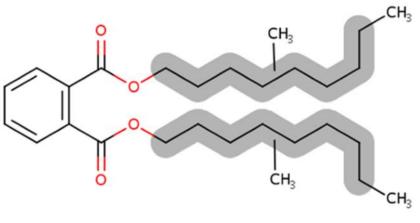


# **Risk Evaluation for Diisodecyl Phthalate** (DIDP)

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



(Representative Structure)

December 2024

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#### Docket

Supporting information can be found in the public dockets Docket IDs (<u>EPA-HQ-OPPT-2018-0435</u> and <u>EPA-HQ-OPPT-2024-0073</u>).

#### Disclaimer

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## **EXECUTIVE SUMMARY**

#### Background

The U.S. Environmental Protection Agency (EPA or the Agency) has evaluated the health and environmental risks of the chemical diisodecyl phthalate (DIDP) under the Toxic Substances Control Act (TSCA). In this risk evaluation, **EPA has determined that DIDP presents an unreasonable risk of injury to human health under the conditions of use**. Of the 49 conditions of use (COUs) that EPA evaluated, 6 have risk estimates that raise concerns for female workers of reproductive age from exposure to DIDP, and none raise such concerns for consumers or the general population. In its risk evaluation, EPA's protective, screening-level approaches demonstrated that DIDP does not pose risk to the environment. This risk evaluation takes into consideration input from the public and independent, expert peer review advice provided during the July 2023 meeting of the Science Advisory Committee on Chemicals (SACC).

EPA has evaluated DIDP because, as allowed under TSCA, the Agency received a request from ExxonMobil Chemical Company, through the American Chemistry Council's High Phthalates Panel, to conduct a TSCA risk evaluation for DIDP. EPA determined that the request met the regulatory criteria and requirements and in 2019 granted the request.

DIDP is used primarily as a plasticizer to make flexible polyvinyl chloride (PVC). It is also used to make building and construction materials; automotive care and fuel products; and other commercial and consumer products including adhesives and sealants, paints and coatings, electrical and electronic products—which are all considered TSCA uses. Workers may be exposed to DIDP when making these products or otherwise using DIDP in the workplace. When it is manufactured or used to make products, DIDP can be released into the water, where because of its properties, most of it will end up in the sediment at the bottom of lakes and rivers, rather than in sources of drinking water. If it is released into the air, DIDP will attach to dust particles and then be deposited onto land or into water. Indoors, DIDP has the potential to be emitted from products and partition into suspended and settled dust particles, which could then be inhaled or ingested such as when an infant crawls around a dusty floor or mouths a sofa with settled dust.

Studies have been conducted to investigate DIDP for a range of cancer and non-cancer effects on people, including effects on the developing male reproductive system. Studies have demonstrated that exposure to DIDP can cause developmental toxicity in experimental laboratory animals, which means that laboratory animals dosed with DIDP had litters where more rodent offspring died than was the case with the litters of rodents that were not dosed with DIDP.

DIDP production in the United States has increased significantly over the past decade. In 2015 the production volume was between 100 and 250 million pounds; in 2019 it had increased to between 100 million and 1 billion pounds. (EPA describes production volumes as a range to protect confidential business information.)

Past assessments of DIDP from other regulatory agencies that addressed a broad range of DIDP uses have concluded that DIDP does not pose risk to human health or the environment based on its concentration in products and the environment. Notably, the U.S. Consumer Product Safety Commission's (CPSC) risk assessment—which included consideration of exposure from children's products as well as from other sources such as personal care products, diet, consumer products, and the environment—concluded that DIDP exposure comes primarily from diet, which is a source of exposure that is not by law subject to TSCA jurisdiction. In this risk evaluation, EPA only evaluated risks resulting from exposure to DIDP from facilities that use, manufacture, or process DIDP under industrial and/or commercial COUs subject to TSCA and the products resulting from such manufacture and processing. Human or environmental exposure to DIDP through uses that are not subject to TSCA (*e.g.*, cosmetics, medical devices, food contact materials) were not evaluated by EPA, or taken into account in reaching its determination of unreasonable risk to injury of human health, because these uses are excluded from TSCA's definition of chemical substances. Thus, while EPA is concluding in this risk evaluation that six TSCA COUs contribute to its 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.

#### Determining Unreasonable Risk to Human Health

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

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

EPA evaluated the risks to people exposed to DIDP at work, indoors, and outdoors. In its human health evaluation, the Agency used a combination of screening-level and more refined approaches to look at how people might be exposed to DIDP through breathing or ingesting dust or other particulates or through skin contact. In determining whether DIDP presents an unreasonable risk of injury to human health, EPA incorporated the following potentially exposed and susceptible subpopulations (PESS) into its assessment: women of reproductive age, pregnant women, infants, children and adolescents, people who frequently use consumer products and/or articles containing high-concentrations of DIDP, people exposed to DIDP in the workplace, and tribes and subsistence fishers whose diets include large amounts of fish. These subpopulations are PESS because some have greater exposure to DIDP per body weight (*e.g.*, infants, children, adolescents) or due to age-specific behaviors (*e.g.*, mouthing of toys, wires, and

erasers by infants and children; hand-to-mouth ingestion from synthetic leather furniture), while some people may experience exposure from multiple sources or experience higher exposure than others. EPA's robust scientific analysis shows DIDP to not result in unreasonable risk to consumers or the general population, including PESS, except for those exposed to DIDP at work for six COUs.

The six COUs that EPA identified as significantly contributing to the unreasonable risk of DIDP were for acute exposure scenarios in which unprotected female workers of reproductive age spray adhesives and sealants; paints and coatings; lacquers, stains, varnishes, and floor finishes; or penetrants and inspection fluids that contain DIDP. This is because doing so could create high concentrations of DIDP in mist that an unprotected female worker or reproductive age could inhale. As the most sensitive health effects of concern relate to exposure of the developing fetus during gestation, the population to which this risk determination is most relevant is female workers of reproductive age.

#### Summary, Considerations, and Next Steps

EPA evaluated a total of 49 TSCA COUs for DIDP. The Agency is determining that the following COUs significantly contribute to the unreasonable risk:

- Industrial use adhesives and sealants;
- Industrial use construction, paint, electrical, and metal products paints and coatings;
- Commercial use construction, paint, electrical, and metal products adhesives and sealants (including plasticizers in adhesives and sealants);
- Commercial use construction, paint, electrical, and metal products paints and coatings (including surfactants in paints and coatings);
- Commercial use construction, paint, electrical, and metal products lacquers, stains, varnishes, and floor finishes (as plasticizer); and
- Commercial use other uses inspection fluid/penetrant.

The remaining COUs, listed below, do not significantly contribute to the unreasonable risk:

- Manufacturing domestic manufacturing;
- Manufacturing importing;
- Processing incorporation into formulation, mixture, or reaction product adhesives and sealants manufacturing;
- Processing incorporation into formulation, mixture, or reaction product laboratory chemicals manufacturing;
- Processing incorporation into formulation, mixture, or reaction product petroleum lubricating oil manufacturing; lubricants and lubricant additives manufacturing
- Processing incorporation into formulation, mixture, or reaction product surface modifier in paint and coating manufacturing;
- Processing incorporation into formulation, mixture, or reaction product plastic material and resin manufacturing;
- Processing incorporation into formulation, mixture, or reaction product plasticizers (paint and coating manufacturing; pigments; rubber manufacturing);
- 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 other (part of the formulation for manufacturing synthetic leather);
- Processing incorporation into articles abrasives manufacturing;
- Processing incorporation into articles 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; ink, toner, and colorant products manufacturing (including pigment); photographic supplies manufacturing; toys, playground, and sporting equipment manufacturing);

- Processing repackaging;
- Processing recycling;
- Distribution in commerce;
- Industrial use abrasives;
- Industrial use functional fluids (closed systems);
- Industrial use lubricant and lubricant additives;
- Industrial use solvents (for cleaning and degreasing);
- Commercial use automotive, fuel, agriculture, outdoor use products– lubricants;
- Commercial use construction, paint, electrical, and metal products building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation);
- Commercial use construction, paint, electrical, and metal products electrical and electronic products;
- Commercial use furnishing, cleaning, treatment/care products furniture and furnishings;
- Commercial use 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]);
- Commercial use packaging, paper, plastic, hobby products ink, toner, and colorant products;
- Commercial use packaging, paper, plastic, hobby products PVC film and sheet;
- Commercial use packaging, paper, plastic, hobby products plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)
- Commercial use other uses laboratory chemicals;
- Commercial use other uses automotive articles;
- Consumer use automotive, fuel, agriculture, outdoor use products lubricants;
- Consumer use construction, paint, electrical, and metal products adhesives and sealants (including plasticizers in adhesives and sealants);
- Consumer use 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);
- Consumer use construction, paint, electrical, and metal products electrical and electronic products;
- Consumer use construction, paint, electrical, and metal products paints and coatings;
- Consumer use furnishing, cleaning, treatment/care products fabrics, textiles, and apparel (as plasticizer);
- Consumer use packaging, paper, plastic, hobby products arts, crafts, and hobby materials (crafting paint applied to craft);
- Consumer use packaging, paper, plastic, hobby products ink, toner, and colorant products;
- Consumer use packaging, paper, plastic, hobby products PVC film and sheet;
- Consumer use packaging, paper, plastic, hobby products plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses);
- Consumer use packaging, paper, plastic, hobby products toys, playgrounds, and sporting equipment;

- Consumer use other uses automotive articles;
- Consumer use other novelty articles, and
- Disposal.

This risk evaluation was released for public comment in May 2024 and underwent independent, expert scientific peer review. Based on new information identified by EPA, information provided by public commenters, and recommendations of the SACC, EPA made several notable changes to the risk evaluation for DIDP from draft to final. In the draft risk evaluation, the Agency preliminarily concluded that one COU significantly contributes to unreasonable risk to unprotected female workers of reproductive age and average adult workers resulting from acute, intermediate, and chronic duration high-pressure spray applications of adhesives and sealants in industrial settings. In this finalized risk evaluation of DIDP, EPA identified six COUs that significantly contribute to unreasonable risk to unprotected female workers of reproductive age resulting from acute duration spray applications of adhesives and sealants in industrial settings; acute duration spray applications of paints and coatings in industrial and commercial settings; acute duration spray applications of inspection fluids and penetrants in commercial settings; and acute duration spray applications of lacquers, stains, varnishes and floor finishes in commercial settings.

The changes made from draft to final were made based on several important considerations. First, from draft to final, EPA concluded that high-end worker risk estimates are no longer represented by only high-pressure spray applications, but rather multiple factors (*e.g.*, spray duration, concentration of DIDP in product, spray equipment, spray booth configuration) contribute to high-end worker inhalation exposures and risk estimates. Although some uncertainty exists, EPA considers these factors plausible for acute high-end worker exposure scenarios, but not for intermediate or chronic duration worker exposure scenarios. Spray applications may be used in industrial and commercial settings for six COUs, and these six COUs significantly contribute to the unreasonable risk of injury to human health based on non-cancer effects in female workers of reproductive age. Acute risk to the average adult worker was reconsidered based on the applicability of the point of departure (POD), which was based on developmental toxicity (*i.e.*, reduced offspring survival), resulting in no risk finding on the basis of average adult worker exposure.

Finally, based on the use of DIDP in automotive undercoatings and a subsequent commercially available product identified by EPA between draft and final, an Industrial use – construction, paints, electrical, and metal products – paints and coatings COU was added to the risk evaluation for DIDP, and this COU was found to significantly contribute to the unreasonable risk of injury to human health.

This completed DIDP risk evaluation takes into consideration input from the public and peer reviewers. In this risk evaluation, **EPA has determined that DIDP presents an unreasonable risk of injury to human health.** As a next step, EPA will initiate regulatory action to mitigate the unreasonable risk.

# **1 INTRODUCTION**

EPA has evaluated diisodecyl phthalate (DIDP) under the Toxic Substances Control Act (TSCA) section 6(b). DIDP is a common chemical name for the category of chemical substances that includes the following substances: 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). Both CASRNs contain mainly C10 dialkyl phthalate esters. DIDP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications. Section 1.1 summarizes the scope of the DIDP risk evaluation and provides information on production volume, a life cycle diagram (LCD), conditions of use (COUs), and conceptual models used for DIDP. Section 1.2 presents the organization of this risk evaluation. Figure 1-1 describes the major inputs, phases, and outputs/components of the <u>TSCA risk evaluation process</u>, from scoping to releasing the final risk evaluation.

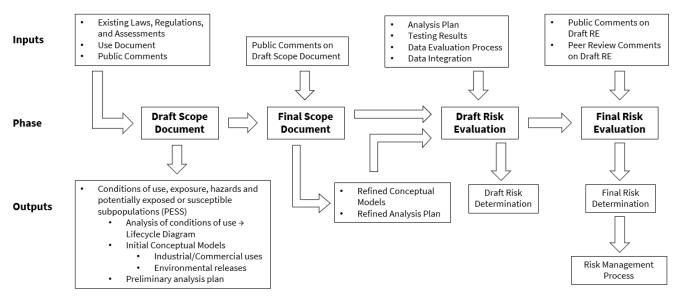


Figure 1-1. TSCA Existing Chemical Risk Evaluation Process

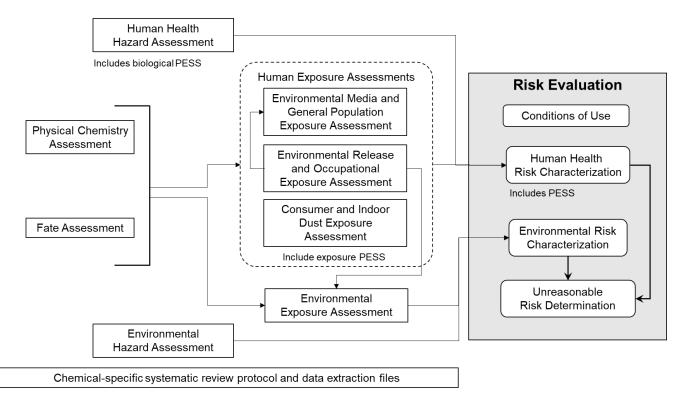
## 1.1 Scope of the Risk Evaluation

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

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

Appendix C incudes a list and citations for all technical support documents and supplemental files included in the risk evaluation for DIDP.

These technical support documents leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Di-isodecyl Phthalate (DIDP), CASRN 26761-40-0 and 68515-49-1* (also referred to as the "final scope document") (U.S. EPA, 2021b). OPPT conducted a comprehensive search for "reasonably available information" to identify relevant DIDP data for use in the risk evaluation. The approach used to identify specific relevant risk assessment information was discipline-specific and is detailed in *Systematic Review Protocol for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024ab), or as otherwise noted in the relevant technical support documents.

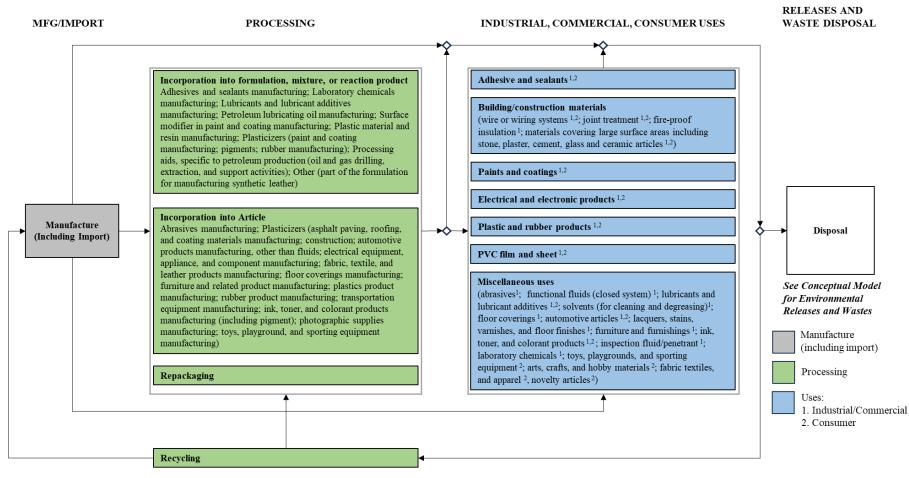


#### Figure 1-2. Risk Evaluation Document Summary Map

#### 1.1.1 Life Cycle and Production Volume

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

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

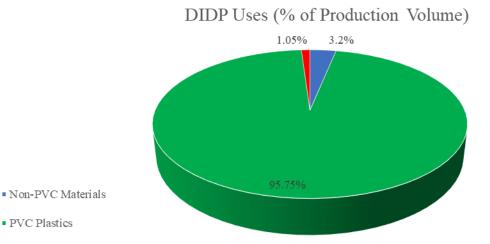


#### Figure 1-3. DIDP Life Cycle Diagram

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

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

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



• Other (Adhesives and Sealants; Paints and Coatings; Laboratory Chemicals; Other Fomulations, Mixtures, and Reaction Products)

#### Figure 1-4. Percentage of DIDP Production Volume by Use

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

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

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

In this risk evaluation, EPA made updates to the COUs listed in the final scope document (U.S. EPA, 2021b) and in the draft risk evaluation of DIDP (U.S. EPA, 2024n). These updates reflect EPA's improved understanding of the COUs based on further outreach, public comments received, and updated industry code names under the CDR for 2020. Updates included (1) additions and clarification of COUs based on new reporting in CDR for 2020 or information received from stakeholders, (2) consolidation of redundant COUs from the processing lifestage based on inconsistencies found in CDR reporting for DIDP processing and uses and communications with stakeholders about the use of DIDP in industry, and (3) correcting typos or editing for consistency. A complete list of updates and explanations of the updates made to COUs for DIDP from the final scope document and draft risk evaluation to this final risk evaluation is provided in Appendix D. Table 1-1 presents the revised COUs that were included and evaluated in this Risk Evaluation for DIDP. Appendix E provides descriptions of the DIDP COUs evaluated by EPA.

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
Manufacturing	Domestic manufacturing	Domestic manufacturing <sup>d</sup>	( <u>U.S. EPA, 2020a, 2019a, c</u> )	( <u>U.S. EPA, 2020a, 2019a, c</u> )
C C	Importing	Importing <sup>d</sup>	( <u>U.S. EPA, 2020a, 2019a, c</u> )	( <u>U.S. EPA, 2020a, 2019a, c</u> )
		Adhesives and sealants manufacturing	( <u>U.S. EPA, 2019a</u> )	( <u>U.S. EPA, 2019a</u> )
		Laboratory chemicals manufacturing	(U.S. EPA, 2020g)	
		Petroleum lubricating oil manufacturing; lubricants and lubricant additives manufacturing	( <u>ACC HPP, 2023; U.S. EPA,</u> <u>2019a</u> )	( <u>ACC HPP, 2023;</u> <u>U.S. EPA,</u> 2020a, <u>2019a</u> )
	Incorporation into	Surface modifier and plasticizer in paint and coating manufacturing		( <u>U.S. EPA, 2020a</u> )
	formulation, mixture,	Plastic material and resin manufacturing		( <u>U.S. EPA, 2019a</u> )
	or reaction product	Plasticizers (paint and coating manufacturing; pigments; rubber manufacturing)	( <u>ACC HPP, 2023;</u> <u>U.S. EPA,</u> 2020a, 2019a)	( <u>ACC HPP, 2023;</u> <u>U.S. EPA,</u> 2020a, 2019a)
		Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities)	( <u>U.S. EPA, 2019c</u> )	( <u>U.S. EPA, 2019a</u> , <u>c</u> )
Processing		Other (part of the formulation for manufacturing synthetic leather)	( <u>U.S. EPA, 2020a</u> )	
		Abrasives manufacturing	( <u>U.S. EPA, 2020f</u> )	
	Incorporation into articles	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 products manufacturing (including pigment); photographic supplies manufacturing; toys, playground, and sporting equipment manufacturing)	( <u>ACC HPP, 2023; U.S. EPA,</u> <u>2020a</u> , <u>f</u> , <u>2019a</u> )	( <u>ACC HPP, 2023; U.S. EPA,</u> 2020a, <u>2019a</u> )

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

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
	Repackaging	Repackaging	( <u>U.S. EPA, 2019a</u> )	( <u>U.S. EPA, 2019a</u> )
	Recycling	Recycling	( <u>U.S. EPA, 2021b</u> )	( <u>U.S. EPA, 2021b</u> )
Distribution in Commerce	Distribution in commerce	Distribution in commerce		
	Abrasives	Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)	( <u>U.S. EPA, 2020f</u> )	
	Adhesive and sealants	Adhesives and sealants <sup>d</sup>	( <u>U.S. EPA, 2019a, c</u> )	( <u>U.S. EPA, 2019a, c</u> )
	Construction, paint, electrical, and metal products	Paints and coatings	( <u>ACC, 2020b</u> )	( <u>ACC, 2020b</u> )
Industrial Uses	Functional fluids (closed systems)	Functional fluids (closed systems) (SCBA compressor oil)	( <u>U.S. EPA, 2020f</u> )	
	Lubricant and lubricant additives	Lubricants and lubricant additives <sup>d</sup>	( <u>U.S. EPA, 2019a, c</u> )	( <u>U.S. EPA, 2019a, c</u> )
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	(Duratherm, 2018; Quincy Compressor, 2012)	
	Automotive, fuel, agriculture, outdoor use products	Lubricants	( <u>ACC HPP, 2023; U.S. EPA,</u> 2019a)	( <u>ACC HPP, 2023; U.S. EPA, 2020a, 2019a</u> )
		Adhesives and sealants (including plasticizers in adhesives and sealants) $^{d}$	( <u>U.S. EPA, 2020a, 2019a, c</u> )	( <u>U.S. EPA, 2020a, 2019a, c</u> )
Commercial	Construction, paint,	Building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation) <sup><math>d</math></sup>	( <u>U.S. EPA, 2019c</u> )	( <u>U.S. EPA, 2019c</u> )
Uses	electrical, and metal	Electrical and electronic products <sup>d e</sup>	( <u>U.S. EPA, 2019c</u> )	( <u>U.S. EPA, 2019a, c</u> )
	products	Paints and coatings (including surfactants in paints and coatings) <sup>d</sup>	( <u>U.S. EPA, 2019a, c</u> )	( <u>U.S. EPA, 2020a, 2019a, c</u> )
		Lacquers, stains, varnishes, and floor finishes (as plasticizer)		( <u>U.S. EPA, 2020a</u> )
		Furniture and furnishings	( <u>U.S. EPA, 2019c</u> )	( <u>U.S. EPA, 2019a</u> , <u>c</u> )

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
Commercial	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)) <sup>d</sup>	(ACC HPP, 2023; U.S. EPA, 2019c)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019c)
	Packaging, paper, plastic, hobby products	Ink, toner, and colorant products <sup>d</sup>	( <u>U.S. EPA, 2020f</u> , <u>2019c</u> )	( <u>U.S. EPA, 2020f, 2019c</u> )
Uses		PVC film and sheet	( <u>U.S. EPA, 2020f</u> )	( <u>U.S. EPA, 2020f</u> )
		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses) <sup><math>d</math></sup>	( <u>ACC HPP, 2023;</u> <u>U.S. EPA,</u> <u>2020f</u> , <u>2019c</u> )	( <u>ACC HPP, 2023;</u> <u>U.S. EPA,</u> <u>2019a</u> , <u>c</u> )
	Other uses	Laboratory chemicals	( <u>U.S. EPA, 2020g</u> )	( <u>U.S. EPA, 2020g</u> )
		Automotive articles	( <u>U.S. EPA, 2019c</u> )	( <u>U.S. EPA, 2019a, c</u> )
		Inspection fluid/penetrant	( <u>U.S. EPA, 2020c</u> )	( <u>U.S. EPA, 2020c</u> )
	Automotive, fuel, agriculture, outdoor use products	Lubricants <sup>d</sup>	( <u>ACC HPP, 2023; U.S. EPA,</u> <u>2019a</u> , <u>c</u> )	(ACC HPP, 2023; U.S. EPA, 2019a, c)
	Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants) $^{d}$	( <u>U.S. EPA, 2019a, c</u> )	( <u>U.S. EPA, 2020a, 2019a, c</u> )
Consumer Uses		Building/construction materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles (wire or wiring systems; joint treatment) <sup>d</sup>	( <u>U.S. EPA, 2019c</u> )	(U.S. EPA, 2019c)
		Electrical and electronic products <sup>d, e</sup>	( <u>U.S. EPA, 2019c</u> )	( <u>U.S. EPA, 2019a, c</u> )
		Paints and coatings <sup>d</sup>	( <u>U.S. EPA, 2019a</u> )	( <u>U.S. EPA, 2019a</u> )
	Furnishing, cleaning, treatment/care products	Fabrics, textiles, and apparel (as plasticizer)	( <u>ACC HPP, 2023</u> )	(ACC HPP, 2023; U.S. EPA, 2020a)
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials (crafting paint applied to craft)		( <u>U.S. EPA, 2020a, 2019a</u> )
		Ink, toner, and colorant products <sup>d</sup>	( <u>ACC HPP, 2023; ACC,</u> 2020b; <u>U.S. EPA, 2019c</u> )	(ACC HPP, 2023; ACC, 2020b; U.S. EPA, 2019c)

Life Cycle Stage <sup>a</sup>	Category <sup>b</sup>	Subcategory <sup>c</sup>	Reference(s) (CASRN 26761-40-0)	Reference(s) (CASRN 68515-49-1)
Consumer Uses		PVC film and sheet	( <u>ACC, 2020b</u> )	( <u>ACC, 2020b</u> )
		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses) <sup><math>d</math></sup>	( <u>ACC HPP, 2023; ACC,</u> 2020b; <u>U.S. EPA, 2019c</u> )	( <u>ACC HPP, 2023;</u> <u>U.S. EPA,</u> <u>2019a</u> , <u>c</u> )
		Toys, playgrounds, and sporting equipment <sup><math>d</math></sup>	(ACC HPP, 2023; U.S. EPA, 2019c)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a, c)
	Other uses	Automotive articles	(ACC, 2020b; U.S. EPA, 2019c)	(ACC, 2020b; U.S. EPA, 2019c)
		Novelty articles	( <u>Sipe et al., 2023; Stabile,</u> <u>2013</u> )	( <u>Sipe et al., 2023; Stabile,</u> 2013)
Disposal	Disposal	Disposal		

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

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

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

- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets
  the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.

<sup>b</sup> 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.

<sup>c</sup> These subcategories reflect more specific conditions of use of DIDP.

<sup>*d*</sup> 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 risk evaluation.

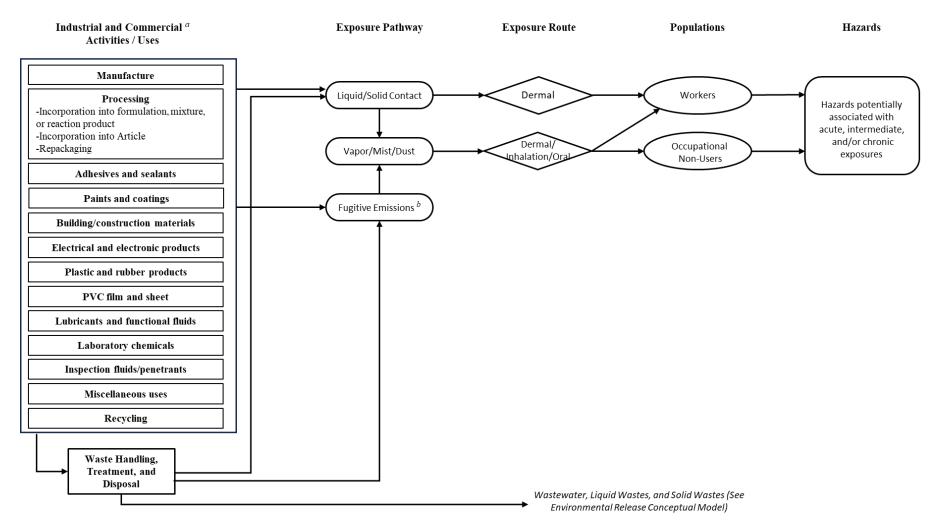
<sup>*e*</sup> New CDR reporting codes of machinery, mechanical appliances, electrical/electronic articles and other machinery, mechanical appliances, electronic/electronic/electronic articles are represented under the electrical and electronic products reporting code, so for commercial and consumer uses these conditions

of use are combined.

#### 1.1.2.1 Conceptual Models

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.



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

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

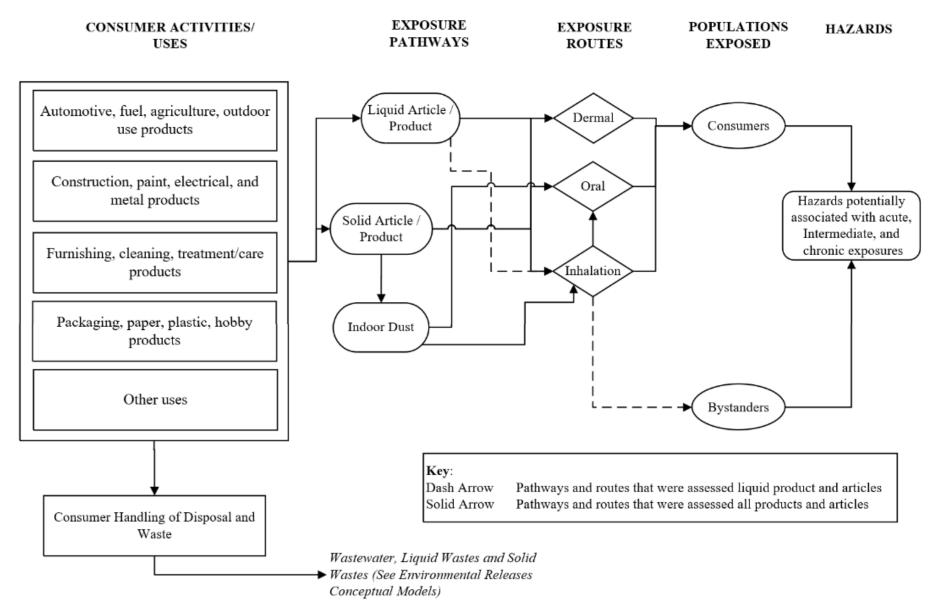
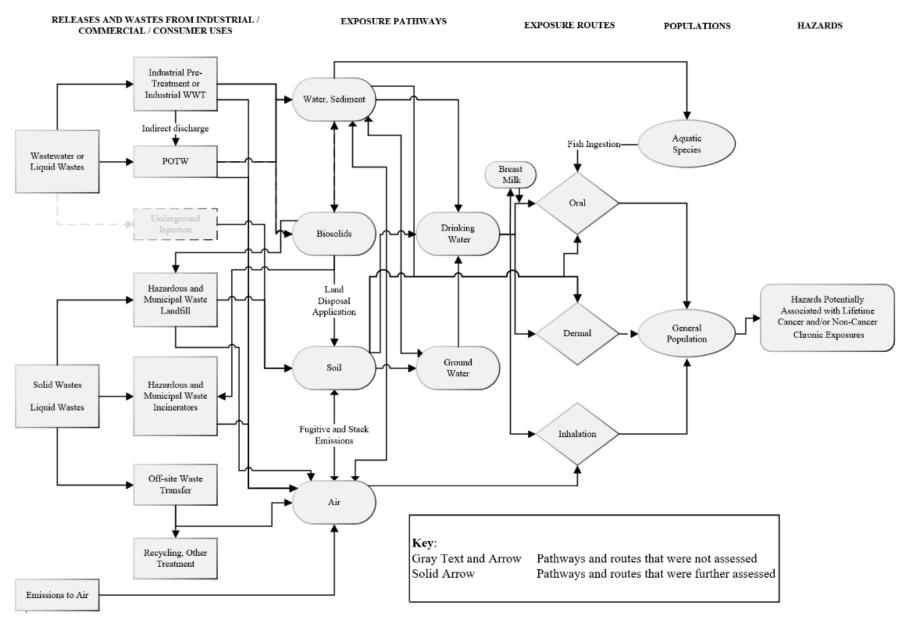


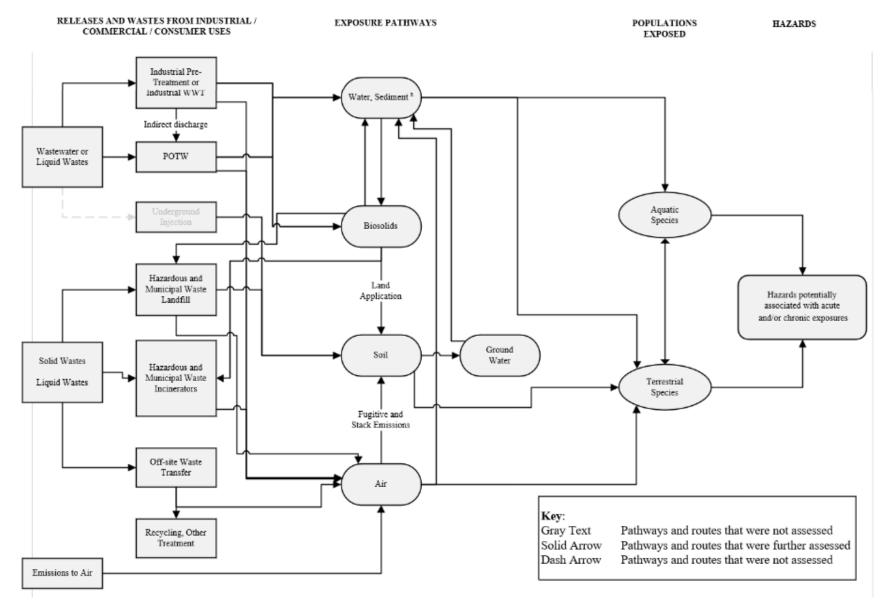
Figure 1-6. DIDP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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



#### 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.



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

#### 1.1.3 Populations and Durations of Exposure Assessed

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

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

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

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

Section 4.3.4 summarizes how PESS were incorporated into the risk evaluation through consideration of potentially increased exposures and/or potentially increased biological susceptibility and summarizes additional sources of uncertainty related to consideration of PESS.

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

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

- Section 2 summarizes basic physical-chemical characteristics as well as the fate and transport of DIDP.
- Section 3 includes an overview of releases and concentrations of DIDP in the environment.
- 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 this 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 this 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 risk evaluation.
- Appendix B provides a brief summary of the federal, state, and international regulatory history of DIDP.
- Appendix C incudes a list and citations for all technical support documents and supplemental files included in the risk evaluation for DIDP.
- Appendix D provides a summary of updates made to COUs for DIDP from the final scope document to this risk evaluation.
- Appendix E provides descriptions of the DIDP COUs evaluated by EPA.
- Appendix F provides the occupational exposure value for DIDP that was derived by EPA.

## 2 CHEMISTRY AND FATE AND TRANSPORT OF DIDP

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

Sections 2.1 and 2.2 summarize the physical and chemical properties, and environmental fate and transport of DIDP, respectively. EPA's *Physical Chemistry Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024w) and *Fate and Transport Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024w) provide further details.

## 2.1 Summary of Physical and Chemical Properties

EPA gathered and evaluated physical and chemical property data and information according to process described in the *Systematic Review Protocol for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024ab). During the evaluation of DIDP, EPA considered both measured and estimated physical and chemical property data/information summarized in Table 2-1, as applicable. Information on the full, extracted dataset is available in the *Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024i).

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

#### Table 2-1. Physical and Chemical Properties of DIDP

## 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<sub>OC</sub>)—are parameters used in the current 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 *Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024g). Other fate estimates were based on modeling results from EPI Suite<sup>TM</sup> (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 *Fate and Transport Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024t).

EPA evaluated the reasonably available information to characterize the environmental fate and transport of DIDP, the key points of the fate assessment for DIDP (<u>U.S. EPA, 2024t</u>) 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  $(t_{1/2} = 0.32 \text{ days})$ .
- 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.

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

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

## 3 RELEASES AND CONCENTRATIONS OF DIDP IN THE ENVIRONMENT

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

### 3.1 Approach and Methodology

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

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

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

#### 3.1.1.1 Crosswalk of Conditions of Use to Occupational Exposure Scenarios

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

Life Cycle Stage	Category	Subcategory	OES	
Manufacturing	Domestic manufacturing	Domestic manufacturing	Manufacturing	
	Importing	Importing	Import and repackaging	
	Repackaging	Repackaging	Import and repackaging	
		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	
	Incorporation into formulation,	Surface modifier in paint and coating manufacturing	Incorporation into paints and coatings	
	mixture, or reaction product	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		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	
		Abrasives manufacturing	Application of adhesives and sealants	
	Incorporation into articles	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	

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

Life Cycle Stage	Category	Subcategory	OES	
	Recycling	Recycling	Recycling	
Disposal	Disposal	Disposal	Disposal	
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution in commerce	
	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	
Industrial uses	Construction, paint, electrical, and metal products	Paints and coatings	Application of paints and coatings	
	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	
	Automotive, fuel, agriculture, outdoor use products	Lubricants	Use of lubricants and functional fluids	
		Adhesives and sealants (including plasticizers in adhesives and sealants)	Application of adhesives and sealants	
Commercial	Construction, paint,	Building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation)	Fabrication or use of final products or articles	
uses	electrical, and metal	Electrical and electronic products	Fabrication or use of final products or articles	
	products	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	
	Furnishing, cleaning,	Furniture and furnishings	Fabrication or use of final products or articles	
	treatment/care products	Construction and building materials covering large surface areas including stone,	Fabrication or use of final products or articles	

Life Cycle Stage	Category	Subcategory	OES
		plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (as plasticizer) (floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats))	
		Ink, toner, and colorant products	Application of paints and coatings
	Packaging, paper, plastic, hobby products	PVC film and sheet	Fabrication or use of final products or articles
Commercial uses		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
		Automotive articles	Fabrication or use of final products or articles
		Inspection fluid/penetrant	Use of inspection fluid and penetrant

#### **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
	Description	or the	0.50 01		IOI Luch	

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.

OES	Use of DIDP
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.
Use of lubricants and functional fluids	DIDP is incorporated into lubricants and functional fluids for air compressors and found in functional fluids 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 products or 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 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.

#### **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 (	Inerating Days net	r Year for Each OES
Lable 5-5. Estimates	or runnoer or c	perading Days per	

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 Chemical Repackaging GS 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>Environmental Release and</i> <i>Occupational Exposure Assessment for DIDP</i> (U.S. EPA,

OES	Operating Days (days/year)	Basis
		2024s)) 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	223–254	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>Environmental Release and Occupational Exposure</i> <i>Assessment for DIDP</i> (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021e, 2014c).
PVC plastics converting	219–251	The 2004 Additives in Plastic Processing (Converting into Finished Products) GS estimated the number of operating days as 137–254 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Environmental Release and Occupational Exposure</i> <i>Assessment for DIDP</i> (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2004a).
Non-PVC material compounding	234–280	The 2014 Plastic Compounding GS, 2021 Plastic Compounding Revised GS, and the 2020 <i>SpERC</i> <i>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>Environmental Release and</i> <i>Occupational Exposure Assessment for DIDP</i> (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 234–280 days/year (U.S. EPA, 2021e; ESIG, 2020b; U.S. EPA, 2014c)
Non-PVC material converting	219–251	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 137–254 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see <i>Environmental Release and</i> <i>Occupational Exposure Assessment for DIDP</i> (U.S. EPA,

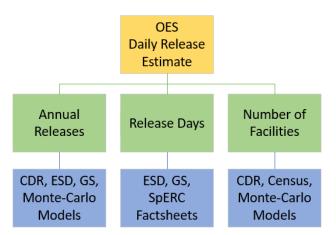
OES	Operating Days (days/year)	Basis
		2024s)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2004a).
Application of adhesives and sealants	232–325	Based on several end use products categories, the 2015 ESD on the Use of Adhesives estimated the total number of operating days as 50–365 days/year. Release estimates that EPA assessed using Monte Carlo modeling ( <i>Environmental Release and Occupational Exposure</i> <i>Assessment for DIDP</i> (U.S. EPA, 2024s) Appendix E.9.2) used a 50th to 95th percentile range of 232–325 days/year (OECD, 2015b).
Application of paints and coatings	257–287	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</i> <i>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>Environmental Release and Occupational</i> <i>Exposure Assessment for DIDP</i> (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 257–287 days/year (ESIG, 2020a; OECD, 2011a, b; U.S. EPA, 2004c).
Use of laboratory chemicals	Liquid: 235– 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>Environmental Release and Occupational Exposure Assessment for DIDP</i> (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 235–258 days/year (U.S. EPA, 2023f).
Use of lubricants and functional fluids	2–4	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>Environmental Release and</i> <i>Occupational Exposure Assessment for DIDP</i> (U.S. EPA, <u>2024s</u> )) used a 50th to 95th percentile range of 2–4 days/year (OECD, 2004b).
Use of penetrants and inspection fluids	247–249	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.

OES	Operating Days (days/year)	Basis
		Release estimates that EPA assessed using Monte Carlo modeling (see <i>Environmental Release and Occupational</i> <i>Exposure Assessment for DIDP</i> (U.S. EPA, 2024s)) estimated a 50th to 95th percentile range of 247–249 days/year (OECD, 2011c).
Recycling and disposal	223–254	<ul> <li>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>Environmental Release</i> <i>and Occupational Exposure Assessment for DIDP</i> (U.S. <u>EPA, 2024s</u>)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021e, 2014c).</li> <li>EPA evaluated disposal releases within the assessments for each OES. EPA provided operating days for individual OES in this table.</li> </ul>
Fabrication and final use of products or articles	N/A	EPA assumed year-round site operation, considering a 2- week downtime, totaling 250 days/year. However, EPA was not able to perform a quantitative release assessment for this OES, because the release parameters were unknown and unquantifiable.

#### 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 *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) 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, the Agency assumed that releases occur to water, air, or disposal to land.



**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

#### 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 *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, 2024r). Based on the low water solubility and log K<sub>OW</sub>, 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 matter, settling, and physical removal. Once products/articles are disposed in landfills there is potential for migration to soils and water. Although there are limited measured data on DIDP in landfill leachates, the data suggest that DIDP is unlikely to be present in landfill leachates. Further, the small amounts of DIDP that could potentially be in landfill leachates will have limited mobility and are unlikely to infiltrate groundwater due to high affinity of DIDP for organic compounds that would be present in receiving soil and sediment (U.S. EPA, 2024r).

## **3.2 Summary of Environmental Releases**

### 3.2.1 Manufacturing, Processing, Industrial and Commercial

EPA combined its estimates for total production volume, release days, number of facilities, and hours of release per day to estimate a range for daily releases for each OES. A summary of these ranges across facilities is presented in Table 3-4. See the *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) for additional detail on deriving the

overall confidence score for each OES. For the Fabrication and final use of products or articles OES EPA was not able to estimate release.

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, <sup><i>a</i></sup> Air Emission, <sup><i>b</i></sup> or	Estimated Release Frequency across Sites (days) <sup>d</sup>		Number of	Weight of Scientific	Sources
	Central Tendency	High-End	Transfer for Disposal <sup>c</sup>	Central Tendency	High- End	<b>Facilities</b> <sup>e</sup>	Evidence Rating <sup>f</sup>	
	2.56E-07	8.52E-07	Fugitive Air					
	1.14E	E-01	Stack Air					
	1.05E-01	1.89E-01	Wastewater to Onsite treatment or Discharge to POTW	- 180		1 – Troy Chemical Corp., Phoenix, AZ	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	2.70	2.84	Onsite Wastewater Treatment, Incineration, or Landfill					
Manufacturing	1.30	2.25	Landfill					
in an	4.24E-06	7.47E-06	Fugitive Air				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	100				
	4.69E03	8.14E03	Onsite Wastewater	180		3 generic sites		
			Treatment, Incineration, or Landfill					
	8.69	E02	Landfill					

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

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, Air Emission, Transfer forEstimated Release Frequency across Sites (days) d		Number of Facilities <sup>e</sup>	Weight of Scientific	Sources	
	Central Tendency	High-End	<b>Disposal</b> <sup>c</sup>	Central Tendency	High- End	racinues	Evidence Rating <sup>f</sup>	
	3.29E01	1.45E02	Fugitive or Stack Air					
	4.29E02	6.80E02	Wastewater,					
DVC plastics			Incineration, or Landfill			08 105 comorio		CDD Deer reviewed
PVC plastics compounding	1.09E02	1.64E02	Wastewater	223	254	98–195 generic sites	Moderate	CDR, Peer-reviewed
compounding	8.29E01	2.73E02	Fugitive air, Wastewater,			sites		literature (GS/ESD)
	2.21E01	1.11E02	Incineration, or landfill Incineration or Landfill					
	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,					
		2.55101	Incineration, or Landfill					
PVC plastics	5.14	7.84	Wastewater					
converting	3.94	1.30E01	Fugitive air, Wastewater, Incineration, or Landfill					
	1.43E01	2.28E01	Incineration or Landfill					
	4.39E01	1.44E02	Fugitive or Stack Air					
Non-PVC	9.07E02	1.66E03	Wastewater, Incineration, or Landfill					
material	8.25E01	1.07E02	Wastewater	234	280	4–9 generic sites	Moderate	CDR, Peer-reviewed
compounding	3.80	1.27E01	Fugitive Air, Wastewater, Incineration, or Landfill		200		Noderate	literature (GS/ESD)
	6.35E01	1.87E02	Incineration or Landfill					

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

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, <sup>a</sup> Air Emission, <sup>b</sup> or Transfer for	Estimated Release Frequency across Sites (days) <sup>d</sup>		Number of Facilities <sup>e</sup>	Weight of Scientific	Sources
	Central Tendency	High-End	Disposal <sup>c</sup>	Central Tendency	High- End	racinues	Evidence Rating <sup>f</sup>	
Application of paints and coatings with overspray controls [No overspray controls]	2.62E-09 [2.62E-09] 6.34E-01 [6.32] 6.29 [5.58E-01]	6.90E-09 [6.87E-09] 2.04 [2.04E01] 1.98E01 [1.55]	Fugitive Air Stack Air [Unknown] Wastewater, Incineration, or Landfill	257	287	222–1,242 generic sites [223-1,226 generic sites]	Moderate	CDR, Peer-reviewed literature (GS/ESD)
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
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	literature (GS/ESD)
Use of lubricants and functional fluids	7.29E01 3.21E01 1.19 2.64E01	2.69E02 1.30E02 6.31 1.40E02	Wastewater Landfill Recycling Fuel Blending (Incineration)	2	4	2,596–18,387 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
Use of penetrants and inspection fluids	3.68E-03 2.14E-02 2.46E-09 2.50E-02	4.80E-3 2.77E-02 4.57E-09 3.25E-02	Fugitive Air Wastewater, Incineration, or Landfill Fugitive Air Wastewater, Incineration, or Landfill	247	249	15,315–21,892 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge, <sup>a</sup> Air Emission, <sup>b</sup> or Transfer for	Estimated Release Frequency across Sites $(days)^d$		Number of	Weight of Scientific	Sources
	Central Tendency	High-End	Disposal <sup>c</sup>	Central Tendency	High- End	<b>Facilities</b> <sup>e</sup>	Evidence Rating <sup>f</sup>	
Recycling	2.33E-02	4.68E-01	Stack Air		254		Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.84	3.36	Fugitive Air, Wastewater, Incineration, or Landfill	223		58 generic sites		CDR, Peer-reviewed literature (GS/ESD)
	7.80E-01	1.70	Wastewater					CDR, Peer-reviewed literature (GS/ESD)
<sup>b</sup> Emissions via f <sup>c</sup> Transfer to surf <sup>d</sup> Where availabl	ugitive air or sta face impoundme e, EPA used ind	ack air, or trea ent, land applic lustry provided	charge to non-POTW; ind tment via incineration cation, or landfills l information, ESDs, or GS	Ss to estimate	the numb	er of release days for		· · · · · · · · · · · · · · · · · · ·
where available				Jounty Dusine	55 FTACUC	es ( <u>U.S. Cellsus Dul</u>	<u>cau, 2022</u> ), and Monte	

number of sites that use DIDP for each condition of use. <sup>*f*</sup> See Section 3.2.2 for details on EPA's determination of the weight of scientific evidence rating.

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

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

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

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

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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	EPA found limited chemical specific data for the manufacturing OES and assessed environmental releases using models and model parameters derived from CDR, the <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. 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
	<ul><li>limitations include uncertainties in the representativeness of the industry-provided operating parameters and the generic EPA/OPPT models for all DIDP manufacturing sites.</li><li>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.</li></ul>
Import and repackaging	EPA found limited chemical specific data for the import and repackaging OES and assessed releases to the environment using the assumptions and values from the Chemical Repackaging GS, which the systematic review process rated high for data quality (U.S. EPA, 2022). EPA also referenced the 2023 Methodology for Estimating Environmental Releases from Sampling Wastes (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.
	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.
	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.

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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
Incorporation into adhesives and sealants	EPA found limited chemical specific data for the incorporation into adhesives and sealants OES and assessed releases to the environment using the ESD on the Formulation of Adhesives, 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 (2020a) and referenced the 2003 <i>EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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.
Incorporation into paints and coatings	plausible estimate of releases, considering the strengths and limitations of the reasonably available data.EPA found limited chemical specific data for the incorporation into paints and coatings OES and assessed releases to the environment using the Draft GS for the Formulation of Waterborne Coatings, 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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	EPA found limited chemical specific data for the incorporation into other formulations, mixtures, and reaction products not covered elsewhere OES and assessed releases to the environment using the Draft GS for the Formulation of Waterborne Coatings, 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 (2020a) and referenced the <i>2003 EU Risk Assessment Report</i> (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
PVC plastics compounding	EPA found limited chemical specific data for the PVC plastics compounding OES and assessed releases to the environment using the Revised Draft GS for the Use of Additives in Plastic Compounding, 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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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-

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
PVC plastics converting	EPA found limited chemical specific data for the PVC plastics converting OES and assessed releases to the environment using the <i>Revised</i> Draft GS on the Use of Additives in the Thermoplastics Converting Industry, which has a medium data quality rating based on systematic review (U.S. EPA, 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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Non-PVC material compounding	EPA found limited chemical specific data for the non-PVC material compounding OES and assessed releases to the environment using the Revised Draft GS for the Use of Additives in Plastic Compounding and the ESD on Additives in the Rubber Industry. 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.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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>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.
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Non-PVC material converting	EPA found limited chemical specific data for the non-PVC material converting OES and assessed releases to the environment using the Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry and the ESD on Additives in the Rubber Industry. 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.
	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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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>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.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of the reasonably available data.
Application of adhesives and sealants	EPA found limited chemical specific data for the application of adhesives and sealants OES and assessed releases to the environment using the ESD on the Use of Adhesives, 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 (2020a), which references the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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.
Application of paints and coatings	plausible estimate of releases, considering the strengths and limitations of reasonably available data.EPA found limited chemical specific data for the application of paints and coatings OES and assessed releases to the environment using the ESD on the Application of Radiation Curable Coatings, Inks and Adhesives, the GS on Coating Application via Spray Painting in the Automotive Refinishing Industry, the GS on Spray Coatings in the Furniture Industry. 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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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-

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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.
	plausible estimate of releases, considering the strengths and limitations of reasonably available data
Use of laboratory chemicals	EPA found limited chemical specific data for the use of laboratory chemicals OES and assessed releases to the environment using the Draft GS on the Use of Laboratory Chemicals, which has a high data quality rating based on systematic review ( <u>U.S. EPA, 2023f</u> ). 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.
	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. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases, considering the strengths and limitations of reasonably available data.
Use of lubricants and functional fluids	EPA found limited chemical specific data for the use of lubricants and functional fluids OES and assessed releases to the environment using the ESD on the Lubricant and Lubricant Additives, 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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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.
	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.
Use of penetrants and inspection fluids	EPA found limited chemical specific data for the use of penetrants and inspection fluids OES and assessed releases to the environment using the ESD on the Use of Metalworking Fluids, 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 diisononyl phthalate (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 (2020a) and referenced the 2003 EU Risk Assessment Report (ECJRC, 2003a) for the expected U.S. DIDP use rates per use scenario.
	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.
Fabrication and final use of products or articles	No data were available to estimate releases for this OES and there were no suitable surrogate release data or models. This release is described qualitatively.
Recycling and disposal	EPA found limited chemical specific data for the recycling and disposal OES. EPA assessed releases to the environment from recycling activities using the Revised Draft GS for the Use of Additives in Plastic Compounding 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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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.
	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.
	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.

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

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

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

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

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

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

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

to landfills. Environmental media concentrations were quantified in ambient air, soil from ambient air deposition, surface water, and sediment. Additional analysis of surface water used as drinking water was conducted for the Human Health Risk Assessment (Section 4.1.3). Given the physical chemical properties and fate parameters of DIDP (Section 2), concentrations of DIDP in soil and groundwater from releases to biosolids and landfills were not quantified. Instead, DIDP in soil and groundwater are discussed qualitatively. EPA relied on its fate assessment to determine which environmental pathways to consider for its screening level analysis of environmental exposure and general population exposure. Details on the environmental partitioning and media assessment can be found in Fate and Transport Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024t) and its use for determining pathways to assess are detailed in Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024r). Briefly, based on DIDP's fate parameters, EPA anticipated DIDP to be expected predominantly in water, soil, and sediment, with DIDP in soils attributable to air to soil deposition and land application of biosolids. Therefore, EPA quantitatively assessed concentrations of DIDP in surface water, sediment, and soil from air to soil deposition. Ambient air concentrations were quantified for the purpose of estimating soil concentrations from air to soil deposition but was not used for the exposure assessment as DIDP was not assumed to be persistent in the air ( $t_{1/2} = 7.6$  hours (Mackay et al., 2006)) and partitioning analysis showed DIDP partitions primarily to soil, compared to air, water, and sediment, even in air releases. Soil concentration of DIDP from land applications and resulting concentrations in groundwater were not quantitatively assessed in the screening level analysis as DIDP was expected to have limited persistence potential and mobility in soils receiving biosolids.

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

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

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

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

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

OES <sup>a</sup>	Release Media	Environmental Media	DIDP Concentration	Environmental or General Population				
		Total Water Column (7Q10)	7,460 µg/L	Environmental				
	Water	Benthic Pore Water (7Q10)	4,760 μg/L	Environmental				
PVC plastics compounding		Benthic Sediment (7Q10)	27,600 mg/kg	Environmental				
compounding	Fugitive	Soil (Air to Soil Deposition 100 m)	1,850 µg/kg	General Population				
	Air	Soil (Air to Soil Deposition 1,000 m)	13 µg/kg	Environmental				
Use of	XX - 4 - 1	Surface Water (30Q5)	9,110 μg/L	General Population				
lubricants and functional fluids	Water	Surface Water (Harmonic Mean)	7,450 μg/L	General Population				
<sup><i>a</i></sup> Table 3-1 provides the crosswalk of OES to COUs.								

#### 3.3.1 Weight of Scientific Evidence Conclusion

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

#### 3.3.1.1 Surface Water

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 citing NHDPlus V2.1 reach codes for receiving waterbodies. From the distributions of flow statistics reported, the median receiving waterbody represented a stream with minimal flow, dominated by the effluent from the facility, while the lower end of the distribution represented a stream with essentially no flow beyond the facility effluent, as described in EPA's *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024r). As there was little variation between the minimum and median stream conditions, the median flow rates selected from the generated distributions represented conservative low flow rates from the distributions of 7Q10, 30Q5, and harmonic mean flows. When coupled with high-end release scenarios, these low flow rates result in high modeled instream concentrations. EPA has slight confidence in the modeled concentrations as being

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

#### 3.3.1.2 Ambient Air – Air to Soil Deposition

Similar to the surface water analysis, due to the lack of release data, releases were modeled using generic scenarios and the high-end estimates for each COU was applied for ambient air modeling. With moderate confidence in the release data detailed in *Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) and conservative assumptions used for modeled air dispersion and particle distribution inputs, EPA has slight confidence in the air and deposition concentrations modeled based on EPA estimated releases being representative of actual releases, but for the purposed of a risk screening level assessment, *EPA has robust confidence that its modeled releases 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 4.1. Human health hazards are described in Section 4.2. Human health risk characterization is described in Section 4.3.

#### Exposure Key Points

- EPA assessed inhalation and dermal exposures for workers and ONUs, as appropriate, for each 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 in scenarios that represent a range of use patterns and behaviors (Section 4.1.2). 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 ingestion (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 rodents 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, adult males) is conservative.
- EPA reviewed the weight of evidence for the carcinogenicity of DIDP and determined that DIDP is *Not Likely to be Carcinogenic to Humans*. The Agency 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 risk evaluation (Section 4.3.4).

## 4.1 Summary of Human Exposures

#### 4.1.1 Occupational Exposures

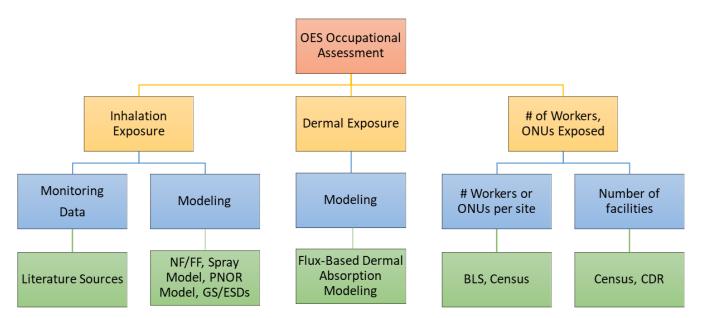
The following subsections briefly describe EPA's approach to assessing occupational exposures and provide exposure assessment results for each OES. As stated in the *Final Scope of the Risk Evaluation for Di-isodecyl phthalate (DIDP)* (U.S. EPA, 2021b), The Agency evaluated exposures to workers and ONUs 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 *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) provides additional details on the development of approaches and the exposure assessment results (see also Figure 4-1).

#### 4.1.1.1 Approach and Methodology

As described in the Final Scope Document (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. The Agency identified relevant inhalation exposure monitoring data for some 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 (U.S. EPA, 2021a). The Agency 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. The Agency considered the assessment approach, the quality of the data and models, as well as 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, the Agency 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, the Agency 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 *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s).



**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, the Agency 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, the Agency 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, the Agency 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 the Agency's overall confidence rating and whether EPA used modeling to estimate inhalation and dermal exposures for workers.

		Inhalation Exposure										Dermal Exposure			
OES	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 <sup><i>a</i></sup>	~	2 <sup><i>a</i></sup>	Medium	×	×	Moderate	Moderate	~	×	Moderate	N/A		
Incorporation into adhesives and sealants	√	2 <sup><i>a</i></sup>	~	2 <sup>a</sup>	High	×	×	Moderate	Moderate	~	×	Moderate	N/A		
Incorporation into paints and coatings	~	2 <sup>a</sup>	~	2 <sup><i>a</i></sup>	High	×	×	Moderate	Moderate	~	×	Moderate	N/A		
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	1	2 ª	✓	2 <sup>a</sup>	High	×	×	Moderate	Moderate	~	×	Moderate	N/A		
PVC plastics compounding	~	1 <sup>b</sup>	~	1 <sup>b</sup>	High	~	~	Moderate	Moderate	~	~	Moderate	Moderate		
PVC plastics converting	~	1	~	1	High	~	~	Moderate	Moderate	~	~	Moderate	Moderate		
Non-PVC material compounding	~	1 <sup>b</sup>	~	1 <sup>b</sup>	High	~	~	Moderate	Moderate	~	~	Moderate	Moderate		
Non-PVC material converting	~	1 <sup>b</sup>	~	1 <sup>b</sup>	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 <sup>a</sup>	~	2 <sup><i>a</i></sup>	Medium	~	~	Moderate	Moderate	~	~	Moderate	Moderate		
Use of lubricants and functional fluids	~	2 <sup><i>a</i></sup>	~	2 <sup><i>a</i></sup>	Medium	×	×	Moderate	Moderate	~	×	Moderate	N/A		

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

		Inhalation Exposure									Dermal Exposure			
OES	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	x	N/A	N/A	~	1	Moderate	Moderate	~	~	Moderate	Moderate	
Recycling and disposal	×	N/A	×	N/A	N/A	~	~	Moderate	Moderate	~	~	Moderate	Moderate	
<sup>a</sup> 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. <sup>b</sup> 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.														

#### 4.1.1.2 Summary of Number of Workers and ONUs

The Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024s) 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 *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) 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 OESs. 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.

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>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Import/ repackaging	151	41	11	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Incorporation into adhesives and sealants	108–903	41–338	6–50	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Incorporation into paints and coatings	91–576	27–170	6–38	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	51–102	24–48	1–2	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
PVC plastics compounding	1,798–3,578	509-1,012	98–195	Number of workers and ONU estimates based on data from the BLS and the U.S.

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

OES	Total Exposed Workers	Total Exposed ONUs	Number of Facilities	Notes
				Census' SUSB ( <u>U.S. BLS, 2016; U.S.</u> Census Bureau, 2015)
PVC plastics converting	39,044–77,739	11,049–22,000	2,128–4,237	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016; U.S.</u> <u>Census Bureau, 2015</u> )
Non-PVC material compounding	90–203	24–54	4–9	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Non-PVC material converting	4,016–4,783	1,068–1,272	178–212	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Application of adhesives and sealants	4,523–56,857	1,433–18,012	84–1,056	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016; U.S.</u> <u>Census Bureau, 2015</u> )
Application of paints and coatings	2,615–14,631	1,140–6,375	222–1,242	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016; U.S.</u> <u>Census Bureau, 2015</u> )
Use of laboratory chemicals (liquid)	223–2,075	1,964–18,290	225–2,095	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
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>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Use of lubricants and functional fluids	228,779– 1,620,403	56,176– 397,887	2,596– 18,387	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
Use of penetrants and inspection fluids	203,772– 291,282	85,651– 122,433	15,315– 21,892	Number of workers and ONU estimates based on data from the BLS and the U.S. Census' SUSB ( <u>U.S. BLS, 2016</u> ; <u>U.S.</u> <u>Census Bureau, 2015</u> )
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>U.S. BLS, 2016; U.S.</u> <u>Census Bureau, 2015</u> )

OES	Total Exposed Workers	Total ExposedNumberONUsFacilitie		Notes			
<sup><i>a</i></sup> 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>Environmental Release and Occupational Exposure</i>							

#### 4.1.1.3 Summary of Inhalation Exposure Assessment

Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024s).

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 *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) provides exposure results for females of reproductive age and ONUs. The *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) also provides additional details regarding AD, IADD, and ADD calculations along with EPA's approach and methodology for estimating inhalation exposures.

	Inhalation Estimates (Average Adult Worker)									
OES	Vapor/Mist 8-h TWA (mg/m <sup>3</sup> )			PNOR 8-h TWA (mg/m <sup>3</sup> )		AD xg/day)		ADD (g/day)		DD g/day)
	HE	СТ	HE	СТ	HE	СТ	HE	СТ	HE	СТ
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-0 3
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 – spray application	22	0.14	N/A	N/A	2.8	1.7E-02	2.0	1.2E-02	1.9	1.1E-02
Application of adhesives and sealants – non- spray application	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

Table 4-3. Summary of Average Adult Worker Inhalation Exposure Results for Ea	ch OES

			In	halation	Estimates	(Average	Adult Wo	rker)		
OES	Vapor/Mist 8-h I TWA (mg/m <sup>3</sup> )			PNOR 8-h TWA (mg/m <sup>3</sup> )		AD (mg/kg/day)		ADD xg/day)	ADD (mg/kg/day)	
	HE	СТ	HE	СТ	HE	СТ	HE	СТ	HE	СТ
Application of paints and coatings – spray application	2.2	0.14	N/A	N/A	0.28	1.7E-02	0.20	1.2E-02	0.19	1.2E-02
Application of paints and coatings – non-spray application	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	3.1E-03
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-02	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
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 AD, the IADD, and the ADD. The *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) provides exposure results for females of reproductive age and ONUs. The *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s) also provides additional details regarding AD, IADD, and ADD calculations along with EPA's approach and methodology for estimating dermal exposures.

			]	Dermal E	stimates (	Average A	Adult Wo	rker)		
OES	Exposure Type		APDR (mg/day)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	Liquid	Solid	HE	СТ	HE	СТ	HE	СТ	HE	СТ
Manufacturing	Х		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	Х		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02

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

	Dermal Estimates (Average Adult Worker)										
OES	Exposure Type			APDR (mg/day)		AD (mg/kg/day)		IADD (mg/kg/day)		DD g/day)	
	Liquid	Solid	HE	СТ	HE	СТ	HE	СТ	HE	СТ	
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	Х		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	Х	Х	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		Х	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	Х	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 – spray & non-spray application	Х		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 – spray & non- spray application	Х		7.3	3.7	9.2E-02	4.6E-02	6.7E-02	3.4E-02	6.3E-02	3.1E-02	
Use of laboratory chemicals – liquid	Х		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		Х	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	Х		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	Х		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		Х	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		Х	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 (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 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 (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.

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
Manufacturing	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the full-shift TWA inhalation exposure estimates for the Manufacturing OES. The primary strength is the use of directly applicable monitoring data, which are preferrable to other assessment approaches such as modeling or the use of OELs. EPA used personal breathing zone (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.
	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.
	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.
Import and repackaging	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 preferrable 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.
	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. Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into adhesives and sealants	EPA 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 preferrable to other assessment approaches such as modeling or the use of OELs. EPA used both PBZ and

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

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	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 di(2-propylheptyl) phthalate (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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into paints and coatings	EPA 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 preferrable 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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into other formulations, mixtures, and reaction products not	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 preferrable 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).

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
covered elsewhere	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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
PVC plastics compounding	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. 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 preferrable 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 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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
PVC plastics converting	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 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 preferrable 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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Non-PVC material compounding	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. 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 preferrable 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

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	data quality ( <u>OSHA, 2020</u> ). 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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Non-PVC material converting	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. 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 preferrable 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 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.
	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.

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Application of adhesives and sealants	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. For inhalation exposure from spray application, EPA used surrogate monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry ( <u>OECD, 2011a</u> ), which the systematic review process rated high for data quality, to estimate inhalation exposures. For inhalation exposures from non-spray application, EPA estimated vapor inhalation exposures using monitoring data from a manufacturing facility that produces DIDP ( <u>ExxonMobil, 2022a</u> ). EPA used SDSs and product data sheets from identified DIDP-containing adhesive and sealant products to identify product concentrations.
	The primary limitation is the lack of DIDP-specific monitoring data for the application of adhesives and sealants. For the spray application scenario, data outlined in the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry is representative of the level of mist exposure that could be expected at a typical work site for the given spray application method, but the data are not specific to DIDP. For the non-spray application scenario, vapor exposure from volatilization is estimated using DIDP-specific data, but for a different scenario which imposes uncertainty. 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 232–250 days of exposure per year based on workers applying adhesives or sealants on every working day; however, application sites may use DIDP-containing coatings at much lower or variable frequencies. The exposure days represent the 50th to 95th percentile range of exposure days per year.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Application of paints and coatings	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. For inhalation exposure from spray application, EPA used surrogate monitoring data from the ESD on Coating Application Via Spray-Painting in the automotive refinishing industry ( <u>OECD</u> , <u>2011a</u> ), which the systematic review process rated high for data quality, to estimate inhalation exposures. For inhalation exposure from non-spray application, EPA estimated vapor inhalation exposures using monitoring data from a manufacturing facility that produces DIDP ( <u>ExxonMobil</u> , <u>2022a</u> ). EPA used SDSs and product data sheets from identified DIDP-containing paint and coating products to identify product concentrations.
	The primary limitation is the lack of DIDP-specific monitoring data for the application of paints and coatings. For the spray application scenario, data outlined in the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry is representative of the level of mist exposure that could be expected at a typical work site for the given spray application method, but the data are not specific to DIDP. For the non-spray application scenario, vapor exposure from volatilization is estimated using DIDP-specific data, but for a different scenario which imposes uncertainty. 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

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	depending on the job site. EPA assessed 250 days of exposure per year based on workers applying paints and coatings on every working day; however, application sites may use DIDP-containing coatings at much lower or variable frequencies.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Use of laboratory chemicals	EPA 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 preferrable 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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Use of lubricants and functional fluids	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 preferrable 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.
	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.

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Use of penetrants and inspection fluids	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. EPA 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. 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. 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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Fabrication and final use of products or articles	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. 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.
	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.
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
Recycling and disposal	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. 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.
	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.
	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.
Dermal – liquids	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.
	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 cm <sup>2</sup> ), or two hands ( <i>i.e.</i> , 1,070 cm <sup>2</sup> ), 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.
	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.

OES	Weight of Scientific Evidence Conclusion in Occupational Exposures
Dermal – solids	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>Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)</i> (U.S. EPA, 2024s). 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 the aqueous absorption of a saturated solution of DIDP serves as a reasonable upper bound for the potential dermal absorption of DIDP from solid matrices, and the modeling approach received a medium rating through EPA's systematic review process.
	For the 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 cm <sup>2</sup> ), or two hands ( <i>i.e.</i> , 1,070 cm <sup>2</sup> ), 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.
	For modeling potential dermal exposure levels from solids containing DIDP, EPA used the mean value of water solubility from available data. These data sources for water solubility all received high ratings through EPA's systematic review process. By using the mean value of water solubility from available data, rather than a water solubility value near the low-end of available data, EPA is providing a protective assessment for human health.
	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 protective but plausible estimate of occupational dermal exposures.

# 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, the Agency'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, the Agency'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 the Agency'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 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 *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (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 *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate* (*DIDP*) (U.S. EPA, 2024a) for details about the consumer modeling approaches, sources of data, model parameterization, and assumptions.

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

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

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

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

				Evaluated Routes						
						Ingestion				
Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Inhalation	Dermal	Dust (Air)	Dust (Surface)	Mouthing	Qualitative / Quantitative / None	
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 <sup>c</sup> small-scale nome repair and hobby activities. Direct contact during use; nhalation 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 <sup>c</sup> 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 <sup>c</sup> 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	
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	<b>√</b> a	~	√ a	√ a	×	Quantitative	

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

					Evaluated Routes				
					Ingestion				
Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Inhalation	Dermal	Dust (Air)	Dust (Surface)	Mouthing	Qualitative / Quantitative / None
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	~	<b>√</b> 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>⊁</b> 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) because similar use patterns are expected.	See lacquers and sealants (small and large projects)			Quantitative		
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>x</b> b	~	×	×	×	Quantitative

				Evaluated Routes						
		nsumer Use		Ingestion		n				
Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Inhalation	Dermal	Dust (Air)	Dust (Surface)	Mouthing	Qualitative / Quantitative / None	
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	~	<b>√</b> 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	
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	

				Evaluated Routes							
			Ingesti						Ingestio	n	
Consumer Use Category	Consumer Use Subcategory	Product/Article	Exposure Scenario and Route	Inhalation	Dermal	Dust (Air)	Dust (Surface)	Mouthing	Qualitative / Quantitative / None		
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	~	<b>√</b> a	✓ a	~	Quantitative		
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Children's toys (legacy)	by mouthing Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing		~	<b>√</b> a	√ a	~	Quantitative		
Other uses	Automotive articles	Products 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	×	~	×	×	×	Quantitative		
Other uses	Novelty products	Adult toys	Direct contact during use, ingestion by mouthing	<b>X</b> b	~	×	×	~	Quantitative		
Disposal	Disposal	Down the drain products and articles	Down the drain and releases to environmental media	×	×	×	×	×	Qualitative Discussion		

✓ Scenario is considered either qualitatively or quantitatively in this assessment.

 $\sqrt{a}$  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 age groups, and low possibility of dust on surface due to barriers or low surface area for dust ingestion.

Scenario was deemed unlikely based low volatility and small surface area and likely negligible gas and suspended particle phase concentration.

DIY <sup>c</sup> – Do-it-yourself

# Inhalation and Ingestion Exposure Routes Modeling Approaches

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

- weight fraction (articles and products),
- density (articles and products),
- duration of use (products),
- frequency of use for chronic, acute, and intermediate (products),
- product mass used (products),
- article surface area (articles),
- chemical migration rate to saliva (articles),
- area mouthed (articles), and
- use environment volume (articles and products).

Low, medium, and high scenarios correspond to the use of reported statistics, or single values usually an average, or range of maximum and minimum or when different values are reported for low, medium, and high, the corresponding statistics are maximum, calculated average from maximum and minimum, and minimum. Each input in the list was parameterized according to the article data found via systematic review, or provided by CEM if article specific parameters were not available, or an assumption based on article use descriptions by manufactures always leaning on the health protective values. For example, the chemical migration rate of DIDP was estimated based on data compiled in a review published by the Denmark Environmental Protection Agency (Danish EPA, 2016). DINP chemical migration rates were used as surrogates because such data was not readily available for DIDP. The physical and chemical characteristics of DIDP and DINP that affect chemical migration rates are similar, but the larger size, higher molecular weight, and lower solubility of DIDP as compared to DINP can be expected to result in a slower rate of migration through the polymer matrix of the article and less partitioning to saliva for DIDP is expected in comparison to DINP. Thus, using chemical migration rates for DINP to calculate the DIDP dose received during mouthing will provide a health protective estimate, and it would still be a reasonable DIDP exposure estimate. For all scenarios, the near-field modeling option was selected to account for a small personal breathing zone around the user during product use in which concentrations are higher, rather than employing a single well-mixed room. A near-field volume of 1 m<sup>3</sup> was selected.

### Dermal Exposure Routes Modeling Approaches

Dermal modeling was done outside of CEM. The use of the CEM model for dermal absorption, which relies on total concentration rather than aqueous saturation concentration, would greatly overestimate exposure to DIDP in liquid and solid products and articles. See *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a) and (U.S. EPA, 2024b) for more details. The dermal dose of DIDP associated with use of both liquid products and solid articles was calculated in a spreadsheet outside of CEM; see also *Consumer Exposure Analysis for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024b). For each product or article, high, medium, and low exposure scenarios were developed. Values for duration or dermal contact and area of exposed skin were determined based on reasonably expected use for each item. In addition, high, medium, and low estimates for dermal flux (liquid products) or absorption (solid products) were calculated and applied in the corresponding scenario. Key parameters for the dermal model are shown in Section 2.2 in (U.S. EPA, 2024a).

### 4.1.2.2 Modeling Dose Results by COU for Consumer and Indoor Dust

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

### Acute, Intermediate, and Chronic Dose Rate Results, Conclusions, and Data Patterns

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

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

In addition to assessing users of various lifestages EPA consider bystanders exposures to consumer products and articles where applicable. Bystanders are people that are not in direct use or application of the product but can be exposed to DIDP by proximity to the use of the product via inhalation of gas-phase emissions or suspended dust. All bystander scenarios were assessed for children under 10 years for products that are not targeted for the use of children under 10 and assessed as users for older than 11 years because the products can be used by children 11 and older. People older than 11 years can also be bystander scenarios would have lower risk estimates. Bystander scenarios and COUs include (1) Automotive, fuel, agriculture, outdoor use products; lubricants; auto transmission conditioner; (2) Construction, paint, electrical, and metal products; Adhesives and sealants); Construction adhesive for small scale projects, Construction sealant for large scale projects, and Epoxy floor patch; and (3) Construction, paint, electrical, and metal products; Adhesives and sealants, and Paints and Coatings; and Spray and non-spray lacquer sealer.

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

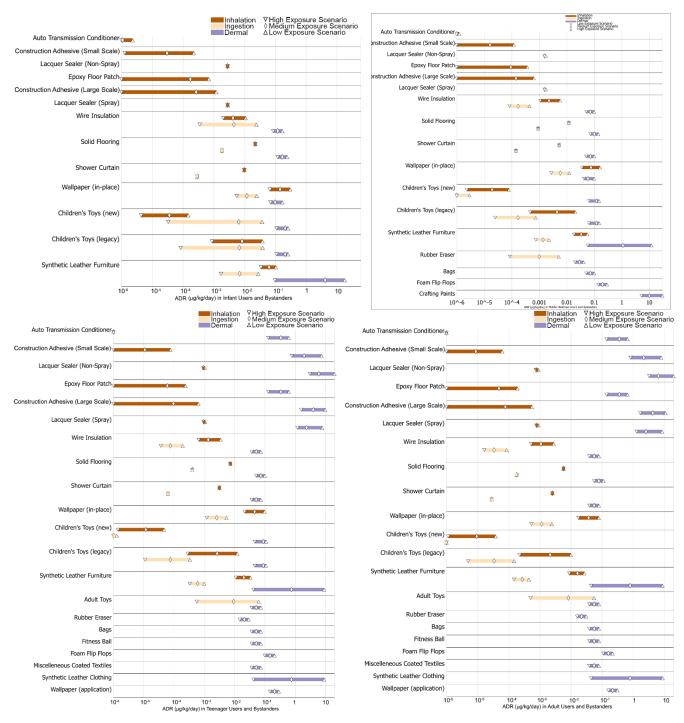
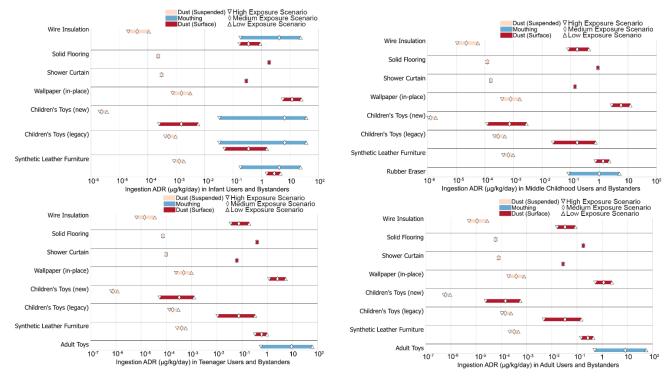


Figure 4-2. Acute Dose Rate for DIDP from Ingestion, Inhalation, Dermal Exposure Routes in Infant, Children, Teenagers and Young Adults, and Adults

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

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  $\mu$ m) particles in air as inhalation exposure,

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



### 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

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

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

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

# 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. Although 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 U.S. 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 U.S. 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 *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a).

# Indoor Dust Monitoring Data

Because no U.S. indoor dust monitoring data for DIDP were identified, EPA evaluated non-U.S. 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 1,110  $\mu$ g/g, and the range of median values was from 26  $\mu$ g/g in the Belgian samples from Christia et al. (2019), to 140.2  $\mu$ g/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  $\mu$ g/g and 72  $\mu$ g/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.

# Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the Indoor Dust Monitoring Data

Indoor dust concentrations were derived from Kubwabo et al. (2013), which in turn subsampled the Canadian House Dust Study which was conducted from 2007 through 2010. That study sampled residential house dust in approximately 1,000 randomly selected households in 13 large Canadian municipalities. It is possible that sampling biases were introduced by the choice of large municipalities and by differences among households that chose to participate in the study. Differences in consumer behaviors, housing type and quality, tidiness, and other variables that affect DIDP concentrations in household dust are possible between participating households and the general population. Additionally, because the underlying samples for Kubwabo et al. (2013) were taken between 2007 through 2010, uncertainty is introduced due to the length of time that has elapsed.

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

# Table 4-7. Sources of Uncertainty in DIDP Dust Monitoring Data

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 (*e.g.*, 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

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

# Weight of Scientific Evidence Conclusions for Indoor Dust Monitoring Data

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

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

	Confidence in Model		n Model Inputs					
Scenario	Confidence in Data Used <sup>a</sup>	Body Weight <sup>b</sup>	Dust Ingestion Rate <sup>c</sup>	Weight of Scientific Evidence Conclusion				
Indoor exposure to residential dust via ingestion	++	+++	++	++				
$\begin{array}{c} \text{+= slight; ++ = moderate; +++ = robust} \\ & \underline{\text{Kubwabo et al. (2013); with Giovanoulis et al. (2017)}} \text{ and } \underline{\text{Christia et al. (2019)}} \text{ as comparators} \\ & \underline{\text{V.S. EPA (2011a)}} \\ & \underline{\text{C} \ \text{Ozkaynak et al. (2022)}} \end{array}$								

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

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

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

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

# 4.1.2.4 Indoor Aggregate Dust Exposure Approach and Methodology

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

For the modeling indoor dust assessment EPA identified article specific information by COU to construct relevant and representative exposure scenarios from the consumer assessment, Section 4.1.2.1. Exposure to DIDP via ingestion of dust was assessed for all articles expected to contribute significantly

to dust concentrations due to high surface area (>  $\sim 1 \text{ m}^2$ ) for either a single article or collection of like articles as appropriate, including:

- solid flooring (including large surface area lacquer sealer used for floor finish);
- wallpaper; •
- synthetic leather furniture (including car interiors); •
- shower curtains;
- children's toys, legacy; •
- children's toys, new; and •
- wire insulation. •

These exposure scenarios were modeled in CEM for inhalation, ingestion of suspended dust, and ingestion dust from surfaces. See Section 4.1.2.1 for CEM parameterization, input values, and article specific scenario assumptions and sources. Other non-residential environments can have these articles, such as daycares, offices, malls, schools, car interiors, and other public indoor spaces. The indoor consumer articles exposure scenarios were modeled with stay-at-home parameters that consider use patterns similar or higher than those in other indoor environments. Therefore, EPA concludes that exposures to similar articles in other indoor environments are included in the residential assessment as a health protective upper bound scenario.

#### Indoor Dust Comparison between Monitoring and Modeling Ingestion Estimates

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

Lifestage	Daily DIDP Intake Estimate from Dust, μg/kg-day, Modeled Exposure <sup>a</sup>	Daily DIDP Intake Estimate from Dust, μg/kg-day, Monitoring Exposure <sup>b</sup>					
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	8.56	0.045					
Years)							
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					
<sup><i>a</i></sup> Sum of chronic daily doses for indoor dust ingestion for "medium" intake scenario for all seven dust COUs							

#### Table 4-9. Comparison between Modeled and Monitored Daily Dust Intake Estimates for DIDP

modeled in CEM

<sup>b</sup> Central tendency estimate of daily dose for indoor dust ingestion from monitoring data

<sup>c</sup> Weighted average by month of monitored lifestages from birth to 12 months

<sup>d</sup> Weighted average by year of monitored lifestages from 21–80 years

The sum of DIDP intakes from dust in CEM modeled scenarios were, in all cases, considerably higher than those predicted by the monitoring approach. These discrepancies partially stem from differences in the exposure assumptions of the CEM model vs. the assumptions made when estimating daily dust intakes in Özkaynak et al. (2022). Dust intakes in Özkaynak et al. (2022) decline rapidly as a person ages due to behavioral factors including walking upright instead of crawling, cessation of exploratory mouthing behavior, and a decline in hand-to-mouth events. This age-mediated decline in dust intake,

which is more rapid for the Özkaynak et al. (2022) study than in CEM, partially explains why the margin between the modeled and monitoring results grows larger with age. Additional discussion of the differences between modeled and monitored approaches for estimating DIDP exposure from indoor dust ingestion can be found in Section 4.4 of the *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a). Because the daily DIDP intake estimates from the modeled exposure approach were, in all cases, higher than those predicted by the monitoring approach, the higher modeled exposures were used in the derivation of risk estimates for aggregate indoor dust exposure. Because the modeled DIDP dust risk estimates were higher than the monitored DIDP risk estimates, EPA is confident that the resulting risk characterizations are health protective.

### 4.1.2.5 Weight of Scientific Evidence Conclusions for Consumer Exposure

Key sources of uncertainty for evaluating exposure to DIDP in consumer goods and strategies to address those uncertainties are described in detail in Section 5.1 of Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024a). Generally, designation of 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 exposure estimate. The designation of moderate confidence suggests some understanding of the scientific evidence and uncertainties. More specifically, the supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize exposure estimates. The designation of 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 and there are additional uncertainties that may need to be considered. Although the uncertainty for some of the scenarios and parameters ranges from slight to robust the overall confidence to use the results for risk characterization ranges from moderate to robust, depending on COU scenario. The basis for the moderate to robust confidence in the overall exposure estimates is a balance between using parameters that will represent various populations use patterns and lean on protective assumptions that are not excessive or unreasonable.

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

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

# Product Formulation and Composition

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

# **Product Use Patterns**

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

# Article Surface Area

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

### Human Behavior

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

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

# Modeling Parameters for DIDP Flux, Dermal Absorption, and Chemical Migration

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

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

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

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

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

# 4.1.3 General Population Exposures

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

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

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

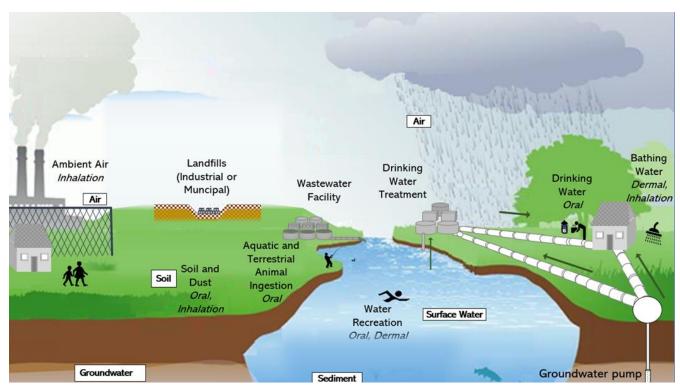


Figure 4-4. Potential Human Exposure Pathways to DIDP for the General Population

High-end estimates of DIDP concentration in the various environmental media presented in Table 3-6 and the *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024r) were used for screening-level purposes in the general population exposure assessment. EPA's *Guidelines for Human Exposure Assessment* (U.S. EPA, 2019b) defines high-end exposure estimates as a "plausible estimate of individual exposure for those individuals at the upper end of an exposure distribution, the intent of which is to convey an estimate of exposure in the upper range of the distribution while avoiding estimates that are beyond the true distribution." If risk is not found for these individuals with high-end exposure, no risk is anticipated for central tendency exposures, which is defined as "an estimate of individuals in the middle of the distribution." 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, refinement of exposure estimates, and exposure estimates for additional subpopulations and OES/COUs.

Identifying individuals at the upper end of an exposure distribution included consideration of 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. As described in Section 3.3, EPA focused on estimating high-end concentrations of DIDP from the largest estimated releases for the purpose of its screening level assessment for environmental and general population exposures. This means that the Agency considered the environmental concentration of DIDP in a given environmental media resulting from the OES that had the highest release compared to any other OES for the same releasing media. Release estimates from OES resulting in lower environmental media concentrations were not considered for this screening-level assessment. Additionally, individuals with the greatest intake rate of DIDP per body weight were considered to be those at the upper end of the exposure.

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

OES <sup>a</sup>	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)
All	Biosolids	No speci	fic exposure scenarios were as qualitative assessments	sessed for	Qualitative
All	Landfills	No speci	fic exposure scenarios were as qualitative assessments	Qualitative	
Use of lubricants and functional fluids	Surface	Dermal	Dermal exposure to DIDP in surface water during swimming	Adults	Quantitative
	Water	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

Table 4 10 Eunogum	Soonaniaa Acces	and in Commo	Donulation S	anooning Lovel Anolys	
1 able 4-10. Exposure	e Scenarios Asses	sed in General	Population 5	creening Level Analys	IS

OES <sup>a</sup>	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	r r r	Infant through middle childhood	Quantitative
<sup><i>a</i></sup> Table 3-1 provides the crosswalk of OES to COUs					

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

### 4.1.3.1 General Population Screening Level Exposure Assessment Results

# Land Pathway

EPA evaluated general population exposures via the land pathway (*i.e.*, application of biosolids, landfills) qualitatively. Due to its water solubility (0.00017 mg/L) and affinity for sorption to soil and organic constituents in soil (log  $K_{OC} = 5.09$ ), DIDP is unlikely to migrate to groundwater via runoff after land application of biosolids. Additionally, the half-life of 28 to 52 days in aerobic soils (<u>U.S. EPA</u>, <u>2024t</u>) indicates that DIDP will have low persistence potential in the aerobic environments associated with freshly applied biosolids. Because the physical and chemical properties of DIDP indicate that it is unlikely to migrate from land applied biosolids to groundwater via runoff, EPA did not model groundwater concentrations resulting from land application of biosolids.

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

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

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

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

### Surface Water Pathway – Drinking Water

For the drinking water pathway, modeled surface water concentrations were used to estimate drinking water exposures. For screening-level purposes, only the OES scenario resulting in the highest modeled surface water concentrations, Use of lubricants and functional fluids, was included in the drinking water exposure analysis. COUs mapped to this OES are shown in Table 3-1. EPA evaluated drinking water scenarios that assumed a wastewater treatment removal efficiency of 94 percent and no further drinking water treatment, as well as a scenario that assumed a wastewater treatment removal efficiency of 94 percent (Table 4-11). ADR and ADD values from drinking water exposure to DIDP were calculated for adults (21+ years), youth (11–15 years), and children (6–10 years). Exposure scenarios leading to the highest ADR and ADD are shown in Table 4-11.

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

Occupational Exposure Scenario <sup>a</sup>	Water Column Concentrations			l Dermal Water <sup>b</sup>	Incidental Surface		Drinking Water <sup>d</sup>				
	30Q5 (µg/L)	Harmonic Mean (µg/L)	ADR <sub>POT</sub> (mg/kg- day)	Acute MOE	ADR <sub>POT</sub> (mg/kg- day)	Acute MOE	ADR <sub>POT</sub> (mg/kg- day)	Acute MOE			
Use of lubricants and functional fluids <i>without</i> <i>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	2.93E-03	3,070	7.71E-02	117			
Use of lubricants and functional fluids <i>with</i> <i>wastewater and drinking</i> <i>water treatment</i>	202	167	_		_		2.84E-02	316			
<sup>b</sup> Most exposed lifestage: Adul <sup>c</sup> Most exposed lifestage: Yout <sup>d</sup> Most exposed lifestage: Infan	water treatment       a         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)										

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

## Fish Ingestion

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 *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024r) for further details. DIDP within suspended solids found in wastewater could result in concentrations greater than the water solubility limit. However, DIDP is expected to have limited bioavailability 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.

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, 2024r). 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 fishers, and the general population*.

	Current Mean In	ngestion Rate	Heritage Ingestion Rate		
Calculation Method	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	

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

## Ambient Air Pathway – Air to Soil Deposition

EPA used the American Meteorological Society (AMS)/EPA Regulatory Model (AERMOD) to estimate ambient air concentrations and air deposition of DIDP from EPA estimated releases. The highest modelled 95th percentile annual ambient air and soil concentrations across all release scenarios were 4.7  $\times 10^2 \,\mu$ g/m<sup>3</sup> and 1.85 mg/kg at 100 m from the releasing facility for the PVC plastic compounding OES, based on the high-end meteorology and rural land category scenario in AERMOD (Table 3-6). COUs mapped to this OES are shown in Table 3-1. PVC plastic compounding was the only OES assessed for the purpose of a screening-level assessment as it was the OES associated with the highest ambient air concentration. Next, using conservative exposure assumptions for infants and children (ages 6 months to <12 years), EPA estimated the acute dose rate (ADR) for soil ingestion and the dermal absorbed dose (DAD) for soil dermal contact to be 0.0228 and 0.0617 mg/kg-day. The Agency did not estimate inhalation exposure to ambient air because it was not expected to be a pathway of concern (see Section 4 of (U.S. EPA, 2024r) for more details).

Using the highest modelled 95th percentile air concentration, ADR, and DAD, MOEs for general population exposure through a combined soil ingestion and dermal soil contact is 107 (Table 4-13 compared to a benchmark of 30). *Based on risk screening results, risk for non-cancer health effects are not expected for the ambient air pathway, and the ambient air pathway is not considered to be a pathway of concern to DIDP for the general population.* 

	S	oil Ingestion		Dermal Soil Contact				
OES	Soil Concentration <sup>a</sup> (mg/kg)	ADD (mg/kg-day)	MOE <sup>b</sup>	Soil Concentration <sup>a</sup> (mg/kg)	DAD (mg/kg-day)	MOE <sup>b</sup>		
PVC plastic compounding	1.85	0.0228	107	1.85	0.0617	107		
	ncentrations are 95t ngestion and dermal			emitting facility. Sosure through soil ing	sestion and dermal s	soil contact.		

Table 4-13. General Po	pulation Ambient	Air to Soil De	position Ex	posure Summarv
	Pulation ministerie		JUSICION LA	posure summary

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

Herein, EPA used a screening-level approach to calculate sentinel exposures to the general population from TSCA releases. The Agency also analyzed urinary biomonitoring data from the CDC's NHANES dataset to provide context for aggregate exposures in the U.S. non-institutionalized civilian population. Reverse dosimetry was used to calculate estimated daily intake of DIDP using NHANES reported urinary concentrations of one metabolite of DIDP, mono-(carboxynonyl) phthalate (MCNP), which has been measured in the 2005 to 2018 NHANES cycles. Urinary MCNP levels reported in the most recent NHANES survey (*i.e.*, 2017–2018) were used to calculate daily intake estimates across demographic

groups ranged from 0.97 to 1.59  $\mu$ g/kg-day, while 95th percentile daily intake estimates ranged from 2.7 to 13.1  $\mu$ g/kg-day. The highest daily intake value estimated was for female children (6–11 years) and was 13.1  $\mu$ g/kg-day at the 95th exposure percentile. Detailed results of the NHANES analysis can be found in Section 10.2 of EPA's *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024r).

Using 50th and 95th percentile daily intake values calculated from reverse dosimetry, EPA calculated MOEs ranging from 5,700 to 9,300 at the 50th percentile and 685 to 3,300 at the 95th percentile across demographic groups using the acute/intermediate/chronic POD (*i.e.*, an HED of 9,000  $\mu$ g/kg-day) based on developmental toxicity (Table 4-14). The lowest calculated MOE of 685 was for female children (6–11 years), based on the 95th percentile exposure estimate. All calculated MOEs at the 50th and 95th percentiles were above the benchmark of 30, indicating that aggregate exposure to DIDP does not pose a risk to the non-institutionalized, U.S. civilian population.

General population exposure estimates calculated herein from exposure to ambient air, surface water, fish ingestion, and soil from TSCA releases are not directly analogous to daily intake values estimated via reverse dosimetry from NHANES. While NHANES may be used to provide context for aggregate exposures in the U.S. population, NHANES is not expected to capture exposures from specific TSCA COUs that may result in high-dose exposure scenarios (*e.g.*, occupational exposures to workers), as compared to EPA's general population exposure assessment, which evaluates sentinel exposures for specific general population exposure estimates calculated herein were compared to daily intake values calculated using reverse dosimetry of NHANES biomonitoring data. Comparison of the values shows that many of the exposure estimates resulting from incidental dermal contact or ingestion of surface water (assuming no wastewater treatment) (Table 4-11), ingestion of fish for adults in tribal populations (assuming heritage ingestion rate) (Table 4-13) from sentinel exposure scenarios exceed the total daily intake values estimated using NHANES (Table 4-14).

Exposure estimates for the general population via ambient air, surface water, and drinking water resulting from TSCA releases quantified in this document are likely overestimates. This is because exposure estimates from individual pathways exceed the total intake values calculated from NHANES measured even at the 95th percentile of the U.S. population for all ages. Further, this is consistent with the U.S. CPSC's conclusion that DIDP exposure comes primarily from diet for women, infants, toddlers, and children and that the outdoor environment is not a major source of exposure to DIDP (U.S. CPSC, 2014). Thus, although the general population exposure estimates calculated using a screening-level approach likely represent an overestimation of exposure, in no case did MOEs for these sentinel exposures exceed the benchmark MOE of 30, indicating no need for further refinement.

Demographic	50th Percentile Daily Intake (95% CI) (µg/kg-day)	95th Percentile Daily Intake (95% CI) (μg/kg-day)	50th Percentile MOE (Benchmark = 30)	95th Percentile MOE (Benchmark = 30)
All	1.21 (1.12–1.29)	6.38 (2.43–10.33)	7,400	1,400
Females	1.19 (1.07–1.31)	6.45 (-1.65-14.54)	7,600	1,400
Males	1.22 (1.11–1.33)	5.23 (1.59-8.86)	7,400	1,700
White non-Hispanic	1.3 (1.09–1.51)	7.39 (-2.25-17.03)	6,900	1,200
Black non-Hispanic	1.08 (0.89–1.28)	4.94 (2.12–7.76)	8,300	1,800
Mexican-American	1.14 (1.04–1.25)	2.84 (-0.1-5.78)	7,900	3,200
Other race	1.2 (1.08–1.32)	5.01 (1.79-8.23)	7,500	1,800
Above poverty level	1.14 (1.05–1.24)	6.22 (1.43–11.01)	7,900	1,400
Below poverty level	1.24 (1.12–1.37)	5.05 (1.34-8.75)	7,300	1,800
3–5 years old (all)	1 (0.91–1.1)	4.65 (1.52–7.79)	9,000	1,900
Males 3–5 years old	1.02 (0.88–1.16)	3.6 (0.1–7.1)	8,800	2,500
Females 3–5 years old	0.97 (0.82–1.12)	7.32 (-0.38-15.02)	9,300	1,200
6–11 years old	1.19 (1.07–1.3)	6.35 (-4.37-17.07)	7,600	1,400
Males 6–11 years old	1.14 (1–1.28)	2.7 (2.18–3.23)	7,900	3,300
Females 6–11 years old	1.25 (0.99–1.51)	13.14 <sup><i>a</i></sup>	7,200	685
12–15 years old (all)	1.37 (1.1–1.64)	4.27 (0.65–7.88)	6,600	2,100
Males 12–15 years old	1.51 (1.19–1.83)	9.66 <sup><i>a</i></sup>	6,000	930
Females 12–15 years old	1.32 (0.94–1.7)	3.38 (2.01-4.76)	6,800	2,300
Adults 16+ years old	1.29 (0.92–1.66)	7.18 <sup><i>a</i></sup>	7,000	1,300
Males 16+ years old	1.59 (1.06–2.12)	7.41 <sup><i>a</i></sup>	5,700	1,200
Females 16+ years old	1.17 (0.8–1.54)	3.5 <sup><i>a</i></sup>	7,700	2,600
Women of reproductive age (16–49 years old)	1.17 (0.8–1.54)	3.5 <sup><i>a</i></sup>	7,700	2,600
<sup>a</sup> 95% confidence intervals (CI) could not be calc	ulated due to small	sample size or a stan	dard error of ze	ro.

# Table 4-14. Daily Intake Values and MOEs for DIDP Based on Urinary Biomonitoring from the2017 to 2018 NHANES Cycle

4.1.3.3 Overall Confidence in General Population Screening Level Exposure Assessment

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

EPA determined robust confidence in its qualitative assessment of biosolids and landfills. For its quantitative assessment, the Agency modeled exposure due to various general population exposure scenarios resulting from different pathways of exposure. Exposure estimates utilized high-end inputs for

the purpose of risk screening. When available, monitoring data was compared to modeled estimates to evaluate overlap, magnitude, and trends. EPA has robust confidence that modeled releases used are appropriately conservative for a screening level analysis. Therefore, the Agency has robust confidence that no exposure scenarios will lead to greater doses than presented in this evaluation. Despite slight and moderate confidence in the estimated values themselves, confidence in exposure estimates capturing high-end exposure scenarios was robust given that many of the modeled values exceeded those of monitored values and exceeded total daily intake values calculated from NHANES biomonitoring data (see Section 10 of (U.S. EPA, 2024r) for more details regarding the NHANES analysis), adding to confidence that exposure estimates captured high-end exposure scenarios.

## 4.1.4 Human Milk Exposures

Infants are a potentially susceptible lifestage because of their higher exposure per body weight, immature metabolic systems, and the potential for chemical toxicants to disrupt sensitive developmental processes, among other reasons. As discussed further in Section 4.2, DIDP is a developmental toxicant, and developmental toxicity occurs following gestational exposure to DIDP. EPA considered exposure and human health hazard information, as well as pharmacokinetic models, to determine how to evaluate infant exposure to DIDP from human milk ingestion. Biomonitoring data, albeit limited, have not demonstrated the presence of DIDP in human milk. Human health hazard values are based on developmental toxicity following maternal exposure, and no studies have evaluated only lactational exposure from quantified levels of DIDP in milk. Lastly, uncertainties in the toxic moiety for DIDP and 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 Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024r).

## 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 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. As described in Section 7.1 of the *Human Health Hazard Assessment for DIDP* (U.S. EPA, 2024v), EPA considers it possible to aggregate risks across exposure routes because the POD is based on systemic effects (*i.e.*, developmental toxicity) and because EPA conducted route-to-route extrapolation of the POD derived from an oral study for use in the dermal and inhalation risk calculations. The Agency did not consider aggregate exposure for the general population from TSCA releases. As described in Section 4.1.3, EPA employed a risk screening 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, and fish ingestion) to DIDP exposure were identified for the generation population. EPA did analyze urinary biomonitoring data from the CDC's NHANES dataset, which provides an estimate of non-attributable (*i.e.*, cannot distinguish between TSCA and non-TSCA exposures) aggregate exposure to DIDP for the U.S. civilian population (Section 4.1.3).

EPA did not consider aggregate exposure scenarios across COUs because the Agency did not find any evidence to support such an aggregate analysis, such as statistics of populations using certain products represented across COUs, or workers performing tasks across COUs. However, EPA considered 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 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, the Agency 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 non-cancer and cancer human health hazards of DIDP. Additional information on the human health hazards of DIDP are provided in the *Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024v).

## Non-cancer Human Health Hazards

A robust toxicological database is available for DIDP. Available studies include: one intermediate duration (>1 to 30 days) inhalation study of rats (General Motors, 1983); seven intermediate duration 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 (>30 to 90 days) dietary studies (2 of rats, 1 of beagles) (BASF, 1969; Hazelton Labs, 1968a, b); two chronic (>90 days) dietary studies (1 of each of rats and mice) (Cho et al., 2011; Cho et al., 2010; Cho et al., 2008); two prenatal developmental studies of rats (Waterman et al., 1999; Hellwig et al., 1997); one developmental/reproductive toxicity screening study of mice (Hazleton Labs, 1983); and a pair of two-generation dietary studies of rats (Hushka et al., 2001; Exxon Biomedical, 2000, 1998). No repeated dose studies investigating the systemic toxicity of DIDP are available for the dermal route of exposure. Additionally, although the anti-androgenicity of DIDP is not discussed in detail in this document (see U.S. EPA (2023b) for further discussion), several mechanistic studies have demonstrated that gestational exposure during the critical window of development to DIDP does not induce antiandrogenic effects on the developing male reproductive system consistent with phthalate syndrome (Furr et al., 2014; Hannas et al., 2012). This conclusion was supported by the SACC (U.S. EPA, 2023d).

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. Liver and developmental toxicity were also identified as the most sensitive and robust non-cancer effects following oral exposure to DIDP by the U.S. Consumer Product Safety Commission (U.S. CPSC, 2014), Health Canada (ECCC/HC, 2020), European Chemicals Agency (ECHA, 2013), European Food Safety Authority (EFSA, 2019), and the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2015). Consistent, dose-related effects on development were observed across available experimental studies of rodent models. In two prenatal studies, increased incidences of skeletal and visceral variations were observed in SD and Wistar rats at non-maternally toxic doses (Waterman et al., 1999; Hellwig et

al., 1997). No-observable-adverse-effect levels (NOAELs)/lowest-observable-adverse-effect level (LOAELs) for developmental and maternal toxicity were 40/200 and 200/1000 mg/kg-day, respectively, in the study by Hellwig et al. (1997), and 200/500 and 500/1000 mg/kg-day, respectively, in the study by Waterman et al. (1999). The biological significance of the observed increases in skeletal and visceral variations are difficult to assess. However, EPA's Guidelines for Developmental Toxicity Risk Assessment (U.S. EPA, 1991b) states that, "if variations are significantly increased in a dose-related manner, these should also be evaluated as a possible indication of developmental toxicity" and "Agents that produce developmental toxicity at a dose that is not toxic to the maternal animal are especially of concern." Therefore, EPA considered the increase in skeletal and visceral variations following gestational exposure to DIDP to be treatment-related adverse effects. Effects on developing offspring have also been observed consistently in two two-generation studies of reproduction of Sprague-Dawley rats (Hushka et al., 2001; Exxon Biomedical, 2000, 1998). In the first two-generation study by Exxon Biomedical (1998), DIDP exposure reduced F1 offspring survival on postnatal day (PND) PND4, reduced F1 and F2 offspring body weight on PND0, and reduced F1 and F2 offspring body weight gain through PND 21 at doses equal to 524 to 637 mg/kg-day DIDP, and reduced F2 offspring survival on PND1 and PND4 at doses of 135 mg/kg-day and above. In the second two-generation study by Exxon Biomedical (2000), which tested lower doses than the first study (high-dose group received 254 to 356 mg/kg-day DIDP), reduced F2 offspring survival on PND1 and PND4 was observed at doses of 134 mg/kg-day and above.

To calculate non-cancer risks from oral exposure to DIDP for acute, intermediate, and chronic durations of exposure in the risk evaluation of DIDP, EPA preliminarily selected a no-observed-adverse-effect level (NOAEL) of 38 mg/kg-day from a two-generation study of reproduction of rats based on reduced F2 offspring survival on PND1 and PND4 (Hushka et al., 2001; Exxon Biomedical, 2000). The NOAEL of 38 was converted to a human equivalent dose (HED) of 9.0 mg/kg-day based on allometric body weight scaling to the three-quarter power (U.S. EPA, 2011c). A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure (based on an interspecies uncertainty factor (UF<sub>A</sub>) of 3 and an intraspecies uncertainty factor (UF<sub>H</sub>) of 10). The critical effect, reduced F2 offspring survival on PND1 and PND4, is clearly adverse and is assumed to be human relevant. It is unclear whether decreased pup survival was due to a single, acute exposure or from repeated exposures. It is plausible that reduced offspring survival could result from a single exposure during gestation. However, it is also plausible that reduced offspring survival could result from repeated exposure during gestation or the postnatal period. Since repeated dose studies were used to investigate these hazard endpoints and the mode of action for DIDP is uncertain, and other studies did not provide a more sensitive or reliable endpoint, EPA considered reduced F2 offspring survival relevant for all exposure durations (U.S. EPA, 1996, 1991b). Several additional acute, short-term and chronic duration studies of DIDP provide similar, although slightly less-sensitive, candidate PODs, which further supports EPA's decision to use the selected POD of 9.0 mg/kg-day to assess non-cancer risks for acute, intermediate, and chronic durations of exposure.

EPA reviewed the weight of scientific evidence and has *robust overall confidence in the selected POD* based on developmental outcomes for use in characterizing risk from exposure to DIDP for acute, intermediate, and chronic exposure scenarios. This conclusion was based on several weight of scientific evidence considerations. First, exposure to DIDP resulted in consistent, dose-related, developmental toxicity in two prenatal developmental studies and a pair of two-generation studies that adhered to relevant EPA guidelines (*i.e.*, OPPTS 870.3700 and OPPTS 870.3800). Further, developmental toxicity occurred at doses lower that those that caused overt maternal and/or parental toxicity. Second, across available studies, developmental toxicity was observed consistently at LOAELs ranging from 134 to 200 mg/kg-day. Third, the selected POD (NOAEL of 38 mg/kg-day) for developmental toxicity was the

most sensitive and robust POD considered for acute, intermediate, and chronic exposures. Five additional acute, short-term and chronic duration studies of DIDP provide similar, although slightly less-sensitive, candidate PODs (*i.e.*, HEDs ranging from 9.3–13 mg/kg-day based on developmental or liver toxicity), which further supports EPA's decision to use the selected POD to assess non-cancer risks for acute, intermediate, and chronic durations of exposure. Finally, other regulatory and authoritative bodies have also concluded that DIDP is a developmental toxicant and that developmental effects are relevant for estimating human risk (EFSA, 2019; EC/HC, 2015b; NICNAS, 2015; ECHA, 2013; U.S. CPSC, 2010; EFSA, 2005; ECJRC, 2003a; NTP-CERHR, 2003).

For purposes of assessing non-cancer risks, the selected acute/intermediate/chronic POD based on developmental toxicity is considered most applicable to pregnant women, women of reproductive age, and infants. Use of this POD to calculate risks for other age groups (*e.g.*, older children and adult males) is conservative.

No data were available for the dermal or inhalation routes that were suitable for deriving route-specific PODs. Therefore, EPA used the oral POD to evaluate risks from dermal exposure to DIDP. Differences in absorption are accounted for in dermal exposure estimates in the risk evaluation for DIDP. For the inhalation route, the Agency extrapolated the oral HED to an inhalation human equivalent concentration (HEC) using a human body weight and breathing rate relevant to a continuous exposure of an individual at rest (U.S. EPA, 1994). The oral HED and inhalation HEC values selected by EPA to estimate non-cancer risk from acute, intermediate and chronic exposure to DIDP in the risk evaluation of DIDP are summarized in Table 4-15.

## Cancer Human Health Hazards

Available data indicate that DIDP is not genotoxic or mutagenic (see Section 4 of (U.S. EPA, 2024v)). In a 2-year dietary study of F344 rats (Cho et al., 2010; Cho et al., 2008), increased incidence of mononuclear cell leukemia (MNCL) was observed in high-dose male and female rats dosed with up to 479 to 620 mg/kg-day DIDP. No other carcinogenic activity of DIDP was observed in this study. MNCL is a spontaneously occurring neoplasm of the hematopoietic system that reduces lifespan and is one of the most common tumor types occurring at a high background rate in the F344 strain of rat (also referred to as Fisher rat leukemia because it is so common) (Thomas et al., 2007). The mode of action for induction of MNCL in F344 rats is unknown and there is uncertainty related to the human correlate to MNCL in F344 rats (Maronpot et al., 2016). The F344 strain of rat was used in NTP 2-year chronic and carcinogenicity bioassays for nearly 30 years. However, in the early 2000s NTP stopped using the F344 strain of rat in large part because of high background incidence of MNCL and testicular Leydig cell tumors that confounded bioassay interpretation (King-Herbert et al., 2010; King-Herbert and Thayer, 2006). Given these considerations, EPA is not further considering MNCL as a factor in the determination of the cancer classification for DIDP, which is consistent with the recommendations of the SACC during the July 2024 peer review of the draft risk evaluation of DIDP (U.S. EPA, 2024z).

In a 26-week study of male and female wild-type and rasH2 transgenic mice (<u>Cho et al., 2011</u>), increased incidence of hepatocellular adenomas were observed in high-dose rasH2 males treated with 1,500 mg/kg-day DIDP. No other tumors were observed in any tissues in male or female wild-type mice or female rasH2 mice treated with up to 1,500 mg/kg-day. However, hepatocellular adenomas were only observed in high-dose male rasH2 transgenic mice at a dose that exceeded the limit dose, causing a 31 percent decrease in terminal body weight. Per EPA's *Guidelines for Carcinogen Risk Assessment* (<u>U.S.</u> <u>EPA, 2005</u>) "overt toxicity or qualitatively altered toxicokinetics due to excessively high doses may result in tumor effects that are secondary to the toxicity rather than directly attributable to the agent." No carcinogenic activity was observed in mid-dose male rasH2 mice treated with 495 mg/kg-day DIDP (a dose that caused no overt toxicity).

Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), EPA reviewed the weight of the evidence for the carcinogenicity of DIDP and determined that DIDP is *not likely to be carcinogenic to humans*. Consistent with this classification, EPA is not conducting a dose-response assessment for DIDP or evaluating DIDP for carcinogenic risk to humans.

Exposure Scenario	Target Organ System	Species	Duration	POD (mg/kg- day)	Effect	HEC (mg/m <sup>3</sup> ) [ppm]	HED (mg/ kg-day)	Benchmark MOE	Reference(s)
Acute, intermed., chronic	Dev. toxicity	Rat	~35 weeks	NOAEL = 38	Reduced F2 offspring survival on PND1 and PND4	49 [2.7]		$UF_{H}=10$ Total UF=30	( <u>Hushka et al.,</u> 2001; <u>Exxon</u> <u>Biomedical,</u> 2000)

 Table 4-15. Non-cancer HECs and HEDs Used to Estimate Risks

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

<sup>*a*</sup> 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<sub>A</sub> was reduced from 10 to 3.

# 4.3 Human Health Risk Characterization

## 4.3.1 Risk Assessment Approach

The exposure scenarios, populations of interest, and toxicological endpoints used for evaluating risks from acute, short-term/intermediate, and chronic/lifetime exposures are summarized in Table 4-16.

Table 4 16 Eve	Source Soonania	Donulatio	ma of Intonast	and Harand Values
1 able 4-10. Exp	Josure Scenario	is, Populatio	ins of interest	, and Hazard Values

Tuble I Ioi Emposare	e Secharios, i opulations of interest, and mazaru values					
	Workers					
	Male and female adolescents and adults (≥16 years) and females of reproductive age directly					
	working with DIDP under light activity (breathing rate of 1.25 m <sup>3</sup> /h)					
	Exposure Durations					
	• <i>Acute</i> – 8 hours for a single workday					
	• Intermediate – 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					
	Exposure routes					
	Inhalation and dermal					
	Occupational Non-users					
Population of Interest	Male and female adolescents and adults (≥16 years) indirectly exposed to DIDP within the same					
and Exposure Scenario	work area as workers (breathing rate of $1.25 \text{ m}^3/\text{h}$ )					
and Exposure Scenario	Exposure Durations					
	• Acute, Intermediate, and Chronic – same as workers					
	Exposure routes					
	• Inhalation, dermal (mist and dust deposited on surfaces)					
	Consumers					
	Male and female infants (<1 year), toddlers (1–2 years), children (3–5 and 6–10 years), young					
	teens (11–15 years), teenagers (16–20 years) and adults (21+ years) exposed to DIDP through					
	product or articles use					
	Exposure Durations					
	• Acute – 1 day exposure					
	• Intermediate – 30 days per year					

	• <i>Chronic</i> – 365 days per year					
	Exposure routes					
	*					
	Inhalation, dermal, and oral					
	Bystanders					
	Male and female infants (<1 year), toddlers (1–2 years), and children (3–5 and 6–10 years)					
	incidentally exposed to DIDP through product use					
	Exposure Durations					
	• Acute – 1 day exposure					
	• <i>Intermediate</i> – 30 days per year					
	• <i>Chronic</i> – 365 days per year					
	Exposure routes					
	Inhalation					
	General Population					
	Male and female infants, children, youth, and adults exposed to DIDP through drinking water,					
	surface water, ambient air, soil, and fish ingestion					
	Exposure durations					
	• Acute – Exposed to DIDP continuously for a 24-hour period					
	<ul> <li>Chronic – Exposed to DIDP continuously up to 33 years</li> </ul>					
	Exposure routes – Inhalation, dermal, and oral (depending on exposure scenario)					
	Non-cancer Acute/Intermediate/Chronic Values					
	Sensitive health effect: Developmental toxicity					
	HEC Daily, continuous = $49 \text{ mg/m}^3$ (2.7 ppm)					
Health Effects,	HED Daily = $9.0 \text{ mg/kg}$ ; dermal and oral					
Concentration and	Total UF (benchmark MOE) = 30 (UF <sub>A</sub> = 3; UF <sub>H</sub> = 10)					
Time Duration	EPA considers the non-cancer acute/intermediate/chronic values based on developmental toxicity					
	to be most directly applicable to pregnant women, women of reproductive age, and infants. Use					
	of this hazard value to calculate risks for other age groups (e.g., older children and adult males) is					
	conservative.					

#### 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**

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

Where:

MOE	=	Margin of exposure for acute, short-term, or chronic
		risk comparison (unitless)
Non-cancer Hazard Value (POD)	=	HEC (mg/m <sup>3</sup> ) or HED (mg/kg-day)
Human Exposure	=	Exposure estimate (mg/m <sup>3</sup> 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 "brightline" 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:

Total MOE	=	Margin of exposure for aggregate scenario (unitless)
MOEoral	=	Margin of exposure for oral route (unitless)
MOE <sub>Dermal</sub>	=	Margin of exposure for dermal route (unitless)
<b>MOE</b> Inhalation	=	Margin of exposure for inhalation route (unitless)

Total MOE risk estimates may be interpreted in relation to benchmark MOEs similarly as 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 4-17. This section provides discussion and characterization of risk estimates for workers, including females of reproductive age and ONUs, for the various OESs and COUs.

## 4.3.2.1 Application of Adhesives and Sealants

## 4.3.2.1.1 Overview of Risk Estimates

EPA distinguished exposure estimates between *spray* and *non-spray* application of adhesive and sealant products containing DIDP. For the *spray* application of adhesives and sealants, inhalation exposure from mist generation is expected to be the dominant route of exposure; however, for the *non-spray* application of adhesives and sealants, inhalation exposure is expected to be minimal compared to the dermal route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure from the spray scenario 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). For central tendency of the spray scenario, MOEs for the same populations ranged from 483 to 839 for inhalation exposure from the non-spray application scenario ranged from 905 to 1,460 for average adult workers and women of reproductive age, while high-end dermal MOEs for central tendency of the non-spray application scenario ranged from 905 to 1,460 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 98 to 156. For central tendency of the non-spray application scenario ranged populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 1,811 to 3,147 for inhalation exposure and 196 to 336 for dermal exposure.

Aggregation of inhalation and dermal exposures led to negligible differences in MOEs when compared to MOE estimates from the dominant route of exposure alone (inhalation is dominant for spray scenarios, dermal is dominant for non-spray scenarios). Also, it is important to note that there were large variations between the central tendency and high-end estimates of worker inhalation exposure, which is largely due to the range of potential product concentrations as described in the section below.

## 4.3.2.1.2 Overview of Exposure Data

For *spray* application of adhesives and sealants, 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 mist concentrations from automotive refinishing was 3.38 mg/m<sup>3</sup> and the high-end (*i.e.*, 95th percentile) was 22.1 mg/m<sup>3</sup>. These mist concentration data were derived from a variety of industrial and commercial automotive refinishing scenarios (e.g., different gun types, booth configurations, spray durations), but all scenarios considered in the ESD commonly used the spray application of auto refinishing coatings. Though the tasks evaluated for mist concentrations varied in duration with the 95th percentile of spray times among tasks being 141 minutes, EPA assumed that these mist concentrations may be persistent in an environment where spraying occurs throughout all or most of the workday. The more highly pressurized spray guns generally lead to higher inhalation exposure levels, and less pressurized spray guns generally lead to lower inhalation exposure levels. The same trend is expected for dermal exposure. Specifically, highpressure spray applications are more likely to lead to higher levels of dermal exposure, and low-pressure spray guns are more likely to lead to lower levels of dermal exposure. However, there are a variety of factors other than spray equipment type that affect exposure levels, such as spray booth ventilation configuration, product concentration, and spray duration.

High-end levels of exposure represent scenarios where one or more factors are contributing to unusually elevated exposure levels, whereas central tendency levels of exposure represent more typical levels of exposure for scenarios where there are few factors contributing to increased exposure. There is uncertainty regarding the particular combination of factors that would lead to high-end levels of exposure. Also, there was one study noted in the EU Risk Assessment for DIDP (2003a) that measured concentrations of di-ethylhexyl phthalate (DEHP), DIDP, and DINP during spray coating or spread coating in an automobile factory. Specifically, the study by King (1996) showed inhalation exposure levels that ranged from 0 to 0.11 mg/m<sup>3</sup> for DEHP, DIDP, and DINP, according to the 2003 EU Risk Assessment for DIDP. However, EPA has been unable to locate this study to determine key study details including sample duration, concentration of DIDP in coating materials, type of equipment and application methods examined. Without access to the study, EPA has low confidence integrating the results from King (1996) into the risk evaluation of DIDP.

For *non-spray* application of adhesives and sealants, EPA assumed that inhalation exposures come from vapor generation alone and that these exposures are similar to other vapor-generating activities such as manufacture or import. More specifically, EPA used surrogate monitoring data provided in an exposure study conducted by ExxonMobil at their DIDP manufacturing site (ExxonMobil, 2022a) to estimate inhalation exposure for this scenario. The low volatility and slow dermal absorption of DIDP are reflected in the low levels of exposure estimated for the non-spray scenario. Because the majority of adhesive and sealant products that contain DIDP identified by EPA are intended for non-spray application, the non-spray application scenario is much more likely in occupational settings.

Regarding product concentrations, the various commercial adhesive and sealant products considered are summarized in Appendix F of the *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s). Although 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 for the spray application scenario, there was a larger range of potential inhalation exposures for the spray application of adhesives and sealants.

#### 4.3.2.1.3 Risk Characterization of COUs

The range of exposure estimates shown in Table 4-17 for "Application of adhesives and sealants – spray application" are potentially reflective of industrial or commercial operations where adhesives and sealants are applied using spray methods (*i.e.*, Industrial COU: Adhesives and sealants; Commercial COU: Adhesives and sealants [including plasticizers in adhesives and sealants]). As described in the preceding section, EPA assumed that task-based mist concentrations may be persistent throughout the entirety of a workday for exposure estimation, which is realistic but on the conservative end of expected exposure duration for spray coating scenarios. The central tendency estimates of the spray application scenario represent the mode of available product concentrations and the mist concentration from the 50th percentile of the data presented in the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), and these levels of exposure are expected to be typical for standard working conditions where workers are spray applying adhesive and sealant products containing DIDP for up to 8 hours per day. However, it is noted that there are several factors that affect exposure levels related to the spray application of adhesive and sealant chemicals including spray equipment type, spray booth ventilation configuration, product concentration, and spray duration. Although high-end levels of exposure may occur if one or more of these factors contribute to elevated levels of exposure, there is uncertainty regarding the conditions associated with high-end exposures.

Because the high-end risk estimates are based on high-end mist concentration levels, high-end product concentration, and high-end exposure duration, the high-end risk values presented in Table 4-17 for Application of adhesives and sealants – spray application may overestimate exposures for typical working conditions. EPA does expect spray application of adhesive and sealant products based on public feedback regarding the industrial and commercial applications of adhesives and sealants containing DIDP (see EPA-HQ-OPPT-2024-0073-0069). Specifically, public comments indicate that there are DIDP-containing adhesive/sealant products with concentrations up to 30 percent, and these products are intended for high-volume, low-pressure spray for tank linings and large areas. For a 2-hour spraying task with HVLP equipment and 30 percent product concentration, mist levels exceeding 16 mg/m<sup>3</sup> (*i.e.*, 92nd percentile of the distribution of mist monitoring data) would result in risk values below the benchmark MOE. For an 8-hour workday spent spraying with HVLP equipment and 30 percent product concentration, mist levels exceeding  $4 \text{ mg/m}^3$  (*i.e.*, 56th percentile of the distribution of mist monitoring data) would result in risk values below the benchmark MOE. Though there is uncertainty in the relevance of a high-end exposure estimate that is based on all high-end input values, the two spray scenarios described above (*i.e.*, 2- and 8-hour spray duration of 30% product with HVLP equipment) may be relevant based on the expected product use.

Although most worker exposures to DIDP through spray application of adhesives and sealants are expected to be closer to the central tendency exposure values for this COU, a confluence of a subset of variables (*e.g.*, low ventilation, high-pressure spray) would result in risk below the benchmark. While most workers are not expected to experience these conditions, they are considered plausible and expected for an acute 1-day exposure.

Based on the reasonably available information, the range of exposure estimates shown in Table 4-17 for Application of adhesives and sealants – non-spray application are believed to be reflective of industrial or commercial operations where adhesives and sealants are applied using non-spray methods (*i.e.*, Industrial COU: Adhesives and sealants; Commercial COU: Adhesives and sealants [including plasticizers in adhesives and sealants]; Processing: Abrasives manufacturing). The adhesive and sealant products containing DIDP that were identified by EPA during systematic review and summarized in Appendix F of *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate* (U.S. EPA, 2024s) are not intended for spray application. More specifically, the products are to be applied through non-spray methods such as bead, brush, or roll applications. Similarly, non-spray methods are generally used in the application of adhesive and sealant products for abrasives manufacturing. The exposure and risk estimates associated with non-spray application scenarios for adhesives and sealants containing DIDP show low variability between central tendency and high-end, and the range of exposure estimates are expected to be representative of various non-spray application scenarios for adhesive and sealant chemicals containing DIDP.

## 4.3.2.2 Application of Paints and Coatings

#### 4.3.2.2.1 Overview of Risk Estimates

EPA distinguished exposure estimates between *spray* and *non-spray* application of paint and coating products containing DIDP. For the *spray* application of paints and coatings, inhalation exposure from mist generation is expected to be the dominant route of exposure; however, for the *non-spray* application of paints and coatings, inhalation exposure is expected to be minimal compared to the dermal route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure from the spray scenario 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). For central tendency of the spray scenario, MOEs for the same populations ranged from 483 to 779 for inhalation exposure and 196 to 312 for dermal exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure from the non-spray application scenario ranged from 905 to 1,460 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 98 to 156. For central tendency of the non-spray application scenario ranged from 905 to 1,460 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 98 to 156. For central tendency of the non-spray scenario, MOEs for the same populations ranged from 1,811 to 2,920 for inhalation exposure and 196 to 312 for dermal exposure.

Aggregation of inhalation and dermal exposures led to negligible differences in MOEs when compared to MOE estimates from the dominant route of exposure alone (inhalation is dominant for spray scenarios, dermal is dominant for non-spray scenarios). Also, it is important to note that there were large variations between the central tendency and high-end estimates of worker inhalation exposure, which is largely due to the range of potential product concentrations as described in the section below.

#### 4.3.2.2.2 Overview of Exposure Data

For *spray* application of paints and coatings, 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 mist concentrations from automotive refinishing was 3.38 mg/m<sup>3</sup> and the high-end (*i.e.*, 95th percentile) was 22.1 mg/m<sup>3</sup>. 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. Although the tasks evaluated for mist concentrations varied in time, with the 95th percentile of spray times among tasks being 141 minutes, EPA assumed that these mist concentrations may be persistent in an environment where spraying occurs throughout all or most of the workday. The more highly pressurized spray guns generally lead to higher inhalation exposure levels, and less pressurized spray guns generally lead to lower inhalation exposure levels.

The same trend is expected for dermal exposure. Specifically, high-pressure spray applications are more likely to lead to higher levels of dermal exposure, and low-pressure spray guns are more likely to lead to lower levels of dermal exposure. However, there are a variety of factors other than spray equipment type that affect exposure levels, such as spray booth ventilation configuration, product concentration, and spray duration. High-end levels of exposure represent scenarios where one or more factors are contributing to unusually elevated exposure levels, whereas central tendency levels of exposure represent more typical levels of exposure for scenarios where there are few factors contributing to increased exposure. There is uncertainty regarding the particular combination of factors that would lead to high-end levels of exposure. Also, there was one study noted in the EU Risk Assessment for DIDP (2003a) that measured concentrations of DEHP, DIDP, and DINP during spray coating or spread coating in an automobile factory. Specifically, the study by King (1996) showed inhalation exposure levels that ranged from 0 to 0.11 mg/m<sup>3</sup> for DEHP, DIDP, and DINP, according to the 2003 EU Risk Assessment for DIDP. However, EPA has been unable to locate this study to determine key study details including sample duration, concentration of DIDP in coating materials, type of equipment and application methods examined. Without access to the study, EPA has low confidence integrating the results from King (1996) into the risk evaluation of DIDP.

For *non-spray* application of paints and coatings, EPA assumed that inhalation exposures come from vapor generation alone and that these exposures are similar to other vapor-generating activities such as manufacture or import. More specifically, EPA used surrogate monitoring data provided in an exposure study conducted by ExxonMobil at their DIDP manufacturing site (ExxonMobil, 2022a) to estimate inhalation exposure for this scenario. The low volatility and slow dermal absorption of DIDP are reflected in the low levels of exposure estimated for the *non-spray* scenario.

Regarding product concentrations, the various commercial paint and coating products considered are summarized in Appendix F of the *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s). Though the concentrations are representative of commercial products, similar DIDP concentrations are expected for industrial paints and coatings. EPA used the mode product concentration (*i.e.*, 1%) to represent the central tendency product concentration and the upper bound product concentration (*i.e.*, 5%) to represent the high-end product concentration. Due to the 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 of the spray application scenario, there was a larger range of potential inhalation exposures for the spray application of paints and coatings.

#### 4.3.2.2.3 Risk Characterization of COUs

The range of exposure estimates shown in Table 4-17 for Application of paints and coatings – spray application are potentially reflective of industrial or commercial operations where paints and coatings are applied using spray methods (*i.e.*, Industrial COU: Paints and coatings; Commercial COU: Paints and coatings [including surfactants in paints and coatings]; Lacquers, stains, varnishes, and floor finishes [as plasticizer]). As described in the preceding section, EPA assumed that task-based mist concentrations may be persistent throughout the entirety of a workday for exposure estimation, which is realistic but on the conservative end of expected exposure duration for spray coating scenarios. The central tendency estimates of the spray application scenario represent the mode of available product concentrations and the mist concentration from the 50th percentile of the data presented in the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), and

these levels of exposure are expected to be typical for standard working conditions where workers are spray applying paint and coating products containing DIDP for up to 8 hours per day. However, it is noted that there are several factors that affect exposure levels related to the spray application of paint and coating chemicals including spray equipment type, spray booth ventilation configuration, product concentration, and spray duration. Although high-end levels of exposure may occur if one or more of these factors contribute to elevated levels of exposure, there is uncertainty regarding the conditions associated with high-end exposures.

Because the high-end risk estimates are based on high-end mist concentration levels, high-end product concentration, and high-end exposure duration, the high-end risk values presented in Table 4-17 for Application of paints and coatings – spray application may overestimate exposures for typical working conditions. EPA does expect spray application of paint and coating products containing DIDP based on the available product information (PPG Industries, 2024), as well as public comments indicating that there are DIDP-containing automotive undercoating products with concentrations up to 9 percent DIDP (EPA-HQ-OPPT-2024-0073-0069). For a 2-hour spraying task with a paint/coating product containing 9 percent DIDP, mist levels exceeding 53 mg/m<sup>3</sup> would result in risk values below the benchmark MOE which is well beyond the expected level of mist exposure for spray coating applications. However, for an 8-hour workday spent spraying with a paint/coating product containing 9 percent DIDP, mist levels exceeding 13.3 mg/m<sup>3</sup> (*i.e.*, 91st percentile of the distribution of mist monitoring data) would result in risk values below the benchmark MOE. These two spray scenarios described above (i.e., 2- and 8-hour spray duration of 9% product) seem relevant based on the expected product use; however, these scenarios show that the mist concentrations that would result in risk values below the benchmark MOE would be at a high level (*i.e.*, mist must be >90th percentile of mist concentration data for an 8-hour period).

Although most worker exposures to DIDP through spray application of paints and coatings are expected to be closer to the central tendency exposure values for this COU, a confluence of a subset of variables (*e.g.*, low ventilation, high-pressure spray) would result in risk below the benchmark. While most workers are not expected to experience these conditions, they are considered plausible and expected for an acute 1-day exposure.

Most commercial paint and coating products that were identified through the risk evaluation process (summarized in Appendix F of Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024s)) are not generally applied through highly pressurized spray application, but rather low-pressure hand pump sprayers and buff coating applications. The occupational applications of paints and coatings through spray equipment are reflected by the exposure and risk estimates for Application of paints and coatings – spray application shown in Table 4-17, as described in the paragraph above, and the occupational applications of paints and coatings through nonspray methods such as brush or roll application are reflected by the range of exposure and risk estimates for Application of paints and coatings - non-spray application shown in Table 4-17. The exposure and risk estimates associated with non-spray application scenarios for paints and coatings containing DIDP show low variability between central tendency and high-end, and the range of exposure estimates are expected to be representative of various non-spray application scenarios for paint and coating chemicals containing DIDP. These non-spray application estimates are relevant for industrial or commercial uses of paint and coating products that are not spray applied (*i.e.*, Industrial COU: Paints and coatings; Commercial COUs: Paints and coatings [including surfactants in paints and coatings]); Lacquers, stains, varnishes, and floor finishes [as plasticizer]; Ink, toner, and colorant products).

## 4.3.2.3 Use of Penetrants and Inspection Fluids

### 4.3.2.3.1 Overview of Risk Estimates

For the use of penetrants and inspection fluids, inhalation exposure from aerosol 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 12 to 19 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 157 (benchmark = 30). 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 moderate variations between the central tendency and high-end estimates of worker inhalation exposure (central tendency inhalation MOEs ranged from 43 to 69 for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

## 4.3.2.3.2 Overview of Exposure Data

EPA based the central tendency and high-end exposure estimates on a near-field/far-field approach (<u>AIHA, 2009</u>) for aerosol modeling, and the product concentration was based on the range provided by the singular surrogate product which contained DINP (*i.e.*, 10–20%) rather than DIDP. It is important to note that reliance on a single surrogate product for this OES adds uncertainty to the representativeness of the modeled inhalation exposures. Further, the surrogate product information indicates that the product may be aerosol or brush-applied, and EPA assessed only aerosol application due to limited data for this OES that may lead to overestimation of inhalation exposure values for some applications.

## 4.3.2.3.3 Risk Characterization of COUs

There are multiple application methods for penetrant or inspection fluid products containing DIDP (*i.e.*, Commercial COU: Inspection fluid/penetrant), and the modeling of aerosol application may overestimate inhalation and dermal exposures for lower-exposure application methods such as brush application. Also, there is uncertainty related to the concentration of DIDP in penetrant or inspection fluid products since the only available product data were for DINP. However, central tendency levels of exposure from the near-field/far-field exposure modeling are expected to represent the 50th percentile of worker exposures from the use of aerosols containing DIDP. High-end levels of exposure are generally associated with higher product concentrations and use rates. For modeling aerosol applications, concentration ranged from 10 to 20 percent and use rate ranged from 0.8 to 2 cans (10.5-oz/can) per workday within a near-field/far-field model.

Although most worker exposures to DIDP through aerosol application of inspection fluids and penetrants are expected to be closer to the central tendency exposure values for this COU, a confluence of a subset of variables (*e.g.*, low ventilation, high concentration, high use rate) would result in risk below the benchmark. While most workers are not expected to experience these conditions, they are considered plausible and expected for an acute 1-day exposure.

## 4.3.2.4 PVC Plastics and Non-PVC Material Compounding

## 4.3.2.4.1 Overview of Risk Estimates

For PVC plastics compounding and non-PVC material compounding, inhalation exposure from dust generation is expected to be the dominant route of exposure. In support of this, for PVC plastics compounding, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 30 to 49 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). Similarly, for non-

PVC material compounding MOEs for high-end acute, intermediate, and chronic inhalation exposure 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 98 to 156. Aggregation of inhalation and dermal exposures led to small differences in MOEs when compared to MOE estimates from inhalation exposure alone (high-end MOEs based on aggregate exposure ranged from 24 to 37 (PVC plastics compounding) and 41 to 62 (Non-PVC material compounding) for acute, intermediate, and chronic duration exposures for average adult workers and women of reproductive age). 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 883 (PVC plastics compounding) and 858 to 1,478 (Non-PVC material compounding) for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

#### 4.3.2.4.2 Overview of Exposure Data

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 maximum product concentrations provided by industry for PVC (i.e., 45%) and non-PVC (i.e., 20%) products, respectively, to conservatively estimate DIDP particulate concentrations in the air. The differences in the central tendency and high-end dust concentrations 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 compounding 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.

## 4.3.2.4.3 Risk Characterization of COUs

Though the dust monitoring data from the PNOR model are based on a robust dataset, there is uncertainty regarding the concentration of DIDP in workplace dust. Specifically, it was assumed that the concentration of DIDP in workplace dust is equal to that in PVC or non-PVC products for both high-end and central tendency estimates. However, the concentration of DIDP in workplace dust is likely much lower than the concentrated product due to the presence of other constituents. Further, it was noted during the public comment period (EPA-HQ-OPPT-2024-0073-0069) that liquid plasticizers are generally added to dry mixtures during the compounding process, and any dust generated would come from the dry material rather than the plasticizer.

Inhalation exposure from dust generation is expected to be the dominant route of exposure, though dermal and aggregate exposures were also assessed. Inhalation risk estimates were on the borderline of the benchmark MOE at the high-end for the PVC plastics compounding OES, and the aggregation of inhalation and dermal exposures showed risk values just below the benchmark MOE at the high-end. However, high-end estimates of inhalation exposure are based on high-end dust levels and high-end product concentration (*i.e.*, 45% for PVC and 20% for non-PVC), which likely overestimate worker

exposures due to the conservatism of the input values. Central tendency estimates of inhalation exposure are based on central tendency dust levels, but also high-end product concentration (*i.e.*, 45% for PVC and 20% for non-PVC), which leads to a conservative assessment of worker central tendency exposure.

Therefore, due to the uncertainty regarding DIDP concentrations in workplace dust and potential overestimation at the high-end, central tendency values of exposure are expected to be more reflective of worker exposures within the COUs covered under the "PVC plastics compounding" and "non-PVC material compounding" OESs (*i.e.*, Industrial COUs: Plastic material and resin manufacturing, Plasticizers [rubber manufacturing], and Other [part of the formulation for manufacturing synthetic leather]).

#### 4.3.2.5 PVC Plastics and Non-PVC Material Converting

#### 4.3.2.5.1 Overview of Risk Estimates

For PVC plastics converting and non-PVC material converting, inhalation exposure from dust generation is expected to be the dominant route of exposure. In support of this, for PVC plastics converting, MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 30 to 49 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). Similarly, for non-PVC material converting MOEs for high-end acute, intermediate, and chronic inhalation exposure 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, thus indicating that inhalation is the main exposure contributing to aggregated risk. 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.

#### 4.3.2.5.2 Overview of Exposure Data

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 maximum product concentrations provided by industry for PVC (*i.e.*, 45%) and non-PVC (*i.e.*, 20%) products, respectively, to conservatively estimate DIDP particulate concentrations in the air. The differences in the central tendency and high-end dust concentrations 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.

#### 4.3.2.5.3 Risk Characterization of COUs

Though the dust monitoring data from the PNOR model are based on a robust dataset, there is uncertainty regarding the concentration of DIDP in workplace dust. Specifically, it was assumed that the concentration of DIDP in workplace dust is equal to that in PVC or non-PVC products for both high-end and central tendency estimates. Because the concentration of DIDP in workplace dust is likely much lower than the concentrated product due to the presence of other constituents, the range of inhalation exposure values may overestimate exposures for typical working conditions. Also, dermal exposures to solids containing DIDP are estimated to be minimal at both high-end and central tendency levels. Nevertheless, the aggregated exposure estimates for all worker populations and levels of exposure yielded MOE values above the benchmark MOE for 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]).

## 4.3.2.6 Recycling and Disposal

#### 4.3.2.6.1 Overview of Risk Estimates

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 604–1,091 for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

#### 4.3.2.6.2 Overview of Exposure Data

EPA estimated worker inhalation exposures using the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) for dust exposures (U.S. EPA, 2021d). 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 56 (Administrative and Support and Waste Management and Remediation Services). EPA multiplied these dust concentrations by the industry provided maximum DIDP concentration in PVC (*i.e.*, 45%) to estimate DIDP particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust concentrations led to significant differences between the central tendency and high-end risk estimates. Although the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may experience in the recycling and disposal 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 maximum concentration of DIDP in PVC plastics. 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 recycled or disposed products or articles.

## 4.3.2.6.3 Risk Characterization of COUs

Although the dust monitoring data from the PNOR model are based on a robust dataset, there is uncertainty regarding the concentration of DIDP in workplace dust. Specifically, it was assumed that the concentration of DIDP in workplace dust is equal to that in PVC products (*i.e.*, 45%) for both high-end and central tendency estimates. Because the concentration of DIDP in workplace dust is likely much lower than the concentrated product due to the presence of other constituents, the range of inhalation exposure values may overestimate exposures for typical working conditions. Also, dermal exposures to solids containing DIDP are estimated to be minimal at both high-end and central tendency levels. Nevertheless, the aggregated exposure estimates for all worker populations and levels of exposure yielded MOE values above the benchmark MOE for COUs covered under the Recycling and the Disposal OESs (*i.e.*, Industrial COUs: Recycling and Disposal).

## 4.3.2.7 Fabrication and Final Use of Products or Articles

## 4.3.2.7.1 Overview of Risk Estimates

For fabrication and final use of products or articles, 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 80 to 130 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 724 to 1,168 for acute, intermediate, and chronic exposure scenarios for adult workers and women of reproductive age). Reasons for these variations are described below.

#### 4.3.2.7.2 Overview of Exposure Data

EPA estimated worker inhalation exposures using the *Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR)* for dust exposures (U.S. EPA, 2021d). 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 337 (Furniture and Related Product Manufacturing). EPA multiplied these dust concentrations by the industry provided maximum DIDP concentration in PVC (*i.e.*, 45%) to estimate DIDP particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust concentrations led to significant differences between the central tendency and high-end risk estimates. Though the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may experience in the end use and fabrication 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 maximum concentration of DIDP in PVC plastics. 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 final products or articles.

## 4.3.2.7.3 Risk Characterization of COUs

Although the dust monitoring data from the PNOR model are based on a robust dataset, there is uncertainty regarding the concentration of DIDP in workplace dust. Specifically, it was assumed that the concentration of DIDP in workplace dust is equal to that in PVC products (*i.e.*, 45%) for both high-end and central tendency estimates. Because the concentration of DIDP in workplace dust is likely much lower than the concentrated product due to the presence of other constituents, the range of inhalation

exposure values may overestimate exposures for typical working conditions. Also, dermal exposures to solids containing DIDP are estimated to be minimal at both high-end and central tendency levels. Nevertheless, the aggregated exposure estimates for all worker populations and levels of exposure yielded MOE values above the benchmark MOE for COUs covered under the Fabrication and final use of products and articles OES (*i.e.*, Industrial COU: Abrasives [surface conditioning and finishing discs; semi-finished and finished goods] and Commercial COUs: Automotive products, other than fluids; Building/construction materials [wire or wiring systems; joint treatment, fire-proof insulation]; Electrical and electronic 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]; PVC film and sheet; Furniture and furnishings; Plastic and rubber products [textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses]).

## 4.3.2.8 Distribution in Commerce

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

Worker activities associated with distribution in commerce (*e.g.*, loading, unloading) are not expected to generate mist or dust, similar to other COUs such as manufacturing and import. Therefore, inhalation exposures to workers during distribution in commerce are expected to be from the vapor phase only. Dermal contact with the neat material or concentrated formulations may occur during activities associated with distribution in commerce, also similar to COUs such as manufacturing and import. Though some worker activities associated with distribution in commerce are similar to COUs like manufacturing or import, it is expected that workers involved in distribution in commerce spend less time exposed to DIDP than workers in manufacturing or import facilities since only part of the workday is spent in an area with potential exposure. In conclusion, occupational exposures associated with the distribution in commerce COU are expected to be less than other OESs/COUs without dust or mist generation, such as manufacturing or import, and the COU is described in the following section.

## 4.3.2.9 OESs/COUs without Dust or Mist Generation

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

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

- Manufacturing; Import and repackaging; Incorporation into adhesives and sealants; Incorporation into paints and coatings; Incorporation into other formulations, mixtures, and reaction products not covered elsewhere; Use of laboratory chemicals – liquids; Use of lubricants and functional fluids; and Distribution in commerce.
- Although there is dust generation expected during the OES for Use of laboratory chemicals solids, the industry provided maximum DIDP concentration is very low (*i.e.*, 3%), which leads to

very low levels of potential worker inhalation exposure similar to that of vapor-generating activities.

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

- **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 4-17 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).

## 4.3.2.10 Overall Confidence in Worker Risks

As described in Section 4.1.1.5 and the *Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate* (U.S. EPA, 2024s), 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, 2024v)). For purposes of assessing non-cancer risks for works, the selected acute/intermediate/chronic POD based on developmental toxicity is considered most applicable to female workers of reproductive age. Use of this POD to calculate risks for other age groups (*e.g.*, average adult workers) is conservative. 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.

## Table 4-17. Occupational Risk Summary Table

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

Industrial/Con	Industrial/Commercial COUs			Exposure		ation Risk E chmark MC			nal Risk Est chmark MO		00	0	
Life Cycle Stage/ Category	Subcategory	OES	Population	Level	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
	Surface modifier in paint and		Worker: Average Adult	High-End	2,400	3,273	3,504	98	134	143	94	129	138
Incorporation into formulation, mixture, or reaction product	coating manufacturing		Worker	Central Tendency	2,400	3,273	3,504	196	268	287	181	247	265
	Plasticizers	Incorporation	Worker: Female of	High-End	2,173	2,963	3,172	107	146	156	102	139	149
	xture, or coating	into paints and coatings		Central Tendency	2,173	2,963	3,172	214	291	312	195	265	284
1		ng,		High-End	120,000	163,636	175,200	N/A	N/A	N/A	120,000	163,636	175,200
			ONU	Central Tendency	240,000	327,273	350,400	N/A	N/A	N/A	240,000	327,273	350,400
	Laboratory chemicals manufacturing		Worker: Average Adult	High-End	2,400	3,273	3,504	98	134	143	94	129	138
	Petroleum lubricating oil		Worker	Central Tendency	2,400	3,273	3,504	196	268	287	181	247	265
Incorporation	manufacturing; Lubricants and lubricant	Incorporation into other	Worker: Female of	High-End	2,173	2,963	3,172	107	146	156	102	129       1         247       2         139       1         265       2         163,636       175         327,273       350         129       1         247       2         139       1         247       2         139       1         247       2         139       1         265       2         163,636       175	149
into formulation, mixture, or	additives manufacturing	formulations, mixtures, and reaction		Central Tendency	2,173	2,963	3,172	214	291	312	195	265	284
reaction product	Processing aids.	products not covered elsewhere		High-End	120,000	163,636	175,200	N/A	N/A	N/A	120,000	163,636	175,200
			ONU	Central Tendency	240,000	327,273	350,400	N/A	N/A	N/A	240,000	327,273	350,400

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

Industrial/Cor	nmercial COUs			Eurogram		ation Risk E chmark MC			nal Risk Est chmark MO				
Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Worker:	High-End	74	101	108	9,356	12,758	13,659	74	100	108
			Average Adult Worker	Central Tendency	947	1,292	1,579	18,711	25,515	31,185	902	1,230	1,503
Incorporation into articles		Non-PVC	Worker: Female of	High-End	67	92	98	10,183	13,885	14,867	67	91	97
	Plasticizers <sup>b</sup>	material converting	Reproductive Age	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
			ONU	Central Tendency	1,555	2,121	2,592	18,711	25,515	31,185	1,436	1,958	2,393
			Worker:	High-End	3.3	4.4	4.8	98	134	143	3.2	4.3	4.6
			Average Adult Worker	Central Tendency	533	727	839	196	268	309	143	196	226
Industrial uses – Adhesives and	Adhesives and		Worker:	High-End	2.9	4.0	4.3	107	146	156	2.9	3.9	4.2
sealants	sealants	Application of adhesives and	Female of Reproductive Age	Central Tendency	483	658	760	214	291	336	148	202	233
		sealants – spray application		High-End	533	727	779	196	268	287	143	100       1,230       91       1,122       1,946       1,958       4.3       196       3.9	209
Commercial uses – Construction, paint, electrical, and metal products	Adhesives and sealants (including plasticizers in adhesives and sealants)		ONU	Central Tendency	533	727	839	196	268	309	143	196	226

Industrial/Con	nmercial COUs			P		lation Risk E Ichmark MC			mal Risk Est chmark MO			egate Risk E chmark MO	
Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Incorporation	Abrasives		Worker:	High-End	1,000	1,364	1,460	98	134	143	89	122	130
into articles	manufacturing		Average Adult Worker	Central Tendency	2,000	2,727	3,147	196	268	309	179	244	281
Industrial uses -			Worker:	High-End	905	1,235	1,322	107	146	156	96	130	140
Adhesives and sealants	sealants	Application of adhesives and sealants – non-	Female of Reproductive Age	Central Tendency	1,811	2,469	2,849	214	291	336	191	261	301
Commercial	Adhesives and	spray application		High-End	2,000	2,727	2,920	N/A	N/A	N/A	2,000	2,727	2,920
uses – Construction, paint, electrical, and metal products	(including	аррисанон	ONU	Central Tendency	2,000	2,727	3,147	N/A	N/A	N/A	2,000	2,727	3,147
Industrial uses – Construction, paint, electrical, and metal products	Paints and coatings			High-End	33	44	48	98	134	143	24	33	36
I C S F		Application of paints and coatings – spray	Worker: Average Adult Worker										
uses – Construction,		application		Central Tendency	533	727	779	196	268	287	143	196	209
paint, electrical, and metal	Lacquers, stains,		Worker: Female of	High-End	29	40	43	107	146	156	23	32	34
products	varnishes, and floor finishes (as plasticizer)			Central Tendency	483	658	705	214	291	312	148	202	216
	plasticizer)			High-End	533	727	779	196	268	287	143	196	209
pla			ONU	Central Tendency	533	727	779	196	268	287	143	196	209

Industrial/Con	nmercial COUs				Inhalation Risk Estimates (Benchmark MOE = 30)			nal Risk Est chmark MO		Aggregate Risk Estimates (Benchmark MOE = 30)			
Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Industrial uses – Construction, paint, electrical, and metal products	Paints and coatings		Worker:	High-End	1,000	1,364	1,460	98	134	143	89	122	130
Commercial coatings uses – coatings	(including surfactants in paints and	Application of paints and coatings – non-	Average Adult Worker	Central Tendency	2,000	2,727	2,920	196	268	287	179	244	261
and metal products	Lacquers, stains, varnishes, and	spray application	Worker: Female of	High-End	905	1,235	1,322	107	146	156	96	130	140
	floor finishes (as plasticizer)		Reproductive Age	Central Tendency	1,811	2,469	2,644	214	291	312	191	261	279
Commercial uses –	Ink, toner, and			High-End	2,000	2,727	2,920	N/A	N/A	N/A	2,000	2,727	2,920
Packaging, paper, plastic, hobby products	colorant products		ONU	Central Tendency	2,000	2,727	2,920	N/A	N/A	N/A	2,000	2,727	2,920
			Worker:	High-End	1,000	1,364	1,460	98	134	143	89	122	130
			Average Adult Worker	Central Tendency	2,000	2,727	3,106	196	268	305	179	244	278
Commercial		Use of	Worker:	High-End	905	1,235	1,322	107	146	156	96	130	140
uses – Other uses	chemicals	laboratory chemicals – liquids	Female of Reproductive Age	Central Tendency	1,811	2,469	2,812	214	291	332	191	261	297
				High-End	2,000	2,727	2,920	N/A	N/A	N/A	2,000	2,727	2,920
			ONU	Central Tendency	2,000	2,727	3,106	N/A	N/A	N/A	2,000	2,727	3,106

Industrial/Co	mmercial COUs			Exposure		ation Risk E chmark MC			nal Risk Est chmark MO			egate Risk E chmark MO	
Life Cycle Stage/ Category	Subcategory	OES	Population	Level	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Worker:	High-End	889	1,212	1,298	9,356	12,758	13,659	812	1,107	1,185
			Average Adult Worker	Central Tendency	12,632	17,225	18,442	18,711	25,515	27,318	7,541	10,283	11,010
lloog ()thor		Use of	Worker:	High-End	805	1,097	1,175	10,183	13,885	14,867	746	Intermed.         I           1,107         1           10,283         1           1,017         9           9,986         1           10,283         1           10,283         1           10,283         1           10,283         1           670         2           2,681         1           2,866         1           15,000         1	1,089
	Laboratory chemicals	laboratory chemicals – solids	Female of Reproductive Age	Central Tendency	11,436	15,594	16,696	20,365	27,771	29,733	7,323	9,986	10,692
				High-End	12,632	17,225	18,442	18,711	25,515	27,318	7,541	10,283	11,010
			ONU	Central Tendency	12,632	17,225	18,442	18,711	25,515	27,318	7,541	10,283	11,010
	Functional		Worker:	High-End	1,000	7,500	91,250	98	736	8,956	89	670	8,155
Functional fluids (closed systems)	fluids (closed systems) (SCBA compressor oil)		Average Adult Worker	Central Tendency	2,000	30,000	365,000	196	2,944	35,823	179	2,681	32,622
Industrial uses – Lubricant and lubricant additives	Lubricant and lubricant additives	Use of	Worker: Female of Reproductive	High-End	905	6,790	82,610	107	801	9,748	96	717	8,719
Industrial uses - Solvents (for	DOI VOILD (101	Use of lubricants and functional fluids	Age	Central Tendency	1,811	27,159	330,439	214	3,205	38,990	191	2,866	34,875
cleaning or degreasing)	degreasing)	asing)		High-End	2,000	15,000	182,500	N/A	N/A	N/A	2,000	15,000	182,500
Commercial uses – Automotive, fuel, agriculture outdoor use products	Lubricants		ONU	Central Tendency	2,000	30,000	365,000	N/A	N/A	N/A	2,000	30,000	365,000

Industrial/Co	mmercial COUs			F		lation Risk E Ichmark MC		-	nal Risk Est chmark MO			egate Risk Es chmark MO	
Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
			Worker: Average Adult Worker	High-End Central Tendency	13 47	18 64	19 69	98 196	134 268	144 290	11 38	16 52	17 56
Commercial uses – Other uses	Inspection	Use of penetrants and inspection fluids	Worker: Female of Reproductive Age	High-End Central Tendency	12 43	16 60	17 64	107 214	146 291	157 316	11 36	14 50	16 53
			ONU	High-End Central Tendency	190 1,413	259 1,927	280 2,088	196 196	268 268	288 290	97         132           172         235           9         88         120	142 255	
Industrial uses - Abrasives	Abrasives (surface conditioning and finishing discs; semi-finished and finished goods)		Worker: Average Adult	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	Fabrication and final use of	Worker	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	construction materials (wire or wiring systems; joint treatment, fire- proof insulation)	products or articles	Worker: Female of Reproductive Age	High-End	80	110	117	10,183	13,885	14,867	80	109	117
products	Electrical and electronic products			Central Tendency	724	988	1,057	20,365	27,771	29,733	699	954	1,021
Commercial uses – Furnishing,	Construction and building <sup>c</sup>		ONU	High-End	800	1,091	1,168	18,711	25,515	27,318	767	1,046	1,120

Industrial/Co	mmercial COUs			F		ation Risk E chmark MC		-	nal Risk Est chmark MO			egate Risk E chmark MO	
Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	-				Intermed.	Chronic	Acute	Intermed.	Chronic
cleaning, treatment/care products	Furniture and furnishings					1,091	1,168	18,711	25,515	27,318	767	1,046	1,120
		Fabrication and											
Commercial uses – Packaging, paper, plastic, hobby products	Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	final use of products or articles		Central Tendency	800								
				High-End	46	62	67	9,356	12,758	13,659	45	62	66
Recycling	Recycling		Average Adult Worker	Central Tendency	667	909	1,091	18,711	25,515	30,626	644	878	1,054
				High-End	41	56	60	10,183	13,885	14,867	41	56	60
		Recycling and disposal	Female of Reproductive Age	Central Tendency	604	823	988	20,365	27,771	33,333	586	799	959
Disposal	Disposal			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

<sup>*a*</sup> 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)

<sup>b</sup> 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)

<sup>c</sup> 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))

#### 4.3.3 Risk Estimates for Consumers

Table 4-18 summarizes the dermal, inhalation, ingestion, and aggregate MOEs used to characterize noncancer 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 4-18 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  $\sim 1 \text{ m}^2$ ) 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 4-18.

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 *Consumer Risk Calculator for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024c).

## 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 (<1 year) to 11,221,891,082 for chronic duration ingestion of suspended dust from new children's toys for adults (21+ years) (Table 4-18). 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 *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a) and *Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024v), 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 ranged from 27 to 30 (Table 4-18). This COU is discussed further below and in more detail in *the Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (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 (<1 year), toddlers (1–2 years), preschoolers (3–5 years), children (6–10 years), teens (11–15 and 16–20 years), and adults (21+ years). The acute MOE was 30 for the high-intensity acute inhalation exposure scenario for infants (<1 year) and ranged from 31 to 39 for toddlers and preschoolers, and 56 to 115 for all other evaluated lifestages, while high-intensity chronic MOEs ranged from 33 to 43 for infants, toddlers, and preschoolers, and 62 to 128 for all other lifestages. Medium-intensity MOEs for the inhalation route ranged from 63 to 272 for acute and chronic inhalation exposure scenarios for all evaluated lifestages. EPA also considered aggregate exposure to DIDP for this COU. High-intensity aggregate MOEs ranged from 27 to 34 and 31 to 38 for acute and chronic duration exposures, respectively, for infants (<1 year), toddlers (1–2 years) and preschoolers (3–5 years). High-intensity aggregate MOEs for other lifestages for this COU ranged from 52 to 125. For this COU, the primary pathway is inhalation exposure to consumers in the indoor environment, while dermal exposure and ingestion of suspended dust and dust on surfaces were comparatively minor pathways.

Variability in high-intensity inhalation MOEs across lifestages result from use of different lifestagespecific exposure factors such as body weight and inhalation rate. Differences in MOEs between the high- and medium-intensity inhalation exposure scenarios result from use of different exposure parameters in CEM. Key parameters that differed between high- and medium-intensity scenarios include weight fraction (*i.e.*, 0.26 vs. 0.245), article surface area (*i.e.*, 200 vs. 100 m<sup>2</sup>), and inhalation rates used per lifestage. Inhalation rates for lifestages range from 0.74 to 0.46 m<sup>3</sup>/h for adults to infants respectively, with the largest difference between infants and the next lifestage. Other CEM exposure factors were kept constant between high- and medium-intensity inhalation scenarios (*e.g.*, surface layer thickness, volume of use environment, interzone ventilation rate). Overall, EPA has moderate confidence in the inhalation exposure estimates and robust confidence in the non-cancer hazard value used to estimate non-cancer risk for this COU (U.S. EPA, 2024a, v).

The in-place wallpaper inhalation scenario in this assessment applies to stay-at-home infants to adults. In this scenario DIDP in wallpaper is released into the gas-phase, the article inhalation scenario tracks chemical transport between the source, air, airborne and settled particles, and indoor sinks by accounting for emissions, mixing within the gas phase, transfer to particulates by partitioning, removal due to ventilation, removal due to cleaning of settled particulates and dust to which DIDP has partitioned, and sorption or desorption to/from interior surfaces. The emissions from the wallpaper were modeled with a single exponential decay model. This means that chronic and acute exposure duration scenario uses the same emissions/air concentration data based on the weight fraction but have different averaging times for the air concentration used. The acute data uses concentrations for a 24-hour period at the peak, while the chronic data were averaged over the entire 1-year period. Because air concentrations for most of the year are significantly lower than the peak value, the air concentration used in chronic dose calculations is lower than acute, resulting in a lower dose per day rate and risk estimate. Additionally, chemical emissions from articles to the gas phase and particulate also decreases in time as wallpaper has a finite amount of DIDP. However, the rate of this emission is not known and the impact to the modeled estimates is also not well understood, adding uncertainty to the estimates.

The in-place wallpaper assessment provides a range of reasonable values which reflect possible exposures. The high values likely represent an upper boundary for exposure and may, in some cases, overestimate the highest possible dose expected. One such case is inhalation-ingestion of DIDP in dust and particulates. CEM assumes that 100 percent of the chemical that is on the dust or particulate matter will be absorbed when the dust or particulate matter is inhaled or ingested. This is highly unlikely to be the case as bioavailability is generally reduced in inhaled particulate sa compared to gas phase or aerosol chemicals. The bioavailable fraction of DIDP in dust and particulate matter would be difficult to quantify due to the absence of quantitative data in literature. However, EPA recognizes that the

assumption of 100 percent absorption through inhalation of DIDP in dust/particulate matter and ingestion of DIDP in dust/particulate matter likely overestimate exposure by these routes.

The difference between high and medium intensity scenarios risk estimates is driven by the weight fraction and article surface area. For this specific article, the confidence in the data used for weight fraction is slight because a surrogate chemical, DINP, concentration was used in the absence of DIDP specific data and a communication with ACC (U.S. EPA, 2024o) confirmed that the vinyl component of wallpaper can be up to 23 percent w/w of plasticizer, which is not DIDP-specific, but it can be matched to the low intensity use scenario. The confidence in the surface area is moderate because the source was the *Exposure Factors Handbook*. Although it is unclear how representative the risk estimates for the high and medium intensity scenarios are because of the high uncertainty from the weight fraction data source, EPA made a conservative assumption for the high-intensity exposure scenario. The difference in risk estimates among lifestages is driven by the inhalation rate to body weight ratio. Because the high intensity use scenario for infants MOE resulted in 30, the parameters driving the differences between high and medium intensity use scenarios serve as sensitivity indicators: weight fractions, surface area, and the inhalation rate to body weight ratio.

The aggregation across routes for a high-intensity exposure scenario for infants resulted in an MOE value of 27. The inhalation and ingestion of surface dust are the main contributors to the overall aggregate MOE value. The inhalation scenarios are explained above. The surface dust ingestion scenario model estimates the DIDP concentration in settled dust on the wallpaper surface, assuming primarily that DIDP partitions directly from the wallpaper to settled dust. The model assumes exposure to occur through dust intake via incidental ingestion assuming a daily stay-at-home dust ingestion rate per lifestage. The model, assuming instantaneous equilibrium is achieved for partitioning, represents an upper bound scenario. Overestimation of DIDP concentration in the dust compartment happens when incidental ingestion after inhalation and hand-to-mouth are both included in every ingestion estimate. The model estimates that DIDP enters the air phase and while suspended it can partition to dust, particles generated by material wear, and surfaces, which makes incidental ingestion after inhalation possible. Then the suspended particulate settles, which makes hand-to-mouth ingestion possible. The overestimation magnitude and effect cannot be quantified with any accuracy or certainty based on current literature. There is no difference between chronic and acute exposure, as both rely on the same upper end dust concentration. The aggregated MOE overall confidence originates from compounding and intensifying the uncertainties from each aggregated exposure route. The overall confidence for each exposure route aggregated, dermal, inhalation, and ingestion, were moderate for in-place wallpaper scenario. The uncertainties about weight fraction sources and overestimation for all three high intensity exposure routes suggest that the high intensity use aggregate scenario may not reflect or capture realistic exposures.

#### 4.3.3.1 Overall Confidence in Consumer Risks

As described in Section 4.1.2.5 and in more technical details in Section 5.1 in the *Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a), EPA has moderate to robust confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios, 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, 2024v)). The exposure doses used to estimate risk relied on conservative, health protective inputs and parameters that are considered representative of a wide selection of use patterns. Further, the non-cancer POD selected to characterize risk is based on reduced F2 offspring survival on PND1 and PND4 in rats. The developmental effect that serves as the basis of the POD is considered most relevant for assessing risk to women of reproductive age, pregnant women, and infants. Use of this POD to assess risk for other lifestages (*e.g.*, toddlers,

preschoolers, and other children) is a conservative approach. Sources of uncertainty associated with this consumer COUs are discussed above in Section 4.3.3. While the conservative approaches used for consumer risks, in particular the in-place wallpaper use, constitute a defensible screen to eliminate with confidence risk concerns, where benchmark exceedances are indicated the conservative nature of the assumptions, as well as uncertainties in the assumptions, should be considered when using these estimates to inform a risk determination.

			ľ	_			L	ifestage (yea	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
			Dermal	Н	_	_	_	_	_	122,178	114,331	M/ R
		Acute	Ingestion by Mouthing	Н	_	_	_	_	_	288	321	M/ R
Consumer Uses:			Aggregate	Н	_	_	_	—	_	287	321	_
Other uses: Novelty	Adult toys	Intermediate	_	-	_	_	_	_	_	_	_	_
Articles	-	Chronic	Dermal	Н	_	_	_	—	_	122,178	114,331	M/ R
			Ingestion by Mouthing	Н	_	_	_	_	_	288	321	M/ R
			Aggregate	Н	_	_	_	_	_	287	321	_
Consumer Uses:	Auto	Acute	Dermal	Н	_	_	_	_	13,256	14,495	13,564	M/ R
Automotive, fuel,	Transmission		Inhalation	Н	†3,905,883	†4,146,245	†5,100,539	†7,325,032	9,624,741	11,245,617	14,001,320	R/ R
agriculture, outdoor	Conditioner		Aggregate	Н	_	_	_	_	13,237	14,476	13,551	_
use products: Lubricants	$(\dagger = MOE \text{ for }$	Intermediate	-	_	_	_	_	_	_	-		_
Lubricants	(1 = MOE for bystander	Chronic	Dermal	Н	_	_	_	_	4,838,273	5,290,655	4,950,860	M/ R
	scenario)		Inhalation	Н	†12,323,061	†13,081,404	†16,092,203	†23,110,480	28,451,314	33,446,036	41,423,821	R/ R
	,		Aggregate	Н	_	_		_	4,135,084	4,568,058	4,422,317	_
Consumer Uses: Other uses: Automotive articles	Products Are Like Synthetic Leather Fabrics in Furniture	See synth	1		rios. Use patte	erns for derma	furniture.			fabric has sar		
Consumer Uses:		Acute	Dermal	Н	—	—	71,198	88,311	111,731	122,178	114,331	M/ R
Packaging, paper,		Intermediate	_	-	—	—	_	_	_	—	_	_
(textiles, apparel, and leather; vinyl tape; flexible tubes;	Bags	Chronic	Dermal	Н	_	_	71,198	88,311	111,731	122,178	114,331	M/ R
profiles; hoses												

				-			L	ifestage (yea	rs)			Overall
Life Cycle Stage: COU: Subcategory		Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
			Dermal	Н	34,824	40,724	47,118	58,443	73,942	80,855	_	R/ R
			Ingestion suspended dust**	Н	9,444,466	10,025,664	12,333,158	17,712,006	25,108,365	29,323,429	36,523,366	R/ R
Legacy Consumer Uses: Children's Packaging, paper, Toys	Acute	Ingestion dust on surface**	Н	5,862	4,735	4,194	11,950	21,345	26,907	266,106	R/ R	
		Ingestion by mouthing	Н	240	917	1,796	_	_	_	_	R/ R	
		Inhalation**	Н	235	249	307	440	624	729	908	R/ R	
	Toys		Aggregate	Н	116	187	245	422	602	704	905	—
· ·	(** – Part of	Intermediate	_	_	-	_	_	_	_	_	_	—
plastic, hobby products: Toys, (** = Part of Playground, and indoor Sporting Equipment exposure scenario)		Dermal	Н	34,824	40,724	47,118	58,443	73,942	80,855	_	R/ R	
	osure	Ingestion suspended dust**	Н	11,160,902	11,847,727	14,574,585	20,930,985	29,671,556	34,652,666	43,161,119	R/ R	
		Chronic	Ingestion dust on surface**	Н	6,665	5,383	4,768	13,586	24,268	30,591	68,359	R/ R
			Ingestion by mouthing	Н	240	917	1,796	_	_	_	_	R/ R
			Inhalation**	Н	263	279	343	492	698	815	1,015	R/ R
			Aggregate	Н	123	205	270	471	672	786	1,000	

				_			L	ifestage (yea)	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>		Toddler (1-2)	Preschooler (3–5)	(6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
			Dermal	Н	34,824	40,724	47,118	58,443	73,942	80,855	—	R/R
			Ingestion suspended dust**	Н	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
		Acute	Ingestion dust on surface**	Н	1,524,204	1,231,088	1,090,392	3,107,031	5,549,665	6,995,705	61,204,411	R/ R
	New		Ingestion by mouthing	Н	240	917	1,796	_	_	_	_	R/ R
Consumer Uses:	Children's		Inhalation**	Н	61,047	64,804	79,719	114,487	162,296	189,541	236,080	R/ R
Packaging, paper,	Toys		Aggregate	Н	238	884	1,691	38,215	50,337	56,222	235,167	_
plastic, hobby products: Toys,	(** = Part of	Intermediate	_	-	_	_	—	_	—	_	-	_
	<b>X</b>		Dermal	Н	34,824	40,724	47,118	58,443	73,942	80,855	—	R/ R
Playground, and indoor Sporting Equipment exposure	exposure scenario)		Ingestion suspended dust**	Н	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
		Chronic	Ingestion dust on surface**	Н	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 mouthing	Н	240	917	1,796	_	_	_	_	R/ R
			Inhalation**	Н	68,266	72,467	89,146	128,026	181,488	211,955	263,998	R/ R
			Aggregate	Н	238	885	1,695	39,675	52,103	58,100	260,128	_
		Acute	Dermal	Н	_	_	_	_	1,105	1,208	1,130	M/ R
Consumer Uses:	Construction		Inhalation	Н	†41,580	†44,139	†54,298	†77,979	99,614	117,533	145,107	R/ R
Construction, paint, electrical, and metal small Small S	Adhesive for		Aggregate	Н	_	_	_		1,093	1,196	1,122	_
	Small Scale	Intermediate	Dermal	Н	_	_	_		828	906	848	M/ R
and sealants	Projects		Inhalation	Н	†31,185	†33,104	†40,723	†58,484	74,710	88,150	108,830	R/ R
(including	$(\dagger = MOE \text{ for }$		Aggregate	Н	_	_	_	_	819	897	841	_
lasticizers in		Chronic	Dermal	Н	-	-	_	_	23,261	25,436	23,802	M/ R
adhesives and sealants)	scenario)		Inhalation	Н	†7,982	†8,473	†10,423	†14,969	17,668	21,146	25,788	R/ R
scurulits)			Aggregate	Н	-	-		_	10,041	11,547	12,378	_

							L	ifestage (yea	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
Consumer Uses:		Acute	Dermal	Н	_	_	_	_	828	906	848	M/ R
Consumer Uses: Construction, paint,	Construction		Inhalation	Н	†7,489	†7,950	†9,780	†14,045	11,043	14,001	16,241	R/ R
electrical, and metal	Sealant for		Aggregate	Н	-	_	_	_	771	851	806	_
products: Adhesives	Large Scale	Intermediate	Dermal	Н	-	_	_	_	3,681	302	283	M/ R
and sealants	Projects		Inhalation	Н	†2,496	†2,650	†3,260	†4,682	276	4,667	5,414	R/ R
(including	$(\dagger = MOE \text{ for }$		Aggregate	Н	_	—	_	_	257	284	269	_
nlasticizars in	bystander	Chronic	Dermal	Н	_	_	_	_	100,797	110,222	103,143	M/ R
sealants)	scenario)		Inhalation	Н	†8,319	†8,831	†10,864	†15,602	13,080	16,462	19,220	R/ R
scarants)			Aggregate	Н	-	-	_	_	11,578	14,323	16,201	_
Consumer Uses:		Acute	Dermal	Н	-	-	_	_	13,256	14,495	13,564	R/ R
Construction, paint,	Epoxy Floor		Inhalation	Н	†13,041	†13,844	†17,030	†24,457	32,137	37,550	46,751	M/ R
electrical, and metal	Patch		Aggregate	Н	_	_	_	_	9,385	10,458	10,514	_
1		Intermediate	_	-	_	_	_	_	_	_	_	_
(including	$\dagger = MOE$ for	Chronic	Dermal	Н	_	_	_	_	4,838,273	5,290,655	4,950,860	R/ R
plasticizers in	bystander		Inhalation	Н	†41,298	†43,839	†53,929	†77,449	95,348	112,086	138,822	M/ R
adhesives and sealants)	scenario)		Aggregate	Н	-	—	_	_	93,505	109,761	135,036	-
Consumer Uses:		Acute	Dermal	Н	-	-	_	_	111,731	122,178	114,331	M/ R
Packaging, paper,		Intermediate	_	_	_	_	_	_	_	_	—	_
plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses	Fitness Ball	Chronic	Dermal	Н	_	-	-	_	111,731	122,178	114,331	M/ R
Consumer Uses:		Acute	Dermal	Н	-	-	25,172	31,223	39,503	43,196	40,422	M/ R
Packaging, paper,		Intermediate		-	_		-	_		-	-	_
	Foam Flip Flops	Chronic	Dermal	Η	_		25,172	31,223	39,503	43,196	40,422	M/ R

COU: Subcategory Consumer Uses: La Construction, paint, lectrical, and metal roducts: Adhesives nd sealants († ncluding lasticizers in dhesives and ealants); and Paints nd Coatings							L	ifestage (yea	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1–2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
Consumer Uses:	Lacquer	Acute	Dermal	Н	_	_	_	_	414	453	424	M/ R
	· ·		Inhalation	Н	†3,192	†3,388	†4,168	†5,178	6,778	8,656	9,978	M/ R
,	spray)		Aggregate	Н	_	_	_	_	390	430	407	—
<b>^</b>	(+ – MOE for	Intermediate	Dermal	Н	_	_	_	_	207	226	212	M/ R
	X =		Inhalation	Н	†1,596	†1,694	†2,084	†2,589	3,389	4,328	4,989	M/ R
plasticizers in	scenario)		Aggregate	Н	_	—	_	_	195	215	203	—
adhesives and	Ihesives and alants); and Paints d Coatings onsumer Uses: onstruction, paint,	Chronic	Dermal	Н	_	—	_	_	75,598	82,666	77,357	M/ R
sealants); and Paints	COU: SubcategoryArticleconsumer Uses: onstruction, paint, ectrical, and metal oducts: Adhesives ad sealants ncluding asticizers in thesives and alants); and Paints ad CoatingsLacquer Sealer (Non- spray)consumer Uses: onsumer Uses: onstruction, paint, ectrical, and metal oducts: Adhesives ad CoatingsLacquer scenario)consumer Uses: onsumer Uses: onstruction, paint, ectrical, and metal oducts: Adhesives ancluding asticizers in thesives and alants); and Paints ad CoatingsLacquer Sealer (Spray)(† = MOE for bystander scenario)Sealer (Spray)(† = MOE for bystand		Inhalation	Н	†5,724	<b>†6,077</b>	†7,475	†9,790	10,345	13,077	15,210	M/ R
and Coatings	COU: SubcategoryArticleonsumer Uses: onstruction, paint, lectrical, and metal roducts: Adhesives nd sealants ncluding lasticizers in thesives and ealants); and Paints nd CoatingsLacquer Sealer (Non- spray)onsumer Uses: onstruction, paint, lectrical, and metal roducts: Adhesives ad coatingsLacquer scenario)onsumer Uses: onstruction, paint, lectrical, and metal roducts: Adhesives ncluding lasticizers in thesives and ealants); and Paints ncluding lasticizers in thesives and ealants); and Paints nd CoatingsLacquer Sealer (Spray)(† = MOE for bystander scenario)Sealer (Spray)(astic, hobby roducts: PVC film nd sheetMiscellaneous Awnings)onsumer Uses: ackaging, paper, lastic, hobby roducts: Arts, crafts, nd hobby materialsRubber Eraser		Aggregate	Н	_	_	_	_	9,100	11,291	12,711	_
Consumer Uses:		Acute	Dermal	Н	_	_	_	_	1,036	1,132	1,060	M/ R
Construction, paint,			Inhalation	Н	†3,173	†3,368	†4,143	†5,143	6,659	8,514	9,804	M/ R
electrical, and metal			Aggregate	Н	_	_	_	_	896	999	956	_
	Sealer (Spray)	Intermediate	Dermal	Н	_	_	_	_	518	566	530	M/ R
and sealants(includingplasticizers inadhesives andscenario)			Inhalation	Н	†1,586	†1,684	†2,072	†2,571	3,329	4,257	4,902	M/ R
	S 1		Aggregate	Н	_	_	_	_	448	500	478	_
	2	Chronic	Dermal	Н	_	_	_	_	188,995	206,666	193,393	M/ R
sealants); and Paints	~		Inhalation	Н	†5,724	<i>†6,076</i>	†7,475	†9,789	10,343	13,074	15,206	M/ R
ealants); and Paints nd Coatings		Aggregate	Н	_	=	=	=	9,806	12,296	14,098	_	
Consumer Uses:	Miscellaneous	Acute	Dermal	Н	_	_	_	_	111,731	122,178	114,331	M/ R
Packaging, paper,		Intermediate	_	_	_	_	_	_	_	_	_	_
plastic, hobby products: PVC film and sheet	(Truck	Chronic	Dermal	Н	_	-	-	—	111,731	122,178	114,331	M/ R
		Acute	Dermal	Н	_	_	177,996	220,778	279,328	305,445	285,828	R/ R
Consumer Uses: Packaging, paper, plastic, hobby			Ingestion by mouthing	Н	_	-	1,027	1,755	_	—	_	R/ R
			Aggregate	Н	_	_	1,021	1,741	_	_	_	_
1 / J	Rubber Eraser	Intermediate	-	-	_	-	-	-	_	_	_	_
and hobby materials		Chronic	Dermal	Н	_	_	177,996	220,778	279,328	305,445	285,828	R/ R
(crafting paint applied to craft)			Ingestion by mouthing	Н	_	-	1,027	1,755		=	_	R/ R
			Aggregate	Н	_	_	1,021	1,741	_	_	_	_

				_			Ι	Lifestage (yea	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup><i>a</i></sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
Consumer Uses: Packaging, paper, plastic, hobby products: Arts, crafts, and hobby materials (crafting paint applied to craft)	Current p	roducts were n	ot identified.	Foreseeable	uses were mai		lacquers, and ected.	sealants (sma	ll and large pr	ojects) becaus	e similar use p	atterns are
Consumer Uses: Packaging, paper, plastic, hobby products: Ink, toner, and colorant products	Current p	roducts were n	ot identified.	Foreseeable	uses were mat		lacquers, and ected.	sealants (sma	ll and large pr	ojects) becaus	e similar use p	atterns are
			Dermal	Н	-	—	71,198	88,311	111,731	122,178	114,331	R/ R
			Ingestion suspended dust**	Н	29,349,444	31,155,564	38,326,289	55,041,496	78,026,279	91,124,933	113,499,321	M/ R
Consumer Uses:		Acute	Ingestion dust on surface**	Н	31,099	25,118	22,248	63,394	113,232	142,737	318,964	M/ R
Packaging, paper, plastic, hobby	Shower Curtain		Inhalation**	Н	914	970	1,194	1,714	2,430	2,838	3,535	R/ R
products: Plastic and	Curtain		Aggregate	Н	888	934	1,115	1,638	2,330	2,721	3,393	_
	(** = Part of	Intermediate	—	-	-	-	_	-	_	_	_	-
(textiles, apparel, and			Dermal	Н	-	-	71,198	88,311	111,731	122,178	114,331	R/ R
leather; vinyl tape; flexible tubes; profiles; hoses	exposure scenario)	posure In enario) su	Ingestion suspended dust**	Н	33,861,044	35,944,801	44,217,811	63,502,482	90,020,489	105,132,669	130,946,451	M/ R
		Chronic	Ingestion dust on surface**	Н	35,360	28,560	25,296	72,080	128,747	162,294	362,668	M/ R
			Inhalation**	Н	35,360	28,560	25,296	72,080	128,747	162,294	362,668	R/ R
1	1	1	Aggregate	Н	17,671	14,274	10,738	25,584	40,824	48,739	70,083	

				-			I	lifestage (yea	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
			Dermal	Н	37,209	43,513	50,345	62,445	79,006	86,393	80,844	M/ R
			Ingestion suspended dust**	Н	38,746,871	41,131,294	50,598,021	72,665,287	103,009,591	120,302,315	149,840,781	R/ R
Consumer Uses: Construction, paint, electrical, and metal		Acute	Ingestion dust on surface**	Н	4,861	3,926	3,478	9,909	17,700	22,312	49,859	R/ R
products: Building/construction	Solid Flooring		Inhalation**	Н	402	426	524	753	1,067	1,247	1,553	R/ R
motorials opyoning			Aggregate	Н	367	381	452	692	994	1,165	1,478	-
large surface areas	(** = Part of indoor	Intermediate	_	-	_	_	—	_	_	_	_	_
including stone,	exposure		Dermal	Н	37,209	43,513	50,345	62,445	79,006	86,393	80,844	M/ R
plaster cement glass expo	scenario)		Ingestion suspended dust**	Н	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**	Н	5,525	4,463	3,953	11,263	20,117	25,359	56,669	R/ R
			Inhalation**	Н	450	477	587	843	1,195	1,396	1,739	R/ R
			Aggregate	Н	411	427	506	775	1,112	1,303	1,653	_
Consumer Uses:		Acute	Dermal	Н	-	_	_	_	894	974	1,018	M/ R
Furnishing, cleaning,	Synthetic	Intermediate	_	_	-	_	_	_	_	—	—	M/ R
treatment/care products: Fabrics, textiles, and apparel (as plasticizer)	Leather	Chronic	Dermal	Н	_	_		_	894	974	1,018	M/ R

COU: Subcategory Consumer Uses: urnishing, cleaning, eatment/care roducts: Fabrics, extiles, and apparel as plasticizer)				_			L	ifestage (yea	rs)			Overall
	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>
			Dermal	Н	491	553	613	737	894	974	1,018	R/ R
			Ingestion suspended dust**	Н	4,860,228	5,159,319	6,346,781	9,114,796	12,921,045	15,090,164	18,795,332	M/ R
		Acute	Ingestion dust on surface**	Н	1,949	1,574	1,394	3,973	7,097	8,946	19,991	M/ R
	Synthetic		Ingestion by mouthing	Н	384	659	1,027	_	_	_	—	M/ R
Consumer Uses:	Leather		Inhalation**	Н	86	91	112	161	229	267	333	R/ R
Furnishing, cleaning,	Furniture		Aggregate	Н	60	67	82	128	178	205	248	_
	(** = Part of	Intermediate	_	-	_	_	_	_	_	_	_	_
1 ·	indoor		Dermal	Н	491	553	613	737	894	974	1,018	R/ R
(as plasticizer) exp	exposure scenario)		Ingestion suspended dust**	Н	5,898,111	6,261,072	7,702,112	11,061,227	15,680,285	18,312,612	22,809,004	M/ R
		Chronic	Ingestion dust on surface**	Н	2,217	1,791	1,586	4,519	8,071	10,175	22,737	M/ R
			Ingestion by mouthing	Н	384	659	1,027	_	_	-	-	M/ R
			Inhalation**	Н	96	102	126	181	256	299	372	R/ R
			Aggregate	Н	65	73	89	141	194	224	269	_
Consumer Uses:	Wallpaper	Acute	Dermal	Н	_	_	_	_	27,933	30,545	28,583	M/ R
Packaging, paper,	(Application)	Intermediate	_	_	_	_	_	_	_	—	_	_
plastic, hobby products: Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes;		Chronic	Dermal	Н	_	_	-	_	10,195,466	11,148,750	10,432,715	M/ R

				_			L	ifestage (yea	rs)			Overall	
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence <sup>b</sup>	
		Acute	Dermal	Н	52,622	61,536	71,198	88,311	_	_	_	M/ R	
				М	91,144	106,584	123,319	152,959	_	_	_	M/ R	
			Ingestion	Н	2,859,011	3,034,950	3,733,471	5,361,746	7,600,758	8,876,734	11,056,286	M/ R	
Consumer Uses: Packaging, paper, Wallpaper (In plastic, hobby Place)	llpaper (In	suspended dust**	М	5,900,182	6,263,270	7,704,816	11,065,110	15,685,791	18,319,041	22,817,012	M/ R		
		Ingestion	Н	359	290	257	731	1,306	1,647	3,680	M/ R		
		dust on surface**	М	761	614	544	1,551	2,770	3,491	7,802	M/ R		
		Inhalation**	Н	30	31	39	56	79	92	115	M/ R		
			М	63	67	82	118	167	195	243	M/ R		
		Aggregate	Н	27	28	34	52	74	87	111	_		
	T face)			М	58	60	71	110	158	185	236	_	
products: Plastic and rubber products (** = Part of I	Intermediate		_	-	_	_	_	_	_	_	_		
	Chronic	Dermal	Н	52,622	61,536	71,198	88,311	_	—	—	M/ R		
			М	91,144	106,584	123,319	152,959	_	—	—	M/ R		
		Ingestion	Н	3,551,514	3,770,069	4,637,783	6,660,455	9,441,796	11,026,836	13,734,314	M/ R		
		s	su	suspended dust**	М	7,308,222	7,757,959	9,543,520	13,705,727	19,429,102	22,690,761	28,262,144	M/ R
			Ingestion	Н	408	329	292	831	1,485	1,872	4,183	M/ R	
			dust on surface**	М	865	698	618	1,762	3,148	3,968	8,867	M/ R	
			Inhalation**	Н	33	35	43	62	88	103	128	M/ R	
				М	70	75	92	132	187	219	272	M/ R	
			Aggregate	Н	31	32	38	58	83	98	125	_	
				М	65	67	80	123	177	207	264	_	

				_			L	ifestage (year	rs)			Overall
Life Cycle Stage: COU: Subcategory	Product / Article	Duration	Exposure Route	Exposure Scenario (H, M, L) <sup>a</sup>	Infant (<1)	Toddler (1-2)	Preschooler (3–5)	Middle Childhood (6–10)	Young Teen (11–15)	Teenagers (16–20)	Adult (≥21)	Exposure/ Hazard Confidence
			Dermal	Н	52,622	61,536	71,198	88,311	111,731	122,178	114,331	M/ R
			Ingestion suspended dust**	Н	82,715,538	87,805,725	108,014,979	155,123,448	219,901,463	256,817,398	319,875,137	M/ R
		Acute	Ingestion dust on surface**	Н	10,095	8,154	7,222	20,579	36,757	46,335	103,542	M/ R
COU: SubcategoryArticleConsumer Uses: Construction, paint, electrical, and metal products: Electrical and Electronic ProductsWire Insulation (** = Part of indoor exposure scenario)		Ingestion by mouthing	Н	384	659	1,027	_	_		_	M/ R	
		Inhalation**	Н	833	884	1,088	1,562	2,215	2,586	3,221	M/ R	
		Aggregate	Н	255	359	489	1,428	2,050	2,401	3,041	_	
	Intermediate	_	-	_	—	—	_	—	_	—	_	
		Dermal	Н	52,622	61,536	71,198	88,311	111,731	122,178	114,331	M/ R	
		Ingestion suspended dust**	Н	103,065,270	109,407,748	134,588,897	193,287,022	274,001,768	319,999,787	398,571,032	M/ R	
	Chronic	Ingestion dust on surface**	Н	11,475	9,268	8,209	23,392	41,781	52,668	117,694	M/ R	
			Ingestion by mouthing	Н	384	659	1,027	_	_		—	M/ R
			Inhalation**	Н	933	990	1,218	1,749	2,480	2,896	3,607	M/ R
			Aggregate	Н	264	377	518	1,598	2,293	2,685	3,396	-

## 4.3.4 Risk Estimates for General Population

As described in the Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024r) 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 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 Human Health Hazard Assessment for Diisodecyl Phthalate (U.S. EPA, 2024y), 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 risk evaluation. For example, women of reproductive age were evaluated for occupational exposures to DIDP for each COU (Section 4.3.2) and infants (<1 year), toddlers (1–2 years), and middle school children (6-10 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 and a sensitive subpopulation (*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<sub>H</sub> to account for human variability in addition to relying on the most sensitive endpoint from a sensitive subpopulation. 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 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 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.

- 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, and hand-to-mouth ingestion from synthetic leather furniture).
- 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).

# 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:

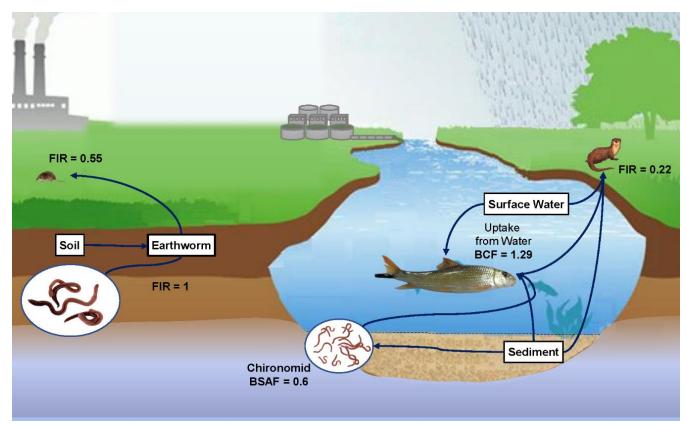
- EPA expects the main environmental exposure pathway for DIDP to be released to surface water and subsequent deposition to sediment.
- The OES with the highest environmental media release to surface water or wastewater and fugitive or stack air release was the PVC plastics compounding OES.
- Although 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

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

1.29 L/kg, the calculated concentration of DIDP in fish was  $2.2 \times 10^{-4}$  mg/kg, which was two orders of magnitude lower than the highest DIDP measured concentrations reported in aquatic biota in the peerreviewed literature (McConnell, 2007; Mackintosh et al., 2004). Deposition of DIDP from air was modeled via AERMOD, then daily deposition values were modeled with VVWM-PSC to represent surface water and sediment concentrations. Exposure to terrestrial species through air deposition to soil was also assessed using data modeled using American Meteorological Society/Environmental Protection Agency Regulatory Model (AERMOD). DIDP is not considered bioaccumulative; however, within the aquatic environment, relevant environmental exposures are possible through incidental ingestion of sediment while feeding and/or ingestion of food items that have become contaminated due to uptake from sediment. Exposure through diet was assessed through a trophic transfer analysis with representative species, which estimated the transfer of DIDP from soil through the terrestrial food web, from surface water and sediment through the aquatic food web via releases to surface waters, and air deposition to surface water and sediment (Figure 5-1). The results of the trophic transfer analysis indicate 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.

The OES resulting in the highest environmental media concentrations from surface water or wastewater release and fugitive or stack air release was the PVC plastics compounding OES. The PVC plastics compounding OES is 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). The highest OES estimate (PVC plastics compounding) resulted in DIDP exposure concentrations in a modeled terrestrial ecosystem of 0.05 mg DIDP/kg in the earthworm (Eisenia fetida) consuming soil with an estimated dietary intake of 0.03 mg DIDP/kg-bw/day in shorttail shrews (Blarina brevicauda). Within the aquatic modeled ecosystem, the highest OES estimate (PVC plastics compounding) resulted in a DIDP dietary exposure concentration of 92.4 mg DIDP/kg-bw/day in American mink (Mustela vison) when VVWM-PSC modeled DIDP in sediment with a P50 7Q10 flow. Mink DIDP dietary exposure rates using VVWM-PSC modeled DIDP in sediment with P75 and P90 7Q10 flows were 9.16 mg DIDP/kg-bw/day and  $6.1 \times 10^{-1}$  mg DIDP/kg-bw/day, respectively. The inclusion of modeled sediment concentrations of DIDP from varying percentile 7Q10 flow rates allowed for this analysis to demonstrate an array of dietary exposure rates of DIDP for a representative mammal based on low flow conditions across the distribution of flow data from NAICS codes comprising the COU/OES with the highest release to surface water and sediment.



# 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 (<u>Parkerton and Konkel, 2000</u>); however, previous assessments have found few to no effects of DIDP on organism survival and fitness (<u>EC/HC, 2015a</u>; <u>ECJRC, 2003a</u>). 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 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. 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). No avian studies were reasonably available to assess potential hazards from DIDP exposure. Avian hazard data available for DEHP; however, EPA has less confidence in DEHP to use in a quantitative read-across for DIDP. DEHP can serve as a comparator compound in the absence of avian hazard data from DIDP.

# 5.3 Environmental Risk Characterization

# 5.3.1 Risk Assessment Approach

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 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	e
(Qualitative) for the DIDP Environmental Risk Characterization	

Exposure Pathway	Receptor	<b>Risk Assessment</b>
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 <sup>a</sup>
Air deposition to surface water, sediment	Aquatic dependent mammal	Qualitative <sup>a</sup>
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 <sup><i>a</i></sup>
Biosolids	Terrestrial mammal	Qualitative
<sup><i>a</i></sup> Screening level trophic transfer analysis conducted by pr	oducing exposure estimates from the	high_end exposure

<sup>*a*</sup> 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>U.S. EPA (2024p)</u>.

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 within hazard studies consistently indicating a lack of toxicity for this compound. For aquatic and

benthic species all the available high/medium hazard data indicates a consistent lack of toxicity. A hazard threshold was determined for mammals and represented as a TRV evaluated within the screening level trophic transfer analysis on aquatic mammals and terrestrial mammals within <u>U.S. EPA (2024p)</u>.

Lack of reasonably available information on plant and avian hazard data precluded EPA's ability to designate hazard thresholds for these taxa. However, previous risk assessments provided insight into DIDP hazard for terrestrial plants, while a low confidence analog, DEHP, serves as a qualitative comparison in the absence of avian hazard data for DIDP or the quantitative read-across analog DINP. Environment Canada's State of the Science report on DIDP summarized previous terrestrial hazard studies and found no adverse effects were observed for acute 5-day seed germination toxicity testing conducted with lettuce (Luctuca sativa) and rye grass (Lolium sp.) with treatment concentrations at or greater than 8,630 mg DIDP/kg dw soil (EC/HC, 2015b). EPA did not have access to the terrestrial plant hazard studies summarized within Environment Canada's State of the Science report on DIDP (EC/HC, 2015b). The resulting NOAELs for these species are both five orders of magnitude greater than the highest modeled value for air to soil deposition from PVC compounding and the maximum DIDP concentrations reported from environmental monitoring in Tran et al. (2015). Within birds, an egg injection study in chicken indicated a behavioral impact associated with chick imprinting at the highest DEHP concentration of 100 mg/kg (Abdul-Ghani et al., 2012). DEHP exposures of 45 days within the diet (gavage) quail (Coturnix coturnix) have demonstrated histological based alterations of cardiac tissue at DEHP concentrations of 500 mg/kg-bw/day and kidneys at 250 mg/kg-bw/day (Wang et al., 2020; Wang et al., 2019). The hazard values from the low confidence analog, DEHP, allow for comparisons between tissue and egg concentrations from reasonably available biomonitoring studies.

Mackintosh et al. (2004) reported DIDP and DEHP concentrations within liver tissue of a marine avian species, surf scooter (Melanitta perspicillata), at a mean of 0.031 mg/kg and 0.005 mg/kg wet weight, respectively. Although no reasonably available data report measurement of DIDP or its quantitative analog DINP within bird eggs, two papers do report DEHP within eggs as a comparison to this egg injection study. Schwarz et al. (2016) collected samples from failed peregrine falcon eggs within Germany as part of a large survey of pollutants within eggs. Concentrations of DEHP within peregrine falcon eggs within Schwarz et al. (2016) were reported as "traces of DEHP" with no concentration reported within the study (detection limit reported as 0.001 mg/kg dw). A more comprehensive study on environmental pollutants within egg samples was conducted on seabird species within coastal Norway (Huber et al., 2015). Concentrations of DEHP recorded within pooled eggs of the European herring gull (Larus argentatus) were between 0.011 to 0.024 mg/kg ww and 0.003 to 0.042 mg/kg ww in European shag eggs (Phalacrocorax aristotelis aristotelis) (Huber et al., 2015). These measured phthalate concentrations found in eggs of wild bird populations are four orders of magnitude lower than that used in the laboratory administered injection treatment of 100 mg/kg DEHP in species chicken eggs by Abdul-Ghani et al. (2012). Additionally, Mackintosh et al. (2004) determined Food-Web Magnification Factors (FWMF) for both phthalates and polychlorinated biphenyls with 18 aquatic species (including one avian species) representing approximately 4 trophic levels and found trophic dilution for both DIDP and DINP with FWMFs of 0.44 and 0.46, respectively. Taken together, data from environmental monitoring and biomonitoring indicate limited intersection of exposure from DIDP at the hazard concentrations described.

DIDP is expected to partition primarily to soil and sediment, regardless of the compartment of environmental release (U.S. EPA, 2024t). DIDP is not expected to undergo long-range transport and is expected to be found predominantly in sediments near point sources, with a decreasing trend in sediment concentrations downstream. This is primarily due to DIDP's strong affinity and sorption potential for organic carbon in soil and sediment. Transport of DIDP is further limited by its low water solubility

 $(1.7 \times 10^{-4} \text{ mg/L})$ , which in combination with high sorption coefficients indicate that freely dissolved and bioavailable concentrations, would be reduced due to strong sorption to suspended solids (Mackintosh et al., 2006). Although DIDP is predicted to have an overall environmental half-life of 35 days, DIDP is expected to have a low biodegradation potential within low oxygen conditions indicating longer persistence within subsurface sediments and soils (ECJRC, 2003a; Ejlertsson et al., 1996).

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

EPA assessed exposures based on the COU/OES that resulted in the highest environmental media concentrations for a given pathway. If exposure did not exceed hazard from the concentrations associated with that COU/OES then EPA did not proceed to evaluate environmental media concentrations for the remaining COU/OESs detailed within the *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024r). DIDP concentrations within surface water, sediment, and soil serve as exposure pathways and were used to determine exposures to aquatic and terrestrial species. EPA assessed DIDP concentrations in surface water, sediment, and soil via modeled concentrations (VVWM-PSC, AERMOD) representing COU-based releases of DIDP. Using COU/OES-specific estimated days of release, high-end release distribution of COU/OES-specific annual releases to surface water were assessed under conservative flow assumptions in VVWM-PSC to generate conservative modeled environmental concentrations as described in U.S. EPA (2024r). As stated in U.S. EPA (2024r), conservative estimates of DIDP within sediment from VVWM-PSC modeling resulted in increased confidence that exposures were not underestimated. Air deposition of DIDP to soil, sediment, and surface water were modeled to represent COU-based releases to air using AERMOD with conservative estimates increasing confidence that exposures were not underestimated.

The OES with the highest environmental media concentrations from surface water or wastewater and fugitive or stack air release was the PVC plastics compounding OES and is 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). For COUs with water-based releases, sediment concentrations modeled using VVWM-PSC resulted in the highest DIDP concentration for the PVC plastics compounding OES at 27,600 mg/kg, 2,750 mg/kg and 16.3 mg/kg for P50, P75, P90, respectively (U.S. EPA, 2024t). Deposition of DIDP from air to soil and surface water was modeled via AERMOD, then daily deposition values were modeled with VVWM-PSC to represent surface water and sediment concentrations. The highest DIDP concentration in sediment from air deposition into water at 1,000 m from an annual fugitive release (254 consecutive operating days of release) was from the PVC plastics compounding OES with a modeled sediment concentration of 0.35 mg/kg. The highest DIDP concentration in soil from air deposition at 1,000 m from a fugitive release was from the PVC plastics compounding OES with a concentration of 0.05 mg/kg (U.S. EPA, 2024r). EPA used a distance of 1,000 m from a fugitive/stack release to represent an ecologically representative area to characterize risk to terrestrial receptors. Maximum concentrations of DIDP in sediment within published literature originate from studies with ambient monitoring at 3.4 and 3.7 mg/kg from urban

sediments in Sweden and Taiwan, respectively (<u>Chen et al., 2016</u>; <u>Cousins et al., 2007</u>). Concentrations of DIDP within biosolids were reported in two published studies as ranging from 3.8 to 8.0 and 4.3 to 24.9 mg/kg (<u>Armstrong et al., 2018</u>; <u>ECJRC, 2003a</u>).

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

# 5.3.2 Qualitative Risk Assessment for Aquatic and Terrestrial Species

The landscape of hazard data for DIDP provides information for qualitative risk assessment connecting relevant exposure pathways to aquatic and terrestrial organisms. DIDP demonstrated no aquatic toxicity up to and beyond the limit of solubility under both acute and chronic exposure durations (U.S. EPA, 2024q). Two exceptions were observed under acute exposure conditions with durations of 72- and 96-hours where two studies on zebrafish (*D. rerio*) identified acute mortality hazard values only by testing six orders of magnitude greater than the limit of water solubility identified by EPA ( $1.7 \times 10^{-4}$  mg/L, (U.S. EPA, 2024t) (Poopal et al., 2020; Chen et al., 2014)). Therefore, these two studies were not considered environmentally relevant for establishing hazard thresholds. Acute and chronic duration hazard studies conducted on the aquatic invertebrate, *Daphnia magna*, consistently observed undissolved DIDP on the water surface and attributed these concentrations (0.06 and 0.14 mg/L) above solubility to mortality associated with entrapment of test organisms and not to the chemical (Rhodes et al., 1995).

Due to previous observations and impacts of entrapment on test organisms, a similar 21-day exposure study conducted by (Brown et al., 1998) increased the solubility of DIDP in solution with the addition of a dispersant, castor oil 40 ethoxylate (10 mg/L) and found no differences in reproduction, growth, or mortality from a 1 mg/L exposure to DIDP when compared to the control or dispersant control. DIDP within sediment demonstrated no toxicity up to the highest concentrations tested for chronic exposure durations. The highest measured concentration of DIDP tested within sediment in a chronic duration study was 4,300 mg/kg with an exposure duration of 28 days for larval midge (*Chironomus riparius*) (Brown et al., 1996). Similarly, effects on mortality within C. tentans were not observed for 10-day exposures up to the highest measured DIDP concentration in sediment at 2,680 mg/kg (Call et al., 2001). Studies on the algae (Selenastrum capricornatum) reported no effects up to observed maximum concentrations of 1.3 mg/L (Adams et al., 1995; Springborn Bionomics, 1984). Empirical toxicity data for laboratory rats indicated ecologically-relevant hazard for reproductive, growth, and mortality endpoints. These data were used to estimate a toxicity reference value (TRV) for terrestrial mammals at 128 of mg/kg-bw/day. The TRV was used as a hazard threshold for representative aquatic-dependent (mink) and terrestrial insectivorous (shrew) mammals for comparison to dietary exposure estimates generated by aquatic and terrestrial trophic transfer of DIDP from environmental releases.

# Water Releases to Surface Water and Sediment

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

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

The Swedish National Screening Program for phthalates analyzed DIDP in sediments collecting from areas within the country representing (1) national background lakes, (2) a diffuse urban source, and (3) a point source for phthalates (Cousins et al., 2007). DIDP in urban sediments ranged from less than 0.1 to 3.4 mg/kg and sediments near a suspected point source landfill site were recorded at a maximum DIDP concentration of 0.29 mg/kg. Mackintosh et al. (2006) sampled sediment from False Creek Harbor, Vancouver, British Columbia, Canada, characterized by the authors as an urbanized marine ecosystem, reported maximum DIDP concentration in the sediment from 12 samples at 0.58 mg/kg with a geometric mean of 0.38 mg/kg. Chen et al. (2016) reported a maximum concentration of DIDP within sediments collected from Kaohsiung Harbor, Taiwan where DIDP was detected at all 20 collection sites within the industrialized harbor with a maximum mean concentration of  $3.7 \pm 1.1$  mg/kg. Björklund et al. (2009) reported a maximum DIDP concentration of 60 mg/kg from an underground sedimentation facility within Göteborg, Sweden. This measured concentration is within the range of modeled DIDP sediment concentrations employed within the screening level trophic transfer analysis from the P75 and P90 7Q10 flows of 2,750 and 16.3 mg/kg, respectively, presented within the *Environmental Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024p).

The above assessment employs the median, 75th and 90th percentile flow rates and resulted in DIDP sediment concentrations of 27,600 mg/kg, 1,750 mg/kg, and 16.3 mg/kg, respectively, with the lowest of these three concentrations one order of magnitude greater than the highest environmental monitored concentration of DIDP within sediment from reasonably available literature (3.7 mg/kg from Chen et al. (2016)). Modeled sediment concentrations were used in the trophic transfer analysis for dietary exposure to an aquatic-dependent mammal, as shown in U.S. EPA (2024p). The reasonably available literature monitoring DIDP within surface water and sediment includes collections from suspected point sources, landfills, and urbanized areas, which builds confidence in the role of monitored concentrations for this qualitative analysis. The use of bounded and modeled sediment values and monitored values from reasonably available literature both demonstrated that the DIDP dietary exposures to representative mammals do not approach the TRV. The utilization of these different sources of information as a comparative approach with similar results ensures, with a high degree of confidence, that dietary exposure of DIDP does not approach concentrations which may cause hazard within mammals. For invertebrates, concentrations within experimental hazard studies failed to produce impacts to larval midge at DIDP sediment concentration up to 4,300 mg/kg and 2,680 mg/kg from 28- and 10-day sediment exposures, respectively. Therefore, DIDP within surface water and sediment are not expected to produce hazardous effects within aquatic organisms and represent lack of risk based on available hazard and monitoring data.

Based on the weight of scientific evidence for DIDP within the environment, limited biomagnification, and hazard value for an aquatic dependent mammal in the form of a toxicity reference value (TRV), qualitative analysis indicates that reaching a TRV with a daily rate of 128 mg/kg-day is highly unlikely and was not reached even with conservative quantitative modeling and trophic transfer assumptions. The

use of wildlife exposure factors to calculate dietary exposure (mg DIDP/kg-day) within the conservative screening level trophic transfer analysis presented within the *Environmental Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024p) allows for the ability to project the sediment concentration needed to produce a risk quotient equal to or greater than one within a representative aquatic dependent mammal. For example, a DIDP sediment concentration of  $3.8 \times 10^4$  mg/kg would be needed for a representative aquatic mammal to ingest enough DIDP daily within their diet and prey to exceed the TRV hazard threshold value of 128 mg/kg-bw/day. Based on the conservative VVWM-PSC outputs for surface water and sediment shown in (U.S. EPA, 2024r), the COU/OES based water releases of DIDP are not expected to produce environmental concentrations leading to hazardous effects within aquatic dependent wildlife.

#### Air Deposition to Water, Sediment

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

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

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

## Air Deposition to Soil

Modeling results indicate a rapid decline in DIDP concentrations from air deposition to soil. The PVC plastics compounding OES resulted in the highest fugitive release of DIDP with daily deposition rates to soil at 100, 1,000, and 5,000 m of 1.8,  $5.1 \times 10^{-2}$ , and  $2.4 \times 10^{-3}$  mg/kg, respectively. These modeled daily deposition rates from 100 and 5,000 m from a release source are 2 to 5 orders of magnitude below the mammalian TRV value of 128 mg/kg-bw/day. Comparatively, the highest reported soil concentration of DIDP reported within the reasonably available literature is from Tran et al. (2015), indicate a DIDP concentration of  $1.3 \times 10^{-2}$  and  $4.0 \times 10^{-2}$  mg/kg in rural and agricultural soils, respectively (Doue, Seineet-Marne, France; population 1,029). Although no hazard data for soil invertebrates was reasonably available for DIDP, read-across from a suitable analog (DINP) indicated a NOEC for DINP of 1,000 mg/kg, which demonstrates no hazardous effects within this soil invertebrate even when testing DINP to high concentrations. No terrestrial plants studies were reasonably available to assess potential hazards from DIDP exposure; however, Environment Canada's State of the Science report on DIDP ((EC/HC, 2015b) summarized previous terrestrial hazard studies and found no adverse effects were observed for acute 5-day seed germination toxicity testing conducted with lettuce (Luctuca sativa) and rve grass (Lolium sp.) with concentrations exceeding 8,630 mg DIDP/kg dw soil. Therefore, COU/OES based fugitive and stack air releases of DIDP and subsequent deposition to soil are not expected to produce environmental concentrations leading to hazardous effects within soil invertebrates or terrestrial mammals.

## Landfill (to Surface Water, Sediment)

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

#### **Biosolids**

EPA did not pursue using generic release scenarios to model potential DIDP concentrations in biosolids because the high-end release scenarios were not considered to be applicable to the evaluation of land application of biosolids. One monitoring report conducted in Sweden reported concentration of DIDP in sludge from sewage treatment plants ranging 19.0 to 51.0 mg/kg (Cousins et al., 2007). Two additional studies reported DIDP concentrations in biosolids of 3.80 to 8.03 mg/kg and 4.3 to 24.9 mg/kg (Armstrong et al., 2018; ECJRC, 2003a). The half-life of 28 to 52 days in aerobic soils (SRC, 1983) indicates that DIDP is not persistent in the aerobic environments associated with freshly applied biosolids. High-end releases from industrial facilities are unlikely to be released directly to municipal wastewater treatment plants without pre-treatment or to be directly land-applied following on-site treatment at the industrial facility itself. In comparison to hazard values, the highest reported DIDP concentrations within biosolids from reasonably available literature are two orders of magnitude below

the read-across NOEC value within earthworms of 1,000 mg/kg from a 28-day exposure. The NOEC value of greater than 8,630 mg DIDP/kg dw soil from acute 5-day seed germination toxicity testing was also two orders of magnitude greater than the highest reported monitoring concentrations of biosolids. The combination of factors such as biodegradation (SRC, 1983) and the weight of evidence supporting a lack of bioaccumulation and biomagnification (Mackintosh et al., 2004; ECJRC, 2003a; Gobas et al., 2003) supports this qualitative assessment that potential DIDP concentrations in biosolids do not present concentrations able to produce hazardous effects within soil invertebrates or terrestrial mammals.

#### Distribution in Commerce

EPA evaluated activities resulting in exposures associated with distribution in commerce (*e.g.*, loading, unloading) throughout the various life cycle stages and COUs (*e.g.*, manufacturing, processing, industrial use, commercial use, disposal) rather than a single distribution scenario. EPA lacks data to assess risks to the environment from environmental releases and exposures related to distribution of DIDP in commerce as a single OES. However, most of the releases from this COU/OES are expected to be captured within the releases of other COU/OES since most of the activities (loading, unloading) generating releases from distribution of commerce are release points of other COU/OESs. Because the exposure estimates from these other COU/OESs did not exceed hazard to ecological receptors, EPA expects that a similar release from distribution in commerce also would not result in exposure estimates exceeding hazard to ecological receptors.

#### Aggregate Media of Release

Table 5-2 represents COU/OES with aggregated media of release, where the environmental release assessment did not provide individual release estimates associated within singular release media. Specifically, these COU/OESs detailed fugitive air and stack air releases in addition to water releases as an aggregate of "wastewater, incineration, or landfill" rather than water or wastewater only. All COU/OESs within Table 5-2 have annual release per site (kg/site-year) values lower than PVC plastic compounding—the OES with the highest annual releases to water. As detailed within <u>U.S. EPA (2024p)</u> the PVC plastic compounding OES Exposure pathways with aquatic-dependent mammals and terrestrial mammals as receptors were not examined further since, even with conservative assumptions, exposure concentrations from this analysis are not equal to or greater than the terrestrial mammal TRV of 128 mg/kg-day.

COU (Life Cycle Stage <sup>a</sup> / Category <sup>b</sup> / Subcategory <sup>c</sup> )	OES(s)	Media of Release
Processing/ Incorporation into formulation, mixture, or reaction product/ Adhesives and sealants manufacturing	Incorporation into adhesives/sealants	Water, incineration, or landfill
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/	
Processing/ Incorporation into articles/ Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; miscellaneous manufacturing)	adhesives and sealants manufacturing	
Processing/ Incorporation into formulation, mixture, or reaction product/ surface modifier in paint and coating manufacturing	Incorporation into paints and coatings	

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

COU (Life Cycle Stage <sup>a</sup> / Category <sup>b</sup> / Subcategory <sup>c</sup> )	OES(s)	Media of Release
Processing/ Incorporation into formulation, mixture, or reaction product/ Plasticizers (construction materials other; paint and coating manufacturing; pigments; all other chemical product and preparation manufacturing)		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		Water, incineration, or landfill
Processing/ Incorporation into formulation, mixture, or reaction product/ Lubricants and lubricant additives manufacturing		
Processing/ Incorporation into formulation, mixture, or reaction product/ Petroleum lubricating oil manufacturing		
Processing/ Incorporation into formulation, mixture, or reaction product/ Plasticizers	Incorporation into other formulations,	
Processing/ Incorporation into formulation, mixture, or reaction product/ Processing aids, specific to petroleum production (oil and gas drilling, extraction, and support activities)	mixtures, or reaction products	
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		Water, incineration, or landfill
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	
Commercial uses/ Furnishing, cleaning, treatment & care products/ Furnisher and furnishings	sealants	
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)		

COU (Life Cycle Stage <sup>a</sup> / Category <sup>b</sup> / Subcategory <sup>c</sup> )	OES(s)	Media of Release	
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 points	Water, incineration, or landfill	
Commercial uses/ Furnishing, cleaning, treatment & care products/ Furnisher and furnishings	Application of paints and coatings		
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)			
<ul> <li><sup>a</sup> Life Cycle Stage Use Definitions (40 CFR 711.3):</li> <li>"Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.</li> <li>"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.</li> <li>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.</li> <li><sup>b</sup> 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.</li> <li><sup>c</sup> These subcategories reflect more specific COUs of DIDP.</li> </ul>			

# **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 *Environmental Release and Occupational Exposure Assessment for DIDP* (U.S. EPA, 2024s) 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 (2024r), the *Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)*, represented by modeled and monitored data. Trophic transfer confidence is represented by evidence type as reported previously in (U.S. EPA, 2024p), *Environmental Exposure Assessment for Diisodecyl Phthalate (DIDP)*. Hazard confidence was represented by evidence type as reported previously in (U.S. EPA, 2024q), *Environmental Hazard Assessment for Diisodecyl Phthalate (DIDP)*. The confidence determinations for risk characterization inputs are (1) robust confidence for the aquatic evidence, and (2) robust 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, 75th, and 90th percentile flow rates of the 7Q10 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, <u>Cousins et al. (2007)</u> 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 2 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.

## **Terrestrial Species**

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

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

# 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		+ + +	N/A			
Chronic aquatic assessment	+ PSC	+++	N/A	Robust		
Chronic benthic assessment	+ AERMOD	+ +	N/A			
Algal assessment		+++	N/A			
Terrestrial						
Chronic avian assessment	N/A	N/A	N/A	Indeterminate		
Chronic mammalian assessment	+ PSC + AERMOD	+++	+ +	Robust		
Terrestrial invertebrates	+ AERMOD	++	N/A	Moderate		
Terrestrial plant assessment	N/A	N/A	N/A	Indeterminate		

+ + + Robust confidence suggests thorough understanding of the scientific evidence and uncertainties. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the risk estimate.

+ + Moderate confidence suggests some understanding of the scientific evidence and uncertainties. The supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize risk estimates.

+ Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the scenario, and when the assessor is making the best scientific assessment possible in the absence of complete information. There are additional uncertainties that may need to be considered.

N/A or Indeterminant corresponds to entries in evidence tables where information is not available within a specific evidence consideration.

# **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 PESS identified by EPA as relevant to the risk evaluation, under the COUs.

EPA has determined that DIDP presents an unreasonable risk of injury to human health under the COUs. These unreasonable risks result from high-end exposure scenarios to female workers of reproductive age for 6 out of 49 total conditions of uses of DIDP. EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk of DIDP. This unreasonable risk determination is based on the information in previous sections of this risk evaluation, the appendices, and technical support documents of this risk evaluation in accordance with TSCA section 6(b). It is also based on the best available science (TSCA section 26(h)), weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

EPA will initiate risk management for DIDP 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. The risk management requirements will likely focus on the six COUs significantly contributing to the unreasonable risk. However, under TSCA section 6(a), EPA is not limited to regulating the specific COUs found to significantly contribute to unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal to address the unreasonable risk. For instance, EPA may regulate upstream COUs (*e.g.*, processing, distribution in commerce) to address downstream COUs that significantly contribute to unreasonable risk (*e.g.*, consumer use)—even if the upstream COUs are not significant contributors to the unreasonable 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.

EPA notes that human or environmental exposure to DIDP through non-TSCA uses (e.g., cosmetics, medical devices, and food contact materials) were not evaluated by the Agency or taken into account in reaching this determination of unreasonable risk of injury to human health, because these uses are explicitly excluded from TSCA's definition of chemical substance. EPA's finding for DIDP should not be extrapolated to conclusions about uses of DIDP that are not subject to TSCA and that the Agency did not evaluate. Although EPA is not making a determination of unreasonable risk based on non-TSCA uses, the Agency did analyze urinary biomonitoring data from the CDC's NHANES dataset, which provides an estimate of non-attributable (i.e., cannot distinguish between TSCA and non-TSCA exposures) aggregate exposure to DIDP for the U.S. civilian population (Section 4.1.3). Results of this screening-level analysis of NHANES biomonitoring data are discussed in Section 6.1.6 for the general population. Regarding cumulative exposure and cumulative risk, EPA did not include DIDP in its technical support document for cumulative risk of DINP, DEHP, butyl benzyl phthalate (BBP), di-butyl phthalate (DBP), diisobutyl phthalate (DIBP), and dicyclohexyl phthalate (DCHP) because DIDP does not cause phthalate syndrome in experimental animal models. The phthalates chosen for inclusion into the technical support document are toxicologically similar and can induce effects on the developing male reproductive system consistent with a disruption of androgen action and phthalate syndrome.

The COUs evaluated for DIDP are listed in Table 1-1.

The following TSCA COUs are determined to significantly contribute to the unreasonable risk due to high-end acute exposures to female workers of reproductive age:

- Industrial use adhesives and sealants;
- Industrial use construction, paint, electrical, and metal products paints and coatings;
- Commercial use construction, paint, electrical, and metal products adhesives and sealants (including plasticizers in adhesives and sealants);
- Commercial use construction, paint, electrical, and metal products paints and coatings (including surfactants in paints and coatings);
- Commercial use construction, paint, electrical, and metal products lacquers, stains, varnishes, and floor finishes (as plasticizer); and
- Commercial use other uses inspection fluid/penetrant.

The following COUs do *not* significantly contribute to the unreasonable risk:

- Manufacturing domestic manufacturing;
- Manufacturing importing;
- Processing incorporation into formulation, mixture, or reaction product adhesives and sealants manufacturing;
- Processing incorporation into formulation, mixture, or reaction product laboratory chemicals manufacturing;
- Processing incorporation into formulation, mixture, or reaction product petroleum lubricating oil manufacturing; lubricants and lubricant additives manufacturing;
- Processing incorporation into formulation, mixture, or reaction product surface modifier in paint and coating manufacturing;
- Processing incorporation into formulation, mixture, or reaction product plastic material and resin manufacturing;
- Processing incorporation into formulation, mixture, or reaction product plasticizers (paint and coating manufacturing; pigments; rubber manufacturing);
- 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 other (part of the formulation for manufacturing synthetic leather);
- Processing incorporation into articles abrasives manufacturing;
- Processing incorporation into articles 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; ink, toner, and
  colorant products manufacturing [including pigment]; photographic supplies manufacturing;
  toys, playground, and sporting equipment manufacturing);
- Processing repackaging;
- Processing recycling;
- Distribution in commerce;
- Industrial use abrasives;
- Industrial use functional fluids (closed systems);
- Industrial use lubricant and lubricant additives;
- Industrial use solvents (for cleaning and degreasing);
- Commercial use automotive, fuel, agriculture, outdoor use products– lubricants;

- Commercial use construction, paint, electrical, and metal products building/construction materials (wire or wiring systems; joint treatment, fire-proof insulation);
- Commercial use construction, paint, electrical, and metal products electrical and electronic products;
- Commercial use furnishing, cleaning, treatment/care products furniture and furnishings;
- Commercial use 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]);
- Commercial use –packaging, paper, plastic, hobby products ink, toner, and colorant products;
- Commercial use furnishing, cleaning, treatment/care products PVC film and sheet;
- Commercial use furnishing, cleaning, treatment/care products plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses);
- Commercial use other uses laboratory chemicals;
- Commercial use other uses inspection fluid/penetrant;
- Consumer use automotive, fuel, agriculture, outdoor use products lubricants;
- Consumer use construction, paint, electrical, and metal products adhesives and sealants (including plasticizers in adhesives and sealants);
- Consumer use 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);
- Consumer use construction, paint, electrical, and metal products electrical and electronic products;
- Consumer use construction, paint, electrical, and metal products paints and coatings;
- Consumer use furnishing, cleaning, treatment/care products fabrics, textiles, and apparel (as plasticizer);
- Consumer use packaging, paper, plastic, hobby products arts, crafts, and hobby materials (crafting paint applied to craft);
- Consumer use packaging, paper, plastic, hobby products ink, toner, and colorant products;
- Consumer use packaging, paper, plastic, hobby products PVC film and sheet;
- Consumer use packaging, paper, plastic, hobby products plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses);
- Consumer use packaging, paper, plastic, hobby products toys, playgrounds, and sporting equipment;
- Consumer use other uses automotive articles;
- Consumer use other novelty articles; and
- Disposal.

Whether EPA makes a determination of unreasonable risk for a particular chemical substance under 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, frequency of exposure, or population exposed—particularly subpopulations with greater exposure or greater susceptibility [PESS]) and the confidence in the information used to inform the hazard and exposure values. For some COUs, EPA integrated reasonably available information in a qualitative risk characterization using professional judgement of read-across evidence. The qualitative analyses are a best estimate of what EPA expects given the weight of scientific evidence without overstating the science. For COUs evaluated quantitatively, as described in the risk characterization, the Agency also considered how the central tendency and high-end risk estimates represented the risk related factors, and

EPA based the risk determination on the risk estimate that best represented the COU. Additionally, in the risk evaluation, the Agency describes the strength of the scientific evidence supporting the human health and environmental assessments as robust, moderate, slight, or indeterminate. Robust confidence suggests thorough understanding of the scientific evidence and uncertainties, and 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. Moderate confidence suggests some understanding of the scientific evidence and uncertainties, and the supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize the risk. Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the risk, and when the Agency is making the best scientific assessment possible in the absence of complete information. In cases where the Agency lacked reasonably available data (e.g., hazard data for avian species and terrestrial plants), EPA's confidence in risk is indeterminate for those receptors. This risk evaluation discusses important assumptions and key sources of uncertainty in the risk characterization, and these are described in more detail in the respective weight of scientific evidence conclusion sections for fate and transport, environmental release, environmental exposures, environmental hazards, and human health hazards. It also includes overall confidence and remaining uncertainties sections for human health and environmental risk characterization.

In the DIDP risk evaluation, EPA has reviewed risk estimates with an overall confidence rating of slight, moderate, robust, or indeterminate. In general, the Agency makes an unreasonable risk determination based on risk estimates that have an overall confidence rating of moderate or robust because those confidence ratings indicate the scientific evidence is adequate to characterize risk despite uncertainties or is such that it is unlikely the uncertainties could have a significant effect on the risk estimates.

# 6.1 Human Health

Calculated risk estimates (MOEs<sup>1</sup>) can provide a risk profile of DIDP by presenting a range of estimates for different health effects for different COUs. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that does not assume use of respiratory protection or other personal protective equipment (PPE<sup>2</sup>).

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.

# 6.1.1 Populations and Exposures EPA Assessed for Human Health

EPA has evaluated risk to workers, including ONUs, female workers of reproductive age and adolescent and adult workers (≥16 years old); 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. EPA has evaluated risk from inhalation and dermal exposure of DIDP to workers, inhalation exposure to ONUs, and, for relevant COUs, dermal exposure to ONUs from contact with mist or dust deposited on surfaces containing DIDP. The Agency has evaluated risk from inhalation, dermal, and oral exposure to consumer users. For relevant COUs, EPA has evaluated risk from inhalation exposure to bystanders and dermal exposures

<sup>&</sup>lt;sup>1</sup> EPA derives non-cancer MOEs by dividing the non-cancer POD (HEC [mg/m<sup>3</sup>] or HED [mg/kg-day] by the exposure estimate [mg/m<sup>3</sup> or mg/kg-day]). Section 4.3.1 has additional information on the risk assessment approach for human health. <sup>2</sup> It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in

place.

where bystanders, including children, could have exposures from the products or articles, such as wallpaper. Finally, EPA also evaluated risk from exposures from surface water, drinking water, fish ingestion, ambient air, and land pathways (*i.e.*, landfills and application of biosolids) to the general population.

Descriptions of the data used for human health exposure and human health hazards are provided in Sections 4.1 and 4.2, respectively. Uncertainties for overall exposures and hazards are presented in this risk evaluation, the *Consumer and Indoor Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a), and the *Environmental Release and Occupational Exposure and Environmental Release Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024a) and are considered in this unreasonable risk determination.

# 6.1.2 Summary of Human Health Effects

EPA has determined that the unreasonable risk presented by DIDP is due to

• non-cancer effects (reduced offspring survival) in female workers of reproductive age from acute inhalation exposures and aggregated acute exposures

With respect to health endpoints upon which EPA has based this unreasonable risk determination, the Agency has robust confidence in the non-cancer developmental toxicity POD. The POD is based on an effect observed in an animal model, which may translate to miscarriages or stillbirths in humans. EPA considers this developmental toxicity POD relevant for assessing risk from acute exposures to DIDP. However, because the developmental toxicity POD is the most protective, it was considered applicable to all durations evaluated in this risk evaluation (acute, intermediate, and chronic). Liver toxicity following intermediate and chronic duration exposures to DIDP in animal models was also identified as a robust and sensitive non-cancer hazard by the EPA. But since the POD for developmental toxicity is protective (*i.e.*, is more sensitive) of the liver toxicity associated with the oral exposure to DIDP in experimental animal models, this unreasonable risk determination is based on developmental toxicity to be most directly applicable to pregnant women, women of reproductive age, and infants. Use of this POD to assess risk for other life stages (*e.g.*, toddlers, preschoolers, children of other ages, and adult males) is conservative.

Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), EPA reviewed the weight of the evidence for the carcinogenicity of DIDP and determined that DIDP is not likely to be carcinogenic to humans. Consistent with this classification, the Agency is not conducting a dose-response assessment for DIDP or evaluating DIDP for carcinogenic risk to humans.

EPA's exposure and overall risk characterization confidence levels are summarized in Section 4, with specific confidence levels presented in Sections 4.3.2.1 (occupational exposure) and 4.3.3.1 (consumer exposure). Additionally, health risk estimates can be found in Sections 4.3.2 (workers, including ONUs), Section 4.3.3 (consumers and bystanders), and Section 4.3.4 (general population). The benchmarks are not bright lines and EPA has discretion to consider other risk-related factors when determining if a COU significantly contributes to the unreasonable risk of the chemical substance.

# 6.1.3 Basis for Unreasonable Risk to Human Health

In developing the exposure and hazard assessments for DIDP, EPA has analyzed reasonably available information to ascertain whether some human populations may have greater exposure and/or susceptibility than the general population to the hazard posed by DIDP. For the DIDP risk evaluation, EPA has accounted for the following PESS: people who are expected to have greater exposure to DIDP

at work; people who frequently use consumer products and/or articles containing high concentrations of DIDP; people who may have greater intake of DIDP per body weight (*e.g.*, infants, children, adolescents); people exposed to DIDP through certain age-specific behaviors (*e.g.*, mouthing of toys, wires, and erasers by infants and children, and hand-to-mouth ingestion from synthetic leather furniture assessed in the consumer exposure scenarios); people using toys before restrictions were in place, leading to greater exposure; and subsistence fishers and tribal populations whose diets include large amounts of fish ingestion. Additionally, EPA identified people who may have greater susceptibility to the health effects of DIDP as PESS—including women of reproductive age, pregnant women, infants, children, and adolescents. The aggregate and high-end risk estimates reflect expected risk to PESS. A full PESS analysis and the risk estimates that represent their risk is provided in Section 4.3.4.

Risk estimates based on high-end exposure levels (e.g., 95th percentile, or high intensity scenarios) are generally intended to cover individuals with sentinel exposure whereas risk estimates for the central tendency exposure are intended to cover average or typical exposure. However, because EPA was able to calculate risk estimates for PESS groups in this assessment (e.g., female workers of reproductive age, and infants and children), the Agency did not always use risk estimates based on high-end exposure levels as the basis of the unreasonable risk determination for DIDP. The use of either central tendency or high-end risk estimates for female workers of reproductive age to make a determination of unreasonable risk was based on assumptions about the COU using reasonably available information about a typical scenario and process within the COU. To determine the risk to consumers (e.g., infants and children) EPA considered high-intensity exposure levels. For example, high-intensity consumer indoor dust exposure scenarios assumed that people are in their homes for longer periods than the medium- or lower-intensity scenarios. The parameters were varied between the high-, medium-, and low-intensity scenarios, for example, weight fraction (i.e., 0.26 vs. 0.245 for high vs. medium, respectively) and article surface area (*i.e.*, 200 vs. 100 m<sup>2</sup> for high vs. medium, respectively). Health parameters were also adjusted for each population, such as inhalation rates used per lifestage. Additionally, 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 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.

EPA also aggregated exposures across routes for workers, including ONUs, consumers, and bystanders for TSCA COUs with quantitative risk estimates. More information on how EPA characterized aggregate risks is provided in Section 4.1.5. For most occupational COUs, aggregation of inhalation and dermal exposures led to negligible differences in risk estimates when compared to risk estimates from inhalation alone, since the inhalation exposure is the predominant route of exposure. For consumers, the dermal, oral, and inhalation routes were aggregated. Section 6.1.5 provides more detail regarding the consumer COUs.

#### 6.1.4 Workers

EPA analyzed mist or dust concentration inhalation exposure in the occupational scenarios using a time weighted average (TWA) for a typical 8-hour shift (see Table 4-3). Separate estimates of central tendency and high-end inhalation and dermal exposures were made for average adult (16+ years) workers, female workers of reproductive age, and ONUs, as appropriate.

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

EPA analyzed the individual COUs in this risk evaluation under both central tendency or high-end estimates for workers, including ONUs, based on the parameters and assumptions used in the occupational exposure scenarios used to evaluate each COU. For the majority of COUs evaluated, risk was not indicated at the high-end or central tendency estimates for inhalation exposure to workers, including ONUs. Risk was not indicated at the high-end or central tendency estimates for the COUs that had risk indicated at the high-end for any of the COUs assessed. For the COUs that had risk indicated at the high-end for all workers after aggregation of the individual routes of exposure, these two COUs represent scenarios where one or more factors are contributing to unusually elevated exposure levels due to a conservative assumption used in the calculations for workers inhaling dust containing DIDP. The MOEs represent total PNOR (*i.e.*, dust) concentrations that contain a variety of constituents besides DIDP, and a conservative assumption that the amount of plasticizer in dust is equal to the weight fraction of plasticizer in the PVC product or article. Further, it was noted during the public comment period (see <u>EPA-HQ-OPPT-2024-0073-0069</u>) that because liquid plasticizers are generally added to dry mixtures during the compounding process, any dust generated would come from the dry material rather than the plasticizer.

EPA has identified unreasonable risk of DIDP for the following subpopulations of workers in occupational settings where spray applications are used and there is mist generation.

# Female Workers of Reproductive Age

Based on the occupational risk estimates and related risk factors, EPA has determined that the following six COUs significantly contribute to the unreasonable risk presented by DIDP due to acute exposures to female workers of reproductive age: Industrial use – adhesives and sealants; Industrial use – construction, paint, electrical, and metal products – paints and coatings; Commercial use – construction, paint, electrical, and metal products – adhesives and sealants (including plasticizers in adhesives and sealants); Commercial use – construction, paint, electrical, and metal products – adhesives and sealants (including plasticizers in adhesives and sealants); Commercial use – construction, paint, electrical, and metal products – paints and coatings); Commercial use – construction, paint, electrical, and metal products – lacquers, stains, varnishes, and floor finishes (as plasticizer); and Commercial use – other uses – inspection fluid/penetrant.

The six COUs that significantly contribute to the unreasonable risk of DIDP have MOEs below the benchmark of 30 at the high-end estimates of acute inhalation exposure. In general, exposures to DIDP through spray applications are expected to be closer to the central tendency risk estimates for these six COUs due to the exposure scenarios inputs and parameters used in the risk evaluation (*e.g.*, low ventilation, high-pressure spray, concentrations of DIDP, total volume of product used). The risk estimates for the spray application scenarios at the central tendency would result in risk above the benchmark MOE. However, high-end risk estimates represent conditions that are still considered plausible and would be reasonably expected to occasionally occur for an acute 1-day exposure.

Therefore, for these six COUs, EPA has determined that the acute inhalation exposures significantly contribute to the unreasonable risk of DIDP. Sections 4.3.2.1, 4.3.2.2 and 4.3.2.3, provide more details regarding the inputs and parameters used in the exposure scenarios and the consideration of central tendency or high-end risk estimates.

#### Average Adult (16+ Years) Workers

For this subpopulation the occupational risk estimates at the high-end indicate that there are non-cancer risks to average adult workers due to either acute, intermediate, chronic or aggregated inhalation exposures from the following eight COUs: Processing – incorporation into formulation, mixture, or reaction product – plastic material and resin manufacturing; Processing – incorporation into formulation,

mixture, or reaction product – other (part of the formulation for manufacturing synthetic leather); Industrial use – adhesives and sealants; Commercial use – construction, paint, electrical, and metal products – adhesives and sealants (including plasticizers in adhesives and sealants); Industrial use – construction, paint, electrical, and metal products – paints and coatings; Commercial use – construction, paint, electrical, and metal products – paints and coatings (including surfactants in paints and coatings); Commercial use – construction, paint, electrical, and metal products – lacquers, stains, varnishes, and floor finishes (as plasticizer); and Commercial use – other uses – inspection fluid/penetrant. This includes some of the same COUs that EPA has determined are significantly contributing to unreasonable risk for female workers of reproductive age.

While high-end intermediate and chronic inhalation risk estimates for average adult workers are below the benchmark MOE, the risk estimates are representative of intermediate and chronic durations, which are exposure durations EPA does not consider plausible at the high-end due to the unlikely confluence of expected associated inputs and parameters with the exposure scenarios used in the risk evaluation that would result in high-end exposures (*e.g.*, low ventilation, high-pressure spray, concentrations of DIDP, total volume of product used). Therefore, the high-end estimates represent conditions that are considered plausible only for the acute exposure duration and would be reasonably expected to occasionally occur for an acute 1-day exposure. However, the endpoint considered for acute exposures (offspring loss) is relevant only for female workers of reproductive age. Therefore, EPA did not identify risk for average adult workers based on acute, intermediate, and chronic inhalation exposures or aggregated acute exposures that would contribute to the unreasonable risk of DIDP.

One COU does not have quantitative risk estimates for workers. EPA has qualitatively evaluated the Distribution in commerce COU. Worker activities associated with Distribution in commerce (*e.g.*, loading, unloading) are not expected to generate mist or dust, similar to other COUs such as Manufacturing and Import. Dermal contact with the neat material or concentrated formulations may occur during activities associated with distribution in commerce, also similar to COUs such as manufacturing and import. Therefore, occupational exposures associated with the distribution in commerce COU are expected to be less than the manufacturing or import COUs, and therefore do not significantly contribute to the unreasonable risk of DIDP. Section 4.3.2.8. provides more details.

#### 6.1.5 Consumers

Based on the consumer risk estimates and related risk factors, EPA has determined that consumer COUs do not significantly contribute to the unreasonable risk of DIDP.

The consumer and bystander exposure scenarios described in this risk evaluation represent a wide range of consumer use patterns. For a given consumer exposure scenario, acute exposure refers to the time frame of 1 day, intermediate refers to an exposure time frame of 30 days, and chronic refers to a time frame of 365 days. Professional judgment and product use descriptions were used to estimate the intermediate timeframe. Consumer and bystander risks representing specific age groups were evaluated for consumer COUs. All age groups assessed under the indoor dust exposure scenarios are considered users (consumers) of the articles being assessed. Consumer and bystander populations assessed were infant (<1 year), toddler (1–2 years), preschooler (3–5 years), middle childhood (6–10 years), young teen (11–15 years), teenager (16–20 years), and adult (21+ years).

No consumer COU had MOEs below the benchmark of 30 due to acute, intermediate, or chronic inhalation, oral, or dermal exposure. One COU had two MOEs below the benchmark of 30 (for infants and toddlers) after aggregation of the oral, dermal, and inhalation routes. Risk was not indicated from acute, intermediate, or chronic inhalation exposure for bystanders for the COUs assessed.

For the consumer COU with aggregate MOEs below the benchmark MOE for infants and toddlers, Packaging, paper, plastic, hobby products – plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses), the risk is due to acute inhalation of DIDP vapors and ingestion of DIDP partitioned to surface dust from in-place wallpaper modeled using a conservative high-intensity exposure scenario, representing an upper bound exposure scenario. As explained in this unreasonable risk determination, benchmarks are not bright-line indicators of risk. While the conservative approaches used for estimating risk constitute a defensible screen to eliminate with confidence risk concerns, EPA is taking into consideration that-based on reasonably available information about DIDP concentrations in wallpaper products-the low-intensity and medium-intensity scenarios are more reflective of the COU than the high-intensity scenario. Based on information provided to EPA about the expected weight fraction of DIDP in vinyl wallpaper, EPA has determined that the weight fraction used to generate a high-intensity scenario resulting in the aggregate MOEs below the benchmark MOE for infants and toddlers was overly conservative (U.S. EPA, 2024o). Furthermore, for all other consumer COUs, all individual and aggregate risk estimates did not indicate risk. Therefore, EPA has determined that consumer COUs do not contribute to unreasonable risk of DIDP. Section 4.3.3 provides more details regarding the exposure scenarios and assumptions.

When applicable, such as the assessment of the Packaging, paper, plastic, hobby products – toys, playground, and sporting equipment COU, oral exposure to DIDP was evaluated through the mouthing of articles during use. To evaluate the migration of DIDP during the mouthing of children's toys, estimates were made for legacy toys (defined as toys that are not limited to the weight fraction of 0.1%) and new toys (toys that may be limited to a weight fraction of 0.1% DIDP). EPA used weight fractions of 0.26, 0.23, and 0.2% for legacy toys in the high-, medium-, and low- scenarios. For new toys, a weight fraction of 0.001% was assumed in all scenarios. The mouthing of articles did not indicate risk for the use of legacy or new toys evaluated for any age group, with MOEs of 240 to 1,1796 for infants, toddlers, and preschoolers across all durations (see Table 4-18 in this risk evaluation for more information).

EPA has moderate to robust confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios, and robust confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to DIDP. The exposure doses used to estimate risk relied on conservative inputs and parameters that are considered representative of a wide selection of use patterns. Further, the non-cancer POD selected to characterize risk, reduced offspring survival, is considered most relevant for assessing risk to women of reproductive age; however, use of this POD to assess risk for other life stages (*e.g.*, toddlers, preschoolers, children of other ages, and adult males) is a conservative approach. Section 4.3.3.1 describes the overall confidence in the consumer risk estimates.

Three consumer COUs do not have quantitative risk estimates: Consumer Uses: Other uses: Automotive articles; Packaging, paper, and plastic, hobby products – arts, crafts, and hobby materials (crafting paint applied to craft); and Packaging, paper, and plastic, hobby products – ink, toner and colorant products. These COUs were evaluated qualitatively, since current products were not identified, and EPA integrated reasonably available information from similar consumer COUs evaluated quantitatively. Specifically, for the automotive articles COU, EPA is using the MOEs for dermal exposure from fabrics, textiles, and apparel (as plasticizer) (MOEs ranged from 491–1,1018); and for arts, crafts, and hobby materials and ink, toner and colorant products COUs, EPA is using the MOEs from Construction, paint, electrical, and metal products: Adhesives and sealants (including plasticizers in adhesives and sealants) (MOEs ranged from 145,107–257); and Paints and coatings (MOEs ranged from 206,666–195). The complete list of risk estimates is found in Table 4-18 of this risk evaluation. Since there were no MOEs below the benchmark of 30, these MOEs did not indicate risk. Therefore, EPA is determining that

automotive articles; arts, crafts, and hobby materials (crafting paint applied to craft); and ink, toner and colorant products do not significantly contribute to the unreasonable risk of DIDP.

### 6.1.6 General Population

Based on a screening level exposure assessment using releases from manufacturing, processing, and industrial uses of DIDP, and related risk factors, EPA did not identify non-cancer risk effects to the general population that would contribute to the unreasonable risk of DIDP. For further information, see Section 4.1.3.1.

Due to DIDP's low water solubility and low persistence under most conditions, DIDP is unlikely to migrate from land applied biosolids to groundwater via runoff and is unlikely to be present in landfill leachate or be mobile in soils. For these reasons, biosolids and landfill were evaluated qualitatively. As such, EPA does not expect general population exposure to DIDP to occur via the land pathway and therefore, does not expect there to be risk to the general population from the land pathway.

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

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

EPA has robust confidence in its qualitative assessment of biosolids and landfills. EPA has robust confidence that modeled releases used are appropriately conservative for a screening level analysis. Therefore, EPA has robust confidence that no exposure scenarios for the general population will lead to greater doses than presented in this evaluation. More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in Section 4.1.3.3.

## 6.2 Environment

EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for DIDP. 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 risk evaluation using conservative environmental release estimates for occupational COUs with the highest releases to determine whether there is risk to the environment. EPA compared the highest release estimates to environmental media for a given pathway to the hazard values for aquatic and terrestrial organisms. If the exposure from the highest releasing COU (or most conservative estimates) did not exceed the hazard threshold for aquatic and terrestrial organisms, it was determined that exposures due to releases from other COUs would not lead to environmental risk.

Qualitative risk characterization indicates that EPA does not expect risk for any pathways assessed for exposure to ecological receptors. Expected lack of risk to aquatic and terrestrial receptors was assigned moderate 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.

### 6.2.1 Populations and Exposures EPA Assessed for the Environment

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

The Agency expects the main environmental exposure pathway for aquatic organisms to be releases to surface water and subsequent deposition to sediment. Releases to ambient air and subsequent deposition to water and sediment also have a limited contribution to environmental exposure for aquatic organisms. EPA determined that DIDP is expected to have a low potential for bioaccumulation and biomagnification in aquatic organisms. As detailed within Section 5.3.2, monitoring data from published literature reported 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.

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

In general, EPA has an overall moderate confidence in environmental releases for acute and chronic aquatic assessment, chronic benthic assessment, algal assessment, chronic mammalian assessment, and terrestrial invertebrates. Although the conservative nature of model outputs resulted in slight 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, as noted in Table 5-3. EPA has also determined an indeterminate confidence in chronic avian and terrestrial plant assessments as there is a lack of reasonably available hazard data. 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.

### 6.2.2 Summary of Environmental Effects

EPA qualitatively assessed risk via release to surface water and subsequent deposition to sediment, as well as the ambient air exposure pathway for its limited contribution via deposition to soil, water, and sediment, and has identified

- no acute or chronic effects to fish and aquatic invertebrates up to and exceeding the limit of water solubility, and
- no acute or chronic effects to sediment-dwelling organisms.

A TRV was used as the hazard threshold for mammals that permitted the use of a screening-level trophic transfer analysis to compare potential environmental concentrations and dietary uptake of DIDP with a daily rate of oral uptake that produces hazard under experimental conditions. Several conservative approaches incorporated within the screening-level trophic transfer analysis likely overrepresent DIDP's ability to accumulate at higher trophic levels; however, this increases confidence that risks are not underestimated. Exposure pathways with aquatic-dependent mammals and terrestrial mammals as receptors were not examined further since, even with conservative assumptions, dietary DIDP exposure concentrations from this analysis are not equal to or greater than the TRV. These results indicate that DIDP has low bioaccumulation potential and will not biomagnify.

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

EPA evaluated down-the-drain releases of DIDP for consumer COUs qualitatively. Although EPA acknowledges that there may be DIDP releases to the environment via the cleaning and disposal of adhesives, sealants, paints, lacquers, and coatings, the Agency did not quantitatively assess down-thedrain and disposal scenarios of consumer products due to limited information from monitoring data or modeling tools. A qualitative assessment was undertaken using physical and chemical properties and monitoring data for environmental media to support conclusions about down the drain and disposal practices and releases to the environment. EPA did not identify data for DIDP in drinking water in the United States. Based on the low water solubility and log K<sub>OW</sub>, DIDP in water it 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. Although there is limited measured data on DIDP in landfill leachates, the data suggest that DIDP is unlikely to be present in landfill leachates. Further, the small amounts of DIDP that could potentially be in landfill leachates will have limited mobility and are unlikely to infiltrate groundwater due to high affinity of DIDP for organic compounds that would be present in receiving soil and sediment. Therefore, the consumer COUs do not significantly contribute to the unreasonable risk of DIDP due to down-thedrain releases.

### 6.2.3 Basis for No Unreasonable Risk of Injury to the Environment

As described in Sections 5.1, 5.2, and 5.3, EPA completed a qualitative risk characterization using worst-case (conservative) exposures to determine whether there is risk to the environment. Surface water and subsequent deposition to sediment were determined to be the main drivers of exposure to DIDP. For aquatic organisms, as detailed in Section 5.3.2, reported monitoring data from published literature indicate that DIDP concentrations in surface water and sediment are lower than the highest NOEC values from several hazard studies for aquatic invertebrates and vertebrates in the water column, benthic invertebrates in the sediment, and aquatic plants and algae. The use of bounded and modeled sediment values and monitored values from reasonably available literature both demonstrated that the DIDP dietary exposures to representative mammals do not approach the TRV. An earthworm study that tested a single concentration of DINP was used to read across to DIDP and indicated no chronic toxicity to soil invertebrates. Therefore, risk is not indicated for any pathways assessed for exposure to ecological receptors. Based on the risk evaluation for DIDP, EPA did not identify risk of injury to the environment that would contribute significantly to the unreasonable risk determination for DIDP. The Agency's overall environmental risk characterization confidence levels were varied and are summarized in the *Environmental Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024p).

## 6.3 Additional Information Regarding the Basis for the Unreasonable Risk

Table 6-1 summarizes the basis for this unreasonable risk determination of injury to human health presented in this risk evaluation. In the table, a checkmark ( $\checkmark$ ) indicates how the COU contributes to the unreasonable risk by identifying the type of effect (*e.g.*, non-cancer for human health) and the exposure route to the population or receptor that results in such contribution. As explained in Section 6, for this unreasonable risk determination, EPA considered the effects of DIDP to human health, including PESS, as well as risk estimates at the central tendency and high-end, risk related factors, and the confidence in the analysis. See Section 4.3 for a summary of risk estimates. In addition, certain exposure routes for some COUs were not assessed because it was determined that there was no viable exposure pathway. These COUs and their respective exposure routes (table cells) are grayed-out in Table 6-1.

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			Adult Worker	Aggregate			
				Dermal			
	Domestic manufacturing	Domestic manufacturing	Worker: Female of Reproductive Age	Inhalation			
	manuracturing		Reproductive Age	Aggregate			
				Dermal			
			ONU	Inhalation			
Mar Gardening				Aggregate			
Manufacturing			Dermal				
			Worker: Average Adult Worker	Inhalation			
		Importing	Adult Worker	Aggregate			
			Worker: Female of Reproductive Age	Dermal			
	Importing			Inhalation			
				Aggregate			
			ONU	Dermal			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
	Incorporation			Aggregate			
	into		W. 1	Dermal			
Processing	formulation, mixture, or	Adhesives and sealants manufacturing	Worker: Female of Reproductive Age	Inhalation			
riocessing	reaction			Aggregate			
	product			Dermal			
			ONU	Inhalation			
				Aggregate			
		I about our about all monotories in a	Worker: Average	Dermal			
		Laboratory chemicals manufacturing	Adult Worker	Inhalation			

 Table 6-1. Supporting Basis for the Unreasonable Risk Determination for Human Health<sup>b</sup> (Occupational Conditions of Use)

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
				Aggregate			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
			inceptoductive rige	Aggregate			
				Dermal			
			ONU	Inhalation			
				Aggregate			
			Dermal				
			Worker: Average Adult Worker	Inhalation			
			Addit Worker	Aggregate			
	Incorporation into	e, or n		Dermal			
	formulation,		Worker: Female of Reproductive Age ONU	Inhalation			
Processing	mixture, or reaction			Aggregate			
	product			Dermal			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
				Aggregate			
				Dermal			
		Surface modifier and plasticizer in paint and coating manufacturing	Worker: Female of Reproductive Age	Inhalation			
				Aggregate			
				Dermal			
			ONU	Inhalation			
				Aggregate			
		Plastic material and resin manufacturing		Dermal			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
			Worker: Average	Inhalation			
			Adult Worker	Aggregate			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
			Reproductive Age	Aggregate			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
	Incorporation	Plasticizers (paint and coating manufacturing; pigments; rubber manufacturing)		Aggregate			
	into formulation,		Worker: Female of Reproductive Age ONU	Dermal			
Processing	mixture, or			Inhalation			
	reaction product			Aggregate			
	product			Dermal <sup>d</sup>			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			riduit Worker	Aggregate			
		Processing aids, specific to petroleum		Dermal			
		production (oil and gas drilling, extraction,	Worker: Female of Reproductive Age	Inhalation			
		and support activities)	Reproductive Age	Aggregate			
				Dermal			
			ONU	Inhalation			
				Aggregate			
				Dermal			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
			Worker: Average	Inhalation			
	Incorporation		Adult Worker	Aggregate			
	into			Dermal			
	formulation, mixture, or	Other (part of the formulation for	Worker: Female of Reproductive Age	Inhalation			
	reaction	manufacturing synthetic leather)	reproductive rige	Aggregate			
	product			Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
		Abrasives manufacturing	Adult worker	Aggregate			
			Worker: Female of Reproductive Age	Dermal			
Processing				Inhalation			
				Aggregate			
			ONU	Dermal <sup>e</sup>			
				Inhalation			
	Incorporation			Aggregate			
	into articles	Plasticizers (asphalt paving, roofing, and		Dermal			
		coating materials manufacturing; construction; automotive products	Worker: Average Adult Worker	Inhalation			
		manufacturing, other than fluids; electrical		Aggregate			
		equipment, appliance, and component manufacturing; fabric, textile, and leather		Dermal			
		products manufacturing; floor coverings	Worker: Female of Reproductive Age	Inhalation			
		manufacturing; furniture and related product manufacturing; plastics product	itepioudenve rige	Aggregate			
		manufacturing; rubber product		Dermal <sup>d</sup>			
		manufacturing; transportation equipment manufacturing; ink, toner, and colorant	ONU	Inhalation			
	manufacturing; ink, toner, and colorant products manufacturing (including pigment); photographic supplies			Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
		manufacturing; toys, playground, and sporting equipment manufacturing)					
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			Addit Worker	Aggregate			
				Dermal			
	Repackaging	Repackaging	Worker: Female of Reproductive Age	Inhalation			
			Reproductive Age	Aggregate			
				Dermal			
			ONU	Inhalation			
Processing				Aggregate			
6		Recycling	Worker: Average Adult Worker	Dermal			
				Inhalation			
			riduit worker	Aggregate			
			Worker: Female of Reproductive Age	Dermal			
	Recycling			Inhalation			
			Reproductive Age	Aggregate			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			
				Dermal			
Distribution in	Distribution in		Worker	Inhalation			
Commerce	commerce	Distribution in commerce	ONU	Dermal			
				Inhalation			
				Dermal			
Industrial Uses	Abrasives		Worker: Average Adult Worker	Inhalation			
	1101051105			Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
				Dermal			
		Abrasives (surface conditioning and	Worker: Female of Reproductive Age	Inhalation			
	Abrasives	finishing discs; semi-finished and finished		Aggregate			
	Abrasives	goods)		Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			riddie († offici	Aggregate			
				Dermal			
	Adhesive and sealants	Adhesive and sealants	ONU	Inhalation	√		
Industrial Uses	seuluns			Aggregate	✓		
				Dermal <sup>e</sup>			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
				Aggregate			
	Construction,			Dermal			
	paint, and	Paints and coatings	Worker: Female of Reproductive Age	Inhalation	√		
	metal products		rieproducer i ge	Aggregate	√		
				Dermal <sup>e</sup>			
			ONU	Inhalation			
				Aggregate			
	Functional	Functional fluids (closed systems) (SCBA	Worker: Average	Dermal			
		compressor oil)	Adult Worker	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
	Functional			Aggregate			
	fluids (closed systems)			Dermal			
	systems)		Worker: Female of Reproductive Age	Inhalation			
			Reproductive Age	Aggregate			
				Dermal			
			ONU	Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			Adult Worker	Aggregate			
Lubricant	Lubricant and	ant Lubricants and lubricant additives		Dermal			
	lubricant additives		Worker: Female of Reproductive Age	Inhalation			
Industrial Uses				Aggregate			
			ONU	Dermal			
				Inhalation			
				Aggregate			
			Worker: Average Adult Worker	Dermal			
				Inhalation			
			Adult Worker	Aggregate			
	Solvents (for			Dermal			
	cleaning or	Solvents (for cleaning or degreasing)	Worker: Female of Reproductive Age	Inhalation			
	degreasing)		Reproductive Age	Aggregate			
				Dermal			
			ONU	Inhalation			
				Aggregate			
	Automotive,	T huis	Worker: Average	Dermal			
	fuel,	Lubricants	Adult Worker	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
	agriculture,			Aggregate			
	outdoor use products			Dermal			
	r		Reproductive Age	Inhalation			
				Aggregate			
				Dermal			
			ONU	Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
		n,		Aggregate			
Commercial				Dermal			
Uses			Worker: Female of Reproductive Age	Inhalation	✓		
				Aggregate	~		
			ONU	Dermal <sup>e</sup>			
	Construction,			Inhalation			
	paint,			Aggregate			
	electrical, and metal products		Worker: Average Adult Worker	Dermal			
				Inhalation			
				Aggregate			
		Building/construction materials (wire or		Dermal			
		wiring systems; joint treatment, fire-proof	Worker: Female of Reproductive Age	Inhalation			
		insulation)	rieproducer i ge	Aggregate			
			ONU	Dermal <sup>d</sup>			
				Inhalation			
				Aggregate			
		Electrical and electronic products	Worker: Average	Dermal			
		Electrical and electronic products	Adult Worker	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
				Aggregate			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
			neproductive rige	Aggregate			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			
			Dermal				
			Worker: Average Adult Worker	Inhalation			
	Construction,		Adult Worker	Aggregate			
Commercial	paint, electrical, and			Dermal			
Use	metal products		Worker: Female of Reproductive Age	Inhalation	✓		
				Aggregate	✓		
			ONU	Dermal <sup><i>e</i></sup>			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			riduit () officer	Aggregate			
				Dermal			
		Lacquers, stains, varnishes, and floor finishes (as plasticizer)	Worker: Female of Reproductive Age	Inhalation	√		
			heproductive rige	Aggregate	√		
				Dermal <sup>e</sup>			
			ONU	Inhalation			
				Aggregate			
				Dermal			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
			Worker: Average	Inhalation			
			Adult Worker	Aggregate			
		Construction and building materials		Dermal			
		covering large surface areas including stone, plaster, cement, glass and ceramic	Worker: Female of Reproductive Age	Inhalation			
		articles; fabrics, textiles, and apparel (as	Reproductive Age	Aggregate			
	Euroiching	plasticizer) (Floor coverings [vinyl tiles, PVC-backed carpeting, scraper mats])		Dermal <sup>d</sup>			
			ONU	Inhalation			
Furnishing, cleaning,				Aggregate			
	treatment/care			Dermal			
	products		Worker: Average Adult Worker	Inhalation			
Commercial			Adult WOIKEI	Aggregate			
Uses		Furniture and furnishings	Worker: Female of Reproductive Age	Dermal			
				Inhalation			
				Aggregate			
			ONU	Dermal <sup>d</sup>			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			Addit Worker	Aggregate			
	Packaging,			Dermal			
	paper, plastic,	Ink, toner, and colorant products	Worker: Female of Reproductive Age	Inhalation			
	hobby products			Aggregate			
	L			Dermal <sup>e</sup>			
			ONU	Inhalation			
				Aggregate			
		PVC film and sheet		Dermal			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
			Worker: Average	Inhalation			
			Adult Worker	Aggregate			
				Dermal			
			Worker: Female of Reproductive Age	Inhalation			
			ineproductive rige	Aggregate			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
Packagi paper, p	Packaging, paper, plastic,			Aggregate			
	hobby			Dermal			
	products		Worker: Average Adult Worker	Inhalation			
~		Plastic and rubber products (textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)		Aggregate			
Commercial Uses			Worker: Female of Reproductive Age	Dermal			
				Inhalation			
				Aggregate			
			ONU	Dermal <sup>d</sup>			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			Adult Worker	Aggregate			
	Other uses	Laboratory chemicals	Worker: Female of	Dermal			
	Ouler uses		Reproductive Age	Inhalation			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
				Dermal			
		Automotive articles	Worker: Average Adult Worker	Inhalation			
				Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
			Western Frankland	Dermal			
			Worker: Female of Reproductive Age	Inhalation			
		Automotive articles		Aggregate			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			
	Other uses		*** 1 .	Dermal			
Commercial			Worker: Average Adult Worker	Inhalation			
Uses			Addit Worker	Aggregate			
				Dermal			
		Inspection fluid/penetrant	Worker: Female of Reproductive Age ONU	Inhalation	✓		
				Aggregate	✓		
				Dermal <sup>e</sup>			
				Inhalation			
				Aggregate			
				Dermal			
			Worker: Average Adult Worker	Inhalation			
			riduit worker	Aggregate			
				Dermal			
Disposal	Disposal	Disposal	Worker: Female of Reproductive Age	Inhalation			
			Reproductive Age	Aggregate			
				Dermal <sup>d</sup>			
			ONU	Inhalation			
				Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route <sup>a</sup>	Acute Non-cancer	Intermediate Non-cancer	Chronic Non- cancer
<sup>a</sup> 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 t	determined that there was a viable exposure pathway.						
<sup>b</sup> Grayed-out boxes indicate certain exposure routes that were not assessed because it was determined that there was no viable exposure pathway.							
<sup>c</sup> 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.							
<sup>d</sup> Dermal exposure to ONUs from contact with dust on surfaces was assessed.							
<sup>e</sup> Dermal exposure to ONUs from contact with mist on the surfaces was assessed.							

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# Appendix A KEY ABBREVIATIONS AND ACRONYMS

I I	
ADD	Average daily dose
ADC	Average daily concentration
AERMOD	American Meteorological Society/EPA Regulatory Model
BLS	Bureau of Labor Statistics
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential business information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CPSC	(U.S.) Consumer Product Safety Commission
CWA	Clean Water Act
DBHP	Di(2-propylheptyl) phthalate
DEHP	Diethylhexyl phthalate
DIDP	Diisodecyl phthalate
DINP	Diisononyl phthalate
DIY	Do-it-yourself
DMR	Discharge Monitoring Report
EPA	(U.S.) Environmental Protection Agency (or the Agency)
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emission Scenario Document
EU	European Union
FDA	(U.S.) Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GS	Generic Scenario
K <sub>OC</sub>	Soil organic carbon: water partitioning coefficient
Kow	Octanol: water partition coefficient
HEC	Human equivalent concentration
HED	Human equivalent dose
IADD	Intermediate average daily dose
IR	Ingestion rate
LCD	Life cycle diagram
LOD	Limit of detection
LOEC	Lowest-observed-effect concentration
Log K <sub>OC</sub>	Logarithmic organic carbon: water partition coefficient
Log Kow	Logarithmic octanol: water partition coefficient
MOE	Margin of exposure
NAICS	North American Industry Classification System
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No-observed-adverse-effect level
NOEC	No-observed-effect-concentration
NPDES	National Pollutant Discharge Elimination System
NTP	National Toxicology Program

OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
OES	Occupational exposure scenario
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBZ	Personal breathing zone
PECO	Population, exposure, comparator, and outcome
PEL	Permissible exposure limit (OSHA)
PESS	Potentially exposed or susceptible subpopulations
PND	Postnatal Day
POD	Point of departure
POTW	Publicly owned treatment works
PVC	Polyvinyl chloride
REL	Recommended Exposure Limit
SACC	Science Advisory Committee on Chemicals
SDS	Safety data sheet
SOC	Standard Occupational Classification
SUSB	Statistics of U.S. Businesses (U.S. Census Bureau)
TRV	Toxicity reference value
TSCA	Toxic Substances Control Act
TWA	Time-weighted average
UF	Uncertainty factor
U.S.	United States
WWTP	Wastewater treatment plant

#### Appendix B **REGULATORY AND ASSESSMENT HISTORY**

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

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 ( <u>76 85 FR 5081620122</u> , 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 ( <u>60 FR 16309</u> , 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	CASRN 26761-40-0 is approved for non-food use (InertFinder, Accessed March 4, 2024).		

## Table\_Apx B-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation	
	(e). In the absence of a tolerance or an exemption from tolerance, or where pesticide 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	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).	
	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.		
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	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	

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	regulated by EPA under FFDCA section 408 (discussed above where applicable).	177.1210; 21 CFR 177.2600; 21 CFR 177.3910).
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 ( <u>16 CFR part</u> <u>1307</u> , 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	California listed CASRN "68515-49-1/26761-40-0" on Proposition 65 in 2007 due to developmental toxicity. (Cal Code Regs. Title 27, § 27001).
	CASRN 26761-40-0 is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253).
	California issued a Health Hazard Alert for DIDP (Hazard Evaluation System and Information Service, 2016).
	California lists DIDP as a designated priority chemical for biomonitoring (California SB 1379).

# **B.3** International Laws and Regulations

### Table\_Apx B-3. International Laws and Regulations

Country/ Organization	Requirements and Restrictions		
Canada	CASRNs 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	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).		
	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		

<b>Country/Organization</b>	Requirements and Restrictions
	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).
	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 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	<ul> <li>CASRNs 26761-40-0 and 68515-49-1 are regulated in Japan under the following legislation:</li> <li>Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)</li> <li>Food Sanitation Act</li> <li>Fire Service Act</li> <li>(National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed February 28, 2024).</li> </ul>
Countries with occupational exposure limits	<ul> <li>Occupational exposure limit for CASRN 26761-40-0 is:</li> <li>Austria: 3 mg/m<sup>3</sup> (8-hour) and 5 mg/m<sup>3</sup> (short-term);</li> <li>Ontario, Canada: 5 mg/m<sup>3</sup> (8-hour);</li> <li>Denmark: 3 mg/m<sup>3</sup> (8-hour) and 6 mg/m<sup>3</sup> (short-term);</li> <li>Ireland: 5 mg/m<sup>3</sup> (8-hour);</li> <li>New Zealand: 5 mg/m<sup>3</sup> (8-hour);</li> <li>South Africa Mining: 5 mg/m<sup>3</sup> (8-hour);</li> <li>Sweden: 3 mg/m<sup>3</sup> (8-hour) and 5 mg/m<sup>3</sup> (short-term); and</li> <li>United Kingdom: 5 mg/m<sup>3</sup> (8-hour).</li> <li>(GESTIS International limit values for chemical agents [Occupational exposure limits, OELs] database. Accessed February 28, 2024).</li> </ul>

## **B.4** Assessment History

## Table\_Apx B-4. Assessment History of DIDP

Authoring Organization	Publication(s)/Hyperlink(s) and Year		
EPA publications			
None	_		
Other U.Sbased 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)		

Authoring Organization	Publication(s)/Hyperlink(s) and Year
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)
Interna	ational
European Union, European Chemicals Agency (ECHA)	Evaluation of New Scientific Evidence Concerning DINP and DIDP (2013)
	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)
European Food Safety Authority (EFSA)	<u>Update of the Risk Assessment of Di-butylphthalate</u> (DBP), Butyl-benzyl-phthalate (BBP), Bis(2- ethylhexyl)phthalate (DEHP), Di-isononylphthalate (DINP) and Di-isodecylphthalate (DIDP) for Use in Food Contact Materials (2019)
	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)
Government of Canada, Environment Canada, Health Canada	Screening Assessment: Phthalate Substance Grouping (2020)
	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)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	Priority Existing Chemical Assessment Report: Diisodecyl Phthalate & Di-n-octyl Phthalate (2015)
	Existing Chemical Hazard Assessment Report: Diisodecyl Phthalate (2008)

## Appendix C LIST OF TECHNICAL SUPPORT DOCUMENTS

Appendix C incudes a list and citations for all supplemental documents included in the 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.

Systematic Review Protocol for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024ab) – In lieu of an update to 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, also referred to as the "2021 Draft Systematic Review Protocol" (U.S. EPA, 2021a), this systematic review protocol for the 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, 2024i) – 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, 2024g) – 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, 2024h) – 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, 2024f) – 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." Data Extraction Information for General Population, Consumer, and Environmental Exposure for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024k) – Provides a compilation of tables for the data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was evaluated from a data source that has information relevant for the evaluation of general population, consumer, and environmental exposure. This supplemental file may also be referred to as the "DIDP Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure."

Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024e) – Provides a compilation of tables for the data extraction for DIDP. Each table shows the data point, set, or information element that was extracted from a data source that has information relevant for the evaluation of general population, consumer, and environmental exposure. This supplemental file may also be referred to as the "DIDP Data Extraction Information for General Population, Consumer, and Environmental Exposure."

*Data Quality Evaluation Information for Human Health Hazard Epidemiology for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024m) – Provides a compilation of tables for the data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was evaluated from a data source that has information relevant for the evaluation of epidemiological information. This supplemental file may also be referred to as the "DIDP Data Quality Evaluation Information for Human Health Hazard Epidemiology."

*Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 20241) – Provides a compilation of tables for the data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was evaluated from a data source that has information relevant for the evaluation of human health hazard animal toxicity information. This supplemental file may also be referred to as the "DIDP Data Quality Evaluation Information for Human Health Hazard Animal Toxicology."

Data Quality Evaluation Information for Environmental Hazard for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024j) – Provides a compilation of tables for the data quality evaluation information for DIDP. Each table shows the data point, set, or information element that was evaluated from a data source that has information relevant for the evaluation of environmental hazard toxicity information. This supplemental file may also be referred to as the "DIDP Data Quality Evaluation Information for Environmental Hazard."

Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024d) – Provides a compilation of tables for the data extraction for DIDP. Each table shows the data point, set, or information element that was extracted from a data source that has information relevant for the evaluation of environmental hazard and human health hazard animal toxicology and epidemiology information. This supplemental file may also be referred to as the "DIDP Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology."

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

Physical Chemistry Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024w).

*Fate and Transport Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024t).

*Environmental Release and Occupational Exposure Assessment for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024s).

*Environmental Media and General Population Exposure for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024r).

Consumer and Indoor Dust Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024a).

Environmental Exposure Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024p).

Environmental Hazard Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024q).

Human Health Hazard Assessment for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024v).

Consumer Exposure Analysis for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024b).

Consumer Risk Calculator for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024c).

*Risk Calculator for Occupational Exposures for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024x).

Fish Ingestion Risk Calculator for Diisodecyl Phthalate (DIDP) (U.S. EPA, 2024u).

*Surface Water Human Exposure Risk Calculator for Diisodecyl Phthalate (DIDP)* (U.S. EPA, 2024aa).

# 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 document (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 amended 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 and draft risk evaluation documents.

## 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 after Scope	Revised Subcategory in the 2024 Draft Risk Evaluation	Occurred Change after Draft	Revised Subcategory in the 2024 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	N/A	N/A
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)	N/A	N/A
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;	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,	N/A	N/A

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change after Scope	Revised Subcategory in the 2024 Draft Risk Evaluation	Occurred Change after Draft	Revised Subcategory in the 2024 Risk Evaluation
	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)		toner, and colorant products manufacturing; photographic supplies manufacturing; toys, playgrounds, and sporting equipment manufacturing)		
Industrial uses, Construction, paint, electrical, and metal products	N/A	N/A	N/A	Added "paints and coatings"	Paints and coatings
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)	N/A	N/A
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)	N/A	N/A
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)	N/A	N/A
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])	N/A	N/A

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change after Scope	Revised Subcategory in the 2024 Draft Risk Evaluation	Occurred Change after Draft	Revised Subcategory in the 2024 Risk Evaluation
Commercial uses, Furnishing, cleaning, treatment/care products	N/A	Added "PVC film and sheet"	PVC film and sheet	N/A	N/A
Commercial uses, Other uses	Automotive care products	Removed "care," added "other than fluids"	Automotive products, other than fluids	Removed "products, other than fluids" and added "articles"	Automotive articles
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)	N/A	N/A
Consumer uses, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere ( <i>e.g.</i> , 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)	N/A	N/A
Consumer uses, Furnishing, cleaning, treatment/care products	N/A	Added category and "Fabrics, textiles, and apparel (as plasticizer)"	Fabrics, textiles, and apparel (as plasticizer)	N/A	N/A
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)	N/A	N/A
Consumer uses, Packaging, paper, plastic, hobby products	N/A	Added "PVC film and sheet"	PVC film and sheet	N/A	N/A
Consumer uses, Other uses	Automotive care products	Removed "care," added "other than fluids"	Automotive products, other than fluids	Removed "products, other than fluids" and added "articles"	Automotive articles
Consumer uses, Other Uses	N/A	Added category and "Novelty products"	Novelty products	Removed "product" and added "articles"	Novelty articles

The changes based on CDR reporting, research, or stakeholder activity from the draft risk evaluation to the final risk evaluation are provided below:

- *Manufacturing Domestic manufacturing –* "Domestic manufacturing" and *Manufacturing Importing –* "Importing" was listed under a single COU description in Appendix E of the draft risk evaluation. These COUs are now separated in Appendix E and consistent with their presentation in Table 1-1 in the risk evaluation.
- Industrial uses, Construction, paint, electrical, and metal products, "Paints and coatings" was split from the Commercial uses, Construction, paint, electrical, and metal products, Paints and coatings COU to provide additional clarity on the use of DIDP in industrial and commercial sectors. The inclusion of the Industrial COU will also provide consistency with other phthalates designated as high-priority substances or a manufacturer requested risk evaluations. EPA also identified a DIDP-containing paint and coating that could be applied in industrial settings (PPG Industries, 2024; Industries., 2018). The Commercial uses, Construction, paint, and electrical, and metal products, "Paints and coatings" was already assessed in the draft risk evaluation, and the same analysis used in for the industrial uses COU. The public was provided notice to comment on the analysis.
- *Consumer uses, Other*, was edited to *Consumer uses, Other uses* to be consistent with the *Commercial uses* category and to provide clarification.
- *Consumer uses, Other uses, "Novelty products*" subcategory was edited to "*Novelty articles*" to clarify that "articles" as defined by 40 CFR part 751 were assessed under this COU.
- For the *Commercial uses and Consumer uses, Automotive, fuel, agriculture, outdoor use products*, "Automotive products, other than fluids" COUs, the category and subcategory were edited. The category "*Automotive, fuel, agriculture, outdoor use products*" was edited to "*Other uses*" to reflect that this use was not reported to the CDR in either the 2016 or 2020 CDR cycles. The subcategory of "Automotive products other than fluids" was changed to "Automotive articles." This was to clarify that "articles" as defined by 40 CFR part 751 were assessed under this COU.
- The COU description for the updated COUs, *Commercial uses and Consumer uses, Other uses*, "Automotive articles" was updated to clarify that "products" as defined by 40 CFR part 751 were not being assessed under this COU. The COU description was updated to clarify that window glazing and automotive protective undercoatings were assessed under the *Industrial uses and Commercial uses, Construction, paint, electrical, and metal products,* "Paints and coatings" COUs. The COU description was updated to clarify that bonding adhesives used in automobiles was assessed under the *Industrial uses, Commercial uses, and Consumer uses,* "Adhesive and sealant" COUs.

The changes based on CDR reporting, research, or stakeholder activity from the scope are provided below:

- *Processing, incorporation into formulation, mixture, or reaction product, "other (part of the formulation for manufacturing synthetic leather)*" was added because it was a new reporting sector in the 2020 CDR (U.S. EPA, 2020a).
- *Processing, incorporation into articles, "Plasticizers*" was updated to include the construction and furniture and related product manufacturing industrial sector based on 2020 CDR reporting (U.S. EPA, 2020a).
- For Commercial and Consumer uses, construction, paint, electrical and metal products, "Adhesives and sealants (including plasticizers in adhesives and sealants)", the reference to

plasticizers was added after feedback from a stakeholder notifying the EPA that DIDP can be used as a component in adhesives and sealants as a plasticizer (<u>ACC HPP, 2023</u>).

- 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 (plasticizer) floor coverings (vinyl tiles, PVC-backed carpeting, scraper mats)" was updated due to a change in the 2020 CDR reporting codes. The 2020 CDR code for floor coverings was changed to "construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel". The original subcategory of floor coverings and examples were combined with the new reporting code in the subcategory. The term "as plasticizer" was added to specify the use of DIDP in these floor coverings (U.S. EPA, 2020a).
- Commercial uses, Construction, paint, electrical, and metal products, "Paints and coatings" was edited to include "(including surfactants in paints and coatings)" because surfactants were referenced in 2020 CDR reporting data (U.S. EPA, 2020a).
- Commercial uses, Construction, paint, electrical, and metal products, "Lacquers, stains, varnishes, and floor finishes (as plasticizer)" was added because it was added as a reporting category to the 2020 CDR (U.S. EPA, 2020a).
- For *Commercial and Consumer uses, Furnishing, cleaning, treatment/care products, "PVC film and sheet"* was added after stakeholder notification that DIDP is used in the production of these products (U.S. EPA, 2020g).
- Consumer uses, Furnishing, cleaning, treatment/care products, "Fabrics, textiles and apparel (as plasticizer)" was added after stakeholder notification that DIDP was used in these industries (ACC HPP, 2023).
- Consumer uses, 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)" was changed based on the updated 2020 CDR codes. The subcategory was updated to "Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles." The specific examples of "(wire or wiring systems; joint treatment)" were kept (U.S. EPA, 2020a).
- Consumer uses, Packaging, paper, plastic, hobby products, Arts, crafts, and hobby materials was edited to add "(crafting paint applied to craft)" to reflect a use reported in the 2020 CDR (U.S. EPA, 2020a).
- *Consumer uses, Other, "Novelty products"* was added after EPA did further research and found this use among the reasonably available information (Sipe et al., 2023; Stabile, 2013).

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

When developing this risk evaluation, EPA concluded that some subcategories of the COUs listed in the final scope document (U.S. EPA, 2021b) were redundant and consolidation was needed to avoid evaluation of the same COU multiple times. The Agency concluded that there were some instances where subcategory information on the processing and uses of DIDP was misreported by CDR reporters based on outreach with stakeholders. For these instances, EPA recategorized the COU to fit the actual description of the COU. Finally, the Agency determined that wording changes were needed to accurately describe COUs. Therefore, EPA has made changes to the COU for the risk evaluation. Table\_Apx D-2 summarizes the changes to the COU subcategory descriptions.

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation	Occurred Change	Revised Subcategory in the 2024 Risk Evaluation
Processing, Incorporation into formulation, mixture, or reaction product	Intermediates ( <i>e.g.</i> , plastic material and resin manufacturing)	Removed	N/A	N/A	N/A
Processing, Incorporation into formulation, mixture, or reaction product	Plastic product manufacturing	Removed	N/A	N/A	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	N/A	N/A
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	N/A	N/A
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)"	Plasticizers (paint and coating manufacturing; pigments; rubber manufacturing)	N/A	N/A
		Removed "product" from rubber product manufacturing			
Processing, Incorporation into articles	Lubricants and lubricants additives manufacturing	Removed "Lubricants and lubricants	N/A	N/A	N/A

 Table\_Apx D-2. Subcategory Consolidations and Editing from the Final Scope Document to the

 Risk Evaluation

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation	Occurred Change	Revised Subcategory in the 2024 Risk Evaluation
		additives manufacturing"			
Processing, Incorporation into articles	Adhesive and sealant manufacturing	Removed "Adhesive and sealant manufacturing"	N/A	N/A	N/A
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 coverings manufacturing; plastics product manufacturing; rubber product manufacturing; textiles, apparel, and leather manufacturing; transportation equipment manufacturing; ink, toner, and colorant products manufacturing; plastic manufacturing; photographic supplies manufacturing; plastic material and resin manufacturing; textiles, apparel, and leather manufacturing; plastic material and resin manufacturing; textiles, apparel, and leather manufacturing; textiles, apparel, and leather manufacturing; textiles, apparel, and leather manufacturing; toys, playgrounds, and sporting equipment manufacturing)	Removed "not covered elsewhere from, fabric, textile, and leather products not covered elsewhere manufacturing," Removed "miscellaneous manufacturing, plastic 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."	Plasticizers (asphalt paving, roofing, and coating materials manufacturing; construction; 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 (including pigment) manufacturing; toys, playgrounds, and sporting equipment manufacturing)	N/A	N/A
Industrial uses, Functional fluids (open systems)	Functional fluids (open systems) ( <i>e.g.</i> , ground injection equipment)	Removed	N/A	N/A	N/A
Commercial uses, Other uses	Automotive care products	Removed "care", added "other than fluids"	Automotive products, other than fluids	Removed "products, other than fluids" and	Automotive articles

Life Cycle Stage and Category	and in the Final Scope Occurred in the 2024 Draft		Occurred Change	Revised Subcategory in the 2024 Risk Evaluation	
				added "articles"	
Commercial uses, Automotive, fuel, agriculture, outdoor use products	Lubricants and greases	Removed "greases"	Lubricants	N/A	N/A
Commercial uses, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere ( <i>e.g.</i> , 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)	N/A	N/A
Commercial uses, Furnishing, cleaning, treatment/care products	Furniture and furnishings not covered elsewhere	Removed "not covered elsewhere"	Furniture and furnishings	N/A	N/A
Commercial uses, Packaging, paper, plastic, hobby products	Plastic and rubber products not covered elsewhere ( <i>e.g.</i> , 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)	N/A	N/A
Consumer uses, Other uses	Automotive care products	Removed "care," added "other than fluids"	Automotive products, other than fluids	Removed "products, other than fluids" and added "articles"	Automotive articles
Consumer uses, Automotive, fuel, agriculture, outdoor use products	Lubricants and greases	Removed "greases"	Lubricants	N/A	N/A
Consumer uses, Packaging, paper, plastic, hobby products	Photographic supplies ( <i>e.g.</i> , graphic films)	Removed	N/A	N/A	N/A

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

- 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.
- References to "greases" throughout the COU table were removed when referring to lubricants because of stakeholder clarification that DIDP is not used in greases (ACC HPP, 2023).

- 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.
- 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.
- 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.
- 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.
- *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 (U.S. EPA, 2020a).
- 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,
  - The references to adhesive and sealant manufacturing, custom compounding of purchased resin, and plastic material and resin manufacturing were removed because the uses are assessed under other categories.
  - Ground injection equipment was removed because it was already addressed under the functional fluids COU. The functional fluids (open systems) COU category was also removed (please see the explanation for removal of the *"Industrial uses, Functional fluids (open systems)"* category for additional information.
  - Construction materials other was removed because it is assessed under the "processing, incorporation into articles" COU and was redundant.
  - Product was removed from "rubber product manufacturing" to differentiate it from the *Processing, incorporation into article, "Plasticizer (rubber product manufacturing)"* COU.
- *Processing, Incorporation into articles,* "Lubricant and lubricant additive manufacturing" was removed because it was assessed under *Processing, Incorporation into formulation, mixture, or reaction product* and was considered redundant.

- *Processing, Incorporation into articles,* "adhesive and sealant manufacturing" was removed because EPA determined that it was better assessed under *Processing, incorporation into articles,* "plasticizers" and *Industrial use, Adhesive and sealants,* "Adhesive and sealants."
- Processing, Incorporation into articles, "plasticizers" was updated for the following industries:
  - Miscellaneous manufacturing after stakeholder outreach, EPA concluded that this industry was misreported under the CDR and was addressed under other COUs (U.S. EPA, 2023e).
  - Plastic material and resin manufacturing EPA determined that this industry was assessed under "plastics product manufacturing" within this COU.
  - Automotive products manufacturing, other than fluids this subcategory refers to the plastic moldings in automobiles. Automobile-related fluids, such as transmission conditioner, are addressed under the lubricants COU.
  - Automotive care product manufacturing after investigation by EPA it was determined that DIDP is not incorporated into products associated with automotive care (*e.g.*, waxes, soaps, etc).
  - Added "including pigment" to the ink, toner, and colorant manufacturing to indicate that this COU describes the mixing of DIDP pigments into materials such as, polyurethane or plastisol.
- *Industrial uses, functional fluids (closed systems)* COU, the reference to heat transfer fluid was removed after review of notes from a stakeholder found that there was only discussion of SCBA compressor fluid (U.S. EPA, 2020f).
- Industrial uses, Functional fluids (open systems), Functional fluids (open systems) (e.g., ground injection equipment) was removed; this COU is not included in CDR reporting, and upon further investigation and outreach with the stakeholder, EPA was unable to confirm that the COU exists (EPA-HQ-OPPT-2018-0435-0015).
- *Commercial uses, Packaging, paper, plastic, hobby products, Arts, crafts, and hobby materials* was removed after a stakeholder notified the EPA that DIDP is not used in this manner commercially (ACC HPP, 2023).
- *Commercial* and *Consumer uses, Packaging, paper, plastic, hobby products, Photographic supplies (e.g., graphic films)* was removed because EPA confirmed with a stakeholder that DIDP is not used in this manner (ACC HPP, 2023).

## Appendix E CONDITIONS OF USE DESCRIPTIONS

The following descriptions are intended to include examples of uses so as not to exclude other activities that may also be included in the COUs of the chemical substance. To better describe the COU, EPA considered CDR submissions from the last two CDR cycles for DIDP (CASRN 68515-49-1and CASRN 26761-40-0), and the COU descriptions reflect what EPA identified as the best fit for that submission. Examples of articles, products, or activities are included in the following descriptions to help describe the COU but are not exhaustive. EPA uses the terms "articles" and "products" or product mixtures in the following descriptions and is generally referring to articles and products as defined by 40 CFR part 751. There may be instances where the terms are used interchangeably by a company or commenters, or by EPA in reference to a code from the CDR reports which are referenced; for example, "plastic products manufacturing," or "fabric, textile, and leather products." The Agency clarifies as needed when these references are included throughout the COU descriptions below.

## E.1 Manufacturing – Domestic Manufacturing

Domestic manufacturing means to manufacture or produce DIDP within the Unites States. For purposes of the DIDP risk evaluation, this includes the extraction of DIDP from a previously existing chemical substance or complex combination of chemical substances and loading and repackaging (but not transport) associated with the manufacturing and/or production of DIDP.

At a typical manufacturing site, DIDP is formed 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 (U.S. EPA, 2021b). Typical manufacturing operations consist of reaction, followed by crude filtration, where the product is distilled or separated, and final filtration. Manufacturing operations may also include quality control sampling of the DIDP product. Additionally, manufacturing operations include equipment cleaning/reconditioning and product transport to other areas of the manufacturing facility or offsite shipment for downstream processing or use. No changes to chemical composition occur during transportation (ExxonMobil, 2022a).

#### Examples of CDR Submissions

In the 2016 CDR cycle, one company reported domestic manufacturing of DIDP (CASRN 68515-49-1), and one company reported domestic manufacturing of DINP (CASRN 26761-40-0) with all manufacturers producing a liquid (U.S. EPA, 2019a).

In the 2020 CDR cycle, three CDR companies reported domestic manufacturing of DIDP (CASRN 68515-49-1), and a fourth company, did not report any activity specific to DIDP but did report their overall site activity for their NAICS code as "manufacture"; therefore, EPA assessed this site as a domestic manufacturer of DIDP (U.S. EPA, 2020a). All companies reported the manufacture of DIDP (CASRN 68515-49-1) as a liquid. No sites reported domestic manufacturing of DIDP under CASRN 26761-40-0 (U.S. EPA, 2020a).

## **E.2** Manufacturing – Importing

Import refers to the import of DIDP into the customs territory of the United States. This condition of use includes loading/unloading and repackaging (but not transport) associated with the import of DIDP. In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal shipments. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers (U.S. EPA, 2021b). Imported DIDP is shipped in either dry powder/crystal

pellets/solid form or liquid form with concentrations ranging from 1 to 100 percent DIDP (<u>U.S. EPA, 2020a</u>).

#### **Examples of CDR Submissions**

In the 2016 CDR cycle, two companies reported importation of DIDP (CASRN 26761-40-0) with one company reporting importing DIDP as a liquid or wet solid (U.S. EPA, 2019a). In the 2016 CDR cycle, three companies reported the importation of DIDP (CASRN 68515-49-1) with companies reporting importing as a dry powder, other solids, or liquid (U.S. EPA, 2019a).

In the 2020 CDR cycle, eight companies reported importation of DIDP (CASRN 26761-40-0) with companies reporting importing as a liquid, dry powder, pellets or other large crystals, or other solid (U.S. EPA, 2020a). In the 2020 CDR cycle, three companies reported the importation of DIDP (CASRN 68515-49-1) with companies reporting importing DIDP as a liquid (U.S. EPA, 2020a).

## E.3 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Adhesive and Sealants Manufacturing

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

#### Example of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DIDP as a plasticizer in adhesives manufacturing (CASRN 68515-49-1), and in the 2020 CDR cycle, one company reported the use of DIDP as a plasticizer in adhesives manufacturing (CASRN 68515-49-1) (U.S. EPA, 2020a, 2019a).

## E.4 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Laboratory Chemicals Manufacturing

Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation of a chemical substance or mixture; that is, adding DIDP to a product (or product mixture) after its manufacture, for distribution in commerce, in this case into laboratory chemicals. Various companies have reported DIDP use for chemical synthesis or as a reference standard alone or in a mixture (Supelco, 2024; AccuStandard, 2021).

This COU was not reported during the 2016 or 2020 CDR reporting cycles.

## E.5 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Petroleum Lubricating Oil Manufacturing; Lubricants and Lubricant Additive Manufacturing

Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation of a chemical substance or mixture; that is, adding DIDP to a product (or product mixture) after its manufacture, for distribution in commerce, in this case incorporating DIDP into petroleum lubricating oil and greases. DIDP is used as lubricant additive in products such as compressor fluids (<u>Anderol</u>, <u>2015</u>).

#### Example of CDR Submissions

In the 2016 CDR cycle, one company reported this type of processing of DIDP (CASRN 26761-40-0) as a lubricant and lubricant additive (U.S. EPA, 2019a). In the 2020 cycle, one company reported this type of processing of DIDP (CASRN 68515-49-1) as a lubricating agent in petroleum lubricating oil and grease manufacturing (U.S. EPA, 2020a). Additionally, in the 2020 CDR cycle, one company reported the processing of DIDP (CASRN 68515-49-1) as a reactant in petroleum lubricating oil and grease manufacturing when DIDP (CASRN 68515-49-1) as a reactant in petroleum lubricating oil and grease manufacturing when DIDP functions as a plasticizer (U.S. EPA, 2020a). However, as DIDP is not used as a reactant in a chemical reaction in the manufacture of the petroleum lubricating oil, EPA considers this report to be better captured under "processing – incorporation into formulation, mixture, or reaction product" (U.S. EPA, 2020e).

## E.6 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Surface Modifier and Plasticizer in Paint and Coating Manufacturing

Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation of a chemical substance or mixture. That is, adding DIDP to a product (or product mixture) after its manufacture, for distribution in commerce, in this case as a surface modifier and plasticizer in paint and coating manufacturing. The term "surface modifier" encompasses DIDP's use as an inert ingredient that is included in a coating as a plasticizer as well as other paint and coatings products used for downstream industrial, commercial, and consumer uses.

#### Example of CDR Submissions

In the 2020 CDR cycle, one company reported the processing of DIDP (CASRN 68515-49-1) as a reactant in paint and coating manufacturing when DIDP functions as a surface modifier (U.S. EPA, 2020a). As DIDP is not used as a reactant in a chemical reaction in the manufacture of paints and coatings, EPA considers this report to be better captured under "processing – incorporation into formulation, mixture, or reaction product" (U.S. EPA, 2020e).

## E.7 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Plastic Material and Resin Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of DIDP into formulation, mixture, or a reaction product that occurs when a chemical substance is added to a product (or product mixture) after its manufacture, for distribution in commerce—in this case as a plasticizer in various industrial sectors, specifically to provide flexibility to PVC. In manufacturing of plastic material and resin through non-PVC and PVC compounding, DIDP is blended into polymers. Compounding involves the mixing of the polymer with the plasticizer and other chemical such as, fillers and heat stabilizers. The plasticizer needs to be absorbed into the particle to impart flexibility to the polymer. For PVC compounding, compounding occurs through mixing of ingredients to produce a powder (dry blending) or a liquid (Plastisol blending). The most common process for dry blending involves heating the ingredients in a high intensity mixer and transfer to a cold mixer. The Plastisol blending is done at ambient temperature using specific mixers that allow for the breakdown of the PVC agglomerates and the absorption of the plasticizer into the resin particle.

#### Example of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) in this type of processing in plastic product manufacturing. EPA considers this report to be better captured under "processing – incorporation into article," and plastic and resin manufacturing to be synonymous with plastic product manufacturing (U.S. EPA, 2019a). PVC compounding and non-compounding would

need to occur to prior to the manufacture of the final article or product. In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 26761-40-0) as a plasticizer under processing as a reactant in plastic product manufacturing. EPA has determined not to include this COU and considers it captured under "processing, incorporation into articles" and the upstream process of PVC compounding and non-PVC compounding was included under this COU (U.S. EPA, 2020e).

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer under processing as a reactant in plastics material and resin manufacturing. Upon outreach with the submitter, it was clarified that there is no use where DIDP is used as a chemical reactant in and of itself (<u>ACC HPP, 2023</u>). EPA considers this report to be better captured under "processing – incorporation into formulation, mixture, or reaction product"(<u>U.S. EPA, 2020e</u>).

## E.8 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Plasticizers (Paint and Coating Manufacturing; Pigments; Rubber Manufacturing)

Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation of a chemical substance or mixture; that is, adding DIDP to a product (or product mixture) after its manufacture, for distribution in commerce, in this case as a plasticizer in paint and coating manufacturing, pigments and rubber manufacturing. This COU does not include the use as surface modifier or resin manufacturing covered by other COUs.

#### Example of CDR Submissions

In the 2016 CDR reporting cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in the processing – incorporation into formulation, mixture, or reaction product – paint and coating manufacturing (U.S. EPA, 2019a). In the 2020 reporting cycles, one company reported the use of DIDP (CASRN 26761-40-0) in processing – incorporation into formulation, mixture, or reaction product – rubber product manufacturing (U.S. EPA, 2020a).

## E.9 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Processing Aids, Specific to Petroleum Production (Oil and Gas Drilling, Extraction, and Support Activities)

Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation of a chemical substance or mixture; that is, adding DIDP to a product (or product mixture) after its manufacture, for distribution in commerce—in this case as a processing aid, specific to petroleum production (oil and gas drilling, extraction, and support activities). The use was also reported in the Manufacturer Request for Risk Evaluation Di-isodecyl Phthalate (DIDP) (<u>ACC HPP, 2019</u>). In addition, DIDP is found in produced wastewaters from oil and gas drilling and extraction (<u>U.S. EPA, 2016</u>).

#### **Examples of CDR Submissions**

In the 2016 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a processing aid for petroleum production, such as oil and gas drilling activities (U.S. EPA, 2019a).

## E.10 Processing – Incorporation into a Formulation, Mixture, or Reaction Product – Other (Part of the Formulation for Manufacturing Synthetic Leather)

Processing to incorporate DIDP into a formulation, mixture, or reaction product refers to the preparation of a chemical substance or mixture; that is, adding DIDP to a product (or product mixture) after its

manufacture, for distribution in commerce—in this case as a plasticizer that is mixed with non-PVC (polyurethane) or PVC and other additives to make a liquid suspension that can be applied to paper in the manufacturing of synthetic leather (EPA-HQ-OPPT-2018-0435-0021).

#### **Examples of CDR Submissions**

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 26761-40-0) as part of the formulation in the manufacturing of synthetic leather (U.S. EPA, 2020a).

## E.11 Processing – Incorporation into Articles – Abrasives Manufacturing

Processing to incorporate DIDP into articles refers to the preparation of a chemical substance or mixture. That is, DIDP becoming a component of an article, after its manufacture, for distribution in commerce, in this case as abrasives. Abrasives are manufactured by first applying adhesives and sealants to paper and then applying an abrasive to create a sandpaper type product. DIDP is a part of the adhesive and sealant product as a plasticizer, and it would be incorporated into the abrasive.

DIDP has been reported to be in abrasives during a meeting with an external stakeholder (U.S. EPA, 2020f).

The use of DIDP for processing – incorporation into articles – abrasive manufacturing was not reported in the 2016 and 2020 CDR cycles.

## E.12 Processing – Incorporation into Articles – 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 Products Manufacturing (Including Pigment); Photographic Supplies Manufacturing; Toys, Playground, and Sporting Equipment Manufacturing)

Processing to incorporate DIDP into articles refers to the preparation of a chemical substance or mixture, (*i.e.*, DIDP becoming a component of an article, after its manufacture, for distribution in commerce). In this case, DIDP is present in a raw material that contains a mixture of plasticizers and other additives. This COU refers to the manufacturing of PVC articles using those raw materials that contain DIDP. The manufacturing of PVC articles from the raw materials entails processes such as calendaring, extrusion, injection molding, and plastisol spread coating (ACC, 2020b). This COU includes incorporating DIDP into other articles. For example, plastisol technology or film calendaring technology is used in the production of plastic and rubber products such as textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses (ACC HPP, 2023). The incorporation of DIDP-containing colorants into material such as polyurethane or plastisol. Plastisol mixed with DIDP-containing colorants are applied through processes such as dipping, roto-molding, or slush molding to produce coated fabrics, vinyl sealants, wall coverings, toys, and sporting goods (ACC, 2020b). DIDP is also present in colorants used to color two-part polyurethane, foam, and epoxy resin systems used for production of prototypes, miniature models, and taxidermy (BJB Enterprises, 2023a, b, c, d; U.S. EPA, 2021b, c; ACC HPP, 2019). Another activity

that would be included in this COU is the gluing of the synthetic leather to a fabric backing to create the final article.

#### **Examples of CDR Submissions**

In the 2016 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in plastic products manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in electrical equipment, appliance, and component manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in adhesive manufacturing; one company reported DIDP (CASRN 68515-49-1) as a plasticizer in miscellaneous manufacturing; and one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in rubber product manufacturing (U.S. EPA, 2019a). For the uses of DIDP in miscellaneous manufacturing, after stakeholder outreach, EPA concluded that this use was misreported and better assessed under other COUs (U.S. EPA, 2023e).

Additionally, in the 2016 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as adhesive and sealant chemicals in transportation equipment manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as an adhesive and sealant chemical in miscellaneous manufacturing; and one company reported the use of DIDP (CASRN 26761-40-0) as an adhesive and sealants chemical in adhesives and sealants (U.S. EPA, 2019a). However, based on the understanding of DIDP is used as an adhesive and sealant, the activity represented by this CDR report is included under industrial uses of adhesive and sealants too.

In the 2020 CDR, one company reported the use of DIDP (CASRN 26761-40-0) as a plasticizer in plastic products manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in transportation equipment manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in furniture and related product manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) and 26761-40-0) as a plasticizer in miscellaneous manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in construction; and one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in rubber product manufacturing (U.S. EPA, 2020a). For the uses of DIDP in miscellaneous manufacturing, after stakeholder outreach, EPA concluded that this use is better assessed under other COUs (U.S. EPA, 2023e).

## E.13 Processing – Repackaging

Repackaging refers to the preparation of DIDP for distribution in commerce in a different form, state, or quantity than originally received or stored by various industrial sectors, including chemical product and preparation manufacturing, wholesale and retail trade, and laboratory chemicals manufacturing. This COU includes the transferring of DIDP from a bulk container into smaller containers. This COU would not apply to the relabeling or redistribution of a chemical substance without removing the chemical substance from the original container it was supplied in.

#### Examples of CDR Submissions

In the 2016 CDR cycle, one company reported repackaging DIDP (CASRN 6761-40-0) as a plasticizer in wholesale and retail trade.

## **E.14 Processing – Recycling**

This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be disposed of as waste), containing DIDP that are collected, either on-site or at a third-party site, for commercial purpose. DIDP is primarily recycled industrially in the form of DIDP-containing PVC waste streams, including roofing membranes, vinyl window frame profiles, and carpet squares. Based on a

report by Sika Corporation, all roofing membrane recycling is completed using mechanical recycling technology, in the form of scrap regrinding and recycling (Irwin, 2022). New PVC can be manufactured from recycled and virgin materials at the same facility. Some (ENF Plastic, 2024) estimate a total of 228 plastics recyclers operating in the United States of which 58 accept PVC wastes for recycling. It is unclear if the total number of sites includes some or all circular recycling sites—facilities where new PVC can be manufactured from recycled and virgin materials on the same site. As stated in the Final Scope Document, EPA expects that recycling streams could contain DIDP (U.S. EPA, 2021b). DIDP is not reported to the TRI.

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.15 Distribution in Commerce – Distribution in Commerce

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

## E.16 Industrial Use – Abrasives – Abrasives (Surface Conditioning and Finishing Discs; Semi-finished and Finished Goods)

This COU refers to DIDP as it is used in various industrial sectors as a component of finished, abrasive products or articles, meaning the use of DIDP after it has already been incorporated into an abrasive, as opposed to when it is used upstream, (*e.g.*, when DIDP is processed into the abrasive).

DIDP is present in products that are used for surface conditioning. Surface conditioning is needed for such tasks as smoothing a surface prior to the application of paints and coatings or blending parting lines on cast parts (U.S. EPA, 2021b). DIDP is present at low concentrations (<1.5%) in the line of non-woven abrasives supplied by one company (U.S. EPA, 2021b). DIDP is also present in one company's abrasive products at concentrations ranging from 1 to 8 percent with applications as an abrasive system for semi-finished and finished goods (U.S. EPA, 2020f).

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.17 Industrial Use – Adhesives and Sealants – Adhesives and Sealants

This COU refers to DIDP as it is used in various industrial sectors as a component of adhesive or sealant mixtures, meaning the use of DIDP after it has already been incorporated into an adhesive and/or sealant product or mixture, as opposed to when it is used upstream (*e.g.*, when DIDP is processed into the adhesive and sealant formulation).

According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is used in non-PVC applications such as those associated with adhesives and sealants (U.S. EPA, 2019c). EPA understands that DIDP is used as a plasticizer in the manufacture of industrial adhesives and sealant end products; however, it is primarily used in commercial and consumer end products at concentrations ranging between 1 percent to less than 60 percent in products such as automotive interiors, electrical products, and plastic products (U.S. EPA, 2021b).

Other examples of applications for DIDP-containing adhesive and sealant products include products that are used in marine environments, automobiles, joint sealants in mechanical equipment, concrete and

masonry, and wood/engineered wood flooring. Adhesives and sealants may be applied through automated or mechanical spraying in industrial applications (*i.e.*, in large manufacturing or processing facilities where exposure controls can be expected to be in place). However, products containing DIDP that are categorized as spray adhesives have not currently been identified by EPA (U.S. EPA, 2021c). Furthermore, EPA received public comment that high-volume, low-pressure spray is used to apply adhesive and sealants to tank linings and large areas. Plasticizer content for that application ranges from 15 to 30 percent (EPA-HQ-OPPT-2024-0073-0069).

#### Examples of CDR Submissions

In the 2016 CDR cycles, one company reported the use of DIDP (CASRN 68515-49-1) as an adhesive and sealant chemical in processing – incorporation into article – transportation equipment manufacturing; one company reported the use of DIDP (CASRN 68515-49-1) as an adhesive and sealant chemical in processing – incorporation into article -miscellaneous manufacturing (CASRN 26761-40-0) (U.S. EPA, 2019a). EPA considers that these reports are inclusive of the use of the adhesive and sealant chemical and the processing.

In the 2020 CDR cycle, one company reported the use of DIDP (CASRNs 26761-40-0 and 68515-49-1) as a plasticizer in miscellaneous manufacturing (U.S. EPA, 2020a). However, upon further outreach with the stakeholder, they clarified that DIDP (CASRN 68515-49-1) is used in industrial adhesive sealant products, which are ultimately used in automotive sealant bonding applications (U.S. EPA, 2023e). EPA considers this report better assessed under this COU.

## E.18 Industrial Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings

This COU refers to DIDP as it is used in various industrial sectors as a component of industrial paints and coatings. This is a use of DIDP after it has already been incorporated into a paint or coating product or mixture, as opposed to when it is used upstream (*e.g.*, when DIDP is processed into the paint or coating formulation). EPA expects that the industrial application of these paints and coatings would be in the use of anti-fouling and anti-corrosion paints (ACC, 2020b). The Agency also expects that these products would be applied in the industrial sector; however, notes that it is possible for these products to be purchased by commercial users and applied in the commercial sector as well.

DIDP is used in window glazing (PVC window encapsulate) and in underbody coatings for automobiles (<u>ACC, 2024</u>; <u>U.S. EPA, 2019c</u>). Any product containing DIDP that is applied as an undercover coating would most likely be applied by spraying the coating on the underside of the vehicle. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), 11 percent of DIDP applications are used for protective autobody coatings (<u>U.S. EPA, 2019c</u>).

This COU was not reported in the 2016 or 2020 CDR reporting cycles.

## E.19 Industrial Use – Functional Fluids (closed systems) – Functional Fluids (Closed Systems) (SCBA Compressor Oil)

This COU refers to DIDP as it is used in various industrial sectors as a component of functional fluids, meaning the use of DIDP after it has already been incorporated into a functional fluid, as opposed to when it is used upstream (*e.g.*, when DIDP is processed into the functional fluid).

The phthalates' generally low melting points and high boiling points make them useful as heat-transfer liquids and carriers, which includes the changing of liquids and carriers in the pipelines of the facility.

DIDP is incorporated into these products at concentrations of 10 to 30 percent (<u>Duratherm, 2019a, b</u>). Examples of heat transfer fluids that use DIDP are listed in the *Final Use Report for Di-isodecyl Phthalate (DIDP) (1,2-Benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich) (CASRN 26761-40-0 and 68515-49-1) (U.S. EPA, 2021c).* 

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.20 Industrial Use – Lubricant and Lubricant Additives

This COU refers to DIDP as it is used in various industrial sectors as a component of lubricants, meaning the use of DIDP after it has already been incorporated into a lubricant to when it is used upstream (*e.g.*, when DIDP is processed into the lubricant).

According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is used in PVC and non-PVC applications in automotive products for consumer and industrial applications in synthetic lubricants and engine oils (U.S. EPA, 2019c). EPA understands that DIDP is used in the manufacture of various lubricant additives that then are used in the manufacture of lubricating oils and greases (U.S. EPA, 2021b). DIDP is also used in commercial lubricants (and lubricating oils, compressor fluids for maintenance and repair, and transmission conditioner) at a concentration of at least 90 percent by weight (U.S. EPA, 2021c).

This use does not have CDR data reported for the 2016 and 2020 cycles.

## **E.21 Industrial Use – Solvents (for Cleaning or Degreasing)**

This COU refers to DIDP as it is used in various industrial sectors as a component of solvents, meaning the use of DIDP after it has already been incorporated into a solvent when it is used upstream (e.g., when DIDP is processed into the solvent).

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

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.22 Commercial Use – Automotive, Fuel, Agriculture, Outdoor Use Products – Lubricants

This COU is referring to the commercial use of DIDP in lubricant, which already have DIDP incorporated into them. This is a use of DIDP-containing lubricant in a commercial setting or use in an industrial setting.

According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is used in PVC and non-PVC applications in automotive products for commercial applications including synthetic lubricants and engine oils (U.S. EPA, 2019c). For the commercial use of these products, EPA expects them to be poured or applied by workers in auto repair and other maintenance shops. The Agency understands that DIDP is used in the manufacture of various lubricant additives that then are used in the manufacture of commercial lubricants (and lubricating oils, compressor fluids for maintenance and repair, and transmission conditioner) at a concentration of at least 90 percent by weight (U.S. EPA, 2021c). The commercial use of lubricants applies to the use of lubricants such as DIDPcontaining auto transmission conditioner (<u>BG Products Inc., 2016</u>).

#### Example of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial use of DIDP (CASRN 26761-40-0) in lubricant and greases (U.S. EPA, 2019a).

In the 2020 CDR cycle, one company reported the commercial use of DIDP (CASRN 68515-49-1) as a lubricating agent in liquid lubricants and greases (U.S. EPA, 2020a).

## E.23 Commercial Use – Construction, Paint, Electrical, and Metal Products – Adhesives and Sealants (Including Plasticizers in Adhesives and Sealants)

This COU is referring to the commercial use of DIDP in adhesives and sealants. This is a use of DIDPcontaining adhesives and sealants in a commercial setting, such as a business or at a job site, as opposed to upstream use of DIDP (e.g., when DIDP containing products are used in the manufacturing of the construction products) or use in an industrial setting.

Workers in a commercial setting generally apply adhesives and sealants that already have DIDP incorporated as a plasticizer. According to the Manufacturer Request for Risk Evaluation Diisodecyl Phthalate (DIDP), DIDP is used in non-PVC applications such as those associated with adhesives and sealants (U.S. EPA, 2019c). DIDP-containing adhesives and sealants are also used in marine environments, as joint sealants in mechanical equipment, automobiles, concrete and masonry, and wood/engineered flooring (U.S. EPA, 2021c). They are commonly applied using a syringe, caulk gun, or are spread on a surface using a trowel. EPA expects that most commercial applications of adhesives and sealants containing DIDP would occur using non-pressurized methods based on products identified in the marketplace. However, the Agency received public comment that high-volume, low-pressure spray is used to apply adhesive and sealants to tank linings and large areas. Plasticizer content for that application ranges from 15 to 30 percent (EPA-HQ-OPPT-2024-0073-0069).

#### Example of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial use of DIDP (CASRN 26761-40-0) in adhesives and sealants, and one company reported the commercial and consumer use of DIDP (CASRN 68515-49-1) in adhesives and sealants (U.S. EPA, 2019a).

In the 2020 CDR cycle, one company reported the commercial use of DIDP (CASRN 26761-40-0) in adhesives and sealants as adhesive and sealant chemicals, and one company reported the commercial and consumer use of DIDP (CASRN 68515-49-1) in adhesives and sealants as a plasticizer (U.S. EPA, 2020a).

## E.24 Commercial Use – Construction, Paint, Electrical, and Metal Products – Building/Construction Materials (Wire or Wiring Systems; Joint Treatment, Fire-Proof Insulation)

This COU is referring to the commercial use of DIDP in building/construction materials, which already have DIDP incorporated into them. This is a use of DIDP-containing building/construction materials, such as wire or wiring systems, joint treatment, and fire-proof insulation, such as at a business or job site, as opposed to upstream use of DIDP (*e.g.*, when DIDP is processed into the building/construction material) or use in an industrial setting.

The Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) reports that a major use of the use of DIDP is as a plasticizer in building wire and electrical insulation (<u>U.S. EPA, 2019c</u>). DIDP is also a component in fire-proof building insulation (<u>Campine, 2024</u>).

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.25 Commercial Use – Construction, Paint, Electrical, and Metal Products – Electrical and Electronic Products

This COU is referring to the commercial use of DIDP in electrical and electronic products or articles, which already have DIDP incorporated into them. The Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) states that a major use of DIDP is as a general-purpose plasticizer for electronic articles such as power cable jacketing and appliance cords (U.S. EPA, 2019c). This COU describes the workers handling the electric articles during installation and use. The users of products under this category would be expected to apply these articles through hand contact with the wire and electronic components through various commercial applications.

#### **Examples of CDR Submissions**

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in machinery, mechanical appliances, electrical and electronic articles (U.S. EPA, 2020a).

## E.26 Commercial Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings (Including Surfactants in Paints and Coatings)

This COU is referring to the commercial use of DIDP already incorporated as a plasticizer in paints and coatings. This COU encompasses the application of DIDP-containing paints and coatings. The Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) reports that approximately 17 percent off all DIDP applications are outside of its role as a general-purpose plasticizer in plastic article manufacturing such as those associated with paints and coatings (U.S. EPA, 2019c). DIDP is used in window glazing (PVC window encapsulate) (ACC, 2024; U.S. EPA, 2019c). Any product containing DIDP that is applied as an undercover coating would most likely be applied by spraying the coating on the underside of the vehicle. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), 11 percent of DIDP applications are used for protective autobody coatings (U.S. EPA, 2019c). EPA expects undercoating to be used in industrial and commercial settings.

The application procedure depends on the type of paint or coating formulation and the type of substrate. The formulation is loaded into the application reservoir or apparatus and applied to the substrate via brush, spray, roll, dip, curtain, or syringe or bead application. After application, the paint or coating is allowed to dry or cure.

#### Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported the use of DIDP (CASRN 26761-40-0) in paints and coatings, with one company reporting the commercial use and the other reporting that the use was not reasonably known or ascertainable (U.S. EPA, 2019a).

In the 2020 CDR cycle, one company reported the commercial use of DIDP (CASRN 68515-49-1) as surface active agent in paints and coatings (<u>U.S. EPA, 2020a</u>).

## E.27 Commercial Use – Construction, Paint, Electrical, and Metal Products – Lacquers, Stains, Varnishes, and Floor Finishes (as Plasticizer)

This COU is referring to the commercial use of lacquers, stains, varnishes, and floor finishers that have DIDP already incorporated into them. EPA has identified a lacquer product that contains DIDP (<u>SpecChem, 2018</u>). The Agency expects the most common application methods for lacquers, stains, varnishes, and floor finishes will involve brush or roll applications but notes that the lacquer products could be spray applied (<u>SpecChem, 2018</u>).

#### Example of CDR Submission

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in lacquers, stains, varnishes, and floor finishes in the 2020 CDR (U.S. EPA, 2020a).

## E.28 Commercial Use – Furnishing, Cleaning, Treatment/Care Products – Furniture and Furnishings

This COU is referring to the commercial use of furniture and furnishings that already have DIDP incorporated in them. DIDP is a component of synthetic leather, which may be used in furniture (ACC HPP, 2023). Information for products that have DIDP incorporated into an adhesive and sealant chemical or paint and coating that is used in the manufacture of furniture has not been identified at this time.

#### Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) in processing – incorporation into article – furniture and related product manufacturing, and it assumed that this COU represents the downstream use of the manufactured related articles (U.S. EPA, 2020a).

## E.29 Commercial Use – 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)

This COU is referring to the commercial use of DIDP in various floor coverings and construction and building materials. The Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) states that DIDP is used as a general-purpose plasticizer for PVC used in building and construction materials such as vinyl tiles, resilient flooring, PVC-backed carpeting, scraper mats, and wall coverings (U.S. EPA, 2019c). EPA anticipates that these products would be used in commercial applications. The COU describes the workers handling and installing the construction materials, tiles, carpeting, etc. that have DIDP incorporated into the products and may involve cutting and shaping the products for installation.

#### Example of CDR Submissions

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel (U.S. EPA, 2020a).

## E.30 Commercial Use – Packaging, Paper, Plastic, Hobby Products– Ink, Toner, and Colorant Products

This COU is referring to the commercial use of DINP in ink, toner, and colorant products. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) and information received from stakeholders, this COU refers to the use of DIDP-containing PVC ink by workers in a commercial setting (U.S. EPA, 2019c). DIDP can be used in formulation of screen-printing ink, typically referred to as plastisol. Plastisol consists of PVC particles and a plasticizer that allows the PVC to retain a liquid form during use. Plastisol can be used to produce finished goods such as t-shirts, sweatshirts, jackets, and tote bags (Sharprint, 2019). However, according to public comments, DIDP likely is not used in practice to create plastisol because less than 0.1 percent DIDP is allowed in textiles, per the OEKO-TEX standard (ACC HPP, 2023). EPA identified colorant products produced by a sealant manufacturing company that are used to tint a polyurethane sealant (U.S. EPA, 2021c).

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.31 Commercial Use – Packaging, Paper, Plastic, Hobby Products– PVC Film and Sheet

This COU is referring to the commercial use of DIDP in PVC film and sheet. DIDP is used as a general plasticizer in PVC calendered sheet and film and specifically, DIDP-containing PVC film is used in casting and masking fixtures (HSDB, 2024; U.S. EPA, 2020f). This use of DIDP-PVC film and sheet is done in a commercial setting, such as the cutting and shaping of final articles, as opposed to the upstream use of DIDP (*e.g.*, when DIDP is used in the manufacturing of the PVC film/sheet) or use in an industrial setting.

The Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) notes that film and sheet applications include use in roofing, wall coverings, pool liners etc. (U.S. EPA, 2019c). The use covers other coated textiles such as truck awnings.

This use does not have CDR data reported for the 2016 and 2020 cycles.

## E.32 Commercial Use – Packaging, Paper, Plastic, Hobby Products– Plastic and Rubber Products (Textiles, Apparel, and Leather; Vinyl Tape; Flexible Tubes; Profiles; Hoses)

This COU is referring to the commercial use of DIDP already incorporated into plastic and rubber products and articles used in textiles, apparel, leather, vinyl tape, flexible tubes, profiles, and hoses. This COU also encompasses the assembly or use of the finished products and/or articles—as opposed to the upstream use of DIDP (*e.g.*, when DIDP is processed into the product and/or article) or use in an industrial setting. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is used for automotive upholstery and interior finishes such as synthetic leather and in flexible tubes, profiles, and hoses. As DIDP is incorporated into synthetic leather, it may be found in synthetic leather furniture (U.S. EPA, 2019a).

This use does not have CDR data reported for the 2016 and 2020 cycles.

## **E.33** Commercial Use – Other Uses – Laboratory Chemicals

This COU is referring to the use of DIDP in laboratory chemicals. DIDP can be used as a laboratory chemical, such as a chemical standard or reference material during analyses. Some laboratory chemical

manufacturers identify use of DIDP as a certified reference material and research chemical. The users of products under this category would be expected to apply these products in general laboratory use applications. Use of laboratory chemicals may involve handling DIDP by hand-pouring or pipette and either adding to the appropriate labware in its pure form to be diluted later or added to dilute other chemicals already in the labware. EPA expects that laboratory DIDP products are pure DIDP in neat liquid form. The Agency notes that the same applications and methods used for quality control can be applied in industrial and commercial settings.

Two chemical companies identify use of DIDP as a certified reference material and research chemical (U.S. EPA, 2021c). One chemical company identifies DIDP as a dispersion chemical (U.S. EPA, 2021c).

This use was not reported during the 2016 or 2020 CDR reporting cycles.

## E.34 Commercial Use – Other Uses – Automotive Articles

This COU is referring to the commercial use of DIDP in automotive articles, which already have DIDP incorporated into them—that is, the use of DIDP-containing automotive articles in a commercial setting, such as an automotive parts business or a worker using (driving) a vehicle, as opposed to upstream use of DIDP (*e.g.*, when DIDP containing products are used in the manufacturing of the automotive) or use in an industrial setting.

According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is primarily used as a plasticizer in automotive articles, such as interior PVC skins (dashboards and shift boot covers), body-side molding, molded interior applications, and insulation for wire and cable and wire harnesses (<u>3M, 2024</u>; <u>ACC HPP, 2019</u>).

This use was not reported during the 2016 or 2020 CDR reporting cycles.

## **E.35** Commercial Use – Other Uses – Inspection Fluid/Penetrant

This COU is referring to the use of DIDP in inspection fluid/penetrant (U.S. EPA, 2020c). Penetrant testing can be used to detect imperfections and flaws that are not detectable by the eye. For the use of penetrants and inspection fluids, EPA expects inhalation exposure from aerosol generation to be the dominant route of exposure. However, aircraft components are submerged in inspection fluid, and workers pull the component out of the fluid using their hands (Isbell, 2018).

This use was not reported during the 2016 or 2020 CDR reporting cycles.

## E.36 Consumer Use – Automotive, Fuel, Agriculture, Outdoor Use Products – Lubricants

This COU is referring to the consumer use of DIDP-containing lubricants and greases used in automotive care.

According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is used in PVC and non-PVC applications in automotive products for consumer and industrial applications including synthetic lubricants and engine oils (<u>ACC HPP, 2019</u>). EPA understands that DIDP is used in the manufacture of various lubricant additives in the manufacture of lubricating oils and greases. DIDP is also used in consumer lubricants and greases (U.S. EPA, 2021c). This use was not reported during the 2016 or 2020 CDR reporting cycles.

## E.37 Consumer Use – Construction, Paint, Electrical, and Metal Products – Adhesives and Sealants (Including Plasticizers in Adhesives and Sealants)

This COU is referring to the consumer use of DIDP in adhesives and sealants. Consumers generally use adhesives and sealants containing DIDP in an indoor environment and DIYers handle the adhesives and sealants that have DIDP incorporated into the product.

According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is used in non-PVC applications such as those associated with adhesives and sealants (<u>ACC HPP, 2019</u>). According to the 2020 CDR cycle, DIDP is primarily used as a plasticizer in the manufacture of commercial and consumer adhesive and sealant products at concentrations ranging between 1 percent to less than 30 percent (<u>U.S. EPA, 2020a</u>). DIDP is used in adhesive and sealant products used in automobiles, electrical products, and plastic products/articles (<u>U.S. EPA, 2021b</u>).

The Agency does expect the primary use of the automotive adhesives and sealants to be industrial and commercial in nature but the possibility for consumer use is still possible. EPA understands this COU to include more than one type of consumer use (*i.e.*, driving with or without other vehicle passengers vs. consumer DIYers who may perform exterior or interior car maintenance involving adhesives and sealants).

DIY users of adhesives and sealants spray, caulk bead, and roll apply the various adhesives and sealants based on application. Heat is likely to be used depending on the application as well. Consumer users include bystanders.

#### Example of CDR Submissions

In the 2016 CDR cycle, one company reported the commercial and consumer use of DIDP (CASRN 68515-49-1) in adhesives and sealants (U.S. EPA, 2019a).

In the 2020 CDR cycle, one company reported the commercial and consumer use of DIDP in adhesives and sealants (CASRN 68515-49-1) as a plasticizer (U.S. EPA, 2020a).

## E.38 Consumer Use – 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)

This COU is referring to the consumer use of DIDP in solid flooring and construction and building materials. Consumers generally use flooring containing DIDP in an indoor environment and DIYers handle the construction materials (*e.g.*, tiles, carpeting) that have DIDP incorporated into the articles, which may involve cutting and shaping the articles for installation.

As reported in the Manufacturer Request for Risk Evaluation: Diisodecyl phthalate (DIDP), DIDP is used in PVC-backed carpet, vinyl tiles and resilient flooring (U.S. EPA, 2019c). In this risk evaluation, the weight fraction used of DIDP was 1.9 percent in PVC flooring products, based on a European report (ECHA, 2012).

#### Example of CDR Submissions

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) in construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel as not known or reasonably ascertainable (U.S. EPA, 2020a).

## E.39 Consumer Use – Construction, Paint, Electrical, and Metal Products – Electrical and Electronic Products

This COU refers to consumer handling of electric products or articles, wiring, etc. and related insulation during installation and use that may have DIDP incorporated into the products or articles.

The Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) states that a major use of DIDP is as a general-purpose plasticizer for electronics such as power cable jacketing and appliance cords (U.S. EPA, 2019c).

#### **Examples of CDR Submissions**

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in machinery, mechanical appliances, electrical and electronic articles and one company reported the use of DIDP (CASRN 68515-49-1) as a plasticizer in other machinery, mechanical appliances, electronic/electronic articles. Both companies reported the use as not known or reasonably ascertainable (U.S. EPA, 2020a).

## E.40 Consumer Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings

This COU is referring to the consumer use of DIDP in paints and coatings. Consumers generally use paints and coatings containing DIDP in an indoor environment and DIYers handle the paints and coatings that have DIDP incorporated into the product.

DIDP is used in a variety of paint and coating products and often used as a surfactant in paints and coatings. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), approximately 17 percent of DIDP is used in non-PVC applications such as those associated with adhesives and sealants (U.S. EPA, 2019c).

The application procedure depends on the type of paint or coating formulation and the type of substrate. The formulation is loaded into the application reservoir or apparatus and applied to the substrate via brush, spray, roll, dip, curtain, or syringe or bead application. After application, the paint or coating is allowed to dry or cure.

#### Examples of CDR Submissions

In the 2016 CDR cycle, once company reported the not known or reasonably ascertainable use of DIDP (CASRN 26761-40-0) in paints and coatings (<u>U.S. EPA, 2019a</u>).

In the 2020 CDR cycle, one company reported the consumer use of DIDP (CASRN 68515-49-1) as a plasticizer in crafting paint (applied to craft) (U.S. EPA, 2020a).

## E.41 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Fabrics, Textiles, and Apparel (as Plasticizer)

This COU refers to the consumer use of synthetic leather and vinyl fabrics articles that contain DIDP and in the fabrication of various textiles that are likely to be used by consumers. The COU encompasses

plastic furniture and vinyl textiles on cushions and other upholstery and synthetic leather clothing (<u>ACC</u><u>HPP, 2023</u>).

#### Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of DIDP (CASRN 68515-49-1) in processing – incorporation into article – furniture and related product manufacturing, and it assumed that this COU represents the downstream use of the manufactured related articles (U.S. EPA, 2020a).

## E.42 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Arts, Crafts, and Hobby Materials (Crafting Paint Applied to Craft)

This COU is referring to the consumer use of arts, crafts, and hobby materials that contain DIDP. Consumers would be expected to handle products under this COU with their hands. DIDP is in two-component urethane casting resin used in casting, prototyping, miniatures, models, and taxidermy. DIDP is present in one of the two components of a polyurethane casting resin in concentrations of 10 to 40 percent (Environmental Technology, 2021). DIDP has also been reported to be used in erasing rubber made of PVC (ECHA, 2012).

#### Example of CDR Submissions

In the 2020 CDR cycle, one company reported the consumer use of DIDP (CASRN 68515-49-1) as a plasticizer in crafting paint (applied to craft) (U.S. EPA, 2020a). However, EPA has been unable to find a specific example of crafting paint that contains DIDP.

## E.43 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Ink, Toner, and Colorant Products

This COU is referring to the consumer use of DINP in ink, toner, and colorant products. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP) and information received from stakeholders, DIDP-containing PVC ink by consumers in non-commercial settings (U.S. EPA, 2020f, 2019c). DIDP can be used in the formulation of screen-printing ink, typically referred to as plastisol. Plastisol consists of PVC particles and a plasticizer that allows the PVC to retain a liquid form during use. Plastisol can be used to produce finished goods such as t-shirts, sweatshirts, jackets, and tote bags (Sharprint, 2019). However, according to public comments, DIDP likely is not used in practice to create plastisol because less than 0.1 percent DIDP is allowed in textiles, per the OEKO-TEX standard (ACC HPP, 2023). EPA identified colorant products produced by a sealant manufacturing company that are used to tint a polyurethane sealant (U.S. EPA, 2021c).

This use was not reported during the 2016 or 2020 CDR cycles.

## E.44 Consumer Use – Packaging, Paper, Plastic, Hobby Products – PVC Film and Sheet

This COU refers to the consumer use of PVC film and sheet. Consumers may be exposed to DIDP during the handling and use of articles covered under this COU.

DIDP is used in PVC film used in casting and masking fixtures, and as a "plasticizer for polyvinyl chloride for calendered film, sheet" (HSDB, 2024; U.S. EPA, 2020f). The Manufacturer Request for Risk Evaluation: Diisodecyl phthalate (DIDP) notes that film and sheet applications include use in roofing, wall coverings, pool liners, etc. (U.S. EPA, 2019c). The consumer use of PVC film and sheet includes consumer use of pool liners, wall coverings, truck awnings, and so on.

This use was not reported during the 2016 or 2020 CDR cycles.

## E.45 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Plastic and Rubber Products (Textiles, Apparel, and Leather; Vinyl Tape; Flexible Tubes; Profiles; Hoses)

This COU is referring to the consumer use of DIDP in various consumer products used with routine direct contact such as vinyl tape, flexible tubes, profiles, and hoses.

Additionally, this COU refers to the consumer use of articles such as the wearing of synthetic leather bags and foam flip-flops, and the household use of shower curtains and wallpaper. The COU also refers to the DIY application of the wallpaper (<u>ACC HPP, 2023</u>; <u>U.S. EPA, 2019c</u>). The weight fraction of DIDP varies based on the article (0.047–0.35%), although EPA does not have information regarding DIDP weight fraction for all articles identified (<u>U.S. EPA, 2024a</u>).

This use was not reported during the 2016 or 2020 CDR cycles.

## E.46 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Toys, Playgrounds, and Sporting Equipment

This COU is referring to the consumer use of DIDP in toys, playground, and sporting equipment. The COU includes the consumer use or storage of toys, playgrounds, and sporting equipment that contain DIDP in an indoor environment (<u>ACC HPP, 2023</u>; <u>U.S. EPA, 2019c</u>). The use also refers to the DIY building of home sporting equipment.

DIDP can be used as a plasticizer to provide flexibility to toys. The Consumer Product Safety Improvement Act (CPSIA) of 2008 placed an interim restriction on the manufacturer's use of DIDP in children's toys to 0.1 percent (16 CFR part 1307). Upon the effective date of the final rule in 2018, the restriction on DIDP was lifted (U.S. EPA, 2020d).

EPA expects that the use of DIDP in toys manufactured or processed prior to the ban may also still be occurring. Consumers would be expected to handle products made under this COU with their hands or mouth products. For several articles, the weight fraction of DIDP was reported as DINP + DIDP. For example, concentrations of DINP + DIDP in four teether samples at 32 to 40 percent and in two of three doll samples at approximately 20 and 26 percent (Rastogi, 1998).

This use was not reported during the 2016 or 2020 CDR cycles.

## E.47 Consumer Use – Other Uses – Automotive Articles

This COU is referring to the consumer use of DIDP in automotive articles. This COU includes the use of DIDP-containing automotive articles in a consumer DIY setting or by consumers driving a vehicle. According to the Manufacturer Request for Risk Evaluation: Diisodecyl Phthalate (DIDP), DIDP is primarily used as a plasticizer in automotive articles, such as interior PVC skins (dashboards and shift boot covers), body-side molding, molded interior applications, and insulation for wire and cable and wire harnesses (<u>3M, 2024</u>; <u>ACC HPP, 2019</u>).

This use was not reported during the 2016 or 2020 CDR reporting cycles.

## E.48 Consumer Use – Other Uses – Novelty Articles

This COU is referring to the consumer use of DIDP in adult novelty articles. This COU is describing adult sex toys that are available for consumer use in the United States. Although the U.S. Food and Drug Administration (FDA) classifies certain sex toys (such as vibrators) as obstetrical and gynecological therapeutic medical devices many manufacturers label these articles "for novelty use only" and are not subject to the FDA regulations (Stabile, 2013). This same study indicated tested concentrations of phthalates between 24 and 49 percent of the tested sex toys for creating a softer, more flexible plastic (Stabile, 2013), and EPA assumed that the concentration of DIDP in these products to be analogous to the overall content of the mix of phthalates tested and found in this study. Consumers could experience dermal and oral exposure to DIDP using the articles covered by this COU.

This use was not reported during the 2016 or 2020 CDR cycles.

## E.49 Disposal

For purposes of the DIDP risk evaluation, this COU refers to the DIDP in a waste stream that is collected from facilities and households and are unloaded at and treated or disposed at third-party sites. Each of the COUs of DIDP may generate waste streams of the chemical. This COU also encompasses DIDP contained in wastewater discharged by consumers or occupational users to POTW or other, non-POTW for treatment, as well as 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). Additionally, DIDP has been 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*, December 2016 document to be a chemical reported to be detected in produced water, which is subsequently disposed (U.S. EPA, 2016). Recycling of DIDP and DIDP-containing products/articles is considered a different COU. Environmental releases from industrial sites are assessed in each condition of use.

## Appendix F OCCUPATIONAL EXPOSURE VALUE DERIVATION

EPA has calculated an 8-hour existing chemical occupational exposure value to summarize the occupational exposure scenario and sensitive health endpoints into a single value. This calculated value may be used to support risk management efforts for DIDP under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the value rounded to 2.40 mg/m<sup>3</sup> 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 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 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 value for DIDP represents the exposure concentration below which workers and occupational non-users (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 occupational exposure value of 0.131 ppm (2.40 mg/m<sup>3</sup>), a worker or ONU also would be protective against liver toxicity from intermediate and chronic occupational exposures if ambient exposures are kept below this occupational exposure value. The Agency has not separately calculated a 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 U.S. 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/m<sup>3</sup> in Austria, Denmark, and Sweden to 5 mg/m<sup>3</sup> in Ireland and South Africa. Additionally, EPA found that the province of <u>Ontario, Canada, New Zealand</u>, and the <u>United Kingdom</u> all have an established occupational exposure limit of 5 mg/m<sup>3</sup> (8-hour TWA) in each country's code of regulation that is enforced by each country's worker safety and health agency.

## F.1 Occupational Exposure Value Calculations

This appendix presents the calculations used to estimate occupational exposure values using inputs derived in this 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/m<sup>3</sup>.

#### Acute Non-cancer Occupational Exposure Value

The acute occupational exposure value ( $EV_{acute}$ ) was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using Equation\_Apx F-1 below:

#### **Equation\_Apx F-1.**

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

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

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

#### Intermediate Non-cancer Occupational Exposure Value

The intermediate occupational exposure value ( $EV_{intermediate}$ ) was calculated as the concentration at which the intermediate MOE would equal the benchmark MOE for intermediate occupational exposures using Equation\_Apx F-2 below:

#### **Equation\_Apx F-2.**

$$EV_{intermediate} = \frac{HEC_{intermediate}}{Benchmark MOE_{intermediate}} * \frac{AT_{HEC intermediate}}{ED * EF} * \frac{IR_{resting}}{IR_{workers}}$$
$$= \frac{2.68 \text{ ppm}}{30} * \frac{\frac{24h}{d} * 30d}{\frac{8h}{d} * 22d} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.179 \text{ ppm} = 3.27 \frac{\text{mg}}{\text{m}^3}$$

#### Chronic Non-cancer Exposure Value

The chronic occupational exposure value ( $EV_{chronic}$ ) was calculated as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures using Equation\_Apx F-3 below:

#### **Equation\_Apx F-3.**

$$EV_{chronic} = \frac{HEC_{chronic}}{Benchmark MOE_{chronic}} * \frac{AT_{HEC chronic}}{ED * EF * WY} * \frac{IR_{resting}}{IR_{workers}}$$
$$= \frac{2.68 \text{ ppm}}{30} * \frac{\frac{24h}{d} * \frac{365d}{y} * 40 \text{ y} * 0.6125 \frac{\text{m}^3}{hr}}{\frac{8h}{d} * \frac{250d}{y} * 40 \text{ y} * 1.25 \frac{\text{m}^3}{hr}} = 0.192 \text{ ppm} = 3.50 \frac{\text{mg}}{\text{m}^3}$$

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AThecate	=	Averaging time for the POD/HEC used for evaluating non-cancer acute occupational risk based on study conditions and HEC adjustments (24 h/day).
$AT_{HEC}$ intermediate	=	Averaging time for the POD/HEC used for evaluating non-cancer intermediate occupational risk based on study conditions and/or any HEC adjustments (24 h/day for 30 days).
AT <sub>HECchronic</sub>	=	
Benchmark MOE <sub>acute</sub>	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30
Benchmark MOE <sub>intermedia</sub>	te =	Intermediate non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30
Benchmark MOE <sub>chronic</sub>	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30
$EV_{acute}$	=	Occupational exposure value based on acute toxicity
$EV_{intermediate}$	=	Occupational exposure value based on intermediate toxicity
EVchronic	=	Occupational exposure value based on chronic toxicity
ED	=	Exposure duration (8 h/day)
EF	=	Exposure frequency (1 day for acute, 22 days for intermediate, and 250 days/yr for chronic and lifetime)
HEC	=	Human equivalent concentration for acute, intermediate, or chronic non-cancer occupational exposure scenarios
IR	=	Inhalation rate (default is 1.25 m <sup>3</sup> /h for workers and 0.6125 m <sup>3</sup> /h assumed from "resting" animals from toxicity studies)
Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW	=	Molecular weight of DIDP (446.7 g/mole)
WY	=	Working years per lifetime at the 95th percentile (40 years)
		( <u>U.S. EPA, 2024s</u> ).

Unit conversion:

1 ppm = 18.3 mg/m<sup>3</sup> (see equation associated with the  $EV_{acute}$  calculation)