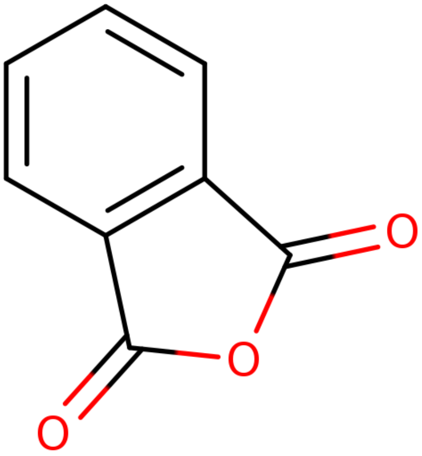
EPA Document# EPA-740-D-26-015
March 2026
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Risk Evaluation for Phthalic Anhydride

CASRN 85-44-9



March 2026

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDIX TABLES

ACKNOWLEDGEMENTS

The Assessment Team gratefully acknowledges participation, input, and review comments from U.S. Environmental Protection Agency (EPA or the Agency) Office of Pollution Prevention and Toxics (OPPT) and Office of Chemical Safety and Pollution Prevention (OCSPP) senior managers and science advisors. The Agency is also grateful for assistance from the following EPA contractors: General Dynamics Information Technology, Inc. (Contract No. 68HERD24A000 1-4); ICF, Inc. (Contract Nos. 68HERC23D0007 and 68HERC24D0001); SpecPro Professional Services, LLC (Contract No. 68HERC25D0004); and SRC, Inc. (Contract No. 68HERC25D0001).

Special acknowledgement is given for the contributions of technical experts from the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicology Methods (NICEATM) and Inotiv, Inc. for their support in the evaluation and quantitative dose-response assessment of dermal and respiratory sensitization data, including Emily Reinke and Dori Germolec.

Docket

Supporting information can be found in the public docket, Docket ID (EPA-HQ-OPPT-2018-0459).

Disclaimer

Authors: Collin Beachum, Daniel Chang, and Marc Edmonds (Management Leads); Ashley Peppriell (Assessment Lead, Human Health Hazard Assessment Lead); Anthony Luz (Human Health Hazard Assessment Lead); Christelene Horton (Epidemiologist), Andrew Sayer (Environmental Hazard Leads); Ryan Sullivan (General Population Exposure Assessment Lead, Physical Chemistry and Fate Assessment Lead), Juan Bezares Cruz (Physical Chemistry and Fate Assessment Lead); J. Aaron Murray (Occupational Exposure and Environmental Release Lead); Laura Krnavek (Consumer Exposure Lead); Wyn Zenni and Robert Landolfi (Risk Managers); Aderonke Adegbul, Maiko Arashiro, and James S. Brown

Contributors: Devin Alewel, Nicholas Castaneda, Maggie Clark, Ana Corado, Jone Corrales, Daniel DePasquale, Marc Edmonds, Victoria Ellenbogen, Patricia Fontenot, Lauren Gates, Ross Geredien, Keith Jacobs, June Kang, Grace Kaupas, Edward Lo, Yadi Lopez, Yashfin Mahid, Catherine Ngo, Geoffrey Colin Peterson, Ganesh Pokhrel, Christina Robichaud, Kelley Stanfield, Cory Strope, Joseph Valdez, Leora Vegosen, Kevin Vuilleumier, Susanna Wegner, Jason Wight, and Miyoung Yoon

Technical Support: Mark Gibson and Hillary Hollinger

EXECUTIVE SUMMARY

Background

EPA evaluated the human health and environmental risks of the chemical phthalic anhydride under section 6 of the Toxic Substances Control Act (TSCA). In this draft risk evaluation, 38 out of 44 assessed conditions of use (COUs) for phthalic anhydride contribute to a preliminary determination of unreasonable risk of injury to human health. As shown in Table ES-1, of these 38 COUs for phthalic anhydride that contribute to a preliminary determination of unreasonable risk, 36 COUs result in dermal and/or inhalation risk to workers and occupational non-users (ONUs)—including 4 COUs that only contribute to acute dermal exposure to workers and 4 COUs that include inhalation risk to ONUs. Additionally, two COUs result in dermal and/or inhalation risk to consumers (1 from acute dermal exposures for consumers only; 1 from acute dermal and inhalation exposures, including bystanders). These are also shown in Table ES-1. No COUs for phthalic anhydride preliminarily contribute to any unreasonable risk of injury to the general population, including to fenceline communities, or to the environment.

Phthalic anhydride is primarily used as an industrial intermediate during the manufacture and processing of alkyd resins, plasticizers, polyester resins, pigments, and coatings. Workers may be exposed to phthalic anhydride through inhalation or dermal contact when making these products or otherwise using it in the workplace (Section 4.1.1). When it is manufactured or used to make products, phthalic anhydride can be released into water (Section 3.3.1.1), where it will rapidly hydrolyze (hydrolysis half-life of 30–90 seconds) to *ortho (o)*-phthalic acid.

Based on available product information (*i.e.,* safety data sheets [SDSs]) and available monitoring data, workers are expected to be primarily exposed to phthalic anhydride, not *o*-phthalic acid, for all COUs under TSCA. For worker exposures, phthalic anhydride and products containing phthalic anhydride are produced in a closed system in the absence of water, otherwise, the chemical would not serve its intended purpose as a monomer for building ortho-phthalates. All occupational monitoring studies measured for the anhydride form rather than the acid, and no industrial or commercial product containing phthalic anhydride listed *o*-phthalic acid as a product component. Indoors, consumer, and bystander inhalation exposure to phthalic anhydride is expected to occur during the use of products containing phthalic anhydride, primarily through direct inhalation of sprays and mists; however, dermal contact during product use may also occur. Exposure to *o*-phthalic acid from consumer products was not evaluated because all products that were quantitatively evaluated are oil-based or non-water-based and *o*-phthalic acid is not expected to be present in the final products (per SDSs).

When released to the air (*i.e.,* through stack or fugitive emissions) in the ambient environment (Section 3.3.1.2), phthalic anhydride is expected to rapidly hydrolyze to *o*-phthalic acid due to moisture in the air. Because of the rapid hydrolysis of phthalic anhydride to *o*-phthalic acid in the presence of water, the general population is expected to be primarily exposed to *o*-phthalic acid resulting from releases of phthalic anhydride to the environment. Therefore, EPA evaluated risk to the general population, fenceline communities, and the environment from exposure to *o*-phthalic acid following releases of phthalic anhydride. The Agency also evaluated risk to consumers and workers from exposure to phthalic anhydride.

Observational studies in exposed worker populations as well as experimental studies conducted in laboratory animals and/or with computational new approach methodologies (NAMs) were reasonably available and reviewed by EPA to determine whether phthalic anhydride and/or its immediate hydrolysis product *o*-phthalic acid causes a range of non-cancer and cancer health effects on people. After reviewing the available studies, the Agency has preliminarily concluded that there is robust evidence that phthalic anhydride causes dermal and respiratory sensitization following dermal and inhalation exposure, and that phthalic anhydride exhibits low systemic toxicity through the oral route of exposure (Section 4.2). In contrast, *o*-phthalic acid is not a dermal or respiratory sensitizer based on reasonably available information. Data are not available for other health outcomes for *o*-phthalic acid for the dermal route of exposure and dermal absorption of *o*-phthalic acid is not expected; therefore, route-to-route extrapolation was conducted from oral toxicity data to estimate dermal toxicity for *o*-phthalic acid.

In December 2019, EPA designated phthalic anhydride as a high-priority substance for TSCA risk evaluation and in August 2020 released the *Final Scope of the Risk Evaluation for Phthalic Anhydride (1,3-Isobenzofurandione*[1]*); CASRN 85-44-9* (U.S. EPA, 2020d). Manufacturers report phthalic anhydride production volumes through the Chemical Data Reporting (CDR) rule under CASRN 85-44-9. The production volume for phthalic anhydride each year between 2016 and 2019 was between 250 to 500 million pounds per year (lb/yr) based on the 2020 CDR data (U.S. EPA, 2020b). Review of preliminary 2024 CDR data indicates that total production volumes for the years 2020 to 2023 are similar to the previously reported range from the 2020 CDR dataset. The Agency has evaluated phthalic anhydride across its COUs, ranging from manufacture to disposal. Limits on worker exposure to phthalic anhydride exist in the United States, Canada, the European Union, Australia, and elsewhere. Additional international regulatory requirements for the use of phthalic anhydride also exist (see Appendix B).

In this draft risk evaluation, EPA assesses human health risk to workers, including ONUs; consumers, including bystanders exposed to phthalic anhydride; and the general population exposed to environmental releases of phthalic anhydride. It also assesses risk to the environment. EPA did not evaluate human or environmental exposure to phthalic anhydride or *o*-phthalic acid following environmental releases of phthalic anhydride from uses that are excluded from TSCA's definition of a chemical substance under TSCA section 3(2)(B). Thus, conclusions in this draft evaluation cannot be extrapolated to form conclusions about uses of phthalic anhydride that are not subject to TSCA and that EPA did not evaluate.

Determining Unreasonable Risk to Human Health

In TSCA section 6 risk evaluations, EPA must determine whether a chemical substance does or does not present unreasonable risk of injury to human health or the environment, under the COUs. The unreasonable risk determination must be consistent with the best available science. In determining whether phthalic anhydride *presents unreasonable risk of injury to human health*, EPA considered risk-related factors (see TSCA section 6(b)(4)(F); 89 Fed. Reg. 37028, 37037 [May 3, 2024]). Risk-related factors include but are not limited to the type of health effect under consideration; reversibility of the health effect being evaluated; exposure-related considerations (*e.g.,* duration, magnitude, frequency of exposure); and population exposed (including any potentially exposed or susceptible subpopulations [PESS]). EPA must also consider confidence in the information used to inform the hazard and exposure values. If the margin of exposure for non-cancer effects (MOE, see Section 4.3.1.1) for a specific scenario is below or above the relevant risk benchmark, this does not necessarily lead to a determination that those risks do or do not significantly contribute to unreasonable risk, and the formal determination of whether those risks significantly contribute to the unreasonable risk of phthalic anhydride under TSCA must be a case-by-case decision.

EPA evaluated the risks to people from being exposed to phthalic anhydride at work (indoors and outdoors). For worker exposures, the draft risk estimates do not reflect use of personal protective

---

[1] 1,3-Isobenzofurandione is a primary synonym for phthalic anhydride.

equipment (PPE) because EPA does not currently have sufficient information regarding use of PPE under the COUs. The Agency is requesting comment on this and will consider any additional information in the development of the final risk evaluation (see Sections 4.3.2.1 and 6.1 for more discussion on PPE use). Risks were also characterized for consumer exposures from use (indoors and outdoors) of products containing phthalic anhydride and for general population exposures to *o*-phthalic acid. 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 phthalic anhydride through breathing or ingesting dust or other particulates as well as through skin contact. In preliminarily determining whether phthalic anhydride presents an unreasonable risk of injury to human health, EPA considered the following PESS in its assessment: people exposed to phthalic anhydride in the workplace, people who frequently use consumer products and/or articles containing high concentrations of phthalic anhydride, and people exposed to *o*-phthalic acid following releases of phthalic anhydride to the environment.

EPA weighed the scientific evidence to determine confidence levels in underlying datasets and risk estimates for human health (see Section 4.3). For the general population, the Agency has robust confidence that the risk estimates calculated were conservative and appropriate for a screening-level analysis. For workers, EPA has moderate confidence in the risk estimates calculated for inhalation and dermal exposure scenarios; for ONUs, EPA has slight-to-moderate confidence in the risk estimates calculated for inhalation and dermal exposure due to greater uncertainties in ONU exposure scenarios (see Section 4.1.1). For consumers, the Agency has moderate confidence in the risk estimates calculated for inhalation and dermal exposure scenarios.

Determining Unreasonable Risk to the Environment

In preliminarily determining whether phthalic anhydride releases, which rapidly hydrolyze into *o*-phthalic acid in the presence of moisture, present an unreasonable risk to the environment, EPA considered the following groups of organisms in its assessment: aquatic vertebrates, invertebrates, plants, and algae; sediment-dwelling invertebrates; terrestrial mammals and plants; and soil invertebrates. The Agency weighed the scientific evidence in order to determine confidence levels in underlying datasets and risk estimates for the environment (see Section 5.3.5). EPA has slight-to-moderate confidence in its environmental data and risk estimates, depending on the source of environmental release information for each COU (see Section 5.3.5).

Summary and Considerations

The full list of 44 COUs evaluated for phthalic anhydride under TSCA is presented in Table 1-1. Table ES-1 shows the 38 COUs for phthalic anhydride that contribute to a preliminary determination of risk of injury to human health due to non-cancer risks driven by acute dermal exposures or both dermal and inhalation exposures. Thirty-six of those COUs are driven by risk to workers, and of those, 4 also indicate acute inhalation risk to ONUs as noted below.

Table ES-1. Conditions of Use Contributing to a Preliminary Determination of Unreasonable Risk for Phthalic Anhydride for Human Health from Acute Exposures

Conditions of Use of Phthalic Anhydride Contributing to a Preliminary Determination of Unreasonable Risk of Injury to Human Health				
Condition of Use	**Workers**		**ONUs**	
	Dermal	**Inhalation**	**Dermal**	**Inhalation**
Manufacturing – Domestic manufacturing	×	×		
Manufacturing – Importing	×	×		

Conditions of Use of Phthalic Anhydride Contributing to a Preliminary Determination of Unreasonable Risk of Injury to Human Health

Condition of Use	Workers		ONUs	
	Dermal	Inhalation	Dermal	Inhalation
Processing – As a reactant – Intermediate in all other basic organic chemical manufacturing; Plastic material and resin manufacturing; Construction; Paint and coating manufacturing; Flame retardant manufacturing	×	×		
Processing – As a reactant – Monomer in plastic material and resin manufacturing; All other basic organic chemical manufacturing	×	×		
Processing – As a reactant – Ion exchange agent in all other basic organic chemical manufacturing	×	×		
Processing – As a reactant – Pigments in printing ink manufacturing	×	×		
Processing – As a reactant – Polymerization promoter in synthetic dye and pigment manufacturing	×	×		
Processing – As a reactant – Plasticizer in plastics product manufacturing; Adhesive manufacturing; Lubricant additive manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Binder in paint and coating manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Dyes in synthetic dye and pigment manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Flame retardant in plastics product manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Hardener in adhesive manufacturing; Epoxy resin casting; Paint and coating manufacturing; Solvent-based paint; Rubber product manufacturing; Utilities	×	×		×
Processing – Incorporation into formulation, mixture, or reaction product – Intermediate in all other basic inorganic chemical manufacturing; All other basic organic chemical manufacturing; Adhesive manufacturing; Plastic material and resin manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Monomer in plastic material and resin manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Paint additives and coating additives not described by other categories in plastics material and resin manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Plasticizer in plastic material and resin manufacturing; Paint and coating manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Polymerization promoter in all other basic organic chemical manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Pre-catalyst manufacturing	×	×		

Conditions of Use of Phthalic Anhydride Contributing to a Preliminary Determination of Unreasonable Risk of Injury to Human Health

Condition of Use	Workers		ONUs	
	Dermal	**Inhalation**	**Dermal**	**Inhalation**
Processing – Incorporation into formulation, mixture, or reaction product – Processing aid in paint and coating manufacturing; Rubber product manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Retarder in rubber product manufacturing	×	×		
Processing – Incorporation into formulation, mixture, or reaction product – Solvent in paint and coating manufacturing plastic material and resin manufacturing	×	×		
Processing – Repackaging	×	×		
Industrial use – Automotive and aerospace products – Transportation equipment manufacturing	×	×		
Industrial use – Construction products – Construction and building materials covering large surface areas	×	×		
Industrial use – Other – Laboratory chemical	×	×		×
Industrial use – Paints and coatings	×	×		
Commercial use – Construction products – Construction and building materials covering large surface	×	×		
Commercial use – Fillers – Hardeners	×	×		×
Commercial use – Other – Laboratory chemical	×	×		×
Commercial use – Paints and coatings	×	×		
Commercial use – Transportation equipment manufacturing	×	×		
Commercial use – Furniture and furnishings – Oil treatment of wood	×	×		
Industrial use – Adhesives and sealants	×			
Industrial use – Metal and electrical products – Machinery, and mechanical appliances; Electrical/electronic articles	×			
Commercial use – Adhesives and sealants	×			
Commercial use – Metal and electrical products – Machinery, and mechanical appliances; Electrical/electronic articles	×			
Conditions of Use	**Consumers**		**Bystanders**	
	Dermal	**Inhalation**	**Dermal**	**Inhalation**
Consumer use – Adhesives and sealants	×			
Consumer use – Paints and coatings	×	×		×

Shaded cells with × are COUs that contribute to a preliminary determination of unreasonable risk of injury for workers, ONUs, consumers, or bystanders resulting from acute dermal and/or inhalation exposure.

No COUs for phthalic anhydride preliminarily contribute to unreasonable risk of injury to the general population, including fenceline communities, exposed to environmental releases of phthalic anhydride or to the environment.

Next Steps and Public Input

This draft risk evaluation, including EPA's preliminary determination that 38 of 44 assessed COUs for phthalic anhydride contribute to unreasonable risk of injury to human health as well as the accompanying technical support documents (TSDs) and supplemental files (see Appendix C), have been released for public comment. The draft risk evaluation package for phthalic anhydride will undergo independent, expert scientific peer review by the Science Advisory Committee on Chemicals (SACC) during its June 2026 meeting.

Recommendations from the SACC, as well as public comments on the draft risk evaluation package, will inform the final risk evaluation of phthalic anhydride—including the Agency determination of whether phthalic anhydride presents unreasonable risk of injury to human health or the environment, under the COUs. If, in the final risk evaluation, the Agency determines that phthalic anhydride presents unreasonable risk of injury to human health or the environment, EPA will initiate regulatory action under TSCA section 6(a) to the extent necessary so that phthalic anhydride no longer presents such risk.

The Agency seeks public comment on the aforementioned aspects of this draft risk evaluation package. In particular, the Agency seeks comment on the following topics:

- Workplace exposure information including air monitoring data and including task-based exposure durations, air monitoring methods (including uncertainties in existing methods such as OSHA 90), engineering controls, PPE practices and usage;
- EPA's approach to estimate dermal exposures from spray products for consumers and workers;
- EPA's approach to estimate dermal exposure from contact with solids for occupational exposure scenarios using the study by Lansink et al. (1996), including additional studies or information that may inform dermal loading for contact with solids;
- EPA's approach to determine dermal loadings for products using the U.S. EPA (1992b) study wipe experiment, which incorporates wiping off the excess product with a saturated cloth after application as advised in the products' use instructions (*e.g.,* Adhesives and sealants);
- Product-specific phthalic anhydride concentration ranges and use patterns, including updated publicly available SDSs related to the use of phthalic anhydride in products considered under COUs in this assessment (*e.g.,* Paint and coating products);
- EPAs approach to assess inhalation exposures for acute exposure durations of phthalic anhydride from consumer COUs using an 8-hour time-weighted average (TWA);
- EPAs approach to assess inhalation exposures for acute exposure durations of phthalic anhydride using an 8-hour TWA rather than a short-term inhalation value (STEV) based on assumed task durations;
- EPA's derivation of a STEV and occupational exposure values (OEV) and the scientific robustness of deriving OEVs and STEVs based on the dataset and the endpoints (*i.e.,* respiratory sensitization);
- Newly available or recently published hazard/toxicology studies relevant to phthalic anhydride;
- The selection of environmental hazard thresholds based on a relatively small hazard datasets;
- The strengths and uncertainties of the methodology and data used to derive acute and chronic concentrations of concern (COCs) for aquatic thresholds and the strength of the data to support the quantitative aquatic assessment;
- The following weight of evidence conclusions from the human health hazard assessment:
    - phthalic anhydride and *o*-phthalic acid have low systemic toxicity via the oral exposure route
    - phthalic anhydride is a skin sensitizer
    - phthalic anhydride is a respiratory sensitizer; and
- The underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride (see Appendix F in the *Draft Human Health Hazard Assessment for Phthalic Anhydride*; (U.S. EPA, 2026p)).

1 INTRODUCTION

EPA has evaluated phthalic anhydride pursuant to section 6(b) of the Toxic Substances Control Act (TSCA). Phthalic anhydride is primarily used in large-scale production of plastics. Section 1.1 summarizes the scope of the draft phthalic anhydride risk evaluation and provides information on production volume and a life cycle diagram (LCD). Section 1.2 describes TSCA conditions of use (COUs), discipline-specific conceptual models for used for phthalic anhydride, and an overview of the populations (including subpopulations) and durations of exposure assessed. Section 1.3 presents the organization of the remainder 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.

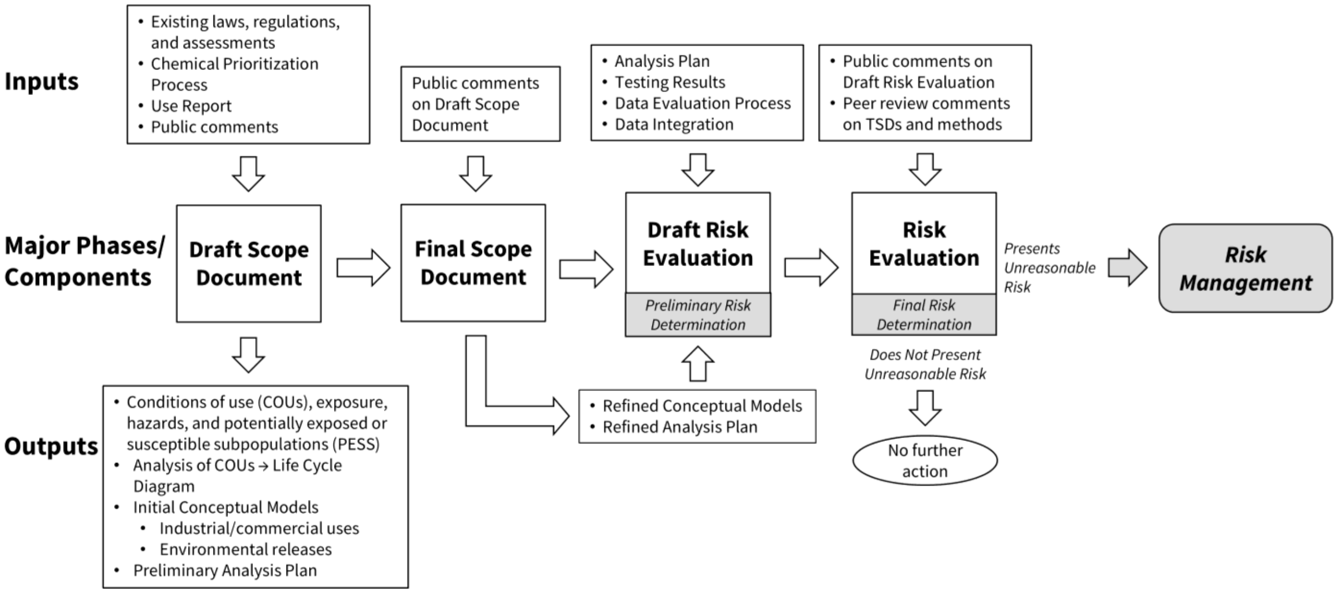


Figure 1-1. TSCA Section 6 Chemical Risk Evaluation Process

1.1 Scope of the Risk Evaluation

EPA evaluated risk to human and environmental populations for phthalic anhydride. Specifically for human populations, the Agency evaluated risk to workers including occupational non-users (ONUs) via inhalation and dermal routes; risk to consumers via inhalation and dermal routes; and risks to bystanders via the inhalation route. Additionally, EPA incorporated potentially exposed and susceptible populations (PESS) into its assessment, including people exposed to phthalic anhydride in the workplace, and people who frequently use consumer products and/or articles containing high concentrations of phthalic anhydride, and people exposed to *o*-phthalic acid following releases of phthalic anhydride to the environment. As described further in Section 4.1.4, EPA assessed risks to the general population, which considered risk from exposure to *o*-phthalic acid resulting from releases of phthalic anhydride to the environment via oral ingestion of surface water, drinking water, ambient air, and soil from air-to-soil deposition. For environmental populations, EPA evaluated risk to aquatic species via water and sediment as well as risk to terrestrial species via soil and, qualitatively, through trophic transfer. As mentioned above, phthalic anhydride is highly reactive and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, also known as *ortho*-phthalic acid (or *o*-phthalic acid; CASRN 88-99-3), when it comes into contact with water or atmospheric moisture. Therefore, *o*-phthalic acid is expected to be the product found in the environment and the proximal toxicant in contact with living organisms.

The draft risk evaluation for phthalic anhydride comprises a series of technical support documents (TSDs). Each TSD contains subassessments that inform adjacent, "downstream" TSDs (and other supplemental files). A basic diagram showing the layout and relationship of these assessments/TSDs is provided below in Figure 1-2. High-level summaries of each relevant TSD are presented throughout this draft risk evaluation. Detailed information for each TSD can be found in the corresponding documents, which are listed with citations along with supplemental files in Appendix C.

All phthalic anhydride TSDs leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Phthalic Anhydride (1,3-Isobenzofurandione); CASRN 85-44-9* (also called the "final scope for phthalic anhydride" or "final scope document"; 1,3-isobenzofurandione is a synonym) (U.S. EPA, 2020d). EPA/OPPT conducted a comprehensive search for "reasonably available information" to identify relevant data on phthalic anhydride and/or *o*-phthalic acid for use in the draft risk evaluation. The approach used to identify specific relevant risk assessment information was discipline-specific and is detailed in the *Draft Systematic Review Protocol for Phthalic Anhydride* (U.S. EPA, 2026u), or as otherwise noted in the relevant TSDs.

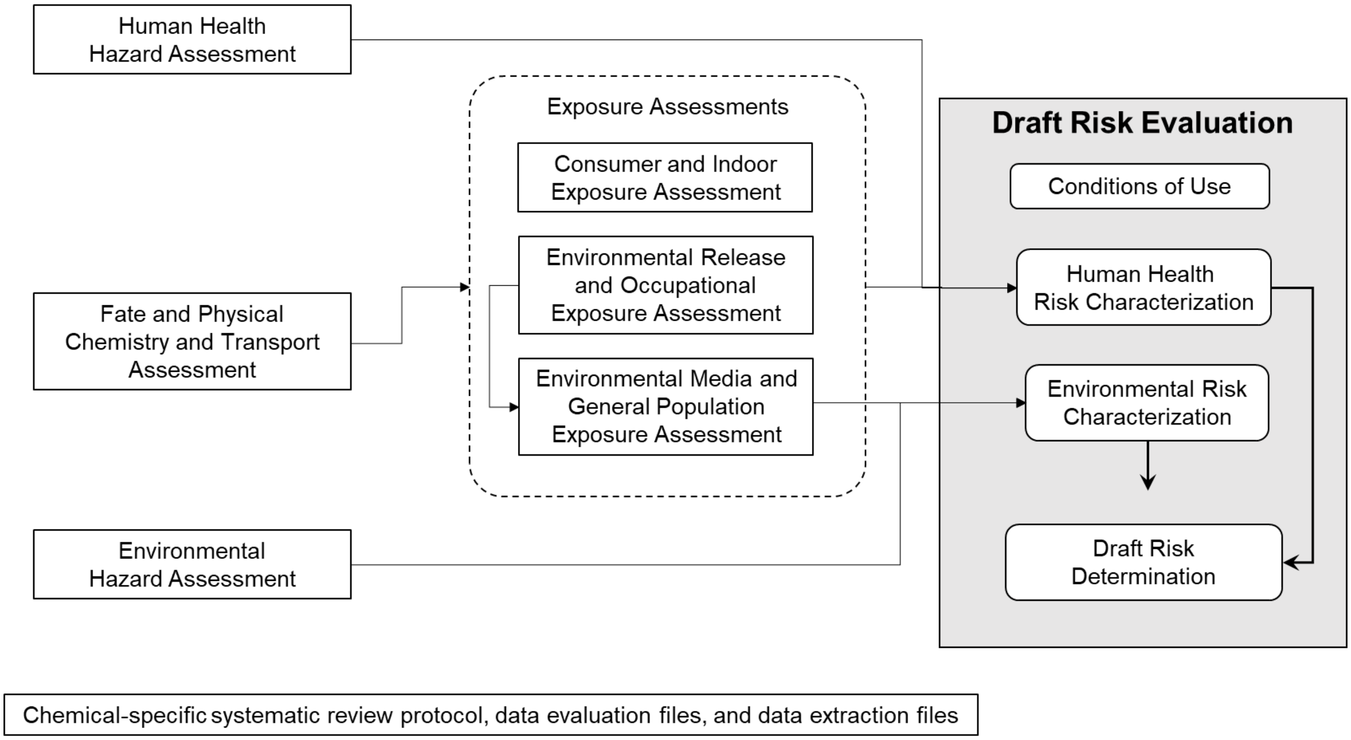


Figure 1-2. Draft Risk Evaluation Document Summary Map

1.1.1 Life Cycle and Production Volume

The LCD shown in Figure 1-3 depicts the COUs 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 information in the LCD is grouped according to EPA's Chemical Data Reporting Rule (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 certain 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.

EPA included descriptions of the industrial, commercial, and consumer use categories identified from the 2020 and preliminary 2024 CDR data in the LCD (Figure 1-3) (U.S. EPA, 2020b).[2] The descriptions provide a brief overview of the use category; the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) contains more detailed descriptions (*e.g.,* process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacturing, processing, use, and disposal category.

---

[2] Review of preliminary 2024 CDR data indicates that total production volumes for the years 2020 to 2023 are similar to the previously reported range from the 2020 CDR dataset.

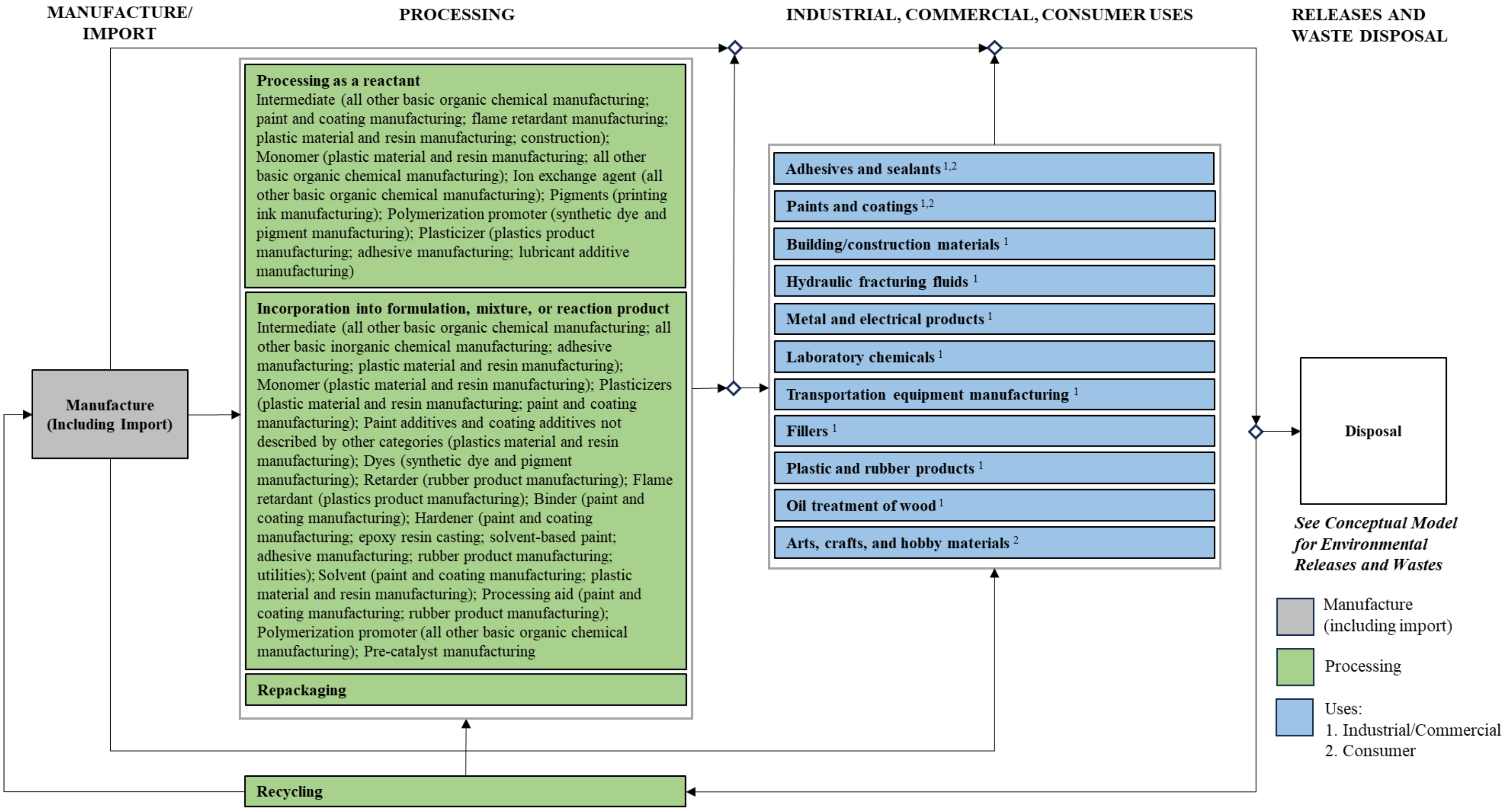


Figure 1-3. Phthalic Anhydride Life Cycle Diagram

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

The production volume (PV) for phthalic anhydride each year between 2016 and 2019 was between 250 to 500 million pounds per year (lb/yr) based on the 2020 CDR data (U.S. EPA, 2020b). Also, review of preliminary 2024 CDR data indicates that total production volumes for the years 2020 to 2023 are similar to the previously reported range from the 2020 CDR dataset. EPA described production volumes as a range to protect production volume data claimed as confidential business information (CBI). For the 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).

In the 2020 CDR, there were 33 sites reporting manufacturing and/or import of phthalic anhydride, and 10 of these sites claimed their PVs as CBI. Also, EPA identified three manufacturing sites from information reported to TRI (U.S. EPA, 2023c), and it was assumed that these three sites may be producing up to the CDR reporting threshold of 25,000 lb/yr. Using the maximum reported PVs from the 23 sites that quantified their PVs, along with the 25,000 lb/yr CDR threshold for three additional manufacturing sites, the total known annual PV within the United States was estimated as 235 million lb/yr. Subtracting the known annual PV from the national aggregate range provided by the 2020 CDR (*i.e.,* 250–500 million lb/yr), the remaining PV associated with manufacturing and/or import sites that claimed PV as CBI is 15 to 265 million lb/yr. The range of remaining PVs was divided evenly among the 10 sites that claimed CBI such that each manufacturing and/or import site claiming their PV as CBI is expected to contribute 1.5 to 26.5 million lb/site-yr to the national aggregate annual PV.

Of the 33 sites reporting manufacturing and/or import of phthalic anhydride to the 2020 CDR (U.S. EPA, 2020b), 5 sites reported manufacturing activities and 28 sites reported import activities. The overall annual PV associated with the five manufacturing sites reporting to the 2020 CDR, plus the three manufacturing sites identified from TRI (U.S. EPA, 2023c), was estimated as 167 to 244 million lb/yr. The overall annual PV associated with the 28 sites reporting to the 2020 CDR was estimated as 81 to 256 million lb/yr. Some import sites reported that the imports do not occur on-site, so there may be more than 28 facilities importing phthalic anhydride from the sites reporting to the 2020 CDR. For more information regarding PVs associated with phthalic anhydride manufacturers and/or importers, refer to Section 3.1 (manufacturing) and Section 3.2 (import) of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anydride* (U.S. EPA, 2026o).

1.2 Conditions of Use Included in the Risk Evaluation

The final scope for phthalic anhydride (U.S. EPA, 2020d) identified and described the life cycle stages, categories, and subcategories that comprise COUs that EPA planned to consider in the risk evaluation. All COUs for phthalic anhydride included in this draft risk evaluation are reflected in the LCD (Figure 1-3) and conceptual models (Section 1.2.1). Table 1-1 below presents all COUs under TSCA for phthalic anhydride.

In this draft risk evaluation, EPA made updates to the COUs listed in the final scope document (U.S. EPA, 2020d). 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 include (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 life stage based on inconsistencies found in CDR reporting for phthalic anhydride processing and uses as well as communications with stakeholders about the use of phthalic anhydride in industry, and (3) correction of typos or edits for consistency. Appendix D provides a complete list of updates to the COUs between the final scope document and the draft risk evaluation, including an explanation of these updates. EPA may further refine the COU descriptions for phthalic anhydride that are included in the draft risk evaluation when the final risk evaluation is released, based upon further outreach, peer-reviewer comments, and public comments. Table 1-1 presents all revised COUs that were included and evaluated in this draft risk evaluation for phthalic anhydride. Appendix E provides descriptions of the phthalic anhydride COUs evaluated by EPA.

Table 1-1. Life Cycle Stage, Categories, and Subcategories of Use the Draft Risk Evaluation [a] [b] for Phthalic Anhydride

Life Cycle Stage [c]	Category [d]	Subcategory [e]	Reference(s)
Manufacture	Domestic manufacture	N/A [f]	(U.S. EPA, 2024, 2020a)
	Import	N/A	(U.S. EPA, 2024, 2020a)
Processing	As a reactant	Intermediate in: all other basic organic chemical manufacturing; plastic material and resin manufacturing; construction; paint and coating manufacturing; flame retardant manufacturing	(U.S. EPA, 2024; Stepan Co., 2020; U.S. EPA, 2020a, 1994c)
		Ion exchange agent in: all other basic organic chemical manufacturing	(U.S. EPA, 2020a)
		Monomer in: plastic material and resin manufacturing; all other basic organic chemical manufacturing	(U.S. EPA, 2024, 2020a)
		Pigments in: printing ink manufacturing	(U.S. EPA, 2024, 2020a)
		Plasticizer in: plastics product manufacturing; adhesive manufacturing; lubricant additive manufacturing	(U.S. EPA, 2024, 2020a)
		Polymerization promoter in: synthetic dye and pigment manufacturing	(U.S. EPA, 2024, 2020a)
	Incorporation into formulation, mixture, or reaction product	Binder in: paint and coating manufacturing	(U.S. EPA, 2024)
		Dyes in: synthetic dye and pigment manufacturing	(U.S. EPA, 2024)
		Flame retardant in: plastics product manufacturing	(U.S. EPA, 2024)
		Hardener in: adhesive manufacturing; epoxy resin casting; paint and coating manufacturing; solvent-based paint; rubber product manufacturing; utilities	(U.S. EPA, 2024, 2020a)
		Intermediate in: all other basic inorganic chemical manufacturing; all other basic organic chemical manufacturing; adhesive manufacturing; plastic material and resin manufacturing	(U.S. EPA, 2024, 2020a)
		Monomer in: plastic material and resin manufacturing	(U.S. EPA, 2024)
		Paint additives and coating additives not described by other categories in: plastics material and resin manufacturing	(U.S. EPA, 2024); EPA-HQ-OPPT-2018-0459-0024
		Plasticizer in: plastic material and resin manufacturing; paint and coating manufacturing	(U.S. EPA, 2024; Koppers, 2018)
		Polymerization promoter in: all other basic organic chemical manufacturing	(U.S. EPA, 2020a)
		Pre-catalyst manufacturing	(W.R. Grace, 2024)
		Processing aid in: paint and coating manufacturing; rubber product manufacturing	(U.S. EPA, 2024, 2020a)
		Retarder in: rubber product manufacturing	(U.S. EPA, 2020a)

Life Cycle Stage [c]	Category [d]	Subcategory [e]	Reference(s)
Processing		Solvent in: paint and coating manufacturing; plastic material and resin manufacturing	(U.S. EPA, 2024, 2020a)
	Repackaging	Repackaging	(ThermoFisher Scientific, 2022); EPA-HQ-OPPT-2018-0459-0041
	Recycling	N/A	(U.S. EPA, 2024, 2020a)
Distribution in commerce	N/A	N/A	N/A
Industrial	Automotive and aerospace products	Transportation equipment manufacturing	EPA-HQ-OPPT-2018-0459-0041; EPA-HQ-OPPT-2019- 0131-0022
Industrial	Adhesives and sealants	N/A	(3M, 2023; Aremco, 2023; Lord Corporation, 2023)
Industrial	Construction products	Construction and building materials covering large surface areas	(U.S. EPA, 2024; Durcon, 2020; U.S. EPA, 2020a; OSHA, 2019b; Durcon, 2011)
Industrial	Metal and electrical products	Machinery, and mechanical appliances; electrical/electronic articles	(U.S. EPA, 2020a)
Industrial	Other	Laboratory chemical	(ThermoFisher Scientific, 2022); EPA-HQ-OPPT-2018-0459-0041
Industrial	Paints and coatings	N/A	(U.S. EPA, 2024, 2020a)
Industrial	Processing aids, specific to petroleum production	Hydraulic fracturing	(U.S. EPA, 2025b; Finoric LLC, 2019; U.S. EPA, 2015a; Committee on Energy and Commerce's Minority Staff, 2011; Whittemore, 2011)
Commercial	Adhesives and sealants	N/A	(3M, 2023; Aremco, 2023; Lord Corporation, 2023; U.S. EPA, 2020a)
Commercial	Construction products	Construction and building materials covering large surface areas	(U.S. EPA, 2024, 2020a)
Commercial	Fillers	Hardener	(ResinLab, 2023; Lord Corporation, 2020)

Life Cycle Stage [c]	Category [d]	Subcategory [e]	Reference(s)
Commercial	Furniture and furnishings	Oil treatment of wood	(Junckers Industries A/S, 2023)
Commercial	Metal and electrical products	Machinery, mechanical appliances, electrical/electronic articles	(U.S. EPA, 2020a)
Commercial	Other	Laboratory chemical	(ThermoFisher Scientific, 2022; Phenova, 2017, 2015); EPA-HQ-OPPT-2018-0459-0041
Commercial	Paints and coatings	N/A	(U.S. EPA, 2024, 2020a)
Commercial	Plastic and rubber products	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) Other (rubber products)	(U.S. EPA, 2024, 2020a)
Commercial	Transportation equipment manufacturing	Transportation equipment manufacturing	(Lord Corporation, 2023); EPA-HQ-OPPT-2019-0131-0022
Consumer	Adhesives and sealants	N/A	(U.S. EPA, 2020a); EPA- HQ-OPPT-2018-0459-0004; EPA-HQ-OPPT-2018-0459-0022
Consumer	Arts, crafts, and hobby materials	Clear casting resins	(Environmental Technology, 2017)
Consumer	Paints and coatings	Solvent-based paints	(U.S. EPA, 2024, 2020a)
Disposal	N/A	N/A	N/A

[a] Due to additional information from stakeholder outreach, public comments, and further research, conditions of use (COUs) have been added or modified after the publication of the final scope document.

[b] EPA is aware that phthalic anhydride quickly hydrolyzes to 1,2-benzenedicarboxylic acid (see details in Section 2). However, the COUs, identified in Table 2-2, are only associated with uses of phthalic anhydride. Activities and releases associated with 1,2-benzenedicarboxylic acid produced as a result of the use of phthalic anhydride will be considered in EPA's risk evaluation. In addition, though EPA is aware of other uses of 1,2-benzenedicarboxylic acid that are not associated with the use of phthalic anhydride, these will not be considered in the risk evaluation.

[c] Life cycle stage use definitions (40 CFR 711.3):

- "Industrial use" means use at a site at which 1 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.

Life Cycle Stage [c]	Category [d]	Subcategory [e]	Reference(s)

– 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.

[d] These categories of COUs appear in the life cycle diagram, reflect Chemical Data Reporting (CDR) codes, and broadly represent COUs of phthalic anhydride in industrial and/or commercial settings.

– "N/A" means not applicable where the category name, subcategory name, or both are duplicative and therefore unnecessary for identifying the COU.

[e] These subcategories reflect more specific uses of phthalic anhydride.

[f] "N/A" means not applicable where the category name, subcategory name, or both are duplicative and therefore unnecessary for identifying the COU.

1.2.1 Conceptual Models

Figure 1-4 presents the exposure pathways, exposure routes, and hazards to human populations from industrial and commercial activities and uses of phthalic anhydride. 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 phthalic anhydride from 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, Disposal). Dashed lines in Figure 1-7 were not evaluated because they are not expected to be major routes of exposure. The following pathways were not evaluated.

Air Deposition to Water and Sediment

Phthalic anhydride is expected to rapidly convert to *o*-phthalic acid in the air due to the presence of moisture. This transformation is immediate and the hydrolysis half-life is estimated to be between 30 to 90 seconds, depending upon pH; complete hydrolysis is achieved in approximately 8 minutes (U.S. EPA, 2026r). Once in the receiving water body, *o*-phthalic acid is expected to have high mobility, remain in water column, and have limited partitioning to suspended organic matter and aquatic sediments. Fugacity modeling results indicated a negligible partitioning of *o*-phthalic acid in sediments. The biodegradation rate in water and sediment is expected to be days and days-to-weeks, respectively.

Biosolids to Water and Sediment

There is currently no direct evidence that biosolids containing *o*-phthalic acid that may enter surface water and sediment via runoff are being consistently applied to agricultural fields in any part of the United States, and there is similarly very limited direct evidence that *o*-phthalic acid is present in agricultural products resulting from the applications of biosolids to agricultural fields. Biosolids generated during the treatment of industrial and municipal wastewater may be applied to agricultural fields or pastures as fertilizer in either its dewatered form or as a water-biosolid slurry. However, *o*-phthalic acid is not expected to be persistent in soils and would likely hydrolyze rapidly given the relative humidity of the environment and moisture present in biosolids.

Soil to Groundwater

o-Phthalic acid present in soil is expected to be mobile in water and may leach into groundwater due to the low tendency of *o*-phthalic acid to sorb to organic media and soil (log K_{OW} = 0.73; log K_{OC} = 1.07). Biodegradation of *o*-phthalic acid in groundwater is expected to be rapid with a half-life of days (Tang et al., 2017; Fujita et al., 2005), which will result in its transport or transfer to groundwater. Biodegradation data show that *o*-phthalic acid will biodegrade rapidly in soil and groundwater and thus is not expected to persist.

Water and Sediment to Terrestrial Species

Phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid, which is water soluble and likely to partition to surface and groundwater, not likely to volatilize from water and dry surfaces, and will rapidly biodegrade under normal environmental conditions as described in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r) and *Draft Environmental Media, General Population, and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2025g). The high water solubility of 6,200 mg/L, a log K_{OC} of 1.43, a log K_{OW} of 0.73, and an aquatic bioaccumulation factor (BAF) of 1.32 L/kg collectively indicate a high potential to remain in the water and low likelihood of adsorbing to organic matter present in soils and sediments. *o*-Phthalic acid is not expected to bioaccumulate or undergo trophic transfer in fish or aquatic organisms in significant amounts or be exposed to terrestrial species through this pathway.

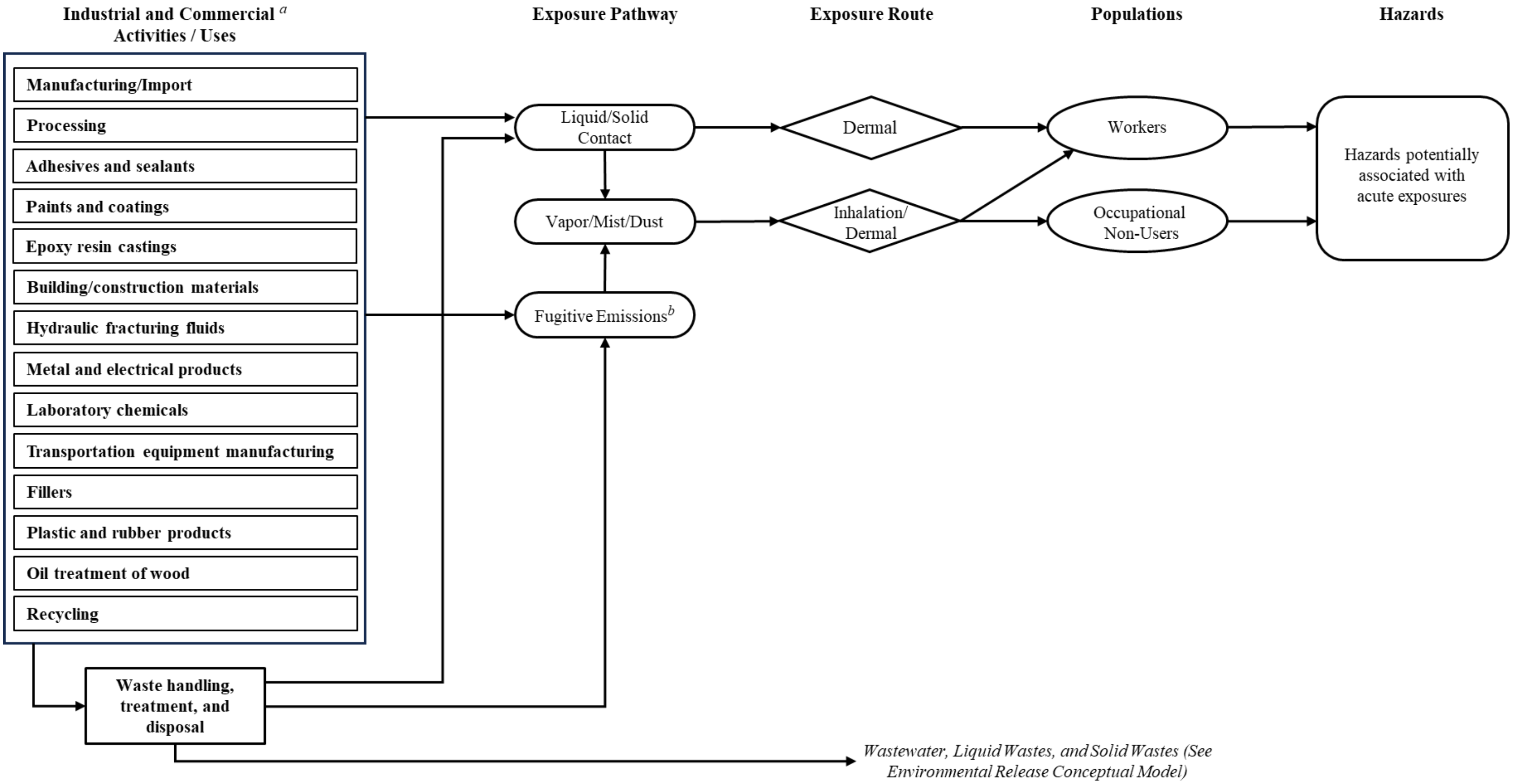


Figure 1-4. Phthalic Anhydride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

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

[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.

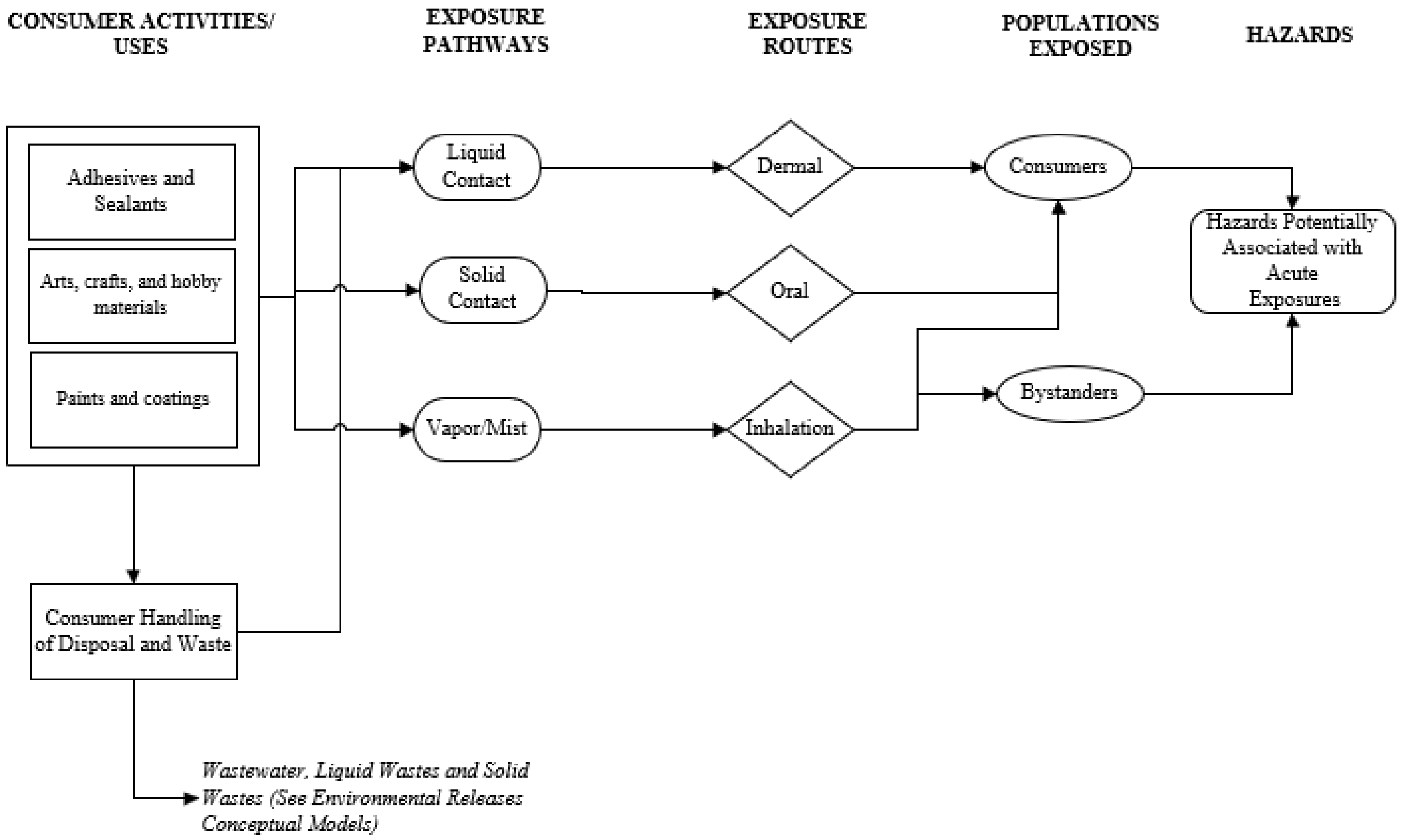


Figure 1-5. Phthalic Anhydride Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

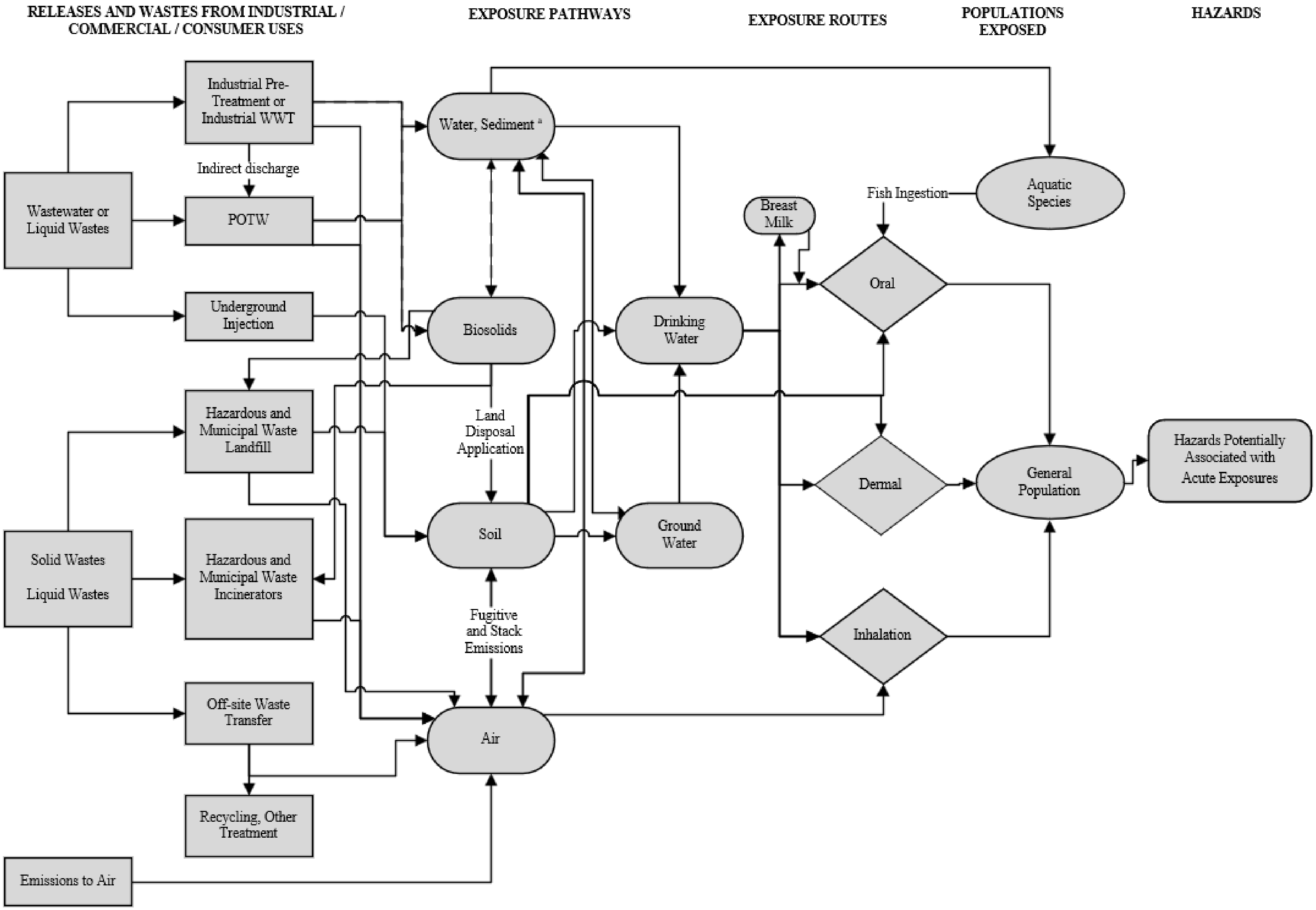
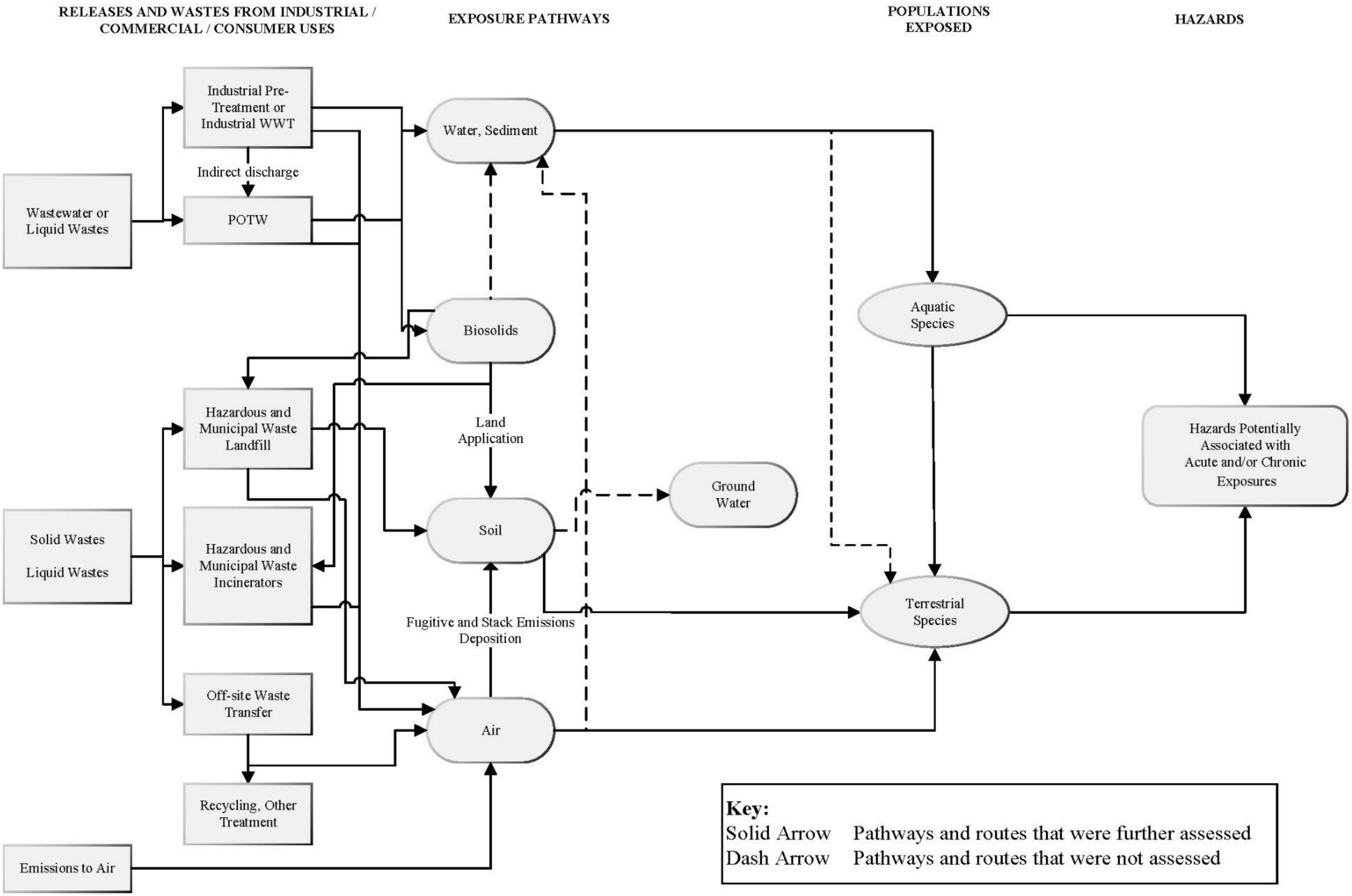


Figure 1-6. Phthalic Anhydride Conceptual Model for Environmental Releases and Wastes: General Population Hazards



732

733 **Figure 1-7. Phthalic Anhydride Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards**

1.2.2 Populations and Durations of Exposure Assessed

Based on the conceptual models presented in Section 1.2.10, 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 and chronic exposure scenarios, as applicable based on reasonably available exposure and hazard data, as well as the relevant populations for each. Human populations assessed include the following:

- Workers, including average adults
- ONUs, including average adult workers (individuals of both sexes age 16+ years, including pregnant workers)
- Consumers and bystanders
- General population, including infants (<1 year), toddlers (1–5 years), children (6–10 years), youth (11–15 and 16–20 years), and adults (21+ years).

Note that the age groups for consumers, bystanders, and general population are different because each life stage used unique exposure factors (*e.g.,* mouthing, drinking water ingestion). These exposure factors used in this evaluation are provided in EPA's *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011b).

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

This draft 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. Incorporated PESS include people exposed to phthalic anhydride in the workplace, people who frequently use consumer products and/or articles containing high concentrations of phthalic anhydride, and people exposed to *o*-phthalic acid following releases of phthalic anhydride to the environment (*i.e.,* the general population). Section 4.3.5 summarizes how PESS were incorporated into the draft 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.

1.3 Organization of the Risk Evaluation

This draft risk evaluation for phthalic anhydride includes five additional major sections, and several appendices:

- Section 2 summarizes basic physical and chemical characteristics as well as the fate and transport of phthalic anhydride.
- Section 3 includes an overview of releases and concentrations of phthalic anhydride 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 the 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 phthalic anhydride. 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 preliminary determination of whether phthalic anhydride presents an unreasonable risk of injury to human health or the environment, under the 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 phthalic anhydride.
- Appendix C incudes a list and citations for all TSDs and supplemental files included in the draft risk evaluation package for phthalic anhydride.
- Appendix D provides a summary of updates made to COUs for phthalic anhydride from the final scope document to this draft risk evaluation.
- Appendix E provides descriptions of the phthalic anhydride COUs evaluated by EPA.
- Appendix F provides the draft occupational exposure value for phthalic anhydride that was derived by EPA.

2 CHEMISTRY AND FATE AND TRANSPORT OF PHTHALIC ANHYDRIDE

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 phthalic anhydride informs the specific exposure pathways, and potential human and environmental exposed populations that EPA considered in this risk evaluation. In the natural ambient environment, phthalic anhydride is expected to rapidly hydrolyze to *o*-phthalic acid in the presence of water (Figure 2-1). The hydrolysis half-life is estimated to be between 30 to 90 seconds in surface water, depending on pH, with complete hydrolysis in approximately 8 minutes in simulated seawater or physiological fluids (Andres et al., 2001). Within the atmosphere, the rate of hydrolysis is directly influenced by atmospheric conditions such as humidity and temperature and is generally assumed to occur on the order of minutes. However, phthalic anhydride industrial processes require dry and well-ventilated environments and therefore phthalic anhydride is expected to persist longer under industrial settings. Therefore, the Agency evaluated both chemical substances as described in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r).

Sections 2.1 summarizes the physical and chemical properties of phthalic ahydride as well as its immediate hydrolysis product, *o*-phthalic acid. Section 2.2 summarizes the environmental fate and transport of phthalic anhydride and *o*-phthalic acid. For more information, see the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r).

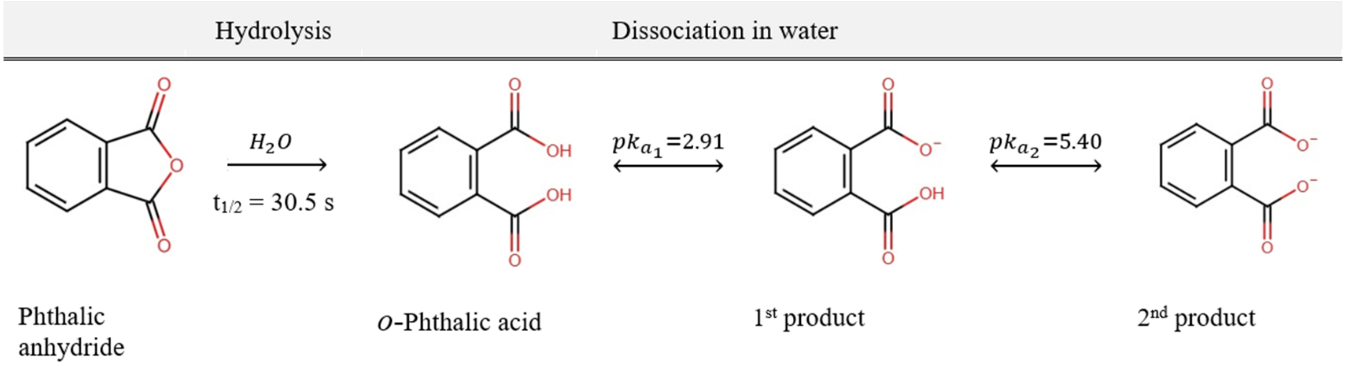


Figure 2-1 General Illustration of Phthalic Anhydride Rapid Hydrolysis and Expected Dissociation of *o*-Phthalic Acid in Water

2.1 Summary of Physical and Chemical Properties

EPA gathered and evaluated data and information on the physical and chemical properties of phthalic anhydride and *o*-phthalic acid as described in the *Draft Systematic Review Protocol for Phthalic Anhydride* (U.S. EPA, 2026u). EPA considered both measured and estimated physical and chemical property data/information as described in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r). The selected values are 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 Phthalic Anhydride* (U.S. EPA, 2026i).

In general, phthalic anhydride is a white solid with the melting and boiling points of 130.8 °C and 284.05 °C, respectively (NIST, 2022; DOE, 2016). Phthalic anhydride has a water solubility of 6,200 mg/L at 25 °C (U.S. EPA, 2019b). Once in water, phthalic anhydride will rapidly hydrolyze to *o*-phthalic acid. *o*-Phthalic acid is a white solid with the melting and boiling points of 206.75 °C and 324.85 °C, respectively (NCBI, 2020b; Booth et al., 2012). *o*-Phthalic acid has a water solubility of 6,994 mg/L at 24 °C (U.S. EPA, 2020c) and a log K_{OW} of 0.73 (U.S. EPA, 2020c). With a vapor pressure of 6.36×10^{-7} mmHg at 25 °C (U.S. EPA, 2020c), *o*-phthalic acid is not expected to volatilize from dry non-adsorbing surfaces. The selected Henry's Law constant for *o*-phthalic acid is less than 1×10^{-10} atm·m^3/mol at 25 °C (U.S. EPA, 2012), which indicates that is not expected to volatilize from water. The physical and chemical properties of *o*-phthalic anhydride and *o*-phthalic acid are also summarized below in Table 2-1.

Table 2-1. Physical and Chemical Properties of Phthalic Anhydride and *o*-Phthalic Acid

Property	**Phthalic Anhydride Selected Value(s)**	***o*-Phthalic Acid Selected Value(s)**	**Reference(s)**	**Overall Data Quality Rating**
Molecular formula	$C_8H_4O_3$	$C_8H_6O_4$	–	–
Molecular weight	148.11 g/mol	166.13 g/mol	–	–
Physical form	Colorless to white lustrous solid	White crystals or fine white powder	Elsevier (2020); NCBI (2020a)	High
Melting point	130.8 °C	206.75 °C	DOE (2016); Booth et al. (2012)	High
Boiling point	284.05 °C	324.85 °C	NIST (2022); NCBI (2020b)	High
Density	1.527 g/cm^3	1.593 g/cm^3	NCBI (2020b); Elsevier (2019)	High
Vapor pressure	5.17E−04 mmHg at 25 °C	6.36E−07 mmHg at 25 °C	U.S. EPA (2020c); NLM (2015)	High
Vapor density	5.1 at 25 °C	5.7 at 25 °C	NCBI (2020b, 2020c)	High
Water solubility	6,200 mg/L at 25 °C	6,994 mg/L at 25 °C	U.S. EPA (2020c, 2019b)	High
Octanol:water partition coefficient (log K_{OW})	1.43	0.73	U.S. EPA (2020c); Elsevier (2019)	High
Octanol:air partition coefficient (log K_{OA})	5.656[a]	11.120[a]	U.S. EPA (2017)	High
Henry's Law constant	1.70E−08 atm·m^3/mol at 25 °C	<1E−10 atm·m^3/mol at 25 °C (calculated from VP/WS)[a]	NCBI (2020a); U.S. EPA (2012)	Medium
Flash point	152 °C	168 °C	Rumble (2018)	High
Autoflammability	584 °C	–	Park and Sheehan (2000)	High
Viscosity	1.125 cP (centipoise)	–	NCBI (2020a)	High
Dissociation constants (pKa)	–	pKa_1= 2.91 pKa_2= 5.399	Tummanapelli and Vasudevan (2015); Partanen and Covington (2006)	High

[a] Predicted value determined with EPI Suite U.S. EPA (2017).

2.2 Summary of Environmental Fate and Transport

Under normal environmental conditions, solid phthalic anhydride is expected to react with available water by breaking the anhydride ring (hydrolysis) and forming solid *o*-phthalic acid in the order of minutes (NCBI, 2020c), as shown in Figure 2-1. Therefore, EPA focused on the environmental fate and transport of *o*-phthalic acid as it is the main transformation product of phthalic anhydride released into the environment.

In assessing the environmental fate and transport of *o*-phthalic acid, EPA considered reasonably available environmental fate data including biotic and abiotic biodegradation rates, removal of *o*-phthalic acid during wastewater treatment, volatilization from lakes and rivers, and its organic carbon:water partition coefficient (log K_{OC}). The full range of results from data sources that were rated high- and medium-quality were evaluated. Medium-quality data sources were considered for fate endpoints when no high-quality data sources were available for the chemical.

Information on the full extracted dataset is available in the file *Draft Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport for Phthalic Anhydride* (U.S. EPA, 2026g). When no measured data were available from high- or medium-quality data sources, fate values were derived from EPI Suite™ (U.S. EPA, 2017), a predictive tool for physical and chemical properties and environmental fate estimation. Information regarding the model inputs is available in Section 3.2.1 of the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r).

EPA evaluated the reasonably available information to characterize the environmental fate and transport of phthalic anhydride; the key points of the fate assessment for phthalic anhydride (U.S. EPA, 2026r) are summarized below and listed in Table 2-2.

Given the consistent results from numerous high-quality studies, there is robust confidence that phthalic anhydride will rapidly hydrolyze into *o*-phthalic acid in the presence of water.

Below is a summary of the environmental fate and transport characteristics of *o*-phthalic acid in the environment, *o*-phthalic acid:

- has chromophores that absorb in the visible range of the solar light spectrum and is expected to undergo direct and indirect photolysis;
- is expected to be subject wet and dry deposition reducing its persistence in the atmosphere;
- will biodegrade in aerobic surface water, soil, groundwater, landfills;
- will not be efficiently removed during sorption-based wastewater treatment, expected to be partially removed during aerobic biodegradation (based on mean hydraulic retention times of 50 U.S. publicly owned treatment works facilities), and with a major fraction being present in effluent;
- is not bioaccumulative;
- is not expected to be efficiently removed during conventional drinking water treatment; and
- is expected to have negligible sorption to organic content in landfills and will rapidly migrate to landfill leachate and groundwater.

Table 2-2. Summary of Environmental Fate Information for *o*-Phthalic Acid[a]

Parameter	Value	Reference(s)	Overall Data Quality Rating
Octanol:Water Partition Coefficient (log K_{OW})	0.73	U.S. EPA (2020c)	High
Organic Carbon:Water Partition Coefficient (log K_{OC})	1.07 (average of experimental K_{OC} values) 0.89 (average of predicted K_{OC} values)	NCBI (2020b); U.S. EPA (2020c)	Medium
Adsorption Coefficient (log K_d)	2.65–3.10 (suspended particulate matter/water)	Dagnelie et al. (2014)	High
Octanol:Air Partition Coefficient (log K_{OA})	11.120 (EPI Suite estimate)	U.S. EPA (2017)	High
Air:Water Partition Coefficient (log K_{AW})	−9.087 (air/water part. coef.) (estimated)	U.S. EPA (2017)	High
Aerobic primary biodegradation in water – removal	100% in 14 days $t_{1/2} < 3$ days at pH = 7.2	Fujita et al. (2005)	High
Aerobic ultimate biodegradation water	40 to 50% loss and $t_{1/2}$= 9–18 days (AS)	Fujita et al. (2005)	High
Anaerobic biodegradation in water	85% to complete mineralization after 8 weeks	Shelton and Tiedje (1984)	High
Aerobic biodegradation in soil	Complete biodegradation at initial concentrations lower than 100 mg/L under aerobic conditions. $t_{1/2}$ = 0.6 days (25 mg/L) $t_{1/2}$ = 7 days (500 mg/L)	Zhao et al. (2016)	High
Anaerobic biodegradation in landfill – removal	50 mg/L *o*-phthalic acid completely mineralized under simulated anaerobic landfill conditions after 100 days and pH of 7	Ejlertsson et al. (1996)	High
Anaerobic biodegradation in sediment – removal	82.7% degradation of 20 mg/L *o*-phthalic acid after 44 days on water and sediment slurry solutions under anaerobic conditions at room temperature	Liu et al. (2005)	High
Photolysis	Direct: Expected to be susceptible to direct photolysis by sunlight; contains chromophores that absorb at wavelengths >290 nm	NCBI (2020b)	High
	Indirect: $t_{1/2}$ = 8.65 days (estimated; based on a 12-hour day with 1.5×10^{6} ·OH/cm^3 and ·OH rate constant of 1.237×10^{-12} cm^3/molecule-sec)	U.S. EPA (2017)	High

Parameter	Value	Reference(s)	Overall Data Quality Rating
Environmental degradation half-lives (selected values for modeling)	8.65 days (air) 3 days (water) 6 days (soil) 27 days (sediment)	U.S. EPA (2017)	High
Wastewater treatment plant (WWTP) Removal	2 % (predicted sorption) 10–20 % (estimated based on hydraulic retention time of 1.4 days and aerobic biodegradation)	U.S. EPA (2017)	High
Aquatic bioconcentration factor (BCF)	3.2 L/kg, calculated from the octanol-water partition coefficients (log Kow = 0.73)	OECD (2005)	High
Aquatic bioaccumulation factor (BAF)	1.32 L/kg wet weight (upper trophic Arnot-Gobas estimation)	U.S. EPA (2020c)	High

[a] Additional information on value selection can be found in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r).

3 RELEASES AND CONCENTRATIONS OF PHTHALIC ANHYDRIDE IN THE ENVIRONMENT

EPA estimated environmental releases and concentrations of phthalic anhydride. 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 phthalic anhydride in the environment.

3.1 Approach and Methodology

This section provides an overview of the approach and methodology for assessing releases to the environment from industrial, commercial, and consumer uses. Specifically, Sections 3.1.1 through 3.1.2 describe the approach and methodology for estimating releases to the environment from industrial and commercial uses.

3.1.1 Manufacturing, Processing, Industrial and Commercial

This subsection describes the grouping of manufacturing, processing, industrial and commercial COUs into occupational exposure scenarios (OESs) as well as the use of phthalic anhydride 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 phthalic anhydride 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, whereas Table 3-2 provides the reverse: a crosswalk of OESs to COUs. 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, whereas 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 Phthalic Anhydride* (U.S. EPA, 2026o) provides further information on specific OESs.

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

COU			OES
Life Cycle Stage	**Category**	**Subcategory**	
Manufacturing	Domestic manufacturing	Domestic manufacturing	Manufacturing
	Importing	Importing	Import and repackaging
Processing	Repackaging	Repackaging	Import and repackaging
	Processing as a reactant	Intermediate (all other basic organic chemical manufacturing; Paint and coating manufacturing; Flame retardant manufacturing)	Processing as a reactant
		Intermediate (plastic material and resin manufacturing; construction)	Plastic compounding

COU			OES
Life Cycle Stage	**Category**	**Subcategory**	
Processing	Processing as a reactant	Monomer (plastic material and resin manufacturing)	Plastic compounding
		Monomer (all other basic organic chemical manufacturing)	Processing as a reactant
		Ion exchange agent (all other basic organic chemical manufacturing)	Processing as a reactant
		Pigments (printing ink manufacturing)	Processing as a reactant
		Polymerization promoter (synthetic dye and pigment manufacturing)	Processing as a reactant
		Plasticizer (plastics product manufacturing)	Plastic compounding; Plastic converting
		Plasticizer (adhesive manufacturing; Lubricant additive manufacturing)	Processing as a reactant
	Incorporation into formulations, mixtures, or reaction products	Intermediate (all other basic organic chemical manufacturing; All other basic inorganic chemical manufacturing; Adhesive manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Intermediate (plastic material and resin manufacturing)	Plastic compounding
		Monomer (plastic material and resin manufacturing)	Plastic compounding
		Plasticizers (plastic material and resin manufacturing)	Plastic compounding
		Plasticizers (paint and coating manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Paint additives and coating additives not described by other categories (plastics material and resin manufacturing)	Plastic compounding
		Dyes (synthetic dye and pigment manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Retarder (rubber product manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Flame retardant (plastics product manufacturing)	Plastic compounding; Plastic converting
		Binder (paint and coating manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Hardener (paint and coating manufacturing; Solvent-based paint; adhesive manufacturing; Rubber product manufacturing; Utilities)	Incorporation into formulations, mixtures, or reaction products

COU			OES
Life Cycle Stage	**Category**	**Subcategory**	
Processing	Incorporation into formulations, mixtures, or reaction products	Hardener (epoxy resin casting)	Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)
		Solvent (paint and coating manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Solvent (plastic material and resin manufacturing)	Plastic compounding
		Processing aid (paint and coating manufacturing; rubber product manufacturing)	Incorporation into formulations, mixtures, or reaction products
		Pre-catalyst manufacturing	Incorporation into formulations, mixtures, or reaction products
		Polymerization promoter (all other basic organic chemical manufacturing)	Incorporation into formulations, mixtures, or reaction products
	Recycling	Recycling	Disposal and recycling
Disposal	Disposal	Disposal	Disposal and recycling
Distribution in commerce	N/A	N/A	Distribution in commerce
Industrial use	Processing aids, specific to petroleum production	Hydraulic fracturing	Use of lubricants and functional fluids
	Adhesives and sealants	Adhesives and sealants	Application of paints, coatings, adhesives, and sealants (non-spray)
	Paints and coatings	Paints and coatings	Application of paints, coatings, adhesives, and sealants (spray and non-spray)
Industrial use	Construction products	Construction and building materials covering large surface areas	Fabrication or use of final products or articles (fabrication)
	Metal and electrical products	Machinery, mechanical appliances, electrical/electronic articles	Application of paints, coatings, adhesives, and sealants (non-spray)
	Other	Laboratory chemicals	Use of laboratory chemicals
	Automotive and aerospace products	Transportation equipment manufacturing	Application of paints, coatings, adhesives, and sealants (spray and non-spray)

COU			OES
Life Cycle Stage	**Category**	**Subcategory**	
Commercial use	Adhesives and sealants	Adhesives and sealants	Application of paints, coatings, adhesives, and sealants (non-spray)
Commercial use	Fillers	Hardener (*e.g.,* epoxy hardener)	Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)
	Other	Laboratory chemicals	Use of laboratory chemicals
	Transportation equipment manufacturing	Transportation equipment manufacturing	Application of paints, coatings, adhesives, and sealants (spray and non-spray)
	Plastic and rubber products	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); other (rubber products)	Fabrication or use of final products or articles (routine use)
	Furniture and furnishings	Oil treatment of wood	Application of paints, coatings, adhesives, and sealants (spray and non-spray)
	Paints and coatings	Paints and coatings	Application of paints, coatings, adhesives, and sealants (spray and non-spray)
	Construction products	Construction and building materials covering large surface areas	Fabrication or use of final products or articles (fabrication)
	Metal and electrical products	Machinery, mechanical appliances, electronic/electronic articles	Application of paints, coatings, adhesives, and sealants (non-spray)

[a] Life cycle stage use definitions (40 CFR 711.3):

- "Industrial use" means use at a site at which 1 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 (COUs) appear in the life cycle diagram, reflect Chemical Data Reporting (CDR) codes, and broadly represent COUs of phthalic anhydride in industrial and/or commercial settings.

[c] These subcategories represent more specific activities within the life cycle stage and category of the COU of phthalic anhydride.

[d] An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within an occupational COU. The occurrence of releases/exposures may be similar across multiple COUs (multiple COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given COU (single COU mapped to multiple OESs).

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

OES [a]	COU		
	Life Cycle Stage [b]	Category [c]	Subcategory [d]
Manufacturing	Manufacturing	Domestic manufacturing	Domestic manufacturing
Import and repackaging	Manufacturing	Importing	Importing
	Processing	Repackaging	Repackaging
Processing as a reactant	Processing	Processing as a reactant	Intermediate (all other basic organic chemical manufacturing; Paint and coating manufacturing; flame retardant manufacturing)
			Monomer (all other basic organic chemical manufacturing)
			Ion exchange agent (all other basic organic chemical manufacturing)
			Pigments (printing ink manufacturing)
			Polymerization promoter (synthetic dye and pigment manufacturing)
			Plasticizer (adhesive manufacturing; Lubricant additive manufacturing)
Plastic compounding	Processing	Processing as a reactant	Intermediate (plastic material and resin manufacturing; Plastic product manufacturing; Construction)
			Monomer (plastic material and resin manufacturing)
			Plasticizer (plastics product manufacturing)
		Incorporation into formulations, mixtures, or reaction products	Intermediate (plastic material and resin manufacturing)
			Monomer (plastic material and resin manufacturing)
			Plasticizers (plastic material and resin manufacturing)
			Paint additives and coating additives not described by other categories (plastics material and resin manufacturing)
			Flame retardant (plastics product manufacturing)
			Solvent (plastic material and resin manufacturing)

OES [a]	**COU**		
	Life Cycle Stage [b]	**Category** [c]	**Subcategory** [d]
Incorporation into formulations, mixtures, or reaction products	Processing	Incorporation into formulations, mixtures, or reaction products	Intermediate (all other basic organic chemical manufacturing; All other basic inorganic chemical manufacturing; Adhesive manufacturing)
			Plasticizers (paint and coating manufacturing)
			Dyes (synthetic dye and pigment manufacturing)
			Retarder (rubber product manufacturing)
			Binder (paint and coating manufacturing)
			Hardener (paint and coating manufacturing; Solvent-based paint; Adhesive manufacturing; Rubber product manufacturing; Utilities)
			Solvent (paint and coating manufacturing)
			Processing aid (paint and coating manufacturing; Rubber product manufacturing)
			Pre-catalyst manufacturing
			Polymerization promoter (all other basic organic chemical manufacturing)
Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	Processing	Incorporation into formulations, mixtures, or reaction products	Hardener (epoxy resin casting)
	Commercial use	Fillers	Hardener (*e.g.*, epoxy hardener)
Plastic converting	Processing	Processing as a reactant	Plasticizer (plastics product manufacturing)
		Incorporation into formulations, mixtures, or reaction products	Flame retardant (plastics product manufacturing)
Disposal and recycling	Processing	Recycling	Recycling
	Disposal	Disposal	Disposal
Application of paints, coatings, adhesives, and sealants (non-spray)	Industrial uses	Adhesives and sealants	Adhesives and sealants
		Metal and electrical products	Machinery, mechanical appliances, electrical/electronic articles
	Commercial use	Adhesives and sealants	Adhesives and sealants
		Metal and electrical products	Machinery, mechanical appliances, electronic/ electronic articles

OES [a]	COU		
	Life Cycle Stage [b]	Category [c]	Subcategory [d]
Application of paints, coatings, adhesives, and sealants (spray and non-spray)	Industrial use	Paints and coatings	Paints and coatings
		Automotive and aerospace products	Transportation equipment manufacturing
	Commercial use	Furniture and furnishings	Oil treatment of wood
		Paints and coatings	Paints and coatings
		Transportation equipment manufacturing	Transportation equipment manufacturing
Use of laboratory chemicals	Industrial use	Other	Laboratory chemicals
	Commercial use	Other	Laboratory chemicals
Use of lubricants and functional fluids	Industrial use	Processing aids, specific to petroleum production	Hydraulic fracturing
Fabrication or use of final products or articles (fabrication)	Industrial use	Construction products	Construction and building materials covering large surface areas
	Commercial use	Construction products	Construction and building materials covering large surface areas
Fabrication or use of final products or articles (routine use)	Commercial use	Plastic and rubber products	Other articles with routine direct contact during normal use including rubber articles; Plastic articles (hard); Other (rubber products)

[a] An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within an occupational condition of use (COU). The occurrence of releases/exposures may be similar across multiple conditions of use (multiple COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given COU (single COU mapped to multiple OESs).

[b] Life cycle stage use definitions (40 CFR 711.3):
- "Industrial use" means use at a site at which 1 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.

[c] These categories of COU appear in the life cycle diagram, reflect Chemical Data Reporting (CDR) codes, and broadly represent COUs of phthalic anhydride in industrial and/or commercial settings.

[d] These subcategories represent more specific activities within the life cycle stage and category of the COU of phthalic anhydride.

3.1.1.2 Description of Phthalic Anhydride Use for Each OES

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

Table 3-3. Description of the Function of Phthalic Anhydride for Each OES

OES	Role/Function of Phthalic Anhydride
Manufacturing	Phthalic anhydride is typically produced through the catalytic vapor-phase air oxidation of either *o*-xylene or naphthalene.
Import and repackaging	Phthalic anhydride may be imported in molten liquid or flaked solid form for use, repackaging, storage, and/or redistribution. Also, molten liquid phthalic anhydride may be processed into a flaked solid upon import.
Processing as a reactant	Phthalic anhydride is primarily used as an intermediate or monomer in the development of plasticizers used in plastics, rubbers, and other products such as paints, coatings, adhesives, sealants, dyes, and pigment products.
Incorporation into formulations, mixtures, or reaction products	Phthalic anhydride is incorporated into formulations as an intermediate or monomer in the development of plasticizers used in plastics, rubbers, and other products such as paints, coatings, adhesives, sealants, dyes, and pigment products.
Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	This OES is a subset of incorporation into formulations, mixtures, or reaction products, and is specifically intended to characterize elevated inhalation exposures from the use of phthalic anhydride as a filler in casting hardening operations for applications such as countertop manufacturing.
Plastic compounding	Phthalic anhydride is processed as an intermediate or monomer in the development of plasticizers used in plastics and rubbers. Phthalic anhydride may serve as a hardener or flame retardant in these products.
Plastic converting	Phthalic anhydride may exist in plastic or resin material intended for conversion into final plastic articles. Phthalic anhydride may serve as a hardener or flame retardant in final plastic articles.
Application of paints, coatings, adhesives, and sealants	Phthalic anhydride is processed in formulations that become paint, coating, adhesive, and sealant products. Although largely consumed in reaction, several products indicate the presence of phthalic anhydride.
Use of laboratory chemicals	Phthalic anhydride is a laboratory chemical used for laboratory analyses in liquid and solid forms. The solid form is typically concentrated (90 – 100%) and the liquid form is typically a low concentration mixture (< 1%).
Use of lubricants and functional fluids	Phthalic anhydride is used in processing lubricant and hydraulic fluid formulations and may exist in low concentrations in these products.
Fabrication or use of final product or articles	Phthalic anhydride is found in a wide array of different final articles not found in other OES such as building and construction materials.
Disposal and recycling	Upon fabrication or use of phthalic anhydride-containing products, residual chemicals are disposed and released to air, wastewater, or disposal facilities. Some materials that contain phthalic anhydride may be recycled either in-house or at recycling facilities to manufacture new materials.
Distribution in commerce	Distribution in commerce consists of the transportation associated with the moving of phthalic anhydride-containing products and/or articles between sites manufacturing, processing, and use COUs, or the transportation of phthalic anhydride containing wastes to recycling sites or for final disposal.

3.1.2 Daily Release Estimation

For each OES, EPA estimated releases to each media of release using Toxics Release Inventory (TRI) data (2019–2023) and National Emissions Inventory (NEI) data (2017 and 2020) as shown in Figure 3-1. As mentioned in Section 4.1.2, EPA used NEI, generic scenarios (GSs), or emission scenario documents (ESDs) to estimate number of release days, which EPA used to convert between annual release estimates and daily release estimates. EPA used 2020 CDR, TRI, NEI, GSs, and ESDs to estimate the number of sites using phthalic anhydride within an OES. The *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) describes EPA's approach and methodology for estimating daily releases and provides detailed facility level results for each OES.

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

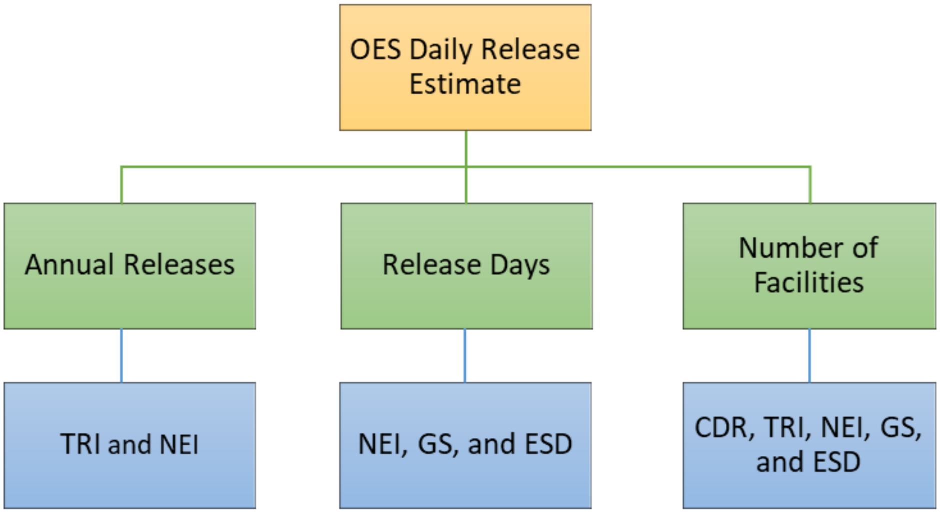


Figure 3-1. Overview of EPA's Approach to Estimate Daily Releases for Each OES
TRI = Toxics Release Inventory; NEI = National Emissions Inventory; CDR = Chemical Data Reporting; GS = generic scenario; ESD = emission scenario document

3.1.3 Consumer (Down-the-Drain) and Landfills

For down-the-drain releases of phthalic anhydride from consumer COUs, EPA used the quantitative (modeling) exposures to the general population from environmental releases as an appropriate screening and upper bound approach to consumer products down-the-drain environmental release assessment.

Phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid when it reacts with water or moisture in the air. This transformation is immediate with the hydrolysis half-life estimated to be between 30 to 90 seconds, depending upon pH. Given the rapid hydrolysis of phthalic anhydride to *o*-phthalic acid, EPA assumed that all phthalic anhydride that is released down the drain is transformed to the acid form. EPA acknowledges that there may be *o*-phthalic acid releases to the environment via the cleaning and disposal of adhesives, sealants, paints, and coatings; however, the Agency did not quantitatively assess down-the-drain and disposal scenarios of consumer products because the limited information from monitoring data show very low concentrations in surface waters (see Section 4.2.1 in the *Draft Environmental Media and General Population Exposure Technical Support Document* (U.S. EPA, 2026n)). The surface water and drinking water modeling and subsequent general population exposure analysis is used to estimate exposures from releases to the environment.

Adhesives, sealants, paints, and coatings can be disposed of down-the-drain while 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. Any solid products and articles listed 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. Sections 3.1 and 3.2 in the *Draft Environmental Media and General Population Exposure for Phthalic Anhydride)* (U.S. EPA, 2026n) summarizes phthalic anhydride and *o*-phthalic acid monitoring data identified for biosolids and soils, and landfills respectively. Briefly, no studies were identified that reported the concentration of phthalic anhydride in landfills or in the surrounding areas in the United States. *o*-Phthalic acid may be present in soil through the application of biosolids or otherwise introduced to topsoil is expected to be mobile in water and may leach into groundwater due to the low tendency of *o*-phthalic acid to sorb to organic media and soil (log K_{OW} = 0.73; log K_{OC} = 1.07). Biodegradation of *o*-phthalic acid in groundwater is expected to be rapid with a half-life of days (Tang et al., 2017; Fujita et al., 2005). It is also expected to biodegrade rapidly in soil with a half-life of days to weeks, which will retard its movement to groundwater (Zhao et al., 2016; Fujita et al., 2005; Shelton and Tiedje, 1984). In summary, while phthalic anhydride in the form of *o*-phthalic acid releases into the environment are possible from down-the-drain and disposal of consumer products to landfills, biodegradation data show that *o*-phthalic acid will biodegrade rapidly in soil and groundwater and thus is not expected to persist in the environment.

3.2 Summary of Environmental Releases

3.2.1 Manufacturing, Processing, Industrial and Commercial

EPA combined its estimates for annual releases, release days, and number of facilities to estimate a range of daily releases for each OES. Table 3-4 presents a summary of these ranges across facilities, and Table 3-5 provides additional detail on deriving the overall confidence score for each OES. For OESs without data from TRI or NEI, EPA provided a qualitative assessment of environmental release.

Table 3-4. Summary of EPA's Annual and Daily Release Estimates for Each OES

OES	Type of Discharge [a], Air Emission [b], or Disposal [c]	Estimated Annual Release (kg/site-year) [d]		Estimated Daily Release (kg/site-day) [e]		Number of Facilities [f]	Sources
		Central Tendency	High-End	Central Tendency	High-End		
Manufacturing	Stack air	64	2.6E04	0.21	70	8	NEI
	Stack air	1.4E03	2.9E04	3.8	80	8	TRI
	Fugitive air	4.6	6.8E03	1.5E−02	19	8	NEI
	Fugitive air	61	1.4E04	0.20	39	8	TRI
	Wastewater	0	0	0	0	8	TRI
	Land	0	2.7E03	0	7.4	8	TRI
Import and repackaging	Stack air	113	227	0.44	0.87	4	TRI
	Fugitive air	113	227	0.44	0.87	4	TRI
	Wastewater	113	227	0.44	0.87	4	TRI
	Land	0	0	0	0	4	TRI
Processing as a reactant	Stack air	0.14	982	5.0E−04	2.7	39	NEI
	Stack air	84	912	0.31	3.3	58	TRI
	Fugitive air	1.3	291	3.7E−03	1.2	39	NEI
	Fugitive air	104	338	0.37	1.4	58	TRI
	Wastewater	2.3	351	9.1E−03	1.4	58	TRI
	Land	0	2.6E03	0	11	58	TRI
Incorporation into formulations, mixtures, or reaction products	Stack air	0.93	37	3.7E−03	0.15	4	NEI
	Stack air	1.1	151	4.5E−03	0.60	9	TRI
	Fugitive air	2.3	20	9.1E−03	8.0E−02	4	NEI
	Fugitive air	4.5E−02	153	1.8E−04	0.61	9	TRI
	Wastewater	0	136	0	0.54	9	TRI
	Land	0	1.5E03	0	6.0	9	TRI

OES	Type of Discharge [a], Air Emission [b], or Disposal [c]	Estimated Annual Release (kg/site-year) [d]		Estimated Daily Release (kg/site-day) [e]		Number of Facilities [f]	Sources
		Central Tendency	High-End	Central Tendency	High-End		
Plastic compounding	Stack air	9.7	970	3.3E−02	3.8	46	NEI
	Stack air	61	1.5E03	0.25	6.0	51	TRI
	Fugitive air	6.6	621	2.7E−02	2.3	46	NEI
	Fugitive air	60	903	0.24	3.2	51	TRI
	Wastewater	0	227	0	0.92	51	TRI
	Land	0	2.4E03	0	9.6	51	TRI
Plastic converting	Stack air	90	794	0.36	3.1	4	NEI
	Fugitive air	0	135	0	0.52	4	NEI
	Wastewater, Land	Q [g]	Q [g]	Q [g]	Q [g]	N/A	N/A
Application of paints, coatings, adhesives, and sealants [h]	Stack air	0	176	0	0.83	32	NEI
	Stack air	73	336	0.29	1.3	7	TRI
	Fugitive air	0	88	0	0.32	32	NEI
	Fugitive air	267	1.1E03	1.1	4.4	7	TRI
	Wastewater	0	0	0	0	7	TRI
	Land	0	3.0E03	0	12	7	TRI
Use of laboratory chemicals	Stack air	0	0.50	0	1.9E−03	5	NEI
	Fugitive air	9.1E−03	0.20	3.5E−05	5.7E−04	5	NEI
	Wastewater, land	Q [i]	Q [i]	Q [i]	Q [i]	N/A	N/A
Use of lubricants and functional fluids	Air, water, land	Q [i]	Q [i]	Q [i]	Q [i]	N/A	N/A
Fabrication or final use of products or articles	Air, water, land	Q [j]	Q [j]	Q [j]	Q [j]	N/A	N/A

OES	Type of Discharge [a], Air Emission [b], or Disposal [c]	Estimated Annual Release (kg/site-year) [d]		Estimated Daily Release (kg/site-day) [e]		Number of Facilities [f]	Sources
		Central Tendency	High-End	Central Tendency	High-End		
Disposal and recycling	Stack air	9.1E−02	56	2.5E−04	0.15	15	NEI
	Stack air	3.2E−02	72	8.7E−05	0.20	18	TRI
	Fugitive air	0	29	0	8.0E−02	15	NEI
	Fugitive air	2.7E−02	5.7	7.5E−05	1.6E−02	18	TRI
	Wastewater	0	0	0	0	18	TRI
	Land	0	6.8E03	0	19	18	TRI

[a] Direct discharge to surface water; indirect discharge to non-POTW; indirect discharge to POTW. Details on wastewater release streams for each facility are presented in the *Draft Summary of Facility Release Data for Phthalic Anhydride* (U.S. EPA, 2025i).
[b] Emissions via fugitive air and/or stack air.
[c] Land releases were reported to on-site underground class 1 wells, on-site and off-site underground injection, on-site and off-site RCRA subtitle C landfills, off-site landfills, other off-site land disposal, off-site surface impoundments, and transfers to off-site waste brokers.
[d] For EPA release data (*i.e.,* TRI and NEI), the presented central tendency is calculated from the median reported release amounts and high-end from the reported maximum release amounts. The specific central tendency and high-end values presented depends on the number of sites with EPA data. For databases with 6 or more reporting facilities, EPA estimated central tendency and high-end releases using the 50th and 95th percentile values, respectively. For 3–5 facilities, EPA estimated the central tendency and high-end releases using the 50th percentile and maximum values, respectively. For two sites, EPA presented the midpoint and the maximum value. Finally, EPA presented sites with only 1 data point as-is from the EPA database.
[e] Where available, EPA used NEI data from facility operating schedules to estimate number of release days per year. Otherwise, EPA used peer-reviewed literature (*e.g.,* GSs or ESDs) to estimate the number of release days of phthalic anhydride within a COU.
[f] Number of facilities reporting releases is based on data from TRI and NEI databases.
[g] Qualitative assessment - Facilities that reported plastic compounding activities to TRI and NEI may also be involved with plastic converting. Therefore, it is assumed that releases to water and land from plastic converting activities are less than or equal to releases from plastic compounding facilities.
[h] Paints, coatings, adhesives, and sealants may be applied through spray application methods (*e.g.,* conventional spray gun) or through non-spray application methods (*e.g.,* brush). TRI and NEI databases do not provide the level of detail needed to determine the application method from each facility. Release estimates for paints, coatings, adhesives, and sealants are expected to be representative of the various application methods for products containing phthalic anhydride.
[i] Qualitative assessment – The uses of laboratory chemicals and lubricants/functional fluids are associated with a low production volumes (*i.e.,* <0.1% of total annual PV of phthalic anhydride). Therefore, it is expected that releases to air, water, and land from these uses are less than manufacturing and processing uses and will not significantly contribute to environmental concentrations of phthalic anhydride.
[j] Qualitative assessment – EPA expects releases from this OES to be small and disperse in comparison to other upstream OES, as EPA expects phthalic anhydride to be present in smaller amounts and predominantly remain in the final article, limiting the potential for release.

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

For each OES, EPA considered the assessment approach and the quality of the data, as well as 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 sources to develop environmental release estimates for phthalic anhydride. The Agency 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-to-robust, moderate, slight-to-moderate, or slight.

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, 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 with 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* (also called the "Draft Systematic Review Protocol") (U.S. EPA, 2021) 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. NEI obtained a high data quality rating and TRI obtained a medium quality rating from EPA's systematic review process.

1025 **Table 3-5. Summary of Overall Confidence in Environmental Release Estimates by OES**

OES(s)	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	Environmental releases to air, land, and water were assessed using reported releases from 2019–2023 TRI (U.S. EPA, 2023c) and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019d), and these sources received medium and high ratings from EPA's systematic review process, respectively. The assessment of release data from multiple EPA environmental release reporting databases increases confidence in release estimates. Further, these data capture environmental releases from eight manufacturing sites, which include all sites that reported manufacturing activities to the 2020 CDR. Because the EPA data provide a holistic assessment of releases from manufacturers of phthalic anhydride, there is increased confidence that the release data cover all known manufacturing releases in the United States. However, the most recent manufacturing data at the time of this assessment (*i.e.,* 2020 CDR) and the most recent release data (*i.e.,* 2023 TRI and 2020 NEI) may not capture the current market as manufacturers enter and exit the industry. The lack of manufacturing and release data for the current year creates uncertainty in the assessment. Nevertheless, manufacturing and associated release data remain stable and consistent across the available datasets. As discussed above, the main strength of the analysis includes using industry reported release data to various EPA databases. However, the limitations of the analysis include the uncertainties discussed above, such as the temporal relevancy of the release data compared with the current year. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate-to-robust.
Import and repackaging	Environmental releases to air, land, and water were assessed using reported releases from 2019–2023 TRI (U.S. EPA, 2023c), and this source received a medium rating from EPA's systematic review process. Sites reporting releases to TRI using Form A indicate that the sites could potentially release up to 500 lb total to all media; therefore, EPA conservatively assumed that 500 lb were released to each media for purposes of downstream exposure assessment. These values may overestimate releases since the facility would not be releasing the total amount to all media at the same time. This assumption strengthens confidence that the environmental releases evaluated are conservative with respect to the known reporting requirements of TRI. These data capture environmental releases from four import and repackaging sites; however, it was estimated that there may be 28–37 sites involved in import and repackaging of phthalic anhydride. Therefore, there are likely additional sites involved in import and repackaging activities without known or reported release quantities. However, facility releases that are reported to EPA databases are expected to represent the highest release levels throughout the industry since these facilities are exceeding program reporting thresholds. EPA expects the reported releases to reliably estimate the release potential from import and repackaging of phthalic anhydride. As discussed above, the strengths of the analysis includes using industry reported release data to various EPA databases and the conservatism of the assumptions regarding TRI Form A submissions. However, the limitations of the analysis include the uncertainties discussed above, such as not capturing all release sources. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate.
Processing as a reactant; Incorporation into	Environmental releases to air, land, and water were assessed using reported releases from 2019–2023 TRI (U.S. EPA, 2023c) and 2017–2020 NEI (U.S. EPA, 2023a, 2019d), and these sources received medium and high ratings from EPA's systematic review process, respectively. The assessment of release data from multiple EPA environmental release reporting databases increases

OES(s)	Weight of Scientific Evidence Conclusion in Release Estimates
formulations, mixtures, or reaction products; Plastic compounding	confidence in release estimates. Sites reporting releases to TRI using Form A indicate that the sites could potentially release up to 500 lb total to all media; therefore, EPA conservatively assumed that 500 lb were released to each media for purposes of downstream exposure assessment for these sites. These values may overestimate releases since the facility would not be releasing the total amount to all media at the same time. This assumption strengthens confidence that the environmental releases evaluated are conservative with respect to the known reporting requirements of TRI. These data capture environmental releases from 66 sites that process phthalic anhydride as a reactant; 9 sites that incorporate phthalic anhydride into formulations, mixtures or reaction products; and 55 sites that are involved in plastic compounding. However, it was estimated that there may be 108–321 sites involved in processing phthalic anhydride as a reactant, 34–180 sites involved in incorporative activities, and 47–153 involved in plastic compounding. Although there are release data for a large number of processing sites, there are likely additional sites involved in processing activities without known or reported release quantities. However, facility releases that are reported to EPA databases are expected to represent the highest release levels throughout the industry since these facilities are exceeding program reporting thresholds. EPA expects the reported releases to reliably estimate the release potential from processing of phthalic anhydride. As discussed above, the strengths of the analysis includes using industry reported release data to various EPA databases, the conservatism of the assumptions regarding TRI Form A submissions, and the large availability of release data for sites processing phthalic anhydride. However, the limitations of the analysis include the uncertainties discussed above, such as not capturing all release sources. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate-to-robust.
Plastic converting	Environmental releases to air were assessed using reported releases from 2017–2020 NEI (U.S. EPA, 2023a, 2019d), and these sources received high ratings from EPA's systematic review process. However, there were only 4 sites identified that reported air releases from plastic converting, and EPA estimated that there may be 110–300 sites involved in plastic converting of materials containing phthalic anhydride. Therefore, there is uncertainty regarding the representativeness of the air release data across all plastic converting sites. Furthermore, there were no release data for water or land from plastic converting facilities. Consequently, EPA provided a qualitative assessment of releases for plastic converting activities. Specifically, 55 facilities reported plastic compounding activities to TRI and NEI, and these facilities may also be involved with plastic converting. Therefore, it is assumed that releases to air, water, and land from plastic converting activities are less than or equal to releases reported by plastic compounding facilities. Because there are robust data reported by plastic compounding facilities, and the assumption that releases from plastic converting facilities are less than or equal to plastic compounding facilities is logical based on the overlap of compounding and converting activities, there is increased confidence in the qualitative assessment of releases from plastic converting facilities. As discussed above, the strengths of the qualitative analysis includes the comparison with robust plastic compounding data. However, the limitations of the analysis include the uncertainties discussed above, such as not capturing all release sources. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate.

OES(s)	Weight of Scientific Evidence Conclusion in Release Estimates
Application of paints, coatings, adhesives, and sealants	Environmental releases to air, land, and water were assessed using reported releases from 2019 to 2023 TRI (U.S. EPA, 2023c) and 2017 to 2020 NEI (U.S. EPA, 2023a, 2019d), and these sources received medium and high ratings from EPA's systematic review process, respectively. The assessment of release data from multiple EPA environmental release reporting databases increases confidence in release estimates. These data capture air releases from 36 sites total (NEI and TRI) and water/land releases from 7 sites (TRI only), and it was estimated that there may be 108 to 1,128 industrial and commercial sites using paints, coatings, adhesives, sealants containing phthalic anhydride. Therefore, there are likely additional sites involved in paint, coating, adhesive, and sealant application without known or reported release quantities. However, facility releases that are reported to EPA databases are expected to represent the highest release levels throughout the industry since these facilities are exceeding program reporting thresholds. EPA expects the reported releases to reliably estimate the release potential from industrial use of phthalic anhydride. As discussed above, the strengths of the analysis includes using industry reported release data to various EPA databases. However, the limitations of the analysis include the uncertainties discussed above, such as not capturing all release sources. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate-to-robust.
Use of laboratory chemicals	Environmental releases to air were assessed using reported releases from 2017 to 2020 NEI (U.S. EPA, 2023a, 2019d), and these sources received high ratings from EPA's systematic review process. However, there were only 5 sites identified that reported air releases from laboratories, and EPA estimated that there may be 2,020 to 2,260 laboratory sites using phthalic anhydride. Therefore, there is uncertainty regarding the representativeness of the air release data across all chemical laboratories. Further, there were no release data for water or land from laboratory facilities. Consequently, EPA provided a qualitative assessment of releases for laboratory activities. Specifically, the use of laboratory chemicals is associated with a low production volume (*i.e.,* <0.1% of total annual PV of phthalic anhydride). Therefore, it is expected that releases to air, water, and land from laboratory uses will be less than manufacturing and processing uses. Because there are robust data reported by manufacturing and processing facilities, and the assumption that releases from laboratory uses are less than releases from manufacturing and processing uses is logical based on the low PV of laboratory use, there is increased confidence in the qualitative assessment of releases from laboratory facilities. As discussed above, the strengths of the qualitative analysis includes the comparison with robust manufacturing and processing data. However, the limitations of the analysis include the uncertainties discussed above, such as not capturing all release sources. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate.
Use of lubricants and functional fluids	There were no release data for air, water, or land from facilities using lubricants and functional fluids containing phthalic anhydride. Consequently, EPA provided a qualitative assessment of releases. Specifically, the use of lubricants and functional fluids is associated with a low production volume (*i.e.,* <0.1% of total annual PV of phthalic anhydride). Therefore, it is expected that releases to air, water, and land from uses of lubricants and functional fluids will be less than manufacturing and processing uses. Because there are robust data reported by manufacturing and processing facilities, and the assumption that releases from lubricant and functional fluid

OES(s)	Weight of Scientific Evidence Conclusion in Release Estimates
	uses are less than releases from manufacturing and processing uses is logical based on the low PV of lubricant and functional fluid use, there is increased confidence in the qualitative assessment of releases from facilities using lubricants and functional fluids containing phthalic anhydride. As discussed above, the strengths of the qualitative analysis includes the comparison with robust manufacturing and processing data. However, the limitations of the analysis include the uncertainties discussed above, such as a lack of release data. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate.
Fabrication or use of final product or articles	There were no release data for air, water, or land from fabrication or use of final products or articles containing phthalic anhydride. Consequently, EPA provided a qualitative assessment of releases. Specifically, EPA expects releases from this OES to be small and disperse in comparison to other upstream OES, as EPA expects phthalic anhydride to be present in smaller amounts and predominantly remain in the final article, limiting the potential for release. Because there are robust data reported from upstream OESs such as manufacturing and processing, and the assumption that releases from fabrication uses are less than releases from upstream OESs is logical based on the low PV of fabrication uses, there is increased confidence in the qualitative assessment of releases from fabrication or final use of products or articles. As discussed above, the strengths of the qualitative analysis includes the comparison with robust data from upstream OESs such as manufacturing and processing. However, the limitations of the analysis include the uncertainties discussed above, such as a lack of release data. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate.
Disposal and recycling	Environmental releases to air, land, and water were assessed using reported releases from 2019 to 2023 TRI (U.S. EPA, 2023c) and 2017 to 2020 NEI (U.S. EPA, 2023a, 2019d), and these sources received medium and high ratings from EPA's systematic review process, respectively. The assessment of release data from multiple EPA environmental release reporting databases increases confidence in release estimates. These data capture environmental releases from 22 disposal and recycling facilities. Although there are release data from a sufficient number of disposal and recyling sites, there are likely additional sites without known or reported release quantities. However, facility releases that are reported to EPA databases are expected to represent the highest release levels throughout the industry since these facilities are exceeding program reporting thresholds. EPA expects the reported releases to reliably estimate the release potential from disposal and recycling of phthalic anhydride. As discussed above, the strengths of the analysis includes using industry reported release data to various EPA databases and the sufficient pool of release data available for disposal and recycling facilities. However, the limitations of the analysis include the uncertainties discussed above, such as not capturing all release sources. Therefore, considering the strengths and limitations of reasonably available data, EPA concluded that the weight of scientific evidence for this assessment is moderate-to-robust.

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

Strengths

EPA compiled release information using reported releases from the 2019 through 2023 TRI (U.S. EPA, 2023c) and 2017 through 2020 NEI (U.S. EPA, 2023a, 2019d). NEI obtained a high data quality rating and TRI obtained a medium quality rating from EPA's systematic review process. Furthermore, TRI-reporting facilities are required to submit their "best available data" to EPA for TRI reporting purposes. Some facilities are required to measure or monitor emission or other waste management quantities due to regulations unrelated to the TRI Program (*e.g.,* permitting requirements) or due to company policies. These existing, reasonably available data are often used by facilities for TRI reporting purposes, as representing the best available data. For example, stack releases can be directly measured by stack testing using EPA reference methods providing a directly measured emission rate, which can then be used to calculate annual emissions. Although NEI does not require stack testing or continuous emissions monitoring and reporting, agencies may use different emission estimation methods, reasonable estimates may be obtained through mass-balance calculations, the use of emission factors, and engineering calculations.

Limitations

Facilities are only required to report to TRI if the facility has 10 or more full-time employees, is included in an applicable NAICS (North American Industry Classification System) code, and manufactures, processes, or uses the chemical in quantities greater than a certain threshold (25,000 lb for manufacturers and processors and 10,000 lb for users). Therefore, facilities that exceed TRI reporting thresholds have larger capacity for releases than facilities that do not exceed TRI reporting thresholds. Consequently, it is expected that facilities reporting releases to TRI represent the upper end of facilities releases in the United States. Although most OESs do not have release data from all facilities in the United States, it is expected that the available release data provides a conservative estimate of releases. For NEI, the Air Emissions Reporting Requirements (AERR) only requires Criteria Air Pollutants (CAP) data reporting, but Hazardous Air Pollutants (HAP) data reporting is voluntary. As a result, EPA augments SLT-provided HAP data with other information to better estimate point, nonpoint, and mobile source HAP emissions. For point sources, HAP augmentation is performed on each emissions source using the WebFIRE database or data from TRI. Due to these limitations across programs, some sites may release phthalic anhydride but are not included in TRI or NEI. It is uncertain, the extent to which, sites not captured in these databases release phthalic anhydride into the environment.

Manufacturers and importers of phthalic anhydride submit CDR data to EPA if they meet reporting threshold requirements. Sites are only required to report production data to 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 phthalic anhydride may not be included in the CDR dataset and the total production volume for a given OES may be underestimated.

Assumptions and Uncertainties

When monitoring or direct measurement data are not reasonably available or are known to be non-representative for TRI reporting purposes, the TRI regulations require that facilities determine release and other waste management quantities of TRI-listed chemicals by making reasonable estimates. There is additional uncertainty in daily release estimates for air emissions. Facilities reporting to TRI report annual air emissions while NEI reports annual air emissions and, in some cases, the estimated number of release days. To assess daily air emissions for TRI, EPA used relevant data from NEI, ESDs, or GSs to estimate the expected number of release days. However, phthalic anhydride 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.

CDR information on the downstream processing and use of phthalic anhydride 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 developed potential production volume ranges given reported CDR data, known reporting thresholds, and the national aggregate annual production volume of 250 million to 500 million lb/yr for phthalic anhydride in years 2016 to 2019. To understand environmental releases for an OES without EPA data, EPA used the potential production volume ranges to determine the potential for release in comparison to other OES.

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

- **Number of Reporting Sites:** The number of sites reporting releases to TRI and NEI databases are expected to capture the most significant environmental releases of phthalic anhydride from manufacturing, imports, processing, and downstream uses. However, there are likely other sites releasing phthalic anhydride to the environment that do not report to TRI and NEI databases, and the existence of unknown releases provides some uncertainty in the overall releases of phthalic anhydride to the environment.
- **Lack of Release Data for an OES:** For some OESs, environmental release data were not available and qualitative assessments were provided. For these OESs, use characteristics (*e.g.,* production volume) were compared with other OESs to determine the potential magnitude of releases. The lack of data for some OESs introduces uncertainty in the overall estimate of releases of phthalic anhydride to the environment.
- **Uncertainties Associated with Number of Release Days Estimate:** For estimating the number of release days for an OES, it was assumed that the number of release days is equal to the number of operating days. For most OESs, the Agency estimated the number of release days using EPA data where available, or from GSs or ESDs when no EPA data were found. In such cases, EPA used applicable sources to estimate a range of release days over the course of an operating year. Due to uncertainty in phthalic anhydride-specific facility operations, release days may be under or overestimated.

3.3 Summary of Concentrations of Phthalic Anhydride in the Environment

Based off the environmental release assessment summarized in Section 3.2 and presented in EPA's *Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o), phthalic anhydride is expected to be released to the environment via air, water and disposal to landfills.

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 *Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r). In the environment, phthalic anhydride rapidly hydrolyzes to *ortho*-phthalic acid or *o*-phthalic acid, when contact occurs with water or moisture in the air. Given the rapid hydrolysis of phthalic anhydride to *o*-phthalic acid in the environment, the environmental and general population exposure assessments focused on exposure to *o*-phthalic acid. Based on the physical and chemical properties and environmental fate data, EPA determined that *o*-phthalic acid is likely to exhibit high mobility in soils. However, its low persistence potential in soils and groundwater hinders its mobility over time. Therefore, groundwater concentrations resulting from releases to the landfill or to agricultural lands via biosolids applications were not quantified.

EPA conducted the *o*-phthalic acid exposure assessment for the general population and the environment using a screening-level approach. The screening approach relied on conservative assumptions for the input parameters for modeling environmental media concentrations to characterize exposure resulting from the upper-bound of the expected distribution. Details on the screening-level assessments of each environmental pathway can be found in EPA's *Environmental Media, General Population, and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n). EPA performed each quantitative screening-level analysis for environmental and general population exposure assessment using the highest modeled environmental media concentrations. Further 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, 2019c). Additional details of the screening-level approaches used for general population exposure are discussed in Section 4.1.4.

In summary, the screening-level approach used the high-end environmental media concentrations that were estimated using the release estimates for an OES that, when combined with conservative assumptions of environmental conditions, resulted in the greatest modeled concentration of *o*-phthalic acid in a given environmental medium. Therefore, EPA did not estimate environmental concentrations of *o*-phthalic acid resulting from all OESs presented in Table 3-1. The OESs resulting in the highest environmental concentration of *o*-phthalic acid are shown in Table 3-6. 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, 2019c). Table 3-6 also indicates whether the highest estimate was used for environmental exposure assessment or general population exposure assessment.

Table 3-6. Summary of Upper-Bound *o*-Phthalic Acid Concentrations in Environmental Media from Environmental Releases

OES [a] and Scenario	Release Media	Environmental Media	*o*-Phthalic Acid Concentrations	Environmental and/or General Population
Processing as a reactant *Without Wastewater Treatment or Drinking Water Treatment*	Water	Surface water harmonic mean	2.15E04 µg/L	Environmental and general population
Processing as a reactant *With Wastewater Treatment*	Water	Surface water harmonic mean	1.72E04 µg/L	Environmental and general population
Manufacturing (without engineering controls)	Ambient air	Daily-averaged total (fugitive and stack, 100 m)	105.36 µg/m^3	General population
		Annual-averaged total (fugitive and stack, 100 m)	99.39 µg/m^3	General population

OES = occupational exposure scenario
[a] Table 3-1 provides the crosswalk of OES to COUs.

For the water pathway, EPA conducted modeling using the Variable Volume Water Model (VVWM) in the Point Source Calculator (PSC) tool (U.S. EPA, 2019e) to estimate surface water concentrations of *o*-phthalic acid resulting from COU releases. PSC inputs include physical and chemical properties of *o*-

phthalic acid and reported phthalic anhydride releases to water (U.S. EPA, 2026o), which are used to predict receiving water column concentrations. The standard EPA "farm pond" water body characteristics were used to parameterize the water column and sediment parameters (see Section 4.1.1 in U.S. EPA (2026n)), which is applied consistently as a conservative screening scenario. Standardized water body geometry was also applied consistently across runs, with a standardized width of 5 m, length of 40 m, and depth of 1 m. Only the release parameters (daily release amount and days of release) and the hydrologic flow rate were changed between model runs for this chemical to reflect facility-specific release conditions.

A required input for the PSC model is the hydrologic flow rate of the receiving water body. For facilities reporting releases to TRI, relevant flow data from the associated receiving water body were collected. EPA queried several databases to estimate a flow rate, for example EPA's Enforcement and Compliance History Online (ECHO), National Hydrography Dataset Plus (NHDPlus), and NHDPlus V2.1 Flowline Network Enhanced Runoff Method (EROM) Flow. The complete methods for retrieving and processing flow data are detailed in Appendix B in U.S. EPA (2026n). The annual average flow represents long-term flow rates, but a harmonic mean provides a more conservative estimate and is preferred for assessing potential chronic human exposure via drinking water. EPA selected the lowest average flow from the receiving water body from the distribution of resulting receiving water body flow rates across the pooled flow data of all relevant NAICS codes as a conservative low-flow condition across modeled releases.

Receiving water body *o*-phthalic acid concentrations were estimated at the point of release (*i.e.,* in the immediate receiving water body receiving the effluent). For this conservative screening analysis, EPA utilized releases associated with the Processing as a reactant OES. The selection of the Processing as reactant OES, with the highest modeled surface water, was based on high volumes of releases paired with the assumption of harmonic mean flow in the receiving water body. EPA determined the surface water concentration associated with this OES represented conservative, upper-bound exposure scenarios and was appropriate to use in its screening-level assessment to assess all other OESs and their associated COUs. Biodegradation, photolysis, and removal in wastewater treatment were not considered as this was meant to be an upper-bound, screening-level value. Due to uncertainty about the prevalence of wastewater treatment from *o*-phthalic acid-releasing facilities, one scenario assumed all releases are initially to be released to surface water without treatment to represent the worst-case exposure scenario and set an upper bound for water concentrations. Another scenario assumed releases are initially subject to removal treatment to represent a more realistic exposure scenario in the upper bound of possible water concentrations. However, these scenarios use of a mismatch of higher release amounts with lower flows, result in overestimation of concentrations. The mismatch of flows with releases assumption was due to the generic nature of the release assessment and hydrologic flow data, and lack of site-specific data. These values were carried through to the drinking water risk assessment for further evaluation as a conservative upper bound to screen for general population risk discussed in Section 4.1.4.1.2.

For the air pathway, EPA used the Integrated Indoor/Outdoor Air Calculator (IIOAC) Model to estimate daily- and annual-average ambient air concentrations of *o*-phthalic acid, as well as annual average wet, dry, and total air deposition rates of *o*-phthalic acid from the ambient air. EPA used the maximum reported releases from a single facility across all COUs as direct inputs to the IIOAC Model to estimate concentrations and deposition rates for both stack and fugitive emissions. The selected facilities were both associated with the Manufacturing (without engineering controls) COU. To evaluate exposures and total deposition rates, EPA assumed the fugitive and stack releases occur simultaneously throughout the day and year. Therefore, the total concentration and deposition rate used is the sum of the separately modeled fugitive and stack concentrations and total deposition rates at 100 m from a releasing facility.

The IIOAC Model outputs used in this assessment are as follows:

- *Upper bound* of all modeled hourly concentrations across the entire distribution of modeled concentrations at 100 m.
- *Upper-bound* annual-average concentration across the entire distribution of modeled concentrations at 100 m.
- *Upper-bound* annual-average deposition rate across the entire distribution of modeled deposition rates at 100 m.

3.3.1 Weight of Scientific Evidence Conclusions

Detailed discussion of the strengths, limitations, and sources of uncertainty for presented environmental media concentrations leading to a weight of scientific evidence conclusion can be found in the *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n). However, the weight of scientific evidence conclusion is summarized below for the modeled concentrations for surface water and ambient air.

For the screening-level assessment, EPA used the release estimates presented in Table 3-4 to model *o*-phthalic acid concentrations in different environmental media. The Agency considers additional variables when considering the weight of scientific evidence for its estimation of environmental media concentrations. Some additional considerations include the use of multiple models for appropriate media (*e.g.,* PSC, IIOAC, etc.) using the release as an input, the applicability of the release data to the environmental media being considered, likelihood of an occurrence of a release to the specific environmental compartment, and available monitoring data. These considerations are largely discussed for surface water and ambient air within the proceeding Sections 3.3.1.1 and 3.3.1.2, respectively. Additional information is provided within the EPA's *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n).

3.3.1.1 Surface Water

Due to the lack of reported release data and lack of reasonably available information for facilities discharging phthalic anhydride to surface waters, the high-end, EPA-estimated releases for each COU were applied for surface water modeling. Additionally, due to the lack of reasonably available site-specific release information, a generic distribution of hydrologic flows was developed from facilities that had been classified under relevant NAICS codes and that had National Pollutant Discharge Elimination System (NPDES) permits.

For the screening-level assessment, EPA utilized releases associated with the Processing as a reactant OES as it resulted in the highest surface water concentrations for use in environmental risk and general population risk estimates, respectively. EPA determined the surface water concentration associated with this OES represented a conservative high-end exposure scenario and was appropriate to use in this screening-level assessment to assess all other OESs and their associated COUs.

EPA utilized daily release information as an input to the Variable Volume Water Model with Point Source Calculator Tool (VVWM-PSC) Model to estimate surface water concentrations for use in general population and environmental exposure assessment. As mentioned in Section 3.2, EPA estimated a range of daily releases for each OES. For the Plastic converting, Use of laboratory chemicals, Use of lubricants and functional fluids, and Fabrication and final use of products or articles OESs, the Agency was not able to estimate releases, but EPA does not expect them to be greater than releases associated with the Processing as a reactant OES. The Agency also did not estimate releases from the Waste handling, treatment and disposal OES, since such releases are generally considered to be from waste transferred from upstream life cycle stages. The amounts transferred are generally not known; however, estimates from upstream activities identified as to incineration, landfill, or indirect discharges may include either on-site or off-site treatment activities, so EPA assumed that releases are captured in the upstream OESs. For the screening-level assessment, the Agency used the release estimates presented in Table 3-4 to model *o*-phthalic acid concentrations in different environmental media summarized in Table 3-6. In addition, when modeling with PSC, EPA modeled considering no water treatment removal and water treatment removal. For the scenario without prior treatment, EPA assumed all releases were directly discharged to surface waters, and that no releases were routed through publicly owned treatment works prior to release. EPA recognizes that this is a conservative assumption that results in no removal of *o*-phthalic acid prior to release to surface water. Direct releases to surface water reported via TRI and DMR were applied as the actual loading to surface water.

Daily releases of phthalic anhydride for each OES were estimated using generic scenarios. EPA has moderate confidence in the modeled phthalic anhydride concentrations as being representative of actual releases, with a bias toward overestimation. EPA has a robust confidence that the modeled *o*-phthalic acid surface water concentrations represent an upper bound overestimate that can be used to assess drinking water risk to the general population and environmental exposures. Some model inputs (*e.g.,* molecular weight, sorption coefficient, water column half-life, photolysis half-life, benthic half-life)) were derived from reasonably available literature collected and evaluated through EPA's systematic review process for TSCA risk evaluations.

3.3.1.2 Ambient Air and Air to Soil Deposition

EPA used the IIOAC Model, previously peer-reviewed methodology for fenceline communities (U.S. EPA, 2022a) and integrated recommendations from that and other peer-reviews to evaluate exposures and deposition rates via the ambient air pathway for this assessment. The IIOAC Model was developed based on a series of pre-run scenarios within AERMOD (the Agency's regulatory model), which gives EPA greater confidence in the IIOAC results. However, since results from IIOAC are based on the pre-run AERMOD scenarios, IIOAC modeling is limited to the parameters (*e.g.,* stack parameters, meteorological data, and other factors) used as inputs to those pre-run AERMOD scenarios. The screening-level analyses presented in this assessment, IIOAC provides reliable and reproduceable results that can be used to characterize upper-bound exposures and derive screening-level risk estimates, giving EPA moderate confidence in the results and findings.

Modeled phthalic anhydride as *o*-phthalic acid ambient air concentrations were estimated using the maximum TRI daily ambient air release, conservative meteorological data, and a distance of 100 m from a releasing facility. EPA considered the strengths, limitations, and sources of uncertainty for the modeled air and deposition concentrations. Any limitations and uncertainties of these releases, as described in the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o), are carried over to this ambient air exposure assessment. The IIOAC Model has limitations regarding which inputs can be modified and which cannot. Since it is based on pre-run scenarios within AERMOD, default input parameters (*e.g.,* stack characteristics and 2011–2015 meteorological data) are already predefined and cannot be changed without fully rebuilding the IIOAC Model. This is a limitation of the IIOAC Model, though the default parameters are typically based on national averages identified during development of the IIOAC Model. Certain parameters like building dimensions, release elevation, and land use cannot be considered by the model. Furthermore, IIOAC does not consider the presence or location of residential areas relative to the 100 m distance from releasing facilities, the size of the facility, and the release point within a facility. For larger facilities, 100 m from a release point may still fall within the facility property where individuals within the general population do not live or frequent. In contrast, for smaller facilities, there may be individuals within the general population that do live or frequent locations 100 m away from the release point and therefore could be exposed continuously. Most individuals may not stay within their residences 24 hours per day, 7 days per week throughout the year, which introduces a level of uncertainty to the exposure.

The use of annual release data and number of operating days to calculate daily average releases assumed operations are continuous and releases are the same for each day of operation. This can underestimate short-term or daily exposure and deposition rates because results may miss actual peak releases (and associated exposures and risks) if higher and lower releases occur on different days.

For the ambient air assessment, EPA used the highest stack and fugitive release reported among all data sets (TRI and NEI) identified. TRI had the highest reported releases for phthalic anhydride between 2019 and 2023. For modeling purposes, EPA acknowledges the highest stack and fugitive releases across all 5 years of TRI data considered may not align either spatially (from the same facility) or temporally (at the same time and year). However, for this assessment EPA assumes the two highest releases do occur from the same facility, at the same time, and the same year. This provides a conservative assumption for each individual release type (fugitive or stack) ensuring possible upper-bound exposures are not missed and may overestimate exposures and associated risks for this screening analysis.

In summary, EPA has slight confidence in the predictiveness of the exposure scenario modeled for this assessment since the stack and fugitive emissions are assumed to occur in the same year when in fact, they occurred in different years (2020 for the highest fugitive release and 2023 for the highest stack release), and the Agency added results together as if they occurred in the same year. However, EPA has high confidence that this exposure scenario overestimates exposure. EPA has moderate confidence in the IIOAC-modeled results used to characterize exposures and deposition rates since EPA used conservative inputs, considers a series of exposure scenarios under varying operating scenarios, multiple particle sizes, is based on previously peer reviewed methodology, and incorporates recommendations received during previous peer review and public comment. EPA has robust confidence that the modeled *o*-phthalic acid ambient air concentrations are appropriate for use in an upper-bound, screening-level assessment for assessing exposure in ambient air for the general population.

4 HUMAN HEALTH RISK ASSESSMENT

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

EPA evaluated all reasonably available information to support human health risk characterization of phthalic anhydride for workers, ONUs, consumers, bystanders, and the general population. Exposures and human health hazards are described in Section 4.1 and Section 4.2, respectively. Human health risk characterization is described in Section 4.3.

Exposure Key Points

- EPA assessed inhalation and dermal exposures to phthalic anhydride for workers and ONUs, as appropriate, for each OES (Section 4.1.1). Monitoring data indicate potential for occupational inhalation exposure for all 41 occupational COUs. There are dermal exposures for 37 occupational COUs.
- EPA assessed via modeling inhalation exposures for consumers and bystanders and dermal exposures to consumers from phthalic anhydride for each COU (Section 4.1.2) in scenarios that represent a range of use patterns and behaviors. Inhalation and dermal are the primary routes of exposure for consumers.
- EPA assessed inhalation, oral, and dermal exposures from *o*-phthalic acid following environmental releases of phthalic anhydride for the general population via ambient air, surface water, drinking water, human milk, and fish ingestion for tribal populations (Sections 4.1.4).

Hazard Key Points

- For dermal exposures to phthalic anhydride, EPA identified dermal sensitization as the most sensitive and robust human health hazard. A non-cancer point of departure (POD) of 45 μg/cm^2 based on skin sensitization was used to characterize non-cancer risks from acute durations of exposure. A total uncertainty factor of 10 was selected for use as the benchmark margin of exposure (Section 4.2.2.1).
- For the inhalation exposures, EPA identified respiratory sensitization as the most sensitive and robust human health hazard. A non-cancer POD of 0.4 mg/m^3 (0.07 ppm) based on respiratory and immune effects consistent with respiratory sensitization was used to characterize non-cancer risks from exposure to phthalic anhydride for workers and consumers. A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure for each (Section 4.2.2.1). As discussed in Appendix F, EPA calculated a draft 8-hour TWA occupational exposure level of 0.01 mg/m^3 and a draft 15-minute short-term exposure value (STEV) of 0.28 mg/m^3 based on the same endpoint (respiratory sensitization).
- For oral exposures, EPA concluded that phthalic anhydride and *o*-phthalic acid have low systemic toxicity via the oral route of exposure. For use in the general population screening-level risk assessment, a non-cancer POD of 66 mg/kg-day was selected based on decreased body weight gain. This POD was used to characterize risk from chronic durations of exposure in the general population screening assessment. A total uncertainty factor of 30 was selected for use as the benchmark MOE (Section 4.2.2.1).
- Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), EPA has preliminarily determined that phthalic anhydride is *Not Likely to Be Carcinogenic to Humans* for the oral exposure route. Consistent with the guidelines, the Agency did not quantitatively evaluate phthalic anhydride for cancer risk (Section 4.2.2.2).

Risk Assessment Key Points

- Inhalation and dermal exposures to phthalic anhydride drive acute non-cancer risks to workers in occupational settings (Section 4.3.2) and consumers and bystanders (inhalation only) (Section 4.3.3).
- For the general population, exposures to *o*-phthalic acid (following environmental releases of phthalic anhydride) through biosolids, landfills, surface water, drinking water, human milk, fish ingestion, and ambient air were determined to not have significant or any exposures (Section 4.3.4.
- EPA considered PESS throughout the exposure assessment and hazard identification supporting this draft risk evaluation (Section 4.3.5).

4.1 Summary of Human Exposures

As described in Section 2, hydrolysis of phthalic anhydride to *o*-phthalic acid is expected to occur in the order of minutes within the ambient environment, but persist longer in dry and well-ventilated environments (*i.e.,* with a limited amount of water). Therefore, the general population screening-level risk assessment evaluates exposures to *o*-phthalic acid, not phthalic anhydride (Section 4.3.4), while exposures to phthalic anhydride were evaluated for workers and consumers. Additionally, worker and consumer exposure assessments were based on identified consumer and worker products that list phthalic anhydride (but not phthalic acid) as a product component and/or monitoring studies that measured the anhydride form rather than the acid (Figure 1-3) in industrial settings. EPA also assumed that oral exposures are not relevant given the intended use of the products identified for consumer use (*e.g.,* adhesives and paints, Section 4.1.3.1), and oral exposure is not an anticipated route of exposure for workers (Section 4.1.1.1).

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 for phthalic anhydride (U.S. EPA, 2020d), EPA evaluated exposures to workers and ONUs via the inhalation route, including incidental ingestion of inhaled dust, as well as exposures to workers via the dermal route associated with the manufacturing, processing, use, and disposal of phthalic anhydride. EPA also assessed dermal exposure to ONUs for scenarios where dust may be deposited on surfaces around the workplace. It is known that phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid in the presence of water. However, phthalic anhydride and products containing phthalic anhydride are produced in the absence of water; otherwise, the chemical would not serve its intended purpose as a monomer for building ortho-phthalates. Furthermore, all occupational monitoring studies measured for the anhydride form rather than the acid, and no industrial or commercial product containing phthalic anhydride listed phthalic acid as a product component. Therefore, during manufacturing, processing, and industrial/commercial use of products containing phthalic anhydride, workers could experience direct exposures to phthalic anhydride itself and exposures to *o*-phthalic acid from industrial and commercial uses were not evaluated in this risk evaluation. The *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) 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 for phthalic anhydride (U.S. EPA, 2020d), 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 phthalic anhydride and have direct contact with the phthalic anhydride, while ONUs work in the general vicinity of phthalic anhydride but do not handle phthalic anhydride. For manufacturing and processing, EPA identified specific tasks (*i.e.,* bag handling, unclogging baghouse chutes, filling drums with process impurities, and cleaning equipment with high solids content) that lead to higher levels of inhalation and dermal exposure. Consequently, EPA categorized manufacturing and processing workers that engage in short-term, high exposure tasks as "high exposure" workers. Specifically, high exposure workers are those engaged in short-term, high exposure tasks as well as routine equipment operations or maintenance.

As discussed in Section 3.1.1.1, EPA established OESs to assess the exposure scenarios within each COU. Table 3-1 provides a crosswalk between COUs and OESs. For occupational inhalation exposures, EPA primarily used chemical-specific inhalation exposure monitoring data for the OESs. In the absence of chemical- or use-specific inhalation monitoring data, the Agency used surrogate data to estimate central tendency and high-end exposures.

EPA evaluated the quality of data sources using the data quality review evaluation metrics and rating criteria described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances, Version 1.0: A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies* (U.S. EPA, 2021). The Agency assigned an overall quality level of high, medium, or low to the relevant data. In addition, EPA established an overall confidence level for the data when integrated into the occupational exposure assessment. The Agency considered the assessment approach, quality of the data and models, and uncertainties in assessment results to assign an overall weight of scientific evidence rating of robust, moderate-to-robust, moderate, slight-to-moderate, or slight.

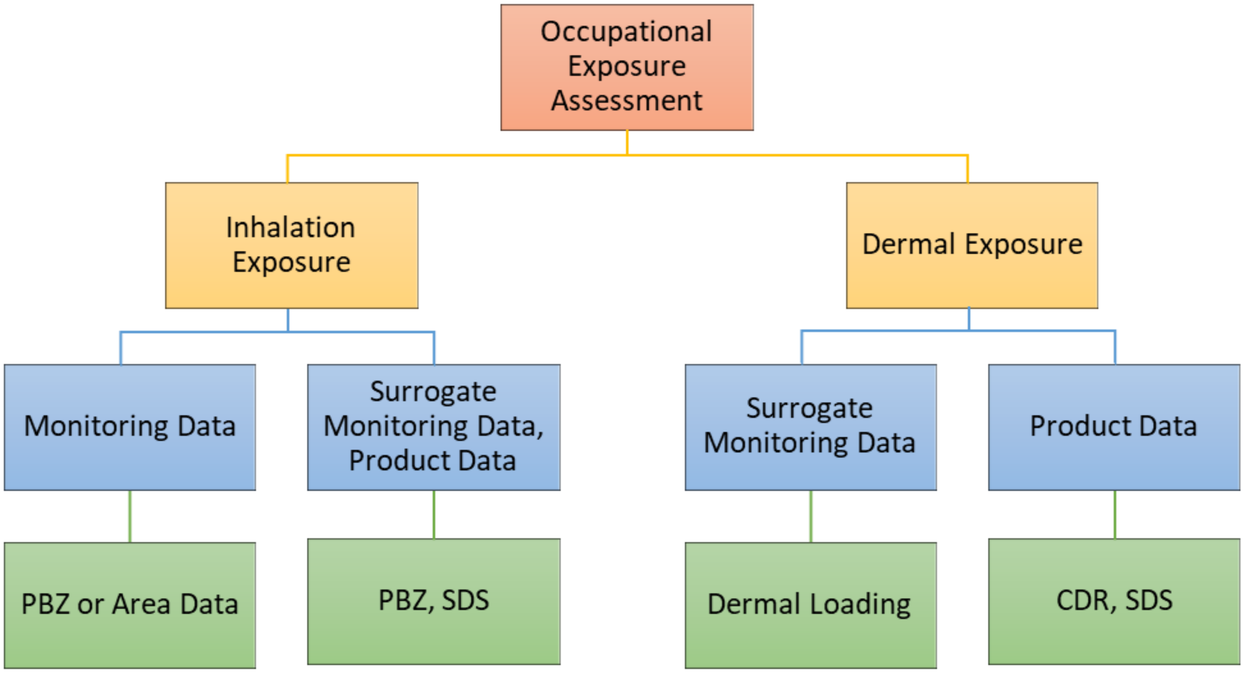


Figure 4-1. Approaches Used for Each Component of the Occupational Assessment for Each OES
PBZ = personal breathing zone; SDS = safety data sheet; CDR = Chemical Data Reporting (Rule)

For the inhalation and dermal exposure routes, EPA provided occupational exposure results that are representative of central tendency and high-end exposure conditions. The central tendency is expected to represent occupational exposures in the center of the exposure 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. The Agency 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 greater than or equal to the 90th percentile, but below the highest exposure for any individual (U.S. EPA, 1992a). 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 and Table 4-5 provide summaries of the data and approaches used to assess worker and ONU exposures and EPA's weight of scientific evidence rating for the given exposure assessments.

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

OES	Data Type [a]	Worker Category	Number of Samples	Number of Non-Detects [b]	Data Quality Rating [c]	Weight of Scientific Evidence Conclusion [d]
Manufacturing	• PBZ • Discrete • Chemical-specific • Use-specific	High exposure worker [e]	8	0	H	Moderate-to-Robust
		Worker [f]	26	3	H	Robust
		ONU [g]	6	5	H	Moderate-to-Robust
Import and repackaging	• PBZ • Discrete • Chemical-specific • Surrogate use from manufacturing	High exposure worker [e]	8	0	H	Moderate
		Worker [f]	26	3	H	Moderate-to-Robust
		ONU [g]	6	5	H	Moderate
Processing as a reactant; Incorporation into formulations, mixtures or reaction products; Plastic compounding	• PBZ • Discrete • Chemical-specific • Use-specific	High exposure worker [e]	5	0	H	Moderate-to-Robust
		Worker [f]	30	10	H	Robust
		ONU [g]	6	5	H	Moderate-to-Robust
Incorporation into formulations, mixtures or reaction products (epoxy resin casting hardener)	• PBZ • Discrete • Chemical-specific • Use-specific	Worker [h]	22	0	H	Robust
Plastic converting	• Area • Summary • Chemical-specific • Use-specific	Worker [h]	42	2	M	Moderate
Application of paints, coatings, adhesives, and sealants (non-spray)	• Area • Summary • Chemical-specific • Use-specific	Worker [h]	20	0	H	Moderate
Application of paints, coatings, adhesives, and sealants (spray) [i]	• PBZ • Discrete • Surrogate mist levels from various paint/ coating products • Use-specific	Worker	88	2	H	Moderate

OES	Data Type [a]	Worker Category	Number of Samples	Number of Non-Detects [b]	Data Quality Rating [c]	Weight of Scientific Evidence Conclusion [d]
Use of laboratory chemicals	• PBZ • Discrete • Chemical-specific • Use-specific	Worker [h]	4	0	M to H	Moderate-to-Robust
Use of lubricants and functional fluids	• Area • Summary • Chemical-specific • Surrogate use from non-spray paints, coatings, adhesives, and sealants	Worker [h]	20	0	H	Moderate
Fabrication or use of final products or articles	• PBZ • Discrete and summary • Chemical-specific • Use-specific	Worker	13	0	M to H	Moderate
	• Area • Summary • Chemical-specific • Use-specific	ONU	8	0	M	Moderate
Disposal and recycling	• PBZ • Discrete • Chemical-specific • Use-specific	Worker [h]	4	4	H	Moderate
Dermal exposures (liquids)	• Dermal loading • Discrete • Surrogate chemical [j] • Surrogate use	Worker	240	0	H	Moderate
Dermal exposures (solids)	• Dermal loading • Summary • Surrogate chemical [j] • Use-specific	Worker	45	0	H	Moderate
		ONU [k]	14	0	H	Slight-to-Moderate

OES	Data Type [a]	Worker Category	Number of Samples	Number of Non-Detects [b]	Data Quality Rating [c]	Weight of Scientific Evidence Conclusion [d]

[a] Data type may be personal breathing zone inhalation monitoring data (PBZ), inhalation area monitoring data (Area), or dermal loading data (mg/cm^2). The term "surrogate" may be associated with data that were initially measured for a different chemical than phthalic anhydride, but the data were for the same use under investigation. Alternately, the term "surrogate" may be associated with data that were measured for a use of phthalic anhydride that is similar, but different, than the use under investigation. Discrete data were provided as individual data measurements, whereas summary data were provided as statistical parameters (*e.g.,* arithmetic mean, standard deviation, *etc.*) of a dataset.

[b] For datasets that included exposure data reported as below the limit of detection (LOD), EPA estimated exposure concentrations using the $\frac{LOD}{\sqrt{2}}$ if the geometric standard deviation of the data is <3.0 and $\frac{LOD}{2}$ if the geometric standard deviation is 3.0 or greater (U.S. EPA, 1994a). For datasets with non-detect measurements, LODs are provided in Table 4-5.

[c] Data quality ratings for reported data are based on EPA systematic review and include ratings Low (L), Medium (M), and High (H).

[d] See Table 4-5 for further details on weight of scientific evidence conclusions.

[e] High exposure workers are those engaged in short-term, high exposure tasks, as well as routine equipment operations or maintenance. For phthalic anhydride production, high exposure tasks include flaking and bagging phthalic anhydride, unclogging baghouse chutes, filling drums with process impurities, and cleaning equipment with high solids content.

[f] Workers associated with manufacturing and processing data include equipment operators and maintenance workers.

[g] ONUs associated with manufacturing and processing data include instrument technicians, warehouse workers, office engineers, and supervisors.

[h] When ONU inhalation data were not available, EPA used worker central tendency exposure values to estimate potential inhalation exposures to ONUs. In these cases, exposure estimates for ONUs have reduced confidence in comparison to worker exposure estimates.

[i] Spray applications are expected to occur in enclosed spaces with ventilation controls, as specified in the *Paint Stripping and Surface Coating NESHAP* [73 FR 1738; January 9, 2008], and EPA does not expect exposures to occur outside the application area. Therefore, inhalation and dermal exposures from spray applications were not considered a route of concern for ONUs. See Section 3.7.4 of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for additional details.

[j] Surrogate data used for dermal loading estimation are described in Section 4.1.1.4.

[k] Incidental dermal exposures to ONUs were estimated from the 10th percentile of dermal loading data for workers handling empty bags. It is assumed that handling an empty bag leads to similar dermal loading as contacting a surface contaminated with phthalic anhydride dust. See Section 4.1.1.4 for more details.

4.1.1.2 Number of Workers and ONUs

Table 4-2 summarizes the number of facilities and total number of exposed workers for all OESs. For scenarios in which the results are expressed as a range, the low-end and high-end of the range represent the estimated lower and upper bounds for the scenario, respectively. The number of workers and ONUs are based on data from the Bureau of Labor Statistics (BLS). Specifically, NAICS codes associated with the OES and categories of employment from the BLS were used to identify worker and ONU populations. See the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for additional details. For some OESs, the estimated number of facilities is based on the number of reporting sites to the 2020 CDR (U.S. EPA, 2020b), NEI (U.S. EPA, 2023a, 2019d), and TRI databases (U.S. EPA, 2023c). Alternatively, for some OESs, the estimated number of facilities is based on typical use rate and overall PV for the OES.

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

OES [a]	Total Exposed Workers	Total Exposed ONUs [b]	Number of Facilities
Manufacturing	280	120	8
Import and repackaging	560–740	224–296	28–37
Processing as a reactant	3,132–9,309	1,296–3,852	108–321
Incorporation into formulations, mixtures, or reaction products	884–4,680	340–1,800	34–180
Plastic compounding	1,034–3,366	329–1,071	47–153
Plastic converting	2,200–6,600	660–1,980	110–330
Application of paints, coatings, adhesives, and sealants	2,592–27,072	1,404–14,664	108–1,128
Laboratory chemicals	6,060–6,780	6,060–6,780	2,020–2,260
Lubricants and functional fluids	<42,192	<9,376	<4,688
Fabrication	N/A [c]		
Disposal and recycling	>154	>88	>22

[a] An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within an occupational COU. The occurrence of releases/exposures may be similar across multiple COUs (multiple COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given COU (single COU mapped to multiple OESs).
[b] ONUs do not directly handle phthalic anhydride, but may be exposed to dust, vapors. or mists while working in locations near where phthalic anhydride is handled by workers.
[c] Number of sites unavailable for OES.

4.1.1.3 Summary of Inhalation Exposure Assessment

Table 4-3 presents a summary of inhalation exposure results based on reasonably available monitoring data for each OES. As shown in the Table 4-4, all exposure estimates are based on measured monitoring data. EPA calculated exposures from the monitoring datasets provided in the sources discussed in Table 4-5 using different methodologies depending on the size of the dataset. For datasets with six or more data points, the Agency estimated central tendency and high-end exposures using the 50th and 95th percentile values, respectively. For datasets with three to five data points, EPA estimated the central tendency and high-end exposures using the 50th percentile and maximum values, respectively. For datasets with two data points, the Agency presented the midpoint and the maximum value. Finally, EPA presented datasets with only one data point as-is. Generally, EPA expects ONUs to have lower inhalation exposures than workers who handle the chemicals directly. In absence of data specific to ONU inhalation exposure, the Agency assumed that worker central tendency exposure was representative of ONU exposure and used this data to generate estimates for ONUs. The *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) provides more details regarding the underlying studies and data selected for estimating inhalation exposures for each OES.

EPA did not apply a breathing rate adjustment in its occupational inhalation exposure assessment for phthalic anhydride because the assessed population (*i.e.,* workers) is similar to the population assessed in the occupational epidemiologic study by Nielsen et al. (1988) used to derive the inhalation point of departure (POD) (*i.e.,* workers; see Section 4.2.2.1). Therefore, a similar worker breathing rate was expected.

Table 4-3. Summary of Occupational Inhalation Exposure Results for Each OES

OES(s)	Worker Category	Full-Shift Exposure (mg/m^3)	
		CT	HE
Manufacturing; Import and repackaging	High exposure worker [a]	0.58	2.3
	Worker [b]	1.3E−02	0.13
	ONU [c]	2.8E−03	8.2E−03
Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; Plastic compounding [d]	High exposure worker [a]	0.22	1.2
	Worker [b]	8.5E−03	5.6E−02
	ONU [c]	2.8E−03	8.2E−03
Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	Worker	2.8	16.4
	ONU [e]	2.8	
Plastic converting	Worker	2.6E−04	3.0E−04
	ONU [e]	2.6E−04	
Application of paints, coatings, adhesives, and sealants	Worker (non-spray application)	1.7E−03	2.2E−03
	ONU [e] (non-spray application)	1.7E−03	
	Worker [f] (spray application)	1.4	11.1
Use of laboratory chemicals	Worker	1.5E−02	3.0E−02
	ONU [e]	1.5E−02	
Use of lubricants and functional fluids	Worker	2.6E−04	3.0E−04
	ONU [e]	2.6E−04	
Fabrication or use of final products or articles	Worker (fabrication)	0.11	0.32
	ONU (fabrication)	5.0E−03	
	Worker, ONU (routine use)	No inhalation exposure from routine use of final products or articles.	
Disposal and recycling	Worker	2.8E−03	
	ONU [e]	2.8E−03	

OES(s)	Worker Category	Full-Shift Exposure (mg/m^3)	
		CT	HE

CT = central tendency; HE = high-end; OES = occupational exposure scenario

[a] High exposure workers are those engaged in short-term, high exposure tasks, as well as routine equipment operations or maintenance. For phthalic anhydride production, high exposure tasks include flaking and bagging phthalic anhydride, unclogging baghouse chutes, filling drums with process impurities, and cleaning equipment with high solids content. For phthalic anhydride processing, high exposure tasks include dumping and mixing bags of phthalic anhydride, as well as disposal of the empty bags. It is conservatively assumed that high exposure tasks is 2 hours in duration and the worker may be exposed at the average exposure concentration of an equipment operator or maintenance worker (*i.e.,* 3.4E−02 mg/m^3 for manufacturing and 1.8 E−02 mg/m^3 for processing) for the remaining duration of a typical 8-hour work shift. For example, full-shift exposure for a manufacturing worker engaged in high exposure activities for a 2-hour duration is calculated as [(2-hour) × (Task concentration (mg/m^3)) + (6-hour) × (3.4 E−02 mg/m^3)]/(8-hour). See the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for more details.

[b] Workers associated with manufacturing and processing data include equipment operators and maintenance workers.

[c] ONUs associated with manufacturing and processing data include instrument technicians, warehouse workers, office engineers, and supervisors.

[d] Due to similarities in worker activities and sources of inhalation exposure among processing COUs (with the exception of the incorporation of phthalic anhydride as a hardener in epoxy resin mixtures for casting operations), inhalation exposure estimates are expected to be consistent across processing COUs.

[e] When ONU inhalation data were not available, EPA used worker central tendency exposure values to estimate potential inhalation exposures to ONUs.

[f] Spray applications are expected to occur in enclosed spaces with ventilation controls, as specified in the *Paint Stripping and Surface Coating NESHAP* [73 FR 1738; January 9, 2008], and EPA does not expect exposures to occur outside the application area. Therefore, inhalation exposures from spray applications were not considered a route of concern for ONUs. See Section 3.7.4 of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for additional details.

4.1.1.4 Summary of Dermal Exposure Assessment

This section summarizes the available dermal exposure data and results related to occupational dermal exposures to phthalic anhydride. Because the health endpoint associated with dermal exposure to phthalic anhydride is dermal sensitization, the relevant exposure metric to estimate risk for phthalic anhydride is the acute dermal exposure level in units of milligrams of phthalic anhydride per square centimeter of exposed skin (mg phthalic anhydride/cm^2). Consequently, EPA quantified the dermal loading of materials being handled (mg product/cm^2), as well as phthalic anhydride weight fraction of the materials being handled (mg phthalic anhydride/mg product), in order to estimate the dermal exposure of phthalic anhydride. Specifically, the dermal exposure of phthalic anhydride (mg phthalic anhydride/cm^2) is the mathematical product of the material dermal loading (mg product/cm^2) and the phthalic anhydride weight fraction of the material being handled (mg phthalic anhydride/mg product). EPA also identified scenarios where dust may be deposited on surfaces because ONUs may experience incidental dermal contact in these scenarios.

EPA used data from Lansink et al. (1996) as surrogate to estimate dermal loading of materials from worker activities associated with handling solid materials. Lansink et al. (1996) conducted an analysis of skin exposure to workers handling calcium carbonate during a variety of activities including collection of the raw material, handling of empty bags, and manual dumping and mixing. Calcium carbonate is a powdered material that may be physically similar to the solid form of phthalic anhydride, and the activities evaluated are relevant to the uses of phthalic anhydride in occupational settings. Dermal loading values were measured from cotton gloves worn by the workers, which covered their hands and part of their forearms, to obtain estimates of skin exposure in units of milligrams per day. The study reported the minimum, maximum, geometric mean, and 90th percentile of skin exposure measurements for each activity. For each OES where phthalic anhydride is handled in solid form, EPA identified the activity from Lansink et al. (1996) that is most representative of the OES and used the 50th and 90th percentiles of measurements for central tendency and high-end estimates, respectively, for workers handling phthalic anhydride. Because there are several scenarios where dust may become deposited on surfaces and potentially contacted by ONUs, dermal exposure from solid materials is considered a route of concern for ONUs as well. For scenarios where ONUs may experience incidental contact with dust deposited on surfaces, EPA used the 10th percentile of data for handling empty bags as surrogate to represent potential dermal loading for ONUs.

EPA used data from U.S. EPA (1992b) to estimate dermal loading of materials from worker activities associated with handling liquid formulations containing phthalic anhydride. U.S. EPA (1992b) investigated dermal loading from common worker exposures scenarios including rag handling and full hand immersion. EPA utilized the raw data to determine 50th and 95th percentile dermal loading values from rag handling scenarios of 1.4 mg/cm^2 and 2.1 mg/cm^2, respectively, and 50th and 95th percentile dermal loading values from full immersion scenarios of 3.8 mg/cm^2 and 10.3 mg/cm^2, respectively. As described in the *ChemSTEER User Guide – Chemical Screening Tool for Exposures and Environmental Releases* (also called the "ChemSTEER Manual") (U.S. EPA, 2015b), data from rag handling experiments of U.S. EPA (1992b) are considered relevant for typical occupational tasks such as product sampling, loading/unloading, and cleaning since rag handling is a common activity during these tasks. Also described in the ChemSTEER Manual (U.S. EPA, 2015b), data from full immersion experiments of U.S. EPA (1992b) are considered relevant for spray coating scenarios. Spray coating scenarios may lead to significant dermal exposure to workers similar to the immersion scenarios investigated in U.S. EPA (1992b), and this empirically supported by Marquart et al. (2006). Marquart et al. (2006) reported a dermal loading range of 4.15 mg/cm^2 (typical) to 16.6 mg/cm^2 (worst case) based on 25 data points for spraying marine anti-fouling paint, which is similar to spray products within this assessment. Therefore, dermal loading values from liquid immersion measurements are used to estimate dermal loading for tasks such as spray coating. Spray coating is the only use of phthalic anhydride-containing products expected to generate mist, and application of sprayable products are typically conducted within enclosed areas with ventilated controls as specified in the Paint Stripping and Surface Coating NESHAP [73 FR 1738; January 9, 2008]. Consequently, dermal exposure to ONUs from mist is not considered as an exposure route of concern in occupational settings.

Product or material concentrations were determined based on CDR reporting and SDS information for products containing phthalic anhydride. Product or material concentrations are described in the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o).

Table 4-4. Summary of Occupational Dermal Exposure Results for Each OES

OES(s)	Worker Category	Exposure Type	Dermal Loading (mg product/cm^2)		Phthalic Anhydride Concentration (%)		Dermal Exposure (mg phthalic anhydride/cm^2)	
			CT	HE	CT	HE	CT	HE
Manufacturing; Import and repackaging	High exposure worker [a]	Solid	0.26	0.57	90	100	0.23	0.57
	Worker [b]	Solid	0.12	0.56	90	100	0.10	0.56
	ONU [c]	Solid	3.0E−02		90		2.7E−02	
Processing as a reactant; Incorporation into formulations, mixtures, or reaction products (including incorporation as epoxy hardener); Plastic compounding [d]	High exposure worker [a]	Solid	0.48	1.6	90	100	0.43	1.6
	Worker [b]	Solid	0.12	0.56	90	100	0.10	0.56
	ONU [c]	Solid	3.0E−02		90		2.7E−02	
Plastic converting	Worker, ONU	Plastics	No dermal exposure expected from routine handling of final products or articles.					
Application of paints, coatings, adhesives, or sealants	Worker (non-spray application) [e]	Liquid products	1.4	2.1	10	25	0.14	0.53
	Worker (spray application) [f]	Liquid products	3.8	10.3	10	25	0.38	2.6
Use of laboratory chemicals	Worker	Liquid products	1.4	2.1	0.1	0.2	1.4E−03	4.2E−03
		Solid	0.12	0.56	90	100	0.10	0.56
	ONU	Solid	3.0E−02		90		2.7E−02	
Use of lubricants and functional fluids	Worker [e]	Liquid products	1.4	2.1	4.0E−02	0.5	5.6E−04	1.1E−02
Fabrication or use of final products or articles	Worker (fabrication)	Dust	0.12	0.56	52	80	6.0E−02	0.45
	ONU (fabrication)	Dust	3.0E−02		52		1.5E−02	
	Worker, ONU (routine use)	Final products or articles	No dermal exposure expected from routine handling of final products or articles.					
Disposal and recycling	Worker, ONU	Waste	No dermal exposure expected from routine handling of final products or articles.					

CT = central tendency; HE = high-end; OES = occupational exposure scenario;

[a] High exposure workers are those engaged in short-term, high exposure tasks, as well as routine equipment operations or maintenance. For phthalic anhydride production, high exposure tasks include flaking and bagging phthalic anhydride, unclogging baghouse chutes, filling drums with process impurities, and cleaning

OES(s)	Worker Category	Exposure Type	Dermal Loading (mg product/cm^2)		Phthalic Anhydride Concentration (%)		Dermal Exposure (mg phthalic anhydride/cm^2)	
			CT	HE	CT	HE	CT	HE

equipment with high solids content. For phthalic anhydride processing, high exposure tasks include dumping and mixing bags of phthalic anhydride, as well as disposal of the empty bags. This includes incorporation of phthalic anhydride as an epoxy resin hardener.

[b] Workers associated with manufacturing and processing COUs include equipment operators and maintenance workers.

[c] ONUs associated with manufacturing and processing COUs include instrument technicians, warehouse workers, office engineers, and supervisors.

[d] Due to similarities in worker activities and sources of dermal exposure among processing COUs, dermal exposure estimates are expected to be consistent across processing COUs.

[e] Dermal exposures to ONUs expected to be *de minimis* for OES.

[f] Spray applications are expected to occur in enclosed spaces with ventilation controls, as specified in the *Paint Stripping and Surface Coating NESHAP* [73 FR 1738; January 9, 2008], and EPA does not expect exposures to occur outside the application area. Therefore, dermal exposures from spray applications were not considered a route of concern for ONUs. See Section 3.7.4 of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for additional details.

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 exposure estimates. EPA 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 to robust, moderate, slight-to-moderate, slight, or indeterminant, in accordance with the Draft Systematic Review Protocol (U.S. EPA, 2021). For example, a conclusion of moderate is appropriate where exposure data are generated from a generic model with high data quality and some chemical-specific or industry-specific inputs, such that the exposure estimate is a reasonable representation of potential sites within the OES. A conclusion of slight 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 and EPA is unable to use other lines of evidence to inform exposures. See the Draft Systematic Review Protocol (U.S. EPA, 2021) 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.

1521 **Table 4-5. Summary of Assumptions, Uncertainty, and Overall Confidence in Exposure Estimates by OES**

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
Manufacturing; Import and repackaging	For assessing inhalation exposures from phthalic anhydride manufacturing and import/repackaging, EPA used personal breathing zone (PBZ) air concentration data sourced from four occupational monitoring studies (Cardno ChemRisk, 2020; Bookman, 2017; Rietz, 1985; Liss and Hartel, 1983). Rietz (1985) and Bookman (2017) reported data for high exposure tasks (*i.e.,* bag handling), Cardno ChemRisk (2020) reported data for equipment operations and high exposure tasks (*i.e.,* unclogging baghouse chutes, filling drums with process impurities, and cleaning equipment with high solids content), and Liss (1983) reported data for equipment operations, maintenance, and ONUs including supervisors, instrument technicians, warehouse workers, and office engineers. All four data sources received high ratings from EPA's systematic review process. Measurements from these studies were also used as surrogate data for estimating inhalation exposure during import and repackaging since worker activities are similar to manufacturing. ***Manufacturing*** The primary strengths of this assessment are based on the underlying data used for inhalation exposure estimation. All data were gathered in phthalic anhydride manufacturing or processing facilities and reported as discrete PBZ monitoring measurements with most associated metadata such as sampling durations and worker activities, and these data received high data quality ratings. For data associated with equipment operators and maintenance workers, there were no factors identified that would lead to a reduction in confidence and the resulting weight of scientific evidence is robust for exposure estimates of equipment operators and maintenance workers. For data associated with high exposure workers, the primary limitation relates to the unknown durations of task-based monitoring samples and EPA assumed up to 2 hours in duration for high exposure tasks. The reduction in confidence from this limitation results in a weight of scientific evidence of moderate-to-robust for exposure estimates of high exposure workers. For data associated with ONUs (supervisors, instrument technicians, warehouse workers, and office engineers), the primary limitation is the high percentage of non-detectable data. There were 6 data measurements across the 4 ONU worker types, and 5 out of the 6 data measurements were non-detectable (LOD ranged from 3.0E−03 to 4.0E−03 mg/m^3). However, Cardno ChemRisk (2020) provided full-shift area measurements in offices, control rooms, and rail tank area of a manufacturing facility (9 measurements total ranging from 1.2E−03 to 1.1E−02 mg/m^3), and these measurements are consistent with the range of PBZ measurements for ONUs (*i.e.,* 2.1E−03 to 1.0E−02 mg/m^3) from the NIOSH HHE conducted by Liss (1983). Therefore, the reduction in confidence from this limitation results in a weight of scientific evidence of moderate-to-robust for exposure estimates of ONUs. ***Import and Repackaging*** EPA did not identify exposure data from import and repackaging facilities. However, because worker activities at import and repackaging facilities are similar to those in manufacturing facilities (*e.g.,* loading, unloading, equipment cleaning, maintenance), EPA used surrogate inhalation monitoring data from manufacturing facilities to estimate exposures at import and repackaging facilities. Although inhalation exposure estimates for import and repackaging activities are based on the same high-quality, discrete PBZ monitoring data as manufacturing, there is an additional limitation imposed by the use of surrogate data. Therefore, the confidence is reduced for each worker category, and the resulting weights of scientific evidence for exposure estimates are moderate-to-robust for equipment operators and maintenance workers and moderate for high exposure workers and ONUs.

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; Plastic compounding	For assessing inhalation exposures from phthalic anhydride processing, EPA used personal breathing zone (PBZ) air concentration data sourced from five occupational monitoring studies (Milford, 2018; Bookman, 2017; Griesenbrock, 2017; Rietz, 1985; Liss and Hartel, 1983). Reitz (1985) and Bookman (2017) reported data for high exposure activities (*i.e.,* bag handling), Griesenbrock (2017) and Milford (2018) reported data for equipment operations, and Liss (1983) reported data for equipment operations, maintenance workers, and ONUs including supervisors, instrument technicians, warehouse workers, and office engineers. All five data sources received high ratings from EPA's systematic review process. The primary strengths of this assessment are based on the underlying data used for inhalation exposure estimation. All data were gathered in phthalic anhydride processing facilities and reported as discrete PBZ monitoring measurements with most associated metadata such as sampling durations and worker activities, and these data received high data quality ratings. For data associated with equipment operators and maintenance workers, there were no factors identified that would lead to a reduction in confidence and the resulting weight of scientific evidence is robust for exposure estimates of equipment operators and maintenance workers. For data associated with high exposure workers, the primary limitation relates to the task-based monitoring durations (*i.e.,* 60–120 minutes rather than full-shift). However, the studies provided EPA with adequate data to develop confident full-shift exposure estimates, and the reduction in confidence from this limitation results in a weight of scientific evidence of moderate-to-robust for exposure estimates of high exposure workers. For data associated with ONUs (supervisors, instrument technicians, warehouse workers, and office engineers), the primary limitation is the high percentage of non-detectable data. There were 6 data measurements across the 4 ONU worker types, and 5 out of the 6 data measurements were non-detectable (LOD ranged from 3.0×10^{-3} to 4.0×10^{-3} mg/m^3). However, Cardno ChemRisk (2020) provided full-shift area measurements in offices, control rooms, and rail tank area of a manufacturing facility (9 measurements total ranging from 1.2E−03 to 1.1E−02mg/m^3), and these measurements are consistent with the range of PBZ measurements for ONUs (*i.e.,* 2.1E−03 to 1.0E−02 mg/m^3) from the NIOSH HHE conducted by Liss (1983). Therefore, the reduction in confidence from this limitation results in a weight of scientific evidence of moderate-to-robust for exposure estimates of ONUs.
Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	For assessing inhalation exposures from the use of phthalic anhydride in epoxy resin casting operations, EPA used personal breathing zone (PBZ) air concentration data from the OSHA Chemical Exposure Health Data (CEHD) (OSHA, 2019a), as well as an inhalation monitoring study from a countertop manufacturing facility (Tustin et al., 2022). Both data sources received high ratings from EPA's systematic review process. The primary strengths of this assessment are based on the underlying data used for inhalation exposure estimation. All data were gathered in epoxy resin casting facilities and reported as discrete PBZ monitoring measurements with most associated metadata such as sampling durations and worker activities, and these data received high data quality ratings. These data measurements were measured for workers within the casting operations department, so the results are applicable to workers in casting operation areas. Since there were no factors identified that would lead to a reduction in confidence, the resulting weight of scientific evidence is robust for exposure estimates of workers within epoxy resin casting operation areas. However, data were not available for inhalation exposure of ONUs, and EPA used central tendency estimates from worker inhalation monitoring data to estimate potential ONU inhalation exposure. Consequently, reduction in confidence from this limitation results in a weight of scientific evidence of moderate for inhalation exposure estimates of ONUs.

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
Plastic converting	For assessing inhalation exposures of phthalic anhydride from plastic converting, EPA used area concentration data sourced from two studies (Vainiotalo and Pfaffli, 1990; Pfaffli, 1986). Both data sources provided summary statistics and received medium ratings from EPA's systematic review process. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of occupational exposure limits (OELs). The primary limitation of these data is the uncertainty of the representativeness of full-shift exposure levels since some measurements were below 8 hours in duration. Further, the best available phthalic anhydride-specific data relevant to plastic converting were provided as summary statistics of area monitoring data rather than discrete PBZ measurements. According to the *Guidelines for Statistical Analysis of Occupational Exposure Data* (U.S. EPA, 1994a), discrete PBZ monitoring data are preferred over summary statistics and area monitoring data. Based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence is moderate for inhalation exposure estimates of workers. However, data were not available for inhalation exposure of ONUs, and EPA used central tendency estimates from worker inhalation monitoring data to estimate potential ONU inhalation exposure. Consequently, reduction in confidence from this limitation results in a weight of scientific evidence of slight-to-moderate for inhalation exposure estimates of ONUs.
Application of paints, coatings, adhesives, and sealants	***Non-Spray Application of Paints, Coatings, Adhesives, and Sealants*** For assessing inhalation exposures of phthalic anhydride from non-spray application of paints, coatings, adhesives, or sealants, EPA used area concentration data sourced from one study (Pfaeffli, 1994). The data source provided summary statistics of 20 data points and received a high rating from EPA's systematic review process. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of OELs. The primary limitation of these data is the uncertainty of the representativeness of full-shift exposure levels since measurements were below 8 hours in duration. Further, the best available phthalic anhydride-specific data relevant to non-spray application of paints, coatings, adhesives, and sealants were provided as summary statistics of area monitoring data rather than discrete PBZ measurements. According to the *Guidelines for Statistical Analysis of Occupational Exposure Data* (U.S. EPA, 1994a), discrete PBZ monitoring data are preferred over summary statistics and area monitoring data. Based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence is moderate for inhalation exposure estimates of workers. However, data were not available for inhalation exposure of ONUs, and EPA used central tendency estimates from worker inhalation monitoring data to estimate potential ONU inhalation exposure. Consequently, reduction in confidence from this limitation results in a weight of scientific evidence of slight-to-moderate for inhalation exposure estimates of ONUs. ***Spray Application of Paints, Coatings, and Epoxy Resins (Conventional, Airless, and Aerosol Spray)*** For inhalation exposure from spray application of paints, coatings, and epoxy resins, EPA used surrogate monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011), which received a high rating from EPA's systematic review process. EPA also used SDSs and product data sheets from identified phthalic anhydride-containing paint and coating products to identify product concentrations.

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
	The strengths of the inhalation assessment include the availability of discrete, highly rated PBZ monitoring data that are use-specific, along with concentration data specific to products containing phthalic anhydride. The primary limitations of the assessment are the lack of phthalic anhydride-specific monitoring data and the representativeness of full-shift exposure levels. Data outlined in the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry are representative of mist levels that could be expected at a typical work site during spray applications, but the data are not specific to phthalic anhydride. Further, the monitoring periods were <8 hours in duration. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence is moderate for inhalation exposure estimates of workers.
Use of laboratory chemicals	For assessing inhalation exposures of phthalic anhydride from the use of laboratory chemicals, EPA used PBZ air concentration data sourced from 2 studies (van Tongeren et al., 1995; Liss and Hartel, 1983). These studies received medium-to-high ratings from EPA's systematic review process. There were also summary statistics of PBZ monitoring data for laboratory workers from 19 full-shift measurements provided by van Tongeren (1995). The primary strengths of this assessment are based on the underlying data used for inhalation exposure estimation. All data were gathered in laboratory settings and reported as discrete PBZ monitoring measurements with most associated metadata such as sampling durations and worker activities, and these data received medium to high data quality ratings. The primary limitation of these data is the uncertainty of the representativeness of full-shift exposure levels since discrete PBZ measurements were below 8 hours in duration. Furthermore, there were only four discrete data measurements of laboratory workers provided by the available sources. However, the summary statistics of PBZ monitoring data for laboratory workers from 19 full-shift measurements provided by van Tongeren (1995) show agreement with the four discrete PBZ measurements used in inhalation exposure evaluation. Therefore, the uncertainties of the representativeness of full-shift exposure levels and limited number of discrete data measurements only yield a slight decrease in confidence. Based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence is moderate-to-robust for inhalation exposure estimates of workers. However, data were not available for inhalation exposure of ONUs, and EPA used central tendency estimates from worker inhalation monitoring data to estimate potential ONU inhalation exposure. Consequently, reduction in confidence from this limitation results in a weight of scientific evidence of moderate for inhalation exposure estimates of ONUs.
Use of lubricants and functional fluids	EPA did not identify any inhalation data specific to the use of lubricants and functional fluids containing phthalic anhydride. However, inhalation exposure from lubricants and functional fluids would be due to volatilization of phthalic anhydride, similar to scenarios of non-spray application of paints, coatings, adhesives, and sealants. Therefore, EPA has used monitoring data from the non-spray application of paints, coatings, adhesives, and sealants (Pfaeffli, 1994) as surrogate data for estimating potential inhalation exposures from the use of lubricants and functional fluids. The sole data source provided area summary statistics of 20 data points and received a high rating from EPA's systematic review process. The primary strength of this approach is the use of chemical-specific monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of OELs. However, there are a few uncertainties associated with the assessment. First, the data are not use-specific, and the use of surrogate data leads to uncertainty in the exposure estimates. Second, there is uncertainty in the representativeness of full-shift exposure levels since measurements were below 8 hours in duration. Lastly, data were provided as summary statistics of area monitoring data rather than discrete PBZ measurements. Based on the strengths and limitations of the

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
	assessment, EPA concluded that the weight of scientific evidence is moderate for inhalation exposure estimates of workers. However, data were not available for inhalation exposure of ONUs, and EPA used central tendency estimates from worker inhalation monitoring data to estimate potential ONU inhalation exposure. Consequently, reduction in confidence from this limitation results in a weight of scientific evidence of slight-to-moderate for inhalation exposure estimates of ONUs.
Fabrication or use of final products or articles	For assessing inhalation exposure during fabrication or use of final products or articles, EPA used PBZ air concentration data from three sources (OSHA, 2019a; Pfaffli et al., 2002; Anas et al., 1990), as well as 1 additional source that specified the sampling methodology but did not specify whether area or PBZ sampling was used (Ramkissoon et al., 2023). Further, there were 2 sources of area monitoring data (Vainiotalo and Pfaffli, 1990; Pfaffli, 1986) that are applicable to ONUs in the vicinity of fabrication activities. All data sources received medium or high ratings from EPA's systematic review process. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of OELs. The primary limitation of these data is the uncertainty regarding the representativeness of full-shift exposure levels since all measurements were below 8 hours in duration. Also, there is uncertainty in the sampling methodology for data presented in Ramkissoon et al. (2023); however, the elevated levels measured during the fabrication of engineered stone indicate that measurements were taken in close proximity to the emission source. Regarding uncertainty in OSHA data, the exact worker activities represented by the discrete PBZ inhalation monitoring data are unclear. Although EPA has high confidence that the data are relevant for the fabrication or final use of products based on the NAICS codes associated with the reporting facilities, OSHA CEHD does not provide information such as worker activities or reason for monitoring. However, due to the elevated levels of the PBZ measurement by OSHA, it is likely that the worker handles the phthalic anhydride-containing materials directly. Therefore, this uncertainty does not significantly impact the level of confidence. Lastly, some worker PBZ data were reported with summary statistics, and the area monitoring data for ONUs were also reported with summary statistics. According to the *Guidelines for Statistical Analysis of Occupational Exposure Data* (U.S. EPA, 1994a), discrete PBZ monitoring data are preferred over summary statistics and area monitoring data. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence is moderate for inhalation exposure estimates of workers and ONUs.
Disposal and recycling	EPA identified 1 source of data that quantified the inhalation exposure of phthalic anhydride during waste handling activities in a phthalic anhydride manufacturing and processing plant (Liss and Hartel, 1983), and these data were used for estimating the inhalation exposure of workers involved in disposal and recycling activities. There were 4 discrete PBZ monitoring data points presented for waste treatment and boiler operators, and all measurements were below the LOD of 4.0E−03mg/m^3. However, these data received a high rating from EPA's systematic review process. The primary strengths of this assessment are based on the underlying data used for inhalation exposure estimation. All data were gathered from waste treatment workers in phthalic anhydride manufacturing or processing facilities and reported as discrete PBZ monitoring measurements with all associated metadata such as sampling durations and worker activities, and these data received high data quality ratings. However, the inhalation exposure assessment contains some limitations. First, there are limited data for the OES, and all available data were below the LOD. Because concentrations of phthalic anhydride in waste streams are expected to be low, EPA does not expect significant levels of inhalation exposure from this OES. Nevertheless, inhalation exposure estimates are

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
	based on replacement of the LOD as described in the *Guidelines for Statistical Analysis of Occupational Exposure Data* (U.S. EPA, 1994a), and this introduces uncertainty in the quantitative inhalation exposure estimates for the OES. Further, there is additional uncertainty regarding the representativeness of full-shift exposure levels since some measurements were below 8 hours in duration. Based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence is moderate for inhalation exposure estimates of workers. However, data were not available for inhalation exposure of ONUs, and EPA used central tendency estimates from worker inhalation monitoring data to estimate potential ONU inhalation exposure. Consequently, reduction in confidence from this limitation results in a weight of scientific evidence of slight-to-moderate for inhalation exposure estimates of ONUs.
Dermal exposures	EPA assessed dermal exposures (mg/cm^2) of solids containing phthalic anhydride, as well as liquid products containing phthalic anhydride, that a worker may experience for each OES. In order to estimate dermal exposures of phthalic anhydride from worker activities, EPA estimated the overall dermal loading of products from each OES as well as the concentration of phthalic anhydride in the products. For estimating product concentrations of phthalic anhydride, EPA relied on CDR reporting data and product SDS, which both provide highly reliable information regarding product concentration. All product SDS and CDR data received high ratings in EPA's systematic review process, and there are no significant limitations suggested by these data. ***Solids*** The dermal loading of solid materials was estimated using surrogate data from a study on industrial handling of calcium carbonate (Lansink et al., 1996). Specifically, Lansink et al. (1996) conducted an analysis of skin exposure to workers handling powdered calcium carbonate during a variety of activities including collection of the raw material (12 samples), handling of empty bags (14 samples), and manual dumping and mixing (19 samples). Dermal loading values were assessed using cotton gloves worn by the workers, which covered their hands and part of their forearms, to obtain estimates of skin exposure in units of milligrams per day. The study reported the minimum, maximum, geometric mean, and 90th percentile of skin exposure measurements for each activity, and the study received a high rating through EPA's systematic review process. The applicability of the activities from the Lansink et al. (1996) study is a strength in the dermal exposure assessment of solid materials to workers. The primary limitation is that there were only summary statistics available; however, the summary statistics provided a wide range of parameters to assist in understanding the data landscape for each use. Further, these data were used to estimate potential levels of dermal exposure to ONUs with incidental contact on dusty surfaces, and there is uncertainty in the direct applicability of these data for scenarios of incidental contact. The strengths of the dermal exposure assessment to workers include the use of highly rated dermal loading data for applicable worker activities, as well as the use of highly rated concentration data for products containing phthalic anhydride. For solid material handling by workers, the only assessment limitation is related to the use of dermal loading summary statistics rather than discrete data. Further, the surrogate use of worker exposure data for ONU incidental contact imposes additional uncertainty for exposures to ONUs experiencing incidental contact with dusty surfaces. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weights of scientific evidence for this assessment are moderate for worker exposures and slight-to-moderate for ONU exposures.

OES(s)	Weight of Scientific Evidence Conclusion in Exposure Estimates
	Liquids The dermal loading of liquid materials was estimated using surrogate data from a study on dermal transfer of 3 different types of oil (*i.e.,* bath oil, mineral oil, and cooking oil) from handling saturated rags and also from full immersion (U.S. EPA, 1992b). Measurements from the handling of saturated rags are applicable to worker tasks such as product sampling, loading/unloading, and cleaning, and measurements from full immersion are applicable to scenarios of spray coating. There were 96 discrete measurements of dermal loading from rag handling and 144 discrete measurements of dermal loading from immersion. The main strength of these data are the robust amount of data measured. However, the study limitations include the type of chemicals used as well as the type of activities investigated. This study received a high rating in EPA's systematic review process. The strengths of the dermal exposure assessment to workers include the use of highly rated dermal loading data for applicable worker activities, as well as the use of highly rated concentration data for products containing phthalic anhydride. The only limitations noted are related to the study of liquid chemical handling. Specifically, the type of liquid materials and activities investigated may introduce uncertainty when used for surrogate chemicals and uses. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence for this assessment is moderate for worker exposures. As described in Section 4.1.1.4, dermal exposure to liquid materials containing phthalic anhydride is not a route of concern for ONUs based on the use scenarios.

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

The number of release days associated with the releases is included in the release tables for different OES in Section 3 of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o). Unless EPA identified conflicting information, it was assumed that the number of release days per year for a given release source equals the number of operating days at the facility. EPA used information from NEI, GSs, ESDs, and other literature sources obtained through systematic review to assess the number of operating days for releases. The number of release days used in the assessment is expected to be reasonable because EPA used information directly reported by facilities or information from sources that were identified through EPA's systematic review process.

4.1.3 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 Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b) provides additional details on the development of approaches and the exposure assessment results. This assessment considers human exposure to phthalic anhydride in consumer products resulting from COUs as defined under TSCA. EPA considered all the major routes of exposure before determining which routes were of significance for consumer exposures to phthalic anhydride. The routes of phthalic anhydride exposures considered were ingestion via mouthing, ingestion of suspended dust, ingestion of settled dust, inhalation of suspended dust and gas phase, and dermal contact. See Section 4.1.3.1 for a discussion of the exposure routes considered for quantitative and qualitative assessments and exposure route considerations.

4.1.3.1 Scope of Consumer and Indoor Exposure Assessment

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

- Identification and mapping of product and article examples following the consumer COU table (Table 4-6), product, and article identification.
- Compilation of products and articles according to manufacturer's use instructions to determine patterns of use.
- Selection of exposure routes and exposed populations according to product/article use descriptions.
- Identification of data gaps and further search to fill gaps with studies, chemical surrogates or product and article proxies, or professional judgement.
- Selection of appropriate modeling tools based on available information and chemical properties.
- Gathering of appropriate modeling input parameters per exposure scenario.
- Parameterization (*i.e.,* entering inputs) of selected modeling tools per exposure route (*i.e.,* inhalation, ingestion, and dermal).

Consumer products and articles containing phthalic anhydride 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, and whether the analysis was conducted qualitatively or quantitatively. When a quantitative analysis of reasonably available information was conducted, exposure from the consumer COUs was estimated by modeling. Inhalation exposure from sprayed products was modeled using EPA's Consumer Exposure Model (CEM), Version 3.2 (U.S. EPA, 2023b), see Section 4.1.3.2 for approach description, and U.S. EPA (2026b) and U.S. EPA (2026c) for model inputs and results. Dermal exposures for liquid and spray products were calculated using dermal loading information in U.S. EPA (1992b). Dermal exposure calculations and inputs are provided in U.S. EPA (2026b), as well as the *Draft Consumer Exposure Analysis and Risk Calculator for Phthalic Anhydride* (U.S. EPA, 2026c). To assess phthalic anhydride dermal exposures from individual liquid products and spray products for each COU, EPA used the wipe and immersion experiment dermal loading information, respectively, in U.S. EPA (1992b) for a product in direct contact with the skin and product specific weight fractions, see Section 4.1.3.3 for approach description.

EPA assessed acute exposure durations to phthalic anhydride from consumer COUs. Acute exposures are for an 8-hour time-weighted average. The consumer 8-hour time-weighted average (TWA) was selected to align with POD calculations that also used an 8-hour TWA. Acute exposures are most relevant because phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid in the presence of water and because acute exposures elicit adverse effects (Section 4.2). Exposure to *o*-phthalic acid from consumer products was not evaluated because all products that were quantitatively evaluated (see Section 2.1 in U.S. EPA (2026b) and Table 4-6 in this document) are oil based or non-water based and *o*-phthalic acid is not expected to be present in the final product. For the assessment of acute exposures see description in Section 4.2 and the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p). The dermal and inhalation POD values are based on skin and inhalation sensitization, which is only relevant to acute exposures.

Product weight fraction data used as inputs for the inhalation and dermal exposure modeling were extracted from the identified product SDSs and technical data sheets (TDSs). EPA used the minimum and maximum of the reported range as the low and high-intensity use exposure scenario input values, respectively. The 50th percentile (midpoint) of the reported data were used for the medium-intensity use exposure scenarios and when multiple products reported a range, the average of each midpoint was used for the medium-intensity use exposure scenario weight fraction input. If only a single value was reported, EPA used that value for the low-, medium-, and high-intensity use exposure scenarios weight fraction while changing other use parameters (*e.g.,* duration of use, amount of product used). See the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b) for details about the consumer modeling approaches, sources of data, model parameterization, and assumptions. Low-, medium-, and high-intensity use exposure scenarios serve to provide a sensitivity analysis with insight on the impact of the main modeling input parameters (*e.g.,* duration of use, frequency of use) in the exposure concentrations and risk estimates.

Inhalation Exposure Route Considerations – Spray Applications

Consumer and bystander inhalation exposure to phthalic anhydride is expected to be the most significant route of exposure through the direct inhalation of sprays. Users and bystanders are expected to inhale sprayed products via dispersion while the spray is suspended. EPA assumed mists containing phthalic anhydride sprayed from consumer products are absorbed following inhalation, rather than following ingestion via the oral route.

Indoor Inhalation Exposure Route Considerations – Non-Spray Applications

The indoor air assessment discusses the potential exposures from consumer cured and/or solid articles/products that may release phthalic anhydride to the indoor air via gas phase or particulate/dust emissions. EPA qualitatively evaluated indoor inhalation and ingestion in the indoor exposure assessment in Section 4 in U.S. EPA (2026b). Briefly, consumer exposure to phthalic anhydride via inhalation from off-gassing or evaporation from products used during do-it-yourself activities or cured products, was not quantitatively evaluated. Due to low vapor pressure (5.17×10^{-4} mmHg) and low volatility (1.70×10^{-8} atm·m^3/mol at 25 °C) gas-phase inhalation exposures are expected to be negligible. Additionally, phthalic anhydride is mainly used as an intermediate (consumed in the production steps and not expected in the final product) or as a retarder or scorcher to promote hardening and durability. Based on the potential chemical role of phthalic anhydride in formulation and manufacturing (*i.e.,* as an intermediate or scorcher), it is unlikely to leach or migrate out of the cured adhesives or paints. As such, phthalic anhydride dust inhalation exposures are not expected from chemical migration from cured products to dust. Section 4 in *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b) provides a description and discussion of phthalic anhydride indoor monitoring data.

Oral Exposure Route Considerations

Oral exposures are possible through incidental ingestion during product use, transfer of chemical from hand-to-mouth, or mouthing of articles. Hand-to-mouth and ingestion of phthalic anhydride containing dust was not quantitatively evaluated because phthalic anhydride migration from cured product is not expected to occur. Based on physical and chemical properties and on the chemical role of phthalic anhydride in formulation and manufacturing (*i.e.,* as an intermediate or scorcher), it is unlikely to leach or migrate out of the cured adhesives or paints. Oral ingestion via mouthing of cured products (*e.g.,* crafting resin) is not expected to occur because phthalic anhydride is either not expected to be present in final product or to readily migrate from product/article to saliva from chemically bonded phthalic anhydride. In summary, mouthing or incidental hand-to-mouth exposures are not expected to occur for do-it-yourself (DIY) projects with adhesives and sealants, paints and coatings, and arts, crafts, and hobby materials COUs.

Dermal Exposure Route Considerations

Dermal exposure may occur via direct contact with liquid products and contact with mist deposition on the skin during use of spray products. Phthalic anhydride is mainly used as a retarder or scorch inhibitor in rubber articles, and as an intermediate. As such, it is expected that the chemical either remains chemically bonded to articles or it is transformed (intermediate) in the production/manufacturing process and likely to not be present (as phthalic anhydride or *o*-phthalic acid) in the final product/article. Migration from solid articles to skin and sweat via direct contact is not expected to occur and result in dermal exposures. Dermal exposures from direct contact with cured craft/paint/coating/adhesive were not quantitatively evaluated because phthalic anhydride is not expected to leach/migrate from the solid to the skin.

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 [a]	Dermal	Ingestion		
						Suspended Dust	Settled Dust	Mouthing
Adhesives and sealants	Adhesives and sealants	Adhesive for small DIY projects	Direct contact during use	*QL*	**QT**	*QL*	*QL*	*QL*
Arts, crafts, and hobby materials	Clear casting resins	Castin' Craft Casting Resin DIY	Dermal, inhalation, and ingestion exposures are not expected	*QL*	*QL*	*QL*	*QL*	*QL*
Arts, crafts, and hobby materials	Clear casting resins	Castin' Craft Casting Resin cured	Direct contact with cured solid for subsequent craft (*e.g.,* painting)	*QL*	*QL*	*QL*	*QL*	*QL*
Paints and coatings	Solvent-based paints	Liquid paints and coatings (brush application)	Use of product in DIY home repair and hobby activities. Direct contact during use.	*QL*	**QT**	*QL*	*QL*	*QL*
Paints and coatings	Solvent-based paints	Spray paints and coatings small project (aerosol can application)	Use of product in DIY home repair and hobby activities. Direct contact during use; inhalation of emissions during use of sprays	**QT**	**QT**	*QL*	*QL*	*QL*
Paints and coatings	Solvent-based paints	Spray paints and coatings large project (sprayer gun application)	Use of product in DIY home repair and hobby activities. Direct contact during use; inhalation of emissions during use of sprays	**QT**	**QT**	*QL*	*QL*	*QL*

DIY– do-it-yourself

[a] Inhalation scenario considered suspended product aerosol spray.

QT Quantitative consideration

QL Qualitative consideration

4.1.3.2 Inhalation Exposure Routes Modeling Approaches

Key parameters for spray products and articles modeled in CEM Version 3.2 are summarized in detail in Section 2.2 in the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b). Calculations, sources of data/inputs, input parameters, and results are also available in *Draft Consumer Exposure Analysis and Risk Calculator for Phthalic Anhydride* (U.S. EPA, 2026c). Model parameters were determined based on specific product identified in this assessment and CEM defaults were only used where specific information was not available or the CEM default was deemed appropriate based on product SDSs and TDSs. A list of some of the most important input parameters in developing representative scenarios for the selected modeling tools and approaches for exposure from products is included below. Duration, frequency and amount used have been determined to be key determinants of estimated exposure concentrations according to a sensitivity analysis conducted for CEM, Version 3.2 (U.S. EPA, 2023b):

- weight fraction (from product SDS);
- density (from product SDS);
- duration of use based on product SDS and TDS, and online retailers and product label instructions);
- frequency of use (based on product SDS and TDS, and online retailers and product label instructions);
- product mass used (based on product SDS and TDS, and online retailers and product label instructions);
- use environment volume (CEM defaults and based on product SDS and TDS, online retailers, and product label instructions).

For each scenario, low-, medium-, and high-intensity use exposure scenarios were developed in which values for duration of use, frequency of use, and amount of product used were determined based on reasonably available information. For this assessment, EPA consulted the SDS and TDSs, and online retailer product use recommendations to build scenarios that represent the upper and lower bounds of the potential exposure range. Each input parameter listed above was parameterized according to the product-specific data found via systematic review. If CEM default parameters were not applicable an input based on product use descriptions by manufacturers was used, always leaning on the values recommended by the specific product instructions. For example, 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 to obtain inhalation exposures to users, and a stay-at-home and full-time worker (a consumer that spends time at work and at home) activity patterns was selected to obtain bystander inhalation exposures. See Section 2.1 for weight fraction selection and Section 2.2.1 for CEM parameterization details in U.S. EPA (2026b).

4.1.3.3 Dermal Exposure Routes Modeling Approaches

EPA estimated dermal exposure for phthalic anhydride-containing products using dermal loading information in U.S EPA (1992b). Details are discussed in Section 2.3 in the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b). Calculations, references, input parameters, and results are also available in *Draft Consumer Exposure Analysis and Risk Calculator for Phthalic Anhydride* (U.S. EPA, 2026c). Specific dermal loading data related to phthalic anhydride were not identified in the literature. However, EPA identified one study that reported data collected in three laboratory trials designed to quantify the amount of oil-based liquids deposited onto the surface of hands (U.S. EPA, 1992b). The amount of liquid retained, liquid/spray product dermal loading, on the subjects' hands and the density of the liquid were measured to determine the liquid film thickness. The amount of liquid retained (dermal loading) was measured as a function of the hand surface area of the experimental subject, the type of liquid applied, and the method of experimental application and a subsequent removal.

4.1.3.4 Consumer Inhalation and Dermal Exposure Modeling Results

Detailed tables showing the acute dermal and inhalation exposures results by COU by scenario are available in the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b). Calculations, sources, input parameters and results are also available in *Draft Consumer Exposure Analysis and Risk Calculator for Phthalic Anhydride* (U.S. EPA, 2026c).

4.1.3.5 Weight of Scientific Evidence Conclusions for Consumer Exposure

Key sources of uncertainty for evaluating exposure to phthalic anhydride in consumer goods and strategies to address those uncertainties are described in detail in Section 5 of the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b). Generally, designation of robust confidence suggests that supporting scientific evidence weighted against the uncertainties is adequate to characterize exposure assessments. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the exposure estimate. The designation of moderate confidence suggests that the supporting evidence weighed against the uncertainties is reasonably adequate to characterize exposure assessments. The designation of slight confidence is assigned when the weight of scientific evidence may (1) not be adequate to characterize the scenario, and (2) in the absence of complete information and there are additional uncertainties that may need to be considered. The designation of slight-to-moderate confidence suggests that some aspects of the analysis are reasonably adequate but other aspects are not adequate or well understood to characterize the exposure. The overall confidence to use the results for risk characterization ranges from moderate-to-robust, depending on COU scenario, see Table 4-6 for scenario specific confidence designation and explanation. The basis for the moderate-to-robust confidence in the overall exposure estimates reflects a balance between using parameters that will represent various populations' use patterns and emphasizing inputs that represent actual values that are not excessive or unreasonable.

The exposure assessment of chemicals from consumer products 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 can also alter physical and/or chemical behavior of the product or article. While there can be a large variability in weight fractions, product application times (exposure durations), amount of product used, and dermal loading inputs, the scenarios in this assessment used representative inputs based on product specific information and provided the upper and lower bound range of possible exposures. A large variability is representative of a wide range of possible exposures and does not decrease confidence in using the exposure concentrations for subsequent risk calculation and characterization.

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 phthalic anhydride in consumer goods. EPA obtained phthalic anhydride weight fractions in various products from SDSs (Section 2.1 in U.S. EPA (2026b)). The four SDS for Adhesives and sealants COU were published in 2018, 2019, and 2020. The SDSs used for the Paints and coatings COU exposure scenarios were published in 2015, 2024, and 2025. Where possible, EPA obtained multiple values for weight fractions for similar products. The minimum reported value was used in the low-intensity use exposure scenario; the maximum reported value was used in the high-intensity use exposure scenario. The midpoint of the reported range and the average of all midpoint values when more than one range was reported in a specific exposure scenario was used for the medium-intensity use exposure scenario. EPA decreased uncertainty in exposure and subsequent risk estimates in the low-, medium-, and high-intensity use scenarios by capturing the weight fraction variability and obtaining a better characterization of the varying composition of products within one COU. Overall weight fraction confidence is *robust* for all products in the Adhesives and sealants, and Paints and coatings COUs with more than one source and recently updated SDS. *Moderate* confidence was assigned for weight fraction data for crafting resins because only one source was identified and confirmed one reported value.

Product Use Patterns

Consumer use patterns such as frequency of use, duration of use, method of application, and dermal loading are expected to differ. Low-, medium-, and high-intensity use inhalation exposure scenario input values used for CEM Version 3.2 modeling like mass of product used, duration of use, and frequency of use were estimated based on the manufacturers' product descriptions. In this assessment, EPA consulted product specific TSDs and SDSs, and online retailer product use recommendations to build scenarios that represent the upper and lower bounds of the potential exposure range. The Agency decreased uncertainty by selecting use pattern inputs that represent product 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. All use patterns' overall confidence is rated *robust*. However, it is important to note that because EPA does not have information to select which consumer exposure scenario (low-, medium-, or high-intensity use), these are more likely to represent the bulk/majority of the consumers using the specific products.

Human Behavior

For inhalation exposures 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, though for all products modeled for inhalation, the stay-at-home activity pattern was chosen as an upper bound exposure. The activity patterns were developed based on the Consolidated Human Activity Database (CHAD). One of the main inputs for the estimation of user inhalation exposure is the duration of use, which is a value based on manufacturer and online retailer product application specifications. The user is modeled using the near-field CEM calculations, while the bystander exposure concentration is based on zone 1 and zone 2 CEM inhalation exposure calculations. Users and bystanders can leave their residences to go to work, school, or recreational activities. However, the current stay-at-home activity pattern is representative of a population that spends most of their time at home when performing DIY activities. Using the stay-at-home activity pattern results in an upper-bound inhalation exposure concentration; for a sensitivity analysis using the CEM full-time worker activity pattern that provides the lower bound of possible exposures, see Section 4.3.3.

Inhalation 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. The model used, CEM Version 3.2, has been peer reviewed (ERG, 2016), is publicly available, and has been applied in the manner intended by estimating exposures associated with uses of household products. 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 of Phthalic Anhydride Exposure for Liquids and Sprays

Only one applicable exposure study was identified for the consumer exposure assessment, U.S. EPA (1992b). That study, albeit over 30 years old, published by EPA's OPPT, has been used extensively in previous dermal exposure assessments by OPPT and the Office of Pesticide Programs (OPP). It was used to estimate potential phthalic anhydride dermal loading following the use of a relevant consumer product.

Several dermal loading values (U.S. EPA, 1992b) for oil-based liquid products were used to approximate dermal exposures. The experiments used oil-based products expected to have longer residence times on the skin relative to water-based products. All adhesives and paints assessed for dermal exposures were identified as oil base by the manufacturers. Thus, providing a representative potential residence time for the products assessed in this evaluation. Dermal exposures are only reasonably foreseen for consumers but not bystanders. It is possible that the expected occlusion scenarios (*i.e.,* if gloves are used) might not occur in certain circumstances. However, EPA believes the quantitatively assessed scenarios are representative of most expected dermal exposures to phthalic anhydride. This is because the Agency identified additional references that support the use of the selected product dermal loading values. For example, for the use of the immersion experiment from the U.S. EPA (1992b) study for the spray paints dermal loading was supported by Marquart et al. (2006) experiment on similar products to those in this assessment. For the liquid products dermal loading value, EPA used the suggestion from the ChemSTEER Manual for tasks that represent direct dermal contact with liquid products. In general, based upon the applicability of the approach described in Section 2.3 in U.S. EPA (2026b) and supporting evidence discussed above, the overall confidence in the dermal exposure assessment is moderate for spray applications and moderate for non-spray applications.

Table 4-7 summarizes the overall uncertainty per COU and includes a discussion of rationale used to assign the overall uncertainty. The subsections preceding 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 per Table 4-7.

Table 4-7. Weight of Scientific Evidence Summary Per Consumer COU

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
Adhesives and sealants	One exposure scenario was assessed under this COU. The exposure scenario utilized information from three products with similar use patterns. The exposure scenario was labeled adhesives for small repairs based on manufacturer description of use for each product. Adhesives for small repairs were assessed for dermal exposures only due to the small product amount and surface area used in each application. Inhalation would have low exposure potential for this scenario because of phthalic anhydride's low volatility and vapor pressure. For dermal exposure, EPA used the product weight fraction and experimental amount of liquid retained on the skin (dermal loading) for oil-based liquid products for wiping applications. The wipe experiment in U.S. EPA (1992b) consisted of each subject's hands were first thoroughly washed and then the liquids were applied to their hands from a cloth saturated in the liquid. This experiment setup was selected to represent how non-spray liquid products like adhesives and sealants are applied. The application of adhesives can be done using a small brush, cloth, or directly spreading with finger/hand. The liquid product dermal loading values used in this assessment are representative of direct dermal contact and thus the dermal exposure concentrations are considered representative of direct contact with the adhesive. Weight fractions were from the product SDSs and reported as a range. The confidence in these parameters, liquid product dermal loading values and weight fraction is robust. The only limitations noted are related to the study of liquid chemical handling. Specifically, the type of liquid materials and activities investigated may introduce uncertainty when used for surrogate chemicals and uses. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence for this assessment is moderate for consumer exposures. The overall confidence considers confidence in the approach and the inputs used in the calculations. The overall confidence in dermal loading for this COU is moderate.	Dermal – Moderate
Paints and coatings: Solvent-based paints	Four different scenarios were assessed under this COU for four product examples with various use patterns. The product examples were matched to each scenario according to exposure route (inhalation and dermal) and application approach (spray can, sprayer gun, or brush/roller). Scenarios assessed for dermal exposures were labeled as the following: spray paints and coatings (can and sprayer application), and liquid paints and coatings (brush or roller application). Scenarios assessed for inhalation exposures were labeled spray paints and coating for small project (spray can applications) and spray paints and coatings for large project (sprayer gun application). For dermal exposure, EPA used the product weight fraction and liquid/spray product dermal loading for oil-based products for wiping (non-spray products) and immersion (spray products) applications. The wipe experiment in U.S. EPA (1992b) consisted of each subject's hands were first thoroughly washed and then the liquids were applied to their hands from a cloth saturated in the liquid. This experiment setup was selected to represent how non-spray liquid products like paints and coatings are applied and in direct dermal contact. The use of the wiping dermal loading values was supported by ChemSTEER Manual (U.S. EPA, 2015b), which reported similar range of liquid product dermal loading with similar viscosity. The paints and coatings evaluated in this assessment can have direct dermal contact during	Inhalation– Robust Dermal spray application – Moderate Dermal non-spray application – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	application and cleaning after application. For this scenario the selected experimental dermal loading is an upper bound estimate within the range of potential exposures for the high-intensity use exposure scenario and a lower-bound estimate for the low-intensity use exposure scenario. This is because the inputs used are considered representative of actual dermal loading and weight fractions in products. The spray product dermal loading values used for spray paints and coatings scenarios were experimentally determine from the immersion experiments in U.S. EPA (1992b). The use of the experimental immersion dermal loading values was supported by Marquart et al. (2006), which reported similar spray paint dermal loading values. Weight fractions were from the product SDSs and reported as a range. The confidence in these parameters, dermal loading rate, and weight fraction is robust for liquid paints and coatings and spray paints and coatings. The only limitations noted are related to the study of liquid chemical handling. Specifically, the type of liquid materials and activities investigated may introduce uncertainty when used for surrogate chemicals and uses. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence for this assessment is moderate for consumer exposures. The overall confidence considers confidence in the approach and the inputs used in the calculations. See Sections 4.3.3.1 and 4.3.3.2 for specific dermal and inhalation inputs per exposure scenario. The overall confidence in dermal loading for spray and non-spray applications this COU is moderate. Inhalation of spray paints was assessed in two scenarios: spray paints and coatings for small projects via spray can application, and spray paints and coatings for large projects via spray gun application. The overall confidence in the inhalation exposure estimates is robust because the CEM input parameters represent typical use patterns and location of use. The stay-at-home activity input parameter is considered a high-intensity use input that, although representative of actual uses for some populations, is also believed to result in an upper bound exposure relevant for bystanders and users after they have finalized application of product tasks. Using the stay-at-home activity pattern results in an upper bound inhalation exposure concentration, for a sensitivity analysis using the CEM full-time worker activity pattern that provides the lower bound of possible exposures, see Section 4.3.3.2.	
Arts, crafts, and hobby materials: Clear casting resins	Two different scenarios were qualitatively assessed under this COU for one product example with different use patterns. The identified product was a crafting casting resin (Environmental Technology, 2017) used to embed or encase objects in crystal clear plastic. Examples of encapsulation possibilities are coins, shells, rocks, dried flowers, insects, paper, and photographs. The two scenarios are casting resin DIY and casting resin cured. The casting resin use instructions (Environmental Technology, 2012b) recommend no dermal contact during mixing of catalyst and resin and when the mixture is transferred to a mold and allowed to cure for 24 hours or until solid. Therefore, dermal exposure while mixing and curing was not modeled. Inhalation of phthalic anhydride from off-gassing or evaporation from products used during DIY activities (mixing resin and catalyst) or from articles (cured resin) is unlikely because of its low vapor pressure (5.17×10^{-4} mmHg) and low volatility (1.70×10^{-8} atm·m^3/mol at 25 °C).	Qualitative – Robust

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	Additionally, phthalic anhydride is mainly used as an intermediate (consumed in the production steps and not expected in final product) or as a retarder or scorcher to promote hardening and durability. Based on the role of phthalic anhydride in the finished product, it is unlikely to leach or migrate out of the cured products. EPA has a robust confidence in the qualitative exposure assessment of this COU and the rationale to conclude negligible to no exposure.	

1817

4.1.4 General Population Exposures

General population exposures occur when phthalic anhydride is released into the environment and undergoes rapid hydrolysis to *o*-phthalic acid as described in Section 2. The environmental media is then a pathway for exposure. As described in the *Draft Environmental Media and General Population Exposure for Phthalic Anhydride* (U.S. EPA, 2026n), releases of phthalic anhydride are expected in air and water. Figure 4-2 provides a graphic representation of where and in which media *o*-phthalic acid is estimated to be found due to environmental releases and the corresponding route of exposure for the general population.

Table 4-8. Exposure Scenarios Assessed for *o*-Phthalic Acid for General Population Screening-level Assessment

OES	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)
All	Biosolids	All considered qualitatively			Qualitative
All	Landfills	All considered qualitatively			Qualitative
All	Underground injection wells	All considered qualitatively			Qualitative
Processing as a reactant	Drinking water	Oral	Ingestion of drinking water	Adult, youth, and children	Quantitative
Manufacturing	Ambient air	Inhalation	Inhalation of *o*-phthalic acid in ambient air resulting from industrial releases	All	Quantitative
		Oral	Ingestion of soil from air to soil deposition resulting from industrial releases	Infants and Children	Quantitative

EPA began its phthalic anhydride exposure assessment using a screening-level approach that relies on conservative assumptions. Conservative assumptions help characterize exposure resulting from the high-end of the expected distribution. Several of the OESs presented in Table 1-1 report facility location data and releases in the TRI, NEI, and DMR databases. When facility location- or scenario-specific information were unavailable, EPA used generic EPA models and default input parameter values as described in the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026n). 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, 2019c).

EPA considered a subset of the general population living near facilities releasing phthalic anhydride to the ambient air, which includes fenceline communities, as part of the ambient air exposure assessment. The Agency utilized a pre-screening methodology described in EPA's *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Version 1.0)* (U.S. EPA, 2022a) for the ambient air exposure risk assessment. For other exposure pathways, EPA's screening method assessing high-end exposure scenarios used release data that reflect exposures expected to occur in proximity to releasing facilities, which include fenceline populations.

EPA evaluated the reasonably available information for releases of phthalic anhydride from facilities that use, manufacture, or process phthalic anhydride under industrial and/or commercial COUs subject to TSCA regulations detailed in the *Draft Environmental Release and Occupational Exposure*

Assessment for Phthalic Anhydride (U.S. EPA, 2026n). As described in Section 3.3, using the release data, EPA modeled predicted concentrations of phthalic anhydride in surface water, sediment, drinking water, and ambient air in the United States. Section 3.3 summarizes the high-end phthalic anhydride 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 the *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n).

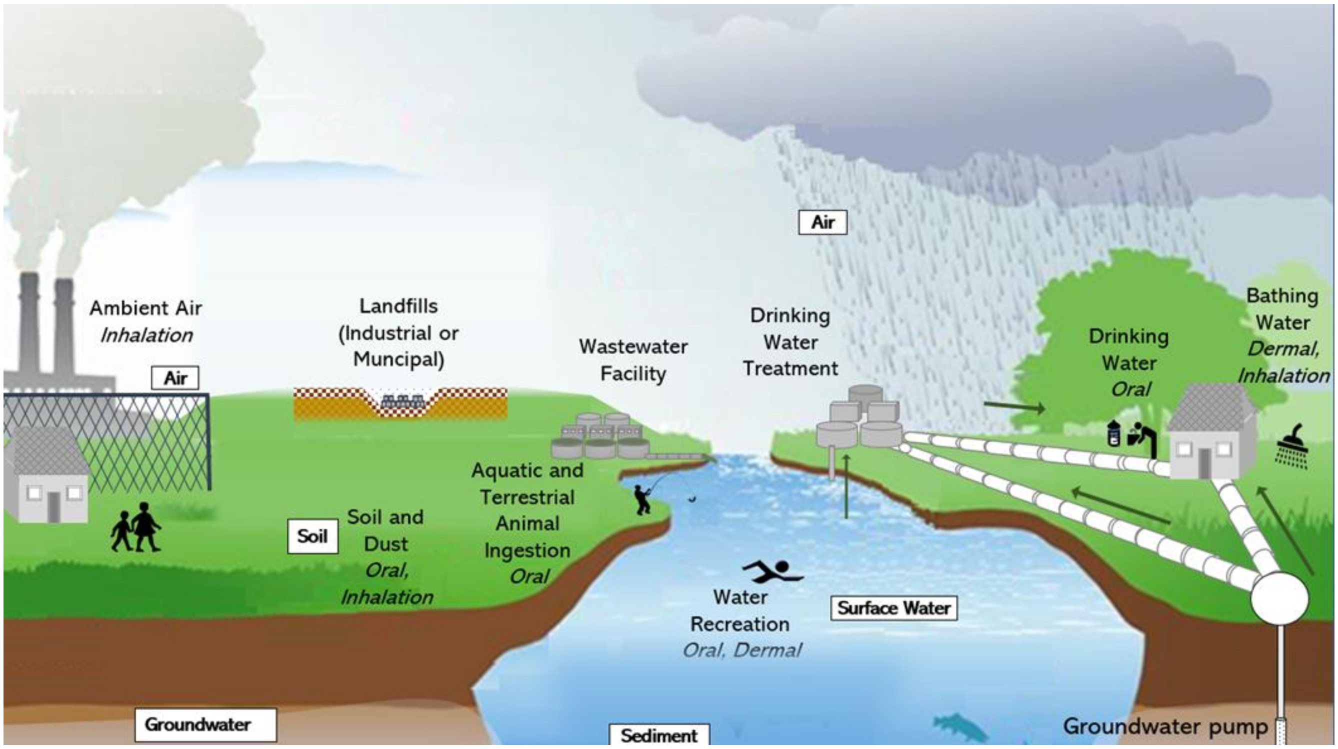


Figure 4-2. Potential Human Exposure Pathways to Phthalic Anhydride for the General Population

Potential routes of exposure are shown in italics under each potential pathway of exposure.

High-end estimates of phthalic anhydride concentration in the various environmental media were used for screening-level purposes in the general population exposure assessment, as described in the *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n). EPA's *Guidelines for Human Exposure Assessment* (U.S. EPA, 2019c) 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."

EPA estimated high-end concentrations in each environmental media using the highest reported (or estimated) releases within a given OES/COU. OES resulting in lower environmental media concentrations were not considered for this screening-level assessment. Additionally, individuals with the greatest intake rate of phthalic anhydride per body weight were considered to be those at the upper end of the exposure. EPA used exposure factors associated with individuals with the greatest intake rates per body weight to represent a conservative exposed population as presented above in Table 4-8.

4.1.4.1 General Population Screening-Level Exposure Assessment Results

4.1.4.1.1 Land Pathway

EPA evaluated general population exposures via the land pathway (*i.e.,* application of biosolids, landfills) qualitatively. Due to the low persistence of phthalic anhydride and *o*-phthalic acid in the environment due to rapid biodegradation in aerobic environment, phthalic anhydride and *o*-phthalic acid are unlikely to migrate to groundwater via runoff after land application of biosolids. Additionally, the half-life of days to weeks in aerobic soils (U.S. EPA, 2026r) indicates that *o*-phthalic acid will have low persistence potential in the aerobic environments associated with freshly applied biosolids. Because the physical and chemical properties of *o*-phthalic acid indicate that it is unlikely to migrate from land applied biosolids to groundwater via runoff due to rapid biodegradation, EPA did not model groundwater concentrations resulting from land application of biosolids.

Although there are limited measured data on *o*-phthalic acid in landfill leachates, *o*-phthalic acid may leach from landfill material but is expected to have limited mobility beyond the landfill. *o*-Phthalic acid in leachate is unlikely to infiltrate groundwater due to the rapid biodegradation. Interpretation of the high-quality physical and chemical property data also suggest that *o*-phthalic acid is unlikely to be present in landfill leachate. Therefore, EPA concludes that further assessment of *o*-phthalic acid in landfill leachate is not needed.

4.1.4.1.2 Surface Water Pathway – Drinking Water

EPA assessed the Processing as a reactant OES, which TRI data indicate had the highest releases to water, as described below. Because of relevance to the exposure routes, chronic drinking water exposures were derived from the harmonic mean flow concentrations. As described above and in Section 3.3, surface water concentrations modeled using releases associated with the Processing as a reactant OES represent an upper-bound based on many conservative assumptions—including all of the estimated total release going to surface water, high releases paired with low flow assumptions (P50), and no treatment of wastewater before release to the environment. Furthermore, environmental degradation due to biodegradation or photolysis were not considered as part of the screening-level approach.

ADR and ADD values from drinking water exposure to *o*-phthalic acid were calculated for various age groups but the most exposed lifestage, infants (birth to <1 year). EPA summarizes findings for the three highest lifestages in Table 4-9. Of the three presented, infants are the most exposed lifestage. Detailed results for all exposures can be found in the *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n). Exposure scenarios leading to the highest modeled dose are shown in Table 4-9.

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

Scenario	Surface Water Concentrations, Harmonic Mean, (µg/L)	ADD Adult (≥21 years) (mg/kg-day)	ADD Infant (Birth to <1 year) (mg/kg-day)	ADD Toddler (1–5 years) (mg/kg-day)
Processing as a reactant *Without Wastewater Treatment or Drinking Water Treatment*	2.15E04	1.62E−01	4.14E−01	1.77E−01

Scenario	Surface Water Concentrations, Harmonic Mean, (µg/L)	ADD Adult (≥21 years) (mg/kg-day)	ADD Infant (Birth to <1 year) (mg/kg-day)	ADD Toddler (1–5 years) (mg/kg-day)
Processing as a reactant *With Wastewater Treatment*	1.72E04	1.3E−01	3.31E−01	1.42E−01
High Dose from Monitoring *With Wastewater Treatment*	9.5	7.4E–05	1.9E−04	8.1E−05

EPA estimated surface water concentrations using ColorCon reported releases and receiving water body flow of the ColorCon location. Using release data from the ColorCon facility, and assuming no wastewater removal, EPA estimated a drinking water exposure of 0.414 mg/kg-day *o*-phthalic acid for the population with the highest exposure.

Because the ColorCon facility does not report direct discharges to surface water, but instead discharges to a POTW, EPA next refined the exposure scenario and used the actual water release from the ColorCon facility paired with flow values from the POTW for a more accurate estimate of surface water concentrations at point of discharge. The Agency considers this refinement appropriate, given that the ColorCon facility does not directly release to water bodies, its waste is sent to an offsite POTW as reported in TRI Form R. Using this refinement to estimate surface water concentrations using the POTW receiving water body flow resulted in a drinking water exposure of 0.00019 mg/kg-day *o*-phthalic acid for the population with the highest exposure (*i.e.,* infants, birth to <1 year).

Using this refined drinking water intake value and the candidate human equivalent dose (HED) of 66 mg/kg-day, a margin of exposure (MOE) of 347,368 (benchmark = 30) was calculated for infants through drinking water intake for the facility with the highest releases.

4.1.4.1.3 Fish Ingestion

EPA did not conduct a quantitative analysis of *o*-phthalic acid trophic transfer, as *o*-phthalic acid is expected to have low bioaccumulation potential, no apparent biomagnification potential, and thus low potential for uptake into fish overall. For further information on the bioaccumulation and biomagnification of phthalic anhydride/*o*-phthalic acid as well as other physical and chemical properties, please see the *Draft Chemistry, Fate, and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r).

4.1.4.1.4 Ambient Air Pathway

As part of the ambient air exposure assessment, EPA considered exposures to the general population in proximity to releasing facilities, including fenceline communities, by utilizing a previously peer-reviewed, pre-screening methodology described in EPA's *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Version 1.0)* (U.S. EPA, 2022a). EPA used the IIOAC Model to estimate ambient air concentrations and deposition rates using pre-run results from a suite of dispersion scenarios in a variety of meteorological and land-use settings within American Meteorological Society/EPA Regulatory Model (AERMOD). EPA relied on the IIOAC-modeled concentrations and deposition rates to characterize human and ecological exposures for the ambient air exposure assessment. Modeled phthalic anhydride as *o*-phthalic acid ambient air concentrations were estimated using the maximum TRI daily ambient air release, conservative meteorological data, and a distance of 100 m from a releasing facility based off of the manufacturing OES (highest reported releases according to TRI). The modeled concentrations are higher than measured concentrations Sections 6.1 and 6.2 respectively in the Draft Environmental Media and General Population exposure TSD. Caution is needed when interpreting such a comparison, because modeled concentrations are near a releasing facility (100 m away), and for the monitoring data, it is unknown if the sampling sites are located at a similar distance. The maximum release value represents the maximum release reported across all facilities, all datasets evaluated (TRI and NEI) and all COUs. These maximum releases are used as direct inputs to the IIOAC Model to estimate concentrations and deposition rates. EPA used the maximum 95th percentile modeled concentrations and deposition rates across a series of exposure scenarios considering particle size and urban/rural topography to characterize exposures and derive risk estimates. Calculations for general population exposure to ambient air via inhalation and ingestion from air to soil deposition for lifestages expected to be highly exposed based on exposure factors can be found in *Ambient Air IIOAC Exposure Results and Risk Calculations Phthalic Anhydride* (U.S. EPA, 2026a). Inhalation exposure to Phthalic anhydride from ambient air and soil ingestion resulting from air to soil deposition is presented below.

All results for each scenario described below are included in the *Draft Ambient Air IIOAC Exposure Results and Risk Calculations for Phthalic Anhydride* (U.S. EPA, 2026a). EPA used the highest estimated concentrations across all modeled scenarios to evaluate exposures and deposition rates near a releasing facility. This exposure scenario represents a national level exposure estimate inclusive of sensitive and locally impacted populations who live next to a releasing facility.

The IIOAC Model provides source apportioned concentrations and deposition rates (fugitive and stack) based on the respective releases. To evaluate exposures and total deposition rates for this ambient air assessment, EPA assumes the fugitive and stack releases occur simultaneously throughout the day and year. Therefore, the total concentration and deposition rate used to evaluate exposures and derive risk estimates in this ambient air assessment is the sum of the separately modeled fugitive and stack concentrations and total deposition rates at 100 m from a releasing facility. The source apportioned concentrations and the total concentrations for the scenario used are provided in Table 4-10.

Table 4-10. Source Apportioned and Total Daily-Averaged and Annual-Averaged IIOAC Modeled Concentrations at 100 m from Releasing Facility

Source Type	Daily-Average Concentration (µg/m^3)	Annual-Average Concentration (µg/m^3)
Fugitive	97.4	93.19
Stack	7.96	6.21
Total	105.36	99.41

The source apportioned wet and dry deposition rates and the total deposition rates for the scenario used are provided in Table 4-11.

Table 4-11. Source Apportioned and Total Annual-Average IIOAC Modeled Wet, Dry, and Total Deposition Rates at 100 m from Releasing Facility

Source Type	Total Annual-Average Deposition Rates (g/m^2)		
	Total	Wet	Dry
Fugitive	1.56E–03	1.55E–03	2.25E–05
Stack	4.98E–04	4.80E–04	2.97E–05
Total	2.06E–03	2.03E–03	5.21E–05

As mentioned in Section 1, for general population exposure, only exposure to *o*-phthalic acid was considered based on the assumption of rapid hydrolysis of phthalic anhydride to *o*-phthalic acid upon release to the ambient environment. Therefore, EPA utilized the non-cancer hazard values for *o*-phthalic acid, described in detail in the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p), for its screening-level analysis. Briefly, after considering hazard identification and evidence integration, dose-response evaluation, and weight of scientific evidence of POD candidates, EPA chose one non-cancer POD for chronic oral exposure scenarios and one non-cancer POD for chronic inhalation exposure scenarios (Table 4-12). Human equivalent concentrations (HECs) are based on daily continuous (24-hour) exposure and HEDs are daily values.

EPA estimated ambient air concentrations of *o*-phthalic acid for the highest releasing facility (see (U.S. EPA, 2026n)). The highest calculated ambient air concentration (annual outdoor air concentration ($\mu g/m^3$) from fugitive plus stack releases) was 99.41 $\mu g/m^3$. The highest ambient air inhalation values reflect the highest air release facility, and actual air releases from facilities were used to estimate ambient air concentrations. Conservative assumptions were made by combining the highest fugitive emissions with highest stack emissions from different facilities. Using the ambient air concentration calculated above and the candidate HEC of 322 mg/m^3 (extrapolated from HED of 59 mg/kg-day, see Table 45), EPA calculated an MOE of 3,240 (benchmark MOE = 300). Because the HEC was derived for adults, MOEs for other lifestages were not calculated. However, considering similar or smaller inhalation rates for younger lifestages and greatest body weight difference of a factor of 16.7 between an adult (80 kg) and newborn (4.8 kg) based on EPA's *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011b), MOEs for all lifestages will still exceed the benchmark based on the estimates for adults.

4.1.4.2 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. These are discussed in detail for ambient air, surface water, drinking water, and fish ingestion in the *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n). EPA summarized its weight of scientific evidence using confidence descriptors: robust, moderate, slight, or indeterminate. The Agency 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 has robust confidence in its qualitative assessment of biosolids and landfills. For its quantitative assessment for surface water, drinking water, and ambient air, the Agency modeled exposure due to various general population exposure scenarios resulting from different pathways of exposure. Exposure estimates utilized high-end inputs for the purpose of risk screening. EPA has robust confidence that the modeled releases used are appropriately conservative for a screening-level analysis. Therefore, EPA also has robust confidence that no exposure scenarios will lead to greater doses than presented in this evaluation. Despite slight-to-moderate confidence in the estimated values themselves, confidence in exposure estimates capturing high-end exposure scenarios was robust. This adds to the confidence that exposure estimates captured high-end exposure scenarios.

4.1.5 Human Milk Exposures

EPA did not conduct a quantitative assessment for exposure through human milk ingestion. Based on the physical and chemical properties of *o*-phthalic acid, EPA does not expect *o*-phthalic acid to be present in human milk, it is highly water soluble, not lipophilic (log K_{OW} = 0.73), and has low bioaccumulation potential (BAF = 1.32 L/kg). Therefore, EPA does not expect *o*-phthalic acid to be present or be expected to accumulate in human milk.

4.1.6 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)."

EPA qualitatively considered aggregate exposures and risks across inhalation and dermal routes of exposure for consumers and workers. Oral exposure was not considered relevant for consumers or workers. For phthalic anhydride, the Agency considered the non-cancer risks for the dermal and inhalation routes highly route-specific and each route-specific hazard value was based on effects that occur near the portal of entry. Because the non-cancer effects are specific to the route of exposure, EPA concluded that the non-cancer risks are not additive across routes. Similarly, because EPA determined that risks are not additive across routes, the Agency did not aggregate exposure and risk across pathways for which exposure routes are not the same (*e.g.,* EPA did not aggregate inhalation exposure through outdoor air with dermal exposure associated through use of consumer products).

EPA did not consider aggregate exposure for the general population. As described in Section 4.1.4, a risk screening approach was used for the general population exposure assessment.

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

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, the Agency 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 (workers) and modeling approaches (consumers). Where statistical data are available, the Agency typically uses the 95th percentile value of the available dataset to characterize high-end exposure for a given condition of use. For consumer exposures, EPA characterized all sentinel exposure through a "high-intensity use" category based on the highest possible user-specific factors. For general population sentinel exposures were assessed using the statistical 95th percentile value of the available data and elevated breathing rates to characterize high-end exposure for a given condition of use.

4.2 Summary of Human Health Hazard

4.2.1 Background

This section briefly summarizes the non-cancer (Section 4.2.2.1) and cancer (Section 4.2.2.2) human health hazards of phthalic anhydride. Additional information on the non-cancer and cancer human health hazards of phthalic anhydride are provided in the *Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p).

The HED and HEC values for use in estimating risks from various exposure scenarios and relevant populations in the risk evaluation are available in Table 4-12.

4.2.2 Human Health Hazards of Phthalic Anhydride

EPA considered the non-cancer human health hazard information (Section 4.2.2.1) and cancer human health hazard information (Section 4.2.2.2) on phthalic anhydride and/or its immediate hydrolysis product, *o*-phthalic acid. As described in Section 2, phthalic anhydride exhibits rapid ($t_{½}$ = 30–90 seconds) and complete hydrolysis (approximately 8 minutes under conditions simulating sea water or physiological fluids (Andres et al., 2001)) to *o*-phthalic acid in the presence of moisture. Within the atmosphere, the rate of hydrolysis is directly influenced by atmospheric conditions such as humidity and temperature and is generally assumed to occur on the order of minutes (Section 2). Therefore, the general population screening-level risk assessment evaluates exposures to *o*-phthalic acid, not phthalic anhydride (Section 4.3.4). Exposures to *o*-phthalic acid were not considered for workers and consumers because phthalic anhydride and products containing phthalic anhydride are produced in the absence of water due to the intended uses of the product(s) or, in occupational settings, phthalic anhydride as a monomer for building ortho-phthalates, as described in the risk characterizations for workers (Section 4.3.2) and consumers (Section 4.3.3). Additionally, although hydrolysis of phthalic anhydride would be expected from oral exposures, oral exposures are not relevant given the intended use of the products identified for consumer use, and oral exposure is not an anticipated route of exposure for workers. Therefore, EPA considered hazards from *o*-phthalic acid for use in the general population risk characterization and considered hazards from phthalic anhydride for use in the consumer and occupational risk characterizations.

For *o*-phthalic acid exposure via the oral route, EPA assumed 100% absorption because available data indicate that *o*-phthalic acid is readily absorbed following oral exposure. Available data indicate that dermal absorption of *o*-phthalic acid can occur; however, the Agency did not derive dermal absorption estimates because dermal exposure was not quantitatively assessed. For *o*-phthalic acid exposure via the inhalation route (*i.e.,* the air pathway), EPA assumed 100% absorption of *o*-phthalic acid.

4.2.2.1 Non-Cancer Human Health Hazards

TSCA section 4(h)(1) promotes the use of alternative test methods that reduce or replace vertebrate animals to the extent practicable when scientifically justified and consistent with TSCA's science standards. Consistent with this mandate, EPA, on January 22, 2026,[3] recommitted to phasing-out mammalian animal testing and further incorporating New Approach Methods (NAMs) into chemical risk evaluations. This assessment exemplifies this commitment by applying several computational approaches, *in vitro* studies in human tissues, and adverse outcome pathways (AOPs) throughout the hazard assessment and preferentially using human data over animal data, where appropriate. The data supporting this draft risk evaluation is significantly informed by EPA's collaborations with organizations such as the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), animal welfare organizations, and *in vitro* method developers (*e.g.,* Invitrolize) enabled the inclusion of cutting edge science, consistent with EPA's statutory mandate to use the best available science.

---

[3] Reference: U.S. Environmental Protection Agency. (2026, January 22). Administrator Zeldin Gets EPA Back on Track to Eliminate Animal Testing After Biden Admin Halted Phase Out [Press release]. https://www.epa.gov/newsreleases/administrator-zeldin-gets-epa-back-track-eliminate-animal-testing-after-biden-admin

EPA identified dermal and respiratory sensitization as the most sensitive and robust health effects following dermal and inhalation exposure to phthalic anhydride, respectively. In contrast, *o*-phthalic acid is not a dermal or respiratory sensitizer. These findings are based on observational studies in exposed worker populations and experimental studies in laboratory animals and with NAMs. Notably, previous assessments, including the Organization for Economic Co-operation and Development (OECD, 2005), Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2013), Health Canada (2019), and the American Conference of Government Industrial Hygienists (ACGIH, 2025) have also concluded that phthalic anhydride is a dermal and respiratory sensitizer. Further, phthalic anhydride is classified (Globally Harmonised System [GHS]) as Skin Sens. 1 (H317: May cause an allergic skin reaction) and Resp. Sens. 1 (H344: May cause allergy or asthma symptoms or breathing difficulties if inhaled) in the European Union (EU).

The HED and HEC values for use in estimating risks to workers and consumers from various exposure scenarios in the risk evaluation are available in Table 4-12 for phthalic anhydride. The HED and HEC values used to estimate risks to the general population from exposure to *o*-phthalic acid in the risk evaluation are available in Table 4-13.

Dermal Exposure Route – Consumers and Workers

EPA identified dermal sensitization as the most sensitive and robust human health hazard for the dermal route of exposure to phthalic anhydride. This conclusion is supported by reasonably available evidence from human studies of exposed workers and consumers, animal toxicology studies (*i.e.,* local lymph node assays [LLNAs], Guinea Pig Maximization Tests [GPMTs], Buehler tests), as well as mechanistic *in vitro* assays (*i.e.,* U-SENS and GARDskin assays) and *in chemico* assays (*i.e.,* Direct Peptide Reactivity Assay [DPRA] and kinetic DPRA [kDPRA]). Available data were evaluated in the context of the OECD (2014) AOP for skin sensitization, which describes the series of linked key events (KEs) at different levels of biological organization (*e.g.,* cell, tissue, organ) that ultimately manifest as the adverse outcome of skin sensitization. In the AOP, the linked KEs occur during the immune priming phase following initial exposure (*i.e.,* induction), while the adverse outcome occurs after subsequent exposure to reflect that skin sensitization is a biphasic response (*i.e.,* an induction and subsequent elicitation phase).

Consistent with OECD's *Guideline No. 497: Defined approaches on skin sensitization* (OECD, 2025), EPA used the Skin Allergy Risk Assessment – Integrated Chemical Environment (SARA-ICE) model to derive a dermal POD based on skin sensitization expected in humans. SARA-ICE is a computational NAMs based approach that provides a non-animal, human based option for hazard and risk assessment. Using SARA-ICE, EPA derived a draft POD of 45 $\mu g/cm^2$ (Table 4-12). The draft POD is based on the SARA-ICE predicted estimate of the ED_{01}, which is the effective dose at which there is a 1% chance of inducing sensitization in a human predictive patch test (HPPT). A total uncertainty factor (UF) of 1× was selected for use as the benchmark MOE.

EPA did not derive dermal absorption estimates for phthalic anhydride because the dermal POD is based on skin sensitization and was therefore derived in terms of an applied dose. Skin sensitization is most relevant to acute exposures because a single exposure to phthalic anhydride may elicit immunological events during the induction phase of skin sensitization.

Inhalation Exposure Route – Consumers and Workers

EPA identified respiratory sensitization as the most sensitive and robust human health hazard for the inhalation route of exposure to phthalic anhydride. This conclusion is based on the best available science and weight of scientific evidence across reasonably available data from epidemiology studies of exposed workers, experimental studies of laboratory animals, and *in vitro* mechanistic data. Similar to dermal sensitization, data supporting respiratory sensitization is organized in the context of AOP 39 (*i.e.,* the AOP for respiratory sensitization). AOP 39 describes the series of linked key events at different levels of biological organization in the respiratory tract (*e.g.,* cell, tissue, organ) that ultimately manifest as the adverse outcome of an allergic respiratory hypersensitivity response. In the AOP, the linked KEs occur during the immune priming phase following initial exposure (*i.e.,* induction), while the adverse outcome occurs after subsequent exposure to reflect the biphasic response of respiratory sensitization (*i.e.,* an induction and subsequent elicitation phase). Unlike dermal sensitization, there are not yet validated approaches or *in vivo* or *in vitro* test methods for identifying respiratory sensitizers for use in a regulatory context. Although AOP 39 sensitization is used as an organizing principle in this assessment, it is under development and not yet endorsed by OECD (although endorsement is expected by April 2026). Unlike dermal sensitization, there are not yet validated approaches or *in vivo* or *in vitro* test methods for identifying respiratory sensitizers for use in a regulatory context.

EPA integrated available dose-response information from candidate PODs with existing hazard values from other organizations, including other regulatory agencies. EPA is proposing a POD of 0.4 mg/m^3 (8-hour TWA) from an occupational exposure study by Nielsen et al. (1988). The POD is based on a LOAEC for increased prevalence of respiratory symptoms (including asthma and rhinitis) and increased serum specific IgG consistent with respiratory sensitization. The POD from Nielsen et al. (1988) was also selected for use in risk characterization by Health Canada (2019) and for setting an inhalation reference exposure level by California EPA (CalEPA, 2008). For the risk evaluation for phthalic anhydride, EPA selected a total UF of 30× for use as the benchmark MOE (based on an UF_H of 10× to account for human variability, and a LOAEC-to-NOAEC UF (UF_L) of 3× to account for the lack of NOAEC in the critical study).

The 10× UF_H can be divided into two components: one for toxicodynamic differences ($UF_{H\text{-}TK}$ of 3×) and a second for toxicokinetic differences ($UF_{H\text{-}TD}$ of 3×) (U.S. EPA, 2002, 1994b). For input into the draft risk evaluation of phthalic anhydride, EPA selected a factor of 3× for the toxicodynamics component of the UF_H because very limited data were available to inform the range in variability of the allergic response across the human population associated with exposure to phthalic anhydride. EPA initially considered two options for the $UF_{H\text{-}TK}$ factor for the draft risk evaluation of phthalic anhdyride. For Option 1, EPA considered reducing the toxicokinetic component of the UF_H from 3× to 1× based on evaluation of multiple exposure scenarios using the using the Multi-Path Particle Dosimetry (MPPD) model, which overall supported an intersubject variability factor of 1.5 under occupational settings (*i.e.,* there is a 1.5-fold increase in the dose rate of particles depositing in the tracheobronchial region, when employee activity increases from light to heavy activity). Option 2 reflects application of dosimetric modeling of the Nielsen et al. (1988) study to understand interindividual (intraspecies) variability that is expected to occur even when factors such as activity level, breathing conditions, and particle size are held constant. As such, Option 2 represents interindividual (intraspecies) variability in particle deposition due to morphometric and physiologic differences among individuals. In contrast, Option 1 is based on MPPD simulation analysis of interindividual variability based on the exposure conditions reflective of the Nielsen et al. (1988) study. The results of modeling in support of Option 2 show that the upper bound for particle deposition in the tracheobronchial region is about 3 times the central tendency estimate regardless of activity level, particle size, or sex of the hypothetical individuals, supporting a factor of 3×.

As described further in Section 4.3.1.3.1 of (U.S. EPA, 2026p), EPA has weighted the strengths and uncertainties associated with Option 1 ($UF_{H\text{-}TK}$ = 1×) and Option 2 ($UF_{H\text{-}TK}$ = 3×). For this draft risk evaluation, EPA selected Option 2 ($UF_{H\text{-}TK}$ of 3×), which more fully captures the anatomical and physiological factors expected to drive the overall toxicokinetic variability expected in the worker population. Option 2 is a data derived approach reflecting interindividual (intraspecies) variability in particle deposition due to morphometric and physiologic differences among individuals that is expected to occur even when other factors (*e.g.,* activity level, breathing conditions, and particle size) are held constant. EPA is soliciting comments from the SACC and the public on the underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride.

EPA applied a UF_L to capture the uncertainty associated with the use of a LOAEC as the candidate POD from Nielsen et al. (1988). EPA's *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* guidance states to use "up to an additional 10-fold factor when deriving an RfC from a LOAEL instead of a NOAEL" (U.S. EPA, 1994b). The Agency considered two options for the UF_L. Option 1 assumes that respiratory sensitization is a severe outcome, that there is insufficient information to inform the slope of the dose-response curve, and that there are exposure uncertainties that, altogether, warrant a UF_L of 10×. Option 2 considers that a UF_L of 3× is reasonable given the limitations of the Nielsen et al. (1988) study and the prevalence of outcomes reported relative to the observed symptom prevalences of general population benchmarks (*e.g.,* ≈8% adult asthma (CDC, 2026) and roughly ≈26% seasonal allergy (primarily including allergic rhinitis) in adults (Ng and Boersma, 2023)). As described further in Section 4.3.1.3.1 of (U.S. EPA, 2026p), EPA has weighted the strengths and uncertainties associated with Option 1 (UF_L = 1×) and Option 2 (UF_L = 3×). For input into the draft risk evaluation of phthalic anhydride, EPA selected Option 2 (UF_L of 3×) based on considerations of the severity of the effect observed in the epidemiological study by Nielsen et al. Both Options are described in further detail in Section 4.3.1.3.1 of (U.S. EPA, 2026p). EPA is soliciting comments from the SACC and the public on the uncertainties in the endpoint in the study by Nielsen et al.

Although EPA has preliminarily concluded that the best available science supports application of a benchmark MOE of 30× in the draft risk evaluation, the overall benchmark MOE may be revised in the final phthalic anhydride risk evaluation to either 10 or 100 based on SACC peer-review and public comments on the underlying science. Because the benchmark MOE may be revised in the final phthalic anhydride risk evaluation, EPA has also provided a characterization of consumer (Appendix G.1) and worker (Appendix G.2) inhalation MOEs at alternative benchmarks of 10 and 100.

Oral Exposure Route – General Population Exposures

The general population is expected to be primarily exposed to *o*-phthalic acid from TSCA releases of phthalic anhydride. This is because phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid in the presence of moisture. *o*-Phthalic acid is not a dermal or respiratory sensitizer and no hazards were identified for the dermal and inhalation exposure routes. EPA evaluated hazards associated with oral exposure to *o*-phthalic acid in addition to phthalic anhydride. Reasonably available studies of *o*-phthalic acid were primarily limited to the oral exposure route. Of the 11 reasonably available oral studies (9 in rats; 2 in mice), five report no-effect levels over 1,000 mg/kg-day following gavage or dietary exposure to *o*-phthalic acid or phthalic anhydride and the LOAELs of most studies reflect decreases in body weight or food consumption ranging from 250 to 5,000 mg/kg-day. Overall, EPA has preliminarily concluded that phthalic anhydride and *o*-phthalic acid have low systemic toxicity via the oral route of exposure. Notably, OECD (2005), Australia NICNAS (2013), and Health Canada (2019) have also concluded that phthalic anhydride has low systemic toxicity via the oral route of exposure. For use in the general population screening-level assessment of *o*-phthalic acid, EPA is proposing a POD derived from a NOAEL of 278 mg/kg-day (HED = 66 mg/kg-day) based on decreased body weight gain in male F344 rats fed diets containing phthalic anhydride for 2 years (NCI, 1979). Although the key study used to derive the proposed oral POD is based on dietary exposure to phthalic anhydride, this POD is considered suitable for use in characterizing risk in its general population screening-level risk assessment because the hazard profiles of phthalic anhydride and *o*-phthalic acid are similar via the oral exposure route. Both chemicals exhibit low systemic toxicity and cause similar effects, which are primarily limited to decreases in body weight gain, terminal body weight, and food consumption. This is in contrast to the hazard profiles of each chemical through the inhalation and dermal exposure routes, where phthalic anhydride is a dermal and respiratory sensitizer, while *o*-phthalic acid is not. EPA selected a total UF of 30× for use as the benchmark MOE (UF_H = 10×; interspecies UF [UF_A] = 3×) in its general population screening-level risk assessment (Section 4.3.4).

Inhalation Exposure Route – General Population Exposures

For use in the general population screening assessment, no data are reasonably available for the inhalation route for *o*-phthalic acid that are suitable for deriving route-specific PODs, therefore, EPA is using the oral POD to estimate risks from inhalation exposures to *o*-phthalic acid by extrapolating the oral HED to inhalation HECs assuming the human body weight and breathing rates of an individual at rest (U.S. EPA, 1994b). According to EPA guidelines, route-to-route extrapolation is appropriate in the absence of a suitable physiologically based pharmacokinetic (PBPK) model and/or absence of data to determine dosimetry via inhalation in cases where there is not portal of entry toxicity (U.S. EPA, 1994b).

The HED and HEC values for use in estimating risks from various exposure scenarios and relevant populations in the risk evaluation are available in Table 4-12.

4.2.2.2 Cancer Human Health Hazards

As discussed in the *Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p), available *in vivo* and *in vitro* data indicate that neither phthalic anhydride nor *o*-phthalic acid has the potential for genotoxicity. Available human data and *in vivo* data (including NCI (1979) dietary exposure cancer bioassays of rats and mice) indicate that phthalic anhydride does not have the potential for carcinogenicity. Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), EPA reviewed the weight of evidence for the carcinogenicity of phthalic anhydride and preliminarily concluded that phthalic anhydride is *Not Likely to Be Carcinogenic to Humans*.

Table 4-12. Non-Cancer Hazard Values for Phthalic Anhydride for Use in the Human Health Risk Assessment for Workers and Consumers

Relevant Populations in Draft Risk Evaluation	Exposure/ Scenario	Hazard Value	Uncertainty Factors	Total Uncertainty Factors	Study and Toxicological Effects
Workers and consumers only	Dermal	HED = 45 µg/cm^2	UF_H = 1	Total UF = 1	Data from 3 LLNAs, 1 DPRAs, and 1 kDPRA were input into the SARA-ICE model to estimate ED_{01}, which is the HPPT dermal dose at which there is 1% chance of inducing sensitization. The POD is the geometric mean of the distribution.
	Inhalation	HEC = 0.4 mg/m^3 = 0.07 ppm	UF_L = 3 UF_H = 10	Total UF = 30	Epidemiological study of factory workers in Sweden. Workers were classified as “heavily” (n = 28 reactor loaders; n = 7 repair men) or “slightly” (n = 25) exposed based on their job. Mean peak (30 minute) air concentrations were 6.6 mg/m^3 in heavily exposed workers, equivalent to an 8 h TWA of 0.4 mg/m^3 (LOAEL). Mean peak air concentrations in lightly exposed workers were below the limit of detection (0.1 mg/m^3) (Nielsen et al., 1988)

DPRA = direct peptide reactivity assay; HED = human equivalent dose; HEC = human equivalent concentration; HPPT = human predictive patch test; kDPRA= kinetic DPRA; LLNA = local lymph node assay; LOAEL = lowest-observed-adverse-effect level; SARA-ICE = Skin Allergy Risk Assessment – Integrated Chemical Environment; UF = uncertainty factor; UF_H = intraspecies uncertainty factor; UF_L = LOAEL-to-NOAEL uncertainty factor.

Table 4-13. Non-Cancer Hazard Values for *o*-Phthalic Acid for Use in the Human Health Risk Assessment for the General Population

Relevant Populations in Risk Evaluation	Exposure/ Scenario	Hazard Value	Uncertainty Factors	Total Uncertainty Factors	Study and Toxicological Effects
General population only	Oral, Dermal, & Inhalation/ Chronic	HED = 66 mg/kg-day HEC = 358 mg/m^3 = 52.6 ppm	UF_A = 3 UF_H = 10	Total UF = 30	NOAEL of 278 mg/kg-day based on 10% decrease in body weight gain in male F344 rats fed diets containing phthalic anhydride for 2 years (NCI, 1979)

HEC = human equivalent concentration; HED = human equivalent dose; NOAEL = no-observed-adverse-effect level; UF = uncertainty factor; UF_A = interspecies uncertainty factor; UF_H = intraspecies uncertainty factor

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 4-14.

Table 4-14. 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 phthalic anhydride under light activity (for further details see (U.S. EPA, 2026o)) Exposure Durations • *Acute* – 8 hours for a single workday Exposure Routes • Inhalation and dermal
	Occupational Non-users Male and female adolescents and adults (≥16 years old) indirectly exposed to phthalic anhydride within the same general vicinity as workers (for further details see (U.S. EPA, 2026o)) Exposure Durations • *Acute* – same as workers Exposure Routes • Inhalation, dermal (for COUs where mist and dust deposited on surfaces)
	Consumers Male and female users exposed to phthalic anhydride through product use (for further details see (U.S. EPA, 2026b)) Exposure Durations • *Acute* – 1 day exposure Exposure Routes • Inhalation and dermal
	Bystanders Male and female of all ages incidentally exposed to phthalic anhydride through product use (for further details see (U.S. EPA, 2025a)) Exposure Durations • *Acute* – 1 day exposure Exposure Routes • Inhalation
	General Population Exposed to *o*-Phthalic Acid Following Environmental Releases of Phthalic Anhydride Male and female infants, children, youth, and adults exposed to *o*-phthalic acid through drinking water, surface water, soil from air to soil deposition, and fish ingestion (for further details see (U.S. EPA, 2026n)) Exposure Durations • *Chronic* – Exposed to *o*-phthalic acid daily/continuously up to 33 years Exposure Routes – Inhalation, dermal, and oral (depending on exposure scenario)

Health Effects, Concentration and Time Duration	**Dermal Exposures to Phthalic Anhydride | Non-cancer Value** • Sensitive health effect: skin sensitization ○ Acute exposures are most relevant to skin sensitization, as a single exposure to phthalic anhydride may elicit immunological events during the induction phase of skin sensitization. The POD is applicable to acute, intermediate, and chronic durations of exposure to phthalic anhydride as acute would represent the most sensitive effect. • HED = 45 $\mu g/cm^2$; dermal • Total UF (benchmark MOE) = 1× (UF_H = 1×) **Inhalation Exposures to Phthalic Anhydride** • Sensitive health effect: respiratory sensitization ○ Acute exposures are most relevant to respiratory sensitization, as a single exposure to phthalic anhydride may elicit immunological events during the induction phase of respiratory sensitization. The POD is applicable to acute, intermediate, and chronic durations of exposure to phthalic anhydride as acute would represent the most sensitive effect. • HEC = 0.4 mg/m^3 ○ Reflects 8-hour TWA air concentration for exposed workers • Total UF (benchmark MOE) = 30× (UF_H = 10×; UF_L = 3×) **Oral, Dermal, Inhalation Exposures to the General Population of *o*-Phthalic Acid Following Releases of Phthalic Anhydride | Non-cancer Intermediate/Chronic Value** • Sensitive health effect: Reduced body weight gain • HED Daily = 66 mg/kg-day; dermal and oral • HEC Daily, continuous (assumes breathing rate of 0.6125 m^3/h and 24 hours/day for continuous exposure (U.S. EPA, 2011a)) = 358 mg/m^3 (52.6 ppm) • 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 of injury to human health or the environment, calculated risk estimates are not "bright-line" indicators of unreasonable risk, and EPA considers other risk-related factors in addition to risks identified in the risk characterization.

4.3.2 Risk Estimates for Workers

4.3.2.1 Occupational Inhalation Risk Characterization

Standard Respiratory Protective Equipment

OSHA's Respiratory Protection Standard (29 CFR 1910.134) requires employers in certain industries to address workplace hazards by implementing engineering control measures and, if these are not feasible, providing respirators that are applicable and suitable for the purpose intended. Respirator selection provisions are provided in section 1910.134(d) and require that appropriate respirators be selected based on the respiratory hazard(s) to which the worker will be exposed, in addition to workplace and user factors that affect respirator performance and reliability. Assigned protection factors (APFs) are provided in Table 1 under section 1910.134(d)(3)(i)(A) (see below in Table 4-15) and refer to the level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a respiratory protection program according to the requirements of OSHA's Respiratory Protection Standard. Based on the APF, inhalation exposures may be reduced by a factor of 5 to 10,000, if respirators are properly worn and fitted.

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

Type of Respirator	Quarter Mask	Half Mask	Full Facepiece	Helmet/ Hood	Loose-Fitting Facepiece
1. Air-Purifying Respirator	5	10	50	–	–
2. Power Air-Purifying Respirator (PAPR)	–	50	1,000	25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	–	10	50	–	–
• Continuous flow mode	–	50	1,000	25/1,000	25
• Pressure-demand or other positive-pressure mode	–	50	1,000	–	–
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	–	10	50	50	–
• Pressure-demand or other positive-pressure mode (*e.g.,* open/closed circuit)	–	–	10,000	10,000	–

Source: 29 CFR 1910.134(d)(3)(i)(A)

Respiratory Protection for Occupational Exposures to Phthalic Anhydride

Phthalic anhydride is a known respiratory sensitizer, and occupational exposure limits vary among regulatory and scientific agencies, as shown in Table 4-16. The OSHA 8-hour TWA permissible exposure limit (PEL) is 12 mg/m^3, the NIOSH 10-hour TWA recommended exposure limit (REL) is 6 mg/m^3 , and the ACGIH 8-hour TWA threshold limit value (TLV) is 0.002 mg/m^3 . The OSHA PEL is based on the 1971 value. The NIOSH REL is based on the 1989 value. The ACGIH TLV is based on the most recent 2017 value. As described in Section 4.3, EPA has established a POD of 0.4 mg/m^3 for inhalation exposure (8-hour TWA) and a benchmark MOE of 30. Table 4-17 shows the MOE values associated with inhalation exposure estimates for each OES, and any MOE value below the benchmark is highlighted. Table 3-1 provides a map indicating which COUs are associated with each OES, and Table 4-1 provides confidence ratings for occupational inhalation exposure estimates. All inhalation exposure estimates are based on measured monitoring data; therefore, it is foreseeable that workers may experience high-end exposure levels on an acute basis. Consequently, worker risks are based on high-end exposure estimates and MOE values outlined in Table 4-3 and Table 4-17, respectively. Detailed occupational exposure data and risk calculations can be found in the *Draft Occupational Exposure and Risk Calculator for Phthalic Anhydride* (U.S. EPA, 2026q).

Regarding current respiratory protection practices in phthalic anhydride manufacturing and processing facilities, EPA identified a few recent studies that demonstrate the types of respiratory protection currently used in industrial settings (Tustin et al., 2022; Cardno ChemRisk, 2020; Griesenbrock, 2017). Griesenbrock (2017) reported one full-shift PBZ measurement of a worker unloading phthalic anhydride from a truck, and the worker was wearing a full-face respirator; however, the APF of the respirator was not reported. Cardno ChemRisk (2020) conducted an occupational exposure monitoring assessment at a phthalic anhydride production facility, and the assessment indicated that about half of equipment operation workers wore full-face 3M6900 respirators with P100 filters (APF 50) and the other half did not wear any respiratory protection. Also, the study indicated that one worker who was monitored during a high exposure task (*i.e.,* unclogging a baghouse chute) wore a SCBA respirator with APF 10,000. However, it was also reported that some workers wore only an APF 50 respirator during similar high exposure tasks. Lastly, EPA identified one study that measured full-shift phthalic anhydride levels for workers in a facility that manufactures countertops using phthalic anhydride as a hardener in epoxy resin casting mixtures (Tustin et al., 2022). Tustin et al. (2022) notes that full-face respirators were available for workers, but some workers failed to wear the supplied respirators. Although these recent studies indicate that respiratory protection is generally available to workers handling phthalic anhydride, there are noted cases where workers are not wearing the available respiratory protection or the APF of the respirator may not be sufficient for the exposure levels of the tasks.

Product SDSs also provide recommendations for ventilation and respiratory protection for products containing phthalic anhydride. EPA identified 29 industrial and commercial products containing phthalic anhydride produced within the last 10 years and are expected to be in current use. All product SDSs specified that there should be adequate ventilation during product use, and that NIOSH approved respiratory protection should be used if ventilation is not adequate. Most product SDSs did not define "adequate ventilation," but two adhesive product SDSs (Henkel, 2025, 2018) specified the use of down-draft exhaust ventilation and two sprayable epoxy resin product SDSs (Polynt, 2024, 2016) specified air exchange rates of 3 to 5 air exchanges per hour. Similarly, most product SDSs did not specify a type of respirator, but the two aforementioned sprayable epoxy resin product SDSs (Polynt, 2024, 2016) specified an APF 40 for applications lasting less than 1 hour and APF 200 for applications lasting longer than one hour. See Appendix A of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for product details.

As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p) and Section 4.2.2 of this draft risk evaluation, EPA has preliminarily concluded that the best available science supports application of a benchmark MOE of 30× in the draft risk evaluation. However, EPA is seeking SACC and public input on the underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride, as well as the severity of the effect observed at the LOAEC that serves as the basis of the inhalation POD. Based on SACC and public feedback, the overall benchmark MOE may be revised in the final phthalic anhydride risk evaluation to 10 or 100. Because the benchmark MOE may be revised in the final phthalic anhydride risk evaluation, EPA has also provided a characterization of worker inhalation MOEs at alternative benchmarks of 10 and 100 in Appendix G.2.

Table 4-16. Summary of Select Occupational Exposure Limits for Phthalic Anhydride Set by Various Organizations

Administrative Agency or Other Authoritative Source	Publication Year	Inhalation Hazard Value (mg/m^3)
ACGIH TLV (8-hour TWA)	2017	0.002
NIOSH REL (10-hour TWA)	1989	6
OSHA PEL (8-hour TWA)	1971[a]	12

NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; REL = recommended exposure limit; TLV = threshold limit value; TWA = time-weighted average

[a] In 1971, OSHA revised an existing occupational safety and health standards for phthalic anhydride to include an 8-hour TWA PEL of 12 mg/m^3 TWA. (29 CFR 1910.1000, accessed March 3, 2026). In 1989, OSHA lowered the 8-hour TWA PEL to 6 mg/m^3; however, the rule was vacated in 1991 and the prior PEL of 12 mg/m^3 from 1971 was reinstated.

Table 4-17. Occupational MOE Estimates and the Effects of Respiratory Protection

OES(s)	Worker Category	Inhalation MOE (Benchmark MOE = 30) [a]		APF 10 (Benchmark MOE = 30) [a]		APF 50 (Benchmark MOE = 30) [a]		APF 1,000 (Benchmark MOE = 30) [a]		APF 10,000 (Benchmark MOE = 30) [a]	
		CT	HE	CT	HE	CT	HE	CT	HE	CT	HE
Manufacturing; Import and repackaging	High exposure worker [b]	0.68	0.17	6.8	1.7	34	8.6	6.8E02	1.7E02	6.8E03	1.7E03
	Worker [c]	31	3.0	3.1E02	30	1.6E03	1.5E02	3.1E04	3.0E03	3.1E05	3.0E04
	ONU [d]	1.4E02	49	N/A		N/A		N/A		N/A	
Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; Plastic compounding	High exposure worker [b]	1.8	0.32	18	3.2	90	16	1.8E03	3.2E02	1.8E04	3.2E03
	Worker [c]	47	7.1	4.7E02	71	2.4E03	3.6E02	4.7E04	7.1E03	4.7E05	7.1E04
	ONU [d]	1.4E02	49	N/A		N/A		N/A		N/A	
Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	Worker	0.14	2.4E−02	1.4	0.24	7.1	1.2	1.4E02	24	1.4E03	2.4E02
	ONU [e]	0.14		N/A		N/A		N/A		N/A	
Plastic converting	Worker	1.6E03	1.3E03	1.6E04	1.3E04	7.8E04	6.7E04	1.6E06	1.3E06	1.6E07	1.3E07
	ONU [e]	1.6E03		N/A		N/A		N/A		N/A	
Application of paints, coatings, adhesives, and sealants	Worker (non-spray application)	2.4E02	1.8E02	2.4E03	1.8E03	1.2E04	9.1E03	2.4E05	1.8E05	2.4E06	1.8E06
	ONU [e] (non-spray application)	2.4E02		N/A		N/A		N/A		N/A	
	Worker [f] (spray application)	0.30	3.6E−02	3.0	0.36	15	1.8	3.0E02	36	3.0E03	3.6E2
Use of laboratory chemicals	Worker	27	14	2.7E02	1.4E02	1.3E03	6.8E02	2.7E04	1.4E04	2.7E05	1.4E05
	ONU [e]	27		N/A		N/A		N/A		N/A	

OES(s)	Worker Category	Inhalation MOE (Benchmark MOE = 30) [a]		APF 10 (Benchmark MOE = 30) [a]		APF 50 (Benchmark MOE = 30) [a]		APF 1,000 (Benchmark MOE = 30) [a]		APF 10,000 (Benchmark MOE = 30) [a]	
		CT	**HE**	**CT**	**HE**	**CT**	**HE**	**CT**	**HE**	**CT**	**HE**
Use of lubricants and functional fluids	Worker	1.6E03	1.3E03	1.6E04	1.3E04	7.8E04	6.7E04	1.6E06	1.3E06	1.6E07	1.3E07
	ONU [e]	1.6E03		N/A		N/A		N/A		N/A	
Fabrication or use of final products or articles	Worker (fabrication)	3.5	1.3	35	13	1.8E02	63	3.5E03	1.3E03	3.5E04	1.3E04
	ONU (fabrication)	80		8.0E02		4.0E03		8.0E04		8.0E05	
	Worker, ONU (routine use)	No inhalation exposure from routine use of final products or articles.									
Disposal and recycling	Worker	1.4E02		1.4E03		7.1E03		1.4E05		1.4E06	
	ONU [e]	1.4E02		N/A		N/A		N/A		N/A	

APF = assigned protection factor; CT = central tendency; HE = high-end; OES = occupational exposure scenario

[a] MOE values below the benchmark are highlighted.

[b] High exposure workers are those engaged in short-term, high exposure tasks, as well as routine equipment operations or maintenance. For phthalic anhydride production, high exposure tasks include flaking and bagging phthalic anhydride, unclogging baghouse chutes, filling drums with process impurities, and cleaning equipment with high solids content. For phthalic anhydride processing, high exposure tasks include dumping and mixing bags of phthalic anhydride, as well as disposal of the empty bags.

[c] Workers associated with manufacturing and processing data include equipment operators and maintenance workers.

[d] ONUs associated with manufacturing and processing data include instrument technicians, warehouse workers, office engineers, and supervisors.

[e] When ONU inhalation data were not available, EPA used worker central tendency exposure values to estimate potential inhalation exposures to ONUs.

[f] Spray applications are expected to occur in enclosed spaces with ventilation controls and EPA does not expect exposures to occur outside the application area. Therefore, inhalation exposures from spray applications were not considered a route of concern for ONUs.

4.3.2.2 Occupational Dermal Risk Characterization

Phthalic anhydride is a known dermal sensitizer, and EPA has determined a POD for dermal exposure to phthalic anhydride of 4.5×10^{-2} mg/cm^2 and a benchmark margin of exposure (MOE) of 1. Table 4-18 shows the MOE values associated with dermal exposure estimates for each OES, and any MOE value below the benchmark is highlighted. Table 3-2 provides a map indicating which COUs are associated with each OES; Table 4-1 provides confidence ratings for occupational dermal exposure estimates. Detailed occupational exposure data and risk calculations can be found in the *Draft Occupational Exposure and Risk Calculator for Phthalic Anhydride* (U.S. EPA, 2026q).

Phthalic anhydride is a solid at room temperature and typically exists in a concentrated form in solid materials (*i.e.,* 90 to 100%). Although there were no reasonably available chemical-specific dermal loading data identified through the EPA systematic review process for phthalic anhydride, EPA identified two studies that measured dermal loading for similar tasks and materials (UK IOM, 2003; Lansink et al., 1996). These two studies were identified in a detailed analysis of available dermal loading data conducted by Marquart et al. (2006); however, EPA is seeking input on additional data through the public comment of this draft assessment. It is important to note that dermal loading estimates for solid materials vary depending on factors including task, physical and chemical properties, and sampling methodology. Lansink et al. (1996) measured ranges of dermal loading (10th to 90th percentile) of calcium carbonate during collection of raw material (0.13 to 0.57 mg/cm^2), handling of empty bags (3.0×10^{-2} to 0.56 mg/cm^2), and manual dumping and mixing (0.12 to 1.6 mg/cm^2). Cotton gloves were used for measuring dermal loading of calcium carbonate by Lansink et al. (1996), and the study states that this may overestimate or underestimate skin adherence.

In comparison, Hughson et al. (2003) measured ranges of dermal loading (10th to 90th percentile) of zinc oxide during manual dumping (3.0×10^{-2} to 0.18 mg/cm^2) and contact with a dusty surface (0.10 to 0.40 mg/cm^2). Wipe samples were used to collect zinc oxide from bare skin to determine dermal loading values presented by Hughson et al. (2003), and it is noted that this method may underestimate dermal exposure (Marquart et al., 2006). Calcium carbonate and zinc oxide are both solid materials similar in form to phthalic anhydride. However, according to Hughson et al. (2003), zinc oxide tends to agglomerate into larger particles and the material has low adherence to the skin. Further, the density of zinc oxide (5.6 g/cm^3) is greater than the densities of calcium carbonate (2.7 g/cm^3) and phthalic anhydride (1.5 g/cm^3). Comparing the evaluations of Hughson et al. (2003) and Lansink et al. (1996) for use in the assessment of phthalic anhydride, Lansink et al. (1996) evaluated a wider range of tasks applicable to occupational uses of phthalic anhydride and used a substance with physical and chemical properties that more closely resemble phthalic anhydride. Although there are uncertainties presented by both sets of data, there is greater scientific evidence to support the use of dermal loading data from Lansink et al. (1996) as surrogate for the various occupational uses of phthalic anhydride. Figure 4-3 illustrates a comparison of the dermal loading values for relevant tasks for both studies in terms of the impact on the dermal MOE. While there is variation in dermal loading between the two studies, the dermal MOE is below the benchmark for the 50th percentile of each dataset.

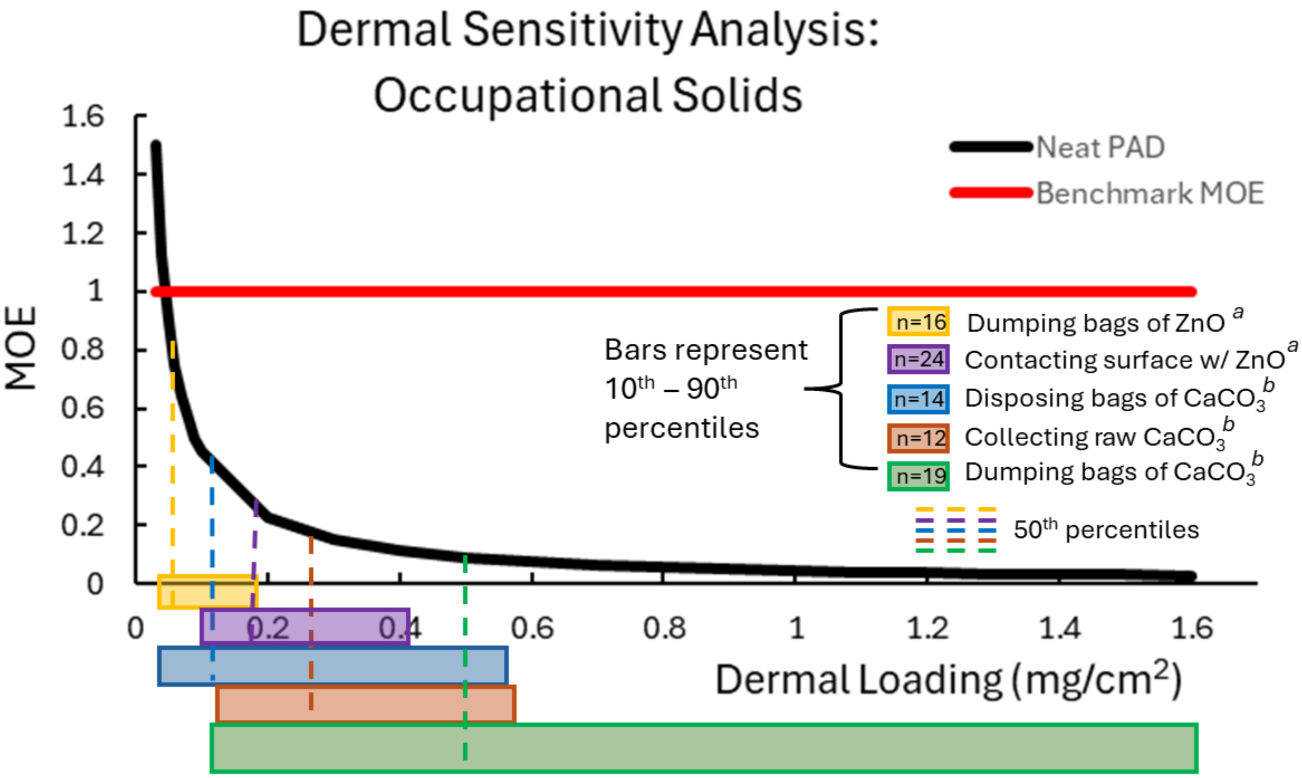


Figure 4-3. Sensitivity Analysis of Dermal Loading Measurements on Dermal MOE

Colored bars beneath x-axis represent the range of dermal loadings for specific activities, from empirical studies (activities and study are detailed in legend on right side of figure). For example, the yellow horizontal bar represents the range of dermal loadings from dumping bags of ZnO, as demonstrated in the Hughson and colleagues study.

[a] Hughson et al. (2003) (n = number of samples)

[b] Lansink et al. (1996) (n = number of samples)

In liquid formulations containing phthalic anhydride, concentrations may vary from below 0.1% up to 25%. EPA has preliminarily determined that dermal PPE should be considered for handling any non-sprayable liquid formulation with phthalic anhydride concentration greater than 2.25% and any sprayable liquid formulation with phthalic anhydride concentration greater than 0.44%. These values are based on the dermal loading of liquid formulations for non-spray (*i.e.,* 2.1 mg product/cm^2) and spray (*i.e.,* 10.3 mg product/cm^2) scenarios (see Table 4-4), the dermal POD of 4.5×10^{-2} mg/cm^2, and the benchmark MOE of 1. Handling non-sprayable and sprayable liquid formulations containing phthalic anhydride at levels below 2.25% and 0.44%, respectively, are not expected to lead to dermal sensitization.

Because the majority of occupational dermal exposure estimates lead to MOE values below the benchmark, it is important to consider appropriate dermal PPE for phthalic anhydride. Gloves are selected in industrial settings based on characteristics such as permeability, durability, and required task. Many product SDSs provide recommendations for minimizing dermal exposure to products containing phthalic anhydride. EPA identified 29 industrial and commercial products containing phthalic anhydride produced within the last 10 years and are expected to be in current use. Most product SDSs specified that users should wear gloves made from nitrile or some polymer laminate material such as neoprene, rubber, polyethylene, polypropylene, or polyvinyl alcohol. Furthermore, some product SDSs indicate that gloves made of cotton or polyvinyl chloride (PVC) should not be used, and that used all gloves should be discarded after use. For handling sprayable materials or the neat material, product SDSs indicated that the users should also wear a polymer laminate apron, protective boots, and head/face protection. The NIOSH Recommendations for Chemical Protective Clothing (NIOSH, 2000) suggest Silver Shield/4H gloves for handling phthalic anhydride, which is a polymer laminate material made from polyethylene and ethylene vinyl alcohol. NIOSH (2000) indicates that the Silver Shield/4H glove material prevents breakthrough of phthalic anhydride for up to four hours, and that phthalic anhydride may penetrate the gloves after four hours of exposure. Therefore, Silver Shield/4H gloves are expected to effectively mitigate occupational dermal exposure as long as gloves are changed out after 4 hours of exposure. In agreement with the NIOSH Recommendations for Chemical Protective Clothing, the New Jersey Department of Health (NJDH, 2010) also suggests the use of Silver Shield/4H gloves for handling phthalic anhydride. Further, NJDH also suggests the use of Tyvek suits for handling solid phthalic anhydride and Tychem (CPF3, BR, Responder, TK) or Trellchem (HSP, VPS) suits (or equivalent) for handling liquid phthalic anhydride.

Table 4-18. Occupational MOE Estimates for Dermal Exposure to Phthalic Anhydride

OES(s)	Worker Category	Exposure Type	Dermal Exposure (mg Phthalic Anhydride/cm^2)		Dermal MOE [a] (Benchmark MOE = 1)	
			CT	HE	CT	HE
Manufacturing; Import and repackaging	High exposure worker [b]	Solid [c]	0.23	0.57	0.19	7.8E−02
	Worker [d]	Solid [c]	0.10	0.56	0.43	8.0E−02
	ONU [e]	Solid [c]	2.7E−02		1.7	
Processing as a reactant; Incorporation into formulations, mixtures, or reaction products (including incorporation as epoxy hardener); Plastic compounding	High exposure worker [b]	Solid [c]	0.43	1.6	0.10	2.7E−02
	Worker [d]	Solid [c]	0.10	0.56	0.43	8.0E−02
	ONU [e]	Solid [c]	2.7E−02		1.7	
Plastic converting	Worker, ONU	Plastics	No dermal exposure expected from routine handling of final products or articles.			
Application of paints, coatings, adhesives, or sealants	Worker (non-spray application) [f]	Liquid products	0.14	0.53	0.32	8.6E−02
	Worker (spray application) [g]	Liquid products	0.38	2.6	0.12	1.7E−02
Use of laboratory chemicals	Worker	Liquid products	1.4E−03	4.2E−03	32	11
		Solid [c]	0.10	0.56	0.43	8.0E−02
	ONU	Solid [c]	2.7E−02		1.7	
Use of lubricants and functional fluids	Worker [f]	Liquid products	5.6E−04	1.1E−02	80	4.3
Fabrication or use of final products or articles	Worker (fabrication)	Dust [c]	6.0E−02	0.45	0.75	0.10
	ONU (fabrication)	Dust [c]	1.5E−02		2.9	
	Worker, ONU (routine use)	Final products or articles	No dermal exposure expected from routine handling of final products or articles.			
Disposal and recycling	Worker, ONU	Waste	No dermal exposure expected from routine handling of final products or articles.			

OES(s)	Worker Category	Exposure Type	Dermal Exposure (mg Phthalic Anhydride/cm²)		Dermal MOE [a] (Benchmark MOE = 1)	
			CT	HE	CT	HE

CT = central tendency; HE = high-end; OES = occupational exposure scenario; ONU = occupational non-user

[a] MOE values below the benchmark are highlighted.

[b] High exposure workers are those engaged in short-term, high exposure tasks, as well as routine equipment operations or maintenance. For phthalic anhydride production, high exposure tasks include flaking and bagging phthalic anhydride, unclogging baghouse chutes, filling drums with process impurities, and cleaning equipment with high solids content. For phthalic anhydride processing, high exposure tasks include dumping and mixing bags of phthalic anhydride, as well as disposal of the empty bags. This includes incorporation of phthalic anhydride as an epoxy resin hardener.

[c] MOE values associated with occupational contact with phthalic anhydride solids are based on dermal loading data presented in Lansink et al. (1996). Comparison of MOE values for various datasets of Lansink *et al.* (1996) and Hughson et al. (2003) are presented in Figure 4-3.

[d] Workers associated with manufacturing and processing COUs include equipment operators and maintenance workers.

[e] ONUs associated with manufacturing and processing COUs include instrument technicians, warehouse workers, office engineers, and supervisors.

[f] Dermal exposures to ONUs expected to be *de minimis* for OES.

[g] Spray applications are expected to occur in enclosed spaces with ventilation controls and EPA does not expect exposures to occur outside the application area. Therefore, dermal exposures from spray applications were not considered a route of concern for ONUs. See Section 3.7.4 of the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026o) for additional details.

4.3.3 Risk Estimates for Consumers

The next two subsections summarize the consumer dermal (Section 4.3.3.1) and inhalation (Section 4.3.3.2) risk estimate characterization and calculation of MOEs for dermal and inhalation. Section 4.3.3.3 summarizes EPA's overall confidence in the consumer risk estimates.

4.3.3.1 Consumer Dermal Risk Characterization

The dermal risk assessment used non-cancer human hazards (Section 4.2) to characterize acute exposures to phthalic anhydride from consumer products and presents these values for each COU. This assessment for consumer exposures and subsequent risk considers a range of high to low-intensity use exposure scenario risk estimates and relies on representative input parameters to assess exposures that would be expected to be the upper and lower end of the expected exposure distribution. MOEs for low- , medium-, and high-intensity exposure scenarios are shown for all consumer COUs. Table 4-19 summarizes the weight fraction (%) and liquid product dermal loading (μg/cm^2) inputs used to obtain acute dermal exposures (μg phthalic anhydride/cm^2) and acute dermal MOE values by COU and exposure scenario. In addition, the table shows sensitivity analysis results that provide resolution for which combination of weight fraction and liquid product dermal loading is needed to obtain MOEs above or below the dermal benchmark of 1. COU specific detailed discussion subsections are available under Table 4-19.

Although EPA acknowledges that consumers may be dermally exposed via multiple individual COUs (*i.e.,* use adhesives, as well as paints and coatings), EPA is not aggregating individual COUs across the dermal route of exposure because the MOEs are already below the dermal benchmark (Table 4-19). Mathematically, the MOEs resulting from an aggregate calculation would be even further below the dermal benchmark MOE of 1.

Table 4-19. Consumer Dermal MOE Estimates

Consumer COU Category and Subcategory	Exposure Scenario	Exposure Level	Weight Fraction (%) [a]	Liquid Product Dermal Loading ($\mu g/cm^2$) [b]	Acute Dermal Exposure (μg Phthalic Anhydride $/cm^2$) [b]	Acute Dermal MOE (Benchmark = 1)
Adhesives and sealants	Adhesives and sealants for small projects	Low	0.1 (4 adhesive products)	7.0E02	0.7	64
		Low WF high DL [c]		2.1E03	2.1	21 [c]
		High WF low DL [c]	1 (3 Henkel products high WF and epoxy low WF)	7.0E02	7.0	6 [c]
		High WF high DL [c]		2.1E03	21	2 [c]
		Medium WF low DL [c]	1.2 (4 adhesive products)	7.0E02	8.1	6 [c]
		Medium		1.4E03	16	3
		Medium WF high DL [c]		2.1E03	24	2 [c]
		High WF low DL [c]	5 (4 adhesive products)	7.0E02	35	1 [c]
		High		2.1E03	105	**0.4**
Paints and coatings; Solvent-based paints	Liquid paints and coating [d]	Low	0.1	7.0E02	0.7	64
		Low WF high DL [c]		2.1E03	2.1	21 [c]
		Medium WF low DL [c]	7.7	7.0E02	54	**0.8** [c]
		Medium		1.4E03	108	**0.4**
		Medium WF high DL [c]		2.1E03	162	**0.3** [c]
		High WF low DL [c]	25	7.0E02	175	**0.3** [c]
		High		2.1E03	525	**0.1**
	Spray paints and coating [d]	Low	1	1.3E03	13	4
		Low WF med DL [c]		3.8E03	38	1 [c]
		Low WF high DL [c]		1.03E04	103	**0.4** [c]
		Medium WF low DL [c]	12	1.3E03	150	**0.3** [c]
		Medium		3.8E03	437	**0.1**
		High	25	1.03E04	2,575	**0.02**

[a] Modeling input. Weight fraction values for low-, medium-, and high-intensity use exposure levels were obtained from product SDSs, see Section 2.1.1 *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b).

[b] Dermal exposure was calculated using amount of oil-based liquid product deposited on the skin, dermal loading, values from U.S. EPA (1992b). Dermal loading values (modeling input) for liquid paints and coatings and adhesives and sealants were based on hand wiping experiments in the study. For spray paints and coatings dermal exposures, the dermal loading inputs were based on immersion experiments in the study. The study used mineral, cooking, and bath oils for the wipe and immersion experiments to consider high viscosity liquids and higher content of product during wiping and immersion activities. The high viscosity liquid experiments are a good proxy for products like paints and adhesives in this assessment.

[c] Sensitivity analysis consisted of matching weight fractions (WF) and dermal loading (DL) values across low-, medium-, and high-intensity use scenarios to capture MOE distribution for each exposure level (low, medium, and high).

[d] During the development of this preliminary draft risk evaluation, EPA received additional information from Harris Paints indicating that phthalic anhydride is not present in paint products at certain weight fractions (*i.e.,* 10–25% by weight) as previously indicated in reasonably available SDSs. EPA is working to obtain updated information related to paint products. If received, this may impact dermal exposures and MOEs under this COU in the final risk evaluation.

Adhesives and Sealants

This section summarizes the risk estimates, MOEs, below the dermal benchmark of 1 for the Consumer Use of Adhesives and Sealants COU. One exposure scenario was assessed under this COU. The exposure scenario was labeled adhesives and sealants for small repairs. The exposure scenario utilized information from the four adhesive products with confirmed (SDSs) phthalic anhydride content and similar use patterns based on manufacturer description of use. The four products were grouped because weight fractions for three of the four products reported the same range and the fourth product provides an upper bound of possible weight fractions in consumer products. In addition, application description and expected direct dermal contact with product are similar. The weight fractions used in modeling were, 0.1, 1.2, and 5% for the low-, medium-, and high-intensity use exposure scenarios, respectively. Note that three products reported the same range of weight fractions while another product reported a range with a minimum weight fraction value, 1%, was the maximum of the other three products and its maximum weight fraction was 5%. The medium-intensity use exposure scenario weight fraction was calculated from the average of the midpoints of all four reported ranges. Adhesives and sealants for small repairs were assessed for dermal exposures only due to the small product amount and surface area used in each application, inhalation would have low exposure potential for this scenario. Consumer exposure to phthalic anhydride via inhalation from off-gassing or evaporation from adhesives and sealants used during do-it-yourself activities, is unlikely. Due to low vapor pressure (5.17×10^{-4} mmHg) and low volatility (1.70×10^{-8} atm·m^3/mol at 25 °C) gas-phase inhalation exposures are expected to be negligible.

One adhesive, LOCTITE 426 (Henkel, 2025; RS Hughes, 2019), was described as a black, gel viscosity, rubber-toughened, instant adhesive with a fixture time of 20 seconds and suitable for use on metals, elastomers, and plastics, especially where 0.05 mm bond gaps are present. The gap size coverage of 0.05 mm and the available product size for purchase of 20 g or 0.70 oz indicate that the surface area coverage is not very large (>1 m^2). The second adhesive, LOCTITE 435 (Henkel, 2025; RS Hughes, 2019), was described as a clear, toughened, low-viscosity (medical device grade) instant adhesive and suitable for bonding plastics, rubber, metals, magnets, porous and absorbent substrates and acidic surfaces used for small area coverage. The third adhesive, LOCTITE 4105 (Henkel, 2023; Quality Bearings Online, 2019), was described as a black, rubber-toughened, ethyl cyanoacrylate-based instant adhesive with increased flexibility and peel strength, ideal for bonding metals, plastics and rubbers. Product application, bond gap, and weight fraction are the same as the previous two adhesives. In addition, to the three adhesives above, EPA included consumer use of certain specialty products that contain phthalic anhydride in amounts above 1% such as in two-part electronic encapsulant adhesives (Epoxy Technology, 2020). In two-part adhesives, phthalic anhydride is used to trigger polymerization when consumers mix a hardener containing 1 to 5% phthalic anhydride (Part A) with a separate resin material (Part B) to create a solid, durable material (Epoxy Technology, 2020). Direct dermal exposures could occur when mixing and spreading during product application. EPA used the reported weight fraction range of 1 to 5% to represent these specialty adhesive products.

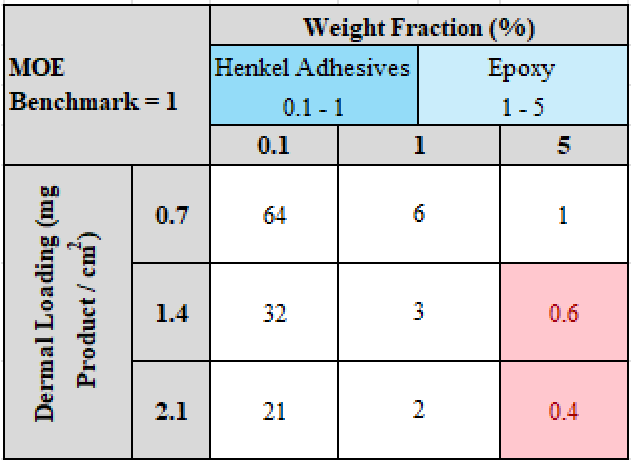
Table 4-19 shows the adhesives and sealants for small repairs acute dermal MOE for high- and medium-intensity use exposure scenarios below the dermal benchmark of 1. The acute dermal high-intensity use exposure scenario MOE was 0.4, the acute dermal medium-intensity use exposure scenario MOE was 3, and the acute dermal low-intensity use exposure scenario MOE was equal to 64. For dermal exposure, EPA used the product weight fraction, and the liquid product dermal loading (amount of liquid retained on the skin) value for oil-based products for applications that result in direct dermal contact. The experimental use of oil-based formulations is considered representative of the adhesives and sealants consistency. The liquid product dermal loading values (0.7, 1.4, and 2.1 mg of product/cm^2 for low-, medium-, and high-intensity use exposure scenario) used for adhesives and sealants for small repairs scenario were evaluated using U.S. EPA (1992b) study saturated cloth wipe experiment. The use of the saturated cloth wipe experiment liquid product dermal loading value for direct dermal contact with liquid adhesives and sealants is appropriate because the use instructions recommend wiping the excess of the product after application and because direct dermal contact with product is expected during application. The dermal exposure to phthalic anhydride from direct dermal contact with adhesives was calculated using the U.S. EPA (1992b) study wipe experiment dermal loading, which applied the product to the hands with an oil-based liquid product saturated cloth. The use of the saturated cloth wipe experiment dermal loading for the assessment of dermal exposures from adhesive products is considered an upper bound for the high-intensity use exposure scenario and a lower bound or the low-intensity use exposure scenario.

The products SDSs recommend using nitrile gloves and aprons as necessary to prevent contact, and do not recommend the use of PVC, nylon, or cotton skin protective materials. While these recommendations are mainly for occupational settings, consumers that follow SDSs can chose to wear appropriate gloves and skin protective materials. For this assessment, EPA did not include the use of skin protective materials for the calculation of dermal exposures from adhesives and sealants.

Weight fractions were from the product SDSs and reported as a range. Three products reported the same range and one epoxy specialty product reported a higher range. The confidence in these parameters, dermal loading rate and weight fraction is robust as they represent actual product uses. The only limitations noted are related to the study of liquid chemical handling. Specifically, the type of liquid materials and activities investigated may introduce uncertainty when used for surrogate chemicals and uses. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence for this assessment is moderate for consumer exposures. The overall confidence considers confidence in the approach and the inputs used in the calculations. The overall confidence in dermal loading for this COU is moderate.

Additionally, EPA performed a sensitivity analysis that provides the distribution of MOEs with varying combinations of weight fractions with the liquid product dermal loading values. See Table 4-19 footnote “c” and the corresponding values within the table for each combination MOE results and Figure 4-4 for a visual representation of the sensitivity analysis for adhesives. The low-intensity use exposure scenario that combined the low weight fraction with the high dermal loading values resulted in MOEs is above the dermal benchmark of 1. For the low- to medium-intensity use exposure scenarios, no combination of weight fraction and dermal loading would result in MOEs below the dermal benchmark of 1. For the high-intensity use exposure scenario the only two combinations that resulted in MOEs below the dermal benchmark of 1 was when using the medium and high dermal loading values. Every other combination of weight fraction and dermal loading after high weight fraction and low dermal loading resulted in MOEs below the dermal benchmark of 1.

EPA calculated a sensitivity analysis MOE for the three Henkel adhesives with the highest reported weight fraction for the three products, 1%. The fourth adhesive product, epoxy, is considered a specialty product and its reported weight fraction range minimum was equal to the Henkel adhesives maximum. While all four products are adhesives and direct dermal contact is expected to occur, the niche use of the epoxy and its higher weight fraction range needed further resolution. This sensitivity analysis provides resolution of MOE values by product type within the boundaries of the possible exposures. That is, while considering the liquid product dermal loadings identified range (0.7–2.1 mg product/cm^2) and reported weight fractions by product type. For the spray paints sensitivity analysis, EPA calculated MOEs using the low-intensity use exposure scenario weight fraction in combination with the low and high liquid product dermal loading values. Both sensitivity analysis resulted in MOEs above the dermal benchmark of 1, indicating that there is no combination of reported weight fractions and dermal loadings that would result in MOEs below the dermal benchmark of 1. For the Epoxy sensitivity analysis, the combination of the highest weight fraction, 5% and the lowest dermal loading, 0.7 mg product/cm^2, yielded an MOE right above the dermal benchmark of 1. All other combinations of weight fractions above 5% and 0.7 mg product/cm^2, would result in MOEs below the dermal benchmark of 1.



MOE Benchmark = 1		Weight Fraction (%)		
		Henkel Adhesives 0.1 - 1		Epoxy 1 - 5
		0.1	1	5
Dermal Loading (mg Product / cm^2)	0.7	64	6	1
	1.4	32	3	0.6
	2.1	21	2	0.4

Figure 4-4. Adhesives and Sealants MOE Sensitivity Analysis Matrix

Figure shows the upper and lower bounds of liquid dermal loadings and product type weight fractions. Liquid dermal loading values sourced from U.S. EPA (1992b) study wipe experiment, 0.7 to 2.1 mg product/cm^2. Liquid dermal loading range is supported by ChemSTEER Manual (U.S. EPA, 2015b). ChemSTEER recommends to use 0.7 mg product/cm^2 as the low dermal loading value, 1.4 mg product/cm^2 as the 50th percentile, and 2.1 mg product/cm^2 as the 95th percentile and high value of the recommended ChemSTEER liquid dermal loading range.

The typical volume of a liquid droplet can range from 0.03 to 0.05 mL. Using the products' SDS reported density of 1.1 g/cm^3, and assuming the volume of a droplet of adhesive like those identified in this assessment is 0.03 mL (or 0.03 cm^3), and assuming that the skin surface area of contact by the droplet is 1 cm^2, EPA estimated the amount of phthalic anhydride in contact with the skin for the 0.1 and 5% (weight-by-weight [w/w]) adhesives. For example, the 0.1% weight fraction is equal to 0.001 g of phthalic anhydride by g of product. Multiplying this value by the reported product density (g/cm^3) and assumed droplet volume (0.03 cm^3), and dividing by the surface area of skin in contact (1 cm^2), yields a value of 33 µg/cm^2 for the amount of phthalic anhydride in contact with the skin in one droplet for a weight fraction of 0.1%, which is also shown in the calculation below:

$$\frac{0.001\,\frac{g\ phthalic\ anhydride}{g\ product}\times 1.1\,\frac{g\ product}{cm^3}\times 0.03cm^3\times 10^6\,\frac{\mu g}{g}}{1cm^2} = 33\,{}^{\mu g}/_{cm^2}$$

A similar calculation for the 5% weight fraction results in 1,650 µg/cm^2.

The amount of phthalic anhydride in a droplet from a 1% by weight adhesive is 33 µg/cm^2, which is below the POD (45 µg/cm^2) and thus no sensitization occurs. The amount of phthalic anhydride in a droplet from a 5% by weight adhesive is 1650 µg/cm^2, which is above the POD (45 µg/cm^2) and thus sensitization occurs. EPA also estimated the weight fraction (w/w) expected to result in sensitization from one droplet. Using the same droplet volume of 0.03 mL, density of 1.1 g/cm^3, and skin surface area in contact with the droplet volume of 1 cm^2, and an amount of phthalic anhydride equivalent to the POD, 45 µg/cm^2, the weight fraction is equal to 0.136% by weight. For weight fractions above 0.14%, sensitization would be expected because it is above the POD of 45 µg/cm^2.

Paints and Coatings; Solvent-Based Paints

This section summarizes the risk estimates, MOEs, below the dermal benchmark of 1 for the Paints and coatings COU. Four different scenarios were assessed under this COU for four product examples with various use patterns. The product examples were matched to each scenario according to exposure route (inhalation and dermal) and application approach (spray can or sprayer gun or brush/roller). Scenarios assessed for dermal exposures were labeled: spray paints and coatings (can and sprayer application), and liquid paints and coatings (brush or roller application). Scenarios assessed for inhalation exposures under this COU (Section 4.3.3.2) were labeled spray paints and coating for small project (spray can applications) and spray paints and coatings for large project (sprayer gun application).

Three products have non-spray applications for the assessment of dermal exposures from liquid paints and coatings:

- Junckers clear rustic oil, was described as a hardening urethane oil in paraffinic solvent used to coat wooden surfaces like flooring. The product is available in several sizes ranging from 0.75 to 25 L, which confirms the application on small and large surfaces such as furniture and entire house flooring. The SDS reported phthalic anhydride content was provided as a range of 0.1 to less than 0.25% (Junckers Industries A/S, 2023). This product was not confirmed as a spray application and thus only assessed for dermal exposures during the application in the liquid (non-spray) paints and coatings exposure scenario.
- A Harris Paints T.O.V. marine clear spar varnish was described as an oil-based product used to restore wood surfaces such as cabinets and countertops to protect from sun and water damage. The product is available in 1-gallon cans that can cover 400 ft^2 and need two coats and 4 hours between coats. The suggested application method is via brush or rollers (Harris Paints, 2017b). The concentration was reported in the SDS as a range of 10 to 25% by weight (Harris Paints, 2025b). This product was not confirmed as a spray application and thus only assessed for dermal exposures during the application in the liquid (non-spray) paints and coatings exposure scenario.
- Harris Paints Co. metal primer red, was described as an oil-based primer to resist corrosion and rust, fast-drying to the touch in 45 minutes, and ready for the second coat in 4 hours. This primer is designed for application on exterior metal surfaces, but also can be used in interior metal surfaces and the suggested application method is via brush or rollers or sprayer (Harris Paints, 2017a). The concentration was reported in the SDS as a range of 1 to 10% by weight (Harris Paints, 2025a). This product was confirmed as a spray application and thus assessed for dermal exposures during the application in the liquid (non-spray) and spray paints and coatings exposure scenarios.

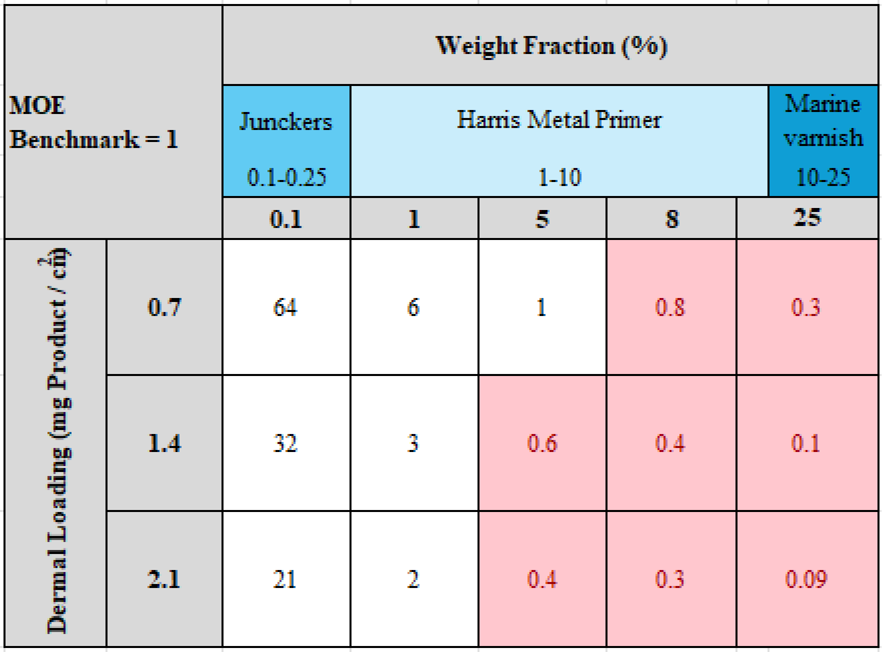
For the non-spray liquid paints and coatings application dermal exposure scenarios, the three weight fraction ranges from each product were grouped, EPA used the minimum and maximum value the reported range for the low and high-intensity use exposure scenario respectively. For the medium-intensity exposure scenario, EPA used the average of each reported range midpoint. The weight fractions used in modeling were 0.1, 7.7, and 25% for the low-, medium-, and high-intensity use exposure scenarios, respectively.

Table 4-19 shows the liquid paints and coatings acute dermal MOE for high- and medium-intensity use exposure scenarios below the dermal benchmark of 1. The acute dermal high-intensity use exposure scenario MOE was 0.1 and the acute dermal medium-intensity use exposure scenario MOE was 1. The acute dermal low-intensity use exposure scenario MOE was equal to 64. For dermal exposure, EPA used the product weight fraction and the dermal loading (amount of liquid retained on the skin) values for oil-based products for wiping applications (U.S. EPA, 1992b). The experimental use of oil-based liquid products is considered representative of the paints and coatings viscosity and potential dermal contact duration. The liquid product dermal loading values (0.7, 1.4, and 2.1 mg/cm^2 for low-, medium-, and high-intensity use exposure scenario) used for non-spray paints and coatings scenario were evaluated using U.S. EPA (1992b) study wipe experiment. The use of the wipe test liquid product dermal loading value for dermal contact with liquid paints and coatings is appropriate because the use instructions recommend wiping the excess of the product after application and during application there can be direct skin contact. Also, for tasks such as product cleaning and wiping the ChemSTEER Manual (U.S. EPA, 2015b) recommends using 2.1 mg/cm^2 for high-intensity use exposure scenarios and 1.4 mg/cm^2 for the medium-intensity use exposure scenario.

For the low-intensity use exposure scenario EPA used the lowest value of the available range for the initial wipe test from U.S. EPA (1992b). The U.S. EPA (1992b) study wipe experiment dermal loading, applied the product to the hands with an oil-based liquid product saturated cloth. The paints and coatings evaluated in this assessment can be used in large amounts that when removing the excess of the applied product may saturate a cloth and direct dermal contact with product is expected during application. For this scenario the selected experimental dermal loading is representative of direct dermal contact with the liquid product. The high-intensity use exposure scenario is considered an upper bound while the low-intensity use exposure scenario is considered the lower bound of the expected exposure range. The products SDSs specified that skin protection is not required for these products. As such, for this assessment, EPA did not include the use of skin protective materials for the calculation of dermal exposures from paints and coatings.

Weight fractions were from the product SDSs and reported as a range. EPA has robust confidence in the weight fraction data used. However, the three products reported different ranges, which indicates a wide distribution in manufacturing approaches and high variability in exposure estimates for products within this COU exposure scenario. The confidence in the input parameters, amount of liquid retained on the skin is robust for liquid paints and coatings. The only limitations noted are related to the study of liquid chemical handling. Specifically, the type of liquid materials and activities investigated may introduce uncertainty when used for surrogate chemicals and uses. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence for this assessment is moderate for consumer exposures. The overall confidence considers confidence in the approach and the inputs used in the calculations. The overall confidence in dermal loading for this COU is moderate.

Additionally, EPA performed a sensitivity analysis that provides the distribution of MOEs with varying combinations of weight fractions with the liquid product dermal loading values. See Table 4-19 footnote c and the corresponding values within the table for each combination MOE results and Figure 4-5 for a visual representation matrix of by product type reported weight fractions and liquid dermal loadings. Figure 4-5 shows additional weight fractions, 5 and 8% combinations with the liquid dermal loadings to provide resolutions in the weight fraction vs dermal loading range that MOEs bordered the dermal benchmark of 1. The sensitivity exposure scenario that combined the low weight fraction, 0.1%, with the medium and high dermal loading values, 1.4 and 2.1 mg of product/cm^2, yielded MOEs above the dermal benchmark of 1. For this low-intensity use exposure scenario no combination of weight fraction and dermal loading would yield MOEs below the dermal benchmark of 1. Similarly, every other combination of 1% weight fraction and dermal loading values would yield MOEs above the dermal benchmark of 1. The combination of 5% weight fraction with the lowest dermal loading, 0.7 mg/cm^2 yields an MOE right at the dermal benchmark of 1. Every other combination of weight fraction above 5% and dermal loading above 0.7 mg/cm^2 would result in MOEs below the dermal benchmark of 1.



MOE Benchmark = 1		Weight Fraction (%)				
		Junckers 0.1-0.25	Harris Metal Primer 1-10			Marine varnish 10-25
		0.1	1	5	8	25
Dermal Loading (mg Product / cm^2)	0.7	64	6	1	0.8	0.3
	1.4	32	3	0.6	0.4	0.1
	2.1	21	2	0.4	0.3	0.09

Figure 4-5. Liquid Paints and Coatings MOE Sensitivity Analysis Matrix

Figure shows the upper and lower bounds of liquid dermal loadings and product type weight fractions. Liquid dermal loading values sourced from U.S. EPA (1992b) study wipe experiment, 0.7 to 2.1 mg product/cm^2. Liquid dermal loading range is supported by ChemSTEER Manual (U.S. EPA, 2015b). ChemSTEER recommends to use 0.7 mg product/cm^2 as the low dermal loading value, 1.4 mg product/cm^2 as the 50th percentile, and 2.1 mg product/cm^2 as the 95th percentile and high value of the recommended ChemSTEER liquid dermal loading range. During the development of this preliminary draft risk evaluation, EPA received additional information from Harris Paints indicating that phthalic anhydride is not present in paint products at certain weight fractions (*i.e.,* 10 to 25% by weight) as previously indicated in reasonably available SDSs. EPA is working to obtain updated information related to paint products. If received, this may impact dermal exposures and MOEs under this COU in the final risk evaluation.

Two products have spray application applications for the assessment of dermal exposures from spray paints and coatings:

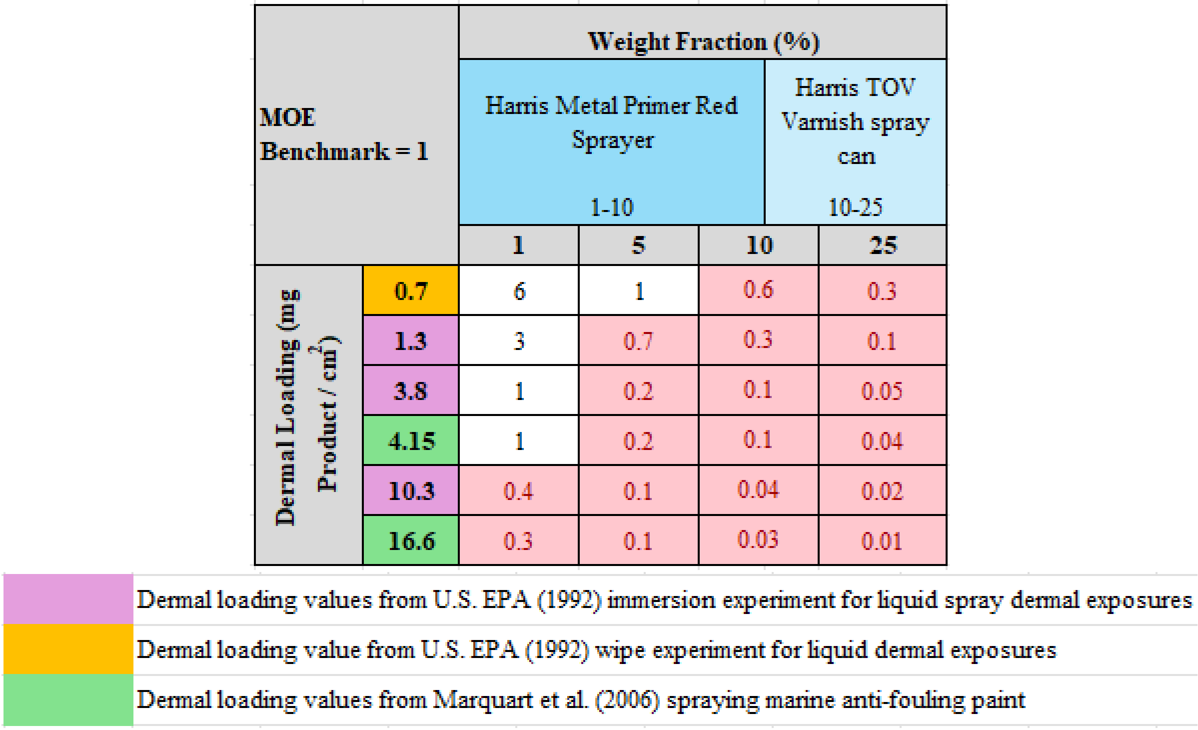
- One Harris Paints Co. T.O.V. varnish product is available in 11 oz spray cans. This oil-based product has an acrylic polyurethane formula, with a 5-minute drying time to promote water resistance and a high-gloss finish. It can be used on brick, concrete, galvanized metal, metal, and wood. The concentration was reported in the SDS as a range of 10 to 25% by weight (Harris Paints, 2025c). This product was assessed for dermal and inhalation exposures.
- Harris Paints Co. metal primer red described before. The suggested application methods are via brush or rollers or sprayer (Harris Paints, 2017a).

For the spray paints and coatings application dermal exposure scenarios, the two weight fraction ranges from each product were grouped, EPA used the minimum and maximum value in the reported range for the low and high-intensity use exposure scenarios, respectively. For the medium-intensity use exposure scenario, EPA used the average of the midpoint for each reported range (4 total). The weight fractions used in modeling were, 1, 12, and 25% for the low-, medium-, and high-intensity use exposure scenarios, respectively.

Table 4-19 shows the spray paints and coatings acute dermal MOE for all exposure scenarios assessed (high-, medium-, and low-intensity use exposure scenarios) was below the dermal benchmark of 1. For dermal exposure, EPA used the product weight fraction and dermal loading (amount of liquid retained on the skin) value for oil-based products for immersion applications (U.S. EPA, 1992b). The experimental use of oil-based formulations is considered representative of the paints and coatings viscosity and potential dermal contact duration. The spray product dermal loading values (1.3, 3.8, and 10.3 mg of product/cm^2 for low-, medium-, and high-intensity exposure scenarios respectively) used for spray paints and coatings scenario were experimentally designed for direct dermal applications. Immersion experiments in U.S. EPA (1992b) entailed full immersion of the user hands in the product, while spray products are expected to cover a significant surface of the exposed hands similar but not equal to immersion the dermal loading values obtained from the immersion experiment were found to agree spray application experiments. The use of the immersion dermal loading values was supported by Marquart et al. (2006), which reported similar spray paint dermal loading values. The products SDSs specified that skin protection is not required for these products. As such, for this assessment, EPA did not include the use of skin protective materials for the calculation of dermal exposures from paints and coatings.

Weight fractions were from the product SDSs and reported as a range, EPA has a robust confidence in these data because these represent actual consumer product uses. However, the two products reported different ranges, which indicates a wide distribution in manufacturing approaches and high variability in potential exposure estimates for products within this COU. The confidence in the input parameters, amount of liquid retained on the skin is robust for spray paints and coatings, because EPA is using a range of possible values that captured the distribution of possible risk estimates. The only limitations noted are related to the study of liquid chemical handling. Specifically, the type of liquid materials and activities investigated may introduce uncertainty when used for surrogate chemicals and uses. Therefore, based on the strengths and limitations of the assessment, EPA concluded that the weight of scientific evidence for this assessment is moderate for consumer exposures. The overall confidence considers confidence in the approach and the inputs used in the calculations. The overall confidence in dermal loading for this COU is moderate.

Figure 4-6 shows a visual representation matrix of by product type reported weight fractions and dermal loadings. This sensitivity analysis included dermal loadings from U.S. EPA (1992b) study wipe experiment, 0.7 mg/cm^2 (yellow square) and dermal loading values from Marquart et al. (2006), 4.15 and 16.6 mg/cm^2 (green squares). The U.S. EPA (1992b) study wipe experiment dermal loading was recommended by the ChemSTEER Manual (U.S. EPA, 2015b) for dermal exposures to liquids for paint applications like rollers and brushes. The Marquart et al. (2006) study reported dermal loadings from spraying anti-fouling marine paint that are considered to be a good surrogate for the spray paints in this assessment. For the spray paints sensitivity analysis, EPA calculated MOEs for the low (1%) and medium (10%) weight fractions combining with three spray product dermal loading values to provide resolution on which combination of weight fraction and dermal loading resulted in MOEs below the dermal benchmark of 1. The sensitivity analysis combining the lowest weight fraction reported (1%) with medium dermal loading (3.8 mg/cm^2) resulted in an MOE of 1.2 and when combining the lowest weight fraction of 1% with high dermal loading (10.3 mg/cm^2) the MOE was 0.4. EPA added a weight fraction sensitivity analysis between 1 and 10% to increase the resolution of weight fraction and dermal loading combinations MOEs. The 5% weight fraction combination with lowest spray paint dermal loading value, 1.3 mg/cm^2 are below the dermal benchmark of 1. When combining the 5% with the lowest dermal loading used for liquid paint brushing/rolling the MOE is at the dermal benchmark of 1. All other weight fractions above 1% and dermal loading of 4.15 mg/cm^2 combinations resulted in MOEs below the dermal benchmark of 1.



MOE Benchmark = 1		Weight Fraction (%)			
		Harris Metal Primer Red Sprayer 1-10		Harris TOV Varnish spray can 10-25	
		1	5	10	25
Dermal Loading (mg Product / cm^2)	0.7	6	1	0.6	0.3
	1.3	3	0.7	0.3	0.1
	3.8	1	0.2	0.1	0.05
	4.15	1	0.2	0.1	0.04
	10.3	0.4	0.1	0.04	0.02
	16.6	0.3	0.1	0.03	0.01

🟪	Dermal loading values from U.S. EPA (1992) immersion experiment for liquid spray dermal exposures
🟧	Dermal loading value from U.S. EPA (1992) wipe experiment for liquid dermal exposures
🟩	Dermal loading values from Marquart et al. (2006) spraying marine anti-fouling paint

Figure 4-6. Spray Paints and Coatings MOE Sensitivity Analysis Matrix
Figure shows the upper and lower bounds of spray dermal loadings (pink squares) and product type weight fractions (blue squares). The spray paints dermal loading values are from U.S. EPA (1992b) study immersion experiment, 1.3, 3.8, and 10.3 mg product/cm^2. The U.S. EPA (1992b) study immersion experimental dermal loading values are lower than those reported by Marquart et al., (2006), 4.15 and 16.6 mg/cm^2 (green squares). Marquart et al. (2006) dermal loadings are from spraying marine anti-fouling paint, which is considered similar to the products in this spray paints dermal assessment. During the development of this preliminary draft risk evaluation, EPA received additional information from Harris Paints indicating that phthalic anhydride may no longer be present in paint products at certain weight fractions (*i.e.,* 10 to 25% by weight) as discussed below.

During the development of this preliminary draft risk evaluation, EPA received updated SDSs from Harris Paints (Harris Paints, 2026a, b, c) indicating that phthalic anhydride may no longer be present in paint products at certain weight fractions (*i.e.,* certain products that contain phthalic anhydride at a concentration of 10–25% by weight) as previously indicated in reasonably available SDSs (Harris Paints, 2025a, b, 2015). EPA is working to confirm with the company whether the update was due to a recent change in formulation or if phthalic anhydride was never in these paint products. Once received, this may impact the Agency's final risk characterization for this COU. Excepting these products, the maximum concentration of phthalic anhydride in paint or coating products is 10% by weight. EPA is requesting comment on the use of phthalic anhydride in these paint and coating products and will consider any additional information in the development of the final risk evaluation.

4.3.3.2 Consumer Inhalation Risk Characterization

As described in Section 4.2.2, EPA proposed a quantitative approach for characterizing risks of inhalation exposures to phthalic anhydride with a POD equal to 0.4 mg/m^3 for inhalation exposure (8-hour TWA) and an inhalation benchmark of 30 for the calculated MOEs. EPA assessed consumer and bystander inhalation exposure to phthalic anhydride through the direct inhalation of sprays. Users and bystanders are expected to inhale sprayed products via dispersion while the spray is suspended during application. The only COU with spray applications was the Paints and coatings COU, which is summarized below.

Paints and Coatings; Paints and Coatings (e.g., Commercial and Residential Paint Coatings, Stains, Exterior Architectural and Marine Paints, and Solvent-Based Paints)

For the inhalation exposure assessment EPA assessed exposures from the application of the spray can product separated from sprayer gun application products because the use patterns and weight fractions were different and to provide a representative distribution of exposures. Inhalation of spray paints was assessed in two scenarios: spray paints and coatings for small projects via spray can application, and spray paints and coatings for large projects via spray gun application. The overall confidence in the inhalation exposure estimates is robust because the CEM input parameters used in this assessment represent typical use patterns and location of use for spray paints. The stay-at-home activity input parameter is expected to result in upper bound exposures that are representative of actual uses for some populations. As such the application of the stay-at-home activity pattern in CEM provides an upper bound exposure and the full-time worker represents a lower bound because they spend the least amount of time in the home exposed to spray paint application as bystanders. EPA performed a series of sensitivity analyses, changing one input while keeping the rest of the inputs static to obtain insight on which inputs had the most significant impact in exposures and subsequent MOE calculations. See Table 4-20 for sensitivity analyses results.

EPA assessed inhalation exposures to spray paints in two scenarios:

Spray Paints and Coatings for Small Projects, Spray Can Application: One product was used in this scenario, Harris Paints Co. T.O.V. varnish product available in 11-ounce spray cans. This oil-based product has an acrylic polyurethane formula, with a 5-minute drying time to promote water resistance and a high-gloss finish. It can be used on brick, concrete, galvanized metal, metal, and wood. The concentration was reported in the SDS as a range of 10 to 25% by weight (Harris Paints, 2025c).

For the small paints and coatings spray application scenario, only one product was identified and sold in 11-ounce cans (Harris Paints, 2025c). The high-intensity use exposure scenario assumed that the entire container was used. For the medium- and low-intensity use scenarios it was assumed that half (5.5 oz) and a quarter (2.75 oz) of the entire container were used, respectively. The total mass of product used (assuming 2 coats of product) were 76, 152, and 304 g for the low-, medium-, and high-intensity use exposure scenarios, respectively. The mass of product in grams (g) was obtained using the ounces to cm^3 conversion factor of 29.57 cm^3/oz and product density, 0.935 g/cm^3.

For duration of use for the small paints and coatings spray application, products are expected to be used in small scale projects and were thus modeled at use durations of 5, 10, and 15 minutes in the low-, medium-, and high-intensity use scenarios. The duration of use selected time values agree with the total volume use for one spray can. For the small project paints and coatings, EPA used the estimated high, medium, and low-intensity use exposures for an overall project duration of 8-hour TWA inhalation exposure concentrations. This means that while the total duration of product use during application was 5, 10, and 15 minutes of intermittent use, the overall project was performed during an 8-hour period. This 8-hour TWA was selected to be aligned with the POD that was estimated as an 8-hour TWA.

Regarding frequency of use for small paints and coatings spray application products, the frequency is not anticipated to be routine because of the relatively niche purposes of the product. EPA assumed two events per day to consider painting either multiple items or the same item from various angles. For example, a wooden door can be painted on one side first and then the other side, resulting in two events. For the location or environment (room) of application, EPA modeled using CEM defaults for all parameters in the specified room of use, garage. Because of the small size item that can be painted in this scenario it is likely that DIYers will remove the items to a ventilated, and better suited location like a garage for spray painting and drying time. The product SDSs recommend using the product in a well-ventilated location, and for occupational settings the SDSs recommend when spraying this material to use a NIOSH approved cartridge respirator or gasmask. When using in poorly ventilated and confined spaces, the SDS recommends the use of a fresh air supplying respirator or a self-contained breathing apparatus. For this assessment, EPA used the garage setting as a well-ventilated location and no mask or respirator was considered in the modeling.

For bystanders, EPA used the stay-at-home activity pattern to obtain the upper bound of exposures, The stay-at-home activity pattern assumes that occupants are inside the home a total of 21 hours per day and move from room to room according to the schedule shown in Appendix A in the consumer technical support document (U.S. EPA, 2026b). For this scenario the bystander is in indoor environments other than the garage when the product is applied and CEM uses the appropriate zone and exchange rate with the various rooms to calculate exposure concentrations.

The MOEs for high-, medium-, and low-intensity exposure scenarios for spray paints and coating small projects were all below the inhalation benchmark of 30, Table 4-20. EPA has a robust confidence in the inhalation exposure concentrations and the inputs used in the modeling of each exposure scenario. The use patterns are representative of realistic and actual uses. See Table 4-20 for a summary of inputs per scenario and MOE values.

For the spray paints and coatings small project inhalation assessment, EPA calculated a sensitivity analysis using the lowest weight fraction reported, 10% and all other inputs the same as the low-intensity use exposure scenario and changing the duration of application to 1 minute and the amount of the product sprayed to 37 g (half of the amount used for the low-intensity use exposure scenario). The resulting MOEs were 2 for users and 5 for bystanders, below the inhalation benchmark of 30. These inputs are the lowest possible for a small project spray application using the lowest reported weight fraction. EPA also calculated the MOE of a product application that falls under the low-intensity use exposure scenario input parameters but using a weight fraction 2 orders of magnitude lower than the reported minimum. The weight fraction used was 0.1% and the MOE was 85 for the user and 261 for the bystander. While there is no realistic or representative value to the weight fraction sensitivity analysis it provides insight on which inputs have the most significant impact in calculating exposures and MOEs. In this small project spray paints scenario, weight fraction has a significant impact in resulting exposures and MOEs.

Spray Paints and Coatings for Large Projects, Spray Gun Application: One of Harris Paints Co. product was identified for sprayer applications, the metal primer (not sold in spray cans). This spraying application is normally used for larger projects using more product and taking longer to complete the task. Harris Paints Co. metal primer red, was described as an oil-based primer to resist corrosion and rust, fast-drying to the touch in 45 minutes, and ready for the second coat in 4 hours. This primer is designed for application on exterior metal surfaces, but also can be used in interior metal surfaces and the suggested application method is via brush or rollers or sprayer (Harris Paints, 2017a). The concentration was reported in the SDS as a range of 1 to 10% by weight (Harris Paints, 2025a).
For the large paints and coatings spray application scenario, one product was identified to be potentially applied with a sprayer gun (Harris Paints, 2025a). The largest available container volume was a 1-gallon can. For this product, the high-intensity use exposure scenario assumed that the entire 1-gallon container was used. For the medium and low-intensity use scenarios it was assumed half of the 1-gallon can and a quarter of the 1-gallon can were used respectively. This approach is consistent with observations of consumer reviews for individual products on vendor websites, which indicated diverse usage patterns among consumers including small, medium, and large projects. The room of application was assumed to be the living room, which is CEM's largest room and therefore likely to provide a higher exposure

concentration. The living room in CEM has a square footage of approximately 200 ft^2. Technical specifications for these products indicated that each gallon of product would cover between 350 to 400 ft^2 per gallon, and per the manufacturer instructions two coats are recommended. Assuming two coats and that the 1-gallon container product coverage is 400 ft^2 the selected room specifications can be covered with one container. Based on this information, the total mass of product used (assuming 2 coats of product) were 885, 1,770, and 3539 g for the low-, medium-, and high-intensity use exposure scenarios, respectively. The mass of product in grams was obtained using the gallon to cm^3 conversion factor of 3,785.41 cm^3/gal and product density, 0.935 g/cm^3.

For duration of use for large paints and coatings spray application exposure scenario, EPA reviewed public forums dedicated to DIY home renovation projects and determined that most consumers spend between 30 minutes and 1 hour applying each coat when refinishing floors. Refer to the Product Research tab in U.S. EPA (2026c). EPA assumed that mixing and product preparation for spray application takes approximately 30 minutes for each coat. The removal of product excess after application was recommended in the product use instructions by the manufacturer (Harris Paints, 2017a). EPA assumed that removal of excess product after each applied coat takes approximately 45 minutes. Based on this information, the total time to apply 2 coats plus additional time for preparation of the product (*e.g.,* mixing and removing excess product with a rag after application) was estimated to be 90, 120, and 270 minutes in low-, medium-, and high-intensity use scenarios, respectively. Some products may result in relatively higher and shorter-lived exposure concentrations during use. For this product, an averaging time of less than 24 hours seemed appropriate. A per event average of an 8-hour TWA was considered for the large project paints and coatings sprayer application. This means that while the total duration of product use during application was 90, 120, and 270 minutes of intermittent use, the overall project was performed during an 8-hour period. EPA used the estimated high-, medium-, and low-intensity use exposures for an overall project duration of 8 hours' TWA inhalation exposure concentrations.

Regarding frequency of use for large paints and coatings spray application products, the frequency is not anticipated to be routine because of the large level of work required to prepare and clean up after each use, as well as the relatively niche purposes of the product. The one room was also assumed to be finished in a single day.

For room of use and application for the large project sprayer gun scenario, the living room environment was used with some modifications to the CEM activity patterns. The living room environment in CEM default spent time includes additional time in the room than product application. The modifications to the living room activity patterns reflect the fact that occupants are not expected to spend time in rooms with recently refinished floors outside of time spent actively applying the products. For this model, room volume and ventilation rates were changed from CEM default values for a garage to CEM default values for a living room, with the duration of use as established. The product SDSs recommend using the product in a well-ventilated location, and for occupational settings the SDSs recommend when spraying this material to use a NIOSH approved cartridge respirator or gasmask. When using in poorly ventilated and confined spaces, the SDS recommends the use of a fresh air supplying respirator or a self-contained breathing apparatus. For this assessment, EPA used the living room setting and no mask or respirator was considered in the modeling. EPA calculated exposures and MOEs for a well-ventilated living room location in a sensitivity analysis for the low-intensity use exposure scenario in which all inputs remain static and the interzone ventilation rate was changed to be outside ventilation rates, see Table 4-20. The MOE for the user resulting from that simulation was equal to 0.5, well below the inhalation benchmark of 30.

For bystanders, EPA used the stay-at-home activity pattern to obtain the upper bound of exposures and performed a sensitivity analysis for the lower bound of exposures using full-time worker activity pattern, The stay-at-home activity pattern assumes that occupants are inside the home a total of 21 hours per day and move from room to room according to the schedule shown in Appendix A in the consumer technical support document (U.S. EPA, 2026b). For the full-time worker activity pattern, the bystander spends 8 hours in the office/school in addition to 1 hour in an automobile and 1 hour outdoors, and for the remining time see Appendix A in the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b) for time spent in other indoor environments. For this scenario the bystander is in indoor environments other than the living room when the product is applied and CEM uses the appropriate zone and exchange rate with the various rooms to calculate exposure concentrations.

The MOEs for high-, medium-, and low-intensity exposure scenarios for spray paints and coating large projects were all below the inhalation benchmark of 30, Table 4-20. EPA has a robust confidence in the inhalation exposure concentrations and the inputs used in the modeling of each exposure scenario. The use patterns are representative of realistic and actual uses. See Table 4-20 for a summary of inputs per scenario and MOE values.

Additional sensitivity analyses were performed, see Table 4-20, to provide insight into which inputs had significant impact in exposures, like the stay-at-home activity pattern, and a shorter application duration with smaller amounts of product applied, and a non-realistic below the reported weight fraction sensitivity analyses. The activity pattern changed from stay-at-home to full-time worker. The full-time worker activity pattern is likely to result in lower bound exposures because of less time spent in the environment and home. The activity pattern sensitivity analyses was performed in all three intensity use exposure scenarios only changing the activity pattern and when the application started. In the stay-at-home scenarios the activity started at 9 a.m. while for the full-time worker the activity started at 6 pm after a workday and all other inputs remained static. All MOEs for low to high-intensity use exposure scenarios were below the inhalation benchmark of 30. The sensitivity analysis using shorter application times and smaller amounts of product also resulted in MOEs below the benchmark for users and bystanders. And finally, the sensitivity analysis using a weight fraction 2 orders of magnitude, 0.01%, below the reported minimum, 1%, resulted in MOEs above the inhalation benchmark of 30.

Although EPA acknowledges that consumers may be exposed to phthalic anhydride via multiple routes of exposure within an individual COU (*i.e.,* Paints and coatings or Adhesives and sealants), EPA is not aggregating risk across dermal and inhalation routes of exposure. As noted above (Section 4.3.3.1), the dermal MOEs are already below the inhalation benchmark MOE used to inform risk determinations (Table 4-20), and mathematically, MOEs resulting from an aggregate calculation would be even further below the inhalation benchmark MOE of 30. Table 4-20 summarizes the most sensitive inputs used to obtain inhalation MOE values by exposure scenario for spray paints and coatings.

During the development of this preliminary draft risk evaluation, EPA received additional information from Harris Paints indicating that phthalic anhydride is not present in paint products at certain weight fractions (*i.e.,* certain products that contain phthalic anhydride at a concentration of 10–25% by weight) as previously indicated in reasonably available SDSs. EPA is working to obtain updated information related to the weight fractions within the 10 to 25% by weight for paint products. If received, this may impact inhalation exposures and MOEs under this COU in the final risk evaluation. EPA is requesting comment on the use of phthalic anhydride in these paint and coating products and will consider any additional information in the development of the final risk evaluation.

As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p) and Section 4.2.2 of this draft risk evaluation, EPA has preliminarily concluded that the best available science supports application of an inhalation benchmark MOE of 30 in the draft risk evaluation. However, EPA is seeking SACC and public input on the underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride, as well as the severity of the effect observed at the LOAEC that serves as the basis of the inhalation POD. Based on SACC and public feedback, the overall benchmark MOE may be revised in the final phthalic anhydride risk evaluation to 10 or 100. Because the benchmark MOE may be revised in the final phthalic anhydride risk evaluation, EPA has also provided a characterization of consumer inhalation MOEs at alternative benchmarks of 10 and 100 in Appendix G.1.

Table 4-20. Consumer Inhalation MOE Estimates

Spray Paints and Coatings Scenario	**Exposure Scenario Level**	**Weight Fraction (%) [a]**	**Duration of Use (min) [b]**	**Product Mass Used (g) [c]**	**Acute Freq. of Use (day $^{-1}$) [d]**	**Use Environ. Volume (m^3) [e]**	**User MOE (Based on 8-hour TWA)**	**Bystander MOE (Based on 8-hour TWA) [g]**
Small project (aerosol can application) [h]	L	10	5	77	2	Garage; 90	**0.6**	**2**
	M	17.5	10	154			**0.2**	**0.4**
	H	25	15	307			**0.2**	**0.4**
	Sensitivity [f]	10	1	37			**2**	**5**
	Sensitivity [f]	0.1	5	77			85	261
Large project (sprayer gun) [i]	L	1	90	894	1	Living room, 50	**0.9**	**3**
	M	5.5	180	1,789			**0.5**	**0.7**
	H	10	270	3,577			**0.4**	**0.4**
	Sensitivity outside exchange rates [f]	1	90	894			**0.5**	**NA**
	Sensitivity [f]	1	30	442			**1**	**4**
	Sensitivity full-time-worker [h] activity pattern [f]	1	90	894			**0.6**	**2**
		5.5	180	1,789			**0.3**	**0.6**
		10	270	3,577			**0.2**	**0.6**
	Sensitivity [f]	0.01	90	894			59	183

H =high-intensity use exposure scenario; M = medium-intensity use exposure scenario; L = low-intensity use exposure scenario; TWA = time-weighted average

[a] See Section 2.1.2 in U.S EPA (2026b). High-intensity use value is the reported range maximum, the low-intensity use value is the reported range minimum, and the medium-intensity use value is the average of all the reported product weight fraction ranges midpoints (50th percentile).

[b] Based on product use descriptions, product labels, and online retailers. Information available in phthalic anhydride Product Research tab in U.S. EPA (2026c).

[c] Based on product use descriptions from product labels, and online retailers. Information available in phthalic anhydride Product Research tab in U.S. EPA (2026c).

[d] based on product use descriptions from TDSs, and product use instructions.

[e] Use environment was determined based on product manufacturer use description.

Bolded and orange highlighted MOE values were below the inhalation benchmark of 30.

[f] The sensitivity analysis consisted of changing one parameter and keeping other input parameters static to gain insight on which inputs are more sensitive to change and to provide higher resolution within the expected range of exposures and MOEs.

Spray Paints and Coatings Scenario	Exposure Scenario Level	Weight Fraction (%) [a]	Duration of Use (min) [b]	Product Mass Used (g) [c]	Acute Freq. of Use (day^{-1}) [d]	Use Environ. Volume (m^3) [e]	User MOE (Based on 8-hour TWA)	Bystander MOE (Based on 8-hour TWA) [g]

[g] For the bystander, EPA used the stay-at-home and full-time worker activity patterns from CEM. The stay-at-home activity pattern assumes that occupants are inside the home a total of 21 hours per day and move from room to room according to the schedule shown in Appendix A in the consumer technical support document (U.S. EPA, 2026b). For the full-time worker activity pattern, the bystander spends 8 hours in the office/school in addition to 1 hour in an automobile and 1 hour outdoors, and for the remining time see Appendix A in the consumer technical support document (U.S. EPA, 2026b) for time spent in other indoor environments. For both small and large spray paint scenarios the bystander was not in the room of product application, garage for the small project scenario and living room for the large project scenario.

[h] Full-time worker refers to the activity pattern within CEM for people that spend time in an office/school outside of the home. The time spent in the office/school is therefore time not exposed as a bystander in any indoor environment/room in the home where the product is in use.

[i] During the development of this preliminary draft risk evaluation, EPA received additional information from Harris Paints indicating that phthalic anhydride is not present in paint products at certain weight fractions (*i.e.,* 10–25% by weight) as previously indicated in reasonably available SDSs. EPA is working to obtain updated information related to paint products. If received, this may impact inhalation exposures and MOEs under this COU in the final risk evaluation.

4.3.3.3 Overall Confidence in Consumer Risks

As described in Section 4.1.2 and in more detail in the *Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026b), EPA has moderate confidence in the assessed dermal exposures for spray applications and moderate confidence in the assessed dermal exposures for non-spray applications and inhalation consumer exposure scenarios. EPA has robust confidence in the non-cancer POD selected to characterize risk from acute duration exposure to phthalic anhydride via the dermal route (see Section 4.2 and (U.S. EPA, 2026p)). The exposure concentrations used to estimate risk relied on product specific inputs and parameters that are considered representative of a wide selection of use patterns. Overall EPA has moderate confidence in dermal MOEs for spray products and moderate confidence in dermal MOEs for liquid products.

EPA has moderate confidence in the non-cancer POD selected to characterize risk from acute duration exposure to phthalic anhydride via the inhalation route. The moderate confidence stems from uncertainty related to the endpoint of respiratory sensitization for use in quantitative dose-response and subsequent risk characterization (See Section 4.2.2). However, EPA has robust overall confidence that respiratory sensitization is the most sensitive adverse outcome following inhalation exposure based on the weight of scientific evidence. For inhalation, modeled exposure concentrations were used to support exposure occurrences from spray products. The Agency has a robust confidence that the inhalation exposure concentrations are representative of exposures and that subsequent sensitization to phthalic anhydride occurs from inhalation of spray products. Overall, EPA has moderate confidence for inhalation of spray products MOE values.

4.3.4 Risk Estimates for General Population

4.3.4.1 Risk Characterization for General Population

As described in the *Draft Environmental Media and General Population Exposure for Phthalic Anhydride* (U.S. EPA, 2026n) and Section 4.1.4, EPA employed a screening-level approach for general population exposures for phthalic anhydride releases associated with each COU. Fenceline communities were considered as part of the general population in proximity to releasing facilities as part of the ambient air exposure assessment by utilizing pre-screening methodology described in EPA's *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Version 1.0)* (U.S. EPA, 2022a). For the screening-level analysis, EPA used the highest phthalic anhydride releases into ambient air and surface water OESs combined with inputs that would result in the highest possible inhalation and drinking water exposures. Thus, any combination of OESs and matching COUs with lower release concentrations would result in lower exposures. As such, if the highest possible inhalation and oral exposures do not result in MOEs below the benchmark by default all other COUs will result in lower exposures and higher MOEs.

Phthalic anhydride exhibits rapid ($t_{½}$ = 30–90 seconds) and complete hydrolysis of phthalic anhydride to *o*-phthalic acid is expected to occur in the order of minutes within the ambient environment as discussed in Section 2. Therefore, the general population screening-level risk assessment evaluates exposures to *o*-phthalic acid, not phthalic anhydride. As described further in the *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n), EPA is quantifying general population exposure and risk from surface water, ingestion of drinking water, and inhalation exposure to ambient air and summarized in the text below. Other exposure pathways were qualitatively evaluated and EPA concluded that inhalation, oral, and dermal exposures were not expected via the following pathways: land, incidental ingestion, dermal exposure from swimming, human milk, and fish ingestion.

The proposed oral POD (HED of 66 mg/kg-day) was selected as described in the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p), to estimate risks to the general population from exposure to releases of phthalic anhydride. A total uncertainty factor of 30 was selected for use as the benchmark MOE (based on a UF_A of 3× and a UF_H of 10×). The POD is derived from a NOAEL of 278 mg/kg-day based on decreased body weight gain in male F344 rats fed diets containing phthalic anhydride for two years (NCI, 1979).

For the screening-level analysis, upper bound exposures were estimated for each exposure pathway assessed.

4.3.4.1.1 Surface Water and Drinking Water Risk Characterization

EPA estimates low potential exposure to *o*-phthalic acid via drinking water, when considering expected treatment removal efficiencies, even under upper-bound release scenarios. Environmental degradation due to photolysis or biodegradation as well as treatment in conventional drinking water treatment processes (flocculation, UV treatment) would suggest that actual measured concentrations in raw drinking water would be higher than finished water. Upper-bound releases such as the one modeled in this screening exercise would more likely be discharged to water bodies with more substantial flow, reducing the environmental concentrations further, as drinking water sources are more likely to be from larger water bodies (reservoirs, rivers) than the relatively low flow regime that was modeled in this conservative screening analysis.

Based on the estimated drinking water doses in Table 5-1 in the *Draft Environmental Media and General Population Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026n), EPA used the MOE screening approach for exposures to adults, youth, and children. Table 4-21 summarizes the chronic MOEs based on the drinking water doses. Acute MOEs were not estimated because no acute hazards were identified for *o*-phthalic acid. Using the total chronic dose based on the highest modeled 95th percentile concentration, the MOEs are greater than relevant benchmarks presented in the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p). Based on the conservative modeling parameters for drinking water concentration and exposure factors parameters, all MOEs were above the benchmark of 30.

This assessment assumed that concentrations at the point of intake for the drinking water system are equal to the concentrations in the receiving water body at the point of release, where treated effluent is being discharged from a facility. In fact, some distance between the point of release and a drinking water intake would be expected, providing space and time for additional reductions in water column concentrations via degradation, partitioning, and dilution. Some form of additional treatment would typically be expected for surface water at a drinking water treatment plant, including coagulation, flocculation, sedimentation, and/or filtration. This treatment would likely result in even greater reductions in *o*-phthalic acid concentrations due to adsorption and settling prior to releasing finished drinking water to customers.

Table 4-21. MOE Screening (Chronic MOE Screening) for Modeled Drinking Water Exposure for Adults, Youths, and Children, for the Upper-Bound Release Estimate from Modeling and Monitoring results

Scenario	Water Column Concentrations Harmonic Mean Conc. (µg/L)	MOE Adult (≥21 years)	MOE Infant (Birth to <1 year)	MOE Toddler (1–5 years)
Processing as a reactant *Without Wastewater Treatment or Drinking Water Treatment*	21,500	408	160	372
Processing as a reactant *With Wastewater Treatment*	17,200	510	199	465
High from Monitoring	9.5	890,000	350,000	810,000

MOE = margin of exposure

4.3.4.2 Ambient Air and Inhalation Risk Characterization

For the air pathway, EPA used the Integrated Indoor/Outdoor Air Calculator (IIOAC) model to estimate daily- and annual-average ambient air concentrations of *o*-phthalic acid, as well as annual average wet, dry, and total air deposition rates of *o*-phthalic acid from the ambient air. EPA used the maximum reported releases from a single facility across all COUs as direct inputs to the IIOAC Model to estimate concentrations and deposition rates for both stack and fugitive emissions. The selected facilities were both associated with the Manufacturing (without engineering controls) COU. To evaluate exposures and total deposition rates, EPA assumed the fugitive and stack releases occur simultaneously throughout the day and year. Therefore, the total concentration and deposition rate used is the sum of the separately modeled fugitive and stack concentrations and total deposition rates at 100 m from a releasing facility.

The IIOAC outputs used in this assessment are

- *Upper bound* of all modeled hourly concentrations across the entire distribution of modeled concentrations at 100 m.
- *Upper-bound* annual-average concentration across the entire distribution of modeled concentrations at 100 m.
- *Upper-bound* annual-average deposition rate across the entire distribution of modeled deposition rates at 100 m.

Based on the estimated average daily concentration in Table 7-1 in the *Draft Environmental Media and General Population Exposure for Phthalic Anhydride* (U.S. EPA, 2026n), EPA screened for inhalation MOEs to the general population. Table 4-22 summarizes the chronic MOE based on the highest average annual concentration. Acute MOEs were not estimated because no acute hazards were identified for *o*-

phthalic acid. Using the average annual concentration based on the highest modeled 95th percentile annual average concentration, the chronic MOE was greater than the benchmark of 30 (see Table 4-22). Based on the estimated average daily dose, EPA screened for soil ingestion to children between 3 and 6 years old. The chronic MOE for soil ingestion was greater than the benchmark of 30 (Table 4-23). Based on the conservative modeling parameters for air concentrations and exposure factors parameters, the resulting MOE values are all significantly above the benchmark of 30.

Table 4-22. Screening Analysis (Chronic MOE) for Modeled Ambient Air Exposure for the General Population Inhalation for the Upper-Bound Release Estimate from Modeling Results

OES	Annual Average Concentration (µg/m^3)	Chronic MOE (MOE=30)
Manufacturing	99.4	3,602
MOE = margin of exposure; OES = occupational exposure scenario		

Table 4-23. Screening Analysis (Chronic MOE) for Modeled Soil Ingestion Doses for Children Based on the Upper-Bound Release Estimate

OES	Average Daily Dose (mg/kg-day)	Chronic MOE (MOE=30)
Manufacturing	2.61E−09	2.53E10
MOE = margin of exposure; OES = occupational exposure scenario		

EPA has high confidence that the conservative assumptions and inputs used in the screening-level approach for the ambient air exposure scenario modeled represent an overestimate that is inclusive of all possible exposures.

4.3.4.3 Overall Confidence in General Population Risk

As described in the *Draft Environmental Media and General Population Exposure for Phthalic Anhydride* (U.S. EPA, 2026n), EPA has robust confidence that modeled releases used are appropriately conservative for screening-level analyses. EPA also has robust confidence that no exposure scenarios will lead to greater doses than presented in this evaluation. The confidence assigned was based on the use of conservative assumptions for the screening approach resulting in an upper-bound of exposure in which MOE results were all above the benchmark of 30. EPA has robust confidence that the risk estimates calculated for the general population were conservative and appropriate for a screening-level analysis.

4.3.5 Risk Estimates for Potentially Exposed or Susceptible Subpopulations

EPA considered PESS throughout the hazard identification and dose-response analysis as well as throughout the exposure assessment supporting the *Draft Risk Evaluation for Phthalic Anhydride.*

Some population group lifestages may be more susceptible to the health effects of exposure to phthalic anhydride. As discussed in Section 4.2.1 and 4.3.1 of EPA's *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p), EPA focused on the most sensitive hazards associated with exposure to phthalic anhydride including dermal sensitization and respiratory sensitization.

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

- EPA evaluated a range of OESs for workers and ONUs, including high-end exposure scenarios for the various occupational uses of phthalic anhydride.
- EPA quantitatively evaluated a range of consumer exposure scenarios including the high-intensity use exposure scenarios for exposures to users and bystanders of all ages from products like adhesives and sealants, and paints and coatings. While infants and children under 10 years of age are not expected to be regular users of the identified products, if they are users they would be exposed to the same exposure concentrations reported for users in this assessment and their exposures via inhalation is considered in the bystander scenarios. For articles, EPA qualitatively evaluated cured crafting resin, 35% w/w, and highest phthalic anhydride concentration in the consumer assessment. Exposures via inhalation and dermal routes to cured crafting resins (article) are not expected, see Table 4-7 for a description of the crafting resin exposure scenarios. The crafting resin as a liquid product exposure assessment was performed qualitatively and similar to the article, dermal exposure was not expected to occur.
- EPA evaluated a range of general population exposure scenarios for the general population screening-level assessment focusing on the OES from the highest releasing facilities, including upper-bounded exposure scenarios for infants and children (susceptible subpopulations). These populations had greater intake per body weight.

3247 5 ENVIRONMENTAL RISK ASSESSMENT

Phthalic Anhydride – Environmental Risk Assessment (Section 5):
Key Points

EPA evaluated the reasonably available information for environmental exposures and hazard to ecological receptors following releases of *o*-phthalic acid to surface water, sediment, air deposition of *o*-phthalic acid to soil, landfill release, and agricultural application of municipal biosolids. The following bullets summarize the key points.

Environmental Exposure Key Points

- Using TRI data, the highest surface water concentration from this screening-level assessment resulted from the Processing as a reactant OES with a 7Q10 (lowest 7-day average flow that occurs [on average] once every 10 years) value of 1.51 mg/L for releases.
- Using TRI data, the highest air release from this screening-level assessment resulted from the Manufacturing OES with an annual soil concentration of 1.2×10^{-2} mg/kg.

Hazard Key Points

- The acute aquatic COC of 20.6 mg/L was derived from an acute value of 103 mg/L divided by an assessment factor (AF) of 5.
- The chronic aquatic COC of 3.2 mg/L was derived from a chronic value (ChV) of 32 mg/L divided by an assessment factor (AF) of 10.
- The aquatic plants and algae COC of 227 mg/L was derived from a hazard value of 2,270 mg/L divided by an AF of 10.
- The hazard value for terrestrial mammals was 250 mg/kg-day, based on a LOAEL value from two rat studies via gavage.
- The terrestrial invertebrate hazard threshold was 253.3 mg/kg, based on ECOSAR Model output for earthworms.
- The terrestrial plant hazard threshold was 166.1 mg/L, based on a LOAEC value in a hydroponic study.

Risk Assessment Key Points

- Aquatic species
    - The OES representing the highest surface water concentrations from TRI release (Processing as a reactant) resulted in RQs less than 1 for acute and chronic exposure to aquatic organisms.
    - RQs were less than 1 for surface water exposures to aquatic plants and algae with the highest TRI release (Processing as a reactant).
- Terrestrial species
    - The OES representing the highest air concentrations from TRI release (Manufacturing) resulted in RQs less than 1 for terrestrial plants and terrestrial invertebrates exposed via air deposition (fugitive or stack release).
    - Risk to terrestrial mammals from phthalic ahydride through trophic transfer is not expected.
    - Risk to terrestrial organisms through landfill or municipal biosolid exposure is not expected.
- EPA has moderate confidence in the risk characterization for the acute and chronic aquatic assessments, respectively; moderate confidence in the risk characterization to aquatic plants and algae; and moderate confidence in the terrestrial plant assessment through air deposition to soil.
    - Although there is uncertainty in hazard due to the limited amount of reasonably available data for each taxa, overall confidence is higher based the low level of expected environmental exposure to this chemical.

5.1 Summary of Environmental Exposures

As discussed in the final scope document for phthalic anhydride (U.S. EPA, 2020d) and in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r), phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid (CASRN 88-99-3) when allowed contact with water or atmospheric moisture. This transformation is immediate with the hydrolysis half-life estimated between 30 to 90 seconds, depending upon pH; complete hydrolysis is achieved in approximately 8 minutes in simulated seawater or physiological fluids (U.S. EPA, 2026r). Given the rapid hydrolysis of phthalic anhydride to *o*-phthalic acid, EPA considered environmental hazard data for both phthalic anhydride and *o*-phthalic acid in this draft risk evaluation. EPA estimated concentrations and discharge of *o*-phthalic acid following release to the environment. 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 *o*-phthalic acid in the environment.

o-Phthalic acid is expected to be released to the environment via air, water, and biosolids and landfills as detailed within the environmental release assessment presented in the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2025a). Environmental media concentrations were estimated in ambient air, soil from ambient air deposition, biosolids, and surface water. Further details on the environmental partitioning and media assessment can be found in the *Draft Fate and Physical Chemistry Assessment for Phthalic Anhydride* (U.S. EPA, 2026r). A summary of relevant exposure pathways to receptors and resulting risk characterization summaries are presented in Table 5-1.

For the water pathway, EPA's VVWM-PSC tool (PSC) (U.S. EPA, 2019e) was used to estimate surface water and sediment concentrations of *o*-phthalic acid resulting from COU releases. Industrial releases of *o*-phthalic acid to surface waters were reported to EPA via TRI and DMR databases. Generic scenarios were not considered because reported releases were obtained by EPA for all OES using TRI and NEI databases (See section 3.3.3.1 of (U.S. EPA, 2026o)). PSC inputs include physical and chemical properties of *o*-phthalic acid (*i.e.,* K_{OW}, K_{OC}, water column half-life, photolysis half-life, hydrolysis half-life, and benthic half-life) and estimated *o*-phthalic acid releases to water (U.S. EPA, 2025h), which are used to predict receiving water column concentrations. Site-specific parameters including the concentration of suspended sediments, water depth, and weather patterns influence how partitioning occurs over time. However, physical and chemical properties of the chemical have a major influence on partitioning and half-lives in aqueous environments. *o*-Phthalic acid has a water solubility of 6,994 mg/L and a log K_{OC} of 1.43 indicating a high potential to remain in the water column, but not likely to adsorb or bioaccumulate under normal environmental conditions (U.S. EPA, 2026r). Physical, chemical, and environmental fate properties selected by EPA for this assessment were used as inputs to the PSC model described in detail in the *Draft Fate and Physical Chemistry Assessment for Phthalic Anhydride* (U.S. EPA, 2026r) and *Draft Environmental Media, General Population, and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2025g).

It is difficult for EPA to quantify end-of-life and down-the-drain exposures due to limited information on source attribution of the consumer COUs. Section 3.1.3 further details on the qualitative assessment of consumer disposal of *o*-phthalic acid -containing products and articles. Although EPA acknowledges that there may be *o*-phthalic acid releases to the environment, the Agency did not quantitatively assess these scenarios due to limited information and expected low concentrations, monitoring data, or modeling tools. Consumer releases to the environment are anticipated to be more dispersed and less direct than *o*-phthalic acid releases from COUs/OESs quantified for risk estimates for aquatic and terrestrial receptors detailed within Section 3.1.3. *o*-Phthalic acid and *o*-phthalic acid from down-the-drain disposal of consumer products or landfill disposal of consumer articles is not likely to lead to environmental concentrations that exceed hazard values for aquatic and terrestrial organisms. It is unlikely that phthalic anhydride or and *o*-phthalic will migrate from landfills via groundwater infiltration.

In the terrestrial environment, *o*-phthalic acid may be present in soil from the application of biosolids to topsoil, although there are no U.S.-based studies that report detection. It is expected to be mobile in water and may leach into groundwater due to the low tendency of *o*-phthalic acid to sorb to organic media and soil (log K_{OW} = 0.73; log K_{OC} = 1.07). Biodegradation of *o*-phthalic acid in groundwater is expected to be rapid with a half-life of days (Tang et al., 2017; Fujita et al., 2005). It is also expected to biodegrade rapidly in soil with a half-life of days to weeks, which will retard its movement to groundwater (Zhao et al., 2016; Fujita et al., 2005; Shelton and Tiedje, 1984). Phthalic anhydride or *o*-phthalic acid is expected to biodegrade in the upper, aerobic portions of landfills. In lower landfills where anaerobic conditions are likely, biodegradation is expected to be slower (Huang et al., 2013; Jonsson et al., 2003). Despite the expected biodegradation of *o*-phthalic acid in landfills, there is still a possibility for *o*-phthalic acid to be present in landfill leachate, which if improperly managed may contaminate groundwater. However, no studies were identified in systematic review determining concentrations in landfills or landfill leachate, and biodegradation of *o*-phthalic acid in groundwater is expected to be rapid with a half-life of days (Tang et al., 2017; Fujita et al., 2005). Therefore, *o*-phthalic acid is not expected to persist in groundwater.

Modeled *o*-phthalic acid concentrations from air deposition to soil the OES with the resulting highest concentrations to soil were assessed quantitatively using environmental hazard thresholds (U.S. EPA, 2025f) for relevant soil-dwelling organisms and plants within the *Draft Environmental Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2025e). A complete review of exposure pathways can be found in the *Draft Environmental Media, General Population, and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2025g).

Biosolids generated during the treatment of industrial and municipal wastewater may be applied to agricultural fields or pastures as fertilizer in either its dewatered form or as a water-biosolid slurry. Exposures via the land pathway (*i.e.,* biosolids, landfills) were qualitatively assessed because *o*-phthalic acid is not expected to be persistent in soils. No monitoring data for p *o*-phthalic acid in biosolids or landfills were available. There is currently no direct evidence that biosolids containing *o*-phthalic acid are being consistently applied to agricultural fields in any part of the United States. Because there is limited data that any biosolids containing *o*-phthalic acid are being consistently applied to biosolids, there is similarly very limited direct evidence that *o*-phthalic acid is present in agricultural products or subsequently that the general populus may be regularly exposed to *o*-phthalic acid resulting from the applications of biosolids to agricultural fields. Although experimental data are limited, physical and chemical properties suggest that *o*-phthalic acid present in biosolid-amended soils will likely not be absorbed by any plants or crops growing in the soil, and soil-dwelling organisms are not expected to readily accumulate *o*-phthalic acid through ingestion or absorption.

Table 5-1. Relevant Exposure Pathway to Receptors and Corresponding Risk Assessment for the *o*-Phthalic Acid Environmental Risk Characterization

Exposure Pathway		Receptor	Risk Assessment [a]
Aquatic environment	Surface water	Acute exposure to aquatic invertebrates (mortality in *Daphnia magna*)	Quantitative; No risk [a]
	Surface water	Chronic exposure to aquatic vertebrates, reduced growth/development of Japanese medaka (*Oryzias latipes*)	Quantitative; No risk [a]
	Surface water	Aquatic plants and algae (*Pseudokirchneriella subcapitata*) inhibition of growth	Quantitative; No risk [a]
Terrestrial environment	Soil	Terrestrial invertebrate (earthworm) LC50 modeled via ECOSAR	Qualitative; Unlikely to result in risk
	Soil (air to soil)	Terrestrial plant reduction in weight and root and shoot length in the crabapple (*Malus prunifolia*)	Quantitative; No risk [a]
	Soil (biosolids)	Terrestrial invertebrates, plants, and mammals	Qualitative; Unlikely to result in risk
	Trophic transfer	Terrestrial mammals and Birds	Qualitative; unlikely to result in risk

[a] Table 5-3 and Table 5-5 detail the risk estimates calculated from hazard thresholds and TRI data representing the COU/OESs with the highest concentrations from surface water or air release.

5.2 Summary of Environmental Hazards

EPA considered four aquatic toxicity studies that were rated high or medium quality to determine hazard to aquatic organisms. For terrestrial organisms, two mammalian and two terrestrial plant studies were considered for quantitative assessment, as well as terrestrial invertebrates assessed using the Ecological Structure Activity Relationships (ECOSAR) Model. Although no studies were received for birds, exposure to this taxa is not expected. Although low and uninformative studies were not used, data were reviewed for comparison. No studies were available for sediment-dwelling organisms. Therefore, hazard thresholds could not be established for these taxa. For an overview of the studies considered and environmental hazards refer to the *Draft Environmental Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2025e).

For acute exposure to aquatic organisms, one invertebrate and one vertebrate study were available. The acute invertebrate LC50 was determined to be 103 mg/L (Jonsson and Baun, 2003) and the acute vertebrate aquatic LOAEC and NOAEC were determined to be 100 mg/L and greater than 100 mg/L due to the absence of any measured effects on rainbow trout (Author Withheld, 1996).

For subchronic and chronic exposures, two aquatic vertebrate studies were available. EPA reviewed *o*-phthalic acid exposure in both the zebrafish and rainbow trout for 7 and 60 days, respectively (Van Leeuwen et al., 1990), to represent subchronic and chronic exposure. Although there was uncertainty in the test concentrations used and analytical verification the seven-day zebrafish study, the LC50 was determined to be 560 mg/L. In the 60-day rainbow trout study, the LC50 was 44.2 mg/L and the LOAEC was reported to be 32 mg/L.

One freshwater green algae study was reviewed(Jonsson and Baun, 2003). Green algae showed effects from exposure to the *o*-phthalic acid over 72 hours in which an EC50 value of 2,270 mg/L was estimated.

Although there is no data for sediment-dwelling organisms, in the presence of water, *o*-phthalic acid is expected to rapidly hydrolyze to *o*-phthalic acid and. *o*-Phthalic acid is not expected to show strong affinity and sorption potential for organic carbon in sediment, is a soluble chemical, undergoes limited partitioning to suspended organic matter, and is not likely to partition to be sorbed into sediments (log K_{OC} = 1.07). Higher tier fugacity modeling results indicated a negligible partitioning in sediments, and any *o*-phthalic acid present in sediments is expected to biodegrade withing weeks. Therefore, sediment is considered a minor compartment for *o*-phthalic acid. A more detailed analysis of *o*-phthalic acid sediment partitioning can be found in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r).

For aquatic hazard, uncertainties exist and there is slight confidence in the quality of the database strength and precision of endpoints, and moderate confidence in consistency, as described in in the *Draft Environmental Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026m). However, effects on aquatic species were observed at concentrations that are relatively high in aquatic species across taxonomic groups, habitats, exposure types, and exposure durations. In some aquatic studies, no effects were seen up to the highest tested concertation. Overall, EPA has high confidence in the evidence that *o*-phthalic acid has low hazard potential to aquatic species.

In the terrestrial environment, the potential for *o*-phthalic acid to pose a hazard to mammals, terrestrial plants, and terrestrial invertebrates was evaluated. To evaluate the potential for *o*-phthalic acid to pose hazard to terrestrial mammals, EPA considered laboratory rodent studies conducted for use as human health models. The Agency acknowledges that human health rodent models may not be fully representative of effects in a more diverse array of wild animal populations; however, it is important to note that the hazard value was derived from the most sensitive ecologically relevant endpoint from the data set. The terrestrial mammalian hazard threshold of 250 mg/kg-day is the most sensitive value shared by two studies based on a 14 and 22% reduction of male body weight over the study duration (Kwack et al., 2010; Kwack et al., 2009).

The conclusion that *o*-phthalic acid poses hazard to terrestrial plants is supported by two terrestrial plant studies that identified effects (Hua et al., 2019; Bai et al., 2009). The study with the Lanzhou lily demonstrated a dose-response relationship for a reduction of root length establishing a NOAEL/LOAEL of 0.25/0.5 µmol/g and plant and bulb weight reduction NOAEL/LOAEL of 0.05/0.25 µmol/g (Hua et al., 2019). Although effects were observed, the methodology of administering the test solution and the normalization of the units (µmol/g soil) introduce uncertainty int the study design (Hua et al., 2019). The second study with the crabapple showed reduced dry weight and root and shoot length at 166.1 mg/L in a hydroponic study and was used to determine the COC. However, although apical and subapical endpoints were reported, plants were not dying at the concentration tested (Bai et al., 2009).

No studies were available to assess the hazard thresholds of *o*-phthalic acid to terrestrial invertebrates on apical endpoints (growth, mortality, reproduction). The LC50 value was 253.3 mg/kg estimated using the ECOSAR predictive model (U.S. EPA, 2022b) for earthworms exposed to *o*-phthalic acid over 14 days.

Overall, EPA has moderate confidence in the evidence that *o*-phthalic acid may pose hazard to terrestrial mammals, slight-to-moderate confident confidence that it may pose hazard to soil invertebrates, and moderate confidence that it may pose hazard to terrestrial plants. No studies on *o*-phthalic acid exposure to birds were available, suggesting that no hazard has been observed in these groups under natural exposure conditions.

5.3 Environmental Risk Characterization

5.3.1 Risk Assessment Approach

EPA characterized the environmental risk of *o*-phthalic acid using risk quotients (RQs) (U.S. EPA, 1998; Barnthouse et al., 1982). The RQ is defined in Equation 5-1. Risk was also characterized qualitatively using a weight-of-evidence approach to support conclusions.

Equation 5-1. Calculating the Risk Quotient

$$RQ = Predicted\ Environmental\ Concentration / Hazard\ Threshold$$

Environmental exposure concentrations for each compartment (*i.e.,* surface water, pore water, sediment, and soil) were based on measured (*i.e.,* monitored data and/or available literature) and/or modeled (*i.e.,* E-FAST 2014, VVMW-PSC, AERMOD, IIOAC) concentrations of *o*-phthalic acid from Section 3. EPA calculates hazard thresholds to identify potential concerns to aquatic and terrestrial species. These terms describe how the values are derived and can encompass multiple taxa or ecologically relevant groups of taxa as the environmental risk characterization serves populations of organisms within a wide diversity of environments. For hazard thresholds, EPA used the COCs calculated for aquatic organisms, and the hazard values calculated for terrestrial organisms as detailed within the *Draft Environmental Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2025e).

RQs equal to 1 indicate that environmental exposures are the same as the hazard threshold. If the RQ is above 1, the exposure is greater than the hazard threshold. If the RQ is below 1, the exposure is less than the hazard threshold. Risk is indicated when the RQ greater than or equal to 1. RQs derived from modeled data for *o*-phthalic acid are described in Section 5.3.2 for aquatic organisms and Section 5.3.3 for terrestrial organisms. RQs derived from measured data for *o*-phthalic acid are presented within the *Draft Environmental Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2025e) in Table 3-1 for aquatic organisms, and Table 4-1 for terrestrial organisms. For aquatic species, acute risk is indicated when the RQ is greater than or equal to 1 for acute exposures. The chronic COC was derived from a 60-day exposure; therefore, the days of exceedance to demonstrate risk reflects the exposure period for that hazard value. For terrestrial species, RQ values are calculated using the hazard value for terrestrial invertebrates and terrestrial plants.

5.3.2 Risk Characterization for Aquatic Receptors

Releases of *o*-phthalic acid to surface water were identified for 44 COUs (Life cycle stage/ Category/Subcategory) represented by 14 OESs. The OES with the highest *o*-phthalic acid surface water releases was Processing as a reactant (Table 5-2). Calculated acute and chronic RQs for aquatic organisms and aquatic plants and algae can be found in Table 5-3, and they were represented by the concentrations from TRI release data and hazard thresholds for aquatic organisms (Section 5.2). EPAs aquatic risk assessment includes multiple inputs that align with long standing EPA practices (*i.e.,* use of 7Q10 from EPA Office of Water's Water Quality Standards Handbook; accessed March 26, 2026). The maximum daily average release value to surface water for the Processing as a reactant OES was 1,510 µg/L (1.51 mg/L) for all acute or chronic hazard study durations for aquatic receptors as modeled by VVWM-PSC. Acute and chronic duration was 2 and 60 days, respectively, and the aquatic plants and algae study duration was 3 days. All days of exceedance were greater than the hazard threshold value study duration for the release scenario.

Because this analysis is using TRI site data and not modeled generic scenario data (*i.e.,* P50, P75, and P90), only one release value is reported using the 7Q10 flow scenario. Inputs for the TRI OES with the highest release (*i.e.,* Processing as a reactant) are in Table 5-2. The flow data were represented by self-reported hydrologic reach codes on NPDES permits and represents the best available flow estimation from Enhanced Run Off Method (EROM) flow data. Direct releases to surface water reported via TRI and DMR were applied as the actual loading to surface water, including any onsite treatment prior to discharge.

Table 5-2. Releases to Water Based on Data from TRI and Resulting Water Concentrations Modeled Using PSC and Different Flow Conditions

OES	Annual Release (kg/year)	Maximum Number of Release Days [a]	Daily Release (kg/site-day)	Flow Rate 7Q10 [b] (m^3/day)
Processing as a reactant [c]	2,030.7	250	8.12	5,361.92

[a] Maximum days of release based on total number of operating days

[b] 7Q10 is defined as 7 consecutive days of lowest flow over a 10-year period. These flows are used to calculate estimates of chronic surface water concentrations to compare with the COCs for aquatic life (Versar, 2014).

[c] The TRI Processing as a reactant OES had the highest untreated releases to surface water and was the most protective realistic release relevant to environmental receptors as detailed in the *Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2025a).

Processing as a Reactant

The surface water concentration was 1.51 mg/L for the 7Q10 flow scenario. The acute, chronic and algal COCs were 20.6, 3.2, and 227 mg/L, respectively, derived from waterflea, rainbow trout, and green algae hazard values, respectively. Surface water chronic RQ values for the Processing as a reactant OES did not exceed 1 for any taxa (Table 5-3).

Table 5-3. Aquatic Environmental Risk Quotients (RQs) by *o*-Phthalic Acid TRI Release Surface Water Concentrations (mg/L) Modeled by VVWM-PSC

COU (Life Cycle Stage/Category/Subcategory)	OES [a]	Flow Scenario (Flow Rate)	Surface Water Concentration (mg/L)	Risk Quotient (RQ) [b]		
				Acute	Chronic	Algae
Processing/Processing as a reactant/Intermediate (All other basic organic chemical manufacturing; Paint and coating manufacturing; Flame retardant manufacturing)	Processing as a reactant	7Q10	1.51	0.07	0.47	6.7E−03
Processing/Processing as a reactant/Monomer (All other basic organic chemical manufacturing)						
Processing/Processing as a reactant/Ion exchange agent (All other basic organic chemical manufacturing)						
Processing/Processing as a reactant/Pigments (Printing ink manufacturing)						
Processing/Processing as a reactant/Polymerization promoter in (synthetic dye and pigment manufacturing)						
Processing/Processing as a reactant/Plasticizer (Adhesive manufacturing; Lubricant additive manufacturing)						

[a] The OES with the highest surface water release was Processing as a reactant

[b] RQ = exposure water concentration divided by the acute COC of 20.6, chronic COC of 3.2, and algal COC of 227 mg/L derived from studies with the waterflea, rainbow trout, and green algae, respectively.

5.3.3 Risk Characterization for Terrestrial Receptors

EPA conducted an assessment for *o*-phthalic acid release to the terrestrial environment by preforming quantitative risk characterization using the COU/OES with the highest values of fugitive releases or stack atmospheric deposition to soil (Table 5-5).

The OES with the highest fugitive and stack air release, selected using TRI, NEI, and/or generic scenario data, was manufacturing (Section 7.1 of the *Draft Environmental Media, General Population, and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2025g)). Soil concentrations were calculated from estimated soil catchment concentrations that could be in soil via maximum daily air deposition (95th percentile) of *o*-phthalic acid at a distance of 100 m from a facility based on releases reported to TRI, resulting in a daily soil concentration of 4.85×10^{-5} mg/kg. This screening-level assessment used the protective assumption of no loss of chemical to degradation (aside from the expected hydrolysis of phthalic anhydride to *o*-phthalic acid). RQs were less than 1 for terrestrial invertebrates and terrestrial plants from exposure scenarios using the highest IIOAC predictions for annual air deposition to soil with a maximum release of 250 days at 100 m and an annual soil concentration of 1.2×10^{-2} mg/kg.

Table 5-4. Integrated Indoor/Outdoor Air Calculator (IIOAC) Input Parameters and Release Values

Total Annual Particle Deposition (g/m^2)	Max Days Release/Year	Total Deposition (mg/day)	Soil Concentration (mg/kg-day)	Annual Soil Concentration [a] (mg/kg)
5.21E−05	250	741.9	4.85E−05	1.2E−02

[a] Based on max days release/year

Terrestrial Vertebrates (Mammals) and Birds

Using laboratory rodents from the human health model, the terrestrial mammal hazard of 250 mg/kg-day from two human health laboratory rodent studies was based on the best available LOAEL value shared by two studies resulting in a reduction in male body weight after exposure to *o*-phthalic acid via oral gavage (Kwack et al., 2010; Kwack et al., 2009). In the environment, terrestrial mammals and birds may be exposed via trophic transfer. *o*-Phthalic acid has a water solubility of 6,200 mg/L, a log K_{OC} of 1.43, a log K_{OW} of 0.73, and a BAF of 1.32 L/kg, indicating a high potential to remain in the water column and not adsorb or bioaccumulate under normal environmental conditions (U.S. EPA, 2026r). Additionally, *o*-phthalic acid rapidly hydrolyzes to *o*-phthalic acid. *o*-Phthalic acid is a water soluble solid that maybe present in the atmosphere as suspended particles/dust, is likely to partition to surface and ground water, not likely to volatilize from water and dry surfaces, not likely to bioaccumulate, and will rapidly biodegrade under normal environmental conditions as described in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r). Based on the chemical and physical properties of *o*-phthalic acid exposure is expected to be negligible, and EPA has determined that *o*-phthalic acid is unlikely to pose risk to terrestrial mammals and birds.

Terrestrial Invertebrates

The terrestrial invertebrate hazard value of 253.3 mg/kg was estimated using ECOSAR (U.S. EPA, 2022b). The OES with the highest fugitive and stack release to air was Manufacturing with an annual release of 1.2×10^{-2} mg/kg resulting in a risk quotient less than 1. Therefore, based on the RQ value, there is no risk to terrestrial invertebrates from exposure to *o*-phthalic acid via atmospheric deposition.

There is, however, uncertainty regarding the ECOSAR dataset used to determine the terrestrial invertebrate hazard threshold. Although log K_{OW} is the main driver of toxicity in the ECOSAR model in the aquatic environment, it may not be a suitable model for organisms in the terrestrial environment. Terrestrial invertebrate (earthworm) data for *o*-phthalic acid are in mg/kg, which may not be appropriate in ECOSAR's log K_{OW}-based linear regression. The ECOSAR Model output was in mg/L whereas the dataset used to model *o*-phthalic acid was in mg/kg. Furthermore, there are few chemicals or datapoints for neutral organics in the ECOSAR dataset, which *o*-phthalic acid is classified, with many of those studies being limit tests. Therefore, risk to terrestrial invertebrates cannot be assessed quantitatively at this time.

Terrestrial Plants

The terrestrial plant hazard threshold of 166.1 mg/L was derived from a 15-day hydroponic exposure of *o*-phthalic acid to the crabapple, which resulted in significant a reduction in fresh and dry plant weight and root and shoot length (Bai et al., 2009). The OES with the highest fugitive and stack release to air was manufacturing with an annual release of 1.2×10^{-2} mg/kg. To make a comparison between the hazard and exposure values, a conversion was incorporated. The bulk density of soil was assumed to be 1,700 kg/m^3 or 1.7 kg/dm^3 (ECB, 2003). This screening-level assessment incorporated the protective assumption of no loss of chemical through degradation (aside from the expected hydrolysis of phthalic anhydride to *o*-phthalic acid). Taking the annual soil concentration 1.2×10^{-2} mg/kg and multiplying by soil density 1.7 kg/dm^3 results in an exposure value of 0.02 mg/L (0.02 mg/dm^3), with the resulting RQ less than 1. (Table 5-5). Therefore, there is no risk to terrestrial plants from exposure to *o*-phthalic acid via atmospheric deposition.

Table 5-5. Risk Quotients (RQs) for Terrestrial Plants Based on Modeled Air Deposition of *o*-Phthalic Acid to Soil from Reported or Modeled Fugitive Emissions

COU (Life Cycle Stage/Category/Subcategory)	OES	Annual Soil Concentration (mg/L)	Hazard Value (mg/L)	RQ
Domestic manufacturing/Domestic manufacturing/Manufacturing	Manufacturing	0.02	166.1	1.2E–4

Biosolids and Landfills

Biosolids generated during the treatment of industrial and municipal wastewater may be applied to agricultural fields or pastures as fertilizer in either its dewatered form or as a water-biosolid slurry. Biosolids exposures were qualitatively assessed because *o*-phthalic acid is not expected to be persistent in soils and would likely hydrolyze to *o*-phthalic acid given the relative humidity of the environment and moisture present in biosolids. No monitoring data for *o*-phthalic acid in biosolids or landfills were available. There is currently no direct evidence that biosolids containing *o*-phthalic acid are being consistently applied to agricultural fields in any part of the United States, and there is similarly very limited direct evidence that *o*-phthalic acid is present in agricultural products resulting from the applications of biosolids to agricultural fields. Although experimental data are limited, physical and chemical properties suggests that *o*-phthalic acid present in biosolid amended soils will likely not be absorbed by any plants or crops growing in the soil and soil-dwelling organisms are not expected to readily accumulate *o*-phthalic acid through ingestion or absorption. Therefore, risk to terrestrial receptors through landfills and biosolids is unlikely.

5.3.4 Risk Characterization Based on Trophic Transfer

Few studies have evaluated the bioaccumulation potential of *o*-phthalic acid.

o-Phthalic acid is not expected to persist or bioaccumulate in terrestrial mammals. In two toxicokinetic rat studies, peak plasma concentrations were achieved 30 minutes post-dosing of single doses of 20, 100, or 500 mg/kg *o*-phthalic acid in corn oil using gavage to simulate direct oral exposure (Lim et al., 2007). Peak plasma concentrations of *o*-phthalic acid were achieved 30 minutes post-dosing. Approximately 13 to 26% of *o*-phthalic acid was excreted unchanged in urine 24 hours post-dosing. Samples were not monitored for other *o*-phthalic acid metabolites, and the total percentage of excreted *o*-phthalic acid could not be determined (Lim et al., 2007).

Excretion of *o*-phthalic acid in urine and feces was assessed in male Wistar rats intubated with a single-dose of radiolabeled *o*-phthalic acid (14C-phthalic acid) at 0.4, 4, and 40 mg/kg and examined up to 48 hours post intubation (Williams and Blanchfield, 1974). Nearly 100% 14C-phthalic acid was recovered in urine and feces within 48 hours post exposure for all dose groups. No radiolabeled *o*-phthalic acid was detected in any organs at 24 hours after dosing (Williams and Blanchfield, 1974).

Based on available data, *o*-phthalic acid is readily absorbed following oral exposure and most of the administered dose is eliminated in urine and feces within 48 hours in rats. A comprehensive overview of the *o*-phthalic acid rat studies can be found in the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p).

Based on the physical and chemical properties of *o*-phthalic acid EPA does not expect *o*-phthalic acid to accumulate or be detected in fish tissue in significant amounts. *o*-Phthalic acid has a water solubility of 6,200 mg/L, a log K_{OC} of 1.43, a log K_{OW} of 0.73, and a BAF of 1.32 L/kg, indicating a high potential to remain in the water column and not likely to adsorb to organic matter present in soils and sediments under normal environmental conditions (U.S. EPA, 2026r). *o*-Phthalic acid is a water soluble solid that maybe present in the atmosphere as suspended particles/dust, is likely to partition to surface and ground water, not likely to volatilize from water and dry surfaces and will rapidly biodegrade under normal environmental conditions as described in the *Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride* (U.S. EPA, 2026r) and *Draft Environmental Media, General Population, and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2025g). Therefore, *o*-phthalic acid exposure is not expected to bioaccumulate or undergo trophic transfer in fish or other aquatic organisms in significant amounts.

5.3.5 Overall Confidence and Remaining Uncertainties Confidence in Environmental Risk Characterization

The overall confidence in the risk characterization synthesizes the confidence from the environmental exposure, hazard threshold, and trophic transfer sections. This approach aligns with the Draft Systematic Review Protocol (U.S. EPA, 2021) and *Draft Systematic Review Protocol for Phthalic Anhydride* (U.S. EPA, 2025j). Confidence was evaluated from environmental exposures and environmental hazards. Hazard confidence was represented by evidence type as reported previously in the *Draft Environmental Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2025e). Exposure confidence has been synthesized from Section 3 and is further detailed within Section 5.1. All studies that factored into the environmental hazard and environmental exposures sections received an overall quality determination of high or medium. Synthesis of confidence for exposure and hazard resulted in the following confidence for risk characterization:

- **Acute aquatic risk characterization** – moderate confidence that EPA's assessment is protective; there is uncertainty in hazard due to the limited amount of reasonably available data but higher confidence in the low level of exposure,

- **Chronic aquatic risk characterization** – moderate confidence that EPA's assessment is protective; there is uncertainty in hazard due to the limited amount of reasonably available data but higher confidence in the low level of exposure,
- **Aquatic plants and algae risk characterization** – moderate confidence that EPA's assessment is protective; there is uncertainty in hazard due to the limited amount of reasonably available data but higher confidence in the low level of exposure,
- **Terrestrial plant risk characterization evidence based on air deposition** – moderate confidence that EPA's assessment is protective; there is uncertainty with regard to the limited reasonably available terrestrial plant data but higher confidence based on IIOAC-modeled results and assumptions.

Aquatic Assessment – Hazard

Based on the evaluation criteria, EPA has slight-to-moderate confidence in the data used to determine the acute and chronic aquatic hazard thresholds, including aquatic plants and algae, due to the limited amount of reasonably available data. Because of this, there is uncertainty on effects of *o*-phthalic acid for these and other types of aquatic organisms. Observed hazard thresholds indicate that *o*-phthalic acid has low observed toxicity. However, based on the weight of scientific evidence across all aquatic taxa where data are reasonably available, EPA has higher confidence that *o*-phthalic acid poses little hazard to aquatic species.

Aquatic Assessment – Exposure

Different COU/OES release scenarios (Section 5.3.2) were used to estimate and quantify concentrations of *o*-phthalic acid within surface water add confidence to the exposure RQ inputs. PSC considers model inputs of physical and chemical properties of *o*-phthalic acid (*i.e.,* K_{OW}, K_{OC}, water column half-life, photolysis half-life, hydrolysis half-life, benthic half-life) and allows EPA to estimate concentrations of *o*-phthalic acid within surface water based on COU/OES releases. The physical and chemical properties of *o*-phthalic acid increases confidence in the application of the PSC tool. Only the chemical release amount, days-on of chemical release, and the receiving water body hydrologic flow were changed for each COU/OES. As presented in Section 3, EPA compiled release information using reported releases from the 2019 through 2023 TRI (U.S. EPA, 2023c) and 2017 through 2020 NEI (U.S. EPA, 2023a, 2019d).

EPA's aquatic risk assessment includes multiple inputs that align with long standing EPA practices (*i.e.,* use of 7Q10 from EPA Office of Water's *Water Quality Standards Handbook*). However, EPA recognizes the combination of these inputs may lead to RQs that potentially overestimate exposure for some scenarios. Flow data are geospatially linked to TRI data. The 7Q10 (Table 5-1 of the Handbook) is standard practice for aquatic life; however, EPA acknowledges that it represents a protective low-flow condition. The *o*-phthalic acid concentration for Processing as a reactant OES 7Q10 is 1.51 mg/L. This protective value input resulted in no risk to aquatic life on an acute or chronic exposure basis.

Terrestrial Assessment

Inputs for the terrestrial plant assessment are protective for this taxa. The conclusion that *o*-phthalic acid poses hazard to terrestrial plants is supported by two terrestrial plant studies that identified effects (Hua et al., 2019; Bai et al., 2009). The study with the Lanzhou lily demonstrated a clear dose-response relationship for root length establishing a NOAEL/LOAEL of 0.25/0.5 µmol/g soil and plant and bulb weight NOAEL/LOAEL of 0.05/0.25 µmol/g soil (Hua et al., 2019). Different concentrations of *o*-phthalic acid solution were used to water soil before planting to achieve concentrations of 0 (control), 0.01, 0.05, 0.25, 0.5, and 1 µM/g soil. However, no further information was provided on the volume of solution used and no analytical measurements were described. This introduces uncertainty regarding the actual exposure of *o*-phthalic acid onto the plants since it may have been unevenly poured and distributed, and whether any of the test chemical adsorbed to the soil or material in the container reducing bioavailability. Additionally, the units were reported in µmol/g soil with an unknown amount of soil used to normalize the endpoint. However, although the study design standardized *o*-phthalic acid concentrations to grams of soil, effects occurred after exposure to the *o*-phthalic acid solution (Hua et al., 2019). It may have been possible to still use these endpoints with assumptions (*i.e.* as porewater) if a second study with a more certain measurement was not available. The second hydroponic study with the crabapple showed effects on dry weight and root and shoot length at 166.1 mg/L and was used to determine the COC, but it was the only test concentration used. However, since it was the only test concentration used resulting in an unbound LOAEL, there is uncertainty regarding the threshold of toxicity and actual hazard value to terrestrial plants. Fresh and dry weights were 3.09 and 1.61 g in control plants compared with 2.63 and 0.79 g in plants treated with 166.1 mg/L *o*-phthalic acid. While significant effects on weight and root and shoot length were observed, plants were not dying at the test concentration suggesting a higher concentration of *o*-phthalic acid is needed before mortality occurs. Furthermore, the RQ value was less than 1 using protective assumptions (*i.e.,* no partition of water to soil and no degradation of *o*-phthalic acid) (Bai et al., 2009).

The ECOSAR training data set used for earthworms and soil-dwelling invertebrates introduces uncertainty regarding the predicted hazard value of 253.3 mg/kg. Log K_{OW} is the main driver of aquatic toxicity in the ECOSAR Model, but it may not be translatable to terrestrial organisms. Data for *o*-phthalic acid were in mg/kg and may not be appropriate in the ECOSAR's log K_{OW}-based linear regression where the output for terrestrial invertebrates (earthworms) was reported in mg/L. Furthermore, there are few chemicals or datapoints for neutral organics in the *o*-phthalic acid ECOSAR dataset with many of those studies being limit tests. Despite the slight-to-moderate confidence in the hazard value used in the RQ input, EPA has higher confidence that there is no risk to terrestrial invertebrates from exposure to *o*-phthalic acid given its physical chemical properties and rapid biodegradation.

The IIOAC is based on pre-run scenarios within AERMOD and therefore has limitations on input parameters since default inputs (*i.e.,* stack characteristics and 2011–2015 meteorological data) are already predefined. Site-specific information like building dimensions, stack heights, elevation, and land use cannot be changed in IIOAC and therefore present a limitation on the modeled results for *o*-phthalic acid. This is in addition to the data gap EPA has on certain parameters including building dimensions, stack heights, and release elevation since such information has not been provided by industry to the Agency for consideration creating additional limitations on using other models to their full potential. The use of annual release data and number of operating days to calculate daily average releases assumes operations are continuous and releases are the same for each day of operation. This can underestimate short-term or daily exposure and deposition rates because results may miss actual peak release (and associated exposures) if higher and lower releases occur on different days. However, terrestrial organisms may not stay in the same location throughout the year.

The inputs and assumptions may lead to overestimation of exposure and deposition rates, providing a high confidence the exposure estimates are protective. Based on the risk estimates presented in the *Draft Ambient Air IIOAC Exposure Results and Risk Calculations for Phthalic Anhydride* (U.S. EPA, 2026a) and described in the *Draft Risk Evaluation for Phthalic Anhydride* (U.S. EPA, 2026s), EPA has robust confidence the ambient air pathway is not a pathway of concern for either exposure to or deposition rates of *o*-phthalic acid. The Agency has slight confidence in the exposure scenario modeled for this assessment since the stack and fugitive emissions are assumed to occur in the same year when in fact, they occurred in different years (2020 for the highest fugitive release and 2023 for the highest stack release), and the Agency still adds results together as if they occur at the same time. EPA has moderate confidence in the IIOAC-modeled results used to characterize exposures and deposition rates because EPA used protective inputs, considers a series of exposure scenarios under varying operating scenarios, multiple particle sizes, and based on previously peer reviewed methodology.

Uncertainties Related to the Environmental Release Estimates

For each OES, EPA considered the assessment approach and the quality of the data, as well as uncertainties in the assessment results to determine a level of confidence for the environmental release estimates. EPA integrated numerous evidence streams across systematic review sources to develop environmental release estimates for *o*-phthalic acid. Table 3-5 provides EPA's weight of scientific evidence rating for each OES.

5.3.6 Summary of Environmental Risk Characterization

Aquatic Organisms

TRI data demonstrated that the highest surface water concentration of *o*-phthalic acid is from the Processing as a reactant OES. Direct releases to surface water reported via TRI were applied as the actual loading to surface water, including any onsite treatment prior to discharge (Table 3-6). Risk quotients were calculated for acute and chronic aquatic exposures based on COCs for aquatic organisms described within Section 5.3.2. All acute and chronic aquatic organism RQs calculated were less than 1 when using the 7Q10 flow rate (Table 5-3). For aquatic plants and algae, RQ values were also less than 1.

EPA has confidence in the risk characterization RQ inputs for the acute and chronic aquatic assessments, including aquatic plants and algae, are protective. RQ values did not exceed 1 for any aquatic taxa. Based on surface water concentrations of *o*-phthalic acid and COCs for hazard to aquatic organisms, EPA expects that all COUs would result in *o*-phthalic acid concentrations that are unlikely to result in risk to aquatic organisms on an acute or chronic exposure basis, or aquatic plants and algae (Table).

Although there is no data for sediment-dwelling organisms, *o*-phthalic acid is not expected to show strong affinity and sorption potential for organic carbon in sediment. In the presence of water, phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid; thus, it is not expected to be present in sediments under normal environmental conditions. *o*-Phthalic acid is a very soluble chemical substance, is expected to remain in the water not likely partition to be sorbed into sediments (log $K_{OC} = 1.07$). Higher tier fugacity modeling results indicated a negligible partitioning of *o*-phthalic acid in sediments, and any *o*-phthalic acid present in sediments is expected to biodegrade withing weeks. Therefore, sediment is considered a minor compartment for *o*-phthalic acid.

Terrestrial Vertebrates

Risk to terrestrial mammals and birds from *o*-phthalic acid exposure through ingestion of terrestrial invertebrates is expected to be limited and not approach a threshold to cause risk. EPA has high confidence that *o*-phthalic acid has limited bioaccumulation and bioconcentration potential based on its physical, chemical, and fate properties, and biotransformation. The Agency has robust confidence that reasonably available information indicates that *o*-phthalic acid would not be present within biota, prey, or environmental media approaching concentrations that produce hazard within mammals. Therefore, *o*-phthalic acid is unlikely to pose risk to terrestrial mammals and birds.

Terrestrial Plants

An assessment of air release and subsequent air to soil deposition was conducted to produce quantified risk estimates for terrestrial plants. The OES with the highest fugitive or stack air release was

Manufacturing with an annual release of 1.2×10^{-2} mg/kg and was used in the determination of risk of *o*-phthalic acid air deposition to soil. It is also expected to biodegrade rapidly in soil with a half-life of days to weeks and is expected to biodegrade in the upper, aerobic portions of landfills. In lower landfills where anaerobic conditions are likely, biodegradation is expected to be slower. The RQ value from this assessment was less than 1 using protective assumptions (Table). EPA has moderate confidence in the risk characterization RQ inputs for the terrestrial plant assessment for air deposition to soil. Therefore, EPA has determined that *o*-phthalic acid is unlikely to result in risk for terrestrial plants.

Terrestrial Invertebrates

The terrestrial invertebrate hazard value of 253.3 mg/kg was estimated using ECOSAR (U.S. EPA, 2022b). The OES with the highest fugitive and stack release to air was manufacturing with an annual release of 1.2×10^{-2} mg/kg resulting in a RQ less than 1.

There is uncertainty, however, in the terrestrial invertebrate hazard value estimated by ECOSAR. The hazard value of 253.3 mg/kg may not be appropriate for a model that relies on log K_{OW}-based linear regression. There were few studies available for the dataset in ECOSAR that generated the regression with many of those studies being limit tests. Therefore, there is slight-to-moderate confidence in the hazard value for this taxa. EPA has higher confidence that there is no risk to terrestrial invertebrates from exposure to *o*-phthalic acid via atmospheric deposition given its physical chemical properties and rapid biodegradation.

Biosolids and Landfills

Although experimental and monitoring data are limited, physical and chemical properties suggests that *o*-phthalic acid present in biosolid amended soils will likely not be absorbed by any plants or crops growing in the soil and soil-dwelling organisms are not expected to readily accumulate *o*-phthalic acid through ingestion or absorption. There is similarly very limited direct evidence that *o*-phthalic acid is present in agricultural products resulting from the applications of biosolids to agricultural fields. It is also unlikely that *o*-phthalic acid will migrate from landfills via groundwater infiltration. EPA expects that *o*-phthalic acid would not produce hazards within terrestrial plants from the application of biosolids.

Table 5-6. Environmental Risk Summary and Basis for Quantified Risk Characterization for *o*-Phthalic Acid

COU (Life Cycle Stage [a]/Category [b]/ Subcategory [c])	OES [d]	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Manufacturing/Domestic manufacturing/Domestic manufacturing	Manufacturing	Included in screening-level assessment	COU resulting in highest environmental concentration for air to soil deposition and serving as a screening-level assessment [g]; RQ <1
Manufacturing/Importing/Importing	Import and repackaging	Included in screening-level assessment	Included in screening-level assessment
Processing/Repackaging/Repackaging			
Processing/Processing as a reactant/Intermediate (All other basic organic chemical manufacturing; Paint and coating manufacturing; Flame retardant manufacturing)	Processing as a reactant	COU resulting in highest environmental concentration for aquatic release and serving as a screening-level assessment [f]; RQ <1	Included in screening-level assessment
Processing/Processing as a reactant/Monomer (All other basic organic chemical manufacturing)			
Processing/Processing as a reactant/Ion exchange agent (All other basic organic chemical manufacturing)			
Processing/Processing as a reactant/Pigments (Printing ink manufacturing)			
Processing/Processing as a reactant/Polymerization promoter in (Synthetic dye and pigment manufacturing)			
Processing/Processing as a reactant/Plasticizer (Adhesive manufacturing; Lubricant additive manufacturing)			
Processing/Processing as a reactant/Intermediate (Plastic material and resin manufacturing; Plastic product manufacturing; Construction)	Plastic compounding	Included in screening-level assessment	Included in screening-level assessment
Processing/Processing as a reactant/Monomer (Plastic material and resin manufacturing)			
Processing/Processing as a reactant/Plasticizer (Plastics product manufacturing)			

COU (Life Cycle Stage [a]/Category [b]/ Subcategory [c])	OES [d]	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Processing/Incorporation into formulations, mixtures, or reaction products/Intermediate (Plastic material and resin manufacturing)	Plastic compounding	Included in screening-level assessment	Included in screening-level assessment
Processing/Incorporation into formulations, mixtures, or reaction products/Monomer (Plastic material and resin manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Plasticizers (Plastic material and resin manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Paint additives and coating additives not described by other categories (Plastics material and resin manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Flame retardant (Plastics product manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Solvent (Plastic material and resin manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Intermediate (All other basic organic chemical manufacturing; All other basic inorganic chemical manufacturing; Adhesive manufacturing)	Incorporation into formulations, mixtures, or reaction products	Included in screening-level assessment	Included in screening-level assessment
Processing/Incorporation into formulations, mixtures, or reaction products/Plasticizers (Paint and coating manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Dyes (Synthetic dye and pigment manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Retarder (Rubber product manufacturing)			

COU (Life Cycle Stage [a]/Category [b]/ Subcategory [c])	OES [d]	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Processing/Incorporation into formulations, mixtures, or reaction products/Binder (Paint and coating manufacturing)	Incorporation into formulations, mixtures, or reaction products	Included in screening-level assessment	Included in screening-level assessment
Processing/Incorporation into formulations, mixtures, or reaction products/Hardener (Paint and coating manufacturing; Solvent-based paint; Adhesive manufacturing; Rubber product manufacturing; Utilities)			
Processing/Incorporation into formulations, mixtures, or reaction products/Solvent (Paint and coating manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Processing aid (Paint and coating manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Pre-catalyst manufacturing			
Processing/Incorporation into formulations, mixtures, or reaction products/Polymerization promoter (All other basic organic chemical manufacturing)			
Processing/Incorporation into formulations, mixtures, or reaction products/Hardener (Epoxy resin casting)	Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	Included in screening-level assessment	Included in screening-level assessment
Commercial uses/Fillers/Hardener/*e.g.,* epoxy hardener)			
Processing/Processing as a reactant/Plasticizer (Plastics product manufacturing)	Plastic converting	Included in screening-level assessment	Included in screening-level assessment
Processing/Incorporation into formulations, mixtures, or reaction products/Flame retardant (Plastics product manufacturing)			
Processing/Recycling/Recycling	Disposal and recycling	Included in screening-level assessment	Included in screening-level assessment
Disposal/Disposal/Disposal			

COU (Life Cycle Stage [a]/Category [b]/ Subcategory [c])	OES [d]	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Industrial Uses/Adhesives and sealants/Adhesives and Sealants	Application of paints, coatings, adhesives, and sealants (non-spray [e])	Included in screening-level assessment	Included in screening-level assessment
Industrial Uses/Electrical and electronic products/Machinery, mechanical appliances, electrical and electronic articles			
Commercial Uses/Adhesives and sealants/Adhesives and sealants			
Commercial Uses/Metal and electrical products/Machinery, mechanical appliances, electronic/electronic articles			
Industrial Uses/Paints and coatings/Paints and coatings	Application of paints, coatings, adhesives, and sealants (spray and non-spray [e])	Included in screening-level assessment	Included in screening-level assessment
Industrial Uses/Automotive and aerospace products/Transportation equipment manufacturing			
Commercial Uses/Furniture and furnishings/Oil treatment of wood			
Commercial Uses/Paints and coatings/Paints and coatings			
Commercial Uses/Transportation equipment manufacturing/Transportation equipment manufacturing			
Industrial Uses/Other/Laboratory chemicals	Use of laboratory chemicals	Included in screening-level assessment	Included in screening-level assessment
Commercial Uses/Other/Laboratory chemicals			
Industrial Uses/Processing aids specific to petroleum production/Hydraulic fracturing	Use of lubricants and functional fluids	Included in screening-level assessment	Included in screening-level assessment
Industrial Uses/Construction Products/Construction and building materials covering large surface areas	Fabrication or use of final products or articles (fabrication)	Included in screening-level assessment	Included in screening-level assessment
Commercial Uses/Construction products/ Construction and building materials covering large surface areas			

COU (Life Cycle Stage [a]/Category [b]/ Subcategory [c])	OES [d]	Basis for Risk Characterization for Aquatic Receptors	Basis for Risk Characterization for Terrestrial Receptors (Air Deposition to Soil)
Commercial uses/Plastic and rubber products/Other articles with routine direct contact during normal use including rubber articles; Plastic articles (hard); Other (rubber products)	Fabrication or use of final products or articles (routine use)	Included in screening-level assessment	Included in screening-level assessment

[a] Life cycle stage use definitions (40 CFR 711.3):

- "Industrial use" means use at a site at which 1 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 (COUs) appear in the life cycle diagram, reflect Chemical Data Reporting (CDR) codes, and broadly represent COUs of *o*-phthalic acid in industrial and/or commercial settings.

[c] These subcategories represent more specific activities within the life cycle stage and category of the COU of *o*-phthalic acid.

[d] An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within an occupational COU. The occurrence of releases/exposures may be similar across multiple COUs (multiple COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given condition of use (single COU mapped to multiple OESs).

[e] The occupational exposure assessment of paints, coatings, adhesives, and sealants reports some COUs with no spray applications. The environmental release assessment data for paints, coatings, adhesives, and sealants COUs include facilities that may be involved with both spray and non-spray product applications.

[f] See Section 5.3.2; the COU resulting in the highest environmental concentration of *o*-phthalic acid for the aquatic environment

[g] See Section 5.3.3; the COU resulting in the highest environmental concentration of *o*-phthalic acid from soil deposition for terrestrial risk estimates

6 UNREASONABLE RISK DETERMINATION

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

EPA preliminarily determined that phthalic anhydride presents unreasonable risk of (non-cancer) injury to human health. In this draft risk evaluation, a total of 38 (of 44) COUs for phthalic anhydride contribute to a preliminary determination of unreasonable risk of injury to human health, including risk to workers and ONUs from 4 COUs driven by acute dermal and/or inhalation exposures, 32 COUs to workers but not ONUs (4 from acute dermal exposures and 28 from acute dermal and inhalation exposures), and 2 COUs to consumers (1 from acute dermal exposures for consumers only; 1 from acute dermal and inhalation exposures, including inhalation for bystanders). No COUs for phthalic anhydride contribute to any unreasonable risk of injury to the general population, including fenceline communities, exposed to environmental releases of phthalic anhydride. The full list of COUs evaluated for phthalic anhydride under TSCA and their identified preliminary unreasonable risk is presented in Table ES-1.

EPA also preliminarily determined that phthalic anhydride does not present an unreasonable risk of injury to the environment under the COUs due to exposures to assessed terrestrial or aquatic organisms. Accordingly, no COUs contribute to any preliminary determination of unreasonable risk to the general population, including fenceline communities.

Based on screening-level analyses, no COUs for phthalic anhydride contribute to a preliminarily determination of unreasonable risk of injury to workers, consumers, the general population, or the environment due to phthalic anhydride's formation of its hydrolysis product, *o*-phthalic acid. EPA's preliminary unreasonable risk determination is based on the information in previous sections of this draft risk evaluation, the appendices, and accompanying TSDs and supplemental files in accordance with TSCA section 6(b). This preliminary unreasonable risk determination for phthalic anhydride and the underlying evaluation are consistent with the best available science (TSCA section 26(h)) and based on the weight of scientific evidence (TSCA section 26(i)).

As noted in the Executive Summary, phthalic anhydride is primarily used as a reactant in the large-scale production of plastics. It is specifically used as a reactant in manufacturing phthalic esters (*i.e.,* plasticizers), resins, and to synthesize other chemical substances. For example, companies report that a major use of phthalic anhydride is as a chemical intermediate in the production of polyvinyl chloride plastics and the production of polyester and alkyd resins (Use Report, The Chemical Company). The resulting phthalate esters, resins, and chemical substances that could contain residual amounts, if any, of unreacted phthalic anhydride can be used in a variety of products such as PVC, wire or cables, roofing membranes, water filtration products, and swimming pool liners (The Chemical Company). Other uses include the manufacture of dye intermediates and pigments, polyester polyols, and flame retardants (Koppers, 2019). Workers may be exposed to phthalic anhydride when making these products or otherwise using phthalic anhydride in the workplace and consumers may be exposed when using the final products for DIY projects.

When it is manufactured or used to make products, phthalic anhydride is highly reactive and only exists under conditions devoid of moisture and can rapidly hydrolyze to 1,2-benzenedicarboxylic acid, also known as *o*-phthalic acid, when allowed contact with water or moisture present in the air. Based on reasonably available information, inhalation of phthalic anhydride and/or *o*-phthalic acid is possible through either incidental ingestion of inhaled dust during product usage or indoor air/dust (see Section

4.1.1). Dermal exposure may occur via direct contact with liquid products and contact with mist deposition on the skin during the manufacturing, processing, use, and disposal of phthalic anhydride-containing products (see Sections 4.1.1 and 4.1.2).

EPA notes that human or environmental exposure to phthalic anhydride through uses that are not subject to TSCA (*e.g.,* cosmetics, use of shells and cartridges as identified in 26 U.S.C. § 4181 and food additives like food contact materials) were not evaluated as COUs by the Agency because these uses are explicitly excluded from TSCA's definition of a chemical substance. It is not appropriate to extrapolate from this draft risk determination to form conclusions about uses of phthalic anhydride that are not subject to TSCA and that EPA did not evaluate.

For some COUs, such as Distribution in commerce, the Agency has limited reasonably available information to derive risk estimates, such as margins of exposure (MOEs) or risk quotients (RQs), to support a determination of whether the COU contributes to the unreasonable risk of injury to human health or the environment. In such cases, EPA integrates reasonably available information, such as physical and chemical properties and available monitoring data, in a risk characterization using a weight-of-evidence approach and professional judgment to support conclusions. The risk characterizations of COUs that were evaluated qualitatively present what EPA expects given the weight of scientific evidence. The Agency considers the resulting characterization in this preliminary unreasonable risk determination.

An unreasonable risk determination must be informed by science and in making a finding of "presents unreasonable risk," EPA considers risk-related factors beyond exceedance of benchmarks. Risk-related factors include the type and severity of health effects under consideration, the reversibility of the health effects being evaluated, exposure-related considerations (*e.g.,* duration, magnitude, frequency of exposure), or population exposed—particularly populations with greater exposure or greater susceptibility (*i.e.,* PESS)—and the confidence in the information used to inform the hazard and exposure values. For COUs evaluated quantitatively, as described in the risk characterizations (see Sections 4 and 5), EPA based the preliminary determination of unreasonable risk of injury to human health or the environment on the risk estimate that best represents the COU. The Agency describes the strength of the scientific evidence supporting the human health and environmental assessments as robust, moderate-to-robust, moderate, slight-to-moderate, slight, or indeterminate.

In general, EPA makes a determination of unreasonable risk based on risk estimates that have an overall confidence rating of moderate or robust[4] because 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.

This draft risk evaluation discusses important assumptions and key sources of uncertainty in the risk characterization; these are described in more detail in the respective weight of scientific evidence conclusions sections for fate and transport (Section 2.2), environmental release (Section 3.3.1), environmental exposures (Section 5.1), environmental hazards (Section 5.3.5), human health hazards (Section 4.2), human health risk characterization (Section 4.3), and Appendix F describing EPA's draft occupational exposure value (OEV) derivation and short-term exposure value (STEV) derivation. It also includes overall confidence and remaining uncertainties sections for human health and environmental risk characterizations.

---

[4] Descriptions of the various levels of confidence used in this draft risk evaluation are provided in Section 4.1.3.5.

6.1 Human Health

Calculated non-cancer risk estimates (margins of exposure [MOEs[5]]) can provide a risk profile of phthalic anhydride by presenting a range of estimates for different health effects for different COUs. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk in a manner that takes into consideration reasonably available information (*e.g.,* information submitted by manufacturers and processors of phthalic anhydride) regarding whether use of respiratory protection or other PPE is standard practice at all sites.[6] This allows EPA to make unreasonable risk determinations based on the information regarding workers wearing PPE where the Agency has such reasonably available information. In addition, the risk estimates are based on exposure scenarios with monitoring data that reflect existing requirements, such as those established by OSHA or industry sector best practices.

In this draft risk evaluation, the risk estimates calculated reflect use both with and without PPE, including information on PPE that could be used to reduce exposures. EPA has reviewed the reasonably available information on worker protections at facilities producing and processing phthalic anhydride. This includes information in occupational studies, public comment submissions by trade associations, and individual submissions from companies. However, the information currently available to EPA does not demonstrate that PPE is being used consistently or effectively. In deciding how to incorporate existing PPE use for the purposes of determining unreasonable risk, the Agency considers how the information available represents the different facilities associated with a COU and the evidence of PPE being worn or fitted properly when exposures are present. Because EPA does not currently have sufficient information regarding use of PPE under the COUs, this draft risk determination is based on risk estimates that do not reflect use of PPE. EPA is requesting comment on the consistency and effectiveness of PPE use and will consider any additional information in the development of the final risk evaluation for phthalic anhydride. See Section 4.3.2.1 for more discussion on information regarding PPE use.

6.1.1 Populations and Exposures EPA Assessed for Human Health

EPA has evaluated risk to workers including ONUs, consumer users and bystanders (*e.g.,* adults and children), and the general population (including fenceline communities), using reasonably available monitoring and modeling data for inhalation, dermal, and ingestion exposures, as applicable. The Agency evaluated these risks using reasonably available monitoring and modeling data for inhalation, dermal, and ingestion exposures, as applicable. Specifically, EPA assessed the risks of two occupational exposure groups (workers and ONUs) via inhalation and dermal routes. Workers are defined as those who may handle or have direct contact with phthalic anhydride, wherea ONUs do not directly handle phthalic anhydride but may work in the general vicinity of phthalic anhydride and be indirectly exposed to it as part of their employment. EPA also assessed the risk to consumers via inhalation and dermal routes and risk to bystanders via the inhalation route. Finally, the Agency evaluated risk from exposures from surface water, drinking water, soil from air to soil deposition, and land pathways (*i.e.,* landfills and application of biosolids) to the general population. EPA's evaluation of the general population included populations living near facilities releasing phthalic anhydride to the ambient air, which includes fenceline communities, as part of the ambient air exposure assessment.

---

[5] EPA derives non-cancer MOEs by dividing the non-cancer POD (HEC in mg/m^3 or HED in mg/kg-day) by the exposure estimate (mg/m^3 or mg/kg-day). Section 4.1.3.5 has additional information on the risk assessment approach for human health.

[6] In some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

Because phthalic anhyride rapidly hydrolyzes into *o*-phthalic acid when it encounters moisture, EPA did not conduct a quantitative assessment for exposure through human milk ingestion. Based on the physical and chemical properties of *o*-phthalic acid, EPA does not expect *o*-phthalic acid to be present in human milk because it is highly water soluble, not lipophilic (log K_{OW} = 0.73), and has low bioaccumulation potential (BAF = 1.32 L/kg). Therefore, EPA does not expect *o*-phthalic acid to be present or be expected to accumulate in human milk and has confidence that the risk estimates calculated based on maternal exposures are protective of a nursing infant's greater susceptibility during this unique lifestage.

Descriptions of the data used for human health exposure and human health hazards are provided in Sections 4.1 and 4.2. Uncertainties for overall exposures are presented in the respective occupational, consumer, and general population exposure sections of this risk evaluation and 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 phthalic anhydride is driven by non-cancer effects in workers, ONUs, and consumers from inhalation and dermal exposure, specifically due to respiratory and dermal sensitization in some COUs. These effects are due to exposure to phthalic anydride; no risk was identified for exposure to its hydrolysis product, *o*-phthalic acid. The effects of phthalic anhydride and the preliminary unreasonable risk determination under its COUs can be summarized as follows:

- non-cancer effects in workers from acute inhalation and dermal exposures under 32 COUs;
- non-cancer effects in ONUs from acute inhalation exposures under 4 COUs,
- non-cancer effects in workers from acute dermal exposures under 4 COUs, and
- non-cancer effects in consumers from acute dermal exposures under 1 COU and from acute dermal and inhalation exposures under 1 COU.

EPA identified respiratory and dermal sensitization as the most sensitive and robust human health hazards for the inhalation and dermal routes of exposure to phthalic anhydride, respectively. This conclusion is based on the weight of scientific evidence across reasonably available data from epidemiology studies of exposed workers, experimental studies of laboratory animals, and *in vitro* and *in chemico* mechanistic data (see Section 4.2.2.1). For respiratory hazard, the observed changes in lung function and/or breathing rate as well as changes in immune-related endpoints such as increased lymphocyte proliferation in the mandibular lymph node and increased serum levels of IgG and IgG1 indicate phthalic anhydride-related outcomes, which are characterized as adverse effects on human health. For dermal hazard, available data were evaluated in the context of the OECD (2014) adverse outcome pathway (AOP) for skin sensitization.

Human health risk estimates for this draft risk evaluation are solely based on acute exposures because a single exposure to phthalic anhydride may elicit immunological events during the induction phase of skin sensitization. Therefore, only acute exposures are likely relevant to skin sensitization and respiratory sensitization. These acute exposures are based on an exposure duration of 1 day.

For inhalation exposure, EPA derived a POD of 0.4 mg/m^3 from an occupational exposure study by Nielsen et al. (1988). The POD is based on a LOAEC for increased incidence of respiratory symptoms and increased serum-specific IgG consistent with respiratory sensitization. A total uncertainty factor of 30 was selected for use as the benchmark MOE based on an intraspecies uncertainty factor (UF_H) of 10 to account for human variability, and a LOAEC-to-NOAEC uncertainty factor (UF_L) of 3 to account for the lack of NOAEC in the critical study. As discussed in Section 4.2.2.1 and the *Draft Human Health*

Hazard Assessment for Phthalic Anhydride (U.S. EPA, 2026p), EPA is soliciting comments from the public and SACC peer reviewers on the underlying science of the inhalation benchmark MOE.

For dermal exposure to phthalic anhydride, EPA determined a POD of 0.045 mg/cm^2 using a Skin Allergy Risk Assessment – Integrated Chemical Environment (SARA-ICE) Model based on skin sensitization. A total uncertainty factor of 1 was selected for use as the dermal benchmark MOE based on a UF_H of 1 because variability in the human population is accounted for in selection of the ED01 value for the POD.

For the general population, the proposed oral POD (HED of 66 mg/kg-day) was selected to estimate risks from exposure to releases of phthalic anhydride (U.S. EPA, 2026p). A total uncertainty factor of 30 was selected for use as the benchmark MOE (based on a UF_A of 3 and a UF_H of 10). The POD was derived from a NOAEL of 278 mg/kg-day based on decreased body weight gain in male F344 rats fed diets containing phthalic anhydride for 2 years (NCI, 1979).

EPA's exposure and overall risk characterization PODs and MOEs are summarized in Section 4.3, with specific health risk estimates for workers (including ONUs), consumers, bystanders, and the general population presented in Section 4.3.2 (workers), Section 4.3.3 (consumers and bystanders), Section 4.3.4 (general population), and Section 4.3.5 (PESS). These MOEs and benchmarks are not "bright lines," and EPA considers other risk-related factors when concluding whether a COU significantly contributes to the unreasonable risk.

6.1.3 Basis for Unreasonable Risk to Human Health

In developing the exposure and hazard assessments for phthalic anhydride, EPA has analyzed reasonably available information to ascertain whether some human populations may have greater exposure and/or susceptibility than the general population to the hazard posed by phthalic anhydride. For this draft risk evaluation, EPA has accounted for the following PESS: people who frequently use consumer products and/or articles containing high concentrations of phthalic anhydride, as well as people exposed to phthalic anhydride in the workplace. 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.

As explained in Section 4.3.2, most occupational exposure estimates are based on measured monitoring data; therefore, the Agency's risk estimates—including estimates at the high-end (95th percentile)—reflect working conditions at facilities handling phthalic anhydride, and based on EPA's risk characterization for phthalic anhydride COUs, it is foreseeable that workers and ONUs may experience high-end exposure levels on an acute basis for most COUs. In the absence of data specific to ONU inhalation exposure, EPA assumed that worker central tendency exposure was representative of ONU exposure for that COU and used this as the basis for its determination for ONUs. For estimating exposures to the "high exposure worker" category in manufacturing and processing COUs, some task-based monitoring data did not contain task duration. In those cases, EPA assumed a task-based duration of 2 hours based on similar high-exposure tasks (*e.g.,* bag handling).

Similarly, for the three consumer uses, EPA considered a range of high- to low-intensity use exposure scenario risk estimates and relied on representative input parameters to inform its risk determination. Based on the reasonably available information, including expected consumer behavior and product weight fractions, high-intensity exposure scenario risk estimates were considered representative of realistic exposures for some users and these were used to determine unreasonable risk. The UF of 10×

for human variability that EPA has applied to the inhalation and oral MOE benchmarks accounts for potential increased susceptibility of subpopulations. The non-cancer POD EPA selected for phthalic anhydride is based on the most sensitive endpoint (*i.e.,* sensitization) and is relevant for susceptible subpopulations; for example, people who frequently use products containing phthalic anhydride and people exposed to phthalic anhydride in the workplace.

More information on how EPA characterized sentinel and aggregate risks is provided in Section 4.1.5, and more information on how PESS risks were characterized is provided in Section 4.3.5. EPA did not quantitatively assess aggregate exposure scenarios across COUs because the Agency did not find evidence to support such an aggregate analysis based on the reasonably available information, such as statistics of populations using certain products represented across COUs, or workers performing tasks across COUs. However, EPA qualitatively assessed aggregate exposures and risks across inhalation and dermal routes of exposure for consumers and workers and determined that the non-cancer risks for the dermal and inhalation routes should not be aggregated because they are highly route-specific.

6.1.4 Workers

Based on the occupational risk estimates from the individual analysis and related risk factors, a total of 36 COUs of phthalic anhydride contribute to a preliminary determination of unreasonable risk of injury to human health. This is driven by significant contributions to non-cancer risks from acute inhalation and/or dermal exposure to workers and ONUs. Of the 36 occupational COUs, 32 have risk to workers driven by both acute inhalation and dermal exposures and 4 from acute dermal exposures only. Four of the 36 COUs also have risk to ONUs from acute inhalation exposures.

Table 6-1. Number of Occupational COUs that Preliminarily Contribute to Unreasonable Risk

	Workers		**ONUs**	
	Inhalation and Dermal	**Dermal**	**Inhalation**	**Dermal**
Number of COUs	32	4	4	0

For 37 occupational COUs (*i.e.,* all but Distribution in commerce), EPA used measured monitoring data from workplaces with acute phthalic anhydride exposures to describe the distribution of inhalation exposures. In some instances, because the data were related to specific activities that take place under multiple COUs (*e.g.,* bagging phthalic anhydride, unclogging baghouse chutes, cleaning equipment with high solids content) the same risk monitoring data were used to estimate exposures across multiple COUs. In total, 15 OESs were used to represent all the occupational COUs. Therefore, EPA is making the assumption that the high-end estimates drawn from monitoring distributions in some COUs reflect real-world conditions experienced by workers in all of these COUs. Although EPA has made assumptions about exposure windows for some tasks, when determining whether a COU significantly contributes to the unreasonable risk to phthalic anhydride via inhalation exposure, EPA is relying on high-end exposure estimates for occupational inhalation risks (see Section 4.3.2.1).

For dermal exposure routes to workers, EPA also used monitoring data, but with surrogate chemicals (*i.e.,* calcium carbonate solids handling for solids and a few types of oil handled for liquids). These data were for job activities that occur under multiple COUs and are representative of exposures under multiple COUs. Note that as discussed in Section 4.3.2.2, the dermal loading input for each job activity with solid materials is the median from data reported for similar tasks, but as shown in Figure 4-3 (*i.e.,* sensitivity analysis), even if EPA had assumed the 10th percentile dermal loading values from the available studies, the dermal MOEs currently below the benchmark would still be below the benchmark with this less conservative assumption. This further supports determinations of contribution to unreasonable risk based on occupational dermal exposures.

For the dermal risk estimates, EPA used occupational results that are representative of central tendency and high-end exposure conditions, based on inputs and assumptions discussed later for each group of COUs. The central tendency is expected to represent occupational exposures in the center of the exposure distribution for a given COU, while the high-end is expected to represent occupational exposures that occur at probabilities greater than or equal to the 90th percentile, but below the highest exposure for any individual (U.S. EPA, 1992a). For this draft 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 for dermal exposure. Use of these risk estimates to inform the draft risk determination under the COUs is supported by EPA's level of confidence in both the inhalation and dermal risk characterizations.

Processing Uses that Significantly Contribute to Unreasonable Risk

The following 19 occupational COUs (*i.e.,* all processing uses, including 1 also associated with the Epoxy resin casting OES, which is discussed in the following section on *Epoxy Resin Processing and Commercial COUs That Significantly Contribute to Unreasonable Risk*) are represented by 3 OESs (Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; and Plastic compounding). Due to similarities in worker activities and sources of inhalation exposure among processing COUs (with the exception of Incorporation of phthalic anhydride as a hardener in epoxy resin mixtures for casting operations), inhalation exposure estimates are expected to be consistent across processing COUs; therefore, all three OESs have the same calculated MOEs and used the same exposure monitoring data.

- Processing – As a reactant – Intermediate (All other basic organic chemical manufacturing; Plastic material and resin manufacturing; Construction; Paint and coating manufacturing; Flame retardant manufacturing)
- Processing – As a reactant – Monomer (Plastic material and resin manufacturing; all other basic organic chemical manufacturing)
- Processing – As a reactant – Ion exchange agent (All other basic organic chemical manufacturing)
- Processing – As a reactant – Pigments (Printing ink manufacturing)
- Processing – As a reactant – Polymerization promoter (Synthetic dye and pigment manufacturing)
- Processing – As a reactant – Plasticizer (Plastics product manufacturing; Adhesive manufacturing; Lubricant additive manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Intermediate (All other basic inorganic chemical manufacturing; All other basic organic chemical manufacturing; Adhesive manufacturing; Plastic material and resin manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Monomer (Plastic material and resin manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Flame retardant (Plastics product manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Paint additives and coating additives not described by other categories (Plastics material and resin manufacturing),
- Processing – Incorporation into formulation, mixture, or reaction product – Plasticizers (Plastic material and resin manufacturing; Paint and coating manufacturing)

- Processing – Incorporation into formulation, mixture, or reaction product – Dyes (Synthetic dye and pigment manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Retarder (Rubber product manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Binder (Paint and coating manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Hardener (Adhesive manufacturing; Epoxy resin casting; Paint and coating manufacturing; Solvent-based paint; Rubber product manufacturing; utilities)
- Processing – Incorporation into formulation, mixture, or reaction product – Solvent (Paint and coating manufacturing; Plastic material and resin manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Processing aid (Paint and coating manufacturing; Rubber product manufacturing)
- Processing – Incorporation into formulation, mixture, or reaction product – Pre-catalyst manufacturing
- Processing – Incorporation into formulation, mixture, or reaction product – Polymerization promoter (All other basic organic chemical manufacturing)

The acute inhalation high-end MOE for the 18 COUs listed above is 0.32 for highly exposed workers (*i.e.,* those engaged in short-term, high exposure tasks like bagging and cleaning equipment). Although EPA considers the high-end estimate to be most appropriate for determining risk under these COUs, the central tendency MOE for highly exposed workers is also below the benchmark at 1.8. For 18 of the 19 COUs (*i.e.,* not Epoxy resin hardener), the acute inhalation MOEs for ONUs were both above the benchmark (*i.e.,* 49 for high-end exposure and 140 for central tendency exposure). For these phthalic anhydride processing uses, EPA used PBZ air concentration data sourced from five occupational monitoring studies representing both workers and ONUs (*e.g.,* supervisors and office engineers) and all five data sources received high ratings from EPA's systematic review process. Although there are limitations in the high exposure workers data based on the task-based monitoring durations (*i.e.,* 60–120 minutes rather than a full shift), the studies provided EPA with adequate data to develop confident full-shift exposure estimates. Based on these MOEs and EPA's consideration of risk-related factors (*e.g.,* the confidence in the underlying inhalation data, the plausibility of the exposure scenario, the population exposed, and severity of health effects), EPA is preliminarily determining that these 18 COUs significantly contribute to the unreasonable risk of phthalic anhydride due to acute inhalation exposure to workers, but not ONUs.

The acute dermal MOEs for these 18 COUs are below the benchmark of 1, with high-end MOEs of 0.027 and central tendency MOEs of 0.1 for highly exposed workers. The acute dermal MOE for ONUs is above the benchmark at 1.7. Although there were no reasonably available chemical-specific dermal loading data identified through the EPA systematic review process for phthalic anhydride, for exposures from solids, the Agency identified two studies that measured dermal loading for similar tasks and chemicals. Dermal loading estimates for solid materials vary depending on factors including task and physical-chemical properties. While there is variation in dermal loading between the two studies, the dermal MOE is below the benchmark for the 50th percentile of each dataset. Based on these MOEs and EPA's consideration of other risk-related factors (*e.g.,* the plausibility of the exposure scenario, the population exposed, and severity of health effects), EPA is preliminarily determining that these 18 COUs significantly contribute to unreasonable risk of phthalic anhydride due to acute dermal exposure to workers, but not ONUs.

Epoxy Resin Processing and Commercial COUs That Significantly Contribute to Unreasonable Risk

Two COUs were mapped to the Incorporation into formulations, mixtures, or reaction products OES:

- Processing – Incorporation into formulations, mixtures, or reaction products – Hardener in adhesive manufacturing; Epoxy resin casting; Paint and coating manufacturing; Solvent-based paint; Rubber product manufacturing; utilities; and
- Commercial use – Fillers – Hardeners (*e.g.,* epoxy hardeners).

The processing use is also mapped to the Incorporation into formulations, mixtures, or reaction products OES, which as discussed above, informed EPA's preliminary determination that this Processing COU significantly contributes to unreasonable risk. For the Epoxy resin casing OES, all of the inhalation MOEs are also well below the benchmark at both the high-end and central tendency exposures for workers. In the absence of data specific to ONU inhalation exposure for this OES, EPA assumed that worker central tendency exposure was representative of ONU exposure for that COU and used this as the basis for its determination (*i.e.,* an MOE of 0.14). The data that informed these estimates were gathered in epoxy resin casting facilities and reported as discrete PBZ monitoring measurements with information such as sampling durations and worker activities. EPA has high confidence in the representativeness of this data to workers in casting operation areas including any ONUs that may be present.

The acute dermal high-end MOEs for this COU are the same under both OESs: 0.027 for highly exposed workers and 0.080 for equipment and maintenance workers while the central tendency dermal MOE for ONUs is 1.7. As discussed for the previous OES grouping, there were no reasonably available chemical-specific dermal loading data identified through the EPA systematic review process for phthalic anhydride. However, EPA identified two studies that measured dermal loading for similar tasks and chemicals, and the dermal MOE is below the benchmark for the 50th percentile of each dataset. Based on these MOEs and EPA's consideration of risk-related factors (*e.g.,* the plausibility of the exposure scenario, the population exposed, severity of health effects), these COUs for phthalic anhydride contribute to EPA's preliminary determination of unreasonable risk of injury due to acute dermal and inhalation exposures to workers and acute inhalation exposures to ONUs.

Manufacturing, Importing, and Repackaging COUs That Significantly Contribute to Unreasonable Risk

The Domestic manufacturing, Importing, and Repackaging COUs were modeled using the same inhalation and dermal exposures based on monitoring data for manufacturing processes. Although inhalation exposure estimates for import and repackaging activities are based on the same high-quality, discrete PBZ monitoring data as manufacturing, there is an additional limitation imposed by the use of surrogate data. Therefore, the confidence is reduced for each worker category, and the resulting weights of scientific evidence for exposure estimates are moderate-to-robust for equipment operators and maintenance workers and moderate for high exposure workers and ONUs. For acute inhalation exposures, highly exposed workers in these three COUs have a high-end MOE of 0.17, and equipment operators and maintenance workers have a high-end MOE of 3.0. The central tendency MOE for highly exposed workers is also below the benchmark at 0.68. Inhalation MOEs for ONUs are well above the inhalation benchmark of 30. Worker MOEs for acute dermal exposures are below the dermal benchmark of 1 for these three COUs, with MOEs ranging from 0.078 to 0.43; ONUs have a central tendency MOE of 1.7. As previously discussed, EPA considered two studies that measured dermal loading for similar tasks and chemicals to inform the COU dermal loading and risk.

Based on the measured monitoring data from manufacturing facilities used to calculate these exposure estimates, it is foreseeable that workers may experience high-end exposure levels on an acute basis for the manufacturing COU. Although EPA does not know the actual duration of the high-end tasks, EPA used high-end risk estimates that include the measured high-end exposure as part of an 8-hour shift for determining unreasonable risk to workers (not including ONUs). Therefore, based on these high-end MOEs and EPA's consideration of risk-related factors (*e.g.,* the plausibility of the exposure scenario, the population exposed, and severity of health effects), the three COUs for phthalic anhydride listed below contribute to a preliminarily determination of unreasonable risk of injury to human health. These risks are driven by acute dermal and inhalation exposures to workers (but not ONUs):

- Manufacturing – Domestic manufacturing;
- Manufacturing – Importing; and
- Processing – Repackaging.

Industrial and Commercial COUs That Significantly Contribute to Unreasonable Risk

The Industrial and Commercial use of laboratory chemicals COUs were modeled for uses of liquids and solids separately. Based on measured monitoring data gathered from laboratory settings, the risk estimates for use of liquids did not indicate risk, as they were all above the benchmark. The risk estimates for laboratory use of solids resulted in dermal and inhalation MOEs below the benchmark for workers as well as inhalation MOEs below the benchmark for ONUs. For solids, the acute inhalation high-end MOE for workers is 14 and the central tendency MOE for workers and ONUs is 27. Monitoring data for all workers inside of tested laboratories support use of these MOEs for workers who directly handle phthalic anhydride as well as for ONUs who work in the same laboratories but do not handle phthalic anhydride. For acute dermal exposures to workers, the high-end MOE for solids is 0.08 and the central tendency MOE is 0.43. As use of solids in laboratories is reasonably expected and monitoring data support a range of inhalation and dermal exposures for all workers, including ONUs, the high-end MOEs are indicative of reasonably expected risks under these COUs. Although there was some uncertainty in the data on the representativeness of full-shift exposure levels, the confidence in the exposure estimates remain moderate-to-robust, and the results are applicable to all workers in the laboratory, including ONUs who may be present. Based on the MOEs for solids and EPA's consideration of other risk-related factors (*e.g.,* the plausibility of the exposure scenario, the population exposed, severity of health effects), the following two COUs for phthalic anhydride contribute to a preliminary determination of unreasonable risk for phthalic anhydride to human health driven by both acute inhalation and acute dermal exposures to workers as well as inhalation risk to ONUs:

- Industrial use – Laboratory chemicals; and
- Commercial use – Laboratory chemicals.

The Fabrication or use of final products or articles OES uses two different scenarios: one representing fabrication of the construction materials and one representing use of the final products. Two COUs were modeled with the first scenario: Industrial – Construction products – Construction and building materials covering large surface areas, and Commercial – Construction products – Construction and building materials covering large surface areas. In addition, a third COU was modeled with the second scenario: Commercial – Plastic and rubber products – Other articles with routine direct contact during normal use including rubber articles, plastic articles (hard), other (rubber products). The Industrial and Commercial use of construction products COUs have acute exposures leading to both inhalation and dermal MOEs below the benchmark for workers. The workplace exposure estimates in the fabrication scenario are also based on monitoring studies. The acute inhalation high-end and central tendency MOEs for workers are 1.3 and 3.5, respectively, and the MOE for ONUs is 80, with a benchmark of 30. Acute dermal exposures have MOEs of 0.10 and 0.75 for workers and 2.9 for ONUs, with a benchmark of 1. Based on these MOEs and EPA's consideration of other risk-related factors (*e.g.,* the plausibility of the exposure scenario, the population exposed, severity of health effects), the following two COUs for phthalic anhydride contribute to a preliminary determination of unreasonable risk driven by acute dermal and inhalation exposures to workers (but not ONUs):

- Industrial use – Construction products – Construction and building materials covering large surface areas; and
- Commercial use – Construction products – Construction and building materials covering large surface areas.

The Commercial use – Plastic and rubber products – Other articles with routine direct contact during normal use including rubber articles, plastic articles (hard), other (rubber products) COU was modeled under a different scenario under this OES. This was done to represent use of the final products rather than their fabrication. No inhalation or dermal exposures are reasonably expected under these conditions. EPA is preliminarily determining that this COU for phthalic anhydride does not significantly contribute to the unreasonable risk of injury to human health.

The following five COUs were modeled using spray and non-spray scenarios under the Application of paints, coatings, adhesives, or sealants OES:

- Industrial use – Automotive and aerospace products – Transportation equipment manufacturing;
- Industrial use – Paints and coatings;
- Commercial use – Paints and coatings;
- Commercial use – Transportation equipment manufacturing; and
- Commercial use – Furniture and furnishings – Oil treatment of wood.

As described in Table 4-5, EPA identified paint and coating products containing phthalic anhydride intended to be applied by spraying and that would be reasonably expected to be used in these COUs. The Agency EPA used SDSs to determine the weight fraction of phthalic anhydride in the products. A strength of the spray application scenario is that it incorporates actual weight fractions as listed by manufacturers and high-quality monitoring data, rather than requiring assumptions for inputs. Because EPA did not identify phthalic anhydride-specific monitoring data for exposures during use of these spray products, surrogate monitoring data from the ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011) were used. These are expected to be representative of mist exposures under the spray application scenario. In this scenario, workers (but not ONUs) have an acute inhalation high-end MOE of 0.036 and a central tendency MOE of 0.30—at least two orders of magnitude below the benchmark. Acute dermal MOEs for workers (but not ONUs) were similarly well below the benchmark with a high-end MOE of 0.017 and a central tendency MOE of 0.12. As explained in a note under Table 4-3 and Table 4-4, spray applications are expected to occur in enclosed spaces with ventilation controls, as specified in the *Paint Stripping and Surface Coating NESHAP* (see 73 FR 1738; January 9, 2008), and EPA does not expect exposures to occur outside the application area. Therefore, inhalation and dermal exposures from spray applications were not considered a route of concern for ONUs.

Using the non-spray application scenario, the five COUs listed above have MOEs below the benchmark for dermal exposures but not inhalation exposures. For workers (but not including ONUs), the acute inhalation high-end MOE is 180 and the central tendency MOE for workers and ONUs is 240. The high-end MOE for acute dermal exposure to workers is 0.086 and the central tendency MOE is 0.32. For these five COUs, this scenario provides additional support to dermal risks indicated using the spray application. Therefore, EPA is preliminarily determining that these five industrial and commercial use COUs for phthalic anhydride significantly contribute to unreasonable risk. The risk is driven by both inhalation and dermal acute exposure to workers (but not including ONUs) in the spray application scenario, as well as acute dermal exposures in the non-spray application scenario.

Four additional COUs were modeled with the Application of paints, coatings, adhesives, or sealants OES, but only using a non-spray application scenario:

- Industrial use – Adhesives and sealants;
- Industrial use – Metal and electrical products – Machinery, and mechanical appliances; electrical/electronic articles;
- Commercial use – Adhesives and sealants; and
- Commercial use – Metal and electrical products – Machinery, and mechanical appliances; Electrical/electronic articles.

EPA did not identify products that would reasonably expected to be sprayed upon or used under these COUs. As explained previously, no inhalation risk is indicated using the non-spray scenario. However, the acute dermal high-end MOE is 0.086 and the central tendency MOE is 0.32, both of which are well below the benchmark of 1. Therefore, these preceding four industrial and commercial use COUs for phthalic anhydride contribute to a preliminary determination of unreasonable risk of injury to human health. The risk is driven by acute dermal exposure to workers but not ONUs.

COUs That Do Not Significantly Contribute to Unreasonable Risk

EPA conducted a risk analysis but did not identify the following four COUs for phthalic anhydride as contributing to a preliminary determination of unreasonable risk of injury to workers or ONUs:

- Processing use – Recycling;
- Industrial use – Processing aids, specific to petroleum production – Hydraulic fracturing;
- Distribution in commerce; and
- Disposal.

The inhalation MOE for disposal and recycling is well above the benchmark (*i.e.,* 140) and no dermal exposure is expected from routine handling of final products or articles during these activities. The distribution in commerce COU consists of the moving of phthalic anhydride-containing products and/or articles between sites manufacturing, processing, and use COUs, or the transportation of phthalic anhydride containing wastes to recycling sites or for final disposal. EPA expects under standard operating procedures, along with the expectation that phthalic anhydride would be transported in a closed system, that there is negligible potential for releases. Therefore, no occupational exposures are reasonably expected to occur, and EPA is determining that phthalic anhydride exposures and releases that could occur during distribution in commerce, recycling, and disposal do not significantly contribute to the unreasonable risk of phthalic anhydride.

As described in Section 4.1.1.5 and the *Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride* (U.S. EPA, 2026n), EPA has overall moderate confidence in the inhalation and dermal exposure risk estimates for the assessed OESs for workers and ONUs. Sources of uncertainty associated with the occupational OESs and COUs are discussed in Section 4.1.1 and Table 4-5.

6.1.5 Consumers

Based on the risk estimates and related risk factors, EPA is preliminarily determining that phthalic anhydride presents unreasonable risk to consumers from two COUs (including bystanders for one COU) driven by the following:

- non-cancer effects from acute inhalation exposure and acute dermal exposure to consumers and acute inhalation exposure to bystanders associated with the use of spray paints and coatings for small and large projects,

- non-cancer effects from acute dermal exposure to consumers associated with the use of liquid paints and coatings, and
- non-cancer effects from acute dermal exposure to consumers associated with the use of adhesives and sealants for small projects.

EPA assessed consumer risks from inhalation and dermal exposures, when relevant, for each consumer COU. The consumer and bystander populations assessed were 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). A screening-level assessment for consumers considers high-intensity exposure scenario risk estimates and relies on conservative assumptions to assess exposures that would be expected to be on the high -end of the expected exposure distribution. For those COUs that indicated risk, including the two that contribute to the preliminary finding of unreasonable risk for phthalic anhydride, EPA conducted a sensitivity analysis to assess what inputs were driving risk, with concentration being the most sensitive input. The suitability of the exposure intensity scenario depends on the various exposure assumptions or uncertainties. EPA based the preliminary risk determination on the risk estimates that best represent the COUs. Because the weight fractions driving the low-, medium-, and high-intensity risk estimates for these two COUs are consistent with the phthalic anhydride present in commercially available consumer products, the low-, medium-, and high-intensity exposures are considered as a part of EPA's preliminary determination. More information about the individual consumer analysis is provided in Section 4.3.3 of this draft risk evaluation.

Based on the calculated risk estimates and EPA's consideration of risk-related factors (*e.g.,* the plausibility of the exposure scenario, the population exposed, severity of health effects), the following two COUs contribute to a preliminary determination of unreasonable risk of injury to human health for consumers (including bystanders for one COU) due to non to phthalic anhydride's unreasonable risk to consumers:

- Consumer use – Adhesives and sealants (consumers dermal risk only); and
- Consumer use – Paints and coatings (consumers dermal and inhalation risk; bystanders inhalation risk).

The Paints and coatings COU was evaluated under four scenarios: liquid-application and spray-application for dermal exposures and small projects and large projects for inhalation exposures. All exposure scenarios for the dermal and inhalation assessment for these COUs resulted in MOEs below the benchmark for the high- and medium-intensity use scenarios. EPA assessed consumer and bystander inhalation exposure to phthalic anhydride through the direct inhalation of sprays. Users and bystanders are expected to inhale sprayed products via dispersion while the spray is suspended during application. The only COU with spray applications was the Paints and coatings COU. The exposures for product users are the same across all age groups because the modeling is based on phthalic anhydride concentrations in the personal breathing zone (PBZ) of the user. In other words, air concentrations and thus inhalation exposure only vary based on the designation as a product user or bystander (children <10 years) while phthalic anhydride's weight fraction, duration of product use, mass of product used, frequency of use, room volume, and ventilation rate remain constant across all lifestages.

The Adhesives and sealants COU was quantitatively assessed for dermal exposure only because the small product amount and surface area used in each application results in low inhalation exposure potential. Dermal exposure was evaluated for one exposure scenario: adhesives and sealants for small repairs. Information from three adhesive products with confirmed phthalic anhydride content and similar use patterns, weight fractions, and application descriptions were used to model the small project scenario using the dermal loading information from U.S. EPA (1992b) for wiping applications (see Section 4.3.3.1 for more details). In addition to the three adhesive products above, EPA assessed consumer use of certain specialty products that contain phthalic anhydride in amounts above 1% such as in two-part electronic encapsulant adhesives (Epoxy Technology, 2020; Lord Corporation, 2020). EPA used the reported weight fraction range of 1 to 5% to represent these specialty adhesive products. Overall, the weight fractions used in modeling were 0.1, 1.2, and 5% for the low-, medium-, and high-intensity use exposure scenarios, respectively. The dermal loadings (amount of liquid retained on the skin) were calculated using the U.S. EPA (1992b) study wipe experiment, which incorporates wiping off the excess product with a saturated cloth after application as advised in the products' use instructions. The use of the study wipe experiment to determine dermal loadings from adhesive products is an upper bound estimate for the high-intensity use exposure scenario and a lower bound for the low-intensity use exposure scenario because the liquid product dermal loading and weight fractions are within the representative range (see section 4.3.3.1 for more details).

Dermal exposure to phthalic anhydride from the Adhesives and sealants COU resulted in a high-intensity scenario acute dermal MOE of 0.4 and a medium-intensity scenario MOE of 3. Given that the MOE for the high-intensity exposure scenario is below the benchmark of 1, and considering the representative exposure scenarios and other risk-related factors, EPA is preliminarily determining that the Adhesives and sealants COU significantly contributes to the unreasonable risk of phthalic anhydride due to acute dermal exposure to users/consumers. Dermal exposure to bystanders is not expected nor is post-application dermal contact with a dry or cured product because phthalic anhydride is not likely to easily migrate from dried/cured products. Consumer exposure to phthalic anhydride via inhalation from off-gassing or evaporation from adhesives and sealants is unlikely.

For the Consumer – Paints and coatings COU, dermal exposure was assessed for two scenarios: spray application and non-spray liquid application. For the non-spray liquid paints and coatings scenario, information from three paint products with confirmed phthalic anhydride content and similar use patterns, weight fractions, and application descriptions were used to model the non-spray liquid paint scenario using the dermal loading information from U.S. EPA (1992b). The weight fractions used in modeling were 0.1, 7.7, and 25% for the low-, medium-, and high-intensity scenarios, respectively. The dermal loadings were calculated using the U.S. EPA (1992b) study wipe experiment that incorporates wiping off the excess non-spray paint product with a saturated cloth after application as advised in the products' use instructions (see section 4.3.3.1 for more details). The use of the wipe experiment dermal loading for the assessment of dermal exposures from liquid paint products is an upper bound estimate for the high-intensity use exposure scenario and a lower bound for the low-intensity use exposure scenario because the liquid product dermal loading and weight fractions are within the representative range. Dermal exposure to phthalic anhydride under the liquid scenario resulted in an acute dermal MOE of 0.1 in the high-intensity scenario and an MOE of 0.4 in the medium-intensity scenario. EPA qualitatively assessed inhalation exposure to phthalic anhydride via off-gassing or evaporation from non-spray liquid paints and coatings and determined that such exposure is unlikely.

For the spray application scenario under dermal exposure, two paint products containing phthalic anhydride were identified as having spray applications. EPA used the weight fractions of these products to establish modeling parameters of 1, 12, and 25% for the low-, medium-, and high-intensity use exposure scenarios. The dermal loadings used for the spray paints and coatings scenario were experimentally designed for immersion applications and are within a representative range that includes an upper bound estimate of reasonably expected exposure for the high-intensity use exposure scenario and a lower bound for the low-intensity use exposure scenario. This is because immersion experiments entail full immersion of the user's hands in the product, while spray products are expected to cover a significant surface of the exposed hands that is similar but not equal to immersion (see section 4.3.3.1 for more details). Dermal exposure to phthalic anhydride under the spray paint scenario resulted in an acute dermal MOE of 0.02 in the high-intensity scenario and an MOE of 0.1 in the medium-intensity scenario.

The inhalation of spray paints was assessed in two scenarios: spray paints and coatings for small projects via spray can application, and spray paints and coatings for large projects via spray gun application. For small paints and coatings spray application, EPA assumed that one-quarter of an 11-ounce spray can of paint was used in the low-intensity scenario, half a can in the medium-intensity scenario, and the entire can in the high-intensity scenario. The duration of use varied from 5, 10, and 15 minutes in the low-, medium-, and high-intensity scenarios and assumed two events per day to paint multiple items or the same item from various angles. Finally, EPA assumed users would apply paint in a garage, because DIYers painting smaller items are more likely to remove the items to a ventilated, and better-suited location like a garage for spray painting and drying time. Using these assumptions, the small paints and coatings spray application scenario resulted in acute inhalation high-intensity MOEs of 0.16 and 0.39 and medium-intensity MOEs of 0.23 and 0.39 for users and bystanders, respectively.

For the large paints and coatings sprayer gun application scenario under inhalation exposure, the Agency assumed that a quarter of a 1-gallon can, half a can, or the entire can was used in the low-, medium-, and high-intensity scenarios, respectively. This approach is consistent with observations of consumer reviews for individual products on vendor websites, which indicated diverse usage patterns among consumers including small, medium, and large projects. The application was assumed to be in the living room. The assumed total time to apply and prepare two coats were 90, 120, and 270 minutes over an 8-hour period in low-, medium-, and high-intensity scenarios. Projects were not anticipated to be routine because of the large level of work required to prepare and clean up after each use so the one room was assumed to be finished in a single day. The sprayer gun application scenario resulted in acute inhalation high-intensity MOEs of 0.36 and 0.38 and medium-intensity MOEs of 0.46 and 0.72 for users and bystanders, respectively.

Based on MOEs that are below the benchmark in all four scenarios for dermal and inhalation exposure, as well as consideration of other risk-related factors, EPA is preliminarily determining that the Consumer use – paints and coatings COU significantly contributes to the unreasonable risk of phthalic anhydride to consumers. The risk is driven by acute dermal exposure to consumers (but not bystanders), supported by both liquid application and spray application scenarios and also driven by acute inhalation exposure to consumers and bystanders, supported by both small and large spray application scenarios.

EPA conducted a qualitative risk analysis for but did not identify significant contributions to unreasonable risk for the Consumer use – Arts, crafts, and hobby materials – clear casting resin COU. As part of the analysis, EPA assessed one identified product that is used to embed objects in clear plastic under a casting DIY and casting resin cured scenario (Environmental Technology, 2017). For both scenarios, dermal contact and exposure while mixing and curing is unlikely to occur as is inhalation exposure due to phthalic anhydride's low vapor pressure and low volatility. Based on the potential chemical role of phthalic anhydride in formulation and manufacturing, it is also unlikely to leach or migrate out of the finished cured products. Therefore, no dermal or inhalation exposures are reasonably expected to occur, and EPA is determining that the Consumer use – Arts, crafts, and hobby materials – Clear casting resin COU does not significantly contribute to the unreasonable risk of phthalic anhydride. Since 2017, EPA has compiled additional information from the product company that also indicates a possible change of formulation for these products (Environmental Technology, 2020, 2019).

Overall, EPA has moderate confidence in the assessed dermal exposures and MOEs for spray applications and non-spray applications (see Section 4.2). For inhalation exposure, EPA has moderate confidence in the inhalation consumer exposure scenarios and moderate confidence in the inhalation of spray products MOE values.

6.1.6 General Population

Based on the risk estimates and other risk-related factors, EPA did not identify significant contributions to unreasonable risk to the general population from the following exposure routes and pathways for phthalic anhydride or its hydrolysis product, *o*-phthalic acid:

- exposure via the land pathway (*i.e.,* application of biosolids and landfills);
- incidental ingestion and dermal contact from swimming;
- acute and chronic ingestion of drinking water;
- acute and chronic ingestion exposure from fish ingestion;
- acute and chronic ingestion of human milk;
- acute and chronic inhalation exposure to ambient air in proximity to releasing facilities, including fenceline communities; and
- soil ingestion exposure from air deposition to soil.

Because phthalic anhydride exhibits rapid and complete hydrolysis to *o*-phthalic acid in the presence of moisture, the general population screening-level risk assessment evaluated exposures to *o*-phthalic acid resulting from phthalic anhydride releases for each COU. Because no acute hazards were identified for *o*-phthalic acid, only chronic exposures were further assessed. For the screening-level analysis, EPA used OESs with the highest phthalic anhydride releases into ambient air and surface water combined with inputs that would result in the highest possible inhalation and drinking water exposures to *o*-phthalic acid. Thus, any combination of OESs and matching COUs with lower release concentrations would result in lower exposures. As such, if the highest possible inhalation and oral exposures did not result in MOEs below the benchmark, all other COUs would have lower exposures and higher MOEs.

EPA quantitatively evaluated risks from surface water, ingestion of drinking water, and inhalation exposure to ambient air (see Section 4.3.4 for more details). For surface and drinking water, EPA estimated low potential exposure to *o*-phthalic acid when considering expected treatment removal efficiencies, even under upper-bound release scenarios. For ambient air inhalation exposure, the Agency used the maximum reported releases from a single facility across all COUs as direct inputs to the IIOAC Model to estimate concentrations and deposition rates for both stack and fugitive emissions containing *o*-phthalic acid. Based on the modeling and exposure factor parameters for these quantitatively assessed pathways including exposure via surface water, ingestion of drinking water, and inhalation exposure to ambient air, all MOEs were well above the benchmark of 30 and did not result in significant contributions to unreasonable risk to the general population. Additionally, EPA qualitatively assessed inhalation, oral, and dermal exposures via land pathways (*i.e.,* landfills and application of biosolids), incidental ingestion and dermal exposure from swimming, human milk, and fish ingestion (see Section 4.3.4.1 for more details) and determined that risk from these pathways is not expected.

Overall, EPA has robust confidence that the modeled releases and risk estimates are appropriately representative of the expected uses and exposures of phthalic anhydride, as described in Section 4.3.4.2. Therefore, the Agency has robust confidence that no exposure scenarios will lead to greater doses than presented in this draft risk evaluation.

6.2 Environment

Based on the draft risk evaluation for phthalic anhydride—including the risk estimates, the environmental effects of phthalic anhydride, the exposures, physical and chemical properties of phthalic anhydride, and consideration of uncertainties—EPA preliminarily did not identify any COUs for phthalic anhydride that contribute to any unreasonable risk of injury to the environment.

Because phthalic anhydride rapidly hydrolyzes to *o*-phthalic acid (CASRN 88-99-3) when allowed contact with water or moisture in air, EPA considered environmental hazard data for both phthalic anhydride and *o*-phthalic acid in this draft risk evaluation. For the environmental exposure assessment, the Agency evaluated potential environmental exposures and hazard to ecological receptors following releases of phthalic anhydride to surface water, sediment, air deposition of phthalic anhydride to soil, landfill release, and agricultural application of municipal biosolids.

Readily available information on phthalic anhydride's biodegradation rates and physical and chemical properties (see Section 5.3) indicate that phthalic anhydride will have limited persistence and mobility in water and soil due to its rapid hydrolysis into *o*-phthalic acid. Due to this reaction, phthalic anhydride is also not expected to be readily found in aquatic or terrestrial organisms and has limited bioaccumulation and bioconcentration potential. In comparison, *o*-phthalic acid may be mobile in water and leach into groundwater due to its low tendency to sorb to organic media and soil; however, biodegradation of *o*-phthalic acid in groundwater is expected to be rapid and should not persist (Tang et al., 2017; Fujita et al., 2005). Although data are limited, biosolid-amended soils that may contain *o*-phthalic acid will likely not be absorbed by any plants or crops growing in the soil and soil-dwelling organisms are not expected to readily accumulate *o*-phthalic acid through ingestion or absorption.

6.2.1 Basis for No Unreasonable Risk to the Environment

Environmental risks of phthalic anhydride were characterized using risk quotients (RQs) (U.S. EPA, 1998; Barnthouse et al., 1982). Calculated RQs can provide a risk profile by presenting a range of estimates for different environmental hazard effects for different COUs. For phthalic anhydride, the RQs were calculated for aquatic exposures based on concentrations of concern (COCs) for aquatic organisms described within Section 5.3.2. Risk was also characterized qualitatively using a weight of evidence approach to support conclusions (Section 5). An RQ equal to 1 indicates that environmental exposures are the same as the hazard threshold. An RQ less than 1, when the exposure is less than the hazard threshold, generally indicates that there is no risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure is greater than the hazard threshold, generally indicates that there is risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. To summarize, risk is indicated when the RQ is greater than or equal to 1. Additionally, if an RQ exceeds 1, EPA considers the days of exceedance before determining unreasonable risk.

As explained in Section 5.3, EPA used a screening-level approach in this draft risk evaluation using conservative environmental release estimates for occupational COUs for phthalic anhydride with the highest releases to determine whether there is risk to the environment. The Agency 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 assessed in the risk evaluation. 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. Calculated RQs for exposures were represented by the concentrations from TRI release data and hazard thresholds (Section 5.2).

Using TRI data, releases of phthalic anhydride to surface water were identified for a total of 44 COUs represented by 14 OESs. The highest surface water concentration from the screening-level assessment resulted from the Processing as a reactant OES, with a 7Q10 (*i.e.,* lowest 7-day average flow that occurs once every 10 years) value of 1.51 mg/L for both acute and chronic releases. This OES representing the highest TRI release resulted in RQs less than 1 for acute and chronic exposure to all aquatic animals, aquatic plants and algae—indicating no unreasonable risk. For terrestrial species, the highest air release from this screening-level assessment resulted from the manufacturing OES with an annual soil concentration of 1.2×10^{-2} mg/kg. This OES representing the highest air concentrations from TRI release data resulted in RQs less than 1 for all terrestrial plants and terrestrial invertebrates exposed via air deposition. In addition, the physical characteristics and environmental fate of phthalic anhydride make exposures to terrestrial organisms through trophic transfer and municipal biosolid exposure unlikely, indicating no unreasonable risk.

Although there are no data for sediment-dwelling organisms and soil metabolism rates, phthalic anhydride is not expected to show strong affinity and sorption potential for organic carbon in sediment due to its physical characteristics and environmental fate. In the presence of water, the primary degradation pathway for phthalic anhydride is rapid hydrolysis to *o*-phthalic acid. Consequently, phthalic anhydride is not expected to be present in sediments under normal environmental conditions since *o*-phthalic acid is a very soluble substance that is not likely to be sorbed into sediments. Any *o*-phthalic acid present in sediments is expected to biodegrade within days to weeks. Therefore, EPA determined that exposures to terrestrial organisms and sediment-dwelling organisms via deposition from air or transport from biosolids or landfills do not significantly contribute to the unreasonable risk of phthalic anhydride (see Section 5.3 for more details on the environmental risk characterization).

Overall, EPA has robust and moderate confidence in the risk characterization for the acute and chronic aquatic assessments, respectively; moderate confidence in the risk characterization to aquatic plants and algae; and robust confidence for the terrestrial plant and terrestrial invertebrate assessment. For the aquatic assessment, EPA expects that all COUs would result in phthalic anhydride and *o*-phthalic acid concentrations that are unlikely to result in risk to aquatic vertebrates, aquatic plants, or algae due to the rapid biodegradation of these chemicals (Table 5-6). This is based on surface water concentrations of phthalic anhydride and *o*-phthalic acid concentrations from COU/OES releases, and COCs for hazard to aquatic organisms. For the terrestrial assessment, EPA expects that there is no risk to terrestrial vertebrates, invertebrates, or plants from phthalic anhydride or *o*-phthalic acid due to their limited bioaccumulation and bioconcentration potential, biotransformation, as well as physical-chemical and fate properties. Once phthalic anhydride hydrolyzes, the resulting *o*-phthalic acid is not likely to volatilize from water and dry surfaces, not likely to bioaccumulate, and will rapidly biodegrade under normal environmental conditions. Biosolids containing phthalic anhydride are also not expected to be absorbed by any plants or crops growing in the soil, nor are soil-dwelling organisms expected to readily accumulate phthalic anhydride through ingestion or absorption.

There is some uncertainty in the terrestrial invertebrate hazard value estimated by ECOSAR (253.3 mg/kg) due to few available studies for the dataset; however, EPA has higher confidence that there is no risk to terrestrial invertebrates from exposure to phthalic anhydride or *o*-phthalic acid via atmospheric deposition given their physical and chemical properties and rapid biodegradation. Furthermore, it is unlikely that phthalic anhydride will migrate from landfills via groundwater infiltration since, after phthalic anhydride hydrolyzes into *o*-phthalic acid when exposed to water, it will biodegrade rapidly with a half-like of days. See Sections 5.3.5 and 5.3.6 for a more detailed explanation of the confidence in the hazards and exposures.

6.3 Additional Information Regarding the Basis for the Risk Determination

Table 6-2 and Table 6-3 summarize the basis for this preliminary unreasonable risk determination of injury to human health for occupational and consumer exposures, respectively. In both tables, **bold/shaded text** indicates that a COU for phthalic anhydride significantly contributes to a preliminary determination of unreasonable risk of injury to human health. Both tables also identify the duration of exposure (*i.e.,* acute) and the exposure route to the population. Columns marked "APF" in Table 6-2 give the minimum level of PPE that would be necessary to raise the calculated MOE above the benchmark. Table 6-2 and Table 6-3 provide the MOEs used in making preliminary unreasonable risk determinations; the underlying release estimates, media concentrations, exposure doses, and hazard values, as well as the equations used to calculate MOEs from these values. These are presented in Sections 4.3.2 for workers and 4.3.3 for consumers, respectively, and include the underlying TSDs.

As explained in preceding Sections 6.1 and 6.2, for this preliminary unreasonable risk determination, EPA considered the effects of phthalic anhydride on human health, including PESS, and the environment using a range of risk estimates, as appropriate. The Agency also considered risk-related factors and confidence in the analysis. See Sections 4.3 and 5.3 for a summary of risk estimates.

Table 6-2. Supporting Basis for the Preliminary Unreasonable Risk Determination for Human Health: Occupational COUs [a]

COU		OES	Worker Population	Exposure Type	Dermal Risk Estimates (Benchmark MOE = 1)			Acute Inhalation Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage – Category	**Subcategory**				**CT**	**HE**	**PPE [b]**	**CT**	**HE**	**APF [b]**
Manufacturing	Domestic manufacturing	Manufacturing	High exposure	Solid	**0.19**	**7.8E−02**	Silver Shield/ 4H gloves	**0.68**	**0.17**	1,000
	Importing	Import and repackaging	Equipment operators Maintenance	Solid	**0.43**	**8.0E−02**		31	**3.0**	10
Processing	Repackaging		ONUs	Solid	1.7		N/A	140	49	N/A
Processing – processing as a reactant	Intermediate (All other basic organic chemical manufacturing; Paint and coating manufacturing; Flame retardant manufacturing)	Processing as a reactant	High exposure	Solid	**0.10**	**2.7E−02**	Silver Shield/ 4H gloves	**1.8**	**0.32**	1,000
	Monomer (All other basic organic chemical manufacturing)									
	Ion exchange agent (All other basic organic chemical manufacturing)		Equipment operators Maintenance	Solid	**0.43**	**8.0E−02**		47	**7.1**	10
	Pigments (Printing ink manufacturing)									
	Polymerization promoter (Synthetic dye and pigment manufacturing)		ONUs	Solid	1.7		N/A	140	49	N/A
	Plasticizer (Adhesive manufacturing; Lubricant additive manufacturing)									
	Plasticizer (Plastics product manufacturing)	Plastic compounding	High exposure	Solid	**0.10**	**2.7E−02**	Silver Shield/ 4H gloves	**1.8**	**0.32**	1,000
	Intermediate (Plastic material and resin manufacturing; construction)		Equipment operators Maintenance	Solid	**0.43**	**8.0E−02**		47	**7.1**	10
	Monomer (Plastic material and resin manufacturing)		ONUs	Solid	1.7		N/A	140	49	N/A
	Plasticizer (Plastics product manufacturing)	Plastic converting	Workers, ONUs	Plastics	No dermal exposure expected			1,600	1,300	N/A

COU		**OES**	**Worker Population**	**Exposure Type**	**Dermal Risk Estimates (Benchmark MOE = 1)**			**Acute Inhalation Risk Estimates (Benchmark MOE = 30)**		
Life Cycle Stage – Category	**Subcategory**				**CT**	**HE**	**PPE [b]**	**CT**	**HE**	**APF [b]**
Processing – Incorporation into formulations, mixtures, or reaction products	Intermediate (All other basic organic chemical manufacturing; All other basic inorganic chemical manufacturing; Adhesive manufacturing)	Incorp. into formulations, mixtures, or reaction products	High exposure	Solid	**0.10**	**2.7E−02**	Silver Shield/ 4H gloves	**1.8**	**0.32**	1,000
	Plasticizers (Paint and coating manufacturing)									
	Dyes (Synthetic dye and pigment manufacturing)									
	Retarder (Rubber product manufacturing)									
	Binder (Paint and coating manufacturing)									
	Hardener (Paint and coating manufacturing; Solvent-based paint; adhesive manufacturing; Rubber product manufacturing; Utilities)		Equipment operators Maintenance	Solid	**0.43**	**8.0E−02**		47	**7.1**	10
	Solvent (Paint and coating manufacturing)									
	Processing aid (Paint and coating manufacturing; rubber product manufacturing)									
	Pre-catalyst manufacturing		ONUs	Solid	1.7		N/A	140	49	N/A
	Polymerization promoter (All other basic organic chemical manufacturing)									
	Hardener (Epoxy resin casting)	Incorp. into formulations, mixtures, or reaction products (epoxy resin casting hardener)	Workers	Solid	Same dermal risk estimates as above		Silver Shield/ 4H gloves	**0.14**	**2.4E−02**	10,000
			ONUs				N/A	**0.14**	N/A	

COU		OES	Worker Population	Exposure Type	Dermal Risk Estimates (Benchmark MOE = 1)			Acute Inhalation Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage – Category	Subcategory				CT	HE	PPE [b]	CT	HE	APF [b]
Processing – Incorporation into formulations, mixtures, or reaction products	Intermediate (Plastic material and resin manufacturing)	Plastic compounding	High exposure	Solid	**0.10**	**2.7E−02**	Silver Shield/ 4H gloves	**1.8**	**0.32**	1,000
	Monomer (Plastic material and resin manufacturing)									
	Plasticizers (Plastic material and resin manufacturing)		Equipment operators Maintenance	Solid	**0.43**	**8.0E−02**		47	**7.1**	10
	Paint additives and coating additives not described by other categories (Plastics material and resin manufacturing)									
	Flame retardant (Plastics product manufacturing)		ONUs	Solid	1.7		N/A	140	49	N/A
	Solvent (Plastic material and resin manufacturing)									
	Flame retardant (Plastics product manufacturing)	Plastic converting	Workers	Plastics	No dermal exposure expected			1,600	1,300	N/A
			ONUs					1,600		
Industrial Use – Processing aids, specific to petroleum production	Hydraulic fracturing	Use of lubricants and functional fluids	Workers	Liquid products	80	4.3	N/A	1,600	1,300	N/A
			ONUs		No dermal exposure expected		N/A	1,600		

COU		OES	Worker Population	Exposure Type	Dermal Risk Estimates (Benchmark MOE = 1)			Acute Inhalation Risk Estimates (Benchmark MOE = 30)		
Life Cycle Stage – Category	**Subcategory**				**CT**	**HE**	**PPE** [b]	**CT**	**HE**	**APF** [b]
Industrial Use – Adhesives and sealants	Adhesives and sealants	Application of paints, coatings, adhesives, and sealants	Workers (non-spray application)	Liquid products	**0.32**	**8.6E−02**	Silver Shield/ 4H gloves	240	180	N/A
Commercial Use – Adhesives and sealants	Adhesives and sealants		ONUs (non-spray application)		No dermal exposure expected		N/A	240		
Industrial Use – Metal and electrical products	Machinery, mechanical appliances, electrical/electronic articles		Workers, (spray application) [c]	Liquid products	**0.12**	**1.7E−02**	Silver Shield/ 4H gloves	**0.30**	**3.6E−02**	1,000
Commercial Use – Metal and electrical products	Machinery, mechanical appliances, electrical/electronic articles									
Industrial Use – Paints and coatings	Paints and coatings		Workers (non-spray application)	Liquid products	**0.32**	**8.6E−02**	Silver Shield/4H gloves	240	180	N/A
Commercial Use – Paints and coatings	Paints and coatings									
Industrial Use – Automotive and aerospace products	Transportation equipment manufacturing		ONUs (non-spray application)		No dermal exposure expected		N/A	240		
Commercial use – Transportation equipment manufacturing	Transportation equipment manufacturing		Workers, (spray application) [c]	Liquid products	**0.12**	**1.7E−02**	Silver Shield/ 4H gloves	**0.30**	**3.6E−02**	1,000
Commercial Use – Furniture and furnishings	Oil treatment of wood									

COU		**OES**	**Worker Population**	**Exposure Type**	**Dermal Risk Estimates (Benchmark MOE = 1)**			**Acute Inhalation Risk Estimates (Benchmark MOE = 30)**		
Life Cycle Stage – Category	**Subcategory**				**CT**	**HE**	**PPE [b]**	**CT**	**HE**	**APF [b]**
Industrial Use – Construction products	Construction and building materials covering large surface areas	Fabrication or use of final products or articles (fabrication)	Workers (fabrication)	Dust	**0.75**	**0.10**	Silver Shield/ 4H gloves	**3.5**	**1.3**	50
Commercial Use – Construction products	Construction and building materials covering large surface areas		ONUs (fabrication)	Dust	2.9		N/A	80		N/A
Commercial Use – Plastic and rubber products	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard); Other (rubber products)		Workers, ONUs (routine use)	Final products or articles	No dermal exposure from routine handling of final products or articles.			No inhalation exposure from routine use of final products or articles.		
Industrial Use – Other	Laboratory chemicals	Use of laboratory chemicals	Workers	Solids	**0.43**	**8.0E−02**	Silver Shield/ 4H gloves	**27**	**14**	10
				Liquid products	32	11	N/A	N/A		N/A
Commercial Use – Other	Laboratory chemicals		ONUs	Solids	1.7		N/A	**27**		
Processing – Recycling	Recycling	Disposal and recycling	Workers, ONUs	Waste	No dermal exposure expected from routine handling of final products or articles.			140		N/A
Disposal – Disposal	Disposal									

COU = condition of use; CT = central tendency; HE = high-end; OES = occupational exposure scenario; ONU = occupational non-user

[a] In this table, bold/shaded text indicates that a COU significantly contributes to unreasonable risk.

[b] This value is the type or protection factor of personal protective equipment (PPE) required to raise the acute MOE above the dermal or inhalation benchmark. For dermal risks, use of listed PPE would raise the MOE above 1. For inhalation risks, the assigned protection factors (APF) associated with different types of safety equipment based on function (air-purifying, powered air purifying, supplied air) and fit (quarter mask, half-mask, full-face piece, helmet/hood, loose-fitting facepiece) would raise the MOE above 30. For inhalation exposure, certain respirators are only applicable to specific types of inhalation exposure. See the OSHA Small Entity Compliance Guide for the Respiratory Protection Standard for detailed descriptions on the respirators corresponding to the APFs in the table.

Table 6-3. Supporting Basis for the Preliminary Unreasonable Risk Determination for Human Health: Consumer COUs [a]

Consumer COU Category and Subcategory	Dermal Exposure Scenario	Exposure Scenario Level	Acute Dermal Risk Estimates (Benchmark MOE = 1)	Inhalation Exposure Scenario	Exposure Scenario Level	Acute Inhalation Risk Estimates (Benchmark MOE = 30)	
						User MOE (Based on 8-Hour TWA)	**Bystander MOE (Based on 8-Hour TWA)**
Adhesives and Sealants	Adhesives and sealants for small projects	Low	64	No inhalation exposure is expected	Low	No inhalation exposure is expected	No inhalation exposure is expected
		Medium	3		Medium		
		High	**0.4**		High		
Paints and coatings (*e.g.*, commercial and residential paint coatings, stains, exterior architectural and marine paints)	Liquid paints and coating	Low	64	Small project (aerosol can application)	Low	**0.59**	**1.8**
		Medium	**0.4**		Medium	**0.23**	**0.39**
		High	**0.1**		High	**0.16**	**0.39**
	Spray paints and coating	Low	4	Large project (sprayer gun)	Low	**0.91**	**2.5**
		Medium	**0.1**		Medium	**0.46**	**0.72**
		High	**0.02**		High	**0.36**	**0.38**

COU = condition of use; MOE = margin of exposure; TWA = time-weighted average

[a] In this table, **bold/shaded text** indicates that a COU significantly contributes to unreasonable risk.

REFERENCES

3M. (2023). Safety Data Sheet (SDS): 3M Aerospace Sealant AC-770 B-2. St. Paul, MN. https://www.3m.com/3M/en_US/p/d/b40067563/

ACGIH. (2025). TLV: Phthalic anhydride [Database]. Cincinnati, OH.

Anas, E; Engstrom, B; Henriks-Eckerman, ML. (1990). Exposure to paint degradation products when welding, flame cutting, or straightening painted steel. Am Ind Hyg Assoc J 51: 561-565.

Andres, GO; Granados, AM; De Rossi, RH. (2001). Kinetic study of the hydrolysis of phthalic anhydride and aryl hydrogen phthalates. J Org Chem 66: 7653-7657. https://dx.doi.org/10.1021/jo010499v

Aremco. (2023). Safety Data Sheet (SDS): Crystalbond 509-1, 509-2, 509-3. Valley Cottage, NY.

Author Withheld. (1996). Phthalic acid: Acute toxicity test with rainbow trout (Oncorhynchus mykiss) under static conditions: Lab project number: 1026.013.103. (MRID 45784602). [Redacted].

Bai, R; Ma, FW; Liang, D; Zhao, X. (2009). Phthalic acid induces oxidative stress and alters the activity of some antioxidant enzymes in roots of Malus prunifolia. J Chem Ecol 35: 488-494.

Barnthouse, LW; DeAngelis, DL; Gardner, RH; O'Neill, RV; Suter, GW; Vaughan, DS. (1982). Methodology for Environmental Risk Analysis. (ORNL/TM-8167). Oak Ridge, TN: Oak Ridge National Laboratory.

Bookman, S. (2017). Final inhalation exposure monitoring report, phthalic anhydride, March 2017 [redacted] [TSCA Submission]. Bookman, S.

Booth, AM; Bannan, T; McGillen, MR; Barley, MH; Topping, DO; McFiggans, G; Percival, CJ. (2012). The role of ortho, meta, para isomerism in measured solid state and derived sub-cooled liquid vapour pressures of substituted benzoic acids. RSC Adv 2: 4430-4443. https://dx.doi.org/10.1039/c2ra01004f

CalEPA. (2008). TSD for noncancer RELs - Appendix D.3 Chronic RELs and toxicity summaries using the previous version of the Hot Spots Risk Assessment guidelines (OEHHA 1999). Sacramento, CA: California Office of Environmental Health Hazard Assessment :: OEHHA.

Cardno ChemRisk. (2020). Phthalic anhydride risk management limit project [redacted] [TSCA Submission].

CDC. (2024). About epoxies and resins and reproductive health. Available online at https://www.cdc.gov/niosh/reproductive-health/prevention/epoxies-resins.html

CDC. (2026). 2020 Archived National Asthma Data. Available online (accessed 2026-02-02 05:00:00+00:00).

CDPH. (1989). Epoxy resin systems. Available online at https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/HESIS/CDPH%20Document%20Library/epoxy.pdf

Committee on Energy and Commerce's Minority Staff. (2011). Chemicals Used in Hydraulic Fracturing. U.S. House of Representatives. http://ecolo.org/documents/documents_in_english/gas-_Hydraulic-Fract-chemicals-2011-report.pdf

Dagnelie, RVH; Descostes, M; Pointeau, I; Klein, J; Grenut, B; Radwan, J; LeBeau, D; Georgin, D; Giffaut, E. (2014). Sorption and diffusion of organic acids through clayrock: Comparison with inorganic anions. J Hydrol 511: 619-627. https://dx.doi.org/10.1016/j.jhydrol.2014.02.002

DOE. (2016). Table 1: Chemicals of concern and associated chemical information. PACs. Washington, D.C.

Douwin Chemical. (2026). Things You Should Know About Phthalic Anhydride (PA). Available online at https://www.douwin-chem.com/things-you-should-know-about-phthalic-anhydride-pa.html

Durcon. (2011). Material Safety Data Sheet (MSDS): Durcon Epoxy Resin Work Surface. Taylor, TX: Durcon, Inc.

Durcon. (2020). Durcon Epoxy Resin: Epoxy Worksurfaces. Available online at https://www.durcon.com/epoxy-resin-worksurfaces/durcon-epoxy-resin (accessed May 15, 2025).

ECB. (2003). Technical guidance document on risk assessment: Part II. (EUR 20418 EN/2). Luxembourg: Office for Official Publications of the European Communities.

Ejlertsson, J; Johansson, E; Karlsson, A; Meyerson, U; Svensson, BH. (1996). Anaerobic degradation of xenobiotics by organisms form municipal solid waste under landfilling conditions. Antonie Van Leeuwenhoek 69: 67-74. https://dx.doi.org/10.1007/BF00641613

Elsevier. (2019). Reaxys: physical-chemical property data for phthalic anhydride. CAS Registry Number: 85-44-9. Available online

Elsevier. (2020). Reaxys: physical-chemical property data for phthalic acid. CAS Registry Number: 88-33-9 [Database]: Elsevier Information Systems GmbH.

Environmental Technology. (2012a). Castin'Craft Casting Resin basics: Instructions and tips. Fields Landing, CA: Environmental Technology, Inc. https://www.eplastics.com/pdf/Casting-Resin-Instructions.pdf?srsltid=AfmBOop7xynEs_YFz6mkk6W4qAs5TldF-PZ1bIz48ZJzcDK161Ior749

Environmental Technology. (2012b). Technical Data Sheet (TDS): Castin'Craft Casting Resin Basics, Instructions and Tips. Fields Landing, CA. https://www.eplastics.com/pdf/Casting-Resin-Instructions.pdf?srsltid=AfmBOop7xynEs_YFz6mkk6W4qAs5TldF-PZ1bIz48ZJzcDK161Ior749

Environmental Technology. (2017). Safety Data Sheet (SDS): Castin' Craft Casting Resin. (SDS Number 7211750). Fields Landing, CA.

Environmental Technology. (2019). Safety Data Sheet (SDS): Castin' Craft Casting Resin. (SDS Number 7211750). Fields Landing, CA. https://www.tapplastics.com/image/catalog/pdf/CastinCraftResinSpray2019-07-22SDS.pdf?srsltid=AfmBOopNfpnwqZi_23ZnOhckJF5Nmr3ozJ1sxzjPSvrQXuTGIirw4XqU

Environmental Technology. (2020). Material Safety Data Sheet (MSDS): Castin Craft Resin. St. Galesburg, MI.

Epoxy Technology. (2020). Safety Data Sheet (SDS): EPO-TEK H77 Part A. Billerica, MA. https://www.rikei.co.jp/wp/wp-content/uploads/download/epotek-H77-sds-1.pdf

ERG. (2016). Peer review of EPA's Consumer Exposure Model and draft user guide (final peer review report). Washington, DC: U.S. Environmental Protection Agency.

Finoric LLC. (2019). Material Safety Data Sheet (MSDS): Phthalic Anhydride. Beasley, TX.

Fujita, M; Ike, M; Ishigaki, T; Sei, K; Jeong, JS; Makihira, N; Lertsirisopon, R. (2005). Biodegradation of Three Phthalic Acid Esters by Microorganisms from Aquatic Environment. Nihon Mizushori Seibutsu Gakkaishi 41: 193-201. https://dx.doi.org/10.2521/jswtb.41.193

Green Gubre Group. (2021). Phthalic anhydride: Key intermediate for plasticizers and resins. Available online at https://www.greengubregroup.com/Our-Products/Chemical/Phthalic-Anhydride

GreenChem. (2026). Phthalic anhydride. Available online at https://greenchemindustries.com/entry/257/phthalic-anhydride

Gregory, P. (2009). Dyes and Dye Intermediates. In RE Kirk; DF Othmer (Eds.), Kirk-Othmer Encyclopedia of Chemical Technology. New York, NY: Wiley. https://dx.doi.org/10.1002/0471238961.0425051907180507.a01.pub2

Griesenbrock, A. (2017). Final inhalation exposure monitoring report, phthalic anhydride, April 2017 [redacted] [TSCA Submission]. Griesenbrock, A.

Harris Paints. (2015). Safety Data Sheet (SDS): T.O.V. Varnish. Harris Paints Company.

Harris Paints. (2017a). Technical Data Sheet (TDS): Harris Red Oxide Primer. https://images.thdstatic.com/catalog/pdfImages/4f/4f5698cf-9f0e-41f8-946d-b75fb433575f.pdf

Harris Paints. (2017b). Technical Data Sheet (TDS): Tung-O-Var Varnish Stain Interior-Exterior (Marine clear spar). https://images.thdstatic.com/catalog/pdfImages/57/57e40629-72eb-4f8c-8c6a-6cda4390fe80.pdf

Harris Paints. (2025a). Safety Data Sheet (SDS): Harris Red Oxide Primer. San Juan, PR.

Harris Paints. (2025b). Safety Data Sheet (SDS): T.O.V. Marine Clear Spar Varnish. San Juan, PR.

Harris Paints. (2025c). Safety Data Sheet (SDS): T.O.V. Varnish. San Juan, PR.

Harris Paints. (2026a). Safety Data Sheet (SDS): Harris Red Oxide Primer. San Juan, PR.

Harris Paints. (2026b). Safety Data Sheet (SDS): T.O.V. Marine Clear Spar Varnish. San Juan, PR.

Harris Paints. (2026c). Safety Data Sheet (SDS): T.O.V. Varnish. Harris Paints Company.

Health Canada. (2019). Screening assessment carboxylic acid anhydrides group. https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-carboxylic-acid-anhydrides-group.html#toc10

Henkel. (2018). Safety Data Sheet (SDS): Loctite 435 Rubber Tough. Inst ADH known as Loctite 435 Instant Adhesive. Rocky Hill, CT. https://static.rshughes.com/wm/p/wm-asis/495e28687576479167a79bf908cd01fc6fc84642.pdf?uf=

Henkel. (2023). Safety Data Sheet (SDS): Loctite 4105. (SDS No: 173363). Rocky Hill, CT.

Henkel. (2025). Safety Data Sheet (SDS): LOCTITE 426 BLACK INSTANT ADHESIVE known as 426 Prism® Black Max® Gel Inst. Rocky Hill, CT. https://api.henkeldx.com/v2/mysds/SafetyDataSheetSet?Appid=%27YPSSW_SDSUA_EXT%27&Matnr=%27229732%27&Laiso=%27EN%27&Rvlid=%27US%27&Dmskey=%27%27&X-Api-Key=Auy4a2t5e00VU2Ju93GSKHeybHFVjYLX

Hernon. (2020). Safety Data Sheet: Instantbond 120. Sanford, FL. https://www.hernon.com/instantbond-120-4

Hua, CP; Xie, ZK; Wu, ZJ; Zhang, YB; Guo, ZH; Qiu, Y; Wang, L; Wang, YJ. (2019). The Physiological and Biochemical Effects of Phthalic Acids and the Changes of Rhizosphere Fungi Diversity under Continuous Cropping of Lanzhou Lily (Lilium davidii var. unicolor). HortScience 54: 253-261.

Huang, J; Nkrumah, PN; Li, Y; Appiah-Sefah, G. (2013). Chemical behavior of phthalates under abiotic conditions in landfills [Review]. Rev Environ Contam Toxicol 224: 39-52. https://dx.doi.org/10.1007/978-1-4614-5882-1_2

J Mark Systems. (2022). Where Is Ion Exchange Used? Available online at https://www.jmarksystems.com/blog/where-is-ion-exchange-used

Jonsson, S; Baun, A. (2003). Toxicity of mono- and diesters of o-phthalic esters to a crustacean, a green alga, and a bacterium. Environ Toxicol Chem 22: 3037-3043.

Jonsson, S; Ejlertsson, J; Svensson, BH. (2003). Transformation of phthalates in young landfill cells. Waste Manag 23: 641-651. https://dx.doi.org/10.1016/S0956-053X(03)00099-0

Junckers Industries A/S. (2023). Safety Data Sheet (SDS): Junckers Rustic Oil, Clear. Denmark.

Koppers. (2018). PHTHALIC ANHYDRIDE – MOLTEN. SDS ID: 00227845. Material Safety Data Sheet.

Koppers. (2019). Phthalic Anhydride. Available online at https://web.archive.org/web/20190522184753/http://www.koppers.com/pages/phthalic-anhydride

Kwack, S; Kim, K; Kim, H; Lee, B. (2009). Comparative toxicological evaluation of phthalate diesters and metabolites in Sprague-Dawley male rats for risk assessment. J Toxicol Environ Health A 72: 1446-1454.

Kwack, SJ; Han, EY; Park, JS; Bae, JY; Ahn, IY; Lim, SK; Kim, DH; Jang, DE; Choi, L; Lim, HJ; Kim, TH; Patra, N; Park, KL; Kim, HS; Lee, BM. (2010). Comparison of the short term toxicity of phthalate diesters and monoesters in Sprague-Dawley male rats. Toxicological Research 26: 75-82.

Lansink, CJM; Breelen, MSC; Marquart, J; van Hemmen, JJ. (1996). Skin exposure to calcium carbonate in the paint industry. Preliminary modelling of skin exposure levels to powders based on field data. (V96.064). Rijswijk, The Netherlands: TNO Nutrition and Food Research Institute.

Larranaga, MD; Lewis, RJ; Lewis, RA. (2016). Dictionary entries: alpha to 10-acetyldithranol. In Hawley's Condensed Chemical Dictionary, 16th Edition. Hoboken, NJ: John Wiley & Sons, Inc. https://content.e-bookshelf.de/media/reading/L-7697027-dfc5bd77d7.pdf

Lim, DS; Shin, BS; Yoo, SD; Kim, HS; Kwack, SJ; Ahn, MY; Lee, BM. (2007). Toxicokinetics of phthalic acid: The common final metabolite of phthalic acid esters in rats. J Toxicol Environ Health A 70: 1344-1349.

Liss, GM; Hartel, RW. (1983). Health Hazard Evaluation Report No. HETA-82-032-1384, Badische Corporation, Kearny, New Jersey (pp. 82-032). (NIOSH/00178915). Liss, GM; Hartel, RW.

Liu, SM; Lin, YL; Tsai, TL. (2005). Growth dynamics of major microbial populations during biodegradation of o-phthalate in anaerobic sediment slurries under a CO2/H2 atmosphere. Chemosphere 59: 91-98. https://dx.doi.org/10.1016/j.chemosphere.2004.09.074

Lord Corporation. (2020). Safety Data Sheet (SDS): Parker CoolTherm EP-6029 Epoxy Hardener. Cary, NC.

Lord Corporation. (2023). Safety Data Sheet (SDS): Parker VERSILOK 253S. Cary, NC.

Lott, S; Vallette, J. (2013). Full disclosure required: A strategy to prevent asthma through building product selection. Washington, DC: Healthy Building Network. https://habitablefuture.org/wp-content/uploads/2024/03/93-full-disclosure-required-a-strategy-to-prevent-asthma-through-building-product-selection.pdf

Marquart, H; Warren, ND; Laitinen, J; Van Hemmen, JJ. (2006). Default values for assessment of potential dermal exposure of the hands to industrial chemicals in the scope of regulatory risk assessments. Ann Occup Hyg 50: 469-489.

Milford, E. (2018). Final inhalation exposure monitoring report, phthalic anhydride, April 2018 [redacted] [TSCA Submission]. Milford, E.

NCBI. (2020a). PubChem Compound Summary for CID 6811 Phthalic anhydride.

NCBI. (2020b). PubChem Database: Compound Summary: Phthalic acid. Available online at https://pubchem.ncbi.nlm.nih.gov/compound/Phthalic-acid (accessed March 8, 2021).

NCBI. (2020c). PubChem Database: Compound Summary: Phthalic anhydride. Available online at https://pubchem.ncbi.nlm.nih.gov/compound/Phthalic-anhydride

NCI. (1979). Bioassay of phthalic anhydride for possible carcinogenicity. (NCI-CG-TR-159). Bethesda, MD: National Institutes of Health, National Cancer Institute, Division of Cancer Cause and Prevention. https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr159.pdf

Ng, AE; Boersma, P. (2023). Diagnosed allergic conditions in adults: United States, 2021. (NCHS Data Brief No. 460). Atlanta, GA: National Center for Health Statistics.

NICNAS. (2013). 1,3-Isobenzofurandione: Human health tier II assessment. Canberra, Australia: Australian Government Department of Health.

Nielsen, J; Welinder, H; Schutz, A; Skerfving, S. (1988). Specific serum antibodies against phthalic anhydride in occupationally exposed subjects. J Allergy Clin Immunol 82: 126-133.

NIOSH. (2000). Recommendations for chemical protective clothing: A companion to the NIOSH Pocket Guide to Chemical Hazards. Available online (accessed 2025-07-22 00:00:00+00:00).

NIOSH. (2013). Derivation of immediately dangerous to life or health (IDLH) values. (DHHS (NIOSH) Publication No. 2014–100). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. https://www.cdc.gov/niosh/docs/2014-100/

NIST. (2022). NIST Chemistry WebBook. Phthalic anhydride (85-44-9). Standard Reference Database No. 69. Washington, DC: US Sec Commerce. https://webbook.nist.gov/cgi/cbook.cgi?ID=85-44-

9&Units=SI&cTG=on&cIR=on&cTC=on&cTZ=on&cTP=on&cMS=on&cTR=on&cUV=on&cIE=on&cGC=on&cIC=on&cES=on&cDI=on&cSO=on

NJDH. (2010). Hazardous Substance Fact Sheet: Phthalic anhydride [Fact Sheet]. Trenton, NJ.

NLM. (2015). PubChem: Hazardous Substance Data Bank: Phthalic anhydride, 85-44-9. Available online at https://pubchem.ncbi.nlm.nih.gov/compound/6811#source=HSDB

Nordson. (2023). Complete Guide to Powder Coating, by Nordson Industrial Coating Systems. Available online at https://www.nordson.com/eN/About-us/newsroom/industrial-coating-systems-news/complete-guide-to-powder-coating

NRC. (2001). Standing operating procedures for developing acute exposure guideline levels (AEGLs) for hazardous chemicals. Washington, DC: National Academies Press.

OECD. (2005). SIDS Initial Assessment Report: Phthalic anhydride [OECD SIDS] (pp. 213). Paris, France: UNEP Publications. https://hpvchemicals.oecd.org/ui/handler.axd?id=CE1BE9D2-C97E-414A-B21F-60E9F4923A38

OECD. (2011). Emission scenario document on coating application via spray-painting in the automotive refinishing industry. (ENV/JM/MONO(2004)22/REV1). Paris, France: Organization for Economic Co-operation and Development.

OECD. (2014). The adverse outcome pathway for skin sensitisation initiated by covalent binding to proteins. Paris, France.

OECD. (2025). Guideline No. 497: Defined approaches on skin sensitisation. Paris, France.

OSHA. (2019a). Chemical exposure health data (CEHD) sampling results: CASRNs 75-34-3, 85-68-7, 84-74-2, 78-87-5, 117-81-7, 106-93-4, 50-00-0, 95-50-1, 85-44-9, 106-46-7, 79-00-5, and 115-86-6. Washington, DC: U.S. Department of Labor.

OSHA. (2019b). Sampling Search: Phthalic anhydride. https://www.osha.gov/pls/samp/sampling_search.search?establishment=&State=--&zip=&startyear=&endyear=&sic=&naics=&imis=&substance=phthalic+anhydride&beginresult=&endresult=

Park, C; Sheehan, RJ. (2000). Phthalic acids and other benzenepolycarboxylic acids. In Kirk-Othmer encyclopedia of chemical toxicology. New York: John Wiley & Sons. https://dx.doi.org/10.1002/0471238961.1608200816011811

Partanen, JI; Covington, AK. (2006). Re-evaluation of the first and second stoichiometric dissociation constants of phthalic acid at temperatures from (0 to 60) degrees C in aqueous phthalate buffer solutions with or without potassium chloride. 1. Estimation of the parameters for the Huckel model activity coefficient equations for calculation of the second dissociation constant. Journal of Chemical and Engineering Data 51: 777-784. https://dx.doi.org/10.1021/je0504921

PENPET. (2026). Phthalic anhydride (PA). Available online at https://www.penpet.com/products/synthetic-resins/phthalic-anhydride-pa

Pfaeffli, P. (1994). Sampling of airborne combustion fume for chemical analysis: Application to determination of phthalic anhydride in condensed powder paint fume. Staub Reinhalt Luft 54: 403-407.

Pfaffli, P. (1986). Phthalic anhydride as an impurity in industrial atmospheres: Assay in air samples by gas chromatography with electron-capture detection. Analyst 111: 813-817.

Pfaffli, P; Hameila, M; Keskinen, H; Wirmoila, R. (2002). Exposure to cyclic anhydrides in welding: A new allergen-chlorendic anhydride. Appl Occup Environ Hyg 17: 765-767.

Phenova. (2015). Safety Data Sheet (SDS): Phthalic Anhydride Standard. Golden, CO.

Phenova. (2017). Safety Data Sheet: Custom 8270 Misc Mix. Golden, CO.

Polynt. (2016). Safety Data Sheet (SDS): NORSODYNE H 23100 TA. (SDS no: FP17366). France. https://grpukltd.com/wp-content/uploads/2017/03/H23100TA-MSDS.pdf

Polynt. (2024). Safety Data Sheet (SDS): EASYLAM LSE. (SDS no: FP16542). https://www.cfsnet.co.uk/media/attachments/Stock/0000002554/EASYLAM%20LSE.pdf?srsltid=AfmBOor731ZL7o4zQU1MRJtotYHJIL8MfjkNlDizfFRpvsBZqvKRnuVb

Quality Bearings Online. (2019). Quality Bearings Online: Loctite 4105 – Black Rubber Toughened. Available online at https://www.qualitybearingsonline.com/4105/20g-loctite/?setCurrencyId=2&gclid=CjwKCAiAluLvBRASEiwAAbX3GQcpPo7ca2ZHbD6vquABJO6xU1ZXi15IvP-EH7IQ3dwCJvyeh1MUbhoCiDkQAvD_BwE (accessed May 15, 2025).

Ramkissoon, C; Gaskin, S; Hall, T; Pisaniello, D; Zosky, G. (2023). Engineered stone fabrication work releases volatile organic compounds classified as lung irritants. Ann Work Expo Health 67: 288-293.

ResinLab. (2023). Safety Data Sheet (SDS): SEC1244 B. Germantown, WI. https://www.resinlab.com/adhesives/electrically-conductive-adhesives/resinlab-sec1244-electrically-conductive-adhesive/

Rietz, B. (1985). The use of HPLC for the analytical determination of diisocyanates and acid anhydrides in the air of working environments. Anal Lett 18: 1193-1207.

RS Hughes. (2019). Loctite Black Max 426 Cyanoacrylate Adhesive – 10 G Syringe – 21921, IDH 231339. Available online at https://www.rshughes.com/p/Loctite-Black-Max-426-Cyanoacrylate-Adhesive-10-G-Syringe-21921-IDH-231339/079340_21921/?gclid=CjwKCAiAluLvBRASEiwAAbX3GfqUzL25pUegXi88bQhqwXwRQ8NpqaGnyxcSLf-Ha8Nn2ozk26JtyxoCXlAQAvD_BwE

Rumble, JR. (2018). Flammability of chemical substances. In CRC Handbook of Chemistry and Physics (99 ed.). Boca Raton, FL: CRC Press. Taylor & Francis Group.

Sahoo, P; Das, SK; Davim, JP. (2017). 3.3: Surface Finish Coatings. In MSJ Hashmi (Ed.), Comprehensive Materials Finishing (pp. 38-55). Amsterdam: Elsevier. https://dx.doi.org/10.1016/B978-0-12-803581-8.09167-0

Shelton, DR; Tiedje, JM. (1984). General method for determining anaerobic biodegradation potential. Appl Environ Microbiol 47: 850-857. https://dx.doi.org/10.1128/AEM.47.4.850-857.1984

Stepan Co. (2020). Phthalic Anhydride. Available online at https://www.stepan.com/Markets/Phthalic_Anhydride.aspx

Tang, Y; Zhang, Y; Jiang, L; Yang, C; Rittmann, BE. (2017). Enhanced dimethyl phthalate biodegradation by accelerating phthalic acid di-oxygenation. Biodegradation 28: 413-421. https://dx.doi.org/10.1007/s10532-017-9805-x

ten Berge, WF; Zwart, A; Appelman, LM. (1986). Concentration-time mortality response relationship of irritant and systemically acting vapours and gases. J Hazard Mater 13: 301-309. https://dx.doi.org/10.1016/0304-3894(86)85003-8

The Chemical Company. (2026). Phthalic Anhydride. Available online at https://thechemco.com/chemical/phthalic-anhydride/

ThermoFisher Scientific. (2022). Safety Data Sheet (SDS): Phthalic anhydride. Fair Lawn, NJ: Fisher Scientific Company.

Tomer, A; Kane, J. (2015). The great port mismatch: U.S. goods trade and international transportation. Brookings and JPMorgan Chase. https://www.brookings.edu/wp-content/uploads/2015/06/brgkssrvygcifreightnetworks.pdf

Topfine Chemical. (2026). Phthalic anhydride: The cornerstone of the dye and paint industry. Available online at https://www.topfinechem.com/phthalic-anhydride-the-cornerstone-of-the-dye-and-paint-industry.html

Tummanapelli, AK; Vasudevan, S. (2015). Estimating successive pKa values of polyprotic acids from ab initio molecular dynamics using metadynamics: the dissociation of phthalic acid and its isomers. Phys Chem Chem Phys 17: 6383-6388. https://dx.doi.org/10.1039/c4cp06000h

Tustin, T; Kundu-Orwa, S; Lodwick, J; Cannon, DL; McCarthy, RB. (2022). An outbreak of work-related asthma and silicosis at a US countertop manufacturing and fabrication facility. Am J Ind Med 65: 12-19.

U.S. EPA. (1988). Integrated risk information system (IRIS) chemical assessment summary for Phthalic anhydride; CASRN 85-44-9. Washington, DC: National Center for Environmental Assessment, Integrated Risk Information System.

U.S. EPA. (1992a). Guidelines for exposure assessment. Federal Register 57(104):22888-22938 [EPA Report]. In Risk Assessment Forum. (EPA/600/Z-92/001). Washington, DC.

U.S. EPA. (1992b). A laboratory method to determine the retention of liquids on the surface of hands [EPA Report]. (EPA/747/R-92/003). Washington, DC.

U.S. EPA. (1994a). Guidelines for Statistical Analysis of Occupational Exposure Data: Final. United States Environmental Protection Agency :: U.S. EPA.

U.S. EPA. (1994b). Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry [EPA Report]. (EPA600890066F). Research Triangle Park, NC.

U.S. EPA. (1994c). OPPT chemical fact sheets: phthalic anhydride fact sheet: support document (CAS no. 84-44-9). (EPA749F95016a). https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P1004R0D.TXT

U.S. EPA. (1998). Guidelines for ecological risk assessment [EPA Report]. (EPA/630/R-95/002F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum.

U.S. EPA. (2002). A review of the reference dose and reference concentration processes [EPA Report]. (EPA630P02002F). Washington, DC.

U.S. EPA. (2005). Guidelines for carcinogen risk assessment [EPA Report]. (EPA630P03001F). Washington, DC.

U.S. EPA. (2011a). Exposure factors handbook: 2011 edition [EPA Report]. (EPA/600/R-090/052F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment.

U.S. EPA. (2011b). Exposure factors handbook: 2011 edition (final) (EPA/600/R-090/052F). Washington, DC. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252

U.S. EPA. (2012). Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11 [Computer Program]. Washington, DC. Retrieved from https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

U.S. EPA. (2015a). Assessment of the potential impacts of hydraulic fracturing for oil and gas on drinking water resources: Appendices A-J. (EPA/600/R-15/047b). https://yosemite.epa.gov/sab/sabproduct.nsf/0/F7A9DB9ABBAC015785257E540052DD54/$File/HF_Appendices.pdf

U.S. EPA. (2015b). ChemSTEER user guide - Chemical screening tool for exposures and environmental releases. Washington, D.C.

U.S. EPA. (2016). Hydraulic fracturing for oil and gas: Impacts from the hydraulic fracturing water cycle on drinking water resources in the United States [EPA Report]. (EPA/600/R-16/236F). Washington, DC. https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990

U.S. EPA. (2017). Estimation Programs Interface Suite™ v.4.11. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention Toxics. Retrieved from https://www.epa.gov/tsca-screening-tools/download-epi-suitetm-estimation-program-interface-v411

U.S. EPA. (2019a). Chemical data reporting (2012 and 2016 public CDR database). Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from https://www.epa.gov/chemical-data-reporting

U.S. EPA. (2019b). Chemistry Dashboard Information for Phthalic anhydride. 85-44-9. Available online at https://comptox.epa.gov/dashboard/dsstoxdb/results?search=DTXSID2021159

U.S. EPA. (2019c). Guidelines for human exposure assessment [EPA Report]. (EPA/100/B-19/001). Washington, DC: Risk Assessment Forum.

U.S. EPA. (2019d). National Emissions Inventory (NEI) [database]: CASRNs 79-00-5, 75-34-3, 107-06-2, 78-87-5, 84-61-7, 106-99-0, 106-93-4, 50-00-0, 85-44-9, 106-46-7, 85-68-7, 84-74-2, and 117-81-7 [Database]. Washington, DC.

U.S. EPA. (2019e). Point Source Calculator: A Model for Estimating Chemical Concentration in Water Bodies. Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.

U.S. EPA. (2019f). TRI Explorer (2018 dataset released November 2019). Washington, DC. Retrieved from https://enviro.epa.gov/triexplorer/tri_release.chemical

U.S. EPA. (2020a). 2020 CDR data [Database]. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from https://www.epa.gov/chemical-data-reporting/access-cdr-data

U.S. EPA. (2020b). 2020 CDR: Commercial and consumer use. Washington, DC.

U.S. EPA. (2020c). Chemistry Dashboard Information for Phthalic Acid. 88-99-3. Available online at https://comptox.epa.gov/dashboard/dsstoxdb/results?search=DTXSID8021484

U.S. EPA. (2020d). Final scope of the risk evaluation for phthalic anhydride (1,3-isobenzofurandione); CASRN 85-44-9 [EPA Report]. (EPA 740-R-20-020). Washington, DC: Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/default/files/2020-09/documents/casrn_85-44-9_phthalic_anhydride_finalscope.pdf

U.S. EPA. (2020e). Use Report for Phthalic Anhydride (CASRN 85-44-9). Washington, DC: Office of Chemical Safety and Pollution Prevention. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0459-0029

U.S. EPA. (2021). Draft systematic review protocol supporting TSCA risk evaluations for chemical substances, Version 1.0: A generic TSCA systematic review protocol with chemical-specific methodologies. (EPA Document #EPA-D-20-031). Washington, DC: Office of Chemical Safety and Pollution Prevention. https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0005

U.S. EPA. (2022a). Draft TSCA screening level approach for assessing ambient air and water exposures to fenceline communities (version 1.0) [EPA Report]. (EPA-744-D-22-001). Washington, DC: Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency.

U.S. EPA. (2022b). Ecological structure activity relationships (ECOSAR) predictive model, v2.2. Washington, DC.

U.S. EPA. (2023a). 2020 National Emissions Inventory (NEI) Data (August 2023 version) (Version August 2023). Washington, DC: US Environmental Protection Agency.

U.S. EPA. (2023b). Consumer Exposure Model (CEM) Version 3.2 User's Guide. Washington, DC. https://www.epa.gov/tsca-screening-tools/consumer-exposure-model-cem-version-32-users-guide

U.S. EPA. (2023c). Toxics Release Inventory (TRI) data: Phthalic anhydride, reporting years 2019-2023. Washington, DC.

U.S. EPA. (2024). 2024 CDR data [Database]. Washington, DC.

U.S. EPA. (2025a). Consumer and Indoor Exposure Assessment for Dibutyl Phthalate (DBP). (EPA-740-R-25-033). Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2025b). Email from Finoric on the use of phthalic anhydride in oil and gas drilling activities for the draft risk evaluation. Available online

U.S. EPA. (2025c). Email from Henkel on the use of phthalic anhydride in water filtration activities for the draft risk evaluation. Available online

U.S. EPA. (2025d). Email from Huntsman on the use of phthalic anhydride in utilities for the draft risk evaluation. Available online

U.S. EPA. (2025e). Environmental Hazard Assessment for Dibutyl Phthalate (DBP). (EPA-740-R-25-035). Washington, DC: Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0503-0162

U.S. EPA. (2025f). Environmental Hazard Assessment for Diethylhexyl Phthalate (DEHP). (EPA-740-R-25-067). Washington, DC: Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0433-0174

U.S. EPA. (2025g). Environmental Media and General Population and Environmental Exposure for Dibutyl Phthalate (DBP). (EPA-740-R-25-034). Washington, DC: Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0503-0151

U.S. EPA. (2025h). Environmental Release and Occupational Exposure Assessment for Diethylhexyl Phthalate (DEHP). (EPA-740-R-25-064). Washington, DC: Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0433-0177

U.S. EPA. (2025i). Summary of Facility Release Data for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), and Butyl Benzyl Phthalate (BBP). Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2025j). Systematic Review Protocol for Dibutyl Phthalate (DBP). Washington, DC: Office of Pollution Prevention and Toxics. https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0503-0146

U.S. EPA. (2026a). Draft Ambient Air IIOAC Exposure Results and Risk Calculations for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026b). Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026c). Draft Consumer Exposure Analysis and Risk Calculator for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026d). Draft Data Evaluation Information for Environmental Hazard for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026e). Draft Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026f). Draft Data Extraction Information for General Population, Consumer, and Environmental Exposure for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026g). Draft Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026h). Draft Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026i). Draft Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026j). Draft Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026k). Draft Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026l). Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026m). Draft Environmental Hazard Assessment for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026n). Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026o). Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026p). Draft Human Health Hazard Assessment for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026q). Draft Occupational Exposure Calculator for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026r). Draft Physical Chemistry and Fate and Transport Assessment for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026s). Draft Risk Evaluation for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026t). Draft Surface Water Human Exposure Risk Calculator for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

U.S. EPA. (2026u). Draft Systematic Review Protocol for Phthalic Anhydride. Washington, DC: Office of Pollution Prevention and Toxics.

UK IOM. (2003). Identification of practical maximum levels of dermal dust exposure for zinc oxide and zinc metal dusts. (Research Report TM/02/03). Geneva: World Health Organization.

Vainiotalo, S; Pfaffli, P. (1990). Air impurities in the PVC plastics processing industry. Ann Occup Hyg 34: 585-590. https://dx.doi.org/10.1093/annhyg/34.6.585

Van Leeuwen, CJ; Grootelaar, EM; Niebeek, G. (1990). Fish embryos as teratogenicity screens: A comparison of embryotoxicity between fish and birds. Ecotoxicol Environ Saf 20: 42-52.

van Tongeren, MJ; Barker, RD; Gardiner, K; Harris, JM; Venables, KM; Taylor, AJ; Harrington, JM. (1995). Exposure to acid anhydrides in three resin and one cushioned flooring manufacturing plants. Ann Occup Hyg 39: 559-571.

Versar. (2014). Exposure and Fate Assessment Screening Tool (E-FAST 2014) - Documentation manual. Washington, DC: U.S. Environmental Protection Agency. https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014

W.R. Grace. (2024). Memorandum For The Record: Meeting with W. R. Grace & Co.-Conn. (Grace) and EPA to Discuss Phthalates in Catalyst Systems Used in the Manufacture of Plastics. Available online

Waterlox Coatings Corporation. (2015). Safety Data Sheet (SDS): Original Marine Finish High Gloss. Cleveland, OH. https://www.waterlox.com/images/products/marine/marine_gloss_sds.pdf

Whittemore, D. (2011). Water quality and hydraulic fracturing. Whittemore, D. http://www.kgs.ku.edu/Hydro/Publications/2012/Fracturing/index.html

Williams, D; Blanchfield, B. (1974). Retention, excretion and metabolism of phthalic acid administered orally to the rat. Bull Environ Contam Toxicol 12: 109-112.

Zhao, H; Du, H; Feng, N; Xiang, L; Li, Y; Li, H; Cai, QY; Mo, C. (2016). Biodegradation of di-n-butylphthalate and phthalic acid by a novel Providencia sp 2D and its stimulation in a compost-amended soil. Biol Fertil Soils 52: 65-76. https://dx.doi.org/10.1007/s00374-015-1054-8

APPENDICES

Appendix A KEY ABBREVIATIONS AND ACRONYMS

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
ADD	Average daily dose
ADC	Average daily concentration
AERMOD	American Meteorological Society/EPA Regulatory Model
AOP	Adverse outcome pathways
BAF	Aquatic bioaccumulation factor
BLS	Bureau of Labor Statistics (U.S.)
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential business information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CFR	Code of Federal Regulations
COC	Concentration of concern
DIY	Do-it-yourself
DMR	Discharge Monitoring Report
EPA	Environmental Protection Agency (U.S.)
ESD	Emission Scenario Document
EU	European Union
K_{OC}	Soil organic carbon: water partitioning coefficient
K_{OW}	Octanol: water partition coefficient
HEC	Human equivalent concentration
HED	Human equivalent dose
IIOAC	Integrated Indoor/Outdoor Air Calculator (IIOAC) Model
IR	Ingestion rate
LCD	Life cycle diagram
LOD	Limit of detection
LOAEL	Lowest-observed-adverse-effect level
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
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No-observed-adverse-effect level
OCSPP	Office of Chemical Safety and Pollution Prevention (EPA)
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
OES	Occupational exposure scenario
OEV	Occupational exposure value
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics (EPA)
OSHA	Occupational Safety and Health Administration (U.S.)
P50	The 50th percentile or median flow rate of a distribution of hydrologic flows

P75	The 75th percentile flow rate of a distribution of hydrologic flows
P90	The 90th percentile flow rate of a distribution of hydrologic flows
PBZ	Personal breathing zone
PBPK	Physiologically based pharmacokinetic (PBPK) (model)
PEL	Permissible exposure limit (OSHA)
PESS	Potentially exposed or susceptible subpopulations
POD	Point of departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PV	Production volume
PVC	Polyvinyl chloride
REL	Recommended Exposure Limit
SACC	Science Advisory Committee on Chemicals
SDS	Safety data sheet
TDS	Technical data sheet
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
TSD	Technical support document
TWA	Time-weighted average
UF	Uncertainty factor
U.S.	United States
VVWM-PSC	Variable Volume Water Model with Point Source Calculator Tool

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 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Phthalic anhydride was designated as a High-Priority Substance for risk evaluation under TSCA on December 20, 2019 (84 FR 71924, accessed March 3, 2026). Designation of phthalic anhydride as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities, and uses of chemical substances produced domestically and imported into the United States.	Phthalic anhydride manufacturing (including importing), processing and use information is reported under the CDR rule (final rule effective May 11, 2020) (85 FR 20122, accessed March 3, 2026).
Toxic Substances Control Act (TSCA) – section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Phthalic anhydride was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (final rule effective May 30, 1995) (60 FR 16309, accessed March 3, 2026).
Emergency Planning and Community Right-To-Know Act (EPCRA) – section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (*e.g.,* quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (*i.e.,* air, land and water).	Phthalic anhydride is a listed substance subject to reporting requirements under 40 CFR 372.65 (accessed March 3, 2026) effective as of January 01, 1987.

Statutes/ Regulations	Description of Authority/ Regulation	Description of Regulation
Clean Air Act (CAA) – section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER), which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated	Phthalic anhydride is subject to the NSPS for equipment leaks of volatile organic compounds (VOCs) in the synthetic organic chemicals manufacturing industry for which construction, reconstruction or modification began after January 5, 1981 (40 CFR 60.489, Subpart VV, accessed March 3, 2026).
Clean Air Act (CAA) – section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has modified the original list through rulemaking leaving 188 at present.	Phthalic anhydride is listed as a HAP (42 U.S.C. 7412, accessed March 3, 2026).
Clean Air Act (CAA) – section 112(d) and section 112 (f)	Risk and technology review (RTR) of section 112(d) national emission standards for hazardous air pollutants (NESHAP). Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) NESHAP that require maximum achievable control technology (MACT), and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the emission standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP and will do so, as required, for the remaining source categories with NESHAP. Although phthalic anhydride-emitting source categories would be subject to NESHAP and MACT standards that control phthalic anhydride, if risk has not been identified for phthalic anhydride emissions, there would not be a 112(f) standard to target phthalic anhydride.
Resource Conservation and Recovery Act (RCRA) – section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability,	Phthalic anhydride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U190 (40 CFR 261.33, accessed March 3, 2026).

Statutes/ Regulations	Description of Authority/ Regulation	Description of Regulation
	corrosiveness, and other hazardous characteristics.	
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances that, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Phthalic anhydride is a hazardous substance under CERCLA. Releases of phthalic anhydride in excess of 5000 pounds must be reported (40 CFR 302.4, accessed March 3, 2026).
Other federal statutes/regulations		
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	In 1971, OSHA revised an existing occupational safety and health standards for phthalic anhydride to include an 8-hour TWA PEL of 2 ppm TWA or 12 mg/m^3 TWA. (29 CFR 1910.1000, accessed March 3, 2026). In 1989, OSHA lowered the 8-hour TWA PEL to 1 ppm or 6 mg/m^3; however, the rule was vacated in 1991 and the prior PEL of 2 ppm or 12 mg/m^3 from 1971 was reinstated.
Federal Hazardous Materials Transportation Act (FHMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property.	Phthalic anhydride is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials (70 FR 34381, June 14 2005, accessed March 3, 2026).

Statutes/ Regulations	Description of Authority/ Regulation	Description of Regulation
	• Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	

B.2 State Laws and Regulations

Table_Apx B-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: Rhode Island 7,000 μg/m^3 (24 hours), 20 μg/m^3 (annual) (Air Pollution Regulation No. 22, accessed March 3, 2026). New Hampshire 0.0071 μg/m^3 (24 hours), 0.0048 μg/m^3 (annual) (Env-A 1400: Regulated Toxic Air Pollutants; accessed March 3, 2026).
State Drinking Water Standards and Guidelines	Michigan (Generic Groundwater Cleanup Criteria, Mich. Admin. Code R.299.44; Generic Groundwater Cleanup Criteria, R.299.46; Generic Soil Cleanup Criteria for Residential Category, R. 299.46; and Generic Soil Cleanup Criteria for Nonresidential Category, R.299.48, 2017; accessed March 3, 2026).
State PELs	California PEL of 1 ppm (Cal Code Regs. Title 8, § 5155, accessed March 3, 2026) Hawaii PEL of 1 ppm (Hawaii Administrative Rules Section 12-60-50; accessed March 3, 2026).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A, accessed March 3, 2026), New Jersey (N.J.A.C. 7:1G, accessed March 3, 2026), and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323; accessed March 3, 2026).
Chemicals of High Concern to Children	Vermont (18 V.S.A § 1776, accessed March 3, 2026) has adopted reporting laws for chemicals in children's products containing Phthalic anhydride.
Other	Phthalic anhydride is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code § 25252 and 25253 (California, Candidate Chemicals List), accessed March 3, 2026. Phthalic anhydride is on the Massachusetts Toxic Use Reduction Act (TURA) list of 2019 (Toxics Use Reduction Act (TURA), accessed March 3, 2026), MGL, Chapter 21I, Section 1 to Section 23)

B.3 International Laws and Regulations

Table_Apx B-3. Regulatory Actions by Other Governments, Tribes and International Agreements

Country/Tribe/ Organization	Requirements and Restrictions
Canada	Phthalic anhydride is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search; accessed March 3, 2026) and Canada's National Pollutant Release Inventory (NPRI).
European Union	Phthalic anhydride is registered for use in the EU (European Chemicals Agency (ECHA) database; accessed March 3, 2026).

Country/Tribe/ Organization	Requirements and Restrictions
Australia	Phthalic anhydride is listed on Australia's Inventory of Chemical Substance (AICS). Phthalic anhydride was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritization (IMAP). (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed April 19, 2019). Uses include coatings applications (for home appliances, automobiles, medical devices and furniture), non-agricultural pesticides, preservatives, paints, lacquers, varnishes, tanning and curing agents, solvents, cleaning/washing agents, adhesives, binding agents, corrosion inhibitors, construction materials, scorch inhibitor, surface treatment and the manufacture of other chemicals (NICNAS Human Health Tier II assessment for 1,3-Isobenzofurandione; accessed March 3, 2026).
Japan	Phthalic anhydride is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL, accessed March 3, 2026) • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]; accessed April 10, 2019).
Australia, Austria, Belgium, Canada (Ontario and Quebec), Denmark, Finland, France, Hungary, Ireland, Latvia, New Zealand, China, Poland, Romania, Singapore, South Korean, Spain, Sweden, Switzerland.	Occupational exposure limits for phthalic anhydride GESTIS International limit values for chemical agents (Occupational exposure limits, OELs database; accessed March 3, 2026) (see Table_Apx for a summary of occupational exposure limits).

B.4 Assessment History

Table_Apx B-4. Assessment History of Phthalic Anhydride

Authoring Organization	Publication(s)/Hyperlink(s) and Year
EPA publications	
Center for Public Health and Environmental Assessment	Integrated risk information system (IRIS) chemical assessment summary for Phthalic anhydride; CASRN 85-44-9 (U.S. EPA, 1988)
Other U.S.-based organizations	
American Conference of Governmental Industrial Hygienists	TLV: Phthalic Anhydride (ACGIH, 2025)
Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency	Appendix D.3 Chronic RELs and toxicity summaries using the previous version of the Hot Spots Risk Assessment guidelines (CalEPA, 2008)
International	

Government of Canada, Environment Canada, Health Canada	*Screening Assessment Carboxylic Acid Anhydrides Group* (Health Canada, 2019)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	*1,3-Isobenzofurandione: Human Health Tier II Assessment* (NICNAS, 2013)
The Organization for Economic Co-operation and Development (OECD)	*SIDS Initial Assessment Report: Phthalic Anhydride* (OECD, 2005)

Appendix C LIST OF TECHNICAL SUPPORT AND SUPPLEMENTAL FILES

This appendix provided the name and citation for all technical support documents and supplemental files included in this *Draft Risk Evaluation for Phthalic Anhydride*.

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 Phthalic Anhydride (U.S. EPA, 2026u) – 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, 2021), this systematic review protocol for the Draft Risk Evaluation for phthalic anhydride 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 “Phthalic Anhydride Systematic Review Protocol.”

Draft Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties for Phthalic Anhydride (U.S. EPA, 2026i) – Provides a compilation of tables for the data extraction and data quality evaluation information for phthalic anhydride. 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.

Draft Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport for Phthalic Anhydride (U.S. EPA, 2026g) – Provides a compilation of tables for the data extraction and data quality evaluation information for phthalic anhydride. 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.

Draft Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure for Phthalic Anhydride (U.S. EPA, 2026h) – Provides a compilation of tables for the data extraction and data quality evaluation information for phthalic anhydride. 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.

Draft Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure for Phthalic Anhydride(U.S. EPA, 2026j) – Provides a compilation of tables for the data quality evaluation information for phthalic anhydride. 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.

Draft Data Extraction Information for General Population, Consumer, and Environmental Exposure for Phthalic Anhydride (U.S. EPA, 2026f) – Provides a compilation of tables for the data extraction for phthalic anhydride. 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.

Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology for Phthalic Anhydride (U.S. EPA, 2026l) – Provides a compilation of tables for the data quality evaluation information for phthalic anhydride. 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.

Draft Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for Phthalic Anhydride (U.S. EPA, 2026k) – Provides a compilation of tables for the data quality evaluation information for phthalic anhydride. 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.

Draft Data Quality Evaluation Information for Environmental Hazard for Phthalic Anhydride (U.S. EPA, 2026d) – Provides a compilation of tables for the data quality evaluation information for phthalic anhydride. 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.

Draft Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology for Phthalic Anhydride (U.S. EPA, 2026e) – Provides a compilation of tables for the data extraction for phthalic anhydride. 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 and Fate and Transport Assessment for Phthalic Anhydride (U.S. EPA, 2026r).

Draft Environmental Release and Occupational Exposure Assessment for Phthalic Anhydride (U.S. EPA, 2026o).

Draft Consumer and Indoor Exposure Assessment for Phthalic Anhydride (U.S. EPA, 2026b).

Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride (U.S. EPA, 2026n).

Draft Environmental Hazard Assessment for Phthalic Anhydride (U.S. EPA, 2026m).

Draft Human Health Hazard Assessment for Phthalic Anhydride (U.S. EPA, 2026p).

Draft Consumer Exposure Analysis for Phthalic Anhydride (U.S. EPA, 2026c).

Draft Consumer Risk Calculator for Phthalic Anhydride (U.S. EPA, 2026c).

Draft Risk Calculator for Occupational Exposures for Phthalic Anhydride (U.S. EPA, 2026q).

Draft Surface Water Human Exposure Risk Calculator for Phthalic Anhydride) (U.S. EPA, 2026t)

Draft Ambient Air IIOAC Exposure Results and Risk Calculations for Phthalic Anhydride (U.S. EPA, 2026a)

Draft Summary of Facility Release Data for Phthalic Anhydride (U.S. EPA, 2025i).

Appendix D UPDATES TO THE PHTHALIC ANHYDRIDE CONDITIONS OF USE TABLE

After the publication of the final scope document (U.S. EPA, 2020d), EPA received updated submissions from the 2020 CDR cycle (U.S. EPA, 2020a). In addition to new submissions received under the 2020 CDR cycle, the use and processing codes changed for the 2020 CDR cycle. Therefore, EPA amended the description of certain phthalic anhydride COUs based on those new submissions and new use and processing codes. Also, EPA received information from stakeholders about uses of phthalic anhydride. For cases where COUs were consolidated under a category, if the category was not present in the scope, the nomenclature was taken directly from the 2020 CDR cycle codes and categories. Table_Apx D-1 below summarizes the changes to the COUs based on the new codes in the 2020 CDR and any other additional information reasonably available to EPA since the publication of the final scope document.

Table_Apx D-1. Changes to Categories and Subcategories of Conditions of Use (COUs) Based on CDR and Stakeholder Engagement

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Processing – As a reactant	Intermediate (All other basic organic chemical manufacturing; all other basic inorganic chemical manufacturing; plastic material and resin manufacturing; and paint and coating manufacturing.)	Removed “all other basic inorganic chemical manufacturing” based on the 2020 and 2024 CDR reporting cycles. “All other basic inorganic chemical manufacturing” is still under “Processing – incorporation into formulation, mixture, or reaction product – Intermediate (All other basic inorganic chemical manufacturing)” Added "plastic product manufacturing,” and “construction” to this use based on the 2020 CDR reporting cycle. Added “flame retardant manufacturing” because additional research phthalic anhydride is used as a reactant to manufacture flame retardants such as tetrabromophthalic anhydride (TBPA) (The Chemical Company). Recategorized “Intermediate (all other basic inorganic chemical manufacturing)” under “Processing – incorporation into formulation, mixture, or reaction product” based on the 2020 and 2024 CDR reporting cycles.	Processing – As a reactant – Intermediate (All other basic organic chemical manufacturing; Plastic material and resin manufacturing; Plastics product manufacturing; Construction; Paint and coating manufacturing; and Flame-retardant manufacturing) Processing – Incorporation into formulation, mixture, or reaction product – Intermediate (All other basic inorganic chemical manufacturing)
Processing – As a reactant	N/A	Added based on the 2020 and 2024 CDR reporting cycles.	Processing – As a reactant – Monomer (All other basic organic chemical manufacturing; Plastic material and resin manufacturing)
Processing – As a reactant	Adhesives and sealant chemicals in (Paint and coating manufacturing)	Removed based on the 2020 or 2024 CDR reporting cycles. “Paint and coating manufacturing” is still under “Processing – as a reactant – Intermediate (Paint and coating manufacturing)”	Processing – As a reactant – Intermediate (Paint and coating manufacturing)
Processing – As a reactant	Lubricants and lubricant additives (Petroleum lubricating oil and grease manufacturing)	Use is no longer ongoing and not reported in the 2020 or 2024 reporting cycles.	N/A
Processing – As a reactant	Paint additives and coating additives not described by other categories (Paint and coating manufacturing; and Plastic material and resin manufacturing)	Removed “paint and coating manufacturing” based on the 2020 or 2024 CDR reporting cycles. “Paint and coating manufacturing” is still under “Processing – as a reactant – Intermediate (Paint and coating manufacturing)” Recategorized “Plastic material and resin manufacturing” under the functional code “Processing – as a reactant – Monomer” based on 2020 and 2024 CDR reporting cycles.	Processing – As a reactant – Intermediate (Paint and coating manufacturing) Processing – As a reactant – Monomer (Plastic material and resin manufacturing)

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Processing – As a reactant	Pigments (Synthetic dye and pigment manufacturing)	Recategorized under the "polymerization promoter" functional code based on the 2020 and 2024 CDR reporting cycle.	Processing – As a reactant – Polymerization promoter (Synthetic dye and pigment manufacturing)
Processing – As a reactant	Inks (Printing ink manufacturing)	Recategorized under the "Pigments" functional code based on the 2020 and 2024 CDR reporting cycle.	Processing – As a reactant – Pigments (Printing ink manufacturing)
Processing – As a reactant	Plastic (Plastics product manufacturing)	Corrected the functional code to say "Plasticizer" based on 2020 CDR data. Added "Adhesive manufacturing" based on the 2020 CDR reporting cycle. Added "Lubricant additive manufacturing" based on two online sources (Greenchem website; Boshan Hengtai website) that describe phthalic anhydride's use to make plasticizers that are then added to lubricant additives to enhance the lubricant's performance and longevity.	Processing – Aas a reactant – Plasticizer (Plastics product manufacturing; Adhesive manufacturing; Lubricant additive manufacturing)
Processing – As a reactant	Corrosion inhibitors and anti-scaling agents (Miscellaneous manufacturing)	Use is no longer ongoing and not reported in the 2020 or 2024 reporting cycles.	N/A
Processing – As a reactant	Plating agents and surface treating agents (Rubber product manufacturing)	Use is no longer ongoing and not reported in the 2020 or 2024 reporting cycles.	N/A
Processing – Incorporation into formulation, mixture, or reaction product	Intermediate (Paint and coating manufacturing; all other basic organic chemical manufacturing; all other chemical product and preparation manufacturing; and plastic material and resin manufacturing)	Added "all other basic inorganic chemical manufacturing" based on the 2020 and 2024 CDR reporting cycles; and "adhesive manufacturing" and "plastic product manufacturing" based on the 2024 CDR reporting cycles. Recategorized "paint and coating manufacturing" under the "plasticizer" functional code based on the 2020 CDR reporting cycle. Removed "all other chemical product and preparation manufacturing" based on outreach with the 2024 CDR reporting company who confirmed that phthalic anhydride is used as a reactant, not in incorporation. This use is captured under "Processing – as a reactant – intermediate (plastic material and resin manufacturing; paint and coating manufacturing)"	Processing – Incorporation into formulation, mixture, or reaction product – Intermediate (All other basic inorganic chemical manufacturing; All other basic organic chemical manufacturing; All other chemical product and preparation manufacturing; Adhesive manufacturing; Plastic product manufacturing; Lubricant and lubricant additive manufacturing) Processing – Incorporation into formulation, mixture, or reaction

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		Recategorized "plastic material and resin manufacturing" under the "monomer" functional code based on the 2024 CDR reporting cycle.	product – Plasticizer (Paint and coating manufacturing) Processing – Incorporation into formulation, mixture, or reaction product – Fillers (All other chemical product and preparation manufacturing) Processing – Incorporation into formulation, mixture, or reaction product – Monomer (Plastic material and resin manufacturing)
Processing – Incorporation into formulation, mixture, or reaction product	Plasticizers (Plastic material and resin manufacturing; petrochemical manufacturing; construction; polyester and alkyd resins; curing agent for epoxy resins; plastic product manufacturing; and custom compounding of purchased resin)	Added "paint and coating manufacturing" based on the 2020 and 2024 CDR reporting cycles. Recategorized "plastic product manufacturing" under the "intermediate" functional code based on the 2024 CDR reporting cycle. Recategorized "construction" as "Processing – as a reactant – Intermediate" based on the 2020 CDR reporting cycle. Removed "petrochemical manufacturing" and "custom compounding of purchased resin" since the uses are no longer ongoing and not reported in the 2020 or 2024 reporting cycles.	Processing – Incorporation into formulation, mixture, or reaction product – Plasticizers (Plastic material and resin manufacturing; Paint and coating manufacturing) Processing – Incorporation into formulation, mixture, or reaction product – Intermediate (plastic product manufacturing) Processing – As a reactant – Intermediate (Construction)
Processing – Incorporation into formulation, mixture, or reaction product	Paint additives and coating additives not described by other categories in: Plastics material and resin manufacturing; Synthetic dye and pigment manufacturing; Paint and coating manufacturing; Solid color stains; and Asphalt paving, roofing, and coating materials manufacturing.	Industry subcategories updated based on reporting from more recent CDR cycles	Processing – Incorporation into formulation, mixture, or reaction product – Paint additives and coating additives not described by other categories in: Plastics material and resin manufacturing

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Processing – Incorporation into formulation, mixture, or reaction product	Adhesives and sealant chemicals in: Paint and coating manufacturing	The functional code for "Paint and coating manufacturing" has been changed based on 2020 or 2024 reporting cycles.	Processing – Incorporation into formulation, mixture, or reaction product – Binder in: Paint and coating manufacturing Processing – Incorporation into formulation, mixture, or reaction product – Hardener in: Adhesive manufacturing; Epoxy resin casting; Paint and coating manufacturing; Solvent-based pain; Rubber product manufacturing; Utilities Processing – Incorporation into formulation, mixture, or reaction product – Plasticizer in: Plastic material and resin manufacturing; Paint and coating manufacturing Processing – Incorporation into formulation, mixture, or reaction product – Processing aid in: Paint and coating manufacturing; Rubber product manufacturing Processing – Incorporation into formulation, mixture, or reaction product – Solvent in: Paint and coating manufacturing; Plastic material and resin manufacturing
Processing – Incorporation into formulation, mixture, or reaction product	Fillers in: Textile, apparel, and leather manufacturing.	Use is no longer ongoing and not reported in the 2020 or 2024 reporting cycles.	N/A
Processing – Incorporation into formulation, mixture, or reaction product	Oxidizing/reducing agents (Synthetic rubber manufacturing; adhesive manufacturing; plastic material and resin	Use is no longer ongoing and not reported in the 2020 or 2024 reporting cycles.	N/A

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
	manufacturing; and wholesale and retail trade)		
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing – Incorporation into formulation, mixture, or reaction product – Retarder (Rubber product manufacturing)
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing – Incorporation into formulation, mixture, or reaction product – Flame retardant in: Plastics product manufacturing.
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing - incorporation into formulation, mixture, or reaction product – Binder (Paint and coating manufacturing)
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing – Incorporation into formulation, mixture, or reaction product – Hardener (Adhesive manufacturing; Epoxy resin casting; Paint and coating manufacturing; Solvent-based paint; Rubber product manufacturing; Utilities)
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing – Incorporation into formulation, mixture, or reaction product – Solvent (Paint and coating manufacturing; Plastic material and resin manufacturing)
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing – Incorporation into formulation, mixture, or reaction product – Processing aid (paint and coating manufacturing; and rubber product manufacturing)
Processing – Incorporation into formulation, mixture, or reaction product	N/A	Category and subcategory added based on reporting in the 2020 CDR cycle.	Processing – Incorporation into formulation, mixture, or reaction product – Polymerization promoter (all other basic organic chemical manufacturing)

Life Cycle Stage and Category in the Final Scope Document	**Subcategory in the Final Scope Document**	**Occurred Change**	**Revised COU in the 2025 Draft Risk Evaluation**
Industrial Use – Aerospace	Acceptance testing of foams used on human-rated spaceflight vehicles	Recategorized into the category and subcategory “Automotive and aerospace products –Transportation equipment manufacturing.”	Industrial use – Automotive and aerospace products –Transportation equipment
Industrial – Fillers	Hardener (*e.g.,* epoxy hardener)	Removed from the industrial use category but kept in the commercial use category	Commercial Use – Fillers – Hardener
Industrial – Flame retardants	Flame retardants	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Industrial – Fuel and related products	Fuel and related products	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Industrial – Textiles, apparel, and leather manufacturing	Tanning and curing	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Industrial – Lubricants and greases	Lubricants and greases	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Industrial – Plating agents and surface treating agents	Surface treating	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Industrial – Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Updated subcategory to better reflect 2020 CDR reporting codes	Industrial Use – Construction products – Construction and building materials covering large surface areas
Industrial – Electrical and electronic products	Electrical and electronic products	Updated subcategory to better reflect 2020 CDR reporting codes	Industrial Use – Metal and electric products – Machinery, mechanical appliances, electrical/electronic articles
Industrial – Transportation Equipment Manufacturing	Used in the body/exterior, interior, and electrical systems of a vehicle, wiring assemblies, seat and console assemblies, and lamp assemblies.	Recategorized into the category and subcategory “Automotive and aerospace products – Transportation equipment manufacturing.”	Industrial use – Automotive and aerospace products –Transportation equipment manufacturing.
Industrial – Water treatment products	Water filtration applications	Removed category and subcategory in response to information provided by the company.	N/A
Commercial – Fuel and related products	Fuel and related products	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A

Life Cycle Stage and Category in the Final Scope Document	**Subcategory in the Final Scope Document**	**Occurred Change**	**Revised COU in the 2025 Draft Risk Evaluation**
Commercial – Textiles, apparel, and leather manufacturing	Tanning and curing	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Commercial – Lubricants and greases	Lubricants and greases	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Commercial – Plating agents and surface treating agents	Surface treating	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Commercial – Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	Updated subcategory to better reflect 2020 CDR reporting codes	Commercial use – Construction products – Construction and building materials covering large surface areas
Commercial – Electrical and electronic products	Electrical and electronic products	Updated subcategory to better reflect 2020 CDR reporting codes	Commercial use – Metal and electric products – Machinery, mechanical appliances, electrical/electronic articles
Commercial Use – Transportation equipment manufacturing	Used in the body/exterior, interior, and electrical systems of a vehicle, wiring assemblies, seat and console assemblies, and lamp assemblies	Recategorized into the category and subcategory “Automotive and aerospace products – Transportation equipment manufacturing.”	Commercial use – Automotive and aerospace products –Transportation equipment manufacturing.
Commercial Use – Water treatment products	Water filtration applications	Removed category and subcategory in response to information provided by the company.	N/A
Commercial – Ink, toner, and colorant products	Ink, toner, and colorant products	Removed; no recent information was reasonably available to support this as an ongoing use of phthalic anhydride.	N/A
Commercial Use – Plastic and rubber products	Plastic and rubber products	Updated subcategory to “Other articles with routine direct contact during normal use including rubber articles; plastic articles” to better reflect 2020 and 2024 CDR reporting codes.	Commercial Use – Other articles with routine direct contact during normal use including rubber articles; plastic articles
Commercial Use – Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere (*e.g.,* epoxy resin work surface)	Updated subcategory to better reflect 2020 CDR reporting codes	Commercial use – Construction products – Construction and building materials covering large surface areas

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Commercial – Furniture and furnishings not covered elsewhere	Oil treatment of wood, indoors	Updated subcategory to better reflect 2020 CDR reporting codes	Commercial use – Furniture and furnishings – Oil treatment of wood
Consumer Use – Arts, Crafts, and Hobby Materials	N/A	Category and subcategory added based on 2024 CDR reporting and reasonably available consumer products	Arts, crafts, and hobby materials (*e.g.,* clear casting resins)

Appendix E CONDITIONS OF USE DESCRIPTIONS

The following COU descriptions are based on CDR use codes and reflect the reasonably available information regarding COUs that the Agency has identified during the risk evaluation. The descriptions are intended to include examples of uses, so as not to exclude other activities that may also be included, in the COUs of phthalic anhydride. To better describe the COUs, EPA considered CDR submissions for phthalic anhydride from the last two CDR cycles (U.S. EPA, 2024, 2020a) for and other reasonably available information, including stakeholder engagements, published literature, company websites, government and commercial trade databases and publications.

The COU descriptions reflect what EPA identified as the best fit for that submission. Examples of articles, products, or activities are included in the following descriptions to help describe the COU but are not exhaustive. EPA uses the terms "articles" and "products" or "product mixtures" in the following descriptions and is generally referring to articles and products as defined by 40 CFR Part 751. There may be instances where the terms are used interchangeably by a company or commenters, or by the Agency in reference to a code from the CDR reports that are referenced; for example, "plastics products manufacturing," or "fabric, textile, and leather products." EPA will clarify as needed when these references are included throughout the COU descriptions below.

E.1 Manufacture – Domestic Manufacture

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

Phthalic anhydride is largely manufactured through the oxidation of *o*-xylene in the vapor phase over a fixed bed of catalyst (Park and Sheehan, 2000). The fixed bed reactors comprise multiple tubes and use catalysts of vanadium oxide and titanium oxide. Phthalic anhydride can also be manufactured through the oxidation of coal-tar naphthalene in a fixed-bed reactor in the presence of catalyst; however, this method is less popular due to lower phthalic anhydride yield compared with using *o*-xylene (Park and Sheehan, 2000). Manufacturers have reported producing phthalic anhydride as a liquid, dry powder, and pellets/large crystals.

Examples of CDR Submissions

In the 2020 CDR cycle, four companies reported importing of phthalic anhydride.

E.2 Manufacture – Import

This COU refers to the import of phthalic anhydride into the customs territory of the United States. In general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal shipments (Tomer and Kane, 2015). These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers.

Phthalic anhydride is shipped in liquid, pellet/large crystal, dry powder, and other solid form. EPA expects that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into different sized containers, depending on customer demand, and QC samples may be taken for analyses.

Examples of CDR Submissions

In the 2020 CDR cycle, 15 companies reported importing of phthalic anhydride.

E.3 Processing – As a Reactant – Intermediate in: All Other Basic Organic Chemical Manufacturing; Plastics Material and Resin Manufacturing; Plastics Product Manufacturing; Construction; Paint and Coating Manufacturing; Flame Retardant Manufacturing

This COU refers to the use of phthalic anhydride as a feedstock in the production of another chemical via a chemical reaction in which phthalic anhydride is typically consumed to form the product. Specifically, phthalic anhydride is used as an intermediate to produce (U.S. EPA, 2024, 2020a; Park and Sheehan, 2000):

- phthalates that are subsequently used as plasticizers in polyvinyl chloride (PVC);
- polyester that is used in building and construction materials;
- alkyd resins used in coatings; and
- a variety of other product mixtures and formulations including construction materials, flame retardants, and other chemicals.

Phthalic anhydride is often used as a reactant to create phthalic esters (*i.e.,* plasticizers), resins, and to synthesize other chemical substances. The resulting phthalate esters are expected to contain residual amounts, if any, of unreacted phthalic anhydride and can be used in a variety of products such as PVC, wire or cables, roofing membranes, water filtration products, and swimming pool liners (The Chemical Company, 2026). Although a reporting company confirmed that phthalic anhydride was not directly added to water filtration technologies, it is expected that phthalic anhydride is processed as a reactant to make plasticizers (with little to no remaining phthalic anhydride) that are later added to certain water filtration products (U.S. EPA, 2025c).

For flame retardant manufacturing, the bromination of phthalic anhydride in oleum results in tetrabromophthalic anhydride (TBPA), a common flame retardant incorporated during other product manufacturing such as plastics product manufacturing (The Chemical Company, 2026). Phthalic anhydride is expected to be fully consumed in the bromination reaction, so only residual amounts of phthalic anhydride, if any, are expected to remain in the resulting flame retardant.

Following completion of the reaction, the produced substance may be purified further, thus removing unreacted phthalic anhydride (if any exists). EPA plans to investigate the amount of residual phthalic anhydride that may be present in reaction products.

Examples of CDR Submissions

In the 2020 CDR cycle, seven companies reported processing as a reactant of phthalic anhydride as an intermediate in: all other basic organic chemical manufacturing, construction, paint and coating manufacturing, plastic material and resin manufacturing, and plastics product manufacturing. In the 2024 CDR cycle, five companies reported processing phthalic anhydride as a reactant as an intermediate: all other basic organic chemical manufacturing, paint and coating manufacturing, and plastic material and resin manufacturing.

There were no reports in the 2020 or 2024 CDR cycles for the use of phthalic anhydride in flame retardant manufacturing.

E.4 Processing – As a Reactant – Ion Exchange Agent in All Other Basic Organic Chemical Manufacturing

This COU refers to the use of phthalic anhydride in reactions for the manufacturing of another chemical substance or product, in this case the use of phthalic anhydride to produce an ion exchange agent used in basic organic chemical manufacturing processes.

The NLM's Hazardous Substances Databank identifies the use of phthalic anhydride in the manufacture of synthetic organic resins (glyptal) (citing the 2013 Merck Index) (U.S. EPA, 2020e). The artificial resins can be used as ion exchange agents to purify and control the composition of various chemicals and solutions by selectively removing ions from a solution (J Mark Systems, 2022).

Examples of CDR Submissions
In the 2020 CDR cycle, one company reported processing as a reactant of phthalic anhydride to produce an ion exchange agent in all other basic organic chemical manufacturing.

E.5 Processing – As a Reactant – Monomer Used in Plastics Material and Resin Manufacturing; All Other Basic Organic Chemical Manufacturing

This COU refers to the use of a phthalic anhydride in reactions for the manufacturing of another chemical substance or product, in this case the use of phthalic anhydride as a monomer used in plastic material and resin manufacturing as well as all other basic organic chemical manufacturing.

Chemicals used as monomers usually contain carbon, are of a low molecular weight, and have a simple structure that is capable of conversion to polymers, synthetic resins, or elastomers by repetitive combination with itself or other similar molecules.

Phthalic anhydride is used as a monomer in the synthesis of polymers, synthetic resins, or elastomers. Specifically, phthalic anhydride is used as a monomer in the preparation of synthetic resins such as glyptal, alkyd resins, epoxy resins, and polyester resins (PENPET, 2026; NCI, 1979).

Examples of CDR Submissions
In the 2020 CDR cycle, there were five company reports for the processing of phthalic anhydride as a reactant for use as a monomer in plastics material and resin manufacturing In the 2024 CDR cycle, five companies reported processing as a reactant of phthalic anhydride as a monomer in making plastic materials and resins and one company reported processing as a reactant of phthalic anhydride as a monomer in all other basic organic chemical manufacturing.

E.6 Processing – As a Reactant – Pigments in Printing Ink Manufacturing

This COU refers to the use of a phthalic anhydride in reactions for the manufacturing of another chemical substance or product, in this case the use of phthalic anhydride to produce pigments in printing ink manufacturing.

Phthalic anhydride is used as a raw material to synthesize organic pigments (Topfine Chemical, 2026). The resulting pigments usually come in the form of a dry powder and with a positive colorant value, and they impart color to another substance or mixture by attaching to the surface of the substrate through binding or adhesion.

Examples of CDR Submissions

In the 2020 and 2024 CDR cycles, one company reported processing as a reactant of phthalic anhydride to make pigment used in printing inks. In the final scope for phthalic anhydride, the 2016 CDR listed inks in printing ink manufacturing as a use, however the functional code was updated to "pigments" in the 2020 and 2024 CDR cycles. The updated code and COU is reflected here.

E.7 Processing – As a Reactant – Plasticizer in Plastics Product Manufacturing; Adhesive Manufacturing; Lubricant Additive Manufacturing

This COU refers to the use of phthalic anhydride in reactions for the manufacturing of another chemical substance or product, in this case the use of phthalic anhydride to produce plasticizers used in plastics product manufacturing, adhesive manufacturing, and lubricant additive manufacturing. Plasticizers soften synthetic polymers by increasing the flexibility, plasticity, fluidity and toughness of the final product by internal modification (solution) of the polymer molecule. A rigid polymer can also be externally plasticized by addition of a plasticizer, which imparts the desired flexibility but is not chemically changed by reaction with the polymer.

In this case, phthalic anhydride is expected to be fully consumed as a reactant in the production of plasticizers that are then added during plastics product manufacturing to enhance the flexibility and durability of plastics such as PVC. Similarly, phthalic anhydride is used to make plasticizers that are later used to produce lubricant additives that enhance lubricant's performance, reduce wear and tear, and increase their longevity. Only small residual (<5%) quantities of phthalic anhydride, if any, are expected to be present in the final products (U.S. EPA, 2020d).

For adhesive manufacturing, phthalic anhydride may be used as a reactant to make adhesives where polymerization takes place as part of the manufacturing process or to manufacture two-part adhesives where polymerization occurs later when users mix the two parts together. In both cases, high concentrations of phthalic anhydride may be used in the manufacturing process. In mounting adhesives, for example, 60 to 90% phthalic anhydride is added during polymerization to manufacture resins that are used to formulate the adhesives (Aremco, 2023).

In cases where polymerization takes place during the manufacturing process (like the mounting adhesives), most or all of the phthalic anhydride would be expected to be consumed in the chemical reaction, and has been recorded in residual quantities (<1%) in the final adhesive (Henkel, 2023; Hernon, 2020; Henkel, 2018). However, a higher concentration of phthalic anhydride has been identified in a subset of products where the polymerization takes place later during the use of the adhesive, such as two-part electronic encapsulant adhesives where a hardener containing 5 to 10% phthalic anhydride is mixed with a separate resin material to trigger polymerization and create a solid, durable material (Lord Corporation, 2020).

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as a plasticizer in adhesive manufacturing. In the 2020 and 2024 CDR cycles, another company reported the use of phthalic anhydride as a plasticizer in plastics product manufacturing.

There were no submissions in the 2020 or 2024 CDR cycles reporting the use of phthalic anhydride in lubricant and lubricant additive manufacturing.

E.8 Processing – As a Reactant – Polymerization Promoter in Synthetic Dye and Pigment Manufacturing

This COU refers to the use of phthalic anhydride in reactions for the manufacturing of another chemical substance or product, in this case the use of phthalic anhydride as a polymerization promoter in synthetic dye and pigment manufacturing.

Polymerization promoters enable a reaction between two or more dissimilar polymers. In this case, EPA expects that phthalic anhydride is fully consumed in the reaction to synthesize dye intermediates such as anthraquinone, chloroanthraquinone, phenolphthalein, and other phthalein's that are later used to produce ink, dye, toner, and colorant products (Douwin Chemical, 2026; U.S. EPA, 2020e; Larranaga et al., 2016).

Kirk-Othmer also identifies the use of phthalic anhydride to derive D&C Yellow Nos. 10 & 11 (Gregory, 2009). Phthalic anhydride is fully consumed in the reaction and only residual amounts of phthalic anhydride are expected to remain in the resulting dye intermediates.

Examples of CDR Submissions

In the 2020 and 2024 CDR cycles, one company reported the use of phthalic anhydride to make polymerization promoters used in synthetic dye and pigment manufacturing.

E.9 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Binder in Paint and Coating Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 binder in paint and coating manufacturing.

Chemical binders are either synthetic or polymeric resins that further polymerize, provide structure and cohesiveness or are substances added to compounded dry powders to provide adhesive qualities during and after compression to make tablets or cakes.

Phthalic anhydride may be directly added into a paint or coating formulation as a binder or processed as a reactant to manufacture alkyd resins that are added as a binder to paint and coating formulations to improve their flexibility, adhesion, and durability (Green Gubre Group, 2021). Only residual (<5%) amounts of phthalic anhydride are expected to remain in the alkyd resins that are added to paint and coating formulations.

Examples of CDR Submissions

In the 2024 CDR cycle, one company reported the use of phthalic anhydride as a binder in paint and coating manufacturing.

E.10 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Dyes in Synthetic Dye and Pigment Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 dye in synthetic dye and pigment manufacturing.

Chemical dyes are used to impart color to other materials or mixtures and generally require some degree of solubility to allow the dye to dissolve or disperse in mixtures or diffuse into the polymeric matrix. The chemical dyes are generally molecularly dispersed within a liquid, transferred to a material, and bound to that material through intermolecular forces.

In this case, EPA expects that phthalic anhydride is not directly added as a raw material in synthetic dye and pigment manufacturing. Rather, it is likely used as a reactant to synthesize dye intermediates such as anthraquinone, chloroanthraquinone, phenolphthalein, and other phthaleins that are later used to produce ink, dye, toner, and colorant products (Douwin Chemical, 2026; U.S. EPA, 2020e; Larranaga et al., 2016).

Examples of CDR Submissions

In the 2024 CDR cycle, one company reported the use of phthalic anhydride in dyes used in synthetic dye and pigment manufacturing.

E.11 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Flame Retardant in Plastics Product Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 flame retardant in plastics product manufacturing.

Flame retardants alter the normal degradation or combustion processes of plastics, rubbers, textiles, papers and woods. They are used on the surface of or incorporated into combustible materials to reduce or eliminate their tendency to ignite when exposed to heat or a flame for a short period of time.

In this case, phthalic anhydride is processed as a reactant via the bromination of phthalic anhydride in oleum, producing tetrabromophthalic anhydride (TBPA), a common flame retardant. This flame retardant is then incorporated into formulation during plastics product manufacturing (The Chemical Company, 2026). Phthalic anhydride is expected to be fully consumed during the bromination reaction, and only residual amounts, if any, of phthalic anhydride are expected to remain in the resulting flame retardant that is used in plastics product manufacturing.

Examples of CDR Submissions

In the 2024 CDR cycle, one company reported the use of phthalic anhydride to make flame retardants used in plastics product manufacturing.

E.12 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Hardener in Adhesive Manufacturing; Epoxy Resin Casting; Paint and Coating Manufacturing; Rubber Product Manufacturing; Solvent-based Paint Manufacturing; Utilities

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 hardener in adhesive manufacturing, epoxy resin casting, paint and coating manufacturing, solvent-based paint manufacturing, rubber product manufacturing, and utilities.

Chemical hardeners are used to increase the strength, hardness, and abrasion resistance of coatings, adhesives, sealants, elastomers, and other products. They're also referred to as curative or curing agents. For utilities, the CDR reporting company (Huntsman) shared that unreacted phthalic anhydride is present in the hardener side of a two-part system used to make heavy electrical parts such as electrical insulators and bushings, switchgears, and instrument transformers. These parts are then used in power transmission (U.S. EPA, 2025d).

An inhalation monitoring study reported the use of raw phthalic anhydride as a hardener/curing agent in epoxy resin casting operations for manufacturing countertops (Tustin et al., 2022). The epoxy resin casting mixture containing phthalic anhyride is heated and used to help shape and solidify the countertops. Dust emitted when sawing the countertops into their final form contained 2 to 14% phthalic anhydride, with the resin-specific particles in the dust containing 26 to 85% phthalic anhydride countertops (Tustin et al., 2022). Another study identified 26 to 76% phthalic anhydride in engineered stone materials (Ramkissoon et al., 2023).

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as a hardener in adhesive manufacturing and rubber product manufacturing. In the 2020 CDR cycle, one company also reported the use of phthalic anhydride as a solvent in the utilities sector. However, based on information provided by the reporter, EPA understands that unreacted phthalic anhydride is generally used as a hardener for power infrastructure applications such as making heavy electrical parts (*e.g.,* electrical insulators and bushings, switchgears, and instrument transformers). These parts are then used in power transmission. EPA has recategorized the reported use as a hardener in power infrastructure utilities to more accurately reflect its application.

In the 2024 CDR cycle, one company reported the use of phthalic anhydride as a hardener in paint and coating manufacturing.

E.13 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Intermediate in All Other Basic Inorganic Chemical Manufacturing; All Other Basic Organic Chemical Manufacturing; Adhesive Manufacturing; Plastics Material and Resin Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 an intermediate in a variety of industrial uses.

Phthalic anhydride is often used as a reactant to create phthalic esters (*i.e.,* plasticizers), resins, and to synthesize other chemical substances. The resulting phthalate esters are expected to contain residual amounts, if any, of unreacted phthalic anhydride and are frequently used to make PVC. NLM's Hazardous Substance Databank (2015) explains that phthalic anhydride can be used as an intermediate during the manufacture of chemicals such as phthalates (including diallyl, dibutyl, diethyl, and dimethyl phthalates), benzoic acid, urethane polyester polyols, dioctyl phthalates (*e.g.,* di(2-ethylhexyl), isatoic anhydride, halogenated phthalic anhydrides, and phenolphthalein) (U.S. EPA, 2020e; NLM, 2015).

Phthalic anhydride has also been reportedly used as an intermediate in pharmaceutical and medicine manufacturing (U.S. EPA, 2024, 2020a). Pharmaceuticals meet the definition of "drug" in section 201 of the FFDCA, 21 U.S.C. § 321. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not considered a condition of use in the final scope document (U.S. EPA, 2020d).

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as an intermediate in processing for incorporation into formulation, mixture, or reaction product in all other inorganic chemical manufacturing. Although there was another company that reported the use of phthalic anhydride as an intermediate in plastics materials and resin manufacturing, EPA confirmed that phthalic anhydride is used as an intermediate during processing as a reactant. Therefore, EPA is not including the company's report under this COU.

In the 2024 CDR cycle, six companies reported the use of phthalic anhydride as an intermediate in processing for incorporation into formulation, mixture, or reaction product. Two companies reported the use of phthalic anhydride during plastic material and resin manufacturing. One company reported the use of phthalic anhydride in adhesive manufacturing, and another company reported the use of phthalic anhydride in plastics product manufacturing. One company reported the use of phthalic anhydride in all other inorganic chemical manufacturing, and another company reported the use of phthalic anhydride in all other organic manufacturing.

E.14 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Monomer in Plastic Material and Resin Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 monomer in plastic material and resin manufacturing.

Chemicals used as monomers usually contain carbon, are of a low molecular weight, and have a simple structure that is capable of conversion to polymers, synthetic resins, or elastomers by repetitive combination with itself or other similar molecules.

In this case, EPA expects that phthalic anhydride is not directly added as a raw material during plastic material and resin manufacturing. Rather, it is processed as a monomer to manufacture synthetic resins such as glyptal, alkyd resins, and polyester resins that are later used as a raw material to formulate plastic products. Since phthalic anhydride is chemically bound and fully consumed within the polymer via an esterification reaction, the resulting resins that are formulated into plastic materials contain either residual amounts or no phthalic anhydride (EPA-HQ-OPPT-2018- 0459-0004).

Examples of CDR Submissions

In the 2024 CDR cycle, five companies reported the use of phthalic anhydride as a monomer in plastic material and resin manufacturing.

E.15 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Paint Additives and Coating Additives in Plastics Material and Resin Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 paint and coating additive in plastic material and resin manufacturing.

Chemical paint and coating additives are used in a paint or coating formulation to enhance properties such as water repellence, increased gloss, improved fade resistance, ease of application, and foam prevention.

In this case, phthalic anhydride is likely not added directly as a raw material in paint and coating additives in plastics materials and resins. Rather, it can be processed as a reactant to manufacture alkyd resins/polymers that are later added to product formulations such as alkyd-based paint, roofing and coating materials, and solid color stains (EPA-HQ-OPPT-2018-0459; (The Chemical Company, 2026)). During the resin manufacturing process, phthalic anhydride is chemically bound and fully consumed within the polymer via an esterification reaction that results in either residual amounts or no phthalic anhydride in the alkyd polymers (EPA-HQ-OPPT-2018-0459-0051).

Examples of CDR Submissions

In the 2024 CDR cycle, one company reported the use of phthalic anhydride as a paint and coating additive in plastics material and resin manufacturing.

There were no reports in the 2020 or 2024 CDR cycles for the use of phthalic anhydride as a paint and coating additive in roofing and coating materials manufacturing or solid color stains manufacturing.

E.16 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Plasticizers in Plastic Material and Resin Manufacturing; Paint and Coating Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride into formulation, mixture, or a reaction product that occurs when phthalic anhydride is added to a product (or product mixture) after its manufacture, for distribution in commerce—in this case as a plasticizer in plastic material and resin manufacturing and paints and coatings manufacturing.

Plasticizers soften synthetic polymers by increasing the flexibility, plasticity, fluidity and toughness of the final product by internal modification (solution) of the polymer molecule. A rigid polymer can also be externally plasticized by addition of a plasticizer, which imparts the desired flexibility but is not chemically changed by reaction with the polymer.

In this case, phthalic anhydride is likely consumed in the production of plasticizers that are then added during plastic material and resin manufacturing and paint and coating manufacturing (*i.e.,* consumed as a reactant in the production of plasticizers used in these products) and is either not present or is present in small quantities in the final product (U.S. EPA, 2020d).

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as a plasticizer in paint and coating manufacturing. In the 2024 CDR cycle, two companies reported the use of phthalic anhydride as a plasticizer in plastics material and resin manufacturing and paint and coating manufacturing.

E.17 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Polymerization Promoter in All Other Basic Organic Chemical Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 polymerization promoter in all other basic organic chemical manufacturing.

Polymerization promoters enable a reaction between two or more dissimilar polymers, allowing them to become more intimately mixed than before. In this case, phthalic anhydride can be used as a polymerization promoter to facilitate the formation of polymer chains and synthesize polyester, polyamides, and other polymer materials (Topfine Chemical, 2026).

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as a polymerization promoter in all other basic organic chemical manufacturing.

E.18 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Pre-Catalyst Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 catalyst component in pre-catalyst manufacturing.

Phthalic anhydride is used in the manufacture of some pre-catalysts but_is not present in the final pre-catalyst products as it is completely degraded and consumed during the manufacture of polyolefins (W.R. Grace, 2024).

Phthalates and phthalic anhydride are included in the solids in the pre-catalyst at about 10%. The phthalate itself is not a catalyst but is a solid that is suspended in a solvent or an oil. The solid is 20 to 25% weight dry pre-catalyst, resulting in 2 to 2.5% of phthalate in the drums. That material is then sold to their customers (W.R. Grace, 2024).

Examples of CDR Submissions

This use was not reported during the 2020 or 2024 CDR cycles (U.S. EPA, 2019a). EPA was informed of this COU as a pre-catalyst component for polyolefins production during a meeting between W. R. Grace & Co and EPA to discuss phthalates in catalyst systems used in the manufacture of plastics (W.R. Grace, 2024).

E.19 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Processing Aid in Paint and Coating Manufacturing; Rubber Product Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 processing aid in paint and coating manufacturing and rubber product manufacturing.

Chemicals used as a processing aid improve the processing characteristics or the operation of process equipment when added to a process or to a substance or mixture to be processed. They do not become a part of the product, nor do they have a function in the product.

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as a processing aid in paint and coating manufacturing. In the 2024 CDR cycle, one company reported the use of phthalic anhydride as a processing aid in rubber product manufacturing.

E.20 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Retarder in Rubber Product Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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, this case as a retarder in rubber product manufacturing.

A chemical retarder is generally used to change the rate of a chemical reaction, start or stop the reaction, or otherwise influence the course of the reaction. Retarders may or may not be consumed or become a part of the reaction product.

According to one company, phthalic anhydride is primarily used as a scorch inhibitor and retarder in rubber product manufacturing, meaning it helps delay the curing process of the rubber mix and is typically added to the rubber compound during mixing as a powder or liquid solution (The Chemical Company, 2026).

Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of phthalic anhydride as a retarder in rubber product manufacturing.

E.21 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Solvent in Paint and Coating Manufacturing; Plastic Material and Resin Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of phthalic anhydride 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 solvent in paint and coating manufacturing and plastic material and resin manufacturing.

Chemical solvents are primarily used to dissolve another substance (solute) to form a uniformly dispersed mixture (solution) at the molecular or ionic size level; to suspend solid particles or colloidal materials to yield suspensions or gels, to provide dissolving capability required for a stable formulation; to dissolve certain components of the formulation to aid dispersion of components; and to aid in oil cleansing power and control film drying rate.

For paint and coating manufacturing, phthalic anhydride is used as a reactant to manufacture alkyd polymer resins, which are subsequently used to make industrial paints and coatings. Since phthalic anhydride is typically fully consumed in the reaction, only residual amounts, if any, of phthalic anhydride are expected to remain in the alkyd resins that are later used to formulate paints and coatings (EPA-HQ-OPPT-2018-0459).

Examples of CDR Submissions

In the 2020 cycle, one company reported the use of phthalic anhydride as a solvent in paint and coating manufacturing. In the 2024 CDR cycle, two companies reported the use of phthalic anhydride as a solvent in paint and coating manufacturing and plastics material and resin manufacturing.

In the 2020 and 2024 CDR cycles, one company reported the use of phthalic anhydride as a solvent in the utilities sector. However, based on information provided by the reporter, EPA understands that unreacted phthalic anhydride is generally used as a hardener for power infrastructure applications such as making heavy electrical parts (*e.g.,* electrical insulators and bushings, switchgears, and instrument transformers). These parts are then used for power transmission. EPA has therefore recategorized the reported use as a hardener during power infrastructure utility manufacturing to more accurately reflect its application.

E.22 Processing – Repackaging

This COU refers to the preparation of phthalic anhydride 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 phthalic anhydride from a bulk container into smaller containers but would not apply to the relabeling or redistribution of phthalic anhydride without removing the chemical substance from the original container in which it was supplied.

Examples of CDR Submissions

This use was not reported during the 2020 or 2024 CDR cycles.

E.23 Processing – Recycling

This COU refers to the process of treating generated waste streams (*i.e.,* which would otherwise be disposed of as waste), containing phthalic anhydride, that are collected, either on-site or transported to a third-party site, for commercial purpose.

According to 2018 TRI, 2,314,977 lb of phthalic anhydride were recycled. Of the phthalic anhydride waste that was recycled, 99.9% was recycled on site. EPA did not identify additional information related to phthalic anhydride recycling (U.S. EPA, 2019f).

E.24 Distribution in Commerce

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

E.25 Industrial and/or Commercial Use – Adhesives and Sealants

This COU refers to the industrial and commercial use of phthalic anhydride as a component of adhesive or sealant mixtures, meaning the use of phthalic anhydride after it has already been incorporated into an adhesive or sealant product or mixture, as opposed to when it is used upstream (*e.g.,* when phthalic anhydride is processed into the adhesive or sealant formulation). Examples of this COU include sealants for fuel tanks, temporary mounting adhesives, acrylic adhesives, aerospace sealants, and hot-melt adhesives.

Adhesives and sealants (including fillers and putties) are highly malleable materials used to repair, smooth over, or fill minor cracks in holes and buildings.

EPA expects that workers in an industrial or commercial setting are generally applying adhesives and sealants that already have phthalic anhydride incorporated as a plasticizer or synthetic resin. However, phthalic anhydride is largely consumed in reaction and/or is incorporated into polymers when used to manufacture plasticizers and resins, so no phthalic anhydride or only residual amounts (<1%) are expected to remain in the finished product (Henkel, 2023; Hernon, 2020; Henkel, 2018) (EPA-HQ-OPPT-2018-0459-0004).

Some formulators note that certain specialty products may contain amounts above 5%, such as in an SDS for an electronic encapsulant adhesive (5 to 10% phthalic anhydride) (Lord Corporation, 2020).

Examples of CDR Submissions

According to the 2020 CDR cycle, there was one report for the commercial use of phthalic anhydride in hot melt adhesives (*e.g.,* hot glue). There were no reports for this use in the 2024 CDR cycle.

E.26 Industrial and/or Commercial Use – Automative and Aerospace Products – Transportation Equipment Manufacturing

This COU refers to the industrial use of phthalic anhydride as a component of the transportation equipment manufacturing sector. This means the use of phthalic anhydride after it has already been incorporated into the product or mixture, as opposed to when it is used upstream.

For transportation equipment manufacturing, EPA understands examples of this COU include phthalic anhydride's use in the body/exterior, interior, and electrical systems of a vehicle, wiring assemblies, seat and console assemblies, and lamp assemblies. One comment from the Alliance and MEMA explained that phthalic anhydride is used in 253 production and replacement parts within the automobile industry, including in wiring assemblies, seat and console assemblies, and lamp assemblies (EPA-HQ-OPPT-2019-0131-0022). Within those products, the average scope of the relative mass of phthalic anhydride is less than 0.13 grams, rendering the amount of phthalic anhydride used to be small (EPA-HQ-OPPT-2019-0131-0022).

One comment from NASA also reported that phthalic anhydride is used for acceptance testing of foams used on human-rated spaceflight vehicles (EPA-HQ-OPPT-2018-0459-0041).

This COU was not reported in the 2020 or 2024 CDR cycles.

E.27 Industrial and/or Commercial Use – Construction Products – Construction and Building Materials Covering Large Surface Areas

This COU refers to the industrial and commercial use of phthalic anhydride as a component of building or construction materials covering large surface areas, meaning the use of phthalic anhydride after it has already been incorporated into the product or mixture, as opposed to when it is used upstream. This means the use of phthalic anhydride after it has already been incorporated into the product or mixture, as opposed to when it is used upstream.

The type of products being reported under this code are likely to be industrial, commercial, and consumer in nature. Examples of this use could include construction and building materials covering large surface areas such as paper articles, metal articles, stone, plaster, cement, glass, and ceramic articles.

Earthjustice commented that building materials known to contain phthalic anhydride include alkyd and epoxy coatings, paints, varnishes, adhesives, high-performance coatings; and rubber flooring that can expose construction workers and building occupants to phthalic anhydride when coatings containing the chemical are applied (EPA-HQ-OPPT-2018-0459-0015). Earthjustice also commented that phthalic anhydride is present, unreacted, in "wet-applied" building materials as they are delivered to a job site, including homes, schools, and workplaces (EPA-HQ-OPPT-2018-0459-0015).

According to Healthy Building Network, cyclic acid anhydrides, such as phthalic and maleic anhydrides, are commonly used in building materials such as polyester and alkyd resins and epoxy resin hardeners, which in turn are ingredients for a variety of products such as paints, varnishes, adhesives, high-performance coatings, and rubber flooring. These coatings may be factory-applied to other products or site-applied in buildings (Lott and Vallette, 2013)(EPA-HQ-OPPT-2018-0459-0015).

Examples of CDR Submissions

According to the 2020 and 2024 CDR cycle, there was one report for the commercial use of phthalic anhydride in building or construction materials covering large surface areas.

E.28 Industrial and/or Commercial Use – Metal and Electrical Products – Machinery, Mechanical Appliances, Electrical/Electronic Articles

This COU refers to the industrial and commercial use of phthalic anhydride as a component of machinery, mechanical appliances, and electrical or electronic articles, meaning the use of phthalic anhydride after it has already been incorporated into the product or mixture, as opposed to when it is used upstream.

The type of products being reported under this code are likely to be industrial, commercial, and consumer in nature. Examples of this use could include computers, office equipment, appliances, electric lighting, electrical wire and cables, radios, televisions and monitors, telephones, multimedia devices, digital cameras, adapters, alarms (burglar, fire, smoke), and communication equipment.

MEMA and the Alliance reported that their members use phthalic anhydride in electronic production parts for automobiles, including speaker and door wiring assemblies and door power seat wiring harnesses (EPA-HQ-OPPT-2019-0131-0022). In their internal data collection, the Alliance identified phthalic anhydride in 253 parts, including those in the electrical systems of the vehicle such as wiring, seat and console assemblies, and lamp assemblies. In total, the IMDS data system listed approximately 22,250 parts containing phthalic anhydride (EPA-HQ-OPPT-2019-0131-0022). Several other chemical companies list that phthalic anhydride is used in the manufacturing of phthalate plasticizers and resins for use in electrical and electronic components such as wires and cables (Douwin Chemical, 2026; GreenChem, 2026; The Chemical Company, 2026).

Examples of CDR Submissions

According to the 2020 CDR cycle, there was one report for the commercial use of phthalic anhydride in machinery and electronics. There were no reports for this use in the 2024 CDR cycle.

E.29 Industrial and/or Commercial Use – Other Uses – Laboratory Chemical

This COU refers to the commercial use of phthalic anhydride in laboratory chemicals as a chemical standard or reference material during analyses (ThermoFisher Scientific, 2022; Phenova, 2017, 2015) (EPA-HQ-OPPT-2018-0459-0041).

Some laboratory chemical manufacturers identify use of phthalic anhydride 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 phthalic anhydride by hand-pouring 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 understands that phthalic anhydride could be used as a product in analytical chemistry, research, equipment calibration, and sample preparation applications. Additionally, phthalic anhydride could be a component of resin products that are used in research (EPA-HQ-OPPT-2018-0451-0039). The Agency notes that the same applications and methods used for quality control can be applied in industrial and commercial settings, and both are included in this COU.

This use was not reported during the 2020 or 2024 CDR cycles.

E.30 Industrial and/or Commercial Use – Paints and Coatings

This COU refers to the industrial and commercial use of phthalic anhydride as a component of paints and coatings, meaning the use of phthalic anhydride after it has already been incorporated into the product or mixture, as opposed to when it is used upstream. EPA expects that phthalic anhydride may be present as a residual in resins incorporated into paints and coatings.

The type of products being reported under this code are likely to be industrial, commercial, and consumer in nature. Commercial manufacturers reported that phthalic anhydride can be added during the manufacturing of solvent-based paints, aerosol spray paints, and powder coatings. The largest outlet for phthalic anhydride in this category is producing solvent-based paints that have been formulated to have a solvent as the vehicle, such as alkyd-based paints (The Chemical Company, 2026). In powder coating applications, pre-prepared and electrostatically charged coating powder is applied directly to the surface and undergoes a curing process to produce a thicker coating than liquid paint (Nordson, 2023; Sahoo et al., 2017). Aerosol spray paints contain pigments or resins that are applied from a pressurized can and can help protect surfaces from abrasion, corrosion, grease, and slipping.

One comment from the American Coatings Association (ACA) explains that for these cases, phthalic anhydride is directly used as a reactant to manufacture alkyd resins that are later added as raw materials to formulate paints and coatings (EPA-HQ-OPPT-2018-0459-0039). Because phthalic anhydride is consumed in the reaction, only a residual amount (<1%) is expected to remain in the alkyd resins that go into paints and coatings, and the ACA claims that phthalic anhydride is not present in the resulting alkyd resins (EPA-HQ-OPPT-2018-0459-0039).

Examples of CDR Submissions

According to the 2020 CDR cycle, there were four reports for the commercial use of phthalic anhydride in paints and coatings. In the 2024 CDR cycle, three manufacturers reported the use of phthalic anhydride in solvent-based paints.

E.31 Industrial Use – Processing Aids, Specific to Petroleum Production – Hydraulic Fracturing

This COU refers to phthalic anhydride as it is used in various industrial sectors as a component of processing aids specific to petroleum production and hydraulic fracturing. This means the use of phthalic anhydride after it has already been incorporated into the product or mixture, as opposed to when it is used upstream. EPA expects that phthalic anhydride may be formulated into products used in the petroleum production industry and that phthalic anhydride may be present as a residual in additives incorporated into such products.

Chemical processing aids specific to petroleum manufacturing are added to water-, oil-, or synthetic-drilling muds or other petroleum production fluids to control viscosity, foaming, corrosion, alkalinity and pH, microbiological growth, formation of hydrates, etc., during the production of oil, gas, and other products from beneath the earth's surface.

In this case, one company, Finoric LLC, reported that phthalic anhydride is not typically used directly in oil and gas drilling operations. Rather, it is commonly incorporated as a chemical intermediate in the production of various additives used in drilling and completion fluids. These include dispersants, corrosion inhibitors, fluid loss additives, and epoxy curing agents. In these applications, phthalic anhydride contributes to the thermal stability, chemical resistance, and performance of the final formulated products (U.S. EPA, 2025b; Finoric LLC, 2019).

This use was not reported during the 2020 or 2024 CDR cycles.

E.32 Commercial Use – Fillers – Hardener

This COU refers to the commercial use of phthalic anhydride already incorporated in fillers, specifically in hardeners such as epoxy hardeners. This means the use of phthalic anhydride-containing fillers in a commercial setting, such as a business or at a job site, as opposed to upstream use of phthalic anhydride or in an industrial setting.

Chemical hardeners are used to increase the strength, hardness, and abrasion resistance of coatings, adhesives, sealants, elastomers, and other products. There are existing epoxy hardeners that contain phthalic anhydride. A safety data sheet from 2020 reports 1 to 5% of phthalic anhydride as an ingredient in an epoxy hardener product called CoolTherm EP-6029 that is a rigid, two-component epoxy system that is used for potting high voltage transformers where thermal shock is expected, specifically in units designed for high temperature service (Lord Corporation, 2023, 2020).

Another safety data sheet from 2023 reports 0.1 to 0.5% of phthalic anhydride as an ingredient in a silver-filled epoxy hardener product called SEC1244 B, which is a two-component, elevated temperature curing epoxy adhesive that provides conductivity for many electronic applications (ResinLab, 2023).

This use was not reported during the 2020 or 2024 CDR cycles.

E.33 Commercial Use – Furniture and Furnishings– Oil Treatment of Wood

This COU refers to the commercial use of phthalic anhydride already incorporated in furniture and furnishings not covered elsewhere, specifically in oil treatment of wood used indoors. This means the use of phthalic anhydride-containing furniture and furnishing materials in a commercial setting, such as a business or at a job site, as opposed to upstream use of phthalic anhydride or in an industrial setting.

Chemical substances contained in furniture and furnishings made from wood that are intended for consumer or commercial use fall under this use. A SDS from 2023 reports less than 1 to 15% of phthalic anhydride as an ingredient in a Rustic Worktop Oil, a hardening urethane oil for priming and protecting untreated or sanded wooden surfaces such as worktops and floors (Junckers Industries A/S, 2023).

This use was not reported during the 2020 or 2024 CDR cycles.

E.34 Commercial Use – Other Articles with Routine Direct Contact During Normal Use Including Rubber Articles; Plastic Articles (Hard); Other (Rubber Products)

This COU refers to the commercial use of phthalic anhydride as it is used as a component of plastic and rubber products not covered elsewhere, meaning the use of phthalic anhydride-containing articles in a commercial setting, such as a business or at a job site, as opposed to upstream use of phthalic anhydride or in an industrial setting. EPA expects that phthalic anhydride may be formulated into products used in the plastic rubber industry and that phthalic anhydride may be present as a residual in plasticizers incorporated into such products.

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

NLM's Hazardous Substance Databank explains that phthalic anhydride can be used during the manufacture of phthalate plasticizers such as dibutyl, isatoic anhydride, halogenated phthalic anhydrides, diallyl phthalate, urethane polyester polyols, and phenolphthalein (U.S. EPA, 2020e; NLM, 2015).

Examples of CDR Submissions

According to the 2020 CDR cycle, there was one report for the commercial use of phthalic anhydride in other (rubber products). In the 2024 CDR cycle, one manufacturer reported the use of phthalic anhydride in other articles with routine direct contact during normal use including rubber articles and hard plastic articles.

E.35 Consumer Use – Adhesives and Sealants

This COU refers to the consumer use of phthalic anhydride in adhesives and sealants. EPA understands phthalic anhydride is primarily used to manufacture synthetic resins that are later used to make sealants and adhesives for consumer markets, specifically hot-melt adhesives. However, phthalic anhydride is expected to be largely consumed in reaction and/or incorporated into polymers in this use case scenario, so only residual amounts would be expected to remain in the finished product.

In some cases, formulators note that certain specialty products may contain phthalic anhydride in amounts above 1%, such as in two-part electronic encapsulant adhesives (Lord Corporation, 2020). In two-part adhesives, phthalic anhydride is used to trigger polymerization when consumers mix a hardener containing 1 to 5% phthalic anhydride (Part A) with a separate resin material (Part B) to create a solid, durable material (Epoxy Technology, 2020; Lord Corporation, 2020).

Examples of CDR Submissions

According to the 2020 CDR cycle, one company reported use of phthalic anhydride as a consumer use in hot-melt adhesives (*i.e.,* hot glue). This consumer use was not reported in the 2024 CDR cycle.

E.36 Consumer Use – Arts, Crafts, and Hobby Materials – Clear Casting Resin

This COU refers to the consumer use of phthalic anhydride in arts, crafts, and hobby materials, specifically in clear casting resins. Phthalic anhydride is often added to a catalyst or curing agent mixture that combines with resin monomers to make clear casting resin (Environmental Technology, 2012a; CDPH, 1989). The finished product can be used to embed or encase almost any object in clear plastic. Some common consumer applications include casting coins, shells, rocks, dried flowers, insects, paper and photographs (Environmental Technology, 2012a).

This condition of use was originally covered under the Consumer use – other articles with routine direct contact during normal use including rubber articles; plastic articles (hard) COU and the Consumer use – other – rubber products COU (U.S. EPA, 2020d). However, it was later determined that the use is its own COU because exposure to the casting resin curing agent or uncured casting resin has been found to have unique adverse side effects on users. These side effects can include fertility problems; irritation of the eyes, nose, throat, and skin; skin allergies; asthma; and burns on the inside of user's lungs following their use of the resin (CDC, 2024; CDPH, 1989).

This use was not reported during the 2020 or 2024 CDR cycles.

E.37 Consumer Use – Paints and Coatings – Solvent-Based Paints

This COU refers to the consumer use of phthalic anhydride in paints and coatings, meaning the use of phthalic anhydride-containing paints and coatings in a consumer setting, as opposed to upstream use of phthalic anhydride. EPA expects that phthalic anhydride may be formulated into products used in the paints and coatings industry and that phthalic anhydride may be present as a residual in plasticizers and synthetic resins incorporated into such products.

EPA understands examples of this COU could include commercial and residential solvent-based paints. According to a commenter, one example of phthalic anhydride's use in paints and coatings to manufacture plasticizers that are then used in synthetic resins. In turn, the synthetic resins act as raw materials used to make paints and coatings for consumer markets. Specifically, phthalic anhydride is used as a monomer to make synthetic resins such as alkyd resins. Alkyd resins are then used as binders in several types of coatings for consumer use. As such, alkyd resins aid the curing process to form a solid as paint dries. Coatings with alkyd resins have fast drying times and can be applied to a variety of substrates (EPA-HQ-OPPT-2018-0459-0004). In these cases, only residual amounts of phthalic anhydride in the alkyd resin are expected to remain in the final paint products (Junckers Industries A/S, 2023). However, in other cases, higher concentrations of phthalic anhydride ranging from 1 to 25% have also been identified in paint and coating formulations (Harris Paints, 2025b, 2015; Waterlox Coatings Corporation, 2015). EPA is requesting comment on the use of phthalic anhydride in these paint and coating products and will consider any additional information in the development of the final risk evaluation.

Examples of CDR Submission

According to the 2020 and 2024 CDR cycles, one company reported the consumer use of phthalic anhydride in paints and coatings, specifically in solvent-based paints.

E.38 Disposal

Each of the COUs of phthalic anhydride may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. For purposes of the phthalic anhydride risk evaluation, this COU refers to phthalic anhydride in a waste stream that is collected from facilities or commercial sites and is unloaded at and treated or disposed at third-party sites.

This COU also encompasses phthalic anhydride contained in wastewater discharged by occupational users to a POTW or other, non-POTW for treatment, as well as other wastes. Phthalic anhydride 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 phthalic anhydride or transport containers). Disposal may also include destruction and removal by incineration. Recycling of phthalic anhydride and phthalic anhydride-containing products is considered a different COU. Environmental releases from manufacturing and processing sites that treat or dispose onsite waste are assessed in each COU.

Additionally, phthalic anhydride has been identified in EPA’s Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States, December 2016 appendices document to be a chemical reported to be detected in produced water, which is subsequently disposed (U.S. EPA, 2016).

Appendix F DRAFT OCCUPATIONAL EXPOSURE VALUE DERIVATION

Based on the available hazard and exposure profile for phthalic anhydride, EPA has calculated an 8-hour time-weighted average (TWA) existing chemical occupational exposure value and a 15-minute short-term occupational exposure value (STEV). The calculated values may be used to support risk management efforts for phthalic anhydride under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the value rounded to 0.01 mg/m^3 (0.002 ppm) for inhalation exposures to phthalic anhydride as an 8-hour TWA and for consideration in workplace settings (see Appendix F.1 below) based on the non-cancer human equivalent concentration (HEC) for respiratory sensitization. EPA expects that at the occupational exposure value of 0.01 mg/m^3 (0.002 ppm) (including a total uncertainty factor of 30×), workers and occupational non-users (ONUs) also would be protected against non-cancer health effect from acute, intermediate, and chronic duration occupational exposures. EPA has also separately calculated a 15-minute STEV of 0.28 mg/m^3 (approximately 0.046 ppm) for phthalic anhydride (see Appendix F.2 for details).

TSCA requires risk evaluations to be conducted without consideration of cost and other nonrisk factors, and thus this occupational exposure value represents a risk-only number. If risk management for phthalic anhydride is implemented following public release of the final risk evaluation, EPA may consider cost and other nonrisk factors, such as analytical feasibility, technological feasibility, the availability of alternatives, and the potential for critical or essential uses. Any existing chemical exposure limit (ECEL) established for occupational safety risk management purposes could differ from the occupational exposure value presented in this appendix based on additional consideration of exposures and nonrisk factors consistent with TSCA section 6(c).

This calculated value for phthalic anhydride represents the exposure concentration below which the corresponding MOEs will fall below the benchmark MOE for exposed workers and occupational non-users, accounting for PESS. The value is derived based on the most sensitive human health effect (*i.e.,* respiratory sensitization) relative to benchmarks and a standard occupational scenario assumption of an 8-hour workday. The calculated value is intended to protect against new cases of respiratory sensitization.

EPA conducted a search to identify relevant NIOSH, OSHA, and EPA analytical methods used to monitor the presence of phthalic anhydride in air. Table_Apx F-1 presents validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for phthalic anhydride. The sources used for the search included the following:

1. NIOSH Manual of Analytical Methods (NMAM); 5th Edition
2. NIOSH NMAM; 4th Edition (accessed November 12, 2025)
3. OSHA Index of Sampling and Analytical Methods (accessed November 12, 2025)
4. EPA Environmental Test Method and Monitoring Information (accessed November 12, 2025)

The OSHA 90 analytical method can be used for detecting phthalic anhydride in occupational air sampling. The reliable limit of quantification (LOQ) of the OSHA 90 method is 0.008 ppm (0.048 mg/m^3) based on a 75-liter air sample (Table_Apx F-1). The draft 8-hour TWA occupational exposure value (0.01 mg/m^3), but not the draft 15-minute STEV (0.28 mg/m^3), is below the reliable quantitative limit of the OSHA 90 method. However, of the identified occupational monitoring data for phthalic anhydride, there have been measured workplace air concentrations below the calculated occupational exposure value as part of this draft risk evaluation (Section 4.1.1). EPA considered that increasing the sampling duration and sampled air volume to 480 L (using the same flow rate of 1.0 L/min × 480 min =

480 L sample) can decrease the analytical method limit of detection (LOD) and LOQ to 0.005 mg/m³ and 0.008 mg/m³, respectively. However, OSHA selected a 75-liter sampling volume with a flow rate of 1 L/min for the OSHA 90 Method, rather than a higher value; it is possible that a higher value of 480 L would result in sample breakthrough and therefore there is additional uncertainty in the LOD and LOQs for an 8-hour TWA. EPA is seeking input on air monitoring methods (including uncertainties in existing methods such as OSHA 90) through public comment of this draft assessment.

The calculated STEV is above the LOD and LOQ using at least one of the monitoring methods identified in Table_Apx F-1; the occupational exposure value is below the LOD and LOQ.

Table_Apx F-1. Limit of Detection (LOD) and Limit of Quantification (LOQ) Summary for Air Sampling Analytical Methods Identified for Phthalic Anhydride

Air Sampling Analytical Methods	Year Published	Scenario	LOD[a]	LOQ[b]	Source and Notes
OSHA Method 90	1991	Based on Method reporting Limit	0.005 ppm (0.031 mg/m^3)	0.008 ppm (0.048 mg/m^3)	OSHA Index of Sampling and Analytical Methods (accessed March 27, 2026) LOD and LOQ are based on a 75 L sample
		15-min Sample	0.16 mg/m^3	0.24 mg/m^3	Note: Flow rate 1.0 L/min × 15 min = 15 L sample

LOD = limit of detection; LOQ= limit of quantification; ppm = parts per million

[a] The detection limit of the overall procedure is 2.34 µg per sample (0.005 ppm, 0.031 mg/m^3). This is the amount of analyte spiked on the sampling device that allows recovery of an amount equivalent to the detection limit of the analytical procedure.

[b] The reliable quantitation limit is 3.59 µg per sample (0.008 ppm, 0.048 mg/m^3). This is the smallest amount of analyte spiked on the sampling device that can be quantified within the requirements of ta recovery of at least 75% and a precision (±1.96 SD) of ±25% or better.

OSHA has set a permissible exposure limit (PEL) as an 8-hour TWA for phthalic anhydride of 12 mg/m^3 (or 2 ppm) in 1971. In 1989, OSHA lowered the 8-hour TWA PEL for phthalic anhydride to 1 ppm or 6 mg/m^3; however, the rule was vacated in 1991 and the prior PEL of 2 ppm or 12 mg/m^3 from 1971 was reinstated (https://www.osha.gov/annotated-pels; accessed March 27, 2026). As noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSHA) Act in 1970 and have not been updated since that time." Prior to establishing an OSHA PEL, OSHA goes through a process that includes both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act. EPA's calculated occupational exposure value is based on available toxicological and human health information more recent than the OSHA PEL.

Other governmental agencies and independent groups have also set recommended exposure limits for phthalic anhydride (see Table_Apx F-2). Available occupational limit values (TWA) vary by greater than three orders of magnitude, with the lowest value being 0.002 mg/m^3 (U.S. ACGIH and Ontario Canada) and the highest value being 12 mg/m^3 (U.S. OSHA). Similarly, derived short-term exposure values range from 0.005 mg/m^3 (U.S. ACGIH and Ontario Canada) to 24 mg/m^3 (South Africa – Mining).

6228 **Table_Apx F-2. Summary of Occupational Exposure Limits for Phthalic Anhydride**

Country	Limit Value (8-hour TWA)		STEL (15-minute)		Notes / Reference[a]
	ppm	mg/m³	ppm	mg/m³	
U.S. EPA Proposed Values	0.002	0.01	0.046	0.28	- Draft values derived in Appendices F.1 and F.2 of this draft risk evaluation
Australia	1	6.1	–	–	- Based on 1991 ACGIH TLV documentation - Safe Work Australia – Hazardous Chemical Information System
Austria	–	1	–	2	- STEL is a ceiling limit value (5 minutes) - GESTIS – International Limit Values
Belgium	1	6.2	–	–	- GESTIS – International Limit Values
Canada – Ontario	–	0.002	–	0.005	- Based on 2017 ACGIH TLV documentation - Occupational Exposure Limits for Ontario Workplaces
Canada – Quebec	1	6.1	–	–	- GESTIS – International Limit Values
Denmark	–	1	–	2	- GESTIS – International Limit Values
Finland	–	0.2	–	–	- Established in 1993 - Ministry of Social Affairs and Health – HTP values 2025: Concentrations known to be harmful
France	–	–	–	6	- GESTIS – International Limit Values
Hungary	–	1	–	1	- GESTIS – International Limit Values
Ireland	–	1	–	12	- Health and Safety Authority – 2021 Code of Practice
Japan	–	–	0.33	2	- Established in 1998 - STEL is a ceiling limit value - Japan Society for occupational Health
Latvia	–	1	–	–	- GESTIS – International Limit Values
New Zealand	0.002	0.01	–	–	- Established in 2019 - WorkSafe New Zealand
Norway	–	2	–	–	- GESTIS – International Limit Values
People's Republic of China	–	–	–	1	- STEL is a ceiling limit value - GESTIS – International Limit Values
Poland	–	1	–	2	- GESTIS – International Limit Values
Romania	0.3	2	0.8	5	- GESTIS – International Limit Values
Singapore	1	6.1	–	–	Workplace Safety and Health (General Provisions) Regulations
South Africa	0.004	–	0.01	–	- Regulations for Hazardous Chemical Agents, 2021
South Africa Mining	1	6	4	24	- Established in 2006 - Mine Health and Safety Council
South Korea	1	–	–	–	- GESTIS – International Limit Values
Spain	1	6	–	–	- GESTIS – International Limit Values
Sweden	0.03	0.2	0.06	0.4	- Established in 2011 - Swedish Work Environment Authority
Switzerland	–	1	–	1	- GESTIS – International Limit Values
United Kingdom	–	4	–	12	- Health and Safety Executive: EH40/2005 Workplace Exposure Limits
USA – ACGIH	0.0003	0.002	0.0009	0.005	- Adopted in 2017 - ACGIH
USA – NIOSH	1	6	–	–	- NIOSH
USA – OSHA	2	12	–	–	- Adopted in 1971

Country	Limit Value (8-hour TWA)		STEL (15-minute)		Notes / Reference[a]
	ppm	mg/m^3	ppm	mg/m^3	
					- OSHA

[a] All websites/hyperlinks provided in this table were last accessed on February 25, 2026.
'–' indicates that no value is available.

F.1 Occupational Exposure Value Calculations

This appendix section presents the calculations used to estimate the occupational exposure value using inputs derived in this draft risk evaluation. It presents calculations for the non-cancer occupational exposure value, which would be protective against non-cancer health effects from acute, intermediate, and chronic duration occupational exposures. For phthalic anhydride, the occupational exposure value is based on respiratory sensitization and the resulting 8-hour TWA is rounded to 0.01 mg/m^3 (0.002 ppm). EPA has also separately calculated a 15-minute STEV of 0.28 mg/m^3 for phthalic anhydride (see Appendix F.2 for details).

Non-Cancer Occupational Exposure Value

The occupational exposure value (EV) was calculated by dividing the HEC by the total uncertainty factor using Equation_Apx F-1:

Equation_Apx F-1.

$$\mathrm{EV}\,(\mathrm{mg/m^3}) = \frac{\mathrm{HEC}}{Total\ UF} \times \frac{\mathrm{AT_{HEC}}}{ED} \times \frac{\mathrm{IR_{resting}}}{\mathrm{IR_{workers}}} =$$

$$\frac{0.4\ \mathrm{mg/m^3}}{30} \times \frac{\frac{8h}{d}}{\frac{8h}{d}} \times \frac{1.25\,\frac{\mathrm{m^3}}{h}}{1.25\,\frac{\mathrm{m^3}}{h}} = 0.01\ mg/m^3$$

$$\mathrm{EV}\quad (ppm) = \frac{EV\ mg/m^3\ \times\ Molar\ Volume}{MW} = \frac{0.01\ \mathrm{mg/m^3}\ \times\ 24.45\ \frac{L}{mol}}{148.1\ \frac{g}{mol}} = 0.002\ ppm$$

Where:

AT_{HEC} = Averaging time for the POD/HEC used for evaluating non-cancer occupational risk based on study conditions (8 h/day). Note: the HEC for phthalic anhydride is an 8-hour TWA from a human occupational epidemiological study reported by Nielsen et al. (1988) (see Section 4.2.2.1).
Total UF = Total uncertainty factor of 30 (see Section 4.2.2.1)
EV = Occupational exposure value
ED = Exposure duration (8 h/day)
HEC = Human equivalent concentration for non-cancer occupational exposure scenarios. Note: the HEC for phthalic anhydride is an 8-hour TWA from a human occupational epidemiological study reported by Nielsen et al. (1988) (see Section 4.2.2.1).

IR = Inhalation rate (default is 1.25 m^3/h for workers). Note: the HEC for phthalic anhydride is an 8-hour TWA from a human occupational epidemiological study by Nielsen et al. (1988) (see Section 4.2.2.1).
Molar Volume = 24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW = Molecular weight of phthalic anhydride (148.1 g/mole)

As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p) and Section 4.2.2 of this draft risk evaluation, EPA has preliminarily concluded that the best available science supports application of a total uncertainty factor of 30× in the draft risk evaluation. However, EPA is seeking SACC and public input on the underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride, as well as the severity of the effect observed at the LOAEC that serves as the basis of the inhalation POD. Based on SACC and public feedback, the overall total uncertainty factor may be revised in the final phthalic anhydride risk evaluation to 10 or 100. Because the total uncertainty factor may be revised in the final phthalic anhydride risk evaluation, EPA has also calculated 8-hour TWA occupational exposure values of 0.04 mg/m^3 (0.007 ppm) (based on a total UF of 10×) and 0.004 mg/m^3 (0.0007 ppm) (based on a total UF of 100×).

F.2 Short-Term Occupational Exposure Value Derivation

According to *Current Intelligence Bulletin 69: NIOSH Practices in Occupational Risk Assessment* (NIOSH, 2020), a short-term occupational exposure value (described as a short-term exposure limit [STEL] in (NIOSH, 2020)) should be derived if there is a concern for effects following short-term exposure at 15-mine concentrations. The 8-hour TWA most sensitive occupational exposure value would prevent 15-min exposures above 32× that value (based on 32 15-min periods in 8 hours), assuming only a single 15-min chemical exposure in one day. Therefore, if short-term health effects are expected and can be quantified with a derived STEV lower than 32× the most sensitive EV, implementing a short-term exposure value could be justified.

As described in Appendix F.1, EPA derived an exposure value (EV) of 0.01 mg/m^3 (0.002 ppm) as an 8-hour TWA based on respiratory sensitization with a total uncertainty factor of 30. The 8-hour TWA exposure value was extrapolated from a 30-minute peak exposure value of 6.6 mg/m^3 measured in the study by Nielsen et al. (1988). The 30-minute peak exposure value was adjusted to a 15-minute value using the principles of ten Berge (ten Berge et al., 1986), where Haber's Law is adjusted by the use of an exponent to create a more shallow slope, resulting in a more health-protective value when extrapolating to shorter durations. Phthalic anhydride does not have a published exponent value in (ten Berge et al., 1986). Therefore, EPA set the exponent value (n) to a value of 3.0. This is consistent with NIOSH IDLH guidance (NRC, 2001), and the Standard Operating Procedure for AEGLs (NIOSH, 2013), both of which suggest that a default of 3.0 may be used in the absence of chemical-specific data, while some AEGLs have been derived using 2.0 in the absence of data (https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28642.pdf; accessed March 27, 2026).

The most sensitive occupational exposure value for phthalic anhydride is 0.01 mg/m^3 (0.002 ppm) based the non-cancer human equivalent concentration (HEC) for respiratory sensitization, based on an 8-hour TWA. The calculated short-term exposure value of 0.28 mg/m^3 is lower than the 15-min TWA occupational exposure value equivalent value of 0.44 mg/m^3 (Table_Apx F-3), and therefore this short-term exposure value is more sensitive for short-term exposures.

Table_Apx F-3. Comparison Among Occupational Exposure Values for Phthalic Anhydride

Value Type	Most Sensitive Occupational Exposure Value (8-hour TWA)	Possible Short-Term Occupational Exposure Value (15-minute value)	Most Sensitive Occupational Exposure Value (15-minute TWA)
Health Effect	Respiratory Sensitization	Respiratory Sensitization	Respiratory Sensitization
Exposure Value (mg/m^3) (total uncertainty factor of 30×)	0.01	0.28	0.44

Below are the calculations used to derive the short-term occupational exposure value. EPA used study data from Nielsen et al. (1988), which is also the basis of the EV.

The initial step in adjusting an HEC for a shorter duration is to derive the ten Berge constant (*k*) based on the POD and exposure duration from the study along with the ten Berge exponent (*n*) for phthalic anhydride.

$$C^n \times t = k$$

$$6.6^{3.0} \times 0.5 = k$$

$$k = 143.748$$

Where:

C = Air concentration / study POD at duration *t* in mg/m^3 (6.6 mg/m^3 in (Nielsen et al., 1988), as described further in Section 4.2.2.1)
n = ten Berge exponent (3.0 used as a default, in the absence of a specific ten Berge value for phthalic anhdyride)
t = Timepoint of the measured concentration, in hours (0.5 hours in (Nielsen et al., 1988), as described further in Section 4.2.2.1)
K = Calculated ten Berge constant

The new HEC is then calculated using the same equation, where *k* and *n* remain constant.

$$C^n \times t = k$$

$$C^{3.0} \times 0.25 = 0.512$$

$$C_{STEV} = \left(\frac{143.735}{0.25}\right)^{\left(\frac{1}{3}\right)}$$

$$C_{STEV} = 8.31548\, mg/m^3$$

Where:

C_{STEV} = HEC at short-term exposure value duration *t* in mg/m^3
t = Relevant exposure duration for a short-term exposure value (15 minutes, or 0.25 hours)

Finally, the short-term exposure value is calculated from the C_{STEV} by applying the total uncertainty factor of 30 used for non-cancer risk estimates and the EV derivation.

$$\text{STEV} = \frac{C_{STEV}}{Total\ UF}$$

$$\text{STEV}\ (mg/m^3) = \frac{8.31548\ mg/m^3}{30} = 0.28\ mg/m^3$$

$$\text{STEV}\ \ (ppm) = \frac{STEV\ mg/m^3\ \times\ Molar\ Volume}{MW} = \frac{0.28\ \text{mg/m}^3\ \times\ 24.45\ \frac{L}{mol}}{148.1\ \frac{g}{mol}} =\ 0.046\ ppm$$

Where:

STEV = Short-term exposure value
Total UF = Total uncertainty factor of 30 (see Section 4.2.2.1).
Molar Volume = 24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW = Molecular weight of phthalic anhydride (148.1 g/mole)

As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p) and Section 4.2.2 of this draft risk evaluation, EPA has preliminarily concluded that the best available science supports application of a total uncertainty factor of 30× in the draft risk evaluation. However, EPA is seeking SACC and public input on the underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride, as well on as the severity of the effect observed at the LOAEC that serves as the basis of the inhalation POD. Based on SACC and public feedback, the overall total uncertainty factor may be revised in the final phthalic anhydride risk evaluation to 10 or 100. Because the total uncertainty factor may be revised in the final phthalic anhydride risk evaluation, EPA has also calculated 15-minute STEVs of 0.83 mg/m^3 (0.14 ppm) (based on a total uncertainty factor of 10×) and 0.083 mg/m^3 (0.014 ppm) (based on a total UF of 100×).

Appendix G COMPARISON OF CONSUMER AND WORKER RISK AT BENCHMARKS OF 10, 30, AND 100

As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p) and Section 4.2.2 of this draft risk evaluation, EPA selected a benchmark MOE of 30 (UF_H of 10; UF_L of 3) to characterize risk from inhalation exposures to phthalic anhydride for workers and consumers.

The UF_H can be divided into two components: one for toxicodynamic differences ($UF_{H\text{-}TD}$ of 3×) and a second for toxicokinetic differences ($UF_{H\text{-}TK}$ of 3×) (U.S. EPA, 2002, 1994b). For input into this draft risk evaluation of phthalic anhydride, EPA selected a factor of 3× for the toxicodynamics component of the UF_H because very limited data were available to inform the range in variability of the allergic response across the human population associated with exposure to phthalic anhydride. EPA considered two options for the $UF_{H\text{-}TK}$ factor for the draft risk evaluation of phthalic anhdyride: a $UF_{H\text{-}TK}$ factor of 1× (Option 1) and a $UF_{H\text{-}TK}$ factor of 3× (Option 2). As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p), EPA weighted the strengths and uncertainties of both options and concluded that the best available science supports application of a $UF_{H\text{-}TK}$ factor of 3×.

EPA applied a UF_L to capture the uncertainty associated with the use of a LOAEC as the candidate POD from Nielsen et al. (1988). EPA's *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* guidance states to use "up to an additional 10-fold factor when deriving an RfC from a LOAEL instead of a NOAEL" (U.S. EPA, 1994b). EPA considered two options for the UF_L: application of a UF_L of 10× (Option 1) and application of a UF_L of 3× (Option 2). As discussed in Section 4.3.1.3.1 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride* (U.S. EPA, 2026p), EPA weighted the strengths and uncertainties of both options and concluded that the best available science supports application of a UF_L factor of 3×.

Although EPA has preliminarily concluded that the best available science supports application of a benchmark MOE of 30× in the draft risk evaluation, the Agency is soliciting comments from the SACC and the public on the underlying modeling and science used to inform the inhalation toxicokinetics of phthalic anhydride, as well as the severity of the effect observed at the LOAEC that serves as the basis of the inhalation POD. Based on SACC peer-review and public comment, the overall benchmark MOE may be updated in the final phthalic anhydride risk evaluation to either 10 or 100. Because the benchmark MOE may change in the final phthalic anhydride risk evaluation, EPA has also provided a characterization of consumer (Appendix G.1) and worker (Appendix G.2) inhalation MOEs at alternative benchmarks of 10 and 100. This additional characterization focuses on differences in how consumer and worker inhalation MOEs may be interpreted, if they benchmark were to change in the final phthalic anhydride risk evaluation.

G.1 Comparison of Consumer Risk at Benchmarks of 10, 30, and 100

As discussed in Section 4.3.3.2, EPA assessed two inhalation exposure scenarios associated with one COU (*i.e.,* paints and coatings). As can be seen from Table 4-20 and Table_Apx G-1, high-, medium-, and low-intensity inhalation MOEs for consumers and bystanders ranged from 0.2 to 3. Because all MOEs are below 10, the consumer and bystander MOEs would be interpreted similarly, regardless of the benchmark.

Table_Apx G-1. Consumer Inhalation Risk Estimates at Benchmarks of 10, 30, and 100

Spray Paints and Coatings Scenario	Exposure Scenario Level	Weight Fraction	Duration of Use (min)	Product Mass Used (g)	Acute Freq. of Use (day $^{-1}$)	Use Environ. Volume (m^3)	User MOE (Based on 8-hour TWA) [a]	Bystander MOE (Based on 8-hour TWA) [a]
Small project (aerosol can application)	L	0.1	5	77	2	Garage; 90	0.6	2
	M	0.175	10	154			0.2	0.4
	H	0.25	15	307			0.2	0.4
Large project (sprayer gun)	L	0.01	90	894	1	Living room, 50	0.9	3
	M	0.055	180	1,789			0.5	0.7
	H	0.1	270	3,577			0.4	0.4

L, M, H = low-, medium-, or high-intensity; MOE = margin of exposure; TWA = time-weighted average
[a] MOE values below the benchmark of 10, 30, or 100 are shaded gray.

G.2 Comparison of Worker Risk at Benchmarks of 10, 30, and 100

As discussed in Section 4.3.2.1, EPA assessed nine occupational exposure scenarios (OES) for workers. At a benchmark of 10, MOEs for the majority (8 of 9) of OES would be interpreted similarly as at a benchmark of 30. For one OES (Use of laboratory chemicals), central tendency and high-end MOEs ranged from 14 to 27 (Table_Apx G-2 and Table 4-17). These MOEs exceed the benchmark of 10 but are below the benchmark of 30; therefore, MOEs for the Use of laboratory chemicals OES may be interpreted differently depending on the benchmark.

At a benchmark of 100, no new OES would have MOEs below the benchmark of 100. However, MOEs for several worker categories and central tendency MOEs would show additional risk (*i.e.,* MOEs <benchmark of 100, but above the benchmark of 30; see Table_Apx G-2 and Table 4-17), including:

- Manufacturing; Import and repackaging (worker central tendency inhalation MOE = 31)
- Manufacturing; Import and repackaging (ONU high-end MOE = 49)
- Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; Plastic compounding (worker central tendency inhalation MOE = 47)
- Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; Plastic compounding (ONU high-end inhalation MOE = 49)
- Fabrication or use of final products or articles (ONU inhalation MOE = 80).

MOEs for these worker categories and central tendency exposures may be interpreted differently at a benchmark of 100 vs. a benchmark of 30.

Table_Apx G-2. Occupational MOE Estimates at Benchmarks of 10, 30, and 100

OES(s)	Worker Category	Inhalation MOE (Benchmark = 10) [a]		Inhalation MOE (Benchmark = 30) [a]		Inhalation MOE (Benchmark = 100) [a]	
		CT	HE	CT	HE	CT	HE
Manufacturing; Import and repackaging	High exposure worker	0.68	0.17	0.68	0.17	0.68	0.17
	Worker	31	3.0	31	3.0	31	3.0
	ONU	1.4E02	49	1.4E02	49	1.4E02	49
Processing as a reactant; Incorporation into formulations, mixtures, or reaction products; Plastic compounding	High exposure worker	1.8	0.32	1.8	0.32	1.8	0.32
	Worker	47	7.1	47	7.1	47	7.1
	ONU	1.4E02	49	1.4E02	49	1.4E02	49
Incorporation into formulations, mixtures, or reaction products (epoxy resin casting hardener)	Worker	0.14	2.4E−02	0.14	2.4E−02	0.14	2.4E−02
	ONU	0.14		0.14		0.14	
Plastic converting	Worker	1.6E03	1.3E03	1.6E03	1.3E03	1.6E03	1.3E03
	ONU	1.6E03		1.6E03		1.6E03	
Application of paints, coatings, adhesives, and sealants	Worker (non-spray application)	2.4E02	1.8E02	2.4E02	1.8E02	2.4E02	1.8E02
	ONU (non-spray application)	2.4E02		2.4E02		2.4E02	
	Worker (spray application)	0.30	3.6E−02	0.30	3.6E−02	0.30	3.6E−02
Use of laboratory chemicals	Worker	27	14	27	14	27	14
	ONU	27		27		27	
Use of lubricants and functional fluids	Worker	1.6E03	1.3E03	1.6E03	1.3E03	1.6E03	1.3E03
	ONU	1.6E03		1.6E03		1.6E03	
Fabrication or use of final products or articles	Worker (fabrication)	3.5	1.3	3.5	1.3	3.5	1.3
	ONU (fabrication)	80		80		80	
	Worker, ONU (routine use)	No inhalation exposure from routine use of final products or articles.					
Disposal and recycling	Worker	1.4E02		1.4E02		1.4E02	
	ONU	1.4E02		1.4E02		1.4E02	

CT = central tendency; HE = high-end; MOE = margin of exposure; OES = occupational exposure scenario; ONU = occupational non-user

[a] MOE values below the benchmark of 10, 30, or 100 are shaded gray. Yellow-highlighted values indicate MOEs that may be interpreted differently, depending upon the benchmark MOE.

Appendix H GENERAL POPULATION SENSITIVITY ANALYSIS

This appendix describes additional considerations by EPA for its screening-level approach to characterize risks to the general population, as described in Section 4.3.4. In addition to the proposed oral POD (HED of 66 mg/kg-day, total UF of 30×) selected to estimate risks to the general population from exposure to releases of phthalic anhydride, EPA conducted a sensitivity analysis using the lowest available candidate POD to calculate risk estimates. The additional POD, an HED of 59 mg/kg-day (total UF of 300×, based on a UF_A of 3×, UF_H of 10×, and UF_L of 10×), is derived from a LOAEL of 250 mg/kg-day based on decreased terminal body weight in male SD rats exposed to *o*-phthalic acid via gavage for 14 or 28 days (Kwack et al., 2010; Kwack et al., 2009). As described in Sections 4.1.5 and 4.1.6 of the *Draft Human Health Hazard Assessment* (U.S. EPA, 2026p), EPA did not select this candidate HED as the POD for use in the general population screening assessment due to uncertainties associated with the study (*e.g.,* only evaluated 1 dose level, small sample size, only evaluated male rats, route of administration).

Rapid ($t_{½}$ = 30–90 seconds) and complete hydrolysis (approximately 8 minutes) of phthalic anhydride to *o*-phthalic acid occurs in the presence of moisture. Therefore, the general population screening-level risk assessment evaluates exposures to *o*-phthalic acid, not phthalic anhydride. As described further in in Section 4.3.4 and *Draft Environmental Media and General Population and Environmental Exposure for Phthalic Anhydride* (U.S. EPA, 2026n), EPA is quantifying general population exposure and risk from ingestion of drinking water and inhalation exposure to ambient air, whereas other exposure pathways were qualitatively evaluated (*i.e.,* land pathway, incidental ingestion and dermal exposure from swimming, fish ingestion).

For the drinking water ingestion and inhalation exposure to ambient air exposure pathways, EPA considered the highest exposures through ingestion of drinking water using a single high-release facility (*i.e.,* ColorCon facility) reporting TRI from Form R-Publicly Owned Treatment Works (POTW), as described below and in Section 4.3.4. As a screening-level assessment, the highest releasing facility (ColorCon) was used to represent upper-bound chronic exposures to *o*-phthalic acid in drinking water and in ambient air. These exposures were combined with the screening-level POD to obtain screening risk estimates.

Drinking Water Analysis Using the Benchmark MOE of 300 and Highest Release Facility

- EPA estimated surface water concentrations using ColorCon reported release and receiving water body flow of the ColorCon location. Using release data from the ColorCon facility, and assuming no wastewater removal, EPA estimated a drinking water exposure of 0.414 mg/kg-day *o*-phthalic acid for the population with the highest exposure (*i.e.,* infants, birth to <1 year) (see (U.S. EPA, 2026n) for more details).
- Using this drinking water intake value and the candidate HED of 59 mg/kg-day, an MOE of 143 (benchmark = 300) was calculated for infants through drinking water intake.
- Because the ColorCon facility does not report direct discharges to surface water, but instead discharges to a POTW, EPA next refined the exposure scenario and used the actual water release from the ColorCon facility paired with flow values from the POTW for a more accurate estimate of surface water concentrations at point of discharge. EPA considers this refinement appropriate, given that the ColorCon facility does not directly release to water bodies, it is waste is sent to an offsite POTW as reported in TRI Form R.

- Using this refinement to estimate surface water concentrations using the POTW receiving water body flow resulted in a drinking water exposure of 0.00019 mg/kg-day *o*-phthalic acid for the population with the highest exposure (*i.e.,* infants, birth to <1 year).
- Using this refined drinking water intake value and the candidate HED of 59 mg/kg-day, an MOE of 310,000 (benchmark = 300) was calculated for infants through drinking water intake for the facility with the highest releases.
- This sensitivity analysis further indicates that the drinking water pathway is not a pathway of concern.

Ambient Air Inhalation Analysis Using the Benchmark MOE of 300 and Highest Release Facility

- EPA estimated ambient air concentrations of *o*-phthalic acid for the highest releasing facility (see (U.S. EPA, 2026n)). The highest calculated ambient air concentration (annual outdoor air concentration [µg/m^3] from fugitive plus and emissions) was 99.4 µg/m^3. The highest ambient air inhalation values reflect the highest air release facility, and actual air releases from facilities were used to estimate ambient air concentrations. Conservative assumptions were made by combining the highest fugitive emissions with highest stack emissions from different facilities
- Using the ambient air concentration calculated above and the candidate HEC of 322 mg/m^3 (extrapolated from HED of 59 mg/kg-day, see Section 4.3.4 of this assessment and Table 4-5 of the *Draft Human Health Hazard Assessment for Phthalic Anhydride*), EPA calculated an MOE of 3,240 (benchmark MOE = 300).
- This sensitivity analysis further indicates that the ambient air pathway is not a pathway of concern.