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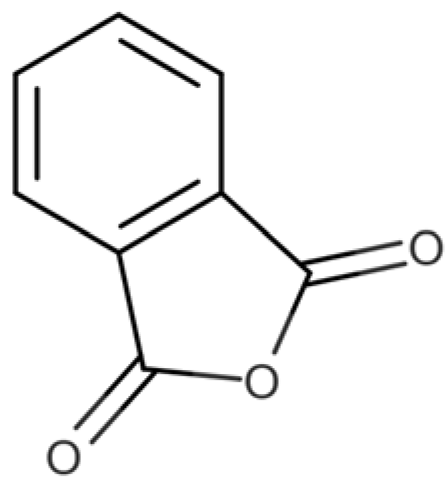
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

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

CASRN 85-44-9



August 2020

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Docket

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

Disclaimer

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
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
ILO	International Labour Organization
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 Inventory
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
PAD	Phthalic anhydride
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, Toxic
PECO	Population, Exposure, Comparator and Outcome
PEL	Permissible Exposure Limit
PESO	Pathways and Processes, Exposure, Setting or Scenario, and Outcomes
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
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
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 as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2019-0131). The first step of the risk evaluation process is the development of the draft scope document. EPA published the *Draft Scope of the Risk Evaluation for Phthalic Anhydride (1,3-Isobenzofurandione) CASRN 85-44-9* (EPA Document No. EPA 740-R-20-020) (U.S. EPA, 2020c) and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0459) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for phthalic anhydride. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The scope for phthalic anhydride includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposure that EPA plans to consider in the 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 substance.

General Information. Phthalic anhydride is a white solid with a total production volume in the United States between 500 million and 750 million pounds (U.S. EPA, 2020a). Phthalic anhydride is highly reactive and only exists under artificial conditions devoid of moisture and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, also known as *o*-phthalic acid, when allowed contact with water or moisture present in the air. This transformation is immediate, with half of the phthalic anhydride hydrolyzed within seconds and essentially complete hydrolysis occurring in approximately 8 minutes under conditions simulating sea water or physiological fluids (Andres et al., 2001). Phthalic anhydride is also hydrolyzed to 1,2-benzenedicarboxylic acid spontaneously upon entering the respiratory tract of the human body (Zhang et al., 2002) Therefore, while this scope includes conditions of use for phthalic anhydride only, hazards, exposures, and PESS for both phthalic anhydride and its immediate hydrolysis product, 1,2-benzenedicarboxylic acid are included when appropriate (*i.e.*, when a COU of phthalic anhyride results in its immediate hydrolysis product), as 1,2-benzenedicarboxylic is expected to be the product found in the environment and the proximal toxicant in contact with living organisms.

Reasonably Available Information. EPA leveraged the data and information sources already described in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) to inform the development of this scope document. Furthermore, 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 are provided in Section 2.1. EPA used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for phthalic anhydride. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. Preliminary review of these data indicated that phthalic anhydride is highly reactive and quickly hydrolyzes to 1,2-benzenedicarboxylic acid under normal environmental or physiological conditions. Therefore, the search of relevant information was subsequently expanded to include information regarding the hazards, exposures, and PESS for 1,2-benzenedicarboxylic acid. The references from this expanded search are not yet available for review and inclusion in this scoping document. EPA plans to evaluate additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

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 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. EPA revised the conditions of use in the final scope of the risk evaluation based on additional information and public comments (Docket ID: EPA-HQ-OPPT-2018-0459) on the draft scope document for phthalic anhydride. 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 the scope of the risk evaluation.

Conceptual Model. The conceptual models for phthalic anhydride, including its hydrolysis into 1,2-benzenedicarboxylic acid, 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. EPA considered reasonably available information as well as public comments received on the draft scope for phthalic anhydride in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for phthalic anhydride on the following exposures, hazards and receptors:

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to evaluate releases to the environment as well as human and environmental exposures resulting from the conditions of use of phthalic anhydride that EPA plans to consider in the risk evaluation. Exposures for phthalic anhydride and/or 1,2-benzenedicarboxylic acid are discussed in Section 2.3. Additional information gathered through systematic review searches will also inform expected exposures.

  EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether and how other EPA administered statutes and regulatory programs cover phthalic anhydride and/or 1,2-benzenedicarboxylic acid in media pathways falling under the jurisdiction of those authorities. Section 2.6.3.1 discusses pathways under the jurisdiction of other EPA-administered laws. In Section 2.6.3.2, 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.

  EPA considered reasonably available information and comments received on the draft scope for phthalic anhydride in determining the human and environmental exposure pathways, routes, receptors and PESS for inclusion in the final scope. EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation:

- *Occupational exposure:* EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with manufacturing, processing, use or disposal of phthalic anhydride including its hydrolysis into 1,2-benzenedicarboxylic acid. EPA plans to analyze dermal exposure for workers and ONUs to mists and dust that deposit on surfaces.
- *Consumer and bystander exposure:* EPA plans to evaluate the inhalation, dermal and oral exposures to phthalic anhydride and/or 1,2-benzenedicarboxylic acid for consumers and bystanders during use of adhesives and sealants and paints and coatings.
- *General population exposure:* EPA plans to evaluate general population exposure to phthalic anhydride and/or 1,2-benzenedicarboxylic acid via oral route from drinking water and fish ingestion, via inhalation routes from drinking water and via dermal route from contact with drinking water and surface water.
- *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.
- *Environmental exposure:* EPA plans to evaluate exposure to phthalic anhydride and/or 1,2-benzenedicarboxylic acid for aquatic receptors.

- *Hazards.* Hazards for phthalic anhydride are discussed in Section 2.4. EPA completed preliminary reviews of information (*e.g.*, federal and international government chemical assessments) to identify potential environmental and human health hazards for phthalic anhydride as part of the prioritization (U.S. EPA, 2019c) and scoping process (U.S. EPA, 2020c). EPA also considered reasonably available information collected through systematic review methods as outlined in Appendix A and public comments received on the draft scope for phthalic anhydride in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. As mentioned above, phthalic anhydride is highly reactive and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, also known as *o*-phthalic acid, when allowed contact with water or if there is moisture present in the air. Therefore, 1,2-benzenedicarboxylic is expected to be the product found in the environment and the proximal toxicant in contact with living organisms. An ongoing systematic review of reasonably available information regarding 1,2-benzenedicarboxylic acid is being conducted (see Appendix A.1.2), and identified hazards of 1,2-benzenedicarboxylic acid will be considered in the risk evaluation. EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for phthalic anhydride and/or 1,2-benzenedicarboxylic acid.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for phthalic anhydride in Sections 2.4.1 and 2.4.2, respectively. Identified through the data screening phase of systematic review, the potential environmental hazard effects and related information that EPA plans to consider for the risk evaluation include: ADME, developmental, endocrine, nutritional and metabolic and reproductive for phthalic anhydride. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for phthalic anhydride that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, mortality, neurological, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue.

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 and/or 1,2-benzenedicarboxylic acid to date which includes review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

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, 2015c) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45).

1 INTRODUCTION

This document presents the 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 TSCA on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

Under TSCA § 6(b), the Environmental Protection Agency (EPA) must 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 to conduct 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 nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use*."

TSCA § 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 (Docker ID: EPA-HQ-OPPT-2019-0131) (84 FR 71924, December 30, 2019), 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. On April 23, 2020, EPA published the *Draft Scope of the Risk Evaluation for Phthalic Anhydride (*EPA Document No. 740-D-20-020) (85 FR 22733, April 23, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments (Docket ID: EPA-HQ-OPPT-2018-0459) received on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

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 final scope for phthalic anhydride. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid. As of the time of this publication, the screening of information gathered in the subsequent search is ongoing and not available for summary in this document.

EPA leveraged the data and information sources already collected in the documents supporting the phthalic anhydride's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure,

[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).

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.

Search terms were used to search each of the literature streams and gather phthalic anhydride studies, and subsequently for 1,2-benzenedicarboxylic acid studies. These terms and the methods used to develop them are listed in Appendix A. The studies resulting from the search process were loaded into the EPA Health and Environmental Research Online (HERO) database and then prioritized to screen first the literature likely relevant for each of the disciplines: fate, physical and chemical properties, engineering, exposure and hazard. The tools and methods used to manage the screening process are also outlined in Appendix A. The studies resulting from the search underwent a title/abstract screening process, which tagged them by topic or category. Following this, a determination was made to move studies forward into full-text screening. The criteria used in the screening process for each discipline are found in the population, exposure, comparator, outcome (PECO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and heat maps in Section 2.1.2. The screening process was conducted based on EPA's planning, execution and assessment activities outlined in Appendix A.

EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the 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.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 145 search results relevant to EPA's risk evaluation needs for phthalic anhydride. Appendix A.3.4 lists the gray literature sources that yielded 145 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 and chemical properties, environmental fate, environmental hazard, human health hazard, exposure, engineering), and the breakdown is shown in Figure 2-1. An ongoing survey of gray literature regarding 1,2-benzenedicarboxylic acid is being conducted (Appendix A), which will be considered in the risk

[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.

evaluation. EPA plans to evaluate additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

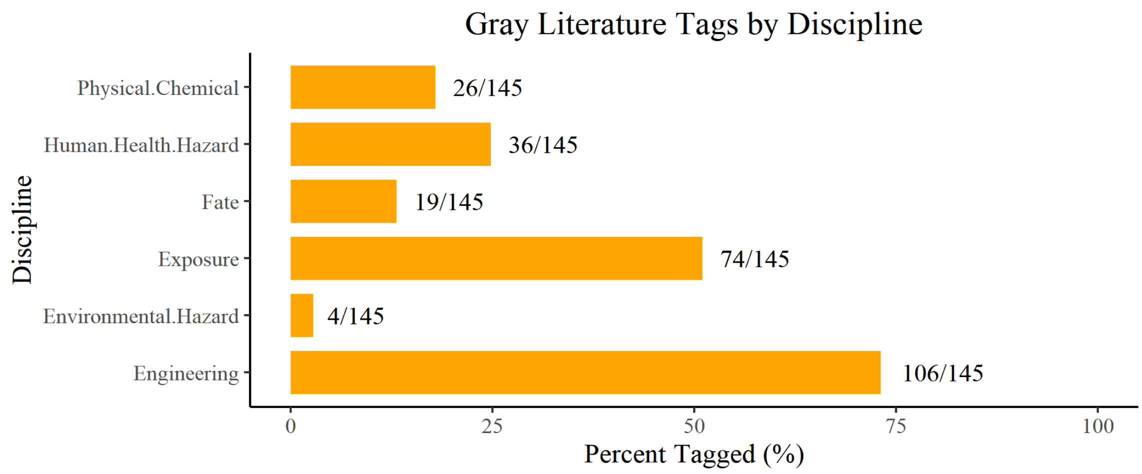

Figure 2-1. Gray Literature Tags by Discipline for Phthalic Anhydride
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

EPA has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature on physical and chemical properties, environmental fate and transport, engineering (environmental release and occupational 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 statements (see Appendix A). 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 (see Appendix A.2). EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation. An ongoing systematic review of reasonably available information regarding 1,2-benzenedicarboxylic acid is being conducted (Appendix A), which will be considered in the risk evaluation.

EPA created literature inventory trees to graphically illustrate the flow of data and information sources following full-text screening (see Figure 2-2, Figure 2-3, Figure 2-5, Figure 2-7, and Figure 2-9). EPA used the Health Assessment Workplace Collaborative (HAWC) tool to develop web-based literature inventory trees illustrating, through interactive links, studies that were included or excluded. These literature inventory trees enhance the transparency of the decisions resulting from the screening process described in Appendix A. For each of the corresponding disciplines, the literature was tagged to be included for evaluation during the risk evaluation. Literature inventory trees for physical and chemical properties are provided as static diagrams (Figure 2-2). For all other disciplines, static screen captures are provided in addition to links within each figure’s caption to the interactive trees. The links show individual studies that were tagged as included, excluded, or supplemental. Supplemental studies did not include all inclusion criteria but may be considered during the risk evaluation as supporting information (see Appendix A). These studies can be accessed through the hyperlink provided in the associated caption below each figure. In some figures, 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.

In addition, EPA tabulated the number and characteristics of the data and information sources included in the full-text screening process in the form of literature inventory heat maps for the fate, engineering, exposure and hazard disciplines (see Figure 2-4, Figure 2-6, Figure 2-8, Figure 2-10). For each of these four disciplines, a static image of the literature inventory heat map is provided, and a link to the interactive version presented in HAWC is included in the caption below each diagram.

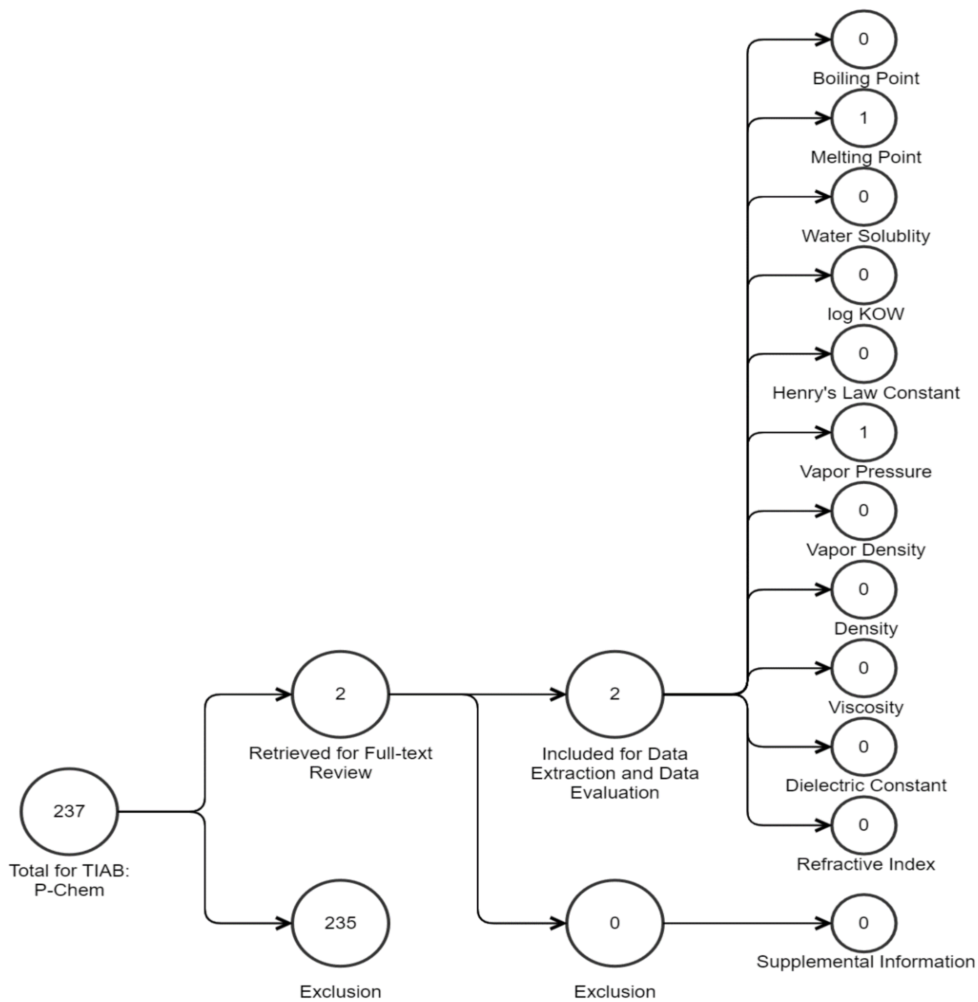

Figure 2-2. Peer-reviewed Literature Inventory Tree - Physical and Chemical Properties Search Results for Phthalic Anhydride

Data in this static figure represent references obtained from the publicly available databases search (Appendix A.1.2) that were included during full-text screening as of June 2, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. TIAB refers to "title and abstract" screening.

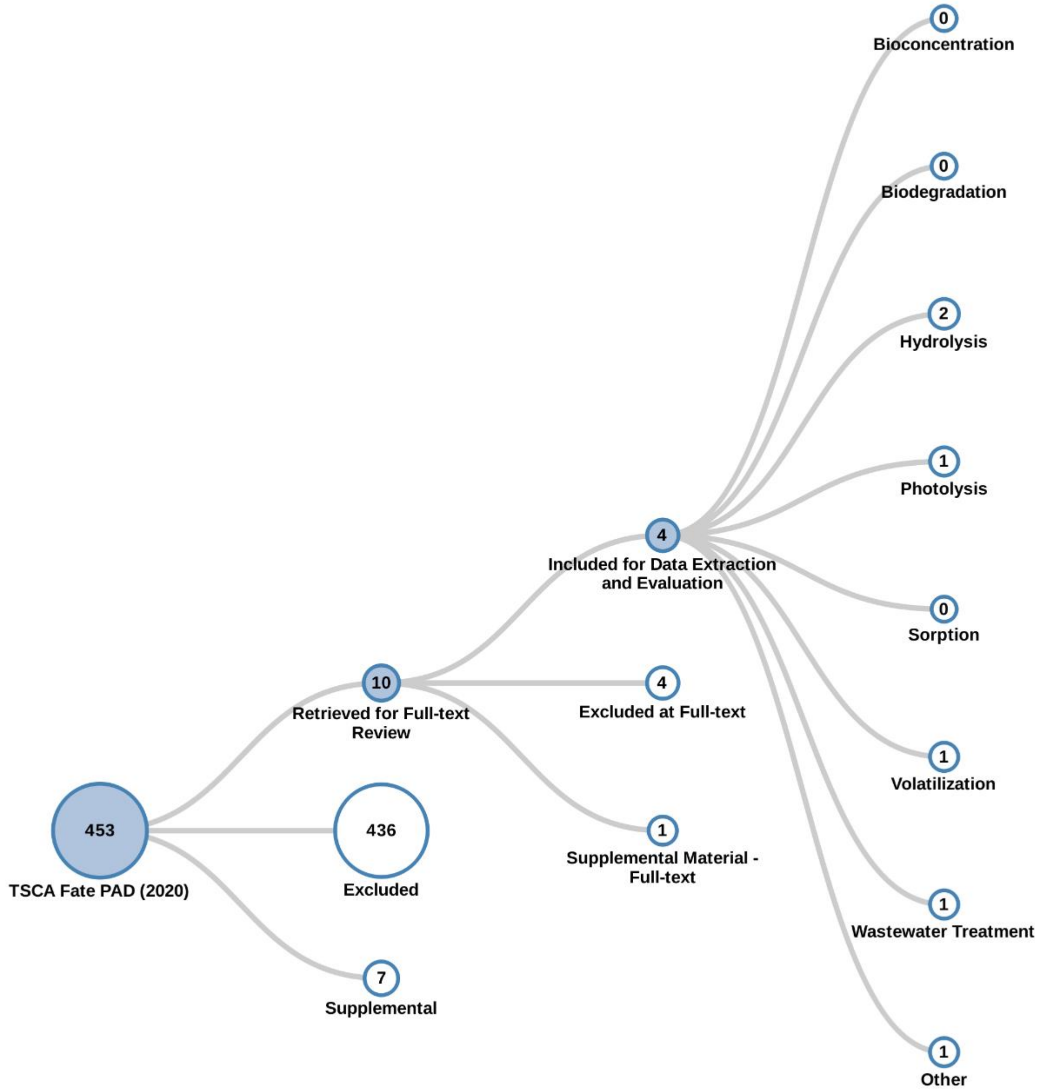

Figure 2-3. Peer-reviewed Literature Inventory Tree – Fate and Transport Search Results for Phthalic Anhydride

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

	Media					
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total
Bioconcentration						
Biodegradation						
Hydrolysis				2		2
Photolysis				1		1
Sorption						
Volatilization			1	1		1
Wastewater Treatment			1	1		1
Other			1	1		1
Grand Total			1	4		4

Figure 2-4. Peer-Reviewed Literature Inventory Heat Map – Fate and Transport Search Results for Phthalic Anhydride

Click here to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by media or endpoint. The darker the color, the more references are available for a given media or endpoint. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

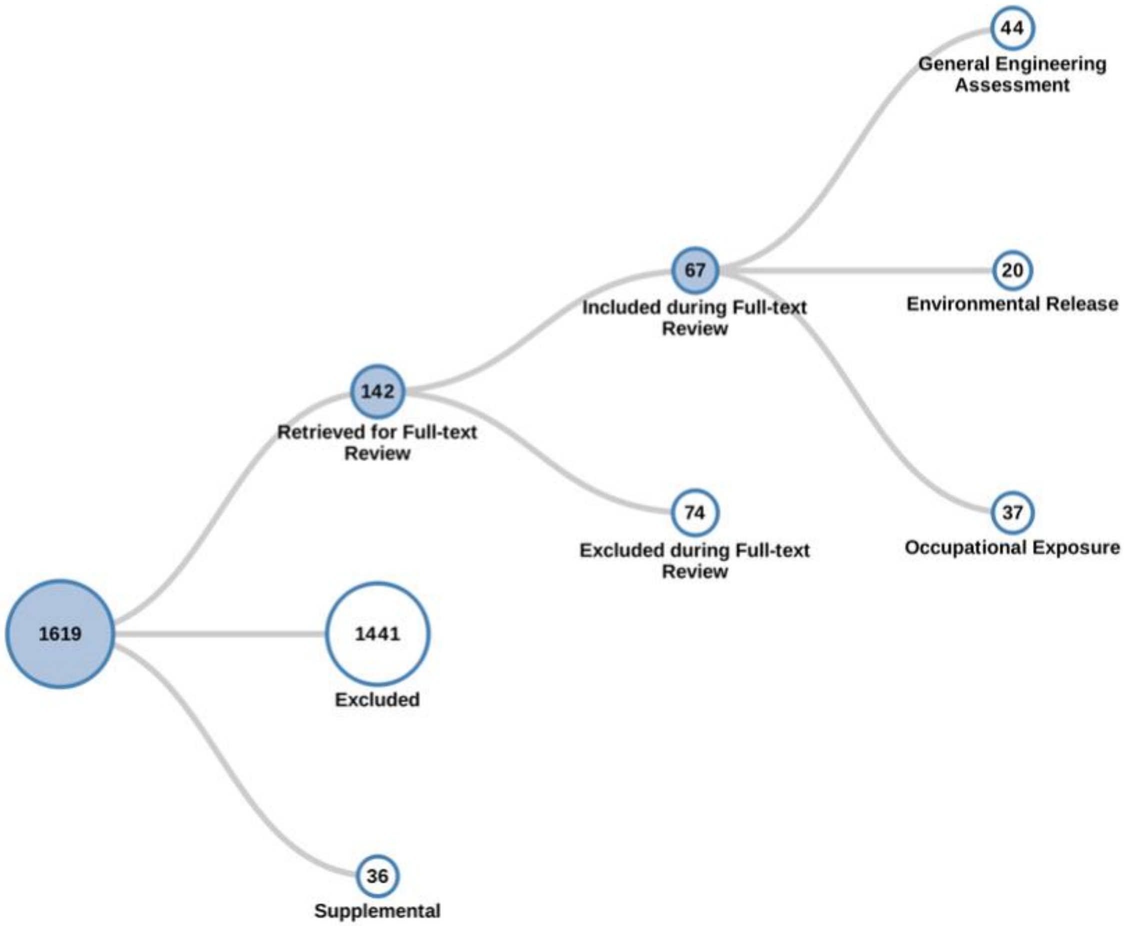

Figure 2-5. Peer-reviewed Literature Inventory Tree - Engineering Search Results for Phthalic Anhydride

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	16
	Release frequency	2
	Release or emission factors	11
	Release quantity	8
	Waste treatment methods and pollution control	8
	Total	20
General Engineering Assessment	Chemical concentration	14
	Life cycle description	8
	Number of sites	6
	Process description	29
	Production, import, or use volume	17
	Throughput	11
	Total	44
Occupational Exposures	Area sampling data	17
	Dermal exposure data	2
	Engineering control	8
	Exposure duration	20
	Exposure frequency	11
	Exposure route	24
	No evidence tag	1
	Number of workers	13
	Particle size characterization	
	Personal protective equipment	12
	Personal sampling data	22
	Physical form	15
	Worker activity description	23
	Total	37
Grand Total		67

Figure 2-6. Peer-reviewed Literature Inventory Heat Map - Engineering Search Results for Phthalic Anhydride

Click here to view the interactive version for additional study details. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

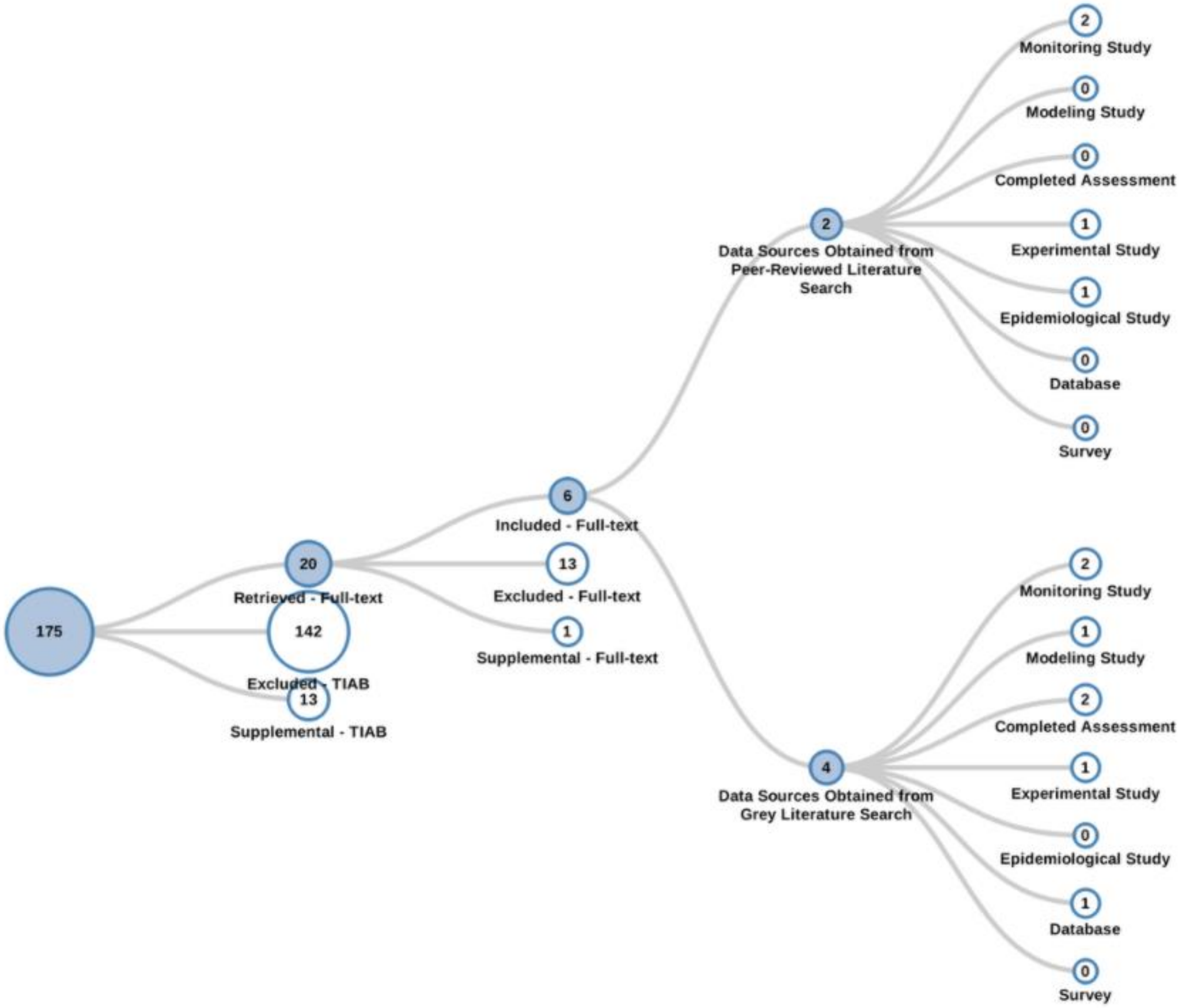

Figure 2-7. Peer-reviewed and Gray Literature Inventory Tree - Exposure Search Results for Phthalic Anhydride

Click here to view the interactive literature inventory tree. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix **A.3**) that were included during full-text screening as of July 31, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

Media (group)	Data Type Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air								
Biosolids/Sludge								
Drinking Water			1					1
Groundwater			1					1
Land Disposal/ Landfill								
Sediment			1					1
Soil								
Surface Water	1		1			1		2
Wastewater			1					1
Aquatic Species								
Terrestrial Species								
Consumer	1		1	1				2
Dietary			1					1
Dust								
Exposure Factors								
Exposure Pathway			1	1				2
Human Biomonitoring	1				1			1
Indoor Air	2	1	1	1				2
Isomers								
Use Information			1	1				2
No Evidence Type								
Grand Total	4	1	2	2	1	1		6

Figure 2-8. Peer-reviewed and Gray Literature Inventory Heat Map – Exposure Search Results for Phthalic Anhydride

Click here to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by exposure media or data type. The darker the color, the more references are available for a given exposure media or data type. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix **A.3**) that were included during full-text screening as of July 31, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

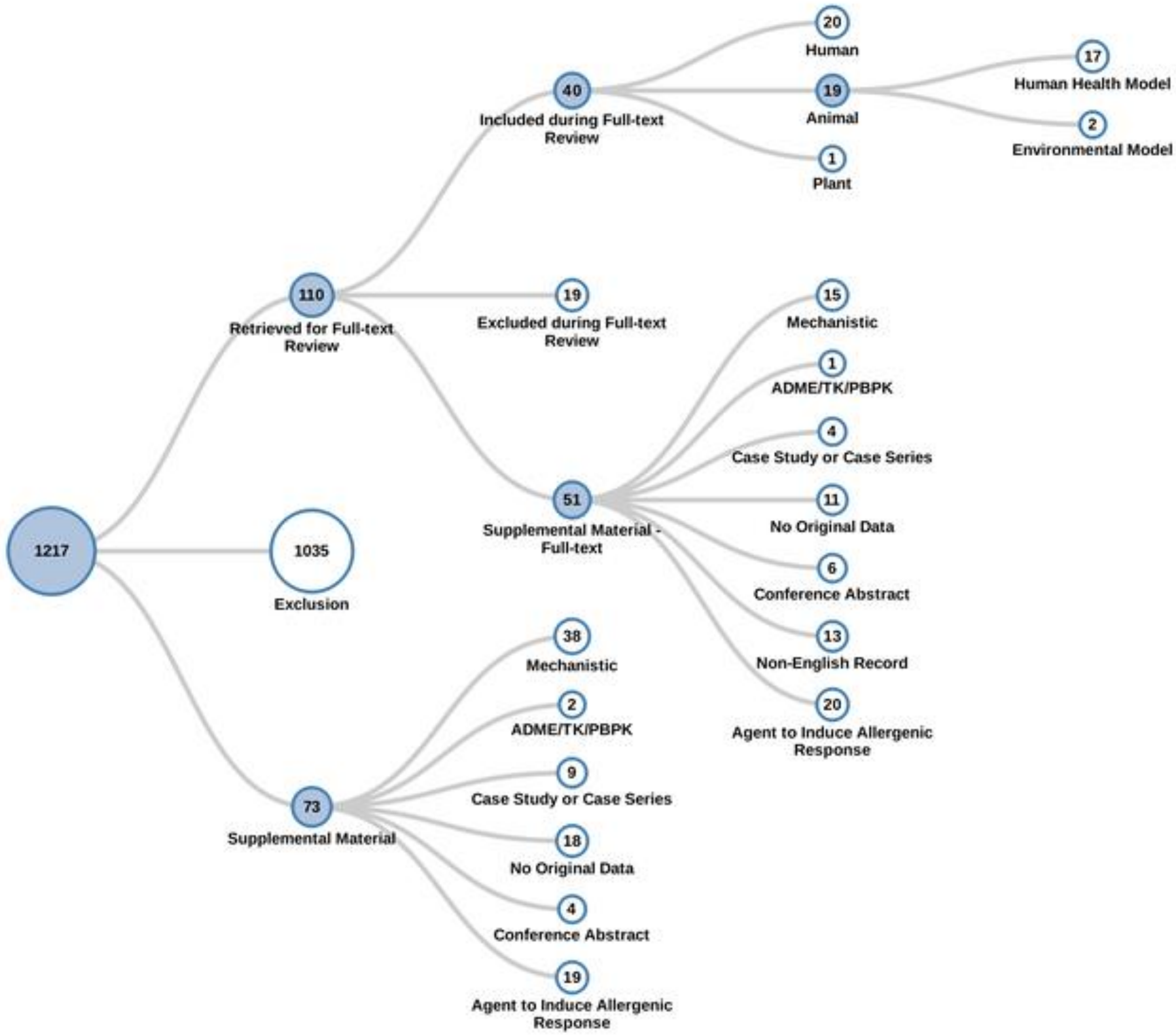

Figure 2-9. Peer-reviewed Literature Inventory Tree – Human Health and Environmental Hazards Search Results for Phthalic Anhydride

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 10, 2020. After preliminary review indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	3	4	1		8
Cancer	4	3			7
Cardiovascular		1			1
Developmental	2	2	1		5
Endocrine	1	1	1		3
Gastrointestinal		1			1
Hematological and Immune	14	13			27
Hepatic					
Mortality	2	1			3
Musculoskeletal					
Neurological		1			1
Nutritional and Metabolic			1		1
Ocular and Sensory	7	8			15
PBPK		2			2
Renal	1				1
Reproductive		1	1		2
Respiratory	11	9			20
Skin and Connective Tissue	8	7			15
No Tag	3		1	1	5
Grand Total	20	17	2	1	40

Figure 2-10. Peer-reviewed Literature Inventory Heat Map – Human Health and Environmental Hazards Search Results for Phthalic Anhydride

Click here to view the interactive version for additional study details. The numbers indicate the number of studies with TIAB keywords related to a particular health outcome, not the number of studies that observed an association with phthalic anhydride. Evidence types were manually extracted, and Health Systems were determined via machine learning. Therefore, the studies examining multiple Health Outcomes and Evidence types, connections between health outcome, and evidence type may not be accurately represented. If a study evaluated multiple health outcomes or included multiple populations or study designs, it is shown here multiple times. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 10, 2020. After preliminary review of these studies indicated that phthalic anhydride is rapidly hydrolyzed to 1,2-benzenedicarboxylic acid, the literature search was expanded to include 1,2-benzenedicarboxylic acid; the results of this expanded search are not yet available for inclusion in this scoping document. Additional data may be added to the interactive version as they become available.

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 TSCA. EPA screened a total of 19 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are presented in Appendix A.1.2. EPA identified 17 submissions that met the inclusion criteria in these statements and identified one submission with supplemental data.[3] EPA excluded one submission because the report was identified as a preliminary report.

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

Discipline	Included	Supplemental [b]
Physical and Chemical 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

[a] Individual submissions may be relevant to multiple disciplines.
[b] Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

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, 2019c), EPA assembled information from the CDR and TRI programs to determine conditions of use[4] or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA will utilize the most recent CDR information. 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) (U.S. EPA, 2019b) 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, EPA incorporated communications with companies, industry groups and public comments to supplement the use information.

EPA identified and described the categories and subcategories of conditions of use for phthalic anhydride that EPA plans to consider in the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use included in the scope of the risk evaluation are those reflected in the life cycle diagrams and conceptual models. Phthalic anhydride is highly reactive and only exists under artificial conditions devoid of moisture and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, when allowed contact with water or moisture present in the air. Therefore, while this scope includes conditions of use for phthalic anhydride only, the hazards, exposures, and PESS for both phthalic anhydride and its immediate hydrolysis product, 1,2-benzenedicarboxylic acid, are included when appropriate (*i.e.*, when a COU of phthalic anhydride could result in the formation of its immediate hydrolysis product).

EPA believes that its regulatory tools under TSCA Section 6(a) are better suited to addressing any unreasonable risks for 1,2-benzenedicarboxylic acid that might arise from conditions of use for phthalic anhydride, rather than addressing those uses through direct regulation of 1,2-benzenedicarboxylic acid.

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[3] EPA may further consider some supplemental or excluded references depending on the reasons for tagging as supplemental or excluded.
[4] *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 (TSCA § 3(4)).

If necessary, EPA will evaluate conditions of use for 1,2-benzenedicarboxylic acid in a separate risk evaluation process.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use and disposal of phthalic anhydride, EPA identified those activities for phthalic anhydride the Agency determined not to be conditions of use or are otherwise excluded from the scope of the risk evaluation. These excluded activities are described in Section 2.2.2.

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.

Table 2-2. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation[a,b]

Life-Cycle Stage [c]	Category [d]	Subcategory [e]	References
Manufacture	Domestic manufacture	Domestic manufacture	U.S. EPA (2020a)
	Import	Import	U.S. EPA (2020a)
Processing	Processing as a reactant	Intermediate in: All other basic organic chemical manufacturing; All other basic inorganic chemical manufacturing; Plastic material and resin manufacturing; and Paint and coating manufacturing.	U.S. EPA (2020a)
		Adhesives and sealant chemicals in: Paint and coating manufacturing.	U.S. EPA (2020a)
		Ion exchange agents in: All other basic organic chemical manufacturing.	U.S. EPA (2020a)
		Lubricants and lubricant additives in: Petroleum lubricating oil and grease manufacturing.	U.S. EPA (2020a)
		Paint additives and coating additives not described by other categories in: Paint and coating manufacturing; and Plastic material and resin manufacturing.	U.S. EPA (2020a)

Life-Cycle Stage [c]	Category [d]	Subcategory [e]	References
		Pigments in: Synthetic dye and pigment manufacturing.	U.S. EPA (2020a)
		Inks in: Printing ink manufacturing.	U.S. EPA (2020a)
		Plastic in: Plastics product manufacturing.	U.S. EPA (2020a)
		Corrosion inhibitors and anti-scaling agents in: Miscellaneous manufacturing.	U.S. EPA (2020a)
		Plating agents and surface treating agents in: Rubber product manufacturing.	U.S. EPA (2020a)
	Incorporation into formulation, mixture, or reaction product Incorporation into formulation, mixture, or reaction product	Intermediate in: Paint and coating manufacturing; All other basic organic chemical manufacturing; All other chemical product and preparation manufacturing; and Plastic material and resin manufacturing.	U.S. EPA (2020a)
		Plasticizers in: Plastic material and resin manufacturing; Petrochemical manufacturing; Construction; Polyester and alkyd resins; curing agent for epoxy resins; Plastic product manufacturing; and Custom compounding of purchased resin.	U.S. EPA (2020a); Broadview Technologies (2015); Koppers (2018)
		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;	U.S. EPA (2020a); EPA-HQ-OPPT-2018-0459-0024

Life-Cycle Stage [c]	Category [d]	Subcategory [e]	References
		Solid color stains; and Asphalt paving, roofing, and coating materials manufacturing.	
		Adhesives and sealant chemicals in: Paint and coating manufacturing.	U.S. EPA (2020a)
		Fillers in: Textile, apparel, and leather manufacturing.	U.S. EPA (2020a)
		Oxidizing/reducing agents in: Synthetic rubber manufacturing; Adhesive manufacturing; Plastic material and resin manufacturing; and Wholesale and retail trade.	U.S. EPA (2020a)
		Dyes in: Synthetic dye and pigment manufacturing.	U.S. EPA (2020a)
		Laboratory chemicals	EPA-HQ-OPPT-2018-0459-0041; Thermo Fisher Scientific (2018)
	Repackaging	Repackaging (*e.g.*, laboratory chemicals)	EPA-HQ-OPPT-2018-0459-0041; Thermo Fisher Scientific (2018)
	Recycling	Recycling	U.S. EPA (2020a)
Distribution in commerce	Distribution in commerce	N/A	N/A
Industrial	Processing aids, specific to petroleum production	Hydraulic fracturing	Finoric LLC (2016); U.S. EPA (2015a); Committee on Energy and Commerce's Minority Staff (2011); Whittemore (2011)

Life-Cycle Stage [c]	Category [d]	Subcategory [e]	References
	Aerospace	Acceptance testing of foams used on human-rated spaceflight vehicles	EPA-HQ-OPPT-2018-0459-0041
	Adhesives and sealants	Adhesives and sealants (*e.g.*, sealant for fuel tanks, temporary mounting adhesive, acrylic adhesive, aerospace sealant)	U.S. EPA (2020a); Royal Adhesives & Sealants (2016); Aremco Products Inc. (2018); 3M Company (2019); Lord (2019)
	Fillers	Hardener (*e.g.*, epoxy hardener)	Resinlab LLC (2015)
	Flame retardants	Flame retardants	Stepan Company (2020); U.S. EPA (1994b)
	Fuel and related products	Fuel and related products	U.S. EPA (2020a)
	Textiles, apparel, and leather manufacturing	Tanning and curing	U.S. EPA (1994b)
	Lubricants and greases	Lubricants and greases	U.S. EPA (2020a)
	Paints and coatings	Paints and coatings (*e.g.*, commercial and residential paint coatings, stains, exterior architectural and marine paints)	U.S. EPA (2020a)
	Plating agents and surface treating agents	Surface treating	U.S. EPA (2020a)
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere (*e.g.*, epoxy resin work surface)	U.S. EPA (2020a); Durcon Inc. (2020); Durcon Inc. (2011); OSHA (2019)
	Electrical and electronic products	Electrical and electronic products	U.S. EPA (2020a); Emerson (2011)
	Laboratory chemical	Laboratory chemical	EPA-HQ-OPPT-2018-0459-0041; Thermo Fisher Scientific (2018)

Life-Cycle Stage [c]	Category [d]	Subcategory [e]	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.	EPA-HQ-OPPT-2019-0131-0022
	Water treatment products	Water filtration applications	EPA-HQ-OPPT-2018-0459-0022
Commercial	Adhesives and sealants	Adhesives and sealants (*e.g.*, sealant for fuel tanks, temporary mounting adhesive, acrylic adhesive, aerospace sealant)	U.S. EPA (2020a); Royal Adhesives & Sealants (2016); Aremco Products Inc. (2018);3M Company (2019); Lord (2019)
	Fillers	Hardener (*e.g.*, epoxy hardener)	Resinlab LLC (2015); Lord Corporation (2017)
	Fuel and related products	Fuel and related products	U.S. EPA (2020a)
	Textiles, apparel, and leather manufacturing	Tanning and curing	U.S. EPA (1994b)
	Lubricants and greases	Lubricants and greases	U.S. EPA (2020a)
	Plating agents and surface treating agents	Surface treating	U.S. EPA (2020a)
	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere (*e.g.*, epoxy resin work surface)	U.S. EPA (2020a); Durcon Inc. (2020); Durcon Inc. (2011); OSHA (2019)
	Electrical and electronic products	Electrical and electronic products	U.S. EPA (2020a)
	Laboratory chemical	Laboratory chemical	Thermo Fisher Scientific (2018); EPA-HQ-OPPT-2018-0459-0041
	Transportation equipment manufacturing	Used in the body/exterior, interior, and electrical systems of a vehicle, wiring assemblies, seat and console assemblies, and lamp assemblies.	EPA-HQ-OPPT-2019-0131-0022; Lord (2019)
	Water treatment products	Water filtration applications	EPA-HQ-OPPT-2018-0459-0022
	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S. EPA (2020a)

Life-Cycle Stage [c]	Category [d]	Subcategory [e]	References
	Plastic and rubber products	Plastic and rubber products	U.S. EPA (2020a)
	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, stains, exterior architectural and marine paints)	U.S. EPA (2020a)
	Fuel and related products	Fuel and related products	U.S. EPA (2020a)
Consumer	Adhesives and sealants	Adhesives	Henkel Corporation (2018); EPA-HQ-OPPT-2018-0459-0022; EPA-HQ-OPPT-2018-0459-0004
	Paints and coatings	Paints and coatings (*e.g.*, commercial and residential paint coatings, stains, exterior architectural and marine paints)	U.S. EPA (2020a); Waterlox Coating (2015)
Disposal	Disposal	Disposal	U.S. EPA (2019d)

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

b. EPA is aware that phthalic anhydride quickly hydrolyzes to 1,2-benzenedicarboxylic acid (discussed in more detail in Section 2.3). However, the conditions of use, identified in Table 2-2, are only associated with uses of phthalic anhydride. Activities and releases associated with 1,2-benzenedicarboxylic acid produced as a result of the use of phthalic anhydride will be considered in EPA's risk evaluation. In addition, although EPA is aware of other uses of 1,2-benzenedicarboxylic acid that are not associated with the use of phthalic anhydride, these will not be considered in the risk evaluation.

c. Life Cycle Stage Use Definitions (40 CFR § 711.3)

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

d. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of phthalic anhydride in industrial and/or commercial settings.

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

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* (82 FR 33726, July 20, 2017), 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). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance[5]. As a result, EPA does not plan to include in this scope or in the risk evaluation the activities described below that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

TSCA Section 3(2) also excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" as well as "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." EPA has determined that the following uses of phthalic anhydride are non-TSCA uses:

Phthalic anhydride is reported as a commercial use in the production of personal care products (U.S. EPA, 2020a). Personal care products meet the definition of "cosmetic" in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 321. Therefore, the-uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of personal care products are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

Phthalic anhydride-containing products' SDS list "food preservatives" as an identified use (Koppers, 2018; InterAtlas Chemical Inc., 2016). Food preservatives meet the definition of "food additive" in Section 201 of the FFDCA, 21 U.S.C. § 321. Therefore, the-uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of food preservatives are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

Phthalic anhydride-containing products' SDS list "insect repellents" as an identified use (Koppers, 2018; InterAtlas Chemical Inc., 2016). Insect repellents meet the definition of "pesticide" in Section 136 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of insect repellents are not "conditions of use"

[5] *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 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 (TSCA § 3(2)).

(defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

Phthalic anhydride-containing products' SDS list "perfume fixatives" as an identified use (Koppers, 2018; InterAtlas Chemical Inc., 2016). Perfume fixatives meet the definition of "cosmetic" in Section 201 of the FFDCA, 21 U.S.C. § 321. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of perfume fixatives are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

Phthalic anhydride-containing products' SDS list "pharmaceuticals" as an identified use (Koppers, 2018; InterAtlas Chemical Inc., 2016). Phthalic anhydride has also been identified as used as an intermediate in pharmaceutical and medicine manufacturing (U.S. EPA, 2019a). Pharmaceuticals meet the definition of "drug" in Section 201 of the FFDCA, 21 U.S.C. § 321. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of pharmaceuticals are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

Phthalic anhydride has been listed as being used in medical devices and the flexible tubing and containers in the medical industry (Stepan Company, 2020) (EPA-HQ-OPPT-2018-0459-0022). These uses meet the definition of a "medical device" in Section 201 of the FFDCA, 21 U.S.C. § 321. Therefore, the uses are excluded from the definition of "chemical substance" in TSCA § 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of medical devices are not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

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 confidential business information (CBI), total production volume of phthalic anhydride in 2015 was between 500 million and 750 million pounds (U.S. EPA, 2020a). 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, 2019c) and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-11 provides the lifecycle diagram for phthalic anhydride. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial and consumer use categories included within the scope of the risk evaluation. 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). Appendix E contains more descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

Phthalic anhydride is highly reactive and only exists under artificial conditions devoid of moisture and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, when allowed contact with water or moisture present in the air (Andres et al., 2001). This immediate hydrolysis product, 1,2-benzenedicarboxylic, is expected to be the product found in the environment and the proximal toxicant in contact with living organisms. Therefore, while this scope includes conditions of use for phthalic anhydride only, EPA plans to evaluate both phthalic anhydride and 1,2-benzenedicarboxylic acid resulting from hydrolysis of phthalic anhydride in the risk analyses.

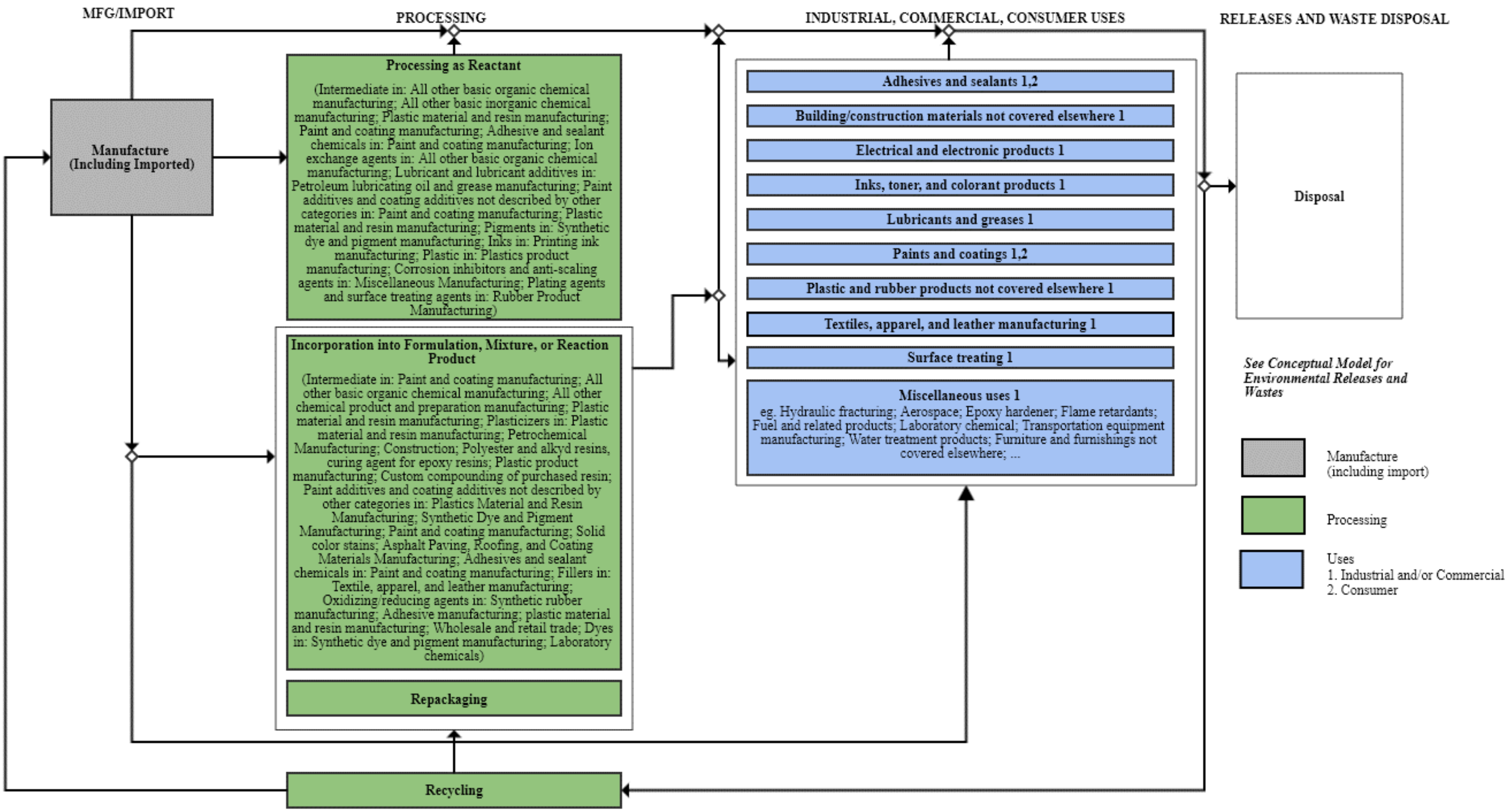

Figure 2-11. Phthalic Anhydride Life Cycle Diagram

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation of phthalic anhydride. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible known sources. Release pathways and routes will be described in Section 2.6 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 plans to consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to phthalic anhydride and its immediate hydrolysis product, 1,2-benzenedicarboxylic acid.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (*i.e.*, transport and transformation) and the eventual environmental concentrations. It can also inform the hazard assessment. Table 2-3 summarizes the physical and chemical property values for phthalic anhydride and the hydrolysis product 1,2-benzenedicarboxylic acid preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 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, 2019c) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-12 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0459).

Phthalic anhydride is highly reactive, existing only under artificial conditions devoid of moisture. It rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, also known as *o*-phthalic acid, when allowed contact with water or moisture present in the air. This transformation is immediate, with half of the phthalic anhydride hydrolyzed within seconds and essentially complete hydrolysis occurring in approximately 8 minutes in an aqueous sodium chloride solution simulating sea water or physiological fluids (Andres et al., 2001). Phthalic anhydride is also hydrolyzed to 1,2-benzenedicarboxylic acid spontaneously upon entering the respiratory tract of the human body (Zhang et al., 2002)

Table 2-3. Physical and Chemical Properties of Phthalic Anhydride and 1,2-benzenedicarboxylic Acid

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_8H_4O_3$	N/A	N/A
Molecular weight	148.12 g/mol	N/A	N/A
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

Property or Endpoint	Value[a]	Reference	Data Quality Rating
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[b]	NLM (2015)	High
Log Octanol/water partition coefficient (Log Kow)	1.6[b]	NLM (2015)	High
Henry's Law constant	<1×10^{-8} atm-m^3/mole (calculated from VP/WS)[b]	U.S. EPA (2012b)	High
Flash point	152°C	RSC (2019)	High
Auto flammability	Not available		
Viscosity	1.19 cP at 132°C	NLM (2015)	High
Refractive index	Not available		
Dielectric constant	Not available		

[a] Measured for phthalic anhydride unless otherwise noted.
[b] Values for 1,2-benzenedicarboxylic acid (CASRN 88-99-3), the rapidly formed hydrolysis product of phthalic anhydride, are presented for endpoints obtained in the presence of water. Phthalic anhydride has reported hydrolysis half-life values of 30.5 seconds at pH 7.24 (NLM (2015) and ECHA (2019)), 61 seconds at pH 6.8 (NLM (2015)) and 1.5 minutes (U.S. EPA (1994b)).

N/A = Not applicable

Figure 2-12 displays a summary of the data collected as of June 2020 for eight physical and chemical values routinely used in TSCA existing chemical risk evaluations. The box and whisker plots for each endpoint illustrate the mean (average, indicated by the blue diamond) and the 10th, 25th, 50th (median), 75th, and 90th percentiles. All individual data points are indicated by black squares, and value preliminarily selected for use in the risk evaluation is overlaid (indicated by the orange circle) to provide context for where it lies within the distribution of the dataset. The number of unique primary data sources is indicated below each box and whisker plot. If multiple sources presented equivalent values and cited the same primary source, only one of those was included in the statistical calculations. As a result, the number of sources listed in Figure 2-12 may differ from the total number of data sources presented in Figure 2-2.

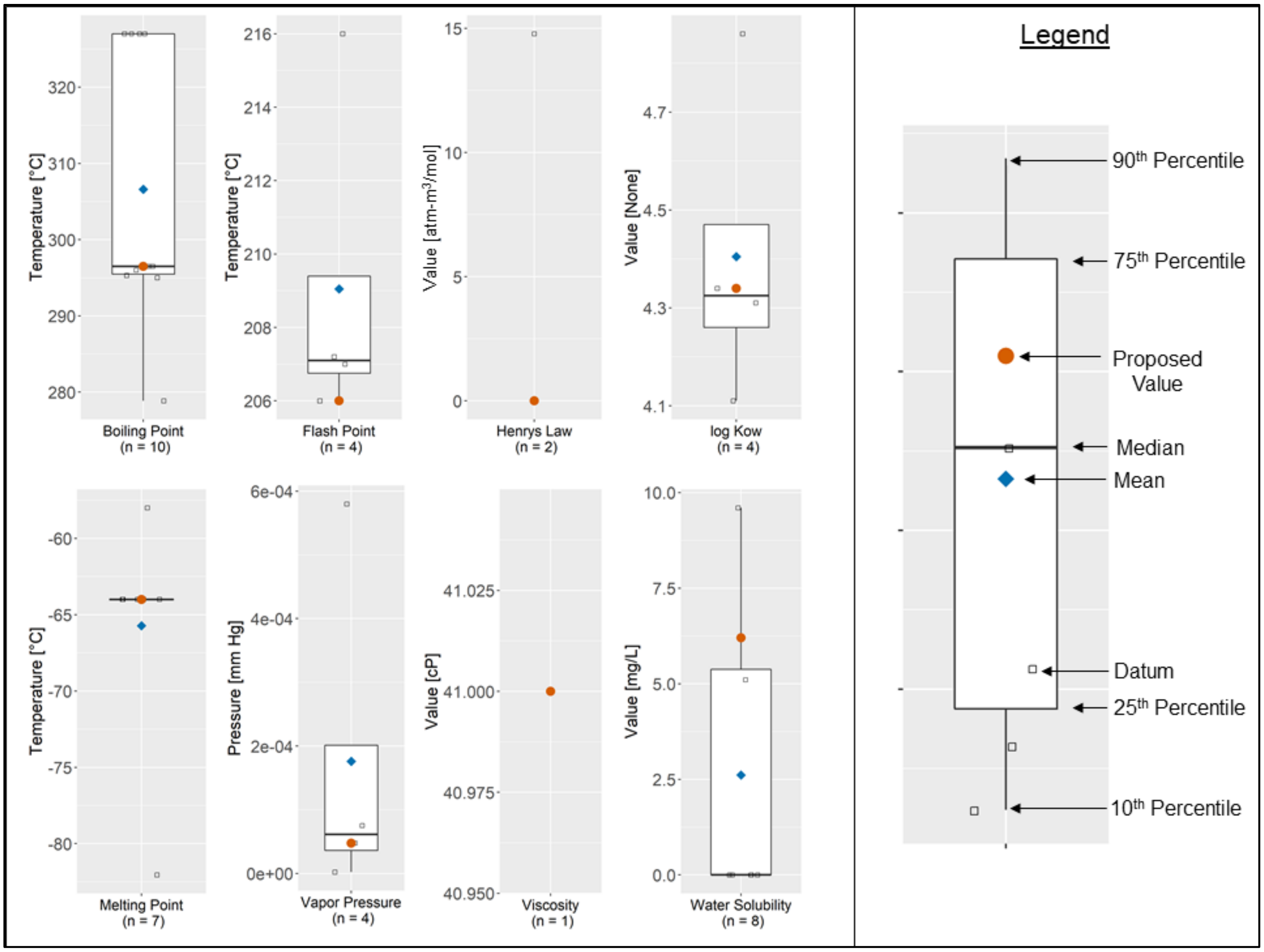

Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

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 Appendix C to support the development of the risk evaluation for phthalic anhydride and its subsequent transformation into 1,2-benzenedicarboxylic acid. The values for the environmental fate properties may be updated as EPA evaluate and collects additional information into the risk evaluation 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 and/or assumptions and models. Upon release into the environment, phthalic anhydride is expected to rapidly hydrolyze into 1,2-benzenedicarboxylic acid.

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, but not 1,2-benzenedicarboxylic acid, is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting[6], 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.

Table 2-4 provides production-related waste management data for phthalic anhydride reported by facilities to the TRI program for reporting year 2018.[7] 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 2-4. 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 (U.S. EPA, 2019d)
[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 events 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 2-5 provides a summary of phthalic anhydride TRI releases to the environment for the same reporting year as Table 2-4.[8] 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 and disposal (19,689 pounds) occurred off site. "Other releases" accounted for disposal of or releases of 25,467 pounds of phthalic anhydride, and includes

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting
[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-4 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.
[8] *Ibid*.

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.

Table 2-5. Summary of Releases of Phthalic Anhydride to the Environment During 2018

Year	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]		
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 (U.S. EPA, 2019d)
[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 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 2-4 excludes any quantities reported as catastrophic or one-time releases (TRI Section 8 data), release quantities shown in Table 2-5 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, 2017).

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 of phthalic anhydride and its immediate hydrolysis product, 1,2-benzenedicarboxylic acid, to the environment and exposure to aquatic and terrestrial receptors. Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available information on environmental exposure in biota to inform development of the environmental exposure assessment for 1,2-benzenedicarboxylic acid and phthalic anhydride, recognizing that phthalic anhydride is not expected to be found in the environment. EPA plans to review reasonably available environmental monitoring data found in the literature for phthalic anhydride and 1,2-benzenedicarboxylic acid.

2.3.5 Occupational Exposures

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

Examples of worker activities associated with the conditions of use within the scope of the risk evaluation for phthalic anhydride that EPA may analyze include, but are not limited to:

- Unloading and transferring phthalic anhydride to and from storage containers to process vessels;
- Handling 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;
- Performing other work activities in or near areas where phthalic anhydride is used.

Phthalic 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 for workers and ONUs 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. In addition, for certain COUs, phthalic anhydride may be present as a component of solid products. For these COUs, EPA plans to consider inhalation exposure to dust/particulates (*e.g.*, particulate generated during handling of plastic resins, finishing operations associated with the manufacture and finishing of plastics and plastic articles and incorporation of plastics and other article components into finished products) for workers and ONUs. EPA plans to evaluate occupational exposure to both phthalic anhydride and its subsequent hydrolysis into 1,2-benzenedicarboxylic acid, recognizing that both forms may be present in occupational scenarios.

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 workday, 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 (NIOSH, 2019) and the Immediately Dangerous to Life or Health Concentration (IDLH) at 60 mg/m^3 (NIOSH, 2016). 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 (IPCS, 2003).

Based on the conditions of use, EPA plans to evaluate worker exposure to liquids and/or solids via the dermal route. EPA plans to analyze dermal exposure for workers and ONUs to mists and dust that deposit on surfaces.

EPA generally does not evaluate occupational exposures through the oral route. Workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. In addition, workers may transfer chemicals from their hands to their mouths. The frequency and significance of this exposure route are dependent on several factors including the physical and chemical properties of the substance during worker activities, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). EPA will consider the relevance of this exposure route on a case-by-case basis, taking into consideration the aforementioned factors and any reasonably available information, and may assess oral exposure for workers for certain COUs and worker activities where warranted.

2.3.6 Consumer Exposures

According to reports to the 2016 CDR (U.S. EPA, 2020a), available SDSs (Henkel, 2017), and reviewed public comments (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 2-14): paints and coatings; and adhesives and sealants.

Based on reasonably available information on consumer conditions of use, inhalation of phthalic anhydride and/or 1,2-benzenedicarboxylic acid is possible through either inhalation of vapor/mist during product usage or indoor air/dust. Oral exposure of phthalic anhydride and/or 1,2-benzenedicarboxylic acid is possible through ingestion during product use via transfer from hand to mouth or via dust. Dermal exposure may occur via contact with vapor, mist, or dust deposition onto the skin or via direct liquid contact during use. Based on these potential sources and pathways of exposure, EPA plans to analyze inhalation, oral and dermal routes of exposures to consumers and bystanders that may result from the conditions of use of phthalic anhydride. The consumer exposure pathways in the scope of this evaluation are described in Sections 2.6.2 and 2.7.2.4.

2.3.7 General Population Exposures

Environmental releases of phthalic anhydride from certain conditions of use, such as manufacturing, processing, distribution, use, or disposal activities, may result in general population exposures. The general population may be exposed to phthalic anhydride and/or 1,2-benzenedicarboxylic acid via ambient air, drinking water, ground water, fish ingestion and/or surface water based on information provided in Section 2.3.3. The general population pathways in the scope of this evaluation are described in Sections 2.6.3 and 2.7.2.5. The general population pathways in the scope of this evaluation are described in Sections 2.6.3 and 2.7.2.5.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on phthalic anhydride as well as public comments received on the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and the draft scope for phthalic anhydride (U.S. EPA, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following potential environmental hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, developmental, endocrine, nutritional and metabolic and reproductive for phthalic anhydride (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). Because phthalic anhydride is highly reactive and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid when allowed contact with water or moisture present in the air, this immediate hydrolysis product is expected to be the product found in the environment and the proximal toxicant in contact with living organisms. Therefore, a systematic review of reasonably available information for 1,2-benzenedicarboxylic acid is being conducted (see Appendix A.1.2), and identified hazards of 1,2-benzenedicarboxylic acid will be considered in the risk evaluation. However, the systematic review for 1,2-benzenedicarboxylic acid is not complete; therefore, references for 1,2-benzenedicarboxylic acid are not included in the literature inventory trees. As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on phthalic anhydride as well as public comments on the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and the draft scope for phthalic anhydride (U.S. EPA, 2020c) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: developmental and systemic effects.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following additional potential human health hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, endocrine, gastrointestinal, hematological and immune, mortality, neurological, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As stated previously, because phthalic anhydride rapidly hydrolyzes to 1,2-benzenedicarboxylic acid when allowed contact with water or moisture present in the air, this immediate hydrolysis product is expected to be the product found in the environment and the proximal toxicant in contact with living organisms. Therefore, a systematic review of reasonably available information for 1,2-benzenedicarboxylic acid is being conducted (see Appendix A.1.2), and identified hazards of 1,2-benzenedicarboxylic acid will be considered in the risk evaluation. However, the systematic review for 1,2-benzenedicarboxylic acid is not complete; therefore, references for 1,2-benzenedicarboxylic acid are not included in the literature inventory trees. As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) 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, 2011a).

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, including ONUs and users, and consumers, including users and bystanders (U.S. EPA, 2019a). EPA plans to evaluate these PESS in the risk evaluation. Following further evaluation of the reasonably available information, EPA may evaluate PESS in the general population as they relate to fence line communities.

In developing exposure scenarios, EPA plans to analyze 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, ingestion of breast milk) 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, 2006b). Likewise, EPA plans to 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). Based on these analyses, EPA may update the list of PESS in the risk evaluation.

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 are under the jurisdiction of other EPA-administered laws, are discussed and depicted in the conceptual model shown in Section 2.6.3.1. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that are under the jurisdiction of other EPA-administered laws, are presented in the conceptual model shown in Section 2.6.3.2.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-13 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. Phthalic anhydride is highly reactive and only exists under artificial conditions devoid of moisture and rapidly hydrolyzes to 1,2-benzenedicarboxylic acid, when allowed contact with water or moisture present in the air (Andres et al., 2001). This immediate hydrolysis product, 1,2-benzenedicarboxylic, is expected to be the product found in the environment and the proximal toxicant in contact with living organisms. Therefore, there is potential for exposures to phthalic anhydride and/or 1,2-benzenedicarboxylic acid to workers and ONUs via inhalation routes and exposures to workers via dermal routes. The conceptual model also includes potential worker and ONU dermal exposure to phthalic anhydride and/or 1,2-benzenedicarboxylic acid in mists and dust. 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, a determination was made as to whether or not EPA plans to evaluate each 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.

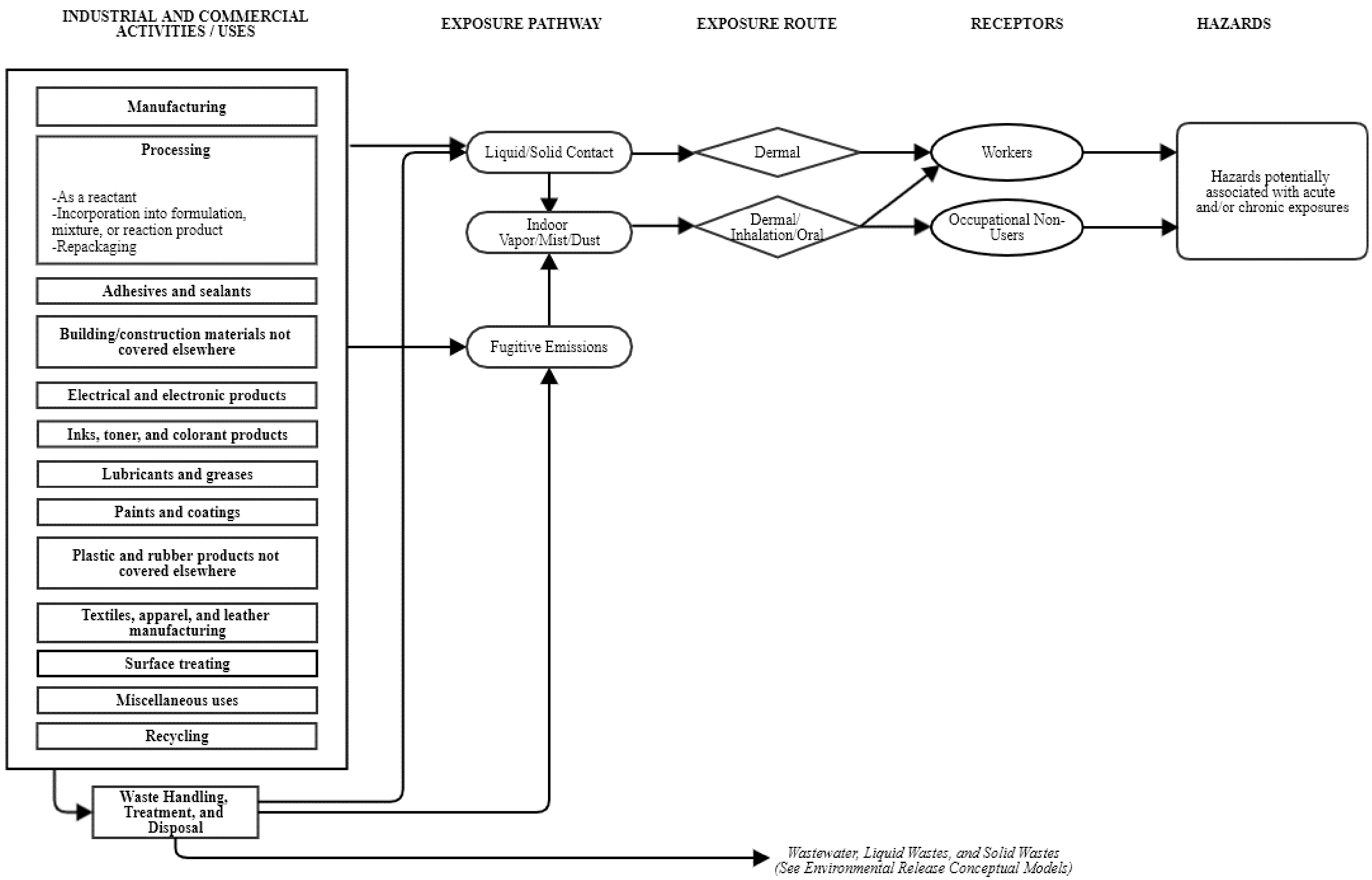

Figure 2-13. Phthalic Anhydride Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from industrial and commercial activities and uses of phthalic anhydride. Within this model, phthalic anhydride is expected to rapidly hydrolyze into 1,2-benzenedicarboxylic acid resulting in potential exposure to either chemical.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-14 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of phthalic anhydride. EPA expects that consumers and bystanders may be exposed to phthalic anhydride and/or 1,2-benzenedicarboxylic acid through product uses containing phthalic anhydride via oral, dermal and inhalation routes. 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.

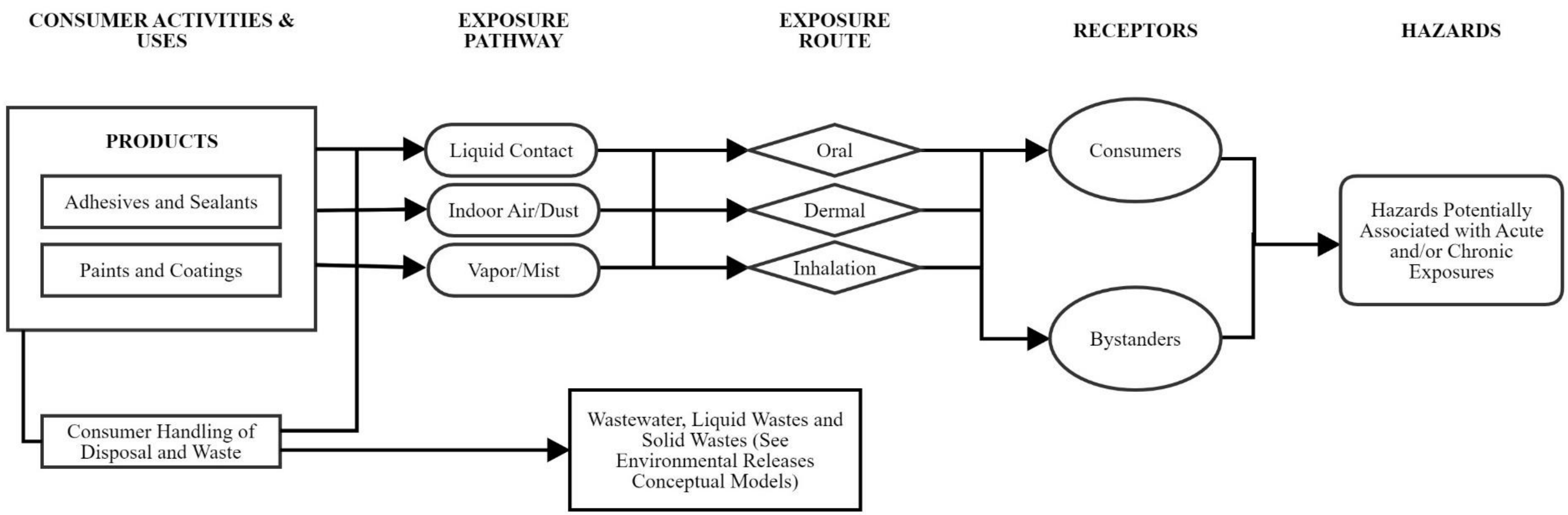

Figure 2-14. Phthalic Anhydride Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of phthalic anhydride. Within this model, phthalic anhydride is expected to rapidly hydrolyze into 1,2-benzenedicarboxylic acid resulting in potential exposure to either chemical.

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 from environmental releases and wastes) and hazards to general population and environmental receptors associated with the conditions of use of phthalic anhydride within the scope of the risk evaluation. This section also discusses those pathways that may be addressed pursuant to other EPA-administered laws.

The conceptual model in Figure 2-15 presents the potential exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and waste streams associated with industrial, commercial and consumer uses of phthalic anhydride. The conceptual model shows the overlays, labeled and shaded to depict the regulatory programs under EPA-administered statutes and associated pathways that EPA considered for the scope of the risk evaluation. The regulatory programs that cover these environmental release and waste pathways are further described in Section 2.6.3.1.

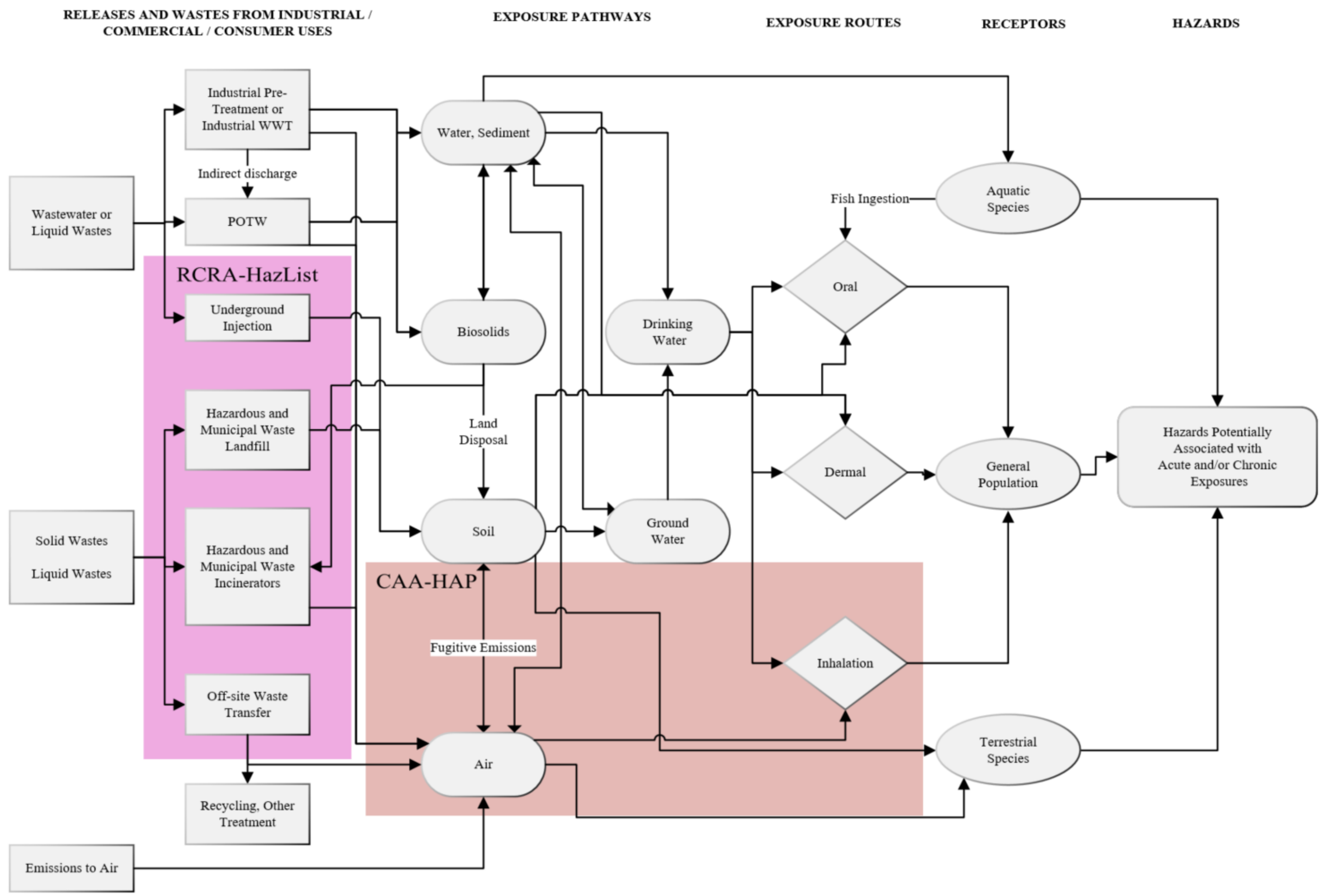

Figure 2-15. Phthalic Anhydride Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay).

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 showing the regulatory laws that adequately assess and manage those pathways. Within this model, phthalic anhydride is expected to rapidly hydrolyze into 1,2-benzenedicarboxylic acid resulting in potential exposure to either chemical.

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).

2.6.3.1 Exposure Pathways and Risks Addressed by Other EPA Administered Statutes

In its TSCA Section 6(b) risk evaluations, EPA is coordinating action on certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. More specifically, EPA is exercising its TSCA authorities to tailor the scope of its risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs or risks that could be eliminated or reduced to a sufficient extent by actions taken under other EPA-administered laws. EPA considers this approach to be a reasonable exercise of the Agency's TSCA authorities, which include:

- o TSCA Section 6(b)(4)(D): "The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider…"
- o TSCA Section 9(b)(1): "The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter."
- o TSCA Section 9(e): "…[I]f the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency."
- o TSCA Section 2(c): "It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter."
- o TSCA Section 18(d)(1): "Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that— (i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law…"

These TSCA authorities supporting tailored risk evaluations and intra-agency referrals are described in more detail below:

TSCA Section 6(b)(4)(D)

TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and PESS the Agency "expects to consider" in a risk evaluation. This language suggests that EPA is not required to consider all conditions of use, hazards, or exposure pathways in risk evaluations. As EPA explained in the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" (82 FR 33726, July 20, 2017) ("Risk Evaluation Rule"), "EPA may, on a case-by-case basis, tailor the scope of the risk evaluation "…in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33729 (July 20, 2017).

In the problem formulation documents for many of the first 10 chemicals undergoing risk evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes." This is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the risk evaluation areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520. Consistent with the approach articulated in the problem formulation documents, and as described in more detail below, EPA is exercising its authority under TSCA to tailor the scope of exposures evaluated in TSCA risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered, media-specific statutes and regulatory programs.

TSCA Section 9(b)(1)

In addition to TSCA Section 6(b)(4)(D), the Agency also has discretionary authority under the first sentence of TSCA Section 9(b)(1) to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator." This broad, freestanding authority provides for intra-agency coordination and cooperation on a range of "actions." In EPA's view, the phrase "actions taken under [TSCA]" in the first sentence of Section 9(b)(1) is reasonably read to encompass more than just risk management actions, and to include actions taken during risk evaluation as well. More specifically, the authority to coordinate intra-agency actions exists regardless of whether the Administrator has first made a definitive finding of risk, formally determined that such risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered Federal laws, and/or made any associated finding as to whether it is in the public interest to protect against such risk by actions taken under TSCA. TSCA Section 9(b)(1) therefore provides EPA authority to coordinate actions with other EPA offices without ever making a risk finding or following an identification of risk. This includes coordination on tailoring the scope of TSCA risk evaluations to focus on areas of greatest concern rather than exposure pathways addressed by other EPA-administered statutes and regulatory programs, which does not involve a risk determination or public interest finding under TSCA Section 9(b)(2).

In a narrower application of the broad authority provided by the first sentence of TSCA Section 9(b)(1), the remaining provisions of Section 9(b)(1) provide EPA authority to identify risks and refer certain of those risks for action by other EPA offices. Under the second sentence of Section 9(b)(1), "[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under [TSCA]." Coordination of intra-agency action on risks under TSCA Section 9(b)(1) therefore entails both an identification of risk, and a referral of any risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the EPA office(s) responsible for implementing those laws (absent a finding that it is in the public interest to protect against the risk by actions taken under TSCA).

Risk may be identified by OPPT or another EPA office, and the form of the identification may vary. For instance, OPPT may find that one or more conditions of use for a chemical substance present(s) a risk to human or ecological receptors through specific exposure routes and/or pathways. This could involve a quantitative or qualitative assessment of risk based on reasonably available information (which might include, *e.g.*, findings or statements by other EPA offices or other federal agencies). Alternatively, risk could be identified by another EPA office. For example, another EPA office administering non-TSCA authorities may have sufficient monitoring or modeling data to indicate that a particular condition of use presents risk to certain human or ecological receptors, based on expected hazards and exposures. This risk finding could be informed by information made available to the relevant office under TSCA Section 9(e), which supports cooperative actions through coordinated information-sharing.

Following an identification of risk, EPA would determine if that risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered laws. If so, TSCA requires EPA to "use such authorities to protect against such risk," unless EPA determines that it is in the public interest to protect against that risk by actions taken under TSCA. In some instances, EPA may find that a risk could be sufficiently reduced or eliminated by future action taken under non-TSCA authority. This might include, *e.g.*, action taken under the authority of the Safe Drinking Water Act (SDWA) to address risk to the general population from a chemical substance in drinking water, particularly if the Office of Water has taken preliminary steps such as listing the subject chemical substance on the Contaminant Candidate List (CCL). This sort of risk finding and referral could occur during the risk evaluation process, thereby enabling EPA to use more a relevant and appropriate authority administered by another EPA office to protect against hazards or exposures to affected receptors.

Legislative history on TSCA Section 9(b)(1) supports both broad coordination on current intra-agency actions, and narrower coordination when risk is identified and referred to another EPA office for action. A Conference Report from the time of TSCA's passage explained that Section 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84. See also H. Rep. No. 114-176 at 28 (stating that the 2016 TSCA amendments "reinforce TSCA's original purpose of filling gaps in Federal law," and citing new language in Section 9(b)(2) intended "to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication"). Exercising TSCA Section 9(b)(1) authority to coordinate on tailoring TSCA risk evaluations is consistent with this expression of Congressional intent.

Legislative history also supports a reading of Section 9(b)(1) under which EPA coordinates intra-agency action, including information-sharing under TSCA Section 9(e), and the appropriately positioned EPA office is responsible for the identification of risk and actions to protect against such risks. See, *e.g.*, Senate Report 114-67, 2016 Cong. Rec. S3522 (under TSCA Section 9, "if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information"); H. Rep. No. 114-176 at 28, 2016 Cong. Rec. S3522 (under Section 9, "if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk"). Legislative history on Section 9(b)(1) therefore supports coordination with and referral of action to other EPA offices, especially when statutes and associated regulatory programs administered by those offices could address exposure pathways or risks associated with conditions of use, hazards, and/or exposure pathways that may otherwise be within the scope of TSCA risk evaluations.

TSCA Sections 2(c) and 18(d)

Finally, TSCA Section 2(c) supports coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs. Section 2(c) directs EPA to carry out TSCA in a “reasonable and prudent manner” and to consider “the environmental, economic, and social impact” of its actions under TSCA. Legislative history from around the time of TSCA’s passage indicates that Congress intended EPA to consider the context and take into account the impacts of each action under TSCA. S. Rep. No. 94-698 at 14 (“the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill”).

Section 18(d)(1) specifies that state actions adopted or authorized under any Federal law are not preempted by an order of no unreasonable risk issued pursuant to TSCA Section 6(i)(1) or a rule to address unreasonable risk issued under TSCA Section 6(a). Thus, even if a risk evaluation were to address exposures or risks that are otherwise addressed by other federal laws and, for example, implemented by states, the state laws implementing those federal requirements would not be preempted. In such a case, both the other federal and state laws, as well as any TSCA Section 6(i)(1) order or TSCA Section 6(a) rule, would apply to the same issue area. See also TSCA section 18(d)(1)(A)(iii). In legislative history on amended TSCA pertaining to Section 18(d), Congress opined that “[t]his approach is appropriate for the considerable body of law regulating chemical releases to the environment, such as air and water quality, where the states have traditionally had a significant regulatory role and often have a uniquely local concern.” Sen. Rep. 114-67 at 26.

EPA’s careful consideration of whether other EPA-administered authorities are available, and more appropriate, for addressing certain exposures and risks is consistent with this Congress’ intent to maintain existing federal requirements and the state actions adopted to locally and more specifically implement those federal requirements, and to carry out TSCA in a reasonable and prudent manner. EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. This approach furthers Congressional direction and EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations.

EPA-administered statutes and regulatory programs that address specific exposure pathways and/or risks are listed as follows:

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. See 42 U.S.C. 7412. 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. See 40 CFR part 63.

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 exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA. As such, EPA does not plan to evaluate exposures to the general population from ambient air in the risk evaluation under TSCA. This regulatory coverage is represented by the red shading in Figure 2-15.

<u>Onsite Releases to Land Pathway</u>
The Comprehensive Environmental Response, Compensation, and Liability Act, otherwise known as CERCLA, provides broad authority under the statute (generally referred to as Superfund) to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other releases of hazardous substances, pollutants and contaminants into the environment. Through CERCLA, EPA was given authority to seek out those parties potentially responsible for the release of hazardous substances and either have them clean up the release or compensate the Federal government for undertaking the response action.

CERCLA Section 101(14) defines "hazardous substance" by referencing other environmental statutes, including toxic pollutants listed under CWA Section 307(a); hazardous substances designated pursuant to CWA Section 311(b)(2)(A); hazardous air pollutants listed under CAA Section 112; imminently hazardous substances with respect to which EPA has taken action pursuant to TSCA Section 7; and hazardous wastes having characteristics identified under or listed pursuant to RCRA Section 3001. See 40 CFR 302.4. CERCLA Section 102(a) also 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 within a 24-hour period must be reported (40 CFR 302.4, 302.6). The scope of this EPA TSCA risk evaluation does not include on-site releases of phthalic anhydride to the environment at Superfund sites and subsequent exposure of the general population or non-human species.

<u>Disposal and Soil Pathways</u>
Phthalic anhydride is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (RCRA) 3001 (40 CFR §§ 261.33) as a listed waste on the U list (U070). 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 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 SDWA)[9].

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.

EPA does not plan to evaluate on-site releases to land that go to underground injection or associated exposures to the general population or terrestrial species in its risk evaluation. 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. See 40 CFR part 144.

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 "all other land disposal" 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. See 40 CFR part 264. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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. See 40 CFR part 258. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle D MSW landfills or exposures of the

[9] This is not an exclusive list of Subtitle C authority, as it also covers, for example, disposal to surface impoundments, waste piles, and land treatment.

general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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. See *e.g.*, RCRA Section 3004(c), 4007; 40 CFR part 257. As a result, EPA does not plan to evaluate on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills or associated exposures to the general population. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

As described in Section 2.6.3.1, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-16 presents the exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of phthalic anhydride that EPA plans to evaluate.

The diagram shown in Figure 2-16 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 receptors, and to the general population via drinking water and fish consumption. EPA plans to evaluate general population exposure to phthalic anhydride and/or 1,2-benzenedicarboxylic acid via oral route from drinking water and fish ingestion, via inhalation routes from drinking water and via dermal route from contact with drinking water and surface water. The supporting basis for environmental pathways considered for phthalic anhydride are included in Appendix H.

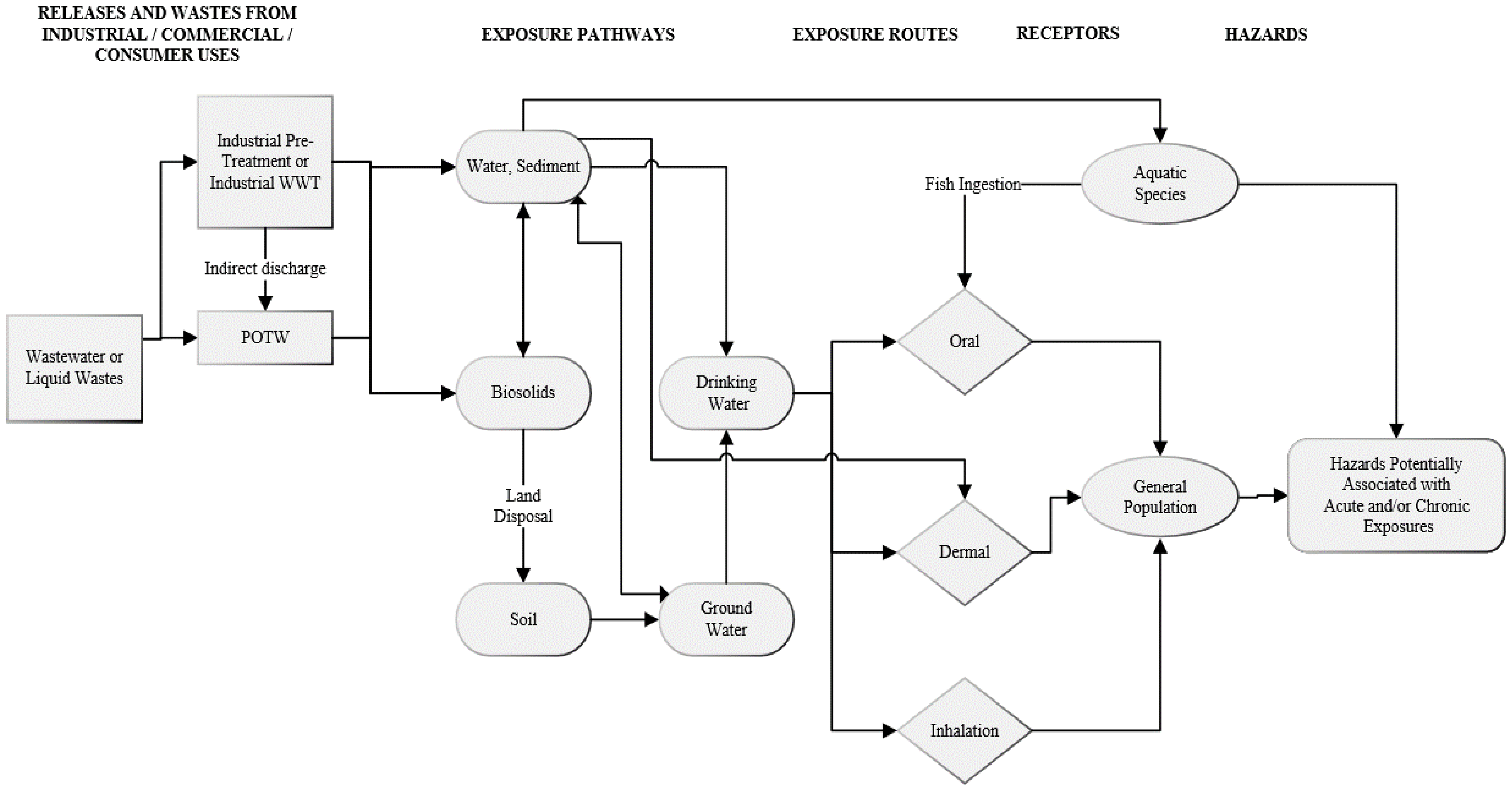

Figure 2-16. Phthalic Anhydride Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards.

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. Within this model, phthalic anhydride is expected to rapidly transform into 1,2-benzenedicarboxylic acid resulting in potential exposure to either chemical.

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.
b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of phthalic anhydride resulting from the full-text screening of reasonably available information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant to EPA's evaluation of conditions of use, exposures, hazards and PESS during risk evaluation. As discussed in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018), targeted supplemental searches during the analysis phase may be necessary to identify additional information (*e.g.*, commercial mixtures) for the risk evaluation of phthalic anhydride and/or 1,2-benzenedicarboxylic acid. For any additional data needs identified during the risk evaluation, EPA may use the Agency's TSCA authorities under Sections 4, 8 or 11, as appropriate.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical properties and environmental fate and transport of phthalic anhydride and 1,2-benzenedicarboxylic acid as follows:

1) **Review reasonably available measured or estimated physical and chemical properties and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to evaluate data and information collected through the systematic review methods and public comments about the physical and chemical 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, 2019c). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or 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 physical and chemical 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 physical and chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of phthalic anhydride and 1,2-benzenedicarboxylic acid within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in 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 physical and chemical properties and environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the environmental fate evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, drinking water, surface water, sediment and aquatic receptors associated with exposure to phthalic anhydride and its hydrolysis into 1,2-benzenedicarboxylic acid. Based on its physical and chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment, phthalic anhydride and 1,2-benzenedicarboxylic acid are more likely to be present in some of these media and less likely to be present in others. EPA has not yet determined the exposure levels in these media. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and estimated exposure levels from modeling approaches. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft exposure scenarios corresponding to various conditions of use for phthalic anhydride are presented in Appendix F, Appendix G, and Appendix H. EPA plans to analyze scenario-specific exposures.

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 identified. Potential sources of environmental release data are summarized in Table 2-6 below:

   Table 2-6. Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
National Emissions Inventory (NEI) data

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 2.3.3. EPA will continue to consider additional reasonably available information and will evaluate it during development of the 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 Exposures and Environmental Releases (ChemSTEER) (U.S. EPA, 2015b).

3) **Review reasonably available release data for surrogate chemicals that have similar uses and physical properties.**
   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. Data for

chemicals used in the same types of applications may be considered as surrogate data for phthalic anhydride and/or 1,2-benzenedicarboxylic acid. 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.

4) **Review reasonably available data that may be used in developing, adapting or applying release 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 and sources (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to consider for release estimation and environmental exposures. 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 (OECD, 2009), the 2011 ESD on Coating Application via Spray-Painting in the Automotive Refinishing Industry (OECD, 2011a), the 2011 ESD on Chemical Industry (OECD, 2011b), the 2011 ESD on Radiation Curable Coating, Inks and Adhesives (OECD, 2010), the 2015 ESD on the Use of Adhesives (OECD, 2015), and the 1994 Synthetic Fiber Manufacture GS (U.S. EPA, 1994c) 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

If ESDs and GSs are not available, other methods may be considered. EPA may also perform supplemental targeted searches of peer-reviewed or gray literature for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. Additionally, for conditions of use where no measured data on releases are 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 completed an initial mapping of release scenarios to relevant conditions of use as shown in Appendix F. EPA plans to refine the mapping/grouping of release scenarios based on factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use using reasonably available information. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop release scenarios.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental release evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). EPA plans to integrate the data using 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 and its hydrolysis into 1,2-benzenedicarboxylic acid:

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
For phthalic anhydride and its subsequent hydrolysis into 1,2-benzenedicarboxylic acid, environmental media which EPA plans to analyze are sediment, 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.**
EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards under TSCA Section 26(h) and that estimate surface water, groundwater, sediment, and biosolids concentrations alongside reasonably available surface water, groundwater, sediment monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations may generally include the following inputs: direct release into surface water, or sediment, and indirect release into surface water, sediment, 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 the last few years. EPA plans to review and characterize monitoring data or modeled estimates to determine how representative they are of applicable use patterns.

   Any studies which relate levels of phthalic anhydride and/or 1,2-benzenedicarboxylic acid 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 and 1,2-benzenedicarboxylic acid, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

    - Estimates of groundwater concentrations, surface water concentrations, sediment 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 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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

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 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).

OSHA has established a PEL of 2 ppm 8-hour TWA (OSHA, 2009). ACGIH set the TLV at 0.002 mg/m^3 TWA, with a STEL of 0.005 mg/m^3 (IPCS, 2003). 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 2-7 . 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 physical and chemical properties similar to phthalic anhydride and 1,2-benzenedicarboxylic acid.**
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 (OECD, 2015) and the 2009 ESD on Adhesive Formulation (OECD, 2009) are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use. EPA may conduct or perform supplemental targeted searches of peer-reviewed or gray literature to understand those

conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted supplemental searches 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 #2 and #3 are completed, and based on information developed from #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. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). 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 completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine mapping or grouping 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. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.

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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. EPA plans to integrate the data using 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 and/or 1,2-benzenedicarboxylic acid, the following are noteworthy considerations in constructing consumer exposure scenarios:

   - Conditions of use
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the potential of indoor exposure pathways based on reasonably available data.**
   Based on the physical and chemical properties of phthalic anhydride and/or 1,2-benzenedicarboxylic acid and the consumer uses identified, inhalation of vapors and mists is expected to be an important indoor exposure pathway for consumers. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air exposures.**
   Indoor exposure models that estimate emissions from use of consumer products are reasonably available. These models generally consider physical and-chemical properties (*e.g.*, vapor pressure, molecular weight), product specific properties (*e.g.*, weight fraction of the chemical in the product), use patterns (*e.g.*, duration and frequency of use), user environment (*e.g.***,** room of use, ventilation rates), and receptor characteristics (*e.g.*, exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

   Models that estimate emission and migration of semi-volatile organic compounds (SVOCs) into the indoor environment models generally consider indoor fate and transport properties such as 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 physical and chemical 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 and/or 1,2-benzenedicarboxylic 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 and/or 1,2-benzenedicarboxylic acid 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 dust, indoor air).**
The availability of phthalic anhydride and/or 1,2-benzenedicarboxylic acid concentration for various conditions of use will be evaluated. This data provides the source term for any subsequent indoor modeling. EPA plans to analyze source attribution between overall indoor air and dust levels and various indoor sources.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
For phthalic anhydride and its transformation into 1,2-benzenedicarboxylic acid, EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults may differ from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

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. EPA plans to integrate the data using 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 the general population by considering sources conditions of use, exposure pathways and routes.**
For phthalic anhydride and/or 1,2-benzenedicarboxylic acid, the following are 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 modeling approaches 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 and relevant.
    - 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).

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 inform exposure scenarios. EPA anticipates that there will be a range in the potential exposures associated with the exposure scenarios identified in Section 2.6.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses. The number of scenarios will depend on the conditions of use, exposure pathways and receptors. 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 may be qualitative, semi-quantitative, or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and include careful consideration of variability and uncertainty.

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 and/or 1,2-benzenedicarboxylic acid, 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, and uptake from aquatic environments into aquatic organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous phthalic anhydride and/or 1,2-benzenedicarboxylic acid 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 and/or 1,2-benzenedicarboxylic acid general population exposure scenarios that are relevant to this assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical and chemical 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).**
Exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations.

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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of phthalic anhydride and 1,2-benzenedicarboxylic acid 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 and 1,2-benzenedicarboxylic acid to aquatic 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 and 1,2-benzenedicarboxylic acid to aquatic organisms.

   EPA plans to evaluate environmental hazard data using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). The study evaluation results will be documented in the risk evaluation phase, and data from acceptable studies will be extracted and integrated in the risk evaluation process.

   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) **Derive hazard thresholds for aquatic 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 and 1,2-benzenedicarboxylic acid to aquatic 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

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

EPA plans to consider aquatic (*e.g.*, water and sediment exposures) pathways in the phthalic anhydride conceptual model. These organisms may be exposed to phthalic anhydride and 1,2-benzenedicarboxylic acid via a number of environmental pathways (*e.g.*, surface water, sediment, diet).

5) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of phthalic anhydride and 1,2-benzenedicarboxylic acid.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of phthalic anhydride and 1,2-benzenedicarboxylic acid after reviewing relevant physical and chemical 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 and 1,2-benzenedicarboxylic acid. 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 and 1,2-benzenedicarboxylic acid with the fate parameters (*e.g.*, BAF, BCF, BMF, TMF).

6) **Conduct an environmental risk estimation and characterization of phthalic anhydride and 1,2-benzenedicarboxylic acid.**
EPA plans to conduct a risk estimation and characterization of phthalic anhydride and 1,2-benzenedicarboxylic acid to identify if there are risks to the aquatic environments from the measured and/or predicted concentrations of phthalic anhydride and 1,2-benzenedicarboxylic acid in environmental media (*e.g.*, water, sediment). 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). Analysis of risk for characterization includes a confidence statement in risk estimation which qualitative judgment describing the certainty of the risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.

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 evaluate human health studies using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018) and updates to the epidemiological data quality criteria released with the first ten risk evaluations. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

   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 and 1,2-benzenedicarboxylic acid hazard(s). Susceptibility of particular human receptor groups 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 and 1,2-benzenedicarboxylic acid exposure. EPA may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (*e.g.*, oral, dermal, inhalation) and by the cancer and noncancer endpoints identified in Section 2.4.2.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011a, 1994a) developing points of departure (POD) for either margins of exposure (MOEs), cancer slope factors (CSFs), oral slope factors (OSFs), and/or inhalation unit risks (IURs). 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) analyses determine the relevancy of animal data to human risk and how data can be quantitatively evaluated. If cancer hazard is determined to be applicable to phthalic anhydride and 1,2-benzenedicarboxylic acid, EPA plans to evaluate information on genotoxicity and the MOA 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, 2005a). In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-life Exposures to Carcinogens* (U.S. EPA, 2005b), EPA plans to determine whether age-dependent adjustment factors (ADAFs) are appropriate for phthalic anhydride and 1,2-benzenedicarboxylic acid for specific conditions of use based upon potential exposures to children.

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* (U.S. EPA, 2012a).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 BW3/4 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 (1994a).

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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

6) **Consider the route(s) of exposure (*e.g.*, 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 reasonably available data to conduct a 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 and 1,2-benzenedicarboxylic acid, 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.

If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994a). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are 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).

If there are acceptable inhalation data after completion of systematic review, EPA may also consider extrapolating from the inhalation to the dermal route if first-pass metabolism through the liver via the oral route is expected because in that case, use of data from the oral route is not recommended (U.S. EPA, 1994a). EPA may also consider inhalation-to-dermal route extrapolation if an inhalation toxicity study with a sensitive hazard endpoint is used to evaluate risks. Based on these considerations, EPA extrapolated from the inhalation to the dermal route for several of the first ten risk evaluations under amended TSCA, including methylene chloride (U.S. EPA, 2020d) and carbon tetrachloride (U.S. EPA, 2020b).

7) **Conduct a human health risk estimation and characterization of phthalic anhydride and 1,2-benzenedicarboxylic acid.**
Analysis of risk for characterization includes a confidence statement in risk estimation. This confidence statement is based on qualitative judgment describing the certainty of the risk estimate considering the strength of the evidence scores for hazard and exposure along with their limitations and relevance. The lowest confidence evaluation for either hazard or exposure will drive the overall confidence estimate.

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" (U.S. EPA, 2000). 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, September 18, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use…" The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (*e.g.*, related to nature and magnitude of effects).

EPA plans to also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA plans to also identify: (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 (U.S. EPA, 2015c) 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 (see

82 Fed. Reg. 33726, 33744; July 12, 2017). 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. The draft risk evaluation for phthalic anhydride will be peer reviewed.

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APPENDICES

Appendix A ABBREVIATED METHODS FOR SEARCHING AND SCREENING

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

To develop the chemical terms for the subsequent literature search for phthalic anhydride and 1,2-benzenedicarboxylic acid, several online sources were queried.

- California Department of Pesticide Regulation: https://www.cdpr.ca.gov/docs/chemical/monster2.htm
- USEPA Chemistry Dashboard: https://comptox.epa.gov/dashboard
- University of Hertfordshire PPDB: Pesticide Properties DataBase: https://sitem.herts.ac.uk/aeru/ppdb/en/search.htm
- USEPA Reregistration Eligibility Decision (RED) documents: https://archive.epa.gov/pesticides/reregistration/web/html/status.html
- Office of Pesticide Programs Pesticide Chemical Search: https://ofmpub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1
- Food and Agriculture Organization of the United Nations: http://www.fao.org/home/en/
- PAN Pesticides Database: http://www.pesticideinfo.org/Search_Chemicals.jsp

Prior to inclusion in the search term string, all forms of chemical names were subjected to verification from several potential sources (*e.g.*, US EPA Chemistry Dashboard, STN International-CAS; see complete list of sources for chemical verification in Table_Apx A-1). From these sources, all chemical names, synonyms, CAS number(s), trade names, etc. were documented and used to generate terms for database searches.

Table_Apx A-1. Sources of Verification for Chemical Names and Structures

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Chemistry Dashboard (https://comptox.epa.gov/dashboard)	CAS Numbers, Synonyms, Structures, Properties, Environmental Fate and Transport.	Online
Dictionary of Chemical Names and Synonyms	Wide assortment of chemical compounds by chemical name and synonym, has CAS index and some structure data	ECOTOX
Farm Chemicals Handbook-1992	Pesticide information, CAS numbers and synonyms, some structure data ***Sometimes CAS number presented for a compound is for the main constituent only	ECOTOX
OPPT SMILES Verification Source	Structure Data	Electronic verification
RTECS (Registry of Toxic Effects of chemical substance, 1983-84 ed., 2 vols)	Chemical names, synonyms and CAS numbers	ECOTOX
Sigma – Aldrich website58784 http://www.sigma-aldrich.com	Organic and inorganic Compounds by chemical name, has CAS index and some structure and Physical Property data	Online

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
STN International (CAS) 1994	***Most complete source of chemical name, synonym and structure information, no physical properties	Online
The Pesticide Manual 10th edition, 1994	Pesticide Compounds by chemical name, synonym, product code, has CAS index and some structure and Physical Property data	ECOTOX
TSCA (Toxic Substances Control Act Chemical Substance Inventory, 1985 ed., 5 vols)	Chemical names, synonyms and CAS numbers	ECOTOX
World Wide Web (misc. web sources) A copy of the verification page is saved to the Attachments tab of the chemical entry. This includes company MSDS sheets or Chemical Labels.	Chemical names, synonyms and CAS numbers	Online
California Department of Pesticide Regulation (http://www.cdpr.ca.gov/dprdatabase.htm)	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online
PAN Pesticide Database (http://www.pesticideinfo.org/Search_Chemicals.jsp)	Pesticides searchable by name or CAS #. Includes CAS #, Name, synonyms, targets, toxicity data, related chemicals and regulatory information.	Online
US EPA Office of Pesticide Programs Pesticide Fate Database – No web access available. An electronic copy of the data file is located at the Contractor site: PFATE_37_Tables.mdb.	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching for phthalic anhydride occurred during April and May of 2019 by an information specialist and the results were stored in the Health and Environmental Research Online (HERO) database and assigned a HERO reference identification number.[10] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

After initial deduplication in HERO[11], these studies were imported into SWIFT Review software (Howard et al., 2016) to identify those references most likely to be applicable to each discipline area (*i.e.*, consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

A.1.2.1 Query Strings for the Publicly Available Database Searches on Phthalic Anhydride and 1,2-benzenedicarboxylic acid

Table_Apx A-2 presents a list of the data sources, the search dates and number of peer-reviewed references resulting from the searches for phthalic anhydride. The sources are found as online databases and the resulting references were gathered and uploaded into the EPA Health and Environmental Research Online (HERO) database for literature screening. For 1,2-benzenedicarboxylic acid, a set of

[10]EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.
[11] Deduplication in HERO involves first determining whether a matching unique ID exists (*e.g.*, PMID, WOSid, or DOI). If one matches one that already exists in HERO, HERO will tag the existing reference instead of adding the reference again. Second, HERO checks if the same journal, volume, issue and page number are already in HERO. Third, HERO matches on the title, year, and first author. Title comparisons ignore punctuation and case.

general search terms have been developed; however, literature searches of publicly available databases have not yet been completed. For this reason, only literature search results for phthalic anhydride are shown in this section. EPA will make literature search results for 1,2-benzenedicarboxylic acid available at a later date.

Table_Apx A-2. Summary of Data Sources, Search Dates and Number of Peer-Reviewed Literature Search Results for Phthalic Anhydride

Source	Date of Search	Number of References
Current Contents	05/01/2019	1573
Web of Science	09/15/2019	2382
ProQuest CSA	04/26/2019	555
Dissertation Abstracts	05/03/2019	8
Science Direct	05/01/2019	767
Agricola	05/01/2019	119
TOXNET	05/01/2019	780
PubMed	05/05/2019	385
UNIFY	05/03/2019	17
Totals:		**6586**

<u>GENERAL</u>:

General search terms were compiled and used in the search strategies for each of the databases/sources listed below. Based upon the online search manuals for the respective databases/sources, it was necessary to construct searches as noted for each of the sources. The search terms are listed below in full for each source and noted if the general search terms or other search terms were used.

General search terms for phthalic anhydride include:

"1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR "1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5" OR "HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride" OR "Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7" OR "TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P"

General search terms for 1,2-benzenedicarboxylic acid include[12]:

“1,2-Benzenedicarboxylic acid” OR “1,2-Phthalic acid” OR “1,3-Benzenedicarboxylic acid” or “1,4-Benzenedicarboxylic acid” OR “1,4-Dicarboxybenzene” OR “12Benzenedicarboxylicacid” OR “14Benzenedicarboxylicacid” OR “3-Carboxybenzoic acid” OR “4-Carboxybenzoic acid” OR “Alizarinate” OR “Alizarinic acid” OR “Amoco TA 33” OR “Benzene-1,2-dicarboxylic acid” OR “Benzene-1,3-dicarboxylic acid” OR “Benzene-1,4-dicarboxylic acid” OR Benzene-p-dicarboxylate”

[12] A set of general search terms have been developed for 1,2-benzenedicarboxylic acid. However, the results of this supplemental search are not yet available for inclusion in this scoping document. For this reason, only literature search results for phthalic anhydride are shown in this section and in the interactive literature inventory trees and heatmaps in Section 2.1.2.

OR “Benzene-p-dicarboxylic acid” OR “Dipotassium phthalate” OR “Disodium phthalate” OR “Disodium salt of phthalic acid” OR “Disodiumsaltofphthalicacid” OR “Hydrogen potassium phthalate” OR “Hydrogenophtalate de potassium” OR “IN-K2122” OR “Isophthalic acid” OR “Isoterephthalic acid” OR “m-Benzenedicarboxylic acid” OR “m-Carboxybenzoic acid” OR “m-Dicarboxybenzene” OR “meta-benzenedicarboxylic acid” OR “Monopotassium 1,2-benzenedicarboxylate” OR “Monopotassium phthalate” OR “m-Phthalic acid” OR “Naphthalinate” OR “Naphthalinic acid” OR “O-Benzenedicarboxylate” OR “o-Benzenedicarboxylic acid” OR “O-Carboxybenzoate” OR “o-Carboxybenzoic acid” OR “o-Dicarboxybenzene” OR “O-Phthalic acid” OR “Orthophthalic acid” OR “ortho-phthalic acid” OR “para-benzenedicarboxylic acid” OR “para-Phthalic acid” OR “p-Benzenedicarboxylate” OR “p-Benzenedicarboxylic acid” OR “p-Carboxybenzoic acid” OR “p-Dicarboxybenzene” OR “PHTHALATE, POTASSIUM HYDROGEN” OR “Phthalic acid” OR “PHTHALIC ACID MONOPOTASSIUM SALT” OR “Phthalic acid, Disodium salt” OR “Phthalic acid, monopotassium salt” OR “Phthalinate” OR “Phthalinic acid” OR “Potassium 2-carboxybenzoate” OR “Potassium acid phthalate” OR “Potassium biphthalate” OR “Potassium hydrogen phthalate” OR “POTASSIUM PHTHALATE” OR “Potassium phthalate monobasic” OR “Potassiumhydrogenphthalate” OR “p-Phthalate” OR “p-Phthalic acid” OR “P-Phthelate” OR “P-Phthelic acid” OR “S-LOP” OR “Sodium 2-carboxybenzoate” OR “Sunftal 20” OR “TA 33LP” OR “Tephthol” OR “Terephthalic acid”

CURRENT CONTENTS CONNECT: (access.webofknowledge.com)
General Search Terms applied to the search strategy for Current Contents.

Date Searched: 05.01.19
Date Range of Search: 1970 to Present
N = 1573

TS=("1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR "1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5" OR "HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride" OR "Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7" OR "TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P")

N = 1,573

WOS Core Collection:
Web of Science Core Collection may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Web of Science Link or copying and pasting (https://apps.webofknowledge.com).

Date Searched: 09/15/2019
Date Range of Search: 1970 to Present
N = 2382

TS=("1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR

"1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5" OR "HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride" OR "Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7" OR "TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P")

N = 2382

<u>PROQUEST Agricultural and Scientific Database</u>: (www.csa.com)
General Search Terms applied to the search strategy for ProQuest Agricultural and Scientific Database.

Date Searched: 04.26.19
Date Range of Search: 1900 to Present
N = 555

ALL("1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR "1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5" OR "HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride" OR "Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7" OR "TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)

N = 555

<u>PROQUEST Dissertations and Theses</u>: (search.proquest.com)
General Search Terms applied to the search strategy for ProQuest Dissertations and Theses.

Date Searched: 05.03.19
Date Range of Search: 1900 to Present
N = 8

ALL("1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR "1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5" OR "HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride" OR "Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7" OR "TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P") AND LA(ENG)

N = 8

SCIENCE DIRECT: (www.sciencedirect.com)
General Search Terms applied to the search strategy for Science Direct

Date Searched: 05.01.19
Date Range of Search: 1823 to Present
N = 767

Science Direct 01:
"1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR "1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5"

N = 7

Science Direct 02:
"HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride"

N = 19

Science Direct 03:
"Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7"

N = 741

Science Direct 04:
"TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P"

N = 0

AGRICOLA: (www.nal.usda.gov)
General Search Terms applied to the search strategy for Agricola. The Agricola database contains a significant amount of gray literature including proceedings, symposia, and progress reports from government and educational institutions. Agricola is not used when conducting a search for the Office of Water.

Date Searched: 05.01.19
Date Range of Search: 15th century to the Present
N = 119

Agricola 01:
1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE
1,2-Benzenedicarboxylic acid anhydride
1,2-Benzenedicarboxylic anhydride
1,3-Dihydro-1,3-dioxoisobenzofurane
1,3-Isobenzofurandione

1,3-Phthalandione
2-Benzofuran-1,3-dione
Araldite HT 901
EINECS 201-607-5
HT 901

N = 6

Agricola 02:
Isobenzofuran-1,3-dione
NSC 10431
OP 392
o-phthalic acid anhydride
ortho-phthalic acid anhydride
Phthalandione
Phthalanhydride
Phthalic acid anhydride
Phthalic anhydride
Phthalicanhydride

N = 113

Agricola 03:
Retarder AK
Retarder B-C
Retarder ESEN
Retarder PD
Rikacid PA
Sconoc 5
Sconoc 7
TGL 6525
UN 2214
Vulkalent B

N = 0

Agricola 04:
Vulkalent B/C
Wiltrol P

N = 0

TOXNET: (toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TOXLINE)
General Search Terms applied to the search strategy for TOXNET.

Date Searched: 05.01.19
Date Range of Search: 1900 to Present
N = 780

TOXNET 01:
85-44-9 OR 34533-03-4 OR 25950-44-1 OR 39363-63-8

Search	Database	Query	Time	Result
# 1	toxline	(("phthalic anhydride" OR "1 3 isobenzofurandione" OR "retarder pd" OR "retarder ak" OR "phthalsaeureanhydrid german " OR phthalandione OR "ftaalzuuranhydride dutch " OR esen OR "1 3 phthalandione" OR "1 3 dioxophthalan" OR 85-44-9 [rn]) OR 34533-03-4 [rn] OR 25950-44-1 [rn] OR 39363-63-8 [rn]) AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	22:36:28	780

N = 780

PubMed: (https://www.ncbi.nlm.nih.gov/pubmed/)
Below are the search terms compiled from the Chemical Report for Phthalic anhydride and used on the PubMed Advanced search page using the Title and the Title/Abstract fields.

Date Searched: 05.05.19
Date Range of Search: to the Present
N = 385

"1,2-BENZENE DICARBOXYLIC ACID ANHYDRIDE" OR "1,2-Benzenedicarboxylic acid anhydride" OR "1,2-Benzenedicarboxylic anhydride" OR "1,3-Dihydro-1,3-dioxoisobenzofurane" OR "1,3-Isobenzofurandione" OR "1,3-Phthalandione" OR "2-Benzofuran-1,3-dione" OR "Araldite HT 901" OR "EINECS 201-607-5" OR "HT 901" OR "Isobenzofuran-1,3-dione" OR "NSC 10431" OR "OP 392" OR "o-phthalic acid anhydride" OR "ortho-phthalic acid anhydride" OR "Phthalandione" OR "Phthalanhydride" OR "Phthalic acid anhydride" OR "Phthalic anhydride" OR "Phthalicanhydride" OR "Retarder AK" OR "Retarder B-C" OR "Retarder ESEN" OR "Retarder PD" OR "Rikacid PA" OR "Sconoc 5" OR "Sconoc 7" OR "TGL 6525" OR "UN 2214" OR "Vulkalent B" OR "Vulkalent B/C" OR "Wiltrol P"

N = 385

ECOTOX UNIFY:
This is an internal EPA database that is not accessible to the public. Results from the ECOTOX Unify search strategy.

Date Searched: 05.03.19
Date Range of Search: all years
N = 17

PHAN

N = 17

A.1.2.2 Data Prioritization for Environmental Hazard, Human Health Hazard, Fate and Physical Chemistry

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.*, analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH*)* fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR[13].

A.1.2.3 Data Prioritization for Occupational Exposures and Environmental Releases and General Population, Consumer and Environmental Exposures

To prioritize references related to occupational exposure, environmental release, general population exposure, consumer exposure, and environmental exposure, EPA used positive and negative seed studies to build a classification model in SWIFT Review. The positive seeds were identified using relevant literature pool for the first ten TSCA risk evaluations, while the negative seeds were identified from a subset of literature for the current high-priority substances. The model was then applied to the unclassified literature to generate a classification score for each reference. Scores above a certain threshold value were then prioritized for further review in SWIFT-ActiveScreener.

A.2 Peer-Reviewed Screening Process

The studies identified from publicly available database searches and SWIFT-Review filtering/prioritization were housed in HERO system and imported into SWIFT-ActiveScreener or DistillerSR for title/abstract and full-text screening. Both title/abstract and full-text screening were conducted by two independent reviewers. Screening is initiated with a pilot phase of screening (between 10 and 50) studies to identify areas where clarification in screening criteria might be needed or chemical-specific supplemental material tags might be identified. Records that met PECO (or equivalent criteria (Appendix A.2.1) during title and abstract screening were considered for full-text screening. At both the title/abstract and full-text review levels, screening conflicts were resolved by topic-specific experts and/or discussion among the primary screeners. For citations with no abstract, the articles are initially screened based on all or some of the following: title relevance (titles that suggest a record is not relevant can be excluded rather than marked as unclear), and page numbers (articles two pages in length or less were assumed to be conference reports, editorials, or letters). During title/abstract or full-text level screening in DistillerSR, studies that did not meet the PECO criteria, but which could provide supporting information were categorized (or "tagged") as supplemental information.

It is important to emphasize that being tagged as supplemental material does not mean the study would necessarily be excluded from consideration in an assessment. The initial screening level distinctions between a study meeting the PECO criteria and a supplemental study are often made for practical reasons and the tagging structures (as seen in the literature inventory trees and heat maps in Section 2.1 of this document) are designed to ensure the supplemental studies are categorized for easy retrieval if needed while conducting the assessment. The impact on the assessment conclusions of individual studies

[13] DistillerSR is a web-based systematic review software used to screen studies available at https://www.evidencepartners.com/products/distillersr-systematic-review-software.

tagged as supporting material is often difficult to assess during the screening phase of the assessment. These studies may emerge as being critically important to the assessment and need to be evaluated and summarized at the individual study level (*e.g.*, cancer MOA mechanistic or non-English-language studies), or be helpful to provide context (*e.g.*, summarize current levels of exposure, provide hazard evidence from routes or durations of exposure not pertinent to the PECO), or not be cited at all in the assessment (*e.g.*, individual studies that contribute to a well-established scientific conclusion). Studies may be tagged as supplemental material during either title and abstract or full-text screening. When tagged as supplemental material during title and abstract screening, it may not be completely clear whether the chemical of interest is reported in the study (*i.e.*, abstracts may not describe all chemicals investigated). In these cases, studies are still tagged with the expectation that if full-text retrieval is pursued, then additional screening would be needed to clarify if the study is pertinent.

A.2.1 Inclusion/Exclusion Criteria

A PECO statement is typically used to focus the research question(s), search terms, and inclusion/ exclusion criteria in a systematic review. PECO criteria were developed *a priori* to screening and modified to fit the various discipline areas supporting the TSCA risk evaluations. Variations include the RESO (receptor, exposure, scenario/setting, and outcome) used for the occupational exposure and environmental releases discipline, and PESO (pathways/processes, exposures, setting/scenario, and outcomes) used by the fate and transport discipline. All PECOs and PECO-equivalent criteria can be found in the following sections.

A.2.1.1 PECO for Environmental and Human Health Hazards

The PECO used in this evidence map to identify literature pertinent to phthalic anhydride effects on human health and environmental hazard is presented in Table_Apx A-3. In addition to the PECO criteria, studies containing potentially relevant supplemental material were tracked and categorized during the literature screening process as outlined in Table_Apx A-4.

Table_Apx A-3. Hazards Title and Abstract and Full-text PECO Criteria for Phthalic Anhydride

PECO Element	Evidence
P	• **Human:** Any population and life stage (occupational or general population, including children and other sensitive populations). • **Animal:** Aquatic and terrestrial species (live, whole organism) of any life stage (including preconception, in utero, lactation, peripubertal, and adult stages). Bacteria and viruses are not included. Although certain non-mammalian model systems are increasing used to identify potential human health hazards (*e.g.*, Xenopus, zebrafish), for simplicity animal models will be further inventoried according to the categorization below: − Human health models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig − Ecotoxicological models: wild mammals (*e.g.*, Peromyscus sp.), insects, spiders, crustaceans, fish, birds, mollusks, invertebrates, amphibians, worms and reptiles • **Plants:** Aquatic and terrestrial species (live), all plants including algal, moss, lichen and fungi species.
E	**Relevant forms:** • phthalic anhydride (CASRN 85-44-9). Phthalic anhydride (CASRN 85-44-9) has a number of synonyms that can be found on the EPA Chemistry Dashboard. • **Human:** Any exposure to phthalic anhydride. • **Animal:** Any exposure to phthalic anhydride including via water, injection, diet, and dermal. • **Plants:** Exposure to phthalic anhydride via water or soil, with reported concentration and duration. Studies involving exposures to mixtures will be included only if they also include exposure to phthalic

PECO Element	Evidence
	anhydride alone. Chemical exposures for aquatic plants where only sediment concentrations are reported from field studies are excluded; laboratory-based sediment studies are retained.
C	• **Human:** A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of phthalic anhydride, or exposure to phthalic anhydride for shorter periods of time. However, case series are considered to meet PECO criteria even if no referent group is presented. Case reports describing findings in 1- 3 people in any setting will be tracked as "potentially relevant supplemental information." • **Animal and Plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement).
O	• **Human**: All health outcomes (cancer and noncancer). • **Animal and Plants**: All biological effects.

Table_Apx A-4. Major Categories of Potentially Relevant Supplemental Materials for Phthalic Anhydride

Category	Evidence
Mechanistic studies	Studies reporting measurements related to a health outcome that inform the biological or chemical events associated with phenotypic effects, in both mammalian and non-mammalian model systems, including *in vitro*, *in vivo* (by various non-inhalation routes of exposure), *ex vivo*, and *in silico* studies.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.
Susceptible populations (no health outcome)	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype.
Mixture studies	Mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest.
Case reports	Case reports ($n \leq 3$ cases) will be tracked as potentially relevant supplemental information.
Non-English records	Non-English records will be tracked as potentially relevant supplemental information.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Use of phthalic anhydride as a reference compound to induce a sensitization response	Phthalic anhydride is a known sensitizer and can be used as a reference compound to induce sensitization responses in experimental studies (*e.g.*, dermatitis, airway sensitization, or other allergenic response). Studies were tagged as supplemental in cases where it was (1) used as a reagent to induce sensitization for the purpose of testing another compound (co-exposure); or (2) the endpoints evaluated were only mechanistic or biochemical and not apical (*e.g.*, cytokine mRNA levels). However, studies that focused on characterizing a sensitization response that included an apical outcome (*e.g.*, local lymph node assay) were considered PECO relevant.

A.2.1.2 PECO for Consumer, Environmental, and General Population Exposures.

Table_Apx A-5. Generic Inclusion Criteria for the Data Sources Reporting Exposure Data on General Population, Consumers and Environmental Receptors

PECO Element	Evidence
Population	**Human:** General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (life stages, preexisting conditions, genetic factors), pregnant women; lactating women, women of child bearing age. Many human population groups may be exposed. No chemical-specific exclusions are suggested at this time. **Environmental:** aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only)
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** Pathways: indoor air/vapor/mist; indoor dust; particles; outdoor/ambient air; surface water; biosolids; sediment; breastmilk; food items containing phthalic anhydride including fish; consumer product uses in the home (including consumer product containing chemical); Routes of Exposure: Inhalation, Oral, Dermal
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios. **Environmental:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or indoor air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc) containing phthalic anhydride. **Environmental:** A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

Table_Apx A-6. Pathways Identified as Supplemental for Phthalic Anhydride[a]

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Phthalic anhydride	X	--	--	X	X	X

[a] Supplemental pathways refer to pathways addressed by other EPA administered statutes (see Section 2.6.3.1). Studies tagged under these pathways provide media information that is not prioritized in the screening process.

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

EPA developed a generic RESO statement to guide the screening of engineering and occupational exposure data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria specified in the RESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments. On the other hand, data or information sources that fail to meet the criteria in the RESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific engineering and occupational exposure data needs as part of the process of developing the exposure assessment for each risk evaluation. EPA uses the RESO statement (Table_Apx A-7) along with the information in Table_Apx A-8 when screening the engineering and occupational exposure data and information.

Table_Apx A-7. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

RESO Element	Evidence
Receptors	• Humans: Workers, including occupational non-users • Environment: All environmental receptors (relevant release estimates input to Exposure) Please refer to the conceptual models for more information about the environmental and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant environmental releases of the chemical substance from occupational scenarios: Dermal and inhalation exposure routes (as indicated in the conceptual model) Oral route (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal.
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (*e.g.*, mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8) provides a list of related and relevant general information.
TSCA = Toxic Substances Control Act

Table_Apx A-8. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data [a]
General Engineering Assessment (may apply to Occupational Exposures and / or Environmental Releases)	Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (*e.g.*, each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. Concentration of the chemical of interest
Occupational Exposures	Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Potential routes of exposure (*e.g.*, inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (*e.g.*, liquid, vapor, mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). For solids, bulk and dust particle size characterization data. Dermal exposure data. Exposure duration (hr/day). Exposure frequency (days/yr). Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. PPE types employed by the industries within scope. EC employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental Releases (to relevant environmental media)	Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors. Number of release days per year. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.

[a] These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.

Objective Determined during Scoping	Type of Data [a]
In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis. **Abbreviations:** hr=Hour kg=Kilogram(s) lb=Pound(s) yr=Year PV=Particle volume POTW=Publicly owned treatment works PPE=Personal protective equipment PSD=Particle size distribution TWA=Time-weighted average	

A.2.1.4 PESO for Fate and Transport

EPA developed a generic PESO statement to guide the screening of environmental fate data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data or information sources that fail to meet the criteria in the PESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment for each risk evaluation. EPA uses the PESO statement (Table_Apx A-9) along with the information in Table_Apx A-10 when screening the fate data or information sources to ensure complete coverage of the processes, pathways and data or information relevant to the environmental fate and transport of the chemical substance undergoing risk evaluation.

Table_Apx A-9. Inclusion Criteria for Data or Information Sources Reporting Environmental Fate and Transport Data

PESO Element	Evidence
Pathways and **P**rocesses	Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.

PESO Element	Evidence
Exposure	Environmental exposure of environmental receptors (*i.e.*, aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Environmental exposure of human receptors, including any PESS, to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (*e.g.*, buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (*i.e.*, aquatic and terrestrial organisms) or human receptors (*i.e.*, general population, and PESS)
Outcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)

Table_Apx A-10. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Required Environmental Fate Data					
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X			
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X			
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X	X		X
Biomagnification and related information	Trophic magnification	X			
Desorption information	Sorption, Mobility	X	X	X	
Destruction and removal by incineration	Incineration				X
Hydrolysis rates or half-lives	Hydrolysis	X	X	X	
K_{OC} and other sorption information	Sorption, Mobility	X	X	X	

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Wastewater treatment removal information	Wastewater treatment	X	X		
Supplemental (or Optional) Environmental Fate Data					
Abiotic transformation products	Hydrolysis, Photolysis, Incineration	X			X
Aerobic biotransformation products	Aerobic biodegradation	X	X		
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X	
Atmospheric deposition information	Atmospheric deposition				X
Coagulation information	Coagulation, Mobility	X		X	
Incineration removal information	Incineration				X

A.2.1.5 Generation of Hazard Heat Maps

As stated in Appendix A.1.2.2, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content. The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or MeSH fields content.

After the completion of full-text screening for hazard data, all references tagged as included (or "PECO-relevant) were uploaded to the SWIFT Review tool for further filtering. The SWIFT Review filters applied at this phase focused on types of health outcomes included: "ADME", "PBPK", "cancer", "cardiovascular", "developmental", "endocrine", "gastrointestinal", "hematological and immune", "hepatic", "mortality", "musculoskeletal", "neurological", "nutritional and metabolic", "ocular and sensory", "renal", "reproductive", "respiratory", and "skin and connective tissue". The details of these health outcome search strategies that underlie the filters are available online. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported and used to populate the Hazard Heat Map (Figure 2-10). Studies that were not retrieved using these filters were tagged as "No Tag". The evidence type listed in the heat map (*e.g.*, human, animal-human health model, animal- environmental model, and plant) was manually assigned to each reference by screeners during the full-text screening.

The health outcome tags were originally designed for vertebrate systems, and as such, did not conform well to plant evidence. Therefore, any plant studies tagged for: "cancer", "cardiovascular", "gastrointestinal", "hematological and immune", "hepatic", "musculoskeletal", "neurological", "ocular and sensory" and "renal and respiratory" were manually reviewed and re-tagged to more appropriate health outcomes.

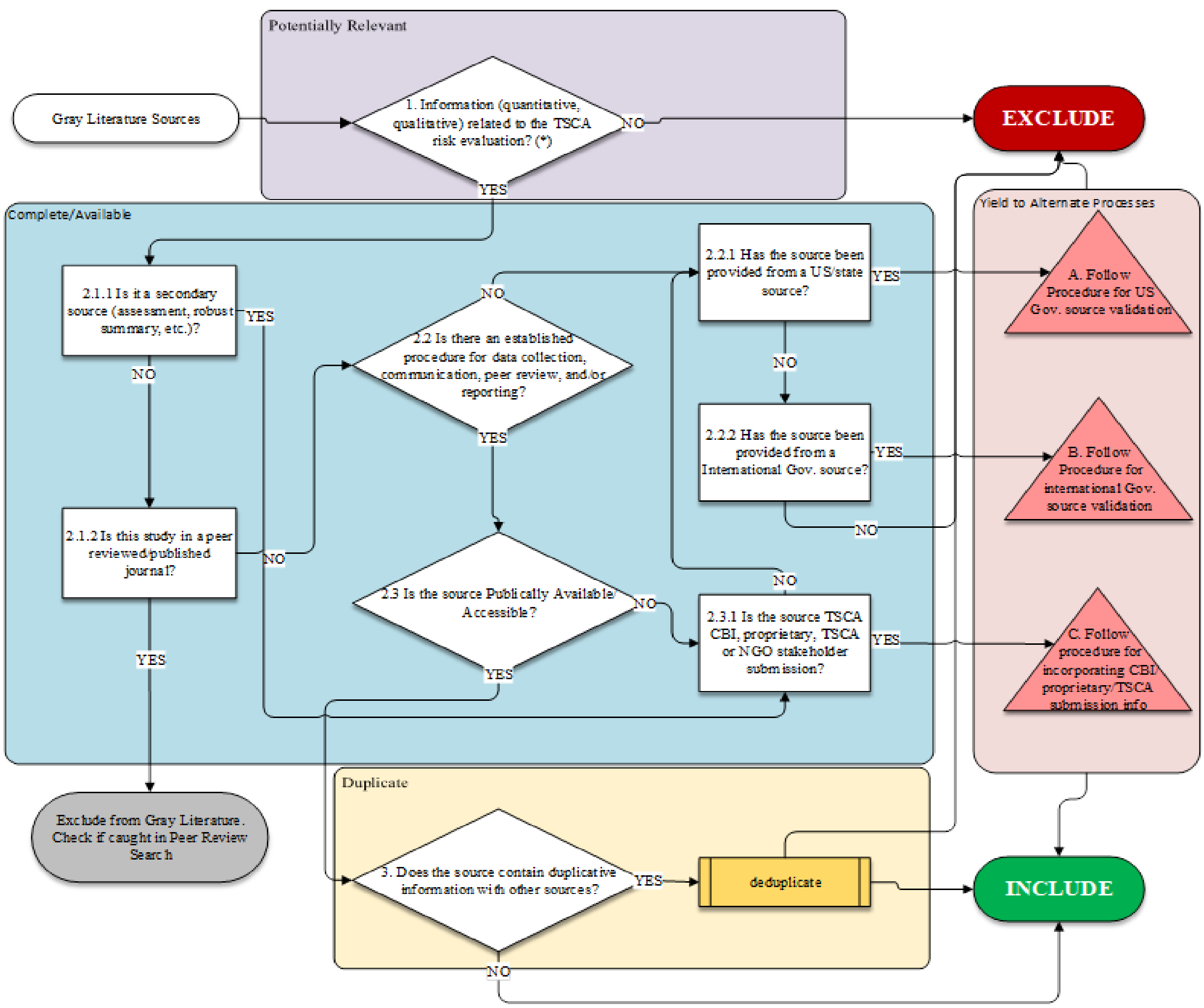
A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. 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. Given the nature of how gray literature is searched and collected, results may not come with a bibliographic citation or abstract and were therefore processed using a decision tree logic described in Appendix A.3.1 for potential relevance prior to entering full text screening where a discipline-specific PECO is applied.

Search terms were variable dependent on source and based on knowledge of a given source to provide discipline-specific information. A summary of sources is provided in Appendix A.3.4. The criteria for determining the potential relevance of documents identified from gray literature sources is described in the following sections for each discipline.

A.3.1 Screening of Gray Literature

To reduce the overall burden of processing gray literature results, EPA developed a screening process to determine the potential relevance of gray literature. This step was introduced prior to collecting the resulting documents. Figure_Apx A-1 describes the decision logic used to screen gray literature results.



Figure_Apx A-1. Decision Logic Tree Used to Screen Gray Literature Results

A.3.2 Initial Screening of Sources using Decision Logic Tree

The purpose of the inclusion/exclusion decision logic tree in Figure_Apx A-1 is to provide a broad, general screening technique to determine whether each gray literature source should be included and further screened or excluded with no additional screening necessary. The diamonds in the decision tree require analysis by the screener, whereas the rectangular boxes are used to classify the type of source. All the questions used in the decision process are provided in Table_Apx A-11**.**

Table_Apx A-11. Decision Logic Tree Overview

Step	**Metric**	**Questions to Consider**
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations? *Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer reviewed/published journal?
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

Results of the gray literature search and decision tree process are included in Appendix A.3.4.

A.3.3 TSCA Submission Searching and Title Screening

EPA screens information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as for your information (FYI) submissions. In the gray literature process defined in Appendix A.3.2, EPA considers the databases that contain TSCA submissions to be secondary sources (Step 1.1) because the metadata in the databases are secondary. These databases then advance to Step 2.3.1 and then to Process C. The Process C steps are described here.

EPA first screens the titles using two screeners per title. EPA conducts this step primarily to reduce the number of full studies to be obtained because some studies are available only on microfiche or in long-term storage. Screening is done using the inclusion and exclusion criteria within the relevant PECOs, PESOs or RESOs for each topic area (Appendix A.2.1). EPA excludes interim reports (*e.g.*, interim sacrifices for toxicity studies) and only final reports are further considered. If the title is not clear regarding the document's contents, EPA obtains the full text and advances to the next steps.

After full texts are obtained, EPA plans to evaluate some sources (prior to full-text screening) based on whether they have several factors; primary data, an established procedure for peer review, data collection, communication and/or reporting and are publicly available. Sources that have these factors will move on to full text screening. Other sources will go straight to full text screening using PECO-type criteria without going through this extra step.

EPA may decide to initiate a backwards search on sources that are deemed to have secondary data. In situations where parameters such as procedures for peer review and data collection are unclear, EPA may reach out to the authors to retrieve information to gauge whether the source should be included or excluded. Studies that are not publicly available (such as proprietary or CBI sources) may undergo additional screening steps.

During the full-text screening step, two individuals screen each source according to the PECOs, PESOs and RESOs (Appendix A.2.1).

Results of the TSCA submission search and decision tree process are included in Appendix A.3.4.

A.3.4 Gray Literature Search Results for Phthalic Anhydride

Table_Apx A-12 provides a list of gray literature sources that yielded results for phthalic anhydride.

Table_Apx A-12. Gray Literature Sources that Yielded Results for Phthalic Anhydride

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.industrialchemicals.gov.au/chemical-information/search-assessments
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document	https://www.canada.ca/en.html
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document	https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values#chemicals
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database	https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata.us/portal/
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha
EPA	Office of Air: TRI	US EPA Resources	Database	https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	Other EPA: Misc sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

Source Agency	Source Name	Source Type	Source Category	Source Website
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List	https://www.env.go.jp/en/chemi/prtr/substances/
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document	http://www.cdc.gov/niosh/topics/chemical.html/
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshtic-2/
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/reports/index.html?type=Technical+Report
OECD	OECD SIDS	International Resources	Assessment or Related Document	https://hpvchemicals.oecd.org/ui/Publications.aspx
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document/46/0,2340,en_2649_201185_2412462_1_1_1_1,00.html
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database	www.osha.gov/opengov/healthsamples.html/

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF PHTHALIC ANHYDRIDE AND 1,2-BENZENEDICARBOXYLIC ACID

Table_Apx B-1 summarizes the physical and chemical 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, 2019c) and may be updated as EPA collects additional information through systematic review methods. All physical and chemical 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 and Chemical Property Studies* (EPA-HQ-OPPT-2018-0459).

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties for Phthalic Anhydride and 1,2-Benzenedicarboxylic Acid

Property or Endpoint[a]	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	-	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	3	-	NA	NA	NA	NA
Physical properties	5	-	NA	NA	NA	NA
Melting point	25	ºC	131	2.2	123	134
Boiling point	10	ºC	290	5.5	284	295
Density	7	g/cm^3	1.48	0.12	1.2	1.53
Vapor pressure	2	mm Hg	0.001009	0.000695	0.000517	0.0015
Vapor density	1	-	6.6		6.6	6.6
Water solubility[b]	5	mg/L	6114	104.8	6000	6200
Octanol/water partition coefficient (log Kow)[b]	3	-	1.543	0.098	1.43	1.6
Henry's Law constant	0	$atm \cdot m^3/mol$	-	-	-	-
Flash point	6	ºC	152	0	152	152
Auto flammability	0	ºC	-	-	-	-
Viscosity	1	cP	1.19	-	1.19	1.19
Refractive index	0	-	-	-	-	-
Dielectric constant	0	-	-	-	-	-

[a] Measured for phthalic anhydride unless otherwise noted.
[b] Values for 1,2-benzenedicarboxylic acid (CASRN 88-99-3), the rapidly formed hydrolysis product of phthalic anhydride, are presented for endpoints obtained in the presence of water.

NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF PHTHALIC ANHYDRIDE

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for phthalic anhydride. This information was presented in the *Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and may be updated as EPA collects additional information through systematic review methods.

Table_Apx C-1. Environmental Fate Characteristics of Phthalic Anhydride and 1,2-Benzenedicarboxylic Acid

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 $\cdot OH/cm^3$)	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 Japan (1992)
Biodegradation (Aerobic)[b]	33% TOC removal, 88% COD removal after 24 hours in aerobic activated sludge	OECD (2005) citing Matsui et al. (1975); Matsui et al. (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;	NLM (2015)

Property or Endpoint	Value[a]	Reference
	bioconcentration in fish may not be an important process due to rapid hydrolysis in water	
Bioconcentration Factor[b]	3.2–3.4	OECD (2005) citing Bayer Industry (2004b) and Bayer Industry (2004a)
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, 1,2-benzenedicarboxyllic 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
Note: ·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. EPA is not aware of laws and regulations that directly apply to 1,2-benzenedicarboxylic acid produced as a result of the use of phthalic anhydride.

D.1 Federal Laws and Regulations

Table_Apx D-1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Statutes/Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Phthalic anhydride 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 (85 FR 20122, April 9, 2020).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed 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	Phthalic anhydride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987. (40 CFR §372.65)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (*i.e.*, air, land and water).	
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 as a HAP (42 U.S. Code Section 7412).
Clean Air Act (CAA) – Section 112(d) and Section 112(f)	Risk and technology review (RTR) of section 112(d) national emission standards for hazardous air pollutants (NESHAP). Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to Section 112(d) NESHAP that require maximum achievable control technology (MACT), and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the emission standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP and will do so, as required, for the remaining source categories with NESHAP.
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Phthalic anhydride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U190 (40 CFR 261.33).
Comprehensive Environmental Response, Compensation and Liability Act	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.	Phthalic anhydride is a hazardous substance under CERCLA. Releases of phthalic anhydride in excess of 5000

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
(CERCLA) – Sections 102(a) and 103	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.	pounds must be reported (40 CFR 302.4).
Other Federal Statutes/Regulations		
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	In 1971, OSHA revised an existing occupational safety and health standards for phthalic anhydride to include an 8-hour TWA PEL of 2 ppm TWA or 12 mg/m^3 TWA. (29 CFR 1910.1000).
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).

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 µg/m^3 (24 hours), 20 µg/m^3 (annual) (Air Pollution Regulation No. 22). New Hampshire 22 µg/m^3 (24 hours), 15 µg/m^3 (annual) (Env-A 1400: Regulated Toxic Air Pollutants).
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 of 1 ppm (Hawaii Administrative Rules Section 12-60-50).

State Actions	Description of Action
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	Vermont (18 V.S.A § 1776) has adopted reporting laws for chemicals in children's products containing Phthalic anhydride.
Other	Phthalic anhydride is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code § 25252 and 25253 (California, Candidate Chemicals List. Accessed April 19, 2019). California issued a Health Hazard Alert for Phthalic anhydride (Hazard Evaluation System and Information Service, 2016). Phthalic anhydride is on the Massachusetts 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). Phthalic anhydride was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritization (IMAP). (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed April 19, 2019). Uses include coatings applications (for home appliances, automobiles, medical devices and furniture), non-agricultural pesticides, preservatives, paints, lacquers, varnishes, tanning and curing agents, solvents, cleaning/washing agents, adhesives, binding agents, corrosion inhibitors, construction materials, scorch inhibitor, surface treatment and the manufacture of other chemicals. (NICNAS *Human Health Tier II assessment for 1,3-Isobenzofurandione*. Accessed April 19, 2019*)*
Japan	Phthalic anhydride is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • 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)

Country/Tribe/ Organization	Requirements and Restrictions
	• (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.

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, 2019a). 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, 2019a).

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, 2019a).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant

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

- Phthalates that are subsequently used as plasticizers in poly (vinyl chloride) (PVC);
- Polyester that is used in 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). EPA plans to investigate the amount of residual phthalic anhydride or 1,2-benzenedicarboxylic acid that may be present in reaction products.

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, 2019a). Phthalic anhydride is also used in the formulation of hydraulic fracturing chemicals (Finoric LLC, 2016; U.S. EPA, 2015a; Committee on Energy and Commerce's Minority Staff, 2011; Whittemore, 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 the extent to which phthalic anhydride is used as an additive in formulations versus the extent to which it or its hydrolysis product, 1,2-benzenedicarboxylic acid, is present only in residual quantities in additives used in formulation.

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, 2019d).

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, 2020a; 3M Company, 2019; U.S. EPA, 2019a; Aremco Products Inc., 2018; Royal Adhesives & Sealants, 2016). However, phthalic anhydride was identified in higher concentrations in a small subset of products, such as mounting adhesives (60 to 90% phthalic anhydride) (Ted Pella Inc., 2019; Aremco Products Inc., 2018), electronics adhesives (5 to 10% phthalic anhydride) (Krayden, 2019; Lord Corporation, 2017), primers (1 to 10% phthalic anhydride) (Harris Paints Company, 2015a), and varnishes (20 to 25% phthalic anhydride) (Harris Paints Company, 2018, 2015b). 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). EPA plans to further investigate the quantity of phthalic anhydride in adhesives, sealants, paints, and coatings during risk evaluation.

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 (Durcon Inc., 2020; Stepan Company, 2020; U.S. EPA, 2020a; OSHA, 2019; U.S. EPA, 2019a; Durcon Inc., 2011) (EPA-HQ-OPPT-2018-0459-0022). 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 further investigate the quantity of 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, 2015a; Committee on Energy and Commerce's Minority Staff, 2011; Whittemore, 2011), acceptance testing of foams used on human-rated spaceflight vehicles which the commenter also indicated was a critical use (EPA-HQ-OPPT-2018-0459-0041), fuel and related products (U.S. EPA, 2019a), flame retardants (Stepan Company, 2020; U.S. EPA, 1994b), tanning and curing of textiles, apparel, and leather (U.S. EPA, 1994b), surface treating (U.S. EPA, 2019a), lubricants and greases (U.S. EPA, 2019a), laboratory chemicals (Thermo Fisher Scientific, 2018)(EPA-HQ-OPPT-2018-0459-0041), water filtration applications (EPA-HQ-OPPT-2018-0459-0022), and oil treatment of wood (Junckers, 2019).

EPA does not know the extent to which phthalic anhydride is present in these products versus 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. Wastes of phthalic anhydride that are generated during a condition of use and sent to a third-party site for treatment or disposal may include wastewater and solid wastes. 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 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).

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 plans to evaluate 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
1987	HETA 87-238-1814	Decorative Vine Wreath Assembly, Gluing, and Painting
1985	HETA 84-239-1586	Meat Cutting and Wrapping
1979	HE 79- 49-631	Machining and Assembly of Universal Joints, Propeller Shafts, and End Yokes
1984	HETA 78-52-1483	Electric Circuit Breaker Manufacture (Epoxy Insulators)

[a] Table includes HHEs identified to date. HHEs can be found at https://www.cdc.gov/niosh/hhe/.

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 [a]
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

[a] Number of data points in Table_Apx E-2 was populated from data found at https://www.osha.gov/opengov/healthsamples.html.

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	Dermal exposure by ONU is not expected for this condition of use as they are not

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								expected to directly handle the chemical.
	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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Processing as a Reactant	Intermediate in: All other basic organic chemical manufacturing; All other basic inorganic chemical manufacturing; Plastic material and resin manufacturing; Paint and coating 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; Plastic material and resin 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:	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	Dermal exposure by ONU is not expected

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		Miscellaneous Manufacturing Plating agents and surface treating agents in: Rubber Product Manufacturing						for this condition of use as they are not expected to directly handle the chemical.
	Incorporated into formulation, mixture or reaction product	Intermediate in: Paint and coating manufacturing; All other basic organic chemical manufacturing; All other chemical product and preparation manufacturing; Plastic material and resin manufacturing Plasticizers in: Plastic material and resin manufacturing; Petrochemical Manufacturing; Construction; Polyester and alkyd resins, curing agent for epoxy resins; Plastic product manufacturing; Custom compounding of purchased resin 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	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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
		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						(incorporation into formulation, mixture, or reaction product), as phthalic anhydride is in solid form.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	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	Dermal exposure by ONU is not expected for this condition of

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								use as they are not expected to directly handle the chemical.
	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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								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.
				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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Hydraulic fracturing; Aerospace; Epoxy hardener; Fuel and related products; Epoxy resin in building and construction; tanning and curing of textiles; lubricants and greases; Laboratory chemical; inks, toners and colorant products	Hydraulic fracturing; Aerospace; Epoxy hardener; Fuel and related products; 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 in acceptance testing of foams for aerospace Use of epoxy hardeners and resins containing PA Use in fuels and related products 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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Plastic and rubber products; electrical and electronic products; Flame retardant in polymers; Transportation equipment manufacturing; Water filtration applications	Plastic and rubber products; electrical and electronic products; Flame retardant in polymers; Transportation equipment manufacturing; Water filtration applications	Use of articles made using PA	Liquid Contact	Dermal	Workers	No	The potential for exposures to liquid phthalic anhydride 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 phthalic anhydride is entrained; therefore, phthalic anhydride exposures to workers is unlikely but may occur if cutting /sawing / other machining operations occur.
				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 use of these products.
				Dust	Inhalation/Dermal	Workers, ONU	Yes	These products are solid articles in which phthalic anhydride is

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
								entrained; therefore, phthalic anhydride exposures to workers and ONUs is unlikely but may occur if cutting /sawing / other machining operations occur.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Disposal	Disposal	Disposal of phthalic anhydride 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 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 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	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

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
			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
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	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	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 Receptors	Yes	Release of phthalic anhydride into surface water and indirect partitioning to sediment exposure pathways to aquatic 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 Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population and aquatic species.
				TBD	Aquatic Receptors	Yes	
		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		

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
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		