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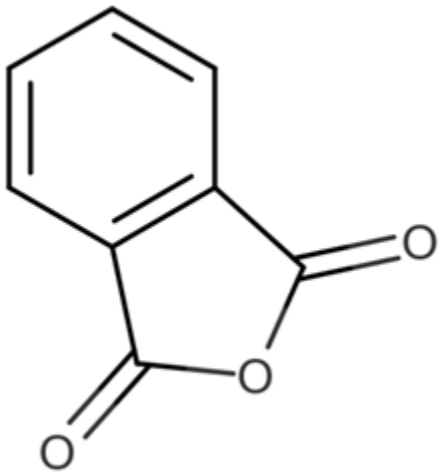
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for Phthalic Anhydride (1,3-Isobenzofurandione)

CASRN 85-44-9



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Docket

Supporting information can be found in public docket: Docket ID: EPA-HQ-OPPT-2018-0459.

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADME	Absorption, distribution, metabolism, and excretion
AEGL	Acute Exposure Guideline Level
AICS	Australian Inventory for Chemical Substances
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification factor
BOD	Biochemical oxygen demand
BP	Boiling point
BSER	Best System of Emission Reduction
BW	Body weight
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CHRIP	Chemical Risk Information Platform
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DMR	Discharge Monitoring Report
EC	Engineering Controls
EC_x	Effective Concentration
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
GACT	Generally Available Control Technology
GDIT	General Dynamics Information Technology
GESTIS	International Occupational Exposure Limit Database
GS	Generic Scenario
HAP	Hazardous Air Pollutant
Hg	Mercury
HHE	Health Hazard Evaluation
HMTA	Hazardous Materials Transportation Act
HSDB	Hazardous Substances Data Bank
ICF	ICF is a global consulting services company
IDLH	Immediately Dangerous to Life and Health

IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
ISHA	Industrial Safety and Health Act
K_{OC}	Organic Carbon: Water Partition Coefficient
K_{OW}	Octanol: Water Partition Coefficient
LC_x	Lethal Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MITI	Ministry of International Trade and Industry
MOA	Mode of Action
MP	Melting point
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NASA	National Air and Space Administration
NEI	National Emissions Laboratory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPRI	National Pollutant Release Inventory
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, Toxic
P-Chem	Physical-chemical
PECO	Population, Exposure, Comparator and Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed Susceptible Populations
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Limit
RQ	Risk Quotient
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SRC	SRC Inc., formerly Syracuse Research Corporation
STEL	Short-term Exposure Limit
STORET	STORage and RETrieval (water quality data warehouse)

SVOC	Semivolatile Organic Compound
SYKE	Finnish Environment Institute
TBD	To be determined
TIAB	Title and Abstract
TOC	Total organic carbon
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act (Massachusetts)
TWA	Time-weighted average
VOC	Volatile Organic Compound
VP	Vapor Pressure
WS	Water solubility
WQX	Water Quality Exchange
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated phthalic anhydride (CASRN 85-44-9) as a high-priority substance for risk evaluation following the prioritization process required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR 702) (Docket ID: EPA-HQ-OPPT-2018-0459). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA requirement to issue a draft scope document as required in 40 CFR 702.41(c)(7). The draft scope for phthalic anhydride includes the following information: the conditions of use, hazards, potentially exposed or susceptible subpopulations (PESS), hazards, and exposure that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. Phthalic anhydride is a white (lustrous needles) solid with a total production volume in the United States between 500 million and 750 million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High Priority Substance designation for phthalic anhydride to inform the scope of the development of this draft scope document. To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) and the search and screening results to date are provided in Section 2.1. EPA is seeking public comment on this draft scope document and will consider additional information identified following publication of this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for phthalic anhydride.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of phthalic anhydride in the risk evaluation. Phthalic anhydride is manufactured within the U.S. as well as imported into the U.S. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction products, and incorporated into articles. The identified processing activities also include the repackaging and recycling of phthalic anhydride. Several industrial and commercial uses were identified that ranged from use in plastic and rubber products to use in lubricants. The only two reported consumer uses were adhesives and paints and coatings. EPA identified these conditions of use from information reported to EPA through Chemical Data Reporting (CDR) and Toxics Release Inventory (TRI) reporting, published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. Although EPA is aware that phthalic anhydride is used in personal care products, food preservatives, insect repellents, perfume fixatives, pharmaceuticals, and medical devices, they are not conditions of use as defined in TSCA § 3(4) and therefore will not evaluated in the risk evaluation. Section 2.2 provides details about the conditions of use within – and outside – the scope of the risk evaluation. In addition, EPA plans to analyze distribution in commerce and disposal as part of the risk evaluation.

Conceptual Model. The conceptual models for phthalic anhydride are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards, and receptors throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, or use, to release or disposal. EPA plans to focus the risk evaluation for phthalic anhydride on the following exposures, hazards and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to evaluate both human and environmental exposures resulting from the conditions of use of phthalic anhydride that EPA plans to consider in risk evaluation. Exposures for phthalic anhydride are discussed in Section 2.3. EPA anticipates releases of phthalic anhydride into the environment based on the conditions of use. Phthalic anhydride is subject to reporting to EPA's Toxics Release Inventory (TRI), which is reasonably available information that EPA anticipates using to inform phthalic anhydride's environmental release assessment. For the 2018 reporting year, 121 facilities reported to EPA releases of phthalic anhydride to air, water, and via land disposal. Additional information gathered through systematic review searches will also inform expected exposures.

  EPA's plan as to evaluating environmental exposure pathways in the draft scope document considers whether and how other EPA-administered statutes and regulatory programs address the presence of phthalic anhydride in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of phthalic anhydride within the scope of the risk evaluation.

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and/or occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of phthalic anhydride (Section 2.2.1).
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate the inhalation, dermal and oral exposures to phthalic anhydride for consumers and inhalation exposures to bystanders during use of adhesives and sealants and paints and coatings.
  - *General population pathways:* EPA plans to evaluate exposure to phthalic anhydride via drinking water, surface water, groundwater and fish ingestion for the general population.
  - *Receptors and PESS:* EPA plans to evaluate children, women of reproductive age (e.g., pregnant women), and workers and consumers as receptors and PESS in the risk evaluation.

- *Hazards.* Hazards for phthalic anhydride are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for phthalic anhydride as part of the

prioritization process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for phthalic anhydride. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-response assessment. EPA plans to evaluate all the potential human health hazards for phthalic anhydride identified in Section 2.4.2. The broad health effect categories include acute toxicity, repeat dose toxicity, genetic toxicity, developmental toxicity, toxicokinetic findings, irritation/corrosion, dermal sensitization, respiratory sensitization, carcinogenicity, and epidemiology or biomonitoring findings.

Analysis Plan. The analysis plan for phthalic anhydride is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various information streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of phthalic anhydride to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for phthalic anhydride, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for phthalic anhydride will be peer reviewed. Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations, including using EPA's Peer Review Handbook (U.S. EPA, 2015a) and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for phthalic anhydride under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the TSCA on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a PESS identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. Phthalic anhydride is one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this draft scope for phthalic anhydride. EPA leveraged the data and information sources already identified in the documents supporting the chemical substance's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases.
3. Data and information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening processes were conducted based on EPA's general expectations for

[1] *Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA Section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA Section 14 (40 CFR 702.33).

the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). EPA plans to publish supplemental documentation on the systematic review methods supporting the phthalic anhydride risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for phthalic anhydride upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 151 search results relevant to EPA's risk assessment needs for phthalic anhydride. Appendix A lists the gray literature sources that yielded 151 discrete data or information sources relevant to phthalic anhydride. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical-chemical (p-chem) properties, environmental fate, environmental hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments) and the reported numbers in Figure 2-1 may change.

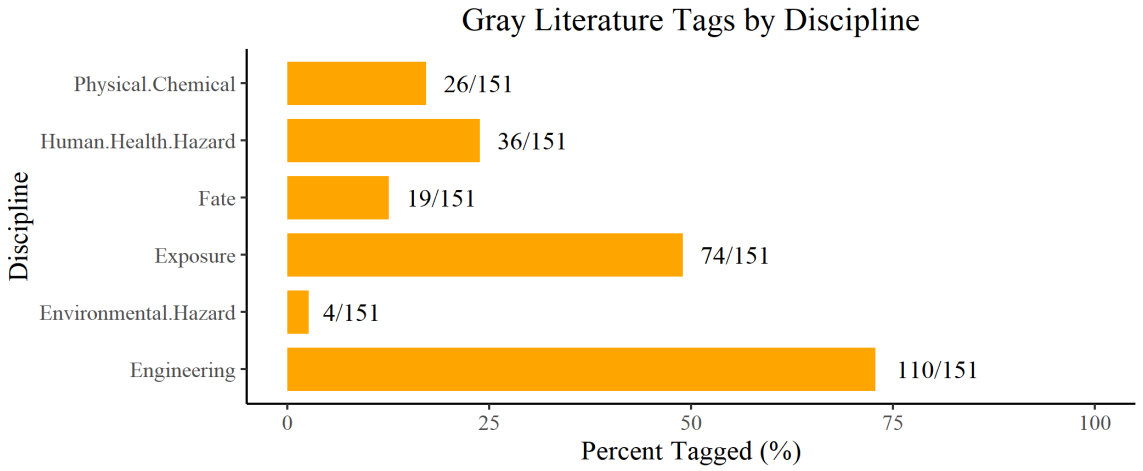

Figure 2-1. Gray Literature Tags by Discipline for Phthalic Anhydride
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

2.1.2 Search of Literature from Publicly Available Databases (Peer-reviewed Literature)

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on p-chem properties, environmental fate and transport, engineering (environmental release and occupational

[2] *Gray literature* is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (e.g., PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases.

exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of phthalic anhydride. Eligibility criteria were applied in the form of PECO (population, exposure, comparator, outcome) statements. Included references met the PECO criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure **2-2** through Figure 2-6. "TIAB" in these figures refer to "title and abstract" screening. Note that the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

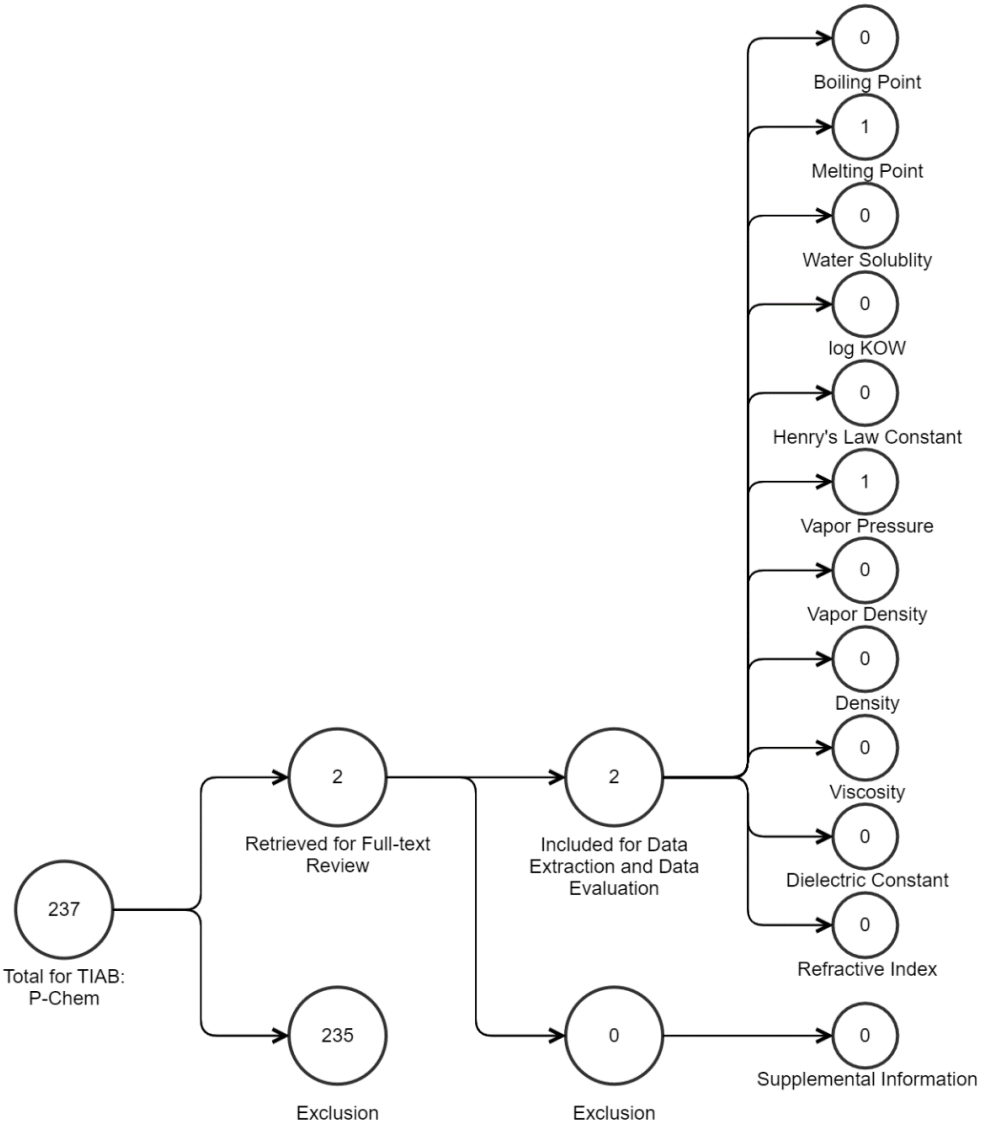

Figure 2-2. Peer-reviewed Literature – Physical-Chemical Properties Search Results for Phthalic Anhydride

Figure 2-3. Peer-reviewed Literature – Fate and Transport Search Results for Phthalic Anhydride
Click here for interactive Health Assessment Workplace Collaborative (HAWC) Diagram.

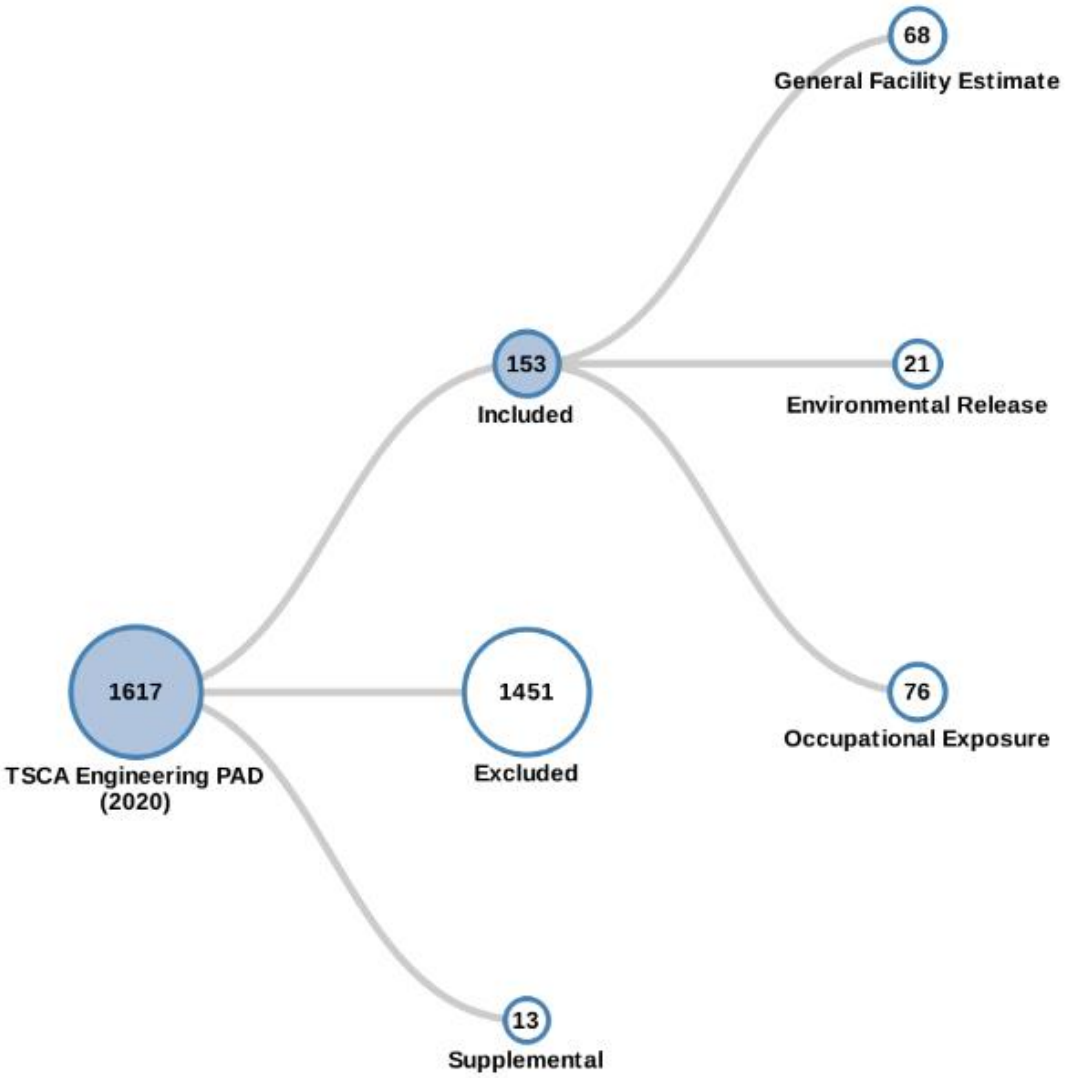

Figure 2-4. Peer-reviewed Literature – Engineering Search Results for Phthalic Anhydride
Click here for interactive HAWC Diagram.

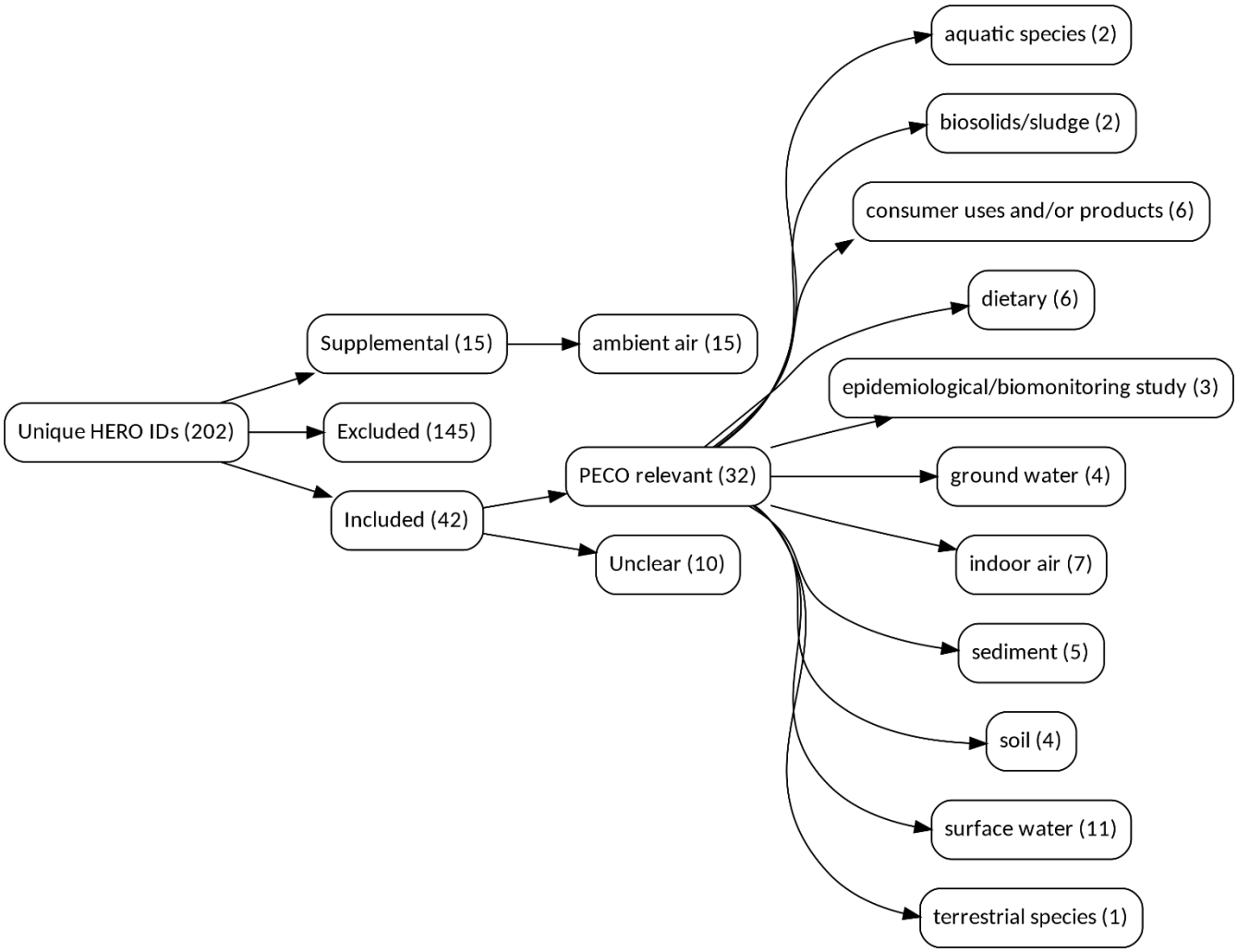

Figure 2-5. Peer-reviewed Literature – Exposure Search Results for Phthalic Anhydride

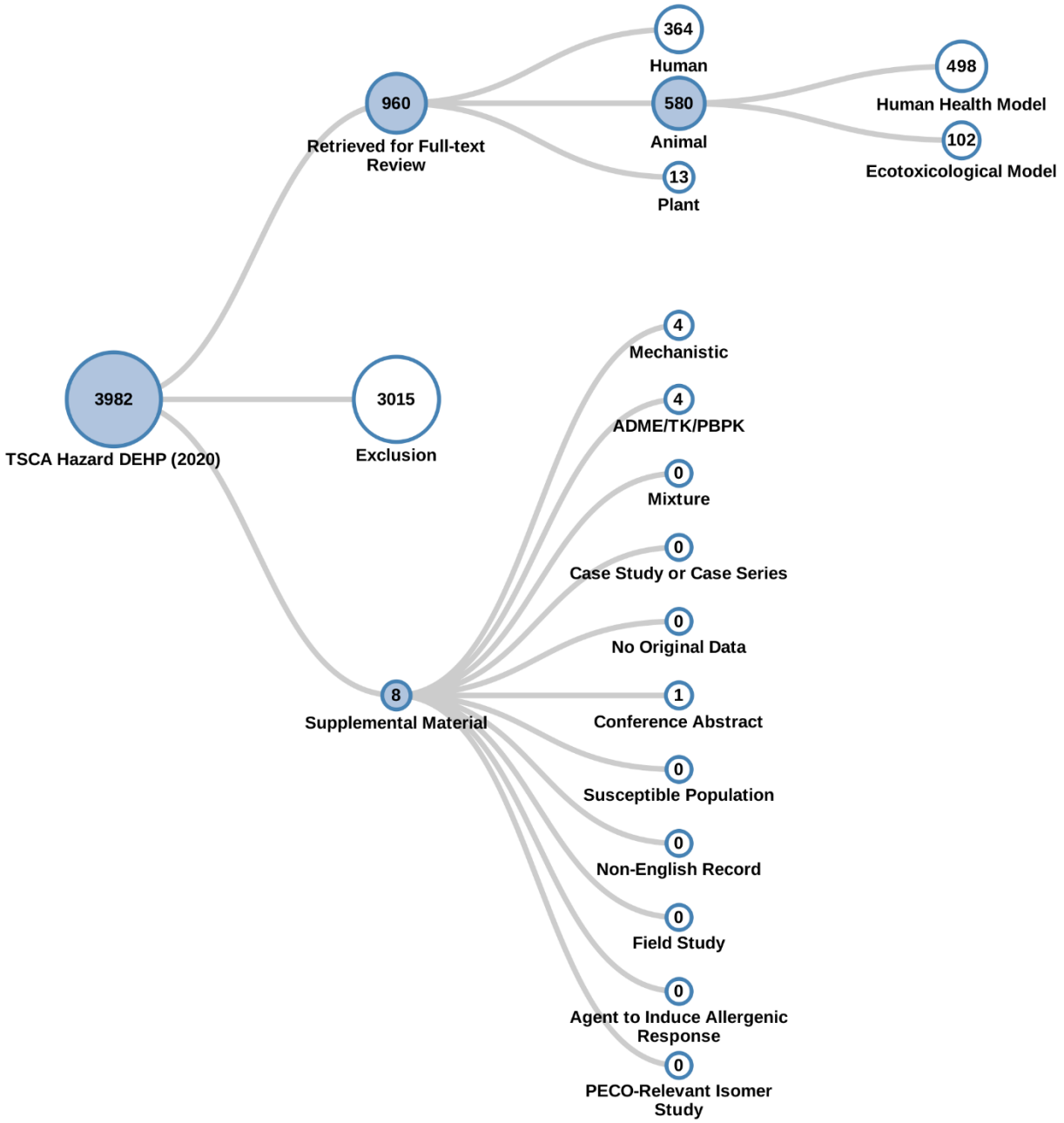

Figure 2-6. Peer-reviewed Literature – Hazard Search Results for Phthalic Anhydride

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of the TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 19 submissions using inclusion/ exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 17 submissions that met the inclusion criteria in these statements and identified one submission with supplemental data. EPA excluded one submission because the report was identified as a preliminary report. EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full text screening), when more information regarding the reports is reasonably available.

Table 2-1. Results of Title Screening of Submissions to EPA under Various Sections of TSCA

Discipline	Included	Supplemental
P-Chem Properties	0	0
Environmental Fate and Transport	1	0
Environmental and General Population Exposure	3	0
Occupational Exposure/Release Information	9	0
Environmental Hazard	3	0
Human Health Hazard	12	1

2.2 Conditions of Use

As described in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of phthalic anhydride, including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing phthalic anhydride, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, and when applicable, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

After gathering the conditions of use, EPA identified those categories or subcategories of use activities for phthalic anhydride the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.1.

Also, EPA identified and described the categories and subcategories of conditions of use that will be included in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use included in the scope are those reflected in the life cycle diagrams and conceptual models.

2.2.1 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Table 2-2 lists the conditions of use that are included in the scope of the risk evaluation.

[3] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

Table 2-2. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life-Cycle Stage	Category	Subcategory	References
Manufacture	Domestic Manufacture	Domestic manufacture	U.S. EPA (2019b)
Manufacture	Import	Import	U.S. EPA (2019b)
Processing	Processing as a reactant	Intermediate in: - All other basic organic chemical manufacturing; and - Plastic material and resin manufacturing.	U.S. EPA (2019b)
		Adhesives and sealant chemicals in: - Paint and coating manufacturing.	U.S. EPA (2019b)
	Processing as a reactant	Ion exchange agents in: - All other basic organic chemical manufacturing.	U.S. EPA (2019b)
		Lubricants and lubricant additives in: - Petroleum lubricating oil and grease manufacturing.	U.S. EPA (2019b)
		Paint additives and coating additives not described by other categories in: - Paint and coating manufacturing.	U.S. EPA (2019b)
		Pigments in: - Synthetic dye and pigment manufacturing.	U.S. EPA (2019b)
		Inks in: - Printing ink manufacturing.	U.S. EPA (2019b)
		Plastic in: - Plastics product manufacturing.	U.S. EPA (2019b)
		Corrosion inhibitors and anti-scaling agents in: - Miscellaneous Manufacturing	U.S. EPA (2019b)
		Plating agents and surface treating agents in: - Rubber Product Manufacturing	U.S. EPA (2019b)
	Incorporation into formulation, mixture, or reaction product	Intermediate in: - Paint and coating manufacturing;	U.S. EPA (2019b)

Life-Cycle Stage	Category	Subcategory	References
		- All other basic organic chemical manufacturing; and - All other chemical product and preparation manufacturing. - Pharmaceutical and medicine manufacturing	
		Plasticizers in: - Plastic material and resin manufacturing - Petrochemical Manufacturing - Construction - Polyester and alkyd resins, curing agent for epoxy resins	U.S. EPA (2019b), Broadview Technologies (2015), & Koppers (2018)
	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; and - Solid color stains; and - Asphalt Paving, Roofing, and Coating Materials Manufacturing.	U.S. EPA (2019b), Meeting Sherwin Williams (2019)
		Adhesives and sealant chemicals in: - Paint and coating manufacturing.	U.S. EPA (2019b)
		Fillers in: - Textile, apparel, and leather manufacturing.	U.S. EPA (2019b)
		Oxidizing/reducing agents in: - Synthetic rubber manufacturing; - Adhesive manufacturing; plastic material and resin manufacturing; and - Wholesale and retail trade.	U.S. EPA (2019b)
		Dyes in: - Synthetic dye and pigment manufacturing.	U.S. EPA (2019b)
		Laboratory chemicals	Email NASA (2020), Thermo Fisher Scientific (2018)

Life-Cycle Stage	Category	Subcategory	References
	Repackaging	Repackaging (e.g., laboratory chemicals)	Email NASA (2020), Thermo Fisher Scientific (2018)
	Recycling	Recycling	U.S. EPA (2019b)
Distribution in Commerce	Distribution in Commerce	N/A	N/A
Industrial	Oil and Gas Drilling, Extraction, and Support Activities	Hydraulic fracturing	Finoric, LLC. (2016), U.S. EPA (2015b), Committee on Energy and Commerce's Minority Staff (2011), & Whittemore, D., (2011)
	Aerospace	Acceptance testing of foams used on human-rated spaceflight vehicles	Email NASA (2020)
	Electrical and electronic products	Load absorber (electrical)	Emerson (2011)
	Adhesives and sealants	Adhesives and sealants (e.g., sealant for fuel tanks, temporary mounting adhesive, acrylic adhesive, Aerospace sealant)	U.S. EPA (2019b), Royal Adhesives & Sealants (2016), Aremco Products, Inc. (2018) & 3M Company (2019)
	Fillers	Hardener (e.g., epoxy hardener)	ResinLab (2015)
	Flame retardants	Flame retardants	Stepan (2020) & U.S. EPA (1994a)
	Textiles, apparel, and leather manufacturing	Tanning and curing	U.S. EPA (1994a)
	Lubricants and greases	Lubricants and greases	U.S. EPA (2019b)
	Plating agents and surface treating agents	Surface treating	U.S. EPA (2019b)
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere (e.g., epoxy resin work surface)	U.S. EPA (2019b), Durcon Inc. (2011), Durcon Inc. (2020), & OSHA (2019)
	Electrical and electronic products	Electrical and electronic products	U.S. EPA (2019b)
	Laboratory chemical	Laboratory chemical	Email NASA (2020), Thermo Fisher Scientific (2018)

Life-Cycle Stage	Category	Subcategory	References
	Transportation Equipment Manufacturing	Used in the body/exterior, interior, and electrical systems of a vehicle, wiring assemblies, seat and console assemblies, and lamp assemblies.	Public Comment (EPA-HQ-OPPT-2019-0131-0022)
	Water treatment products	Water filtration applications	Meeting Henkel (2019)
Commercial	Adhesives and sealants	Adhesives and sealants (e.g., sealant for fuel tanks, temporary mounting adhesive, acrylic adhesive, aerospace sealant)	U.S. EPA (2019b), Royal Adhesives & Sealants (2016), Aremco Products, Inc. (2018) & 3M Company (2019)
	Fillers	Hardener (e.g., epoxy hardener)	ResinLab (2015), Lord (2017)
	Textiles, apparel, and leather manufacturing	Tanning and curing	U.S. EPA (1994a)
	Lubricants and greases	Lubricants and greases	U.S. EPA (2019b)
	Plating agents and surface treating agents	Surface treating	U.S. EPA (2019b)
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere (e.g., Epoxy Resin Work Surface)	U.S. EPA (2019b), Durcon Inc. (2011), Durcon Inc. (2020), & OSHA (2019)
	Electrical and electronic products	Electrical and electronic products	U.S. EPA (2019b)
	Laboratory chemical	Laboratory chemical	Email NASA (2020), Thermo Fisher Scientific (2018)
	Transportation Equipment Manufacturing	Used in the body/exterior, interior, and electrical systems of a vehicle, wiring assemblies, seat and console assemblies, and lamp assemblies.	Public Comment (EPA-HQ-OPPT-2019-0131-0022)
	Water treatment products	Water filtration applications	Meeting Henkel (2019)
	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S. EPA (2019b)
	Plastic and rubber products	Plastic and rubber products	U.S. EPA (2019b)
	Furniture and furnishings not covered elsewhere	Oil treatment of wood, indoors	Junckers (2019)
	Paints and coatings	Paints and coatings (e.g., Commercial and residential paint coatings)	U.S. EPA (2019b) & Stepan (2020)

Life-Cycle Stage	Category	Subcategory	References
	Miscellaneous	Boat hulls, shower stalls, wire coating and insulation, garden hoses, vinyl wallpaper	Stepan (2020)
Consumer	Adhesives and sealants	Adhesive (e.g., Super glue)	Henkel (2017), Meeting Henkel (2019), & Public Comment (EPA-HQ-OPPT-2018-0459-0004)
	Paints and coatings	Paints and coatings	U.S. EPA (2019b), Stepan (2020)
Disposal	Disposal	Disposal	U.S. EPA (2019c)

- Life Cycle Stage Use Definitions
  - "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
  - "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
  - "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- The Agency has included information in this draft scope document sourced from the 2012 and 2016 Chemical Data Reporting (CDR) Rule collections. In instances where representations of fact derived from CDR data included in this document were claimed as confidential business information (CBI) in the CDR datasets, the Agency reviewed the claims and secured the necessary declassifications.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). As a result, EPA does not plan to include in this scope or in the risk evaluation the activities described below that the Agency has concluded do not constitute conditions of use. However, processing and industrial uses of these products are covered by TSCA and will be considered a condition of use.

Personal Care Products. Phthalic anhydride is reported as a commercial use in the production of personal care products (U.S. EPA, 2019a), but these activities are not TSCA conditions of use and will not be evaluated during the risk evaluation. These products meet the definition of "cosmetic" in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 321 and are therefore excluded from the definition of chemical substance[4] as regulated by TSCA.

[4] *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Chemical substance does not include (1) any mixture; (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product; (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by Section 4182 or 4221 or any other provision of such Code), and; (6) any food, food

Food Preservatives. Phthalic anhydride-containing products' SDS list "food preservatives" as an identified use (InterAtlas 2016, Koppers 2018). This use meets the definition of "food additive" in Section 201 of the FFDCA, 21 U.S.C. § 321, and is therefore excluded from the definition of chemical substance[4] as regulated by TSCA.

Insect Repellents. Phthalic anhydride-containing products' SDS list "insect repellents" as an identified use (InterAtlas 2016, Koppers 2018). This product meets the definition of "pesticide" in Section 136 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq, and is therefore excluded from the definition of chemical substance[4] as regulated by TSCA.

Perfume Fixatives. Phthalic anhydride-containing products' SDS list "perfume fixatives" as an identified use (InterAtlas 2016, Koppers 2018). These products meet the definition of "cosmetic" in Section 201 of the FFDCA, 21 U.S.C. § 321, and are therefore excluded from the definition of chemical substance[4] as regulated by TSCA.

Pharmaceuticals. Phthalic anhydride-containing products' SDS list "pharmaceuticals" as an identified use (InterAtlas 2016, Koppers 2018). Phthalic anhydride has also been identified as used as an intermediate in pharmaceutical and medicine manufacturing (U.S. EPA, 2019a). The phthalic anhydride-containing products' SDS use meet the definition of "drug" in Section 201 of the FFDCA, 21 U.S.C. § 321, and is therefore excluded from the definition of chemical substance[4] as regulated by TSCA. However, processing and industrial uses of pharmaceutical and medicine manufacturing falls under the "conditions of use" defined as circumstances associated with a chemical substance, TSCA § 3(4) and as a result will be evaluated during risk evaluation.

Medical Devices. Phthalic anhydride has been listed as being use in medical devices and the flexible tubing and containers in the medical industry (Stepan, 2020 & Meeting Henkel, 2019). EPA determined these uses meet the definition of a "medical device" according to the FFDCA and therefore its consumer use is excluded from the definition of chemical substance[4] as regulated by TSCA.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of phthalic anhydride in 2015 was between 500 million and 750 million pounds (U.S. EPA 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and will include future production volume information as it becomes reasonably available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7. depicts the conditions of use that are considered within the scope of the risk evaluation for the various life cycle stages as presented in Section 2.2.1. This section provides a brief overview of the industrial, commercial and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

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additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). The production volume of phthalic anhydride in 2015 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period, as a range between 500 million and 750 million pounds (U.S. EPA, 2017).

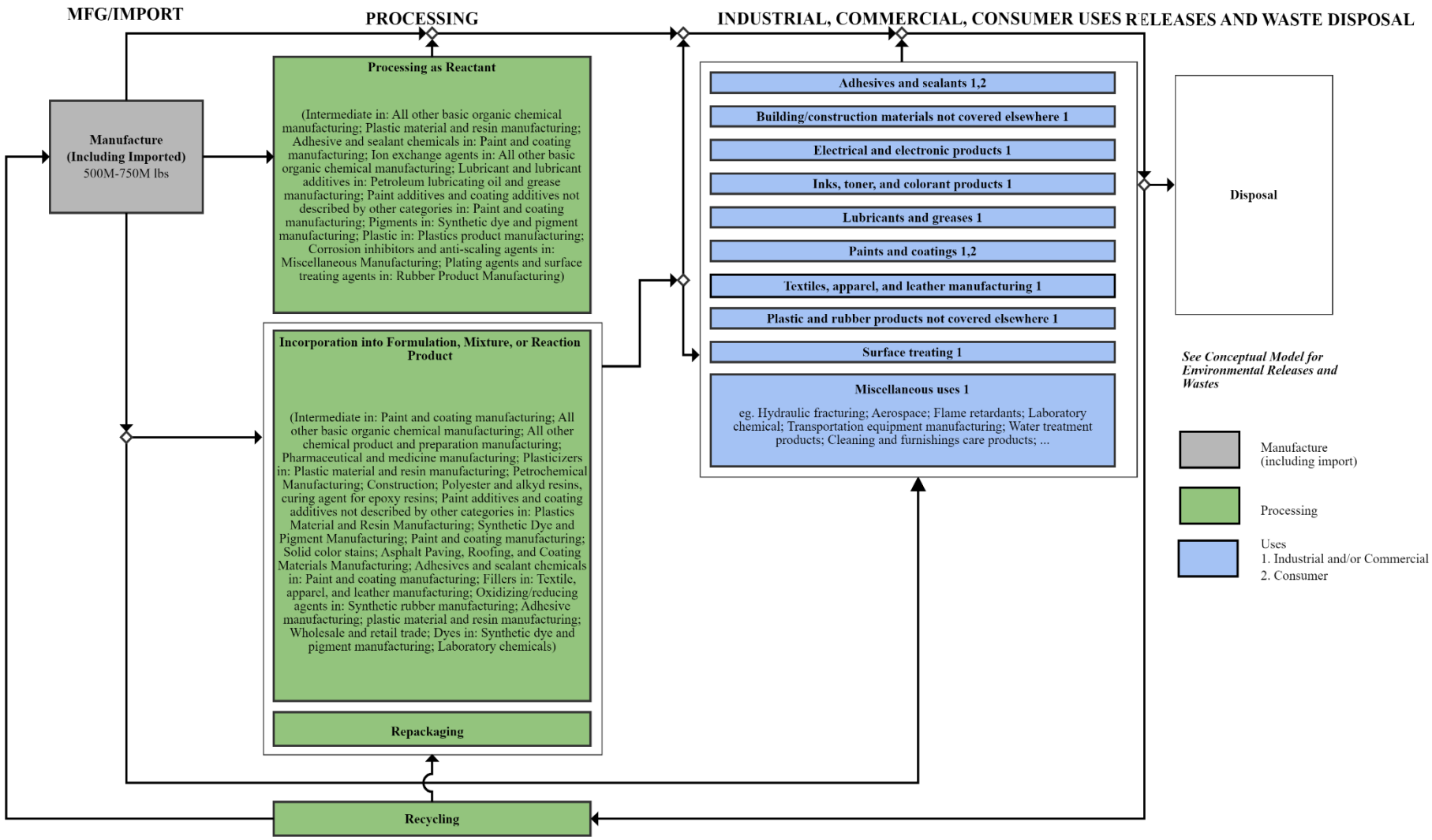

Figure 2-7. Phthalic Anhydride Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and industrial, commercial, and consumer uses as specific production volume is claimed confidential business information (CBI) or withheld pursuant to TSCA Section § 14.

2.3 Exposures

For TSCA exposure assessments, EPA plans to evaluate exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for phthalic anhydride. Pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS, and environmental receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to phthalic anhydride.

2.3.1 Physical and Chemical Properties

Physical and chemical properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) to support the development of the risk evaluation for phthalic anhydride (see Appendix B). The values for the physical and chemical properties may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for phthalic anhydride. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) to support the development of the risk evaluation for phthalic anhydride (see Appendix C). The values for the environmental fate properties may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use are a component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data or assumptions and models.

A source of information that EPA plans to consider in evaluating exposure are data reported to the Toxics Release Inventory (TRI) program. EPA's TRI database contains information on chemical waste management activities that are reported to EPA by industrial and federal facilities, including quantities released into the environment (i.e., to air, water, and disposed of to land), treated, burned for energy, recycled, or transferred off-site to other facilities for these purposes.

Under the Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) phthalic anhydride is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting[5], facilities in covered sectors in the United States are required to disclose release and other waste management activity quantities of phthalic anhydride under the CASRN 85-44-9 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

[5] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

Table 2-3 provides production-related waste management data for phthalic anhydride reported by facilities to the TRI program for reporting year 2018.[6] As shown in the table, 121 facilities reported a total of 12,592,162 pounds of production-related waste managed. Of this total, 9,206,555 pounds were treated, 2,314,977 pounds were recycled, 807,346 pounds were burned for energy recovery, and 260,284 pounds were released to the environment. Treatment accounted for 73% of phthalic anhydride waste managed, with 8,006,296 pounds treated on site and 1,203,259 pounds sent off site for treatment. Of the phthalic anhydride waste that was recycled, 99.9% was recycled on site. Phthalic anhydride waste burned for energy recovery made up 8% of the total, with 55% burned on site and 45% sent off site for energy recovery. Only 2% of the total phthalic anhydride waste was released to the environment.

Table 2-3. Summary of Phthalic Anhydride TRI Production-Related Waste Managed in 2018

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released[a,b,c] (lbs)	Total Production Related Waste (lbs)
2018	121	2,314,977	807,346	9,209,555	260,284	12,592,162

Data source: 2018 TRI Data (Updated November 2019)

[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.

[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.

[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-4 provides a summary of phthalic anhydride TRI releases to the environment for the same reporting year as Table 2-3.[7] Phthalic anhydride releases to air accounted for 77% of all releases reported for the chemical in 2018; 199,400 pounds were released on site to air, with point source air emissions accounting for 86% of these air emissions. A total of 35,202 pounds were disposed of to land. Of this total, 11,431 pounds of phthalic anhydride were disposed of in Class I underground injection wells, the vast majority of which were on site. Conversely, the vast majority of disposal to RCRA Subtitle C landfills (4,082 pounds) and all other land disposal (19,689 pounds) occurred off site. "Other releases" accounted for disposal of or releases of 25,467 pounds of phthalic anhydride, and includes transfer quantities for off-site storage, potential releases from transfers to publicly owned treatment works (POTW), and waste sent off site to a waste broker for disposal.

[6] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

[7] *Ibid*.

Table 2-4. Summary of Releases of Phthalic Anhydride to the Environment During 2018

	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases (lbs) [a]	Total Releases [b, c] (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal (lbs) [a]		
Totals 2018	121	170,683	28,716	27	11,431	4,082	19,689	25,467.03	260,096
		199,400			35,202				

Data source: 2018 TRI Data (Updated November 2019)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While production-related waste managed shown in Table 2-3 excludes any quantities reported as catastrophic or one-time releases (TRI Section 8 data), release quantities shown in Table 2-4 include both production-related and non-production-related quantities. As a result, the total release quantities between the two tables differ slightly, and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2019c).

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for phthalic anhydride.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of phthalic anhydride can result in releases to the environment and exposure to aquatic and terrestrial receptors. Environmental exposures to are informed by releases into the environment, overall persistence, degradation, and bioaccumulation, and partitioning across different media. Concentrations of chemical substances in environmental media provide evidence of exposure. EPA plans to review reasonably available information on environmental exposures to inform the development of the environmental exposure assessment for phthalic anhydride. EPA plans to review reasonably available environmental monitoring data found in the literature for phthalic anhydride. EPA also plans to review reasonably available monitoring data found in the literature on the presence of phthalic anhydride in biomonitoring samples.

2.3.5 Occupational Exposures

EPA plans to evaluate worker activities where there is a potential for exposure under the various conditions of use (manufacturing, processing, and industrial/commercial uses) described in Section 2.2. In addition, EPA plans to evaluate exposure to ONUs, workers, who do not directly handle the chemical but perform work in an area where the chemical is present, depending on reasonably available information. EPA also expects to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with these conditions of use within the scope of the risk evaluation for phthalic anhydride will be analyzed, including, but not limited to:

- Unloading and transferring phthalic anhydride to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing phthalic anhydride;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing phthalic anhydride for quality control;
- Repackaging chemicals, formulations or products containing phthalic anhydride.

Phthalate anhydride is a solid at room temperature and has a vapor pressure of 5.17×10^{-4} mm Hg at 25 ºC/77 °F (NLM 2015) and inhalation exposure to vapor is expected to be low when working with the material at room temperature. However, EPA plans to evaluate inhalation exposure in occupational scenarios where phthalic anhydride is applied via spray or roll application methods or is handled as a dry powder or at elevated temperatures.

Phthalic anhydride has an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) (OSHA 2009). The PEL is 2 ppm or 12 mg/m^3 over an 8-hour work day, time weighted average (TWA). National Institute for Occupational Safety and Health (NIOSH) has set the Recommended Exposure Limit (REL) at 1 ppm (6 mg/m^3) TWA and the Immediately Dangerous to Life or Health Concentration (IDLH) at 60 mg/m^3 (NIOSH 2005). The American Conference of Governmental Industrial Hygienists (ACGIH) set the threshold limit value (TLV) at 0.002 mg/m^3 TWA, with a Short-Term Exposure Limit (STEL) of 0.005 mg/m^3 (ICPS 2003).

Based on the conditions of use, EPA plans to evaluate worker exposure to liquids and/or solids via the dermal route. EPA does not plan to evaluate dermal exposure for ONUs that do not directly handle phthalic anhydride.

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths or ingest inhaled particles that deposit in the upper respiratory tract. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider oral exposure on a case-by-case basis for certain COUs and worker activities where there is information and data on incidental ingestion of inhaled dust. EPA will consider ingestion of inhaled dust as an inhalation exposure for phthalic anhydride.

2.3.6 Consumer Exposures

According to reports to the 2016 CDR (U.S. EPA, 2017), available SDSs (Henkel, 2017), and reviewed public comment (EPA-HQ-OPPT-2018-0459-0004), two consumer product conditions of use containing phthalic anhydride were identified (as noted in Section 2.6.2 and Figure 2-9): paints and coatings; and adhesives and sealants.

Based on reasonably available information on consumer conditions of use, inhalation of phthalic anhydride is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of phthalic anhydride is possible through ingestion during product use via transfer from hand to mouth. Dermal exposure may occur via contact with vapor or mist deposition onto the skin, via direct liquid contact during use. Based on these potential sources and pathways of exposure, EPA plans to evaluate oral, dermal and inhalation exposures to consumers and inhalation exposures to bystanders that may result from the conditions of use of phthalic anhydride.

2.3.7 General Population Exposures

Environmental releases of phthalic anhydride from certain conditions of use, such as manufacturing, processing, or disposal activities, may result in general population exposures. The general population may be exposed to phthalic anhydride via ambient air, drinking water, ground water, and/or surface water based on information provided in Section 2.3.3. EPA plans to review reasonably available information for the presence of phthalic anhydride in environmental media relevant to general

population exposure. EPA also plans to review reasonably available human biomonitoring data in the risk evaluation.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for phthalic anhydride. EPA considers all the potential environmental hazards for phthalic anhydride identified during prioritization (U.S. EPA 2019) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with phthalic anhydride. If necessary, EPA plans to update the list of potential hazards in the final scope document of phthalic anhydride. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for phthalic anhydride. EPA plans to evaluate all of the potential human health hazards for phthalic anhydride identified during prioritization. The health effect categories identified during prioritization include acute toxicity, repeat dose toxicity, genetic toxicity, developmental toxicity, toxicokinetic findings, irritation/corrosion, dermal sensitization, respiratory sensitization, carcinogenicity, and epidemiology or biomonitoring findings and adsorption, distribution, metabolism, and excretion (ADME).

EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA will update the list of potential hazards in the final scope document of the phthalic anhydride risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' 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 for adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

During the Prioritization process, EPA identified the following PESS based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (e.g., pregnant women), workers and consumers (U.S. EPA 2019b). EPA plans to evaluate these PESS in the risk evaluation.

In developing exposure scenarios, EPA will evaluate reasonably available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a). Likewise, EPA will evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of phthalic anhydride. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted in the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws, are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of phthalic anhydride that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or ONUs via inhalation routes and exposures to workers via dermal routes. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not EPA plans to assess each unique combination of exposure pathway, route, and receptor in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

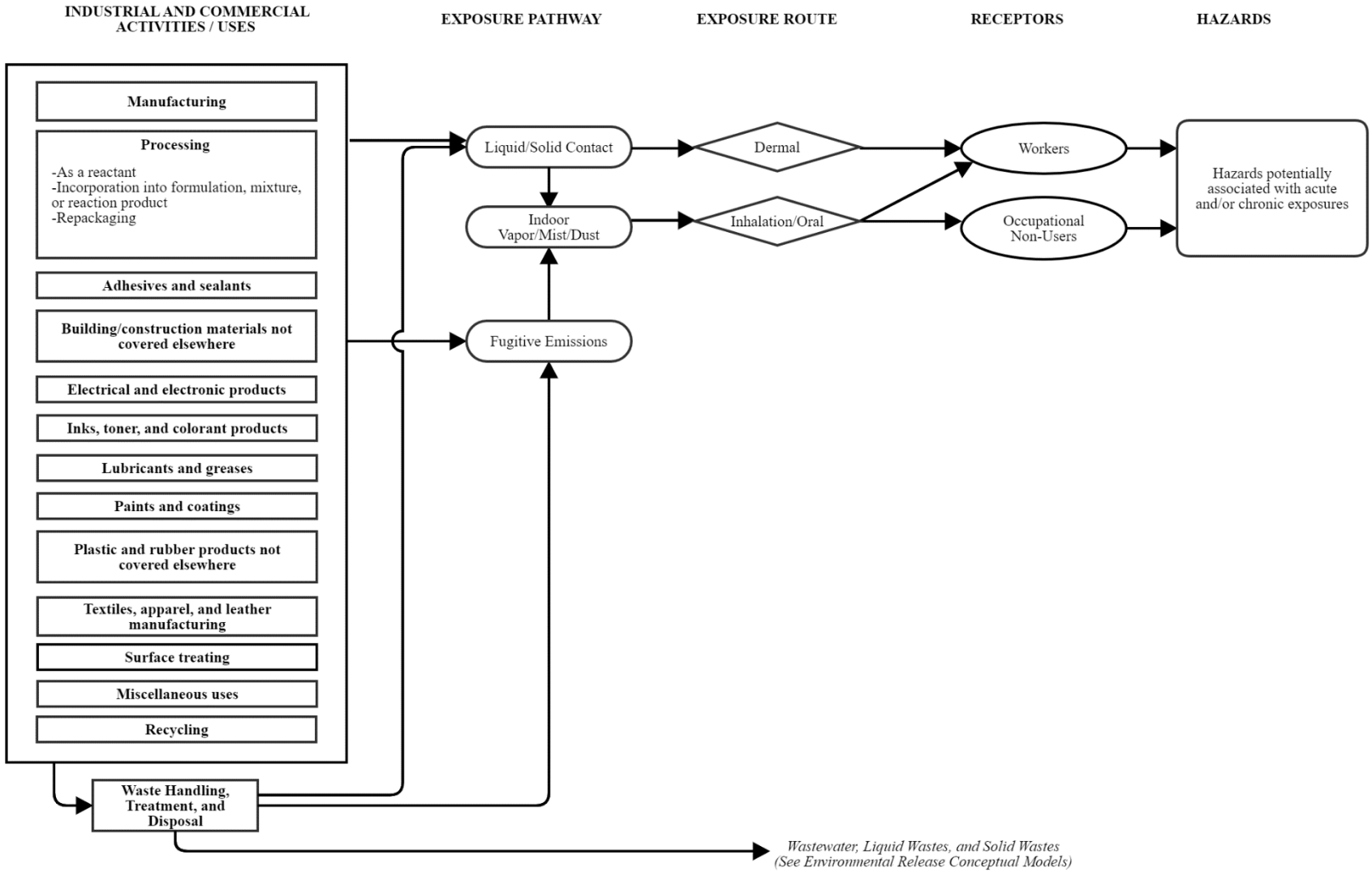

Figure 2-8. Phthalic Anhydride Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from industrial and commercial activities and uses of phthalic anhydride.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of phthalic anhydride. EPA expects that consumers may be exposed through product uses containing phthalic anhydride via oral, dermal and inhalation routes. Bystanders are expected to be exposed through product use via inhalation. EPA plans to evaluate pathways and routes of exposure that may occur during the varied identified consumer activities and uses. The supporting rationale for consumer pathways considered for phthalic anhydride are included in Appendix G.

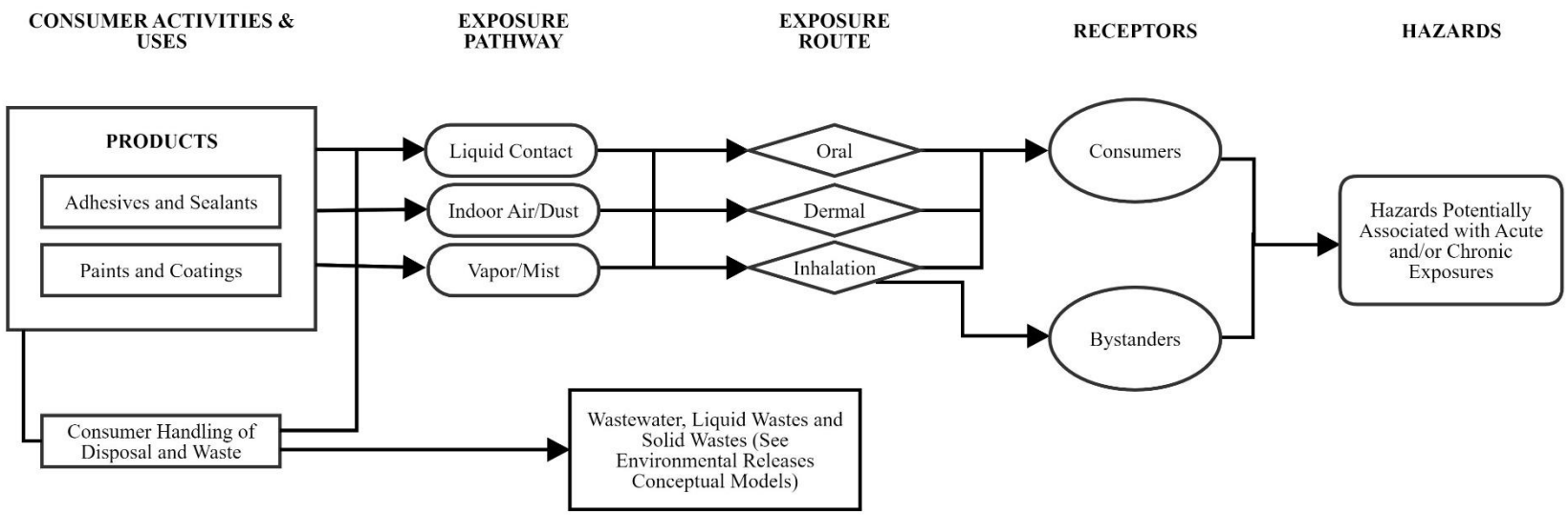

Figure 2-9. Phthalic Anhydride Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of phthalic anhydride.

2.6.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of phthalic anhydride within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of phthalic anhydride in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial and commercial uses of phthalic anhydride. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 and Section 2.6.3.2.

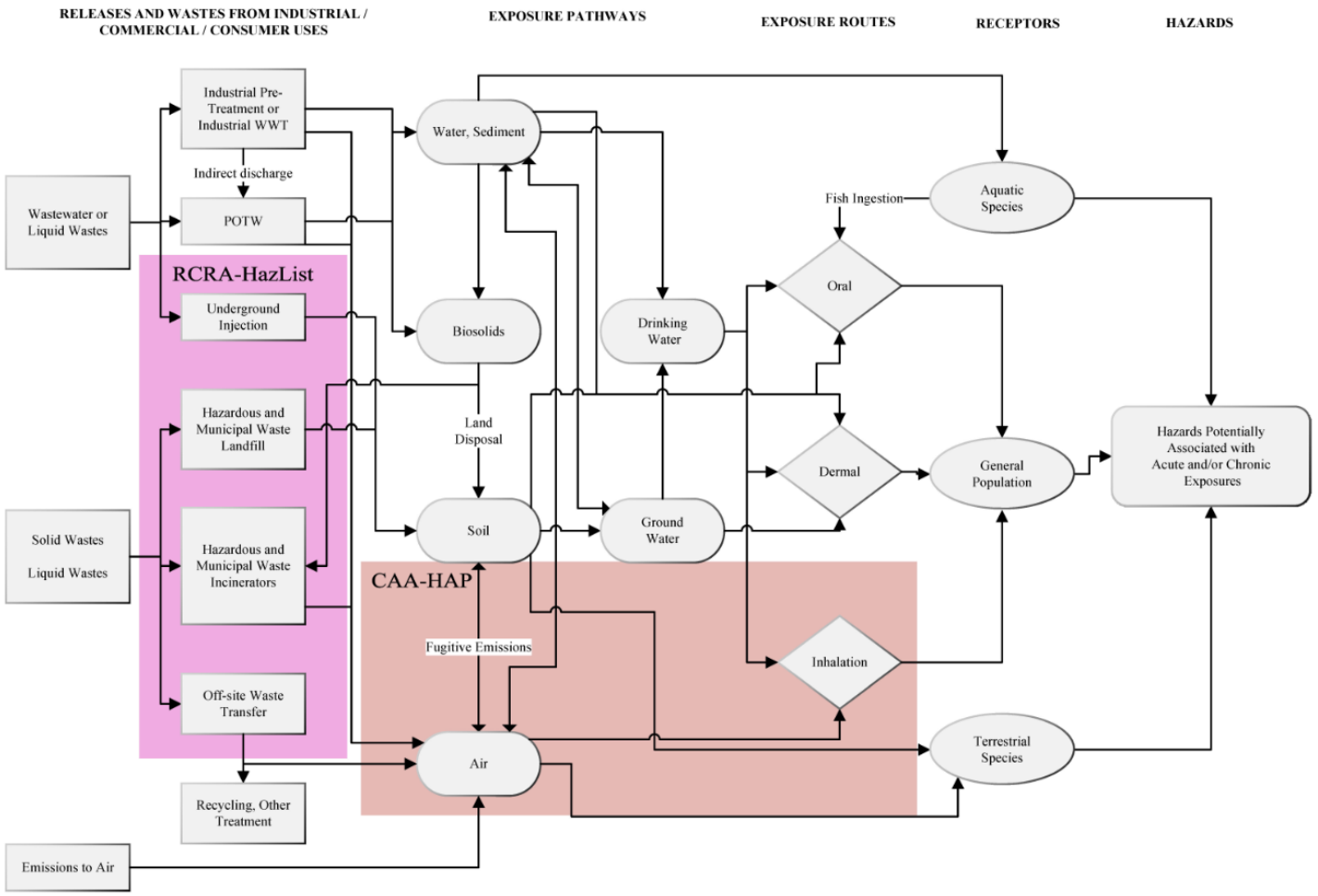

Figure 2-10. Phthalic Anhydride Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay).

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of phthalic anhydride including the environmental statutes covering those pathways.

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering

b) Receptors include PESS (see Section 2.5).

c) For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

2.6.3.1 Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant.

Phthalic anhydride is a HAP. EPA has issued a number of technology-based standards for source categories that emit phthalic anhydride to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks. Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of phthalic anhydride to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.2 Disposal and Soil Pathways

Phthalic anhydride is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U190 list. The general standard in RCRA Section 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to "*tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics*." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products from incineration treatment of phthalic anhydride wastes may be subject to regulations, as would phthalic anhydride that is burned for energy recovery.

TRI reporting in 2018 indicated 11,431 pounds released to underground injection to Class I wells. Environmental disposal of phthalic anhydride injected into Class I well types fall under the jurisdiction of RCRA and SDWA; and the disposal of phthalic anhydride via underground injection to Class I hazardous waste wells is not likely to result in environmental and general population exposures.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills. Based on 2018 reporting, TRI land disposal includes 4,082 pounds sent to Subtitle C landfills and 19,689 pounds disposed of in "other landfills" both on-site and off. Phthalic anhydride is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste landfills. Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems,

leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

Phthalic anhydride is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste (MSW) landfills. On-site releases to land from RCRA Subtitle D municipal solid waste landfills or exposures of the general population (including susceptible populations) or terrestrial species from such releases in this TSCA evaluation may occur. While permitted and managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lb per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land may occur from industrial non-hazardous and construction/demolition waste landfills. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so.

2.6.4 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2 11 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of phthalic anhydride that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of phthalic anhydride in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 includes releases from industrial, commercial and/or consumer uses to water/sediment; biosolids and soil, via direct and indirect discharges to water, that may lead to exposure to aquatic and terrestrial receptors., and to the general population via drinking water and fish consumption. The supporting rationales for general population and environmental exposure pathways that are in scope for phthalic anhydride are included in Appendix H.

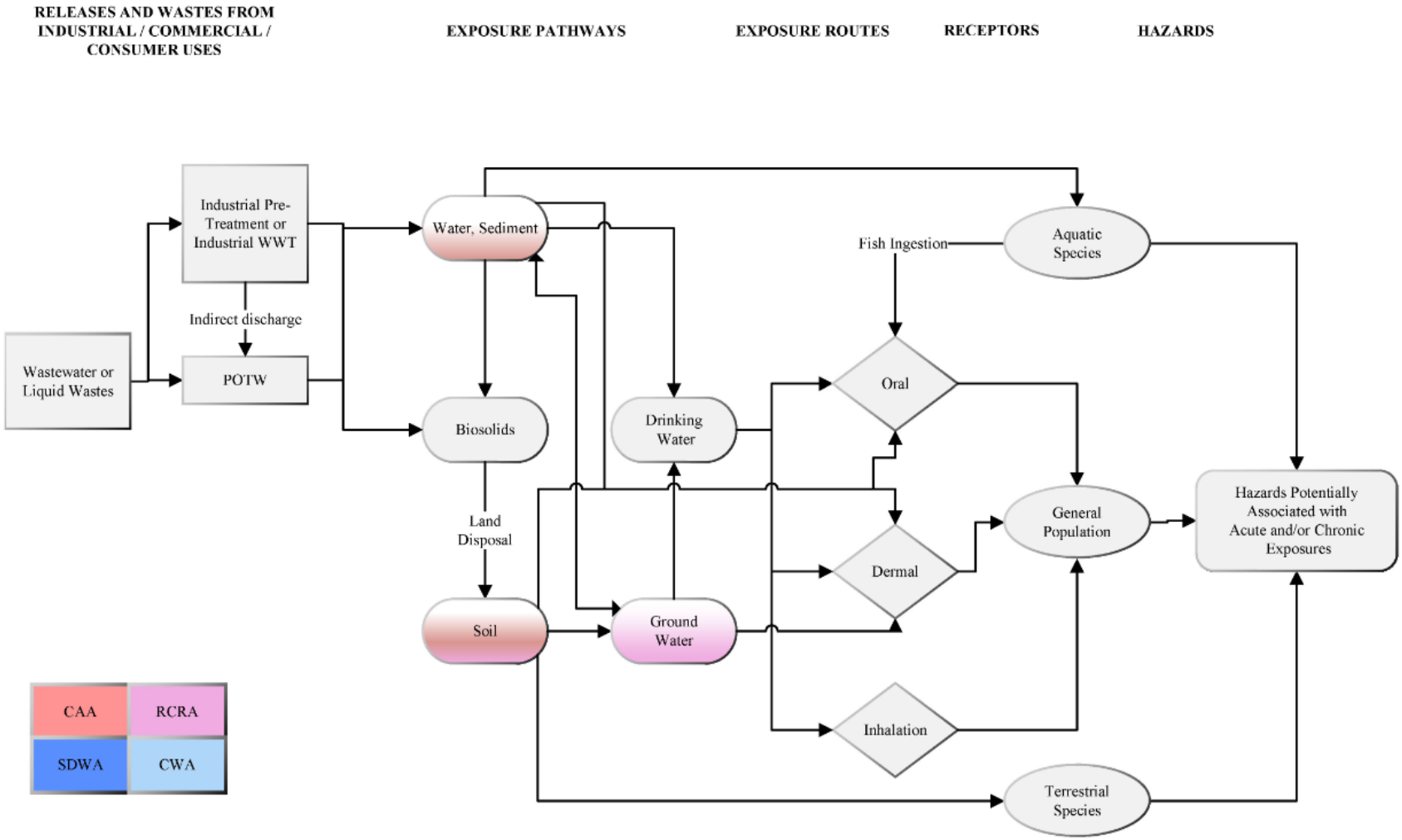

Figure 2-11. Phthalic Anhydride Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards.

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of phthalic anhydride that EPA plans to consider in the risk evaluation.

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering.

b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of phthalic anhydride to date which includes a partial, but not complete review of identified information as described in Section 2.1. EPA encourages submission of additional data, such as full study reports or workplace monitoring from industry sources, that may be relevant for EPA's evaluation of conditions of use, exposures, hazards and PESS during risk evaluation. Further, EPA may consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the p-chem properties and environmental fate and transport of phthalic anhydride as follows:

1) **Review reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the p-chem properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of p-chem properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**
   Measured data and, where necessary, model predictions of p-chem properties and environmental fate endpoints will be used to characterize the persistence and movement of phthalic anhydride within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight of the scientific evidence evaluation of p-chem and environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the p-chem and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, drinking water, surface water, sediment, soil, aquatic and terrestrial biota associated with exposure to phthalic anhydride. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. EPA plans to analyze

scenario-specific exposures. Based on their p-chem properties, expected sources, and transport and transformation within the outdoor and indoor environment, chemical substances are more likely to be present in some media and less likely to be present in others. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to continue to review data sources during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-5 below:

   Table 2-5. Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).**
   EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.2. EPA plans to continue to review relevant data sources during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
   Data for chemicals used in the same types of applications may be considered as surrogate data for phthalic anhydride. As with phthalic anhydride, maleic anhydride is used in the manufacture of polyester resins. EPA plans to evaluate the use of data for chemicals such as maleic anhydride as surrogates to fill data gaps where uses of phthalic anhydride and other chemicals align. If surrogate data are used, EPA normally converts air concentrations using the ratio of the vapor pressures of the two chemicals. EPA plans to review literature sources identified and if surrogate data are found, EPA plans to match these data to applicable conditions of use for potentially filling data gaps.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**
This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. EPA plans to consider relevant regulatory requirements in estimating releases during risk evaluation.

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Adhesive Formulation, the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry, the 2011 ESD on Chemical Industry, the 2011 ESD on Radiation Curable Coating, Inks and Adhesives, the 2015 ESD on the Use of Adhesives, and the 1994 Synthetic Fiber Manufacture GS may be useful to assess potential releases. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed.

EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not reasonably available, other methods may be considered. Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix H. EPA may further refine the mapping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and release sources and usage rates of phthalic anhydride and articles and formulations containing phthalic anhydride, or professional judgement) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of phthalic anhydride:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
   For phthalic anhydride, environmental media which will be analyzed are sediment, soil, ground water and surface water.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   Reasonably available environmental exposure models that meet the TSCA Section 26(h) and (i) Science Standards and that estimate water, sediment, and soil concentrations will be analyzed and considered alongside reasonably available water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into water, sediment, or soil, indirect release into water, sediment, or soil *(*i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
   There may have been changes to use patterns of phthalic anhydride over time. Monitoring data or modeled estimates will be reviewed to determine how representative they are of ongoing use patterns.

   Any studies which relate levels of phthalic anhydride in the environment or biota with specific sources or groups of sources will be evaluated.

4) **Group each condition(s) of use to environmental assessment scenario(s).**
   Refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For phthalic anhydride, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:
   - Estimates of groundwater concentrations, surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on reasonably available monitoring data.
   - Consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
   - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
   - Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic and terrestrial populations.
   - Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2.3 Occupational Exposures

EPA plans to analyze both worker and ONU exposures as follows:

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
EPA plans to review exposure data including workplace monitoring data collected by government agencies such as the Occupational Safety and Health Administration (OSHA) and NIOSH, and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

   EPA has preliminarily reviewed reasonably available monitoring data collected by OSHA and NIOSH and plans to match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources (identified in Table 2-6) and extract relevant data for consideration and analysis during risk evaluation.

   OSHA has established a PEL of 2 ppm 8-hour TWA. ACGIH set the TLV at 0.002 mg/m^3 TWA, with a STEL of 0.005 mg/m^3. EPA plans to consider the influence of these regulatory limits and recommended exposure guidelines on occupational exposures in the occupational exposure assessment. The following are some data sources identified thus far:

   Table 2-6. Potential Sources of Occupational Exposure Data

OSHA Chemical Exposure Health Data (CEHD) program data
NIOSH Health Hazard Evaluation (HHE) Program reports

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to phthalic anhydride.**
EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps. For example, maleic anhydride is a solid with a similar vapor pressure used in the manufacture of polyester resins and may provide surrogate data for these conditions of use.

3) **For conditions of use where data are limited or not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
EPA has identified potentially relevant OECD ESDs and EPA GSs corresponding to some conditions of use. For example, the 2015 ESD on the Use of Adhesives and the 2009 ESD on Adhesive Formulation are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GS's corresponding to some conditions of use. EPA plans to perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA or other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to ONUs.

5) **Consider and incorporate applicable EC and/or PPE into exposure scenarios.**
EPA plans to review potentially relevant data sources on EC and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). As presented in Table_Apx F-1, EPA has grouped the scenarios into representative release/exposure scenarios. EPA was not able to identify occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may refine the mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA will rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

EPA plans to analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) **Group each condition of use to consumer exposure assessment scenario(s).**
Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

For phthalic anhydride, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use
- Duration of exposure
- Weight fraction of chemical in products
- Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
   Indoor exposure pathways expected to be relatively higher include inhalation of vapors from indoor air during phthalic anhydride use and disposal. Indoor exposure pathways expected to be relatively lower include dermal contact to liquid. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds have not yet been conducted.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air.**
   Indoor exposure models that estimate emission and migration of SVOCs into the indoor environment are available. These models generally consider mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient, and the material-air partition coefficient. These properties vary based on p-chem properties and properties of the material. The OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.**
   To the extent other organizations have already modeled a phthalic anhydride consumer exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to phthalic anhydride have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) **Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting phthalic anhydride in specific media (e.g., indoor air).**
   The availability of phthalic anhydride concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air levels and various indoor sources will be analyzed.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**
   EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering sources and uses, exposure pathways including routes, and exposed populations.**
   For phthalic anhydride, the following are noteworthy considerations in constructing exposure scenarios for the general population:
   - Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
   - For exposure pathways where data are not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.
   - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
   - Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.
   - Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.
   - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need be further defined.
   - Evaluate the weight of the scientific evidence of general population exposure data.
   - Map or group each condition of use to general population exposure assessment scenario(s).
   - Environmental Exposure pathways regulated by non-TSCA EPA laws and regulations will be excluded from analysis.

   EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix H. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon reasonably available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with reasonably available monitoring

data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to receptor groups.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is reasonably available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty. Should data become reasonably available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **For exposure pathways where empirical data is not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
   For phthalic anhydride, media where exposure models will be considered for general population exposure include models that estimate drinking water concentrations, surface water concentrations, groundwater concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous phthalic anhydride chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are reasonably available.**
   To the extent other organizations have already modeled phthalic anhydride general population exposure scenario that is relevant to this assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar p-chem properties and similar uses are reasonably available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

4) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   The expected releases from industrial facilities are changing over time. Any modeled concentrations based on recent release estimates will be carefully compared with reasonably available monitoring data to determine representativeness.

5) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).**
   For phthalic anhydride, exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for soil than adults.

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of phthalic anhydride as follows:

1) **Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies).**
   EPA plans to analyze the hazards of phthalic anhydride to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g., analogue and read-across data) when characterizing the potential hazards of phthalic anhydride to aquatic and/or terrestrial organisms.

   Environmental hazard data will be evaluated using the environmental toxicity data quality criteria outlined in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

   Hazard endpoints (e.g., mortality, growth, immobility, reproduction) will be evaluated, while considering data availability, relevance, and quality.

2) **Derive hazard thresholds for aquatic and/or terrestrial organisms.**
   Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x, LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of phthalic anhydride to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

3) **Evaluate the weight of the scientific evidence of environmental hazard data.**
   During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other reasonably available approaches to integrate exposure and hazard assessments.**

EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the phthalic anhydride conceptual model. These organisms may be exposed to phthalic anhydride via a number of environmental pathways (e.g., surface water, sediment, soil, diet).

5) **Conduct an environmental risk characterization of phthalic anhydride.**
EPA plans to conduct a risk characterization of phthalic anhydride to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of phthalic anhydride in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of phthalic anhydride.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of phthalic anhydride after reviewing relevant p-chem properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of phthalic anhydride. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC_{50}, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for phthalic anhydride with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).**
EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for phthalic anhydride. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

   Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to phthalic anhydride hazard(s). Susceptibility of particular human receptor groups to phthalic anhydride will be determined by evaluating information on factors that influence susceptibility.

   EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for phthalic anhydride's exposure. EPA plans to

review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

3) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

   Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011b, 1994b). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not reasonably available or would not alter the analysis.

   The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to phthalic anhydride, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.**
Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

   EPA plans to evaluate whether the reasonably available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011b), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient data to conduct dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to phthalic anhydride, which could be important for worker, consumer, and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes. This may include using route-to-route extrapolation methods where appropriate and depending on the nature of reasonably available data.

If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures.

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's Risk Characterization Policy, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726). For instance, in the risk characterization summary, EPA plans to further carry out the obligations under TSCA Section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

EPA will also be guided by EPA's Information Quality Guidelines (U.S, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, EPA plans to identify in the risk characterization the following: (1) Each population addressed by an estimate of applicable risk effects; (2) The expected risk or central estimate of risk for the PESS affected; (3) Each appropriate upper-bound or lower-bound estimate of risk; (4) Each significant uncertainty identified in the process of the

assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) Peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1 Gray Literature Sources for Phthalic Anhydride

Source/Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Aus. Assm.	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	Office of Air: TRI	US EPA Resources	Database
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document
EPA	Support document for AEGLS	US EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database

Source/Agency	Source Name	Source Type	Source Category
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine's Hazardous Substance Databank	Other US Agency Resources	Database
NLM	National Library of Medicine's HazMap	Other US Agency Resources	Database
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD SIDS	International Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
OECD	OECD: General Site	International Resources	General Search
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF PHTHALIC ANHYDRIDE

This appendix provides p-chem information and data found in preliminary data gathering for phthalic anhydride. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0459).

Table_Apx B-1. Physical and Chemical Properties of Phthalic Anhydride

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_8H_4O_3$	NA	NA
Molecular weight	148.12 g/mol	NA	NA
Physical state	Solid white needles	Rumble, 2018	High
Physical properties	White solid (flake) or a clear colorless liquid (molten), characteristic, acrid odor	NLM, 2015	High
Melting point	131.4°C	NLM, 2015	High
Boiling point	285.3°C	Rumble, 2018	High
Density	1.527 g/cm^3 at 20°C	Elsevier, 2019	High
Vapor pressure	5.17×10^{-4} mm Hg at 25°C	NLM, 2015	High
Vapor density	6.6 (air = 1)	NLM, 2015	High
Water solubility	6000 mg/L at 25°C	NLM, 2015	High
Log Octanol/water partition coefficient (Log Kow)	1.6	NLM, 2015	High
Henry's Law constant	6.35×10^{-6} atm·m^3/mole at 25°C (Bond method)	U.S. EPA, 2012b	
Flash point	152°C	RSC, 2019	High

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Auto flammability	Not available		
Viscosity	1.19 cP at 132°C	NLM, 2015	High
Refractive index	Not available		
Dielectric constant	Not available		

[a] Measured unless otherwise noted.
NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for phthalic anhydride.

Table_Apx C-1. Environmental Fate Characteristics of Phthalic Anhydride

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	Phthalic anhydride absorbs at wavelengths >290 nm, and therefore, may be susceptible to direct photolysis by sunlight	NLM (2015)
Indirect Photodegradation	$t_{1/2}$ = 54.6 days from ·OH rate constant 1.96 × 10^{-13} cm^3/molecules-second (12-hour day; 1.5 × 10^6 ·OH/cm^3)	U.S. EPA (2012b)
Hydrolysis	$t_{1/2}$ = 24.8 minutes based on first-order hydrolysis of 4.29 × 10^{-4}/second at 25.1 ºC; $t_{1/2}$ = 70 seconds measured at pH 0–6 and 25 ºC in buffered solutions; $t_{1/2}$ = 2.4 seconds measured at pH 8.9	NLM (2015)
Biodegradation (Aerobic)[b]	85.2%/14 days with 30 mg/L sludge based on BOD; 90.5%/30 days in predominantly domestic sewage (OECD 301D); 99%/14 days (OECD 301E)	SYKE (2018)
Biodegradation (Aerobic)[b]	85.2%/14 days in activated sludge (method comparable to OECD TG 301C)	OECD (2005) citing MITI (1992)
Biodegradation (Aerobic)[b]	33% TOC removal, 88% COD removal after 24 hours in aerobic activated sludge	OECD (2005) citing Matsui (1975) and Matsui (1988)
Wastewater Treatment[b]	94% total removal (93% by biodegradation, 0.34% by sludge, 0% by volatilization to air; estimated)[c]	U.S. EPA (2012b)
Bioconcentration Factor[b]	4,053 in Oedogonium (alga); did not concentrate in water flea or snail; bioconcentration in fish may not be an important process due to rapid hydrolysis in water	NLM (2015)

Property or Endpoint	Value[a]	Reference
Bioconcentration Factor[b]	3.2–3.4	OECD (2005) citing Bayer Industry Services (2004a and 2004b)
Bioaccumulation Factor[b]	4.9[c]	U.S. EPA (2012b)
Soil Organic Carbon:Water Partition Coefficient (Log KOC)[b]	0.3–1.5 (K_{OC} = 2–31 in various soils)	OECD (2005)

[a]Measured unless otherwise noted

[b]Due to the rapid rate of hydrolysis, these data likely pertain to the hydrolysis byproduct, phthalic acid

[c]EPI Suite™ physical property inputs: Log Kow = 1.60, BP = 295.00 °C, MP = 130.80 deg C, VP = 0.000517 mm Hg, WS = 6200 mg/L, BioP = 4, BioA = 1 and BioS = 1 SMILES O=C(OC(=O)c1cccc2)c12

·OH = hydroxyl radical; HPLC = high performance liquid chromatography; BOD = biological oxygen demand; OECD = Organisation for Economic Co-operation and Development; MITI = Ministry of International Trade and Industry, Japan; TOC = total organic carbon; COD = chemical oxygen demand

Appendix D REGULATORY HISTORY

The chemical substance, phthalic anhydride, is subject to federal and state laws and regulations in the United States (Table_Apx D-1 and Table_Apx D-2). Regulatory actions by other governments, tribes and international agreements applicable to phthalic anhydride are listed in Table_Apx D-3.

D.1 Federal Laws and Regulations

Table_Apx D-1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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 is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of 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 (76 FR 50816, August 16, 2011).
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 (60 FR 16309, March 29, 1995).
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 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).
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 removed two pollutants from the original list leaving 187 at present.	Phthalic anhydride is listed on the "initial list" of HAPs (42 U.S.C.7412(b)(1)).
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has established NESHAPs for a number of source categories that emit phthalic anhydride to air.
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	Phthalic anhydride is a VOC but is unregulated.
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	Phthalic anhydride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U190 (40 CFR 261.33).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	factors such as flammability, 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 which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Phthalic anhydride is a hazardous substance under CERCLA. Releases of phthalic anhydride in excess of 5000 pounds must be reported (40 CFR 302.4).
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.	OSHA revised an existing occupational safety and health standards for phthalic anhydride to include a PEL of 2 ppm or 12 mg/m^3 as an 8-hour, TWA (29 CFR 1910.1000).
Federal Hazardous Materials Transportation Act (HMTA)	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. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	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). 49 CFR part 172.101Appendix A"

D.2 State Laws and Regulations

Table_Apx D-2 State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: Rhode Island 7,000 $\mu g/m^3$ (24 hours), 20 $\mu g/m^3$ (annual) (Air Pollution Regulation No. 22). New Hampshire 22 $\mu g/m^3$ (24 hours), 15 $\mu g/m^3$ (annual) (Env-A 1400: Regulated Toxic Air Pollutants).

State Actions	Description of Action
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).
State PELs	California (PEL of 1 ppm) (Cal Code Regs. Title 8, § 5155) Hawaii PEL: 1 ppm (Hawaii Administrative Rules Section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (N.J.A.C. 7:1G), and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing Phthalic anhydride including Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015) and Vermont (18 V.S.A § 1776).
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 April 19, 2019). California issued a Health Hazard Alert for Phthalic anhydride (Hazard Evaluation System and Information Service, 2016). Phthalic anhydride is on the MA Toxic Use Reduction Act (TURA) list of 2019 (Toxics Use Reduction Act (TURA), MGL, Chapter 21I, Section 1 to Section 23)

D.3 International Laws and Regulations

Table_Apx D-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. Database accessed April 19, 2019) 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 April 10, 2019).
Australia	Phthalic anhydride is listed on Australia's Inventory or Chemical Substance (AICS). The chemical 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 April 19, 2019*)*
Japan	Phthalic anhydride is regulated in Japan under the following legislation:

Country/Tribe/ Organization	Requirements and Restrictions
	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof 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 April 18, 2019.

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for phthalic anhydride.

E.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities. EPA plans to consider this information in combination with available monitoring data and estimation methods and models, as appropriate, to quantify occupational exposure and releases for the various conditions of use in the risk evaluation.

E.1.1 Manufacture (Including Import)

The 2016 CDR reports 35 facilities that submitted activity data for 2015. 18 of these facilities stated that they imported phthalic anhydride in 2015, two stated that they manufactured phthalic anhydride in 2015, and the remaining 15 facilities' 2015 manufacture or import activity is withheld or claimed as CBI (U.S. EPA, 2019b). According to 2016 public CDR data, phthalic anhydride is both domestically manufactured in and imported into the United States in liquid and solid form (U.S. EPA, 2019b).

E.1.1.1 Domestic Manufacturing

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 to using o-xylene (Park and Sheehan, 2000).

E.1.1.2 Import

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, or dry powder form according to 2016 CDR. Of the facilities in 2016 CDR that imported phthalic anhydride in 2015 (excluding facilities for which the importation /manufacturing activity was withheld or claimed CBI), EPA has identified 10 sites that imported phthalic anhydride directly to their sites for on-site processing or use and eight that imported phthalic anhydride directly to other sites for processing or use (the importing sites of record do not directly handle or store the imported phthalic anhydride) (U.S. EPA, 2019b).

E.1.2 Processing and Distribution

E.1.2.1 Reactant or Intermediate

Processing as a reactant is the primary use of phthalic anhydride. Processing as a reactant or intermediate is the use of phthalic anhydride as a feedstock in the production of another chemical via a chemical reaction in which phthalic anhydride is consumed to form the product. Specifically, phthalic anhydride is used as an intermediate to produce (Park and Sheehan, 2000; U.S. EPA, 2019b):

- Other phthalates that are subsequently used as plasticizers in poly (vinyl chloride) (PVC);
- Polyester that is used in boat hulls, tubs, and building and construction materials;
- Alkyd resins used in coatings; and
- A variety of other products including dyes, flame retardants, lubricants and greases, and other chemicals.

Exact operations for the use of phthalic anhydride as a reactant to produce other chemicals are not known at this time. For using a chemical as a reactant, operations would typically involve unloading the chemical from transport containers and feeding the chemical into a reaction vessel(s), where the chemical would react either fully or to a lesser extent. Following completion of the reaction, the produced substance may be purified further, thus removing unreacted phthalic anhydride (if any exists).

E.1.2.2 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. In the 2016 CDR, companies reported use of phthalic anhydride in the manufacturing of paint and coating, adhesives, synthetic dye and pigment, textiles, apparel, and leather, as well as in the manufacturing of plastic material and resin and synthetic rubbers (U.S. EPA, 2019b). Phthalic anhydride is also used in the formulation of hydraulic fracturing chemicals (Finoric LLC., 2016; U.S. EPA, 2015b; Committee on Energy and Commerce's Minority Staff, 2011; Whittemore, D., 2011). The exact processes used to formulate products containing phthalic anhydride are not known at this time; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products. EPA plans to investigate processing uses of phthalic anhydride during risk evaluation.

E.1.2.3 Repackaging

Repackaging refers to preparation of a chemical substance for distribution into commerce in a different form, state, or quantity than originally received/stored, where such activities include transferring a chemical substance form a bulk storage container into smaller containers.

E.1.2.4 Recycling

According to 2018 TRI, 2,314,977 pounds 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, 2019c)

E.1.3 Uses

E.1.3.1 Adhesives, Sealants, Paints, and Coatings

Phthalic anhydride was mainly identified in residual quantities (<1%) in adhesives, sealants, paints, and coatings (U.S. EPA, 2019b; 3M Company, 2019; Royal Adhesives & Sealants, 2016; Aremco Products, Inc., 2018). However, phthalic anhydride was identified in higher concentrations in a small subset of products, such as mounting adhesives (60 to 90% phthalic anhydride) (Aremco Products, Inc., 2018; Ted Pella, 2019), electronics adhesives (5 to 10% phthalic anhydride) (Lord, 2017; Krayden, 2019), primers (1 to 10% phthalic anhydride) (Harris Paints Co, 2015a), and varnishes (20 to 25% phthalic anhydride) (Harris Paints Co, 2015b; Harris Paints Co, 2018). The application procedure depends on the type of adhesive, sealant, paint, or coating formulation and the type of substrate. The formulation is loaded into the application reservoir or apparatus and applied to the substrate via brush, spray, roll, dip, curtain, or syringe or bead application. Application may be manual or automated. After application, the adhesive, sealant, paint, or coating is allowed to dry or cure (OECD, 2015). The drying/curing process may be promoted through the use of heat or radiation (radiation can include ultraviolet (UV) and electron beam radiation (OECD, 2010).

E.1.3.2 Plastic and Rubber Products

Phthalic anhydride is used in the production of plastic and rubber products, which may be used industrially, commercially, and by consumers. These products are used in a variety of products,

including building and construction materials, electronics, personal care products, and medical devices (U.S. EPA, 2019b; Durcon Inc., 2020; OSHA 2019; Stepan 2020; Meeting Henkel, 2019; Durcon Inc., 2011). Phthalic anhydride is likely consumed in the production of these plastic and rubber products (e.g., consumed as a reactant in the production of plasticizers used in these products) and is either not present or is present in small quantities entrained in the products. EPA plans to investigate the use phthalic anhydride in plastic and rubber product manufacturing during risk evaluation.

E.1.3.3 Other Uses

Phthalic anhydride is also used in hydraulic fracturing (Finoric, LLC., 2016; U.S. EPA, 2015b; Committee on Energy and Commerce's Minority Staff, 2011; Whittemore, D., 2011), acceptance testing of foams used on human-rated spaceflight vehicles (Email NASA, 2020), flame retardants (Stepan, 2020; US EPA, 1994a), tanning and curing of textiles, apparel, and leather (US EPA, 1994a), surface treating (U.S. EPA, 2019b), lubricants and greases (U.S. EPA, 2019b), laboratory chemicals (Email NASA, 2020; Thermo Fisher Scientific, 2018), water filtration applications (Meeting Henkel, 2019), and oil treatment of wood (Junckers, 2019).

EPA does not know the extent to which phthalic anhydride is present in these products versus is used as an intermediate or processing aid in the production of these products. EPA plans to investigate the uses of phthalic anhydride during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of phthalic anhydride may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat or dispose onsite wastes that they themselves generate are assessed in each condition of use assessment. Similarly, point source discharges of phthalic anhydride to surface water are assessed in each condition of use assessment (point source discharges are exempt as solid wastes under RCRA). Wastes of phthalic anhydride that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: phthalic anhydride may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing phthalic anhydride discharged to a POTW may be subject to EPA or authorized NPDES state pretreatment programs. The assessment of wastewater discharges to POTWs and non-public treatment works of phthalic anhydride is included in each of the condition of use assessments.

- Solid Wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

  Phthalic anhydride is both a source-specific and commercial product listed as a hazardous waste denoted as a K-listed waste. Waste fractions from the distillation process used to produce phthalic anhydride from naphthalene and/or o-xylene are listed as RCRA hazardous waste.

Phthalic anhydride is a U-listed hazardous waste under code U190 under RCRA; therefore, discarded, unused pure and commercial grades of phthalic anhydride are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of phthalic anhydride may generate wastes of phthalic anhydride that are exempted as solid wastes under 40 CFR § 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of phthalic anhydride may be exempt as a solid waste.

According to 2018 TRI, 121 facilities reported a total of 12,592,162 pounds of production-related waste managed. Of this total, 9,206,555 pounds were treated, 2,314,977 pounds were recycled, 807,346 pounds were burned for energy recovery, and 260,284 pounds were released to the environment. Treatment accounted for 73% of phthalic anhydride waste managed, with 8,006,296 pounds treated on site and 1,203,259 pounds sent off site for treatment. Of the phthalic anhydride waste that was recycled, 99.9% was recycled on site. Phthalic anhydride waste burned for energy recovery made up 8% of the total, with 55% burned on site and 45% sent off site for energy recovery. Only 2% of the total phthalic anhydride waste was released to the environment.

E.2 Preliminary Occupational Exposure Data

EPA presents below an example of occupational exposure-related information obtained from preliminary data gathering. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

Table Apx E-1 summarizes NIOSH Health Hazard Evaluations identified during EPA's preliminary data gathering.

Table_Apx E-1. Summary of NIOSH HHEs with Monitoring for Phthalic Anhydride [a]

Year of Publication	Report Number	Facility Description
1984	HETA 84-239-1586	Meat Cutting and Wrapping
1979	HE 79- 49-631	Machining and Assembly of Universal Joints, Propeller Shafts, and End Yokes
1978	HETA 78-52-1483	Electric Circuit Breaker Manufacture (Epoxy Insulators)

[a] Table includes HHEs identified to date

Table Apx E-2 summarizes OSHA CEHD identified during EPA's preliminary data gathering.

Table_Apx E-2. Summary of Industry Sectors with Phthalic Anhydride Monitoring Samples Available from OSHA Inspections Conducted Between 2010 and 2019

NAICS	NAICS Description	Number of Data Points
No NAICS code reported		54
325199	All Other Basic Organic Chemical Manufacturing	1
326199	All Other Plastics Product Manufacturing	3
326299	All Other Rubber Product Manufacturing	4
337127	Institutional Furniture Manufacturing	62
926150	Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors	1

Appendix F SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES

Table_Apx F-1 Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture and Packaging	Liquid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in liquid form. Thus, the potential for exposures to workers exists during manufacturing.
				Solid Contact	Dermal	Workers	Yes	2016 CDR references manufacture in pellet form and dry powder form. Thus, the potential for exposures to workers exists during manufacturing.
				Vapor	Inhalation	Workers, ONU	No	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during manufacturing.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	2016 CDR references manufacture in pellet form and dry powder form, which may form dust. Thus, the potential for exposures to workers exists during manufacturing.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								direct contact with the chemicals.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	2016 CDR references import in liquid form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				Solid Contact	Dermal	Workers	Yes	2016 CDR references import in dry powder and pellet form. The potential for exposures to workers exists during import, but exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers, ONU	No	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during repackaging of import containers.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	2016 CDR references dry powder and pellet form, which may create dust. The potential for dust exposures to workers and ONUs exists during import, but exposure will only occur in the event the imported material is repackaged.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								direct contact with the chemicals.
Processing	Processing as a Reactant	Intermediate in: All other basic organic chemical manufacturing; Plastic material and resin manufacturing Adhesives and sealant chemicals in: Paint and coating manufacturing Ion exchange agents in: All other basic organic chemical manufacturing Lubricants and lubricant additives in: Petroleum lubricating oil and grease manufacturing Paint additives and coating additives not described by other categories in: Paint and coating manufacturing Pigments in: Synthetic dye and pigment manufacturing Inks in: Printing ink manufacturing Plastic in: Plastics product manufacturing Corrosion inhibitors and anti-scaling agents in: Miscellaneous Manufacturing Plating agents and surface treating agents in: Rubber Product Manufacturing	Processing as a reactant	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as phthalic anhydride may be in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as phthalic anhydride may be in solid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during manufacturing of other chemicals.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during manufacturing of other chemicals, as phthalic anhydride may be in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								direct contact with the chemicals.
	Incorporated into formulation, mixture or reaction product	Intermediate in: Paint and coating manufacturing; All other chemical product and preparation manufacturing; Pharmaceutical and medicine manufacturing Plasticizers in: Plastic material and resin manufacturing; Petrochemical Manufacturing; Construction; Polyester and alkyd resins, curing agent for epoxy resins 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; Asphalt Paving, Roofing, and Coating Materials Manufacturing Adhesives and sealant chemicals in: Paint and coating manufacturing Fillers in: Textile, apparel, and leather manufacturing Oxidizing/reducing agents in: Synthetic rubber manufacturing; Adhesive manufacturing; plastic material and resin manufacturing; Wholesale and retail trade Dyes in: Synthetic dye and pigment manufacturing Laboratory chemicals	Processing into formulations, mixtures, or reaction product	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as phthalic anhydride is in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (incorporation into formulation, mixture, or reaction product), as phthalic anhydride is in solid form.
				Vapor	Inhalation	Workers, ONU	Yes	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low. However, some of these operations may occur at elevated temperatures, which increase the potential for vapor generation.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product).
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing (incorporation into formulation, mixture, or reaction product), as phthalic anhydride is in solid form.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Repackaging	Repackaging	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (repackaging), as phthalic anhydride is in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during processing (repackaging), as phthalic anhydride is in solid form.
				Vapor	Inhalation	Workers, ONU	No	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during processing (repackaging).
				Dust	Inhalation/Dermal	Workers, ONU	Yes	The potential for dust exposures to workers and ONUs exists during processing (repackaging), as phthalic anhydride is in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	Recycling	Recycling of Phthalic Anhydride	Recycling of phthalic anhydride and products containing phthalic anhydride	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be recycled.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as solid formulations may be recycled.
				Vapor	Inhalation	Workers, ONU	No	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during recycling of liquid wastes.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	Dust generation is possible during recycling of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Industrial/ Commercial Use	Adhesives and sealants; paints and coatings; surface treating; oil treatment of wood	Adhesives and sealants; paints and coatings; surface treating; oil treatment of wood	Spray, brush, roll, dip, and other forms of application	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for phthalic anhydride used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid phthalic anhydride is not expected during the use of these products because they are in liquid form.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	No	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	Yes	Mist generation is possible during application of these products.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to solid phthalic anhydride is not expected during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Hydraulic fracturing; Epoxy hardener; Epoxy resin in building and construction; tanning and curing of textiles; lubricants and greases; Laboratory chemical; inks, toners and colorant products	Hydraulic fracturing; Epoxy hardener; Epoxy resin in building and construction; tanning and curing of textiles; lubricants and greases; Laboratory chemical; inks, toners and colorant products	Use in hydraulic fracturing Use of epoxy hardeners and resins containing PA Use in tanning and curing of textiles Use of lubricants and greases containing PA	Liquid Contact	Dermal	Workers	Yes	These products are in liquid form; therefore, exposures to workers exists for phthalic anhydride used in these products.
				Solid Contact	Dermal	Workers	No	The potential for exposures to solid phthalic anhydride is not expected during the use of these products because they are in liquid form.
				Vapor	Inhalation	Workers, ONU	No	Due to phthalic anhydride's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
			Use in laboratories Use inks, toners, and colorant products (e.g., printing)	Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	No	The potential for exposures to solid phthalic anhydride is not expected during the use of these products because they are in liquid form.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
	Plastic and rubber products; electrical and electronic products (load absorber, etc.); Flame retardant in polymers; Transportation equipment manufacturing (used in exterior, interior, electrical systems, wire assemblies, etc); Water filtration applications; Boat hulls, shower stalls, wire coating and insulation, garden hoses,	Plastic and rubber products; electrical and electronic products (load absorber, etc.); Flame retardant in polymers; Transportation equipment manufacturing (used in exterior, interior, electrical systems, wire assemblies, etc); Water filtration applications; Boat hulls, shower stalls, wire coating and insulation, garden hoses, vinyl wallpaper	Use of articles made using PA	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid PA is not expected during the use of these products because they are solid articles.
				Solid Contact	Dermal	Workers	Yes	These products are solid articles in which PA is entrained; therefore, PA exposures to workers is unlikely but may occur if cutting /sawing / other machining operations occur.
				Vapor	Inhalation	Workers, ONU	No	Due to PA's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	These products are solid articles in which PA is entrained; therefore, PA exposures to workers and ONUs is unlikely

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	vinyl wallpaper							but may occur if cutting /sawing / other machining operations occur.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.
Disposal	Disposal	Disposal of PA wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as liquid formulations may be disposed.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use as solid formulations may be disposed
				Vapor	Inhalation	Workers, ONU	No	Due to PA's vapor pressure (VP) (VP = 5.17 × 10-4 mm Hg) at room temperature, potential for vapor generation is low.
				Mist	Inhalation/Dermal	Workers, ONU	No	Mist generation is not expected during disposal of liquid wastes.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	Dust generation is possible during disposal of solid wastes.
				Liquid/Solid Contact	Dermal	ONU	No	Exposure is expected to be primarily restricted to workers who are directly involved in working with the chemical. ONUs are not expected to come in direct contact with the chemicals.

Appendix G SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USE

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Construction, Paint, Electrical, and Metal Products	Adhesives and Sealants (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible and will be analyzed
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected and analyzed
Consumer Use	Construction, Paint, Electrical, and Metal Products	Paints and Coatings (Product)	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dermal, oral and inhalation exposure from this condition of use may occur and will be analyzed
			Direct contact through application or use of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in using the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible and will be analyzed

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	Yes	If product is applied as a mist, inhalation and dermal exposures would be expected and further analyzed
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	Long-term emission/mass-transfer, Abrasion, Transfer to Dust	Dust	Dermal, Inhalation, Oral	Consumers, Bystanders	Yes	Dust generation is possible during the handling of solid waste
			Direct contact through handling or disposal of products	Liquid Contact	Dermal	Consumers	Yes	Exposure is expected to be primarily restricted to consumers who are directly involved in handling and disposal of the chemical.
			Long-term emission/mass-transfer through application or use of products	Vapor	Inhalation	Consumers and Bystanders	Yes	Inhalation is possible and will be analyzed
			Direct contact through application or use of products	Mist	Inhalation and Dermal	Consumers and Bystanders	No	Mist generation is not expected during handling or disposal

Appendix H SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR ENVIRONMENTAL RELEASES AND WASTES

Table_Apx H-1 General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[8]	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	Phthalic anhydride is a HAP. Stationary source releases of phthalic anhydride to ambient air are under the jurisdiction of the CAA.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	No	
				TBD	Aquatic and Terrestrial Receptors	No	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	Release of phthalic anhydride into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors will be analyzed
				Oral Dermal	General Population	Yes	Release of phthalic anhydride into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population will be analyzed.
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	Yes	Release of phthalic anhydride into surface water and indirect partitioning to drinking water is an expected exposure pathway.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population and terrestrial species.
				TBD	Terrestrial receptors	Yes	

[8] The exposure pathways, exposure routes and hazards EPA plans to consider are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of phthalic anhydride in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[8]	Rationale
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	Phthalic anhydride is released to Class I Underground Injection Hazardous Wells which are covered by SDWA and RCRA.
				TBD	Aquatic and Terrestrial Species		
Disposal	Solid and Liquid Wastes	Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral Dermal	General Population	No	Phthalic anhydride is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
				TBD	Aquatic and Terrestrial Receptors		