United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

Proposed Designation of Phthalic Anhydride (CASRN 85-44-9) as a High-Priority Substance for Risk Evaluation

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Acronyms and Abbreviations

Term	Description
ACGIH	American Conference of Governmental Industrial Hygienists
B	Billion
BOD	Biological Oxygen Demand
BP	Boiling Point
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CPDat	Chemical and Products Database
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
ECHA	European Chemicals Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
HPLC	High Performance Liquid Chromatography
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
IUR	Inventory Update Rule
K_{OC}	Organic Carbon-water Partitioning Coefficient
K_{OW}	Octanol-water Partitioning Coefficient
M	Million
MITI	Ministry of International Trade and Industry, Japan
MP	Melting Point
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
OTS	Office of Toxic Substances

Term	Description
PEL	Permissible Exposure Limit
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Limit
SIDS	Screening Information Data Sets
SMILES	Simplified Molecular-input Line-entry System
STEL	Short-Term Exposure Limit
TBD	To be determined
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time-weighted Average
VP	Vapor pressure
WS	Water Solubility

1. Introduction

In section 6(b)(1)(B) of the Toxic Substances Control Act (TSCA), as amended, and in the U.S. Environmental Protection Agency's (EPA's) implementing regulations (40 CFR 702.3)[1], a high-priority substance for risk evaluation is defined as a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Before designating prioritization status, under EPA's regulations at 40 CFR 702.9 and pursuant to TSCA section 6(b)(1)(A), EPA will generally use reasonably available information to screen the candidate chemical substance under its conditions of use against the following criteria and considerations:

- the hazard and exposure potential of the chemical substance;
- persistence and bioaccumulation;
- potentially exposed or susceptible subpopulations;
- storage near significant sources of drinking water;
- conditions of use or significant changes in the conditions of use of the chemical substance;
- the chemical substance's production volume or significant changes in production volume; and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

This document presents the review of the candidate chemical substance against the criteria and considerations set forth in 40 CFR 702.9 for a may present risk finding. The information sources used are relevant to the criteria and considerations and consistent with the scientific standards of TSCA section 26(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the *TSCA Work Plan Chemicals: Methods Document* (February 2012) (40 CFR 702.9(b)). EPA uses scientific information that is consistent with the best available science. Final designation of the chemical substance as a high-priority substance would immediately initiate the risk evaluation process as described in the EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (40 CFR 702).

Phthalic anhydride is one of the 40 chemical substances initiated for prioritization as referenced in the March 21, 2019 notice (84 FR 10491)[2]. EPA has determined that phthalic anhydride is a suitable candidate for the proposed designation as a high-priority chemical substance. The proposed designation is based on the results of the review against the aforementioned criteria and considerations as well as review of the reasonably available information on phthalic anhydride, including relevant information received from the public and other information as appropriate.

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[1] Note: For all 40 CFR 702 citations, please refer to: https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol33/xml/CFR-2018-title40-vol33-part702.xml and https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108

[2] https://www.federalregister.gov/documents/2019/03/21/2019-05404/initiation-of-prioritization-under-the-toxic-substances-control-act-tsca

EPA will take comment on this proposed designation for 90 days before finalizing its designation of phthalic anhydride. The docket number for providing comments on phthalic anhydride is EPA-HQ-OPPT-2018-0459 and is available at www.regulations.gov.

The information, analysis and basis used for the review of the chemical is organized as follows:

- *Section 1 (Introduction)*: This section explains the requirements of the amended TSCA and implementing regulations - including the criteria and considerations -- pertinent to the prioritization and designation of high-priority chemical substances.

- *Section 2 (Production volume or significant changes in production volume):* This section presents information and analysis on national aggregate production volume of the chemical substance.

- *Section 3 (Conditions of use or significant changes in conditions of use):* This section presents information and analysis regarding the chemical substance's conditions of use under TSCA.

- *Section 4 (Potentially exposed or susceptible subpopulations):* This section presents information and analysis regarding potentially exposed or susceptible subpopulations, including children, women of reproductive age, and workers, with respect to the chemical substance.

- *Section 5 (Persistence and bioaccumulation):* This section presents information and analysis regarding the physical and chemical properties of the chemical substance and the chemical's fate characteristics.

- *Section 6 (Storage near significant sources of drinking water):* This section presents information and analysis considered regarding the risk from the storage of the chemical substance near significant sources of drinking water.

- *Section 7 (Hazard potential):* This section presents the hazard information relevant to the chemical substance.

- *Section 8 (Exposure potential):* This section presents information and analysis regarding the exposures to the chemical substance.

- *Section 9 (Other risk-based criteria):* This section presents the extent to which EPA identified other risk-based criteria that are relevant to the designation of the chemical substance's priority.

- *Section 10 (Proposed designation):* Based on the results of the review performed and the information and analysis presented, this section describes the basis used by EPA to support the proposed designation.

2. Production volume or significant changes in production volume

Approach

EPA considered current volume or significant changes in volume of the chemical substance using information reported by manufacturers (including importers). EPA assembled reported information for years 1986 through 2015 on the production volume for phthalic anhydride reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule[3]. The national aggregate production volume, which is presented as a range to protect individual site production volumes that are confidential business information (CBI), is presented in Table 1.

Table 1. 1986–2015 National Aggregate Production Volume Data (Production Volume in Pounds)

Chemical ID	1986	1990	1994	1998	2002	2006	2011	2012	2013	2014	2015
Phthalic anhydride (85-44-9)	>500M to 1B	>500M to 1B	>500M to 1B	> 1B	>500M to 1B	500M to <1B	597,331,014	1B to 5B	500M to 750M	500M to 750M	500M to 750M

Note: M = million; B = billion
Reference: U.S. EPA (2013) and U.S. EPA (2017)

Results and Discussion

Production volume of phthalic anhydride in 2015, as reported to EPA during the 2016 CDR reporting period, was between 500 million and 750 million pounds. The exact aggregate production volume is available for one year, 2011, in which 600 million pounds of phthalic anhydride was produced or imported.

From 1986 to 2006, production volume was between 500 million and 1 billion pounds except in 1998 when production volume was greater than 1 billion pounds. From 2013 to 2015, production volume was between 500 million and 750 million pounds.

[3] Over time, the requirements for reporting frequency, production volume thresholds, and chemical substances under the Chemical Data Reporting (CDR) rule have changed. CDR was formerly known as the Inventory Update Rule (IUR). The first IUR collection occurred in 1986 and continued every four years through 2006. As part of two rulemakings in 2003 and 2005, EPA made a variety of changes to the IUR, including to change the reporting frequency to every five years to address burdens associated with new reporting requirements. Additional changes to reporting requirements were made in 2011, including to suspend and replace the 2011 submission period with a 2012 submission period, return to reporting every four years, and require the reporting of all years beginning with 2011 production volumes. The reporting of production volumes for all years was added because of the mounting evidence that many chemical substances, even larger production volume chemical substances, often experience wide fluctuations in production volume from year to year. In addition, also as part of the 2011 IUR Modifications final rule (76 FR 50816, Aug 16, 2011), EPA changed the name of the regulation from IUR to CDR to better reflect the distinction between this data collection (which includes exposure-related data) and the TSCA Inventory itself (which only involves chemical identification information).

3. Conditions of use or significant changes in conditions of use

Approach

EPA assembled information to determine conditions of use or significant changes in conditions of use of the chemical substance. TSCA section 3(4) defines the term "conditions of use" to mean the circumstances, as determined by the EPA Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

A key source of reasonably available information that EPA considered for determining the conditions of use for phthalic anhydride was submitted by manufacturers (including importers) under the 2012 and 2016 CDR reporting cycles. CDR requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the United States greater than 25,000 pounds per site, except if certain TSCA actions apply (in which case the reporting requirement is greater than 2,500 pounds per site). CDR includes information on the manufacturing, processing, and use of chemicals substances. Based on the known manufacturing, processing and uses of this chemical substance, EPA assumes distribution in commerce. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). While EPA may be aware of additional uses, CDR submitters are not required to provide information on chemical uses that are not regulated under TSCA.

For chemical substances under review that are included on the Toxics Release Inventory (TRI) chemical list, information disclosed by reporting facilities in Part II Section 3 ("Activities and Uses of the Toxic Chemical at the Facility") of their TRI Form R reports was used to supplement the CDR information on conditions of use (Tables 4, 5 and 6). There is not a one-to-one correlation between conditions of use reported under CDR and information reported in Part II Section 3 of the TRI Form R because facilities are not required to disclose in their Form R submissions the specific uses of TRI chemicals they manufactured on-site or imported. In addition to the information disclosed in Part II Section 3 of the TRI Form R, the information pertaining to waste management activities (i.e., disposal/releases, energy recovery, recycling, and treatment) disclosed in other sections of the Form R was also used to supplement the CDR information on conditions of use as shown in Tables 4, 5 and 6. For purposes of this proposed prioritization designation, EPA assumed end-of-life pathways that include releases to air, wastewater, and solid and liquid waste based on the conditions of use.

CDR and TRI Tables

Based on the publicly available[4] manufacturing information, industrial processing and use information, and consumer and commercial use information reported under CDR, EPA developed a list of conditions of use for the 2016 and 2012 reporting cycles (Tables 2 and 3, respectively).

[4] Some specific chemical uses may be claimed by CDR submitters as confidential business information (CBI) under section 14 of TSCA. In these cases, EPA has indicated that the information is CBI.

Table 2. Phthalic Anhydride (85-44-9) Categories and Subcategories of Conditions of Use[5] (2016 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019a)
Manufacturing	Importing	Importing	U.S. EPA (2019a)
Processing	Processing as a reactant	Intermediate in: – Ion exchange agents – Adhesives and sealant chemicals – Paint additives and coating additives not described – Lubricants and lubricant additives – Oxidizing/reducing agents – Plastics – Inks – Pigments	U.S. EPA (2019a)
Processing	Processing – incorporation into formulation, mixture, or reaction product	– Oxidizing/reducing agents – Plasticizers – Adhesives and sealant chemicals – Intermediates – Paint additives and coating additives not described by other categories – Dyes – Fillers	U.S. EPA (2019a)
Processing	CBI[6]	CBI	U.S. EPA (2019a)
Distribution in Commerce [a,b]	Distribution in commerce		
Commercial	Adhesives and sealants	Adhesives and sealants	U.S. EPA (2019a)
Commercial	Building/construction materials not covered elsewhere	Building/construction materials not covered elsewhere	U.S. EPA (2019a)
Commercial	CBI	CBI	U.S. EPA (2019a)

[5] Certain other uses that are excluded from TSCA are not captured in this table.
[6] At this time, "CBI" indicates that a data element has been claimed confidential business information (CBI) by the information submitter; it does not reflect the result of an EPA substantiation review.

Life-Cycle Stage	Category	Subcategory	Reference
Commercial	Electrical and electronic products	Electrical and electronic products	U.S. EPA (2019a)
Commercial	Ink, toner, and colorant products	Ink, toner, and colorant products	U.S. EPA (2019a)
Commercial	Lubricants and greases	Lubricants and greases	U.S. EPA (2019a)
Commercial	Paints and coatings	Paints and coatings	U.S. EPA (2019a)
Commercial	Personal care products	Personal care products	U.S. EPA (2019a)
Commercial	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2019a)
Commercial	Surface treating	Surface treating	U.S. EPA (2019a)
Consumer	Paints and coatings	Paints and coatings	U.S. EPA (2019a)
Disposal[a]	Disposal		

[a] CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage.

[b] EPA is particularly interested in information from the public on distribution in commerce.

Table 3. Phthalic Anhydride (85-44-9) Categories and Subcategories of Conditions of Use (2012 CDR Reporting Cycle)[7]

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019a)
Manufacturing	Importing	Importing	U.S. EPA (2019a)
Processing	Processing as a reactant	Intermediate in: – Ion exchange agents – Plating agents and surface treating agents – Corrosion inhibitors and anti-scaling agents – Paint additives and coating additives not described	U.S. EPA (2019a)
Processing	Processing –incorporation into formulation, mixture, or reaction product	Oxidizing/reducing agents in: – Plasticizers – Adhesives and sealant chemicals – Intermediates – Paint additives and coating additives not described by other categories	U.S. EPA (2019a)
Processing	CBI[8]	CBI	U.S. EPA (2019a)
Distribution in Commerce [a,b]	Distribution in commerce		
Commercial	Adhesives and sealants	Commercial	U.S. EPA (2012b)
Commercial	Building/construction materials not covered elsewhere	Commercial	U.S. EPA (2012b)
Commercial	Fuels and related products	Commercial	U.S. EPA (2012b)
Commercial	Paints and coatings	Commercial	U.S. EPA (2012b)
Disposal [a]	Disposal		

[a] CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage.
[b] EPA is particularly interested in information from the public on distribution in commerce.

[7] Certain other uses that are excluded from TSCA are not captured in this table.
[8] At this time, "CBI" indicates that a data element has been claimed confidential business information (CBI) by the information submitter; it does not reflect the result of an EPA substantiation review.

EPA used TRI data to identify additional conditions of use and to supplement CDR information about conditions of use. In addition, TRI information from 2017 is useful for demonstrating that a condition of use reported to CDR in 2015 is still ongoing.

Table 4. Activities and Uses Reported to TRI for Phthalic Anhydride (85-44-9), Reporting Year 2011

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
	Import	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Office furniture (including fixtures) manufacturing	3372
		Waste treatment and disposal	5622
	Produce or import for on-site use/ processing	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Office furniture (including fixtures) manufacturing	3372
		Chemical and allied products merchant wholesalers	4246
	Produce or import for sale/ distribution	Basic chemical manufacturing	3251
		Soap, cleaning compound, and toilet preparation manufacturing	3256
	Produce or import as a byproduct	Basic chemical manufacturing	3251
	Produce or import as an impurity	Basic chemical manufacturing	3251
		Waste treatment and disposal	5622
Process		Basic chemical manufacturing	3251

Activity Type	Activity	Industry Group	NAICS Code
	Process as a reactant	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Pharmaceutical and medicine manufacturing	3254
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Office furniture (including fixtures) manufacturing	3372
	Process as an article component	Basic chemical manufacturing	3251
		Household and institutional furniture and kitchen cabinet manufacturing	3371
	Process as an impurity	Basic chemical manufacturing	3251
	Process as a formulation component	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Steel product manufacturing from purchased steel	3312
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Chemical and allied products merchant wholesalers	4246
		Basic chemical manufacturing	3251

Activity Type	Activity	Industry Group	NAICS Code
	Process – repackaging	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
Otherwise Use	Otherwise use – ancillary or other use	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Other chemical product and preparation manufacturing	3259
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
Waste Management	Disposal/ releases	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Cement and concrete product manufacturing	3273
		Steel product manufacturing from purchased steel	3312
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Office furniture (including fixtures) manufacturing	3372
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622
		Basic chemical manufacturing	3251

Activity Type	Activity	Industry Group	NAICS Code
	Energy recovery	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Plastics product manufacturing	3261
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
	Recycling	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Other chemical product and preparation manufacturing	3259
		Chemical and allied products merchant wholesalers	4246
	Treatment	Textile and fabric finishing and fabric coating mills	3133
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Pharmaceutical and medicine manufacturing	3254
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Cement and concrete product manufacturing	3273
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Office furniture (including fixtures) manufacturing	3372
		Chemical and allied products merchant wholesalers	4246
		Waste treatment and disposal	5622

Reference: U.S. EPA, 2019b

Table 5. Activities and Uses Reported to TRI for Phthalic Anhydride, Reporting Year 2015

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Waste treatment and disposal	5622
	Import	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Waste treatment and disposal	5622
	Produce or import for on-site use/processing	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Soap, cleaning compound, and toilet preparation manufacturing	3256
	Produce or import for sale/ distribution	Basic chemical manufacturing	3251
		Soap, cleaning compound, and toilet preparation manufacturing	3256
	Produce or import as a byproduct	Basic chemical manufacturing	3251
		Waste treatment and disposal	5622
	Produce or import as an impurity	Basic chemical manufacturing	3251
Process	Process as a reactant	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Pharmaceutical and medicine manufacturing	3254
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Household and institutional furniture and kitchen cabinet manufacturing	3371

Activity Type	Activity	Industry Group	NAICS Code
	Process as an article component	Paint, coating, and adhesive manufacturing	3255
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Waste treatment and disposal	5622
	Process as an impurity	Basic chemical manufacturing	3251
	Process as a formulation component	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Chemical and allied products merchant wholesalers	4246
	Process – repackaging	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
Otherwise Use	Otherwise use – as a chemical processing aid	Rubber product manufacturing	3262
	Otherwise use – as a manufacturing aid	Basic chemical manufacturing	3251
		Rubber product manufacturing	3262
	Otherwise use – ancillary or other use	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
		Basic chemical manufacturing	3251

Activity Type	Activity	Industry Group	NAICS Code
Waste Management	Disposal/ releases	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Rubber product manufacturing	3262
		Cement and concrete product manufacturing	3273
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Waste treatment and disposal	5622
	Energy recovery	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Plastics product manufacturing	3261
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
	Recycling	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Other chemical product and preparation manufacturing	3259
	Treatment	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261

Activity Type	Activity	Industry Group	NAICS Code
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Waste treatment and disposal	5622

Reference: U.S. EPA, 2019b

Table 6. Activities and Uses Reported to TRI for Phthalic Anhydride, Reporting Year 2017

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
		Soap, cleaning compound, and toilet preparation manufacturing	3256
	Import	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
	Produce or import for on-site use/processing	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Soap, cleaning compound, and toilet preparation manufacturing	3256
	Produce or import for sale/distribution	Basic chemical manufacturing	3251
		Soap, cleaning compound, and toilet preparation manufacturing	3256
	Produce or import as a byproduct	Basic chemical manufacturing	3251
	Produce or import as an impurity	Basic chemical manufacturing	3251
Process	Process as a reactant	Converted paper product manufacturing	3222
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Pharmaceutical and medicine manufacturing	3254
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256

Activity Type	Activity	Industry Group	NAICS Code
		Other chemical product and preparation manufacturing	3259
		Household and institutional furniture and kitchen cabinet manufacturing	3371
	Process as an article component	Paint, coating, and adhesive manufacturing	3255
		Household and institutional furniture and kitchen cabinet manufacturing	3371
	Process as an impurity	Basic chemical manufacturing	3251
	Process as a formulation component	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Household and institutional furniture and kitchen cabinet manufacturing	3371
	Process – repackaging	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Cement and concrete product manufacturing	3273
Otherwise Use	Otherwise use – as a chemical processing aid	Rubber product manufacturing	3262
	Otherwise use – as a manufacturing aid	Basic chemical manufacturing	3251
		Rubber product manufacturing	3262
	Otherwise use – ancillary or other use	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622

Activity Type	Activity	Industry Group	NAICS Code
Waste Management	Disposal/releases	Converted paper product manufacturing	3222
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Rubber product manufacturing	3262
		Cement and concrete product manufacturing	3273
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Waste treatment and disposal	5622
	Energy recovery	Converted paper product manufacturing	3222
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255
		Cement and concrete product manufacturing	3273
		Waste treatment and disposal	5622
	Recycling	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Other chemical product and preparation manufacturing	3259
	Treatment	Converted paper product manufacturing	3222
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	3255

Activity Type	Activity	Industry Group	NAICS Code
		Soap, cleaning compound, and toilet preparation manufacturing	3256
		Other chemical product and preparation manufacturing	3259
		Household and institutional furniture and kitchen cabinet manufacturing	3371
		Waste treatment and disposal	5622

Reference: U.S. EPA, 2019b

CDR and TRI Summary and Additional Information on Conditions of Use

According to 2016 CDR data, phthalic anhydride was processed as a reactant and incorporated into formulation, mixture, or reaction products. As a reactant, its functional uses are reported as intermediates, ion exchange agents, adhesives and sealant chemicals, paint additives and coating additives, lubricants and lubricant additives, oxidizing/reducing agents, plastics, inks and pigments. When incorporated into formulation, mixture or reactions products, its functional uses are reported as oxidizing/reducing agents, plasticizers, dyes, fillers, adhesives and sealant chemicals, intermediates, paint additives and coating additives, dyes and fillers. Commercial uses consist of adhesives and sealants, building/construction materials, electrical and electronic products, ink, toner, and colorant products, lubricants and greases, paints and coatings, personal care products, plastic and rubber products, and surface treating. The only consumer use reported was as the use in paints and coatings.

The 2012 and 2016 CDR data both show phthalic anhydride was processed as a reactant and incorporated into formulation, mixture, or reaction products. However, there were differences between the functional uses reported. Uses of the chemicals as plating agents and surface treating, and corrosion inhibitors and anti-scaling agents were reported in 2012, but not in 2016. Uses reported in 2016, but not in 2012, include adhesives and sealants, lubricants and lubricant additives, plastics, inks, and pigments.

Only one consumer use, paints and coatings, was reported in 2016. This use was not reported in 2012. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8). As for commercial uses, surface treating, electrical and electronic products, ink, toner and colorant products, lubricants and greases, personal care products, and plastic and rubber products were reported in 2016, but not in 2012. Fuels and related products were reported in 2012, but not in 2016.

TRI data reported in Part II Section 3 of the TRI Form R ("Activities and Uses of the Toxic Chemical at the Facility") were compiled for Reporting Year (RY) 2011, RY 2015, and RY 2017. RY 2011, RY 2015, and RY 2017 reflect the chemical activities at reporting facilities in calendar years 2011, 2015, and 2017, respectively. Each facility filing a TRI Form R discloses activities that apply to the TRI chemical at the facility. The TRI data presented above are from the TRI dataset updated in April 2019. Table 4, Table 5, and Table 6 present the activities and

uses reported to TRI by industry group for 2011, 2015, and 2017. Waste management activity type include all industry groups that reported to TRI using each waste management activity for phthalic anhydride.

According to a public comment received, phthalic anhydride is used in synthetic resins (EPA-HQ-OPPT-2018-0459-0004). Another commenter indicated that the chemical is used by the aerospace industry in electrical potting compounds (EPA-HQ-OPPT-2018-0459-0005).

Should the Agency decide to make a final decision to designate this chemical substance as a high-priority substance, further characterization of relevant TSCA conditions of use will be undertaken as part of the process of developing the scope of the risk evaluation.

4. Potentially exposed or susceptible subpopulations

Approach

In this review, EPA considered reasonably available information to identify potentially exposed or susceptible subpopulations, such as children, women of reproductive age, workers, consumers or the elderly. EPA analyzed processing and use information included on the CDR Form. These data provide an indication about whether children or other susceptible subpopulations may be potentially exposed. EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.

Results and Discussion

At this stage, EPA identified children, women of reproductive age, consumers and workers as subpopulations who may be potentially exposed or susceptible subpopulations for phthalic anhydride.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for phthalic anhydride. Based on the 2012 and 2016 CDR data, phthalic anhydride was not reported as used in manufacturing of products intended for children. However, several manufacturers reported that this was not known or reasonably ascertainable.

Women of reproductive age (e.g., pregnant women per TSCA statute)

EPA identified studies that observed developmental effects following exposure to phthalic anhydride (Section 7, Table 9). Although no reproductive hazards were identified, EPA considers women of reproductive age as potentially exposed. During the scoping and risk evaluation process, reproductive hazards will be considered again following a systematic search of the relevant scientific literature.

Consideration of women of reproductive age as a potentially exposed or susceptible subpopulation was also based on exposure because women of reproductive age are potential workers in the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance.

Workers
Please refer to the Exposure Potential section (Section 8) for a summary of potential occupational exposures, which EPA indicates that workers are potentially exposed or susceptible subpopulations based on greater exposure.

Consumers
Please refer to the Exposure Potential section (Section 8) for a summary of potential consumer exposures, which EPA indicates that consumers are potentially exposed or susceptible subpopulations based on greater exposure.

5. Persistence and bioaccumulation

Approach
EPA reviewed reasonably available information, such as physical and chemical properties and environmental fate characteristics, to understand phthalic anhydride's persistence and bioaccumulation.

Physical and Chemical Properties and Environmental Fate Tables

Tables 7 and 8 summarize the physical and chemical properties and the environment fate characteristics of phthalic anhydride, respectively.

Table 7. Physical and Chemical Properties of Phthalic Anhydride

Property or Endpoint	Value[a]	Reference
Molecular Formula	$C_8H_4O_3$	Rumble (2018)
Molecular Weight	148.116 g/mole	Rumble (2018)
Physical State	Solid	HSDB (2015)
Physical Form	White flakes or needles	OECD (2005)
Purity	99.8% purity for commercial grade, Impurities include phthalide (1(3)-isobenzofuranone), maleic anhydride and naphthoquinone	HSDB (2015)
Melting Point	130.8 ºC	U.S. EPA (2012a)
	131.4 ºC	HSDB (2015)
	131.2 ºC	SYKE (2018)
Boiling Point	295 ºC	U.S. EPA (2012a)
	285.3 ºC	HSDB (2015)
	284.5 ºC	Lorz et al. (2012); OECD (2005)
Density	1.527 g/cm^3 at 4 ºC	Park and Sheehan (2000)
	1.53 g/cm^3 at 20 ºC	ECHA (2019) citing Beilstein (2003)

Property or Endpoint	Value[a]	Reference
	0.0002 g/cm^3 at 20 ºC	SYKE (2018)
Vapor Pressure	5.17 × 10^{-4} mm Hg at 25 ºC (extrapolated)	U.S. EPA (2012a) citing Jones (1960)
	0.001 hPa at 26.6 ºC	ECHA (2019) citing Crooks and Feetham (1946)
Vapor Density	6.6	HSDB (2015)
	5.1	ILO (2003)
Water Solubility	6,200 mg/L at 25 ºC	U.S. EPA (2012a) citing Towle et al. (1968)
	735 mg/L at 20 ºC	ECHA (2019) citing McAuliffe (1966)
Log KOW	1.6	U.S. EPA (2012a) citing Hansch et al. (1995); OECD (2005); ECHA (2019) citing Anon. (1995)
	0.7–0.73	SYKE (2018)
Henry's Law Constant	6.19 × 10^{-13} atm-m^3/mol	SYKE (2018)
Flash Point	151.6 v	SYKE (2018)
	152 ºC	HSDB (2015)
Auto Flammability	580 ºC	OECD (2005)
Viscosity	1.125 mPa·second at 155 ºC; 0.875 mPa·second at 180 ºC; 1.19 mPa·second at 132 ºC	ECHA (2019) citing Beilstein (2003) and Kirk-Othmer (2008)
Refractive Index	TBD	TBD
Dielectric Constant	TBD	TBD
Surface Tension	35.5 dynes/cm (0.0355 N/m at 155 ºC)	HSDB (2015)

Notes:
[a]Measured unless otherwise noted;
TBD = to be determined, if reasonably available. **EPA is particularly interested in information from the public on these properties or endpoints.**

Table 8. Environmental Fate Characteristics of Phthalic Anhydride

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	Phthalic anhydride absorbs at wavelengths >290 nm, and therefore, may be susceptible to direct photolysis by sunlight	HSDB (2015)
Indirect Photodegradation	$t_{1/2}$ = 54.6 days from ·OH rate constant 1.96 × 10^{-13} cm^3/molecules-second (12-hour day; 1.5 × 10^6 ·OH/cm^3)	U.S. EPA (2012a)
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	HSDB (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)
	85.2%/14 days in activated sludge (method comparable to OECD TG 301C)	OECD (2005) citing MITI (1992)
	33% TOC removal, 88% COD removal after 24 hours in aerobic activated sludge	OECD (2005) citing Matsui et al. (1975, 1988)
Wastewater Treatment[b]	94% total removal (93% by biodegradation, 0.34% by sludge, 0% by volatilization to air; estimated)[c]	U.S. EPA (2012a)
Bioconcentration Factor[b]	4,053 in Oedogonium (alga); did not concentrate in water flea or snail; bioconcentration in fish may not be an important process due to rapid hydrolysis in water	HSDB (2015)
	3.2–3.4	OECD (2005) citing Bayer Industry Services, 2004a, 2004b
Bioaccumulation Factor[b]	4.9[c]	U.S. EPA (2012a)

Property or Endpoint	Value[a]	Reference
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})[b]	0.3–1.5 (K_{OC} = 2–31 in various soils)	OECD (2005)

Notes:
[a]Measured unless otherwise noted
[b]Due to the rapid rate of hydrolysis, these data likely pertain to the hydrolysis byproduct, phthalic acid
[c]EPI Suite™ physical property inputs: Log Kow = 1.60, BP = 295.00 °C, MP = 130.80 deg C, VP = 0.000517 mm Hg, WS = 6200 mg/L, BioP = 4, BioA = 1 and BioS = 1SMILES O=C(OC(=O)c1cccc2)c12
·OH = hydroxyl radical; HPLC = high performance liquid chromatography; BOD = biological oxygen demand; OECD = Organisation for Economic Co-operation and Development; MITI = Ministry of International Trade and Industry, Japan; TOC = total organic carbon; COD = chemical oxygen demand

Results and Discussion

Phthalic anhydride is a white solid with high water solubility (6,200 mg/L at 25 °C), which rapidly hydrolyzes with a half-life of 24.8 minutes at 25.1 °C to give phthalic acid. Available Henry's Law constant (6.19×10^{-13} atm-m^3/mol) and vapor pressure (5.17×10^{-4} mm Hg) data indicate that phthalic anhydride has negligible volatility. If released directly into the air, phthalic anhydride is estimated to react with photochemically-generated hydroxy radicals at a rate that corresponds to a half-life of 54.6 days.

Multiple aerobic biodegradability studies report high biodegradation for phthalic anhydride (for example, OECD tests 301D: 90.5%/30 days, 301E: 99%/14 days, and 301C: 85.2%/14 days); however, given that phthalic anhydride rapidly hydrolyzes, these results likely reflect degradation of the hydrolysis product, phthalic acid. Similarly, reported bioaccumulation potentials for phthalic anhydride likely reflect the bioaccumulation potential of phthalic acid. Phthalic anhydride is expected to have low potential for persistence in the environment and low potential for bioaccumulation due to rapid hydrolysis.

6. Storage near significant sources of drinking water

Approach

To support the proposed designation, EPA screened each chemical substance under its conditions of use with respect to the seven criteria in TSCA section 6(b)(1)(A) and 40 CFR 702.9. The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of drinking water, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure.

EPA reviewed reasonably available information, specifically looking to identify certain types of existing regulations or protections for the proposed chemical substances. EPA considered the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, by identifying existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (40 CFR Part 141) and regulations under the Clean Water Act (CWA; 40 CFR 401.15). In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA; Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), the Comprehensive Environmental Response, Compensation, and

Liability Act (CERCLA; Hazardous Substances), and the Clean Air Act (CAA) Section 112(r) (Regulated Chemicals for Accidental Release Prevention). Regulation by one of these authorities is an indication that the substance is a potential health or environmental hazard which, if released near a significant source of drinking water, could present an unreasonable risk of injury to human health or the environment.

Results and Discussion

Phthalic anhydride is subject to TRI reporting under Section 313 of EPCRA. It is also considered a CERCLA hazardous substance and releases in quantities equal to or greater than 5,000 pounds are subject to reporting to the National Response Center. Finally, phthalic anhydride is included on the list of hazardous wastes pursuant to Resource Conservation and Recovery Act (RCRA) section 3001 and is assigned the hazardous waste number U190.

7. Hazard potential

Approach

EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health and environmental hazards for phthalic anhydride (Tables 9, and 10, respectively).\

Because there are very few publicly available assessments for phthalic anhydride with cited environmental hazard data, EPA used the infrastructure of ECOTOXicology knowledgebase (ECOTOX) to identify single chemical toxicity data for aquatic and terrestrial life (U.S. EPA, 2018). It uses a comprehensive chemical-specific literature search of the open literature that is conducted according to the Standard Operating Procedures (SOPs)[9]. The environmental hazard information was populated in ECOTOX and is available to the public. In comparison to the approach used to survey human health hazard data, EPA also used a read-across approach to identify additional environmental hazard data for isomers of phthalic anhydride, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa exposed to the phthalic anhydride (Table 10).

Results and Discussion

EPA identified human health and environmental hazards based on a review of the reasonable available information on phthalic anhydride (Tables 9 and 10, respectively).

[9] The ECOTOX Standard Operating Procedures (SOPs) can be found at: https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4

Table 9. Potential Human Health Hazards Identified for Phthalic Anhydride

Human Health Hazards	Tested for Specific Effect	Specific Effect Observed	Reference
Acute Toxicity	X	X	OECD (2005)
Repeated Dose Toxicity	X	X	OECD (2005); CalEPA (2000); NCI (1979)
Genetic Toxicity	X	X	OECD (2005); U.S. EPA (1988)
Reproductive Toxicity			
Developmental Toxicity	X	X	OECD (2005); CalEPA (2000)
Toxicokinetic	X	X	OECD (2005)
Irritation/Corrosion	X	X	OECD (2005)
Dermal Sensitization	X	X	OECD (2005)
Respiratory Sensitization	X	X	U.S. EPA (2015); OECD (2005); CalEPA (2000); U.S. EPA (1988)
Carcinogenicity	X		OECD (2005); CalEPA (2000); NCI (1979)
Immunotoxicity			
Neurotoxicity			
Epidemiological Studies or Biomonitoring Studies	X	X	OECD (2005)

Note: The "X" in the "Effect Observed" column indicates when a hazard effect was reported by one or more of the referenced studies. Blank rows indicate when information was not identified during EPA's review of reasonably available information to support the proposed designation.

Table 10. Potential Environmental Hazards Identified for Phthalic Anhydride

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Phthalic anhydride (CASRN 85-44-9)		Isomers of Phthalic anhydride (CASRN 85-44-9) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Acute exposure	Vegetation	1	X	–		Bollman et al., 1989
		Invertebrate	–		–		
		Fish	–		–		
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	–		–		
	Chronic exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Fish	2	X	–		Van Leeuwen et al., 1990
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	–		–		
Terrestrial	Acute exposure	Vegetation	–		–		
		Invertebrate	–		–		
		Vertebrate	–		–		
	Chronic exposure	Vegetation	–		–		
		Invertebrate	–		–		

Media	Study Duration	Taxa Groups	High-Priority Chemical Candidate Phthalic anhydride (CASRN 85-44-9)		Isomers of Phthalic anhydride (CASRN 85-44-9) NONE		Reference
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
		Vertebrate	2	X	–		Botham et al. (2005); Van Och et al. (2000)

The dash indicates that no studies relevant for environmental hazard were identified during the initial review and thus the "Observed Effects" column is left blank. . The X in the Observed Effects column indicates when a hazard effect was reported by one or more of the referenced studies. The N/A in the Observed Effects column indicates when a hazard effect was not reported by one of the referenced studies' abstract (full reference review has not been conducted)

8. Exposure potential

Approach

EPA considered reasonably available information to identify potential environmental, worker/occupational, consumer, and general population exposures for phthalic anhydride.

Release potential for environmental and human health exposure

In addition to other required information, a submission of a TRI Form R report must include the quantities of a TRI chemical the facility released on-site to air, water, or land, and the quantities it transferred off-site to another facility for further waste management. On-site release quantities are reported in Part II Section 5 of the TRI Form R, and off-site transfers are reported in Part II Section 6. Waste management activities include: transfers of a TRI chemical in wastewater to a publicly owned treatment works (POTW) facility or to a non-POTW wastewater treatment facility for the purpose of treatment for destruction or removal; combustion for energy recovery; treatment (treatment includes treatment via incineration for destruction and waste stabilization); recycling; and release, including disposal. During treatment, combustion for energy recovery, or recycling activities, it is possible that some of the quantities of the TRI chemical will be released to the environment.

Worker/Occupational and consumer exposure

EPA's approach for assessing exposure potential was to review the physical and chemical properties, conditions of use reported in CDR, and information from the National Institutes of Health Consumer Product Database and the Chemical and Products Database (CPDat) for phthalic anhydride's to inform occupational and consumer exposure potential. The result of this review are detailed in the following tables.

General population exposure

EPA did not identify environmental concentration, human and ecological biomonitoring data to inform phthalic anhydride's exposure potential.

Results and Discussion

Release potential for environmental and human health exposure

Aggregated quantities of phthalic anhydride released on-site to air, water, and land, and aggregated quantities of phthalic anhydride transferred off-site to POTW and other wastewater treatment facilities (non-POTW) are presented in Table 11 for RY 2011, 2015, and 2017. The table does not include any of the reported quantities pertaining to other waste management activities (e.g., recycling, combustion for destruction) that occurred on-site or off-site during RY 2011, 2015, and 2017. The "Number of Facilities" is the count of unique facilities that filed a TRI Form R report for phthalic anhydride for RY 2011, 2015, and 2017. The TRI data presented were obtained from the TRI dataset following its update in April 2019.

Table 11. The TRI Data on Phthalic Anhydride from Reporting Years 2011, 2015, and 2017 Used in this Document to Assess Exposure Potential

Year	Number of Facilities That Reported	Total Quantities Released On-Site to Air (lbs.)	Total Quantities Released On-Site to Water (lbs.)	Total Quantities Released (Disposed of) On-Site to Land (lbs.)	Total Quantities Transferred to POTW (lbs.)	Total Quantities Transferred to Other (Non-POTW) Wastewater Treatment Facilities (lbs.)
2011	126	189,122	27	268	36,878	512
2015	122	252,480	30	27,986	29,177	7,479
2017	123	247,208	23	29,748	25,788	15,461

Note: POTW = publicly owned treatment works
Reference: U.S. EPA, 2019b

For RY 2017, 123 facilities submitted TRI reports for phthalic anhydride. The total quantities of phthalic anhydride these facilities released on-site to air (as fugitive and stack emissions), surface water and land are: 247,208 pounds; 23 pounds; and 29,748 pounds, respectfully. These facilities reported 25,788 pounds of the chemical transferred to POTW and 15,461 pounds transferred off-site to other non-POTW wastewater treatment facilities for the purpose of wastewater treatment. These transfer categories represent two types of off-site transfers for wastewater treatment that may lead to releases from the receiving facilities. They do not include quantities sent off-site for other types of waste management activities that include, or may lead to, releases of the chemical.

Quantities transferred off-site represent the amount of a toxic chemical a facility sent off-site prior to any waste management (e.g., treatment) at a receiving facility. Some of the quantities of phthalic anhydride received by the non-POTW wastewater treatment facilities may have been released to surface waters or to air during treatment processes at the facilities.

When chemical substances are used as reactants and as chemical intermediates, the industrial releases may be a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the chemical reacts without excess loss during its use as reactants and chemical intermediates. The actual percentages, quantities, and media of releases of the reported chemical associated with this processing or use are not known.

When chemical substances are incorporated into formulations, mixtures, or reaction products, the industrial releases may be a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the volume is incorporated without significant process losses during its incorporation into a formulation, mixture, or product. The actual percentages, quantities, and media of releases of the reported chemical associated with this processing or use are not known.

When chemical substances have industrial use as dyes, corrosion inhibitors and anti-scaling agents, plating agents, and surface treating agents are used in aqueous processes, releases may occur to aqueous media. The actual percentage and quantity of release of the reported chemical associated with this category are not known.

Worker/Occupational exposure
Worker exposures to this chemical may be affected by many factors, including but not limited to volume produced, processed, distributed, used, and disposed of; physical form and concentration; processes of manufacture, processing, and use; chemical properties such as vapor pressure, solubility, and water partition coefficient; local temperature and humidity; and exposure controls such as engineering controls, administrative controls, and the existence of a personal protective equipment (PPE) program.

Phthalic anhydride has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) (OSHA 2009). The PEL is 2 parts per million (ppm) or 12 milligrams (mg)/cubic meter (m^3) over an 8-hour workday, time-weighted average (TWA). This chemical also has a National Institute for Occupational Safety and Health Recommended Exposure Limit (REL) (NIOSH 2016) of 1 ppm (6 mg/m^3) TWA. 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.

Phthalic anhydride has a vapor pressure of 5.17×10-4 mm Hg at 25 ºC/77 ºF (or 7.5 ×10-4 mm Hg at 26.6 ºC/79.9 ºF). EPA assumes that inhalation exposure is negligible when vapors are generated from liquids with vapor pressures below 0.001 mm Hg at ambient room temperature conditions. Some handling activities of phthalic anhydride may generate dust, particularly, when handled as a dry powder. Workers may be exposed to aerosolized particles.

Phthalic anhydride is indicated as being used in adhesives and sealants, and paints and coatings. Products used as adhesive and sealants, and paints and coatings may be applied via spray or roll application methods. These methods may generate mists to which workers may be exposed.

Consumer exposure
Based on CDR reporting and information from the National Institutes of Health Consumer Product Database and the Chemical and Products Database (CPDat), phthalic anhydride does not appear to be used in consumer products (Table 12). However, consumers may be exposed to phthalic anhydride from the use of plastics, furniture, glues, coatings, and home products from which phthalic anhydride may leach (OECD 2005). Consumers may be exposed to (non-synthetic) phthalic anhydride from natural flavor and oak smoke; oak smoke and its aqueous preparations are used in the production of several smoked foods and alcoholic beverages, furthermore phthalic anhydride is reported to occur in the volatile flavor of baked potatoes (OECD 2005).

Table 12. Exposure Information for Consumers

Chemical Identity	Consumer Product Database
	Consumer Uses (List)
Phthalic Anhydride (85-44-9)	Adhesive, arts crafts products, automotive care, binding, building material, casting agent, cleaner, colorant, electronics, filler, filler building material, flooring, fluid property modulator, hardener, impregnation, insulation, leather impregnation, metal surface treatment, paint, paint binding, paint filler, paint hardener, paper impregnation, photographic, photographic preservatives, plastic building material, plastic, plastic filler, printing, printing ink, rubber, rubber processing, surface treatment, textile, textile furniture chairs, textile impregnation, toys, wall building material, wood impregnation

Reference: CPDat

General population exposure
Although EPA did not identify environmental concentration, human and ecological biomonitoring data to inform phthalic anhydride's exposure potential, releases from certain conditions of use, such as manufacturing and disposal, may result in general population exposures to phthalic anhydride via drinking water ingestion, dermal contact, and inhalation from air releases.

9. Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority

EPA did not identify other risk-based criteria relevant to the designation of the chemical substance's priority.

10. Proposed designation and Rationale

Proposed designation: High-priority substance

Rationale: EPA identified and analyzed reasonably available information for exposure and hazard and is proposing to find that phthalic anhydride may present an unreasonable risk of injury to health and/or the environment, including potentially exposed or susceptible subpopulations, (e.g., workers, consumers, women of reproductive age, consumers, children). This is based on the potential hazard and potential exposure of phthalic anhydride under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacturing, processing, use, and disposal of phthalic anhydride may result in presence of the chemical in surface water, ingestion of the chemical in drinking water, inhalation of the chemical from air releases, exposure to workers, and exposure to consumers, In addition, EPA expects potential environmental (e.g., aquatic toxicity, terrestrial toxicity), and human health hazards (e.g., acute toxicity, repeated dose toxicity, genetic toxicity, developmental toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, and observations in epidemiologic and/or biomonitoring studies).

11. References

Note: All hyperlinked in-text citations are also listed below

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