dose (CADD) and intermediate figures resulted in the same data patterns as the
1415 acute doses, see Section 4 in ([U.S. EPA, 2024a](#)) figure narrative under each lifestyle for data patterns
1416 and discussion. Only four product examples under the *Construction, paint, electrical, and metal*
1417 *products Adhesives and Sealants and Paints and Coatings* COUs were assessed for intermediate
1418 exposure scenarios.

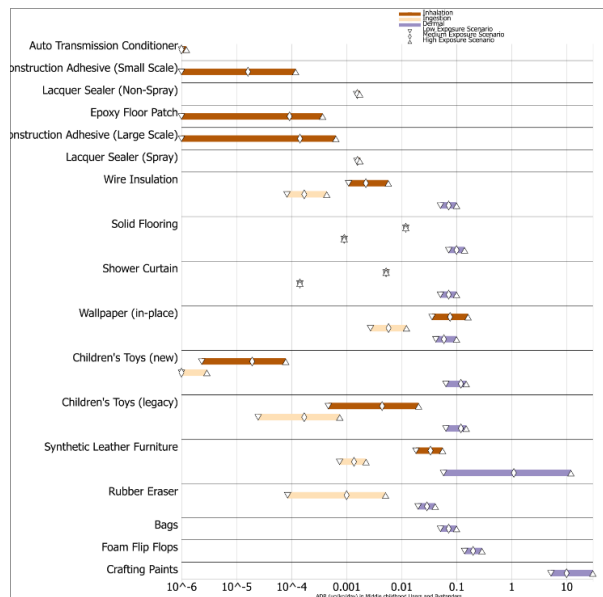
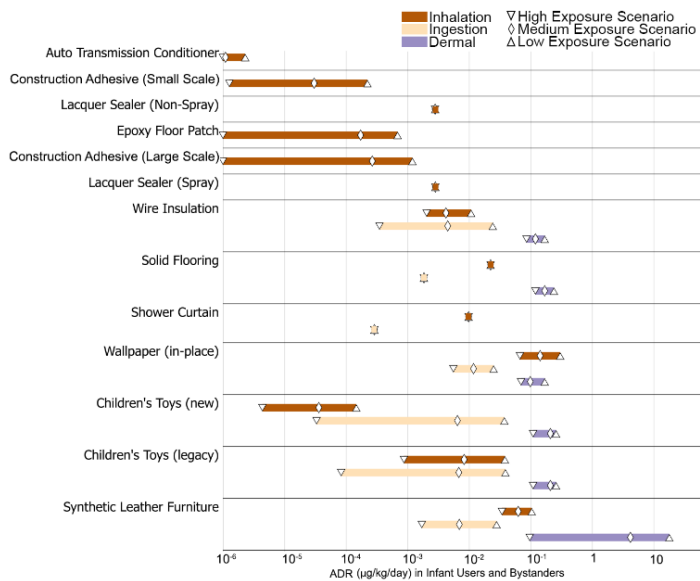
1419 Some products and articles did not have dose results because the product or article was not targeted for
1420 that lifestyle or exposure route. Among the younger lifestyles, there was no clear pattern which showed
1421 a single exposure route most likely to drive exposure. However, for teens and adults, dermal contact was
1422 a strong driver of exposure to DIDP, with the dose received being generally higher or similar (purple
1423 bars in figures) than to the dose received from exposure via inhalation or ingestion.

1424 In addition to assessing users of various lifestyles EPA consider bystanders exposures to consumer
1425 products and articles where applicable. Bystanders are people that are not in direct use or application of
1426 the product but can be exposed to DIDP by proximity to the use of the product via inhalation of gas-
1427 phase emissions or suspended dust. All bystander scenarios were assessed for children under 10 years
1428 for products that are not targeted for the use of children under 10 and assessed as users for older than 11
1429 years because the products can be used by children 11 and older. People older than 11 yrs can also be
1430 bystanders, however the user scenarios utilize inputs that would result in larger exposure doses and thus
1431 the bystander scenarios would have lower risk estimates. Bystander scenarios and COUs include: (1)
1432 Automotive, fuel, agriculture, outdoor use products; lubricants; auto transmission conditioner; (2)
1433 Construction, paint, electrical, and metal products; Adhesives and sealants (including plasticizers in
1434 adhesives and sealants); Construction Adhesive for Small Scale Projects, Construction Sealant for Large
1435 Scale Projects, and Epoxy Floor Patch; and (3) Construction, paint, electrical, and metal products;
1436 Adhesives and sealants, and Paints and Coatings; spray and non-spray lacquer sealer.

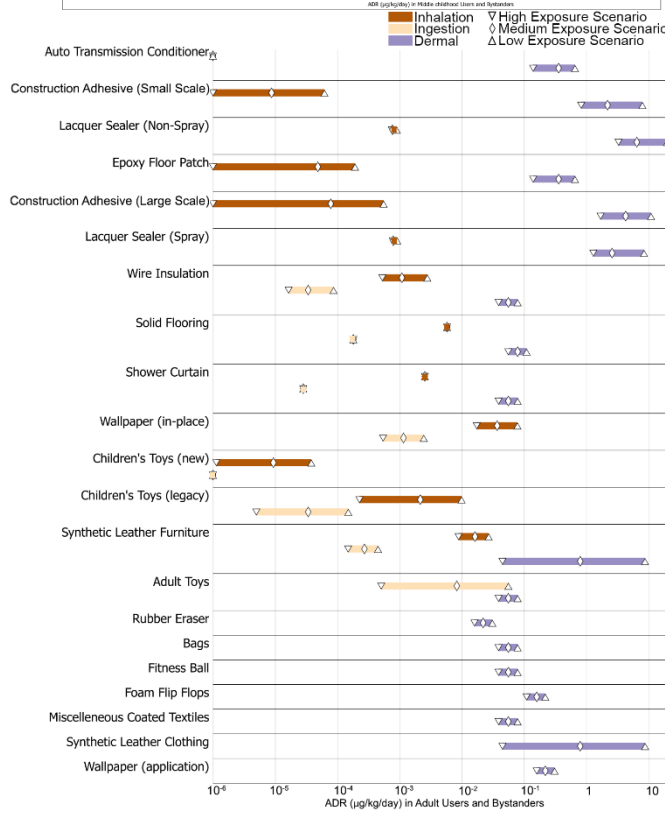
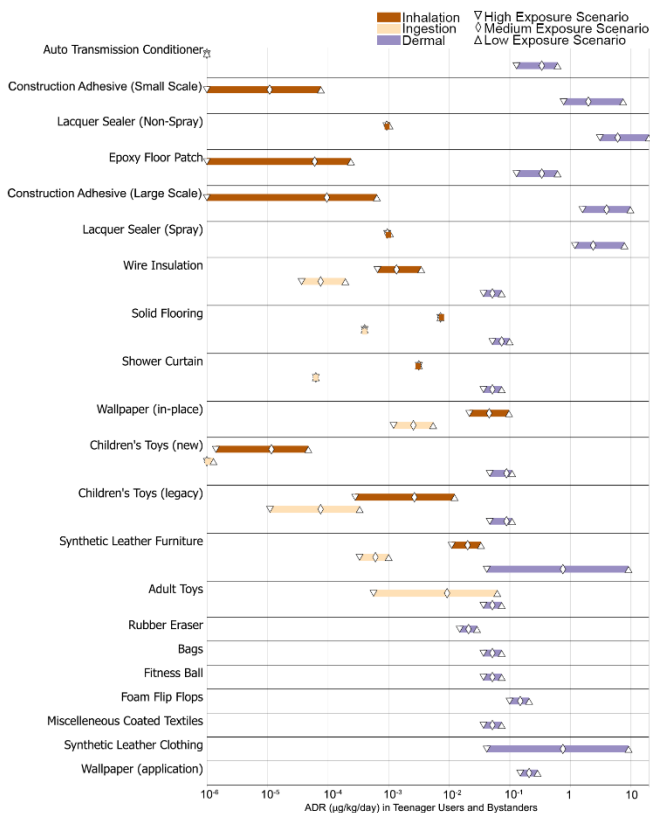
1437 For the assessment of indoor dust exposures and estimating contribution to dust from individual COUs,
1438 EPA recreated plausible indoor environment using consumer products and articles commonly present in
1439 indoor spaces inhalation exposure from toys, flooring, synthetic leather furniture, wallpaper, and wire
1440 insulation include a consideration of dust collected on the surface of a relatively large area, like flooring,
1441 furniture, and wallpaper, but also multiple toys and wires collecting dust with DIDP and subsequent
1442 inhalation and ingestion. All lifestyles assessed under the indoor dust exposure scenarios are considered
1443 users of the articles being assessed.

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Figure 4-2. Acute Dose Rate for DIDP from Ingestion, Inhalation, Dermal Exposure Routes in Infant, Children, Teenagers and Young Adults, and Adults

Infants <1 year old (top left panel); children 6 to 10 years old (top right panel); teenagers and young adults 16 to 20 years old (bottom left panel); and adults older than 21 years old (bottom right panel)

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1459

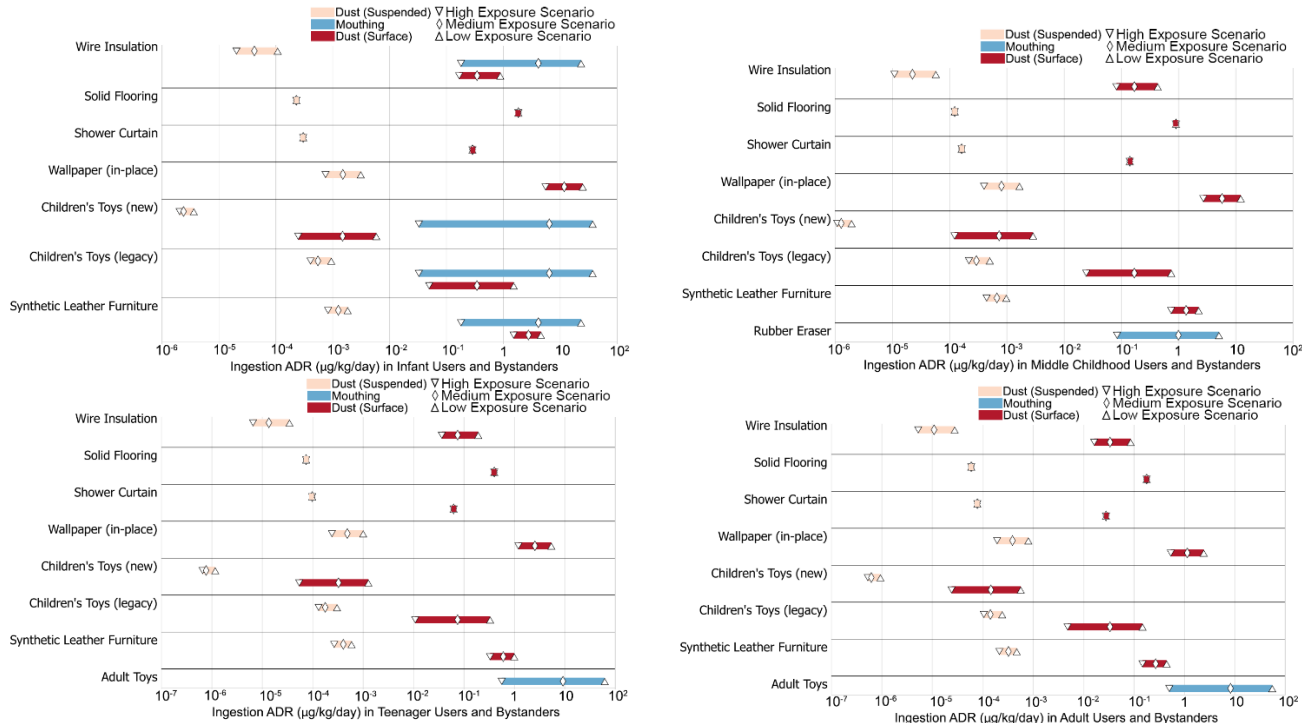
1460

1461

In addition, for each lifestage and additional set of figures is provided which shows the contribution of mouthing, suspended dust ingestion, and settled dust ingestion to the aggregated ingestion value. For all articles modeled in all lifestages, DIDP doses from ingestion of settled dust were higher than those from ingestion of suspended dust. This is likely because the overall ingestion rate of suspended dust is lower than that of settled dust. CEM models intake of small (<10 µm) particles in air as inhalation exposure,

1462 while larger airborne particles are ingested. However, this larger size fraction will settle more quickly,
 1463 resulting in a higher density of ingestible dust on surfaces as compared to air. However, when mouthing
 1464 exposure was included for an article, the dose received was generally higher than or similar to the dose
 1465 received from ingestion of dust, indicating that mouthing may be a significant driver of exposure to
 1466 DIDP when this behavior is present and therefore a particular concern for young children. Mouthing
 1467 tendencies decrease significantly for older than 6 years lifestages; thus, most scenarios do not estimate
 1468 exposure via mouthing. Ingestion and inhalation of surface dust is an exposure route with similar dose
 1469 estimates as dermal for most of the articles used in the indoor dust assessment.
 1470

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1472

Figure 4-3. Acute Dose Rate of DIDP from Ingestion of Airborne Dust, Surface Dust, and Mouthing for Infants, Children, Teenagers and Young Adults, and Adults

1473
1474

1475 Infants <1 year old (top left panel); children 6 to 10 years old (top right panel); teenagers and young adults 16 to
 1476 20 years old (bottom left panel); and adults older than 21 years old (bottom right panel)
 1477

1478

1478 The spread of values estimated for each product or article reflects the aggregate effects of variability and
 1479 uncertainty in key modeling parameters for each item; acute dose rate for some products/articles covers
 1480 a larger range than others primarily due to a wider distribution of DIDP weight fraction values, chemical
 1481 migration rates for mouthing exposures, and behavioral factors such as duration of use or contact time
 1482 and mass of product used as described in Section 4.1.2.1. Key differences in exposures among lifestages
 1483 include designation as product user or bystander; behavioral differences such as mouthing durations,
 1484 hand to mouth contact times, and time spent on the floor; and dermal contact expected from touching
 1485 specific articles which may not be appropriate for some lifestages.
 1486

1487

1487 For wallpaper, dust inhalation and ingestion contribute more to exposure than dermal contact. This is
 1488 likely because the wallpaper scenario only considers in-place exposure rather than the installation
 1489 process. Ingestion of dust on flooring is lower than inhalation likely due to particles in the inhalable size
 1490 fraction can remain suspended for long periods of time and inhalation exposure is continuous while
 1491 ingestion of dust from surfaces is not. Dermal contact with furniture is larger than any other dose,
 1492 followed by wallpaper and furniture inhalation.

1492

4.1.2.3 Monitoring Concentrations of DIDP in the Indoor Environment

For the indoor exposure assessment, EPA considered modeling and monitoring data. This section describes indoor dust monitoring data exclusively while modeling data and approaches are summarized in Sections 4.1.2.1 and 4.1.2.2. Modeling data used in indoor dust assessment originated from the consumer exposure assessment, to reconstruct major indoor sources of DIDP into dust and obtain COU and product specific exposure estimates for ingestion and inhalation.

Monitoring data are expected to represent aggregate exposure to DIDP in dust resulting from all sources present in a home. While it is not a good indicator of individual contributions of specific COUs, it provides a real-world indicator of total exposure through dust. The monitoring data considered are from residential dust samples from studies conducted in countries with comparable standards of living to the United States because no U.S. DIDP dust concentration data was identified. Measured DIDP concentrations were compared to determine consistency among datasets, and data from Canada were ultimately selected as the most representative of United States residential dust exposures. The Canadian data were selected because the underlying study involved a large random sample from municipalities across Canada and because Canadian consumer behavior was expected to be most similar to that of consumers in the United States. The data on DIDP concentrations were used with body weight data representative of the US population taken from the Exposure Factors Handbook ([U.S. EPA, 2011a](#)) and estimated daily dust intake rates taken from [Özkaynak et al. \(2022\)](#) to derive an estimate of daily DIDP intake in residential dust per kilogram body weight. The monitoring studies and assumptions made to estimate exposure are described in detail in Section 3.2 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)).

Indoor Dust Monitoring Data

Because no U.S. indoor dust monitoring data for DIDP were identified, EPA evaluated non-US data. The primary data source was the Canadian House Dust Study, as reported in the Canadian 2015 State of the Science Report ([EC/HC, 2015b](#)). The Canadian assessment used [Kubwabo et al. \(2013\)](#) as the basis for the estimated daily DIDP ingestion dose (intake rate) for dust. [Kubwabo et al. \(2013\)](#) reported DIDP dust concentrations from 126 households, which were sampled as part of the Canadian House Dust Study. EPA compared [Kubwabo et al. \(2013\)](#) reported concentrations to other non-U.S. DIDP household dust concentrations to confirm that observed DIDP concentrations were reasonably similar to one another (within one order of magnitude) and to identify similarities and differences in sampled population and sampling methods. The non-U.S. data used to confirm the Canadian assessment were from residential monitoring data from Canada, Belgium, Holland, Ireland, and Norway in two studies ([Giovanoulis et al., 2017](#)) and ([Christia et al., 2019](#)).

These studies, representing samples from four European countries, showed median DIDP concentrations in house dust that are well within an order of magnitude of the median total house dust value from [Kubwabo et al. \(2013\)](#). The range within an order of magnitude of the median DIDP concentration from [Kubwabo et al. \(2013\)](#) was 11.1 to 1110 µg/g, and the range of median values was from 26 µg/g in the Belgian samples from [Christia et al. \(2019\)](#), to 140.2 µg/g in the vacuum samples from Norway in [Giovanoulis et al. \(2017\)](#). The Dutch and Irish median values in [Christia et al. \(2019\)](#) were 34 µg/g and 72 µg/g, respectively. Therefore, the concentrations from the Canadian House Dust Study are consistent with results from residents in similar income countries during a similar time period. It is thus appropriate to use this data as a surrogate for U.S. exposure assessment.

1539 ***Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the Indoor Dust Monitoring***
 1540 ***Data***

1541 Indoor dust concentrations were derived from [Kubwabo et al. \(2013\)](#), which in turn subsampled the
 1542 Canadian House Dust Study which was conducted from 2007-2010. That study sampled residential
 1543 house dust in approximately one thousand randomly selected households in 13 large Canadian
 1544 municipalities. It is possible that sampling biases were introduced by the choice of large municipalities
 1545 and by differences among households that chose to participate in the study. Differences in consumer
 1546 behaviors, housing type and quality, tidiness, and other variables that affect DIDP concentrations in
 1547 household dust are possible between participating households and the general population. Additionally,
 1548 because the underlying samples for [Kubwabo et al. \(2013\)](#) were taken between 2007-2010, uncertainty
 1549 is introduced due to the length of time that has elapsed.

1551 There are several potential challenges in interpreting available indoor dust monitoring data. The
 1552 challenges are summarized in Table 4-7.

1553 **Table 4-7. Sources of Uncertainty in DIDP Dust Monitoring Data**
 1554

Source of Uncertainty
Samples may have been collected at exposure times or for exposure durations not expected to be consistent with a presumed hazard based on a specified exposure time or duration
Samples may have been collected at a time or location when there were multiple sources of DIDP that included non-TSCA COUs
None of the identified monitoring data contained source apportionment information that could be used to determine the fraction of DIDP in dust samples that resulted from a particular TSCA or non-TSCA COU
Activity patterns may differ according to demographic categories (<i>e.g.</i> , stay at home/work from home individual vs an office worker) which can affect exposures especially to articles that continually emit a chemical of interest

1555
 1556 Other considerations like specific household construction approaches, peoples' use and activity patterns,
 1557 and some indoor environments may have more ventilation than others, which may change across
 1558 seasons.

1560 ***Weight of Scientific Evidence Conclusions for Indoor Dust Monitoring Data***

1561 The weight of scientific evidence conclusion for the indoor dust exposure assessment of DIDP from
 1562 monitored residential data is summarized in Table 4-8. Taken as a whole, with moderate confidence in
 1563 the DIDP concentration monitoring data in indoor residential dust from [Kubwabo et al. \(2013\)](#), robust
 1564 confidence in body weight data from the Exposure Factors Handbook [U.S. EPA \(2011a\)](#), and moderate
 1565 confidence in dust intake data from [Özkaynak et al. \(2022\)](#), EPA has assigned moderate confidence to
 1566 our estimates of daily DIDP intake rates from ingestion of indoor dust in residences.

1567
 1568 The exposure estimate for indoor dust is dependent on studies that include indoor residential dust
 1569 monitoring data. Based on the systematic review SOP, only studies that included indoor dust samples
 1570 taken from residences were included for data extraction. All studies that were included for data
 1571 extraction were rated "High" quality per the exposure systematic review criteria.

1572

1573 **Table 4-8. Weight of Scientific Evidence Conclusions for Indoor Dust Ingestion Exposure**

Scenario	Confidence in Data Used ^a	Confidence in Model Inputs		Weight of Scientific Evidence Conclusion
		Body Weight ^b	Dust Ingestion Rate ^c	
Indoor exposure to residential dust via ingestion	++	+++	++	++

+ = Slight; ++ = Moderate; +++ = Robust
^a [Kubwabo et al. \(2013\)](#); with [Giovanoulis et al. \(2017\)](#) and [Christia et al. \(2019\)](#) as comparators
^b [U.S. EPA \(2011a\)](#)
^c [Özkaynak et al. \(2022\)](#)

1574
1575 Table 4-8 presents EPA’s level of confidence in the data quality of the input datasets for estimating dust
1576 ingestion from monitoring data, including the DIDP dust monitoring data themselves, the estimates of
1577 U.S. body weights, and the estimates of dust ingestion rates, according to the following:

- 1578 • Robust confidence (++++) means the supporting weight of scientific evidence outweighs the
1579 uncertainties to the point that EPA has decided that it is unlikely that the uncertainties could have
1580 a significant effect on the exposure estimate.
- 1581 • Moderate confidence (++) means the supporting scientific evidence weighed against the
1582 uncertainties is reasonably adequate to characterize exposure estimates, but uncertainties could
1583 have an effect on the exposure estimate.
- 1584 • Slight confidence (+) means EPA is making the best scientific assessment possible in the absence
1585 of complete information. There may be significant uncertainty in the underlying data that need to
1586 be considered.

1587 Details on how the confidence conclusions for each of the data sources were reached can be found in
1588 Section 5.2 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate*
1589 (*DIDP*) ([U.S. EPA, 2024a](#)). These confidence conclusions were derived from a combination of
1590 systematic review (*i.e.*, the quality determinations for individual studies) and the assessor’s professional
1591 judgment. It is important to note that these confidence conclusions refer to the assessor's confidence in
1592 the data quality and numerical accuracy of the underlying data and the resulting model estimates. A
1593 confidence evaluation of "moderate" or "slight" confidence in an individual data source or model
1594 estimate does not indicate that the resulting risk characterization is not health protective.

1595 **4.1.2.4 Indoor Aggregate Dust Exposure Approach and Methodology**

1596 EPA considered the available modeling and monitoring data to estimate the aggregate exposures to
1597 DIDP that may occur via dust in a typical indoor environment. Modeling data used in indoor dust
1598 assessment originated from the consumer exposure assessment, Section 4.1.2.1, to reconstruct major
1599 indoor sources of DIDP into dust and obtain COU and product specific exposure estimates for ingestion
1600 and inhalation. The monitoring data considered, described in Section 4.1.2.3, are from residential dust
1601 samples from studies conducted in countries with comparable standards of living to the United States.
1602 Detailed descriptions of the indoor dust approaches and methodologies are available in Section 3 of the
1603 *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA,](#)
1604 [2024a](#)).

1605
1606 For the modeling indoor dust assessment EPA identified article specific information by COU to
1607 construct relevant and representative exposure scenarios from the consumer assessment, Section 4.1.2.1.

1608 Exposure to DIDP via ingestion of dust was assessed for all articles expected to contribute significantly
 1609 to dust concentrations due to high surface area ($> \sim 1 \text{ m}^2$) for either a single article or collection of like
 1610 articles as appropriate, including:

- 1611 • solid flooring;
- 1612 • wallpaper;
- 1613 • synthetic leather furniture;
- 1614 • shower curtains;
- 1615 • children's toys, legacy;
- 1616 • children's toys, new; and
- 1617 • wire insulation.

1618 These exposure scenarios were modeled in CEM for inhalation, ingestion of suspended dust, and
 1619 ingestion dust from surfaces. See Section 4.1.2.1 for CEM parameterization, input values, and article
 1620 specific scenario assumptions and sources.

1621

1622 *Indoor Dust Comparison between Monitoring and Modeling Ingestion Estimates*

1623 The exposure estimates for indoor dust from the CEM model are larger than those indicated by the
 1624 monitoring approach. Table 4-9 compares the sum of the chronic daily dose central tendency for indoor
 1625 dust ingestion from CEM outputs for all COUs to the central tendency predicted daily dose from the
 1626 monitoring approach.

1627

1628 **Table 4-9 Comparison Between Modeled and Monitored Daily Dust Intake Estimates for DIDP**

Lifestage	Daily DIDP Intake Estimate from Dust, $\mu\text{g}/\text{kg}\cdot\text{day}$, Modeled Exposure ^a	Daily DIDP Intake Estimate from Dust, $\mu\text{g}/\text{kg}\cdot\text{day}$, Monitoring Exposure ^b
Infant (<1 Year)	17.46	0.35 ^c
Toddler (1–2 Years)	21.62	0.22
Preschooler (3–5 Years)	24.41	0.09
Middle Childhood (6–10 Years)	8.56	0.045
Young Teen (1–15 Years)	4.79	0.017
Teenager (16–20 Years)	3.80	0.0054
Adult (21+ Years)	1.67	0.0048 ^d

^a Sum of chronic daily doses for indoor dust ingestion for “medium” intake scenario for all seven dust COUs modeled in CEM
^b Central tendency estimate of daily dose for indoor dust ingestion from monitoring data
^c Weighted average by month of monitored lifestages from birth to 12 months
^d Weighted average by year of monitored lifestages from 21 to 80 years

1629

1630 The sum of DIDP intakes from dust in CEM modeled scenarios were, in all cases, considerably higher
 1631 than those predicted by the monitoring approach. These discrepancies partially stem from differences in
 1632 the exposure assumptions of the CEM model versus the assumptions made when estimating daily dust
 1633 intakes in [Özkaynak et al. \(2022\)](#). Dust intakes in [Özkaynak et al. \(2022\)](#) decline rapidly as a person
 1634 ages due to behavioral factors including walking upright instead of crawling, cessation of exploratory
 1635 mouthing behavior, and a decline in hand-to-mouth events. This age-mediated decline in dust intake,
 1636 which is more rapid for the [Özkaynak et al. \(2022\)](#) study than in CEM, partially explains why the
 1637 margin between the modeled and monitoring results grows larger with age. Additional discussion of the
 1638 differences between modeled and monitored approaches for estimating DIDP exposure from indoor dust
 1639 ingestion can be found in Section 4.4 of the *Draft Consumer and Indoor Dust Exposure Assessment for*

1640 *Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024a](#)). Because the daily DIDP intake estimates from the
1641 modeled exposure approach were, in all cases, higher than those predicted by the monitoring approach,
1642 the higher modeled exposures were used in the derivation of risk estimates for aggregate indoor dust
1643 exposure. Because the modeled DIDP dust risk estimates were higher than the monitored DIDP risk
1644 estimates, EPA is confident that the resulting risk characterizations are health protective.

1645 **4.1.2.5 Weight of Scientific Evidence Conclusions for Consumer Exposure**

1646 Key sources of uncertainty for evaluating exposure to DIDP in consumer goods and strategies to address
1647 those uncertainties are described in detail in Section 5.1 of *Draft Consumer and Indoor Dust Exposure*
1648 *Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)). Generally, designation of robust confidence
1649 suggests thorough understanding of the scientific evidence and uncertainties. The supporting weight of
1650 scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties
1651 could have a significant effect on the exposure estimate. The designation of moderate confidence
1652 suggests some understanding of the scientific evidence and uncertainties. More specifically, the
1653 supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize
1654 exposure estimates. The designation of slight confidence is assigned when the weight of scientific
1655 evidence may not be adequate to characterize the scenario, and when the assessor is making the best
1656 scientific assessment possible in the absence of complete information and there are additional
1657 uncertainties that may need to be considered. While the uncertainty for some of the scenarios and
1658 parameters ranges from slight to robust the overall confidence to use the results for risk characterization
1659 ranges from moderate to robust, depending on COU scenario. The basis for the moderate to robust
1660 confidence in the overall exposure estimates is a balance between using parameters that will represent
1661 various populations use patterns and lean on protective assumptions that are not excessive or
1662 unreasonable.

1663 **4.1.2.5.1 Strength, Limitations, Assumptions, and Key Sources of Uncertainty for** 1664 **the Consumer Exposure Assessment**

1665 The exposure assessment of chemicals from consumer products and articles has inherent challenges due
1666 to many sources of uncertainty in the analysis, including variations in product formulation, patterns of
1667 consumer use, frequency, duration, and application methods. Variability in environmental conditions
1668 may also alter physical and/or chemical behavior of the product or article.

1669 ***Product Formulation and Composition***

1670 Variability in the formulation of consumer products, including changes in ingredients, concentrations,
1671 and chemical forms, can introduce uncertainty in exposure assessments. In addition, data were often
1672 limited for weight fractions of DIDP in consumer goods. Where possible, EPA obtained multiple values
1673 for weight fractions for similar products or articles. The lowest value was used in the low exposure
1674 scenario, the highest value in the high exposure scenario, and the average of all values in the medium
1675 exposure scenario. Weight fraction of DIDP in articles was sourced from the available literature and
1676 database values. A confidence of robust was selected for products with multiple sources, moderate was
1677 selected for products with limited sources but more current, and slight was selected for products with
1678 limited and older sources. The uncertainty was improved by using ranges that included either a wide
1679 range or higher values that are considered health protective, but not excessive. The low, medium, and
1680 high exposure estimates capture a range of concentrations that is representative of past, present, and
1681 future practices, encompassing lots of possible exposures.
1682
1683

1684 ***Product Use Patterns***

1685 Consumer use patterns like frequency of use, duration of use, and methods of application are expected to
1686 differ. Use duration and frequency were primarily sourced from manufacturer use instructions, the
1687 EPA's *Exposure Factors Handbook*, and by the judgment of the exposure assessor. A confidence rating
1688 of robust was selected when the used values are well understood and represent a wide range of the
1689 population. Moderate was selected for durations of use sourced from manufacturer use instructions that
1690 had multiple types of products with different use instructions and variability is expected to increase with
1691 numerous products available. The main limitation in this analysis and source of uncertainty in the
1692 selected inputs is in the accuracy of the selected use pattern inputs, however EPA is confident that the
1693 selected inputs include health protective inputs in the low, medium, and high exposure scenarios. The
1694 high duration scenarios represent high intensity users, while the average expected use patterns are
1695 captured in the medium scenarios, and low use patterns for occasional and incidental exposures.

1696 ***Article Surface Area***

1697 The surface area of an article directly affects the potential for DIDP emissions to the indoor
1698 environment. For each article modeled for inhalation exposure, low, medium, and high estimates for
1699 surface area were calculated to represent multiple possibilities that capture upper and lower bounds. This
1700 approach relied on manufacturer-provided dimensions where possible, or values from the EPA Exposure
1701 Factors Handbook for floor and wall coverings. For small items which might be expected to be present
1702 in a home in significant quantities, such as insulated wires and children's toys, aggregate values were
1703 calculated for the cumulative surface area for each type of article in the indoor environment. Surface
1704 area inputs are based on manufacturer use instructions, the EPA's *Exposure Factors Handbook*, and by
1705 the judgment of the exposure assessor. Robust confidence rating was selected for commonly known
1706 product dimensions and moderate for when the assessor made assumptions about the number of products
1707 present in a room.

1708 ***Human Behavior***

1709 CEM 3.2 has three different activity patterns: stay-at-home, part-time out-of-the home (daycare, school,
1710 or work), and full-time out-of-the-home. The activity patterns were developed based on the
1711 Consolidated Human Activity Database (CHAD). For all products and articles modeled, the stay-at-
1712 home activity pattern was chosen as it is the most protective assumption.

1713 Mouthing durations are a source of uncertainty in human behavior. There was considerable variability in
1714 the data due to behavioral differences among children of the same lifestage and due to varying
1715 experimental setup in the studies. EPA opted to use a range that represented the variability in the data so
1716 various mouthing behavior could be captured in the low, medium, and high exposure duration scenarios.
1717 The upper bound used for the high duration scenarios of the reported mouthing durations is likely to
1718 provide a health protective estimate for mouthing of soft plastic items likely to contain DIDP. Mouthing
1719 duration confidence designation of robust is given to scenarios about children toys because the
1720 information used to derive these values is more comprehensive and specific about children toys and
1721 children behaviors while other non-toy scenarios are less specific about mouthing durations and more
1722 generalized, those were given a moderate confidence rating. In addition, mouthing area robust rating
1723 was selected for scenarios in which the mouthing area is well defined by object boundaries, moderate
1724 when object dimensions were based on generalizations and assumptions by the assessor from
1725 manufacturer descriptions.

1726 ***Modeling Parameters for DIDP Flux, Dermal Absorption, and Chemical Migration***

1727 DIDP is considered a data poor chemical with respect to dermal absorption, meaning chemical specific
1728 empirical information is scarce. Data were lacking for key parameters, particularly the skin permeability

1733 coefficient and chemical migration rate from articles mouthed. To address this data gap, a scientifically
1734 informed approach was adopted, wherein values from analogous chemicals sharing comparable physical
1735 and chemical properties were leveraged as surrogates. These surrogate data, drawn from substances with
1736 established empirical evidence and recognized similarity in relevant characteristics, facilitated the
1737 estimation of needed parameters.

1738
1739 For liquid products EPA identified one set of experimental data related to the dermal absorption of neat
1740 DIDP ([Elsisi et al., 1989](#)) which was conducted *in vivo* using male rats. Results from *in vitro* dermal
1741 absorption experiments (([Scott et al., 1987](#))) showed that rat skin was more permeable than human skin.
1742 Though there is uncertainty regarding the magnitude of difference between dermal absorption through
1743 rat skin versus human skin for DIDP, based on DIDP physical and chemical properties (solubility), EPA
1744 is confident that the *in vivo* dermal absorption data using male F344 rats ([Elsisi et al., 1989](#)) provides an
1745 upper bound of dermal absorption of DIDP and therefore health protective.

1746
1747 There is uncertainty with respect to the modeling of dermal absorption of DIDP from solid matrices or
1748 articles. Because there were no available data related to the dermal absorption of DIDP from solid
1749 matrices or articles, EPA assumed that dermal absorption of DIDP from solid objects would be limited
1750 by aqueous solubility of DIDP. Although this assumption introduces significant uncertainty in the
1751 exposure dose, its use in the risk estimate is reasonable. The overall assumption that DIDP partitions to
1752 liquid (sweat) on the skin and due to DIDP affinity to organic material the absorption through the skin is
1753 likely to happen. The uncertainty stands in the accuracy of the amount of DIDP that is absorbed,
1754 however, EPA is confident that the selected approach represents an upper bound of dermal absorption of
1755 DIDP from solid articles.

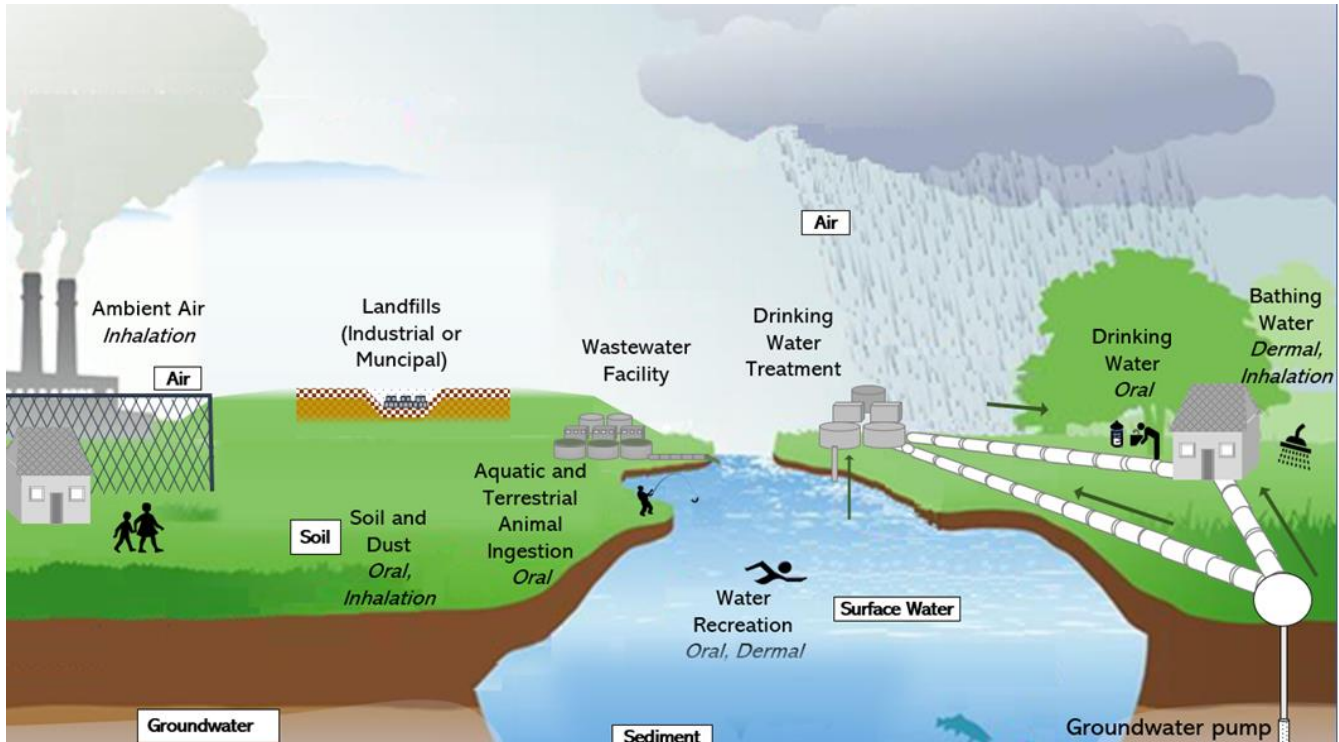
1756
1757 For chemical migration rates to saliva, existing data were highly variable both within and between
1758 studies. This high variability in chemical migration rate values adds on to the uncertainty from
1759 differences among similar items due to variations in chemical makeup and polymer structure. As such,
1760 an effort was made to choose DIDP migration rates likely to be representative of broad classes of items
1761 that make up consumer COUs produced with different manufacturing processes and material
1762 formulations. Based on available data for chemical migration rates of DIDP to saliva, the range of values
1763 used in this assessment (1.6, 13.3, and 44.8 $\mu\text{g}/\text{cm}^2/\text{hr}$) are considered likely to capture the true value of
1764 the parameter.

1765 **4.1.3 General Population Exposures**

1766 General population exposures occur when DIDP is released into the environment and the environmental
1767 media is then a pathway for exposure. As described in the *Draft Environmental Release and*
1768 *Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)), releases of
1769 DIDP are expected in air, water, and disposal to landfills. Figure 4-4 provides a graphic representation
1770 of where and in which media DIDP is estimated to be found due to environmental releases and the
1771 corresponding route of exposure for the general population.

1772
1773 EPA took a screening-level approach to assess DIDP exposure for the general population. Screening
1774 level assessments are useful when there is little location- or scenario-specific information available. EPA
1775 began its DIDP general population exposure assessment using a screening level approach because of
1776 limited environmental monitoring data for DIDP and lack of location data for DIDP releases. A
1777 screening-level analysis relies on conservative assumptions, including default input parameters for
1778 modeling exposure, to assess exposures that would be expected to be on the high end of the expected
1779 exposure distribution. Details on the use of screening-level analyses in exposure assessment can be
1780 found in EPA's *Guidelines for Human Exposure Assessment* ([U.S. EPA, 2019b](#))

1781 EPA evaluated the reasonably available information for releases of DIDP from facilities that use,
1782 manufacture, or process DIDP under industrial and/or commercial COUs subject to TSCA regulations
1783 detailed in the *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl*
1784 *Phthalate (DIDP)* (U.S. EPA, 2024e). As described in Section 3.3, using the release data, EPA modeled
1785 predicted concentrations of DIDP in surface water, sediment, drinking water, and soil from air to soil
1786 deposition in the United States. Table 3-6 summarizes the high-end DIDP concentrations in
1787 environmental media from environmental releases. The reasoning for assessing different pathways
1788 qualitatively or quantitatively is discussed briefly in Section 3.3 and additional detail can be found in
1789 *Draft Environmental Media and General Population Screening for Diisodecyl Phthalate (DIDP)* (U.S.
1790 EPA, 2024d).
1791



1792
1793 **Figure 4-4. Potential Human Exposure Pathways to DIDP for the General Population**
1794

1795 High-end estimates of DIDP concentration in the various environmental media presented in Table 3-6
1796 and the *Draft Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)*
1797 (U.S. EPA, 2024d) were used for screening-level purposes in the general population exposure
1798 assessment. EPA’s *Guidelines for Human Exposure Assessment* (U.S. EPA, 2019b) defines high-end
1799 exposure estimates as a “plausible estimate of individual exposure for those individuals at the upper end
1800 of an exposure distribution, the intent of which is to convey an estimate of exposure in the upper range
1801 of the distribution while avoiding estimates that are beyond the true distribution.” If risk is not found for
1802 these individuals with high-end exposure, no risk is anticipated for central tendency exposures, which is
1803 defined as “an estimate of individuals in the middle of the distribution.” Plainly, if there is no risk for an
1804 individual identified as having the potential for the highest exposure associated with a COU for a given
1805 pathway of exposure, then that pathway was determined not to be a pathway of concern and not pursued
1806 further. If any pathways were identified as a pathway of concern for the general population, further
1807 exposure assessments for that pathway would be conducted to include higher tiers of modeling when
1808 available, refinement of exposure estimates, and exposure estimates for additional subpopulations and
1809 OES/COUs.
1810

1811 Identifying individuals at the upper end of an exposure distribution included consideration of high-end
 1812 exposure scenarios defined as those associated with the industrial and commercial releases from a COU
 1813 and OES that resulted in the highest environmental media concentrations. As described in Section 3.3,
 1814 EPA focused on estimating high-end concentrations of DIDP from the largest estimated releases for the
 1815 purpose of its screening level assessment for environmental and general population exposures. This
 1816 means that EPA considered the environmental concentration of DIDP in a given environmental media
 1817 resulting from the OES that had the highest release compared to any other OES for the same releasing
 1818 media. Release estimates from OES resulting in lower environmental media concentrations were not
 1819 considered for this screening-level assessment. Additionally, individuals with the greatest intake rate of
 1820 DIDP per body weight were considered to be those at the upper end of the exposure.
 1821

1822 Table 4-10 summarizes the high-end exposure scenarios that were considered in the screening level
 1823 analysis, including the lifestage assessed as the most potentially exposed population based on intake rate
 1824 and body weight. Table 4-10 also indicates which pathways were evaluated quantitatively or
 1825 qualitatively. Exposure was assessed quantitatively only when environmental media concentrations were
 1826 quantified for the appropriate exposure scenario. For example, exposure from soil or groundwater
 1827 resulting from DIDP release to the environment via biosolids or landfills was not quantitatively assessed
 1828 because DIDP concentrations to the environment from biosolids and landfills was not quantified. Due to
 1829 the high confidence in the biodegradation rates and physical and chemical data, there is robust
 1830 confidence that in soils receiving DIDP will not be mobile and will have low persistence potential and
 1831 there is robust confidence that DIDP is unlikely to be present in landfill leachates. However, exposure
 1832 was still assessed qualitatively for exposures potentially resulting from biosolids and landfills. Further
 1833 details on the screening level approach and exposure scenarios evaluated by EPA for the general
 1834 population are provided in the *Draft Environmental Media and General Population Exposure for*
 1835 *Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)). Selected OESs represent those resulting in the highest
 1836 modeled environmental media concentrations, for the purpose of a screening-level analysis.
 1837
 1838

Table 4-10. Exposure Scenarios Assessed in General Population Screening Level Analysis

OES ^a	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)
All	Biosolids	No specific exposure scenarios were assessed for qualitative assessments			Qualitative
All	Landfills	No specific exposure scenarios were assessed for qualitative assessments			Qualitative
Use of Lubricants and Functional Fluids	Surface Water	Dermal	Dermal exposure to DIDP in surface water during swimming	Adults	Quantitative
		Oral	Incidental ingestion of DIDP in surface water during swimming	Young teenager and teenager	Quantitative
Use of Lubricants and Functional Fluids	Drinking Water	Oral	Ingestion of drinking water	Infants	Quantitative
All	Fish Ingestion	Oral	Ingestion of fish for general population	Adult	Quantitative

OES ^a	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)
			Ingestion of fish for subsistence fishers	Adult	Quantitative
			Ingestion of fish for tribal populations	Adult	Quantitative
PVC Plastic Compounding	Ambient Air	Oral	Ingestion of DIDP in soil resulting from air to soil deposition	Infant through middle childhood	Quantitative
		Dermal	Dermal exposure to DIDP in soil resulting from air to soil deposition	Infant through middle childhood	Quantitative

^a Table 3-1 provides the crosswalk of OES to COUs

1839

1840 EPA also considered biomonitoring data, specifically urinary biomonitoring data from the Centers for
 1841 Disease Control and Prevention’s (CDC) National Health and Nutrition Examination Survey
 1842 (NHANES), to estimate exposure using reverse dosimetry (see Section 10.2 of EPA’s *Draft*
 1843 *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* ([U.S. EPA,](#)
 1844 [2024d](#)). Reverse dosimetry is a powerful tool for estimating exposure, but reverse dosimetry modeling
 1845 does not distinguish between routes or pathways of exposure and does not allow for source
 1846 apportionment (*i.e.*, exposure from TSCA COUs cannot be isolated from uses that are not subject to
 1847 TSCA). Instead, reverse dosimetry provides an estimate of the total dose (or aggregate exposure)
 1848 responsible for the measured biomarker. Therefore, intake doses estimated using reverse dosimetry is
 1849 not directly comparable the exposure estimates from the various environmental media presented in this
 1850 document. However, the total intake dose estimated from reverse dosimetry can help contextualize the
 1851 exposure estimates from exposure pathways outlined in Table 4-10 as being potentially underestimated
 1852 or overestimated.

1853

4.1.3.1 General Population Screening Level Exposure Assessment Results

Land Pathway

1854 EPA evaluated general population exposures via the land pathway (*i.e.*, application of biosolids,
 1855 landfills) qualitatively. Due to its water solubility (0.00017 mg/L) and affinity for sorption to soil and
 1856 organic constituents in soil (log K_{oc} = 5.09), DIDP is unlikely to migrate to groundwater via runoff after
 1857 land application of biosolids. Additionally, the half-life of 28 to 52 days in aerobic soils ([U.S. EPA,](#)
 1858 [2024f](#)) indicates that DIDP will have low persistence potential in the aerobic environments associated
 1859 with freshly applied biosolids. Since the physical and chemical properties of DIDP indicate that it is
 1860 unlikely to migrate from land applied biosolids to groundwater via runoff, EPA did not model
 1861 groundwater concentrations resulting from land application of biosolids.
 1862

1863

1864 DIDP is expected to be present at low concentrations in landfill leachate. Further, due to its high affinity
 1865 for organic carbon and low water solubility, any DIDP that may present in landfill leachates will not be
 1866 mobile in receiving soils and sediments. Since the physical and chemical properties of DIDP indicate
 1867 that it is unlikely to be mobile in soils, modeling of groundwater contamination due to landfill leachate
 1868 containing DIDP was not performed.
 1869

1869

1870 *Surface Water Pathway – Incidental Ingestion and Dermal Contact from Swimming*

1871 EPA conducted modeling of releases to surface water at the point of release (*i.e.*, in the immediate
1872 receiving waterbody receiving the effluent) to assess the expected resulting environmental media
1873 concentrations from TSCA COUs. EPA conducted modeling with the U.S. EPA's Variable Volume
1874 Water Model with Point Source Calculator tool (VWWM-PSC), to estimate concentrations of DIDP
1875 within surface water. Releases associated with the Use of Lubricants and Functional Fluids OES resulted
1876 in the highest total water column concentrations, ranging from 7,540 to 9,110 µg/L without wastewater
1877 treatment and 452 to 547 µg/L when run under an assumption of 94 percent wastewater treatment
1878 removal efficiency (Table 4-11). Both treated and untreated scenarios were assessed due to uncertainty
1879 about the prevalence of wastewater treatment from discharging facilities, and to demonstrate the
1880 hypothetical disparity in exposures between treated and untreated effluent in the generic release
1881 scenarios. COUs mapped to this OES are shown in Table 3-1. These water column concentrations were
1882 used to estimate the ADR from dermal exposure and incidental ingestion of DIDP while swimming for
1883 adults (21 and older), youth (11 to 15 years), and children (6 to 10 years). Exposure scenarios leading to
1884 the highest modeled ADR are shown in Table 4-11.

1885
1886 For the purpose of a screening-level assessment, EPA used a margin of exposure (MOE) approach using
1887 high-end exposure estimates to determine if exposure pathways were pathways of concern for potential
1888 non-cancer risks. MOEs for general population exposure through dermal exposure and incidental
1889 ingestion during swimming ranged from 190 to 286 for scenarios assuming no wastewater treatment and
1890 from 3,070 to 6,830 for scenarios assuming 94 percent wastewater treatment removal efficiency
1891 (compared to a benchmark of 30) (Table 4-11). Therefore, based on a screening-level assessment, risk
1892 for non-cancer health effects are not expected for the surface water pathway and the surface water
1893 pathway is not considered to be a pathway of concern to DIDP for the general population.

1894
1895 *Surface Water Pathway – Drinking Water*

1896 For the drinking water pathway, modeled surface water concentrations were used to estimate drinking
1897 water exposures. For screening-level purposes, only the OES scenario resulting in the highest modeled
1898 surface water concentrations, Use of Lubricants and Functional Fluids, was included in the drinking
1899 water exposure analysis. COUs mapped to this OES are shown in Table 3-1. EPA evaluated drinking
1900 water scenarios that assumed a wastewater treatment removal efficiency of 94 percent and no further
1901 drinking water treatment, as well as a scenario that assumed a wastewater treatment removal efficiency
1902 of 94 percent and a conservative drinking water treatment removal rate of 63 percent (Table 4-11). ADR
1903 and ADD values from drinking water exposure to DIDP were calculated for adults (21 and older), youth
1904 (11 to 15 years), and children (6 to 10 years). Exposure scenarios leading to the highest ADR and ADD
1905 are shown in Table 4-11.

1906
1907 MOEs for general population exposure through drinking water exposure ranged from 117 to 316 across
1908 the evaluated scenarios for the lifestage (*i.e.*, infants) with the highest exposure (compared to a
1909 benchmark of 30) (Table 4-11). Based on screening-level analysis, risk for non-cancer health effects are
1910 not expected for the drinking water pathway and the drinking water pathway is not considered to be a
1911 pathway of concern to DIDP for the general population.

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Table 4-11. General Population Surface Water and Drinking Water Exposure Summary

Occupational Exposure Scenario ^a	Water Column Concentrations		Incidental Dermal Surface Water ^b		Incidental Ingestion Surface Water ^c		Drinking Water ^d	
	30Q5 (µg/L)	Harmonic Mean (µg/L)	ADR _{POT} (mg/kg-day)	Acute MOE	ADR _{POT} (mg/kg-day)	Acute MOE	ADR _{POT} (mg/kg-day)	Acute MOE
Use of Lubricants and Functional Fluids <i>without Wastewater Treatment</i>	9,110	7,540	4.73E-02	190	3.62E-02	286	–	–
Use of Lubricants and Functional Fluids <i>with Wastewater Treatment</i>	547	452	2.84E-03	3,170	2.92E-03	3,070	7.7E-02	117
Use of Lubricants and Functional Fluids <i>with Wastewater and Drinking Water Treatment</i>	202	167	–	–	–	–	2.8E-02	316

^a Table 3-1 provides crosswalk of COU to OES
^b Most exposed lifestage: Adults (≥21 years)
^c Most exposed lifestage: Youth (11–15 years)
^d Most exposed lifestage: Infant (birth to <1 year)
 Note: ADR_{POT} are derived from 30Q5 flow concentrations.

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Fish Ingestion

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EPA estimated fish tissue concentrations using monitored surface water concentrations and DIDP’s water solubility limit. The highest measured surface water concentration from untreated wastewater exceeded the solubility limit of DIDP by up to two orders of magnitude (see Section 7 in the *Draft Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)) for further details. DIDP within suspended solids found in wastewater could result in concentrations greater than the water solubility limit. However, DIDP is not expected to be bioavailable for uptake by aquatic organisms due to its strong sorption to organic matter and hydrophobicity. Use of the measured DIDP concentrations in wastewater is already expected to overestimate fish tissue concentrations for this reason. As a result, modeled surface water concentrations by COU/OES using VVWM-PSC, which exceeded the estimates of the water solubility limit for DIDP by up to five orders of magnitude, were not considered.

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EPA evaluated exposure and potential risk to DIDP through fish ingestion for adults in the general population, adult subsistence fishers, and adult tribal populations. Exposure estimates were the highest for tribal populations because of their elevated fish ingestion rates compared to the general population and subsistence fisher populations ([U.S. EPA, 2024d](#)). As such, tribal populations represent the sentinel exposure scenario. Risk estimates calculated from the water solubility limit of DIDP as the input surface water concentration were four-to-five orders of magnitude above its non-cancer risk benchmark using both the current and heritage fish ingestion rate (Table 4-12). Using the highest monitored DIDP levels as the input surface water concentration, risk estimates for tribal populations were still two orders of magnitude above its corresponding benchmark for both fish ingestion rates. Exposure estimates based on conservative values such as surface water concentration from untreated wastewater still resulted in risk estimates that are above their benchmarks. Therefore, these results indicate that fish ingestion is not a pathway of concern for DIDP for tribal members, subsistence fisher, and the general population.

1941 **Table 4-12. Fish Ingestion for Adults in Tribal Populations Summary**

Calculation Method	Current Mean Ingestion Rate		Heritage Ingestion Rate	
	ADR/ADD (mg/kg-day)	MOE	ADR/ADD (mg/kg-day)	MOE
Water solubility limit (1.7E-04 mg/L)	4.54E-06	1,980,000	2.62E-05	344,000
Monitored SWC from a WWTP's influent (4.31E-02 mg/L)	1.15E-03	7,810	6.64E-03	1,360

1942

1943 **Ambient Air Pathway – Air to Soil Deposition**

1944 EPA used the American Meteorological Society (AMS)/EPA Regulatory Model (AERMOD) to estimate
 1945 ambient air concentrations and air deposition of DIDP from EPA estimated releases. The highest
 1946 modelled 95th percentile annual ambient air and soil concentrations across all release scenarios were 4.7
 1947 x 10² µg/m³ and 1.85 mg/kg at 100 m from the releasing facility for the PVC Plastic Compounding OES,
 1948 based on the high-end meteorology and rural land category scenario in AERMOD (Table 3-6). COUs
 1949 mapped to this OES are shown in Table 3-1. PVC Plastic Compounding was the only OES assessed for
 1950 the purpose of a screening-level assessment as it was the OES associated with the highest ambient air
 1951 concentration. Next, using conservative exposure assumptions for infants and children (ages 6 months to
 1952 less than 12 years), EPA estimated the acute dose rate (ADR) for soil ingestion and the dermal absorbed
 1953 dose (DAD) for soil dermal contact to be 0.0228 and 0.0617 mg/kg-day. EPA did not estimate inhalation
 1954 exposure to ambient air because it was not expected to be a pathway of concern (see Section 4 of ([U.S.
 1955 EPA, 2024d](#)) for more details).

1956

1957 Using the highest modelled 95th percentile air concentration, ADR, and DAD, MOEs for general
 1958 population exposure through a combined soil ingestion and dermal soil contact is 106.5 (Table 4-13
 1959 compared to a benchmark of 30). Based on risk screening results, risk for non-cancer health effects are
 1960 not expected for the ambient air pathway and the ambient air pathway is not considered to be a pathway
 1961 of concern to DIDP for the general population.

1962

1963 **Table 4-13. General Population Ambient Air to Soil Deposition Exposure Summary**

OES	Soil Ingestion			Dermal Soil Contact		
	Soil Concentration ^a (mg/kg)	ADD (mg/kg-day)	MOE ^b	Soil Concentration ^a (mg/kg)	DAD (mg/kg-day)	MOE ^b
PVC plastic compounding	1.85	0.0228	106.5	1.85	0.0617	107

^a Air and soil concentrations are 95th percentile at 100m from the emitting facility.

^b MOE for soil ingestion and dermal contact based on combined exposure through soil ingestion and dermal soil contact.

1964

1965 **Urinary Biomonitoring Data – NHANES**

1966 EPA analyzed urinary biomonitoring data from NHANES, which reports urinary concentrations for 15
 1967 phthalate metabolites specific to individual phthalate diesters. Specifically, EPA analyzed data for
 1968 mono-(carboxynonyl) phthalate (MCNP), a metabolite of DIDP, which has been reported in the 2005 to
 1969 2018 NHANES survey years. Urinary concentrations of MCNP were quantified for different lifestages
 1970 and, using reverse dosimetry, total daily intake values of DIDP were estimated for different life stages.
 1971 Detailed results of the NHANES analysis can be found in Section 10.2 of EPA's *Draft Environmental
 1972 Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)). The
 1973 highest daily intake value estimated was for female children (6-11 years old) and was 13.14 µg/kg-bw-
 1974 day at the 95th exposure percentile. Median daily intake across all life stages assessed ranged from 0.97-

1975 1.59 µg/kg-bw-day. As described earlier, reverse dosimetry modeling does not distinguish between
1976 routes or pathways of exposure and does not allow for source apportionment (*i.e.*, exposure from TSCA
1977 COUs cannot be isolated from uses that are not subject to TSCA). Therefore, general population
1978 exposure estimates from exposure to ambient air, surface water, and soil are not directly comparable.
1979 However, in contrasting the general population exposures estimated for a screening level analysis with
1980 the NHANES biomonitoring data, many of the acute dose rates or average daily doses from a single
1981 exposure scenario exceed the total daily intake values estimated using NHANES. Taken together with
1982 results from U.S. CPSC (2014) stating that DIDP exposure comes primarily from diet for women,
1983 infants, toddlers, and children and that the outdoor environment did not contribute to DIDP exposures,
1984 the exposures to the general population via surface water, drinking water, and soil from ambient air to
1985 soil deposition quantified in this document are likely overestimates, as estimates from individual
1986 pathways exceed the total intake values measured even at the 95th percentile of the U.S. population for
1987 all ages.

1988 **4.1.3.2 Overall Confidence in General Population Screening Level Exposure** 1989 **Assessment**

1990 The weight of scientific evidence supporting the general population exposure estimate is decided based
1991 on the strengths, limitations, and uncertainties associated with the exposure estimates, which are
1992 discussed in detail for ambient air, surface water, drinking water, and fish ingestion in the *Draft*
1993 *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* ([U.S. EPA,](#)
1994 [2024d](#)). EPA summarized its weight of scientific evidence using confidence descriptors: robust,
1995 moderate, slight, or indeterminate. EPA used general considerations (*i.e.*, relevance, data quality,
1996 representativeness, consistency, variability, uncertainties) as well as chemical-specific considerations for
1997 its weight of scientific evidence conclusions.

1998
1999 EPA determined robust confidence in its qualitative assessment of biosolids and landfills. For its
2000 quantitative assessment, EPA modeled exposure due to various general population exposure scenarios
2001 resulting from different pathways of exposure. Exposure estimates utilized high-end inputs for the
2002 purpose of risk screening. When available, monitoring data was compared to modeled estimates to
2003 evaluate overlap, magnitude, and trends. EPA has robust confidence that modeled releases used are
2004 appropriately conservative for a screening level analysis. Therefore, EPA has robust confidence that no
2005 exposure scenarios will lead to greater doses than presented in this evaluation. Despite slight and
2006 moderate confidence in the estimated values themselves, confidence in exposure estimates capturing
2007 high-end exposure scenarios was robust given that many of the modeled values exceeded those of
2008 monitored values and exceeded total daily intake values calculated from NHANES biomonitoring data
2009 (see Section 10 of ([U.S. EPA, 2024d](#)) for more details regarding the NHANES analysis), adding to
2010 confidence that exposure estimates captured high-end exposure scenarios.

2011 **4.1.4 Human Milk Exposures**

2012 Infants are a potentially susceptible lifestage because of their higher exposure per body weight,
2013 immature metabolic systems, and the potential for chemical toxicants to disrupt sensitive developmental
2014 processes, among other reasons. As discussed further in Section 4.2, DIDP is a developmental toxicant,
2015 and developmental toxicity occurs following gestational exposure to DIDP. EPA considered exposure
2016 and human health hazard information, as well as pharmacokinetic models, to determine how to evaluate
2017 infant exposure to DIDP from human milk ingestion. Biomonitoring data, albeit limited, have not
2018 demonstrated the presence of DIDP in human milk. Human health hazard values are based on
2019 developmental toxicity following maternal exposure, and no studies have evaluated only lactational
2020 exposure from quantified levels of DIDP in milk. Lastly, uncertainties in the toxic moiety for DIDP and
2021 the limited half-life data of its metabolites in the human body that are both sensitive and specific

precluded modeling human milk concentrations by COUs. Overall, EPA concluded that the most scientifically supportable approach is to not model milk concentrations, but rather use human health hazard values that are based on maternal exposure over two generations. It is thus expected to incorporate potential risks to infants from exposure through milk. Further discussion of the human milk pathway is provided in the *Draft Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)).

4.1.5 Aggregate and Sentinel Exposures

TSCA section 6(b)(4)(F)(ii) (15 USC 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.

EPA defines aggregate exposure as “the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33).” For the draft DIDP risk evaluation, EPA considered aggregate risk across all routes of exposure for each individual consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations. EPA did not consider aggregate exposure for the general population. As described in Section 4.1.3, EPA 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 DIDP exposure were identified for the generation population.

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

EPA defines sentinel exposure as “the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures (40 CFR 702.33).” In terms of this draft risk evaluation, EPA considered sentinel exposures by considering risks to populations who may have upper bound exposures; for example, workers and ONUs who perform activities with higher exposure potential, or consumers who have higher exposure potential or certain physical factors like body weight or skin surface area exposed. EPA characterized high-end exposures in evaluating exposure using both monitoring data and modeling approaches. Where statistical data are available, EPA typically uses the 95th percentile value of the available dataset to characterize high-end exposure for a given condition of use. For general population and consumer exposures, EPA occasionally characterized sentinel exposure through a “high-intensity use” category based on elevated consumption rates, breathing rates, or user-specific factors.

4.2 Summary of Human Health Hazard

This section briefly summarizes the human health hazards of DIDP. Additional information on the human health hazards of DIDP are provided in the *Draft Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024h](#)).

A robust toxicological database is available for DIDP. Available studies include: one short-term inhalation study of rats ([General Motors, 1983](#)); seven short-term oral exposure studies (5 of rats, 2 of mice) ([Chen et al., 2019](#); [Kwack et al., 2010](#); [Kwack et al., 2009](#); [Smith et al., 2000](#); [Lake et al., 1991](#); [BIBRA, 1990, 1986a](#)); three subchronic dietary studies (2 of rats, 1 of beagles) ([BASF, 1969](#); [Hazelton Labs, 1968a, b](#)); two chronic dietary studies (1 of each of rats and mice) ([Cho et al., 2011](#); [Cho et al.,](#)

2069 [2010](#); [Cho et al., 2008](#)); two prenatal developmental studies of rats ([Waterman et al., 1999](#); [Hellwig et](#)
2070 [al., 1997](#)); one developmental/reproductive toxicity screening study of mice ([Hazleton Labs, 1983](#)); and
2071 two two-generation dietary studies of rats ([Hushka et al., 2001](#); [Exxon Biomedical, 2000, 1998](#)). No
2072 repeated dose studies investigating the systemic toxicity of DIDP are available for the dermal route of
2073 exposure. Additionally, although the anti-androgenicity of DIDP is not discussed in detail in this
2074 document (see U.S. EPA ([2023b](#)) for further discussion), several mechanistic studies have demonstrated
2075 that gestational exposure during the critical window of development to DIDP does not induce
2076 antiandrogenic effects on the developing male reproductive system ([Furr et al., 2014](#); [Hannas et al.,](#)
2077 [2012](#)). This conclusion was supported by the SACC ([U.S. EPA, 2023d](#)).

2079 EPA identified liver and developmental toxicity as the most sensitive and robust non-cancer hazards
2080 associated with oral exposure to DIDP in experimental animal models. Liver and developmental toxicity
2081 were also identified as the most sensitive and robust non-cancer effects following oral exposure to DIDP
2082 by the U.S. Consumer Product Safety Commission ([U.S. CPSC, 2014](#)), Health Canada ([ECCC/HC,](#)
2083 [2020](#)), European Chemicals Agency ([ECHA, 2013](#)), European Food Safety Authority ([EFSA, 2019](#)),
2084 and the Australian National Industrial Chemicals Notification and Assessment Scheme ([NICNAS,](#)
2085 [2015](#)). Consistent, dose-related effects on development were observed across available experimental
2086 studies of rodent models. In two prenatal studies, increased incidences of skeletal and visceral variations
2087 were observed in SD and Wistar rats at non-maternally toxic doses ([Waterman et al., 1999](#); [Hellwig et](#)
2088 [al., 1997](#)). No-observable-adverse-effect levels (NOAELs)/lowest-observable-adverse-effect level
2089 (LOAELs) for developmental and maternal toxicity were 40/200 and 200/1000 mg/kg-day, respectively,
2090 in the study by Hellwig et al. ([1997](#)), and 200/500 and 500/1000 mg/kg-day, respectively, in the study
2091 by Waterman et al. ([1999](#)). The biological significance of the observed increases in skeletal and visceral
2092 variations are difficult to assess. However, EPA's *Guidelines for Developmental Toxicity Risk*
2093 *Assessment* ([U.S. EPA, 1991b](#)) states that, "if variations are significantly increased in a dose-related
2094 manner, these should also be evaluated as a possible indication of developmental toxicity" and "Agents
2095 that produce developmental toxicity at a dose that is not toxic to the maternal animal are especially of
2096 concern." Therefore, EPA considered the increase in skeletal and visceral variations following
2097 gestational exposure to DIDP to be treatment-related adverse effects. Effects on developing offspring
2098 have also been observed consistently in two two-generation studies of reproduction of SD rats ([Hushka](#)
2099 [et al., 2001](#); [Exxon Biomedical, 2000, 1998](#)). In the first two-generation study by Exxon Biomedical
2100 ([1998](#)), DIDP exposure reduced F1 offspring survival on postnatal day (PND) PND4, reduced F1 and F2
2101 offspring body weight on PND0, and reduced F1 and F2 offspring body weight gain through PND 21 at
2102 doses equal to 524 to 637 mg/kg-day DIDP, and reduced F2 offspring survival on PND1 and PND4 at
2103 doses of 135 mg/kg-day and above. In the second two-generation study by Exxon Biomedical ([2000](#)),
2104 which tested lower doses than the first study (high-dose group received 254 to 356 mg/kg-day DIDP),
2105 reduced F2 offspring survival on PND1 and PND4 was observed at doses of 134 mg/kg-day and above.

2106
2107 To calculate non-cancer risks from oral exposure to DIDP for acute, intermediate, and chronic durations
2108 of exposure in the draft risk evaluation of DIDP, EPA preliminarily selected a no-observed-adverse-
2109 effect level (NOAEL) of 38 mg/kg-day from a two-generation study of reproduction of rats based on
2110 reduced F2 offspring survival on PND1 and PND4 ([Hushka et al., 2001](#); [Exxon Biomedical, 2000](#)). The
2111 NOAEL of 38 was converted to a human equivalent dose (HED) of 9.0 mg/kg-day based on allometric
2112 body weight scaling to the three-quarter power ([U.S. EPA, 2011c](#)). A total uncertainty factor of 30 was
2113 selected for use as the benchmark margin of exposure (based on an interspecies uncertainty factor (UF_A)
2114 of 3 and an intraspecies uncertainty factor (UF_H) of 10). The critical effect, reduced F2 offspring survival
2115 on PND1 and PND4, is clearly adverse and is assumed to be human relevant. It is unclear whether
2116 decreased pup survival was due to a single, acute exposure or from repeated exposures. It is plausible
2117 that reduced offspring survival could result from a single exposure during gestation. However, it is also

2118 plausible that reduced offspring survival could result from repeated exposure during gestation or the
2119 postnatal period. Since repeated dose studies were used to investigate these hazard endpoints and the
2120 mode of action for DIDP is uncertain, and other studies did not provide a more sensitive or reliable
2121 endpoint, EPA considered reduced F2 offspring survival relevant for all exposure durations ([U.S. EPA,
2122 1996, 1991b](#)). Several additional acute, short-term and chronic duration studies of DIDP provide similar,
2123 although slightly less-sensitive, candidate PODs, which further supports EPA's decision to use the
2124 selected POD of 9.0 mg/kg-day to assess non-cancer risks for acute, intermediate, and chronic durations
2125 of exposure.

2126
2127 EPA reviewed the weight of scientific evidence and has **robust overall confidence in the selected POD**
2128 based on developmental outcomes for use in characterizing risk from exposure to DIDP for acute,
2129 intermediate, and chronic exposure scenarios. This conclusion was based on several weight of scientific
2130 evidence considerations. First, exposure to DIDP resulted in consistent, dose-related, developmental
2131 toxicity in two prenatal developmental studies and two two-generation studies that adhered to relevant
2132 EPA guidelines (*i.e.*, OPPTS 870.3700 and OPPTS 870.3800). Further, developmental toxicity occurred
2133 at doses lower than those that caused overt maternal and/or parental toxicity. Second, across available
2134 studies, developmental toxicity was observed consistently at LOAELs ranging from 134 to 200 mg/kg-
2135 day. Third, the selected POD (NOAEL of 38 mg/kg-day) for developmental toxicity was the most
2136 sensitive and robust POD considered for acute, intermediate, and chronic exposures. Several additional
2137 acute, short-term and chronic duration studies of DIDP provide similar, although slightly less-sensitive,
2138 candidate PODs, which further supports EPA's decision to use the selected POD to assess non-cancer
2139 risks for acute, intermediate, and chronic durations of exposure. Finally, other regulatory and
2140 authoritative bodies have also concluded that DIDP is a developmental toxicant and that developmental
2141 effects are relevant for estimating human risk ([EFSA, 2019](#); [EC/HC, 2015b](#); [NICNAS, 2015](#); [ECHA,
2142 2013](#); [U.S. CPSC, 2010](#); [EFSA, 2005](#); [ECJRC, 2003a](#); [NTP-CERHR, 2003](#)).

2143
2144 No data were available for the dermal or inhalation routes that were suitable for deriving route-specific
2145 PODs. Therefore, EPA used the oral POD to evaluate risks from dermal exposure to DIDP. Differences
2146 in absorption are accounted for in dermal exposure estimates in the draft risk evaluation for DIDP. For
2147 the inhalation route, EPA extrapolated the oral HED to an inhalation human equivalent concentration
2148 (HEC) using a human body weight and breathing rate relevant to a continuous exposure of an individual
2149 at rest ([U.S. EPA, 1994](#)). The oral HED and inhalation HEC values selected by EPA to estimate non-
2150 cancer risk from acute, intermediate and chronic exposure to DIDP in the draft risk evaluation of DIDP
2151 are summarized in Table 4-14.

2152
2153 Available data indicate that DIDP is not genotoxic or mutagenic (see Section 4 of ([U.S. EPA, 2024h](#))).
2154 In a two-year dietary study of F344 rats ([Cho et al., 2010](#); [Cho et al., 2008](#)), increased incidence of
2155 mononuclear cell leukemia (MNCL) was observed in high-dose male and female rats dosed with up to
2156 479 to 620 mg/kg-day DIDP. In a 26-week study of male and female wild-type and rasH2 transgenic
2157 mice ([Cho et al., 2011](#)), increased incidence of hepatocellular adenomas were observed in high-dose
2158 rasH2 males treated with 1500 mg/kg-day DIDP. No tumors were observed in any tissues in male or
2159 female wild-type mice or female rasH2 mice treated with up to 1500 mg/kg-day.

2160
2161 Under the *Guidelines for Carcinogen Risk Assessment* ([U.S. EPA, 2005](#)), EPA reviewed the weight of
2162 scientific evidence for the carcinogenicity of DIDP and determined that there is *Suggestive Evidence of*
2163 *Carcinogenic Potential* of DIDP in rodents. EPA's determination is based on evidence of MNCL in
2164 male and female F344 rats and hepatocellular adenomas in male CB6F1-rasH2 transgenic mice.
2165 According to the *Guidelines for Carcinogen Risk Assessment* ([U.S. EPA, 2005](#)), when there is
2166 *Suggestive Evidence* "the Agency generally would not attempt a dose-response assessment, as the nature

2167 of the data generally would not support one.” Consistently, EPA is not conducting a dose-response
 2168 assessment for DIDP or further evaluating DIDP for carcinogenic risk to humans.
 2169

2170 **Table 4-14. Non-cancer HECs and HEDs Used to Estimate Risks**

Exposure Scenario	Target Organ System	Species	Duration	POD (mg/kg-day)	Effect	HEC (mg/m ³) [ppm]	HED (mg/kg-day)	Benchmark MOE	Reference(s)
Acute, intermed., chronic	Develop. toxicity	Sprague-Dawley	Approx. 35 weeks	NOAEL = 38	Reduced F2 offspring survival on PND1 and PND4	49 [2.7]	9.0	UF _A = 3 ^a UF _H =10 Total UF=30	(Hushka et al., 2001 ; Exxon Biomedical, 2000)
HEC = human equivalent concentration; HED = human equivalent dose; MOE = margin of exposure; NOAEL = no-observed-adverse-effect level; POD = point of departure; UF = uncertainty factor ^a EPA used allometric body weight scaling to the three-quarters power to derive the HED. Consistent with EPA guidance (U.S. EPA, 2011c), the UF _A was reduced from 10 to 3.									

2171 **4.3 Human Health Risk Characterization**

2172 **4.3.1 Risk Assessment Approach**

2173 The exposure scenarios, populations of interest, and toxicological endpoints used for evaluating risks
 2174 from acute, short-term/intermediate, and chronic/lifetime exposures are summarized in Table 4-15.
 2175

2176 **Table 4-15. Exposure Scenarios, Populations of Interest, and Hazard Values**

Population of Interest and Exposure Scenario	Exposure Scenarios, Populations of Interest, and Hazard Values
	Workers Male and female adolescents and adults (≥16 years old) and females of reproductive age directly working with DIDP under light activity (breathing rate of 1.25 m ³ /hr) <u>Exposure Durations</u> <ul style="list-style-type: none"> • <i>Acute</i> – 8 hours for a single workday • <i>Intermediate</i> - 8 hours per workday for 22 days per 30-day period • <i>Chronic</i> - 8 hours per workday for 250 days per year for 31 or 40 working years <u>Exposure routes</u> <ul style="list-style-type: none"> • Inhalation and dermal
	Occupational Non-users Male and female adolescents and adults (≥16 years old) indirectly exposed to DIDP within the same work area as workers (breathing rate of 1.25 m ³ /hr) <u>Exposure Durations</u> <ul style="list-style-type: none"> • <i>Acute, Intermediate, and Chronic</i> – same as workers <u>Exposure routes</u> <ul style="list-style-type: none"> • Inhalation, dermal (mist and dust deposited on surfaces)
	Consumers Male and female infants (less than 1 year), toddlers (1 to 2 years), children (3 to 5 years and 6 to 10 years), young teens (11 to 15 years), teenagers (16 to 20 years) and adults (21 years and above) exposed to DIDP through product or articles use <u>Exposure Durations</u> <ul style="list-style-type: none"> • <i>Acute</i> – 1 day exposure • <i>Intermediate</i> – 30 days per year • <i>Chronic</i> – 365 days per year <u>Exposure routes</u> <ul style="list-style-type: none"> • Inhalation, dermal, and oral
	Bystanders Male and female infants (less than 1 year), toddlers (1 to 2 years), and children (3 to 5 years and 6 to 10 years) incidentally exposed to DIDP through product use

	<p><u>Exposure Durations</u></p> <ul style="list-style-type: none"> • <i>Acute</i> – 1 day exposure • <i>Intermediate</i> – 30 days per year • <i>Chronic</i> – 365 days per year <p><u>Exposure routes</u></p> <ul style="list-style-type: none"> • Inhalation
	<p>General Population Male and female infants, children, youth, and adults exposed to DIDP through drinking water, surface water, ambient air, soil, and fish ingestion</p> <p><u>Exposure durations</u></p> <ul style="list-style-type: none"> • <i>Acute</i> – Exposed to DIDP continuously for a 24-hour period • <i>Chronic</i> – Exposed to DIDP continuously up to 33 years <p><u>Exposure routes</u> – Inhalation, dermal, and oral (depending on exposure scenario)</p>
<p>Health Effects, Concentration and Time Duration</p>	<p>Non-cancer Acute/Intermediate/Chronic Values Sensitive health effect: Developmental toxicity HEC Daily, continuous = 49 mg/m³ (2.7 ppm) HED Daily = 9.0 mg/kg; dermal and oral Total UF (benchmark MOE) = 30 (UF_A = 3; UF_H = 10)</p>

4.3.1.1 Estimation of Non-cancer Risks

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

Equation 4-1. Margin of Exposure Calculation

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

Where:

- MOE* = Margin of exposure for acute, short-term, or chronic risk comparison (unitless)
- Non-cancer Hazard Value (POD)* = HEC (mg/m³) or HED (mg/kg-day)
- Human Exposure* = Exposure estimate (mg/m³ or mg/kg-day)

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 concern if the MOE estimate is less than the benchmark MOE (*i.e.*, the total UF). On the other hand, if 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 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-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.

4.3.1.2 Estimation of Non-cancer Aggregate Risks

As described in Section 4.1.5, EPA considered aggregate risk across all routes of exposure for each individual consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations. To identify potential non-cancer risks for aggregate exposure scenarios for workers (Section 4.3.2) and consumers (Section 4.3.3), EPA used the total MOE approach (U.S. EPA, 2001). For the total

MOE approach, MOEs for each exposure route of interest in the aggregate scenario must first be calculated. The total MOE for the aggregate scenario can then be calculated using Equation 4-2.

Equation 4-2. Total Margin of Exposure Calculation

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

Where:

<i>Total MOE</i>	=	Margin of exposure for aggregate scenario (unitless)
<i>MOE_{Oral}</i>	=	Margin of exposure for oral route (unitless)
<i>MOE_{Dermal}</i>	=	Margin of exposure for dermal route (unitless)
<i>MOE_{Inhalation}</i>	=	Margin of exposure for inhalation route (unitless)

Total MOE risk estimates may be interpreted in relation to benchmark MOEs, similarly as to described above in Section 4.3.1.1.

4.3.2 Risk Estimates for Workers

Risk estimates for workers from inhalation and dermal exposures, as well as aggregated exposures, are shown in Table 4-16. This section provides discussion and characterization of risk estimates for workers, including females of reproductive age and ONUs, for the various OESs and COUs. In summary, it was determined that the central tendency estimates of worker exposure and risk are most representative for all manufacturing, processing, industrial and commercial COUs, with the exception of the **Industrial COU: “Adhesives and sealants”** due to the potentially elevated inhalation exposures from pressurized spray operations.

Application of Adhesives and Sealants

For the application of adhesives and sealants, inhalation exposure from mist generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 2.9 to 4.8 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 98 to 156 (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible differences in MOEs when compared to MOE estimates from inhalation exposure alone since the inhalation exposure is the predominant source of worker exposure for this OES. Also, it is important to note that there were large variations between the central tendency and high-end estimates of worker inhalation exposure (central tendency inhalation MOEs ranged from 483 to 839 for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

EPA relied on mist monitoring data from the *ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry* (OECD, 2011a), which showed that the central tendency (*i.e.*, 50th percentile) of 8-hour TWA mist concentrations from automotive refinishing was 3.38 mg/m³ and the high-end (*i.e.*, 95th percentile) was 22.1 mg/m³. These mist concentration data were derived from a variety of industrial and commercial automotive refinishing scenarios (*e.g.*, different gun types and booth configurations), but all scenarios considered in the ESD commonly used the spray application of auto refinishing coatings. The more highly pressurized spray guns led to higher exposure levels, and less pressurized spray guns led to lower exposure levels. Therefore, the high-end inhalation exposure estimates are more representative of high-pressure spray applications whereas the central tendency

estimates are more representative of low-pressure applications including non-spray methods such as brush, roll, dip, bead application, and low-pressure spray guns. Regarding product concentrations, the various commercial adhesive and sealant products considered are summarized in Appendix F of the *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024e). Though the concentrations are representative of commercial products, similar DIDP concentrations are expected for industrial adhesives and sealants. The central tendency product concentration was chosen as the mode of available product concentrations (*i.e.*, 1 wt%) and the high-end product concentration was chosen as 95th percentile of available product concentrations (*i.e.*, 60 wt%). Because there were significant differences between central tendency and high-end values for the mist exposure concentration and the product concentration, which are both inputs to the inhalation exposure distribution, there was a larger range of potential inhalation exposures for the application of adhesives and sealants.

Since the mist exposure data is directly applicable to the spray application of coating, and the range of DIDP concentrations in various commercial products is expected to be similar to industrial adhesive and sealant products, the high-end inhalation exposure estimates are potentially reflective of industrial operations where adhesives and sealants are applied using spray methods (*i.e.*, Industrial COU: Adhesives and sealants). However, it is unlikely that the application of adhesives and sealants through low-pressure applications such as brush, roll, dip, bead application, and low-pressure spray guns would reach the high-end inhalation levels estimated in Table 4-3, and the application of adhesives and sealants through these non-spray methods are reflected by central tendency exposure and risk estimates. Non-spray methods are generally used for the Industrial COU: Abrasives manufacturing and therefore inhalation exposures are represented by the central tendency estimates. Also, the commercial adhesive and sealant products that were identified through the risk evaluation process and summarized in Appendix F of *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024e) are not generally applied through highly pressurized spray application, but rather bead, brush, or roll applications are used for the available commercial adhesive and sealant products containing DIDP. Therefore, occupational exposures to DIDP from the Commercial COUs: Adhesives and sealants (including plasticizers in adhesives and sealants) and “Lacquers, stains, varnishes, and floor finishes (as plasticizer)” are represented by the central tendency levels of exposure.

Application of Paints and Coatings

For the application of paints and coatings, inhalation exposure from mist generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 29 to 48 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 98 to 156 (Benchmark = 30). Aggregation of inhalation and dermal exposures led to small differences in MOEs when compared to MOE estimates from inhalation exposure alone. Also, it is important to note that there were large variations between the central tendency and high-end estimates of worker inhalation exposure (central tendency inhalation MOEs ranged from 483 to 779 for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

EPA relied on mist monitoring data from the *ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry* (OECD, 2011a), which showed that the central tendency (*i.e.*, 50th percentile) of 8-hour TWA mist concentrations from automotive refinishing was 3.38 mg/m³ and the high-end (*i.e.*, 95th percentile) was 22.1 mg/m³. These mist concentration data were derived from a variety of industrial and commercial automotive refinishing scenarios (*e.g.*, different gun types and booth configurations), but all scenarios considered in the ESD commonly used the spray application of

2302 auto refinishing coatings. The more highly pressurized spray guns led to higher exposure levels, and less
2303 pressurized spray guns led to lower exposure levels. Therefore, the high-end inhalation exposure
2304 estimates are more representative of high-pressure spray applications whereas the central tendency
2305 estimates are more representative of low-pressure applications including non-spray methods such as
2306 brush, roll, dip, and bead application. Regarding product concentrations, the various commercial paint
2307 and coating products considered are summarized in Appendix F of the *Draft Environmental Release and*
2308 *Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)). EPA used the
2309 mode product concentration (*i.e.*, 1 percent) to represent the central tendency product concentration and
2310 the upper bound product concentration (*i.e.*, 5 percent) to represent the high-end product concentration.
2311 Due to the differences between central tendency and high-end values for the mist exposure concentration
2312 and the product concentration, which are both inputs to the inhalation exposure distribution, there was a
2313 larger range of potential inhalation exposures for the application of paints and coatings.

2314
2315 The commercial paint and coating products that were identified through the risk evaluation process and
2316 summarized in Appendix F of *Draft Environmental Release and Occupational Exposure Assessment for*
2317 *Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)) are not generally applied through highly pressurized
2318 spray application, but rather low-pressure hand pump sprayers and buff coating applications are used for
2319 the available commercial paint and coating products containing DIDP. Therefore, occupational
2320 exposures to DIDP from the **commercial COUs: “Paints and coatings (including surfactants in**
2321 **paints and coatings)”**, **“Lacquers, stains, varnishes, and floor finishes (as plasticizer)”**, and **“Ink,**
2322 **toner, and colorant products”** are represented by the central tendency levels of exposure.

2323 *Use of Penetrants and Inspection Fluids*

2324
2325 For the use of penetrants and inspection fluids, inhalation exposure from aerosol generation is expected
2326 to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and
2327 chronic inhalation exposure ranged from 12 to 19 for average adult workers and women of reproductive
2328 age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 98 to
2329 157 (Benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible differences in
2330 MOEs when compared to MOE estimates from inhalation exposure alone. Also, it is important to note
2331 that there were moderate variations between the central tendency and high-end estimates of worker
2332 inhalation exposure (central tendency inhalation MOEs ranged from 43 to 69 for acute, intermediate,
2333 and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these
2334 variations are described below.

2335
2336 EPA based the central tendency and high-end exposure estimates on a near-field/far-field approach
2337 ([AIHA, 2009](#)), and the product concentration was based on the range provided by the singular surrogate
2338 product which contained DINP (*i.e.*, 10 to 20 percent) rather than DIDP. As a result of the narrow range
2339 of model inputs, calculated central tendency and high-end risk values were similar. It is important to
2340 note that reliance on a single surrogate product for this OES adds uncertainty to the representativeness of
2341 the modeled inhalation exposures. Further, although the surrogate product information indicates that the
2342 product is aerosol and brush applied, EPA assessed only aerosol application due to limited data for this
2343 OES. Aerosol application may overestimate inhalation exposures for brush application methods.
2344 Therefore, the central tendency exposure levels are expected to be representative of the **commercial**
2345 **COU: “Inspection fluid/penetrant”** due to uncertainties in both product concentration and method of
2346 application.

2347 *PVC Plastics Compounding and Non-PVC Material Compounding*

2348
2349 For PVC plastics compounding and non-PVC material compounding, inhalation exposure from dust
2350 generation is expected to be the dominant route of exposure. In support of this, for PVC plastics

2351 compounding, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 30
2352 to 49 for average adult workers and women of reproductive age, while high-end dermal MOEs for the
2353 same populations and exposure scenarios ranged from 98 to 156 (Benchmark = 30). Similarly, for non-
2354 PVC material compounding MOEs for high-end acute, intermediate, and chronic inhalation exposure
2355 ranged from 67 to 108 for average adult workers and women of reproductive age, while high-end dermal
2356 MOEs for the same populations and exposure scenarios ranged from 98 to 156. Aggregation of
2357 inhalation and dermal exposures led to small differences in MOEs when compared to MOE estimates
2358 from inhalation exposure alone (high-end MOEs based on aggregate exposure ranged from 24 to 37
2359 (PVC plastics compounding) and 41 to 62 (non-PVC material compounding) for acute, intermediate,
2360 and chronic duration exposures for average adult workers and women of reproductive age). Also, it is
2361 important to note that there were large variations between the central tendency and high-end estimates of
2362 worker inhalation exposure (central tendency inhalation MOEs ranged from 488 to 883 (PVC plastics
2363 compounding) and 858 to 1,478 (non-PVC material compounding) for acute, intermediate, and chronic
2364 exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are
2365 described below.

2366
2367 EPA estimated worker inhalation exposures using surrogate monitoring data for vapor exposures and the
2368 *Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable*
2369 *Particulates Not Otherwise Regulated (PNOR)* for dust exposures ([U.S. EPA, 2021d](#)). EPA did not have
2370 sufficient data to define separate central tendency and high-end vapor exposures, and thus a singular
2371 value was used to represent potential exposures from vapor. Regarding the dominant route of exposure,
2372 inhalation exposure of PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust
2373 release data taken from facilities with NAICS codes starting with 326 (Plastics and Rubber
2374 Manufacturing). EPA multiplied these dust concentrations by the industry provided DIDP concentration
2375 range in PVC (*i.e.*, 10 to 45 percent) and non-PVC (*i.e.*, 10 to 20 percent) products, respectively, to
2376 estimate DIDP particulate concentrations in the air. The differences in the central tendency and high-end
2377 dust concentrations, as well as DIDP concentrations in the dust, led to significant differences between
2378 the central tendency and high-end risk estimates.

2379
2380 Though the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a
2381 worker may experience in the compounding industry, the composition of workplace dust is uncertain.
2382 The exposure and risk estimates are based on the assumption that the concentration of DIDP in
2383 workplace dust is the same as the concentration of DIDP in PVC plastics or non-PVC materials,
2384 respectively. However, it is likely that workplace dust contains a variety of constituents and that the
2385 concentration of DIDP in workplace dust is less than the concentration of DIDP in PVC or non-PVC
2386 products. Therefore, central tendency values of exposure are expected to be more reflective of true
2387 worker exposures within the COUs covered under the PVC plastics compounding and non-PVC material
2388 compounding OESs (*i.e.*, Industrial COUs: Plastic material and resin manufacturing, Plasticizers (rubber
2389 manufacturing), and Other [part of the formulation for manufacturing synthetic leather]) due to the
2390 uncertainty of DIDP concentration in workplace dust.

2391 2392 ***PVC Plastics Converting and Non-PVC Material Converting***

2393 For PVC plastics converting and non-PVC material converting, inhalation exposure from dust
2394 generation is expected to be the dominant route of exposure. In support of this, for PVC plastics
2395 converting, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 30 to
2396 49 for average adult workers and women of reproductive age, while high-end dermal MOEs for the
2397 same populations and exposure scenarios ranged from 9,356 to 14,867 (Benchmark = 30). Similarly, for
2398 non-PVC material converting MOEs for high-end acute, intermediate, and chronic inhalation exposure
2399 ranged from 67 to 108 for average adult workers and women of reproductive age, while high-end dermal

MOEs for the same populations and exposure scenarios ranged from 9,356 to 14,867. Aggregation of inhalation and dermal exposures led to negligible differences in MOEs when compared to MOE estimates from inhalation exposure alone. Also, it is important to note that there were large variations between the central tendency and high-end estimates of worker inhalation exposure (central tendency inhalation MOEs ranged from 488 to 899 (PVC plastics converting) and 858 to 1,579 (non-PVC material converting) for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

EPA estimated worker inhalation exposures using surrogate monitoring data for vapor exposures and 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, 2021d](#)). EPA did not have sufficient data to define separate central tendency and high-end vapor exposures, and thus a singular value was used to represent potential exposures from vapor. Regarding the dominant route of exposure, inhalation exposure of PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust release data taken from facilities with NAICS codes starting with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry provided DIDP concentration range in PVC (*i.e.*, 10 to 45 percent) and non-PVC (*i.e.*, 10 to 20 percent) products, respectively, to estimate DIDP particulate concentrations in the air. The differences in the central tendency and high-end dust concentrations, as well as DIDP concentrations in the dust, led to significant differences between the central tendency and high-end risk estimates.

Though the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may experience in the converting industry, the composition of workplace dust is uncertain. The exposure and risk estimates are based on the assumption that the concentration of DIDP in workplace dust is the same as the concentration of DIDP in PVC plastics or non-PVC materials, respectively. However, it is likely that workplace dust contains a variety of constituents and that the concentration of DIDP in workplace dust is less than the concentration of DIDP in PVC or non-PVC products. Therefore, central tendency values of exposure are expected to be more reflective of true worker exposures within the COUs covered under the “PVC Plastics Converting” and the “Non-PVC Material Converting” OESs (*i.e.*, Industrial COUs: “Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive products manufacturing, other than fluids; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant (including pigment) products manufacturing; photographic supplies manufacturing; sporting equipment manufacturing”) due to the uncertainty of DIDP concentration in workplace dust.

Recycling and Disposal

For recycling and disposal of DIDP containing materials, inhalation exposure from dust generation is expected to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 41 to 67 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 9,356 to 14,867 (benchmark = 30). Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone. Also, it is important to note that there were large variations between the central tendency and high-end estimates of worker inhalation exposure (central tendency inhalation MOEs ranged from 604 to 1,091 for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

2449 EPA estimated worker inhalation exposures using the *Generic Model for Central Tendency and High-*
2450 *End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR)* for
2451 dust exposures ([U.S. EPA, 2021d](#)). Regarding the dominant route of exposure, inhalation exposure of
2452 PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust release data taken from
2453 facilities with NAICS codes starting with 56 (Administrative and Support and Waste Management and
2454 Remediation Services). EPA multiplied these dust concentrations by the industry provided maximum
2455 DIDP concentration in PVC (*i.e.*, 45 percent) to estimate DIDP particulate concentrations in the air.
2456 Therefore, the differences in the central tendency and high-end dust concentrations led to significant
2457 differences between the central tendency and high-end risk estimates.

2459 Though the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a
2460 worker may experience in the recycling and disposal industry, the composition of workplace dust is
2461 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DIDP
2462 in workplace dust is the same as the maximum concentration of DIDP in PVC plastics. However, it is
2463 likely that workplace dust contains a variety of constituents and that the concentration of DIDP in
2464 workplace dust is less than the concentration of DIDP in recycled or disposed products or articles.
2465 Therefore, central tendency values of exposure are expected to be more reflective of true worker
2466 exposures within the COUs covered under the “Recycling” and the “Disposal” OESs (*i.e.*, Industrial
2467 COUs: “Recycling” and “Disposal”) due to the uncertainty of DIDP concentration in workplace dust.

2469 ***Fabrication and Final Use of Products or Articles***

2470 For fabrication and final use of products or articles, inhalation exposure from dust generation is expected
2471 to be the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and
2472 chronic inhalation exposure ranged from 80 to 130 for average adult workers and women of
2473 reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged
2474 from 9,356 to 14,867 (Benchmark = 30). Aggregation of inhalation and dermal exposures led to
2475 negligible differences in risk when compared to risk estimates from inhalation exposure alone. Also, it is
2476 important to note that there were large variations between the central tendency and high-end estimates of
2477 worker inhalation exposure (central tendency inhalation MOEs ranged from 724 to 1,168 for acute,
2478 intermediate, and chronic exposure scenarios for adult workers and women of reproductive age).
2479 Reasons for these variations are described below.

2481 EPA estimated worker inhalation exposures using the *Generic Model for Central Tendency and High-*
2482 *End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR)* for
2483 dust exposures ([U.S. EPA, 2021d](#)). Regarding the dominant route of exposure, inhalation exposure of
2484 PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust release data taken from
2485 facilities with NAICS codes starting with 337 (Furniture and Related Product Manufacturing). EPA
2486 multiplied these dust concentrations by the industry provided maximum DIDP concentration in PVC
2487 (*i.e.*, 45 percent) to estimate DIDP particulate concentrations in the air. Therefore, the differences in the
2488 central tendency and high-end dust concentrations led to significant differences between the central
2489 tendency and high-end risk estimates.

2491 Though the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a
2492 worker may experience in the end use and fabrication industry, the composition of workplace dust is
2493 uncertain. The exposure and risk estimates are based on the assumption that the concentration of DIDP
2494 in workplace dust is the same as the maximum concentration of DIDP in PVC plastics. However, it is
2495 likely that workplace dust contains a variety of constituents and that the concentration of DIDP in
2496 workplace dust is less than the concentration of DIDP in final products or articles. Therefore, central
2497 tendency values of exposure are expected to be more reflective of true worker exposures within the

2498 COUs covered under the “Fabrication and final use of products and articles” OES (*i.e.*, Industrial COU:
2499 “Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)” and
2500 Commercial COUs: “Automotive products, other than fluids”, “Building/construction materials (wire or
2501 wiring systems; joint treatment, fire-proof insulation)”, “Electrical and electronic products”,
2502 “Construction and building materials covering large surface areas including stone, plaster, cement, glass
2503 and ceramic articles; fabrics, textiles, and apparel (as plasticizer) (Floor coverings (vinyl tiles, PVC-
2504 backed carpeting, scraper mats))”, “PVC film and sheet”, “Furniture and furnishings”, “Plastic and
2505 rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)”) due to the
2506 uncertainty of DIDP concentration in workplace dust.

2507 ***Distribution in Commerce***

2508 Distribution in commerce includes transporting DIDP or DIDP-containing products between work sites
2509 or to final use sites as well as loading and unloading from transport vehicles. Individuals in occupations
2510 that transport DIDP-containing products (*e.g.*, truck drivers) or workers who load and unload transport
2511 trucks may encounter DIDP or DIDP-containing products.
2512

2513 Worker activities associated with distribution in commerce (*e.g.*, loading, unloading) are not expected to
2514 generate mist or dust, similar to other COUs such as manufacturing and import. Therefore, inhalation
2515 exposures to workers during distribution in commerce are expected to be from the vapor phase only.
2516 Dermal contact with the neat material or concentrated formulations may occur during activities
2517 associated with distribution in commerce, also similar to COUs such as manufacturing and import.
2518 Though some worker activities associated with distribution in commerce are similar to COUs such as
2519 manufacturing or import, it is expected that workers involved in distribution in commerce spend less
2520 time exposed to DIDP than workers in manufacturing or import facilities since only part of the workday
2521 is spent in an area with potential exposure. In conclusion, occupational exposures associated with the
2522 distribution in commerce COU are expected to be less than other *OESs/COUs without Dust or Mist*
2523 *Generation*, such as manufacturing or import, and the COU is captured in the subsection below.
2524

2525 ***OESs/COUs without Dust or Mist Generation***

2526 Due to the low vapor pressure of DIDP, inhalation exposures from vapor-generating activities, without
2527 dust or mist generation, are shown to be quite low. Analysis of each OES relied on either direct or
2528 surrogate vapor monitoring data, and resulting worker risk estimates were far above the benchmark
2529 MOE of 30 (*i.e.*, high-end inhalation MOEs for the OESs listed below were greater than or equal to 905
2530 for all assessed populations and exposure duration). Also, due to the long alkyl chain length of DIDP,
2531 the rate of dermal absorption of DIDP is quite slow which leads to low dermal exposure potential.
2532 Therefore, any OES or COU where inhalation exposure to DIDP comes only from vapor-generating
2533 activities is not expected to lead to significant worker exposures, and such uses are summarized below.
2534

2535 OESs where inhalation exposure comes from vapor-generating activities only:
2536

- 2537 • Manufacturing; Import and repackaging; Incorporation into adhesives and sealants;
2538 Incorporation into paints and coatings; Incorporation into other formulations, mixtures, and
2539 reaction products not covered elsewhere; Use of laboratory chemicals – liquids; Use of lubricants
2540 and functional fluids; and Distribution in Commerce.
- 2541 • Although there is dust generation expected during the OES for “Use of Laboratory chemicals –
2542 solids,” the industry provided maximum DIDP concentration is very low (*i.e.*, 3 percent), which
2543 leads to very low levels of potential worker inhalation exposure similar to that of vapor-
2544 generating activities.

2545 COUs where inhalation exposure comes from vapor-generating activities only:
2546

- **Industrial:** Domestic manufacturing; Import; repackaging; Adhesives and sealants manufacturing; Surface modifier in paint and coating manufacturing; Plasticizers (paint and coating manufacturing; colorants (including pigments)); Laboratory chemicals manufacturing; Petroleum lubricating oil manufacturing; Lubricants and lubricant additives manufacturing; Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities); Functional fluids (closed systems) (SCBA compressor oil); Lubricant and lubricant additives; Solvents (for cleaning or degreasing)
- **Commercial:** Laboratory chemicals; Lubricants
- **Distribution in Commerce**

Table 4-16 summarizes the risk estimates discussed above for all OESs and COUs. Section 4.1.1 presents the occupational exposure assessment. The risk summary below is based on the most sensitive non-cancer endpoints for each scenario (*i.e.*, acute non-cancer, intermediate non-cancer, and chronic non-cancer).

4.3.2.1 Overall Confidence in Worker Risks

As described in Section 4.1.1.5 and the *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024e](#)), EPA has moderate to robust confidence in the assessed inhalation and dermal OESs (Table 4-5), and robust confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to DIDP (see Section 4.2 and ([U.S. EPA, 2024h](#))). Overall, EPA has moderate to robust confidence in the risk estimates calculated for worker and ONU inhalation and dermal exposure scenarios. Sources of uncertainty associated with these occupational COUs are discussed above in Section 4.3.2.

2569

Table 4-16. Occupational Risk Summary Table

Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Manufacturing	Domestic Manufacturing	Manufacturing	Worker: Average Adult Worker	High-End	1,000	1,364	2,028	98	134	199	89	122	181
				Central Tendency	2,000	2,727	4,056	196	268	398	179	244	362
			Worker: Female of Reproductive Age	High-End	905	1,235	1,836	107	146	217	96	130	194
				Central Tendency	1,811	2,469	3,672	214	291	433	191	261	388
			ONU	High-End	2,000	2,727	4,056	N/A	N/A	N/A	2,000	2,727	4,056
				Central Tendency	2,000	2,727	4,056	N/A	N/A	N/A	2,000	2,727	4,056
Manufacturing	Importing	Import and repackaging	Worker: Average Adult Worker	High-End	1,000	1,364	1,460	98	134	143	89	122	130
				Central Tendency	2,000	2,727	3,510	196	268	344	179	244	314
Worker: Female of Reproductive Age	High-End		905	1,235	1,322	107	146	156	96	130	140		
	Central Tendency		1,811	2,469	3,177	214	291	375	191	261	335		
Processing	Repackaging		ONU	High-End	2,000	2,727	2,920	N/A	N/A	N/A	2,000	2,727	2,920
				Central Tendency	2,000	2,727	3,510	N/A	N/A	N/A	2,000	2,727	3,510
Incorporation into formulation, mixture, or reaction product	Adhesives and sealants manufacturing	Incorporation into adhesives and sealants	Worker: Average Adult Worker	High-End	2,400	3,273	3,504	98	134	143	94	129	138
				Central Tendency	2,400	3,273	3,504	196	268	287	181	247	265
			Worker: Female of Reproductive Age	High-End	2,173	2,963	3,172	107	146	156	102	139	149
				Central Tendency	2,173	2,963	3,172	214	291	312	195	265	284
			ONU	High-End	120,000	163,636	175,200	N/A	N/A	N/A	120,000	163,636	175,200
				Central Tendency	240,000	327,273	350,400	N/A	N/A	N/A	240,000	327,273	350,400

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)			
Life Cycle Stage/ Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	
Incorporation into formulation, mixture, or reaction product	Surface modifier in paint and coating manufacturing	Incorporation into paints and coatings	Worker: Average Adult Worker	High-End	2,400	3,273	3,504	98	134	143	94	129	138	
				Central Tendency	2,400	3,273	3,504	196	268	287	181	247	265	
	Plasticizers (paint and coating manufacturing; colorants (including pigments))		Worker: Female of Reproductive Age	High-End	2,173	2,963	3,172	107	146	156	102	139	149	
				Central Tendency	2,173	2,963	3,172	214	291	312	195	265	284	
	ONU			High-End	120,000	163,636	175,200	N/A	N/A	N/A	120,000	163,636	175,200	
				Central Tendency	240,000	327,273	350,400	N/A	N/A	N/A	240,000	327,273	350,400	
Incorporation into formulation, mixture, or reaction product	Laboratory chemicals manufacturing	Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	Worker: Average Adult Worker	High-End	2,400	3,273	3,504	98	134	143	94	129	138	
	Central Tendency			2,400	3,273	3,504	196	268	287	181	247	265		
	Petroleum lubricating oil manufacturing; Lubricants and lubricant additives manufacturing		Worker: Female of Reproductive Age	High-End	2,173	2,963	3,172	107	146	156	102	139	149	
				Central Tendency	2,173	2,963	3,172	214	291	312	195	265	284	
	Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities)		ONU		High-End	120,000	163,636	175,200	N/A	N/A	N/A	120,000	163,636	175,200
					Central Tendency	240,000	327,273	350,400	N/A	N/A	N/A	240,000	327,273	350,400

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/ Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Incorporation into formulation, mixture, or reaction product	Plastic material and resin manufacturing	PVC plastics compounding	Worker: Average Adult Worker	High-End	34	46	49	98	134	143	25	34	37
				Central Tendency	539	735	883	196	268	321	144	196	236
	Other (part of the formulation for manufacturing synthetic leather)		Worker: Female of Reproductive Age	High-End	30	41	44	107	146	156	24	32	35
				Central Tendency	488	666	799	214	291	350	149	203	243
	ONU		High-End	692	943	1,010	18,711	25,515	27,318	667	910	974	
			Central Tendency	694	946	1,135	18,711	25,515	30,626	669	912	1,095	
Incorporation into articles	Plasticizers ^a	PVC plastics converting	Worker: Average Adult Worker	High-End	34	46	49	9,356	12,758	13,659	33	46	49
				Central Tendency	539	735	899	18,711	25,515	31,185	524	715	874
			Worker: Female of Reproductive Age	High-End	30	41	44	10,183	13,885	14,867	30	41	44
				Central Tendency	488	666	814	20,365	27,771	33,942	477	650	795
			ONU	High-End	692	943	1,010	18,711	25,515	27,318	667	910	974
				Central Tendency	694	946	1,156	18,711	25,515	31,185	669	912	1,115
Incorporation into formulation, mixture, or reaction product	Plastic material and resin manufacturing	Non-PVC material compounding	Worker: Average Adult Worker	High-End	74	101	108	98	134	143	42	58	62
				Central Tendency	947	1,292	1,478	196	268	306	163	222	254
	Other (part of the formulation for manufacturing synthetic leather)		Worker: Female of Reproductive Age	High-End	67	92	98	107	146	156	41	56	60
				Central Tendency	858	1,170	1,338	214	291	333	171	233	267
	Plasticizers (rubber manufacturing)		ONU	High-End	1,545	2,107	2,256	18,711	25,515	27,318	1,427	1,946	2,084
				Central Tendency	1,555	2,121	2,426	18,711	25,515	29,186	1,436	1,958	2,240

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/ Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Incorporation into articles	Plasticizers ^b	Non-PVC material converting	Worker: Average Adult Worker	High-End	74	101	108	9,356	12,758	13,659	74	100	108
				Central Tendency	947	1,292	1,579	18,711	25,515	31,185	902	1,230	1,503
			Worker: Female of Reproductive Age	High-End	67	92	98	10,183	13,885	14,867	67	91	97
				Central Tendency	858	1,170	1,429	20,365	27,771	33,942	823	1,122	1,372
			ONU	High-End	1,545	2,107	2,256	18,711	25,515	27,318	1,427	1,946	2,084
				Central Tendency	1,555	2,121	2,592	18,711	25,515	31,185	1,436	1,958	2,393
Incorporation into articles	Abrasives manufacturing	Application of adhesives and sealants	Worker: Average Adult Worker	High-End	3.3	4.4	4.8	98	134	143	3.2	4.3	4.6
Industrial uses – Adhesives and sealants	Adhesives and sealants ^l			Central Tendency	533	727	839	196	268	309	143	196	226
Commercial uses – Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)		Worker: Female of Reproductive Age	High-End	2.9	4.0	4.3	107	146	156	2.9	3.9	4.2
				Central Tendency	483	658	760	214	291	336	148	202	233
	Lacquers, stains, varnishes, and floor finishes (as plasticizer)		ONU	High-End	533	727	779	196	268	287	143	196	209
				Central Tendency	533	727	839	196	268	309	143	196	226

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/ Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Commercial uses – Construction, paint, electrical, and metal products	Paints and coatings (including surfactants in paints and coatings)	Application of paints and coatings	Worker: Average Adult Worker	High-End	33	44	48	98	134	143	24	33	36
	Lacquers, stains, varnishes, and floor finishes (as plasticizer)			Central Tendency	533	727	779	196	268	287	143	196	209
Commercial uses – Furnishing, cleaning, treatment/care products	Ink, toner, and colorant products		Worker: Female of Reproductive Age	High-End	29	40	43	107	146	156	23	32	34
				Central Tendency	483	658	705	214	291	312	148	202	216
			ONU	High-End	533	727	779	196	268	287	143	196	209
				Central Tendency	533	727	779	196	268	287	143	196	209
Commercial uses – Other uses	Laboratory chemicals	Use of laboratory chemicals – liquids	Worker: Average Adult Worker	High-End	1,000	1,364	1,460	98	134	143	89	122	130
				Central Tendency	2,000	2,727	3,106	196	268	305	179	244	278
			Worker: Female of Reproductive Age	High-End	905	1,235	1,322	107	146	156	96	130	140
				Central Tendency	1,811	2,469	2,812	214	291	332	191	261	297
			ONU	High-End	2,000	2,727	2,920	N/A	N/A	N/A	2,000	2,727	2,920
				Central Tendency	2,000	2,727	3,106	N/A	N/A	N/A	2,000	2,727	3,106

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/ Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Commercial uses – Other uses	Laboratory chemicals	Use of laboratory chemicals – solids	Worker: Average Adult Worker	High-End	889	1,212	1,298	9,356	12,758	13,659	812	1,107	1,185
				Central Tendency	12,632	17,225	18,442	18,711	25,515	27,318	7,541	10,283	11,010
			Worker: Female of Reproductive Age	High-End	805	1,097	1,175	10,183	13,885	14,867	746	1,017	1,089
				Central Tendency	11,436	15,594	16,696	20,365	27,771	29,733	7,323	9,986	10,692
			ONU	High-End	12,632	17,225	18,442	18,711	25,515	27,318	7,541	10,283	11,010
				Central Tendency	12,632	17,225	18,442	18,711	25,515	27,318	7,541	10,283	11,010
Industrial uses – Functional fluids (closed systems)	Functional fluids (closed systems) (SCBA compressor oil)	Use of lubricants and functional fluids	Worker: Average Adult Worker	High-End	1,000	7,500	91,250	98	736	8,956	89	670	8,155
Industrial uses – Lubricant and lubricant additives	Lubricant and lubricant additives			Central Tendency	2,000	30,000	365,000	196	2,944	35,823	179	2,681	32,622
			Worker: Female of Reproductive Age	High-End	905	6,790	82,610	107	801	9,748	96	717	8,719
Industrial uses – Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)			Central Tendency	1,811	27,159	330,439	214	3,205	38,990	191	2,866	34,875
			Commercial uses – Automotive, fuel, agriculture, outdoor use products	Lubricants	ONU	High-End	2,000	15,000	182,500	N/A	N/A	N/A	2,000
Central Tendency	2,000					30,000	365,000	N/A	N/A	N/A	2,000	30,000	365,000

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/ Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Commercial uses – Other uses	Inspection fluid/penetrant	Use of penetrants and inspection fluids	Worker: Average Adult Worker	High-End	13	18	19	98	134	144	11	16	17
				Central Tendency	47	64	69	196	268	290	38	52	56
			Worker: Female of Reproductive Age	High-End	12	16	17	107	146	157	11	14	16
				Central Tendency	43	60	64	214	291	316	36	50	53
			ONU	High-End	190	259	280	196	268	288	97	132	142
				Central Tendency	1,413	1,927	2,088	196	268	290	172	235	255
Industrial uses – Abrasives	Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)	Fabrication and final use of products or articles	Worker: Average Adult Worker	High-End	89	121	130	9,356	12,758	13,659	88	120	129
Commercial uses - Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids			Central Tendency	800	1,091	1,168	18,711	25,515	27,318	767	1,046	1,120
Commercial uses - Construction, paint, electrical, and metal products	Building/ construction materials (wire or wiring systems; joint treatment, fire-proof insulation)		Worker: Female of Reproductive Age	High-End	80	110	117	10,183	13,885	14,867	80	109	117
				Central Tendency	724	988	1,057	20,365	27,771	29,733	699	954	1,021
Commercial uses -	Construction and building ^c		ONU	High-End	800	1,091	1,168	18,711	25,515	27,318	767	1,046	1,120

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Industrial/Commercial COUs		OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage/Category	Subcategory				Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Furnishing, cleaning, treatment/care products	PVC film and sheet			Central Tendency	800	1,091	1,168	18,711	25,515	27,318	767	1,046	1,120
	Furniture and furnishings												
	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)												
Recycling	Recycling	Recycling and disposal	Worker: Average Adult	High-End	46	62	67	9,356	12,758	13,659	45	62	66
			Worker:	Central Tendency	667	909	1,091	18,711	25,515	30,626	644	878	1,054
Female of Reproductive Age	High-End		41	56	60	10,183	13,885	14,867	41	56	60		
Disposal	Disposal		Central Tendency	604	823	988	20,365	27,771	33,333	586	799	959	
		ONU	High-End	667	909	973	18,711	25,515	27,318	644	878	940	
			Central Tendency	667	909	1,091	18,711	25,515	30,626	644	878	1,054	
<p>^a Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive products manufacturing, other than fluids; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant (including pigment) products manufacturing; photographic supplies manufacturing; sporting equipment manufacturing)</p> <p>^b Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive products manufacturing, other than fluids; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant (including pigment) products manufacturing; photographic supplies manufacturing; toys, playground, and sporting equipment manufacturing)</p> <p>^c Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer) (Floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats))</p>													

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4.3.3 Risk Estimates for Consumers

Table 4-17 summarizes the dermal, inhalation, ingestion, and aggregate MOEs used to characterize non-cancer risk for acute, intermediate, and chronic exposure to DIDP and presents these values for all lifestages for each COU. A screening level assessment for consumers considers high-intensity exposure scenarios risk estimates and it relies on conservative assumptions to assess exposures that would be expected to be on the high end of the expected exposure distribution. Using the high-intensity risk estimates will assist in developing health protective approaches. MOEs for high-intensity exposure scenarios are shown for all consumer COUs, while MOEs for medium-intensity exposure scenarios are shown only for COUs with high-intensity MOEs close to the benchmark of 30 (*i.e.*, for Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; hoses)). Further, Table 4-17 provides MOEs for the modeling indoor exposure assessment. The main objective in reconstructing the indoor environment using consumer products and articles commonly present in indoor spaces is to calculate exposure and risk estimates by COU, and by product and article from indoor dust ingestion and inhalation. EPA identified article-specific information by COU to construct relevant and representative exposure scenarios. Exposure to DIDP via ingestion of dust was assessed for all articles expected to contribute significantly to dust concentrations due to high surface area (greater than approximately 1 m²) for either a single article or collection of like articles as appropriate. Articles included in the indoor environment assessment included: solid flooring, wallpaper, synthetic leather furniture, shower curtains, children's toys, both legacy and new, and wire insulation. COUs associated with articles included in the indoor environment assessment are indicated with '**' in Table 4-17.

Of note, the risk summary below is based on the most sensitive non-cancer endpoint for all relevant duration scenarios. MOEs for all high-, medium- and low-intensity exposure scenarios for all COUs are provided in the *Draft Consumer Risk Calculator for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024w](#)).

Consumer COUs Evaluated Quantitatively

COUs with MOEs for High-Intensity Exposure Scenarios Ranging from 60 to 11,221,891,082: All consumer COUs and product/article examples, except for in-place wallpaper (discussed more below), resulted in MOEs for high-intensity exposure scenarios ranging from 60 for acute aggregate exposure to DIDP from synthetic leather furniture for infants (less than one) to 11,221,891,082 for chronic duration ingestion of suspended dust from new children's toys for adults (21 years and older) (Table 4-17). Variability in MOEs for these high-intensity exposure scenarios results from use of different exposure factors for each COU and product/article example that led to different estimates of exposure to DIDP. As described in the *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)) and *Draft Human Health Hazard Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024h](#)), EPA has moderate to robust confidence in the exposure estimates and robust confidence in the non-cancer hazard value used to estimate non-cancer risk for these COUs.

COUs with MOEs for High-Intensity Exposure Scenarios ranging from 27 to 30: For one COU, EPA calculated MOEs for high-intensity exposures scenarios that range from 27 to 30 (Table 4-17). This COU is discussed further below and in more detail in the *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate* ([U.S. EPA, 2024a](#)).

- Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses; In-place wallpaper - For in-place wallpaper, EPA evaluated acute and chronic exposure to DIDP through dermal, inhalation, and oral routes for infants (less than 1 year), toddlers (1 to 2 years), preschoolers (3 to 5 years), children (6 to 10

2619 years), teens (11 to 15 and 16 to 20 years), and adults (21 years and above). The acute MOE was
2620 30 for the high-intensity acute inhalation exposure scenario for infants (less than 1) and ranged
2621 from 31 to 39 for toddlers and preschoolers, and 56 to 115 for all other evaluated lifestages,
2622 while high-intensity chronic MOEs ranged from 33 to 43 for infants, toddlers, and preschoolers,
2623 and 62 to 128 for all other lifestages. Medium-intensity MOEs for the inhalation route ranged
2624 from 63 to 272 for acute and chronic inhalation exposure scenarios for all evaluated lifestages.
2625 EPA also considered aggregate exposure to DIDP for this COU. High-intensity aggregate MOEs
2626 ranged from 27 to 34 and 31 to 38 for acute and chronic duration exposures, respectively, for
2627 infants (less than 1 year), toddlers (1 to 2 years) and preschoolers (3 to 5 years). High-intensity
2628 aggregate MOEs for other lifestages for this COU ranged from 52 to 125. For this COU, the
2629 primary pathway is inhalation exposure to consumers in the indoor environment, while dermal
2630 exposure and ingestion of suspended dust and dust on surfaces were comparatively minor
2631 pathways.

2632
2633 Variability in high-intensity inhalation MOEs across lifestages result from use of different
2634 lifestage-specific exposure factors such as body weight and inhalation rate. Differences in MOEs
2635 between the high- and medium-intensity inhalation exposure scenarios result from use of
2636 different exposure parameters in CEM. Key parameters that differed between high- and medium-
2637 intensity scenarios include: weight fraction (*i.e.*, 0.26 versus 0.245), article surface area (*i.e.*, 200
2638 versus 100 m²), and inhalation rates used per lifestage. Inhalation rates for lifestages range from
2639 0.74 to 0.46 m³/hr for adults to infants respectively, with the largest difference between infants
2640 and the next lifestage. Other CEM exposure factors were kept constant between high- and
2641 medium-intensity inhalation scenarios (*e.g.*, surface layer thickness, volume of use environment,
2642 interzone ventilation rate). Overall, EPA has robust confidence in the inhalation exposure
2643 estimates and robust confidence in the non-cancer hazard value used to estimate non-cancer risk
2644 for this COU ([U.S. EPA, 2024a, h](#)).

2645
2646 The in-place wallpaper inhalation scenario in this assessment applies to stay-at-home infants to
2647 adults. In this scenario DIDP in wallpaper is released into the gas-phase, the article inhalation
2648 scenario tracks chemical transport between the source, air, airborne and settled particles, and
2649 indoor sinks by accounting for emissions, mixing within the gas phase, transfer to particulates by
2650 partitioning, removal due to ventilation, removal due to cleaning of settled particulates and dust
2651 to which DIDP has partitioned, and sorption or desorption to/from interior surfaces. The
2652 emissions from the wallpaper were modeled with a single exponential decay model. This means
2653 that chronic and acute exposure duration scenario uses the same emissions/air concentration data
2654 based on the weight fraction but have different averaging times for the air concentration used.
2655 The acute data uses concentrations for a 24-hour period at the peak, while the chronic data was
2656 averaged over the entire one-year period. Because air concentrations for most of the year are
2657 significantly lower than the peak value, the air concentration used in chronic dose calculations is
2658 lower than acute, resulting in a lower dose per day rate and risk estimate. The difference between
2659 high and medium intensity scenarios risk estimates is driven by the weight fraction and article
2660 surface area. For this specific article, the confidence in the data used for weight fraction is slight
2661 because a surrogate chemical, DINP, concentration was used in the absence of DIDP specific
2662 data. The confidence in the surface area is moderate because the source was the Exposure
2663 Factors Handbook. EPA made a conservative assumption for the high-intensity exposure
2664 scenario. The difference in risk estimates results among lifestages is driven by the inhalation rate
2665 to body weight ratio.
2666

2667 The aggregation across routes for a high-intensity exposure scenario for infants resulted in an
2668 MOE value of 27. The inhalation and ingestion of surface dust are the main contributors to the
2669 overall aggregate MOE value. The inhalation scenarios are explained above. The surface dust
2670 ingestion scenario model estimates the DIDP concentration in settled dust on the wallpaper
2671 surface, assuming primarily that DIDP partitions directly from the wallpaper to settled dust. The
2672 model assumes exposure to occur through dust intake via incidental ingestion assuming a daily
2673 stay-at-home dust ingestion rate per lifestage. The model, assuming instantaneous equilibrium is
2674 achieved for partitioning, represents an upper bound scenario. There is no difference between
2675 chronic and acute exposure, as both rely on the same upper end dust concentration.

2676 **4.3.3.1 Overall Confidence in Consumer Risks**

2677 As described in Section 4.1.2.5 and in more technical details in Section 5.1 in the *Draft Consumer and*
2678 *Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024a](#)), EPA has
2679 moderate to robust confidence in the assessed inhalation, ingestion, and dermal consumer exposure
2680 scenarios, and robust confidence in the non-cancer POD selected to characterize risk from acute,
2681 intermediate, and chronic duration exposures to DIDP (see Section 4.2 and ([U.S. EPA, 2024h](#))). The
2682 exposure doses used to estimate risk relied on conservative, health protective inputs and parameters that
2683 are considered representative of a wide selection of use patterns. Further, the non-cancer POD selected
2684 to characterize risk is based on reduced F2 offspring survival on PND1 and PND4 in rats. The
2685 developmental effect that serves as the basis of the POD is considered most relevant for assessing risk to
2686 women of reproductive age, pregnant women, and infants. Use of this POD to assess risk for other
2687 lifestages (*e.g.*, toddlers, preschoolers, and other children) is a conservative approach. Sources of
2688 uncertainty associated with this consumer COUs are discussed above in Section 4.3.3. While the
2689 conservative approaches used for consumer risks, in particular the in-place wallpaper use, constitute a
2690 defensible screen to eliminate with confidence risk concerns, where benchmark exceedances are
2691 indicated the conservative nature of the assumptions, as well as uncertainties in the assumptions, should
2692 be considered when using these estimates to inform a risk determination.

2693

Table 4-17. Consumer Risk Summary Table

Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)						Overall Exposure/ Hazard Confidence ^b		
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)		Adult (≥21)	
Consumer Uses: Other: Novelty Products	Adult Toys	Acute	Dermal	H	–	–	–	–	–	122,178	114,331	M/ R	
			Ingestion by Mouthing	H	–	–	–	–	–	288	321	M/ R	
			Aggregate	H	–	–	–	–	–	287	321	-	
		Intermediate	–	–	–	–	–	–	-	-	-		
		Chronic	Dermal	H	–	–	–	–	–	–	122,178	114,331	M/ R
			Ingestion by Mouthing	H	–	–	–	–	–	–	288	321	M/ R
Aggregate	H		–	–	–	–	–	–	287	321	-		
Consumer Uses: Automotive, fuel, agriculture, outdoor use products: Lubricants	Auto Transmission Conditioner († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	13,256	14,495	13,564	M/ R	
			Inhalation	H	†3,905,883	†4,146,245	†5,100,539	†7,325,032	9,624,741	11,245,617	14,001,320	R/ R	
			Aggregate	H	–	–	–	–	13,237	14,476	13,551	-	
		Intermediate	-	-	-	-	-	-	-	-	-	-	
		Chronic	Dermal	H	–	–	–	–	–	4,838,273	5,290,655	4,950,860	M/ R
			Inhalation	H	†12,323,061	†13,081,404	†16,092,203	†23,110,480	28,451,314	33,446,036	41,423,821	R/ R	
Aggregate	H		–	–	–	–	4,135,084	4,568,058	4,422,317	-			
Consumer Uses: Automotive, fuel, agriculture, outdoor use products: Automotive products, other than fluids	Products are like synthetic leather fabrics in furniture	See synthetic leather furniture scenarios. Use patterns for dermal exposure to automotive synthetic leather fabric has same considerations than for furniture.											
Consumer Uses: Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses	Bags	Acute	Dermal	H	–	–	71,198	88,311	111,731	122,178	114,331	M/ R	
		Intermediate	–	–	–	–	–	–	–	–	–	–	
		Chronic	Dermal	H	–	–	71,198	88,311	111,731	122,178	114,331	M/ R	
Consumer Uses: Packaging, paper, plastic, hobby products: Toys, Playground, and Sporting Equipment	Legacy Children’s Toys (** = Part of indoor	Acute	Dermal	H	34,824	40,724	47,118	58,443	73,942	80,855	–	R/ R	
			Ingestion suspended dust**	H	9,444,466	10,025,664	12,333,158	17,712,006	25,108,365	29,323,429	36,523,366	R/ R	
			Ingestion dust on surface**	H	5,862	4,735	4,194	11,950	21,345	26,907	266,106	R/ R	

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Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b		
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)			
	exposure scenario)		Ingestion by mouth	H	240	917	1,796	–	–	–	–	R/ R		
			Inhalation**	H	235	249	307	440	624	729	908	R/ R		
			Aggregate	H	116	187	245	422	602	704	905	–		
		Intermediate	–	–	–	–	–	–	–	–	–	–		
		Chronic	Dermal	H	34,824	40,724	47,118	58,443	73,942	80,855	–	R/ R		
			Ingestion suspended dust**	H	11,160,902	11,847,727	14,574,585	20,930,985	29,671,556	34,652,666	43,161,119	R/ R		
			Ingestion dust on surface**	H	6,665	5,383	4,768	13,586	24,268	30,591	68,359	R/ R		
			Ingestion by mouth	H	240	917	1,796	–	–	–	–	R/ R		
			Inhalation**	H	263	279	343	492	698	815	1,015	R/ R		
			Aggregate	H	123	205	270	471	672	786	1,000	–		
		Consumer Uses: Packaging, paper, plastic, hobby products: Toys, Playground, and Sporting Equipment	New Children’s Toys (* = Part of indoor exposure scenario)	Acute	Dermal	H	34,824	40,724	47,118	58,443	73,942	80,855	–	R/ R
					Ingestion suspended dust**	H	2,455,561,194	2,606,672,652	3,206,621,119	4,605,121,685	6,528,174,895	7,624,091,579	9,496,075,234	R/ R
					Ingestion dust on surface**	H	1,524,204	1,231,088	1,090,392	3,107,031	5,549,665	6,995,705	61,204,411	R/ R
Ingestion by mouth	H				240	917	1,796	–	–	–	–	R/ R		
Inhalation**	H				61,047	64,804	79,719	114,487	162,296	189,541	236,080	R/ R		
Aggregate	H				238	884	1,691	38,215	50,337	56,222	235,167	–		
Intermediate	–			–	–	–	–	–	–	–	–			
Chronic	Dermal			H	34,824	40,724	47,118	58,443	73,942	80,855	–	R/ R		
	Ingestion suspended dust**			H	2,901,834,661	3,080,409,102	3,789,392,149	5,442,056,080	7,714,604,806	9,009,693,288	11,221,891,082	R/ R		
	Ingestion dust on surface**			H	1,732,910	1,399,658	1,239,697	3,532,470	6,309,569	7,953,612	17,773,434	R/ R		
	Ingestion by mouth			H	240	917	1,796	–	–	–	–	R/ R		
	Inhalation**			H	68,266	72,467	89,146	128,026	181,488	211,955	263,998	R/ R		
	Aggregate			H	238	885	1,695	39,675	52,103	58,100	260,128	–		

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Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b		
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)			
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants (including plasticizers in adhesives and sealants)	Construction Adhesive for Small Scale Projects († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	1,105	1,208	1,130	M/ R		
			Inhalation	H	†41,580	†44,139	†54,298	†77,979	99,614	117,533	145,107	R/ R		
			Aggregate	H	–	–	–	–	1,093	1,196	1,122	–		
		Intermediate	Dermal	H	–	–	–	–	–	828	906	848	M/ R	
			Inhalation	H	†31,185	†33,104	†40,723	†58,484	74,710	88,150	108,830	R/ R		
			Aggregate	H	–	–	–	–	819	897	841	–		
		Chronic	Dermal	H	–	–	–	–	–	23,261	25,436	23,802	M/ R	
			Inhalation	H	†7,982	†8,473	†10,423	†14,969	17,668	21,146	25,788	R/ R		
			Aggregate	H	–	–	–	–	10,041	11,547	12,378	–		
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants (including plasticizers in adhesives and sealants)	Construction Sealant for Large Scale Projects († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	828	906	848	M/ R		
			Inhalation	H	†7,489	†7,950	†9,780	†14,045	11,043	14,001	16,241	R/ R		
			Aggregate	H	–	–	–	–	771	851	806	–		
		Intermediate	Dermal	H	–	–	–	–	–	3,681	302	283	M/ R	
			Inhalation	H	†2,496	†2,650	†3,260	†4,682	276	4,667	5,414	R/ R		
			Aggregate	H	–	–	–	–	257	284	269	–		
		Chronic	Dermal	H	–	–	–	–	–	100,797	110,222	103,143	M/ R	
			Inhalation	H	†8,319	†8,831	†10,864	†15,602	13,080	16,462	19,220	R/ R		
			Aggregate	H	–	–	–	–	11,578	14,323	16,201	–		
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants (including plasticizers in adhesives and sealants)	Epoxy Floor Patch († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	13,256	14,495	13,564	R/ R		
			Inhalation	H	†13,041	†13,844	†17,030	†24,457	32,137	37,550	46,751	M/ R		
			Aggregate	H	–	–	–	–	9,385	10,458	10,514	–		
		Intermediate	–	–	–	–	–	–	–	–	–	–	–	
			Chronic	Dermal	H	–	–	–	–	–	4,838,273	5,290,655	4,950,860	R/ R
				Inhalation	H	†41,298	†43,839	†53,929	†77,449	95,348	112,086	138,822	M/ R	
		Aggregate		H	–	–	–	–	–	93,505	109,761	135,036	–	
		Consumer Uses: Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Fitness Ball	Acute	Dermal	H	–	–	–	–	111,731	122,178	114,331	M/ R
				Intermediate	–	–	–	–	–	–	–	–	–	–
Chronic	Dermal			H	–	–	–	–	–	111,731	122,178	114,331	M/ R	
Consumer Uses: Packaging, paper, plastic, hobby	Foam Flip Flops	Acute	Dermal	H	–	–	25,172	31,223	39,503	43,196	40,422	M/ R		
		Intermediate	–	–	–	–	–	–	–	–	–	–		
		Chronic	Dermal	H	–	–	25,172	31,223	39,503	43,196	40,422	M/ R		

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Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b	
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)		
products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)													
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants (including plasticizers in adhesives and sealants); and Paints and Coatings	Lacquer Sealer (Non-Spray) († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	414	453	424	M/ R	
			Inhalation	H	†3,192	†3,388	†4,168	†5,178	6,778	8,656	9,978	M/ R	
			Aggregate	H	–	–	–	–	390	430	407	–	
		Intermediate	Dermal	H	–	–	–	–	–	207	226	212	M/ R
			Inhalation	H	†1,596	†1,694	†2,084	†2,589	3,389	4,328	4,989	M/ R	
			Aggregate	H	–	–	–	–	195	215	203	–	
		Chronic	Dermal	H	–	–	–	–	–	75,598	82,666	77,357	M/ R
			Inhalation	H	†5,724	†6,077	†7,475	†9,790	10,345	13,077	15,210	M/ R	
			Aggregate	H	–	–	–	–	9,100	11,291	12,711	–	
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants (including plasticizers in adhesives and sealants); and Paints and Coatings	Lacquer Sealer (Spray) († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	1,036	1,132	1,060	M/ R	
			Inhalation	H	†3,173	†3,368	†4,143	†5,143	6,659	8,514	9,804	M/ R	
			Aggregate	H	–	–	–	–	896	999	956	–	
		Intermediate	Dermal	H	–	–	–	–	–	518	566	530	M/ R
			Inhalation	H	†1,586	†1,684	†2,072	†2,571	3,329	4,257	4,902	M/ R	
			Aggregate	H	–	–	–	–	448	500	478	–	
		Chronic	Dermal	H	–	–	–	–	–	188,995	206,666	193,393	M/ R
			Inhalation	H	†5,724	†6,076	†7,475	†9,789	10,343	13,074	15,206	M/ R	
			Aggregate	H	–	–	–	–	9,806	12,296	14,098	–	
Consumer Uses: Packaging, paper, plastic, hobby products: PVC film and sheet	Miscellaneous Coated Textiles (Truck Awnings)	Acute	Dermal	H	–	–	–	–	111,731	122,178	114,331	M/ R	
		Intermediate	–	–	–	–	–	–	–	–	–	–	
		Chronic	Dermal	H	–	–	–	–	111,731	122,178	114,331	M/ R	
Consumer Uses: Packaging, paper, plastic, hobby products: Arts, crafts, and hobby materials (crafting paint applied to craft)	Rubber Eraser	Acute	Dermal	H	–	–	177,996	220,778	279,328	305,445	285,828	R/ R	
			Ingestion by mouth	H	–	–	1,027	1,755	–	–	–	R/ R	
			Aggregate	H	–	–	1,021	1,741	–	–	–	–	
		Intermediate	–	–	–	–	–	–	–	–	–	–	
		Chronic	Dermal	H	–	–	177,996	220,778	279,328	305,445	285,828	R/ R	
			Ingestion by mouth	H	–	–	1,027	1,755	–	–	–	–	R/ R
Aggregate	H		–	–	1,021	1,741	–	–	–	–			

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Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	
Consumer Uses: Packaging, paper, plastic, hobby products: Arts, crafts, and hobby materials (crafting paint applied to craft)	Current products were not identified. Foreseeable uses were matched with the lacquers, and sealants (small and large projects) because similar use patterns are expected.											
Consumer Uses: Packaging, paper, plastic, hobby products: Ink, toner, and colorant products	Current products were not identified. Foreseeable uses were matched with the lacquers, and sealants (small and large projects) because similar use patterns are expected.											
Consumer Uses: Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses	Shower Curtain (* = Part of indoor exposure scenario)	Acute	Dermal	H	–	–	71,198	88,311	111,731	122,178	114,331	R/ R
			Ingestion suspended dust**	H	29,349,444	31,155,564	38,326,289	55,041,496	78,026,279	91,124,933	113,499,321	M/ R
			Ingestion dust on surface**	H	31,099	25,118	22,248	63,394	113,232	142,737	318,964	M/ R
			Inhalation**	H	914	970	1,194	1,714	2,430	2,838	3,535	R/ R
			Aggregate	H	888	934	1,115	1,638	2,330	2,721	3,393	–
		Intermediate	–	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	71,198	88,311	111,731	122,178	114,331	R/ R
			Ingestion suspended dust**	H	33,861,044	35,944,801	44,217,811	63,502,482	90,020,489	105,132,669	130,946,451	M/ R
			Ingestion dust on surface**	H	35,360	28,560	25,296	72,080	128,747	162,294	362,668	M/ R
			Inhalation**	H	35,360	28,560	25,296	72,080	128,747	162,294	362,668	R/ R
			Aggregate	H	17,671	14,274	10,738	25,584	40,824	48,739	70,083	–
		Consumer Uses: Construction, paint, electrical, and metal products: Building/construction materials covering large surface areas including stone, plaster, cement, glass	Solid Flooring (* = Part of indoor exposure scenario)	Acute	Dermal	H	37,209	43,513	50,345	62,445	79,006	86,393
Ingestion suspended dust**	H				38,746,871	41,131,294	50,598,021	72,665,287	103,009,591	120,302,315	149,840,781	R/ R
Ingestion dust on surface**	H				4,861	3,926	3,478	9,909	17,700	22,312	49,859	R/ R
Inhalation**	H				402	426	524	753	1,067	1,247	1,553	R/ R
Aggregate	H				367	381	452	692	994	1,165	1,478	–

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Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	
and ceramic articles (wire or wiring systems; joint treatment)		Intermediate	–	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	37,209	43,513	50,345	62,445	79,006	86,393	80,844	M/ R
			Ingestion suspended dust**	H	48,133,452	51,095,511	62,855,588	90,268,735	127,964,065	149,446,020	186,140,294	R/ R
			Ingestion dust on surface**	H	5,525	4,463	3,953	11,263	20,117	25,359	56,669	R/ R
			Inhalation**	H	450	477	587	843	1,195	1,396	1,739	R/ R
			Aggregate	H	411	427	506	775	1,112	1,303	1,653	–
Consumer Uses: Furnishing, cleaning, treatment/care products: Fabrics, textiles, and apparel (as plasticizer)	Synthetic Leather Clothing	Acute	Dermal	H	–	–	–	–	894	974	1,018	M/ R
		Intermediate	–	–	–	–	–	–	–	–	M/ R	
		Chronic	Dermal	H	–	–	–	–	894	974	1,018	M/ R
Consumer Uses: Furnishing, cleaning, treatment/care products: Fabrics, textiles, and apparel (as plasticizer)	Synthetic Leather Furniture (** = Part of indoor exposure scenario)	Acute	Dermal	H	491	553	613	737	894	974	1,018	R/ R
			Ingestion suspended dust**	H	4,860,228	5,159,319	6,346,781	9,114,796	12,921,045	15,090,164	18,795,332	M/ R
			Ingestion dust on surface**	H	1,949	1,574	1,394	3,973	7,097	8,946	19,991	M/ R
			Ingestion by mouthing	H	384	659	1,027	-	-	-	-	M/ R
			Inhalation**	H	86	91	112	161	229	267	333	R/ R
			Aggregate	H	60	67	82	128	178	205	248	–
		Intermediate	–	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	491	553	613	737	894	974	1,018	R/ R
			Ingestion suspended dust**	H	5,898,111	6,261,072	7,702,112	11,061,227	15,680,285	18,312,612	22,809,004	M/ R
			Ingestion dust on surface**	H	2,217	1,791	1,586	4,519	8,071	10,175	22,737	M/ R
			Ingestion by mouthing	H	384	659	1,027	-	-	-	-	M/ R
			Inhalation**	H	96	102	126	181	256	299	372	R/ R
			Aggregate	H	65	73	89	141	194	224	269	–
Aggregate	H		65	73	89	141	194	224	269	–		

PUBLIC RELEASE DRAFT
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Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b	
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)		
Consumer Uses: Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Wallpaper (application)	Acute	Dermal	H	–	–	–	–	27,933	30,545	28,583	M/ R	
		Intermediate	–	–	–	–	–	–	–	–	–	–	
		Chronic	Dermal	H	–	–	–	–	10,195,466	11,148,750	10,432,715	M/ R	
Consumer Uses: Packaging, paper, plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Wallpaper (In place) (* = Part of indoor exposure scenario)	Acute	Dermal	H	52,622	61,536	71,198	88,311	–	–	–	M/ R	
				M	91,144	106,584	123,319	152,959	–	–	–	M/ R	
			Ingestion suspended dust**	H	2,859,011	3,034,950	3,733,471	5,361,746	7,600,758	8,876,734	11,056,286	M/ R	
				M	5,900,182	6,263,270	7,704,816	11,065,110	15,685,791	18,319,041	22,817,012	M/ R	
			Ingestion dust on surface**	H	359	290	257	731	1,306	1,647	3,680	M/ R	
				M	761	614	544	1,551	2,770	3,491	7,802	M/ R	
			Inhalation**	H	30	31	39	56	79	92	115	M/ R	
				M	63	67	82	118	167	195	243	M/ R	
			Aggregate	H	27	28	34	52	74	87	111	–	
				M	58	60	71	110	158	185	236	–	
			Intermediate	–	–	–	–	–	–	–	–	–	–
			Chronic	Dermal	H	52,622	61,536	71,198	88,311	–	–	–	M/ R
					M	91,144	106,584	123,319	152,959	–	–	–	M/ R
				Ingestion suspended dust**	H	3,551,514	3,770,069	4,637,783	6,660,455	9,441,796	11,026,836	13,734,314	M/ R
		M			7,308,222	7,757,959	9,543,520	13,705,727	19,429,102	22,690,761	28,262,144	M/ R	
		Ingestion dust on surface**		H	408	329	292	831	1,485	1,872	4,183	M/ R	
				M	865	698	618	1,762	3,148	3,968	8,867	M/ R	
		Inhalation**		H	33	35	43	62	88	103	128	M/ R	
				M	70	75	92	132	187	219	272	M/ R	
		Aggregate		H	31	32	38	58	83	98	125	–	
M	65			67	80	123	177	207	264	–			
Consumer Uses: Construction, paint, electrical, and metal products: Electrical	Wire insulation	Acute	Dermal	H	52,622	61,536	71,198	88,311	111,731	122,178	114,331	M/ R	
			Ingestion suspended dust**	H	82,715,538	87,805,725	108,014,979	155,123,448	219,901,463	256,817,398	319,875,137	M/ R	

PUBLIC RELEASE DRAFT
May 2024

Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years)							Overall Exposure/ Hazard Confidence ^b
					Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	
and Electronic Products	(** = Part of indoor exposure scenario)		Ingestion dust on surface**	H	10,095	8,154	7,222	20,579	36,757	46,335	103,542	M/ R
			Ingestion by mouthing	H	384	659	1,027	-	-	-	-	M/ R
			Inhalation**	H	833	884	1,088	1,562	2,215	2,586	3,221	M/ R
			Aggregate	H	255	359	489	1,428	2,050	2,401	3,041	-
		Intermediate	-	-	-	-	-	-	-	-	-	-
		Chronic	Dermal	H	52,622	61,536	71,198	88,311	111,731	122,178	114,331	M/ R
			Ingestion suspended dust**	H	103,065,270	109,407,748	134,588,897	193,287,022	274,001,768	319,999,787	398,571,032	M/ R
			Ingestion dust on surface**	H	11,475	9,268	8,209	23,392	41,781	52,668	117,694	M/ R
			Ingestion by mouthing	H	384	659	1,027	-	-	-	-	M/ R
			Inhalation**	H	933	990	1,218	1,749	2,480	2,896	3,607	M/ R
			Aggregate	H	264	377	518	1,598	2,293	2,685	3,396	-

^a Exposure scenario intensities include high (H), medium (M), and low (L).
^b Overall exposure and hazard confidence judgments ranged from moderate (M) to robust (R).

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4.3.4 Risk Estimates for General Population

As described in the *Draft Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)) and Section 4.1.3, EPA employed a screening-level approach for general population exposures for DIDP releases associated with TCSA COUs. EPA evaluated surface water, drinking water, fish ingestion, and ambient air pathways quantitatively, and land pathways (*i.e.*, landfills and application of biosolids) qualitatively. For pathways assessed quantitatively, high-end estimates of DIDP concentration in the various environmental media were used for screening-level purposes. EPA used a margin of exposure (MOE) approach using high-end exposure estimates to determine whether an exposure pathway had potential non-cancer risks. High-end exposure estimates were defined as those associated with the industrial and commercial releases from a COU and OES that resulted in the highest environmental media concentrations. Plainly, if there is no risk for an individual identified as having the potential for the highest 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 concern for the general population, further exposure assessments for that pathway would be conducted to include higher tiers of modeling when available and exposure estimates for additional subpopulations and COUs. However, using a screening-level approach described in Section 4.1.3, no pathways of exposure were identified as pathways of concern for the general population.

4.3.5 Potentially Exposed or Susceptible Subpopulations and Sentinel Exposures

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

Some population group lifestages may be more susceptible to the health effects of DIDP exposure. As discussed in Section 4.2 and in EPA's *Draft Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024j](#)), exposure to DIDP causes developmental toxicity in experimental animal models and therefore women of reproductive age, pregnant women, infants, children and adolescents are considered to be susceptible subpopulations. These susceptible lifestages were considered throughout the draft risk evaluation. For example, women of reproductive age were evaluated for occupational exposures to DIDP for each COU (Section 4.3.2) and infants (less than 1 year), toddlers (1 to 2 years), and middle school children (6 to 10 years) were evaluated for exposure to DIDP through consumer products and articles (Section 4.3.3). The non-cancer POD for DIDP selected by EPA for use in risk characterization is based on the most sensitive developmental effect (*i.e.*, reduced F2 offspring survival on PND1 and PND4) observed and is expected to be protective of susceptible subpopulations. Additionally, EPA used a value of 10 for the UF_H to account for human variability. The Risk Assessment Forum, in *A Review of 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, 2002](#)).

The available data suggest that some groups or lifestages have greater exposure to DIDP. This includes people exposed to DIDP at work, those who frequently use consumer products and/or articles containing high-concentrations of DIDP, those who may have greater intake of DIDP per body weight (*e.g.*, infants, children, adolescents), and those exposed to DIDP through certain age-specific behaviors (*e.g.*, mouthing of toys, wires, and erasers by infants and children) leading to greater exposure. EPA accounted for these populations with greater exposure in the draft DIDP 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.

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- EPA evaluated a range of consumer exposure scenarios, including high-intensity exposure scenarios for infants and children (susceptible subpopulations). These populations had greater intake per body weight and exposure due to age-specific behaviors (*e.g.*, mouthing of toys, wires, and erasers by infants and children).
 - EPA evaluated a range of general population exposure scenarios, including high-end exposure scenarios for infants and children (susceptible subpopulations). These populations had greater intake per body weight.
 - EPA evaluated exposure of children to DIDP through use of legacy and new toys.
 - EPA evaluated exposure to DIDP 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).

2756 **5 ENVIRONMENTAL RISK ASSESSMENT****DIDP – Environmental Risk Assessment (Section 5):
Key Points**

EPA evaluated the reasonably available information for hazard and environmental exposures to ecological receptors following releases of DIDP to surface water and air deposition of DIDP to soil and surface waters. The key points of the environmental risk assessment are summarized below:

- EPA expects the main environmental exposure pathway for DIDP to be released to surface water and subsequent deposition to sediment.
- The OES with the highest environmental media release to surface water or wastewater and fugitive or stack air release was the PVC plastics compounding OES.
- Although the conservative nature of the VVWM-PSC and AERMOD outputs resulted in reduced confidence for the environmental media concentrations in surface water, sediment, and soil; there is robust confidence that the modeled environmental media concentrations do not underestimate exposure to ecological receptors.
- A trophic transfer analysis indicates that DIDP exposure to terrestrial organisms occurs primarily through diet via the sediment pathway for semi-aquatic terrestrial mammals followed by the soil pathway for terrestrial mammals, with releases to surface water representing the major source.
- Dietary exposure estimates from trophic transfer based on either biomonitoring literature values or COU/OES-based calculated biota concentrations did not exceed the hazard value for representative mammalian species, therefore EPA did not pursue further quantitative analysis for these pathways.
- Hazard data for fish, aquatic invertebrates, and algae indicated no acute or chronic toxicity up to and exceeding the limit of water solubility. No toxicity was observed from hazard studies with bulk sediment or pore water exposure to sediment-dwelling organisms on an acute or chronic exposure basis.
- Earthworm hazard data for DINP indicated no chronic toxicity and was used for read-across to DIDP, which lacked soil invertebrate hazard data.
- Empirical toxicity data for rats were used to estimate a toxicity reference value (TRV) for terrestrial mammals at 128 of mg/kg-bw/day.
- **Qualitative risk characterization indicates that EPA does not expect risk for all pathways assessed for exposure to ecological receptors.** Expected lack of risk to aquatic and terrestrial receptors was assigned moderated confidence except in cases where EPA lacked reasonably available hazard data (*e.g.*, avian and terrestrial plants) in which case, risk is indeterminate for those receptors.

5.1 Summary of Environmental Exposures

2757
2758 EPA expects the main environmental exposure pathway for DIDP to be released to surface water and
2759 subsequent deposition to sediment. The ambient air exposure pathway was also assessed for its limited
2760 contribution via deposition to soil, water, and sediment since sediment represents an ecologically
2761 relevant exposure medium for environmental receptors. DIDP exposure to aquatic species via surface
2762 water and sediment were modeled to estimate concentrations from COU/OES with water releases.
2763 Concentrations of DIDP in representative organisms within the screening level trophic transfer analysis
2764 were calculated using modeled sediment concentrations from Variable Volume Water Model - Point
2765 Source Calculator (VVWM-PSC). Based on a solubility of 1.7×10^{-4} mg/L and the predicted BCF of

2766 1.29 L/kg, the calculated concentration of DIDP in fish was 2.2×10^{-4} mg/kg, which was two orders of
2767 magnitude lower than the highest DIDP measured concentrations reported in aquatic biota in the peer-
2768 reviewed literature. Deposition of DIDP from air was modeled via AERMOD, then daily deposition
2769 values were modeled with VVWM-PSC to represent surface water and sediment concentrations.
2770 Exposure to terrestrial species through air deposition to soil was also assessed using data modeled using
2771 American Meteorological Society/Environmental Protection Agency Regulatory Model (AERMOD).
2772 DIDP is not considered bioaccumulative, however, within the aquatic environment, relevant
2773 environmental exposures are possible through incidental ingestion of sediment while feeding and/or
2774 ingestion of food items that have become contaminated due to uptake from sediment. Exposure through
2775 diet was assessed through a trophic transfer analysis with representative species, which estimated the
2776 transfer of DIDP from soil through the terrestrial food web, from surface water and sediment through the
2777 aquatic food web via releases to surface waters, and air deposition to surface water and sediment (Figure
2778 5-1). The results of the trophic transfer analysis indicate that DIDP exposure to terrestrial organisms
2779 occurs primarily through diet via the sediment pathway for semi-aquatic terrestrial mammals followed
2780 by the soil pathway for terrestrial mammals, with releases to surface water representing the major
2781 source.

2782
2783 The OES resulting in the highest environmental media concentrations from surface water or wastewater
2784 release and fugitive or stack air release was the PVC plastics compounding OES. The PVC plastics
2785 compounding OES is associated with the following COUs: Processing/incorporation into formulation,
2786 mixture, or reaction product/plastic material and resin manufacturing; and Processing/incorporation into
2787 formulation, mixture, or reaction product/other (part of the formulation for manufacturing synthetic
2788 leather). The highest OES estimate (PVC plastics compounding) resulted in DIDP exposure
2789 concentrations in a modeled terrestrial ecosystem of 0.05 mg DIDP/kg in the earthworm (*Eisenia fetida*)
2790 consuming soil with an estimated dietary intake of 0.03 mg DIDP/kg-bw/day in shorttail shrews
2791 (*Blarina brevicauda*). Within the aquatic modeled ecosystem the highest OES estimate (PVC Plastics
2792 Compounding) resulted in a DIDP exposure concentration of 401 mg DIDP/kg in the blacktail redhorse
2793 (*Moxostoma poecilurum*) consuming chironomids and resulted in an estimated dietary intake of 92.4 mg
2794 DIDP/kg-bw/day in American mink (*Mustela vison*).

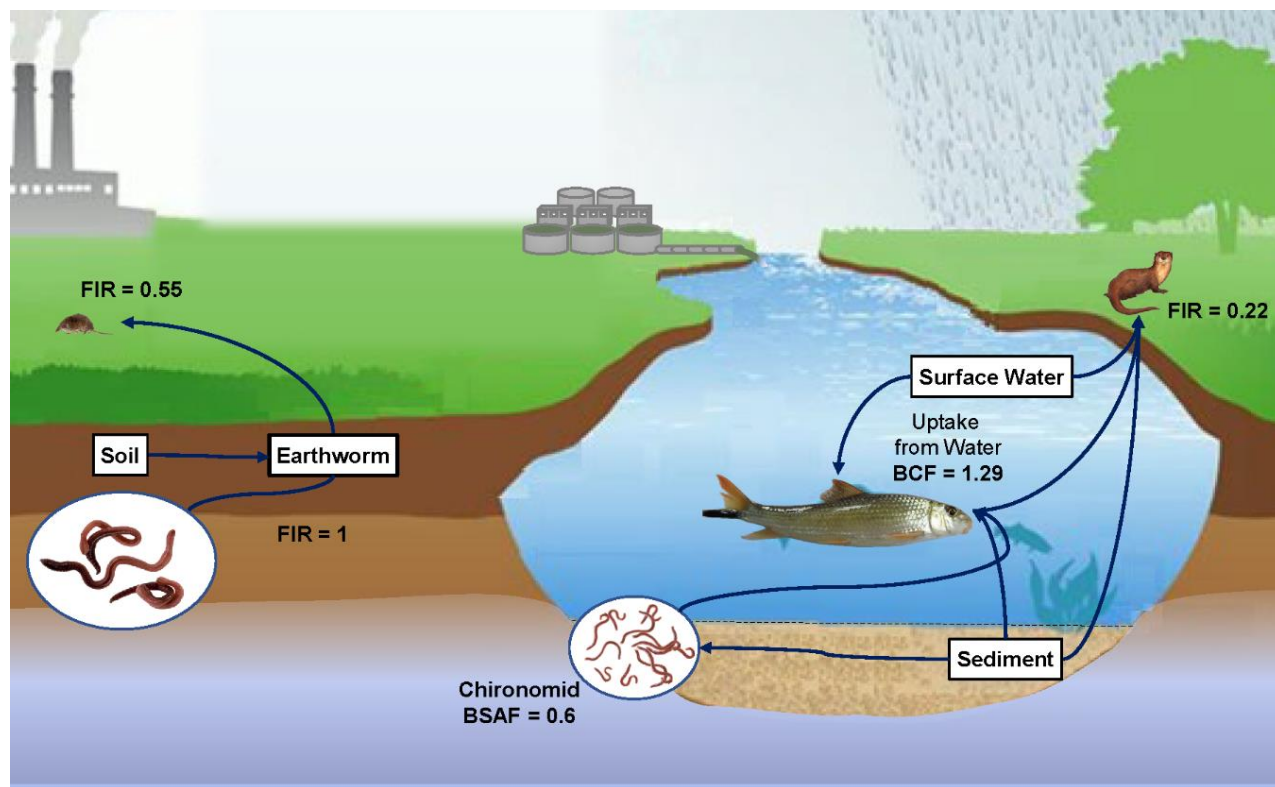


Figure 5-1. Trophic Transfer of DIDP in Aquatic and Terrestrial Ecosystems

5.2 Summary of Environmental Hazards

Like most phthalates, DIDP would be expected to cause adverse effects on aquatic organisms through a non-specific, narcotic mode of toxic action (Parkerton and Konkel, 2000); however, previous assessments have found few to no effects of DIDP on organism survival and fitness (EC/HC, 2015a; ECJRC, 2003a). Hazard data for fish and aquatic invertebrates indicated no acute or chronic toxicity up to and exceeding the limit of water solubility. No toxicity was observed from hazard studies with bulk sediment or pore water exposure to sediment-dwelling organisms on an acute or chronic exposure basis. Two studies were conducted to produce hazard data from an algal species (*Selenastrum capricornutum*) and indicated no toxicity up to the highest tested concentrations (0.8 mg/L and 1.3 mg/L).

Terrestrial hazard data for DIDP were not available for birds or mammalian species, so studies in laboratory rodents were used to derive hazard values for mammalian species. Specifically, five studies conducted on different laboratory strains of Norway rat (*Rattus norvegicus*) were selected for containing definitive data on DIDP for ecologically relevant endpoints (e.g., reproduction, growth, and survival) (Cho et al., 2008; Hushka et al., 2001; Waterman et al., 1999; Hellwig et al., 1997; BIBRA, 1986b). Empirical toxicity data for rats were used to estimate a toxicity reference value (TRV) for terrestrial mammals at 128 of mg/kg-bw/day. Additionally, DINP was considered appropriate for use as an analog for read-across to DIDP in the earthworm (*Eisenia fetida*) based on similarities in structure, physical, chemical and environmental fate and transport properties, and hazard values in relevant taxa (benthic and aquatic invertebrates).

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5.3 Environmental Risk Characterization

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5.3.1 Risk Assessment Approach

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EPA expects the main environmental exposure pathway for DIDP to be released to surface water and subsequent deposition to sediment followed by limited dispersal from fugitive and stack air release. The OES with the highest environmental media concentrations from surface water or wastewater releases and fugitive or stack air release was the PVC plastics compounding OES associated with the following COUs: Processing/ Incorporation into formulation, mixture, or reaction product/ Plastic material and resin manufacturing; and Processing/ Incorporation into formulation, mixture, or reaction product/ Other (part of the formulation for manufacturing synthetic leather). Modeled environmental media concentrations resulting from the PVC plastics compounding OES environmental releases were assessed as a worst-case (conservative) exposure to terrestrial receptors via aquatic and terrestrial trophic transfer pathways. Hazard data for fish, aquatic invertebrates, and algae indicated no acute or chronic toxicity up to and exceeding the limit of water solubility. No toxicity was observed from hazard studies with bulk sediment or pore water exposure to sediment-dwelling organisms on an acute or chronic exposure basis. Earthworm hazard data for DINP indicated no chronic toxicity and was used for read-across to DIDP which lacked soil invertebrate hazard data. Empirical toxicity data for rats were used to estimate a toxicity reference value (TRV) for terrestrial mammals at 128 of mg/kg-bw/day. In no circumstances did exposure exceed the hazard threshold for terrestrial mammals. Qualitative risk characterization indicates that EPA does not expect risk for all pathways assessed for exposure to ecological receptors. Expected lack of risk to aquatic and terrestrial receptors was assigned moderated confidence except in cases where EPA lacked reasonably available hazard data (*e.g.*, avian species and terrestrial plants) in which case, risk is indeterminate for those receptors. A summary of relevant exposure pathways to receptors and resulting qualitative risk estimates are presented in Table 5-1.

Table 5-1. Relevant Exposure Pathway to Receptors and Corresponding Risk Assessment Type (Qualitative) for the DIDP Environmental Risk Characterization

Exposure Pathway	Receptor	Risk Assessment
Surface water, sediment	Aquatic species	Qualitative
Air deposition to surface water, sediment	Aquatic species	Qualitative
Landfill to surface water, sediment	Aquatic species	Qualitative
Surface water, sediment	Aquatic dependent mammal	Qualitative ^a
Air deposition to surface water, sediment	Aquatic dependent mammal	Qualitative ^a
Aggregate media of release (water, incineration, or landfill)	Aquatic dependent mammal	Qualitative
Landfill to surface water, sediment	Aquatic dependent mammal	Qualitative
Air deposition to soil	Terrestrial mammal	Qualitative ^a
Biosolids	Terrestrial mammal	Qualitative

^a Screening level trophic transfer analysis conducted by producing exposure estimates from the high-end exposure scenarios defined as those associated with the industrial and commercial releases from a COU and OES that resulted in the highest environmental media concentrations and presented within [U.S. EPA \(2024b\)](#).

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A qualitative risk assessment for aquatic and terrestrial species was conducted based on a number of factors such as hazard values not observed under environmental conditions (*e.g.*, chemical doses in toxicity studies far exceeding the solubility limit through use of a solvent), a lack of persistence of DIDP in environmental media, and expected DIDP environmental exposures below the concentrations tested

2848 within hazard studies consistently indicating a lack of toxicity for this compound. For aquatic and
2849 benthic species all the available high/medium hazard data indicates a consistent lack of toxicity. A
2850 hazard threshold was determined for mammals and represented as a TRV evaluated within the screening
2851 level trophic transfer analysis on aquatic mammals and terrestrial mammals within [U.S. EPA \(2024b\)](#).
2852

2853 DIDP is expected to partition primarily to soil and sediment, regardless of the compartment of
2854 environmental release ([U.S. EPA, 2024f](#)). DIDP is not expected to undergo long-range transport and is
2855 expected to be found predominantly in sediments near point sources, with a decreasing trend in sediment
2856 concentrations downstream. This is primarily due to DIDP's strong affinity and sorption potential for
2857 organic carbon in soil and sediment. Transport of DIDP is further limited by its low water solubility (1.7
2858 $\times 10^{-4}$ mg/L) which in combination with high sorption coefficients indicate that freely dissolved and
2859 bioavailable concentrations would be reduced due to strong sorption to suspended solids ([Mackintosh et](#)
2860 [al., 2006](#)). Although DIDP is predicted to have an overall environmental half-life of 35 days, DIDP is
2861 expected to have a low biodegradation potential within low oxygen conditions indicating longer
2862 persistence within subsurface sediments and soils ([ECJRC, 2003a](#); [Ejlertsson et al., 1996](#)).
2863

2864 Additional evidence indicates that DIDP is not persistent within other exposure pathways, added by
2865 degradation related fate parameters. Within air, DIDP is expected to have an atmospheric half-life of 7.6
2866 hours attributed to indirect photodegradation with an estimated 75 to 80 percent sorbed to airborne
2867 particulates. The potential removal of DIDP via wastewater treatment was modeled using STPWIN™,
2868 an EPI Suite™ module that estimates chemical removal in sewage treatment plants, predicting greater
2869 than 93 percent removal of DIDP in wastewater by sorption to sludge ([U.S. EPA, 2012](#)). These model
2870 predictions were further supported by two studies with overall quality determinations of high, reporting
2871 aerobic processes have the potential to help biodegrade DIDP from wastewater with 65.8 to 98.9 percent
2872 removal of DIDP ([Armstrong et al., 2018](#); [Tran et al., 2014](#)).
2873

2874 EPA assessed exposures based on the COU/OES which resulted in the highest environmental media
2875 concentrations for a given pathway. If exposure did not exceed hazard from the concentrations
2876 associated with that COU/OES then EPA did not proceed to evaluate environmental media
2877 concentrations for the remaining COU/OESs detailed within the Draft Environmental Media and
2878 General Population Exposure Technical Support Document ([U.S. EPA, 2024d](#)). DIDP concentrations
2879 within surface water, sediment, and soil serve as exposure pathways and were used to determine
2880 exposures to aquatic and terrestrial species. EPA assessed DIDP concentrations in surface water,
2881 sediment, and soil via modeled concentrations (VVWM-PSC, AERMOD) representing COU-based
2882 releases of DIDP. Using COU/OES-specific estimated days of release, high-end release distribution of
2883 COU/OES-specific annual releases to surface water were assessed under conservative flow assumptions
2884 in VVWM-PSC to generate conservative modeled environmental concentrations as described in [U.S.](#)
2885 [EPA \(2024d\)](#). As stated in [U.S. EPA \(2024d\)](#), conservative estimates of DIDP within sediment from
2886 VVWM-PSC modeling resulted in increased confidence that exposures were not underestimated. Air
2887 deposition of DIDP to soil, sediment, and surface water were modeled to represent COU-based releases
2888 to air using AERMOD with conservative estimates increasing confidence that exposures were not
2889 underestimated.
2890

2891 The OES with the highest environmental media concentrations from surface water or wastewater and
2892 fugitive or stack air release was the PVC plastics compounding OES and is associated with the
2893 following COUs: Processing/ Incorporation into formulation, mixture, or reaction product/ Plastic
2894 material and resin manufacturing; and Processing/ Incorporation into formulation, mixture, or reaction
2895 product/ Other (part of the formulation for manufacturing synthetic leather). For COUs with water-based
2896 releases, sediment concentrations modeled using VVWM-PSC resulted in the highest DIDP

2897 concentration for the PVC Plastics Compounding OES at 27,600 mg/kg ([U.S. EPA, 2024f](#)). Deposition
2898 of DIDP from air to soil and surface water was modeled via AERMOD, then daily deposition values
2899 were modeled with VVWM-PSC to represent surface water and sediment concentrations. The highest
2900 DIDP concentration in sediment from air deposition into water at 1,000 m from an annual fugitive
2901 release (254 consecutive operating days of release) was from the PVC Plastics Compounding OES with
2902 a modeled sediment concentration of 0.35 mg/kg. The highest DIDP concentration in soil from air
2903 deposition at 1,000 m from a fugitive release was from the PVC Plastics Compounding OES with a
2904 concentration of 0.05 mg/kg ([U.S. EPA, 2024d](#)). EPA used a distance of 1,000 m from a fugitive/stack
2905 release to represent an ecologically representative area to characterize risk to terrestrial receptors.
2906 Maximum concentrations of DIDP in sediment within published literature originate from studies with
2907 ambient monitoring at 3.4 and 3.7 mg/kg from urban sediments in Sweden and Taiwan, respectively
2908 ([Chen et al., 2016](#); [Cousins et al., 2007](#)). Concentrations of DIDP within biosolids were reported in two
2909 published studies as ranging from 3.8 to 8.0 and 4.3 to 24.9 mg/kg ([Armstrong et al., 2018](#); [ECJRC,
2910 2003a](#)).

2911 DIDP is expected to have a low potential for bioaccumulation and biomagnification in aquatic
2912 organisms ([Blair et al., 2009](#); [McConnell, 2007](#); [Mackintosh et al., 2004](#)). Monitored concentrations of
2913 DIDP within differing aquatic taxa reflect dilution across trophic levels ([McConnell, 2007](#); [Mackintosh
2914 et al., 2004](#)). DIDP exposure to terrestrial organisms occurs primarily through diet via the sediment
2915 pathway for semi-aquatic terrestrial mammals followed by the soil pathway for soil invertebrates and
2916 terrestrial mammals, with releases to surface water representing a major exposure pathway. Exposure
2917 pathways to aquatic-dependant mammals and terrestrial mammals as receptors were not examined
2918 further since, even with conservative assumptions, dietary DIDP exposures were not equal to or greater
2919 than the identified hazard threshold ([U.S. EPA, 2024b](#)).

2921 **5.3.2 Qualitative Risk Assessment for Aquatic and Terrestrial Species**

2922 The landscape of hazard data for DIDP provides information for qualitative risk assessment connecting
2923 relevant exposure pathways to aquatic and terrestrial organisms. DIDP demonstrated no aquatic toxicity
2924 up to and beyond the limit of solubility under both acute and chronic exposure durations ([U.S. EPA,
2925 2024c](#)). Two exceptions were observed under acute exposure conditions with durations of 72 and 96-
2926 hours where two studies on zebrafish (*D. rerio*) identified acute mortality hazard values only by testing
2927 six orders of magnitude greater than the limit of water solubility identified by EPA [1.7×10^{-4} mg/L,
2928 ([U.S. EPA, 2024f](#))] ([Poopal et al., 2020](#); [Chen et al., 2014](#)). Therefore, these two studies were not
2929 considered environmentally relevant for establishing hazard thresholds. Acute and chronic duration
2930 hazard studies conducted on the aquatic invertebrate, *Daphnia magna*, consistently observed
2931 undissolved DIDP on the water surface and attributed these concentrations (0.06 mg/L and 0.14 mg/L)
2932 above solubility to mortality associated with entrapment of test organisms and not to the chemical
2933 ([Rhodes et al., 1995](#)). DIDP within sediment demonstrated no toxicity up to the highest concentrations
2934 tested for chronic exposure durations. The highest measured concentration of DIDP tested within
2935 sediment in a chronic duration study was 4,300 mg/kg with an exposure duration of 28 days for larval
2936 midge (*Chironomus riparius*) ([Brown et al., 1996](#)). Similarly, effects on mortality within *C. tentans*
2937 were not observed for 10-day exposures up to the highest measured DIDP concentration in sediment at
2938 2,680 mg/kg ([Call et al., 2001](#)). Studies on the algae (*Selenastrum capricornatum*) reported no effects up
2939 to observed maximum concentrations of 1.3 mg/L ([Adams et al., 1995](#); [Springborn Bionomics, 1984](#)).
2940 Empirical toxicity data for laboratory rats indicated ecologically-relevant hazard for reproductive,
2941 growth, and mortality endpoints. These data were used to estimate a toxicity reference value (TRV) for
2942 terrestrial mammals at 128 of mg/kg-bw/day. The TRV was used as a hazard threshold for representative
2943 aquatic-dependent (mink) and terrestrial insectivorous (shrew) mammals for comparison to dietary

2944 exposure estimates generated by aquatic and terrestrial trophic transfer of DIDP from environmental
2945 releases.

2946 ***Water Releases to Surface Water and Sediment***

2947 Reasonably available published literature report DIDP concentrations within surface water and sediment
2948 lower than the highest NOEC values reported within several hazard studies for aquatic invertebrates and
2949 vertebrates in the water column, benthic invertebrates in the sediment, and aquatic plants and algae.

2950
2951 Eight studies within the pool of reasonably available information reported DIDP concentrations within
2952 surface water. No U.S. studies were identified, however, primary studies were identified as reporting
2953 DIDP in surface waters from Europe ([Tran et al., 2014](#); [Björklund et al., 2009](#)) and China ([Cheng et al.,
2954 2019](#); [Wen et al., 2018](#); [Shi et al., 2012](#)). The highest concentrations of DIDP reported within these
2955 studies ([Tran et al., 2014](#)) includes mean values collected from the Fontenay-les-Briis WWTP influent
2956 and effluent at 2.3×10^{-2} mg/L and 2.6×10^{-4} mg/L, respectively, the latter of which is the same order of
2957 magnitude as the water solubility limit for DINP [1.7×10^{-4} mg/L ([U.S. EPA, 2024f](#))]. The untreated
2958 influent concentration represents DIDP concentrations above solubility likely due to suspended solids
2959 and other particulate matter.

2960
2961 The Swedish National Screening Program for phthalates analyzed DIDP in sediments collecting from
2962 areas within the country representing: (1) national background lakes, (2) a diffuse urban source, and (3)
2963 a point source for phthalates ([Cousins et al., 2007](#)). DIDP in urban sediments ranged from <0.1 to 3.4
2964 mg/kg and sediments near a suspected point source landfill site were recorded at a maximum DIDP
2965 concentration of 0.29 mg/kg. [Mackintosh et al. \(2006\)](#) sampled sediment from False Creek Harbor,
2966 Vancouver, British Columbia, Canada, characterized by the authors as an urbanized marine ecosystem,
2967 reported maximum DIDP concentration in the sediment from twelve samples at 0.58 mg/kg with a
2968 geometric mean of 0.38 mg/kg. [Chen et al. \(2016\)](#) reported a maximum concentration of DIDP within
2969 sediments collected from Kaohsiung Harbor, Taiwan where DIDP was detected at all 20 collection sites
2970 within the industrialized harbor with a maximum mean concentration of 3.7 ± 1.1 mg/kg.

2971
2972 The highest concentrations of DIDP in sediment modeled by VVWM-PSC were from the PVC plastics
2973 compounding OES at 2.7×10^4 mg/kg, four orders of magnitude higher than the highest sediment
2974 concentrations reported within literature. This modeled sediment concentration was used in the trophic
2975 transfer analysis for dietary exposure to an aquatic-dependant mammal and, as shown in [U.S. EPA
2976 \(2024b\)](#). The reasonably available literature monitoring DIDP within surface water and sediment
2977 includes collections from suspected point sources, landfills, and urbanized areas, which builds
2978 confidence in the role of monitored concentrations for this qualitative analysis. Therefore, DIDP within
2979 surface water and sediment are not expected to produce hazardous effects within aquatic organisms and
2980 represent lack of risk based on available hazard and monitoring data.

2981
2982 Based on the weight of scientific evidence for DIDP within the environment, lack of
2983 bioaccumulation/biomagnification, and hazard value for an aquatic dependent mammal, qualitative
2984 analysis indicates that reaching a daily rate of 128 mg/kg-day is highly unlikely and was not reached
2985 even with conservative quantitative modeling and trophic transfer assumptions. The use of wildlife
2986 exposure factors to calculate dietary exposure (mg DIDP/kg-day) within the conservative screening level
2987 trophic transfer analysis presented within the Environmental Exposure Assessment Technical Support
2988 Package ([U.S. EPA, 2024b](#)) allows for the ability to project the sediment concentration needed to
2989 produce a risk quotient equal to or greater than one within a representative aquatic dependent mammal.
2990 For example, a DIDP sediment concentration of 3.8×10^4 mg/kg would be needed for a representative
2991 mammal to ingest enough DIDP to exceed the TRV hazard threshold value of 128 mg/kg-bw/day. Based
2992

2993 on the conservative VVWM-PSC outputs for surface water and sediment shown in ([U.S. EPA, 2024d](#)),
2994 the COU/OES based water releases of DIDP are not expected to produce environmental concentrations
2995 leading to hazardous effects within aquatic dependent wildlife.

2997 *Air Deposition to Water, Sediment*

2998 Modeling results indicate a rapid decline in DIDP concentrations from air to surface water and sediment
2999 at distances greater than 100 m from fugitive releases. Modeled values of DIDP in surface water and
3000 sediment from air deposition were represented by modeling daily fugitive releases to annual
3001 concentrations based the COU/OES with the highest daily release estimates (which was the PCV plastics
3002 compounding OES). The surface water concentration modeled by VVWM-PSC at 100, 1,000, and 5,000
3003 m from this fugitive release point were 3.5×10^{-3} , 9.5×10^{-5} , and 4.7×10^{-6} mg/L, respectively, with the
3004 100 m DIDP concentration one order of magnitude higher than the reported solubility of 1.7×10^{-4} mg/L
3005 ([U.S. EPA, 2024f](#)). Sediment concentrations modeled by VVWM-PSC at 100, 1,000, and 5,000 m from
3006 this fugitive release point were 13.1, 0.35, and 0.017 mg/kg, respectively. The limited contribution of
3007 DIDP from air to sediment is likely due to its short atmospheric half-life driven by indirect
3008 photodegradation [$t_{1/2} = 7.6$ hours; ([Mackay et al., 2006a](#))] and sorption to airborne particles. Modeled
3009 air concentrations of DIDP based on the COU/OES (PCV plastics compounding OES) are in alignment
3010 with concentrations reported from monitored sites associated with plastics and former rubber production
3011 facilities located within Gislaved and Stenungsund, Sweden as reported by the Sweden national
3012 monitoring program, a co-operative program for the evaluation of long-range transmission of air
3013 pollutants in Europe (EMEP) network ([Cousins et al., 2007](#)).

3015 The concentrations of DIDP in sediment and surface water modeled from air deposition of the highest
3016 releasing COU/OES are lower than the highest NOEC values reported within several hazard studies for
3017 aquatic invertebrates and vertebrates in the water column, benthic invertebrates, and aquatic plants and
3018 algae. For example, the effects on mortality and development within the benthic invertebrate, *C. tentans*,
3019 were not observed from 10-day DIDP exposures up to the highest measured sediment concentrations
3020 averaging 2,680 mg/kg ([Call et al., 2001](#)). Therefore, COU/OES based fugitive and stack air releases of
3021 DIDP and subsequent deposition to surface water and sediment are not expected to produce
3022 environmental concentrations leading to hazardous effects within aquatic organisms.

3024 Modeled daily deposition rates from 100 m and 5,000 m from a release source are 4 to 8 orders of
3025 magnitude below the mammalian TRV value of 128 mg/kg-bw/day. Additionally, as described in [U.S.](#)
3026 [EPA \(2024b\)](#), dietary exposure estimates based on the highest modeled sediment concentration from air
3027 deposition of DIDP at 1,000 m did not overlap with the hazard threshold (TRV) derived for aquatic-
3028 dependant mammal nor did dietary exposure estimates of DIDP based on the available sediment
3029 monitoring data. As a result, the COU/OES based fugitive and stack air releases of DIDP and
3030 subsequent deposition to surface water and sediment are not expected to produce environmental
3031 concentrations leading to hazardous effects within aquatic dependent mammals.

3033 *Air Deposition to Soil*

3034 Modeling results indicate a rapid decline in DIDP concentrations from air deposition to soil. The PVC
3035 plastics compounding OES resulted in the highest fugitive release of DIDP with daily deposition rates to
3036 soil at 100, 1,000, and 5,000 m of 1.8, 5.1×10^{-2} , and 2.4×10^{-3} mg/kg, respectively. These modeled daily
3037 deposition rates from 100 m and 5000 m from a release source are 2 to 5 orders of magnitude below the
3038 mammalian TRV value of 128 mg/kg-bw/day. Comparatively, the highest reported soil concentration of
3039 DIDP reported within the reasonably available literature is from Tran et al. ([2015](#)), indicate a DIDP
3040 concentration of 1.3×10^{-2} and 4.0×10^{-2} mg/kg in rural and agricultural soils, respectively (Doue, Seine-
3041 et-Marne, France; population 1,029). Although no hazard data for soil invertebrates was reasonably

3042 available for DIDP, read-across from a suitable analog (DINP) indicated a NOEC for DINP of 1,000
3043 mg/kg which demonstrates no hazardous effects within this soil invertebrate even when testing DINP to
3044 high concentrations. Therefore, COU/OES based fugitive and stack air releases of DIDP and subsequent
3045 deposition to soil are not expected to produce environmental concentrations leading to hazardous effects
3046 within soil invertebrates or terrestrial mammals.

3047 ***Landfill (to Surface Water, Sediment)***

3048 Given the strong affinity of DIDP to adsorb to organic matter present in soils and sediments (log K_{oc}
3049 5.04 to 6.00, and K_d of 1.66×10^2 to 3.97×10^3) ([U.S. EPA, 2012](#); [Mackay et al., 2006b](#); [Williams et al.,
3050 1995](#)), DIDP is expected to be immobile in soil and groundwater environments. Furthermore, due to the
3051 insoluble nature of DIDP, migration of DIDP to groundwater is unlikely. In instances where DIDP could
3052 reasonably be expected to be present in groundwater environments (proximal to landfills or agricultural
3053 land with a history of land applied biosolids), limited persistence is expected based on rates of
3054 biodegradation of DIDP in aerobic environments (half-life ~14 to 26 days in water and ~28 to 56 days in
3055 soil) ([ECJRC, 2003a](#)). Measured concentrations of DIDP in landfill leachates collected from four
3056 landfills in Sweden were below detection for all samples analyzed (n = 11) ([Kalmykova et al., 2013](#)).
3057 Sediments near a landfill in Sweden were found to have a DIDP concentration of 290 $\mu\text{g}/\text{kg}$ ([Cousins et
3058 al., 2007](#)), well below NOEC values for sediment-dwelling organisms with corresponding dietary
3059 exposure estimate well below the TRV for terrestrial mammals (128 mg/kg-bw/day). DIDP is not likely
3060 to be persistent in groundwater/subsurface environments unless anoxic conditions exist. As a result, the
3061 evidence presented indicates that migration from landfills to surface water and sediment is limited and
3062 not likely to result in hazardous effects within aquatic and terrestrial organisms.

3063 ***Biosolids***

3064 EPA did not pursue using generic release scenarios to model potential DIDP concentrations in biosolids
3065 because the high-end release scenarios were not considered to be applicable to the evaluation of land
3066 application of biosolids. One monitoring report conducted in Sweden reported concentration of DIDP in
3067 sludge from sewage treatment plants ranging 19.0 to 51.0 mg/kg ([Cousins et al., 2007](#)). Two additional
3068 studies reported DIDP concentrations in biosolids of 3.80 to 8.03 mg/kg and 4.3 to 24.9 mg/kg
3069 ([Armstrong et al., 2018](#); [ECJRC, 2003a](#)). The half-life of 28 to 52 days in aerobic soils ([SRC, 1983](#))
3070 indicates that DIDP is not persistent in the aerobic environments associated with freshly applied
3071 biosolids. High-end releases from industrial facilities are unlikely to be released directly to municipal
3072 wastewater treatment plants without pre-treatment or to be directly land-applied following on-site
3073 treatment at the industrial facility itself. In comparison to hazard values, the highest reported DIDP
3074 concentrations within biosolids from reasonably available literature are two orders of magnitude below
3075 the read-across NOEC value within earthworms of 1,000 mg/kg from a 28-day exposure with
3076 corresponding dietary exposure estimate less than the hazard threshold for mammals (128 mg/kg-day).
3077 The combination of factors such as biodegradation ([SRC, 1983](#)) and the weight of evidence supporting a
3078 lack of bioaccumulation and biomagnification ([Mackintosh et al., 2004](#); [ECJRC, 2003a](#); [Gobas et al.,
3079 2003](#)) supports this qualitative assessment that potential DIDP concentrations in biosolids do not present
3080 concentrations able to produce hazardous effects within soil invertebrates or terrestrial mammals.

3081 ***Distribution in Commerce***

3082 EPA evaluated activities resulting in exposures associated with distribution in commerce (*e.g.*, loading,
3083 unloading) throughout the various life cycle stages and COUs (*e.g.*, manufacturing, processing,
3084 industrial use, commercial use, and disposal) rather than a single distribution scenario. EPA lacks data to
3085 assess risks to the environment from environmental releases and exposures related to distribution of
3086 DIDP in commerce as a single OES. However, most of the releases from this COU/OES are expected to
3087 be captured within the releases of other COU/OES since most of the activities (loading, unloading)

3091 generating releases from distribution of commerce are release points of other COU/OESs. Because the
3092 exposure estimates from these other COU/OESs did not exceed hazard to ecological receptors, EPA
3093 expects that a similar release from distribution in commerce also would not result in exposure estimates
3094 exceeding hazard to ecological receptors.
3095

3096 ***Aggregate Media of Release***

3097 Table 5-2 represents COU/OES with aggregated media of release, where the environmental release
3098 assessment did not provide individual release estimates associated within singular release media.
3099 Specifically, these COU/OESs detailed fugitive air and stack air releases in addition to water releases as
3100 an aggregate of “wastewater, incineration, or landfill” rather than water or wastewater only. All
3101 COU/OESs within Table 5-2 have annual release per site (kg/site-year) values lower than PVC plastic
3102 compounding, the OES with the highest annual releases to water. As detailed within [U.S. EPA \(2024b\)](#)
3103 the PVC plastic compounding OES Exposure pathways with aquatic-dependant mammals and terrestrial
3104 mammals as receptors were not examined further since, even with conservative assumptions, exposure
3105 concentrations from this analysis are not equal to or greater than the terrestrial mammal TRV of 128
3106 mg/kg-day.
3107
3108

Table 5-2. Occupational Exposure Scenarios with Aggregate Media of Release

COU (Life cycle stage ^a / Category ^b / Subcategory ^c)	OES	Media of Release
Processing/ Incorporation into formulation, mixture, or reaction product/ Adhesives and sealants manufacturing	Incorporation into adhesives/sealants	
Processing/ Incorporation into formulation, mixture, or reaction product/ Plasticizers (construction materials other; paint and coating manufacturing; pigments; all other chemical product and preparation manufacturing)	Processing/ incorporation into formulation, mixture, or reaction product/ adhesives and sealants manufacturing	Water, incineration, or landfill
Processing/ Incorporation into articles/ Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; miscellaneous manufacturing)		
Processing/ Incorporation into formulation, mixture, or reaction product/ surface modifier in paint and coating manufacturing		
Processing/ Incorporation into formulation, mixture, or reaction product/ Plasticizers (construction materials other; paint and coating manufacturing; pigments; all other chemical product and preparation manufacturing)	Incorporation into paints and coatings	Water, incineration, or landfill
Processing/ Incorporation into articles/ Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; furniture and related product manufacturing; miscellaneous manufacturing; ink, toner, and colorant products manufacturing; photographic supplies manufacturing)		
Processing/ Incorporation into formulation, mixture, or reaction product/ Laboratory chemicals manufacturing		
Processing/ Incorporation into formulation, mixture, or reaction product/ Lubricants and lubricant additives manufacturing	Incorporation into other formulations, mixtures, or reaction products	Water, incineration, or landfill
Processing/ Incorporation into formulation, mixture, or reaction product/ Petroleum lubricating oil manufacturing		
Processing/ Incorporation into formulation, mixture, or reaction product/ Plasticizers		

COU (Life cycle stage ^a / Category ^b / Subcategory ^c)	OES	Media of Release
Processing/ Incorporation into formulation, mixture, or reaction product/ Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities)		
Processing/ Incorporation into formulation, mixture, or reaction product / Plasticizers (construction materials other; all other chemical product and preparation manufacturing)		
Processing/ Incorporation into articles/ Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; miscellaneous manufacturing)		
Processing/ Incorporation into articles/ Abrasives manufacturing		
Industrial uses/ Adhesives and sealants/ Adhesives and sealants		
Commercial uses/ Construction, paint, electrical, and metal products/ Adhesives and sealants (including plasticizers in adhesives and sealants)		
Commercial uses/ Construction, paint, electrical, and metal products/ Lacquers, stains, varnishes, and floor finishes (as plasticizer)	Application of adhesives and sealants	Water, incineration, or landfill
Commercial uses/ Furnishing, cleaning, treatment & care products/ Furnisher and furnishings		
Commercial uses/ Furnishing, cleaning, treatment & care products/ Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer)		
Application of paints and coatings Commercial uses/ Construction, paint, electrical, and metal products/ Paints and coatings (including surfactants in paints and coatings)		
Commercial uses/ Construction, paint, electrical, and metal products/ Lacquers, stains, varnishes, and floor finishes (as plasticizer)	Application of paints and coatings	Water, incineration, or landfill
Commercial uses/ Furnishing, cleaning, treatment & care products/ Furnisher and furnishings		
Commercial uses/ Furnishing, cleaning, treatment & care products/ Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer)		
^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. 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 Life Cycle Diagram, reflect CDR codes, and broadly represent COUs of DIDP in industrial and/or commercial settings. ^c These subcategories reflect more specific COUs of DIDP.		

5.3.3 Overall Confidence and Remaining Uncertainties Confidence in Environmental Risk Characterization

Environmental risk characterization evaluated confidence from environmental exposures and environmental hazards. The *Draft Environmental Release and Occupational Exposure Assessment for DIDP* (U.S. EPA, 2024e) detailed moderate confidence in the release data, where daily releases were estimated using information from (1) Chemical Data Reporting, (2) Generic Scenarios, and (3) Engineering Scenario Documents (Figure 3-1). Exposure confidence is detailed within U.S. EPA (2024d), the Technical Support Document for the Draft Environmental Media and General Population Screening for DIDP, represented by modeled and monitored data. Trophic transfer confidence is represented by evidence type as reported previously in U.S. EPA (2024b), Technical Support Package for the Draft Environmental Exposure Assessment for DIDP. Hazard confidence was represented by evidence type as reported previously in U.S. EPA (2024c), Technical Support Document for the Draft Environmental Hazard Assessment for DIDP. The following confidence determinations for risk characterization inputs are: robust confidence for the aquatic evidence, and moderate confidence for terrestrial evidence (Table 5-3).

Exposure

Conservative approaches within both environmental media modeling (e.g., AERMOD and VVWM-PSC) and the screening level trophic transfer analysis likely overrepresent DIDP ability to transfer among the trophic levels, however, this increases confidence that risks are not underestimated. Due to the lack of release data for facilities discharging DIDP to surface waters, releases were modeled, and the high-end estimate for each COU was applied for surface water modeling. Additionally, due to site-specific release information, a generic distribution of hydrologic flows was developed from facilities which had been classified under relevant NAICS codes, and which had NPDES permits. The median flow rates selected from the generated distributions represented conservative low flow rates. When coupled with high-end release scenarios, these low flow rates result in high modeled concentrations. Although reported measured concentrations for ambient air found in the peer-reviewed and gray literature from the systematic review, Cousins et al. (2007) are within range of the ambient air modeled concentrations from AERMOD for some scenarios, the highest modeled concentrations of DIDP in ambient air were many orders of magnitude higher than any monitored value.

Monitored DIDP concentrations within soil, surface water, and sediment were evaluated and used to represent potential DIDP exposures within a screening level trophic transfer analysis concurrently with the previously described modeled data for the same environmental media. All monitoring and experimental data included in this analysis were from articles rated “medium” or “high” quality from this process with an overall moderate confidence in evidence from monitored data from published literature.

Aquatic Species

The overall confidence in the risk characterization for the aquatic assessment is robust. Studies used for the aquatic environmental hazard assessment consisted of 11 studies with an overall quality determination of high and two studies with an overall quality determination of medium. Consistently, no effects were observed up to the highest DIDP concentration tested within all aquatic hazard studies. As detailed within Section 5.3.2, monitoring data from published literature report DIDP concentrations within surface water and sediment lower than the highest NOEC values presented among several hazard studies for aquatic invertebrates and vertebrates in the water column, benthic invertebrates in the sediment, and aquatic plants and algae.

3158 *Terrestrial Species*

3159 There is moderate confidence in the risk characterization inputs for the terrestrial risk characterization.
3160 For the terrestrial assessment for mammals, EPA assigned an overall quality determination of high or
3161 medium to five acceptable toxicity studies used as surrogates for terrestrial mammals ([Cho et al., 2008](#);
3162 [Hushka et al., 2001](#); [Waterman et al., 1999](#); [Hellwig et al., 1997](#); [BIBRA, 1986b](#)). Moderate confidence
3163 in hazard was assigned for terrestrial invertebrates due to the use of a single earthworm study with a
3164 single test dose, however, the study found no deleterious effects of analog DINP at concentrations up to
3165 1,000 mg/kg dw soil ([ExxonMobil, 2010](#)). DINP was considered appropriate for use as an analog for
3166 read-across to DIDP based on similarities in structure, physical/chemical/environmental fate and
3167 transport properties, and toxicity. The fate properties discussed in [U.S. EPA \(2024f\)](#), soil and biosolid
3168 monitoring presented within [U.S. EPA \(2024d\)](#), and the previous qualitative risk characterization for
3169 terrestrial species (Section 5.3.2) increase confidence that DIDP concentrations at or above 1,000 mg/kg
3170 in the soil are not environmentally relevant.

3171
3172 A hazard threshold was identified for mammals in the form of a TRV (128 mg/kg-day), permitting the
3173 use of a screening level trophic transfer analysis to compare potential environmental concentrations and
3174 dietary uptake of DIDP with a daily rate of oral uptake that produces hazard under experimental
3175 conditions. Several conservative approaches incorporated within the screening level trophic transfer
3176 analysis likely overrepresent DIDP ability to accumulate at higher trophic levels, however, this increases
3177 confidence that risks are not underestimated. Exposure pathways with aquatic-dependant mammals and
3178 terrestrial mammals as receptors were not examined further since, even with conservative assumptions,
3179 dietary DIDP exposure concentrations from this analysis are not equal to or greater than the TRV. These
3180 results align with previous studies indicating that DIDP is not bioaccumulative and will not biomagnify
3181 as summarized within [U.S. EPA \(2024f\)](#). The utilization of both modeled and monitored data as a
3182 comparative approach with similar results increases confidence that dietary exposure of DIDP does not
3183 reach concentrations which would cause hazard within mammals.

3184

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Table 5-3. DIDP Evidence Table Summarizing Overall Confidence Derived for Environmental Risk Characterization

Types of Evidence	Exposure	Hazard	Trophic Transfer	Risk Characterization Confidence
Aquatic				
Acute aquatic assessment	+ PSC + AERMOD	+ + +	N/A	Robust
Chronic aquatic assessment		+++	N/A	
Chronic benthic assessment		+ +	N/A	
Algal assessment		+++	N/A	
Terrestrial				
Chronic avian assessment	N/A	N/A	N/A	Indeterminate
Chronic mammalian assessment	+ PSC + AERMOD	+ +	+ +	Moderate
Terrestrial invertebrates	+ AERMOD	++	N/A	Moderate
Terrestrial plant assessment	N/A	N/A	N/A	Indeterminate
<p>+ + + Robust confidence suggests thorough understanding of the scientific evidence and uncertainties. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the risk estimate.</p> <p>+ + Moderate confidence suggests some understanding of the scientific evidence and uncertainties. The supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize risk estimates.</p> <p>+ Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the scenario, and when the assessor is making the best scientific assessment possible in the absence of complete information. There are additional uncertainties that may need to be considered.</p> <p>N/A Indeterminant corresponds to entries in evidence tables where information is not available within a specific evidence consideration.</p>				

3187

6 UNREASONABLE RISK DETERMINATION

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

EPA is preliminarily determining that DIDP presents an unreasonable risk of injury to human health under the COUs. Risk of injury to the environment does not contribute to EPA's preliminary determination of unreasonable risk. This draft unreasonable risk determination is based on the information in previous sections of this draft risk evaluation, the technical supplements that support this draft risk evaluation and the appendices in accordance with TSCA section 6(b), as well as the best available science (TSCA section 26(h)), the weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

As noted in the Executive Summary, DIDP is a clear, oily, viscous and transparent liquid used as a plasticizer. DIDP is used or can be found in products used in industrial, commercial, and consumer settings. DIDP is a high molecular weight phthalate characterized by its low volatility and insolubility in water. DIDP is not considered bioaccumulative and is expected to biodegrade in the environment under aerobic conditions (half-life on the order of days to weeks) but persists under anaerobic conditions. DIDP may be released into the indoor environment through leaching from products and articles into indoor air and adhere to dust leading to possible exposure through inhalation of vapors, indoor dust and particles or ingestion of indoor dust and particles.

Importantly, human or environmental exposure to DIDP through non-TSCA uses (*e.g.*, food, use in food packaging materials, dental sealants and nail polish, fragrances, medical devices, and pharmaceuticals) were not evaluated by EPA or taken into account in reaching its preliminary determination of unreasonable risk to injury of human health, because these uses are explicitly not subject to TSCA. Further, although the production volume of DIDP has increased over the past decade, it is unknown how TSCA versus non-TSCA sources have contributed to this increase. Thus, while EPA is preliminarily concluding in this draft risk evaluation that only one TSCA COU, Industrial use – adhesives and sealants (due to high-pressure spray application), contributes to its draft unreasonable risk finding for DIDP, this conclusion cannot be extrapolated to form conclusions about uses of DIDP that are not subject to TSCA and that EPA did not evaluate.

As explained in Sections 4.1.3, 4.3.4, 5.3.1 and 5.3.2, EPA used a screening level approach in this draft risk evaluation using conservative environmental release estimates for occupational COUs with the highest releases to determine whether there is risk to the environment and the general population; furthermore, hazard data for fish, aquatic invertebrates, and algae indicated no acute or chronic toxicity up to and exceeding the limit of water solubility. Non-cancer health effects were evaluated in workers, consumers, and the general population. EPA reviewed the weight of scientific evidence for the carcinogenicity of DIDP and determined that there is Suggestive Evidence of Carcinogenic Potential of DIDP and consistent with the *Guidelines for Carcinogen Risk Assessment* ([U.S. EPA, 2005](#)) EPA did not conduct a dose-response assessment or further evaluate DIDP for carcinogenic risk to humans.

Whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

To determine if an occupational COU contributed to unreasonable risk, EPA compared the risk estimates of the OES used to evaluate the COUs, and considered whether the risk from the COU was best represented by the central tendency or high-end risk estimates. For DIDP exposures, whether risk was best characterized by central tendency estimates as opposed to high end estimates for a given COU was based on examination of the specific parameters used in the OES, including (1) the method of application, (2) accuracy of the amount of DIDP found in the product(s) or in dust, and (3) accuracy of the frequency of use for the product(s). The method of application is important for the determination of the exposure level to DIDP, and the estimate of exposure for a particular COU. For example, conventional spray guns use high pressures (typically 30 to 90 psig) that result in excessive spray mist concentrations, whereas high-volume low-pressure (HVLP) spray guns use large quantities of low-pressure air (typically less than 10 psig) which leads to higher transfer efficiency and lower levels of overspray (OECD, 2011a). The higher concentration of mist leads to higher inhalation exposure levels. In comparison, the central tendency estimates are more representative of low-pressure spray applications and non-spray methods such as brush, roll, dip, and bead applications. If the low-pressure applications are used for a particular COU, risk for that COU is best represented by the central tendency estimates. The accuracy of the frequency of use and/or amount of DIDP can also affect the exposure estimates. If the frequency of use and/or the amount of DIDP is overestimated, this leads to a level of uncertainty in the high-end estimates, and therefore the central tendency estimates were more representative of the exposure for the COUs.

For the majority of COUs assessed for occupational exposures, the COUs were best represented by central tendency estimates, and those estimates were used for the unreasonable risk determination. However, high-pressure spray applications could be used in industrial settings for the application of adhesives and sealants. Therefore, workers would be exposed to the potentially elevated inhalation exposures from pressurized spray operations, and the high-end estimates best represent the Industrial use – adhesives and sealants COU (see Table 4-16 of this draft risk evaluation for more details). Conversely, the Processing – incorporation into a formulation, mixture, or reaction product – adhesives and sealants manufacturing COU does not contribute to the unreasonable risk because—due to the low vapor pressure of DIDP—inhale exposures from vapor-generating activities (without dust or mist generation) are quite low.

The consumer and bystander exposure scenarios described in this draft risk evaluation represent a wide selection of consumer use patterns. High-intensity consumer exposure scenarios may use conservative inputs representing sentinel exposures (*e.g.*, 4 vs. 2 hours of exposure, but EPA still has moderate or robust confidence in the majority of inputs used for modeling the high-intensity risk estimates. The high-intensity consumer and bystander risk estimates represent an upper bound exposure scenario.

EPA is preliminarily determining the following COU, considered singularly or in combination with other exposures, contributes to the unreasonable risk:

- Industrial use – adhesives and sealants due to high-pressure spray applications

EPA is preliminarily determining that the following COUs are not expected to contribute to the unreasonable risk:

- Domestic manufacturing (including importing);
- Processing – repackaging;
- Processing – incorporation into a formulation, mixture, or reaction product – adhesives and sealants manufacturing;

- 3283 • Processing – incorporation into a formulation, mixture, or reaction product – laboratory
- 3284 chemicals manufacturing;
- 3285 • Processing – incorporation into a formulation, mixture, or reaction product – petroleum
- 3286 lubricating oil manufacturing; lubricants and lubricant additives manufacturing
- 3287 • Processing – incorporation into a formulation, mixture, or reaction product – surface modifier in
- 3288 paint and coating manufacturing;
- 3289 • Processing – incorporation into a formulation, mixture, or reaction product – plastic material and
- 3290 resin manufacturing;
- 3291 • Processing – incorporation into a formulation, mixture, or reaction product – plasticizers (paint
- 3292 and coating manufacturing; pigments; rubber manufacturing);
- 3293 • Processing – incorporation into a formulation, mixture, or reaction product – processing aids,
- 3294 specific to petroleum production (oil and gas drilling, extraction, and support activities);
- 3295 • Processing – incorporation into a formulation, mixture, or reaction product – other; (part of the
- 3296 formulation for manufacturing synthetic leather);
- 3297 • Processing – incorporation into an article – abrasives manufacturing;
- 3298 • Processing – incorporation into an article – plasticizers (asphalt paving, roofing, and coating
- 3299 materials manufacturing; construction; automotive products manufacturing, other than fluids;
- 3300 electrical equipment, appliance, and component manufacturing; fabric, textile, and leather
- 3301 products manufacturing; floor coverings manufacturing; furniture and related product
- 3302 manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel,
- 3303 and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant
- 3304 (including pigment) products manufacturing; photographic supplies manufacturing; toys,
- 3305 playground, and sporting equipment manufacturing);
- 3306 • Processing – recycling;
- 3307 • Distribution in commerce
- 3308 • Industrial use – abrasives (surface conditioning and finish discs; semi-finished and finished
- 3309 goods);
- 3310 • Industrial use – functional fluids (closed systems) (SBCA compressor oil);
- 3311 • Industrial use – lubricant and lubricant additives;
- 3312 • Industrial use – solvents (for cleaning and degreasing);
- 3313 • Commercial use – automotive, fuel, agriculture, outdoor use products – automotive products
- 3314 other than fluid;
- 3315 • Commercial use – automotive, fuel, agriculture, outdoor use products – automotive, fuel,
- 3316 agriculture, outdoor use products – lubricants;
- 3317 • Commercial use – construction, paint, electrical, and metal products – adhesives and sealants
- 3318 (including plasticizers in adhesives and sealants);
- 3319 • Commercial use – construction, paint, electrical, and metal products – building/construction
- 3320 materials (wire or wiring systems; joint treatment, fire-proof insulation);
- 3321 • Commercial use – construction, paint, electrical, and metal products – electrical and electronic
- 3322 products;
- 3323 • Commercial use – construction, paint, electrical, and metal products – paints and coatings
- 3324 (including surfactants in paints and coatings);
- 3325 • Commercial use – construction, paint, electrical, and metal products – lacquers, stains, varnishes,
- 3326 and floor finishes (as plasticizer);
- 3327 • Commercial use – furnishing, cleaning, treatment/care products – furniture and furnishings;
- 3328 • Commercial use – furnishing, cleaning, treatment/care products – construction and building
- 3329 materials covering large surface areas including stone, plaster, cement, glass and ceramic

3330 articles; fabrics, textiles, and apparel (as plasticizer) (floor coverings (vinyl tiles, PVC-backed
3331 carpeting, scraper mats));

- 3332 • Commercial use – furnishing, cleaning, treatment/care products – ink, toner, and colorant
3333 products;
- 3334 • Commercial use – furnishing, cleaning, treatment/care products – PVC film and sheet;
- 3335 • Commercial use – furnishing, cleaning, treatment/care products – plastic and rubber products
3336 (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)
- 3337 • Commercial use – other uses – laboratory chemicals;
- 3338 • Commercial use – other uses – inspection fluid/penetrant;
- 3339 • Consumer use – automotive, fuel, agriculture, outdoor use products – automotive products other
3340 than fluids;
- 3341 • Consumer use – automotive, fuel, agriculture, outdoor use products – lubricants;
- 3342 • Consumer use – construction, paint, electrical, and metal products – adhesives and sealants
3343 (including plasticizers in adhesives and sealants);
- 3344 • Consumer use – construction, paint, electrical, and metal products – building/construction
3345 materials covering large surface areas including stone, plaster, cement, glass and ceramic articles
3346 (wire or wiring systems; joint treatment)
- 3347 • Consumer use – construction, paint, electrical, and metal products – electrical and electronic
3348 products;
- 3349 • Consumer use – construction, paint, electrical, and metal products – paints and coatings;
- 3350 • Consumer use – Furnishing, cleaning, treatment/care products – fabrics, textiles, and apparel (as
3351 plasticizer)
- 3352 • Consumer use – packaging, paper, plastic, hobby products – arts, crafts, and hobby materials
3353 (crafting paint applied to craft);
- 3354 • Consumer use – packaging, paper, plastic, hobby products – ink, toner, and colorant products;
- 3355 • Consumer use – packaging, paper, plastic, hobby products – PVC film and sheet;
- 3356 • Consumer use – packaging, paper, plastic, hobby products – plastic and rubber products (textiles,
3357 apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)
- 3358 • Consumer use – packaging, paper, plastic, hobby products – toys, playgrounds, and sporting
3359 equipment;
- 3360 • Consumer use – other – novelty products, and
- 3361 • Disposal.

3362 In this draft risk evaluation, the Agency describes the strength of the scientific evidence supporting the
3363 human health and environmental assessments as robust, moderate, slight, or indeterminate. Robust
3364 confidence suggests thorough understanding of the scientific evidence and uncertainties, and the
3365 supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that
3366 the uncertainties could have a significant effect on the exposure estimate. Moderate confidence suggests
3367 some understanding of the scientific evidence and uncertainties, and the supporting scientific evidence
3368 weighed against the uncertainties is reasonably adequate to characterize exposure estimates. Slight
3369 confidence is assigned when the weight of scientific evidence may not be adequate to characterize the
3370 scenario, and when the Agency is making the best scientific assessment possible in the absence of
3371 complete information. The overall confidence in the human health exposure assessment as well as the
3372 hazard assessment is described for each human population in the respective risk estimates section for
3373 that population in Section 4. For the environment, Section 5.3.3 describes weighing the scientific
3374 evidence for exposures and hazards to determine overall confidence in the environmental risk
3375 assessment. The draft DIDP risk evaluation and the supporting technical supplements as well as scoping,

assessments, and other documents and spreadsheets can be accessed in the docket [EPA-HQ-OPPT-2024-0073](#).

In general, the Agency makes an unreasonable risk determination based on risk estimates that have an overall confidence rating of moderate or robust, since those confidence ratings indicate the scientific evidence is adequate to characterize risk estimates despite uncertainties. If in the final TSCA risk evaluation for DIDP, EPA determines that DIDP presents an unreasonable risk of injury to health or the environment under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with DIDP under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that DIDP no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate.

6.1 Unreasonable Risk to Human Health

This assessment provides a risk profile of DIDP by presenting a range of estimates (MOEs¹) 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). Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with existing regulations that may be applicable to. Rather, it reflects the Agency's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements. In addition, the risk estimates are based on exposure scenarios with monitoring data that likely reflects existing requirements, such as those established by OSHA, or industry or sector best practices.

A calculated MOE that is less than the benchmark MOE is a starting point for informing a determination of unreasonable risk of injury to health, based on non-cancer effects. It is important to emphasize that these calculated risk estimates alone are not "bright-line" indicators of unreasonable risk. For example, before determining whether a COU contributed to the unreasonable risk of DIDP due to occupational or consumer exposure, EPA also examined the COU and the exposure scenario to determine the uncertainties and which risk estimates best represented the contribution from that COU to the unreasonable risk.

6.1.1 Populations and Exposures EPA Assessed to Determine Unreasonable Risk to Human Health

EPA evaluated risk to workers, including ONUs; female workers of reproductive age; consumer users and bystanders, including infants and children; and the general population, including infants and children, using reasonably available monitoring and modeling data for inhalation and dermal exposures, as applicable. With respect to health endpoints upon which EPA is basing this preliminary unreasonable

¹ EPA derives non-cancer MOEs by dividing the non-cancer POD (HEC (mg/m³) or HED (mg/kg-day)) by the exposure estimate ((mg/m³ or mg/kg-day)). Section 4.3.1 has additional information on the risk assessment approach for human health.

3420 risk determination, the Agency has robust confidence in the non-cancer developmental toxicity POD.
3421 The POD is based on an effect observed in an animal model, which may translate to miscarriages or
3422 stillbirths in humans. EPA considers this developmental toxicity POD relevant for assessing risk from
3423 acute exposures to DIDP. However, because the developmental toxicity POD is the most protective, it
3424 was considered applicable to all durations evaluated in this risk evaluation (acute, intermediate, and
3425 chronic). Liver toxicity was also identified as a robust and sensitive non-cancer hazard by the EPA, but
3426 the POD for developmental toxicity is protective of the liver toxicity associated with the oral exposure to
3427 DIDP in experimental animal models. EPA evaluated risk from inhalation and dermal exposure of DIDP
3428 to workers, inhalation exposure to ONUs, and, for relevant COUs, dermal exposure to ONUs from
3429 contact with mist or dust deposited on surfaces containing DIDP. The Agency evaluated risk from
3430 inhalation, dermal, and oral exposure to consumer users and for relevant COUs, risk from inhalation
3431 exposure to bystanders. The Agency evaluated risk from inhalation, dermal, and oral exposure to
3432 consumer users and for relevant COUs, risk from inhalation exposure to bystanders. Finally, EPA also
3433 evaluated risk from exposures from surface water, drinking water, fish ingestion, ambient air, and land
3434 pathways (*i.e.*, landfills and application of biosolids) to the general population.
3435

3436 Descriptions of the data used for human health exposure and human health hazards are provided in
3437 Sections 0 and 4.2, respectively, in this draft risk evaluation. Uncertainties for overall exposures and
3438 hazards are presented in this draft risk evaluation, the *Draft Consumer and Indoor Exposure Assessment*
3439 *for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024a](#)), and the *Draft Environmental Release and*
3440 *Occupational Exposure and Environmental Release Assessment for Diisodecyl Phthalate (DIDP)* ([U.S.](#)
3441 [EPA, 2024e](#)) and are considered in this preliminary unreasonable risk determination.

3442 **6.1.2 Summary of Unreasonable Risks to Human Health**

3443 EPA is preliminarily determining that the unreasonable risks presented by DIDP are due to

- 3444 • Non-cancer effects in workers from inhalation exposures.

3445 Table 6-1 provides further detail regarding which COUs contribute to the above risks.
3446

3447 EPA's exposure and overall risk characterization confidence levels are summarized in Section 0, with
3448 specific confidence levels present in Sections 4.3.2.1 (occupational exposure) and 4.3.3.1 (consumer
3449 exposure). Additionally, health risk estimates for workers—including ONUs, consumers, bystanders,
3450 and the general population—can be found in Sections 4.3.2 (workers and ONUs), 4.3.3 (consumers and
3451 bystanders), and 4.3.4 (general population).

3452 **6.1.3 Basis for Unreasonable Risk to Human Health**

3453 In developing the exposure and hazard assessments for DIDP, EPA analyzed reasonably available
3454 information to ascertain whether some human populations may have greater exposure and/or
3455 susceptibility than the general population to the hazard posed by DIDP. The Agency identified as PESS
3456 people who are expected to have greater exposure to DIDP—such as workers who use high-pressure
3457 spray applications of DIDP, those who frequently use consumer products containing high concentrations
3458 of DIDP, subsistence fishers and tribal populations whose diets include large amounts of fish ingestion,
3459 individuals who have aggregated consumer exposures to DIDP, and infants and children using DIDP-
3460 containing toys. Additionally, EPA identified people who may have greater susceptibility to the health
3461 effects of DIDP as PESS, including women of reproductive age, pregnant women, infants, and children.
3462 A full PESS analysis is provided in Section 4.3.5 of this draft risk evaluation.
3463

3464 Risk estimates based on high-end exposure levels (*e.g.*, 95th percentile) are generally intended to cover
3465 individuals with sentinel exposure levels whereas risk estimates at the central tendency exposure are

3466 generally estimates of average or typical exposure. However, EPA was able to calculate risk estimates
3467 for PESS groups in this assessment (*e.g.*, female workers of reproductive age, and infants and children).
3468 The use of either central-tendency or high-end risk estimates for female workers of reproductive age to
3469 make a determination of unreasonable risk was based on assumptions about the COU based on
3470 reasonably available information about a typical scenario and process within the COU (*e.g.*, non-spray
3471 application versus low- or high-pressure spray application). Risk estimates for consumers (*e.g.*, infants
3472 and children) were considered at the high-end exposure level, because parameters used for high-intensity
3473 consumer scenarios were representative of an upper bound exposure scenario. For example, high-
3474 intensity consumer indoor dust exposure scenarios assumed that people are in their homes for longer
3475 periods than the medium- or lower- intensity scenarios. The parameters were varied between the high-,
3476 medium-, and low- intensity scenarios, for example, weight fraction (*i.e.*, 0.26 vs. 0.245 for high versus
3477 medium, respectively), article surface area (*i.e.*, 200 vs. 100 m² for high versus medium, respectively).
3478 Health parameters were also adjusted for each population such as, inhalation rates used per lifestage.
3479 Additionally, EPA aggregated exposures across routes for workers, including ONUs, consumers, and
3480 bystanders for COUs with quantitative risk estimates.

3481
3482 For workers, including ONUs, aggregation of inhalation and dermal exposures led to negligible
3483 differences in risk estimates when compared to risk estimates from inhalation alone, since the inhalation
3484 exposure is the predominant route of exposure. For consumers, dermal, oral, and inhalation routes were
3485 aggregated. For one consumer COU, Packaging, paper, plastic, hobby products – plastic and rubber
3486 products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses), acute, high-intensity
3487 aggregate risk estimates were just below the benchmark of 30 for infants (MOE = 27) while individual
3488 high-intensity risk estimates for this COU did not indicate risk. For all other consumer COUs, all
3489 individual and aggregate risk estimates did not indicate risk. Therefore, EPA is preliminarily
3490 determining that TSCA consumer uses do not contribute to unreasonable risk. However, EPA is not
3491 taking into account consumer exposures through non-TSCA uses (*e.g.*, food, use in food packaging
3492 materials, dental sealants and nail polish, fragrances, medical devices, and pharmaceuticals) regulated by
3493 other U.S. Federal Agencies to reach this conclusion. More detail about this preliminary determination
3494 for consumer uses is in Section 6.1.5 of this preliminary unreasonable risk determination. The
3495 uncertainty factor of 10 for human variability that EPA applied to MOEs accounts for increased
3496 susceptibility of populations such as children and elderly populations. More information on how EPA
3497 characterized sentinel and aggregate risks is provided in Section 0.

3498 **6.1.4 Unreasonable Risk in Occupational Settings**

3499 Based on the occupational risk estimates and related risk factors, EPA is preliminarily determining that
3500 the non-cancer risks from worker acute, intermediate, and chronic inhalation exposure to DIDP in
3501 occupational settings where high-pressure spray applications are used contribute to the unreasonable risk
3502 presented by DIDP.

3503
3504 All occupational COUs were quantitatively assessed, and worker risks were evaluated using the central
3505 tendency and high-end estimates to account for susceptible populations that may be exposed while
3506 working (see Table 4-16 in this draft risk evaluation).

3507
3508 EPA analyzed vapor/mist and/or particulate concentration inhalation exposure in the occupational
3509 scenarios using a time weighted average for a typical 8-hour shift. Separate estimates of central tendency
3510 and high-end inhalation exposures were made for male and female adolescents and adults (≥ 16 years
3511 old) workers, female workers of reproductive age, and ONUs. Dermal exposure in the occupational
3512 exposure scenarios was analyzed using the acute potential dose rate. Dermal exposure for ONUs was
3513 assessed for COUs where exposure to DIDP is likely to occur via mist or dust deposited on surfaces. For

3514 the COUs assessed, dermal exposure for ONUs was evaluated using the central tendency estimates for
3515 workers since the risk to ONUs are assumed to be equal to or less than risk to workers who handle
3516 materials containing DIDP as a part of their job.

3517
3518 Non-cancer risk estimates were calculated from acute, intermediate, and chronic exposures. These terms
3519 are in reference to the duration of exposure to DIDP. For most OESs, acute refers to an exposure time
3520 frame of an 8-hour single workday, intermediate refers to an exposure time frame of 22 workdays, 8
3521 hours per day, and chronic refers to an exposure time frame of 250 days per year for 31 to 40 years, 8
3522 hours per day.

3523
3524 In order to make a preliminary risk determination, EPA analyzed the individual COUs to determine if
3525 the COU was best represented by central tendency or high-end estimates for workers and ONUs based
3526 on the description of the COU and the parameters and assumptions used in the occupational exposure
3527 scenarios. Risk was not indicated at the high-end or central tendency estimates for dermal exposure to
3528 workers and ONUs. There were COUs with MOEs below the benchmark of 30 at the high-end estimates
3529 of inhalation exposure for worker populations. However, the high-end MOEs represent high-pressure
3530 spray-application of coatings. For all COUs with high-end MOEs indicating risk, EPA does not expect
3531 there to be high-pressure spray application since these COUs are in commercial settings where the most
3532 likely methods of applications would be low-pressure applications (*e.g.*, brush, roll, dip, bead
3533 application, and low-pressure spray guns), except for the COU Industrial use – adhesives – adhesives
3534 and sealants. The COUs were: Processing – incorporation into articles – abrasives manufacturing,
3535 Industrial use – adhesives and sealants, Commercial use – construction, paint, electrical, and metal
3536 products – adhesives and sealants (including plasticizers in adhesives and sealants), Commercial use –
3537 construction, paint, electrical, and metal products – lacquers, stains, and floor finishes (as plasticizer),
3538 Commercial use – construction, paint, electrical, and metal products – paints and coatings (including
3539 surfactants and in paints and coatings), Commercial use – packaging, paper, plastic, hobby products –
3540 ink, toner, and colorants, and Commercial use – other uses – inspection fluid/penetrants (Table 4-16).
3541 Therefore, considering that only one COU is expected to have high-pressure spray application, EPA is
3542 preliminarily concluding that the Industrial use – adhesives – adhesives and sealants is the only COU
3543 that contributes to the unreasonable risk to human health based on the high-end acute, intermediate, and
3544 chronic inhalation risk estimates for average male workers and females of reproductive age.

3545
3546 As discussed in Section 4.3.2 of this draft risk evaluation, the high end inhalation exposures are more
3547 representative of high-pressure spray applications for the COUs associated with Processing –
3548 incorporation into articles – abrasives manufacturing; Industrial use – adhesives and sealants;
3549 Commercial use – construction, paint, electrical, and metal products – adhesives and sealants (including
3550 plasticizers in adhesives and sealants); Commercial use – construction, paint, electrical, and metal
3551 products – paints and coatings (including surfactants and in paints and coatings); Commercial use –
3552 packaging, paper, plastic, hobby products – ink, toner, and colorants; and Commercial use –
3553 construction, paint, electrical, and metal products – lacquers, stains, and floor finishes (as plasticizer) .
3554 EPA reviewed the percent of DIDP in products that were associated with each of these COUs,
3555 uncertainties, and their method of application in processing, industrial, and commercial uses. The
3556 primary limitation of the inhalation risk estimates for these COUs is the lack of DIDP-specific
3557 monitoring data. EPA used surrogate monitoring data from the emission scenario document (ESD) on
3558 Coating Application via Spray-Painting in the Automotive Refinishing Industry to Estimate Inhalation
3559 Exposures ([OECD, 2011a](#)). The ESD served as a source of monitoring data representing the level of
3560 exposure that could be expected at a typical work site for a given spray application method. EPA expects
3561 that the percent of DIDP will not vary considerably between products used for processing, industrial and
3562 commercial uses; only uses that have known pressurized spray applications associated with their use

3563 were represented by the high-end inhalation exposure estimates. EPA is preliminarily concluding that
3564 Industrial uses adhesives – adhesives and sealants contributes to the unreasonable risk to human health
3565 based on the high-end acute, intermediate, and chronic inhalation exposure estimates for average male
3566 workers and females of reproductive age, even though the central tendency risk estimates do not indicate
3567 that the COU contributes to the unreasonable risk. An additional uncertainty regarding the high-end
3568 inhalation risk estimates for this COU is whether the automotive refinishing products in the surrogate
3569 data used for estimating inhalation exposure are similar to DIDP-containing adhesives and sealants.
3570 Lastly, the inhalation dose-response value used for the assessment is based on route-to-route
3571 extrapolation from oral data, which is an additional source of uncertainty.
3572

3573 Further, EPA is not determining that other high end inhalation exposure COUs contribute to
3574 unreasonable risk at this time. The other COUs assessed are not generally applied using high-pressure
3575 spray applications and high-end inhalation exposures would not occur. These COUs are in commercial
3576 settings and/or where the most likely methods of applications would be low-pressure applications (*e.g.*,
3577 brush, roll, dip, bead application, and low-pressure spray guns). Therefore, the best representation of
3578 inhalation exposure for the Processing – incorporation into articles – abrasives manufacturing;
3579 Commercial use – construction, paint, electrical, and metal products – adhesives and sealants (including
3580 plasticizers in adhesives and sealants); Commercial use – construction, paint, electrical, and metal
3581 products – paints and coatings (including surfactants and in paints and coatings); Commercial use –
3582 packaging, paper, plastic, hobby products – ink, toner, and colorants; and Commercial use –
3583 construction, paint, electrical, and metal products – lacquers, stains, and floor finishes (as plasticizer) are
3584 the central tendency estimates. The Commercial use – other uses – inspection fluid/penetrant COU was
3585 assessed using conservative estimates of the amount of aerosol exposure and DIDP contained in these
3586 types of products. EPA based the range of the product concentration on a singular surrogate product
3587 which contained DINP (*i.e.*, 10 to 20 percent) rather than DIDP, and the product may be brush or aerosol
3588 applied. Due to the uncertainty in the product concentration, the frequency of use, and the method of
3589 application, EPA concluded that this COU is best represented by central tendency estimates of
3590 inhalation and dermal exposure to workers and ONUs. Therefore, EPA determined that the Commercial
3591 use – other uses – inspection fluid/penetrants COU does not contribute to the unreasonable risk to
3592 human health at this time.
3593

3594 For the Processing – incorporation into formulation, mixture, or reaction product – plastic material and
3595 resin manufacturing; Processing – incorporation into formulation, mixture, or reaction product – other
3596 (part of the formulation for manufacturing synthetic leather); Processing – incorporation into
3597 formulation, mixture, or reaction product – plasticizers (paint and coating manufacturing; pigments;
3598 rubber manufacturing); Processing –incorporation into articles –plasticizers (asphalt paving, roofing, and
3599 coating materials manufacturing; construction; automotive products manufacturing, other than fluids;
3600 electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products
3601 manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics
3602 product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing;
3603 transportation equipment manufacturing; ink, toner, and colorant (including pigment) products
3604 manufacturing; photographic supplies manufacturing; and toys, playground, and sporting equipment
3605 manufacturing) COUs, inhalation exposure estimates were based on inhaling dust containing DIDP for
3606 both workers and ONUs, and dermal exposures were based on exposure to liquid DIDP or DIDP dust on
3607 surfaces for workers or ONUs, respectively. As there was a high uncertainty in the amount of DIDP in
3608 dust and the concentrations were likely overestimated, it was concluded that the central tendency
3609 estimates are the best representation of inhalation exposure for these COUs.
3610

3611 In the overall occupational assessment, EPA has moderate to robust confidence in the assessed
3612 inhalation and dermal occupational exposure scenarios, and robust confidence in the non-cancer POD
3613 selected to characterize risk from acute, intermediate, and chronic duration exposures to DIDP. Overall,
3614 EPA has moderate to robust confidence in the risk estimates calculated for worker and ONU inhalation
3615 and dermal exposure scenarios. More information on EPA's confidence in these risk estimates and the
3616 uncertainties associated with them can be found in Section 4.3.2 in this draft risk evaluation.

3617 **6.1.5 Unreasonable Risk to Consumers**

3618 Based on the consumer risk estimates and related risk factors, EPA is preliminarily determining that
3619 consumer uses covered by TSCA do not contribute to the unreasonable risk at this time. No COU had
3620 MOEs below the benchmark of 30 due to acute, intermediate, or chronic inhalation, oral, or dermal
3621 exposure. One COU had MOEs below the benchmark of 30 after aggregation of the oral, dermal, and
3622 inhalation routes. No risk from acute, intermediate, or chronic inhalation exposure was found for
3623 bystanders for the COUs assessed. Dermal and oral exposures were assessed for non-cancer risks for
3624 consumers only since bystanders would not be expected to be exposed within any consumer COUs.
3625 Non-cancer risk estimates for consumers and bystanders were calculated from acute, intermediate, and
3626 chronic exposures. For a given consumer exposure scenario, acute exposure refers to the time frame of 1
3627 day, intermediate refers to an exposure time frame of 30 days, and chronic refers to a time frame of 365
3628 days. Professional judgment and product use descriptions were used to estimate the intermediate time
3629 frame.

3630
3631 Consumer and bystander risks representing specific age groups were evaluated for consumer COUs.
3632 Typically, consumers are adults since most products purchased are for adult use or application, while
3633 bystanders would include other adults in the home, as well as children. However, for the assessment of
3634 indoor dust exposures and estimating contribution to dust from individual COUs, EPA recreated
3635 plausible indoor environment using consumer products and articles commonly present in indoor spaces.
3636 All age groups assessed under the indoor dust exposure scenarios are considered users (consumers) of
3637 the articles being assessed. Consumer and bystander populations assessed were infant (<1 year), toddler
3638 (1–2 years), preschooler (3–5 years), middle childhood (6–10 years), young teen (11–15 years), teenager
3639 (16–20), and adult (21+ years).

3640
3641 Dermal exposure was evaluated through direct contact with the product or article. Inhalation exposure
3642 was evaluated assuming exposure occurred during the use through the emission of DIDP from the
3643 product or article. When applicable, such as the assessment of the Packaging, paper, plastic, hobby
3644 products – toys, playground, and sporting equipment COU, oral exposure to DIDP was evaluated
3645 through the mouthing of articles during use. To evaluate the migration of DIDP from a children's toy
3646 during the mouthing of toys, estimates were made for legacy toys (defined as toys that are not limited to
3647 the weight fraction of 0.1 percent) and new toys (toys that may be limited to a weight fraction of 0.1
3648 percent DIDP). EPA used weight fractions of 0.26, 0.23, and 0.2 for legacy toys in the high-, medium-,
3649 and low- scenarios. For new toys, a weight fraction of 0.001 was assumed in all scenarios. The article's
3650 surface area and the chemical migration rates of DIDP were varied between the scenarios; for example,
3651 see Table 2-7 in the *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate*
3652 (*DIDP*) ([U.S. EPA, 2024a](#)). The mouthing of articles did not indicate risk for the use of legacy or new
3653 toys evaluated for any age group with MOEs of 240 to 1,1796 for infants, toddlers, and preschoolers
3654 across all durations (see Table 4-17 in this draft risk evaluation for more information).

3655
3656 Due to the low volatility of DIDP, airborne DIDP particles released from household items are more
3657 likely to be found on settled and suspended dust and then inhaled or ingested. EPA included the
3658 ingestion and inhalation of dust for the assessment of the consumer COUs Construction, paint, electrical,

3659 and metal products – electrical and electronic products; packaging, paper, plastic, hobby products –
3660 plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses); and
3661 Packaging, paper, plastic, hobby products – toys, playground, and sporting equipment by estimating the
3662 amount of DIDP-containing dust that would be generated from indoor articles such as, toys, wallpaper,
3663 and wire insulation. Dust on legacy toys and new toys was evaluated by varying the surface area and
3664 number of toys for high, medium, and low-intensity scenarios (see Table 2-8 in the *Consumer and*
3665 *Indoor Exposure Assessment for Diisodecyl phthalate (DIDP)* ([U.S. EPA, 2024a](#))). Risks were not
3666 indicated for any age group through the exposure routes assessed through the use of legacy or new toys
3667 that contain DIDP, and EPA is preliminarily determining that the consumer COU Packaging, paper,
3668 plastic, hobby products – toys, playground, and sporting equipment does not contribute to the
3669 unreasonable risk to human health.

3670
3671 For the consumer COU, Packaging, paper, plastic, hobby products – plastic and rubber products
3672 (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses), the risk to infants and toddlers
3673 is primarily driven by conservative estimates of acute inhalation of DIDP vapors and ingestion of DIDP
3674 partitioned to surface dust from in-place wallpaper. The conservative high-intensity exposure scenario
3675 represents an upper bound exposure scenario. The aggregation of exposures routes for the acute high-
3676 intensity exposure scenario for infants resulted in an MOE value of 27. For infants, the MOEs for the
3677 acute inhalation and ingestion of dust on surface was 30 and 359, respectively. The high-intensity model
3678 conservatively assumes that a relatively large surface area of the house is covered with in-place
3679 wallpaper (200 m²), a DIDP weight fraction of 0.26 percent (based on two wallpaper samples containing
3680 both DINP and DIDP that was reported in 2001 study of four PVC wallpapers), and the infant stays at
3681 home all day long. Further, the non-cancer POD selected to characterize risk is based on reduced F2
3682 offspring survival on PND1 and PND4 in rats, which is applicable for infants exposed to in-place
3683 wallpaper but is a conservative approach for estimating risks to toddlers. Even when all exposures
3684 (inhalation, ingestion of surface dust, ingestion of suspended dust, and dermal) were aggregated, the
3685 MOEs were just below the benchmark MOE of 30. Furthermore, for all other consumer COUs, all
3686 individual and aggregate risk estimates did not indicate risk. As explained in this unreasonable risk
3687 determination, benchmarks are not bright-line indicators of risk. While the conservative approaches used
3688 for estimating risk to infants constitute a defensible screen to eliminate with confidence risk concerns,
3689 EPA is taking into consideration the conservative nature of the assumptions, as well as uncertainties in
3690 the assumptions (*e.g.*, the small and relatively old age of the wallpaper samples used to derive an upper
3691 bound weight fraction for the “high-intensity” consumer use) when making an unreasonable risk
3692 determination. Therefore, EPA is preliminarily determining that consumer uses do not contribute to
3693 unreasonable risk of DIDP.

3694
3695 The overall confidence in the exposure doses used to estimate risk ranges from moderate to robust. EPA
3696 has robust confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and
3697 chronic duration exposures to DIDP. EPA has moderate to robust confidence in the assessed inhalation,
3698 ingestion, and dermal consumer exposure scenarios (see Table 4-17 of this draft risk evaluation). More
3699 information on EPA’s confidence in these risk estimates and the uncertainties associated with them can
3700 be found in this draft risk evaluation, *Draft Consumer and Indoor Dust Exposure Assessment for*
3701 *Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024a](#)), and *Draft Human Health Hazard Assessment for*
3702 *Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024h](#)).

3703 6.1.6 Unreasonable Risk to the General Population

3704 Based on the risk estimates calculated using releases from manufacturing, processing, and industrial
3705 uses of DIDP, and related risk factors, EPA is preliminarily determining that non-cancer risk effects do
3706 not contribute to the unreasonable risk of DIDP to the general population.

3707 Due to DIDP's low water solubility and low persistence under most conditions, DIDP is unlikely to
3708 migrate from land applied biosolids to groundwater via runoff and is unlikely to be present in landfill
3709 leachate or be mobile in soils. For these reasons, biosolids and landfill were evaluated qualitatively. As
3710 such, EPA does not expect general population exposure to DIDP to occur via the land pathway and
3711 therefore, does not expect there to be risk to the general population from the land pathway. For further
3712 information, see Section 4.1.3.1 of this draft risk evaluation.

3713
3714 EPA used the highest possible DIDP concentration in surface water due to facility release to
3715 quantitatively evaluate the risk to the general population from exposure to DIDP from drinking water or
3716 incidental ingestion and dermal contact during recreational swimming. It was concluded that risk for
3717 non-cancer health effects is not expected for the surface water pathway for the general population.
3718 Risk estimates for fish ingestion generated at concentrations of DIDP at the water solubility limit or at
3719 highest measured concentrations in surface water did not indicate risk to tribal populations. As tribal
3720 populations are considered to represent the sentinel exposure scenario, it can be extrapolated that, based
3721 on these results, fish ingestion is also not a pathway of concern for subsistence fishers and the general
3722 population.

3723
3724 EPA also considered concentrations of DIDP in ambient air and deposition of DIDP from air. Inhalation
3725 exposure was not assessed because it is not expected to be a major pathway of exposure to DIDP for the
3726 general population. EPA used the occupational exposure scenario that provided the highest modeled
3727 95th percentile annual ambient air and air deposition concentrations for DIDP to calculate exposure due
3728 to ingestion or contact with DIDP in soil from air to soil deposition. Risks were not indicated for non-
3729 cancer health effects to the general population using these highly conservative estimates, which led to
3730 the preliminary conclusion that the ambient air pathway is not considered to be a major pathway of
3731 exposure to DIDP for the general population.

3732
3733 EPA has robust confidence in its qualitative assessment of biosolids and landfills. EPA had slight
3734 confidence in the surface water exposure scenarios that were used to estimate incidental ingestion and
3735 dermal contact, since the estimated environmental releases were overly conservative. EPA had moderate
3736 confidence in the exposure scenarios used for fish ingestion and slight confidence in the exposure
3737 scenarios used for the estimate of the ingestion and dermal contact with soil from air to soil deposition.
3738 The moderate or slight confidence is based on the scenarios not presenting realistic scenarios of DIDP
3739 exposure, but the exposure estimate capture high-end estimates. It is important to note that these
3740 confidence conclusions refer to the confidence in the data quality and numerical accuracy of the
3741 underlying data and the resulting model estimates. A confidence evaluation of "moderate" or "slight"
3742 confidence in an individual data source or model estimate does not mean that the resulting risk
3743 characterization is inaccurate. Further, EPA's overall confidence that the exposure estimates capture
3744 high-end exposure scenarios is robust, and further refinement of the models is not warranted because
3745 risks were not indicated for the pathways with the highest potential for exposure. More information on
3746 EPA's confidence in these risk estimates and the uncertainties associated with them can be found in this
3747 risk evaluation (Section 4.1.3.2) and the *Draft Environmental Media and General Population Exposure*
3748 *for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)).

3749 **6.2 Unreasonable Risk to the Environment**

3750 Risk of injury to the environment does not contribute to EPA's preliminary determination of
3751 unreasonable risk from DIDP. Calculated RQs can provide a risk profile by presenting a range of
3752 estimates for different environmental hazard effects for different COUs. Although quantitative release
3753 estimates were determined for some pathways, As described in Section 6.2.1 , RQs were not determined
3754 because a qualitative environmental toxicity risk characterization was undertaken for DIDP. The

3755 qualitative approach involved using the COUs associated with the highest environmental releases and
3756 comparing the estimates to the hazard values. Because of DIDP's low water solubility, the Agency did
3757 not identify hazard effects for aquatic organisms. Additionally, even using the highest environmental
3758 release estimates, the Agency did not find environmental risk.

3759 **6.2.1 Populations and Exposures EPA Assessed to Determine Unreasonable Risk to the** 3760 **Environment**

3761 EPA quantitatively determined DIDP concentrations in surface water, sediment, and soil. However, EPA
3762 did not quantitatively evaluate exposures to aquatic organisms and terrestrial species. The use of a
3763 qualitative analysis of exposure for DIDP was chosen due to the fact that (1) DIDP does not persist in
3764 environmental media, (2) hazard thresholds were not identified for some receptors, and (3) DIDP
3765 environmental exposures were consistently below the concentrations tested within hazard studies
3766 indicating a lack of environmental toxicity for this compound.

3767
3768 The Agency expects the main environmental exposure pathway for aquatic organisms to be releases to
3769 surface water and subsequent deposition to sediment. Releases to ambient air and subsequent deposition
3770 to water and sediment also have a limited contribution to environmental exposure for aquatic organisms.
3771 As detailed within Section 5.3.2, monitoring data from published literature report DIDP concentrations
3772 within surface water and sediment lower than the highest NOEC values presented among several hazard
3773 studies for aquatic invertebrates and vertebrates in the water column, benthic invertebrates in the
3774 sediment, and aquatic plants and algae.

3775
3776 EPA expects that DIDP has a low bioconcentration and biomagnification potential across trophic levels.
3777 DIDP exposure to terrestrial organisms occurs primarily through diet via the sediment pathway for semi-
3778 aquatic terrestrial mammals followed by the soil pathway for soil invertebrates and terrestrial mammals,
3779 with releases to surface water representing a major exposure pathway. Direct exposure of DIDP to
3780 terrestrial receptors via air was not assessed quantitatively because dietary exposure was determined to
3781 be the driver of exposure to wildlife, however, air deposition of DIDP to soil, sediment, and surface
3782 water were modeled to represent COU-based releases to air.

3783
3784 In general, EPA has an overall moderate confidence in environmental releases for acute and chronic
3785 aquatic assessment, chronic benthic assessment, algal assessment, chronic mammalian assessment, and
3786 terrestrial invertebrates. Although the conservative nature of model outputs resulted in slight confidence
3787 for the environmental media concentrations in surface water, sediment, and soil, there is robust
3788 confidence that the modeled environmental media concentrations do not underestimate exposure to
3789 ecological receptors and the risk characterization is protective of the environment, as noted in Table 5-3
3790 of this draft risk evaluation. EPA has also determined an indeterminate confidence in chronic avian and
3791 terrestrial plant assessments as there is a lack of reasonably available hazard data. EPA determined that
3792 DIDP is expected to have a low potential for bioaccumulation and biomagnification in aquatic
3793 organisms.

3794 **6.2.2 Summary of Unreasonable Risks to the Environment**

3795 EPA qualitatively assessed risk via release to surface water and subsequent deposition to sediment; as
3796 well as the ambient air exposure pathway for its limited contribution via deposition to soil, water, and
3797 sediment; and is preliminarily identifying

- 3798 • No acute or chronic toxicity risk to fish and aquatic invertebrates up to and exceeding the limit of
3799 water solubility, and
- 3800 • No acute or chronic toxicity risk to sediment-dwelling organisms.

3801 Terrestrial hazard data for DIDP were not available for birds or mammalian species, so studies in
3802 laboratory rodents were used to derive hazard values for mammalian species. However, due to the lack
3803 of bioaccumulation/biomagnification, and hazard value for an aquatic dependent mammal, qualitative
3804 analysis indicates that reaching a daily rate of 128 mg/kg-day is highly unlikely and was not reached
3805 even with conservative quantitative modeling and trophic transfer assumptions. EPA therefore did not
3806 preliminarily identify any acute or chronic toxicity risk with mammalian species either.

3807 **6.2.3 Basis for Unreasonable Risk of Injury to the Environment**

3808 Based on the draft risk evaluation for DIDP—including the risk estimates, the environmental effects of
3809 DIDP, the exposures, physical-chemical properties of DIDP, and consideration of uncertainties—EPA
3810 did not identify risk of injury to the environment that would contribute to the unreasonable risk
3811 determination for DIDP. For aquatic organisms, surface water and subsequent deposition to sediment
3812 were determined to be the drivers of exposure, but EPA does not expect this pathway to contribute to
3813 unreasonable risk to the environment. EPA does not expect exposure to DIDP via water, land, or dietary
3814 pathways to contribute to unreasonable risk to the environment. The Agency’s overall environmental
3815 risk characterization confidence levels were varied and are summarized in the *Draft Environmental*
3816 *Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024d](#)).

3817 **6.3 Additional Information Regarding the Basis for the Unreasonable Risk**

3818 Table 6-1 summarizes the basis for this draft unreasonable risk determination of injury to human health
3819 and the environment presented in this draft risk evaluation. In these tables, a checkmark (✓) indicates
3820 how the COU contributes to the unreasonable risk by identifying the type of effect (*e.g.*, non-cancer for
3821 human health) and the exposure route to the population or receptor that results in such contribution. As
3822 explained in Section 6, for this draft unreasonable risk determination, EPA considered the effects of
3823 DIDP to human health at the central tendency and high-end, as well as effects of DIDP to human health
3824 from the exposures associated from the condition of use, risk estimates, and uncertainties in the analysis.
3825 As explained in Section 6.1.3, checkmarks in Table 6-1 represent risk at the high-end exposure level for
3826 one occupational COU. See *Draft Human Health Risk Assessment for Diisodecyl phthalate (DIDP)* for a
3827 summary of risk estimates. In addition, certain exposure routes for some COUs were not assessed
3828 because it was determined that there was no viable exposure pathway. These COUs and their respective
3829 exposure routes are grayed-out in Table 6-1.

3830 **6.3.1 Additional Information about COUs Characterized Qualitatively**

3831 Two consumer COUs, Packaging, paper, and plastic, hobby products – ink, toner and colorant products
3832 and Packaging, paper, and plastic, hobby products – arts, crafts, and hobby materials (crafting paint
3833 applied to craft) were evaluated qualitatively, since current products were not identified. Foreseeable
3834 uses for these two consumer COUs are likely similar to the consumer COUs evaluated quantitatively,
3835 construction, paint, electrical, and metal products - paints and coatings and construction, paint,
3836 electrical, and metal products – adhesives and sealants (including plasticizers in adhesives and sealants),
3837 which had MOEs that did not indicate risk. Therefore, EPA is determining Ink, toner and colorant
3838 products and arts, crafts, and hobby materials (crafting paint applied to craft) do not contribute to the
3839 unreasonable risk of DIDP.

3840
3841 For the purposes of the unreasonable risk determination, distribution in commerce of DIDP consists of
3842 the transportation associated with the moving of DIDP and DIDP containing products in commerce.
3843 EPA evaluated the distribution in commerce COU qualitatively and did not calculate risk estimates for
3844 the distribution in commerce COU. EPA evaluated activities resulting in exposures associated with
3845 loading and unloading of the chemical throughout the various life cycle stages and conditions of use
3846 (*e.g.*, manufacturing, processing, industrial use, commercial use, and disposal). Most of the

3847 environmental releases (and subsequent general population and environmental receptor exposures) from
3848 the DIDP COUs are expected to be captured in the COUs evaluated qualitatively, including the releases
3849 to the environment from loading and unloading of DIDP and DIDP containing products. EPA expects
3850 that environmental releases from distribution in commerce will be similar or less than the exposure
3851 estimates from the COUs evaluated qualitatively, which did not exceed hazard to ecological receptors;
3852 therefore, EPA expects that distribution in commerce also would not result in exposures that contribute
3853 to the unreasonable risk of DIDP. Therefore, EPA is preliminarily determining that distribution in
3854 commerce does not contribute to the unreasonable risk of DIDP to the risk of injury to the environment.
3855 Similarly, EPA does not expect distribution in commerce to contribute to DIDP's unreasonable risk to
3856 human health because distribution in commerce does not generate dust or mist, and DIDP's low vapor
3857 pressure results in inhalation exposures that are quite low for workers. EPA expects that general
3858 population inhalation exposures from distribution in commerce would be even lower than those for
3859 workers. Therefore, EPA is preliminarily determining that distribution in commerce does not contribute
3860 to the unreasonable risk of DIDP due to the injury to health.

3861

Table 6-1. Supporting Basis for the Draft Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)

Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Manufacturing	Domestic Manufacturing	Domestic manufacturing	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
	Inhalation						
	ONU	Dermal					
		Inhalation					
Manufacturing	Importing	Importing	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
	Inhalation						
	ONU	Dermal					
		Inhalation					
Processing	Incorporation into formulation, mixture, or reaction product	Adhesives and sealants manufacturing	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
		Inhalation					
		ONU	Dermal				
			Inhalation				
		Laboratory chemicals manufacturing	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
	Inhalation						
	ONU	Dermal					
		Inhalation					
	Petroleum lubricating oil manufacturing; Lubricants and lubricant additives manufacturing	Worker: Average Adult Worker	Dermal				
			Inhalation				
			Worker: Female of Reproductive Age	Dermal			
Inhalation							
ONU		Dermal					
		Inhalation					
			Dermal				

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^d	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Processing	Incorporation into formulation, mixture, or reaction product	Surface modifier in paint and coating manufacturing	Worker: Average Adult Worker	Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal			
				Inhalation			
			Plastic material and resin manufacturing	Worker: Average Adult Worker	Dermal		
		Inhalation					
		Worker: Female of Reproductive Age		Dermal			
				Inhalation			
		ONU		Dermal ^d			
				Inhalation			
		Plasticizers (paint and coating manufacturing; colorant (including pigments); rubber manufacturing)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^d			
				Inhalation			
		Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal			
				Inhalation			
		Other (part of the formulation for manufacturing synthetic leather)	Worker: Average Adult Worker	Dermal			
Inhalation							
Worker: Female of Reproductive Age	Dermal						
	Inhalation						
ONU	Dermal ^d						
	Inhalation						
Incorporation into articles	Abrasives manufacturing	Worker: Average Adult Worker	Dermal				
			Inhalation				

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^d	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Processing			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^e			
				Inhalation			
		Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive products manufacturing, other than fluids; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; transportation equipment manufacturing; ink, toner, and colorant [including pigment] products manufacturing; photographic supplies manufacturing; sporting equipment manufacturing)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
	ONU	Dermal ^d					
		Inhalation					
	Repackaging	Repackaging	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
			Inhalation				
ONU		Dermal					
		Inhalation					
Recycling	Recycling	Worker: Average Adult Worker	Dermal				
			Inhalation				
		Worker: Female of Reproductive Age	Dermal				
		Inhalation					
	ONU	Dermal ^d					
		Inhalation					
Distribution in Commerce	Distribution in Commerce	Distribution in commerce	Worker	Dermal			
				Inhalation			

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
			ONU	Inhalation			
			General Population	Inhalation – Ambient Air			
Industrial Use	Abrasives	Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^d			
				Inhalation			
	Adhesive and sealants	Adhesive and sealants	Worker: Average Adult Worker	Dermal			
				Inhalation	✓	✓	✓
			Worker: Female of Reproductive Age	Dermal			
				Inhalation	✓	✓	✓
			ONU	Dermal ^e			
				Inhalation			
	Functional fluids (closed systems)	Functional fluids (closed systems) (SCBA compressor oil)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
ONU			Dermal				
			Inhalation				
Lubricant and lubricant additives	Lubricants and lubricant additives	Worker: Average Adult Worker	Dermal				
			Inhalation				
		Worker: Female of Reproductive Age	Dermal				
			Inhalation				
		ONU	Dermal				
			Inhalation				
Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	Worker: Average Adult Worker	Dermal				
			Inhalation				
		Worker: Female of Reproductive Age	Dermal				
			Inhalation				

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^d	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
			ONU	Dermal			
				Inhalation			
Commercial Use	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^d			
				Inhalation			
		Lubricants	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal			
				Inhalation			
	Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^e			
				Inhalation			
		Building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^d			
				Inhalation			
Electrical and electronic products	Worker: Average Adult Worker	Dermal					
		Inhalation					
	Worker: Female of Reproductive Age	Dermal					
		Inhalation					

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^d	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Commercial Use			ONU	Dermal ^d			
				Inhalation			
		Paints and coatings (including surfactants in paints and coatings)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^e			
				Inhalation			
		Lacquers, stains, varnishes, and floor finishes (as plasticizer)	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
	ONU		Dermal ^e				
			Inhalation				
	Furnishing, cleaning, treatment/care products	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer) (Floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats))	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
			ONU	Dermal ^d			
				Inhalation			
		Furniture and furnishings	Worker: Average Adult Worker	Dermal			
				Inhalation			
			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
ONU			Dermal				
			Inhalation				
Ink, toner, and colorant products	Worker: Average Adult Worker	Dermal					
		Inhalation					
	Worker: Female of Reproductive Age	Dermal					
		Inhalation					
	ONU	Dermal ^e					

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^d	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Commercial Use	Furnishing, cleaning, treatment/care products	PVC film and sheet	Worker: Average Adult Worker	Inhalation			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
			ONU	Inhalation			
				Dermal ^d			
		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Worker: Average Adult Worker	Inhalation			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
			ONU	Inhalation			
				Dermal ^d			
	Other uses	Laboratory chemicals	Worker: Average Adult Worker	Inhalation			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
			ONU	Inhalation			
				Dermal ^d			
		Inspection fluid/penetrant	Worker: Average Adult Worker	Inhalation			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
			ONU	Inhalation			
				Dermal ^e			
Disposal	Disposal	Worker: Average Adult Worker	Inhalation				
			Dermal				
			Dermal				
		Worker: Female of Reproductive Age	Inhalation				
			Dermal				
			Dermal ^d				
ONU	Inhalation						
	Dermal						

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Life Cycle Stage	Category	Subcategory	Population	Exposure Route ^a	Human Health Effects ^b		
					Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
<p>^a Inhalation, dermal, and aggregate risk estimates were generated for each condition of use for workers (average adult and female of reproductive age) and ONUs if it was determined that there was a viable exposure pathway.</p> <p>^b Grayed-out boxes indicate certain exposure routes that were not assessed because it was determined that there was no viable exposure pathway.</p> <p>^c Use of laboratory chemicals was assessed for liquids and solids containing DIDP. Dermal exposure to ONUs was assessed only for solids containing DIDP. No unreasonable risk was found for each occupational exposure scenario.</p> <p>^d Dermal exposure to ONUs from contact with dust on surfaces was assessed.</p> <p>^e Dermal exposure to ONUs from contact with mist on the surfaces was assessed.</p>							

3862

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4380 File: Data Quality Evaluation and Data Extraction Information for Physical and Chemical
4381 Properties. Washington, DC: Office of Pollution Prevention and Toxics.
- 4382 [U.S. EPA](#). (2024r). Draft Risk Evaluation for Diisodecyl Phthalate – Systematic Review Supplemental
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4387 Exposure. Washington, DC: Office of Pollution Prevention and Toxics.
- 4388 [U.S. EPA](#). (2024t). Draft Risk Evaluation for Diisodecyl Phthalate – Systematic Review Supplemental
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4397 File: Consumer Risk Calculator. Washington, DC: Office of Pollution Prevention and Toxics.
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4413

4414 **APPENDICES**4415
4416 **Appendix A ABBREVIATIONS AND ACRONYMS**

4417	ADD	Average daily dose
4418	ADC	Average daily concentration
4419	AERMOD	American Meteorological Society/EPA Regulatory Model
4420	BLS	Bureau of Labor Statistics
4421	CASRN	Chemical Abstracts Service Registry Number
4422	CBI	Confidential business information
4423	CDR	Chemical Data Reporting
4424	CEHD	Chemical Exposure Health Data
4425	CEM	Consumer Exposure Model
4426	CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
4427	CFR	Code of Federal Regulations
4428	CPSC	Consumer Product Safety Commission
4429	CWA	Clean Water Act
4430	DEHP	Diethylhexyl phthalate
4431	DIDP	Diisodecyl phthalate
4432	DINP	Diisononyl phthalate
4433	DIY	Do-it-yourself
4434	DMR	Discharge Monitoring Report
4435	EPA	Environmental Protection Agency
4436	EPCRA	Emergency Planning and Community Right-to-Know Act
4437	ESD	Emission Scenario Document
4438	EU	European Union
4439	FDA	Food and Drug Administration
4440	FFDCA	Federal Food, Drug, and Cosmetic Act
4441	GS	Generic Scenario
4442	K _{oc}	Soil organic carbon: water partitioning coefficient
4443	K _{ow}	Octanol: water partition coefficient
4444	HEC	Human equivalent concentration
4445	HED	Human equivalent dose
4446	IADD	Intermediate average daily dose
4447	IR	Ingestion rate
4448	LCD	Life cycle diagram
4449	LOD	Limit of detection
4450	LOEC	Lowest-observed-effect concentration
4451	Log K _{oc}	Logarithmic organic carbon: water partition coefficient
4452	Log K _{ow}	Logarithmic octanol: water partition coefficient
4453	MOE	Margin of exposure
4454	NAICS	North American Industry Classification System
4455	NHANES	National Health and Nutrition Examination Survey
4456	NICNAS	National Industrial Chemicals Notification and Assessment Scheme
4457	NOAEL	No-observed-adverse-effect level
4458	NOEC	No-observed-effect-concentration
4459	NPDES	National Pollutant Discharge Elimination System
4460	NTP	National Toxicology Program
4461	OCSPP	Office of Chemical Safety and Pollution Prevention

4462	OECD	Organisation for Economic Co-operation and Development
4463	OEL	Occupational exposure limit
4464	OES	Occupational exposure scenario
4465	ONU	Occupational non-user
4466	OPPT	Office of Pollution Prevention and Toxics
4467	OSHA	Occupational Safety and Health Administration
4468	PBZ	Personal breathing zone
4469	PECO	Population, exposure, comparator, and outcome
4470	PEL	Permissible exposure limit (OSHA)
4471	PESS	Potentially exposed or susceptible subpopulations
4472	PND	Postnatal Day
4473	POD	Point of departure
4474	POTW	Publicly owned treatment works
4475	PVC	Polyvinyl chloride
4476	REL	Recommended Exposure Limit
4477	SACC	Science Advisory Committee on Chemicals
4478	SDS	Safety data sheet
4479	SOC	Standard Occupational Classification
4480	SUSB	Statistics of U.S. Businesses (U.S. Census)
4481	TRV	Toxicity reference value
4482	TSCA	Toxic Substances Control Act
4483	TWA	Time-weighted average
4484	UF	Uncertainty factor
4485	U.S.	United States
4486	WWTP	Wastewater treatment plant

4487 **Appendix B REGULATORY AND ASSESSMENT HISTORY**

4488 **B.1 Federal Laws and Regulations**

4489 **Table_Apx B-1. Federal Laws and Regulations**
4490

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA statutes/regulations		
Toxic Substances Control Act (TSCA) – section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	DIDP manufacturing (including importing), processing and use information is reported under the CDR rule (76 85 FR 5081620122 , April 9, 2020).
Toxic Substances Control Act (TSCA) – section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed for commercial purposes in the United States.	1,2-Benzenedicarboxylic acid, 1,2-diisodecyl ester (CASRN 26761-40-0) and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CASRN 68515-49-1) were on the initial TSCA Inventory and therefore were not subject to EPA’s new chemicals review process under TSCA section 5 (60 FR 16309 , March 29, 1995).
Toxic Substances Control Act (TSCA) – section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Two substantial risk reports were received for CASRN 26761-40-0 and six substantial risk reports were received for CASRN 68515-49-1 (1993-2009) (U.S. EPA, ChemView. Accessed February 28, 2024).
Toxic Substances Control Act (TSCA) – section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	One chemical data submission from test rules was received for CASRN 26761-40-0 for sorption to soil and sediments, and 17 chemical data submissions from test rules were received for CASRN 68515-49-1 (1983-1986) (U.S. EPA, ChemView. Accessed February 28, 2024).
Federal Food, Drug, and Cosmetic Act (FFDCA) – section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to establish tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for pesticide residues (including inert ingredients) on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is “safe.” Section 408(b) of the FFDCA defines “safe” to mean a reasonable certainty that no harm will result from aggregate exposures (which includes dietary exposures from food and drinking water as well as nonoccupational exposures) to the pesticide. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation under FFDCA section 408(d) or (e). In the absence of a tolerance or an exemption from tolerance, or where pesticide	CASRN 26761-40-0 is approved for non-food use (InertFinder, Accessed March 4, 2024).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	residues in food exceed an existing tolerance limit, a food containing that pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
Clean Water Act (CWA) – sections 301, 304, 306, 307, and 402	Clean Water Act Section 307(a) established a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR 401.15. The “priority pollutants” specified by those families are listed in 40 CFR part 423 Appendix A. These are pollutants (along with non- conventional 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 National Pollution Discharge Elimination System (NPDES) permits, see Section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	As a phthalate ester, DIDP 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). Note – even if not specified as a toxic pollutant, unless it is a conventional pollutant – it is also subject to effluent limitations based on Best Available Technology Economically Achievable (BAT). All pollutants except conventional pollutants are subject to BAT.
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances, in addition to those referred to in section 101(14) of CERCLA, those elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold. CERCLA Hazardous substances listed under 40 CFR Table 302.4 are subject to EPCRA Section 304 notification requirements.	As a phthalate ester, DIDP is designated as a hazardous substance under CERCLA. No reportable quantity is assigned to the generic or broad class (40 CFR 302.4).
Other federal statutes/regulations		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the 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).	CASRN 26761-40-0 is listed as an Indirect Additives used in Food Contact Substances (21 CFR 175.105; 21 CFR 175.300; 21 CFR 177.1210; 21 CFR 177.2600; 21 CFR 177.3910).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Consumer Product Safety Improvement Act of 2008 (CPSIA)	Under section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC prohibits the manufacture for sale, offer for sale, distribution in commerce or importation of eight phthalates in toys and childcare articles at concentrations > 0.1%: DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP and DCHP.	The interim prohibition on the use of DIDP in childrens toys (15 U.S.C 2057©, August 14, 2008) was lifted in the final rule (16 CFR part 1307 , October 27, 2017).

B.2 State Laws and Regulations

Table_Apx B-2. State Laws and Regulations

State Actions	Description of Action
State Right-to-Know Acts	Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323) includes phthalate esters on the hazardous substance list as an environmental hazard.
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing DIDP, including Maine (chemicals of concern) (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776), and Washington State (Wash. Admin. Code 173-334-130).
Other	<p>California listed CASRN "68515-49-1/26761-40-0" on Proposition 65 in 2007 due to developmental toxicity. (Cal Code Regs. Title 27, § 27001).</p> <p>CASRN 26761-40-0 is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253).</p> <p>California issued a Health Hazard Alert for DIDP (Hazard Evaluation System and Information Service, 2016).</p> <p>California lists DIDP as a designated priority chemical for biomonitoring (California SB 1379).</p>

B.3 International Laws and Regulations

Table_Apx B-3. International Laws and Regulations

Country/ Organization	Requirements and Restrictions
Canada	CASRN 26761-40-0 and 68515-49-1 are on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed March 6, 2024).
European Union	<p>CASRN 26761-40-0 (EC/List no.: 247-977-1) and CASRN 68515-49-1 (EC/List no.: 271-091-4) are registered for use in the EU. (European Chemicals Agency [ECHA] database. Accessed February 28, 2024).</p> <p>DIDP was added to the EC Inventory on the 2nd priority list, and a risk assessment was conducted under the Existing Substances Regulation (ESR) in 2003 that found there was no need for further information and/or testing and for risk reduction measures beyond those which are already applied. (ECHA database. Accessed February 28, 2024). https://echa.europa.eu/documents/10162/b66cca3a-5303-455b-8355-63bf741e263b</p> <p>DIDP was added to the Annex III of REACH (Conditions of restriction) The list supports registrants in identifying whether reduced minimum information requirements or a full Annex VII information set is required. (ECHA database, accessed February 28, 2024).</p> <p>In 2006, a restriction of sale and use of toys and childcare articles which can be placed in the mouth by children containing 0.1% or more CASRN 26761-40-0 and CASRN 68515-49-1</p>

Country/ Organization	Requirements and Restrictions
	was added to Annex XVII of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). (European Chemicals Agency [ECHA] database, accessed February 28, 2024).
Australia	CASRNs 26761-40-0 and 68515-49-1 were assessed under Human Health Tier I of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). (NICNAS, 1,2-Benzenedicarboxylic acid, diisodecyl ester: Human health tier I assessment. Accessed February 28, 2024) CASRNs 26761-40-0 and 68515-49-1 are listed on the Chemical Inventory and subject to secondary notifications when importing or manufacturing the chemical in Australia. (NICNAS database. Accessed February 28, 2024)
Japan	CASRNs 26761-40-0 and 68515-49-1 are regulated in Japan under the following legislation: <ul style="list-style-type: none"> • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Food Sanitation Act • Fire Service Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed February 28, 2024).
Countries with occupational exposure limits	Occupational exposure limit for CASRN 26761-40-0 is: <ul style="list-style-type: none"> • Austria: 3 mg/m³ (8-hour) and 5 mg/m³ (short-term); • Ontario, Canada: 5 mg/m³ (8-hour); • Denmark: 3 mg/m³ (8-hour) and 6 mg/m³ (short-term); • Ireland: 5 mg/m³ (8-hour); • New Zealand: 5 mg/m³ (8-hour); • South Africa Mining: 5 mg/m³ (8-hour); • Sweden: 3 mg/m³ (8-hour) and 5 mg/m³ (short-term); and • United Kingdom: 5 mg/m³ (8-hour). (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed February, 28, 2024).

B.4 Assessment History

Table_Apx B-4. Assessment History of DIDP

Authoring Organization	Publication
EPA publications	
None	–
Other U.S.-based organizations	
U.S. Consumer Product Safety Commission (U.S. CPSC)	Chronic Hazard Panel on Phthalates and Phthalate Alternatives Final Report (With Appendices) (2014) Toxicity Review of DIDP (2010)
National Toxicology Program (NTP), Center for the Evaluation of Risks to Human Reproduction (CERHR), National Institute of Health (NIH)	NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-Isodecyl Phthalate (DIDP) (2003)
Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency	Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di-isodecyl Phthalate (DIDP) (2010)
International	

4497
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Authoring Organization	Publication
European Union, European Chemicals Agency (ECHA)	<p>Evaluation of New Scientific Evidence Concerning DINP and DIDP (2013)</p> <p>European Union Risk Assessment Report: CAS Nos: 68515-49-1 & 26761-40-0: 1,2-benzenedicarboxylic acid, di-C9-11- branched alkyl esters, C10-rich and di-“isodecyl” phthalate (DIDP) (2003)</p>
European Food Safety Authority (EFSA)	<p>Update of the Risk Assessment of Di-butylphthalate (DBP), Butyl-benzyl-phthalate (BBP), Bis(2-ethylhexyl)phthalate (DEHP), Di-isononylphthalate (DINP) and Diisodecylphthalate (DIDP) for Use in Food Contact Materials (2019)</p> <p>Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a Request from the Commission Related to Di-isodecylphthalate (DIDP) for Use in Food Contact Materials (2005)</p>
Government of Canada, Environment Canada, Health Canada	<p>Screening Assessment: Phthalate Substance Grouping (2020)</p> <p>State of the science report: Phthalates Substance Grouping: Long-chain Phthalate Esters. 1,2-Benzenedicarboxylic Acid, Diisodecyl Ester (Diisodecyl Phthalate; DIDP) and 1,2-Benzenedicarboxylic Acid, Diundecyl Ester (Diundecyl Phthalate; DUP). Chemical Abstracts Service Registry Numbers: 26761-40-0, 68515-49-1; 3648-20-2 (2015)</p>
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	<p>Priority Existing Chemical Assessment Report: Diisodecyl Phthalate & Di-n-octyl Phthalate (2015)</p> <p>Existing Chemical Hazard Assessment Report: Diisodecyl Phthalate (2008)</p>

4500

Appendix C LIST OF TECHNICAL SUPPORT DOCUMENTS

Appendix C includes a list and citations for all supplemental documents included in the Draft Risk Evaluation for DIDP.

Associated Systematic Review Protocol and Data Quality Evaluation and Data Extraction

Documents – Provide additional detail and information on systematic review methodologies used as well as the data quality evaluations and extractions criteria and results.

Draft Systematic Review Protocol for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024k](#)) – In lieu 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, 2021a](#)), this systematic review protocol for the Draft Risk Evaluation for DIDP describes some clarifications and different approaches that were implemented than those described in the 2021 Draft 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 “DIDP Systematic Review Protocol.”

Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024q](#)) – Provides a compilation of tables for the data extraction and data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was extracted and evaluated from a data source that has information relevant for the evaluation of physical and chemical properties. This supplemental file may also be referred to as the “DIDP Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties.”

Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024o](#)) – Provides a compilation of tables for the data extraction and data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was extracted and evaluated from a data source that has information relevant for the evaluation for Environmental Fate and Transport. This supplemental file may also be referred to as the “DIDP Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport.”

Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024p](#)) – Provides a compilation of tables for the data extraction and data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was extracted and evaluated from a data source that has information relevant for the evaluation of environmental release and occupational exposure. This supplemental file may also be referred to as the “DIDP Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure.”

Data Quality Evaluation and Data Extraction Information for Dermal Absorption for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024n](#)) – Provides a compilation of tables for the data extraction and data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was extracted and evaluated from a data source that has information relevant for the evaluation for Dermal Absorption. This supplemental file may also be referred to as the “DIDP Data Quality Evaluation and Data Extraction Information for Dermal Absorption.”

4549 *Data Extraction Information for General Population, Consumer, and Environmental Exposure for*
4550 *Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024s](#))* – Provides a compilation of tables for the data
4551 quality evaluation information for DIDP. Each table shows the data point, set, or information
4552 element that was evaluated from a data source that has information relevant for the evaluation of
4553 general population, consumer, and environmental exposure. This supplemental file may also be
4554 referred to as the “DIDP Data Quality Evaluation Information for General Population, Consumer,
4555 and Environmental Exposure.”

4556
4557 *Data Quality Evaluation Information for General Population, Consumer, and Environmental*
4558 *Exposure for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024m](#))* – Provides a compilation of tables
4559 for the data extraction for DIDP. Each table shows the data point, set, or information element that
4560 was extracted from a data source that has information relevant for the evaluation of general
4561 population, consumer, and environmental exposure. This supplemental file may also be referred to as
4562 the “DIDP Data Extraction Information for General Population, Consumer, and Environmental
4563 Exposure.”

4564
4565 *Data Quality Evaluation Information for Human Health Hazard Epidemiology for Diisodecyl*
4566 *Phthalate (DIDP) ([U.S. EPA, 2024u](#))* – Provides a compilation of tables for the data quality
4567 evaluation information for DIDP. Each table shows the data point, set, or information element that
4568 was evaluated from a data source that has information relevant for the evaluation of epidemiological
4569 information. This supplemental file may also be referred to as the “DIDP Data Quality Evaluation
4570 Information for Human Health Hazard Epidemiology.”

4571
4572 *Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for Diisodecyl*
4573 *Phthalate (DIDP) ([U.S. EPA, 2024t](#))* – Provides a compilation of tables for the data quality
4574 evaluation information for DIDP. Each table shows the data point, set, or information element that
4575 was evaluated from a data source that has information relevant for the evaluation of human health
4576 hazard animal toxicity information. This supplemental file may also be referred to as the “DIDP
4577 Data Quality Evaluation Information for Human Health Hazard Animal Toxicology.”

4578
4579 *Data Quality Evaluation Information for Environmental Hazard for Diisodecyl Phthalate (DIDP)*
4580 *([U.S. EPA, 2024r](#))* – Provides a compilation of tables for the data quality evaluation information for
4581 DIDP. Each table shows the data point, set, or information element that was evaluated from a data
4582 source that has information relevant for the evaluation of environmental hazard toxicity information.
4583 This supplemental file may also be referred to as the “DIDP Data Quality Evaluation Information for
4584 Environmental Hazard.”

4585
4586 *Data Extraction Information for Environmental Hazard and Human Health Hazard Animal*
4587 *Toxicology and Epidemiology for Diisodecyl Phthalate (DIDP) ([U.S. EPA, 2024l](#))* – Provides a
4588 compilation of tables for the data extraction for DIDP. Each table shows the data point, set, or
4589 information element that was extracted from a data source that has information relevant for the
4590 evaluation of environmental hazard and human health hazard animal toxicology and epidemiology
4591 information. This supplemental file may also be referred to as the “DIDP Data Extraction
4592 Information for Environmental Hazard and Human Health Hazard Animal Toxicology and
4593 Epidemiology.”

4594
4595 Associated **Technical Support and Supplemental Information Documents** – Provide additional
4596 details and information on exposure, hazard, and risk assessments.

4598 *Draft Physical Chemistry Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024i](#)).

4599
4600 *Draft Fate Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024f](#)).

4601
4602 *Draft Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate*
4603 *(DIDP)* ([U.S. EPA, 2024e](#)).

4604
4605 *Draft Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)*
4606 *(U.S. EPA, 2024d)*.

4607
4608 *Draft Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA,](#)
4609 [2024a](#)).

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4611 *Draft Environmental Exposure Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024b](#)).

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4613 *Draft Environmental Hazard Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024c](#)).

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4615 *Draft Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024h](#)).

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4617 *Draft Consumer Exposure Analysis for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024v](#)).

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4619 *Draft Consumer Risk Calculator for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024w](#)).

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4621 *Draft Risk Calculator for Occupational Exposures for Diisodecyl Phthalate (DIDP)* ([U.S. EPA,](#)
4622 [2024x](#)).

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4624 *Draft Fish Ingestion Risk Calculator for Diisodecyl Phthalate (DIDP)* ([U.S. EPA, 2024g](#)).

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4626 *Draft Surface Water Human Exposure Risk Calculator for Diisodecyl Phthalate (DIDP)* ([U.S. EPA,](#)
4627 [2024y](#)).

Appendix D UPDATES TO THE DIDP CONDITIONS OF USE TABLE

D.1 Additions and Name Changes to COUs Based on Updated 2020 CDR Reported Data and Stakeholder Engagement

After the final scope ([U.S. EPA, 2021b](#)), 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, EPA is amending the description of certain DIDP COUs based on those new submissions and new reporting name codes. Also, EPA received information from stakeholders about other uses of DIDP. 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.

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, Incorporation into formulation, mixture, or reaction product	N/A	Added “Surface modifier and plasticizer in paint and coating manufacturing”	Surface modifier in paint and coating manufacturing
Processing, Incorporation into formulation, mixture, or reaction product	N/A	Added “Other (part of the formulation for manufacturing synthetic leather)”	Other (part of the formulation for manufacturing synthetic leather)
Processing, Incorporation into articles	Plasticizers (<i>e.g.</i> , asphalt paving, roofing, and coating materials manufacturing; automotive care products manufacturing; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products not covered elsewhere manufacturing; floor coverings manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; miscellaneous manufacturing; ink, toner, and colorant products manufacturing; photographic supplies manufacturing; plastic material and resin manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; toys, playgrounds, and sporting equipment manufacturing)	Added “construction” Added “furniture and related product manufacturing”	Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; automotive care products manufacturing; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; transportation equipment manufacturing; ink, toner, and colorant products manufacturing; photographic supplies manufacturing; toys, playgrounds, and sporting equipment manufacturing)

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Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Commercial uses, Construction, paint, electrical, and metal products	Adhesives and sealants	Added “(including plasticizers in adhesives and sealants)”	Adhesives and sealants (including plasticizers in adhesives and sealants)
Commercial uses, Construction, paint, electrical, and metal products	Paints and coatings	Added “(including surfactants in paints and coatings)”	Paints and coatings (including surfactants in paints and coatings)
Commercial uses, Construction, paint, electrical, and metal products	N/A	Added “Lacquers, stains, varnishes, and floor finishes (as plasticizer)”	Lacquers, stains, varnishes, and floor finishes (as plasticizer)
Commercial uses, Furnishing, cleaning, treatment/care products	Floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats)	Name change based on new industry code Added, “(as plasticizer)”	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer); (Floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats))
Commercial uses, Furnishing, cleaning, treatment/care products	N/A	Added “PVC film and sheet”	PVC film and sheet
Consumer uses, Construction, paint, electrical, and metal products	Adhesives and sealants	Added “(including plasticizers in adhesives and sealants)”	Adhesives and sealants (including plasticizers in adhesives and sealants)
Consumer uses, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere (e.g., wire or wiring systems; joint treatment)	Name change based on new industry code	Building/construction materials covering large surface areas including stone, plaster, cement, glass and ceramic articles (wire or wiring systems; joint treatment)
Consumer uses, Furnishing, cleaning, treatment/care products	N/A	Added category and “Fabrics, textiles, and apparel (as plasticizer)”	Fabrics, textiles, and apparel (as plasticizer)
Consumer uses, Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Added “(crafting paint applied to craft)”	Arts, crafts, and hobby materials (crafting paint applied to craft)
Consumer uses, Packaging, paper, plastic, hobby products	N/A	Added “PVC film and sheet”	PVC film and sheet
Consumer uses, Other	N/A	Added category and “Novelty Products”	Novelty Products

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The changes based on CDR reporting, research, or stakeholder activity are:

- 4644 • *Processing, incorporation into formulation, mixture, or reaction product, “other (part of the*
4645 *formulation for manufacturing synthetic leather)”* was added because it was a new reporting
4646 sector in the 2020 CDR.
- 4647 • *Processing, incorporation into articles, “Plasticizers”* was updated to include the construction
4648 and furniture and related product manufacturing industrial sector based on 2020 CDR reporting.
- 4649 • *For Commercial and Consumer uses, construction, paint, electrical and metal products,*
4650 *“Adhesives and sealants (including plasticizers in adhesives and sealants)”*, the reference to
4651 plasticizers was added after feedback from a stakeholder notifying the EPA that DIDP can be
4652 used as a component in adhesives and sealants as a plasticizer.
- 4653 • *Commercial uses, Furnishing, cleaning, treatment/care products, “Construction and building*
4654 *materials covering large surface areas including stone, plaster, cement, glass and ceramic*
4655 *articles; fabrics, textiles, and apparel (plasticizer) floor coverings (vinyl tiles, PVC-backed*
4656 *carpeting, scraper mats)* was updated due to a change in the 2020 CDR reporting codes. The
4657 2020 CDR code for floor coverings was changed to “construction and building materials
4658 covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics,
4659 textiles, and apparel”. The original subcategory of floor coverings and examples were combined
4660 with the new reporting code in the subcategory. The term “as plasticizer” was added to specify
4661 the use of DIDP in these floor coverings.
- 4662 • *Commercial uses, Paints and coatings, Paints and coatings* was edited to include “(including
4663 *surfactants in paints and coatings)*” because surfactants were referenced in 2020 CDR reporting
4664 data.
- 4665 • *Commercial uses, Construction, paint, electrical, and metal products, “Lacquers, stains,*
4666 *varnishes, and floor finishes (as plasticizer)”* was added because it was added as a reporting
4667 category to the 2020 CDR.
- 4668 • *For Commercial and Consumer uses, Furnishing, cleaning, treatment/care products, “PVC film*
4669 *and sheet”* was added after stakeholder notification that DIDP is used in the production of these
4670 products.
- 4671 • *Consumer uses, Furnishing, cleaning, treatment/care products, “Fabrics, textiles and apparel*
4672 *(as plasticizer)”* was added after stakeholder notification that DIDP was used in these industries.
- 4673 • *Consumer uses, Construction, paint, electrical, and metal products, “Building/construction*
4674 *materials covering large surface areas including stone, plaster, cement, glass and ceramic*
4675 *articles (wire or wiring systems; joint treatment)”* was changed based on the updated 2020 CDR
4676 codes. The subcategory was updated to “Construction and building materials covering large
4677 surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic
4678 articles.” The specific examples of “(wire or wiring systems; joint treatment)” were kept.
- 4679 • *Consumer uses, Packaging, paper, plastic, hobby products, Arts, crafts, and hobby materials*
4680 was edited to add “(crafting paint applied to craft)” to reflect a use reported in the 2020 CDR.
- 4681 • *Consumer uses, Other, “Novelty products”* was added after EPA did further research and found
4682 this use among the reasonably available information.

4683 **D.2 Consolidation and Other Changes to Conditions of Use Table**

4684 When developing this draft risk evaluation, EPA concluded that some subcategories of the COUs listed
4685 in the final scope ([U.S. EPA, 2021b](#)) were redundant and consolidation was needed to avoid evaluation
4686 of the same COU multiple times. EPA concluded that there were some instances where subcategory

4687 information on the processing and uses of DIDP was misreported by CDR reporters based on outreach
 4688 with stakeholders. For these instances, EPA recategorized the COU to fit the actual description of the
 4689 COU. Finally, EPA determined that wording changes were needed to accurately describe COUs.
 4690 Therefore, EPA has made changes to the COU for the risk evaluation. Table_Apx D-2 summarizes the
 4691 changes to the COU subcategory descriptions.
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4693 **Table_Apx D-2. Subcategory Consolidations and Editing from the Final Scope Document to the**
 4694 **Draft Risk Evaluation**

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing, Incorporation into formulation, mixture, or reaction product	Intermediates (<i>e.g.</i> , plastic material and resin manufacturing)	Removed	N/A
Processing, Incorporation into formulation, mixture, or reaction product	Plastic product manufacturing	Removed	N/A
Processing, Incorporation into formulation, mixture, or reaction product	Lubricants and lubricant additives manufacturing	Removed “lubricants and lubricant additives manufacturing” as a separate COU and combined with “petroleum lubricating oil manufacturing” subcategory	Petroleum lubricating oil manufacturing; lubricant and lubricant additives manufacturing
Processing, Incorporation into formulation, mixture, or reaction product	Petroleum lubricating oil and grease manufacturing	Removed “grease” Added “lubricant and lubricant additives manufacturing”	Petroleum lubricating oil manufacturing; lubricant and lubricant additives manufacturing
Processing, Incorporation into formulation, mixture, or reaction product	Plasticizers (<i>e.g.</i> , adhesive and sealant manufacturing; custom compounding of purchased resin; construction materials other; ground injection equipment; paint and coating manufacturing; pigments; plastic material and resin manufacturing; rubber product manufacturing)	Removed “(<i>e.g.</i> , adhesive and sealant manufacturing; custom compounding of purchased resin; construction materials other; ground injection equipment; plastic material and resin manufacturing)” Removed “product” from rubber product manufacturing	Plasticizers (paint and coating manufacturing; pigments; rubber manufacturing)
Processing, Incorporation into articles	Plasticizers (<i>e.g.</i> , asphalt paving, roofing, and coating materials manufacturing; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products not covered elsewhere manufacturing; floor	Removed “not covered elsewhere from, fabric, textile, and leather products not covered elsewhere manufacturing,” Removed “miscellaneous manufacturing, plastic	Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; electrical equipment, appliance, and component manufacturing; fabric, textile, and leather products manufacturing; floor coverings

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Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
	coverings manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; miscellaneous manufacturing; ink, toner, and colorant products manufacturing; photographic supplies manufacturing; plastic material and resin manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; toys, playgrounds, and sporting equipment manufacturing)	material and resin manufacturing, and automotive care manufacturing” Added “automotive products manufacturing, other than fluids.” Added “including pigment” Removed duplication of “textiles, apparel and leather manufacturing; rubber product manufacturing; and plastic material and plastics product manufacturing.”	manufacturing; furniture and related product manufacturing; plastics product manufacturing; rubber product manufacturing; transportation equipment manufacturing; ink, toner, and colorant products (including pigment) manufacturing; photographic supplies manufacturing;; toys, playgrounds, and sporting equipment manufacturing)
Industrial uses, Functional fluids (open systems)	Functional fluids (open systems) (e.g., ground injection equipment)	Removed	N/A
Commercial uses, Automotive, fuel, agriculture, outdoor use products	Automotive care products	Removed “care”, added “other than fluids”	Automotive products, other than fluids
Commercial uses, Automotive, fuel, agriculture, outdoor use products	Lubricants and greases	Removed “greases”	Lubricants
Commercial uses, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere (e.g., wire or wiring systems; joint treatment, fire-proof insulation)	Removed “not covered elsewhere”	Building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation)
Commercial uses, Furnishing, cleaning, treatment/care products	Furniture and furnishings not covered elsewhere	Removed “not covered elsewhere”	Furniture and furnishings
Commercial uses, Packaging, paper, plastic, hobby products	Plastic and rubber products not covered elsewhere (e.g., textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Removed “not covered elsewhere” and “e.g.”	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)
Consumer uses, Automotive, fuel, agriculture, outdoor use products	Automotive care products	Removed “care,” added “other than fluids”	Automotive products, other than fluids
Consumer uses, Automotive, fuel,	Lubricants and greases	Removed “greases”	Lubricants

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
agriculture, outdoor use products			
Consumer uses, Packaging, paper, plastic, hobby products	Photographic supplies (e.g., graphic films)	Removed	N/A

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These changes were made from the scope of the risk evaluation for the following reasons:

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- The CDR reporting convention, “not covered elsewhere,” was removed from several COU subcategories. These changes were made to cover all relevant uses under their respective categories. Please see Table_Apx D-2 for the specific changes to the affected COUs.

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- References to “greases” throughout the COU table were removed when referring to lubricants because of stakeholder clarification that DIDP is not used in greases.

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- For processing and commercial uses pertaining to automotive products, the CDR automotive care product category refers to lubricants and transmission conditioner that are already covered under other categories, so the subcategory “automotive care products” was adjusted to “automotive products, other than fluids” to reflect where DIDP is used in plastic framing/molding of automobiles.

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- For subcategories with lists of products or industries assessed, “e.g.” was removed. The list of items provided in these subcategories are the industrial sectors for the COU and not necessarily examples so “e.g.” was removed.

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- *Processing, incorporation into a formulation, mixture, or reaction product, “Intermediates (plastic material and resin manufacturing)”* was removed after further investigation determined that the COU was redundant with the *Processing, incorporation into a formulation, mixture, or reaction product, “Plastic Material and Resin manufacturing”* COU.

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- *Processing, incorporation into a formulation, mixture, or reaction product, “Plastic product manufacturing”* was removed after further investigation determined that it was a redundant COU best evaluated under the *Processing, incorporation into articles, “Plasticizers (plastic product manufacturing)”* COU.

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- *Processing, incorporation into a formulation, mixture, or reaction product, “Lubricants and lubricant additives manufacturing”* was combined with the petroleum lubricating oil manufacturing COU after further investigation determined that lubricant and lubricant additives manufacturing is not an industrial sector under CDR reporting but is a functional use of petroleum lubricating oil manufacturing.

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- *Processing, incorporation into a formulation, mixture, or reaction product, “Plasticizers (construction materials other; paint and coating manufacturing; pigments; rubber manufacturing; all other chemical product and preparation manufacturing)”* was changed to remove “adhesive and sealant manufacturing,” “custom compounding of purchased resin,” “plastic material and resin manufacturing,” “ground injection equipment,” “construction materials other,” and “all other chemical product and preparation manufacturing” because upon further investigation,

- 4730 ○ The references to adhesive and sealant manufacturing, custom compounding of
4731 purchased resin, and plastic material and resin manufacturing were removed because the
4732 uses are assessed under other categories.
- 4733 ○ Ground injection equipment was removed because it was already addressed under the
4734 functional fluids COU. The functional fluids (open systems) COU category was also
4735 removed (please see the explanation for removal of the “*Industrial uses, Functional fluids*
4736 (*open systems*)” category for additional information.
- 4737 ○ Construction materials other was removed because it is assessed under the *processing,*
4738 *incorporation into articles* COU and was redundant.
- 4739 ○ Product was removed from “rubber product manufacturing” to differentiate it from the
4740 *Processing, incorporation into article, “Plasticizer (rubber product manufacturing)”*
4741 COU.
- 4742 ● *Processing, Incorporation into articles, plasticizers* was updated for the following industries:
- 4743 ○ Miscellaneous manufacturing – after stakeholder outreach, EPA concluded that this
4744 industry was misreported under the CDR and was addressed under other COUs.
- 4745 ○ Plastic material and resin manufacturing – EPA determined that this industry was
4746 assessed under “plastics product manufacturing” within this COU.
- 4747 ○ Automotive products manufacturing, other than fluids – this subcategory refers to the
4748 plastic moldings in automobiles. Automobile-related fluids, such as transmission
4749 conditioner, are addressed under the lubricants COU.
- 4750 ○ Automotive care product manufacturing – after investigation it was determined that
4751 DIDP is not incorporated into products associated with automotive care (*e.g.*, waxes,
4752 soaps, etc).
- 4753 ○ Added “including pigment” to the ink, toner, and colorant manufacturing to indicate that
4754 this COU describes the mixing of DIDP pigments into materials such as, polyurethane or
4755 plastisol.
- 4756 ● *Industrial uses, functional fluids (closed systems)* COU, the reference to heat transfer fluid was
4757 removed after review of notes from a stakeholder found that there was only discussion of SCBA
4758 compressor fluid.
- 4759 ● *Industrial uses, Functional fluids (open systems), Functional fluids (open systems) (e.g., ground*
4760 *injection equipment)* was removed; this COU is not included in CDR reporting, and upon further
4761 investigation and outreach with the stakeholder, EPA was unable to confirm that the COU exists.
- 4762 ● *Commercial uses, Packaging, paper, plastic, hobby products, Arts, crafts, and hobby materials*
4763 was removed after a stakeholder notified the EPA that DIDP is not used in this manner
4764 commercially.
- 4765 ● *Commercial and Consumer uses, Packaging, paper, plastic, hobby products, Photographic*
4766 *supplies (e.g., graphic films)* was removed because EPA confirmed with a stakeholder that DIDP
4767 is not used in this manner.

4768 **Appendix E CONDITIONS OF USE DESCRIPTIONS**

4769 **E.1 Manufacturing (Including Import)**

4770 Manufacturing means to manufacture or produce DIDP within the United States or import DIDP into the
4771 customs territory of the United States. For purposes of the DIDP risk evaluation, this includes the
4772 extraction of DIDP from a previously existing chemical substance or complex combination of chemical
4773 substances. For the purposes of this risk evaluation, this COU includes loading and repackaging (but not
4774 transport) associated with the manufacturing, production or import of DIDP.

4775 **E.1.1 Domestic Manufacturing**

4776 The alkyl esters of DIDP are a mixture of branched hydrocarbon isomers in the C9 through C11 range,
4777 comprising primarily C10 isomers of decyl esters. DIDP is manufactured through a reaction of phthalic
4778 anhydride and isodecyl alcohol using an acid catalyst, resulting in a mixture of branched hydrocarbon
4779 isomers in the C9 through C11 range, comprising primarily C10 isomers of decyl esters.

4780 **E.1.2 Import**

4781 In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal
4782 shipments. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and
4783 intermodal tank containers ([EPA-HQ-OPPT-2018-0435-0037](#)). Imported DIDP is shipped in either dry
4784 powder/crystal pellets/solid form or liquid form with concentrations ranging from 1 to 100 percent DIDP
4785 ([U.S. EPA, 2020a](#)).

4786 **E.2 Processing – Incorporation into a Formulation, Mixture, or Reaction 4787 Product – Adhesive and Sealants**

4788 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4789 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4790 manufacture, for distribution in commerce, in this case as an adhesive and sealant. DIDP is blended with
4791 other volatile and nonvolatile chemical components to produce adhesives and sealants ([ACC HPP,
4792 2019a](#); [OECD, 2009](#)).

4793
4794 The 2020, 2016, 2012 CDRs and the *Final Use Report for Di-isodecyl Phthalate (DIDP) (1,2-
4795 Benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-Benzenedicarboxylic acid, di-C9-11-branched
4796 alkyl esters, C10-rich) (CASRN 26761-40-0 and 68515-49-1)* report DIDPs use as a plasticizer for
4797 processing (incorporation into formulation, mixture, or reaction product) in adhesive manufacturing
4798 ([U.S. EPA, 2021c, 2020a](#)).

4799 **E.3 Processing – Incorporation into a Formulation, Mixture, or Reaction 4800 Product – Laboratory Chemicals**

4801 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4802 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4803 manufacture, for distribution in commerce, in this case into laboratory chemicals. Various companies
4804 have reported DIDP use for chemical synthesis or as a reference standard alone or in a mixture ([Supelco,
4805 2024](#)).

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4807 **E.4 Processing – Incorporation into a Formulation, Mixture, or Reaction**
4808 **Product – Petroleum Lubricating Oil Manufacturing; Lubricants and**
4809 **Lubricant Additive Manufacturing**

4810 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4811 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4812 manufacture, for distribution in commerce, in this case incorporating DIDP into petroleum lubricating
4813 oil and greases. The 2016 and 2012 CDRs report this type of processing of DIDP as a lubricant and
4814 lubricant additive ([U.S. EPA, 2019a](#); [Anderol, 2015](#)). DIDP is used as lubricant additive in products
4815 such as compressor fluids. The manufacture of DIDP for use in the industrial sector, “Petroleum
4816 Lubricating Oil and Grease Manufacturing,” was reported in the 2020 CDR ([U.S. EPA, 2020a](#)).

4817 **E.5 Processing – Incorporation into a Formulation, Mixture, or Reaction**
4818 **Product – Surface Modifier and Plasticizer in Paint and Coating**
4819 **Manufacturing**

4820 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4821 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4822 manufacture, for distribution in commerce, in this case as a surface modifier and plasticizer in paint and
4823 coating manufacturing. The term “surface modifier” encompasses DIDP’s use as an inert ingredient that
4824 is included in a coating as a plasticizer as well as other paint and coatings products used for downstream
4825 industrial, commercial, and consumer uses. The 2020 CDR includes a report indicating that DIDP is
4826 used as surface modifier in paint and coating manufacturing ([U.S. EPA, 2020a](#)).

4827 **E.6 Processing – Incorporation into a Formulation, Mixture, or Reaction**
4828 **Product – Plastic Material and Resin Manufacturing**

4829 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4830 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4831 manufacture, for distribution in commerce, in this case describing the manufacture of plastic material
4832 and resin through non-PVC and PVC compounding. Compounding involves the mixing of the polymer
4833 with the plasticizer and other chemical such as, fillers and heat stabilizers. The plasticizer needs to be
4834 absorbed into the particle to impart flexibility to the polymer. For PVC compounding, compounding
4835 occurs through mixing of ingredients to produce a powder (dry blending) or a liquid (Plastisol blending).
4836 The most common process for dry blending involves heating the ingredients in a high intensity mixer
4837 and transfer to a cold mixer. The Plastisol blending is done at ambient temperature using specific mixers
4838 that allow for the breakdown of the PVC agglomerates and the absorption of the plasticizer into the resin
4839 particle. The 2012 and 2020 CDR report use of this chemical as a plasticizer in plastic material and resin
4840 manufacturing ([U.S. EPA, 2020a](#)).

4841 **E.7 Processing – Incorporation into a Formulation, Mixture, or Reaction**
4842 **Product – Plasticizers (Paint and Coating Manufacturing; Pigments;**
4843 **Rubber Manufacturing)**

4844 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4845 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4846 manufacture, for distribution in commerce, in this case as a plasticizer in paint and coating
4847 manufacturing, pigments and rubber manufacturing. This COU does not include the use as surface
4848 modifier or resin manufacturing covered by other COUs. The 2020 CDR reported the import of DIDP
4849 for use as a plasticize in rubber product manufacturing ([U.S. EPA, 2020a](#)). The 2016 and 2012 CDRs

4850 report use of DIDP as a plasticizer for processing (incorporation into formulation, mixture, or reaction
4851 product) in paint and coating manufacturing ([U.S. EPA, 2019a](#)).

4852 **E.8 Processing – Incorporation into a Formulation, Mixture, or Reaction** 4853 **Product – Processing Aids, Specific to Petroleum Production (Oil and** 4854 **Gas Drilling, Extraction, and Support Activities)**

4855 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4856 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4857 manufacture, for distribution in commerce, in this case as a processing aid, specific to petroleum
4858 production (oil and gas drilling, extraction, and support activities). Data reported to the 2016 CDR
4859 indicates DIDP is used as a processing aid for petroleum production, such as oil and gas drilling
4860 activities ([U.S. EPA, 2019a](#)). This was not reported in 2020. In addition, DIDP is found in produced
4861 wastewaters from oil and gas drilling and extraction. ([U.S. EPA, 2016](#)). The use was also reported in the
4862 *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)* ([ACC HPP, 2019a](#)).

4863 **E.9 Processing – Incorporation into a Formulation, Mixture, or Reaction** 4864 **Product – Other (Part of the Formulation for Manufacturing** 4865 **Synthetic Leather)**

4866 Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation
4867 of a chemical substance or mixture, *i.e.*, adding DIDP to a product (or product mixture), after its
4868 manufacture, for distribution in commerce, in this case as a plasticizer that is mixed with non-PVC
4869 (polyurethane) or PVC and other additives to make a liquid suspension that can be applied to paper in
4870 the manufacturing of synthetic leather ([EPA-HQ-OPPT-2018-0435-0021](#)). The 2020 CDR reported the
4871 use of DIDP as part of the formulation in the manufacturing of synthetic leather ([U.S. EPA, 2020a](#)).

4872 **E.10 Processing – Incorporation into Articles – Abrasives Manufacturing**

4873 Processing to incorporate DIDP into articles refers to the preparation of a chemical substance or mixture,
4874 *i.e.*, DIDP becoming a component of an article, after its manufacture, for distribution in commerce, in
4875 this case as abrasives. Abrasives are manufactured by first applying adhesives and sealants to paper and
4876 then applying an abrasive to create a sandpaper type product. DIDP is a part of the adhesive and sealant
4877 product as a plasticizer, and it would be incorporated into the abrasive product. The use of DIDP was
4878 reported in the 2020 CDR as Processing—incorporation into formulation, mixture, or reaction product –
4879 Abrasive Manufacturing, but it was updated to Processing – Incorporation into Articles to reflect the
4880 description of the use more accurately ([U.S. EPA, 2020a](#)).

4881 **E.11 Processing – Incorporation into Articles – Plasticizers (Asphalt**
4882 **Paving, Roofing, and Coating Materials Manufacturing; Construction;**
4883 **Automotive Products Manufacturing, Other than Fluids; Electrical**
4884 **Equipment, Appliance, and Component Manufacturing; Fabric,**
4885 **Textile, and Leather Products Manufacturing; Floor Coverings**
4886 **Manufacturing; Furniture and Related Product Manufacturing;**
4887 **Plastics Product Manufacturing; Rubber Product Manufacturing;**
4888 **Transportation Equipment Manufacturing; Ink, Toner, and Colorant**
4889 **Products Manufacturing (Including Pigment); Photographic Supplies**
4890 **Manufacturing; Toys, Playground, and Sporting Equipment**
4891 **Manufacturing)**

4892 Processing to incorporate DIDP into articles refers to the preparation of a chemical substance or mixture,
4893 *i.e.*, DIDP becoming a component of an article, after its manufacture, for distribution in commerce. In
4894 this case, DIDP is present in a raw material that contains a mixture of plasticizers and other additives.
4895 This COU refers to the manufacturing of PVC articles using those raw materials that contain DIDP. The
4896 manufacturing of PVC articles from the raw materials entails processes such as calendaring, extrusion,
4897 injection molding, and plastisol spread coating ([EPA-HQ-OPPT-2018-0435-0022](#)). This COU includes
4898 incorporating DIDP into other articles. For example, plastisol technology or film calendaring technology
4899 is used in the production of plastic and rubber products such as textiles, apparel, and leather; vinyl tape;
4900 flexible tubes; profiles; hoses ([ACC HPP, 2023](#)). The incorporation of DIDP-containing colorants into
4901 material such as, polyurethane or plastisol. Plastisol mixed with DIDP-containing colorants are applied
4902 through processes such as dipping, roto-molding, or slush molding to produce coated fabrics, vinyl
4903 sealants, wall coverings, toys, and sporting goods ([EPA-HQ-OPPT-2018-0435-0022](#)). DIDP is also
4904 present in colorants used to color two-part polyurethane, foam, and epoxy resin systems used for
4905 production of prototypes, miniature models, and taxidermy ([BJB Enterprises, 2023a, b, c, d](#); [U.S. EPA,](#)
4906 [2021b, c](#); [ACC HPP, 2019a](#)). Another activity that would be included in this COU is the gluing of the
4907 synthetic leather to a fabric backing to create the final article. The 2020, 2016, and 2012 CDRs report
4908 use of DIDP as an adhesive and sealant chemical or plasticizer for processing (incorporation into article)
4909 in transportation equipment manufacturing ([U.S. EPA, 2020a, 2019a](#)). The 2016 and 2012 CDRs report
4910 use of DIDP as a plasticizer for processing (incorporation into article) in electrical equipment, appliance,
4911 and component manufacturing ([U.S. EPA, 2019a](#)). The 2016 and 2012 CDRs report use of DIDP as a
4912 plasticizer for processing (incorporation into formulation, mixture, or reaction product) in paint and
4913 coating manufacturing ([U.S. EPA, 2019a](#)). This COU describes the incorporation of DIDP-containing
4914 paints and coatings into articles. The 2020, 2016, and 2012 CDR report use of DIDP as a plasticizer for
4915 processing (incorporation into article) in plastic product manufacturing ([U.S. EPA, 2020a, 2019a](#)).

4916 **E.12 Processing – Repackaging**

4917 Repackaging refers to preparation of DIDP for distribution into commerce in a different form, state, or
4918 quantity than originally received or stored. Such activities include transferring DIDP from a bulk storage
4919 container into smaller containers ([EPA-HQ-OPPT-2018-0435-0038](#)).

4920 **E.13 Processing – Recycling**

4921 This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be
4922 disposed of as waste) that are collected, either on-site or transported to a third-party site, for commercial
4923 purpose. DIDP is primarily recycled industrially in the form of DIDP-containing PVC waste streams,

4924 including roofing membranes, vinyl window frame profiles, and carpet squares. New PVC can be
4925 manufactured from recycled and virgin materials at the same facility.

4926 **E.14 Distribution in Commerce – Distribution in Commerce**

4927 For purposes of assessment in this risk evaluation, distribution in commerce consists of the
4928 transportation associated with the moving of DIDP or DIDP-containing products between sites
4929 manufacturing, processing or recycling DIDP or DIDP-containing products, or to final use sites, or for
4930 final disposal of DIDP or DIDP-containing products. More broadly under TSCA, “distribution in
4931 commerce” and “distribute in commerce” are defined under TSCA section 3(5).

4932 **E.15 Industrial Use – Abrasives – Abrasives (Surface Conditioning and** 4933 **Finishing Discs; Semi-finished and Finished Goods)**

4934 The COU refers to the use of finished, abrasive articles that contain DIDP to smooth surfaces. DIDP is
4935 present in products that are used for surface conditioning. Surface conditioning is needed for such tasks
4936 as smoothing a surface prior to the application of paints and coatings or blending parting lines on cast
4937 parts ([EPA-HQ-OPPT-2018-0435-0037](#)). DIDP is present at low concentrations (<1.5%) in the line of
4938 non-woven abrasives supplied by one company ([U.S. EPA, 2021b](#)). DIDP is also present in one
4939 company’s abrasive products at concentrations ranging from 1 to 8 percent with applications as an
4940 abrasive system for semi-finished and finished goods ([EPA-HQ-OPPT-2018-0435-0012](#)).

4941 **E.16 Industrial Use – Functional Fluids (closed systems) – Functional Fluids** 4942 **(Closed Systems) (SCBA Compressor Oil)**

4943 The phthalates’ generally low melting points and high boiling points make them useful as heat-transfer
4944 liquids and carriers, which includes the changing of liquids and carriers in the pipelines of the facility.
4945 DIDP is incorporated into these products at concentrations of 10-30% ([Duratherm, 2019a, b](#)). Examples
4946 of heat transfer fluids that use DIDP are listed in the *Final Use Report for Diisodecyl Phthalate (DIDP)*
4947 (*1,2-Benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-Benzenedicarboxylic acid, di-C9-11-*
4948 *branched alkyl esters, C10-rich*) (*CASRN 26761-40-0 and 68515-49-1*) ([U.S. EPA, 2021c](#)).

4949 **E.17 Industrial Use – Adhesives and Sealants – Adhesives and Sealants**

4950 EPA understands that DIDP is used as a plasticizer in the manufacture of industrial adhesives and
4951 sealant end products; however, it is primarily used in commercial and consumer end products at
4952 concentrations ranging between 1 percent to less than 60 percent in products such as automotive
4953 interiors, undercoats, electrical products, and plastic products ([U.S. EPA, 2021b](#)). According to the
4954 manufacturer request for risk evaluation, less than five percent of DIDP is used in non-PVC applications
4955 such as those associated with adhesives and sealants ([ACC HPP, 2019a](#)). Examples of applications for
4956 adhesive and sealant products include products that are used in marine environments, joint sealants in
4957 mechanical equipment, concrete and masonry, and wood/engineered wood flooring. Adhesives and
4958 sealants may be applied through automated or mechanical spraying in industrial applications *i.e.*, in
4959 large manufacturing or processing facilities where exposure controls can be expected to be in place;
4960 however, products containing DIDP that are categorized as spray adhesives have not currently been
4961 identified by EPA ([U.S. EPA, 2021c](#)).

4962 **E.18 Industrial Use – Lubricant and Lubricant Additives**

4963 According to the manufacturer request for risk evaluation, DIDP is used in PVC and non-PVC
4964 applications in automotive products for consumer and industrial applications in synthetic lubricants and
4965 engine oils ([ACC HPP, 2019a](#)). EPA understands that DIDP is used in the manufacture of various

4966 lubricant additives that then are used in the manufacture of lubricating oils and greases ([U.S. EPA,](#)
4967 [2021b](#)). EPA has identified DIDP as a known chemical constituent of industrial/commercial hydraulic
4968 fracturing fluid produced water according to state sources (EPA-600-R-16-236Fb). DIDP is also used in
4969 commercial lubricants (and lubricating oils, compressor fluids for maintenance and repair, and
4970 transmission conditioner) at a concentration of at least 90 percent by weight ([U.S. EPA, 2021c](#)).

4971 **E.19 Industrial Use – Solvents (for Cleaning or Degreasing)**

4972 One company identifies DIDP as an ingredient in cleaners (sludge and carbon removal) for heat transfer
4973 systems. The company makes a variety of products for this purpose ([U.S. EPA, 2021c](#)). Additionally,
4974 another company identifies DIDP as an ingredient in one of its products, which is designed to be used as
4975 a degreasing fluid for its line of air compressors ([Quincy Compressor, 2022](#)).

4976 **E.20 Commercial Use – Automotive, Fuel, Agriculture, Outdoor Use** 4977 **Products – Automotive Products, Other than Fluids**

4978 According to the *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)*, DIDP is
4979 primarily used as a plasticizer in automotive products such as upholstery and interior finishes (e.g.,
4980 synthetic leather for car interiors), interior PVC skins (dashboards and shift boot covers), window
4981 glazing (urethane glass bonding adhesives and PVC window encapsulate), body-side molding,
4982 automotive undercoating, molded interior applications, insulation for wire and cable and wire harnesses
4983 ([3M, 2024](#); [ACC HPP, 2019a](#)). In addition, a product containing DIDP is applied as an undercover
4984 coating, most likely by spraying the coating on the underside of the vehicle.

4985 **E.21 Commercial Use – Automotive, Fuel, Agriculture, Outdoor Use** 4986 **Products – Lubricants**

4987 According to the *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)*, DIDP is used
4988 in PVC and non-PVC applications in automotive products for commercial applications including
4989 synthetic lubricants and engine oils ([ACC HPP, 2019a](#)). For the commercial use of these products, EPA
4990 expects them to be poured or applied by workers in auto repair and other maintenance shops. EPA
4991 understands that DIDP is used in the manufacture of various lubricant additives that then are used in the
4992 manufacture of commercial lubricants (and lubricating oils, compressor fluids for maintenance and
4993 repair, and transmission conditioner) at a concentration of at least 90 percent by weight ([U.S. EPA,](#)
4994 [2021c](#)). The commercial use of lubricants applies to the use of lubricants such as DIDP-containing auto
4995 transmission conditioner ([BG Products, 2016](#)).

4996 **E.22 Commercial Use – Construction, Paint, Electrical, and Metal Products** 4997 **– Adhesives and Sealants (Including Plasticizers in Adhesives and** 4998 **Sealants)**

4999 EPA understands that DIDP is primarily used as a plasticizer in the manufacture of commercial and
5000 consumer adhesive and sealant at concentrations ranging between 1 percent to less than 60 percent in
5001 commercial products such as electrical products, and plastic products ([U.S. EPA, 2021b](#)). These
5002 adhesive and sealants are used in construction settings and commonly applied using a syringe, caulk gun
5003 or spread on the surface using a trowel. These adhesive and sealant products are used in marine
5004 environments, as joint sealants in mechanical equipment, concrete and masonry, and wood/engineered
5005 wood flooring ([U.S. EPA, 2021c](#)).

5006 **E.23 Commercial Use – Construction, Paint, Electrical, and Metal Products**
5007 **– Building/Construction Materials (Wire or Wiring Systems; Joint**
5008 **Treatment, Fire-Proof Insulation)**

5009 The *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)* reports the use of DIDP in
5010 building wire and fire-proof building insulation ([Campine, 2024](#); [ACC HPP, 2019a](#)), and this COU
5011 covers the installation of such types of products.

5012 **E.24 Commercial Use – Construction, Paint, Electrical, and Metal Products**
5013 **– Electrical and Electronic Products**

5014 The *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)* states that DIDP is used as
5015 a general-purpose plasticizer for PVC used in building construction, particularly wire associated with
5016 electronic products ([ACC HPP, 2019a](#)). The 2020 CDR reports use of DIDP in machinery, mechanical
5017 appliances, electrical and electronic articles ([U.S. EPA, 2020a](#)). This COU encompasses handling the
5018 electric products, wiring, etc. and related insulation during installation and use of those products
5019 containing DIDP.

5020 **E.25 Commercial Use – Construction, Paint, Electrical, and Metal Products**
5021 **– Paints and Coatings (Including Surfactants in Paints and Coatings)**

5022 DIDP is used in a variety of paint and coating products, often used as a surfactant in paints and coatings.
5023 The *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)* and the 2020 CDR report
5024 identify use of DIDP in commercial paints and coatings ([U.S. EPA, 2020a](#); [ACC HPP, 2019a](#)). A
5025 company identifies DIDP as a component in surface active agent manufacturing for paints and coatings
5026 in a commercial setting in the 2020 CDR ([U.S. EPA, 2020a](#)). This COU encompasses the handling of
5027 paint and coating products containing DIDP during the application of paints and coatings. The
5028 application procedure depends on the type of paint or coating formulation and the type of substrate. The
5029 formulation is loaded into the application reservoir or apparatus and applied to the substrate via brush,
5030 spray, roll, dip, curtain, or syringe or bead application. After application, the paint or coating is allowed
5031 to dry or cure.

5032 **E.26 Commercial Use – Construction, Paint, Electrical, and Metal Products**
5033 **– Lacquers, Stains, Varnishes, and Floor Finishes (as Plasticizer)**

5034 This COU consists of the application of lacquers, stains, varnishes, and floor finishers that have DIDP
5035 already incorporated as a plasticizer. One company reported the use of DIDP in lacquers, stains,
5036 varnishes, and floor finishes in the 2020 CDR ([U.S. EPA, 2020a](#)). Currently, EPA has been unable to
5037 find any commercially available products containing DIDP that are on the market in the United States.
5038 EPA expects the most common application methods for lacquers, stains, varnishes, and floor finishes
5039 will involve brush or roll applications. EPA does not expect these products to be sprayed.

5040 **E.27 Commercial Use – Furnishing, Cleaning, Treatment/Care Products –**
5041 **Furniture and Furnishings**

5042 This COU consists of handling furniture and furnishings that already have had DIDP incorporated in
5043 them, as reported in the 2012 CDR and the *Manufacturer request for risk evaluation Di-isodecyl*
5044 *Phthalate (DIDP)* ([U.S. EPA, 2021c](#); [ACC HPP, 2019a](#)). EPA has not identified products that have
5045 DIDP and that are used in the manufacture of furniture, but the handling of synthetic leather furniture
5046 falls under this COU.

5047 **E.28 Commercial Use – Furnishing, Cleaning, Treatment/Care Products –**
5048 **Construction and Building Materials Covering Large Surface Areas**
5049 **Including Stone, Plaster, Cement, Glass and Ceramic Articles;**
5050 **Fabrics, Textiles, and Apparel (as Plasticizer); Floor Coverings (Vinyl**
5051 **Tiles, PVC-Backed Carpeting, Scraper Mats)**

5052 The *Manufacturer request for risk evaluation Diisodecyl Phthalate (DIDP)* states that DIDP is used as
5053 a general-purpose plasticizer for PVC used in building and construction materials such as vinyl tiles,
5054 resilient flooring, PVC-backed carpeting, scraper mats, and wall coverings ([ACC HPP, 2019a](#)). This
5055 COU encompasses handling the tiles, carpeting, etc that have DIDP incorporated into the products and
5056 may involve cutting and shaping the products for installation. The use was reported in the 2020 CDR
5057 ([U.S. EPA, 2020a](#)).

5058 **E.29 Commercial Use – Furnishing, Cleaning, Treatment/Care Products –**
5059 **Ink, Toner, and Colorant Products**

5060 According to the *Manufacturer request for risk evaluation Diisodecyl Phthalate (DIDP)* and
5061 information received from stakeholders, this COU refers to the use of DIDP-containing PVC ink by
5062 workers in a commercial setting ([EPA-HQ-OPPT-2018-0435-0005](#); [EPA-HQ-OPPT-2018-0435-0012](#)).
5063 DIDP can be used in formulation of screen-printing ink, typically referred to as plastisol. Plastisol
5064 consists of PVC particles and a plasticizer that allows the PVC to retain a liquid form during use.
5065 Plastisol can be used to produce finished goods such as t-shirts, sweatshirts, jackets, and tote bags
5066 ([Sharprint, 2019](#)). However, according to public comments, DIDP likely is not used in practice to create
5067 plastisol because less than 0.1 percent DIDP is allowed in textiles, per the OEKO-TEX standard ([ACC](#)
5068 [HPP, 2023](#)). EPA identified colorant products produced by a sealant manufacturing company that are
5069 used to tint a polyurethane sealant ([U.S. EPA, 2021c](#)).

5070 **E.30 Commercial Use – Furnishing, Cleaning, Treatment/Care Products –**
5071 **PVC Film and Sheet**

5072 DIDP is used in PVC film used in casting and masking fixtures ([EPA-HQ-OPPT-2018-0435-0012](#)), and
5073 the uses of DIDP has been reported as a “plasticizer for polyvinyl chloride for calendered film, sheet”
5074 ([HSDB, 2024](#)). The *Manufacturer request for risk evaluation: Diisodecyl phthalate (DIDP)* notes that
5075 film and sheet applications include use in roofing, wall coverings, pool liners etc. ([ACC HPP, 2019b](#)).
5076 The use covers other coated textiles such as truck awnings. This COU encompasses the commercial use
5077 of PVC film and sheet, including the cutting and shaping of the final articles.

5078 **E.31 Commercial Use – Furnishing, Cleaning, Treatment/Care Products –**
5079 **Plastic And Rubber Products (Textiles, Apparel, and Leather; Vinyl**
5080 **Tape; Flexible Tubes; Profiles; Hoses)**

5081 DIDP is incorporated into synthetic leather furniture, and this COU refers to the final product
5082 manufacture ([U.S. EPA, 2019a](#)). This COU also encompasses the assembly of the upholstery and
5083 interior finishes (e.g., synthetic leather for car interiors) that contain DIDP in automobiles ([ACC HPP,](#)
5084 [2019a](#)).

5085 **E.32 Commercial Use – Other Uses – Laboratory Chemicals**

5086 This COU refers to the use of DIDP as a laboratory chemical, such as in a chemical standard or
5087 reference material during analyses. Two chemical companies identify use of DIDP as a certified
5088 reference material and research chemical. One chemical company identifies DIDP as a dispersion

5089 chemical ([U.S. EPA, 2021c](#)). Commercial use of laboratory chemicals may involve handling DIDP by
5090 hand-pouring or pipette and either adding to the appropriate labware in its pure form to be diluted later
5091 or added to dilute other chemicals already in the labware. EPA expects that laboratory DIDP products
5092 are pure DIDP in neat liquid form or DIDP present as an impurity in other products.

5093 **E.33 Commercial Use – Other Uses – Inspection Fluid/Penetrant**

5094 This COU refers to the use of DIDP in inspection fluid/penetrant (EPA-HQ-OPPT-2018-0435-0023).
5095 Penetrant testing can be used to detect imperfections and flaws that are not detectable by the eye.
5096 Aircraft components are submerged in inspection fluid, and workers pull the component out of the fluid
5097 using their hands ([Isbell, 2018](#)).

5098 **E.34 Consumer Use – Automotive, Fuel, Agriculture, Outdoor Use Products** 5099 **– Automotive Products, Other than Fluids**

5100 According to the *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)*, DIDP is
5101 primarily used as a plasticizer in automotive products such as upholstery and interior finishes (*e.g.*,
5102 synthetic leather for car interiors), interior PVC skins (dashboards and shift boot covers), window
5103 glazing (urethane glass bonding adhesives and PVC window encapsulate), body-side molding,
5104 automotive undercoating, molded interior applications, insulation for wire and cable and wire harnesses
5105 ([ACC HPP, 2019a](#)). This COU refers to consumer use of cars, *i.e.*, driving, and consumer DIY-ers who
5106 may perform exterior or interior car maintenance involving automotive products containing DIDP other
5107 than fluids.

5108 **E.35 Consumer Use – Automotive, Fuel, Agriculture, Outdoor Use Products** 5109 **– Lubricants**

5110 According to the *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)*, DIDP is used
5111 in PVC and non-PVC applications in automotive products for consumer and industrial applications
5112 including synthetic lubricants and engine oils ([ACC HPP, 2019a](#)). EPA understands that DIDP is used in
5113 the manufacture of various lubricant additives in the manufacture of lubricating oils and greases. DIDP
5114 is also used in consumer lubricants and greases ([U.S. EPA, 2021c](#)). This COU encompasses consumer
5115 use of lubricants and greases used in automotive care.

5116 **E.36 Consumer Use – Construction, Paint, Electrical, and Metal Products –** 5117 **Adhesives and Sealants (Including Plasticizers in Adhesives And** 5118 **Sealants)**

5119 According to the *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)*, less than five
5120 percent of DIDP is used in non-PVC applications such as those associated with adhesives and sealants
5121 ([ACC HPP, 2019a](#)). EPA understands that DIDP is primarily used as a plasticizer in the manufacture of
5122 commercial and consumer adhesive and sealant end products at concentrations ranging between 1
5123 percent to less than 60 percent in products such as automotive interiors, undercoats, electrical products,
5124 and plastic products ([U.S. EPA, 2021b](#)). One company supplied EPA with information on the use of
5125 DIDP in an adhesive product used to affix wall paneling inside of commercial vehicle interior
5126 applications ([3M, 2024](#)). EPA considers that although this product is intended for commercial
5127 applications, this product and other similar products that contain DIDP, could be used in various
5128 consumer level applications as well.

5129 **E.37 Consumer Use – Construction, Paint, Electrical, and Metal Products –**
5130 **Building/Construction Materials Covering Large Surface Areas**
5131 **Including Stone, Plaster, Cement, Glass and Ceramic Articles (Wire or**
5132 **Wiring Systems; Joint Treatment)**

5133 The COU refers to the household use of solid flooring and other building materials. As reported in the
5134 *Manufacturer request for risk evaluation: Diisodecyl phthalate (DIDP)*, DIDP is used in PVC-backed
5135 carpet, vinyl tiles and resilient flooring ([ACC HPP, 2019a](#)). In this draft risk evaluation, the weight
5136 fraction used of DIDP was 1.9 percent in PVC flooring products, based on a European report ([ECHA,](#)
5137 [2012](#)).

5138 **E.38 Consumer Use – Construction, Paint, Electrical, and Metal Products –**
5139 **Electrical and electronic products**

5140 The *Manufacturer request for risk evaluation: Diisodecyl phthalate (DIDP)* indicates that DIDP is used
5141 as a general purpose plasticizer for PVC used in building construction, particularly wire associated with
5142 electronic products ([ACC HPP, 2019a](#)). The 2020 CDR reports use of DIDP in machinery, mechanical
5143 appliances, electrical and electronic articles ([U.S. EPA, 2020a](#)). This COU refers to consumer handling
5144 of electric products, wiring, etc. and related insulation during installation and use that may have DIDP
5145 incorporated into the products.

5146 **E.39 Consumer Use – Construction, Paint, Electrical, and Metal Products –**
5147 **Paints and Coatings**

5148 DIDP is used in a variety of paint and coating products, often used as a surfactant in paints and coatings.
5149 The *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)* and the 2020 CDR report
5150 use of DIDP in consumer paints and coatings ([U.S. EPA, 2020a](#); [ACC HPP, 2019a](#)). This COU refers to
5151 the consumer use of paint and coating products during the application of paints and coatings containing
5152 DIDP. The application procedure depends on the type of paint or coating formulation and the type of
5153 substrate. The formulation is loaded into the application reservoir or apparatus and applied to the
5154 substrate via brush, spray, roll, dip, curtain, or syringe or bead application. After application, the paint or
5155 coating is allowed to dry or cure.

5156 **E.40 Consumer Use – Furnishing, Cleaning, Treatment/Care Products –**
5157 **Fabrics, Textiles, and Apparel (as Plasticizer)**

5158 This COU refers to household use of synthetic leather and vinyl fabrics where DIDP was used as a
5159 plasticizer, which encompasses residential use of plastic furniture and vinyl textiles on cushions and
5160 other upholstery, such as couches, synthetic leather clothing. The consumer use was reported in the 2020
5161 CDR, with one manufacturer reporting use of DIDP as a plasticizer under Furniture and Related Product
5162 Manufacturing, as well as information from a stakeholder provided in 2023 ([ACC HPP, 2023](#); [U.S.](#)
5163 [EPA, 2020a](#)).

5164 **E.41 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Arts,**
5165 **Crafts, and Hobby Materials (Crafting Paint Applied to Craft)**

5166 This COU refers to the consumer use of DIDP in crafting paint applied to paint, hobby materials such as
5167 rubber erasers, and in a two-component urethane casting resin used in casting, prototyping, miniatures,
5168 models, and taxidermy. The use of DIDP as a plasticizer in craft painting applied to craft was reported in
5169 the 2020 CDR ([U.S. EPA, 2020a](#)). However, EPA has been unable to find a specific example of crafting
5170 paint that contains DIDP. DIDP is present in one of the two components of a polyurethane casting resin

5171 in concentrations of 10 to 40 percent ([Environmental, 2021](#)). Weight fractions were reported in Europe
5172 for erasing rubber made of PVC ([ECHA, 2012](#)). In one sample from a 2006 Danish investigation, the
5173 combination of DINP and DIDP was reported as 32 percent.

5174 **E.42 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Ink, 5175 Toner, and Colorant Products**

5176 According to the *Manufacturer request for risk evaluation Di-isodecyl Phthalate (DIDP)* and
5177 information received from stakeholders, this COU refers to the use of DIDP-containing PVC ink by
5178 consumers in non-commercial settings ([EPA-HQ-OPPT-2018-0435-0005](#); [EPA-HQ-OPPT-2018-0435-
5179 0012](#)). DIDP can be used in the formulation of screen-printing ink, typically referred to as plastisol.
5180 Plastisol consists of PVC particles and a plasticizer that allows the PVC to retain a liquid form during
5181 use. Plastisol can be used to produce finished goods such as t-shirts, sweatshirts, jackets, and tote bags
5182 ([Sharprint](#)). However, according to public comments, DIDP likely is not used in practice to create
5183 plastisol because less than 0.1 percent DIDP is allowed in textiles, per the OEKO-TEX standard ([ACC
5184 HPP, 2023](#)). EPA identified colorant products produced by a sealant manufacturing company that are
5185 used to tint a polyurethane sealant ([U.S. EPA, 2021c](#)).

5186 **E.43 Consumer Use – Packaging, Paper, Plastic, Hobby Products – PVC 5187 Film and Sheet**

5188 This COU refers to the consumer use of PVC film and sheet. DIDP is used in PVC film used in casting
5189 and masking fixtures ([EPA-HQ-OPPT-2018-0435-0012](#)), and as a “plasticizer for polyvinyl chloride for
5190 calendered film, sheet” ([HSDB, 2024](#)). The *Manufacturer request for risk evaluation: Diisodecyl
5191 phthalate (DIDP)* note that film and sheet applications include use in roofing, wall coverings, pool
5192 liners, etc. ([ACC HPP, 2019b](#)). The consumer use of PVC film and sheet includes household use of pool
5193 liners, wall coverings, truck awnings, etc.

5194 **E.44 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Plastic 5195 and Rubber Products (Textiles, Apparel, and Leather; Vinyl Tape; 5196 Flexible Tubes; Profiles; Hoses)**

5197 This COU refers to the consumer use of articles such as the wearing of synthetic leather bags and foam
5198 flip-flops, and the household use of shower curtains and wallpaper. The COU also refers to the DIY
5199 application of the wallpaper ([ACC HPP, 2023, 2019b](#)). The weight fraction of DIDP varies based on the
5200 article (approximately 0.047 to 0.35), although, EPA does not have information regarding DIDP weight
5201 fraction for all articles identified.

5202 **E.45 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Toys, 5203 Playgrounds, and Sporting Equipment**

5204 This COU refers to the consumer use of toys, playgrounds, and sporting equipment that contain DIDP.
5205 The use also refers to the do-it-yourself building of home playground equipment ([ACC HPP, 2023,
5206 2019b](#)). A plastisol coating is commonly used on sporting equipment for household use, such as fitness
5207 balls and hand weights. DIDP is used in these articles as a plasticizer to provide flexibility toys. The
5208 Consumer Product Safety Improvement Act of 2008 placed an interim prohibition on DIDP that limited
5209 the concentration of DIDP in children’s toys to 0.1 percent. Upon the effective date of the final rule in
5210 2018, the prohibition on DIDP was lifted (CFR:16 CFR 1307). For several articles, the weight fraction
5211 of DIDP was reported as DINP plus DIDP. For example, concentrations of DINP plus DIDP in four
5212 teether samples at 32 to 40 percent and in 2 of 3 doll samples at approximately 20 and 26 percent.

E.46 Consumer Use – Other – Novelty Products

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This COU refers to adult sex toys that are available for consumer use in the United States. Although the U.S. Food and Drug Administration (FDA) classifies certain sex toys (such as vibrators) as obstetrical and gynecological therapeutic medical devices, many manufacturers label these products “for novelty use only” and they are not subject to the FDA regulations ([Stabile, 2013](#)). Reported tested weight fractions of phthalates on sex toys ranges between 24 percent and 49 percent to create a softer, more flexible plastic ([Stabile, 2013](#)).

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E.47 Disposal

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Each of the COUs of DIDP may generate waste streams of the chemical. For purposes of the DIDP risk evaluation, this COU refers to the DIDP in a waste stream that is collected and transported to third-party sites for disposal or treatment. This COU also encompasses DIDP contained in wastewater discharged to publicly owned treatment works (POTW) or other, non-public treatment works for treatment, and other wastes. DIDP 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 DIDP, plastic and rubber products, textiles, and transport containers). Disposal may also include destruction and removal by incineration ([U.S. EPA, 2021b](#)). Recycling of DIDP and DIDP containing products is considered a different COU. Environmental releases from industrial sites are assessed in each condition of use.

Appendix F DRAFT OCCUPATIONAL EXPOSURE VALUE DERIVATION

EPA has calculated a draft 8-hour existing chemical occupational exposure value to summarize the occupational exposure scenario and sensitive health endpoints into a single value. This calculated draft value may be used to support risk management efforts for DIDP under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the draft value rounded to 2.40 mg/m³ for inhalation exposures to DIDP as an 8-hour time-weighted average (TWA) and for consideration in workplace settings (see Appendix F.1) based on the acute non-cancer human equivalent concentration (HEC) for developmental toxicity.

TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus this draft occupational exposure value represents a risk-only number. If risk management for DIDP follows the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. Any existing chemical exposure limit used for occupational safety risk management purposes could differ from the draft occupational exposure value presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c).

This calculated draft value for DIDP represents the exposure concentration below which workers and ONUs are not expected to exhibit any appreciable risk of adverse toxicological outcomes, accounting for potentially exposed and susceptible populations (PESS). It is derived based on the most sensitive human health effect (*i.e.*, developmental toxicity) relative to benchmarks and standard occupational scenario assumptions of 8 hours per day, 5 days per week exposures for a total of 250 days exposure per year, and a 40-year working life.

EPA expects that at the draft occupational exposure value of 0.131 ppm (2.40 mg/m³), a worker or ONU also would be protected against liver toxicity from intermediate and chronic occupational exposures if ambient exposures are kept below this draft occupational exposure value. EPA has not separately calculated a draft short-term (*i.e.*, 15-minute) occupational exposure value because EPA did not identify hazards for DIDP associated with this very short duration.

EPA did not identify a government-validated method for analyzing DIDP in air.

The Occupational Safety and Health Administration (OSHA) has not set a permissible exposure limit (PEL) as an 8-hour TWA for DIDP (<https://www.osha.gov/annotated-pels>). EPA located several occupational exposure limits for DIDP in other countries (<https://ilv.ifa.dguv.de/limitvalues/21303>). Identified 8-hour TWA values range from 3 mg/m³ in Austria, Denmark, and Sweden to 5 mg/m³ in Ireland and South Africa. Additionally, EPA found that the province of [Ontario, Canada](#), [New Zealand](#), and the [United Kingdom](#) all 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.

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 DIDP, the most sensitive occupational exposure value is based on non-cancer developmental effects and the resulting 8-hour TWA is rounded to 2.40 mg/m³.

5278 **Draft Acute Non-cancer Occupational Exposure Value**

5279 The draft acute occupational exposure value (EV_{acute}) was calculated as the concentration at which the
 5280 acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx
 5281 F-1:

5282

5283 **Equation_Apx F-1.**

5284

$$5285 \quad EV_{acute} = \frac{HEC_{acute}}{Benchmark\ MOE_{acute}} * \frac{AT_{HEC_{acute}}}{ED} * \frac{IR_{resting}}{IR_{workers}} =$$

5286

$$5287 \quad \frac{2.68\ ppm}{30} * \frac{\frac{24h}{d}}{\frac{8h}{d}} * \frac{0.6125 \frac{m^3}{hr}}{1.25 \frac{m^3}{hr}} = 0.131\ ppm$$

5288

$$5289 \quad EV_{acute} \left(\frac{mg}{m^3} \right) = \frac{EV\ ppm * MW}{Molar\ Volume} = \frac{0.131\ ppm * 446.7 \frac{g}{mol}}{24.45 \frac{L}{mol}} = 2.40 \frac{mg}{m^3}$$

5290

5291 **Draft Intermediate Non-cancer Occupational Exposure Value**

5292 The draft intermediate occupational exposure value ($EV_{intermediate}$) was calculated as the concentration at
 5293 which the intermediate MOE would equal the benchmark MOE for intermediate occupational exposures
 5294 using Equation_Apx F-2:

5295

5296 **Equation_Apx F-2.**

5297

$$5298 \quad EV_{intermediate} = \frac{HEC_{intermediate}}{Benchmark\ MOE_{intermediate}} * \frac{AT_{HEC\ intermediate}}{ED * EF} * \frac{IR_{resting}}{IR_{workers}}$$

5299

$$5300 \quad = \frac{2.68\ ppm}{30} * \frac{\frac{24h}{d} * 30d}{\frac{8h}{d} * 22d} * \frac{0.6125 \frac{m^3}{hr}}{1.25 \frac{m^3}{hr}} = 0.179\ ppm = 3.27 \frac{mg}{m^3}$$

5301

5302 **Draft Chronic Non-cancer Exposure Value**

5303 The draft chronic occupational exposure value ($EV_{chronic}$) was calculated as the concentration at which
 5304 the chronic MOE would equal the benchmark MOE for chronic occupational exposures using
 5305 Equation_Apx F-3:

5306

5307 **Equation_Apx F-3.**

5308

$$5309 \quad EV_{chronic} = \frac{HEC_{chronic}}{Benchmark\ MOE_{chronic}} * \frac{AT_{HEC\ chronic}}{ED * EF * WY} * \frac{IR_{resting}}{IR_{workers}}$$

5310

$$5311 \quad = \frac{2.68\ ppm}{30} * \frac{\frac{24h}{d} * \frac{365d}{y} * 40\ y * 0.6125 \frac{m^3}{hr}}{\frac{8h}{d} * \frac{250d}{y} * 40\ y * 1.25 \frac{m^3}{hr}} = 0.192\ ppm = 3.50 \frac{mg}{m^3}$$

5312

5313 Where:

5314 AT_{hecate} = Averaging time for the POD/HEC used for evaluating non-cancer

5315 acute occupational risk based on study conditions and HEC

5316 adjustments (24 hr/day).

5317 $AT_{HECintermediate}$ = Averaging time for the POD/HEC used for evaluating non-cancer

5318 intermediate occupational risk based on study conditions and/or

5319 any HEC adjustments (24 hr/day for 30 days).

5320 $AT_{HECchronic}$ = Averaging time for the POD/HEC used for evaluating non-cancer

5321 chronic occupational risk based on study conditions and/or HEC

5322 adjustments (24 hr/day for 365 days/yr) and assuming the same

5323 number of years as the high-end working years (WY, 40 years) for

5324 a worker.

5325 $Benchmark\ MOE_{acute}$ = Acute non-cancer benchmark margin of exposure, based on the

5326 total uncertainty factor of 30

5327 $Benchmark\ MOE_{intermediate}$ = Intermediate non-cancer benchmark margin of exposure, based on

5328 the total uncertainty factor of 30

5329 $Benchmark\ MOE_{chronic}$ = Chronic non-cancer benchmark margin of exposure, based on the

5330 total uncertainty factor of 30

5331 EV_{acute} = Occupational exposure value based on acute neurotoxicity

5332 $EV_{intermediate}$ = Occupational exposure value based on intermediate reproductive

5333 toxicity

5334 $EV_{chronic}$ = Occupational exposure value based on chronic reproductive

5335 toxicity

5336 ED = Exposure duration (8 hr/day)

5337 EF = Exposure frequency (1 day for acute, 22 days for intermediate, and

5338 250 days/yr for chronic and lifetime)

5339 HEC = Human equivalent concentration for acute, intermediate, or chronic

5340 non-cancer occupational exposure scenarios

5341 IR = Inhalation rate (default is 1.25 m³/hr for workers and 0.6125 m³/hr

5342 assumed from “resting” animals from toxicity studies)

5343 $Molar\ Volume$ = 24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C

5344 MW = Molecular weight of DIDP (446.7 g/mole)

5345 WY = Working years per lifetime at the 95th percentile (40 years)

5346 ([U.S. EPA, 2024e](#)).

Unit conversion:

5347

5348 1 ppm = 18.3 mg/m³ (see equation associated with the EV_{acute} calculation)

5349