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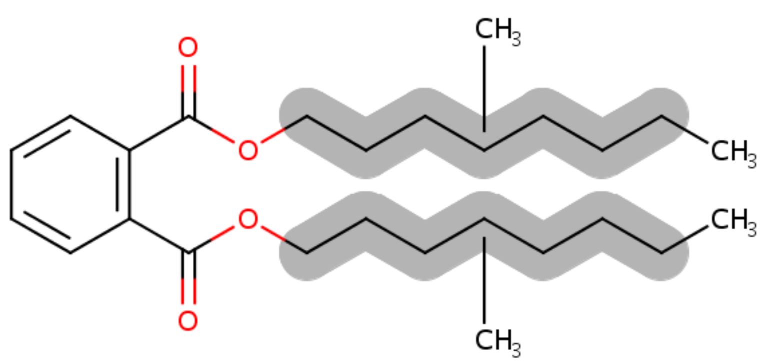
United States
Environmental Protection Agency

Draft Risk Evaluation for Diisononyl Phthalate (DINP)

CASRNs: 28553-12-0 and 68515-48-0



(Representative Structure)

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ACKNOWLEDGEMENTS

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Docket

Supporting information can be found in the public docket, Docket ID (EPA-HQ-OPPT-2018-0436).

Disclaimer

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

EXECUTIVE SUMMARY

Background

The U.S. Environmental Protection Agency (EPA or the Agency) has evaluated the health and environmental risks of the chemical diisononyl phthalate (DINP) under section 6 of the Toxic Substances Control Act (TSCA). In its draft risk evaluation, EPA's protective, screening-level approaches demonstrated that uses of DINP under TSCA do not pose risk to the environment or the general population. Of the 47 conditions of use (COUs) that EPA evaluated, 2 COUs have risk estimates that raise concerns for workers' exposure: Industrial use of adhesives and sealants, and Industrial use of paints and coatings. In addition, one COU has risk estimates that raise concerns for consumers: Use of DINP in construction and building materials that cover large surface areas. These materials include stone, plaster, cement, glass, and ceramic articles, as well as vinyl, carpeting, and other flooring materials. Based on this finding, EPA preliminarily finds that DINP presents an unreasonable risk of injury to human health. Notably, the Science Advisory Committee on Chemicals (SACC) peer reviewed the draft diisodecyl phthalate (DIDP) risk evaluation and draft DINP environmental and human health hazard assessments for DINP during its July 2024 meeting. EPA has not yet incorporated recommendations from SACC or public comments into this draft risk evaluation because the final peer-review report from SACC is not yet available. After this draft risk evaluation is informed by public comment and independent, expert peer review advice from the previous SACC, EPA will issue a final risk evaluation that includes its final determination as to whether DINP presents unreasonable risk of injury to health or the environment under the COUs.

DINP is used primarily as a plasticizer to manufacture 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—all of which are considered TSCA uses. Workers may be exposed to DINP when making these products or otherwise using DINP in the workplace. When it is manufactured or used to make products, DINP can be released into the water, where because of its properties, most will end up in the sediment at the bottom of lakes and rivers. If released into the air, DINP will attach to dust particles and be deposited on land or into water. Indoors, DINP has the potential over time to come out of products and adhere to dust particles. If it does, people could inhale or ingest dust that contains DINP.

In 2019, EPA received a request, pursuant to TSCA and its implementing regulations, from ExxonMobil Chemical Company through the American Chemistry Council's High Phthalates Panel to conduct a TSCA risk evaluation for DINP. EPA determined that the request met the regulatory criteria and requirements and in 2019 granted the request. Manufacturers report DINP production volumes through the TSCA Chemical Data Reporting (CDR) rule under two associated CAS Registry Numbers (CASRNs). The production volume for CASRN 28553-12-0 in 2015 was between 100 to 250 million pounds (lb) and decreased to 50 to 100 million lb in 2019 based on the latest 2020 CDR data. The production volume for CASRN 68515-48-0 in 2015 ranged between 100 to 250 million lb and changed to between 100 million and 1 billion lb in 2019 based on the latest 2020 CDR data. (EPA describes production volumes as a range to protect confidential business information.)

Past assessments of DINP undertaken by other regulatory agencies that addressed a broad range of uses have concluded that DINP does not pose risk to human health or the environment based on its concentration in those 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 DINP exposure comes primarily from diet for women, infants, toddlers, and children. Any food, food additive, drug, cosmetic, or device (as defined in section 201 of the Federal

Food, Drug, and Cosmetic Act [FFDCA]) when manufactured, processed, or distributed in commerce as such, do not meet the definition of chemical substance under TSCA.

In this draft risk evaluation, EPA only evaluated risks resulting from exposure to DINP from or within facilities that use, manufacture, or process DINP under industrial and/or commercial COUs subject to TSCA and the products resulting from such manufacture and processing. Human or environmental exposure to DINP through uses that are not subject to TSCA (*e.g.*, food, use in food packaging) were not evaluated or taken into account by EPA in reaching its preliminary determination of unreasonable risk to injury of human health. Thus, although EPA is preliminarily determining in this draft risk evaluation that three specific TSCA COUs significantly contribute to its draft unreasonable risk finding for DINP, this determination cannot be extrapolated to form conclusions about uses of DINP that are not subject to TSCA and that EPA did not evaluate. The Agency is including DINP in its forthcoming cumulative risk assessment along with five other phthalate chemicals. EPA may consider how uses that are not subject to TSCA or not directly attributable to uses subject to TSCA impact the cumulative risk assessment.

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 COUs. Although the unreasonable risk must be informed by science, EPA, in making the finding of *presents unreasonable risk*, also considers risk-related factors as described in its recently revised risk evaluation framework rule. Risk-related factors beyond the levels of DINP that can cause specific health effects include but are not limited to the type of health effect under consideration; the reversibility of the health effect being evaluated; exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure); population exposed (including any susceptible subpopulations); and EPA's 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 DINP. If an estimate of risk for a specific scenario exceeds the standard risk benchmarks, then the formal determination of whether those risks significantly contribute to the unreasonable risk of DINP under TSCA must be both case-by-case and context-driven.

Laboratory animal studies have been conducted to study DINP for a range of cancer and non-cancer effects on exposed people. After reviewing the available studies, the Agency concluded that oral exposure to DINP can cause adverse developmental effects and non-cancer liver toxicity in experimental animal models. The most sensitive developmental effects include adverse effects on the developing male reproductive system, sometimes referred to as "phthalate syndrome." EPA is including DINP in its cumulative risk assessment along with five other phthalate chemicals that also cause effects on laboratory animals consistent with phthalate syndrome. 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 DINP on development and the liver. EPA also reviewed the studies that investigated DINP's potential to cause cancer in laboratory animals and concluded that DINP can cause liver cancer in rats and mice. However, liver cancer in rats and mice occurred at higher doses than observed for other non-cancer effects on the liver and the developing male reproductive system. Therefore, evaluating and protecting human health from non-cancer risks associated with exposure to DINP will also be protective of cancer effects.

EPA evaluated the risks to people from being exposed to DINP at work, indoors, and outdoors. In its human health evaluation, the Agency used a combination of screening-level and more refined approaches to assess how people might be exposed to DINP through breathing or ingesting dust or other particulates, as well as through skin contact. In determining whether DINP presents an unreasonable risk of injury to human health, as required under TSCA, 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 DINP, people exposed to DINP in the workplace, and tribes whose diets include large amounts of fish. These subpopulations are PESS because some have greater exposure to DINP 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), while some people may experience exposure from multiple sources or experience higher exposure than others. EPA also evaluated exposure to DINP for people living in communities in close proximity to facilities with TSCA releases. This included exposure from incidental dermal contact or ingestion of surface waters receiving TSCA releases, ingestion of fish from surface waters receiving TSCA releases, and soil ingestion and dermal soil contact resulting from air to soil deposition of DINP from TSCA releases. EPA did not estimate inhalation exposure to DINP from ambient air for people living in close proximity to facilities with TSCA releases because ambient air was not expected to be a pathway of concern for DINP, because DINP is not persistent in the air and rapidly partitions to sediment, soil, and surface water. EPA's robust scientific analysis preliminarily finds that exposure of the general population to DINP does not significantly contribute to unreasonable risk of injury to human health.

However, EPA identified two COUs for workers and one COU for consumers as preliminarily contributing to unreasonable risk of injury to human health.

The COUs that EPA identified as preliminarily significantly contributing to unreasonable risk from DINP to workers include those that led to exposures to average adults and women of reproductive age in scenarios in which unprotected workers used spray adhesives and sealants or paints and coatings that contain DINP with high-pressure sprayers. This is because doing so could create high concentrations of DINP in mist that an unprotected worker could inhale.

For consumers, EPA identified one COU as preliminarily significantly contributing to unreasonable risk because it can lead to exposures to infants, toddlers, and preschool children under the age of 5 years who may inhale dust containing DINP as a result from settling onto vinyl flooring, in-place wallpaper, and carpet backing and being resuspended into the indoor environment.

Considerations and Next Steps

EPA evaluated a total of 47 COUs for DINP. The Agency is preliminarily determining that only the following COUs, considered singularly or in combination with other exposures, significantly contribute to the unreasonable risk of DINP via exposures to unprotected workers:

- Industrial use – adhesives and sealant chemicals (sealant [barrier] in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing) due to high-pressure spray application, and
- Industrial use – construction, paint, and metal products – paints and coatings due to high-pressure spray application.

In addition to the COUs significantly contributing to unreasonable risk to workers, the Agency is preliminarily determining the following COU, considered singularly or in combination with other exposures, significantly contributes to the unreasonable risk of DINP via exposures to consumers:

- Consumer use – furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting).

For the remaining COUs, EPA has preliminarily determined that they do not significantly contribute to the unreasonable risk:

- Manufacturing – domestic manufacturing;
- Manufacturing – importing;
- Processing – incorporation into a formulation, mixture, or reaction product – heat stabilizer and processing aid in basic organic chemical manufacturing;
- Processing – incorporation into a formulation, mixture, or reaction product – plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment]);
- Processing – incorporation into an article – plasticizers (toys, playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment]);
- Processing – other uses – miscellaneous processing (petroleum refineries; wholesale and retail trade);
- Processing – repackaging – plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing);
- Processing – recycling;
- Distribution in commerce;
- Industrial use – automotive, fuel, agriculture, outdoor use products – automotive products, other than fluids;
- Industrial use – construction, paint, electrical, and metal products – building/construction materials (roofing, pool liners, window shades, flooring);
- Industrial use – other uses – hydraulic fluids;
- Industrial use – other uses – pigment (leak detection);
- Commercial use – automotive, fuel, agriculture, outdoor use products – automotive products other than fluid;
- Commercial use – construction, paint, electrical, and metal products – adhesives and sealants;
- Commercial use – construction, paint, electrical, and metal products – plasticizer in building/construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles;
- Commercial use – construction, paint, electrical, and metal products – electrical and electronic products;
- Commercial use – construction, paint, electrical, and metal products – paints and coatings;
- Commercial use – furnishing, cleaning, treatment/care products – foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles;
- Commercial use – furnishing, cleaning, treatment/care products – air care products;
- Commercial use – furnishing, cleaning, treatment/care products – floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting);

- Commercial use – furnishing, cleaning, treatment/care products – fabric, textile, and leather products (apparel and footwear care products);
- Commercial use – packaging, paper, plastic, hobby products – arts, crafts, and hobby materials;
- Commercial use – packaging, paper, plastic, hobby products – ink, toner, and colorant products;
- Commercial use – packaging, paper, plastic, hobby products – packaging, paper, plastic, hobby products (packaging [excluding food packaging], including rubber articles; plastic articles [hard]; plastic articles [soft]);
- Commercial use – packaging, paper, plastic, hobby products – plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses);
- Commercial use – packaging, paper, plastic, hobby products – toys, playground, and sporting equipment;
- Commercial use – solvents (for cleaning or degreasing) – solvents (for cleaning or degreasing);
- Commercial use – other uses – laboratory chemicals;
- Consumer use – automotive, fuel, agriculture, outdoor use products – automotive products other than fluid;
- Consumer use – construction, paint, electrical, and metal products – plasticizer in building/construction materials (roofing, pool liners, window shades);
- Consumer use – construction, paint, electrical, and metal products – electrical and electronic products;
- Consumer use – construction, paint, electrical, and metal products – adhesives and sealants;
- Consumer use – construction, paint, electrical, and metal products – paints and coatings;
- Consumer use – furnishing, cleaning, treatment/care products – foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles;
- Consumer use – furnishing, cleaning, treatment/care products – air care products;
- Consumer use – furnishing, cleaning, treatment/care products – fabric, textile, and leather products (apparel and footwear care products);
- Consumer use – packaging, paper, plastic, hobby products – arts, crafts, and hobby materials;
- Consumer use – packaging, paper, plastic, hobby products – ink, toner, and colorant products;
- Consumer use – packaging, paper, plastic, hobby products – other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses;
- Consumer use – packaging, paper, plastic, hobby products – packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft);
- Consumer use – packaging, paper, plastic, hobby products – toys, playground, and sporting equipment;
- Consumer use – other – novelty products; and
- Disposal.

This draft risk evaluation has been released for public comment. Notably, the draft DIDP risk evaluation and draft DINP environmental and human health hazard assessments for DINP were peer reviewed by SACC in July 2024. The entire draft DINP risk evaluation package was not subject to peer review by SACC at that time because EPA applied similar approaches and methodologies for assessing exposure for both the draft DIDP and DINP risk evaluations, while the human health hazard approaches differed across the two risk evaluations. The Agency has not yet incorporated recommendations from the SACC or public comments into this draft risk evaluation because the final peer-review report from the SACC has not yet been released. EPA will issue a final DINP risk evaluation after considering input from the public and recommendations received from SACC. If in the final risk evaluation, the Agency determines that DINP presents unreasonable risk to human health or the environment, EPA will initiate regulatory action to mitigate those risks.

1 INTRODUCTION

EPA has evaluated diisononyl phthalate (DINP) pursuant to section 6(b) of the Toxic Substances Control Act (TSCA). DINP is a common chemical name for the category of chemical substances that includes the following substances: 1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester (CASRN 28553-12-0) and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (CASRN 68515-48-0). Both CASRNs contain mainly C9 dialkyl phthalate esters. DINP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial, and industrial applications—although it is also used in adhesives, sealants, paints, coatings, rubbers, and non-PVC plastics as well as for other applications. Section 1.1 summarizes the scope of the draft DINP risk evaluation and provides information on production volume, a life cycle diagram (LCD), TSCA conditions of use (COUs), and conceptual models used for DINP. Section 1.2 presents the organization of this draft risk evaluation.

Figure 1-1 describes the major inputs, phases, and outputs/components of the [TSCA risk evaluation process](), from scoping to releasing the final risk evaluation.

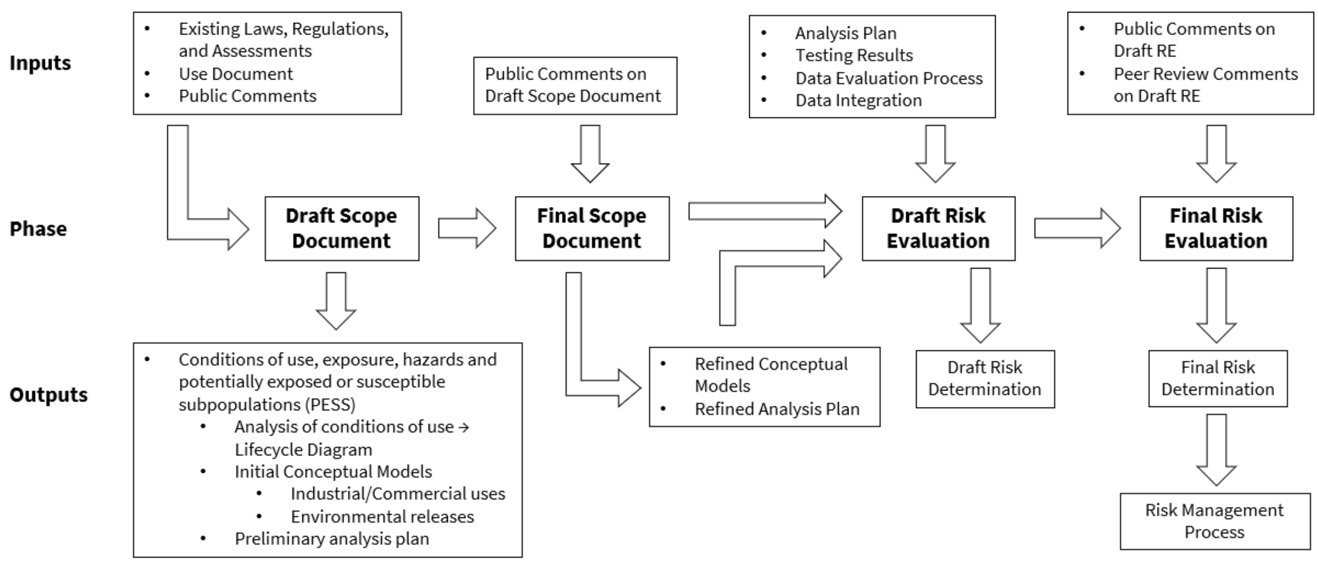


Figure 1-1. TSCA Existing Chemical Risk Evaluation Process

1.1 Scope of the Risk Evaluation

EPA evaluated risk to human and environmental populations for DINP. 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. Additionally, EPA incorporated the following potentially exposed and susceptible populations (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 DINP, people exposed to DINP in the workplace, and tribes whose diets include large amounts of fish. 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 DINP 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 draft DINP risk evaluation comprises a series of technical support documents. Each technical 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 draft risk evaluation for DINP.

These technical support documents leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Di-isononyl phthalate (DINP), CASRNs 28553-12-0 and 68515-48-0* (U.S. EPA, 2021c). OPPT conducted a comprehensive search for "reasonably available information" to identify relevant DINP data for use in the risk evaluation. The approach used to identify specific relevant risk assessment information was discipline-specific and is detailed in *Draft Systematic Review Protocol for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024ac), or as otherwise noted in the relevant technical support documents.

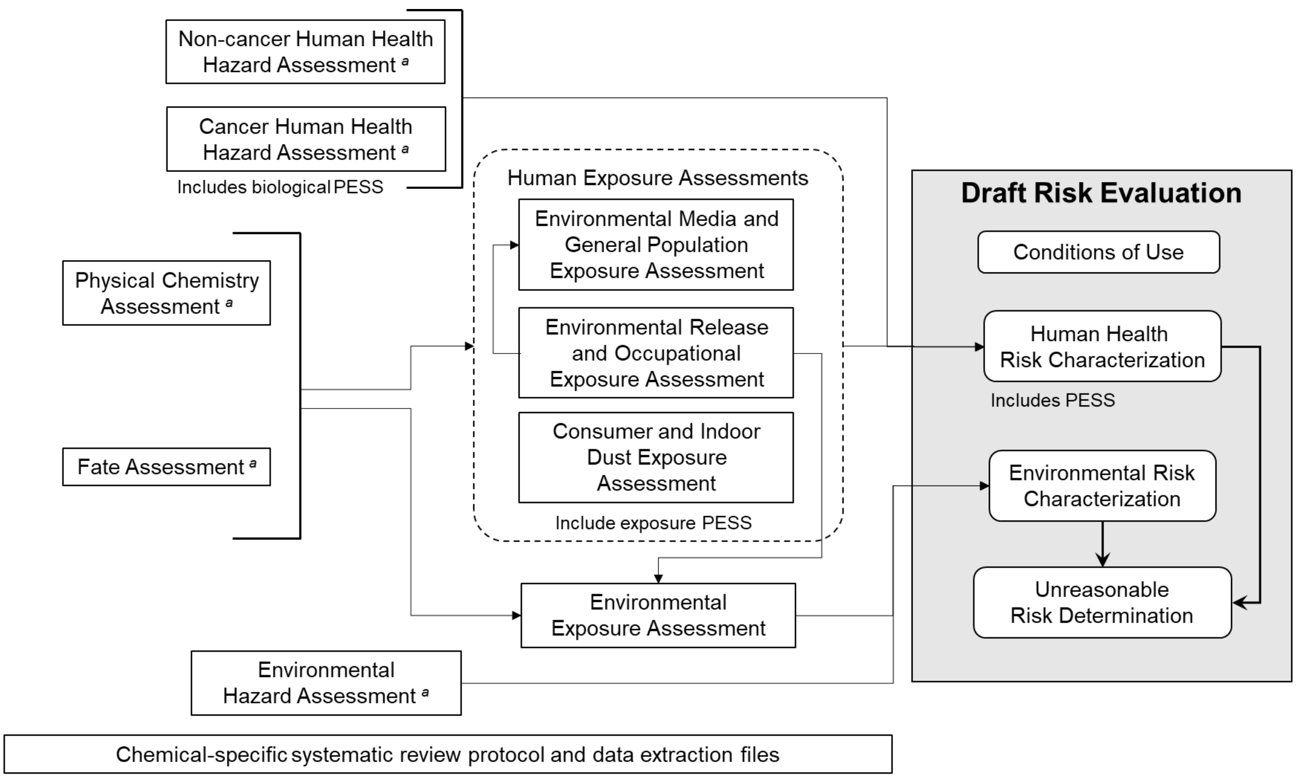


Figure 1-2. Draft Risk Evaluation Document Summary Map

[a] Technical support documents were peer reviewed during the July 2024 meeting of the SACC.

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. A complete list of updates and explanations of the updates made to COUs for DINP from the final scope document to this draft 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.

EPA included descriptions of the industrial, commercial, and consumer use categories identified from the 2020 CDR in the LCD (Figure 1-3) (U.S. EPA, 2020b). The descriptions provide a brief overview of the use category; the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate* (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.

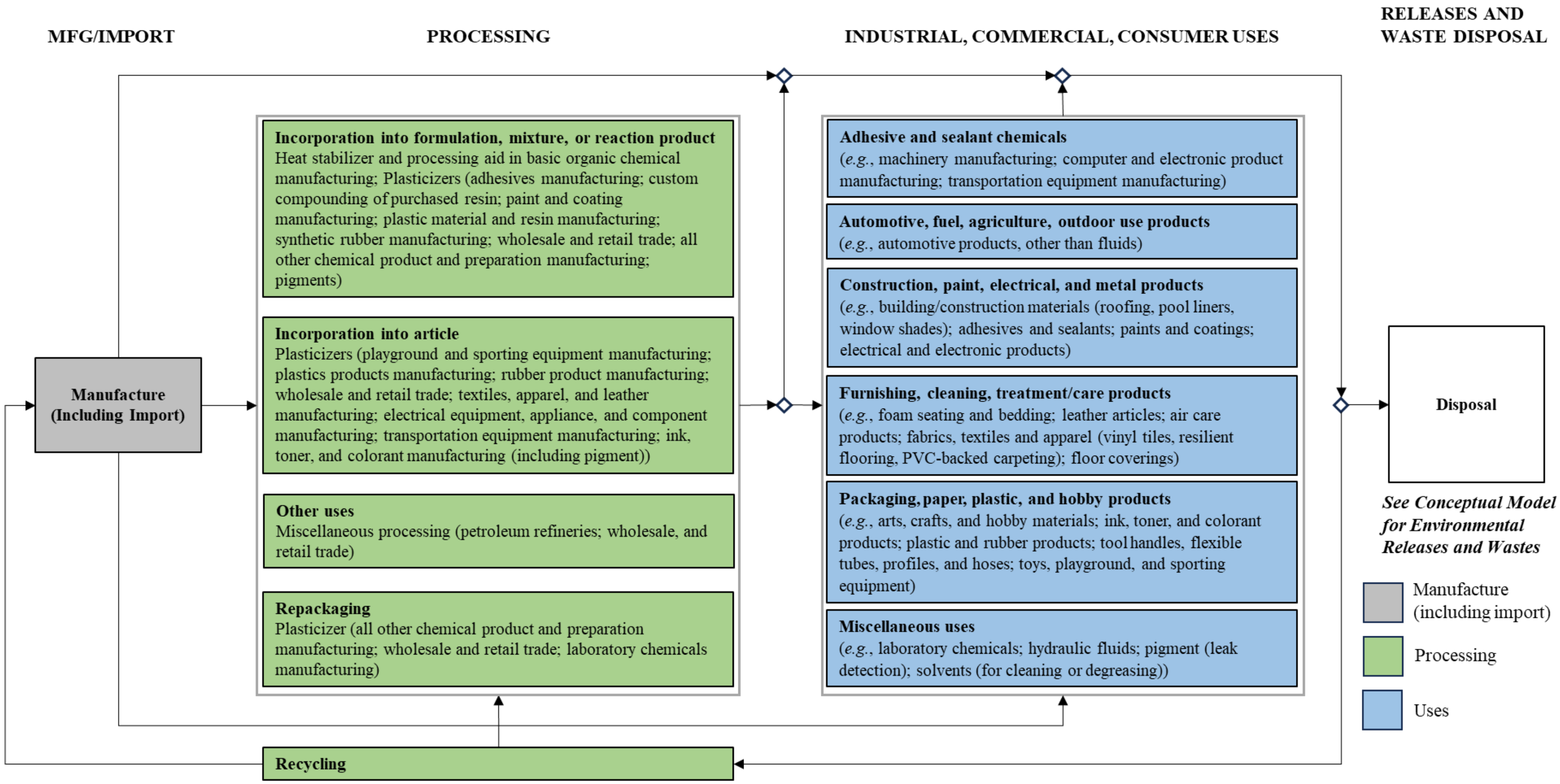


Figure 1-3. DINP Life Cycle Diagram

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 DINP life cycle, as well as qualitatively through a single distribution scenario.

The production volume for CASRN 28553-12-0 in 2015 was between 100 to 250 million lb and decreased to 50 to 100 million lb in 2019 based on the latest 2020 CDR data. The production volume range for CASRN 68515-48-0 in 2015 was between 100 to 250 million lb and changed 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, collected data included the company name, volume of each chemical manufactured/imported, the number of workers at each site, and information on whether the chemical was used in the commercial, industrial, and/or consumer sector(s).

The production volumes for the most recently available CDR reporting year (2019) are split between two CASRNs based on the method of manufacture. Due to facility CBI claims on manufacture and import volumes, EPA presents the known production volume of DINP as a range. For both CASRN 28553-12-0 and CASRN 68515-48-0, production volume information from known sites with known production volumes was insufficient to reduce the uncertainty in total CASRN production volumes due to most sites reporting their production volume as CBI. For example, 23 sites reported importing or manufacturing DINP under CASRN 28553-12-0; however, only 13 sites reported a non-CBI production volume, totaling a combined 29 million lb. In contrast, the CDR national production volume was 50 to 100 million lb, leaving 21 to 71 million lb of DINP unaccounted for. The known production volume gap was larger for CASRN 68515-48-0. Only two of the seven import/manufacturing sites provided their production volumes as non-CBI (combined total of 2 million lb), representing only 2 to 0.2 percent of the total estimated DINP production volume of 100,000,000 to 1,000,000,000 lb. As a result, EPA attributed more than 97 percent of the total DINP manufacturing and import volume to reporting sites that claimed their production volumes as CBI. Consequently, EPA could not specify production volumes for each OES based on CDR data and instead relied on industry submitted data from the American Chemistry Council (ACC) and the EU Risk Assessment to estimate the relative percentages of DINP used in most OES. In Figure 1-4, the OES in the “Other” category include all smaller use case OES, including paints and coatings, adhesives and sealants, laboratory chemicals, and other formulations, mixtures, or reaction products. Due to the limitations discussed above, Figure 1-4 may not accurately reflect actual DINP use, and each OES may comprise a smaller or larger percentage of the overall production volume of DINP.

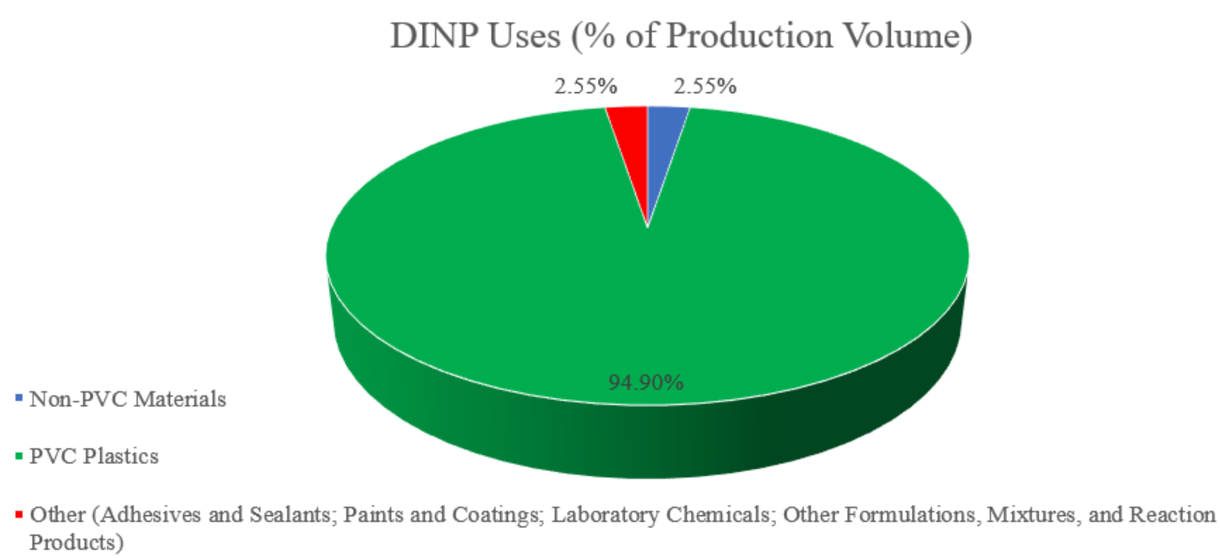


Figure 1-4. Percentage of DINP Production Volume by Use

1.1.2 Conditions of Use Included in the Risk Evaluation

The *Final Scope of the Risk Evaluation for Diisononyl Phthalate (DINP)* (U.S. EPA, 2021c) 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 DINP included in this draft disk evaluation are reflected in the LCD (Figure 1-3) and conceptual models (Section 1.1.2.1). Table 1-1 below presents all COUs for DINP.

In this draft risk evaluation, EPA made updates to the COUs listed in the final scope document (U.S. EPA, 2021c). These updates reflect EPA's improved understanding of the COUs based on further outreach, public comments, 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 DINP processing and uses as well as communications with stakeholders about the use of DINP in industry, and (3) correction of typos or edits for consistency. A complete list of updates and explanations of the updates made to COUs for DINP from the final scope document to this draft risk evaluation is provided in Appendix D. EPA may further refine the COU descriptions for DINP included in the draft risk evaluation when the final risk evaluation for DINP is published, based upon further outreach, peer-review comments, and public comments. Table 1-1 presents the revised COUs that were included and evaluated in this Draft Risk Evaluation for DINP. Appendix E contains descriptions of each COU.

730 **Table 1-1. Categories and Subcategories of Use and Corresponding Exposure Scenario in the Risk Evaluation for DINP**

Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Manufacturing	Domestic manufacturing	Domestic manufacturing[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2019a, c)
	Importing	Importing[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2019a, c)
Processing	Incorporation in formulation, mixture, or reaction product	Heat stabilizer and processing aid in basic organic chemical manufacturing	(U.S. EPA, 2020a, 2019a)	
		Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])	(U.S. EPA, 2020a, 2019a) EPA-HQ-OPPT-2018-0436-0019; EPA-HQ-OPPT-2018-0436-0018	(U.S. EPA, 2020a, 2019a; Polyone, 2018; Silver Fern Chemical Inc., 2015) EPA-HQ-OPPT-2018-0436-0019
	Incorporation into articles	Plasticizers (toys, playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])	(U.S. EPA, 2020a, 2019a; O'Sullivan Films Inc., 2016) EPA-HQ-OPPT-2018-0436-0018; EPA-HQ-OPPT-2018-0436-0019	(U.S. EPA, 2020a, 2019a; Polyone, 2018) EPA-HQ-OPPT-2018-0436-0019
	Other uses	Miscellaneous processing (petroleum refineries; wholesale and retail trade)	(U.S. EPA, 2020a, 2016)	(U.S. EPA, 2020a, 2019a, 2016)
	Repackaging	Plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing)	(U.S. EPA, 2020a; TCI America, 2019; U.S. EPA, 2019a)	(U.S. EPA, 2019a)
	Recycling	Recycling	(U.S. EPA, 2019a)	
Distribution in	Distribution in	Distribution in commerce		

Life Cycle Stage[a]	**Category**[b]	**Subcategory of Use**[c e]	**Reference (CASRN 28553-12-0)**	**Reference (CASRN 68515-48-0)**
Commerce	commerce			
Industrial Use	Adhesive and sealant chemicals	Adhesive and sealant chemicals (sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing) [d]	(U.S. EPA, 2020a; Tremco, 2019; U.S. EPA, 2019a, c)	(U.S. EPA, 2019c)
	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids[d]	(U.S. EPA, 2019c)	(U.S. EPA, 2019c)
	Construction, paint, electrical, and metal products	Building/construction materials (roofing, pool liners, window shades, flooring)[d]	(U.S. EPA, 2019c)	(U.S. EPA, 2019c)
		Paints and coatings[d]	(Freeman Manufacturing and Supply Company, 2018) EPA-HQ-OPPT-2018-0436-0032	EPA-HQ-OPPT-2018-0436-0032
	Other Uses	Hydraulic fluids	EPA-HQ-OPPT-2018-0436-0019	EPA-HQ-OPPT-2018-0436-0019
		Pigment (leak detection)	(U.S. EPA, 2019c) EPA-HQ-OPPT-2018-0436-0019	(U.S. EPA, 2019c) EPA-HQ-OPPT-2018-0436-0019
Commercial Use	Other uses	Automotive products, other than fluids[d]	(U.S. EPA, 2019c)	(U.S. EPA, 2019c)
	Construction, paint, electrical, and metal products	Adhesives and sealants[d]	(U.S. EPA, 2020a, 2019c; 3M, 2017)	(U.S. EPA, 2019c)
		Plasticizer in building/construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles[d]	(U.S. EPA, 2020a, 2019a, c)	(U.S. EPA, 2019a, c)

Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Commercial Use		Electrical and electronic products[d]	(U.S. EPA, 2020a, 2019a, c)	(U.S. EPA, 2020a, 2019a, c)
		Paints and coatings[d]	(U.S. EPA, 2020a, 2019c)	(U.S. EPA, 2019c)
	Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles	(ACC HPP, 2023; U.S. EPA, 2019a; U.S. CPSC, 2015) EPA-HQ-OPPT-2018-0436-0046; EPA-HQ-OPPT-2018-0436-0047; EPA-HQ-OPPT-2018-0436-0048; EPA-HQ-OPPT-2018-0436-0049; EPA-HQ-OPPT-2018-0436-0050	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a; U.S. CPSC, 2015) EPA-HQ-OPPT-2018-0436-0046; EPA-HQ-OPPT-2018-0436-0047; EPA-HQ-OPPT-2018-0436-0048; EPA-HQ-OPPT-2018-0436-0049; EPA-HQ-OPPT-2018-0436-0050
		Air care products		(Rustic Escentuals, 2015)
		Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)[d]	(ACC HPP, 2023; U.S. EPA, 2020a, 2019c)	(ACC HPP, 2023; U.S. EPA, 2019a, c)
		Fabric, textile, and leather products (apparel and footwear care products))	(ACC HPP, 2023; U.S. EPA, 2019a)	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)
	Packaging, paper,	Arts, crafts, and hobby materials	(U.S. EPA, 2021d)	(U.S. EPA, 2021d)
		Ink, toner, and colorant products[d]	(ACC HPP, 2023; Evonik Industries, 2019; U.S. EPA, 2019c; Porelon, 2007) EPA-HQ-OPPT-2018-0436-0055	(ACC HPP, 2023; U.S. EPA, 2019c; Polyone, 2018) EPA-HQ-OPPT-2018-0436-0055
		Packaging, paper, plastic, hobby products (packaging [excluding food packaging], including rubber articles; plastic articles [hard]; plastic articles [soft])	(U.S. EPA, 2020a)	(U.S. EPA, 2020a)
		Plasticizer (plastic and rubber products; tool	(U.S. EPA, 2020a, 2019a, c)	(U.S. EPA, 2019a, c)

Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Commercial Use	plastic, hobby products	handles, flexible tubes, profiles, and hoses)[d]		
		Toys, playground, and sporting equipment[d]	(ACC HPP, 2023; U.S. EPA, 2019a, c)	(ACC HPP, 2023; U.S. EPA, 2019a, c)
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	(CCW, 2020; Green Mountain International, 2008)	
	Other uses	Laboratory chemicals	(Sigma Aldrich, 2024; Spex Certiprep LLC, 2019; TCI America, 2019; Solvents and Petroleum Service, 2009) EPA-HQ-OPPT-2018-0504-0019	EPA-HQ-OPPT-2018-0504-0019
Consumer Use	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2019a, c)
	Construction, paint, electrical, and metal products	Adhesives and sealants[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2019a, c)
		Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)[d]	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a, c)	(ACC HPP, 2023; U.S. EPA, 2019a, c)
		Electrical and electronic products[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2020a, 2019a, c)
		Paint and coatings[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2019a, c)
	Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles	(ACC HPP, 2023; U.S. EPA, 2019a; U.S. CPSC, 2015) EPA-HQ-OPPT-2018-0436-0046; EPA-HQ-OPPT-2018-0436-0047; EPA-HQ-OPPT-2018-0436-0048;	(ACC HPP, 2023; U.S. EPA, 2019a; U.S. CPSC, 2015) EPA-HQ-OPPT-2018-0436-0046; EPA-HQ-OPPT-2018-0436-0047; EPA-HQ-OPPT-

Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Consumer Use			EPA-HQ-OPPT-2018-0436-0049; EPA-HQ-OPPT-2018-0436-0050	2018-0436-0048; EPA-HQ-OPPT-2018-0436-0049; EPA-HQ-OPPT-2018-0436-0050
		Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)[d]	(ACC HPP, 2023; U.S. EPA, 2019a, c)	(ACC HPP, 2023; U.S. EPA, 2019a, c)
		Air care products		(Rustic Escentuals, 2015)
		Fabric, textile, and leather products (apparel and footwear care products)[d]	(ACC HPP, 2023; U.S. EPA, 2020a, 2019a)	(ACC HPP, 2023; U.S. EPA, 2019a)
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	(U.S. EPA, 2021d)	(U.S. EPA, 2021d)
		Ink, toner, and colorant products[d]	(ACC HPP, 2023; Evonik Industries, 2019; U.S. EPA, 2019c; Porelon, 2007) EPA-HQ-OPPT-2018-0436-0055	(ACC HPP, 2023; U.S. EPA, 2019c) EPA-HQ-OPPT-2018-0436-0055
		Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses[d]	(U.S. EPA, 2019a, c)	(U.S. EPA, 2020a, 2019a, c)
	Packaging, paper, plastic, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)	(U.S. EPA, 2020a)	
		Toys, playground, and sporting equipment[d]	(ACC HPP, 2023; U.S. EPA, 2019a, c)	(ACC HPP, 2023; U.S. EPA, 2019a, c)
	Other	Novelty products	(Stabile, 2013)	(Stabile, 2013)

Life Cycle Stage[a]	Category[b]	Subcategory of Use[c e]	Reference (CASRN 28553-12-0)	Reference (CASRN 68515-48-0)
Disposal	Disposal	Disposal		

[a] Life Cycle Stage Use Definitions (40 CFR 711.3)

- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.

[b] These categories of conditions of use appear in the life cycle diagram, reflect CDR codes, and broadly represent conditions of use of DINP in industrial and/or commercial settings.

[c] These subcategories reflect more specific conditions of use of DINP.

[d] Circumstances on which ACC HPP is requesting that EPA conduct a risk evaluation. DINP is no longer processed into toys (processing into articles); however, EPA will evaluate risk from toys already in commerce that contain DINP. In addition, DINP processing into playground and sporting equipment is ongoing.

[e] In the final scope document, EPA added the following TSCA COUs: processing aids not otherwise listed (mixed metal stabilizer); and foam seating and bedding products, air care products, furniture and furnishings not covered elsewhere (EPA-HQ-OPPT-2018-0436-0028). Due to additional information from stakeholder outreach, public comments, and further research, the following COU was removed after the publication of the draft scope document: personal care products.

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 DINP. There is potential for exposures to workers and/or ONUs via inhalation and via dermal contact. The conceptual model also includes potential ONU dermal exposure to DINP 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.

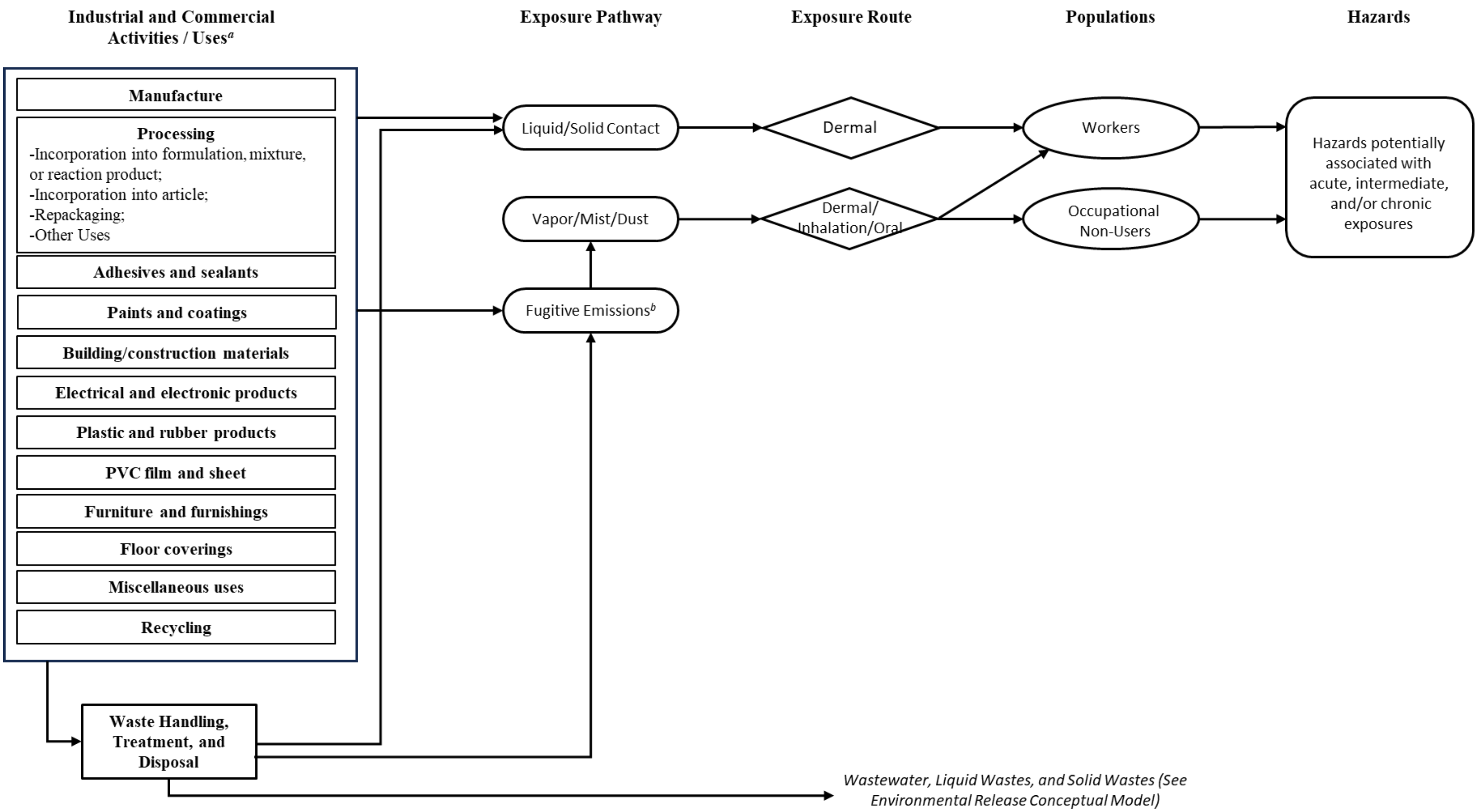
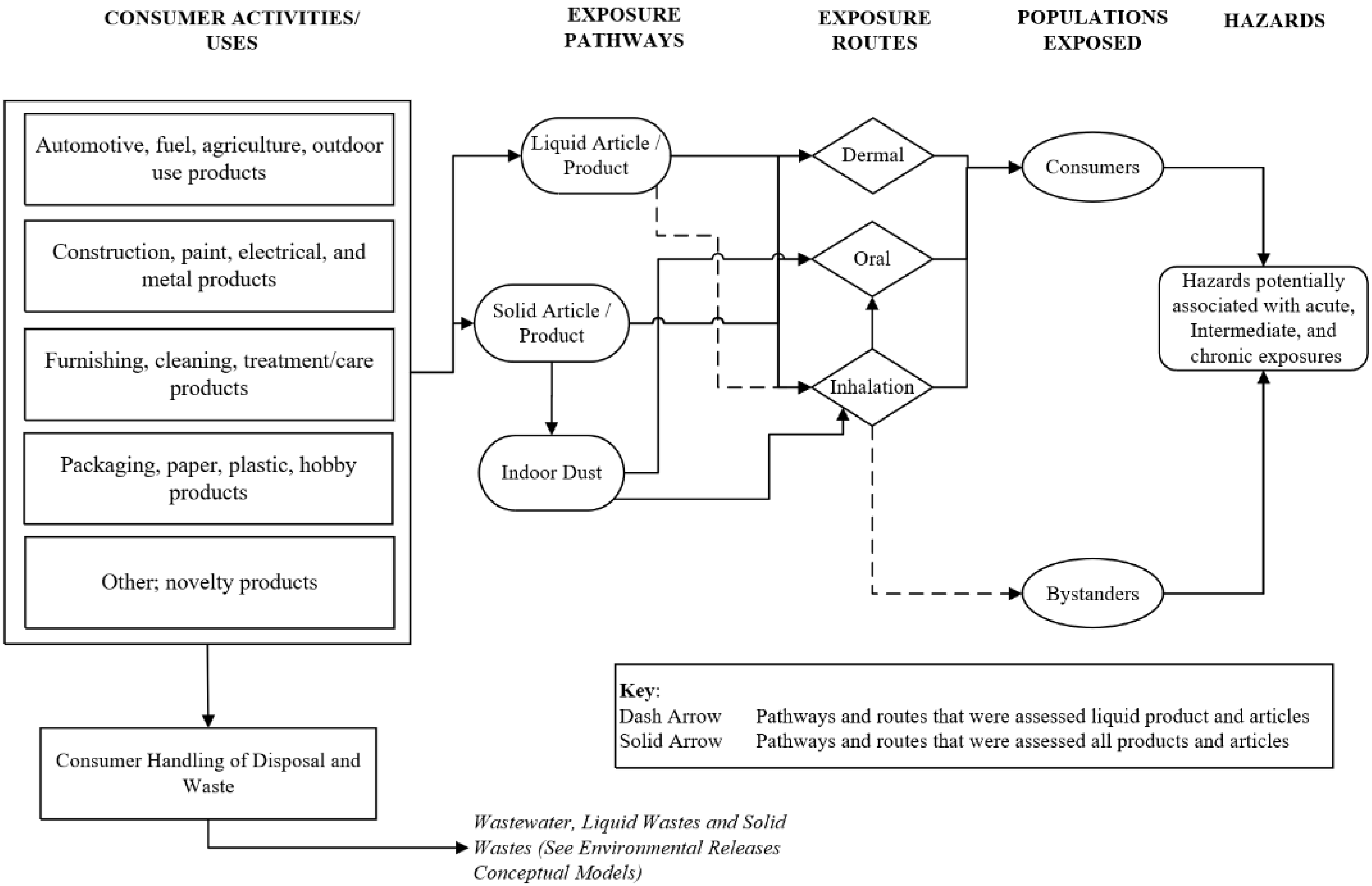


Figure 1-5. DINP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

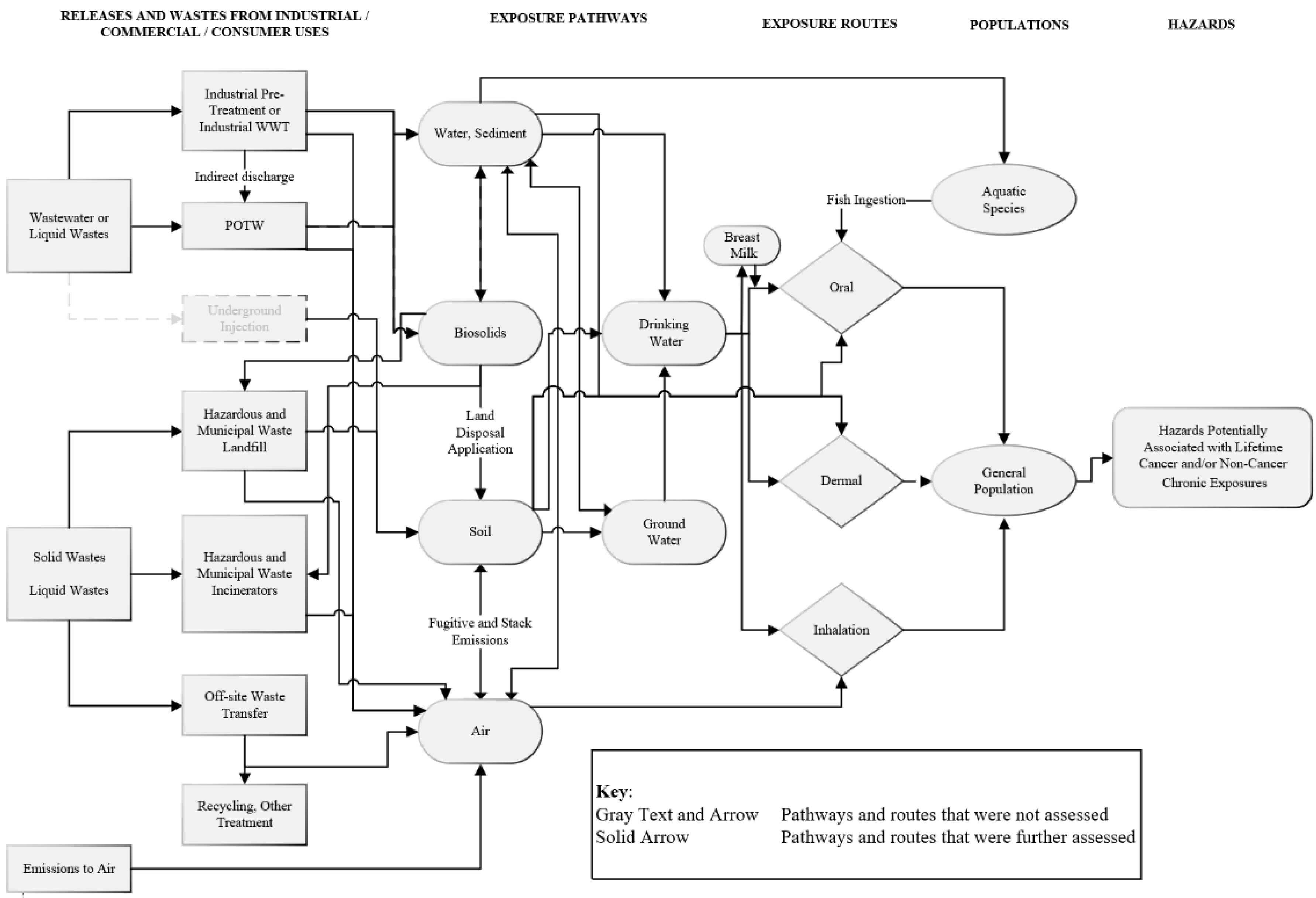
[a] Some products are used in both commercial and consumer applications. See Table 1-1 for categories and subcategories of conditions of use.

[b] Fugitive air emissions are emissions that are not routed through a stack 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.



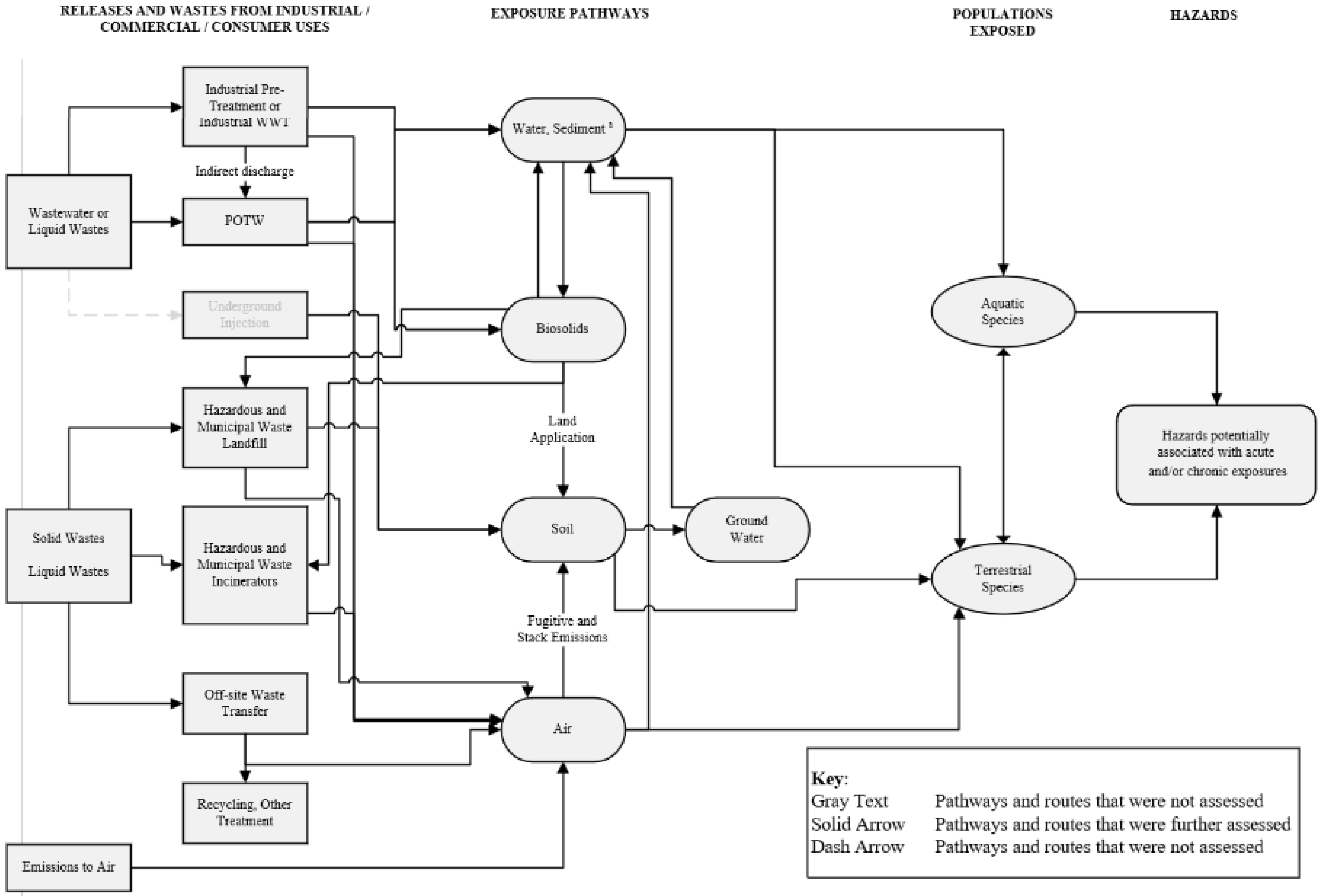
752

753 **Figure 1-6. DINP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards**
754 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from consumer activities and uses of DINP.



755

756 **Figure 1-7. DINP Conceptual Model for Environmental Releases and Wastes: General Population Hazards**
757 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from releases and wastes from industrial,
758 commercial, and/or consumer uses of DINP.



759

760 **Figure 1-8. DINP Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards**
761 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from releases and wastes from industrial,
762 commercial, and/or consumer uses of DINP.

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 and above);
- 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.

1.1.3.1 Potentially Exposed and Susceptible Subpopulations

TSCA section 6(b)(4)(A) requires that risk evaluations "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." TSCA section 3(12) states that "the term 'potentially exposed or susceptible subpopulation' [PESS] means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, 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 DINP, people exposed to DINP in the workplace, and tribes whose diets include large amounts of fish. These subpopulations are PESS because some have greater exposure to DINP 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, assessed in the consumer exposure scenarios), while some experience aggregate or sentinel exposures.

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

1.2 Organization of the Risk Evaluation

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

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

- Section 4 presents the human health risk assessment, including the exposure, hazard, and risk characterization based on the COUs. It includes a discussion of PESS based on both greater exposure and/or susceptibility, as well as a description of aggregate and sentinel exposures. Section 4 also discusses assumptions and uncertainties and how they potentially impact the strength of the evidence of draft risk evaluation.
- Section 5 provides a discussion and analysis of the environmental risk assessment, including the environmental exposure, hazard, and risk characterization based on the COUs for DINP. It also discusses assumptions and uncertainties and how they potentially impact the strength of the evidence of draft risk evaluation.
- Section 6 presents EPA's proposed determination of whether the chemical presents an unreasonable risk to human health or the environment as a whole chemical approach and under the assessed COUs.
- Appendix A provides a list of key abbreviations and acronyms used throughout this draft risk evaluation.
- Appendix B provides a brief summary of the federal, state, and international regulatory history of DINP.
- Appendix C incudes a list and citations for all technical support documents (TSDs) and supplemental files included in the draft risk evaluation for DINP.
- Appendix D provides a summary of updates made to COUs for DINP from the final scope document to this draft risk evaluation.
- Appendix E provides descriptions of the DINP COUs evaluated by EPA.
- Appendix F provides the draft occupational exposure value for DINP that was derived by EPA.

2 CHEMISTRY AND FATE AND TRANSPORT OF DINP

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 DINP informs the specific exposure pathways, and potential human and environmental exposed populations that EPA considered in this draft risk evaluation.

Sections 2.1 and 2.2 summarize the physical and chemical properties, and environmental fate and transport of DINP, respectively. See the *Draft Physical Chemistry Assessment for Diisononyl Phthalate* (U.S. EPA, 2024x) and *Draft Fate Assessment for Diisononyl Phthalate* (U.S. EPA, 2024t) provide further details.

2.1 Summary of Physical and Chemical Properties

EPA gathered and evaluated physical and chemical property data and information according to the process described in the *Draft Systematic Review Protocol for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024ac). During the evaluation of DINP, 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 Diisononyl Phthalate (DINP)* (U.S. EPA, 2024f).

Table 2-1. Physical and Chemical Properties of DINP

Property	Selected Value(s)	Reference(s)	Data Quality Rating
Molecular formula	$C_{26}H_{42}O_4$		
Molecular weight	418.62 g/mol		
Physical form	Clear Liquid	(NLM, 2015)	High
Melting point	−48 °C	(O'Neil, 2013)	High
Boiling point	>400 °C	(ECHA, 2016)	High
Density	0.97578 g/cm^3	(De Lorenzi et al., 1998)	High
Vapor pressure	5.40E−07 mmHg	(NLM, 2015)	High
Water solubility	0.00061 mg/L	(Letinski et al., 2002)	High
Molecular formula	$C_{26}H_{42}O_4$		
Octanol:water partition coefficient (log K_{OW})	8.8	(ECHA, 2016)	High
Octanol:air partition coefficient (log K_{OA})	11.9 (EPI Suite™)	(U.S. EPA, 2017)	High
Henry's Law constant	9.14E−05 atm·m^3/mol at 25 °C	(Cousins and Mackay, 2000)	High
Flash point	213 °C	(O'Neil, 2013)	High
Autoflammability	400 °C	(ECHA, 2016)	High
Viscosity	77.6 cP	(ECHA, 2016)	High

2.2 Summary of Environmental Fate and Transport

Reasonably available environmental fate data—including biotic and abiotic biodegradation rates, removal during wastewater treatment, volatilization from lakes and rivers, and organic carbon:water partition coefficient (log K_{OC})—are the parameters used in the current draft risk evaluation. In assessing the environmental fate and transport of DINP, 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 Diisononyl Phthalate (DINP)* (U.S. EPA, 2024d). Other fate estimates were based on modeling results from EPI Suite™ (U.S. EPA, 2012), a predictive tool for physical and chemical properties and environmental fate estimation.

DINP is considered ubiquitous in various environmental media due to its presence in both point and non-point source discharges from industrial and conventional wastewater treatment effluents, biosolids, and sewage sludge, stormwater runoff, and landfill leachate (Net et al., 2015). As an isomeric mixture, the fate and transport properties of DINP can be difficult to classify. EPA evaluated the reasonably available information to characterize the environmental fate and transport of DINP, the key points of the *Draft Fate Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024t) are summarized below.

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

- Is expected to undergo significant direct photolysis and will rapidly degrade in the atmosphere ($t_{1/2}$ = 8.5 hours).
- 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 via biotic and abiotic processes to form monoisononyl phthalate, isononanol, 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 94 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 be found in, and accumulate in, indoor dust.

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

- Is not expected to biodegrade under anoxic conditions and may have high persistence in anaerobic soils and sediments.
- Is not bioaccumulative in fish in the water column.
- May be bioaccumulative in benthic organisms exposed to sediment with elevated concentrations of DINP proximal to continual sources of release.
- Is expected to be removed in conventional water treatment systems both in the treatment process, and via reduction by chlorination and chlorination byproducts in post-treatment storage and drinking water conveyance.

3 RELEASES AND CONCENTRATIONS OF DINP IN THE ENVIRONMENT

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

3.1 Approach and Methodology

At the time of this risk evaluation, releases of DINP have not been reported to programmatic databases including Discharge Monitoring Report (DMR) or National Emissions Inventory (NEI). Although DINP was added to the Toxics Release Inventory (TRI) in 2023 (88 FR 45089), releases of DINP to this database were not available at the time of this drat risk evaluation. Therefore, EPA utilized models to estimate environmental releases for each OES. This section provides an overview of the approach and methodology for assessing releases to the environment from industrial, commercial, and consumer uses. Specifically, Sections 3.1.1 through 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 DINP 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 DINP 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 the 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 that 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 *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) provides further information on specific OESs.

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

Life Cycle Stage	Category	Subcategory	OES
Manufacturing	Domestic manufacturing	Domestic manufacturing	Manufacturing
	Importing	Importing	Import and repackaging
Processing	Repackaging	Plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing)	Import and repackaging
	Other uses	Miscellaneous processing (petroleum refineries; wholesale and retail trade)	Incorporation into other formulations, mixtures, or reaction products
	Incorporation into formulation, mixture, or reaction product	Heat stabilizer and processing aid in basic organic chemical manufacturing	Incorporation into other formulations, mixtures, or reaction products
		Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing (including pigment))	Incorporation into adhesives and sealants; Incorporation into paints and coatings; Incorporation into other formulations, mixtures, or reaction products; PVC material compounding; Non-PVC material compounding
	Incorporation into articles	Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing (including pigment))	PVC plastics converting; Non-PVC material converting
	Recycling	Recycling	Recycling
Disposal	Disposal	Disposal	Disposal
Distribution in Commerce	Distribution in commerce	Distribution in commerce	Distribution in commerce

Life Cycle Stage	Category	Subcategory	OES
Industrial Uses	Adhesive and sealant chemicals	Adhesive and sealant chemicals (sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing; and adhesion/cohesion promoter in transportation equipment manufacturing)	Application of adhesives and sealants
	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Fabrication or use of final product or articles
	Construction, paint, electrical, and metal products	Building/construction materials (roofing, pool liners, window shades, flooring)	Fabrication or use of final product or articles
		Paints and coatings	Application of paints and coatings
	Other Uses	Hydraulic fluids	Use of lubricants and functional fluids
		Pigment (leak detection)	Application of paints and coatings

Life Cycle Stage	Category	Subcategory	OES
Commercial Use	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Fabrication or use of final product or articles
	Construction, paint, electrical, and metal products	Adhesives and sealants	Application of adhesives and sealants
		Plasticizer in building/construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles	Fabrication or use of final product or articles
		Electrical and electronic products	Fabrication or use of final product or articles
		Paints and coatings	Application of paints and coatings
	Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles	Fabrication or use of final product or articles
		Air care products	Incorporation into other formulations, mixtures, or reaction products
		Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Fabrication or use of final product or articles
		Fabric, textile, and leather products (apparel and footwear care products)	Fabrication or use of final product or articles
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Fabrication or use of final product or articles
		Ink, toner, and colorant products	Application of paints and coatings
		Packaging, paper, plastic, hobby products (packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft))	Fabrication or use of final product or articles
		Plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses)	Fabrication or use of final product or articles
		Toys, playground, and sporting equipment	Fabrication or use of final product or articles
	Other uses	Laboratory chemicals	Use of laboratory chemicals
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	Use of lubricants and functional fluids

3.1.1.2 Description of DINP Use for Each OES

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

Table 3-2. Description of the Function of DINP for Each OES

OES	Role/Function of DINP
Manufacturing	DINP is typically produced through the reaction of phthalic anhydride and isononyl alcohol using an acid catalyst. The first form is manufactured from a C9 alcohol, which is n-butene-based while the second form is manufactured from a C8–C10 alcohol fraction.
Import and repackaging	DINP is imported domestically for use and/or may be repackaged before shipment to formulation sites.
PVC plastics compounding	DINP is used in PVC plastics to increase flexibility.
PVC plastics converting	DINP is used in PVC plastics to increase flexibility.
Incorporation into adhesives and sealants	DINP is a plasticizer in adhesive and sealant products for industrial and commercial use.
Incorporation into paints and coatings	DINP is a plasticizer in paint and coating products for industrial and commercial use.
Incorporation into other formulations, mixtures, or reaction products, not covered elsewhere	DINP is incorporated into products, such as cleaning solvents, penetrants, and printing inks.
Non-PVC material compounding	DINP is used in non-PVC polymers, such as polyurethane resin, rubber erasers, and synthetic rubber.
Non-PVC material converting	DINP is used in non-PVC polymers, such as polyurethane resin, rubber erasers, and synthetic rubber.
Application of adhesives and sealants	Industrial and commercial sites apply DINP-containing adhesives and sealants using roll or bead application methods. Products may also be applied using a syringe, caulk gun, or spray gun.
Application of paints and coatings	Commercial sites apply DINP-containing paints and coatings using roll, brush, trowel, and spray application methods.
Use of laboratory chemicals	DINP is a laboratory chemical used for laboratory analyses in solid and liquid forms.
Use of lubricants and functional fluids	DINP is incorporated into lubricants and functional fluids in both commercial and industrial processes.
Recycling and disposal	Upon manufacture or use of DINP-containing products, residual chemical is disposed and released to air, wastewater, or disposal facilities. A fraction of PVC plastics is recycled either in-house or at PVC recycling facilities for continuous compounding of new PVC material.
Fabrication and final use of products or articles	DINP is found in a wide array of different final articles not found in other OES including floor matting, erasers, glass filaments, and wall coverings.

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

Based on the limited data on the number of release days for the majority of the OESs, EPA developed generic estimates of the number of 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 scenarios (GSs) or emission scenario documents (ESDs) to assess the number of operating days for a given OES. EPA estimated average daily releases for facilities by assuming that the number of release days is equal to the number of operating days.

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

OES	Operating Days (days/year)	Basis
Manufacturing	180	EPA assumed the number of operating days and release days equals 180 days/per year, based on industry-provided information on operating days (ExxonMobil, 2022b).
Import and repackaging	208 to 260	The 2022 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 *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 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 to 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 *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 223–254 days/year (U.S. EPA, 2021f, 2014c).
PVC plastics converting	219 to 251	The 2021 Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry estimated the number of operating days as 138 to 253 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2021g).
Non-PVC material compounding	234 to 280	The 2014 Plastic Compounding GS, 2021 Plastic Compounding Revised GS, and the 2020 *Specific Emission Release Category (SpERC) Factsheet on Rubber Production and Processing* estimated the total number of operating days as 148-300 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 234–280 days/year (U.S. EPA, 2021f; ESIG,

OES	Operating Days (days/year)	Basis
		2020b; U.S. EPA, 2014c)
Non-PVC material converting	219 to 251	The 2021 Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry estimated the number of operating days as 137–254 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 219–251 days/year (U.S. EPA, 2021g).
Application of adhesives and sealants	232 to 325	Based on several end use products categories, the 2015 ESD on the Use of Adhesives estimated the total number of operating days as 50–365 days/year. Release estimates that EPA assessed using Monte Carlo modeling (*Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 232-325 days/year (OECD, 2015b).
Application of paints and coatings	257 to 287	EPA assessed the total number of operating days based on the 2011 ESD on Radiation Curable Coatings, Inks and Adhesives, the 2011 ESD on Coating Application via Spray-Painting in the Automotive Finishing Industry, the 2004 GS on Spray Coatings in the Furniture Industry, and the *SpERC Factsheet for Industrial Application of Coatings and Inks by Spraying*. These sources estimated the total number of operating days as 225–300 days/year. Release estimates that EPA assessed using Monte Carlo modeling (*Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 257–287 days/year (ESIG, 2020a; OECD, 2011a, b; U.S. EPA, 2004b).
Use of laboratory chemicals	Liquid: 235 to 258 Solid: 260	The 2023 Use of Laboratory Chemicals GS estimated the total number of operating days based on the shift lengths of operators over the course of a full year as 174–260 days/year. Shift lengths include 8, 10, or 12 hour/day shifts. Release estimates that EPA assessed using Monte Carlo modeling (*Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (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 to 4	EPA assumed 1–4 changeouts per year based on identified product data for different types of hydraulic fluids and the ESD on the Lubricant and Lubricant Additives. EPA assumed each changeout occurs over one day. Release estimates that EPA assessed using Monte Carlo modeling used a 50th to 95th percentile range of 2–4 days/year (OECD, 2004b).
Recycling and disposal	Recycling: 223 to 254	EPA estimated recycling and disposal releases separately. For the PVC recycling OES, the 2014 Plastic Compounding GS and 2021 Plastic Compounding Revised GS estimated the number of operating days as 148–264 days/year. Release estimates that EPA assessed using Monte Carlo modeling (see *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)) used a 50th to 95th percentile range of 223-254 days/year (U.S. EPA, 2021f, 2014c). EPA evaluated disposal releases within the assessments for each OES. EPA provided operating days for

OES	Operating Days (days/year)	Basis
		individual OES in this table.
Fabrication and final use of products or articles	250	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 to each media of release using CDR, GSs, and ESDs, EPA published models, and the previously published *European Union DINP Risk Assessment*, as shown in Figure 3-1. Generally, EPA used 2020 CDR data (U.S. EPA, 2020a) and the 2003 *EU DINP Risk Assessment* (ECJRC, 2003b) 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 DINP within an OES. Generally, information for reporting sites in CDR was sufficient to accurately characterize each reporting site's OES. The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) describes EPA's approach and methodology for estimating daily releases and provides detailed facility level results for each OES.

For each OES, EPA estimated DINP releases to each release media applicable to that OES. For DINP, EPA assumed that releases occur to water, air, or land (*i.e.*, disposal to land).

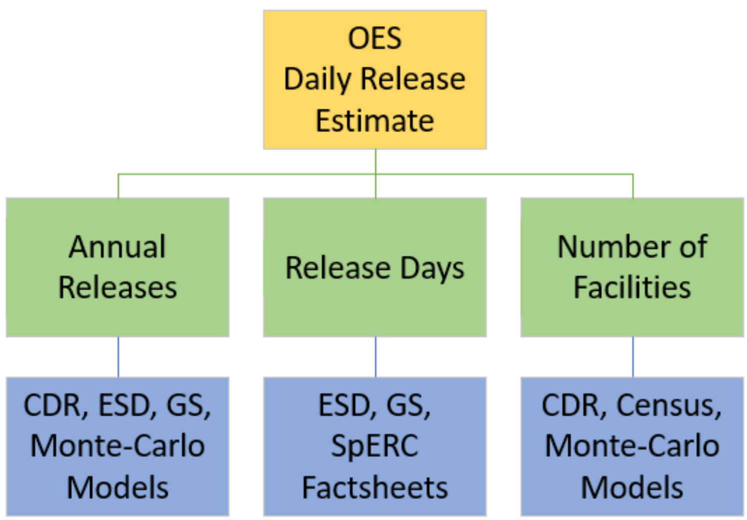


Figure 3-1. An Overview of How EPA Estimated Daily Releases for Each OES
CDR = Chemical Data Reporting; ESD = emission scenario document; GS = generic scenario

3.1.4 Consumer (Down-the-Drain)

EPA evaluated down-the-drain releases of DINP for consumer COUs qualitatively. Although EPA acknowledges that there may be DINP releases to the environment via the cleaning and disposal of adhesives, sealants, paints, lacquers, and coatings, the Agency did not quantitatively assess down-the-drain and disposal scenarios of consumer products due to limited information from monitoring data, or modeling tools but provides a qualitative assessment using physical and chemical properties in this section. See EPA's *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate* (DINP) (U.S. EPA, 2024l) for further details. Adhesives, sealants, paints, 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, paints, lacquers, and coatings. A range of drinking water treatment removal rates from 79 percent to over 96 percent removal was observed in (Shi et al., 2012), and even with the use of 79 percent, all drinking water exposures resulted in minimal human exposure and subsequent risk, see the DINP *Draft Exposure Media Concentration and General Population Technical Support Document*, (U.S. EPA, 2024r). DINP affinity to organic material and low water solubility and log K_{OW} suggest that DINP in down-the-drain water is expected to mainly partition to suspended solids present in water. Also, the available information suggest that the use of flocculants and filtering media could potentially help remove DINP during drinking water treatment by sorption into suspended organic matter, settling, and physical removal.

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 of daily releases for each OES. Table 3-4 presents a summary of these ranges across facilities. See the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) for additional detail on deriving the overall confidence score for each OES. EPA was not able to estimate releases for the fabrication and final use of products or articles OES due to the lack of available process-specific and DINP-specific data; however, EPA expects releases from this OES to be small compared to other upstream uses (see Section 3.14.3 of (U.S. EPA, 2024s) for further description).

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

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge,[a] Air Emission,[b] or Transfer for Disposal[c]	Estimated Release Frequency across Sites (days)[d]		Number of Facilities[e]	Weight of Scientific Evidence Rating[f]	Sources
	Central Tendency	High-End		Central Tendency	High-End			
Manufacturing	1.66E−06	3.78E−06	Fugitive Air	180		1 – Gehring Montgomery, Warminster, PA	Moderate	CDR, Peer–reviewed literature (GS/ESD)
	2.23E−01		Stack Air					
	2.05E−01	3.70E−01	Wastewater to Onsite treatment or Discharge to POTW					
	5.13	5.34	Onsite Wastewater Treatment, Incineration, or Landfill					
	2.16	3.75	Landfill					
	1.80E−06	3.95E−06	Fugitive Air	180		3 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.16E01	1.73E01	Stack Air					
	1.01E01	2.26E01	Wastewater to Onsite Treatment or Discharge to POTW					
	2.35E02	3.50E02	Onsite Wastewater Treatment, Incineration, or Landfill					
	1.00E02	2.38E02	Landfill					
	4.44E−06	7.92E−06	Fugitive Air	180		2 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	2.76E02	4.80E02	Stack Air					
	2.31E02	6.08E02	Wastewater to Onsite Treatment or Discharge to POTW					
	5.61E03	9.75E03	Onsite Wastewater Treatment, Incineration, or Landfill					
	8.69E02		Landfill					

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge,[a] Air Emission,[b] or Transfer for Disposal[c]	Estimated Release Frequency across Sites (days)[d]		Number of Facilities[e]	Weight of Scientific Evidence	Sources
Import and repackaging	1.57E−08	2.90E−08	Fugitive Air	208	260	1 – Henkel Louisville, Louisville, KY	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.47	1.70	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	9.70E−08	1.02E−07	Fugitive Air	208	260	1 – Formosa Global Solutions, Livingston, NJ	Moderate	
	2.03	2.52	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.00E−07	1.06E−07	Fugitive Air	208	260	1 – Chemspec, Uniontown, OH	Moderate	
	5.80	7.17	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.01E−07	1.07E−07	Fugitive Air	208	260	1 – Harwick Standard Distribution Corp. Akron, OH	Moderate	
	6.89	8.52	Wastewater to Onsite Treatment, discharge to POTW, or Landfill					
	7.75E−08	1.07E−07	Fugitive Air	208	260	1 – Silver Fern Chemical, Seattle, WA	Moderate	
	1.12E01	1.38E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.04E−07	1.12E−07	Fugitive Air	208	260	1 – MAK Chemicals Inc. Clifton, NJ	Moderate	
	1.12E01	1.39E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	5.13E−08	6.71E−08	Fugitive Air	208	260	1 – Mercedes Benz, Vance AL	Moderate	
	1.62E01	2.00E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	5.55E−08	7.38E−08	Fugitive Air	208	260	1 – Univar Solutions, Redmond, WA	Moderate	
	2.75E01	3.40E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.22E−07	1.41E−07	Fugitive Air	208	260	1 – Belt Concepts of America, Spring Hope, NC	Moderate	
	3.45E01	4.26E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.29E−07	1.53E−07	Fugitive Air	208	260	1 – Tribute Energy Inc., Houston, TX	Moderate	
	4.37E01	5.40E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge,[a] Air Emission,[b] or Transfer for Disposal[c]	Estimated Release Frequency across Sites (days)[d]		Number of Facilities[e]	Weight of Scientific Evidence	Sources
Import and repackaging	6.15E−08	8.39E−06	Fugitive Air	208	260	1 – Geon Performance Solutions LLC, Louisville, KY	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	4.38E01	5.41E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.54E−07	1.97E−07	Fugitive Air	208	260	1 – Cascade Columbia Distribution	Moderate	
	7.75E01	9.59E01	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	5.10E−07	9.15E−07	Fugitive Air	208	260	1 – Alac International Inc. New York, NY	Moderate	
	1.16E03	1.42E03	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	1.93E−07	3.79E−07	Fugitive Air	208	260	10 generic sites	Moderate	
	2.07E02	3.51E02	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
	2.77E−06	7.88E−06	Fugitive Air	208	260	5 generic sites	Moderate	
	4.94E03	9.58E03	Wastewater to Onsite Treatment, Discharge to POTW, or Landfill					
PVC plastics compounding	3.30E01	1.46E02	Fugitive or Stack Air	223	254	110–215 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	8.23E01	2.74E02	Fugitive Air, Wastewater, Incineration, or Landfill					
	4.28E2	6.81E02	Wastewater, Incineration, or Landfill					
	1.09E02	1.64E02	Wastewater					
	2.23E01	1.11E02	Incineration or Landfill					
PVC plastics converting	1.58	6.94	Fugitive or Stack Air	219	251	2,386–4,662 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	3.92	1.30E01	Fugitive Air, Wastewater, Incineration, or Landfill					
	1.54E01	2.35E01	Wastewater, Incineration, or Landfill					
	5.14	7.85	Wastewater					
	1.43E01	2.27E01	Incineration or Landfill					
Non-PVC material compounding	5.47E01	2.15E02	Fugitive or Stack Air	234	280	5–9 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	4.77	1.86E01	Fugitive Air, Wastewater, Incineration, or Landfill					
	1.20E03	2.60E03	Wastewater, Incineration, or Landfill					
	1.11E02	1.86E02	Wastewater					
	7.96E01	2.81E02	Incineration or Landfill					

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge,[a] Air Emission,[b] or Transfer for Disposal[c]	Estimated Release Frequency across Sites (days)[d]		Number of Facilities[e]	Weight of Scientific Evidence	Sources
Non-PVC material converting	1.39	5.72	Fugitive or Stack Air	219	251	122–190 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.37E−01	5.22E−01	Fugitive Air, Wastewater, Incineration, or Landfill					
	9.65	1.76E01	Wastewater, Incineration, or Landfill					
	2.77	5.32	Wastewater					
	9.23	1.93E01	Incineration or Landfill					
Incorporation into adhesives and sealants	5.19E−09	1.78E−08	Fugitive Air	250		15–59 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	4.97E−09	4.10E−08	Stack Air					
	3.60E01	7.51E01	Wastewater, Incineration, or Landfill					
Incorporation into paints and coatings	2.29E−06	2.06E−05	Fugitive Air	250		4–23 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	9.15E−09	8.24E−08	Stack Air					
	3.00E02	1.01E03	Wastewater, Incineration, or Landfill					
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	9.35E−08	3.16E−07	Fugitive Air	250		1–7 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	7.83E−08	5.81E−07	Stack Air					
	8.64E02	2.68E03	Wastewater, Incineration, or Landfill					
Application of paints and coatings with overspray controls [no overspray controls]	1.06E−08 [1.06E−08]	2.71E−08 [2.71E−08]	Fugitive Air	257	287	145–792 generic sites [145–795 generic sites]	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	2.64 [1.66]	8.25 [4.47]	Stack Air [Unknown]					
	2.55E01 [2.65E01]	7.84E01 [8.22E01]	Wastewater, Incineration, or Landfill					
Application of adhesives and sealants	4.97E−09	1.30E−08	Fugitive or Stack Air	232	325	345–2,383 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.48	6.46	Wastewater, Incineration, or Landfill					
Use of laboratory chemicals high conc. liquid [low conc. liquid]	1.98E−09 [2.38E−12]	3.35E−09 [3.82E−12]	Fugitive or Stack Air	235 [260]	258 [260]	586–4,912 generic sites [36,873 generic sites]	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	1.96 [2.74E−02]	3.68 [2.75E−02]	Wastewater, Incineration, or Landfill					

OES	Estimated Daily Release across Sites (kg/site-day)		Type of Discharge,[a] Air Emission,[b] or Transfer for Disposal[c]	Estimated Release Frequency across Sites (days)[d]		Number of Facilities[e]	Weight of Scientific Evidence	Sources
Use of laboratory chemicals – solid	1.55E−04	4.34E−04	Stack Air	260		36,873	Moderate	
	2.74E−02	2.75E−02	Wastewater, Incineration, or Landfill					
Use of lubricants and functional fluids	7.27E01	2.69E02	Wastewater	2	4	7,033–48,659 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	3.19E01	1.30E02	Landfill					
	1.18	6.27	Recycling					
	2.64E01	1.39E02	Fuel Blending (Incineration)					
Recycling	4.33E−02	8.67E−01	Stack Air	223	254	58 generic sites	Moderate	CDR, Peer-reviewed literature (GS/ESD)
	3.46	6.30	Fugitive Air, Wastewater, Incineration, or Landfill	223	254	58 generic sites		CDR, Peer-reviewed literature (GS/ESD)
	1.46	3.19	Wastewater	223	254	58 generic sites		CDR, Peer-reviewed literature (GS/ESD)

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

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

For each OES, EPA considered the assessment approach, the quality of the data and models, and the uncertainties in the assessment results to determine a level of confidence for the environmental release estimates. Table 3-5 provides EPA's weight of scientific evidence rating for each OES.

EPA integrated numerous evidence streams across systematic review and non-systematic review sources to develop environmental estimates for DINP. EPA made a judgment on the weight of scientific evidence supporting the release estimates based on the strengths, limitations, and uncertainties associated with the 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 release estimate (whether measured or estimated), including quality of the data/information, relevance of the data to the release scenario (including considerations of temporal and 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 (*e.g.*, data from a 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 the sites within the OES. 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* (U.S. EPA, 2021a) (also called the "2021 Draft Systematic Review Protocol") 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 data had data quality ratings of medium. As a result, for releases that used GSs/ESDs, the weight of scientific conclusion was moderate, when used in tandem with Monte Carlo modeling.

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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	EPA found limited chemical specific data for the manufacturing OES and assessed environmental releases using models and model parameters derived from CDR, the *2023 Methodology for Estimating Environmental Releases from Sampling Wastes* (U.S. EPA, 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 DINP manufacturing volumes for all facilities that reported this information to CDR and DINP-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 DINP facility production volume data for some DINP 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.e.,* not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. Additional limitations include uncertainties in the representativeness of the industry-provided operating parameters and the generic EPA/OPPT models for all DINP manufacturing sites. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and the assessment provides a plausible estimate of releases considering the strengths and limitations of the reasonably available data.
Import and repackaging	EPA found limited chemical specific data for the import and repackaging OES and assessed releases to the environment using the assumptions and values from the Chemical Repackaging 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 a 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 DINP 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 DINP. In addition, EPA lacks DINP 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.e.*, not all potential sites represented) and an annual DINP 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.

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 DINP-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 in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 DINP into adhesives and sealants. In addition, EPA lacks data on DINP-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.e.*, not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. The respective share of DINP use for each OES (as presented in the *EU Risk Assessment Report*) may differ from actual conditions adding additional 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.
Incorporation into paints and coatings	EPA found limited chemical specific data for the incorporation into paints and coatings OES and assessed releases to the environment using the Draft GS for the Formulation of Waterborne Coatings, 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 DINP-specific data on concentrations in paint and coating products to provide more accurate estimates of DINP concentrations than the generic values provided by the GS. EPA based the production volume for the OES on rates cited in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 DINP into paints and coatings, particularly for sites formulating other coating types (*e.g.*, solvent-borne coatings). In addition, EPA lacks data on DINP-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.e.*, not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. The share of DINP use for each OES presented in the *EU Risk Assessment Report* 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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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 the 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 DINP-specific data on concentrations in other formulations, mixtures, 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 in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 DINP into other formulations, mixtures, or reaction products. In addition, EPA lacks data on DINP-specific facility production volumes and number of formulation sites; therefore, EPA based the throughput estimates on CDR which has a reporting threshold of 25,000 lb (*i.e.*, not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. Finally, the share of DINP use for each OES presented in the *EU Risk Assessment Report* 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, 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 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 DINP-specific data on concentrations in different DINP-containing PVC plastic products and PVC-specific additive throughputs in the analysis. These data points are more accurate 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 in an ACC report (ACC, 2020), which references the *2003 EU Risk Assessment Report* (ECJRC, 2003b) for the expected U.S. DINP 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 DINP into PVC plastic raw material. In addition, EPA lacks data on DINP-specific facility production volumes and number of compounding sites; therefore, EPA estimated throughput based on CDR which has a

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	reporting threshold of 25,000 lb (*i.e.*, not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. The respective share of DINP use for each OES presented in the *EU Risk Assessment Report* 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 Revised Draft GS on the Use of Additives in the Thermoplastics Converting Industry, which has a medium data quality rating based on systematic review (U.S. EPA, 2021g). 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 DINP-specific data on concentrations in different DINP-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 in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for the expected U.S. DINP 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 DINP-containing PVC raw material into PVC articles using a variety of methods, such as extrusion or calendaring. In addition, EPA lacks data on DINP-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.e.*, not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. The respective share of DINP use for each OES presented in the *EU Risk Assessment Report* 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, 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 DINP-specific concentration data for different DINP-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 in an ACC report (ACC, 2020), which references the

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 DINP-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 DINP into non-PVC material. In addition, EPA lacks data on DINP-specific facility production volumes and number of compounding sites; therefore, EPA estimated throughput based on CDR which has a reporting threshold of 25,000 lb (*i.e.*, not all potential sites represented) and an annual DINP production volume range that spans an order of magnitude. The respective share of DINP use for each OES presented in the *EU Risk Assessment Report* 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, 2021g; 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 DINP-specific data on concentrations in different DINP-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 in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 DINP-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 DINP-containing, non-PVC material into finished articles. In addition, EPA lacks data on DINP-specific facility production volumes and number of converting sites; therefore, EPA based throughput estimates on values from industry SpERC documents, CDR data (which has a reporting threshold of 25,000 lb (*i.e.*, not all potential sites represented), and an annual DINP production volume range that spans an order of magnitude. The share of DINP use for each OES presented in the *EU Risk Assessment Report* 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.
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

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	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 DINP-specific data on concentration and application methods for different DINP-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 production volumes for the OES on rates cited in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 DINP into adhesives and sealants. In addition, EPA lacks data on DINP-specific facility use volumes 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.e.*, not all potential sites represented), and an annual DINP production volume range that spans an order of magnitude. The respective share of DINP use for each OES as presented in the *EU Risk Assessment Report* 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 reasonably available data.
Application of paints and coatings	EPA found limited chemical specific data for the application of paints and coatings OES and assessed releases to the environment using the ESD on the Application of Radiation Curable Coatings, Inks and Adhesives, the GS on Coating Application via Spray Painting in the Automotive Refinishing Industry, and 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, 2004c). 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 spray applied. 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 DINP-specific data on DINP concentration and paint/coating application methods for different DINP-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 in an ACC report (ACC, 2020), which references the 2003 *EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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-world sites that incorporate DINP 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 DINP-specific facility use volumes 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.e.*, not all potential sites represented), and an annual DINP production volume range that spans an order of magnitude. The

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	share of DINP use for each OES presented in the *EU Risk Assessment Report* 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 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.S. EPA, 2023f). 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 DINP-containing laboratory chemicals. 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, DINP-containing laboratory products to inform product concentration and material states. EPA believes the primary limitation to be the uncertainty in the representativeness of values toward the true distribution of potential releases. In addition, EPA lacks data on DINP-containing laboratory chemical throughputs and number of laboratories; therefore, EPA based the number of laboratories and throughput estimates on stock solution throughputs from the Draft GS on the Use of Laboratory Chemicals and on CDR reporting thresholds. Additionally, because no entries in CDR indicate a laboratory use case, and there were no other sources to estimate the volume of DINP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold, which by definition over-estimates 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. EPA did not identify any DINP-containing lubricants and functional fluids for use in Monte Carlo analysis. Therefore, EPA used products containing DIDP as surrogate to develop concentration and use data for 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 in an ACC report (ACC, 2020), which references the *2003 EU Risk Assessment Report* (ECJRC, 2003b) for expected U.S. DINP 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 using DINP-containing lubricants and functional fluids. In addition, EPA lacks information on facility use rates of DINP-containing products and number of use sites; therefore, EPA estimated the number of sites and throughputs based on CDR, which has a reporting

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	threshold of 25,000 lb (*i.e.*, not all potential sites represented), and an annual DINP production volume range that spans an order of magnitude. The respective share of DINP use for each OES presented in the *EU Risk Assessment Report* may differ from actual conditions adding some uncertainty to estimated releases. Furthermore, EPA lacks chemical-specific information on DINP concentrations in lubricants and functional fluids and relied on surrogate data. Actual concentrations may differ 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.
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. Releases for this OES are 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, 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 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 DINP-specific data on DINP concentrations in different PVC 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 *Quantification and Evaluation of Plastic Waste in the United States*, 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 the DINP PVC market share to define an approximate recycling volume of DINP-containing PVC. 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 that contain DINP. In addition, EPA lacks DINP-specific data on PVC recycling rates and facility production volumes; therefore, EPA based throughput estimates on PVC plastics compounding data and U.S. PVC recycling rates, which are not specific to DINP, and may not accurately reflect current U.S. recycling volumes. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate, and 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 DINP submit CDR data to EPA if they meet reporting threshold requirements. Sites are only required to load production data into CDR if their yearly production volume exceeds 25,000 lb. Sites can claim their production volume as CBI, further limiting the production volume information in CDR. As a result, some sites that produce or use DINP 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 DINP into the environment is unknown. The media of release for these sites is also unknown.

CDR information on the downstream use of DINP 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 2003 *DINP Risk Assessment* published by the European Union, Joint Research Centre and a DINP report presented by ACC to determine approximate production volumes (ECJRC, 2003b). The ACC report indicates that the use rate of DINP in the United States is similar to the production volume in the European Union (ACC, 2020). 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. For non-polymer use cases, the EU risk assessment assesses a total production volume percentage of 2.61 percent across all uses. 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, DINP 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, EPA determined the maximum number of sites for use in Monte Carlo modeling from industry data from the U.S. Census Bureau, County and Business Patterns dataset (U.S. Census Bureau, 2022).
- **Uncertainties Associated with Number of Release Days Estimate –** For most OES, EPA estimated the number of release days using data from GSs, ESDs, or Specific Emission Release Category (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 DINP-specific facility operations, release days may be under or overestimated.
- **Uncertainties Associated with DINP-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 DINP concentrations for products in the OES. However, the extent to which these products represent all DINP-containing products within the OES is uncertain. For OES with little-to-no product data, EPA estimated DINP concentrations from GSs or ESDs. Due to these uncertainties, the average product concentrations may be under or overestimated.

3.3 Summary of Concentrations of DINP in the Environment

Based off the environmental release assessment summarized in Section 3.2 and presented in EPA's *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s), DINP 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). Given the physical chemical properties and fate parameters of DINP (Section 2), concentrations of DINP in soil and groundwater from releases to biosolids and landfills were not quantified. Instead, DINP 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 *Draft Fate Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024t) and its use for determining pathways to assess are detailed in *Draft Environmental Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024o). Briefly, based on DINP's fate parameters, EPA anticipated DINP to be expected predominantly in water, soil, and sediment, with DINP in soils attributable to air to soil deposition and land application of biosolids. Therefore, EPA quantitatively assessed concentrations of DINP 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 DINP was not assumed to be persistent in the air ($t_{1/2}$ = 5.36 to 8.5 hours (U.S. EPA, 2017; Lertsirisopon et al., 2009)) and partitioning analysis showed DINP partitions primarily to soil, compared to air, water, and sediment, even in air releases. Soil concentration of DINP from land applications were not quantitatively assessed in the screening level analysis as DINP 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 *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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 DINP 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 DINP exposure based on the fate properties of DINP, 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 paired with conservative assumption of environmental conditions resulted in the greatest modeled concentration of DINP in a given environmental media type. Therefore, EPA did not estimate environmental concentrations of DINP resulting from all OES presented in Table 3-1. The OES resulting in the highest environmental concentration of DINP varied by environmental media as shown in Table 3-6.

High-end concentration of DINP 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 *Draft Environmental Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024o) and for general population exposure described in EPA's *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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 DINP estimated in different environmental media based on releases to the environment from various OES associated with COUs. This means that the Manufacturing OES yielded the highest water concentrations using a 7Q10 flow (the lowest 7-day average flow that occurs [on average] once every 10 years) while the Use of lubricants and functional fluids OES yielded the highest water concentration using a 30Q5 flow (the lowest 30-day average flow that occurs [on average] once every 5 years) compared to any other OES. The Non-PVC plastic compounding OES yielded the highest soil concentration from air to soil deposition. 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 (Manufacturing), 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 DINP Concentrations in Various Environmental Media from Environmental Releases

OES [a]	Release Media	Environmental Media	DINP Concentration	Environmental or General Population
Manufacturing	Water	Total Water Column (7Q10)	24,000 µg/L	Environmental
		Benthic Pore Water (7Q10)	10,100 µg/L	Environmental
		Benthic Sediment (7Q10)	126,000 mg/kg	Environmental
Use of lubricants and functional fluids	Water	Surface Water (30Q5)	9,350 µg/L	General Population
		Surface Water (Harmonic Mean)	8,100 µg/L	General Population
Non-PVC plastic compounding	Fugitive Air	Soil (Air to Soil Deposition 100 m)	1,460 µg/kg	General Population
		Soil (Air to Soil Deposition 1,000 m)	40 µg/kg	Environmental

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

3.3.1 Weight of Scientific Evidence Conclusions

Detailed discussion of the strengths, limitations, and sources of uncertainty for modeled environmental media concentration leading to a weight of scientific evidence conclusion can be found in EPA's *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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 DINP to surface waters, releases were modeled, and the high-end estimate for each COU was applied for surface water modeling. Additionally, due to a lack of 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 flow rates selected from the generated distributions coupled with high-end (95th percentile) release scenarios, resulted in moderate modeled concentrations. EPA has moderate confidence in the modeled concentrations as being representative of actual releases, with a slight bias toward over-estimation, but robust confidence that no surface water release scenarios exceed the 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.

The high-end modeled concentrations in the surface water and sediment identified through systematic review exceeded the highest values available from monitoring studies by more than three orders of magnitude. This confirms EPA's expectation that modeled concentrations presented here are biased toward overestimation, to be applied as a screening-level evaluation for use in environmental and general population exposure assessment.

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 *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (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

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

EPA evaluated all reasonably available information to support human health risk characterization of DINP 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 COU (Section 4.1.1). However, the primary route of exposure was inhalation.
- EPA assessed inhalation, dermal, and oral exposures for consumers and bystanders, as appropriate, for each COU (Section 4.1.2) in scenarios that represent a range of use patterns and behaviors. The primary route of exposure was inhalation.
- EPA assessed oral and dermal exposures for the general population, as appropriate, via surface water, drinking water, soil, and fish ingestion for tribal populations and determined that all exposures assessed for the general population were not of concern (Sections 4.1.30 and 4.3.4). EPA did not assess inhalation exposure to DINP from ambient air for the general population because ambient air is not expected to be a pathway of concern for DINP. This is because DINP is not persistent in the air and rapidly partitions to sediment, soil, and surface water.

Hazard Key Points

- EPA identified liver and developmental toxicity as the most sensitive and robust non-cancer hazards associated with oral exposure to DINP in experimental animal models (Section 4.2).
- A non-cancer POD of 12 mg/kg-day was selected to characterize non-cancer risks for acute and intermediate durations of exposure. A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure.
- A non-cancer POD of 3.5 mg/kg-day was selected to characterize non-cancer risks for chronic durations of exposure. A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure.
- DINP has been shown to cause liver cancer in experimental studies of rats and mice; however, liver cancer in rodents occurred at higher doses than observed for other non-cancer effects on the liver and the developing male reproductive system. Therefore, evaluating and protecting human health from non-cancer risks associated with exposure to DINP will also be protective of cancer effects.

Risk Assessment Key Points

- Dermal and ingestion exposures were not a risk driver for any duration of exposure or population.
- Inhalation exposures drive acute, intermediate, and chronic non-cancer risks to workers in occupational settings (Section 4.3.2).
- Inhalation exposures drive chronic 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).

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 Diisononyl Phthalate (DINP)* (U.S. EPA, 2021c), EPA evaluated exposures to workers and ONUs via the inhalation route, including incidental ingestion of inhaled dust, and exposures to workers via the dermal route associated with the manufacturing, processing, use, and disposal of DINP. Also, EPA assessed dermal exposure to workers and ONUs from mist and dust deposited on surfaces. The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) provides additional details on the development of approaches and the exposure assessment results.

4.1.1.1 Approach and Methodology

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

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

Where monitoring data was reasonably available, EPA used this data to characterize central tendency and high-end inhalation exposures (see also Figure 4-1). Where no inhalation monitoring data was 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, EPA used the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR) (U.S. EPA, 2021e). In all cases of occupational dermal exposure to DINP, EPA used a flux-limited dermal absorption model to estimate both high-end and central tendency dermal exposures for workers in each OES, as described in the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s).

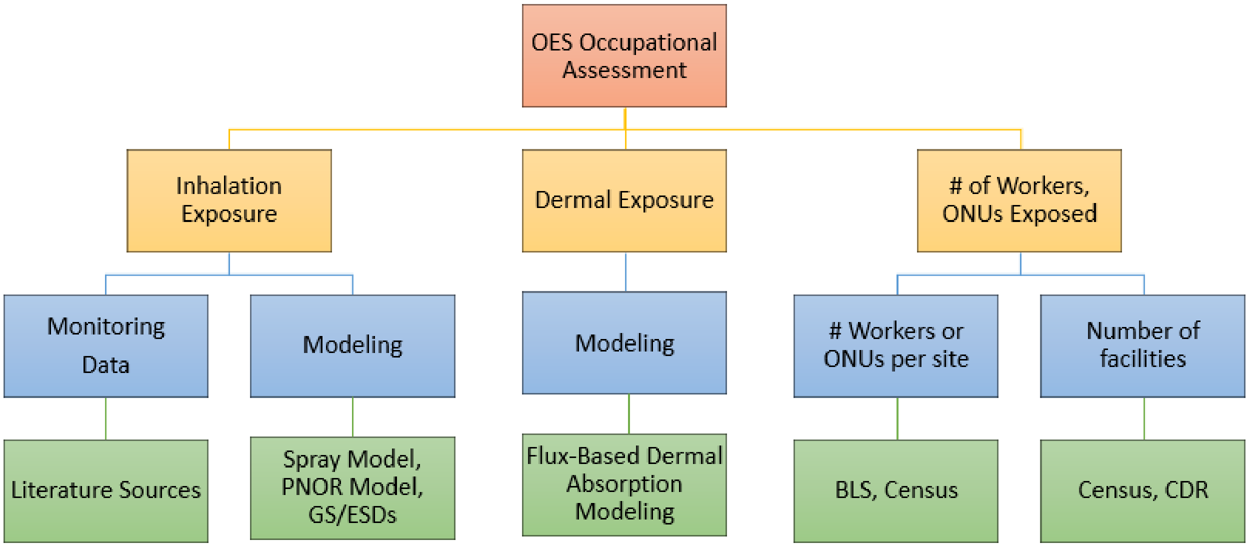


Figure 4.1 Approaches Used for Each Component of the Occupational Assessment for Each OES[a]
CDR = Chemical Data Reporting; GS = generic scenario; ESD = emission scenario document; BLS = Bureau of Labor Statistics; PNOR = particulates not otherwise regulated

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

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

OES	Inhalation Exposure									Dermal Exposure			
	Monitoring					Modeling		Weight of Scientific Evidence Conclusion		Modeling		Weight of Scientific Evidence Conclusion	
	Worker	# Data Points	ONU	# Data Points	Data Quality Ratings	Worker	ONU	Worker	ONU	Worker	ONU	Worker	ONU
Manufacturing	✓	12	✓	1	High	✗	✗	Moderate to Robust	Moderate	✓	✗	Moderate	N/A
Import/ repackaging	✓	12 [a]	✓	1 [a]	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
Incorporation into adhesives and sealants	✓	2 [b]	✓	1 [b]	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
Incorporation into paints and coatings	✓	2 [b]	✓	1 [b]	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	✓	2 [b]	✓	1 [b]	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A
PVC plastics compounding	✓	2	✓	1	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
PVC plastics converting	✓	2	✓	1	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Non-PVC material compounding	✓	2 [b]	✓	1 [b]	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Non-PVC material converting	✓	2 [b]	✓	1 [b]	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Application of adhesives and sealants	✗	N/A	✗	N/A	N/A	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Application of paints and coatings	✗	N/A	✗	N/A	N/A	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Use of laboratory chemicals	✓	12 [a]	✓	1 [a]	High	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Use of lubricants	✓	12 [a]	✓	1	High	✗	✗	Moderate	Moderate	✓	✗	Moderate	N/A

OES	Inhalation Exposure									Dermal Exposure			
	Monitoring					Modeling		Weight of Scientific Evidence Conclusion		Modeling		Weight of Scientific Evidence Conclusion	
	Worker	# Data Points	ONU	# Data Points	Data Quality Ratings	Worker	ONU	Worker	ONU	Worker	ONU	Worker	ONU
and functional fluids													
Fabrication and final use of products or articles	✗	N/A	✗	N/A	N/A	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate
Recycling and disposal	✗	N/A	✗	N/A	N/A	✓	✓	Moderate	Moderate	✓	✓	Moderate	Moderate

[a] Inhalation monitoring data for exposure to vapors from the Manufacturing OES were used as surrogate data for OES where inhalation exposure comes from vapor generating-activities only.
[b] Inhalation monitoring data for exposure to vapors from the PVC Plastics compounding/converting OES were used as surrogate data for OES where inhalation exposure to vapor may occur during the heating and cooling plastic and non-plastic polymer materials.

4.1.1.2 Summary of Number of Workers and ONUs

The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (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 DINP, the total number of workers and ONUs potentially exposed to DINP for each OES were estimated. The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) provides additional details on the approach and methodology for estimating the number of facilities using DINP and the number of potentially exposed workers and ONUs.

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

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

OES	Total Exposed Workers[a]	Total Exposed ONUs	Number of Facilities[a]	Notes
Manufacturing	116–258	53–118	3–6	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Import/repackaging	32–35	11–12	29–32	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Incorporation into adhesives and sealants	425–1,672	187–736	15–59	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Incorporation into paints and coatings	72–415	21–119	4–23	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	22–153	10–71	1–7	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
PVC plastics compounding	3,022–5,907	1,328–2,595	110–215	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).

OES	Total Exposed Workers[a]	Total Exposed ONUs	Number of Facilities[a]	Notes
PVC plastics converting	43,777–85,536	12,389–24,206	2,386–4,662	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Non-PVC material compounding	74–132	13–23	5–9	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Non-PVC material converting	1,793–2,793	307–477	122–190	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Application of adhesives and sealants	18,576–128,306	5,885–40,646	345–2,383	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Application of paints and coatings	1,790–9,817	915–5,016	145–795	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Use of laboratory chemicals (liquid)	564–4,724	5,070–42,499	586–4,912	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Use of laboratory chemicals (solid)	35,463	319,026	36,873	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Use of lubricants and functional fluids	617,370–4,271,378	151,950–1,051,294	7,033–48,659	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
Fabrication and final use of products or articles	N/A			Number of sites data was unavailable for this OES.
Recycling and disposal	377	216	58	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2016; U.S. Census Bureau, 2015).
[a] EPA's approach and methodology for estimating the number of facilities using DINP and the number of workers and ONUs potentially exposed to DINP can be found in the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s)				

4.1.1.3 Summary of Inhalation Exposure Assessment

Table 4-3 presents a summary of inhalation exposure results based on monitoring data and exposure modeling for each OES. This tables provides a summary of the 8 and 10-hour time weighted average (8 or 10-hour TWA) inhalation exposure estimates, as well as the acute dose (AD), the intermediate average daily dose (IADD), and the chronic average daily dose (ADD). The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) provides exposure results for females of reproductive age and ONUs. The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (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.

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

OES	Inhalation Estimates (Average Adult Worker)									
	Vapor/Mist 8-hr or [10-hr] TWA (mg/m³)		PNOR 8-hr TWA (mg/m³)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	HE	**CT**	**HE**	**CT**	**HE**	**CT**	**HE**	**CT**	**HE**	**CT**
Manufacturing	6.9E−02	3.5E−02	–	–	8.6E−03	4.3E−03	6.3E−03	3.2E−03	4.3E−03	2.1E−03
Import/repackaging	6.9E−02	3.5E−02	–	–	8.6E−03	4.3E−03	6.3E−03	3.2E−03	5.9E−03	2.5E−03
Incorporation into adhesives and sealants	[5.0E−04]	[2.5E−04]	–	–	7.8E−05	3.9E−05	5.7E−05	2.9E−05	5.4E−05	2.7E−05
Incorporation into paints and coatings	[5.0E−04]	[2.5E−04]	–	–	7.8E−05	3.9E−05	5.7E−05	2.9E−05	5.4E−05	2.7E−05
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	[5.0E−04]	[2.5E−04]	–	–	7.8E−05	3.9E−05	5.7E−05	2.9E−05	5.4E−05	2.7E−05
PVC plastics compounding	[5.0E−04]	[2.5E−04]	2.1	0.10	0.26	1.3E−02	0.19	9.5E−03	0.18	7.9E−03
PVC plastics converting	[5.0E−04]	[2.5E−04]	2.1	0.10	0.26	1.3E−02	0.19	9.5E−03	0.18	7.8E−03
Non-PVC material compounding	[5.0E−04]	[2.5E−04]	1.9	9.2E−02	0.24	1.2E−02	0.17	8.5E−03	0.16	7.4E−03
Non-PVC material converting	[5.0E−04]	[2.5E−04]	1.9	9.2E−02	0.24	1.2E−02	0.17	8.5E−03	0.16	6.9E−03
Application of adhesives and sealants – spray application	18	1.4	–	–	2.2	0.17	1.6	0.12	1.5	0.11
Application of adhesives and sealants – non-spray application	[5.0E−04]	[2.5E−04]	–	–	7.8E−05	3.9E−05	5.7E−05	2.9E−05	5.4E−05	2.5E−05
Application of paints and coatings – spray application	8.8	0.68	–	–	1.1	8.4E−02	0.81	6.2E−02	0.76	5.8E−02
Application of paints and coatings – non-spray application	[5.0E−04]	[2.5E−04]	–	–	7.8E−05	3.9E−05	5.7E−05	2.9E−05	5.4E−05	2.7E−05
Use of laboratory chemicals – liquid	6.9E−02	3.5E−02	–	–	8.6E−03	4.3E−03	6.3E−03	3.2E−03	5.9E−03	2.8E−03
Use of laboratory chemicals – solid	–	–	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	6.9E−02	3.5E−02	–	–	8.6E−03	4.3E−03	1.2E−03	2.9E−04	9.5E−05	2.4E−05
Fabrication and final use of products or articles	–	–	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	–	–	1.6	0.11	0.20	1.4E−02	0.14	9.9E−03	0.13	8.2E−03

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 table provides a summary of the Acute Potential Dose Rate (APDR) for occupational dermal exposure estimates, as well as the AD, IADD, and Chronic ADD. The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) provides exposure results for females of reproductive age and ONUs. The *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* also provides additional details regarding AD, IADD, and ADD calculations along with EPA's approach and methodology for estimating dermal exposures.

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

OES	Dermal Estimates (Average Adult Worker)									
	Exposure Type		APDR (mg/day)		AD (mg/kg/day)		IADD (mg/kg/day)		ADD (mg/kg/day)	
	Liquid	Solid	HE	CT	HE	CT	HE	CT	HE	CT
Manufacturing	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	7.7E−02	3.8E−02
Import/repackaging	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	4.4E−02
Incorporation into adhesives and sealants	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.3E−02
Incorporation into paints and coatings	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.3E−02
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.3E−02
PVC plastics compounding	X	X	12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	4.8E−02
PVC plastics converting		X	4.9E−02	2.5E−02	6.2E−04	3.1E−04	4.5E−04	2.3E−04	4.2E−04	1.8E−04
Non-PVC material compounding	X	X	12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.0E−02
Non-PVC material converting		X	4.9E−02	2.5E−02	6.2E−04	3.1E−04	4.5E−04	2.3E−04	4.2E−04	1.8E−04
Application of adhesives and sealants – spray & non-spray applications	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.0E−02
Application of paints and coatings – spray & non-spray applications	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.3E−02
Use of laboratory chemicals – liquid	X		12	6.2	0.16	7.8E−02	0.11	5.7E−02	0.11	5.0E−02
Use of laboratory chemicals – solid		X	4.9E−02	2.5E−02	6.2E−04	3.1E−04	4.5E−04	2.3E−04	4.2E−04	2.1E−04
Use of lubricants and functional fluids	X		12	6.2	0.16	7.8E−02	2.1E−02	5.2E−03	1.7E−03	4.3E−04
Fabrication and final use of products or articles		X	4.9E−02	2.5E−02	6.2E−04	3.1E−04	4.5E−04	2.3E−04	4.2E−04	2.1E−04
Recycling and disposal		X	4.9E−02	2.5E−02	6.2E−04	3.1E−04	4.5E−04	2.3E−04	4.2E−04	1.9E−04

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 and 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 2021 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 worker activities or potential exposures. A conclusion of slight weight of scientific evidence is appropriate where there is limited information that does not sufficiently cover all potential exposures within the COU, and the assumptions and uncertainties are not fully known or documented. See the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021a) for additional information on weight of scientific evidence conclusions. Table 4-5 provides a summary of EPA's overall confidence in its occupational exposure estimates for each of the OESs assessed.

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OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
Manufacturing	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the full-shift TWA inhalation exposure estimates for the Manufacturing OES. The primary strength is the use of personal breathing zone (PBZ) directly applicable 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 DINP-specific from a DINP 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 DINP campaign runs (ExxonMobil, 2022b); 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 monitoring data from a DINP manufacturing facility to estimate worker inhalation exposures due to limited data available for import and repackaging inhalation exposures. 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 DINP-specific from a DINP 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. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DINP 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 adhesives and sealants	EPA used surrogate monitoring data from a PVC converting facility to estimate worker inhalation exposures due to limited data. 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 compiled PBZ concentration data from one study to assess inhalation exposures. Worker and ONU PBZ data are for oil mist exposures to DINP at a PVC roofing manufacturing site (Irwin, 2022). The data source has a high data quality rating from the systematic

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	review process. The primary limitation of this data include the uncertainty of the representativeness of the monitoring data, as the data are specific to a PVC plastic converting facility, and it is uncertain whether the measured concentrations accurately represent the incorporation into adhesives and sealants. Another limitation is that the data comes from a singular source, and that the data for both workers and ONUs were reported as below the LOD. Monitoring data points were based on a 10-hour TWA with annual exposure of 200 days/year (Irwin, 2022); it is uncertain whether this captures actual worker schedules and exposures for the entire industry. 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 monitoring data from a PVC converting facility to estimate worker inhalation exposures due to limited data. 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 compiled PBZ concentration data from one study to assess inhalation exposures. Worker and ONU PBZ data are for oil mist exposures to DINP at a PVC roofing manufacturing site (Irwin, 2022). The data source has a high data quality rating from the systematic review process. The primary limitation of this data include the uncertainty of the representativeness of the monitoring data, as the data are specific to a PVC plastic converting facility, and it is uncertain whether the measured concentrations accurately represent the incorporation into paints and coatings. Another limitation is that the data comes from a singular source and that the majority of the data for both workers and ONUs were reported as below the LOD. Monitoring data points were based on a 10-hour TWA with annual exposure of 200 days/year (Irwin, 2022); it is uncertain whether this captures actual worker schedules and exposures for the entire industry. Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	EPA used surrogate monitoring data from a PVC converting facility to estimate worker inhalation exposures due to limited data. 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 compiled PBZ concentration data from one study to assess inhalation exposures. Worker and ONU PBZ data are for oil mist exposures to DINP at a PVC roofing manufacturing site (Irwin, 2022). The data source has a high data quality rating from the systematic review process. The primary limitation of this data include the uncertainty of the representativeness of the monitoring data, as the data are specific to a PVC plastic converting facility, and it is uncertain whether the measured concentrations accurately represent the incorporation into other formulations, mixtures, and reaction products not covered elsewhere. Another limitation is that the data comes from a singular source and that the majority of the data for both workers and ONUs were reported as below the LOD. Monitoring data points were based on a 10-hour TWA with annual exposure of 200 days/year (Irwin, 2022); it is uncertain whether this captures actual worker schedules and exposures for the entire industry.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
PVC plastics compounding	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for PVC plastics compounding. EPA used monitoring data from a single combined plastics compounding and converting site to estimate worker inhalation exposures to vapor. This source provided both worker and ONU exposures (Irwin, 2022). The primary strength of this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches, such as modeling or the use of OELs. Additionally, the data is also well characterized and the study sampled a variety of work areas and has a high data quality rating from the systematic review process. EPA also expects compounding activities to generate dust from solid PVC plastic products; therefore, EPA incorporated the Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR*)* (U.S. EPA, 2021e) into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA Chemical Exposure Health Data (CEHD) datasets, which EPA tailored to the plastics industry and the resulting dataset contains 237 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in plastic using industry provided data on DINP concentration in PVC plastic. These data were also rated high for data quality in the systematic review process. The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just two datapoints for workers and one for ONUs and 100% of the datapoints were reported as below the LOD. The OSHA CEHD dataset used in the PNOR model is not specific to DINP. Finally, EPA also assumed 8 exposure hours per day and 223–250 exposure days per year based on continuous DINP exposure during each working day for a typical worker schedule with the exposure day representing the 50th-95th percentile. It is uncertain whether this assumption 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 converting	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for PVC plastics converting. EPA used monitoring data from a single combined plastics compounding and converting site to estimate worker inhalation exposures to vapor. This source provided both worker and ONU exposures (Irwin, 2022). The primary strength is this approach is that it uses monitoring data specific to this OES, which is preferrable to other assessment approaches such as modeling or the use of OELs. Additionally, the study data is well characterized, sampled from a variety of work areas, and has a high data quality rating from the systematic review process. EPA also expects converting activities to generate dust from solid PVC plastic products; therefore, EPA incorporated the PNOR model into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the plastics industry and the resulting dataset contains 237 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in plastic using industry provided data on DINP concentration in PVC plastic. These data were also rated high for data quality in the systematic review process.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just two datapoints for workers and one for ONUs and 100% of the datapoints were reported as below the LOD. The OSHA CEHD dataset used in the PNOR model is not specific to DINP. Finally, EPA also assumed 8 exposure hours per day and 219–250 exposure days per year based on continuous DINP exposure during each working day for a typical worker schedule with the exposure days representing the 50th-95th percentile. It is uncertain whether this assumption 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 used surrogate monitoring data from a PVC converting facility to estimate worker inhalation exposures to vapor and PNOR model to estimate worker inhalation exposures to particulates. Non-PVC material compounding vapor inhalation exposures were estimated using study data from a single combined plastics compounding and converting site. The source provided worker and ONU exposures to vapor/mist and only worker exposures to dust (Irwin, 2022). The primary strength is the use of monitoring data for a similar OES, which are preferrable to other assessment approaches such as modeling or the use of OELs. Additionally, the data is also well characterized and the study sampled a variety of work areas and has a high data quality rating from the systematic review process. EPA also expects compounding activities to generate dust from solid PVC plastic products; therefore, EPA incorporated the PNOR model into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the plastics industry and the resulting dataset contains 237 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in plastic using industry provided data on DINP concentration in PVC plastic. These data were also rated high for data quality in the systematic review process. The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just two datapoints for workers and one for ONUs and 100% of the datapoints were reported as below the LOD. The OSHA CEHD dataset used in the PNOR model is not specific to DINP. Finally, EPA also assumed 8 exposure hours per day and 234–250 exposure days per year based on continuous DINP exposure during each working day for a typical worker schedule with the exposure days representing the 50th-95th percentile of exposure. It is uncertain whether this assumption 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 used surrogate monitoring data from a PVC converting facility to estimate worker inhalation exposures to vapor and the PNOR model to estimate worker inhalation exposures to particulates. Non-PVC material converting vapor inhalation exposures were estimated using study data from a single combined plastics compounding and converting site. The source provided worker and ONU exposures to vapor/mist and only worker exposures to dust (Irwin, 2022). The primary strength is the use of monitoring data for a similar OES, which are preferrable to other assessment approaches such as modeling or the use of OELs. Additionally, the data is also well characterized and the study sampled a variety of work areas and has a high data quality rating from the systematic review process. EPA also expects compounding activities to generate dust from solid PVC plastic products; therefore, the PNOR model was use in the assessment to estimate

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the plastics industry and the resulting dataset contains 237 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in plastic using industry provided data on DINP concentration in PVC plastic. These data were also rated high for data quality in the systematic review process. The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just two datapoints for workers and one for ONUs and 100% of the datapoints were reported as below the LOD. The OSHA CEHD dataset used in the PNOR model is not specific to DINP. Finally, EPA also assumed 8 exposure hours per day and 219–250 exposure days per year based on continuous DINP exposure during each working day for a typical worker schedule with the exposure days representing the 50th-95th percentile of exposure. It is uncertain whether this assumption 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.
Application of adhesives and sealants	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 (OECD, 2011a), which the systematic review process rated high for data quality. For inhalation exposure from non-spray application, EPA estimated vapor inhalation exposures using DINP monitoring data from PVC compounding and converting (Irwin, 2022), which the systematic review process rated high for data quality. EPA used SDSs and product data sheets from identified DINP-containing adhesives and sealant products to identify product concentrations. The primary limitation is the lack of DINP-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 DINP. For the non-spray application scenario, vapor exposure from volatilization is estimated using DINP-specific data, but for a different scenario which imposes uncertainty. EPA only assessed mist exposures to DINP 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 a high end of 232-250 days of exposure per year based on workers applying coatings on every working day, however, application sites may use DINP-containing coatings at much lower or variable frequencies. The exposure days represent the 50th-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	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 (OECD, 2011a), which the systematic review process rated high for data quality. For inhalation exposure from non-spray application, EPA estimated vapor inhalation exposures using DINP monitoring data from PVC compounding and converting (Irwin, 2022), which the systematic review process rated high for data quality. EPA used SDSs and product

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	data sheets from identified DINP-containing products to identify product concentrations. The primary limitation is the lack of DINP-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 DINP. For the non-spray application scenario, vapor exposure from volatilization is estimated using DINP-specific data, but for a different scenario which imposes uncertainty. EPA only assessed mist exposures to DINP over a full 8-hour work shift to estimate the level of exposure, though other activities may result in vapor exposures other than mist and application duration may be variable depending on the job site. EPA assessed 250 days of exposure per year based on workers applying coatings on every working day, however, application sites may use DINP-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 monitoring data from a DINP manufacturing facility to estimate worker vapor inhalation exposures, and the PNOR model was used to characterize worker particulate inhalation exposures. 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). EPA incorporated the PNOR model into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the plastics industry and the resulting dataset contains 33 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in identified DINP-containing products applicable to this OES. These data were also rated high for data quality in the systematic review process. The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR model in capturing the true distribution of inhalation concentrations for this OES; that the vapor monitoring 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; and that the OSHA CEHD dataset used in the PNOR model is not specific to DINP. EPA also assumed 8 exposure hours per day and 235–250 exposure days per year based on continuous DINP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. The exposure days represent the 50th-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.
Use of lubricants and functional fluids	EPA used surrogate monitoring data from a DINP manufacturing facility to estimate worker inhalation exposures due to limited data. 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 this source are DINP-specific and from a DINP manufacturing facility.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	The primary limitations of these data include the uncertainty of the representativeness of these data toward this OES and the true distribution of inhalation concentrations in this scenario; 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 2 to 4 exposure days per year based on a typical equipment maintenance 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
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 PNOR model to estimate worker inhalation exposure to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the plastics industry and the resulting dataset contains 272 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in plastic using industry provided data on DINP concentration in PVC plastic. These data 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 dataset and the identified DINP concentrations in plastics for this specific fabrication and final use of products or articles is uncertain. EPA lacks facility and DINP-containing product fabrication and use rates, methods, and operating times and EPA assumed 8 exposure hours per day and 250 exposure days per year based on continuous DINP 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.
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 PNOR model to estimate worker inhalation exposure to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the plastics industry and the resulting dataset contains 130 discrete sample data points. The systematic review process rated the source high for data quality (OSHA, 2020). EPA estimated the highest expected concentration of DINP in plastic using industry provided data on DINP concentration in PVC plastic. These data 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 dataset and the identified DINP concentrations in plastics for this specific fabrication and final use of products or articles is uncertain. EPA lacks facility and DINP-containing product fabrication and use rates, methods, and operating times and EPA assumed 8 exposure hours per day and 223–250 exposure days per year based on continuous DINP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. The exposure days represent the 50th-95th percentile range of exposure days per year.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides a plausible estimate of exposures.
Dermal – liquids	EPA used *in vivo* rat absorption data for neat DINP (Midwest Research Institute, 1983) 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 *in vivo* rat absorption data is considered 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 DINP 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 DINP from occupational dermal contact with materials containing DINP may extend up to 8 hours per day (U.S. EPA, 1991b). For average adult workers, the surface area of contact was assumed equal to the area of one hand (*i.e.*, 535 cm^2), or two hands (*i.e.*, 1,070cm^2), 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 DINP 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.
Dermal – solids	EPA used dermal modeling of aqueous materials (U.S. EPA, 2023a, 2004a) to estimate occupational dermal exposures of workers and ONUs to solid materials. However, the modeling approach for determining the aqueous permeability coefficient was used outside the range of applicability given the p-chem parameters of DINP. Also, it is acknowledged that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. To provide the most human health protective assessment, EPA utilized the maximum aqueous solubility value identified through systematic review (NLM, 2015; Howard et al., 1985). These sources of aqueous solubility received high ratings through EPA's systematic review process. Therefore, it is assumed that absorption of aqueous DINP serves as a reasonable upper bound for the dermal absorption of DINP from solid matrices, and the modeling approach 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 DINP 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 DINP from occupational dermal contact with materials containing DINP may extend up to 8 hours per day (U.S. EPA, 1991b). For average adult workers, the surface area of contact was assumed equal to the area of one hand (*i.e.*, 535 cm^2), or two hands (*i.e.*, 1,070cm^2), 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.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	The occupational dermal exposure assessment for contact with solid materials containing DINP was based on dermal absorption modeling of aqueous DINP with the maximum value for aqueous solubility identified through systematic review, 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 but protective 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 high, medium, or low to the exposure assessments, based on the strength of the underlying scientific evidence. When the assessment is supported by robust evidence, EPA's overall confidence in the exposure assessment is high; when supported by moderate evidence, EPA's overall confidence is medium; when supported by slight evidence, EPA's overall confidence is low.

Strengths

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

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

Limitations

The principal limitation of the inhalation monitoring data is uncertainty in the representativeness of the data, as there is limited exposure monitoring data in the literature for some scenarios. Additionally, differences in work practices and engineering controls across sites can introduce variability and limit the representativeness of the monitoring data. The 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 DINP 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." These categorizations are based on descriptions of worker job activity provided in the 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 ADD values assuming 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 DINP, and the actual ADD 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 and applying statistical distributions that mathematically define the parameter's variability. EPA defined statistical distributions for parameters using documented statistical variations where available. Where the statistical variation was unknown, EPA made assumptions to estimate the parameter distribution using available literature data, such as GSs and ESDs. However, there is uncertainty as to the representativeness of the parameter distributions because these data are often not specific to sites that use DINP. 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 DINP. First, BLS' 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 DINP for the assessed applications. EPA addressed this issue by refining the OES estimates using total employment data from the U.S. Census' 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 DINP exposure differs from the overall distribution of workers in each NAICS, then this approach will result in inaccuracy.

4.1.2 Consumer Exposures

The following subsections briefly describe EPA's approach to assessing consumer exposures and provide exposure assessment results for each COU. The *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l) 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 Summary of Consumer and Indoor Dust Exposure Scenarios and Modeling Approach and Methodology

Consumer products or articles containing DINP 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, roughly larger than 1 m^2.

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 Consumer Exposure Model (CEM) Version 3.2 (U.S. EPA, 2023a) and dermal exposures were done using a computational framework implemented within a spreadsheet environment. For each exposure route, EPA used the 10th percentile, average, and 95th percentile value of an input parameter (*e.g.,* weight fraction, surface area and others) where possible to characterize low, medium, and high exposure for a given condition of use. Should only a range be reported as the minimum, average, and maximum EPA used these for the low, medium, and high, respectively. See *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l) for details about the consumer modeling approaches, sources of data, model parameterization, and assumptions.

Exposure via the inhalation route occurs from inhalation of DINP gas-phase emissions or when DINP 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) in which the person can ingest settled dust with DINP or directly ingest DINP from the product. Additionally, ingestion of suspended dust can occur when DINP migrates from product to dust or partitions from gas-phase to suspended dust.

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

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

EPA assessed acute, intermediate, and chronic exposures to DINP from consumer COUs. For the acute dose rate calculations, an averaging time of 1 day is used representing the maximum time-integrated dose over a 24-hour period during the exposure event. The chronic dose rate is calculated iteratively at a 30-second interval during the first 24 hours and every hour after that for 60 days. Intermediate dose is the exposure to continuous or intermittent (depending on product) use during a 30-day period, which is roughly a month. Professional judgment and product use descriptions were used to estimate events per day and per month/year for the calculation of the intermediate/chronic dose.

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

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					
				Inhalation	Dermal	Ingestion			Qualitative / Quantitative / None
						Suspended Dust	Settled Dust	Mouthing	
Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Car mats	Direct contact during use. See routine contact scenario inhalation of emissions / ingestion of dust adsorbed chemical	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants	Adhesive foam	Use of product in DIY [c] large-scale home repair activities. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants	Adhesives for small repairs	Use of product in DIY [c] small-scale home repair activities. Direct contact during use	✗	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants	Automotive adhesives	Use of product in DIY [c] small-scale auto repair. Direct contact during use; inhalation of emissions	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants	Caulking compounds	Use of product in DIY [c] home repair activities. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Adhesives and sealants	Polyurethane injection resin	Use of product in DIY [c] home repair activities. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative

Consumer Condition of Use Category	**Consumer Condition of Use Subcategory**	**Product/Article**	**Exposure Scenario and Route**	**Evaluated Routes**					
Construction, paint, electrical, and metal products	Adhesives and sealants	Roofing adhesives	Use of product in DIY [c] home repair. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)	Roofing membranes (also fabrics and film)	Direct contact while repairing or maintenance	✗ [c]	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)	Electrical tape, spline	Direct contact during application.	✗	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Electrical and Electronic Products	Wire insulation	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical, mouthing by children	✓ [a]	✓	✓ [a]	✓ [a]	✓	Quantitative
Construction, paint, electrical, and metal products	Paints and coatings	Lacquer sealer spray (large project)	Application of product in house via spray. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Construction, paint, electrical, and metal products	Paints and coatings	Paint and lacquer spray (small project)	Application of product in house via spray. Direct contact during use; inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)	Foam cushions	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	✓ [a]	✓	✓ [a]	✓ [a]	✗	Quantitative

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					
Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)	Indoor furniture	Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	✓[a]	✓	✓[a]	✓[a]	✓	Quantitative
Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)	Outdoor furniture	Direct contact during use	✗[c]	✓	✗	✗	✗	Quantitative
Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)	Truck awning	Direct contact during use	✗[c]	✓	✗	✗	✗	Quantitative
Furnishing, cleaning, treatment/care products	Floor coverings/ plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Carpet backing tiles	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative
Furnishing, cleaning, treatment/care products	Floor coverings/ plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel (vinyl	Solid (resilient) vinyl flooring tiles	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					
	tiles, resilient flooring, PVC-backed carpeting)								
Furnishing, cleaning, treatment/care products	Floor coverings/ plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Specialty wall coverings	Direct contact during installation (teenagers and adults) and while in place; inhalation of emissions / ingestion of dust adsorbed chemical	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative
Furnishing, cleaning, treatment/care products	Floor coverings/ plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Wallpaper	Direct contact during installation (teenagers and adults) and while in place; inhalation of emissions / ingestion of dust adsorbed chemical	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative
Furnishing, cleaning, treatment/care products	Air care products	Oil fragrances (making homemade product)	Direct dermal while DIY project (making of a product)	✓	✓	✗	✗	✗	Quantitative
Furnishing, cleaning, treatment/care products	Fabric, textile, and leather products (apparel and footwear care products)	Clothing	Direct contact during use	✗[b]	✓	✗	✗	✗	Quantitative
Furnishing, cleaning, treatment/care products	Fabric, textile, and leather products (apparel and footwear care products)	Footwear, steering wheel covers, bags	Direct contact during use	✗[b]	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Rubber eraser	Direct contact during use; rubber particles may be inadvertently ingested during use. Eraser may be	✗[b]	✓	✗	✗	✓	Quantitative

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					
			mouthed by children						
Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Crafting resin	Direct contact and inhalation of emissions during use	✓	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Hobby cutting board	Direct contact during use	✗	✓	✗	✗	✗	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 paints (small projects) because similar use patterns are expected.	See lacquers, and paints (small and large projects)					
Packaging, paper, plastic, hobby products	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses	Shower curtain	Direct contact during use. See routine contact scenario inhalation of emissions / ingestion of dust adsorbed chemical while hanging in place	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative
Packaging, paper, plastic, hobby products	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses	Work gloves, pet chewy toys, garden hose, cell phone cover, tarpaulin	Direct contact during use.	✗	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)	PVC soap packaging	Direct contact during use.	✗	✓	✗	✗	✗	Quantitative
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Children's toys (legacy)	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne	✓[a]	✓	✓[a]	✓[a]	✓	Quantitative

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route	Evaluated Routes					
			particulate; ingestion by mouthing						
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Children's toys (new)	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne PM; ingestion by mouthing	✓[a]	✓	✓[a]	✓[a]	✓	Quantitative
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Sporting mats	Direct contact during use, inhalation of emissions / ingestion of dust adsorbed chemical while hanging in place	✓[a]	✓	✓[a]	✓[a]	✗	Quantitative
Other	Novelty products	Adult toys	Direct contact during use, ingestion by mouthing	✗[b]	✓	✗	✗	✓	Quantitative
Disposal	Disposal	Down the drain products and articles	Down the drain and releases to environmental media	✗	✗	✗	✗	✗	Qualitative
Disposal	Disposal	Residential end-of-life disposal, product demolition for disposal	Product and article end-of-life disposal and product demolition for disposal	✗	✗	✗	✗	✗	Qualitative

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

✓[a] Scenario used in Indoor Dust Exposure Assessment in Section 4.1.2.3. These indoor dust articles scenarios consider the surface area from multiple articles such as toys and wire insulation, while furniture, curtains, flooring, and wallpaper already have large surface areas in which dust can deposit and contribute to significantly larger concentration of dust than single small articles and products.

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

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

✗[c] Outdoor use with significantly higher ventilation minimizes inhalation.

DIY[c] – 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 in *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l). Calculations, sources, input parameters and results are also available in *Draft Consumer Exposure Analysis for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024m). 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 is included below:

- weight fraction (articles and products);
- density (articles and products);
- duration of use (products);
- frequency of use for chronic, acute, and intermediate (products);
- 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 DINP was estimated based on data compiled in a review published by the Denmark Environmental Protection Agency in 2016 (Danish EPA, 2016). 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^3 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 DINP in liquid and solid products and articles. See (U.S. EPA, 2024l) and (U.S. EPA, 2024m) for more details. The dermal dose of DINP associated with use of both liquid products and solid articles was calculated in a spreadsheet outside of CEM. See *Draft Consumer Exposure Analysis for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024m). 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 2.3 in (U.S. EPA, 2024l).

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 DINP in consumer products and articles. Detailed tables of the dose results for acute, intermediate, and chronic exposures are available in Section 4 of *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l) and *DINP Draft Consumer Risk Calculator* (U.S. EPA, 2024n).

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

Figure 4-1 to Figure 4-12 summarizes modeling results for the high, medium, and low acute dose rate (ADR) for dermal, ingestion, and inhalation 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, 2024l) narrative for each lifestage for data patterns and discussion. Only three product examples under the Construction, paint, electrical, and metal products Adhesives and Sealants COU were candidates (intermittent or consecutive monthly use) 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, less than 10 years, dermal exposure doses were higher followed by ingestion via mouthing, and inhalation. For teens and adults, dermal contact was a strong driver of exposure to DINP, with the dose received being generally higher (purple bars in figures) than to the dose received from exposure via inhalation or ingestion. 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 DINP 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 2 in (U.S. EPA, 2024l). 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.

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 DINP 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 bystanders; however the user scenarios utilize inputs that would result in larger exposure doses and thus the bystander scenarios would have lower risk estimates. Bystander scenarios and COUs include: (1) Construction, paint, electrical, and metal products; Adhesives and sealants and (2) Construction, paint, electrical, and metal products; Paints and coatings.

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, carpet backing, vinyl flooring tiles, indoor furniture, foam cushions, in-place wallpaper, specialty wall coverings, shower curtains, sporting mats, car mats, 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 DINP and subsequent inhalation and ingestion. All lifestages assessed under the indoor dust exposure scenarios are considered users of the articles being assessed.

Acute Dose Results for Infants, Toddlers, Preschoolers, and Middle Childhood (<10 Years)

Figure 4-1 show all exposure routes for infants less than a year old and toddlers 1 to 2 years old and Figure 4-2 show all exposure routes for preschoolers ages 3 to 5 and middle childhood children ages 6 to 10 years. Exposure patterns were very similar for products or articles and routes of exposure across these four lifestages. Ingestion route acute dose results in the figure show the sum of all ingestion scenarios, mouthing, suspended dust and surface dust. Inhalation exposure from toys, flooring, carpet backing, indoor furniture, cushions, wallpaper, shower curtains, and wire insulation include a consideration of dust collected on the surface, settled dust, of a relatively large area, like flooring and wallpaper, but also multiple toys and wires collecting dust with DINP and subsequent inhalation and ingestion.

Compared to all exposure routes inhalation is the highest dose per product and articles, except for new children's toys and wire insulation ingestion via mouthing. The highest ADR estimated for these lifestages was for inhalation of suspended dust exposure to carpet backing, children's toys, indoor furniture, wallpaper and coverings, vinyl flooring, sports mats, and wire insulation. Inhalation of DINP-contaminated dust is an important contributor to indoor exposures. Inhalation doses of adhesives and lacquers for this lifestages represent bystander exposures, which is a person in the proximity of someone else using such products. These products inhalation doses are overall lower than the articles used for indoor inhalation of suspended dust.

Ingestion of DINP has the overall second highest doses. For articles assessed for mouthing, such as toys, furniture, wire insulation, and rubber erasers exposure from mouthing is expected to have a larger impact in the overall ingestion dose. Mouthing tendencies decrease or cease entirely for children 6 to 10 years old. Ingestion of DINP via mouthing of legacy and new toy, have similar high-intensity use doses because the same chemical migration rates were used for all scenarios. However, it is noteworthy that the concentration of DINP in new toys is below the range of values used to derive the chemical migration rates and it is likely that the high-intensity use mouthing exposure estimates are not representative of actual doses that would be received from these items. Articles that were not assessed for mouthing were assessed for ingestion of settled and suspended dust, in which the settled dust exposures tend to be larger than ingestion from suspended dust, see Section 4.3 and Table 4-4 in (U.S. EPA, 2024l) for indoor settled dust ingestion exposure results.

The dermal ADR is the lowest dose in comparison to inhalation and ingestion per product and articles, except for cushions. The dermal assessment of cushions considered direct contact like that of furniture, which may be an overestimation. The ADR range is similar for shower curtains, flooring, wallpaper and specialty coverings, and wire insulation, because of similar contact patterns and frequencies, and from using the same dermal flux rates.

1545


1546 **Figure 4-1. Acute Dose Rate for DINP from Ingestion, Inhalation, Dermal Exposure Routes in**
1547 **Infants <1 Year Old and Toddlers 1 to 2 Years Old**

Figure 4-2. Acute Dose Rate of DINP from Ingestion, Inhalation, and Dermal Exposure Routes for Preschoolers 3 to 5 Years Old and Middle Childhood 6 to 10 Years Old

Young Teens, Teenagers, Young Adults, and Adults (11 to 21 Years and >21 Years)

Figure 4-3 show all exposure routes for young teens (11 to 15 years) and teenagers and young adults (16 to 20 years) combined. Figure 4-4 show all exposure routes for adults above 21 years old. Exposure patterns were very similar for all products and articles and routes of exposure in these four lifestages, except teenagers and young adults, 16 to 20, have added exposures to adult toys. The acute dose rate for some products/articles covers a larger range than others primarily due to a wider distribution of weight fraction values for those examples. Inhalation exposure as a bystander for these lifestages were not targeted for adhesives and lacquers for small projects. Young adults (16- to 20-year-old) can use these products in similar capacity as adults during DIY projects and as bystanders; hence this lifestage was modeled as a user of the product rather than a bystander. Users have higher doses when considering direct contact and use. Dermal exposure resulted in the highest doses overall, for DIY products such as adhesives, paints, lacquers, scented oils, except for paints for large projects in which inhalation exposure was higher likely because of the use of spray paints and the volatilization of the paint and subsequent inhalation of mist and droplets.

For articles considered in the indoor assessment inhalation and ingestion of suspended and settled dust doses were higher than dermal, which decreases significantly. Ingestion via mouthing is either not considered or significantly lower which is expected due to a decrease or ceased in mouthing behavior. Mouthing tendencies decrease significantly for theses lifestages; thus, most scenarios do not estimate exposure via mouthing. Mouthing is still an important exposure route for adult toys and teenagers and adults. Ingestion of settled dust is the only ingestion pathway for other products and articles other than adult toys, which suggests that indoor dust ingestion and inhalation are an important contributor to DINP exposures.

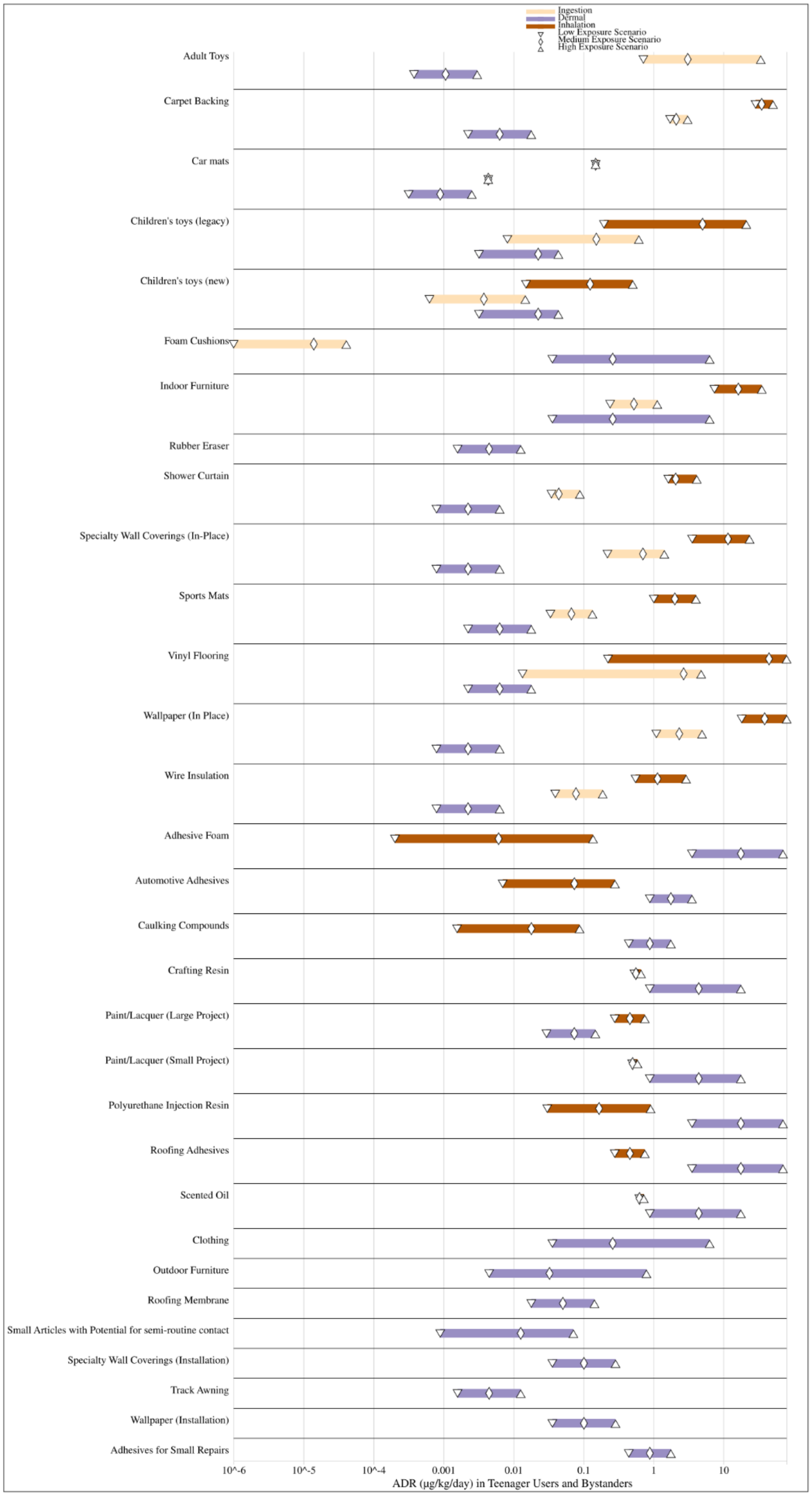


Figure 4-3. Acute Dose Rate of DINP from Ingestion, Inhalation, and Dermal Exposure Routes for Young Teens 11 to 15 Years Old and for Teenagers and Young Adults 16 to 20 Years Old

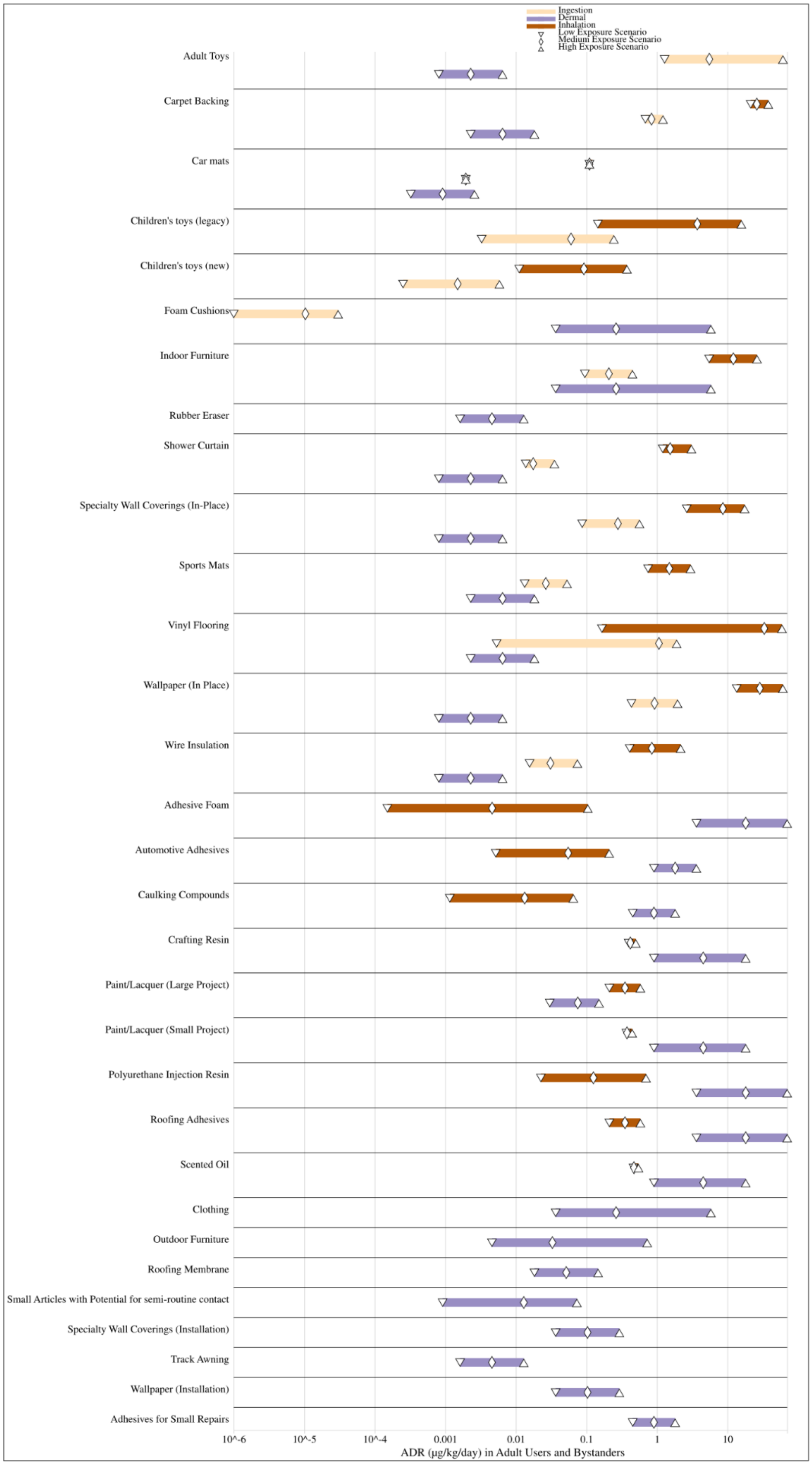


Figure 4-4. Acute Dose Rate of DINP from Ingestion, Inhalation, and Dermal Exposure Routes in Adults 21+ Years Old

Intermediate Dose Results for All Lifestages

Only automotive adhesives and construction adhesives qualified to be used in intermediate scenarios. Based on manufacturer use description and professional judgement/assumption, these products may be used repeatedly within a 30-day period depending on projects. Infants to childhood lifestages do not have dermal doses as these products are not targeted for their use and application. However, starting from young teens through adults, it is possible that these lifestages can use automotive and construction adhesives in home renovation projects or other hobbies. Infants to middle childhood lifestages are considered bystanders when these products are in use and are exposed via inhalation. Direct dermal contact has a larger dose than inhalation for the uses during application. See Figure 4-5 to Figure 4-8 for intermediate dose visual representation.

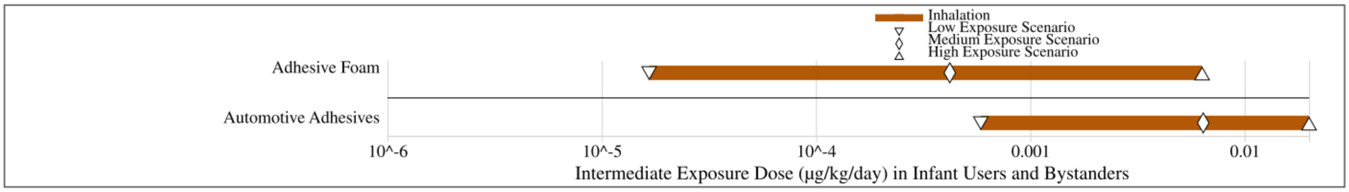


Figure 4-5. Intermediate Dose Rate for DINP from Inhalation Exposure Route in Bystander Infants <1 Year Old and Toddlers 1 to 2 Years Old

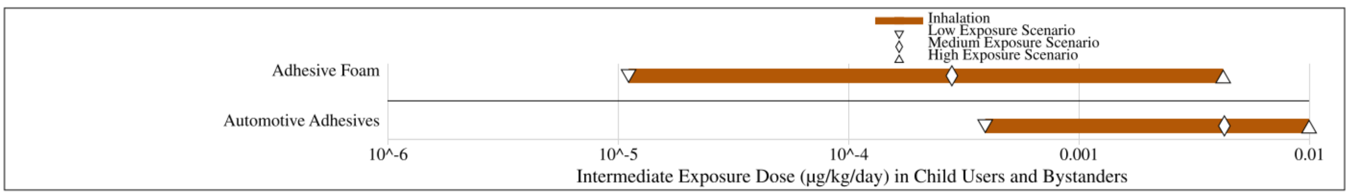


Figure 4-6. Intermediate Dose Rate for DINP from Inhalation Exposure Route in Bystander Preschoolers 3 to 5 Years Old and Middle Childhood 6 to 10 Years Old

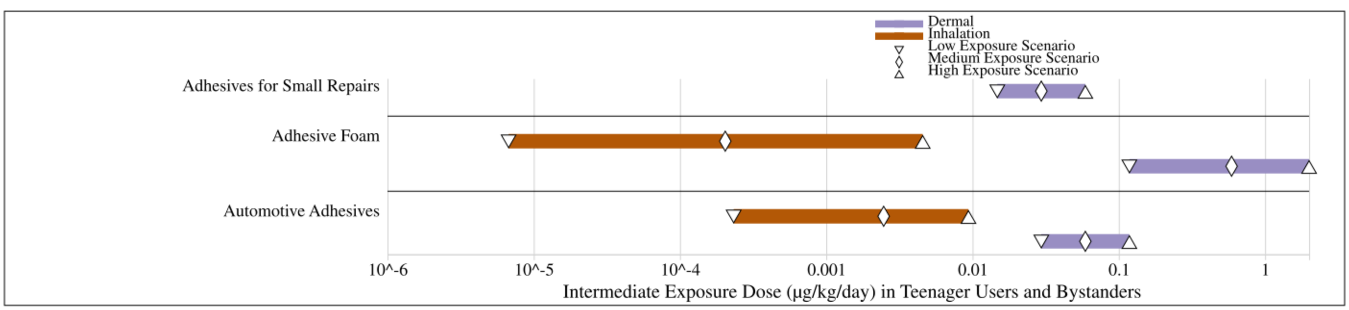


Figure 4-7. Intermediate Dose Rate of DINP from Inhalation, and Dermal Exposure Routes for Young Teen 11 to 15 Years Old and for Teenagers and Young Adults 16 to 20 Years Old

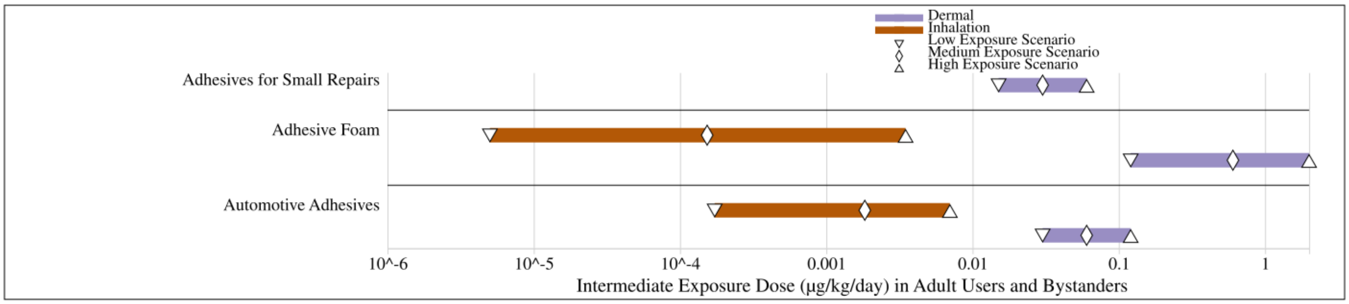


Figure 4-8. Intermediate Dose Rate of DINP from Inhalation, and Dermal Exposure Routes for Adults 21+ Years Old

Chronic Dose Results for All Lifestages

Data patterns are illustrated in figures after the table and includes summary descriptions of the patterns by exposure route and population or lifestage. The following set of figures (Figure 4-9 to Figure 4-12) show chronic average daily dose data for all products and articles modeled in all lifestages. For each lifestage, figures are provided which show CADD estimated from exposure via inhalation, ingestion (aggregate of mouthing, suspended dust ingestion, and settled dust ingestion), and dermal contact. The chronic average daily dose figures resulted in similar overall data patterns as the acute doses.

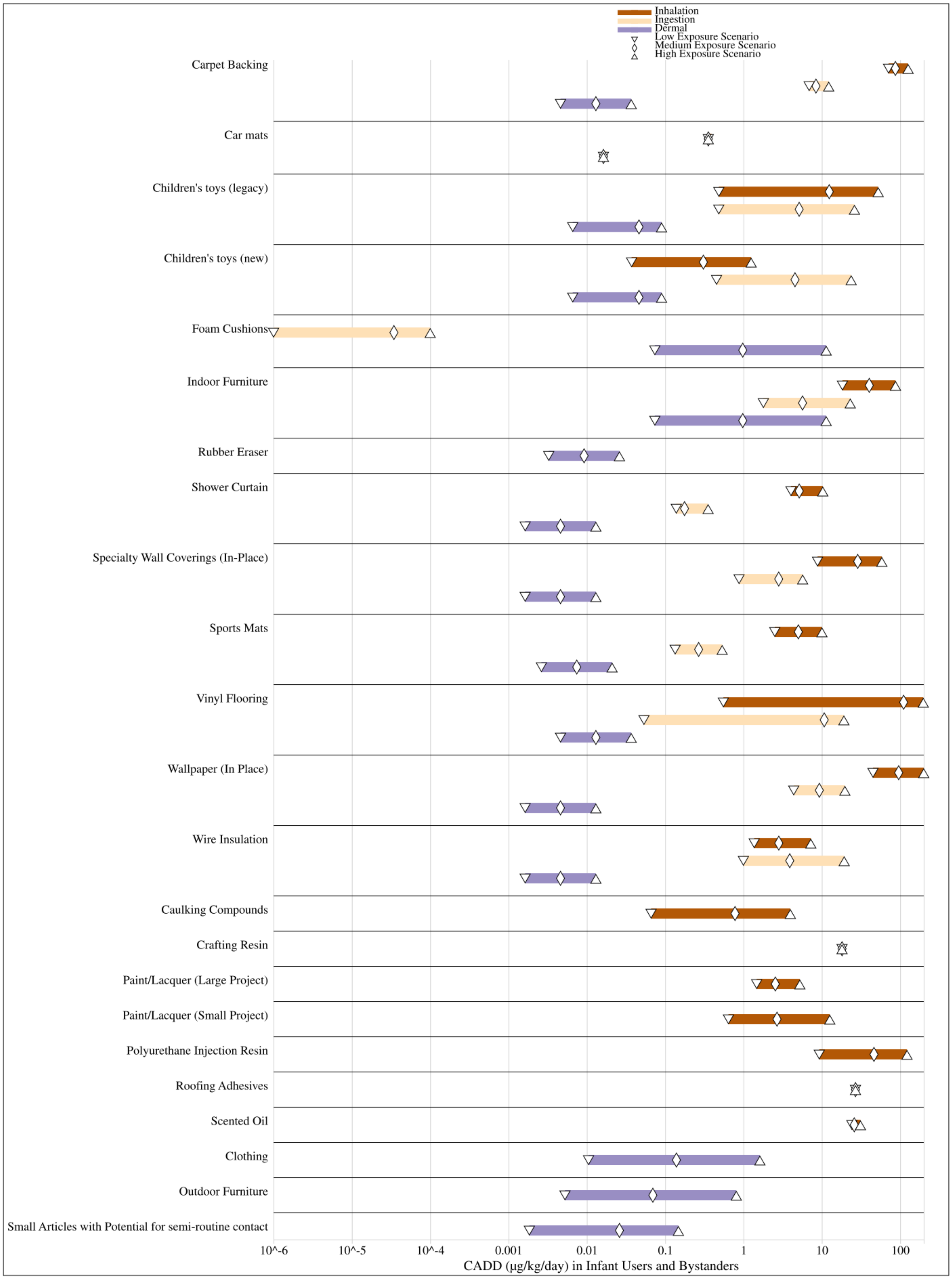
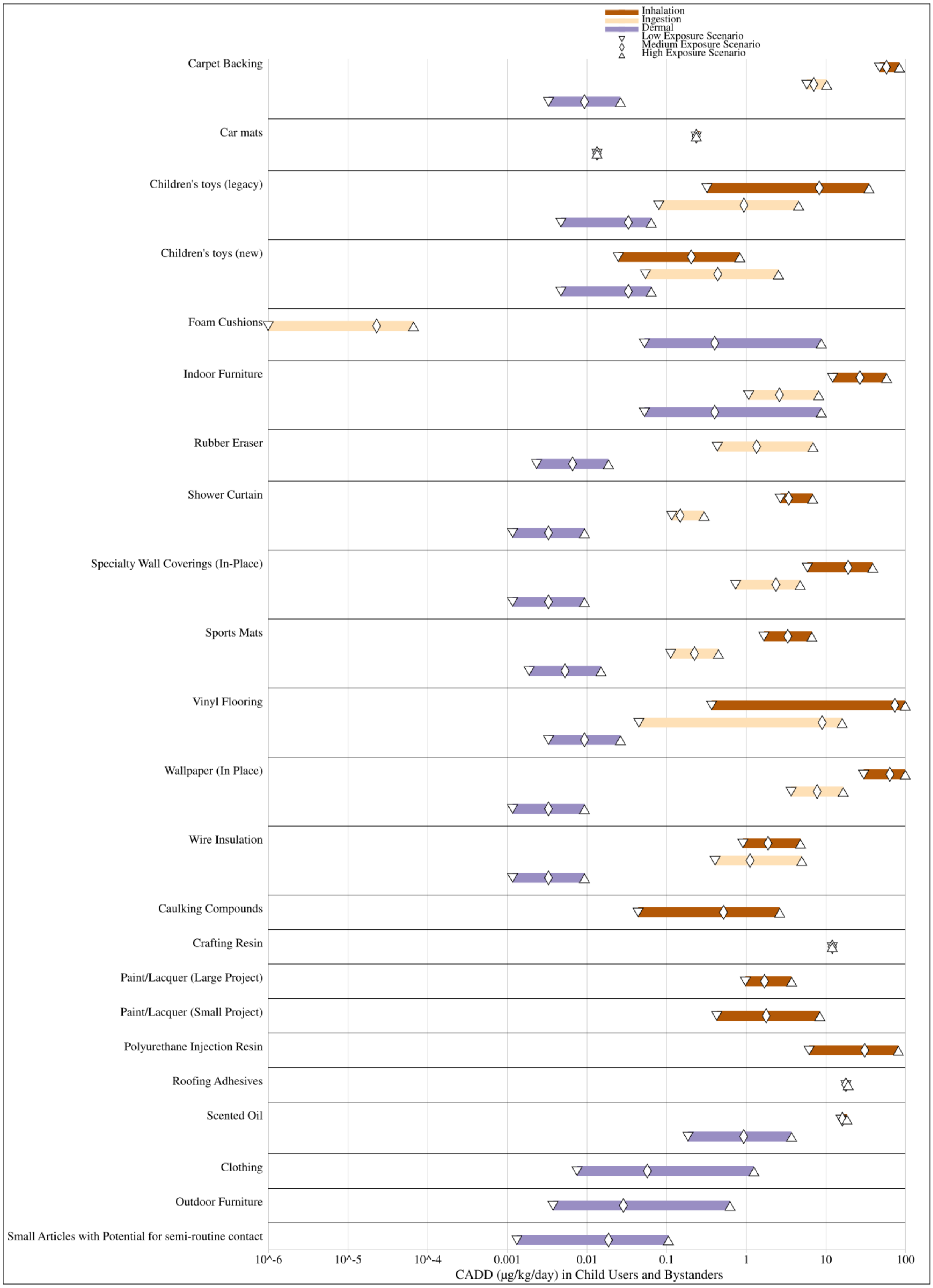


Figure 4-9. Chronic Dose Rate for DINP from Ingestion, Inhalation, and Dermal Exposure Routes in Infants <1 Year Old and Toddlers 1 to 2 Years Old



1621

1622 **Figure 4-10. Chronic Dose Rate of DINP from Ingestion, Inhalation, and Dermal Exposure Routes**
1623 **for Preschoolers 3 to 5 Years Old and Middle Childhood 6 to 10 Years Old**
1624

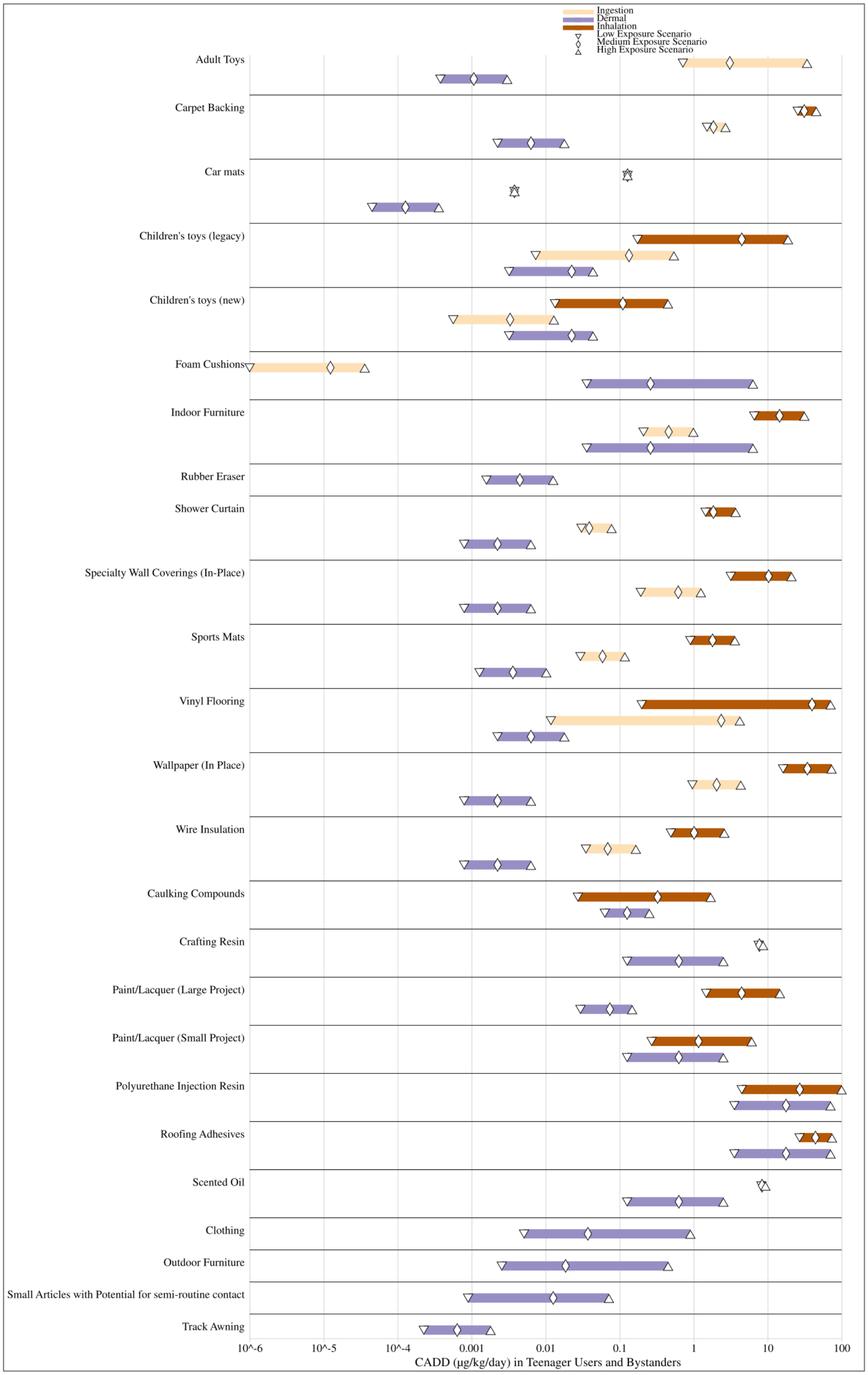


Figure 4-11. Chronic Dose Rate of DINP from Ingestion, Inhalation, and Dermal Exposure Routes for Young Teen 11 to 15 Years Old and for Teenagers and Young Adults 16 to 20 Years Old

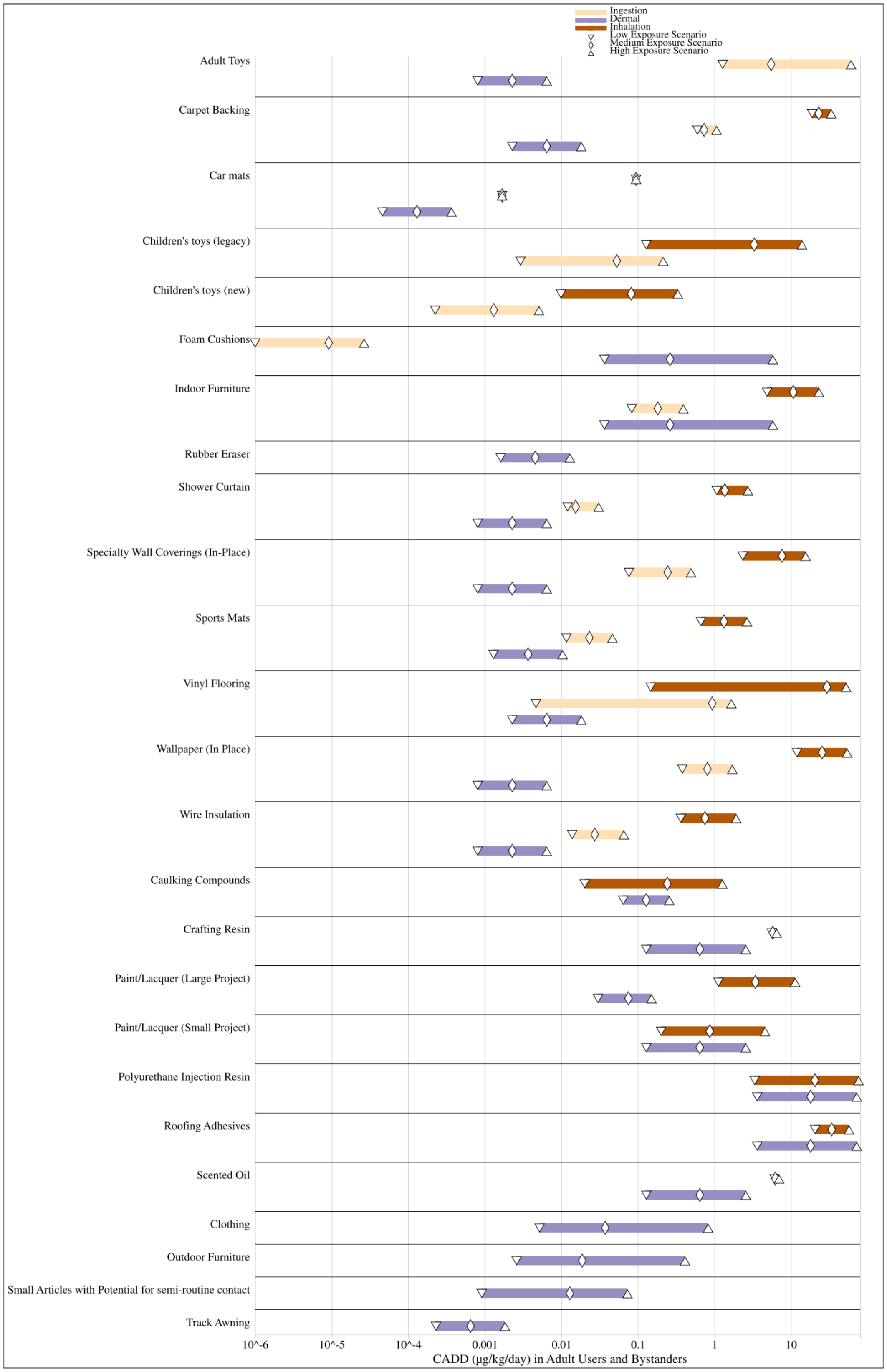


Figure 4-12. Chronic Dose Rate of DINP from Ingestion, Inhalation, and Dermal Exposure Routes in Adults 21+ Years Old

4.1.2.3 Monitoring Concentrations of DINP 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 DINP into dust and obtain COU and product specific exposure estimates for ingestion and inhalation.

Monitoring data are expected to represent aggregate exposure to DINP in dust resulting from all sources present in a home or other indoor environments like gyms for sporting mats and car for car mats. While it is not a good indicator of individual contributions of specific COUs, it provides a real-world indicator of total exposure through dust. The monitoring data considered are from residential dust samples from studies conducted in the United States. Measured DINP concentrations were compared to determine consistency among datasets. The monitoring studies and assumptions made to estimate exposure are described in detail in Section 3.2 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l).

Indoor Dust Monitoring Data

A total of 38 studies were identified as containing measured DINP concentrations in dust during systematic review. Of these, three studies were identified as containing United States data on residential measured DINP concentrations in dust (Hammel et al., 2019; Dodson et al., 2017; Shin et al., 2014). The remaining 35 studies measured DINP dust concentrations in non-residential buildings such as offices, schools, businesses, and day cares, did not present original data, and/or were not conducted in the United States. The studies that contained residential DINP dust monitoring data were compared to identify similarities and differences in sampled population and sampling methods. Evaluating the sampled population and sampling methods across studies was important to determine whether the residential monitoring data were conducted on broadly representative populations (*i.e.*, not focused on a particular subpopulation).

Of the three studies that were identified as containing United States data on residential measured DINP concentrations, two had small sample sizes and sampled subpopulations that were not necessarily broadly representative of the U.S. population. Hammel et al. (2019) was the only U.S. study identifying DINP concentrations in residential dust that was not focused on a particular subpopulation. This study collected paired house dust, hand wipe, and urine samples from 203 children aged 3 to 6 from 190 households in Durham, North Carolina between 2014 and 2016. and additionally analyzed product use and presence of materials in the house. The households were participants in the Newborn Epigenetics Study (NEST), a prospective pregnancy cohort study that was conducted between 2005 and 2011. Participants were re-contacted and invited to participate in a follow-up study on phthalate and SVOC exposure, which was titled the Toddlers' Exposure to SVOCs in the Indoor Environment (TESIE) Study. This study involved home visits conducted between 2014 and 2016. DINP measurements from the Hammel et al. (2019) study reported 188 samples concentrations ranging from no detects to 788 µg/g with a median of 79 µg/g and a detection frequency of 96 percent.

The data on DINP 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 DINP intake in residential dust per kilogram body weight, dose, see Section 4.2 in (U.S. EPA, 2024l).

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

There are several potential challenges in interpreting available indoor dust monitoring data. The challenges are listed below:

1. 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.
2. Samples may have been collected at a time or location when there were multiple sources of DINP that included non-TSCA COUs.
3. None of the identified monitoring data contained source apportionment information that could be used to determine the fraction of DINP in dust samples that resulted from a particular TSCA or non-TSCA COU.
4. 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.

The DINP concentrations in indoor dust were derived from Hammel et al. (2019). In this study, 190 households from the TESIE study conducted between 2014 and 2016 in Durham, North Carolina, were vacuum sampled for indoor residential dust. Study participants were recruited from participants in an existing pregnancy cohort study, and the demographics of the study population matched those of the Durham population. Residents were asked to refrain from vacuuming or otherwise cleaning hard surfaces within the home for 2 days prior to sampling, and dust sampling was conducted by study technicians according to an internationally recognized sampling method (VDI, 2001). Samples were taken from a single room in each home, which was identified as the room in which the child(ren) residing in the home spent the most time. The study identifies these rooms as typically playrooms or living rooms. A key assumption made in this analysis is that dust concentrations in playrooms and living rooms are representative of those in the remainder of the home. It is possible that sampling biases were introduced by the choice of study location, by the choice to include only households that contain children, and by differences among the households that chose to participate in the study. Differences in consumer behaviors, housing type and quality, tidiness, and other variables that affect DINP concentrations in household dust are possible between participating households and the general population.

Body weights were taken from the *Exposure Factors Handbook* (U.S. EPA, 2011a), in which they were derived from the NHANES 1999 to 2006 dataset. The NHANES studies were designed to obtain a nationally representative dataset for the United States and include weight adjustment for oversampling of certain groups (children, adolescents 12–19 years, persons ≥60 years of age, low-income persons, African Americans, and Mexican Americans). Body weights were aggregated across lifestages and averaged by sex. In general, body weights have increased in the United States since 2006 (CDC, 2013), which may lead to an underestimate of body weight in this analysis. This would lead to an overestimate of DINP dose per unit body weight, because actual body weights in the U.S. population may be larger than those assumed in this analysis.

There are several potential challenges in interpreting available indoor dust monitoring data, which includes the following:

- 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 DINP that included non-TSCA COUs, like household dust with skin residue exposed to DINP-containing cosmetics.
- None of the identified monitoring data contained source apportionment information that could be used to determine the fraction of DINP in dust samples that resulted from a particular TSCA or non-TSCA COU. Therefore, these monitoring data represent background concentrations of DINP and are an estimate of aggregate exposure from all residential sources.
- Activity patterns may differ according to demographic categories (*e.g.*, stay at home/work from home individual vs an office worker) that can affect exposures especially to articles that continually emit a chemical of interest.
- 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 for the indoor dust exposure assessment of DINP (Table 4-7**)** is dependent on studies that include indoor residential dust monitoring data. Only studies that included indoor dust samples taken from residences were included for data extraction. In the case of DINP, three studies were identified as containing data on residences in the United States. Of these three, one study was selected for use in the indoor dust monitoring assessment as described in (Hammel et al., 2019). This study was rated "High" quality per the exposure systematic review criteria.

Table 4-7. Weight of Scientific Evidence Conclusions for Indoor Dust Ingestion Exposure

Scenario	**Confidence in Data Used [a]**	**Confidence in Model Inputs**		**Weight of Scientific Evidence Conclusion**
		Body Weight [b]	**Dust Ingestion Rate [c]**	
Indoor exposure to residential dust via ingestion	Robust	Robust	Moderate	Robust

[a] Hammel et al. (2019)
[b] U.S. EPA (2011a)
[c] Özkaynak et al. (2022)

Table 4-7 presents the assessor's level of confidence in the data quality of the input datasets for estimating dust ingestion from monitoring data, including the DINP dust monitoring data themselves, the estimates of US body weights, and the estimates of dust ingestion rates, according to the following rubric:

- Robust confidence means the supporting weight of scientific evidence outweighs the uncertainties to the point that the assessor 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 the assessor is making the best scientific assessment possible in the absence of complete information. There may be significant uncertainty in the underlying data that needs to be considered.

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. Taken as a whole, with robust confidence in the DINP concentration monitoring data in indoor residential dust from Hammel et al. (2019), 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 a weight of scientific evidence rating of robust confidence in our estimates of daily DINP intake rates from ingestion of indoor dust in residences (Table 4-7).

4.1.2.4 Indoor Aggregate Dust Monitoring and Modeling Comparison

Aggregate Indoor Dust Exposure Approach and Methodology for Modeling Data

Given the complexity of source apportionment in exposure assessment for chemicals in indoor dust, EPA considered the available modeling and monitoring data to estimate the aggregate exposures to DINP that may occur via dust in a typical indoor environment. Modeling data used in indoor dust assessment originated from the consumer exposure assessment, Section 4.1.2.2, to reconstruct major indoor sources of DINP into dust and obtain COU and product specific exposure estimates for ingestion and inhalation, although only ingestion of settled dust was used in the monitoring and modeling comparison. The monitoring data considered, described in Section 4.2 in (U.S. EPA, 2024l) and in this document in Section 4.1.2.3, are from residential settled 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 4.1.2 of the *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l).

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 and 4.1.2.2. Although, most of the exposure scenarios for articles used in this indoor assessment were modeled in CEM for inhalation, ingestion of suspended and settled dust, mouthing, and dermal (see Section 4.1.2.1), only ingestion of settled dust exposures was used to compare with monitoring data because that is the information reported in monitoring studies. Exposure to DINP via ingestion of dust was assessed for all articles expected to contribute significantly to dust concentrations due to high surface area (> ~1 m^2) for either a single article or collection of like articles as appropriate, including

- wallpaper;
- specialty wall coverings;
- wire insulation;
- foam cushions;
- solid vinyl flooring tiles;
- carpet backing tiles;
- indoor furniture;
- car mats;
- shower curtains;
- sporting mats; and
- children's toys, both legacy and new.

Of this articles list, specialty coverings, car mats, sporting mats are not expected to be commonly found in homes. Furthermore, because the monitoring data is exclusively for residential locations, EPA did not include these in the modeling aggregate comparison with monitoring data.

Modeling and Monitoring Indoor Dust Ingestion Exposure Comparison

The dose estimates for indoor dust from the CEM model are larger than those indicated by the monitoring approach. Table 4-8 compares the sum of the chronic dose central tendency for indoor dust ingestion from CEM outputs for all COUs to the central tendency predicted daily dose from the monitoring approach. Because monitoring intake rates were only assessed for settled dust ingestion, the comparison between monitoring and modeling only includes settled dust ingestion estimates.

Table 4-8. Comparison between Modeled and Monitored Daily Dust Intake Estimates for DINP

Lifestage	Daily DINP Intake Estimate from Dust, µg/kg-day, Modeled Exposure[a]	Daily DINP Intake Estimate from Dust, µg/kg-day, Monitoring Exposure[b]	Margin of Difference (Modeled ÷ Monitoring)
Infant (<1 Year)	31.03	0.25[c]	124.1
Toddler (1–2 Years)	38.42	0.16	240.2
Preschooler (3–5 Years)	43.38	0.080	542.3
Middle Childhood (6–10 Years)	15.22	0.064	237.9
Young Teen (11–15 Years)	8.52	0.032	266.4
Teenager (16–20 Years)	6.76	0.012	563.5
Adult (21+ Years)	3.03	0.0034[d]	990.0

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

The sum of DINP intakes from dust in CEM modeled scenarios were, in all cases, considerably higher than those predicted by the monitoring approach. The difference between the two approaches ranged from 124 times in infants less than 1 year old, to a high of 990 times in adults 21+ years. These discrepancies partially stem from differences in the exposure assumptions of the CEM model versus 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 of difference between the modeled and monitoring results grows larger with age. Another source of the margin between the two approaches is the assumption that the sum of the indoor dust sources in the CEM modeled scenario is representative of items found in typical indoor residences. It is likely that individual residences have varying assortments and amounts of the products and articles that are sources of DINP, resulting in lower and higher exposures.

In the indoor dust modeling assessment, EPA reconstructed the scenario using consumer articles as the source of DINP in dust. CEM modeling parameters and inputs for dust ingestion can partially explain the differences between modeling and monitoring estimates. For example, surface area, indoor environment volume, and ingestion rates by lifestage were selected to represent common use patterns. CEM calculates DINP concentration in small particles (respirable particles) and large particles (dust) that are settled on the floor or surfaces. The model assumes these particles bound to DINP are available via incidental dust ingestion and estimates exposure based on a daily dust ingestion rate and a fraction of the day that is spent in the zone with the DINP-containing dust. The use of a weighted dust concentration can also introduce discrepancies between monitoring and modeling results.

Indoor Dust Exposure Assessment Conclusions

For the indoor exposure assessment, EPA considered modeling and monitoring data. Monitoring data is expected to represent aggregate exposure to DINP in dust resulting from all sources present in a home. While it is not a good indicator of individual contributions of specific COUs, it provides a real-world indicator of total exposure through dust. For the modeling 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 DINP and subsequent inhalation and ingestion. Other non-residential environments can have these articles, such as daycares, offices, malls, schools, and other public indoor spaces. The indoor consumer articles exposure scenarios were modeled with stay-at-home parameters, which 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.

Given the wide discrepancies between monitoring and modeling of DINP in indoor dust, EPA concluded that there is too much uncertainty in this analysis to support derivation of risk estimates for aggregate indoor dust exposure. Despite the robust confidence evaluation of the monitoring assessment, a risk estimate based on these data was not derived. Instead, they were used as a comparator to show that the modeled DINP exposure estimates were health protective relative to residential monitored exposures (see Table 4-8). This comparison was a key input to having robust confidence in the overall health protectiveness of EPA's exposure assessment for ingestion of DINP in indoor dust. The individual COU scenarios had a moderate to robust confidence in the dose results and protectiveness of parameters used. Hence, the COU scenarios of the articles used in the indoor assessment were utilized in risk estimates calculations.

4.1.2.5 Weight of Scientific Evidence Conclusions for Consumer Exposure

Key sources of uncertainty for evaluating exposure to DINP in consumer goods and strategies to address those uncertainties are described in detail in Section 5.1 of *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l). 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. Table 4-9 summarizes the overall uncertainty per COU, and a discussion of rationale used to assign the overall uncertainty. The subsections ahead of the table describe sources of uncertainty for several parameters used in consumer exposure modeling that apply across COUs and provide an in depth understanding of sources of uncertainty and limitations and strengths within the analysis. The confidence to use the results for risk characterization ranges from moderate to robust, see Table 4-9.

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 sometimes limited for weight fractions of DINP in consumer goods. EPA obtained DINP weight fractions in various products and articles from material safety sheets, data bases, and existing literature. 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. EPA decreased uncertainty in exposure and subsequent risk estimates in the high, medium, and low intensity use scenarios by capturing the weight fraction variability and obtaining a better characterization of the products and articles varying composition within one COU. Overall weight fraction confidence is **moderate** for products/articles with only one source and **robust** for products/articles with more than one source.

Product Use Patterns

Consumer use patterns like frequency of use, duration of use, and methods of application are expected to differ. Where possible, high, medium, and low default values from CEM 3.2's prepopulated scenarios were selected for mass of product used, duration of use, and frequency of use. In instances where no prepopulated scenario was appropriate for a specific product, low, medium, and high values for each of these parameters were estimated based on the manufacturers' product descriptions. EPA decreased uncertainty by selecting use pattern inputs that represent product and article use descriptions and furthermore capture the range of possible use patterns in the high to low intensity use scenarios. Exposure and risk estimates are considered representative of product use patterns and well characterized. Most use patterns overall confidence is rated **robust**.

Article Surface Area

The surface area of an article directly affects the potential for DINP emissions to the environment. For each article modeled for inhalation exposure, low, medium, and high estimates for surface area were calculated Section 2 in (U.S. EPA, 2024l). This approach relied on manufacturer-provided dimensions where possible, or values from EPA's *Exposure Factors Handbook* for floor and wall coverings. For small items that 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. Overall confidence in surface area is **moderate** for articles like wires because there is less understanding of the number of wires exposed to collect dust and the great variability that is expected may not be well represented. Overall confidence in surface area is **robust** for articles like furniture, wall coverings, flooring, toys, and shower curtains because there is a good understanding of the presence and dimensions in indoor environments.

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. The data used in this assessment are based on a study in which parents observed children (n = 236) ages 1 month to 5 years of age for 15 minutes each session and 20 sessions in total (Smith and Norris, 2003). There was considerable variability in the data due to behavioral differences among children of the same lifestage. For instance, while children aged 6 to 9 months had the highest average mouthing duration for toys at 39 minutes per day, the minimum duration was 0 minutes and the maximum was 227 minutes per day. The observers noted that the items mouthed were made of plastic roughly 50 percent of the mouthing time, but this not limited to soft plastic items likely to contain significant plasticizer content. In another study, 169 children aged 3 months to 3 years were monitored by trained observers for 12 sessions at 12 minutes each (Greene, 2002). They reported mean mouthing durations ranging from 0.8 to 1.3 minutes per day for soft plastic toys and 3.8 to 4.4 minutes per day for other soft plastic objects (except pacifiers). Thus, it is likely that the mouthing durations used in this assessment provide a health protective estimate for mouthing of soft plastic items likely to contain DINP.

Modeling Tool

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

Dermal Modeling for DINP

Experimental dermal data was identified via the systematic review process to characterize consumer dermal exposures to liquids or mixtures and formulations containing DINP. EPA has moderate understanding of the scientific evidence and the uncertainties, while the supporting scientific evidence against the uncertainties is reasonably adequate to characterize exposure estimates. The confidence in dermal exposure to liquid products model used in this assessment is **moderate**.

EPA identified only one set of experimental data related to the dermal absorption of neat DINP (Midwest Research Institute, 1983). This dermal absorption study was conducted *in vivo* using male F344 rats. There have been additional studies conducted to determine the difference in dermal absorption between rat skin and human skin. Specifically, Scott (1987) examined the difference in dermal absorption between rat skin and human skin for four different phthalates (*i.e.,* dimethyl phthalate [DMP], diethyl phthalate [DEP], dibutyl phthalate [DBP], and DEHP) using *in vitro* dermal absorption testing. Results from the *in vitro* dermal absorption experiments showed that rat skin was more permeable than human skin for all four phthalates examined. For example, rat skin was up to 30 times more permeable than human skin for DEP, and rat skin was up to 4 times more permeable than human skin for DEHP. Although there is uncertainty regarding the magnitude of difference between dermal absorption through rat skin versus human skin for DINP, EPA is confident that the *in vivo* dermal absorption data using male F344 rats (Midwest Research Institute, 1983) provides an upper bound of dermal absorption of DINP based on the findings of Scott (1987).

Another source of uncertainty regarding the dermal absorption of DINP from products or formulations stems from the varying concentrations and co-formulants that exist in products or formulations containing DINP. For purposes of this draft risk evaluation, EPA assumes that (1) the absorptive flux of neat DINP measured from *in vivo* rat experiments serves as an upper bound of potential absorptive flux of chemical into and through the skin for dermal contact with all liquid products or formulations, and (2) that the modeled absorptive flux of aqueous DINP serves as an upper bound of potential absorptive flux of chemical into and through the skin for dermal contact with all solid products. However, dermal contact with products or formulations that have lower concentrations of DINP might exhibit lower rates of flux since there is less material available for absorption. Conversely, co-formulants or materials within the products or formulations may lead to enhanced dermal absorption, even at lower concentrations. Therefore, it is uncertain whether the products or formulations containing DINP would result in decreased or increased dermal absorption. Based on the available dermal absorption data for DINP, EPA has made assumptions that result in exposure assessments that are the most human health protective in nature.

Experimental dermal data were not identified via the systematic review process to estimate dermal exposures to solid products or articles containing DINP and a modeling approach was used to estimate exposures. EPA has a **slight** confidence in the dermal exposure to solid products or articles modeling approach.

Lastly, EPA notes that there is uncertainty with respect to the modeling of dermal absorption of DINP from solid matrices or articles. Because there were no available data related to the dermal absorption of DINP from solid matrices or articles, EPA has assumed that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. Therefore, to determine the maximum steady-state aqueous flux of DINP, EPA utilized the CEM (U.S. EPA, 2023a) to first estimate the steady-state aqueous permeability coefficient of DINP. The estimation of the steady-state aqueous permeability coefficient within CEM (U.S. EPA, 2023a) is based on quantitative structure-activity relationship (QSAR) model presented by ten Berge (2009), which considers chemicals with log (K_{ow}) ranging from −3.70 to 5.49 and molecular weights ranging from 18 to 584.6. The molecular weight of DINP falls within the range suggested by ten Berge (2009), but the log (K_{ow}) of DINP exceeds the range suggested by ten Berge (2009). Therefore, there is uncertainty regarding the accuracy of the QSAR model used to predict the steady-state aqueous permeability coefficient for DINP.

Modeling Parameters for DINP Chemical Migration

For chemical migration rates to saliva, existing data were highly variable both within and between studies. This indicates the significant level of uncertainty for the chemical migration rate, as it may also differ even among similar items due to variations in chemical makeup and polymer structure. As such, an effort was made to choose DINP migration rates likely to be representative of broad classes of items that comprise consumer COUs produced with different manufacturing processes and material formulations. There is no consensus on the correct value to use for this parameter in past assessments of DINP. The 2003 EU Risk Assessment for DINP used a migration rate of 53.4 µg/cm^2/h selected from the highest individual estimate from a 1998 study by the Netherlands National Institute for Public Health and the Environment (RIVM) (ECJRC, 2003b; RIVM, 1998). The RIVM study measured DINP in saliva of 20 adult volunteers biting and sucking four PVC disks with a surface of 10 cm^2. Average migration to saliva from the samples tested were 8.4, 14, 4, and 9.6 µg/cm^2/h, and there was considerable variability in the results. In a more recent report, ECHA compiled and evaluated new evidence on human exposure to DINP, including chemical migration rates (ECHA, 2013). They concluded that chemical migration rate of 14 µg/cm^2/h was likely to be representative of a "typical mouthing scenario" and a migration rate of 45 ug/cm^2/h was a reasonable worst-case estimate of this parameter. The “typical” value was determined by compiling *in vivo* migration rate data from existing studies (Niino et al., 2003; Sugita et al., 2003; Fiala et al., 2000; Meuling et al., 2000; Chen, 1998; RIVM, 1998). The “worst case” value was midway between the two highest individual measurements among all the studies (the higher of which was used in the 2003 EU risk assessment).

However, a major limitation of all existing data is that DINP weight fractions for products tested in mouthing studies skew heavily towards relatively high weight fractions (30 to 60%) and measurements for weight fractions less than 15 percent are very rarely represented in the data set. Thus, it is unclear whether these migration rate values are applicable to consumer goods with low (<15 percent) weight fractions of DINP, where rates might be lower than represented by “typical” or worst-case values determined by existing data sets. As such, based on available data for chemical migration rates of DINP to saliva, the range of values used in this assessment (1.6, 13.3, and 44.8 $\mu g/cm^2/h$) are considered likely to capture the true value of the parameter.

Table 4-9. Weight of Scientific Evidence Summary Per Consumer COU

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
Automotive, fuel, agriculture, outdoor use products; Automotive care products	This COU was assessed with one indoor scenario for one type of article. The scenario for car mats captures variability in product formulation in the high, medium, and low intensity use estimates. The overall confidence in this indoor COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	Inhalation and Ingestion – Robust Dermal – Moderate
Construction, paint, electrical, and metal products; Adhesives and sealants	Six different scenarios were assessed under this COU for products with differing use patterns for which each scenario had varying number of identified product examples (in parenthesis): adhesives for small repairs (2), adhesive foam (1), automotive adhesives (4), caulking compounds (5), Polyurethane Injection Resin (1), and roofing adhesives (2). The six scenarios and the products within capture the variability in product formulation and are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. For dermal exposure EPA used a dermal flux approach, which was estimated based on DINP *in vivo* dermal absorption in rats. An overall moderate confidence in dermal assessment of adhesives was assigned. Uncertainties about the difference between human and rat skin absorption increase uncertainty. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative.	Inhalation – Robust Dermal – Moderate
Construction, paint, electrical, and metal products; Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)	Two different scenarios were assessed under this COU for four articles with differing use patterns for which each scenario had varying number of identified article examples (in parenthesis): roofing membranes (1) and electrical tape, spline (4). Of these two scenarios roofing membranes were assessed for dermal exposures only because outdoor inhalation and ingestion would have low exposure potential. When available more than one article input parameters capture the variability in product formulations are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation and dust ingestion exposure estimate is moderate because although the CEM default parameters represent actual use patterns and location of use. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption	Inhalation, Dust Ingestion, and Dermal – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	
Construction, paint, electrical, and metal products; Electrical and electronic products	One article was identified for this COU, wire insulation. Inhalation, dust ingestion, mouthing, and dermal exposures were assessed for this article. Inhalation and ingestion of dust scenarios were built to represent indoor presence of this article and therefore this scenario is an aggregate assessment of multiple wire insulations, while mouthing and dermal exposures can only be assessed for the contact area with the article and the frequency and duration of the contact. The weight fraction data used had a large range resulting in higher variability due to changing formulation approaches. The high, medium, and low intensity use scenarios capture the high variability and represent a wide range of possible scenarios. The overall confidence in this COU inhalation and dust ingestion exposure estimate is moderate. Although CEM default parameters are expected to be representative of the use patterns and location of use there are larger uncertainties in the aggregated surface area used. In addition, for dermal and mouthing the overall confidence is also moderate from uncertainties from the solid article to dermal and saliva migration approaches and frequency and durations of the exposure.	Inhalation, Dust Ingestion, Mouthing, and Dermal – Moderate
Construction, paint, electrical, and metal products; Paints and coatings	Two different scenarios were assessed under this COU for products with differing use patterns for which each scenario had varying number of identified product examples (in parenthesis): paint/lacquer (large project) (1) and paint/lacquer (small project) (2). The two scenarios and the products within capture the variability in product formulation and are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. For dermal exposure EPA used a dermal flux approach, which was estimated based on DINP *in vivo* dermal absorption in rats. An overall moderate confidence in dermal assessment of adhesives was assigned. Uncertainties about the difference between human and rat skin absorption increase uncertainty. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative.	Inhalation – Robust Dermal – Moderate
Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles [soft]; leather articles)	Four different scenarios were assessed under this COU for various articles with differing use patterns for which each scenario had varying number of identified article examples (in parenthesis): foam cushions (1), indoor furniture (2), outdoor furniture (1), and truck awnings (1). The outdoor furniture and truck awnings were assessed for dermal exposure only because outdoor inhalation and ingestion would have low exposure potential. Foam cushions and indoor furniture scenarios estimated inhalation, ingestion, and dermal exposures. Foam cushions and indoor furniture scenarios capture potential exposures to their presence in indoor environments. The articles input parameters capture the variability in product formulations and possible surface area present in indoor environments are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation and dust	Inhalation and Dust Ingestion – Robust Dermal – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	ingestion exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use, and the estimated surface area for foam cushions and furniture is well characterized and representative of indoor furniture dimensions. Migration of DINP from product to saliva approach has an overall confidence of moderate due to uncertainties from article formulation differences, but the mouthing parameters and durations are well characterized, resulting in an overall moderate confidence for a health protective estimate. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	
Furnishing, cleaning, treatment/care products; Floor coverings/ Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Four different scenarios were assessed under this COU for various articles with differing use patterns for which each scenario had varying number of identified article examples (in parenthesis): carpet backing (3), vinyl tiles (flooring) (4), specialty wall coverings (3), wallpaper (1). These four scenarios were assessed for dermal, inhalation, and dust ingestion exposures. These articles capture potential dust inhalation and ingestion in indoor environments. The articles input parameters capture the variability in product formulations and possible surface area present in indoor environments are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use and the estimated surface area is well characterized and represents a wide range of plausible uses. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	Inhalation and Dust Ingestion – Robust Dermal – Moderate
Furnishing, cleaning, treatment/care products; Air care products	Two different scenarios were assessed under this COU for one product, scented oil with differing use patterns: scented oil DIY and scented oil in homemade burning candle. The two scenarios capture the variability in product formulation and are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use.	Inhalation – Robust Dermal – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	
Furnishing, cleaning, treatment/care products; Fabric, textile, and leather products (apparel and footwear care products)	Two different scenarios were assessed under this COU for various articles with differing use patterns for which each scenario had varying number of identified article examples (in parenthesis): clothing (2) and small articles with potential for routine contact (4). These two scenarios were assessed for dermal exposures. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. Slight was selected for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence in a health protective estimate moderate.	Dermal – Moderate
Packaging, paper, plastic, hobby products; Arts, crafts, and hobby materials	Three different scenarios were assessed under this COU for various products with differing use patterns for which each scenario had varying number of identified product examples (in parenthesis): rubber eraser (2), crafting resin (4), and hobby cutting board (1). The hobby cutting board was assessed for dermal contact only because inhalation and ingestion would have low exposure potential for such small surface area product. The scenarios for crafting resin and rubber eraser and the products within capture the variability in product formulation and are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. For dermal exposure EPA used a dermal flux approach, which was estimated based on DINP *in vivo* dermal absorption in rats. An overall moderate confidence in dermal assessment of adhesives was assigned. Uncertainties about the difference between human and rat skin absorption increase uncertainty. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative.	Inhalation and Ingestion – Robust Dermal – Moderate
Packaging, paper, plastic, hobby products; Ink, toner, and colorant products	See Construction, paint, electrical, and metal products; Paints and coatings COU. Current products were not identified. Foreseeable uses were matched with the lacquers, and paints (small and large projects) because similar use patterns are expected.	Inhalation – Robust Dermal – Moderate
Packaging, paper, plastic, hobby products; Other articles with routine	Two different scenarios were assessed under this COU for various products and articles with differing use patterns for which each scenario had varying number of identified examples (in parenthesis): shower curtains (1) and small articles with potential for semi-routine contact (5). The small articles with potential	Inhalation and Ingestion – Robust

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses	for semi-routine contact was assessed for dermal contact only because inhalation and ingestion would have low exposure potential for such small surface area products. The scenario for shower curtains is an indoor exposure assessment and it captures possible variability in product formulation in the high, medium, and low intensity use estimates. The overall confidence in this indoor COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	Dermal – Moderate
Packaging, paper, plastic, hobby products; Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)	One scenario was built for this COU for PVC soap packaging. This scenario was assessed for dermal only as inhalation and dust ingestion is unlikely for to be significant for the surface area of this article. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. Slight was selected for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence in a health protective estimate moderate.	Dermal – Moderate
Packaging, paper, plastic, hobby products; Toys, playground, and sporting equipment	Three different scenarios were assessed under this COU for various articles with differing use patterns: sports mats, legacy and non-compliant children's toys, and new children's toys. Inhalation, dust ingestion, mouthing, and dermal were assessed for all three scenarios with varying use patterns and inputs. The high, medium, and low intensity scenarios capture variability and provide a range of representative use patterns. The overall confidence in this COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. The overall confidence in this COU mouthing and dermal exposure assessment is robust. The mouthing parameters used like duration and surface area for infants to children are very well understood, while older groups have less specific information because mouthing behavior is not expected. The chemical migration value is DINP specific and only source of uncertainty are related to article formulation and chemical migration dynamics, which may not be very well characterized, but by assessing high, medium, and low intensity scenarios EPA captures that source of uncertainty and increases confidence in the estimates by using representative scenarios. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. EPA has slight confidence for solid objects because the	Inhalation, Dust Ingestion, and Mouthing – Robust Dermal – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence of moderate in a health protective estimate.	
Other; Novelty products	One scenario was built for this COU for adult toys. This scenario was assessed for dermal only as inhalation and dust ingestion is unlikely for to be significant for the surface area of this article. Dermal absorption estimate based on the assumption that dermal absorption of DINP from solid objects would be limited by aqueous solubility of DINP. Slight was selected for solid objects because the high uncertainty in the assumption of partitioning form solid to liquid and subsequent dermal absorption is not well characterized. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative, making the overall confidence in a health protective estimate moderate.	Dermal – Moderate

4.1.3 General Population Exposures

General population exposures occur when DINP is released into the environment and the environmental media is then a pathway for exposure. As described in the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s), releases of DINP are expected in air, water, and disposal to landfills. Figure 4-13 provides a graphic representation of where and in which media DINP 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 DINP exposure for the general population. Screening-level assessments are useful when there is little location- or scenario-specific information available. EPA began its DINP general population exposure assessment using a screening-level approach because of limited environmental monitoring data for DINP and lack of location data for DINP 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 DINP from facilities that use, manufacture, or process DINP under industrial and/or commercial COUs subject to TSCA regulations detailed in the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s). As described in Section 3.3, using the release data, EPA modeled predicted concentrations of DINP in surface water, sediment, drinking water, and soil from air to soil deposition in the United States. Table 3-6 summarizes the high-end DINP 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 *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r).

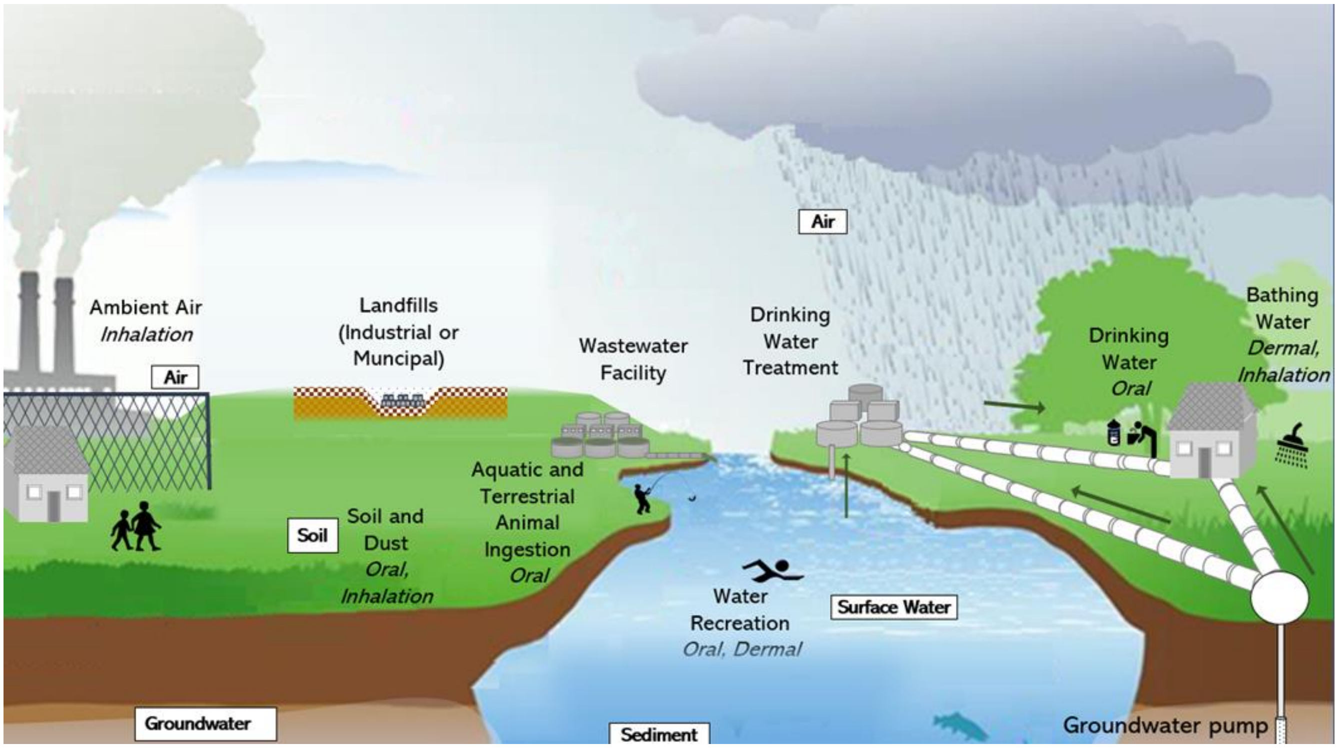


Figure 4-13. Potential Human Exposure Pathways to DINP for the General Population
Potential routes of exposure are shown in italics under each potential pathway of exposure.

High-end estimates of DINP concentration in the various environmental media presented in Table 3-6 and the *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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 DINP from the largest estimated releases for the purpose of its screening-level assessment for environmental and general population exposures. This means that EPA considered the environmental concentration of DINP 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 DINP 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 DINP release to the environment via biosolids or landfills was not quantitatively assessed because DINP concentrations to the environment from biosolids and landfills was not quantified. Due to the high confidence in the biodegradation rates and physical and chemical data, there is robust confidence that in soils receiving DINP will not be mobile and will have low persistence potential and there is robust confidence that DINP 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 *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r). Selected OESs represent those resulting in the highest modeled environmental media concentrations, for the purpose of a screening-level analysis.

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

OES[a]	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)
All	Biosolids	No specific exposure scenarios were assessed for qualitative assessments			Qualitative
All	Landfills	No specific exposure scenarios were assessed for qualitative assessments			Qualitative
Use of lubricants and functional fluids	Surface Water	Dermal	Dermal exposure to DINP in surface water during swimming	Adults (>21 years)	Quantitative
		Oral	Incidental ingestion of DINP in surface water during swimming	Youth (11–15 years)	Quantitative
Use of lubricants and functional fluids	Drinking Water	Oral	Ingestion of drinking water	Infants (<1 year)	Quantitative
All	Fish Ingestion	Oral	Ingestion of fish for general population	Adult (>21 years)	Quantitative
			Ingestion of fish for subsistence fishers	Adult (>21 years)	Quantitative
			Ingestion of fish for tribal populations	Adult (>21 years)	Quantitative
Non-PVC plastic compounding	Ambient Air	Oral	Ingestion of DINP in soil resulting from air to soil deposition	Infant and Children (6 months to 12 years)	Quantitative
		Dermal	Dermal exposure to DINP in soil resulting from air to soil deposition	Infant and Children (6 months to12 years)	Quantitative

[a] 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 *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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 is not directly comparable 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 low water solubility (6.1×10^{-4} mg/L) and affinity for sorption to soil and organic constituents in soil (log K_{OC} = 5.5), DINP 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.S. EPA, 2024t) indicates that DINP will have low persistence potential in the aerobic environments associated with freshly applied biosolids. Because the physical and chemical properties of DINP 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.

Although there is limited measured data on DINP in landfill leachates, the data suggest that DINP is unlikely to be present in the leachate. Further, the small amounts of DINP that could potentially be in landfill leachates will have limited mobility and are unlikely to infiltrate groundwater due to the high affinity of DINP for organic compounds that would be present in receiving soil and sediment. Interpretation of the high-quality physical and chemical property data also suggest that DINP is unlikely to be present in landfill leachate. Therefore, EPA concludes that further assessment of DINP in landfill leachate is not needed.

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 (PSC), to estimate concentrations of DINP within surface water and to estimate settled sediment in the benthic region of streams. Releases associated with the Use of Lubricants and Functional Fluids OES resulted in the highest total water column concentrations, with water concentrations of 9,350 µg/L without wastewater treatment, and 187 µg/L when run under an assumption of 98 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 DINP while swimming for adults (21 and older) and youth (11 to 15 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 240 to 247 for scenarios assuming no wastewater treatment and from 12,000 to 12,300 for scenarios assuming 98 percent wastewater treatment removal efficiency (compared to a benchmark of 30) (Table 4-11). Based on a screening-level assessment, risk for non-cancer health effects are not expected for the surface water pathway; therefore, the surface water pathway is not considered to be a pathway of concern to DINP 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 98 percent and no further drinking water treatment, as well as a scenario that assumed a wastewater treatment removal efficiency of 98 percent and a conservative drinking water treatment removal rate of 79 percent (Table 4-11). ADR and ADD values from drinking water exposure to DINP were calculated for various age groups but the most exposed lifestage, infants (birth to <1 year), is shown below. Exposure scenarios leading to the highest ADR and ADD are shown in Table 4-11.

MOEs for general population exposure through drinking water exposure were 322,000 and 1,530,000 for the drinking water scenario with an assumed wastewater treatment removal and an additional assumption of drinking water treatment, respectively, 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; therefore, the drinking water pathway is not considered to be a pathway of concern to DINP for the general population.

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

Occupational Exposure Scenario [a]	Water Column Concentrations	Incidental Dermal Surface Water [b]		Incidental Ingestion Surface Water [c]		Drinking Water [d]	
	30Q5 Conc. (μg/L)	ADR_{POT} (mg/kg-day)	Acute MOE (Benchmark MOE = 30)	ADR_{POT} (mg/kg-day)	Acute MOE (Benchmark MOE = 30)	ADR_{POT} (mg/kg-day)	Acute MOE (Benchmark MOE = 30)
Use of Lubricants and Functional Fluids *Without Wastewater Treatment*	9,350	4.85E−02	247	5.00E−02	240	N/A	N/A
Use of Lubricants and Functional Fluids *With Wastewater Treatment*	187	9.71E−04	12,300	1.00E−03	12,000	3.7E−05	322,000
Use of Lubricants and Functional Fluids *With Wastewater and Drinking Water Treatment*	0.26	N/A	N/A	N/A	N/A	7.8E−06	1,530,000

[a] Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.
[b] Most exposed age group: Adults (21+ years)
[c] Most exposed age group: Youth (11–15 years)
[d] Most exposed age group: Infant (birth to <1 year)

Fish Ingestion

Surface water concentrations for DINP associated with a particular COU were modeled using VVWM-PSC by COU/OES water release as described in Section 3.3.1.1. However, modeled surface water concentrations exceeded the estimates of the water solubility limit for DINP (approximately 6.1×10^{-4} mg/L) by five-to-eight orders of magnitude based on 7Q10 flow conditions (see *Draft Physical Chemistry Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024x)). Additionally, as described in the *Draft Environmental Exposure Assessment for Diisononyl Phthalate* (U.S. EPA, 2024o), based on the sorption and physical and chemical properties, DINP within suspended solids is not expected to be bioavailable. Therefore, DINP concentrations in fish is calculated in the *Draft Environmental Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024o) based on a solubility and a predicted bioconcentration factor (BCF). For estimating exposure to humans from fish ingestion, calculating fish concentration using a bioaccumulation factor (BAF) is preferred because it considers the animal's uptake of a chemical from both diet and the water column. Therefore, EPA estimated fish tissue concentrations for estimating exposure to humans from fish ingestion using DINP's water solubility limit and a BAF. In addition, EPA calculated fish tissue concentrations using the highest measured DINP concentrations in surface water. Details on the calculated fish tissue concentrations can be found in Section 7 of the *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r).

Using the estimated fish tissue concentrations, EPA evaluated exposure and potential risk to DINP through fish ingestion for adults in the general population, adult subsistence fishers, and adult tribal populations. Children were not considered for reasons explained in Sections 7.2 and 7.3 of the *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r). 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, 2024q). As such, tribal populations represent the sentinel exposure scenario. Risk estimates calculated from the water solubility limit of DINP as surface water concentration were three-to-six orders of magnitude above its non-cancer risk benchmark using both the current and heritage fish ingestion rate (Table 4-12). Using the highest measured DINP levels from a stormwater catchment area in Sweden as the surface water concentration, risk estimates for tribal populations were still one-to-three orders of magnitude above its corresponding benchmark for both fish ingestion rates. Exposure estimates based on conservative values such as surface water concentration from a stormwater catchment area still resulted in risk estimates that are above their benchmarks. Therefore, these results indicate that fish ingestion is not a pathway of concern for DINP for tribal members, subsistence fishers, or the general population.

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

Calculation Method	Current Mean Ingestion Rate (Benchmark MOE = 30)			Heritage Ingestion Rate (Benchmark MOE = 30)		
	ADR/ADD (mg/kg-day)	Acute MOE	Chronic MOE	ADR/ADD (mg/kg-day)	Acute MOE	Chronic MOE
Water solubility limit (6.10E−04 mg/L)	3.46E−05	1,4200,000	434,000	2.64E−04	186,000	56,900
Monitored SWC from stormwater catchment area (8.50E−02 mg/L)	4.82E−03	10,200	3,110	3.67E−02	1,330	408

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 DINP from EPA estimated releases. The highest modelled 95th percentile annual ambient air and soil concentrations across all release scenarios were 4.0×10^{2} µg/m^{3} and 1.46 mg/kg at 100 m from the releasing facility for the Non-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. Non-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 ADR for soil ingestion and the dermal absorbed dose (DAD) for soil dermal contact to be 0.018 and 0.0487 mg/kg-day. EPA did not estimate inhalation exposure to ambient air because it was not expected to be a pathway of concern (see Section 9 of *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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 180 for acute and 53 for chronic (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; therefore, the ambient air pathway is not considered to be a pathway of concern to DINP for the general population.

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

OES[a]	Soil Ingestion (Benchmark MOE = 30)			Dermal Soil Contact (Benchmark MOE = 30)		
	Soil Concentration[b] (mg/kg)	ADD (mg/kg-day)	MOE[c]	Soil Concentration[b] (mg/kg)	DAD (mg/kg-day)	MOE[c]
Non-PVC plastic compounding	1.46	0.018	180 (acute) 53 (chronic)	1.46	0.0487	180 (acute) 53 (chronic)

[a] Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.
[b] Air and soil concentrations are 95th percentile at 100 m from the emitting facility
[c] MOE for soil ingestion and dermal contact represent aggregated exposure

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. EPA 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 DINP using NHANES reported urinary concentrations for three metabolites of DINP: mono-isononyl phthalate (MiNP) (measured in the 1999 to 2018 NHANES cycles), mono-oxoisononyl phthalate (MONP) (measured in the 2017 to 2018 NHANES cycle), and mono-(carboxyoctyl) phthalate (MCOP) (measured in the 2005 to 2018 NHANES cycles). Urinary MiNP, MONP, and MCOP levels reported in the most recent NHANES survey (*i.e.*, 2017 to 2018) were used to calculate daily intake for various demographic groups reported within NHANES (Table 4-14). Median daily intake estimates across demographic groups ranged from 0.6 to 1.7 µg/kg-day, while 95th percentile daily intake estimates ranged from 3.4 to 8.1 µg/kg-day. The highest daily intake value estimated was for female children (6 to 11 years old) and was 8.1 µg/kg-day at the 95th exposure percentile. Detailed results of the NHANES analysis can be found in Section 10.2 of EPA's *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r).

Using 50th and 95th percentile daily intake values calculated from reverse dosimetry, EPA calculated MOEs ranging from 2,300 to 5,800 at the 50th percentile and 430 to 1,030 at the 95th percentile across demographic groups using the chronic POD (*i.e.*, an HED of 3,500 µg/kg-day) based on liver toxicity (Table 4-14). The lowest calculated MOE of 430 was for female children (6 to 11 years old), 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 DINP does not pose a risk to the non-institutionalized, U.S. civilian population. At this time, EPA has not yet completed its cumulative phthalate risk assessment where multiple phthalates will be considered.

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 exposure scenarios corresponding to TSCA releases. However, as a screening-level analysis, media 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 4-12), and soil ingestion and dermal soil contact resulting from air to soil deposition of DINP (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 DINP exposure comes primarily from diet for women, infants, toddlers, and children and that the outdoor environment is not a major source of exposure to DINP (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.

Table 4-14. Daily Intake Values and MOEs for DINP Based on Urinary Biomonitoring from the 2017 to 2018 NHANES Cycle

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	0.6 (0.6–0.7)	4 (3.3–4.8)	5,800	875
Females	0.7 (0.6–0.7)	4.4 (3–5.9)	5,000	800
Males	0.6 (0.6–0.7)	3.6 (2.7–4.6)	5,800	970
White non-Hispanic	0.6 (0.6 - 0.7)	3.6 (2.5–4.8)	5,800	970
Black non-Hispanic	0.6 (0.6–0.7)	4.5 (2.9–6.2)	5,800	780
Mexican-American	0.6 (0.6–0.7)	4.8 (2.1–7.5)	5,800	730
Other Race	0.7 (0.6–0.8)	4.7 (2.1–7.3)	5,000	740
Above Poverty Level	0.7 (0.6–0.8)	7.1 (3.9–10.2)	5,000	490
Below Poverty Level	0.6 (0.6–0.7)	3.7 (2.9–4.6)	5,800	950
3–5 years old	1.5 (1.4–1.6)	5.7 (0.2–11.2)	2,300	610
6–11 years old	1 (0.9–1.2)	6.2 (3.3–9.1)	3,500	560
12–15 years old	0.7 (0.5–0.8)	5.2 (–1.1 to 11.5)	5,000	670
16–49 years old	0.7 (0.6–0.7)	4 (1.9–6.2)	5,000	875
16+ years old	0.6 (0.6–0.6)	3.5 (2.7–4.4)	5,800	1,000
Males 3–5 years old	1.4 (1.3–1.6)	4.8 (–4.7 to 14.4)	2,500	730
Males 6–11 years old	1 (0.8–1.2)	3.4 (1.1–5.7)	3,500	1,030
Males 12–15 years old	0.6 (0.5–0.8)	4.7[a]	5,800	740
Males 16–49 years old	0.6 (0.6–0.7)	3.4 (2–4.9)	5,800	1,030
Males 16+ years old	0.6 (0.5–0.6)	3.4 (2.4–4.4)	5,800	1,030
Females 3–5 years old	1.5 (1.3–1.7)	7.4 (–0.7 to 15.5)	2,300	470
Females 6–11 years old	1 (0.9–1.2)	8.1[a]	3,500	430
Females 12–15 years old	0.7 (0.4–0.9)	5.2[a]	5,000	670
Females 16–49 years old	0.7 (0.6–0.8)	5.6 (2–9.3)	5,000	630

Females 16+ years old	0.6 (0.6–0.7)	3.6 (1.8–5.4)	5,800	970
[a] 95% confidence intervals (CI) could not be calculated due to small sample size or a standard error of zero.				

4.1.3.1 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 *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (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, EPA 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, EPA 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, adding to confidence that exposure estimates captured high-end exposure scenarios.

4.1.4 Human Milk Exposures

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

Although no U.S. biomonitoring studies investigated the presence of DINP or its metabolites in human milk, EPA identified nine studies from foreign countries that did. The highest measured concentration and the high-end milk ingestion rate was used to estimate infant exposure to DINP though human milk ingestion. Despite these conservative inputs, non-cancer risk estimates exceeded their corresponding benchmarks for both intermediate and chronic exposure.

Furthermore, no human health studies have evaluated only lactational exposure from quantified levels of DINP in milk. Uncertainties in the toxic moiety for DINP and the limited half-life data of its metabolites in the human body that are both sensitive and specific also precluded modeling human milk concentrations by COUs. Overall, EPA concluded that the most scientifically supportable approach is to not model milk concentrations. EPA instead used human health hazard values that are based on gestational exposure and biomonitoring data that aggregates exposure to estimate risks to a nursing infant. Further discussion of the human milk pathway is provided in the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r).

4.1.5 Aggregate and Sentinel Exposure

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 chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33)." For the draft DINP risk evaluation, EPA considered aggregate risk across all routes of exposure for each individual consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations. EPA did not consider aggregate exposure for the general population. As described in Section 4.1.3, EPA employed a risk screen approach for the general population exposure assessment. Based on results from the risk screen, no pathways of concern (*i.e.*, ambient air, surface water, drinking water, fish ingestion) to DINP exposure were identified for the generation population.

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

4.2 Summary of Human Health Hazard

Background

This section briefly summarizes the human health hazards of DINP. Additional information on the non-cancer and cancer human health hazards of DINP are provided in the *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w) and *Draft Cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024k), which were subject to peer-review during the July 2024 SACC meeting.

Non-cancer Human Health Hazards

EPA identified developmental, liver, and kidney toxicity as the most sensitive and robust non-cancer hazards associated with oral exposure to DINP in experimental animal models. Liver, kidney, and developmental toxicity were also identified as the most sensitive and robust non-cancer effects following oral exposure to DINP 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, 2015b).

To calculate non-cancer risks from oral to DINP for acute and intermediate durations of exposure in the draft risk evaluation of DINP, EPA selected a benchmark dose (BMD) 95 percent lower confidence limit (BMDL) associated with a benchmark response (BMR) of 5 percent ($BMDL_5$) of 49 mg/kg-day. The $BMDL_5$ was derived through meta-regression analysis and BMD modeling of fetal testicular testosterone data from two prenatal exposure studies of rats by the National Academies of Sciences, Engineering, and Medicine (NASEM, 2017). The $BMDL_5$ of 49 mg/kg-day was converted to a human equivalent dose (HED) of 12 mg/kg-day based on allometric body weight scaling to the three-quarter power (U.S. EPA, 2011c). As discussed in the *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w) several additional developmental toxicity studies of DINP provide similar, although less-sensitive, candidate points of departure (PODs), which further support EPA's decision to use the selected HED of 12 mg/kg-day for decreased fetal testicular testosterone production. The Agency has performed ¾ body weight scaling to yield the HED and is applying the animal to human extrapolation factor (*i.e.*, interspecies extrapolation; UF_A) of 3× and an within human variability extrapolation factor (*i.e.*, intraspecies extrapolation; UF_H) of 10×. Thus, a total uncertainty factor (UF) of 30× is applied for use as the benchmark MOE. Based on the strengths, limitations, and uncertainties discussed in the *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w), EPA has robust overall confidence in the proposed POD based on fetal testicular testosterone for use in characterizing risk from exposure to DINP for acute and intermediate exposure scenarios. 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 age groups (*e.g.*, older children and adult males) is conservative.

To calculate non-cancer risks from oral to DINP for chronic durations of exposure in the draft risk evaluation of DINP, EPA preliminarily selected a no-observed-adverse-effect level (NOAEL) of 15 mg/kg-day from a 2-year study of F344 rats based on liver toxicity. More specifically, liver toxicity in the key study (Lington et al., 1997; Bio/dynamics, 1986) was characterized by increased liver weight, increased serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and histopathological findings (*e.g.*, spongiosis hepatis, focal necrosis). EPA considers the observed liver effects to be adverse and relevant for extrapolating human risk from chronic exposures (U.S. EPA, 2002a). The Agency has performed ¾ body weight scaling to yield an HED of 3.5 mg/kg-day and is applying the animal to human extrapolation factor (*i.e.*, interspecies extrapolation; UF_A) of 3× and an within human variability extrapolation factor (*i.e.*, intraspecies extrapolation; UF_H) of 10×. Thus, a total UF of 30× is applied for use as the benchmark MOE. Overall, based on the strengths, limitations, and uncertainties discussed in the *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w), EPA has robust overall confidence in the proposed POD based on hepatic outcomes for use in characterizing risk from exposure to DINP for chronic exposure scenarios.

No data were available for the dermal or inhalation routes that were suitable for deriving route-specific PODs. Therefore, EPA used the acute/intermediate and chronic oral PODs to evaluate risks from dermal exposure to DINP. Differences in absorption will be accounted for in dermal exposure estimates in the draft risk evaluation for DINP. For the inhalation route, EPA 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). Table 4-15 summarizes the oral HED and inhalation HEC values selected by EPA to estimate non-cancer risk from acute/intermediate and chronic exposure to DINP in this draft risk evaluation.

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

Exposure Scenario	Target Organ System	Species (Sex)	Duration	POD (mg/kg-day)	Effect	HEC (mg/m^3) [ppm]	HED (mg/kg-day)	Benchmark MOE	Reference
Acute and Intermediate	Develop-mental	Rat	5 to 14 days throughout gestation	$BMDL_5$ = 49[a]	↓ fetal testicular testosterone	63 [3.7]	12	UF_A= 3 UF_H=10 *Total UF=30*	(NASEM, 2017)
Chronic	Liver	Rat	2 years	NOAEL = 15	↑ liver weight, ↑ serum chemistry, histopathology[b]	19 [1.1]	3.5	UF_A= 3 UF_H=10 *Total UF=30*	(Lington et al., 1997; Bio/dynamics, 1986)

HEC = human equivalent concentration; HED = human equivalent dose; POD = point of departure; MOE = margin of exposure; BMDL = benchmark dose lower limit; UF = uncertainty factor; NOAEL = no-observed-adverse-effect-level
[a] The $BMDL_5$ was derived by NASEM (2017) through meta-regression and BMD modeling of fetal testicular testosterone data from two studies of DINP with rats (Boberg et al., 2011; Hannas et al., 2011). R code supporting NASEM's meta-regression and BMD analysis of DINP is publicly available through GitHub.
[b] Liver toxicity included increased relative liver weight, increased serum chemistry (*i.e.*, AST, ALT, ALP), and histopathologic findings (*e.g.*, focal necrosis, spongiosis hepatis) in F344 rats following 2 years of dietary exposure to DINP (Lington et al., 1997; Bio/dynamics, 1986).

Cancer Human Health Hazards

DINP has been evaluated for carcinogenicity in two 2-year dietary studies of F344 rats (Covance Labs, 1998b; Lington et al., 1997), one 1-year dietary study of SD rats (Bio/dynamics, 1987), and one 2-year dietary study of B6C3F1 mice (Covance Labs, 1998a). Across available studies, statistically significant increases in renal tubule cell carcinomas, mononuclear cell leukemia (MNCL), and hepatocellular adenomas and carcinomas have been observed. As discussed further below (and in U.S. EPA (2024k)), EPA does not consider the renal tubule cell carcinomas observed only in male rats to occur through a human relevant MOA, and there is significant scientific uncertainty associated with MNCL in F344 rats. Therefore, EPA focused its cancer dose-response assessment to hepatocellular adenomas and carcinomas.

Kidney Tumors: A slight, but statistically significant increase in renal tubule cell carcinomas was observed in high-dose (637 mg/kg-day) male (but not female) F344 rats in one study (Covance Labs, 1998b), while a non-statistically significant increase in renal tubule cell carcinomas was observed in male (but not female) F344 rats in a second study (Lington et al., 1997). Renal tubule carcinomas have not been observed in female SD or F344 rats or mice of either sex. Much of the available literature supports an α_{2u}-globulin MOA to explain the incidences of renal tubule cell carcinomas observed only in male rats exposed chronically to DINP. EPA does not consider kidney tumors arising through a α_{2u}-globulin MOA to be human relevant (U.S. EPA, 1991a). Therefore, EPA did not consider it appropriate to derive quantitative estimates of cancer hazard for data on kidney tumors observed in these studies.

Mononuclear Cell Leukemia: The incidence of MNCL was significantly elevated in male and female F344 rats exposed to DINP in the diet at doses as low as 152 to 359 mg/kg-day when compared to study control animals in two independent carcinogenicity studies (Covance Labs, 1998b; Lington et al., 1997). Inconsistent with findings from the two chronic studies of F344 rats, MNCL was not observed in male or female SD rats treated with up to 553 to 672 mg/kg-day DINP for 2 years (Bio/dynamics, 1987) or male and female B6C3F1 mice treated with up to 1,560 to 1,888 mg/kg-day DINP for two years

(Covance Labs, 1998a). As discussed further in EPA's *Draft Cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024k), there are several sources of scientific uncertainty associated with MNCL. First, 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 (Thomas et al., 2007). Given the high and variable background rate of MNCL in F344 rats, it is important to consider concurrent control data, historical control data, and time to onset of MNCL to assist in determining whether observed increases in MNCL are treatment-related. Historical control data from the laboratories conducting the studies of DINP is not available, although there is some limited evidence available that indicates that time to onset of MNCL was shorter in DINP-treated animals compared to concurrent controls. Another source of uncertainty is lack of MOA information for induction of MNCL in F344 rats. The MOA for induction of MNCL in F344 rats is unknown. Lack of MOA information makes it difficult to determine human relevancy. There is additional uncertainty related to the human correlate to MNCL in F344 rats. Therefore, the significance of MNCL and its biological relevance for human cancer risk remains uncertain. Other regulatory agencies have also considered the human relevance of MNCL. Generally, other agencies such as Australia NICNAS (2012) Health Canada (EC/HC, 2015a), U.S. CPSC (2010), and ECHA (2013) have concluded that MNCL observed in F344 rats is not human relevant or has unclear human relevance and refrained from using MNCL to predict cancer risk in humans.

Overall, considerable scientific uncertainty remains. Therefore, EPA did not consider it appropriate to derive quantitative estimates of cancer hazard for data on MNCL from these two studies in F344 rats.

Liver Tumors: Across available studies, treatment-related hepatocellular adenomas and carcinomas have consistently been observed in F344 and SD rats as well as B6C3F1 mice. Existing assessments of DINP by U.S. CPSC (2014, 2010), Health Canada (ECCC/HC, 2020; EC/HC, 2015a; Health Canada, 2015), ECHA (2013), and NICNAS (2012) have postulated that DINP causes liver tumors in rats and mice through a peroxisome proliferator-activated receptor alpha (PPARα) MOA. Consistent with *EPA Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a) and the IPCS *Mode of Action Framework* (IPCS, 2007), EPA further evaluated the postulated PPARα MOA for liver tumors, as well as evidence for other plausible MOAs for DINP.

Although some uncertainties remain, there is strong evidence to support the postulated, non-genotoxic, PPARα MOA. Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a), EPA determined that DINP is *Not Likely to be Carcinogenic to Humans* at doses below levels that do not result in PPARα activation (key event 1 in the postulated MOA). Further, the non-cancer chronic POD (NOAEL/LOAEL of 15/152 mg/kg-day based on non-cancer liver effects; see EPA's *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w)) will adequately account for all chronic toxicity, including carcinogenicity, which could potentially result from exposure to DINP. Therefore, the non-cancer chronic POD of 15 mg/kg-day is considered protective of PPARα activation and carcinogenicity.

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. Exposure Scenarios, Populations of Interest, and Hazard Values

Population of Interest and Exposure Scenario	**Workers** Male and female adolescents and adults (≥16 years old) and females of reproductive age directly working with DINP under light activity (breathing rate of 1.25 m^3/h) <u>Exposure Durations</u> • *Acute* – 8 hours for a single workday • *Intermediate* – 8 hours per workday for 22 days per 30-day period • *Chronic* – 8 hours per workday for 250 days per year for 31 or 40 working years <u>Exposure Routes</u> • Inhalation and dermal
	Occupational Non-users Male and female adolescents and adults (≥16 years old) indirectly exposed to DINP within the same work area as workers (breathing rate of 1.25 m^3/h) <u>Exposure Durations</u> • *Acute, Intermediate, and Chronic* – same as workers <u>Exposure Routes</u> • Inhalation, dermal (mist and dust deposited on surfaces)
	Consumers Male and female infants (<1 year), toddlers (1–2 years), children (3–5 years and 6–10 years), young teens (11–15 years), teenagers (16–20 years) and adults (21+ years) exposed to DINP through product or articles use <u>Exposure Durations</u> • *Acute* – 1 day exposure • *Intermediate* – 30 days per year • *Chronic* – 365 days per year <u>Exposure Routes</u> • Inhalation, dermal, and oral
	Bystanders Male and female infants (<1 year), toddlers (1–2 years), and children (3–5 years and 6–10 years) incidentally exposed to DINP through product use <u>Exposure Durations</u> • *Acute* – 1 day exposure • *Intermediate* – 30 days per year • *Chronic* – 365 days per year <u>Exposure Routes</u> • Inhalation
	General Population Male and female infants, children, youth, and adults exposed to DINP through drinking water, surface water, soil from air to soil deposition, and fish ingestion <u>Exposure Durations</u> • *Acute* – Exposed to DINP continuously for a 24-hour period • *Chronic* – Exposed to DINP continuously up to 33 years <u>Exposure Routes</u> – Inhalation, dermal, and oral (depending on exposure scenario)
Health Effects, Concentration and Time Duration	**Non-cancer Acute/Intermediate Value** Sensitive health effect: Developmental toxicity (*i.e.*, reduced fetal testicular testosterone content) HEC Daily, continuous = 63 mg/m^3 (3.7 ppm) HED Daily = 12 mg/kg-day; dermal and oral Total UF (benchmark MOE) = 30 (UF_A = 3; UF_H = 10) **Non-cancer Chronic Value** Sensitive health effect: Liver toxicity HEC Daily, continuous = 19 mg/m^3 (1.1 ppm) HED Daily = 3.5 mg/kg-day; dermal and oral Total UF (benchmark MOE) = 30 (UF_A = 3; UF_H = 10)

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^3) or HED (mg/kg-day)
Human Exposure	=	Exposure estimate (mg/m^3 or mg/kg-day)

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

4.3.1.2 Estimation of Non-cancer Aggregate Risks

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

Equation 4-2. Total Margin of Exposure Calculation

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

Where:

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

Total MOE risk estimates may be interpreted in relation to benchmark MOEs, similarly as to described in the preceding 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. In summary, it was determined that the central tendency estimates of worker exposure and risk are most representative for all manufacturing, processing, industrial and commercial COUs—with exception of some industrial COUs for Adhesive and sealant chemicals and Paints and coatings due to the potentially elevated inhalation exposures from pressurized spray operations.

Application of Adhesives and Sealants

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. Therefore, EPA distinguished exposure estimates between *spray* and *non-spray* application of adhesive and sealant products containing DINP. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure from the spray application scenario ranged from 2.1 to 7.4 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 33 to 114 (benchmark = 30). For central tendency of the spray scenario, MOEs for the same populations and exposure scenarios ranged from 30 to 97 for inhalation exposure and 71 to 228 for dermal exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure from the non-spray application scenario ranged from 59,215 to 209,455 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 33 to 114 (benchmark = 30). For central tendency of the non-spray scenario, MOEs for the same populations and exposure scenarios ranged from 127,618 to 418,909 for inhalation exposure and 71 to 228 for dermal exposure. Aggregation of inhalation and dermal exposures led to negligible differences in MOEs when compared to estimates from inhalation exposure alone.

EPA used mist monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a) to evaluate inhalation exposure for the Application of Adhesives and Sealants – Spray Application exposure scenario. The ESD indicated a central tendency (*i.e.*, 50th percentile) of 8-hour TWA mist concentrations from automotive refinishing of 3.38 mg/m^3 and a high-end concentration (*i.e.*, 95th percentile) of 22.1 mg/m^3. The underlying mist concentration data considered in the ESD reflected a variety of industrial and commercial automotive refinishing scenarios (*e.g.*, different gun types and booth configurations), but all scenarios used the spray application of auto refinishing coatings. The more highly pressurized spray guns led to higher exposure levels, and less pressurized spray guns led to lower exposure levels. Therefore, the high-end inhalation exposure estimates are more representative of high-pressure spray applications (*e.g.*, conventional spray guns), whereas the central tendency estimates are more representative of low-pressure applications (*e.g.*, HVLP spray guns).

For inhalation exposure from the Application of Adhesives and Sealants – Non-spray Application ESD, mist generation is not expected and EPA assumed that vapor generation during use would be similar to the vapor exposure experienced during the incorporation of DINP into adhesive and sealant products. Specifically, EPA estimated vapor inhalation exposures using surrogate monitoring data for DINP use during PVC plastics compounding at a PVC roofing manufacturing site (Irwin, 2022). All inhalation datapoints were below the detection limit; therefore, EPA assessed high-end exposure using the detection limit and central tendency exposure using half the detection limit.

Regarding product concentrations, the various commercial adhesive and sealant products considered are summarized in Appendix F of the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s). There are also two industrial adhesive and sealant products (*i.e.*, Tremco JS443 A & B) listed in Appendix F of the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)*. Both products have similar DINP concentrations to the commercial products identified. The central tendency product concentration was chosen as the mode of available product concentrations (*i.e.*, 10 wt%) and the high-end product concentration was chosen as 95th percentile of available product concentrations (*i.e.*, 40 wt%). Because there were significant differences between central tendency and high-end values for the mist exposure concentration and the product concentration, which are both inputs to the inhalation exposure distribution, there was a larger range of potential inhalation exposures for the spray application of adhesives and sealants.

Because the mist monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a) is directly applicable to the spray application of adhesives and sealants, the inhalation exposure estimates from Table 4-17 for Application of Adhesives and Sealants – Spray Application are expected to be representative of industrial operations where adhesives and sealants are applied using spray methods (*i.e.*, Industrial COU: Adhesive and sealant chemicals). Exposures from high-pressure spray applications (*e.g.*, conventional spray guns) are best represented by the high-end exposure estimates, whereas as exposures from low-pressure spray applications (*e.g.*, HVLP spray guns) are best represented by central tendency estimates. However, any occupational use of adhesives and sealants that does not generate mist would be best characterized by exposure estimates under the Application of adhesives and sealants – non-spray application exposure scenario. For example, the Tremco JS443 products are intended for industrial use in the insulated glass (IG) unit manufacturing industry, and the products are precision applied such that mist generation is not expected. Therefore, worker exposures from the industrial use of Tremco JS443 A & B are best characterized under the Application of adhesives and sealants – non-spray application exposure scenario.

Lastly, the commercial adhesive and sealant products that were identified through the risk evaluation process and summarized in Appendix F of *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) are not generally applied through spray methods, but rather bead, brush, or roll applications where mist generation is not expected. Therefore, occupational exposures to DINP from the commercial use of adhesives and sealants (*i.e.*, Commercial COU: adhesives and sealants) is represented by the Application of adhesives and sealants – non-spray application exposure scenario in Table 4-17.

Application of Paints and Coatings

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. Therefore, EPA distinguished exposure estimates between *spray* and *non-spray* application of paint and coating products containing DINP. In support of this, MOEs for high-end acute, intermediate, and chronic inhalation exposure from the spray application scenario ranged from 4.2 to 15 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 33 to 114 (benchmark = 30). For central tendency of the *spray scenario*, MOEs for the same populations and exposure scenarios ranged from 55 to 194 for inhalation exposures and 66 to 228 for dermal exposures. MOEs for high-end acute, intermediate, and chronic inhalation exposure from the non-spray application scenario ranged from 59,215 to 209,455 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 33 to 114 (benchmark = 30). For central tendency of the *non-spray scenario*, MOEs for the same populations and exposure scenarios ranged from 118,429 to 418,909 for inhalation exposure and 71 to 228 for dermal exposure. Aggregation of inhalation and dermal exposures led to small differences in MOEs when compared to MOE estimates from dominant exposure route alone.

EPA used mist monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a) to evaluate inhalation exposure for the Application of paints and coatings – spray application exposure scenario. The ESD indicated a central tendency (*i.e.*, 50th percentile) of 8-hour TWA mist concentrations from automotive refinishing of 3.38 mg/m^3 and a high-end concentration (*i.e.*, 95th percentile) of 22.1 mg/m^3. The underlying mist concentration data considered in the ESD reflected a variety of industrial and commercial automotive refinishing scenarios (*e.g.*, different gun types and booth configurations), but all scenarios used the spray application of auto refinishing coatings. The more highly pressurized spray guns led to higher exposure levels, and less pressurized spray guns led to lower exposure levels. Therefore, the high-end inhalation exposure estimates are more representative of high-pressure spray applications (*e.g.*, conventional spray guns) whereas the central tendency estimates are more representative of low-pressure applications (*e.g.*, HVLP spray guns).

For inhalation exposure from the Application of paints and coatings – non-spray application exposure scenario, mist generation is not expected and EPA assumed that vapor generation during use would be similar to the vapor exposure experienced during the incorporation of DINP into paint and coating products. Specifically, EPA estimated vapor inhalation exposures using surrogate monitoring data for DINP use during PVC plastics compounding at a PVC roofing manufacturing site (Irwin, 2022). All inhalation datapoints were below the detection limit, therefore EPA assessed high-end exposure using the detection limit and central tendency exposure using half the detection limit.

Regarding product concentrations, the various commercial paint and coating products considered are summarized in Appendix F of the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s). There is also one paint and coating product (*i.e.*, Freeman 90 – Burnt Orange Pattern Coating) that is listed as an Industrial COU in Table 1-1, and this product has a similar range of potential DINP concentrations to the commercial products identified. EPA used the mode product concentration (*i.e.*, 5 percent) to represent the central tendency product concentration and the upper bound product concentration (*i.e.*, 20 percent) 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, there was a larger range of potential inhalation exposures for the application of paints and coatings.

Since the mist monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a) is directly applicable to the spray application of paints and coatings, the exposure estimates from Table 4-17 for the Application of paints and coatings – spray application are expected to be representative of industrial operations where paints and coatings are applied using spray methods (*i.e.*, Industrial COU: Paints and coatings). Exposures from high-pressure spray applications (*e.g.*, conventional spray guns) are best represented by the high-end exposure estimates, whereas as exposures from low-pressure spray applications (*e.g.*, HVLP spray guns) are best represented by central tendency estimates. There was one paint and coating product identified for potential industrial use (*i.e.*, Freeman 90 – Burnt Orange Pattern Coating), with a DINP concentration ranging from 1 to 5 percent, and is intended to be brush-applied or spray-applied at low-pressure if thinned. Because the product is intended to be spray-applied at low-pressure when thinned, and the product concentration is near the mode product concentration (*i.e.*, 5 percent), the industrial use of Freeman 90 – Burnt Orange Pattern Coating is best characterized by the central tendency exposure estimates of the Application of paints and coatings – spray application exposure scenario. However, any occupational use of paints and coatings that does not generate mist would be best characterized by exposure estimates under the Application of paints and coatings – non-spray application exposure scenario.

The conditions of use identified for DINP also indicate commercial use of paint and coating products containing DINP. The commercial paint and coating products that were identified through the risk evaluation process and summarized in Appendix F of *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s) are not generally applied through highly pressurized spray methods, but rather low-pressure hand pump sprayers, small volume spray cans, and buff coating applications are used for the available commercial paint and coating products containing DINP. Therefore, occupational exposures to DINP from the commercial use of paint and coating products (*i.e.*, Commercial COU: Paints and coatings) are represented by the central tendency levels of exposure of the Application of Paints and Coatings – Spray Application exposure scenario in Table 4-17. However, any products that are not expected to generate mist during use would be best characterized by exposure estimates under the Application of paints and coatings – non-spray application exposure scenario. For instance, the industrial uses of pigments for leak detection and commercial uses of ink, toner, and colorant products (*i.e.*, Industrial COUs: Pigment [leak detection]; Commercial COUs: Ink, toner, and colorant products) are not expected to generate mist and are best characterized by the Application of paints and coatings – non-spray application exposure scenario.

PVC Plastics Compounding and Non-PVC Material Compounding

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 17 to 62 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 33 to 114 (benchmark = 30). Similarly, for non-PVC material compounding MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 20 to 70 for average adult workers and women of reproductive age, while high-end dermal MOEs ranged from 33 to 114. For central tendency, MOEs for the same population and exposure scenarios ranged from 400 to 1,261 for inhalation exposure and 80 to 228 for dermal exposures during PVC plastics compounding and 428 to 1,418 for inhalation exposure and 70 to 228 for dermal exposures during non-PVC material compounding. The reason for the large variation between high-end and central tendency is described below.

EPA estimated worker inhalation exposures using monitoring data for vapor exposures at a PVC roofing manufacturing site (Irwin, 2022) 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, 2021e). EPA did not have a robust dataset for vapor exposures, with all monitoring data below the limit of detection (LOD); therefore, EPA assessed high-end vapor exposures at the LOD and central tendency vapor exposures at half of the LOD. For inhalation exposures to particulate, EPA determined the 50th and 95th percentiles of the surrogate dust data from facilities with NAICS codes starting with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry provided DINP concentration range in PVC (*i.e.*, 10 to 45 percent) and non-PVC (*i.e.*, 1 to 40 percent) products, respectively, to estimate DINP particulate concentrations in the air. The differences in the central tendency and high-end dust concentrations and DINP concentrations in PVC and non-PVC products, 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 compounding industry, the composition of workplace dust is uncertain. The exposure and risk estimates assume that the concentration of DINP in workplace dust is the same as the concentration of DINP in PVC plastics and non-PVC materials. However, it is likely that workplace dust contains a variety of constituents and that the concentration of DINP in workplace dust is less than the concentration of DINP in PVC or non-PVC products. Due to the uncertainty of DINP concentrations in workplace dust, central tendency values of exposure are expected to be most reflective of worker exposures within the COUs covered under the PVC plastics compounding and Non-PVC material compounding OESs (*i.e.*, Processing COUs: Plasticizers [custom compounding of purchased resin; plastic material and resin manufacturing; synthetic rubber manufacturing]).

PVC Plastics Converting and Non-PVC Material Converting

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 17 to 62 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 8,309 to 28,960 (benchmark = 30). Similarly, non-PVC material converting MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 20 to 70 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 8,309 to 28,960. For central tendency, MOEs for the same population and exposure scenarios ranged from 407 to 1,261 for inhalation exposure and 18,970 to 57,590 for dermal exposures during PVC plastics converting and 458 to 1,418 for inhalation exposure and 18,970 to 57,590 for dermal exposures during non-PVC material converting. Aggregation of inhalation and dermal exposures led to negligible differences in MOEs when compared to estimates from inhalation exposure alone.

EPA estimated worker inhalation exposures using monitoring data for vapor exposures at a PVC roofing manufacturing site (Irwin, 2022) 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, 2021e). EPA did not have a robust dataset for vapor exposures with all monitoring data existing below the LOD, therefore EPA assessed high-end exposure as the LOD and the central tendency as half of the LOD to represent potential exposures from vapor. For inhalation exposure to PNOR, EPA determined the 50th and 95th percentiles of the surrogate dust release data taken from facilities with NAICS codes starting with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the industry provided DINP concentration range in PVC (*i.e.*, 10 to 45 percent) and non-PVC (*i.e.*, 1 to 40 percent) products, respectively, to estimate DINP particulate concentrations in the air. The differences in the central tendency and high-end dust concentrations, as well as DINP concentrations in the dust, led to significant differences between the central tendency and high-end risk estimates.

Though the PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may experience in the converting industry, the composition of workplace dust is uncertain. The exposure and risk estimates are based on the assumption that the concentration of DINP in workplace dust is the same as the concentration of DINP 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 DINP in workplace dust is less than the concentration of DINP in PVC or non-PVC products. Due to the uncertainty of DINP concentration in workplace dust, central tendency values of exposure are expected to be most reflective of worker exposures within the COUs covered under the PVC plastics converting and the Non-PVC material converting OESs (*i.e.*, Processing COUs: Plasticizers [playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; transportation equipment manufacturing; ink, toner, and colorant manufacturing (including pigments)]).

Fabrication and Final Use of Products or Articles

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 46 to 162 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 8,309 to 28,960 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 16,618 to 57,920 for dermal exposure and 411 to 1,455 for inhalation exposure. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone. The large variations between the central tendency and high-end estimates of worker inhalation exposures are described below.

EPA estimated worker inhalation exposures using the PNOR model for dust exposures (U.S. EPA, 2021e). For inhalation exposure to 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 DINP concentration in PVC (*i.e.*, 45 percent) to estimate DINP 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 DINP in workplace dust is the same as the maximum concentration of DINP in PVC plastics. However, it is likely that workplace dust contains a variety of constituents and that the concentration of DINP in workplace dust is less than the concentration of DINP in final products or articles. Due to uncertainty in DINP concentration in workplace dust, central tendency values of exposure are expected to be most reflective of worker exposures within the COUs covered under the "Fabrication and final use of products and articles" OES (*i.e.*, Industrial COUs: Automotive products, other than fluids; Building/construction materials (roofing, pool liners, window shades, flooring). Commercial COUs: Automotive products, other than fluids; Plasticizer in building/construction materials (roofing, pool liners, window shades); Construction and building materials covering large surface areas, including paper articles, metal articles, stone, plaster, cement, glass, and ceramic articles; Electrical and electronic products; Foam seating and bedding products; Floor coverings; Fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting); Fabric, textile, and leather products (apparel and footwear care products); Furniture and furnishings (furniture & furnishings including plastic articles [soft]; leather articles); Plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses); Toys, playground, and sporting equipment), Packaging, paper, plastic, hobby products (packaging [excluding food packaging], including rubber articles; plastic articles [hard]; plastic articles [soft]).

Recycling and Disposal

For recycling and disposal of DINP containing materials, the 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 23 to 83 for average adult workers and women of reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 8,309 to 28,960 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 18,630 to 57,920 for dermal exposure and 384 to 1,212 for inhalation exposure. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure alone. The large variations between the central tendency and high-end estimates of worker inhalation exposures are described below.

EPA estimated worker inhalation exposures using the PNOR model for dust exposures (U.S. EPA, 2021e). For inhalation exposure to 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 DINP concentration in PVC (*i.e.*, 45 percent) to estimate DINP 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 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 DINP in workplace dust is the same as the maximum concentration of DINP in PVC plastics. However, it is likely that workplace dust contains a variety of constituents and that the concentration of DINP in workplace dust is less than the concentration of DINP in recycled or disposed products or articles. Therefore, central tendency values of exposure are expected to be more reflective of worker exposures within the COUs covered under the "Recycling" and the "Disposal" OESs (*i.e.*, Industrial COUs: "Recycling" and "Disposal").

Distribution in Commerce

Distribution in commerce includes transporting DINP or DINP-containing products between work sites or to final use sites as well as loading and unloading from transport vehicles. Individuals in occupations that transport DINP-containing products (*e.g.*, truck drivers) or workers who load and unload transport trucks may encounter DINP or DINP-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 such as manufacturing or import, it is expected that workers involved in distribution in commerce spend less time exposed to DINP 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 captured in the subsection below.

OESs/COUs without Dust or Mist Generation

Due to the low vapor pressure of DINP, 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 536 for all assessed populations and exposure duration). Also, due to the long alkyl chain length of DINP, the rate of dermal absorption of DINP is quite slow which leads to low dermal exposure potential. For all of the below OES the MOE for dermal exposure to DINP, liquid and solid, ranges from greater than 33 for high-end and greater than 66 for central tendency. Aggregation of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates from each exposure alone. Therefore, any OES or COU where inhalation exposure to DINP 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 DINP concentration is very low (*i.e.*, 3 percent), 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 (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing); Miscellaneous processing (petroleum refineries, wholesale and retail trade); Heat stabilizer and processing aid in basic organic chemical manufacturing; Plasticizer (adhesives manufacturing; paint and coating manufacturing; All other chemical product and preparation manufacturing; Wholesale and retail trade; ink, toner, and colorant manufacturing (including pigment), Hydraulic fluids
- **Commercial:** Laboratory chemicals; Air care products; Solvents (for cleaning or degreasing)
- **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).

4.3.2.1 Overall Confidence in Worker Risks

As described in Section 4.1.1.5 and the *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (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 PODs selected to characterize risk from acute, intermediate, and chronic duration exposures to DINP (see Section 4.2 and (U.S. EPA, 2024v)). 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 Aggregate Risk Summary Table

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
					Acute	Intermed.	Chronic	Acute	Intermed.	Chronic	Acute	Intermed.	Chronic
Manufacturing – Domestic Manufacturing	Domestic Manufacturing	Manufacturing	Worker: Average Adult Worker	High-End	1,391	1,897	823	77	105	45	73	99	43
				Central Tendency	2,783	3,794	1,646	154	210	91	146	199	86
			Worker: Female of Reproductive Age	High-End	1,260	1,718	745	84	114	50	79	107	46
				Central Tendency	2,519	3,435	1,490	167	228	99	157	214	93
			ONU	High-End	2,783	3,794	1,646	N/A	N/A	N/A	2,783	3,794	1,646
				Central Tendency	2,783	3,794	1,646	N/A	N/A	N/A	2,783	3,794	1,646
Manufacturing – Importing	Importing	Import and repackaging	Worker: Average Adult Worker	High-End	1,391	1,897	592	77	105	33	73	99	31
				Central Tendency	2,783	3,794	1,424	154	210	79	146	199	75
Processing – Repackaging	Plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing)		Worker: Female of Reproductive Age	High-End	1,260	1,718	536	84	114	36	79	107	33
				Central Tendency	2,519	3,435	1,289	167	228	86	157	214	80
			ONU	High-End	2,783	3,794	1,185	N/A	N/A	N/A	2,783	3,794	1,185
				Central Tendency	2,783	3,794	1,424	N/A	N/A	N/A	2,783	3,794	1,424
Processing – Incorporation into Formulation, Mixture, or Reaction Product	Plasticizers (adhesives manufacturing)	Incorporation into adhesives and sealants	Worker: Average Adult Worker	High-End	153,600	209,455	65,408	77	105	33	77	105	33
				Central Tendency	307,200	418,909	130,816	154	210	66	154	210	65
			Worker: Female of Reproductive Age	High-End	139,056	189,622	59,215	84	114	36	84	114	36
				Central Tendency	278,112	379,244	118,429	167	228	71	167	228	71
			ONU	High-End	153,600	209,455	65,408	N/A	N/A	N/A	153,600	209,455	65,408
				Central Tendency	307,200	418,909	130,816	N/A	N/A	N/A	307,200	418,909	130,816

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Processing – Incorporation into Formulation, Mixture, or Reaction Product	Plasticizers (paint and coating manufacturing; ink, toner, and colorant manufacturing (including pigment))	Incorporation into paints and coatings	Worker: Average Adult Worker	High-End	153,600	209,455	65,408	77	105	33	77	105	33
				Central Tendency	307,200	418,909	130,816	154	210	66	154	210	65
			Worker: Female of Reproductive Age	High-End	139,056	189,622	59,215	84	114	36	84	114	36
				Central Tendency	278,112	379,244	118,429	167	228	71	167	228	71
			ONU	High-End	153,600	209,455	65,408	N/A	N/A	N/A	153,600	209,455	65,408
				Central Tendency	307,200	418,909	130,816	N/A	N/A	N/A	307,200	418,909	130,816
Processing – Other Uses	Miscellaneous processing (petroleum refineries; wholesale and retail trade)	Incorporation into other formulations, mixtures, and reaction products not covered elsewhere	Worker: Average Adult Worker	High-End	153,600	209,455	65,408	77	105	33	77	105	33
Processing – Incorporation into Formulation, Mixture, or Reaction Product	Heat stabilizer and processing aid in basic organic chemical manufacturing			Central Tendency	307,200	418,909	130,816	154	210	66	154	210	65
			Worker: Female of Reproductive Age	High-End	139,056	189,622	59,215	84	114	36	84	114	36
	Plasticizers (wholesale and retail trade; all other chemical product and preparation manufacturing)			Central Tendency	278,112	379,244	118,429	167	228	71	167	228	71
			ONU	High-End	153,600	209,455	65,408	N/A	N/A	N/A	153,600	209,455	65,408
Commercial Use – Furnishing, Cleaning, Treatment/ Care Products	Air care products			Central Tendency	307,200	418,909	130,816	N/A	N/A	N/A	307,200	418,909	130,816

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Processing – Incorporation into Formulation, Mixture, or Reaction Product	Plasticizers (custom compounding of purchased resin; plastic material and resin manufacturing)	PVC plastics compounding	Worker: Average Adult Worker	High-End	45	62	19	77	105	33	29	39	12
				Central Tendency	925	1,261	441	154	210	73	132	180	63
			Worker: Female of Reproductive Age	High-End	41	56	17	84	114	36	28	38	12
				Central Tendency	837	1,142	400	167	228	80	140	190	67
			ONU	High-End	922	1,257	393	39,024	53,215	16,618	901	1,228	385
				Central Tendency	925	1,261	441	39,024	53,215	18,630	903	1,232	431
Processing – Incorporation into Articles	Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])	PVC plastics converting	Worker: Average Adult Worker	High-End	45	62	19	19,512	26,608	8,309	45	62	19
				Central Tendency	925	1,261	450	39,024	53,215	18,970	903	1,232	439
			Worker: Female of Reproductive Age	High-End	41	56	17	21,237	28,960	9,044	41	56	17
				Central Tendency	837	1,142	407	42,475	57,920	20,647	821	1,120	399
			ONU	High-End	922	1,257	393	39,024	53,215	16,618	901	1,228	385
				Central Tendency	925	1,261	450	39,024	53,215	18,970	903	1,232	439

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Processing – Incorporation into Formulation, Mixture, or Reaction Product	Plasticizers (custom compounding of purchased resin; plastic material and resin manufacturing; synthetic rubber manufacturing)	Non-PVC material compounding	Worker: Average Adult Worker	High-End	51	70	22	77	105	33	31	42	13
				Central Tendency	1,040	1,418	473	154	210	70	134	183	61
			Worker: Female of Reproductive Age	High-End	46	63	20	84	114	36	30	41	13
				Central Tendency	941	1,284	428	167	228	76	142	194	65
			ONU	High-End	1,036	1,413	441	39,024	53,215	16,618	1,010	1,377	431
				Central Tendency	1,040	1,418	473	39,024	53,215	17,754	1,013	1,381	461
Processing – Incorporation into Articles	Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])	Non-PVC material converting	Worker: Average Adult Worker	High-End	51	70	22	19,512	26,608	8,309	51	69	22
				Central Tendency	1,040	1,418	506	39,024	53,215	18,970	1,013	1,381	492
			Worker: Female of Reproductive Age	High-End	46	63	20	21,237	28,960	9,044	46	63	20
				Central Tendency	941	1,284	458	42,475	57,920	20,647	921	1,256	448
			ONU	High-End	1,036	1,413	441	39,024	53,215	16,618	1,010	1,377	431
				Central Tendency	1,040	1,418	506	39,024	53,215	18,970	1,013	1,381	492

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Industrial Uses – Adhesives and Sealants	Adhesive and sealant chemicals	Application of adhesives and sealants – spray application	Average Adult Worker	High-End	5.4	7.4	2.3	77	105	33	5.1	6.9	2.2
				Central Tendency	71	97	33	154	210	71	49	66	22
			Female of Reproductive Age	High-End	4.9	6.7	2.1	84	114	36	4.6	6.3	2.0
				Central Tendency	64	88	30	167	228	77	47	63	21
			ONU	High-End	71	97	30	154	210	66	49	66	22
				Central Tendency	71	97	33	154	210	71	49	66	22
Industrial uses – Adhesives and Sealants	Adhesive and sealant chemicals	Application of adhesives and sealants – non-spray application	Worker: Average Adult Worker	High-End	153,600	209,455	65,408	77	105	33	77	105	33
				Central Tendency	307,200	418,909	140,966	154	210	71	154	210	71
			Worker: Female of Reproductive Age	High-End	139,056	189,622	59,215	84	114	36	84	114	36
				Central Tendency	278,112	379,244	127,618	167	228	77	167	228	77
Commercial uses – Construction, Paint, Electrical, and Metal Products	Adhesives and sealants		ONU	High-End	153,600	209,455	65,408	N/A	N/A	N/A	153,600	209,455	65,408
				Central Tendency	307,200	418,909	140,966	N/A	N/A	N/A	307,200	418,909	140,966

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Industrial Uses – Construction, Paint, Electrical, and Metal Products	Paints and coatings	Application of paints and coatings – spray application	Worker: Average Adult Worker	High-End	11	15	4.6	77	105	33	9.5	13	4.1
				Central Tendency	142	194	61	154	210	66	74	101	31
			Worker: Female of Reproductive Age	High-End	9.8	13	4.2	84	114	36	8.8	12	3.7
Commercial uses – Construction, Paint, Electrical, and Metal Products				Central Tendency	129	176	55	167	228	71	73	99	31
			ONU	High-End	142	194	61	154	210	66	74	101	31
				Central Tendency	142	194	61	154	210	66	74	101	31

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Industrial uses – Construction, Paint, Electrical, and Metal Products Commercial Uses – Construction, Paint, Electrical, and Metal Products	Paints and coatings	Application of paints and coatings – non-spray application	Worker: Average Adult Worker	High-End	153,600	209,455	65,408	77	105	33	77	105	33
Industrial uses – Other Uses	Pigment (leak detection)			Central Tendency	307,200	418,909	130,816	154	210	66	154	210	65
			Worker: Female of Reproductive Age	High-End	139,056	189,622	59,215	84	114	36	84	114	36
				Central Tendency	278,112	379,244	118,429	167	228	71	167	228	71
			ONU	High-End	153,600	209,455	65,408	N/A	N/A	N/A	153,600	209,455	65,408
Commercial Uses – Packaging, Paper, Plastic, Hobby Products	Ink, toner, and colorant products			Central Tendency	307,200	418,909	130,816	N/A	N/A	N/A	307,200	418,909	130,816

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Commercial Uses – Other Uses	Laboratory chemicals	Use of laboratory chemicals – liquid	Worker: Average Adult Worker	High-End	1,391	1,897	592	77	105	33	73	99	31
				Central Tendency	2,783	3,794	1,261	154	210	70	146	199	66
			Worker: Female of Reproductive Age	High-End	1,260	1,718	536	84	114	36	79	107	33
				Central Tendency	2,519	3,435	1,141	167	228	76	157	214	71
			ONU	High-End	2,783	3,794	1,185	N/A	N/A	N/A	2,783	3,794	1,185
				Central Tendency	2,783	3,794	1,261	N/A	N/A	N/A	2,783	3,794	1,261
Commercial Uses – Other Uses	Laboratory chemicals	Use of laboratory chemicals – solid	Worker: Average Adult Worker	High-End	1,185	1,616	505	19,512	26,608	8,309	1,117	1,524	476
				Central Tendency	16,842	22,967	7,172	39,024	53,215	16,618	11,765	16,043	5,010
			Worker: Female of Reproductive Age	High-End	1,073	1,463	457	21,237	28,960	9,044	1,021	1,393	435
				Central Tendency	15,247	20,792	6,493	42,475	57,920	18,087	11,220	15,300	4,778
			ONU	High-End	16,842	22,967	7,172	39,024	53,215	16,618	11,765	16,043	5,010
				Central Tendency	16,842	22,967	7,172	39,024	53,215	16,618	11,765	16,043	5,010
Commercial Uses – Solvents (for Cleaning or Degreasing)	Solvents (for cleaning or degreasing)	Use of lubricants and functional fluids	Worker: Average Adult Worker	High-End	1,391	10,435	37,029	77	577	2,047	73	547	1,940
				Central Tendency	2,783	41,739	148,116	154	2,308	8,189	146	2,187	7,760
			Worker: Female of Reproductive Age	High-End	1,260	9,447	33,523	84	628	2,228	79	589	2,089
Industrial uses – Other Uses	Hydraulic fluids			Central Tendency	2,519	37,787	134,091	167	2,512	8,913	157	2,355	8,358
			ONU	High-End	2,783	20,870	74,058	N/A	N/A	N/A	2,783	20,870	74,058
				Central Tendency	2,783	41,739	148,116	N/A	N/A	N/A	2,783	41,739	148,116

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Industrial Uses – Automotive, Fuel, Agriculture, Outdoor Use Products	Automotive products, other than fluids	Fabrication and Final Use of Products or Articles	Worker: Average Adult Worker	High-End	119	162	50	19,512	26,608	8,309	118	161	50
Industrial Uses – Automotive, Fuel, Agriculture, Outdoor Use Products	Building /construction materials (roofing, pool liners, window shades, flooring)			Central Tendency	1,067	1,455	454	39,024	53,215	16,618	1,038	1,416	442
Industrial Uses – Automotive, Fuel, Agriculture, Outdoor Use Products	Automotive products, other than fluids												
Commercial uses - Construction, paint, electrical, and metal products	Plasticizer in building/ construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles		Worker: Female of Reproductive Age	High-End	107	146	46	21,237	28,960	9,044	107	146	45

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
	Electrical and electronic products												
Commercial Uses – Furnishing, Cleaning, Treatment/ Care Products	Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles												
Commercial Uses – Furnishing, Cleaning, Treatment/ Care Products	Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Fabrication and Final Use of Products or Articles	Worker: Female of Reproductive Age	Central Tendency	966	1,317	411	42,475	57,920	18,087	944	1,288	402
	Fabric, textile, and leather products (apparel and footwear care products)												
	Arts, crafts, and hobby materials		ONU	High-End	1,067	1,455	454	39,024	53,215	16,618	1,038	1,416	442

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Commercial Use: Packaging, Paper, Plastic, Hobby Products	Packaging, paper, plastic, hobby products (packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft))	Fabrication and Final Use of Products or Articles	ONU										
Commercial Use: Packaging, Paper, Plastic, Hobby Products	Plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses)			Central Tendency	1,067	1,455	454	39,024	53,215	16,618	1,038	1,416	442
	Toys, playground, and sporting equipment	Fabrication and Final Use of Products or Articles											
Processing –	Recycling	Recycling and	Worker:	High-End	61	83	26	19,512	26,608	8,309	61	83	26

Life Cycle Stage/ Category	Subcategory	OES	Population	Exposure Level	Inhalation Risk Estimates (Benchmark MOE = 30)			Dermal Risk Estimates (Benchmark MOE = 30)			Aggregate Risk Estimates (Benchmark MOE = 30)		
Recycling		Disposal	Average Adult Worker	Central Tendency	889	1,212	424	39,024	53,215	18,630	869	1,185	415
Disposal – Disposal	Disposal		Worker: Female of Reproductive Age	High-End	55	75	23	21,237	28,960	9,044	55	75	23
				Central Tendency	805	1,097	384	42,475	57,920	20,277	790	1,077	377
			ONU	High-End	889	1,212	379	39,024	53,215	16,618	869	1,185	371
				Central Tendency	889	1,212	424	39,024	53,215	18,630	869	1,185	415

4.3.3 Risk Estimates for Consumers

Table 4-18 summarizes the dermal, inhalation, ingestion, and aggregate MOEs used to characterize non-cancer risk for acute, intermediate, and chronic exposure to DINP 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.*, Construction, paint, electrical, and metal products: Adhesives and sealants; Furnishing, cleaning, treatment/care products: Floor coverings/Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting); Furnishing, cleaning, treatment/care products: Furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)). 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 DINP via ingestion of dust was assessed for all articles expected to contribute significantly to dust concentrations due to high surface area (> ~1 m^2) for either a single article or collection of like articles as appropriate. Articles included in the indoor environment assessment included: carpet backing, vinyl flooring, specialty wall coverings, foam cushions, indoor furniture, car mats, sports mats, 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 (*i.e.*, developmental toxicity for acute and intermediate durations; liver toxicity for the chronic duration). MOEs for all high-, medium- and low-intensity exposure scenarios for all COUs are described in the *Draft Consumer Risk Calculator for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024n).

COUs with MOEs for High-Intensity Exposure Scenarios Ranging from 37 to 44,000,000,000

All consumer COUs and product/article examples, except for roofing adhesives, carpet backing, vinyl flooring, in-place wallpaper, and indoor furniture (discussed more below), resulted in MOEs for high-intensity exposure scenarios ranging from 37 for chronic aggregate exposure to DINP from legacy children's toys for infants (less than one) to 44,000,000,000 for acute duration ingestion of suspended dust from foam cushions 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 DINP. Additional variability in MOEs resulting from acute/intermediate exposures and chronic exposures results from use of a POD of 12 mg/kg-day (developmental toxicity) for acute and intermediate durations and a POD of 3.5 mg/kg-day liver toxicity) for chronic durations. As described in the *Draft Consumer and Indoor Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l) and *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w), 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.

Construction, Paint, Electrical, and Metal Products: Adhesives and Sealants

Six different product scenarios were assessed under this COU for products with differing use patterns. For example, adhesives for small repairs, adhesive foams, automotive adhesives, and caulking compounds all are used indoors, while polyurethane injection resin and roofing adhesives are used outdoors. Outdoor uses inhalation exposure is not expected to be significant due to a combination of small surface area, amount of product used, weight fraction, and large ventilation rate, however, for roofing adhesives the expected surface area, amount of product used, and weight fraction are significantly larger than other adhesives. Thus, EPA assessed inhalation exposures. Of the six product scenarios assessed for this COU, only use of roofing adhesives resulted in MOEs less than 30. Roofing adhesives chronic high-intensity use exposure route assessment for dermal and inhalation resulted in MOEs of 47 to 52 and 41 to 61, respectively, for users 11 years old to adults (21+ years), while high-intensity chronic aggregate MOEs ranged from 22 to 27 for users 11 years old to adults (21+ years). MOEs for chronic medium-intensity roofing adhesive use scenarios for dermal and inhalation exposure routes were 190 to 210 and 69 to 100, respectively, for users 11 years old to adults (21+ years), while aggregate MOEs ranged from 51 to 66 for users 11 years old to adults (21+ years).

For the high-intensity scenario, inhalation and dermal exposure routes contribute equally to aggregate risk indicating that for certain higher weight fraction adhesive products used chronically for long duration projects, 8 hours or longer, and relatively high amounts of the product can be used in that duration, 18,000 g/event, there is a possibility of health risks from dermal and inhalation exposures. The six assessed exposure scenarios and the products within capture the high variability in adhesive product formulation and are represented in the high, medium, and low intensity use estimates. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters are representative of actual use patterns and location of use. For dermal exposure EPA used a dermal flux approach, which was estimated based on DINP *in vivo* dermal absorption in rats. An overall moderate confidence in dermal assessment of adhesives was assigned. Uncertainties about the difference between human and rat skin absorption increase uncertainty. However, other parameters like frequency and duration of use, and surface area in contact are well understood and representative. Additionally, EPA has robust overall confidence in the underlying chronic POD based on liver toxicity (Section 4.2).

Furnishing, Cleaning, Treatment/Care Products: Floor Coverings/Plasticizer in Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass, and Ceramic Articles; Fabrics, Textiles, and Apparel (Vinyl Tiles, Resilient Flooring, PVC-Backed Carpeting)

Six different scenarios were assessed under this COU for various articles with differing use patterns for which each scenario had varying number of identified article examples (in parenthesis): carpet backing (3), flooring vinyl tiles (4), specialty wall coverings (both in-place and installation) (3), wallpaper (both in-place and installation) (1). All these scenarios, except installation scenarios, mimic the presence of these articles in indoor environments ranging from low- to high-intensity uses based on the surface area in indoor environments, in addition to weight fraction ranges identified. Of the scenarios evaluated, carpet backing, vinyl tiles, and in-place wallpaper had chronic MOEs less than 30 indicating possible chronic risks to consumers. Chronic high-intensity dermal and ingestion MOEs range from 88,000 to 580,000 and 140 to 3,300, respectively, for carpet backing, vinyl tiles, and in-place wallpaper, indicating little potential for dermal or ingestion risk for either exposure route alone. Chronic high and medium-intensity inhalation MOEs for all three articles range from 17 to 29 and 31 to 46, respectively, for infants and toddlers (2 years) for carpet backing, and for infants to preschoolers (5 years) for vinyl flooring tiles and wallpaper. The MOE values increase with increasing age due to changes in inhalation rate to body weight ratios, thus leading to decreasing exposure with increasing lifestage age.

Aggregate risk from dermal, ingestion, and inhalation exposures to DINP for all three articles was also considered. Inhalation exposure was the primary contributor to aggregate risk for all three articles, while exposure through ingestion was a minor contributor to aggregate risk (*i.e.,* aggregate MOEs were 1 to 3 units less than the MOEs for inhalation route alone for high-intensity scenarios) and the contribution of dermal exposure to aggregate risk estimates was negligible. Chronic high- and medium-intensity aggregate MOEs for the carpet backing scenario ranged from 25 to 30 and 36 to 44, respectively, for infants to preschoolers (5 years). Similarly, chronic high- and medium-intensity aggregate MOEs ranged from 16 to 30 and 29 to 54, respectively, for infants to children aged 6 to 10 years for the vinyl flooring scenario, and 16 to 29 and 32 to 62, respectively, for infants to children aged 6 to 10 years for the in-place wallpaper scenario. The difference in MOEs between carpet backing and vinyl flooring tiles and wallpaper scenarios is mainly driven by weight fractions. Carpet backing weight fractions for the high intensity use scenario was 16 percent while vinyl flooring was 25 percent and wallpaper was 26 percent. The difference among these three articles high to medium intensity use scenarios is driven by surface area, 200 to 100 m^2 from high- to medium-intensity use scenario, as well as weight fraction.

In these article inhalation scenarios DINP 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 DINP 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 was 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. The overall confidence in this COU inhalation and dust ingestion exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use, and the estimated surface area is well characterized and represents a wide range of plausible uses. Additionally, EPA has robust overall confidence in the underlying chronic POD based on liver toxicity used to estimate MOEs (Section 4.2).

4.3.3.1 Overall Confidence in Consumer Risks

As described in Section 4.1.2 and in more technical details in the *Draft Consumer and Indoor Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l), EPA has moderate and robust confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios, and robust confidence in the acute/intermediate and chronic non-cancer PODs selected to characterize risk from acute, intermediate, and chronic duration exposures to DINP (see Section 4.2 and (U.S. EPA, 2024w)). 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. Sources of uncertainty associated with the three consumer COUs with MOEs less than 30 are discussed above in Section 4.3.3.

Table 4-18. Consumer Risk Summary Table

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	**Toddler (1–2 Years)**	**Preschooler (3–5 years)**	**Middle Childhood (6–10 years)**	**Young Teen (11–15 years)**	**Teenagers (16–20 years)**	**Adults (21+ years)**
Consumer Uses: Automotive, fuel, agriculture, outdoor use products: Automotive products, other than fluids	Car Mats (** = Part of indoor exposure scenario)	Acute	Dermal	H	–	–	–	–	4,500,000	5,000,000	4,600,000
			Ingestion**	H	710,000	590,000	530,000	1,400,000	2,500,000	3,100,000	6,200,000
			Inhalation**	H	28,000	30,000	37,000	53,000	75,000	87,000	110,000
			Aggregate	H	27,000	29,000	35,000	51,000	72,000	83,000	110,000
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	9,300,000	10,000,000	9,500,000
			Ingestion**	H	240,000	200,000	180,000	480,000	830,000	1,000,000	2,100,000
			Inhalation**	H	9,600	10,000	12,000	18,000	25,000	30,000	37,000
			Aggregate	H	9,200	9,500	11,000	17,000	24,000	29,000	36,000
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants	Adhesive Foam († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	160	180	170
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†61,000	†65,000	†80,000	†110,000	78,000	100,000	110,000
			Aggregate	H	–	–	–	–	160	180	170
		Intermed.	Dermal	H	–	–	–	–	4,900	5,300	5,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†1,800,000	†2,000,000	†2,400,000	†3,400,000	2,300,000	3,000,000	3,400,000
			Aggregate	H	–	–	–	–	4,900	5,300	5,000
		Chronic	–	–	–	–	–	–	–	–	–
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants	Adhesives for Small Repairs	Acute	Dermal	H	–	–	–	–	6,500	7,100	6,600
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	Dermal	H	–	–	–	–	190,000	210,000	200,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Chronic	–	–	–	–	–	–	–	–	–
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants	Automotive Adhesives († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	3,200	3,500	3,300
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†17,000	†18,000	†23,000	†33,000	39,000	47,000	57,000
			Aggregate	H	–	–	–	–	3,000	3,300	3,100
		Intermed.	Dermal	H	–	–	–	–	97,000	110,000	100,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†520,000	†550,000	†680,000	†980,000	1,200,000	1,400,000	1,700,000
			Aggregate	H	–	–	–	–	90,000	102,000	94,000
		Chronic	–	–	–	–	–	–	–	–	–

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants	Caulking Compounds († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	6,500	7,100	6,600
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†50,000	†53,000	†65,000	†93,000	130,000	150,000	180,000
			Aggregate	H	–	–	–	–	6,200	6,800	6,400
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	13,000	15,000	14,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†860	†910	†1,100	†1,600	1,900	2,300	2,800
			Aggregate	H	–	–	–	–	1,700	2,000	2,300
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants	Polyurethane Injection Resin	Acute	Dermal	H	–	–	–	–	160	180	170
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	47	52	48
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
Consumer Uses: Construction, paint, electrical, and metal products: Adhesives and sealants	Roofing Adhesives († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	160	180	170
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†26,000	†28,000	†34,000	†42,000	14,000	19,000	21,000
			Aggregate	H	–	–	–	–	160	180	170
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	47	52	48
				M	–	–	–	–	190	210	190
			Ingestion	H	–	–	–	–	–	–	–
				M	–	–	–	–	–	–	–
			Inhalation	H	†130	†130	†170	†200	41	56	61
				M	†130	†130	†170	†240	69	92	100
			Aggregate	H	–	–	–	–	22	27	27
				M	–	–	–	–	51	64	66

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Construction, paint, electrical, and metal products: Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)	Roofing Membrane	Acute	Dermal	H	–	–	–	–	80,000	88,000	82,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	–	–	–	–	–	–	–	–	–
Consumer Uses: Construction, paint, electrical, and metal products: Electrical and electronic products	Wire Insulation (** = Part of indoor exposure scenario)	Acute	Dermal	H	850,000	1,000,000	1,200,000	1,400,000	1,800,000	2,000,000	1,900,000
			Ingestion**	H	500	820	1,200	32,000	57,000	72,000	160,000
			Inhalation**	H	1,400	1,500	1,900	2,700	3,800	4,500	5,500
			Aggregate	H	370	530	740	2,500	3,600	4,200	5,300
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	250,000	290,000	340,000	420,000	530,000	580,000	540,000
			Ingestion**	H	150	240	360	11,000	19,000	24,000	53,000
			Inhalation**	H	470	500	610	880	1,200	1,500	1,800
			Aggregate	H	110	160	230	810	1,100	1,400	1,700
Consumer Uses: Construction, paint, electrical, and metal products: Paints and coatings	Paint/Lacquer (Large Project) († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	78,000	85,000	80,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†26,000	†28,000	†34,000	†42,000	14,000	19,000	21,000
			Aggregate	H	–	–	–	–	12,000	16,000	17,000
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	23,000	25,000	23,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†650	†690	†850	†1,000	210	280	310
			Aggregate	H	–	–	–	–	210	280	310
Consumer Uses: Construction, paint, electrical, and metal products: Paints and coatings	Paint/Lacquer (Small Project) († = MOE for bystander scenario)	Acute	Dermal	H	–	–	–	–	650	710	660
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†10,000	†11,000	†13,000	†19,000	18,000	23,000	27,000
			Aggregate	H	–	–	–	–	630	690	640
		Intermed.	–	-	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	1,300	1,500	1,400
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	†270	†290	†350	†500	520	640	760
			Aggregate	H	–	–	–	–	370	450	490

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Furnishing, cleaning, treatment/care products: Air care products	Scented Oil	Acute	Dermal	H	–	–	410	510	650	710	660
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	1,300	1,500	1,400
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
Consumer Uses: Furnishing, cleaning, treatment/care products: Fabric, textile, and leather products (apparel and footwear care products)	Clothing	Acute	Dermal	H	1,000	1,100	1,200	1,500	1,800	2,000	2,100
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	2,000	2,300	2,500	3,100	3,700	4,000	4,200
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
Consumer Uses: Furnishing, cleaning, treatment/care products: Floor coverings/Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Carpet Backing (** = Part of indoor exposure scenario)	Acute	Dermal	H	300,000	350,000	410,000	510,000	640,000	700,000	660,000
				M	850,000	1,000,000	1,200,000	1,400,000	1,800,000	2,000,000	1,900,000
			Ingestion**	H	960	780	690	2,000	3,500	4,400	9,900
				M	1,400	1,100	1,000	2,900	5,100	6,400	14,000
			Inhalation**	H	82	87	110	150	220	250	320
				M	120	130	160	220	320	370	460
			Aggregate	H	76	78	95	140	210	240	310
				M	110	120	140	200	300	350	450
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	88,000	100,000	120,000	150,000	190,000	200,000	190,000
				M	250,000	290,000	340,000	420,000	530,000	580,000	540,000
			Ingestion**	H	320	260	230	650	1,200	1,500	3,300
				M	470	380	330	950	1,700	2,100	4,800
			Inhalation**	H	27	29	35	50	72	84	100
				M	39	42	51	73	100	120	150
			Aggregate	H	25	26	30	46	68	80	97
				M	36	38	44	68	94	110	150

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Furnishing, cleaning, treatment/care products: Floor coverings/Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Specialty Wall Coverings (In-Place) (** = Part of indoor exposure scenario)	Acute	Dermal	H	850,000	1,000,000	1,200,000	1,400,000	1,800,000	2,000,000	1,900,000
			Ingestion**	H	2,100	1,700	1,500	4,200	7,500	9,500	21,000
			Inhalation**	H	180	190	230	330	470	550	690
			Aggregate	H	170	170	200	310	440	520	670
		Intermed.	-	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	250,000	290,000	340,000	420,000	530,000	580,000	540,000
			Ingestion**	H	690	560	490	1,400	2,500	3,200	7,100
			Inhalation**	H	58	62	76	110	150	180	230
			Aggregate	H	53	56	66	100	140	170	220
Consumer Uses: Furnishing, cleaning, treatment/care products: Floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Specialty Wall Coverings (Installation)	Acute	Dermal	H	–	–	–	–	–	–	–
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	–	–	–	–	–	–	–	–	–

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Furnishing, cleaning, treatment/care products: Floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Vinyl Flooring (** = Part of indoor exposure scenario)	Acute	Dermal	H	300,000	350,000	410,000	510,000	640,000	700,000	660,000
				M	850,000	1,000,000	1,200,000	1,400,000	1,800,000	2,000,000	1,900,000
			Ingestion**	H	620	500	440	1,300	2,200	2,800	6,300
				M	1,100	890	790	2,200	4,000	5,000	11,000
			Inhalation**	H	53	56	69	98	140	160	200
				M	94	99	120	180	250	290	360
			Aggregate	H	49	50	60	91	130	150	190
				M	87	89	100	170	240	270	350
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	88,000	100,000	120,000	150,000	190,000	200,000	190,000
				M	250,000	290,000	340,000	420,000	530,000	580,000	540,000
			Ingestion**	H	200	170	150	420	750	940	2,100
				M	370	290	260	740	1,300	1,700	3,700
			Inhalation**	H	17	18	22	32	46	53	67
				M	31	33	40	58	82	95	120
			Aggregate	H	16	16	19	30	43	50	65
				M	29	30	35	54	77	90	120
Consumer Uses: Furnishing, cleaning, treatment/care products: Floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Wallpaper (in-place) (** = Part of indoor exposure scenario)	Acute	Dermal	H	850,000	1,000,000	1,200,000	1,400,000	1,800,000	2,000,000	1,900,000
				M	2,400,000	2,800,000	3,300,000	4,100,000	5,100,000	5,600,000	5,200,000
			Ingestion**	H	600	480	430	1,200	2,200	2,700	6,100
				M	1,300	1,000	910	2,600	4,600	5,800	13,000
			Inhalation**	H	51	54	67	96	140	160	200
				M	110	110	140	200	290	340	420
			Aggregate	H	47	49	58	89	130	150	190
				M	100	99	120	190	270	320	410
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	250,000	290,000	340,000	420,000	530,000	580,000	540,000
				M	700,000	820,000	950,000	1,200,000	1,500,000	1,600,000	1,500,000
			Ingestion**	H	200	160	140	410	720	910	2,000
				M	420	340	300	860	1,500	1,900	4,300
			Inhalation**	H	17	18	22	31	44	52	65
				M	35	38	46	67	94	110	140
			Aggregate	H	16	16	19	29	41	49	63
				M	32	34	40	62	88	100	140

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Furnishing, cleaning, treatment/care products: Floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)	Wallpaper (Installation)	Acute	Dermal	H	–	–	–	–	40,000	44,000	41,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	–	–	–	–	–	–	–	–	–
Consumer Uses: Furnishing, cleaning, treatment/care products: Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)	Foam Cushions (** = Part of indoor exposure scenario)	Acute	Dermal	H	1,000	1,100	1,200	1,500	1,800	2,000	2,100
			Ingestion**	H	100,000,000	110,000,000	130,000,000	190,000,000	270,000,000	320,000,000	400,000,000
			Inhalation**	H	–	–	–	–	–	–	–
			Aggregate	H	1,000	1,100	1,200	1,500	1,800	2,000	2,100
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	290	330	360	440	530	580	600
			Ingestion**	H	34,000,000	36,000,000	44,000,000	64,000,000	90,000,000	110,000,000	130,000,000
			Inhalation**	H	–	–	–	–	–	–	–
			Aggregate	H	290	330	360	440	530	580	600

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Furnishing, cleaning, treatment/care products: Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles [soft]; leather articles)	Indoor Furniture (** = Part of indoor exposure scenario)	Acute	Dermal	H	1,000	1,100	1,200	1,500	1,800	2,000	2,100
				M	8,800	21,000	26,000	34,000	44,000	48,000	46,000
			Ingestion**	H	440	660	860	6,500	12,000	15,000	33,000
				M	2,000	2,300	2,900	14,000	25,000	32,000	71,000
			Inhalation**	H	150	160	190	270	390	450	560
				M	310	330	410	590	840	980	1,200
			Aggregate	H	101	115	138	221	312	359	436
				M	260	285	354	557	798	932	1,151
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	290	330	360	440	530	580	600
				M	2,600	6,000	7,600	9,900	13,000	14,000	13,000
			Ingestion**	H	130	200	260	2,200	3,900	4,900	11,000
				M	620	720	910	4,700	8,300	11,000	23,000
			Inhalation**	H	48	51	63	90	130	150	190
				M	100	110	130	190	270	320	400
			Aggregate	H	31	36	44	72	102	116	142
				M	83	94	112	179	256	304	382
Consumer Uses: Furnishing, cleaning, treatment/care products: Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles [soft]; leather articles)	Outdoor Furniture	Acute	Dermal	H	8,000	9,000	9,900	12,000	15,000	16,000	17,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	4,100	4,600	5,100	6,100	7,400	8,100	8,500
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Furnishing, cleaning, treatment/care products: Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles [soft]; leather articles)	Truck Awning	Acute	Dermal	H	–	–	–	–	910,000	990,000	930,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	1,900,000	2,000,000	1,900,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
Consumer Uses: Packaging, paper, plastic, hobby products: Arts, crafts, and hobby materials	Crafting Resin	Acute	Dermal	H	–	–	–	–	650	710	660
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	9,100	9,700	12,000	17,000	16,000	20,000	24,000
			Aggregate	H	–	–	–	–	630	690	640
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	1,300	1,500	1,400
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	190	200	240	350	370	450	540
			Aggregate	H	–	–	–	–	290	350	390
Consumer Uses: Packaging, paper, plastic, hobby products: Arts, crafts, and hobby materials	Rubber Eraser	Acute	Dermal	H	430,000	500,000	580,000	720,000	910,000	990,000	930,000
			Ingestion	H	–	–	1,400	2,300	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
			Aggregate	H	–	–	1,400	2,300	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	120,000	150,000	170,000	210,000	260,000	290,000	270,000
			Ingestion	H	–	–	400	680	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
			Aggregate	H	–	–	400	680	–	–	–
Consumer Uses: Packaging, paper, plastic, hobby products: Arts, crafts, and hobby materials	Small Articles with Potential for semi-routine contact	Acute	Dermal	H	75,000	88,000	100,000	130,000	160,000	180,000	160,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	22,000	26,000	30,000	37,000	47,000	51,000	48,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
Consumer Uses:	Current products were not identified. Foreseeable uses were matched with the lacquers, and paints (small projects) because similar use patterns are expected.										

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30) Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Packaging, paper, plastic, hobby products: Ink, toner, and colorant products											
Consumer Uses: Packaging, paper, plastic, hobby products: Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses	Shower Curtain (** = Part of indoor exposure scenario)	Acute	Dermal	H	850,000	1,000,000	1,200,000	1,400,000	1,800,000	2,000,000	1,900,000
			Ingestion**	H	33,000	27,000	24,000	68,000	120,000	150,000	340,000
			Inhalation**	H	1,000	1,100	1,300	1,900	2,700	3,100	3,900
			Aggregate	H	970	1,100	1,200	1,800	2,600	3,000	3,800
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	250,000	290,000	340,000	420,000	530,000	580,000	540,000
			Ingestion**	H	11,000	9,000	7,900	23,000	40,000	51,000	110,000
			Inhalation**	H	330	350	430	620	880	1,000	1,300
			Aggregate	H	320	340	410	600	860	980	1,300
Consumer Uses: Packaging, paper, plastic, hobby products: Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses	Small Articles with Potential for semi-routine contact	Acute	Dermal	H	75,000	88,000	100,000	130,000	160,000	180,000	160,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	22,000	26,000	30,000	37,000	47,000	51,000	48,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
Consumer Uses: Packaging, paper, plastic, hobby products: Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)	Small Articles with Potential for semi-routine contact	Acute	Dermal	H	75,000	88,000	100,000	130,000	160,000	180,000	160,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	22,000	26,000	30,000	37,000	47,000	51,000	48,000
			Ingestion	H	–	–	–	–	–	–	–
			Inhalation	H	–	–	–	–	–	–	–

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Packaging, paper, plastic, hobby products: Toys, playground, and sporting equipment	Children's toys (legacy) (** = Part of indoor exposure scenario)	Acute	Dermal	H	120,000	140,000	170,000	210,000	260,000	290,000	-
			Ingestion**	H	300	930	1,400	9,800	17,000	22,000	49,000
			Inhalation**	H	200	210	260	370	530	610	760
			Aggregate	H	120	170	220	360	500	590	750
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	36,000	42,000	49,000	61,000	77,000	84,000	–
			Ingestion**	H	88	280	430	3,200	5,800	7,300	16,000
			Inhalation**	H	65	69	85	120	170	200	250
			Aggregate	H	37	55	71	120	170	190	250
Consumer Uses: Packaging, paper, plastic, hobby products: Toys, playground, and sporting equipment	Children's toys (new) (** = Part of indoor exposure scenario)	Acute	Dermal	H	120,000	140,000	170,000	210,000	260,000	290,000	–
			Ingestion**	H	320	1,200	2,400	410,000	730,000	920,000	2,100,000
			Inhalation**	H	8,300	8,800	11,000	16,000	22,000	26,000	32,000
			Aggregate	H	310	1,000	1,900	14,000	20,000	23,000	32,000
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	36,000	42,000	49,000	61,000	77,000	84,000	–
			Ingestion**	H	93	350	690	140,000	240,000	310,000	680,000
			Inhalation**	H	2,700	2,900	3,500	5,100	7,200	8,400	11,000
			Aggregate	H	90	310	570	4,600	6,400	7,500	11,000
Consumer Uses: Packaging, paper, plastic, hobby products: Toys, playground, and sporting equipment	Sports Mats (** = Part of indoor exposure scenario)	Acute	Dermal	H	300,000	350,000	410,000	510,000	640,000	700,000	660,000
			Ingestion**	H	22,000	18,000	16,000	45,000	80,000	100,000	230,000
			Inhalation**	H	1,000	1,100	1,400	1,900	2,800	3,200	4,000
			Aggregate	H	950	1,000	1,300	1,800	2,700	3,100	3,900
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	150,000	180,000	210,000	260,000	330,000	360,000	340,000
			Ingestion**	H	7,300	5,900	5,200	15,000	27,000	34,000	75,000
			Inhalation**	H	340	360	440	640	900	1,100	1,300
			Aggregate	H	320	340	410	610	870	1,100	1,300
Consumer Uses: Other: Novelty products	Adult Toys	Acute	Dermal	H	–	–	–	–	–	2,000,000	1,900,000
			Ingestion	H	–	–	–	–	–	180	200
			Inhalation	H	–	–	–	–	–	–	–
			Aggregate	H	–	–	–	–	–	180	200
		Intermed.	–	–	–	–	–	–	–	–	–
		Chronic	Dermal	H	–	–	–	–	–	580,000	540,000
			Ingestion	H	–	–	–	–	–	51	57
			Inhalation	H	–	–	–	–	–	–	–
			Aggregate	H	–	–	–	–	–	51	57

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) [a]	Lifestage (years) (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)

[a] Exposure scenario intensities include high (H), medium (M), and low (L).

4.3.4 Risk Estimates for General Population

As described in the *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r) and Section 4.1.3, EPA employed a screening-level approach for general population exposures for DINP releases associated with TSCA 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 DINP concentration in the various environmental media were used for screening-level purposes. EPA used an 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 Risk Estimates for Potentially Exposed or Susceptible Subpopulations

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

Some population group lifestages may be more susceptible to the health effects of DINP exposure. As discussed in Section 4.2 and in EPA's *Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024w), exposure to DINP causes developmental toxicity in experimental animal models and therefore women of reproductive age, pregnant women, infants, children and adolescents are considered to be susceptible subpopulations. These susceptible lifestages were considered throughout the draft risk evaluation. For example, women of reproductive age were evaluated for occupational exposures to DINP 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 DINP through consumer products and articles (Section 4.3.3). The non-cancer POD for DINP selected by EPA for use in risk characterization is based on the most sensitive developmental effect (*i.e.*, reduced fetal testicular testosterone production) observed and is expected to be protective of susceptible subpopulations. Additionally, EPA used a value of 10 for the UF_H to account for human variability. The Risk Assessment Forum, in *A Review of the Reference Dose and Reference Concentration Processes*, discusses some of the evidence for choosing the default factor of 10 when data are lacking—including toxicokinetic and toxicodynamic factors as well as greater susceptibility of children and elderly populations (U.S. EPA, 2002b).

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

4.3.6 Cumulative Risk Considerations

In accordance with EPA's *Draft Proposed Approach for Cumulative Risk Assessment of High-Priority and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act* (U.S. EPA, 2023b) and in agreement with SACC peer-review comments (U.S. EPA, 2023d), EPA is including DINP in its cumulative risk assessment along with five other phthalate chemicals that also cause effects on laboratory animals consistent with a disruption of androgen action and development of phthalate syndrome. For DINP and other toxicologically similar phthalates, EPA considers acute and intermediate duration exposures during the critical window of development most relevant for a disruption of androgen action based on reduced fetal testicular testosterone.

In this draft risk evaluation, EPA identified chronic risk for several individual consumer and occupational COUs based on non-cancer liver toxicity, which is not a health outcome under consideration as part of EPA's phthalate cumulative risk assessment. EPA did not identify any risk for the general population or for consumers from acute or intermediate exposures to individual DINP COUs based on reduced fetal testicular testosterone, while high-end acute and intermediate risk was identified for two occupational COUs (*i.e.*, industrial use of adhesives and sealants, and industrial use of paints and coatings). EPA has not yet accounted for its cumulative phthalate risk assessment nor taken into consideration cumulative phthalate exposure in its risk calculations.

EPA plans to subsequently issue a draft cumulative risk assessment that will go out for public comment and peer review, followed by a final cumulative assessment. Consideration of cumulative risk may impact the final DINP risk evaluation, including which COUs contributed to unreasonable risk.

5 ENVIRONMENTAL RISK ASSESSMENT

DINP – Environmental Risk Assessment (Section 5):
Key Points

EPA evaluated the reasonably available information for environmental exposures and hazard to ecological receptors following releases of DINP to surface water and air deposition of DINP to soil.

- EPA expects the main environmental exposure pathway for DINP are releases to surface water with subsequent deposition to sediment.
- The OES with the highest environmental media concentrations in surface water or wastewater and fugitive or stack air release was manufacturing.
- 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; EPA has robust confidence that the modeled environmental media concentrations do not underestimate real exposures to ecological receptors.
- Hazard data for aquatic invertebrates and algae indicated no acute or chronic exposure toxicity up to and exceeding the limit of DINP water solubility. Because chronic hazard data for fish indicated inconsistent effects and/or lack of dose-response below limit of solubility, no hazard threshold was established for fish chronically exposed to DINP. No toxicity was observed from hazard studies with bulk sediment or pore water acute or chronic exposures to sediment-dwelling organisms.
- A trophic transfer analysis explored potential DINP exposures to terrestrial mammals through their diet via the water to sediment pathway for semi-aquatic terrestrial mammals and by the soil pathway for other 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 modeled biota concentrations did not exceed the hazard value for representative mammalian species. Therefore, EPA did not pursue further quantitative analyses for these pathways.
- Empirical toxicity data for rats were used to estimate a toxicity reference value (TRV) for terrestrial mammals at 139 of mg/kg-bw/day.
- **A qualitative risk characterization supports that EPA's preliminarily determination that there is no risk for all pathways assessed for exposure to ecological receptors**. The Agency has robust confidence in the preliminary determination of no risk to aquatic receptors and moderate confidence in the preliminary determination of no risk to terrestrial receptors. In cases where EPA lacked reasonably available hazard data (*e.g.*, avian and terrestrial plants), risk to those receptors from DINP environmental releases was indeterminate.

5.1 Summary of Environmental Exposures

EPA evaluated the reasonably available information for environmental exposures of DINP to aquatic and terrestrial species. EPA expects the main environmental exposure pathway for DINP is to be released to surface water with subsequent deposition to sediment. The ambient air exposure pathway was also assessed for its limited contribution via deposition to soil. DINP exposure to aquatic species via surface water and sediment were modeled to estimate concentrations from the COU/OES that resulted in the highest environmental media concentrations. EPA calculated concentrations of DINP in representative organisms (Figure 5-1) for a screening-level trophic transfer analysis using modelled sediment concentrations from VVWM-PSC. Based on a water solubility limit of 6.1×10^{-4} mg/L and the predicted BCF of 5.2 L/kg, the modelled concentration of DINP in fish was 3.2×10^{-3} mg/kg, which was one order of magnitude lower than the highest DINP concentrations reported in aquatic biota in the peer-reviewed literature. In a lower trophic level organism, mussel, DINP concentration modeled using a BAF of 209.8 was 0.128 mg/kg-bw for the highest releasing DINP COU/OES. Exposure to terrestrial species through soil via air deposition was also assessed using the AERMOD model. DINP 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 DINP from soil through the terrestrial food web, and from surface water and sediment through the aquatic food web via releases to surface waters. Within the aquatic ecosystem, the highest COU/OES estimate (Non-PVC Material Compounding) resulted in modeled DINP exposure concentrations at least three orders of magnitude greater than measured DINP concentrations in sediment, filter feeding mussels, and fish from the published literature. These modeling predictions also resulted in concentrations at least three orders of magnitude greater than calculated concentrations in an aquatic-dependent mammal based on the maximum measured concentrations from the published literature. In terrestrial ecosystems, the highest COU/OES estimate (Non-PVC Materials Compounding) resulted in DINP exposure concentrations comparable to the maximum measured soil concentrations from the published literature (0.03 mg/kg).

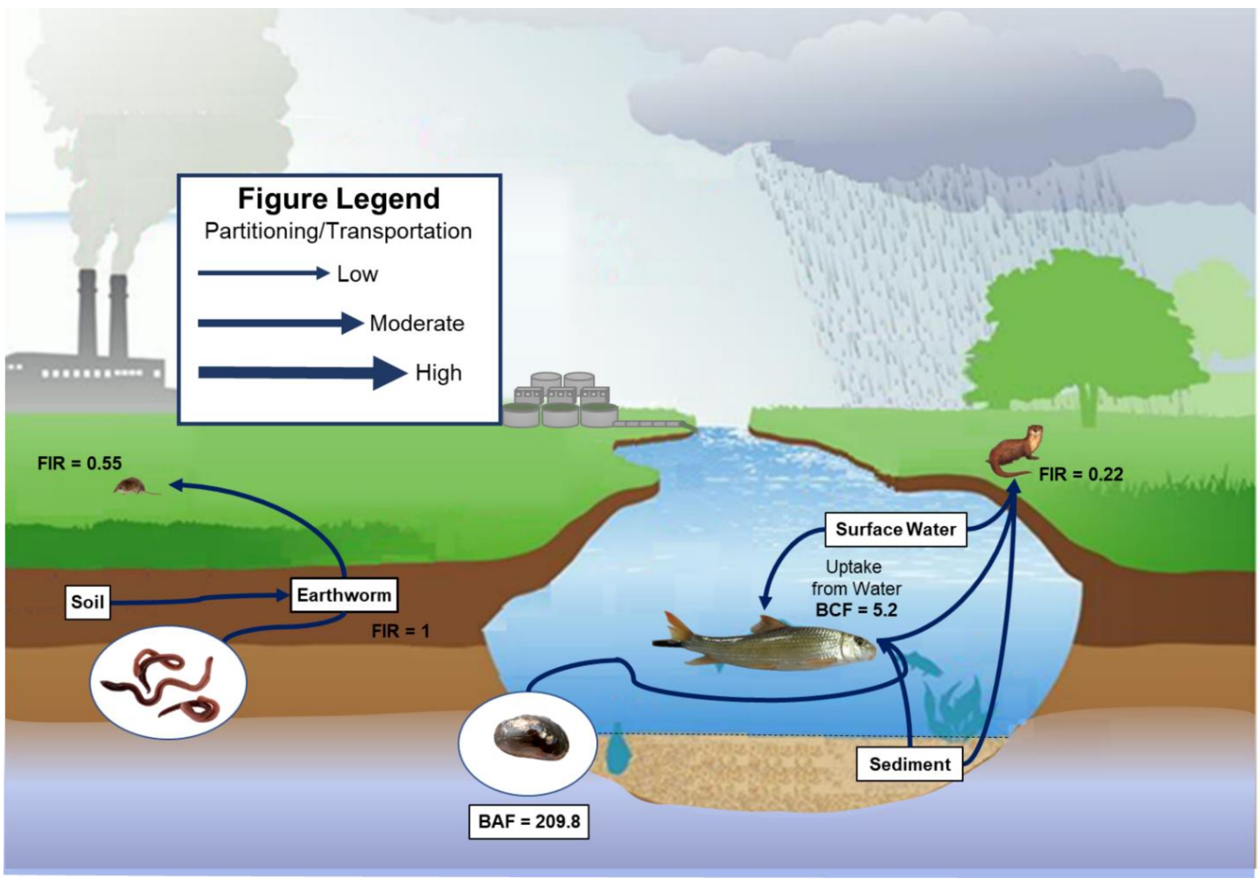


Figure 5-1. Trophic Transfer of DINP in Aquatic and Terrestrial Ecosystems

5.2 Summary of Environmental Hazards

EPA evaluated the reasonably available information for environmental hazard endpoints associated with DINP exposure to ecological receptors in aquatic and terrestrial ecosystems. EPA reviewed 46 references and determined that 32 references had high or medium data quality. These references included acute and chronic exposures via water, soil, sediment, and food.

Experimental aquatic hazard data were available from studies of the effects from acute exposures of DINP on five fish species, one amphibian species, five aquatic invertebrate species, and two algal species. Three fish species were represented in chronic exposure DINP feeding studies. Results from standard laboratory tests suggest that DINP has low hazard potential in aquatic species. Few consistent adverse effects on survival, growth, development, or reproduction were observed in acute and chronic exposure duration tests at concentrations up to and exceeding the DINP solubility and saturation limits.

In terrestrial habitats, a Toxicity Reference Value (TRV) of 139 mg/kg-bw/d was derived for the chronic exposure effects of DINP on a generalized terrestrial mammal. One study of earthworm survival and reproduction found no hazards at the maximum experimental soil concentration of 1,000 mg/kg dw DINP. No toxicity studies on avian or terrestrial plant species were identified.

5.3 Environmental Risk Characterization

5.3.1 Risk Assessment Approach

The environmental risk characterization of DINP was conducted to evaluate whether the potential releases of DINP into the environment exceed the DINP concentrations that result in hazardous effects to aquatic and terrestrial organisms. EPA first characterized risk based upon the COU/OES and associated environmental media with the highest estimated concentrations for a given pathway. Then, if this exposure concentration did not exceed the hazard thresholds harmful to organisms, EPA based the risk determination on this maximum exposure scenario to be most inclusive and protective by encompassing the other exposure COUs/OESs associated with lower estimated environmental media concentrations.

DINP concentrations within surface water, sediment, and soil are potential exposure pathways to aquatic and terrestrial species (U.S. EPA, 2024r). EPA assessed DINP concentrations in surface water, sediment, and soil via modeling (VVWM-PSC and AERMOD, respectively) to represent COU-based DINP releases. Using COU/OES-specific estimated days of release, the highest release distribution of COU/OES-specific annual releases to surface water were assessed under multiple flow assumptions (P50 and P90) in VVWM-PSC to generate modeled environmental concentrations for surface water and sediment (U.S. EPA, 2024r). The median (P50) 7Q10 flow rate was applied as a conservative low flow condition across the modeled releases and refined analyses were conducted for the scenarios resulting in the greatest environmental concentrations by applying the 90th percentile (P90) flow metrics from the distribution, which were expected to be more representative of the flow conditions associated with high-end releases. Air deposition of DINP to soil was modeled to represent COU-based releases to air using AERMOD with conservative parameters and assumptions (U.S. EPA, 2024r).≥

In evaluating the environmental hazard of DINP, a weight of evidence approach was used to (1) determine whether aquatic and terrestrial organisms had documented hazard, and (2) qualitatively evaluate risk from DINP for organisms which demonstrated hazard. A qualitative risk assessment for terrestrial species was conducted because no hazard threshold was established for aquatic organisms exposed to DINP up to and exceeding the solubility in water within the reasonably available published literature that was assigned overall quality determinations of high and medium through EPA's systematic review procedures (U.S. EPA, 2024ac). Similarly, the hazard evidence for benthic organisms exposed to DINP demonstrated no hazard. The weight of scientific evidence of these data demonstrates that DINP has few hazardous effects in aquatic and benthic species under environmental conditions in which DINP may persist in water (*e.g.*, up to and exceeding the limit of solubility). Similarly, in cases where effects in aquatic species were observed at low water concentrations or in dietary exposures to aquatic species, the evidence for hazardous effects are expected was inconsistent and not dose-response dependent. Despite no reasonably available studies of DINP hazard in wildlife, a TRV was derived from laboratory rodent studies to obtain a threshold dose concentration to represent hazard for terrestrial mammals. The TRV was used as a hazard effect threshold for dietary transfers through trophic levels in food webs (*i.e.*, trophic transfer) from water and soil media releases (U.S. EPA, 2024o).

The OES with the highest environmental media release to surface water or wastewater was manufacturing and for and fugitive or stack air release it was the non-PVC plastic compounding OES. For COUs with water-based releases, sediment concentrations modeled using VVWM-PSC resulted in the highest DINP concentration for the Manufacturing OES at 126,000 mg/kg (U.S. EPA, 2024r). Deposition of DINP from air to soil was modeled via AERMOD resulting in a maximum daily deposition rate of 2.5×10^{-1} g/m^2-day at 100 m from a facility, based on higher-end meteorology and a rural land category scenario (U.S. EPA, 2024o). Using these maximum modeled deposition rates from fugitive and stack releases, the high-end concentration of DINP in soil from modeled air to soil deposition at 100 m from a hypothetical release site for the non-PVC plastics compounding OES was 1,460 µg/kg (U.S. EPA, 2024o).

DINP 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 DINP within differing aquatic taxa reflect dilution across trophic levels (McConnell, 2007; Mackintosh et al., 2004). DINP 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. Risk estimates for dietary exposure pathways to aquatic-dependent mammals and terrestrial mammals as receptors were qualitatively and not quantitatively evaluated because even with conservative assumptions, dietary DINP exposures were orders of magnitude less than the identified mammalian hazard threshold (TRV) (U.S. EPA, 2024p).

5.3.2 Risk Estimates for Aquatic and Terrestrial Species

EPA expects the main environmental exposure pathways for DINP to be (1) releases to surface water and subsequent deposition to sediment and (2) limited dispersal from fugitive and stack air release deposition to soil. Risks of DINP exposure to organisms in the environment were qualitatively evaluated based upon comparisons between surface water and air-to-soil exposure pathways and DINP hazard (or lack of hazard) in aquatic and terrestrial organisms. 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 (Qualitative) for the DINP Environmental Risk Characterization

Exposure Pathway	Receptor	Risk Assessment
Surface water	Aquatic species	No risk
Surface water, sediment	Aquatic species; Aquatic dependent mammal	No risk[a]
Air deposition to surface water, sediment	Aquatic species; Aquatic dependent mammal	No risk[a]
Air deposition to soil	Terrestrial mammal	No risk[a]
Landfill to surface water, sediment	Aquatic species	No risk
Aggregate media of release (water, incineration, or landfill)	Aquatic dependent mammal	No risk
Landfill to surface water, sediment	Aquatic dependent mammal	No risk
Biosolids	Terrestrial mammal	No risk
[a] Screening-level trophic transfer analysis conducted by producing exposure estimates from the high-end exposure scenarios defined as those associated with the industrial and commercial releases from a COU and OES that resulted in the highest environmental media concentrations and presented within U.S. EPA (2024o).		

Empirical toxicity data for rats and mice were used to estimate a TRV for terrestrial mammals at 139 mg/kg-bw/day.

DINP is expected to partition primarily to soil and sediment, regardless of the compartment of environmental release (U.S. EPA, 2024t). DINP 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 due to DINP's strong affinity and sorption potential for organic carbon in soil and sediment. Transport of DINP is further limited by its low water solubility (6.1×10^{-4} 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 DINP is predicted to have an overall environmental half-life of 35 days, DINP is expected to have a low biodegradation potential within low oxygen conditions indicating longer persistence within subsurface sediments and soils (U.S. EPA, 2024t).

Additional evidence indicates that DINP is not persistent within other exposure pathways. Within air, DINP is expected to have an atmospheric half-life of 5.36 hours. The potential removal of DINP via wastewater treatment was modeled using STPWIN ™, an EPI Suite™ module that estimates chemical removal in sewage treatment plants, predicting greater than 93 percent removal of DINP in wastewater by sorption to sludge (U.S. EPA, 2024t).

The landscape of hazard data for DINP provides information for qualitative risk assessment connecting relevant exposure pathways to aquatic and terrestrial organisms. DINP demonstrated no consistent aquatic toxicity for the population-level endpoints of survival and reproduction up to and beyond the limit of solubility under both acute and chronic exposure durations (U.S. EPA, 2024p). Thus, with no observed hazard to aquatic organisms, EPA has preliminarily determined that there is no risk from DINP environmental exposures in sediment or surface waters (Table 5-1). In no circumstances did dietary exposures in the surface water, sediment, and air to soil pathways exceed the definitive hazard threshold for terrestrial mammals. EPA has robust confidence in the qualitative risk evaluation for aquatic receptors and moderate confidence in the qualitative risk evaluation for terrestrial receptors. In cases where EPA lacked reasonably available hazard data (*e.g.*, avian and terrestrial plants), risk is indeterminate.

Surface Water

Hazard data for fish, aquatic invertebrates, and algae indicated no acute or chronic toxicity up to and exceeding the limit of water solubility leading to robust confidence that DINP poses little hazard to these organisms (U.S. EPA, 2024p). The fate and transport of DINP in surface water are governed by water solubility, organic carbon partitioning coefficients, and volatility, though volatilization is not expected to be a significant source of loss of DINP from surface water (U.S. EPA, 2024t). DINP has a low water solubility of 6.1×10^{-4} mg/L, but is likely to form a colloidal suspension and may be detected in surface water at higher concentrations (EC/HC, 2015b). These DINP colloidal suspensions are unlikely to be bioavailable to aquatic organisms via absorption across respiratory surfaces or ingestion. Concentrations of DINP above the aqueous solubility of 6.1×10^{-4} mg/L are not uncommon in monitoring studies proximal to releases of DINP to surface water (Wen et al., 2018). EPA has robust confidence in the reasonably available information of DINP concentrations within surface waters (*e.g.*, up to 85 µg/L (U.S. EPA, 2024o)) that were all orders of magnitude lower than unbounded hazard estimates at concentrations up to and above the water solubility limit. Because no hazard effects of DINP on aquatic organisms through acute or chronic water exposures were evident, EPA has robust confidence in the preliminary determination that DINP exposure poses no risk to aquatic organisms via surface water exposures.

Surface Water and Sediment Exposure Pathway

During DINP releases to surface water bodies, greater than 92 percent of DINP is expected to partition to both suspended and benthic sediments (U.S. EPA, 2024t). The OES with the highest environmental media release to surface water was the manufacturing. Modeled environmental media concentrations resulting from this OES were assessed as worst-case (conservative) exposures to organisms (U.S. EPA, 2024o). The highest concentrations of DINP in sediment modeled by VVWM-PSC were from the Manufacturing OES that were almost three orders of magnitude higher than the highest sediment concentrations (212 mg/kg in Sweden) reported within the literature (U.S. EPA, 2024p). No hazard effects of sediment DINP to sediment dwelling animals were documented in the literature (U.S. EPA, 2024p). For example, effects on mortality and development within the benthic invertebrate, *Chironomus tentans*, were not observed from 10-day DINP laboratory exposures up to the highest measured sediment concentration of 2,630 mg/kg, which were comparable to modeled concentrations (Call et al., 2001). Thus, EPA has robust confidence in the preliminary determination that DINP exposure poses no risk to sediment dwelling animals.

The potential hazardous effects of a DINP pathway from surface water to an aquatic dependent mammal were explored using a trophic transfer analysis of DINP food web exposure and comparing it to the hazard threshold (TRV) to terrestrial mammals (139 mg/kg bw/d). DINP has low bioaccumulation potential in aquatic and terrestrial organisms, and no apparent biomagnification across trophic levels in the aquatic food web (U.S. EPA, 2024t). Thus, the trophic transfer analysis included documented bioconcentration estimates and the most conservative assumptions for DINP diet transfer through the ingestion of sediment. The high-end sediment concentration modeled by VVWM-PSC was from the Manufacturing OES and was used in this trophic transfer analysis for dietary exposure to fish and to an aquatic-dependent mammal (U.S. EPA, 2024o). The highest modeled sediment concentration yielded values for potential dietary exposure of DINP to aquatic dependent mammals were 0.02 mg/kg bw/d and were lower than the TRV of 139 mg/kg bw/d (U.S. EPA, 2024q). Based on the conservative VVWM-PSC outputs for surface water and sediment shown in (U.S. EPA, 2024q), the COUs/OESs based water releases of DINP are not expected to produce environmental concentrations leading to hazardous effects within aquatic dependent wildlife. EPA has moderate confidence in the modeled values in sediment, and in animal diets, but because the models used the most conservative assumptions, the Agency has robust confidence that the analyses are protective of the organisms and has preliminarily determined that DINP poses no risk to aquatic dependent animals via dietary exposures.

Based on the weight of scientific evidence for DINP within the environment, lack of bioaccumulation/ biomagnification, and hazard value for an aquatic dependent mammal, qualitative analysis indicates that reaching a daily rate of 139 mg/kg-day is unlikely and was not reached—even with conservative modeling and trophic transfer assumptions.

The reasonably available literature monitoring DINP 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 analysis. Therefore, DINP exposure 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.

Air Deposition to Water, Sediment

The concentrations of DINP in sediment and surface water modeled from air deposition of the highest releasing COU/OES are lower than the highest no-observed-effect-concentration (NOEC) values reported within several hazard studies for aquatic invertebrates and vertebrates in the water column, benthic invertebrates, and aquatic plants and algae. Therefore, COU/OES based fugitive and stack air releases of DINP and subsequent deposition to surface water and sediment are not expected to produce environmental concentrations leading to hazardous effects within aquatic organisms.

Air Deposition to Soil

Modeling results indicate a rapid decline in DINP concentrations from air deposition to soil. The PVC plastics compounding OES resulted in the highest fugitive release of DINP with daily deposition rates to soil at 100, 1,000, and 5,000 m of 1.8, 5.1×10^{-2}, and 2.4×10^{-3} mg/kg, respectively. Because DINP has low bioaccumulation potential (U.S. EPA, 2024t) and biodilutes (Mackintosh et al., 2004), the transfer of DINP through a food web is expected to dilute in each trophic level and this is less than the amount deposited to soil. These modeled daily deposition rates from 100 m and 5,000 m from a release source are two to five orders of magnitude below the mammalian TRV value of 139 mg/kg-bw/day. One study of earthworms and DINP indicated a NOEC of 1,000 mg/kg, which demonstrates no hazardous effects within this soil invertebrate—even when testing DINP to very high concentrations compared to available monitoring information in soil (range 1.3×10^{-3} mg/kg dw to 0.17 mg/kg dw) (Huang et al., 2019; Tran et al., 2015; Zhang et al., 2015; Liu et al., 2010; Zeng et al., 2009; Zeng et al., 2008; Vikelsøe et al., 2002). Therefore, COU/OES based fugitive and stack air releases of DINP and subsequent deposition to soil are not expected to produce environmental concentrations leading to hazardous effects within soil invertebrates or terrestrial mammals. EPA has robust confidence in the preliminary determination that DINP exposure poses no risk to terrestrial animals due to the lack of hazard effects to an invertebrate and low soil exposure concentrations that do not exceed a TRV to mammals.

Landfill (to Surface Water, Sediment)

Due to its low water solubility (6.1×10^{-4} mg/L) and affinity for organic carbon (log K_{OC} = 5.5), DINP is expected to be present at low concentrations in landfill leachate. Concentrations of DINP in landfill leachates outside of the United States ranged from 1 to 70 µg/L (Duyar et al., 2021; Kalmykova et al., 2013). Furthermore, any DINP that may present in landfill leachates will not be mobile in receiving soils and sediments due to its high affinity for organic carbon. Sediments near a landfill in Sweden were found to have a DINP concentration of 290 μg/kg (Cousins et al., 2007). For comparison, the same study reported that sediment taken from background lakes had DINP concentrations below the detection limit of 100 μg/kg for all samples and reported that sediments from urban locations had DINP concentrations ranging from below detection to 3,400 μg/kg (Cousins et al., 2007). These concentrations were well below NOEC values for aquatic sediment organisms and below concentrations that might be expected to transfer up the food web via trophic transfer and potentially affect terrestrial mammals at the estimated TRV of 139 mg/kg-bw/day. DINP is not likely to be persistent in groundwater/subsurface environments unless anoxic conditions exist. As a result, the evidence presented indicates that DINP migration from landfills to surface water and sediment is limited and not likely to result in hazardous effects or pose risk to aquatic and terrestrial organisms.

Biosolids

EPA did not pursue using generic release scenarios to model potential DINP 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 DINP in sludge from sewage treatment plants ranging 19.0 to 51.0 mg/kg (Cousins et al., 2007). Two additional studies reported DINP 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 DINP 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 pretreatment or to be directly land applied following on-site treatment at the industrial facility itself. In comparison to hazard values, the highest reported DINP 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 and one order of magnitude below a daily hazard threshold for mammals of 139 mg/kg-bw/day. 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 DINP 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 conditions of use (*e.g.*, manufacturing, processing, industrial use, commercial use, disposal) rather than a single distribution scenario. Data were not reasonably available for EPA to assess risks to the environment from environmental releases and exposures related to distribution of DINP 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 COUs/OESs since most of the activities (loading, unloading) generating releases from distribution of commerce are release points of other COUs/OESs.

Aggregate Media of Release

COUs/OESs with aggregated media of release, where the environmental release assessment did not provide individual release estimates associated within singular release media, are represented in Table 1-1 in *Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024s). Specifically, these COUs/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 aggregate COUs/OESs have annual release per site (kg/site-year) values lower than Non-PVC plastic compounding.

5.3.3 Overall Confidence and Remaining Uncertainties Confidence in Environmental Risk Characterization

Environmental risk characterization evaluated confidence from environmental exposures and environmental hazards. Exposure confidence is detailed within the Technical Support Document (TSD), *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)* (U.S. EPA (2024r)), represented by modeled and monitored data. Trophic transfer confidence is represented by evidence type as reported in U.S. EPA (2024o), *Draft Environmental Exposure Assessment for Diisononyl Phthalate (DINP)*. Hazard confidence was represented by evidence type as reported previously in U.S. EPA (2024p), *Draft Environmental Hazard Assessment for Diisononyl Phthalate (DINP)*. The following confidence determinations for risk characterization inputs are robust confidence for the aquatic evidence and robust confidence for terrestrial evidence (Table 5-2).

Exposure

Conservative approaches within both environmental media modeling (*e.g.,* AERMOD and VVWM-PSC) and the screening-level trophic transfer analysis likely overrepresent DINP ability to transfer among the trophic levels; however, this increases confidence that risks are not underestimated. Due to the lack of reasonably available release data for facilities discharging DINP to surface waters, releases were modeled, and the high-end estimate for each COU was applied for surface water modeling. Additionally, due to lack of 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 flow rates selected from these generated distributions represented conservative low flow rates. When coupled with high-end release scenarios, these low flow rates result in high modeled concentrations. Additional scenarios were modelled with the median (*e.g.,* faster) flow rates resulting in sediment concentrations within the same order of magnitude to measured concentrations, increasing EPA's confidence that risks were not underestimated. Although reported measured concentrations for ambient air found in the peer-reviewed and gray literature from the systematic review are within range of the ambient air modeled concentrations from AERMOD for some scenarios, the highest modeled concentrations of DINP in ambient air were at least two orders of magnitude higher than any monitored value—providing more confidence that the modelling exercise was conservative and protective.

Monitored DINP concentrations within soil, surface water, and sediment were evaluated and used to represent potential DINP 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 assigned overall quality determination of medium or high 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 19 studies with an overall quality determination of high or medium. Consistently, no effects were observed up to the highest DINP concentration tested within all aquatic hazard studies. As detailed within Section 5.3.2, monitoring data from published literature report DINP 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, which collectively provides more confidence in the risk characterization.

Terrestrial Species

There is moderate 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 12 acceptable toxicity studies used as surrogates for terrestrial mammals. Robust confidence in hazard was assigned for terrestrial invertebrates due to the use of an earthworm study with a single but high test dose; however, the study found no deleterious effects of DINP at concentrations up to 1,000 mg/kg dw soil (ExxonMobil, 2010). The fate properties discussed in U.S. EPA (2024t), in conjunction with the previous qualitative risk characterization for terrestrial species (Section 5.3.2). increase confidence that DINP 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, permitting the use of a screening-level trophic transfer analysis to compare potential environmental concentrations and dietary uptake of DINP 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 DINP 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 DINP exposure concentrations from this analysis are not equal to or greater than the TRV. These results align with previous studies indicating that DINP has low bioaccumulation potential and will not biomagnify as summarized within U.S. EPA (2024t). The utilization of both modeled and monitored data as a comparative approach with similar results increases confidence that dietary exposure of DINP does not reach concentrations that would cause hazard effects within mammals.

Table 5-2. DINP Evidence Table Summarizing Overall Confidence Derived for Environmental Risk Characterization

Types of Evidence	Exposure	Hazard	Trophic Transfer	Risk Characterization Confidence
Aquatic				
Acute aquatic assessment	++ VVWM-PSC [a] + AERMOD [b]	+ + +	N/A	Robust
Chronic aquatic assessment		+ +	N/A	
Chronic benthic assessment		+ + +	N/A	
Algal assessment		+ + +	N/A	
Terrestrial				
Chronic avian assessment	N/A	N/A	N/A	Indeterminate
Chronic mammalian assessment	++ VVWM-PSC [a] + AERMOD	+ +	+ +	Moderate
Terrestrial invertebrates	+ AERMOD	+ + +	N/A	Robust
Terrestrial plant assessment	N/A	N/A	N/A	Indeterminate

[a] EPA conducted modeling with the EPA's VVWM-PSC tool (PSC), to estimate concentrations of DINP within surface water and sediment.
[b] EPA used AERMOD to estimate ambient air concentrations and air deposition of DINP from EPA-estimated releases.
+ + + 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

<table>
<tr><th>Types of Evidence</th><th>Exposure</th><th>Hazard</th><th>Trophic Transfer</th><th>Risk Characterization Confidence</th></tr>
<tr><td colspan="5">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 Indeterminant corresponds to entries in evidence tables where information is not available within a specific evidence consideration.</td></tr>
</table>

6 UNREASONABLE RISK DETERMINATION

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

EPA is preliminarily determining that DINP presents an unreasonable risk of injury to human health under the COUs. Risk of injury to the environment does not contribute significantly to EPA's preliminary determination of unreasonable risk. This draft unreasonable risk determination is based on the information in previous sections of this draft risk evaluation, the TSDs that support this draft risk evaluation, and their appendices in accordance with TSCA section 6(b). It is also based on (1) the best available science (TSCA section 26(h)), (2) the weight of scientific evidence standards (TSCA section 26(i)), and (3) relevant implementing regulations in 40 CFR part 702, including the amendments to the procedures for chemical risk evaluations under TSCA finalized in May of 2024.

As noted in the EXECUTIVE SUMMARY, DINP is used primarily as a plasticizer to make flexible PVC. It is also used to make building and construction materials; automotive care and fuel products; and other commercial and consumer products including adhesives and sealants, paints and coatings, electrical and electronic products, which are all considered TSCA COUs. Workers may be exposed to DINP when making these products or otherwise using DINP in the workplace. When it is manufactured or used to make products, DINP 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. If it is released into the air, DINP will attach to dust particles and then be deposited onto land or into water. Indoors, DINP has the potential over time to come out of products and adhere to dust particles. If it does, people could inhale or ingest dust that contains DINP.

As explained in Sections 4.1.3 and 4.3.4, EPA used a screening-level approach in this draft risk evaluation using conservative environmental release estimates for occupational COUs with the highest releases to determine whether there is risk to the environment and the general population. As explained in Sections 5.3.1 and 5.3.2, EPA first characterized risk based upon the COU with the highest estimated concentrations for a given pathway, based on the OES and the associated environmental media used in the draft risk evaluation. Then, if this exposure concentration did not exceed the hazard thresholds harmful to organisms, EPA based the draft risk determination on this maximum exposure scenario to be most inclusive and protective by encompassing the exposures from other COUs within the OES. EPA determined that the hazard data for fish, aquatic invertebrates, sediment-dwelling organisms, algae, terrestrial invertebrates, and terrestrial mammals indicated no adverse effects from exposures up to and exceeding the limit of water solubility.

Following EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a), EPA determined that DINP is *Not Likely to be Carcinogenic to Humans* at doses below levels that do not result in peroxisome proliferator activated receptor alpha (PPARα) activation. Further, the non-cancer chronic POD based on non-cancer liver effects will adequately account for all chronic toxicity, including carcinogenicity, which could potentially result from exposure to DINP. EPA did not further evaluate DINP for carcinogenic risk to humans, including workers, consumers, and the general population.

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

To determine if an occupational COU contributed significantly to unreasonable risk, EPA compared the risk estimates of the OES used to evaluate the COUs, and considered whether the risk from the COU was best represented by the central tendency or high-end risk estimates. For DINP, whether risk was best characterized by central tendency estimates as opposed to high end estimates for a given COU was based on examination of the specific parameters used in the OES, including: (1) the method of application, (2) accuracy of the amount of DINP found in the product(s) or in dust, and (3) accuracy of the frequency of use for the product(s). The method of application is important for the determination of the exposure level to DINP and the estimate of exposure for a particular COU. For example, if high-pressure spray application is used, there is a higher concentration of mist generated. The higher concentration of mist leads to higher inhalation exposure levels. In comparison, the central tendency estimates are more representative of low-pressure spray applications and non-spray methods such as brush, roll, dip, and bead applications. If the low-pressure applications are used for a particular COU, risk for that COU is best represented by the central tendency estimates. The accuracy of the frequency of use and/or amount of DINP can also affect the exposure estimates. If the frequency of use and/or the amount of DINP is overestimated, this leads to a level of uncertainty in the high-end estimates, and therefore, the central tendency estimates would be more representative of the exposure for some COUs.

EPA did not identify any products containing DINP that are currently used in high-pressure spray applications. However, based on the presence of DINP in products that could be spray applied in various different capacities and the available information regarding industrial settings, EPA expects that high-pressure spray applications could be used in industrial settings for the application of adhesives and sealants and in industrial settings for the application of paints and coatings. Therefore, EPA is preliminarily determining that the high-end estimates best represent the Industrial use – adhesives and sealants COU as well as the Industrial use – construction, paint, electrical, and metal products – paints and coatings COU (see Table 4-17 or more details). EPA notes that it is preliminarily determining that the processing into these formulations do not contribute significantly to the unreasonable risk because—due to the low vapor pressure of DINP—inhalation exposures from vapor-generating activities (without dust or mist generation) are quite low, and the processing does not involve any high-pressure spray of DINP. Additionally, for commercial use of adhesives and sealants EPA is basing its preliminary determination on the non-spray application scenario, which indicated no unreasonable risk, even when considering high-end estimates. For Commercial use of paints and coatings, EPA is basing its preliminary determination on central tendency risk estimates because the Agency expects (1) that commercial users will use low-pressure spray applications in commercial settings, and (2) the central tendency risk estimates indicate no unreasonable risk.

The consumer and bystander exposure scenarios described in this draft risk evaluation represent a wide selection of consumer use patterns. High-intensity consumer exposure scenarios may use conservative inputs representing sentinel exposures (*e.g.,* 24 hours of exposure for consumers who stay at home all day), but EPA still has moderate or robust confidence in the majority of inputs used for modeling the high-intensity risk estimates. The high-intensity consumer and bystander risk estimates represent an upper bound exposure scenario.

EPA is preliminarily determining the following COUs, considered singularly or in combination with other exposures, significantly contribute to the unreasonable risk:

- Industrial use – adhesives and sealant chemicals (sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing) due to high-pressure spray application;

- Industrial use – construction, paint, and metal products – paints and coatings due to high-pressure spray application;
and
- Consumer use – furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting).

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

- Manufacturing – domestic manufacturing;
- Manufacturing – importing;
- Processing – incorporation into a formulation, mixture, or reaction product – heat stabilizer and processing aid in basic organic chemical manufacturing;
- Processing – incorporation into a formulation, mixture, or reaction product – plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing (including pigment));
- Processing – incorporation into an article – plasticizers (toys, playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing (including pigment));
- Processing – other uses – miscellaneous processing (petroleum refineries; wholesale and retail trade);
- Processing – repackaging – plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing);
- Processing – recycling;
- Distribution in commerce;
- Industrial use – automotive, fuel, agriculture, outdoor use products – automotive products, other than fluids;
- Industrial use – construction, paint, electrical, and metal products – building/construction materials (roofing, pool liners, window shades, flooring);
- Industrial use – other uses – hydraulic fluids;
- Industrial use -other uses – pigment (leak detection);
- Commercial use – automotive, fuel, agriculture, outdoor use products – automotive products other than fluid;
- Commercial use – construction, paint, electrical, and metal products – adhesives and sealants;
- Commercial use – construction, paint, electrical, and metal products – plasticizer in building/construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles;
- Commercial use – construction, paint, electrical, and metal products – electrical and electronic products;
- Commercial use – construction, paint, electrical, and metal products – paints and coatings;

- Commercial use – furnishing, cleaning, treatment/care products – foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles;
- Commercial use – furnishing, cleaning, treatment/care products – air care products;
- Commercial use – furnishing, cleaning, treatment/care products – floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting);
- Commercial use – furnishing, cleaning, treatment/care products – fabric, textile, and leather products (apparel and footwear care products);
- Commercial use – packaging, paper, plastic, hobby products – arts, crafts, and hobby materials;
- Commercial use – packaging, paper, plastic, hobby products – ink, toner, and colorant products;
- Commercial use – packaging, paper, plastic, hobby products – packaging, paper, plastic, hobby products (packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft));
- Commercial use – packaging, paper, plastic, hobby products – plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses);
- Commercial use – packaging, paper, plastic, hobby products – toys, playground, and sporting equipment;
- Commercial use – solvents (for cleaning or degreasing) – solvents (for cleaning or degreasing);
- Commercial use – other uses – laboratory chemicals;
- Consumer use – automotive, fuel, agriculture, outdoor use products – automotive products other than fluid;
- Consumer use – construction, paint, electrical, and metal products – plasticizer in building/construction materials (roofing, pool liners, window shades);
- Consumer use – construction, paint, electrical, and metal products – electrical and electronic products;
- Consumer use – construction, paint, electrical, and metal products – adhesives and sealants
- Consumer use – construction, paint, electrical, and metal products – paints and coatings;
- Consumer use – furnishing, cleaning, treatment/care products – foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles;
- Consumer use – furnishing, cleaning, treatment/care products – air care products;
- Consumer use – furnishing, cleaning, treatment/care products – fabric, textile, and leather products (apparel and footwear care products);
- Consumer use – packaging, paper, plastic, hobby products – arts, crafts, and hobby materials;
- Consumer use – packaging, paper, plastic, hobby products – ink, toner, and colorant products;
- Consumer use – packaging, paper, plastic, hobby products – other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses;
- Consumer use – packaging, paper, plastic, hobby products – packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft);
- Consumer use – packaging, paper, plastic, hobby products – toys, playground, and sporting equipment;
- Consumer use – other – novelty products; and
- Disposal.

In this draft risk evaluation, the Agency describes the strength of the scientific evidence supporting the human health and environmental assessments as robust, moderate, or slight. 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 exposure estimate. 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 exposure estimates. Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the scenario, and when the Agency is making the best scientific assessment possible in the absence of complete information. The overall confidence in the human health exposure assessment as well as the hazard assessment is described for each human population in the respective risk estimates section for that population in Section 4.

For the environment, Section 5.3.3 describes weighing the scientific evidence for exposures and hazards to determine overall confidence in the environmental risk assessment. The draft DINP risk evaluation and the supporting technical supplements as well as scoping, assessments, and other documents and spreadsheets can be accessed in the dockets EPA-HQ-OPPT-2018-0436 and EPA-HQ-OPPT-2024-0073. In the draft DINP unreasonable risk determination, EPA has considered COUs with limited reasonably available information. In general, the Agency makes an unreasonable risk determination based on risk estimates that have an overall confidence rating of moderate or robust, since those confidence ratings indicate the scientific evidence is adequate to characterize risk estimates despite uncertainties or is such that it is unlikely the uncertainties could have a significant effect on the risk estimates.

If, in the final TSCA risk evaluation for DINP, EPA determines that DINP presents an unreasonable risk of injury to health or the environment under the COUs, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with DINP under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that DINP no longer presents such risk. Under TSCA section 6(a), EPA is not limited to regulating the specific COUs found to contribute significantly to the 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" activities (*e.g.*, processing, distribution in commerce) to address downstream activities that contribute significantly to unreasonable risk (*e.g.*, use)—even if the upstream activities are not contributing significantly 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), as appropriate.

6.1 Human Health

This assessment provides a risk profile of DINP by presenting a range of estimates (MOEs[1]) 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

[1] EPA derives non-cancer MOEs by dividing the non-cancer POD (HEC [mg/m^3] or HED [mg/kg-day]) by the exposure estimate (mg/m^3 or mg/kg-day). Section 4.3.1 has additional information on the risk assessment approach for human health.

respiratory protection or other personal protective equipment (PPE). Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with existing regulations that may be applicable to. Rather, it reflects the Agency's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are (1) not covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan or because their employer is out of compliance with OSHA standards; or (2) because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements. In addition, some risk estimates are based on exposure scenarios with monitoring data that likely reflects existing requirements, such as those established by OSHA, industry, or sector best practices.

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

6.1.1 Populations and Exposures EPA Assessed for Human Health

EPA evaluated risk to workers—including ONUs; female workers of reproductive age; consumer users and bystanders, including infants and children; and the general population, including infants and children and people who consume fish—using reasonably available monitoring and modeling data for inhalation and dermal exposures, as applicable.

EPA evaluated risk from inhalation and dermal exposure of DINP to workers, inhalation exposure to ONUs, and, for relevant COUs, dermal exposure to ONUs from contact with mist or dust deposited on surfaces containing DINP. The Agency evaluated risk from inhalation, dermal, and oral-exposure to consumer users and for relevant COUs (including COUs where children could have dermal exposures from the products or articles, such as wallpaper), and risk from inhalation exposure to bystanders. 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, in this draft risk evaluation. Uncertainties for overall exposures and hazards are presented in this draft risk evaluation and TSDs—including the *Draft Consumer and Indoor Exposure Assessment for Diisononyl Phthalate (DINP)*, the *Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP)*, and the *Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP)*—and all are considered in this preliminary unreasonable risk determination.

6.1.2 Summary of Human Health Effects

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

- non-cancer effects in workers from inhalation exposures, and
- non-cancer effects in consumers from inhalation exposures.

With respect to health endpoints upon which EPA is basing this preliminary unreasonable risk determination, the Agency has robust overall confidence in the proposed POD based on fetal testicular testosterone for use in characterizing risk from exposure to DINP for acute and intermediate exposure scenarios. Similarly, EPA has robust overall confidence in the proposed POD based on hepatic outcomes for use in characterizing risk from exposure to DINP for chronic exposure scenarios. The confidence on the PODs is described in Section 4.2.

Given the reasonably available information discussed in the risk characterization regarding the confidence in the cancer risk, EPA did not quantify cancer risk and exposures under the COUs do not contribute significantly to the unreasonable risk presented by DINP due to cancer.

Table 6-1 and Table 6-2 provide further detail regarding which COUs contribute significantly to the above risks.

EPA's exposure and overall risk characterization confidence levels are summarized in Section 4.3, with specific confidence levels presented in Sections 4.3.2.1 (occupational exposure) and 4.3.3.1 (consumer exposure). Additionally, health risk estimates for workers—including ONUs, consumers, bystanders, and the general population—can be found in Sections 4.3.2 (workers and ONUs), 4.3.3 (consumers and bystanders), 4.3.4 (general population), and 4.3.5 (PESS).

EPA also reviewed the weight fractions in products associated with COUs contributing significantly to unreasonable risk and has determined that a weight fraction of 0.1 percent does not contribute significantly to the unreasonable risk of DINP to human health. This is consistent with regulation by U.S. CPSC, who banned the sale, distribution in commerce, or importation into the United States of all children's toys and child care articles that contain concentrations of more than 0.1 percent DINP (16 CFR part 1307). Similarly, the cutoff value under OSHA Hazard Communication Standard is 0.1 percent (29 CFR 1910.1200).

For context, the weight fractions identified for COUs and scenarios that contributed significantly to unreasonably risk of DINP are all at least 100-fold higher than 0.1 percent. For industrial use of adhesives and sealants, weight fractions used were 10 and 40 percent for central tendency and high-end exposure estimates, respectively, while a weight fraction of 20 percent was selected for the high-end exposure estimate for the Industrial use of paints and coatings COU. For the one consumer COU that EPA is determining to contribute to the unreasonable risk of DINP in this risk evaluation, Consumer use – furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting), three product use scenarios were found to contribute significantly to the unreasonable risk of DINP, including carpet backing, vinyl flooring, and in-place wallpaper. Weight fractions were 16, 25, and 26 percent for high-intensity use scenarios for carpet backing, vinyl flooring, and in-place wallpaper, respectively.

6.1.3 Basis for Unreasonable Risk to Human Health

In developing the exposure and hazard assessments for DINP, EPA 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 DINP. For the DINP draft risk evaluation, EPA identified as PESS, people who are expected to have greater exposure to DINP, such as workers or consumers, women of reproductive age, infants and children who frequently have contact with consumer products containing high concentrations of DINP, and tribes whose diets include large amounts of fish. Additionally, the Agency identified population group lifestages that may have greater susceptibility to the health effects of DINP as PESS: women of reproductive age, pregnant women, infants, children, and adolescents. A full PESS analysis can be found in Section 4.3.5 of this draft risk evaluation.

Risk estimates based on high-end exposure levels (*e.g.,* 95th percentile) are generally intended to cover individuals with sentinel exposure levels whereas risk estimates at the central tendency exposure are generally estimates of average or typical exposure. However, EPA was able to calculate risk estimates for PESS groups in this assessment (*e.g.*, female workers of reproductive age, infants and children). 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 based on reasonably available information about a typical scenario and process within the COU (*e.g.*, non-spray application versus low- or high-pressure spray application). To make an unreasonable risk determination for consumers, EPA considered risk estimates for consumers (*e.g.*, infants and children) representing 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, exposure duration (8 hours vs. 2 hours for high versus low, respectively, for applying roofing adhesives, hanging wallpaper and for using indoor furniture). Health parameters were also adjusted for each population, such as inhalation rates used per lifestage.

Additionally, EPA aggregated exposures across routes for workers, including ONUs, and consumers for COUs with quantitative risk estimates. For most occupational COUs, aggregation of inhalation and dermal exposures led to negligible differences in risk estimates when compared to risk estimates from inhalation alone, since the inhalation exposure is the predominant route of exposure. For consumers, dermal, oral, and inhalation routes were aggregated. For three consumer COUs, chronic, high-intensity aggregate risk estimates were below the benchmark of 30. For all other consumer COUs, aggregate risk estimates did not indicate risk. However, as explained in Section 6.1.5, the aggregate risks are based on conservative, high intensity use scenarios; therefore, EPA is preliminarily determining that most consumer uses do not contribute significantly to unreasonable risk. Additional detail about this preliminary determination for consumer uses is provided in Section 6.1.5 of this unreasonable risk determination. The uncertainty factor of 30 is based on an interspecies extrapolation to account for the animal to human extrapolation and to account for human variability or intraspecies extrapolation. Further information on how EPA characterized sentinel and aggregate risks is provided in Section 4.1.5 while the calculation of the benchmark MOE in described in Section 4.2.

EPA is including DINP in its cumulative risk assessment along with five other phthalate chemicals that also cause effects on laboratory animals consistent with a disruption of androgen action and development of phthalate syndrome. For DINP and other toxicologically similar phthalates, EPA considers acute and intermediate duration exposures during the critical window of development most relevant for a disruption of androgen action based on reduced fetal testicular testosterone. The Agency has not yet accounted for its cumulative phthalate risk assessment nor taken into consideration cumulative phthalate exposure in its risk estimates and in the unreasonable risk determination. More information on the cumulative risk considerations is provided in Section 4.3.6.

For the following COU, the Agency had limited data available and has assessed the human health risk contribution from this COU qualitatively. Additional explanation regarding the qualitative assessment is included in Section 4.3:

- Distribution in commerce.

6.1.4 Workers

Based on the occupational risk estimates and related risk factors, EPA is preliminarily determining that the non-cancer risks from worker acute, intermediate, and chronic inhalation exposure to DINP and worker aggregate exposures to DINP in industrial uses where high-pressure spray applications are used contribute significantly to the unreasonable risk of DINP.

All occupational COUs were quantitatively assessed, and worker risks were evaluated using the central tendency, with exception of two industrial COUs (Adhesive and sealant chemicals and Paints and coatings) for which high-end estimates were used due to the potentially elevated inhalation exposures from pressurized spray operations. Susceptible populations that may be exposed while working were accounted for by including risk estimates for female workers of reproductive age (see Table 4-17).

EPA analyzed vapor/mist and/or particulate concentration inhalation exposure in the occupational scenarios using a time weighted average (TWA) for a typical 8- or 10-hour shift, depending on the OES (see Table 4-3). Separate estimates of central tendency and high-end exposures were made for male and female adolescents and adults (≥16 years old) workers, female workers of reproductive age, and ONUs. Dermal exposure in the occupational exposure scenarios was analyzed using the acute potential dose rate. Dermal exposure for ONUs was assessed for COUs where exposure to DINP is likely to occur via mist or dust deposited on surfaces. For the COUs assessed, dermal exposure for ONUs was evaluated using the central tendency estimates for workers as the risk to ONUs are assumed to be equal to or less than risk to workers who handle materials containing DINP as a part of their job.

Non-cancer risk estimates were calculated from acute, intermediate, and chronic exposures. For most OESs, acute refers to an exposure time frame of an 8-hour single 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.

To make a preliminary risk determination, EPA analyzed the individual COUs to determine if the COU was best represented by central tendency or high-end estimates for workers and ONUs based on the description of the COU and the parameters and assumptions used in the occupational exposure scenarios. Risk was not indicated to workers including ONUs for any COU at the high-end or central tendency for dermal exposure estimates.

There were COUs with MOEs below the benchmark of 30 at the high-end estimates of inhalation exposure for worker populations. However, the high-end MOEs for some of these COUs represent high-pressure spray-application, and for other COUs, the high-end MOEs represent total PNOR (*i.e.,* dust) concentrations that contain a variety of constituents besides DINP. For some COUs, EPA is preliminarily determining the high-end MOEs represent a high-pressure spray application. The COUs best represented by high-end MOEs indicating high-pressure spray applications were: Industrial use – adhesives and sealants, and Industrial use – construction, paint, electrical, and metal products – paints and coatings (Table 4-17). Therefore, due to the possible use of high-pressure spray application, EPA is preliminarily concluding that these two COUs contribute significantly to the unreasonable risk to human health based on the high-end acute, intermediate, and chronic inhalation risk estimates for average male workers and females of reproductive age. For COUs that had high-end MOEs representing total PNOR concentrations (45% DINP), EPA is preliminarily determining that these COUs do not contribute significantly to the unreasonable risk DINP presents to workers due to the uncertainty of the composition of workplace dust (*i.e.*, the dust may not be comprised solely of PNOR) and is instead relying on central tendency estimates of the PNOR (10% DINP) to estimate risks to workers.

As discussed in Section 4.3.2 of this draft risk evaluation, the high-end inhalation exposures for the COUs associated with spray application are more representative of high-pressure spray applications. EPA reviewed the percent of DINP in products that were associated with each of these COUs, uncertainties, and their method of application in processing, industrial, and commercial uses. The primary limitation of the inhalation risk estimates for these COUs is the lack of DINP-specific monitoring data. EPA used surrogate monitoring data from the emission scenario document (ESD) on Coating Application via Spray-Painting in the Automotive Refinishing Industry to estimate inhalation exposures (OECD, 2011a). The ESD served as a source of monitoring data representing the level of exposure that could be expected at a typical work site for a given spray application method. EPA expects that the percent of DINP will not vary considerably between products used for processing, industrial, and commercial uses; only uses that have known pressurized spray applications associated with their use were represented by the high-end inhalation exposure estimates. EPA is preliminarily concluding that Industrial uses adhesives – adhesives and sealants and Industrial use – construction paint, electrical, and metal products – paints and coatings contribute significantly to the unreasonable risk to human health based on the high-end acute, intermediate, and chronic inhalation exposure estimates for average workers and females of reproductive age—even though the inhalation and dermal central tendency risk estimates do not indicate that the COUs contribute significantly to the unreasonable risk. An additional uncertainty regarding the high-end inhalation risk estimates for these two COUs is whether the automotive refinishing products in the surrogate data used for estimating inhalation exposure are similar to DINP-containing adhesives and sealants. Lastly, the inhalation dose-response value used for the assessment is based on route-to-route extrapolation from oral data, which is an additional source of uncertainty.

Furthermore, EPA is not determining that other COUs with low-pressure spray applications or non-spray applications contribute significantly to unreasonable risk at this time. The other COUs assessed are not generally applied using high-pressure spray applications and high-end inhalation exposures would not occur. These COUs are in commercial settings and/or where the most likely methods of applications would be low-pressure spray applications or non-spray applications (*e.g.,* brush, roll, dip, or bead application). Therefore, the best representation of inhalation exposure for the Commercial use – construction, paint, electrical, and metal products – paints and coatings as well as Commercial use – construction, paint, electrical, and metal products – adhesives and sealants COUs are the central tendency estimates for the spray application scenario (*i.e.,* low-pressure spray application) and both the high-end and central tendency estimates from the non-spray application scenario, respectively.

For all processing COUs represented by plastics compounding and converting scenarios, inhalation exposure estimates were based on inhaling dust containing other constituents besides DINP for both workers and ONUs, and dermal exposures were based on exposure to liquid DINP or DINP mist and dust on surfaces for workers or ONUs, respectively. As there was uncertainty in the amount of DINP in dust, EPA concluded that the central tendency estimates are the best representation of inhalation exposure for these COUs.

For the purposes of the unreasonable risk determination, distribution in commerce of DINP consists of the transportation associated with the moving of DINP or DINP-containing products between sites manufacturing, processing, or recycling DINP or DINP-containing products, or to final use sites, or for final disposal of DINP or DINP-containing products. EPA did not calculate risk estimates for the distribution in commerce COU. Data was not reasonably available for the Agency to determine environmental releases and exposures (and subsequent general population and environmental receptor exposures) related to distribution of DINP in commerce as a single OES. Instead, EPA evaluated distribution in commerce qualitatively. The Agency does not expect distribution in commerce to contribute significantly to DINP's unreasonable risk to human health because distribution in commerce does not generate dust or mist, and DINP's low vapor pressure results in inhalation exposures that are quite low for workers. EPA expects that workers involved in distribution in commerce spend less time exposed to DINP 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 (see Section 4.3.2). Therefore, EPA is preliminary determining that distribution in commerce does not contribute significantly to the unreasonable risk presented by DINP.

In the overall occupational assessment, EPA has moderate to robust confidence in the assessed inhalation and dermal OESs and robust confidence in the non-cancer PODs selected to characterize risk from acute, intermediate, and chronic duration exposures to DINP. Overall, EPA has moderate to robust confidence in the risk estimates calculated for worker and ONU inhalation and dermal exposure scenarios. More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in Section 4.3.2.1.

6.1.5 Consumers

Based on the consumer risk estimates and related risk factors, EPA is preliminarily determining that one consumer use significantly contributes to the unreasonable risk of DINP: Furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting) due to high-intensity modeling of inhalation risks to infants, toddlers, and preschoolers. Although EPA considered MOEs that were below the benchmark for one other consumer COU: Consumer use – construction, paint, electrical, and metal products – adhesives and sealants, the Agency is preliminary finding that this COU does not contribute significantly to the unreasonable risk, and more information is provided below.

Consumer and bystander risks representing specific age groups were evaluated for consumer COUs. Typically, consumers are adults since most products purchased are for adult use or application. Bystanders would include other adults in the home, as well as children. However, 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; therefore, 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 infants (<1 year), toddlers (1–2 years), preschoolers (3–5 years), middle childhood (6–10 years), young teens (11–15 years), teenagers (16–20 years), and adults (21+ years).

Dermal exposure was evaluated through direct contact with the product or article. Inhalation exposure was evaluated assuming exposure occurred through the emission of DINP from the product or article. When applicable, such as the assessment of the Packaging, paper, plastic, hobby products – toys, playground, and sporting equipment COU, oral exposure to DINP was evaluated through the mouthing of articles during use. EPA notes that the Consumer Product Safety Improvement Act of 2008 banned the use of DINP at concentrations of greater than 0.1 percent in children's toys and childcare articles in 2008 for certain articles and the U.S. CPSC finalized a ban in 2018 for all remaining articles. EPA expects that the use of DINP in toys and childcare articles manufactured or processed prior to the bans in 2008 and 2018, respectively, may still be occurring.

Due to the low volatility of DINP, airborne DINP particles released from household items are more likely to be found on settled and suspended dust and then inhaled or ingested. EPA included the ingestion and inhalation of dust for the assessment of six consumer COUs. One of the consumer COUs included in the indoor dust assessment was found to contribute significantly to the unreasonable risk of DINP—Furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting—by estimating the amount of DINP-containing dust that would be generated from indoor articles such as carpet backing, vinyl flooring, in-place wallpaper, and indoor furniture.

For the consumer COU, Furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting), the risk to infants, toddlers, and preschoolers is primarily driven by conservative estimates of chronic inhalation of DINP and to a lesser extent ingestion of DINP partitioned to surface dust from in-place wallpaper and vinyl flooring. The conservative high-intensity exposure scenario represents an upper bound exposure scenario. Additionally, for carpet backing, the aggregation of exposures routes for the chronic high-intensity exposure scenario for infants resulted in an MOE value of 25 and the chronic high-intensity exposure scenario for toddlers resulted in an MOE value of 26. The high-intensity model conservatively assumes that a relatively large surface area of the house is covered with in-place wallpaper (200 m^2), and for vinyl flooring and carpet, the high-intensity model assumed 100 percent of the house was covered (482 m^2). Model parameters for frequency and duration of use were well understood and representative because CEM default parameters represent actual use patterns and location of use; the largest source of modeling uncertainty was DINP weight fraction (16, 25, and 26% for carpet backing, vinyl flooring, and in-place wallpaper, respectively) and dermal absorption of DINP from solid objects. As explained in this draft unreasonable risk determination, benchmarks are not bright-line indicators of risk. While conservative approaches were used for estimating risk to infants, toddlers, and preschoolers, the low MOEs and EPA's confidence in the chronic POD for liver toxicity (which is relevant for all age groups) and other modeling parameters support making an unreasonable risk determination based on in-place wallpaper, vinyl flooring, and carpet backing.

For Construction, paint, electrical, and metal products – adhesives and sealants, chronic, high-intensity aggregate risk estimates were below the benchmark of 30 for young teens (11 to 15 years), teenagers (16 to 20 years), and adults (21+ years). No acute, intermediate (where assessed), or chronic inhalation risk estimates for bystanders indicated risk for the COUs assessed. Dermal and oral exposures were assessed for non-cancer risks for consumers only since bystanders would not be expected to be exposed within any consumer COUs. Non-cancer risk estimates for consumers and bystanders were calculated from acute, intermediate (where assessed), and chronic exposures. 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 time frame. EPA identified one age group, young teens (11 to 15 years) with aggregate risk from inhalation and dermal exposures to DINP in roofing adhesive. To estimate aggregate risk to this age group, EPA assumed a young teen would have dermal contact (inside of two palms) with the adhesive during one large (8-hour) roofing project in 1 year. EPA also identified two roofing adhesion products with weight fractions ranging from 30 to 31 percent and used 31 percent for the high-intensity model. However, for this COU, EPA modeled a well-ventilated, indoor area for roofing adhesives since, although inhalation exposures outdoors are generally expected to be negligible, the size of a typical roofing project and the high weight fraction of DINP in identified roofing adhesive products was such that EPA did not consider the potential for outdoor exposures to be negligible. The Agency does not consider it reasonable for roofing adhesives to be used indoors for roofing projects, but if they were, then the inhalation exposures resulting from high intensity indoor use aggregated with dermal exposures indicate risk for young teens. However, there is uncertainty from dermal absorption due to the extrapolation from animal studies to humans. In addition, EPA was not able to quantify the uncertainty from applying the CEM to outdoor use; therefore, it is unable to quantify the uncertainty from aggregating conservative risk estimates of inhalation and dermal routes of exposure, resulting in an aggregate MOE that overestimates the risk. Therefore, EPA is preliminarily determining that the consumer COU Construction, paint, electrical, and metal products – adhesives and sealants, in an outdoors or well-ventilated setting, does not contribute significantly to the unreasonable risk of DINP.

Therefore, EPA is preliminarily determining that only one consumer use: Furnishing, cleaning, treatment/care products – floor coverings/plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting), contributes significantly to the unreasonable risk of DINP.

The overall confidence in the exposure doses used to estimate risk ranges from moderate to robust. EPA has robust confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to DINP. EPA has moderate to robust confidence in the assessed inhalation, ingestion, and dermal consumer exposure scenarios (Section 4.3.3.1). More information on EPA's confidence in these risk estimates and the uncertainties associated with them can be found in this draft risk evaluation and the *Draft Consumer and Indoor Dust Exposure Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024l).

6.1.6 General Population

EPA employed a screening-level approach for general population exposures for DINP. The Agency evaluated surface water, drinking water, fish ingestion, and ambient air pathways quantitatively, as well as land pathways (*i.e.,* landfills and application of biosolids) qualitatively (see Section 4.3.4). EPA is preliminarily determining that the COUs do not contribute significantly to the unreasonable risk of DINP to the general population, including people living or working near facilities (fenceline populations) from the ambient air, due to non-cancer risk.

Due to DINP's low water solubility, affinity for sorption to soil and organic constituents in soil, and considering the half-life in aerobic soils, DINP 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 DINP to occur via the land pathway and therefore, does not expect there to be risk to the general population from the land pathway. For further information, see Section 4.1.3.1.

EPA used the highest possible DINP concentration in surface water due to facility release to quantitatively evaluate the risk to the general population from exposure to DINP from drinking water or incidental ingestion and dermal contact during recreational swimming. The Agency took the high-end exposure estimates associated with the COU with the highest total water column concentration to calculate an MOE. Since that MOE did not indicate non-cancer risk, based on this screening-level assessment, risk for non-cancer health effects is not expected for the surface water pathway and the surface water pathway is not considered to be a pathway of concern to DINP for the general population. For further information, see Section 4.1.3.1.

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. EPA evaluated drinking water scenarios that assumed a wastewater treatment removal efficiency of 98 percent and no further drinking water treatment, as well as a with a conservative drinking water treatment removal rate of 79 percent. EPA took the high-end exposure estimates associated with the COU with the highest total water column concentration, to calculate an MOE. Because that MOE did not indicate non-cancer risk, based on this screening-level analysis, risk for non-cancer health effects is not expected for the drinking water pathway and the drinking water pathway is not considered to be a pathway of concern to DINP for the general population. For further information, see Section 4.1.3.1.

Risk estimates for fish ingestion generated at concentrations of DINP at the water solubility limit or at highest measured concentrations in surface water did not indicate risk to tribal populations. Using the estimated fish tissue concentrations, EPA evaluated exposure and potential risk to DINP through fish ingestion for adults in the general population, adult subsistence fishers, and adult tribal populations. Tribal populations are considered to represent the sentinel exposure scenario. MOEs based on conservative values, such as surface water concentration from a stormwater catchment area, still resulted in risk estimates that are above their benchmarks. Therefore, based on this screening-level analysis, fish ingestion does not contribute significantly to the unreasonable risk for DINP for tribal members, subsistence fishers, and the general population. For further information, see Section 4.1.3.1.

EPA also considered concentrations of DINP in ambient air and deposition of DINP from air. Inhalation exposure was not assessed because it is not expected to be a major pathway of exposure to DINP for the general population and therefore does not contribute significantly to the unreasonable risk. The Agency used the occupational exposure scenario that provided the highest modeled 95th percentile annual ambient air and air deposition concentrations for DINP to calculate exposure due to ingestion or contact with DINP in soil and used conservative exposure assumptions for infants and children (ages 6 months to <12 years). MOEs based on these conservative estimates were above the benchmark. Therefore, based on this screening-level analysis, risk for non-cancer health effects is not expected for the ambient air pathway and the ambient air pathway is not considered to be a pathway of concern to DINP for the general population. For further information, see Section 4.1.3.1.

In addition, EPA conducted a screening-level analysis of the NHANES biomonitoring data and considered the U.S. CPSC evaluation of DINP exposures. EPA concluded that the exposures to the general population via ambient air, surface water, and drinking water identified in this draft risk evaluation are likely overestimates, since the estimates from individual pathways exceed the total intake values measured, even at the 95th percentile of the U.S. population for all ages. For further information, see Section 4.1.3.1.

EPA expects that general population inhalation exposures from distribution in commerce would be even lower than those for workers. Therefore, the Agency is preliminarily determining that distribution in commerce does not contribute significantly to the unreasonable risk of DINP due to the injury to health.

EPA has robust confidence in its qualitative assessment of biosolids and landfills. EPA has moderate confidence in the surface water exposure scenarios that were used to estimate incidental ingestion and dermal contact, since the estimated environmental releases were slightly biased toward over-estimation. EPA has slight confidence in its fish ingestion estimates that used the monitored surface water concentrations. Additionally, EPA has slight confidence in the modeled exposure doses used for exposure scenarios for soil ingestion and contact. The moderate or slight confidence is based on the scenarios not presenting realistic scenarios of DINP exposure, but the exposure estimate capturing high-end estimates. It is important to note that these confidence conclusions refer to the confidence in the data quality and numerical accuracy of the underlying data and the resulting model estimates. Further, EPA's overall confidence that the exposure estimates capture high-end exposure scenarios is robust, and further refinement of the models is not warranted because risks were not indicated for the pathways with the highest potential for exposure. Additional information on EPA's confidence in these risk estimates and their associated uncertainties can be found in Section 4.1.3.1 and the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024r).

6.2 Environment

Risk of injury to the environment does not contribute significantly to EPA's preliminary determination of unreasonable risk from DINP. The environmental risk characterization for DINP involved determining the COUs associated with the highest release estimates to environmental media for a given pathway and comparing it to the hazard values for aquatic and terrestrial organisms. If the exposure for the most conservative estimates did not exceed the hazard threshold, it was determined that exposures due to releases from other COUs would not lead to environmental risk. Under no circumstances did exposure exceed the hazard threshold for terrestrial mammals. EPA has robust confidence in the expected lack of risk to aquatic receptors and moderate confidence in the lack of risk to terrestrial receptors.

6.2.1 Populations and Exposures EPA Assessed for the Environment

EPA quantitatively determined DINP concentrations in surface water, sediment, and soil. However, the Agency did not quantitatively evaluate exposures to aquatic organisms and terrestrial species. A qualitative analysis of exposure was used because to evaluate whether the potential releases of DINP into the environment exceed the DINP concentrations that result in hazardous effects to aquatic and terrestrial organisms. EPA first characterized risk based upon the COU/OES and associated environmental media with the highest estimated concentrations for a given pathway, and then COUs with lower environmental releases would also have lower risk.

EPA expects the main environmental exposure pathway for aquatic species to be releases to surface water and subsequent deposition to sediment. The Agency also determined the amount of DINP released to surface water, ambient air, and subsequent deposition to water and sediment, as well as landfills and subsequent deposition to water and sediment. DINP 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 or pose risk to aquatic and terrestrial organisms. As detailed in Section 5.3.2, monitoring data from published literature report DINP 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.

DINP 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. Despite no reasonably available studies of the DINP hazard effects on terrestrial mammals in the literature, a Toxicity Reference Value (TRV) was derived from laboratory rodent studies to obtain a threshold dose concentration to represent hazard effects on generic terrestrial mammals. The TRV was used as a hazard effect threshold for dietary transfers through trophic levels in food webs (*i.e.*, trophic transfer) from water and soil media releases (U.S. EPA, 2024o). Empirical toxicity data for rats and mice were used to estimate a TRV for terrestrial mammals at 139 mg/kg-bw/day. EPA expects that DINP has a low bioconcentration and biomagnification potential across trophic levels. Under no circumstances did exposure exceed the hazard threshold for terrestrial mammals.

Although the conservative nature of model outputs resulted in slight confidence for the air releases and moderate confidence in the modeled water releases, there is robust to moderate confidence that the modeled environmental media concentrations do not underestimate exposure to ecological receptors and the risk characterization is protective of the environment, as noted in Table 5-2. EPA has robust confidence in the reasonably available information of DINP concentrations within surface waters. However, due to the lack of reasonably available release data for facilities discharging DINP to surface waters, all releases were modeled.

In general, EPA has an overall robust confidence in the risk characterization for the aquatic assessment. Studies used for the aquatic environmental hazard assessment consisted of 19 studies with an overall quality determination of high or medium from the systematic review process. Consistently, no effects were observed up to the highest DINP concentration tested within all aquatic hazard studies. And monitoring data from published literature report DINP concentrations within surface water and sediment lower than the highest NOEC values for different aquatic species. EPA has an overall moderate confidence in the inputs for the terrestrial risk characterization. EPA assigned an overall quality of high or medium to 12 toxicity studies used as surrogates for terrestrial mammals. Robust confidence in hazard was assigned for terrestrial invertebrates due to an earthworm study. Confidence in the chronic mammalian risk characterization was moderate. EPA has also determined an indeterminate confidence in chronic avian and terrestrial plant assessments as there is a lack of reasonably available hazard data. However, the TRV was used for a screening-level trophic transfer analysis. For more information, please see Section 5.3.3 of this draft risk evaluation and the *Draft Environmental Hazard Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024p).

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 is preliminarily identifying:

- no adverse effects to aquatic organisms up to and exceeding the limit of water solubility;
- no adverse effects to aquatic dependent mammals; and
- no adverse effects to terrestrial mammals.

The 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 DINP 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 DINP'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 DINP exposure concentrations from this analysis are not equal to or greater than the TRV. These results indicate that DINP has low bioaccumulation potential and will not biomagnify, which has been seen in previous studies.

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

EPA evaluated down-the-drain releases of DINP for consumer COUs qualitatively. Although EPA acknowledges that there may be DINP releases to the environment via the cleaning and disposal of adhesives, sealants, paints, lacquers, and coatings, the Agency did not quantitatively assess down-the-drain and disposal scenarios of consumer products due to limited information from monitoring data or modeling tools. However, modeling tools and consideration of the physical and chemical properties of DINP allows EPA to conduct a qualitative assessment. Drinking water treatment removal rates from 79 percent to over 96 percent removal, and even with the use of 79 percent, all drinking water exposures resulted in minimal human exposure and subsequent risk. DINP affinity to organic material and low water solubility and log K_{OW} suggest that DINP in down-the-drain water is expected to mainly partition to suspended solids present in water. Also, the use of flocculants and filtering media could potentially help remove DINP during drinking water treatment. Therefore, the consumer COUs do not significantly contribute to the unreasonable risk of DINP due to down-the-drain releases.

6.2.3 Basis for Risk of Injury to the Environment

Based on the draft risk evaluation for DINP—including the risk estimates, the environmental effects of DINP, the exposures, physical and chemical properties of DINP, and consideration of uncertainties—EPA did not identify risk of injury to the environment that would contribute significantly to the unreasonable risk determination for DINP. For aquatic organisms, surface water and subsequent deposition to sediment were determined to be the drivers of exposure, but EPA does not expect these pathways to contribute significantly to unreasonable risk to the environment. The Agency does not expect exposure to DINP via water, land, or dietary pathways to contribute significantly to unreasonable risk to the environment. EPA's overall environmental risk characterization confidence levels were varied and are summarized in the *Draft Environmental Exposure Assessment for Diisononyl phthalate (DINP)* (U.S. EPA, 2024o).

6.3 Additional Information Regarding the Basis for the Unreasonable Risk Determination

Table 6-1 summarizes the basis for this draft unreasonable risk determination of injury to human health and the environment presented in this draft risk evaluation for those COUs with a qualitative evaluation. In these tables, a checkmark (✓) indicates how the COU significantly 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 draft unreasonable risk determination, EPA considered the effects of DINP to human health at the central tendency and high-end, as well as effects of DINP to human health from the exposures associated from the TSCA COUs, risk estimates, and uncertainties in the analysis. Checkmarks in Table 6-1 and

Table 6-2 represent risk at the high-end and central tendency exposure level as discussed in Section 6.1. See Section 4.3.2 for a summary of risk estimates.

4333 **Table 6-1. Supporting Basis for the Draft Risk Determination for Human Health (Occupational Conditions of Use)**

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Manufacturing	Domestic manufacturing	Domestic manufacturing	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
	Importing	Importing	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
Processing	Incorporation in formulation, mixture, or reaction product	Heat stabilizer and processing aid in basic organic chemical manufacturing	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
		Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Processing	Incorporation into articles	Plasticizers (toys, playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing (including pigment))	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
	Other uses	Miscellaneous processing (petroleum refineries; wholesale and retail trade)	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
	Repackaging	Plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing)	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
	Recycling	Recycling	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Processing	Recycling	Recycling	Reproductive Age	Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
Industrial Use	Adhesive and sealant chemicals	Adhesive and sealant chemicals (sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing)	Worker: Average Adult Worker	Inhalation	✓	✓	✓
				Dermal			
				Aggregate	✓	✓	✓
			Worker: Female of Reproductive Age	Inhalation	✓	✓	✓
				Dermal			
				Aggregate	✓	✓	✓
			ONU	Inhalation			
				Dermal			
				Aggregate			✓
	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluid	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
	Construction, paint, electrical, and metal products	Building/construction materials (roofing, pool liners, window shades, flooring)	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
		Paints and coatings	Worker: Average Adult Worker	Inhalation	✓	✓	✓
				Dermal			
				Aggregate	✓	✓	✓
			Worker: Female of	Inhalation	✓	✓	✓

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Industrial Use	Construction, paint, electrical, and metal products	Paints and coatings	Reproductive Age	Dermal			
				Aggregate	✓	✓	✓
			ONU	Inhalation			
				Dermal			
				Aggregate			
	Other uses	Hydraulic fluids	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
		Pigment (leak detection)	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
Commercial Use	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
	Construction, paint, electrical, and metal products	Adhesives and sealants	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Commercial Use	Construction, paint, electrical, and metal products	Adhesives and sealants	Reproductive Age	Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
		Plasticizer in building/construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles[d]	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Electrical and electronic products	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Paints and coatings	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Commercial Use	Furnishing, cleaning, treatment/care products	Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles	Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Air care products	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
		Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Fabric, textile, and leather products (apparel and footwear care products))	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Commercial Use	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Ink, toner, and colorant products	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
		Packaging, paper, plastic, hobby products (packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles [soft])	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
		Plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses)	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Commercial Use				Aggregate			
	Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
	Solvents (for cleaning or degreasing)	Solvents (for cleaning or degreasing)	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Aggregate			
	Other uses	Laboratory chemicals	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			
				Dermal			
				Aggregate			
Disposal	Disposal	Disposal	Worker: Average Adult Worker	Inhalation			
				Dermal			
				Aggregate			
			Worker: Female of Reproductive Age	Inhalation			
				Dermal			
				Aggregate			
			ONU	Inhalation			

Life Cycle Stage	Category	Subcategory	Population	Exposure Route	Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
				Dermal			
				Aggregate			

Table 6-2. Supporting Basis for the Draft Risk Determination for Human Health (Consumer Conditions of Use)

Life Cycle Stage	Category	Subcategory	Product or Article	Population[a]	Exposure Route	Human Health Effects[b]		
						Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Consumer Use	Automotive, fuel, agriculture, outdoor use products	Automotive products, other than fluids	Car Mats					
	Construction, paint, electrical, and metal products	Adhesives and sealants	Roofing Adhesives	Consumer: Young Teen	Aggregate			✓
		Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)	Roofing Membrane					
		Electrical and electronic products	Wire Insulation					
		Paints and Coatings	Paint/Lacquer					
	Furnishing, cleaning, treatment/care products	Floor coverings/ Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics,	Carpet Backing[c]	Consumer: Infant	Inhalation			
					Aggregate			✓
				Consumer: Toddler	Inhalation			
					Aggregate			✓
			Vinyl Flooring[c]	Consumer: Infant	Inhalation			✓
					Aggregate			✓
				Consumer: Toddler	Inhalation			✓
					Aggregate			✓
				Consumer:	Inhalation			✓

Life Cycle Stage	Category	Subcategory	Product or Article	Population[a]	Exposure Route	Human Health Effects[b]		
						Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Consumer Use	Furnishing, cleaning, treatment/care products	textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)		Preschooler	Aggregate			✓
			Wallpaper (in-place)[c]	Consumer: Infant	Inhalation			✓
					Aggregate			✓
				Consumer: Toddler	Inhalation			✓
					Aggregate			✓
				Consumer: Preschooler	Inhalation			✓
					Aggregate			✓
		Foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)	Indoor Furniture[c]					
		Air care products	Scented Oil					
		Fabric, textile, and leather products (apparel and footwear care products)	Clothing					
	Packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Crafting Resin, Rubber Eraser, Small Articles with Potential for semi-routine contact					
		Ink, toner, and colorant products	N/A					
		Other articles with routine direct contact during normal use including rubber articles; plastic	Shower Curtain; Small Articles with Potential for semi-routine contact					

Life Cycle Stage	Category	Subcategory	Product or Article	Population[a]	Exposure Route	Human Health Effects[b]		
						Acute Non-cancer	Intermediate Non-cancer	Chronic Non-cancer
Consumer Use	Packaging, paper, plastic, hobby products	articles (hard); vinyl tape; flexible tubes; profiles; hoses						
		Packaging (excluding food packaging), including rubber articles plastic articles (hard); plastic articles (soft)	Small Articles with Potential for semi-routine contact					
		Toys, playground, and sporting equipment	Childrens Toys (legacy and new) and Sports Mats					
	Other	Novelty products	Adult Toys					

[a] Only inhalation exposure routes were assessed for bystanders.
[b] Grayed-out boxes indicate certain exposure routes that were not assessed because it was determined that there was no viable exposure pathway.
[c] COUs associated with articles included in the indoor environment assessment.

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APPENDICES

Appendix A KEY ABBREVIATIONS AND ACRONYMS

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	Consumer Product Safety Commission
CWA	Clean Water Act
DEHP	Diethylhexyl phthalate
DIDP	Diisodecyl phthalate
DINP	Diisononyl phthalate
DIY	Do-it-yourself
DMR	Discharge Monitoring Report
EPA	Environmental Protection Agency (or the Agency)
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emission scenario document
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GS	Generic scenario
K_{OC}	Soil organic carbon: water partitioning coefficient
K_{OW}	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_{OC}	Logarithmic organic carbon: water partition coefficient
Log K_{OW}	Logarithmic octanol: water partition coefficient
MOE	Margin of exposure
NAICS	North American Industry Classification System
NEI	National Emissions Inventory
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
PNOR	Particulates not otherwise regulated
POD	Point of departure
POTW	Publicly owned treatment works
PPARα	Peroxisome proliferator activated receptor alpha
PVC	Polyvinyl chloride
REL	Recommended Exposure Limit
SACC	Science Advisory Committee on Chemicals
SDS	Safety data sheet
SOC	Standard Occupational Classification
SpERC	Specific Emission Release Category
SUSB	Statistics of U.S. Businesses (U.S. Census)
TRI	Toxic Release Inventory
TRV	Toxicity reference value
TSCA	Toxic Substances Control Act
TSD	Technical support document
TWA	Time-weighted average
UF	Uncertainty factor
U.S.	United States
WWTP	Wastewater treatment plant
7Q10	The lowest 7-day average flow that occurs (on average) once every 10 years
30Q5	The lowest 30-day average flow that occurs (on average) once every 5 years

Appendix B REGULATORY AND ASSESSMENT HISTORY

B.1 Federal Laws and Regulations

Table_Apx 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.	DINP manufacturing (including importing), processing, and use information is reported under the CDR rule (85 FR 5081620122, April 9, 2020).
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-diisononyl ester (CASRN 28553-12-0) and 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (CASRN 68515-48-0)) were on the initial TSCA Inventory and therefore were not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
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.	Four substantial risk reports were received for CASRN 28553-12-0 and 8 substantial risk reports were received for CASRN 68515-48-0 (1991-1998) (U.S. EPA, ChemView. Accessed March 1, 2024).
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.	Two chemical data submissions from test rules received for CASRN 28553-12-0 for biodegradation (U.S. EPA, ChemView. Accessed March 1, 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 set 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 pesticide residues permitted under the action are "safe." Section 408(b) of the FFDCA defines "safe" to mean a reasonable certainty that no harm will result from aggregate exposures (which includes	CASRN 28553-12-0 is approved for non-food use (InertFinder, Accessed March 1, 2024).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	dietary exposures from food and drinking water as well as nonoccupational exposures) to the pesticide. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation under FFDCA section 408(d) or (e). In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
Clean Water Act (CWA) – Sections 301, 304, 306, 307, and 402	CWA 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 for which best available technology effluent limitations must be established on either a national basis through rules (sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	As a phthalate ester, DINP is designated as a toxic pollutant under section 307(a)(1) of the CWA, and as such is subject to effluent limitations. 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)	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment.	As a phthalate ester, DINP is designated as a hazardous substance under CERCLA. No reportable quantity is assigned to the generic or broad class (40 CFR 302.4).
Other federal statutes/regulations		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the U.S. Food and Drug Administration (FDA) with authority to oversee the safety of food, drugs, and cosmetics, except residues of pesticides in food are regulated by EPA under FFDCA section 408 (discussed above where applicable).	CASRN 28553-12-0 is listed as an Indirect Additive used in Food Contact Substances (21 CFR 178.3740).
Consumer Product Safety Improvement Action of 2008 (CPSIA)	Under section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC prohibits the manufacture	Children's toys and childcare articles that contain concentrations of >0.1% of DINP are prohibited. The interim prohibition on

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	for sale, offer for sale, distribution in commerce or importation of eight phthalates in toys and childcare articles at concentrations >0.1%: DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP and DCHP.	the use of DINP in children's toys and child care articles (15 U.S.C. 2057(c), August 14, 2008) became permanent in the final rule and was expanded to prohibit all children's toys (not just those that can be placed in a child's mouth) and child care articles that contain concentrations >0.1% of DINP (16 CFR part 1307, October 27, 2017).

5011 ## B.2 State Laws and Regulations

5012

5013 **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 but does not specifically list DINP.
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing DINP (CASRN 28553-12-0), including 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 DINP on Proposition 65 in 2013 due to potential to cause cancer. (Cal Code Regs. Title 27, § 27001). DINP (CASRN 28553-12-0) is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code §25252 and 25253). California lists DINP as a designated priority chemical for biomonitoring (California SB 1379). Minnesota designated DINP (28553-12-0) as a chemical of high concern (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407.

5014 ## B.3 International Laws and Regulations

5015

5016 **Table_Apx B-3. International Laws and Regulations**

Country/Organization	Requirements and Restrictions
Canada	CASRNs 28553-12-0 and 68515-48-0 are on the Canadian Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed May 18, 2020).
European Union	CASRN 28553-12-0 (EC/List no.: 249-079-5) and CASRN 68515-48-0 (EC/List no.: 271-090-9) are registered for use in the EU (European Chemicals Agency (ECHA)database. Accessed March 1, 2024). DINP was added to the Annex XVII of REACH (Conditions of restriction) (European Union Chemical Agency [ECHA] database. Accessed March 1, 2024).

Country/Organization	Requirements and Restrictions
	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 28553-12-0 and CASRN 68515-48-0 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 28553-12-0 and 68515-48-0 were assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). (National Industrial Chemicals Notification and Assessment Scheme [NICNAS], 2015, *Diisononyl phthalates and related compounds: Human health tier II assessment*. Accessed January 27, 2021). CASRNs 28553-12-0 and 68515-48-0 are listed on the Chemical Inventory and subject to secondary notifications when importing or manufacturing the chemical in Australia (Australian Inventory of Industrial Chemicals database. Accessed January 27, 2021).
Japan	CASRNs 28553-12-0 and 68515-48-0 are regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law [CSCL]) CASRN 68515-48-0 is also regulated under the following legislation: • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed March 1, 2024).
Countries with occupational exposure limits	Occupational exposure limits for CASRN 28553-12-0 are as follows: • Denmark: 3 mg/m^3 (8-hour) and 6 mg/m^3 (short-term); • Ireland: 5 mg/m^3 (8-hour); • New Zealand: 5 mg/m^3 (8-hour); • South Africa Mining: 5 mg/m^3 (8-hour); and • United Kingdom: 5 mg/m^3 (8-hour). (GESTIS International limit values for chemical agents [Occupational exposure limits, OELs] database. Accessed February, 28, 2024).

B.4 Assessment History

Table_Apx B-4. Assessment History of DINP

Authoring Organization	Publication
U.S. EPA publications	
U.S. EPA, Office of Pollution Prevention and Toxics (OPPT)	Technical Review of Diisononyl Phthalate (Final Assessment) (U.S. EPA, 2023e) Revised Technical Review of Diisononyl Phthalate (U.S. EPA, 2005b)

Authoring Organization	Publication
Other U.S.-based organizations	
U.S. Consumer Product Safety Commission (U.S. CPSC)	Chronic Hazard Panel on Phthalates and Phthalate Alternatives Final Report (With Appendices) (U.S. CPSC, 2014) Toxicity Review of Diisononyl Phthalate (DINP) (U.S. CPSC, 2010) Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP) (U.S. CPSC, 2001)
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-isononyl Phthalate (DINP) (NTP-CERHR, 2003)
Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency	Evidence of the Carcinogenicity of Diisononyl Phthalate (DINP) (Tomar et al., 2013)
International	
European Union, European Chemicals Agency (ECHA)	Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9- rich; [1] di-"isononyl" phthalate; [2] [DINP] (ECHA, 2018) Evaluation of New Scientific Evidence Concerning DINP and DIDP (ECHA, 2013) European union risk assessment report: DINP (ECB, 2003)
European Food Safety Authority (EFSA)	Update of the Risk Assessment of Di-butylphthalate (DBP), Butyl-benzyl-phthalate (BBP), Bis(2-ethylhexyl)phthalate (DEHP), Di-isononylphthalate (DINP) and Diisodecylphthalate (DIDP) for Use in Food Contact Materials (EFSA, 2019) Opinion of the scientific panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the commission related to di-isononylphthalate (DINP) for use in food contact materials. Question N° EFSA-q-2003-194 (EFSA, 2005)
Government of Canada, Environment Canada, Health Canada	Screening Assessment: Phthalate Substance Grouping (ECCC/HC, 2020) State of the science report: Phthalate substance grouping 1,2-Benzenedicarboxylic acid, diisononyl ester; 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (Diisononyl Phthalate;

Authoring Organization	Publication
	DINP). Chemical Abstracts Service Registry Numbers: 28553-12-0 and 68515-48-0 (EC/HC, 2015a)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	Diisononyl phthalates and related compounds: Human health tier II assessment (NICNAS, 2015a) Priority existing chemical assessment report no. 35: Diisononyl phthalate (NICNAS, 2012) Phthalates hazard compendium: A summary of physicochemical and human health hazard data for 24 ortho-phthalate chemicals (NICNAS, 2008)

Appendix C LIST OF TECHNICAL SUPPORT DOCUMENTS

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

Associated **Systematic Review Protocol and Data Quality Evaluation and Data Extraction** Documents – Provide additional detail and information on systematic review methodologies used as well as the data quality evaluations and extractions criteria and results.

Draft Systematic Review Protocol for Diisononyl Phthalate (DINP) (U.S. EPA, 2024ac) – In lieu of an update to the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances*, also referred to as the "2021 Draft Systematic Review Protocol" (U.S. EPA, 2021a), this systematic review protocol for the Draft Risk Evaluation for DINP 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 "DINP Systematic Review Protocol."

Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties for Diisononyl Phthalate (DINP) (U.S. EPA, 2024f) – Provides a compilation of tables for the data extraction and data quality evaluation information for DINP. 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.

Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport for Diisononyl Phthalate (DINP) (U.S. EPA, 2024d) – Provides a compilation of tables for the data extraction and data quality evaluation information for DINP. 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.

Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure for Diisononyl Phthalate (DINP) (U.S. EPA, 2024e) – Provides a compilation of tables for the data extraction and data quality evaluation information for DINP. 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.

Data Quality Evaluation and Data Extraction Information for Dermal Absorption for Diisononyl Phthalate (DINP) (U.S. EPA, 2024c) – Provides a compilation of tables for the data extraction and data quality evaluation information for DINP. 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.

Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure for Diisononyl Phthalate (DINP) (U.S. EPA, 2024h) – Provides a compilation of tables for the data quality evaluation information for DINP. 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.

Data Extraction Information for General Population, Consumer, and Environmental Exposure for Diisononyl Phthalate (DINP) (U.S. EPA, 2024b) – Provides a compilation of tables for the data extraction for DINP. 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.

Data Quality Evaluation Information for Human Health Hazard Epidemiology for Diisononyl Phthalate (DINP) (U.S. EPA, 2024j) – Provides a compilation of tables for the data quality evaluation information for DINP. 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.

Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for Diisononyl Phthalate (DINP) (U.S. EPA, 2024i) – Provides a compilation of tables for the data quality evaluation information for DINP. 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.

Data Quality Evaluation Information for Environmental Hazard for Diisononyl Phthalate (DINP) (U.S. EPA, 2024g) – Provides a compilation of tables for the data quality evaluation information for DINP. 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.

Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology for Diisononyl Phthalate (DINP) (U.S. EPA, 2024a) – Provides a compilation of tables for the data extraction for DINP. 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.

Associated **Technical Support Documents** (TSDs) – Provide additional details and information on exposure, hazard, and risk assessments.

Draft Physical Chemistry Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024x).

Draft Fate Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024t).

Draft Environmental Release and Occupational Exposure Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024s).

*Draft Consumer and Indoor Exposure Assessment for Diisononyl Phthalate (DINP) (*U.S. EPA, 2024l*).*

Draft Environmental Media and General Population Screening for Diisononyl Phthalate (DINP) (U.S. EPA, 2024r).

Draft Environmental Exposure Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024o).

Draft Environmental Hazard Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024p).

Draft Non-cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024w).

Draft Cancer Human Health Hazard Assessment for Diisononyl Phthalate (DINP) (U.S. EPA, 2024k).

Draft Consumer Exposure Analysis for Diisononyl Phthalate (DINP) (U.S. EPA, 2024m).

Draft Consumer Risk Calculator for Diisononyl Phthalate (DINP) (U.S. EPA, 2024n).

Draft Risk Calculator for Occupational Exposures for Diisononyl Phthalate (DINP) (U.S. EPA, 2024y).

Draft Fish Ingestion Risk Calculator for Diisononyl Phthalate (DINP) (U.S. EPA, 2024u)

Draft Surface Water Human Exposure Risk Calculator for Diisononyl Phthalate (DINP) for P50 Flow Rates (U.S. EPA, 2024z)

Draft Surface Water Human Exposure Risk Calculator for Diisononyl Phthalate (DINP) for P75 Flow Rates (U.S. EPA, 2024aa)

Draft Surface Water Human Exposure Risk Calculator for Diisononyl Phthalate (DINP) for P90 Flow Rates (U.S. EPA, 2024ab)

Appendix D UPDATES TO THE DINP CONDITIONS OF USE TABLE

After the final scope (U.S. EPA, 2021b), EPA received updated submissions under the 2020 CDR reported data. In addition to new submissions received under the 2020 CDR, the reporting name codes changed for the 2020 CDR reporting cycle. Therefore, EPA is amending the description of certain DINP COUs based on those new submissions and new reporting name codes. Also, EPA received information from stakeholders about other uses of DINP. Table_Apx D-1 summarizes the changes to the COUs based on the new reporting codes in the 2020 CDR and any other new information since the publication of the final scope.

Table_Apx D-1. Additions and Name Changes to Categories and Subcategories of Conditions of Use Based on CDR Reporting and Stakeholder Engagement

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing; Processing as a reactant	Plasticizers; Plastic material and resin manufacturing; Processing aids not otherwise listed (*e.g.*, mixed metal stabilizer); Rubber product manufacturing; Synthetic rubber manufacturing	Consolidated category and associated subcategories under either "processing, incorporation into article" or "processing, incorporation into formulation, mixture, or reaction products" based on further consultations with the submitters of the manufacturer requested risk evaluation (ACC HPP, 2023).	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing (including pigment)) And Processing – Incorporation into articles – Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])
Processing, Incorporation into articles	Textiles, apparel, and leather manufacturing	Consolidated subcategory into "processing, incorporation into articles, plasticizer" to avoid duplication based on updates to CDR reporting.	Processing – Incorporation into articles – Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])
Processing, Incorporation into articles	Electrical equipment, appliance, and component manufacturing	Consolidated into "processing, incorporation into articles, plasticizer" COU to avoid duplication.	Processing – Incorporation into articles – Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
			colorant manufacturing [including pigment])
Processing, Incorporation into articles	Plasticizers (*e.g.*, toys, playground, and sporting equipment manufacturing)	Consolidated COUs and updated to include CDR reporting during the 2020 CDR reporting cycle: added "plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; transportation equipment manufacturing; ink, toner, and colorant manufacturing (including pigment))	Processing – Incorporation into articles – Plasticizers (toys, playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])
Processing, Incorporation into articles	Finishing agents (*e.g.*, all other chemical products and preparation manufacturing)	Consolidated subcategory based on review of CDR reports to other processing COUs.	Processing – Other uses – Miscellaneous processing (petroleum refineries; wholesale and retail trade)
Processing, Incorporation in formulation, mixture, or reaction product	Adhesives and sealants chemicals (*e.g.*, adhesive and sealant manufacturing; construction; wholesale and retail trade)	Consolidated into "processing, incorporation in formulation, mixture, or reaction product, plasticizer" COU to remove duplication and to reflect the functional use of DINP in these sectors as a plasticizer.	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])
Processing, Incorporation in formulation, mixture, or reaction product	Laboratory Chemicals	Consolidated into the "processing, repackaging" COU, since DINP is not being reformulated and is being used as a technical standard or reference reagent.	Processing – Repackaging – Plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing)
Processing, Incorporation in formulation, mixture, or reaction product	Intermediates (*e.g.*, adhesive manufacturing; all other chemical products and preparation manufacturing; plastic material and resin manufacturing)	Updated based on 2020 CDR reporting cycle and communication with stakeholders who confirmed DINP is used as a processing aid rather than as an intermediate (ACC HPP, 2023). Removed "Intermediate" and consolidated adhesive manufacturing; all other chemical products and preparation manufacturing; plastic material and resin manufacturing with other processing COUs."	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing, Incorporation in formulation, mixture, or reaction product	Plasticizers (*e.g.*, adhesive manufacturing; custom compounding of purchased resin; paint and coating manufacturing; plastic product manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; transportation equipment manufacturing; wholesale and retail trade)	Consolidated and updated COUs; based on review of CDR reports and downstream uses. Removed "plastic products manufacturing," since DINP is being formulated into a plastic material or resin first, before being incorporated into articles, *i.e.*, plastic products. Added "all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])"	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesive manufacturing; custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])
Processing, Incorporation in formulation, mixture, or reaction product	Processing aids, not otherwise listed (*e.g.*, all, other basic organic chemical manufacturing; furniture and related product manufacturing)	Consolidated into "processing, incorporation in formulation, mixture, or reaction product, plasticizer" COU to remove duplication, and added "Heat stabilizer and processing aid in basic organic chemical manufacturing" to reflect updates to CDR reporting codes during the 2020 CDR reporting cycle."	Processing – Incorporation in formulation, mixture, or reaction product – Heat stabilizer and processing aid in basic organic chemical manufacturing
Processing, Incorporation in formulation, mixture, or reaction product	Process regulators (*e.g.*, paint and coating manufacturing)	Consolidated into "processing, incorporation in formulation, mixture, or reaction product, plasticizer" COU to remove duplication and reflect updates to CDR reporting codes during the 2020 CDR reporting cycle.	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])
Processing, Incorporation in formulation, mixture, or reaction product	Not known or reasonably ascertainable (*e.g.*, petroleum refineries)	Consolidated into "processing, other uses, miscellaneous processing" COU to include other sectors from CDR reporting during the 2020 CDR reporting cycle.	Processing – Other uses – Miscellaneous processing (petroleum refineries; wholesale and retail trade)
Processing, Incorporation in formulation, mixture, or reaction product	Viscosity adjustors (*e.g.*, wholesale and retail trade)	Consolidated into "processing, incorporation in formulation, mixture, or reaction product, plasticizer" COU to remove duplication, and reflect updates to CDR reporting codes during the 2020 CDR reporting cycle.	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment])

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing, Other uses	N/A	Added category and subcategory to reflect updates from 2020 CDR reporting cycle.	Processing – Other uses – Miscellaneous processing (petroleum refineries; wholesale and retail trade)
Repackaging	Repackaging	Updated subcategory to show specific examples of where repackaging is used by various industries.	Processing – Repackaging – Plasticizer (all other chemical product and preparation manufacturing; wholesale and retail trade; laboratory chemicals manufacturing)
Industrial uses, Adhesive and sealant chemicals	Adhesive and sealant chemicals	Updated to reflect 2020 CDR reporting cycle and consolidate sectors for which DINP's functional use is as an adhesive, sealant, or barrier. Added "(sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing)"	Industrial uses – Adhesive and sealant chemicals – Adhesive and sealant chemicals (sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing)
Industrial uses, plasticizer	Plasticizer	Consolidated into both "processing, incorporation into an article" and "processing, incorporation into a formulation, mixture, or reactant product" based on Agency research and communication with stakeholders (ACC HPP, 2023).	Processing – Incorporation in formulation, mixture, or reaction product – Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; ink, toner, and colorant manufacturing [including pigment]) And Processing – Incorporation into articles – Plasticizers (playground and sporting equipment manufacturing; plastics products manufacturing; rubber product manufacturing; wholesale and retail trade; textiles, apparel, and leather Manufacturing; electrical equipment, appliance, and component manufacturing; ink, toner, and colorant manufacturing [including pigment])
Industrial use, automotive, fuel, agriculture, outdoor use products	Automotive care products	Updated subcategory to clarify the COU does not include uses already covered under other COUs and to clarify it does not include agricultural, fuel, or outdoor products.	Industrial Uses – Other Uses – Automotive products, other than fluids

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Industrial uses, Construction, paint, electrical, and metal products	Adhesives and sealants	Consolidated the subcategory with the "industrial use, adhesive and sealants" COU.	Industrial uses – Adhesive and sealant chemicals – Adhesive and sealant chemicals (sealant (barrier) in machinery manufacturing; computer and electronic product manufacturing; electrical equipment, appliance, component manufacturing, and adhesion/cohesion promoter in transportation equipment manufacturing)
Industrial uses, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere (*e.g.*, roofing)	Updated to reflect 2020 CDR reporting cycle and consolidate examples of subcategories for more specificity in examples rather than the broader "not covered elsewhere" subcategory.	Industrial uses – Construction, paint, electrical, and metal products – Building/construction materials (roofing, pool liners, window shades, flooring)
Industrial Use, Other Uses	N/A	Added subcategory based on review of the manufacturer requested risk evaluation and additional information from stakeholder meetings (EPA-HQ-OPPT-2018-0436-0019).	Industrial Use – Other Uses – Hydraulic fluids
Industrial Use, Other Uses	N/A	Added subcategory based on review of the manufacturer requested risk evaluation and additional information from stakeholder meetings (EPA-HQ-OPPT-2018-0436-0019).	Industrial Use – Other Uses – Pigment (leak detection)
Commercial use, automotive fuel, agriculture, outdoor use products	N/A	Updated subcategory to clarify the COU does not include uses already covered under other COUs and to clarify it does not include agricultural, fuel, or outdoor products.	Commercial use – Other use – Automotive products, other than fluids
Commercial use, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere (*e.g.*, roofing)	Updated to reflect 2020 CDR reporting cycle and consolidate examples of subcategories to provide more specific examples rather than the broader "not covered elsewhere" subcategory and added "Plasticizer in building/construction materials (roofing); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles"	Commercial use – Construction, paint, electrical, and metal products – Plasticizer in building/construction materials (roofing); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles
Commercial use, Furnishing, cleaning, treatment/care products	Foam seating and bedding products	Updated to reflect the 2020 CDR reporting cycle. Added "furniture and furnishings including plastic articles (soft); leather articles"	Commercial use – Furnishing, cleaning, treatment/care products – Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Commercial use, Furnishing, cleaning, treatment/care products	Cleaning and furniture care products	Consolidated in commercial use, furnishing, cleaning, treatment/care products, foam seating and bedding products, furniture and furnishings including plastic articles (soft); leather articles" subcategory based on review of CDR reports and Agency research on the use of DINP in cleaning and furniture care products. The CDR reference that previously supported this use was corrected by the submitter.	Commercial use – Furnishing, cleaning, treatment/care products – Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles
Commercial use, Furnishing, cleaning, treatment/care products	Floor coverings	Updated to reflect the 2020 CDR reporting cycle. Added "Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)."	Commercial use – Furnishing, cleaning, treatment/care products – Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)
Commercial use, Furnishing, cleaning, treatment/care products	Fabric, textile, and leather products not covered elsewhere	Updated to reflect the 2020 CDR reporting cycle for more specificity in examples rather than the broader "not covered elsewhere" subcategory and added "(apparel and footwear care products)."	Commercial use – Furnishing, cleaning, treatment/care products – Fabric, textile, and leather products (apparel and footwear care products)
Commercial use, Furnishing, cleaning, treatment/care products	Furniture and furnishings not covered elsewhere	Consolidated in commercial use, furnishing, cleaning, treatment/care products, foam seating and bedding products, furniture and furnishings including plastic articles (soft); leather articles" subcategory.	Commercial use – Furnishing, cleaning, treatment/care products – Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles
Commercial use, Packaging, paper, plastic, hobby products	Plastic and rubber products	Updated to better reflect the 2020 CDR reporting cycle. Added "packaging, paper, plastic hobby products (packaging [excluding food packaging], including rubber articles; plastic articles [hard] plastic articles [soft])."	Commercial use – Packaging, paper, plastic, hobby products – Packaging, paper, plastic, hobby products (packaging [excluding food packaging], including rubber articles; plastic articles [hard]; plastic articles [soft])
Commercial use, Packaging, paper, plastic, hobby products	N/A	Added subcategory based on additional information and communications with stakeholders (EPA-HQ-OPPT-2018-0436-0055) (ACC HPP,	Commercial use – Packaging, paper, plastic, hobby products – Ink, toner, and colorant products

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
		2023).	
Commercial use, Packaging, paper, plastic, hobby products	N/A	Added subcategory to better reflect the 2020 CDR reporting cycle.	Commercial use – Packaging, paper, plastic, hobby products -Plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses)
Commercial use, Packaging, paper, plastic, hobby products	Plastic and rubber products not covered elsewhere (*e.g.*, tool handles, flexible tubes, profiles, and hoses)	Consolidated under "plasticizer" subcategory with more specific examples rather than the broader "not covered elsewhere."	Commercial use – Packaging, paper, plastic, hobby products – Plasticizer (plastic and rubber products; tool handles, flexible tubes, profiles, and hoses)
Commercial use, Construction, paint, electrical, and metal products	Building/construction materials not covered elsewhere	Updated with more specificity in examples rather than the broader "not covered elsewhere" Subcategory.	Commercial use – Construction, paint, electrical, and metal products – Plasticizer in building/construction materials (roofing, pool liners, window shades); construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles
Commercial Use, Other Uses	Hydraulic fluids	Redesignated this commercial use as an industrial use based on review of the manufacturer requested risk evaluation and additional information from stakeholder meetings (EPA-HQ-OPPT-2018-0436-0019).	Industrial use – Other uses – Hydraulic fluids
Commercial Use, Other Uses	Pigment (leak detection)	Redesignated this commercial use as an industrial use based on review of the manufacturer requested risk evaluation and additional information from stakeholder meetings (EPA-HQ-OPPT-2018-0436-0019).	Industrial use – Other uses – Pigment (leak detection)
Consumer use, automotive fuel, agriculture, outdoor use products	Automotive care products	Updated subcategory to reflect the 2020 CDR reporting cycle.	Consumer use – Other use – Automotive products, other than fluids
Consumer use, Automotive, fuel, agriculture, outdoor use products	Electrical and electronic products	Consolidated with the Construction, paint, electrical, and metal products.	Consumer use – Construction, paint, electrical, and metal products – Electrical and electronic products
Consumer use, Construction, paint, electrical, and metal products	Building construction materials not covered elsewhere (*e.g.*, wire and cable jacketing, vinyl tiles, resilient flooring, PVC-backed carpeting, wall coverings, roofing, pool applications, etc.)	Updated with more specific examples rather than the broader "not covered elsewhere… vinyl tiles, resilient." flooring, PVC-backed carpeting."	Consumer use – Construction, paint, electrical, and metal products – Building construction materials (wire and cable jacketing, wall coverings, roofing, pool applications, etc.)

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Consumer use, Furnishing, cleaning, treatment/care products	Foam seating and bedding products	Updated based on the 2020 CDR reporting cycle. Added "(furniture and furnishings including plastic articles (soft); leather articles)	Consumer use – Furnishing, cleaning, treatment/care products – Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles
Consumer use, Furnishing, cleaning, treatment/care products	Floor coverings	Updated based on the 2020 CDR reporting cycle. Added "Plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)"	Consumer use – Furnishing, cleaning, treatment/care products – Floor coverings; plasticizer in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles and apparel (vinyl tiles, resilient flooring, PVC-backed carpeting)
Consumer use, Furnishing, cleaning, treatment/care products	Fabric, textile, and leather products not covered elsewhere	Consolidated with "fabric, textile, and leather products" subcategory in the same life cycle stage and category.	Consumer use – Furnishing, cleaning, treatment/care products – Fabric, textile, and leather products (apparel and footwear care products)
Consumer use, Furnishing, cleaning, treatment/care products	Furniture and furnishings not covered elsewhere	Consolidated in "foam seating and bedding products; furniture and furnishings (furniture and furnishings including plastic articles (soft); leather articles)" subcategory within the same category."	Consumer use – Furnishing, cleaning, treatment/care products – Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles
Furnishing, cleaning, treatment/care products	Cleaning and furniture care products	Consolidated in "consumer use, furnishing, cleaning, treatment/care products, foam seating and bedding products, furniture and furnishings including plastic articles (soft); leather articles" subcategory based on review of CDR reports and Agency research on the use of DINP in cleaning and furniture care products. The CDR reference that previously supported this use was corrected by the submitter.	Consumer use – Furnishing, cleaning, treatment/care products – Foam seating and bedding products; furniture and furnishings including plastic articles (soft); leather articles
Consumer use, Packaging, paper, plastic, hobby products	Plastic and rubber products	Updated subcategory to better reflect 2020 CDR reporting codes.	Consumer use – Packaging, paper, plastic, hobby products – Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)
Consumer use, Packaging, paper, plastic, hobby products	Plastic and rubber products not covered elsewhere (*e.g.*, textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; hoses)	Updated subcategory to better reflect 2020 CDR reporting codes.	Consumer use – Packaging, paper, plastic, hobby products – Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); vinyl tape; flexible tubes; profiles; hoses

Life Cycle Stage and Category	Original Subcategory in the Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Consumer use, Packaging, paper, plastic, hobby products	Paper products	Consolidated in "consumer use, packaging, paper, plastic, hobby products, packaging (excluding food packaging). . ." subcategory to better reflect 2020 CDR reporting codes.	Consumer use – Packaging, paper, plastic, hobby products – Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)
Consumer use, Other	N/A	Added category and subcategory based on additional information and Agency research (Stabile, 2013).	Consumer use – Other – Novelty Products

As indicated in the Table_Apx D-1, the changes are based on close examination of the CDR reports, including the 2020 CDR reports that were received after the scope was completed, additional research on the conditions of use, additional comments from stakeholders, and overall systematic review of the use information.

When developing this draft risk evaluation, EPA concluded that some subcategories of the COUs listed in the final scope (U.S. EPA, 2021b) were redundant and consolidation was needed to avoid evaluation of the same COU multiple times. EPA concluded that there were some instances where subcategory information on the processing and uses of DINP was misreported by CDR reporters based on outreach with stakeholders. For these instances, EPA recategorized the activity described in the COU listed in the scope to fit the description of the COU included in this draft risk evaluation. Finally, EPA determined that wording changes were needed to accurately describe COUs. Therefore, as described in Table_Apx D-1, EPA has made changes to COUs for the risk evaluation.

In addition, EPA did further analysis of the following conditions of use, which resulted in the changes already presented on the table which warrant further explanation because these COUs were changed significantly between the final scope and the draft RE:

- "*Industrial use – plasticizer*" was consolidated into both "processing, incorporation into an article" and "processing, incorporation into a formulation, mixture, or reactant product" based on Agency research and communication with stakeholders (ACC HPP, 2023). EPA believes that this consolidation and recategorization more accurately represents the use of DINP as a plasticizer in various processing stages by industry.
- "*Commercial use – hydraulic fluid*" was redesignated as "*Industrial use – hydraulic fluid*" based on review of the manufacturer requested risk evaluation and additional information from stakeholder meetings (EPA-HQ-OPPT-2018-0436-0019). EPA believes that this recategorization better represents the Department of Defense (DoD) referenced presence of DINP in hydraulic fluids better than commercial as any DoD use would be considered industrial rather than commercial. DoD was the only reference for this use.
- "*Commercial use – pigment (leak detection)*" was redesignated as "*Industrial use – pigment (leak detection)*" based on review of the manufacturer requested risk evaluation and additional information from stakeholder meetings (EPA-HQ-OPPT-2018-0436-0019). EPA believes that this recategorization better represents the DoD referenced presence of DINP in leak detection fluids (as a pigment) better than commercial as any DoD use would be considered industrial rather than commercial. DoD was the only reference for this use.

- "*Consumer use – novelty products*" was added to the draft risk evaluation based on Agency research into the use of various phthalate in adult sex toys (*i.e.*, novelty products). EPA was unaware of this use during development of the scope and is therefore adding it during the development of the draft risk evaluation to ensure that it is assessed appropriately given the evidence the Agency has cited on DINP being used in these types of products.
- *Processing, Processing as a reactant, "plasticizers; plastic material and resin manufacturing; processing aids not otherwise listed (e.g., mixed metal stabilizer); rubber product manufacturing; synthetic rubber manufacturing"* were all removed because as part of the outreach with the manufacturer requested risk evaluation submitters it was determined that DINP is not used as a reactant. Although reported in the CDR for various reporting cycles as a reactant, the Agency has consolidated all of those reported reactant uses of DINP under other processing COUs that more accurately reflect the uses.

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 DINP (CASRN 28553-12-0 and CASRN 68515-48-0), and the COU descriptions reflect what EPA identified as the best fit for that submission.

E.1 Manufacturing – Domestic Manufacturing

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

At a typical manufacturing site, DINP is formed through the reaction of phthalic anhydride and isononyl alcohol using an acid catalyst. DINP is manufactured in two forms. The first form, CASRN 28553-12-0, is manufactured from a C9 alcohol, which is n-butene based. The second form, CASRN 68515-48-0, is manufactured from a C8-C10 alcohol fraction (ExxonMobil, 2022b). Typical manufacturing operations consist of reaction, followed by a crude filtration, where the product is distilled or separated, and final filtration. Manufacturing operations may also include quality control sampling of the DINP 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 (ExxonMobil, 2022b). This condition of use includes the typical manufacturing process and any other similar production of DINP.

Examples of CDR Submissions

In the 2016 CDR cycle, two CDR companies reported domestic manufacturing of DINP (CASRN 28553-12-0); and two companies reported domestic manufacturing of DINP (CASRN 68553-12-0) with all manufacturers producing a liquid.

In the 2020 CDR cycle, two CDR companies reported domestic manufacturing of DINP (CASRN 68553-12-0); and one CDR company reported domestic manufacturing of DINP (CASRN 28553-12-0) with all manufacturers producing a liquid.

E.2 Manufacturing – Importing

Import refers to the import of DINP 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 DINP. 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, 2021c). Imported DINP is shipped in either dry powder/crystal pellets/solid form or liquid form with concentrations ranging from 1 to 100 percent DINP (U.S. EPA, 2020a).

Examples of CDR Submissions

In the 2016 CDR cycle, 16 CDR companies reported importation of DINP (CASRN 28553-12-0) with every company importing liquid except one who imported pellets/large crystals. Three of these companies reported importation for the purposes of repackaging in various industries. In 2016, four CDR companies reported importation of DINP (CASRN 68515-48-0) with each importing a liquid.

In the 2020 CDR cycle, 20 CDR companies reported importation of DINP (CASRN 28553-12-0) with every company importing liquid except one who imported pellets/large crystals. Two of these companies reported importation for the purposes of repackaging in various industries. In 2020, three CDR companies reported importation of DINP (CASRN 68515-48-0) with each importing a liquid.

E.3 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Heat Stabilizer and Processing Aid in Basic Organic Chemical Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of DINP into formulation, mixture, or a reaction product which occurs when a chemical substance is added to a product (or product mixture), after its manufacture, for distribution in commerce. In this case, processing of DINP into a product that for use as a heat stabilizer in basic organic chemical manufacturing.

Examples of CDR Submissions

In the 2016 CDR cycle one company reported the use of DINP (CASRN 28553-12-0) as an intermediate and heat stabilizer in all other chemical product and preparation manufacturing.

The 2016 and 2012 CDRs report use of DINP as an intermediate in basic organic chemical manufacturing, which implies that DINP is used as a feedstock in the production of another chemical via a chemical reaction in which DINP is consumed to form the product. EPA's use report determined that there are some reports that list DINP as an intermediate and process regulator in Nordic countries (U.S. EPA, 2021d). However, EPA does not expect DINP to be consumed in chemical reactions; rather, it will be incorporated into the formulation. Therefore, EPA is removing the "intermediate" from this COU description—although those uses reported as "intermediate" in CDR will be considered under this COU.

E.4 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Plasticizers (Adhesives Manufacturing; Custom Compounding of Purchased Resin; Paint and Coating Manufacturing; Plastic Material and Resin Manufacturing; Synthetic Rubber Manufacturing; Wholesale and Retail Trade; All Other Chemical Product and Preparation Manufacturing; Ink, Toner, and Colorant Manufacturing [Including Pigment])

This COU refers to the preparation of a product; that is, the incorporation of DINP 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, DINP 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.

EPA is aware that DINP may be incorporated into PVC plastisol inks, toners, and colorants, including pigments (ACC HPP, 2023).

Examples of CDR Submissions

In the 2016 CDR cycle one company reported the use of DINP as a plasticizer in custom compounding of purchased resin (CASRN 68515-48-0 and CASRN 28553-12-0); one company reported the use of DINP as an plasticizer in synthetic rubber manufacturing (CASRN 28553-12-0); one company reported the use of DINP as an plasticizer in custom compounding of purchased resin and paint and coating manufacturing (CASRN 68515-48-0); several companies reported the use of DINP as a plasticizer in plastic material and resin manufacturing (CASRN 28553-12-0); and one company reported the use of DINP as a plasticizer in wholesale and retail trade (CASRN 68515-48-0). In 2016 one company reported incorporation into a formulation – plasticizer in adhesive manufacturing (CASRN 28553-12-0).

In the 2020 CDR cycle, two companies reported the use of DINP as an plasticizer in custom compounding of purchased resin (CASRN 68515-48-0); two companies reported the use of DINP as an plasticizer in custom compounding of purchased resin, paint and coating manufacturing, and synthetic rubber manufacturing (CASRN 28553-12-0); one company reported the use of DINP as a plasticizer in plastic material and resin manufacturing (CASRN 68515-48-0); two companies reported the use of DINP as a plasticizer in plastic material and resin manufacturing (CASRN 28553-12-0); another reported the use of DINP as an plasticizer in wholesale and retail trade (CASRN 68515-48-0 and CASRN 28553-12-0). Another company reported the use of DINP as a plasticizer in rubber product manufacturing (CASRN 28553-12-0), but the activity included in this report represents the manufacturing of rubber products where DINP is added to an article, and therefore it is better represented under the processing incorporation into articles COU. One company reported the use of DINP as a reactant – plasticizer in all other chemical product and preparation manufacturing (CASRN 68515-48-0), but since EPA does not expect DINP to be consumed in chemical reactions, this activity fits better under this COU. A company reported the use of DINP as a plasticizer in plastics product manufacturing (CASRN 68515-48-0) and another reported the use of DINP as a plasticizer in plastics product manufacturing (CASRN 28553-12-0)—but these activities related to manufacturing plastic products where DINP is added to an article are better represented under the processing – incorporation into an article COU. One company reported incorporation of DINP into formulation, mixture or reaction product for transportation equipment manufacturing (CASRN 28553-12-0), but based on the available information regarding the use of DINP in this sector, the report was referring to incorporating DINP into adhesive and sealant formulations, which are then used in transportation equipment manufacturing in an industrial setting, therefore, transportation equipment manufacturing is not included in this COU description. Rather, the activity described by the CDR report is included under industrial uses – adhesive and sealant chemicals in transportation equipment manufacturing.

Also in the 2020 CDR cycle, one company reported incorporation of DINP into a formulation – adhesives and sealants in adhesive manufacturing (CASRN 28553-12-0), and another reported incorporation into a formulation – plasticizer in adhesive manufacturing (CASRN 28553-12-0).

E.5 Processing – Incorporation into Articles – Plasticizers (Toys, Playground and Sporting Equipment Manufacturing; Plastics Products Manufacturing; Rubber Product Manufacturing; Wholesale and Retail Trade; Textiles, Apparel, and Leather Manufacturing; Electrical Equipment, Appliance and Component Manufacturing; Ink, Toner, and Colorant Products Manufacturing [Including Pigment])

This COU refers to the preparation of an article; that is, the incorporation of DINP into articles, meaning DINP becomes a component of the article, after its manufacture, for distribution in commerce. In this case, DINP is present in a raw material such as rubber or plastic that contains a mixture of plasticizers and other additives, and this COU refers to the manufacturing of PVC and non-PVC articles using those raw materials. PVC articles are manufactured after the formation of a raw material that can contain a mixture of plasticizer and other additives. The raw material is converted by processes such as calendaring, extrusion, injection molding, and plastisol spread coating (EPA-HQ-OPPT-2018-0435-0022, EPA-HQ-OPPT-2018-0436-0032). DINP also is an additive in inks, which are then incorporated into textiles and articles (EPA-HQ-OPPT-2018-0435-0022).

According to information provided to EPA, 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). Additionally, ACC provided examples of sporting equipment containing DINP. This COU refers to the processing of DINP into the sporting equipment articles.

This COU also includes the possibility of the processing of DINP; that is, forming, shaping, or cutting articles containing DINP, in toy manufacturing since toys could contain up to 0.1 percent of DINP. (The CPSC has a regulatory limit of no more than 0.1% for DINP concentration in toys.) Additionally, it is possible that DINP could be incorporated into playground equipment manufacturing due to its use as a plasticizer in PVC and non-PVC articles that may be components of playground equipment.

DINP is incorporated as a general-purpose plasticizer in various textiles including vinyl clothing (*e.g.*, raincoats, boots, and gloves) which would be expected to be used across industrial, commercial, and consumer applications (ACC HPP, 2019). PVC articles are manufactured after the formation of a raw material that can contains a mixture of plasticizer and other additives. Also, this use was reported in the 2016 CDR reporting cycle by one company (CASRN 68515-48-0). EPA expects that the use of DINP in textiles, apparel, and leather manufacturing is associated with PVC applications in these durable vinyl products. EPA expects that the commercial use of substances containing DINP to produce foam seating and bedding would occur through spray and/or mix applications, and then cutting and molding of foam products of pre-formed products that contain DINP for their final commercial form.

According to the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)*, DINP is incorporated as a general-purpose plasticizer in electrical and electronic products which would be expected to be used across industrial, commercial, and consumer applications (ACC HPP, 2019) Electrical equipment and products typically have PVC components or are manufactured with PVC (*e.g.*, wire jacketing, etc.). PVC articles are manufactured after the formation of a raw material that can contains a mixture of plasticizer and other additives. EPA found that DINP (CASRN 68515-48-0) was used in extrusion for wire and cable and in the manufacture of computer, electronic, electrical equipment in other countries (U.S. EPA, 2021d).

Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported the use of DINP (CASRN 68515-48-0) as a plasticizer in plastic products manufacturing; various companies reported the use of DINP (CASRN 28553-12-0) as a plasticizer in plastic products manufacturing; and two companies reported the use of DINP (CASRN 28553-12-0) as a plasticizer in rubber product manufacturing.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 68515-48-0) as a plasticizer in plastic products manufacturing; another reported the use of DINP (CASRN 28553-12-0) as a plasticizer in plastic products manufacturing; another reported the use of DINP (CASRN 28553-12-0) as a plasticizer in rubber product manufacturing; another reported the use of DINP (CASRN 28553-12-0) as a plasticizer in wholesale and retail trade. Another company reported the use of DINP (CASRN 28553-12-0) in adhesive and sealant chemicals in transportation equipment manufacturing, based on the understanding of how DINP is used in the transportation sector, the activity represented by this CDR report is included under industrial uses of adhesives and sealants chemicals in transportation equipment manufacturing. And another company reported the use of DINP (CASRN 28553-12-0) as a plasticizer in both plastic material and resin manufacturing and synthetic rubber manufacturing; however, this CDR report seems to describe the incorporation of DINP into a formulation, mixture, or reaction product COU and therefore this DINP's use in plastic material and resin manufacturing and synthetic rubber manufacturing was included in that COU.

E.6 Processing – Other Uses – Miscellaneous Processing (Petroleum Refineries; Wholesale and Retail Trade)

This COU refers to the preparation of a product; that is, the incorporation of DINP into formulation, mixture, or a reaction product which occurs when DINP is added to a product (or product mixture) after its manufacture, for distribution in commerce; or the preparation of an article—meaning DINP becomes a component of the article, after its manufacture, for distribution in commerce. In this case, petroleum refineries are processing DINP for the purposes of plasticizing various applications.

In the 2016 and 2020 CDR cycles, one company reported processing DINP (CASRN 68515-48-0) in petroleum refineries and rubber product manufacturing; another company reported processing DINP (CASRN 28553-12-0) in wholesale and retail trade.

E.7 Processing – Repackaging – Plasticizer (All Other Chemical Product and Preparation Manufacturing; Wholesale and Retail Trade, Laboratory Chemicals Manufacturing)

Repackaging refers to the preparation of DINP 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 DINP 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 DINP (CASRN 28553-12-0) as a plasticizer in wholesale and retail trade.

In the 2020 CDR cycle, one company reported repackaging DINP as a plasticizer in all other chemical product and preparation manufacturing, while another company reported repackaging DINP (CASRN 28553-12-0) in wholesale and retail trade.

Repackaging DINP as a laboratory chemical was not reported in the 2016 or 2020 reporting cycles. However, EPA identified products containing DINP sold as a liquid for research purposes only and not intended for use as drugs, food additives, households, or pesticides (TCI America, 2019).

E.8 Processing – Recycling

This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be disposed of as waste), containing DINP, that are collected, either on-site or at a third-party site, for commercial purpose. DINP is primarily recycled industrially in the form of DINP-containing PVC waste streams, including roofing membranes, vinyl window frame profiles, and carpet squares. 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. EPA notes that although DINP was not reported for recycling in the 2016 or 2020 CDR reporting periods, EPA is assuming that recycling waste streams could contain DINP.

E.9 Distribution in Commerce

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

E.10 Industrial Uses – Adhesive and Sealant Chemicals – Adhesive and Sealant Chemicals (Sealant (Barrier) in Machinery Manufacturing); Computer and Electronic Product Manufacturing; Electrical Equipment, Appliance, and Component Manufacturing; and Adhesion/Cohesion Promoter in Transportation Equipment Manufacturing)

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

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) for use as an adhesive and sealant chemical in adhesive manufacturing.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) for use as a barrier sealant in machinery manufacturing, computer and electronic product manufacturing, and electrical equipment, appliance, and component manufacturing. In 2020 another company reported the use of DINP (CASRN 28553-12-0) as an adhesive and sealant in transportation equipment manufacturing.

According to the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)*, less than 5 percent of DINP is used in non-PVC applications such as those associated with adhesives and sealants (ACC HPP, 2019). With respect to transportation equipment manufacturing, it should be noted that DINP is used in various automotive adhesive and sealant applications such as window glazing, doors, acrylic plastisol sealants in wheel wells (ACC HPP, 2019). And DINP is used in various transportation equipment manufacturing specific adhesives and sealants (U.S. EPA, 2021d). EPA expects that these sealants would be used on exterior as well as interior applications in this sector.

EPA identified several examples of transportation (or automotive) adhesive and sealant products (U.S. EPA, 2021d). Some of these products appear to have been discontinued or reformulated and may no longer contain DINP. EPA expects that many of these products would be used on the exterior or the vehicle to prevent moisture or water penetrating the dry areas of the equipment.

EPA expects that these adhesives and sealants are likely to be manually and robotically applied through various different methods including spraying and rolling depending on the application.

E.11 Industrial Uses – Automotive, Fuel, Agricultural, Outdoor Use Products – Automotive Products, Other than Fluids

This COU refers to the use of DINP in the automobile manufacturing sector as a component in various automotive products, other than fluids. This is a use of DINP after it has already been incorporated into a plastic product or mixture, as opposed to when it is used upstream (*e.g.*, when DINP is processed into a product).

DINP is used in automotive products for various industrial uses. The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* notes that DINP is used in automotive care products; EPA was unable to identify any specific automotive care products, other than fluids, that contained DINP. However, the American Chemistry Council's website details the use of high phthalates, such as DINP, in automobile interiors, vinyl seat covers, and interior trim because it can prevent degradation of these components (ACC, 2024).

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

E.12 Industrial Uses – Construction, Paint, Electrical, and Metal Products – Building/Construction Materials (Roofing, Pool Liners, Window Shades, Flooring)

This COU refers to the use of DINP in various industrial sectors as a component of building/ construction material, including roofing, pool liner, and window shade products. This is a use of DINP after it has already been incorporated into a plastic product or mixture, as opposed to when it is used upstream (*e.g.*, when DINP is processed into a product or an article).

DINP is used in roofing materials in industrial applications. This COU was included in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* due to DINP's use as a general-purpose plasticizer for PVC in various building and construction applications which includes roofing (ACC HPP, 2019). EPA has been unable to identify DINP is any specific roofing products but expects that due to the general-purpose use as plasticizer, DINP are likely to be used in roofing membranes, sealants, or other adhesives associated with roofing systems, although the sealants and adhesives used with roofing systems would be covered under the adhesives and sealants COU. EPA identified one product which appears to be a penetration sealant for flashing or roofing systems; however, EPA was unable to determine if this is strictly used in industrial, commercial, or consumer applications (U.S. EPA, 2021d). ACC also notes that DINP can be used in window shades, flooring, roofing, pool liners, and wall coverings (ACC, 2024).

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

E.13 Industrial Uses – Construction, Paint, Electrical, and Metal Products – Paints and Coatings

This COU refers to DINP as it is used in various industrial sectors as a component of industrial paints and coatings. This is a use of DINP 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 DINP is processed into the paint or coating formulation).

According to information provided to EPA, approximately 5 percent of DINP in the United States is used in adhesives, caulks & sealants, inks & paints with the predominate use in these sectors as being "industrial" in nature within the printing and metal coating industry (EPA-HQ-OPPT-2018-0436-0032). EPA expects that the industrial application of these paints and coatings would take place on structural steel or during fabrication of structural components that would later be installed by commercial contractors. Other industrially applied products are lacquer-based coatings made up of heat-resistant resins to withstand the chemicals and heat encountered with most air-set and cold-set binders used in the foundry industry (Freeman Manufacturing and Supply Company, 2018). EPA 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.

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

E.14 Industrial Use – Other Uses – Hydraulic Fluids

This COU is referring to the use of DINP as a component of hydraulic fluids in the defense industry. This is a use of DINP after it has already been incorporated into a hydraulic fluid, as opposed to when it is used upstream (*e.g.,* when DINP is processed into the hydraulic fluid).

DoD recommended that EPA include the use of DINP in hydraulic fluid and lubricant oils (EPA-HQ-OPPT-2018-0436-0019). There is limited information and data other than the communication from DoD in support of this COU. EPA will consider distribution of these types of products to DoD under the distribution in commerce or repackaging conditions of use.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.15 Industrial Use – Other Uses – Pigment (Leak Detection)

This COU is referring to the use of DINP in pigments involved with leak detection equipment in the defense industry. This is a use of DINP after it has already been incorporated into a leak detection product or mixture, as opposed to when it is used upstream (*e.g.,* when DINP is processed into the leak detection product).

EPA notes that DoD confirmed that EPA should look at the use of DINP containing pigments as they are used in leak detector products in DoD activities (EPA-HQ-OPPT-2018-0436-0019). EPA will consider distribution these types of products to DoD under the distribution in commerce or repackaging conditions of use.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.16 Commercial Use – Other Use – Automotive Products Other than Fluids

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

The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* notes the use of DINP as a general-purpose plasticizer in automotive applications such as doors, wire and cable jacketing, and use in automotive paints. ACC's website details the use of high-molecular weight phthalates, such as DINP, in automobile interiors, vinyl seat covers, and interior trim because it can prevent degradation of these components (ACC, 2024).

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

E.17 Commercial Use – Construction, Paint, Electrical, and Metal Products – Adhesives and Sealants

This COU is referring to the commercial use of DINP in adhesives and sealants. This is a use of DINP-containing adhesives and sealants in a commercial setting, such as a business or at a job site, as opposed to upstream use of DINP (*e.g.*, when DINP 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 DINP incorporated as a plasticizer. Adhesives and sealants (which could also be fillers and putties) are highly malleable materials used to repair, smooth over or fill minor cracks in holds and buildings. EPA expects that commercial applications of adhesives and sealants containing DINP would occur using non-pressurized methods based on products identified in the marketplace. According to the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* less than 5 percent of DINP is used in non-PVC applications such as those associated with adhesives and sealants.

EPA identified several commercially available (denoted as being possibly industrial, commercial, or consumer viable) adhesive products which contain DINP at various concentrations. These adhesive and sealants are commonly applied using a syringe, caulk gun, or are spread on a surface using a trowel.

DINP is also used in various automotive care product applications EPA expects that the use of these types of products would occur in commercial applications; however, the Agency notes that this product are likely to be sourced by DIY consumers through various online vendors.

EPA also identified several automotive adhesives that are likely to be used in industrial/commercial/consumer applications (U.S. EPA, 2021d). The expected users of products under this category would be expected to apply these products through spray, roll, and brush/caulk on applications depending on the desired end use.

Examples of CDR Submissions

In the 2016 CDR cycle, three companies reported the use of DINP (CASRN 28553-12-0) in adhesives and sealants.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in adhesives and sealants and one company reported the use of DINP (CASRN 28553-12-0) as a plasticizer in adhesives and sealants.

E.18 Commercial Use – Construction, Paint, Electrical, and Metal Products – Plasticizer in Building/Construction Materials (Roofing, Pool Liners, Window Shades); Construction and Building Materials Covering Large Surface Areas; Including Paper Articles; Metal Articles; Stone, Plaster, Cement, Glass, and Ceramic Articles

This COU is referring to the commercial use of DINP in commercial sectors associated with construction products that contain DINP as a plasticizer. This is a use of DINP-containing construction materials such as roofing, pool liners, and window shades in commercial applications, such as at a business or at a job site, as opposed to upstream use of DINP (*e.g.*, when DINP is processed into the construction material) or use in an industrial setting.

This COU was included in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* due to DINP's use as a general-purpose plasticizer for PVC in various building and construction applications that includes roofing (ACC HPP, 2019). EPA has been unable to identify DINP in any specific roofing products but expects that due to the general-purpose use as plasticizer, DINP is likely to be used in roofing membranes, sealants, or other adhesives associated with roofing systems. The Agency identified a penetration sealant for flashing or roofing systems; however, EPA was unable to determine if this is strictly used in industrial, commercial, or consumer applications (U.S. EPA, 2021d). The Agency expects that commercial applications of construction and building materials such as roofing containing DINP would occur using non-pressurized methods based on products identified in the marketplace. EPA expects that workers can install in window shades, flooring, roofing, pool liners, and wall coverings that already have DINP incorporated (ACC, 2024).

Examples of CDR Submissions

In the 2016 CDR cycle, four companies reported the use of DINP (CASRN 28553-12-0) in building/construction materials not covered elsewhere.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in building/construction materials not covered elsewhere and three companies reported the use of DINP (CASRN 28553-12-0) as a plasticizer in construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles.

E.19 Commercial Use – Construction, Paint, Electrical, and Metal Products – Electrical and Electronic Products

This COU is referring to the commercial use of DINP already incorporated as a plasticizer in electrical and electronic products.

The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* states that DINP is used as a general-purpose plasticizer for PVC used in building a construction, particularly wire associated with electronic products (ACC HPP, 2019). This COU describes the workers handling the electric products, wiring, etc. and related insulation during installation and use that may have DINP incorporated into the products. The users of products under this category would be expected to apply these products through hand contact with the wire and electronic components through various commercial applications.

Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported the use of DINP (CASRN 28553-12-0) as a plasticizer in electrical and electronic products, and one company reported the use of DINP (CASRN 68515-48-0) as a plasticizer in electrical and electronic products.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) as a plasticizer in electrical and electronic products, and another company reported the use of DINP (CASRN 68515-48-0) as a plasticizer in electrical and electronic products.

E.20 Commercial Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings

This COU is referring to the commercial use of DINP already incorporated as a plasticizer in paints and coatings.

DINP is used in a variety of paint and coating products, often used as a surfactant in paints and coatings. The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* reports use of DINP in consumer paints and coatings (ACC HPP, 2019). EPA expects that these products would be purchased by commercial operations and applied by professional contractors in various commercial settings. EPA also expects that some of these products are likely to be used for industrial applications; however, they would be available and used in smaller scale commercial settings for similar purposes (*e.g.*, corrosion and water protection on structural components, residential construction).

EPA also notes that this COU was not reported to the CDR in 2016 or 2020 cycles.

E.21 Commercial Use – Furnishing, Cleaning, Treatment/Care Products – Foam Seating and Bedding Products; Furniture and Furnishings Including Plastic Articles (Soft); Leather Articles

This COU is referring to the commercial use of DINP already incorporated in foam seating and bedding products and furnishings. EPA understands that DINP has been used in foam seating and bedding products as well as furniture (including plasticized vinyl seats) at concentrations by weight of at least 30 percent but less than 60 percent (U.S. EPA, 2021d). The Agency also notes that this COU was included in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* due to DINP's use as a plasticizer to impart flexibility to PVC applications (ACC HPP, 2019). EPA was unable to find any specific examples of products containing DINP that would fit under this category; however, a 2015 U.S. CPSC report did identify various commercial/consumer products that contained DINP, which would fit under this COU—including PVC tablecloths and shower curtains (U.S. CPSC, 2015). Information for products that have DINP 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 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in furniture and furnishings not covered elsewhere.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 68515-48-0) in furniture and furnishings including plastic articles (soft); leather articles. As well, in the 2020 CDR, one company reported the use of DINP (CASRN 68515-48-0) in furniture and furnishings including plastic articles (soft); leather articles.

E.22 Commercial Use – Furnishing, Cleaning, Treatment/Care Products – Air Care Products

This COU is referring to the commercial use of DINP in air care products.

DINP is found in certain air care products that are likely to be used in commercial applications. EPA identified one commercially available scent that is available for candle manufacturers containing DINP (U.S. EPA, 2021c). Although the Agency expects that this scent would predominately be used in commercial candle making activities; it is possible that some consumer DIY candle makers could source this product from online vendors. EPA did not identify DINP in any additional commercially available air care products at this time. The expected users of products under this category would be expected to apply these products through mixing DINP containing liquid substances with various waxes and other liquid to semi-solid materials in either cold-press or heated environments to create candles for later sale to consumers.

EPA also notes that this COU was not reported to the CDR in 2016 or 2020 cycles.

E.23 Commercial Use – Furnishing, Cleaning, Treatment/Care Products – Floor Coverings/Plasticizer in Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass, and Ceramic Articles; Fabrics, Textiles, and Apparel (Vinyl Tiles, Resilient Flooring, PVC-Backed Carpeting)

This COU is referring to the commercial use of DINP in various floor coverings and construction and building materials. DINP is a known constituent of various building/construction materials because of its use as a general-purpose plasticizer in PVC applications. Although similar to other COUs, EPA expects that certain commercial uses of building/construction materials covered by this COU use would include items such as vinyl tiles, resilient flooring, PVC-backed carpeting, and other construction/building materials that are covering large areas (ACC HPP, 2019). EPA also identified the use of DINP in a product associated with floor matting (U.S. EPA, 2021d). The Agency 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 DINP incorporated into the products and may involve cutting and shaping the products for installation.

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in floor coverings.

In the 2020 CDR cycle, three companies reported the use of DINP (CASRN 28553-12-0) in construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles.

E.24 Commercial Use – Furnishing, Cleaning, Treatment/Care Products – Fabric, Textile, and Leather Products (Apparel and Footwear Care Products)

This COU is referring to the commercial use of DINP already incorporated as a plasticizer in fabric, textile, and leather products including apparel and footwear products. This COU includes workers cutting and shaping textiles and workers who wear DINP-containing textiles.

EPA understands that DINP has been used in fabric, textile, and leather products including apparel and footwear products (ACC HPP, 2019). EPA also notes that this COU was included in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* due to DINP's use as a plasticizer to impart flexibility to PVC applications such as vinyl clothing which are likely to be used in commercial and consumer applications (*i.e.*, rain boots, gloves, raincoats, etc.) (ACC HPP, 2019). EPA identified DINP in commercial and consumer fabric, textile, and leather products at concentrations of at least 1 percent but less than 60 percent (U.S. EPA, 2021d). The National Library of Medicine 2019 database identified DINP use in injection molding for footwear (U.S. EPA, 2021d).

Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported the use of DINP (CASRN 28553-12-0) in fabric, textile, and leather products not covered elsewhere, and one company reported the use of DINP (CASRN 68515-48-0) in fabric, textile, and leather products not covered elsewhere.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in apparel and footwear care products and one company reported the use of DINP (CASRN 68515-48-0) in fabric, textile, and leather products not covered elsewhere.

E.25 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Arts, Crafts, and Hobby Materials

This COU is referring to the commercial use of DINP in arts, crafts, and hobby materials.

EPA identified use of DINP in various arts, crafts, and hobby materials including glitter board products and in polymer clay bricks, canes, and eraser products (U.S. EPA, 2021d). EPA expects that these products are likely to be used in both commercial and consumer applications. EPA identified two erasers which contained DINP (U.S. EPA, 2021d). The users of products under this category would be expected to make the aforementioned products using DINP containing substances through cutting and shaping (or otherwise adjusting shape for use) for the clay and eraser products and possibly through liquid applications for glitter products. EPA expects that these products would be used by commercial hobbyists who are using these products to create saleable goods. EPA notes that weight fractions were reported in (ECHA, 2012) for erasing rubber made of PVC. In one sample from a 2006 Danish investigation, the combination of DINP and DIDP was reported as 32 percent.

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

E.26 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Ink, Toner, and Colorant Products

This COU is referring to the commercial use of DINP in ink, toner, and colorant products.

DINP is used in printing ink, at least one stamp product, and pigments (U.S. EPA, 2021c). The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* lists the use of pigments in its non-PVC applications (less than 5 percent of DINP use). EPA identified a polyurethane pigment containing more than 60 percent DINP by weight (U.S. EPA, 2021d). The Agency expects that the majority of ink, toner, and colorant products containing DINP would be commercial in nature; however, it is possible that these products are used by DIY consumers as many of the commercial products are available for consumer purchasers through various online vendors. EPA would expect the commercial users of these products to apply them through the typical applications in commercial printing and drafting shops albeit at a larger quantity as those consumer DIYers who may also be using these products.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.27 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Packaging, Paper, Plastic, Hobby Products (Packaging (Excluding Food Packaging), Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft)

This COU is referring to the commercial use of DINP in various packaging, paper, plastic, and hobby products. EPA notes that this reporting code in the 2020 CDR is intended to describe products such as phone covers, personal tablets covers, styrofoam packaging, and bubble wrap. Given the use of DINP as a general-purpose plasticizer for PVC and non-PVC applications, EPA expects that this use of DINP has been identified in previous CDR reports as "plastic and rubber products not covered elsewhere."

The type of products being reported under this code are likely to be both commercial and consumer in nature. The expected users of products under this category would be anticipated to use liquid or solid mixtures containing DINP and mold or otherwise form the various products for commercial and consumer applications.

Examples of CDR Submissions
In the 2020 CDR cycle, two companies reported the use of DINP (CASRN 28553-12-0) in packaging (excluding food packaging); including rubber articles; plastic articles (hard); plastic articles (soft) and one company reported the use of DINP (68515-48-0) in packaging (excluding food packaging); including rubber articles; plastic articles (hard); plastic articles (soft).

E.28 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Plasticizer (Plastic and Rubber Products; Tool Handles, Flexible Tubes, Profiles and Hoses)

This COU is referring to the commercial use of DINP incorporated as a plasticizer in several durable commercial goods such as plastic and rubber products, tool handles, flexible tubes, profiles, and hoses. These products when used by workers in commercial settings may also contain DINP and exposure to commercial end users could occur during the regular use of the product during its lifecycle.

Examples of CDR Submissions
In the 2016 CDR cycle, although not specifically identified as being used as a plasticizer, six companies reported the use of DINP in plastic and rubber products not covered elsewhere (CASRN 28553-12-0) while three companies reported the use of DINP (CASRN 68515-48-0) in plastic and rubber products not covered elsewhere.

Examples of CDR Submissions
In the 2020 CDR cycle, two companies reported the use of DINP (CASRN 28553-12-0) in plastic and rubber products not covered elsewhere and two companies reported the use of DINP (CASRN 68515-48-0) in plastic and rubber products not covered elsewhere. For one of these companies reporting on DINP (CASRN 68515-48-0) in the 2020 CDR cycle they did not explicitly note that it was being used as a plasticizer.

E.29 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Toys, Playground, and Sporting Equipment

This COU is referring to the commercial use of DINP in toys, playground, and sporting equipment. The COU includes the commercial installation, use, and maintenance of toys (such as in daycare or school environments by workers [*e.g.*, teachers or providers]), playgrounds, and sporting equipment that contain DINP.

EPA notes in the final scope that the Consumer Product Safety Innovation Act of 2008 and the U.S. CPSC banned the use of DINP at concentrations greater than 0.1 percent in children's toys and childcare articles in 2008 and 2018, respectively. EPA expects that the use of DINP in toys manufactured or processed prior to the ban may still be occurring.

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in toys, playground, and sporting equipment. This use was not reported in the 2020 CDR cycle.

E.30 Commercial Use – Solvents (for Cleaning or Degreasing)

This COU is referring to the use of DINP in solvents intended for cleaning or degreasing.

DINP was identified in at least one commercial solvent associated with cleaning or degreasing (U.S. EPA, 2021c). Although EPA expects that most of the use will be industrial, there are some products, such as a lithographic press cleaning solvent are likely to be used commercially (U.S. EPA, 2021d). The use of this type of product would be specific to the printing community and would be expected to be applied through mechanical methods but not through aerosolized methods.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.31 Commercial Use – Other Uses - Laboratory Chemicals

This COU is referring to the commercial use of DINP in laboratory chemicals.

DINP can be used as a laboratory chemical, such as a chemical standard or reference material during analyses. Some laboratory chemical manufacturers identify use of DINP as a certified reference material and research chemical. The users of products under this category would be expected to apply these products through general laboratory use applications. Commercial use of laboratory chemicals may involve handling DINP 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 DINP products are pure DINP 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.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.32 Consumer Use – Other Use – Automotive Care Products, Other Than Fluids

This COU is referring to the consumer use of DINP in automotive products other than fluids. This COU includes the use of DINP-containing automotive products in a consumer DIY setting or by consumers driving a vehicle.

DINP is used in various automotive product applications. ACC's website details the use of high phthalates, such as DINP, in automobile interiors, vinyl seat covers, and interior trim because it can prevent degradation of these components (ACC, 2024).

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.33 Consumer Use – Construction, Paint, Electrical, and Metal Products – Adhesives and Sealants

This COU is referring to the consumer use of DINP in adhesives and sealants.

EPA notes in the final scope that DINP is used as an adhesive sealant for automotive care products (U.S. EPA, 2021c). EPA expects that the use of these types of products would occur in commercial applications; however, the Agency notes that this product are likely to be sourced by DIY consumers through various online vendors. The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* also notes the use of DINP as a general-purpose plasticizer in automotive applications such as window glazing, doors, wire and cable jacketing, underbody coatings, and acrylic plastisol sealants in wheel wells, and paints (ACC HPP, 2019). The 2016 CDR reporting identified automotive care products as containing concentrations of DINP of at least 1 percent but less than 30 percent by weight (U.S. EPA, 2021d). EPA identified several automotive adhesives that are likely to be used in industrial/commercial/ consumer applications (U.S. EPA, 2021d). The Agency does expect the primary use of these automotive adhesives and sealants to be industrial/commercial in nature but the possibility for consumer use is still possible. EPA understands this COU to be consumer use of cars (*i.e.,* driving, and consumer DIYers who may perform exterior or interior car maintenance involving adhesives and sealants). Any product containing DINP 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 Diisononyl Phthalate (DINP)*, less than 5 percent of DINP is used in non-PVC applications such as those associated with adhesives and sealants. EPA believes that although this product is intended for commercial applications it, and products like it, are likely to be used in various consumer applications as well. The expected users of these products would be DIY users that spray, caulk bead, and roll apply the various adhesives and sealants based on application, as well as bystanders. Heat is likely to be used depending on the application as well.

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in adhesives and sealants.

E.34 Consumer Use – Construction, Paint, Electrical, and Metal Products – Building Construction Materials (Wire and Cable Jacketing, Wall Coverings, Roofing, Pool Applications, etc.)

This COU is referring to the consumer use of DINP in various building and construction materials such as wire and cable jacketing, wall coverings, roofing, and pool applications. As reported in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)*, DINP is used in PVC-backed carpet, vinyl tiles, wire and cable jacketing, and resilient flooring (ACC HPP, 2019). EPA also notes that DINP is used in wall coverings, roofing, and pool applications as a general plasticizer. The expected consumers and DIY users of products under this category live with or are installing various building materials such as electrical wires and wall coverings that contain DINP as part of the building material in an indoor environment.

The use of DINP in other building materials and joinery installation has been reported in Nordic countries, but no further information about this COU in the United States was found at this time (U.S. EPA, 2021d).

Examples of CDR Submissions

In the 2016 CDR cycle, three companies reported the use of DINP (CASRN 28553-12-0) in building/construction materials not covered elsewhere.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in building/construction materials not covered elsewhere.

E.35 Consumer Use – Construction, Paint, Electrical, and Metal Products – Electrical and Electronic Products

This COU is referring to the consumer use of DINP in electrical and electronic products, including consumer DIY handling of electrical products during installation and use that may have DINP incorporated into the products. The expected users of products under this category would be consumers who are living in indoor environments with various electrical and electronic products that have wires or other components that have DINP as part of their construction.

The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* states that DINP is used as a general-purpose plasticizer for PVC used in building and construction, particularly wire associated with electronic products (ACC HPP, 2019).

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in electrical and electronic products and one company reported the use of DINP (CASRN 68515-48-0) in electrical and electronic products.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 68515-48-0) in electrical and electronic products.

E.36 Consumer Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings

This COU is referring to the consumer use of DINP in paints and coatings, meaning consumer DIY use of DINP-containing paints and coatings in indoor environments applied as part of their construction.

DINP is used in a variety of paint and coating products, often used as a surfactant in paints and coatings. The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* reports use of DINP in consumer paints and coatings (ACC HPP, 2019). 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. It is possible that some paints and coatings containing DINP would be pressure-applied by consumer DIYers through gravity fed and compressed air guns.

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in paints and coatings.

E.37 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Foam Seating and Bedding Products; Furniture and Furnishings Including Plastic Articles (Soft); Leather Articles

This COU is referring to the consumer use of foam seating and bedding products that contain DINP and in the fabrication of various textiles that are likely to be used by consumers in standard household furniture indoors.

EPA understands that DINP has been used in foam seating and bedding products as well as furniture (including plasticized vinyl seats) at concentrations by weight of at least 30 percent but less than 60 percent (U.S. EPA, 2021d). The Agency also notes that this COU was included in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* due to DINP's use as a plasticizer to impart flexibility to PVC applications (ACC HPP, 2019). EPA was unable to find any specific examples of products containing DINP that would fit under this category; however, a 2015 U.S. CPSC report did identify various commercial/consumer level products that contained DINP which would fit under this COU (U.S. CPSC, 2015).

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in furniture and furnishings not covered elsewhere, which EPA understands would be reflected in this COU.

E.38 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Floor Coverings/Plasticizer in Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass, and Ceramic Articles; Fabrics, Textiles, and Apparel (Vinyl Tiles, Resilient Flooring, PVC-Backed Carpeting)

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

DINP is a known constituent of various building/construction materials because of its use as a general-purpose plasticizer in PVC applications. Although similar to other COU's that were captured elsewhere in the final scope, EPA expects that certain building/construction materials that would be covered by this COU in commercial use would include items such as vinyl tiles, resilient flooring, PVC-backed carpeting, and other construction/building materials that are covering large areas (ACC HPP, 2019). EPA identified the use of DINP in a product associated with floor matting (U.S. EPA, 2021d). EPA anticipates that given the nature of DIY home improvement that many of these DINP containing products associated with floor covering could readily be available and used by consumers.

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in floor coverings.

E.39 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Air Care Products

This COU is referring to the consumer use of DINP in air care products.

DINP is found in certain air care products with what EPA believes to be primarily a commercial application; however, it is possible that consumer use does exist for these products as well. EPA identified at least one commercially available scent for candle manufacturers containing DINP (U.S. EPA, 2021c). Although the Agency expects that this scent would predominately be used in commercial candle making activities, it is possible that some consumer DIY candle makers could source this product from online vendors. EPA did not identify DINP in any additional consumer air care products at this time. Consumer DIY users of these products would apply through mixing DINP containing liquid substances with various waxes and other liquid to semi-solid materials in either cold-press or heated environments to create candles for personal use.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.40 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Fabric, Textile, and Leather Products (Apparel and Footwear Care Products)

This COU is referring to the consumer use of DINP in fabric, textile, and leather products including apparel and footwear products. The consumer users of products under this category would be expected to purchase and wear various apparel and footwear products that contain DINP.

EPA understands that DINP has been used in fabric, textile, and leather products including apparel and footwear products (ACC HPP, 2019). The Agency also notes that this COU was included in the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* due to DINP's use as a plasticizer to impart flexibility to PVC applications such as vinyl clothing, which are likely to be used in commercial and consumer applications (*e.g.*, rain boots, gloves, raincoats) (ACC HPP, 2019). EPA identified DINP in commercial and consumer fabric, textile, and leather products at concentrations of at least 1 percent but less than 60 percent (U.S. EPA, 2021d). A National Library of Medicine database identified DINP use in injection molding for footwear (U.S. EPA, 2021d). The manufacturer request also notes that a 2013 ECHA report identified the use of DINP in skinny leather pants, as well (ACC HPP, 2019).

Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported the use of DINP (CASRN 28553-12-0) in fabric, textiles, and leather products not covered elsewhere.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 68515-48-0) in fabric, textiles, and leather products not covered elsewhere, while one company reported the use of DINP (CASRN 28553-12-0) in apparel and footwear care products.

E.41 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Arts, Crafts, and Hobby Materials

This COU is referring to the consumer use of arts, crafts, and hobby materials that contain DINP. Consumers would be expected to handle products under this COU with their hands.

EPA identified uses of DINP in various arts, crafts, and hobby materials, including glitter board products and in polymer clay bricks, canes, and eraser products (U.S. EPA, 2021d). The Agency expects that these products are likely to be used in both commercial and consumer level applications. EPA identified two erasers that contained DINP (U.S. EPA, 2021d). The Agency anticipates that these erasers would be used in both commercial and consumer applications.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.42 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.

DINP is used in printing ink, at least one stamp product, and pigments (U.S. EPA, 2021c). The *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)* lists the use of pigments in non-PVC applications (<5% of DINP use) alongside use in paints (ACC HPP, 2019). EPA expects that the majority of ink, toner, and colorant products containing DINP would be commercial in nature; however, it is possible that these products are used by DIY consumers as many of the commercial products are available for consumer purchasers through various online vendors. EPA would expect that if consumer DIYers were to use these products they would apply them in the same fashion as industrial users, on a smaller scale at their residences.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.43 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Other Articles with Routine Direct Contact During Normal Use Including Rubber Articles; Plastic Articles (Hard); Vinyl Tape; Flexible Tubes; Profiles; Hoses

This COU is referring to the consumer use of DINP in various consumer products used with routine direct contact such as vinyl tape, flexible tubes, profiles, and hoses. DINP is used in various rubber and plastic articles that are intended for consumer use. The CDR reporting category is intended to capture items such as gloves, boots, clothing, rubber handles, gear levers, steering wheels, handles, pencils, and handheld device casing. As such, consumers would be expected to handle products covered by this COU with their hands and wear them on their bodies.

As identified by the *Manufacturer Request for Risk Evaluation Diisononyl Phthalate (DINP)*, tool handles, flexible tubes, profiles, and hoses are several of the uses for DINP as a general-purpose plasticizer for PVC applications (ACC HPP, 2019). The National Library of Medicine's database identified DINP for its use in garden hoses (U.S. EPA, 2021d).

Examples of CDR Submissions

In the 2016 CDR cycle, three companies reported the use of DINP (CASRN 28553-12-0) in plastic and rubber products not covered elsewhere. Two companies reported the use of DINP (CASRN 68515-48-0) in plastic and rubber products not covered elsewhere.

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 68515-48-0) in in plastic and rubber products not covered elsewhere.

E.44 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Packaging (Excluding Food Packaging), Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft)

This COU is referring to the consumer use of DINP in various packaging, paper, plastic, and hobby products.

EPA notes that this use was reported in the 2020 CDR reporting cycle and is intended to describe products such as phone covers, personal tablets covers, styrofoam packaging, and bubble wrap. Given what EPA knows about the use of DINP as a general-purpose plasticizer for PVC and non-PVC applications, the Agency expects that this use of DINP has been identified under other previously reported CDR codes. EPA also expects that the type of products being reported under this COU are likely to be both commercial and consumer in nature. Consumers would be expected to handle products covered by this COU with their hands.

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of DINP (CASRN 28553-12-0) in packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft).

E.45 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Toys, Playground, and Sporting Equipment

This COU is referring to the consumer use of DINP in toys, playground, and sporting equipment. The COU includes the consumer use or storage of toys, playgrounds, and sporting equipment that contain DINP in an indoor environment. The use also refers to the DIY building of home sporting equipment.

EPA notes in the final scope that the Consumer Product Safety Innovation Act of 2008 and the U.S. CPSC banned the use of DINP at concentrations of greater than 0.1 percent in children's toys and childcare articles in 2008 and 2018, respectively. EPA expects that the use of DINP in toys manufactured or processed prior to the ban may 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 DINP was reported as DINP + DIDP. For example, concentrations of DINP + DIDP in four teether samples at 32 to 40 percent and in 2 of 3 doll samples at approximately 20 and 26 percent.

Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DINP in toys, playground, and sporting equipment (28553-12-0).

E.46 Consumer Use – Other – Novelty Products

This COU is referring to the consumer use of DINP in adult novelty products.

This COU is describing adult sex toys that are available for consumer use in the United States. Although the U.S. Food and Drug Administration (FDA) classifies certain sex toys (such as vibrators) as obstetrical and gynecological therapeutic medical devices many manufacturers label these products "for novelty use only," they 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). For this reason, EPA assumed that the concentration of DINP in these products to be analogous to the overall content of the mix of phthalates tested and found in that study. This use was not reported to EPA in the 2016 or 2020 CDR reporting cycles. Consumers could experience dermal and oral exposure to DINP using the products covered by this COU.

E.47 Disposal

Each of the COUs of DINP may generate waste streams of the chemical. For purposes of the DINP risk evaluation, this COU refers to the DINP in a waste stream that is collected from facilities and households and are unloaded at and treated or disposed at third-party sites. This COU also encompasses

DINP contained in wastewater discharged by consumers or occupational users to a POTW or other, non-POTW for treatment, as well as other wastes. DINP 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 DINP, plastic and rubber products, textiles, and transport containers). Disposal may also include destruction and removal by incineration (U.S. EPA, 2021b). Additionally, DINP has been identified in EPA's 2016 report, *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States* (EPA-600-R-16-236Fb), to be a chemical reported to be detected in produced water, which is subsequently disposed. Recycling of DINP and DINP containing products is considered a different COU. Environmental releases from industrial sites are assessed in each COU.

Appendix F DRAFT OCCUPATIONAL EXPOSURE VALUE DERIVATION

EPA has calculated a draft 8-hour existing chemical occupational exposure value to summarize the occupational exposure scenario and sensitive health endpoints into a single value. This calculated draft value may be used to support risk management efforts for DINP under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the draft value rounded to 1.40 mg/m^3 for inhalation exposures to DINP as an 8-hour time-weighted average (TWA) and for consideration in workplace settings (see Appendix F.1) based on the chronic non-cancer human equivalent concentration (HEC) for liver toxicity.

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

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

EPA expects that at the draft occupational exposure value of 0.0808 ppm (1.40 mg/m^3), a worker or ONU also would be protected against developmental and liver toxicity from acute and intermediate duration occupational exposures if ambient exposures are kept below this draft occupational exposure value. EPA has not separately calculated a draft short-term (*i.e.*, 15-minute) occupational exposure value because EPA did not identify hazards for DINP associated with this very short duration.

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

The Occupational Safety and Health Administration (OSHA) has not set a permissible exposure limit (PEL) as an 8-hour TWA for DINP. EPA located several occupational exposure limits for DINP (CASRN 28553-12-0) in other countries. Identified 8-hour TWA values range from 3 mg/m^3 in Denmark to 5 mg/m^3 in Ireland, New Zealand, South Africa, and the United Kingdom (see also Appendix B.3). Additionally, EPA found that New Zealand and the United Kingdom all have an established occupational exposure limit of 5 mg/m^3 (8-hour TWA) in each country's code of regulation that is enforced by each country's worker safety and health agency.

F.1 Draft Occupational Exposure Value Calculations

This appendix presents the calculations used to estimate draft occupational exposure values using inputs derived in this draft risk evaluation. Multiple values are presented below for hazard endpoints based on different exposure durations. For DINP, the most sensitive occupational exposure value is based on non-cancer developmental effects and the resulting 8-hour TWA is rounded to 1.40 mg/m^3.

Draft Acute Non-cancer Occupational Exposure Value

The draft 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:

Equation_Apx F-1.

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

$$\frac{3.68\ \mathrm{ppm}}{30} * \frac{\frac{24h}{d}}{\frac{8h}{d}} * \frac{0.6125\,\frac{\mathrm{m^3}}{hr}}{1.25\,\frac{\mathrm{m^3}}{hr}} = 0.180\ \mathrm{ppm}$$

$$EV_{acute}\left(\frac{\mathrm{mg}}{\mathrm{m^3}}\right) = \frac{EV\ ppm\ *MW}{Molar\ Volume} = \frac{0.180\ \mathrm{ppm} * 418.6\,\frac{g}{mol}}{24.45\,\frac{L}{mol}} = 3.09\ \frac{\mathrm{mg}}{\mathrm{m^3}}$$

Draft Intermediate Non-cancer Occupational Exposure Value

The draft 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:

Equation_Apx F-2.

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

$$= \frac{3.68\ \mathrm{ppm}}{30} * \frac{\frac{24h}{d} * 30d}{\frac{8h}{d} * 22d} * \frac{0.6125\,\frac{\mathrm{m^3}}{hr}}{1.25\,\frac{\mathrm{m^3}}{hr}} = 0.246\ \mathrm{ppm} = 4.21\ \frac{\mathrm{mg}}{\mathrm{m^3}}$$

Draft Chronic Non-cancer Exposure Value

The draft 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:

Equation_Apx F-3.

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

$$= \frac{1.13\ \mathrm{ppm}}{30} * \frac{\frac{24h}{d}*\frac{365d}{y}*40\ y*0.6125\frac{\mathrm{m^3}}{hr}}{\frac{8h}{d}*\frac{250d}{y}*40\ y*1.25\frac{\mathrm{m^3}}{hr}} = 0.0808\ \mathrm{ppm} = 1.38\,\frac{\mathrm{mg}}{\mathrm{m^3}}$$

Where:

AT_{hecate} = Averaging time for the POD/HEC used for evaluating non-cancer acute occupational risk based on study conditions and HEC adjustments (24 h/day).

$AT_{HECintermediate}$ = 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).

$AT_{HECchronic}$ = Averaging time for the POD/HEC used for evaluating non-cancer chronic occupational risk based on study conditions and/or HEC adjustments (24 h/day for 365 days/yr) and assuming the same number of years as the high-end working years (WY, 40 years) for a worker.

$Benchmark\ MOE_{acute}$ = Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30

$Benchmark\ MOE_{intermediate}$ = Intermediate non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30

$Benchmark\ MOE_{chronic}$ = Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30

EV_{acute} = Acute Occupational exposure value

$EV_{intermediate}$ = Intermediate Occupational exposure value

$\mathrm{EV}_{\mathrm{chronic}}$ = Chronic Occupational exposure value

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^3/h for workers and 0.6125 m^3/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 DINP (418.62 g/mole)

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

Unit conversion:

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