

Office of Chemical Safety and Pollution Prevention

Proposed Designation of 4,4'-(1-Methylethylidene)bis [2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation

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Acronyms and Abbreviations

Term	Description
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
CWA	Clean Water Act
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
IARC	International Agency for Research on Cancer
IUR	Inventory Update Reporting
K _{OC}	Organic carbon-water partitioning coefficient
K _{OW}	Octanol-water partitioning coefficient
Μ	Million
MITI	Ministry of International Trade and Industry
NA	Not Available
NAICS	North American Industry Classification System
NIH	National Institutes of Health
NKRA	Not known or reasonably ascertainable
NR	Not reported
OECD	Organisation for Economic Co-operation and Development
·OH	Hydroxyl radical
POTW	Publicly owned treatment works
RY	Reporting Year
SMILES	Simplified Molecular-Input Line-Entry System

Term	Description
TBBPA	4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
TBD	To be determined
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act

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) 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)). Final designation of the chemical substance as a high-priority chemical 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).

4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA) 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 TBBPA 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 TBBPA, including relevant information received from the public and other information as appropriate.

¹ 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 <u>https://www.federalregister.gov/documents/2019/03/21/2019-05404/initiation-of-prioritization-under-the-toxic-substances-control-act-tsca</u>

EPA will take comment on this proposed designation for 90 days before finalizing its designation of TBBPA. The docket number for providing comments on TBBPA is EPA-HQ-OPPT-2018-0462-0002 and is available at <u>www.regulations.gov</u>.

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 0 (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 TBBPA reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule.³

Results and Discussion

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
4,4'-(1- Methylethyliden e)bis[2,6- dibromophenol] (TBBPA) (79-94-7)		>50M to 100M	>100M to 500M	>100M to 500M	>100M to 500M	>100M to 500M	119,837,559	>50M to 100M	>50M to 100M	>50M to 100M	>50M to 100M
Notes: M = million Reference: <u>U.S. EPA (2013)</u> ; <u>U.S. EPA (2017)</u>											

Production volume of TBBPA in 2015, as reported to EPA during the 2016 CDR reporting period, was between 50 and 100 million pounds per year. National aggregate production volume for TBBPA was at its highest from reporting years (RY) 1994 to 2006, during which 100 million to 500 million pounds of the chemical was manufactured or imported. In 2011, 119,837,559 pounds of TBBPA was manufactured or imported. In RY 1990 and again from 2012 to 2015, the aggregate production volume was between 50 million and 100 million pounds. In RY 1986, 10 million to 50 million pounds of TBBPA was manufactured or imported or imported (Table 1).

³ Over time, the requirements for reporting frequency, production volume thresholds, and chemical substances under the Chemical Data Reporting (CDR) 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 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 TBBPA 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 lbs per site). CDR includes information on the manufacturing, processing, and use of chemical 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 chemical substances 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. 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 available⁴ 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 (Table 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.

Life-Cycle Category Subcategory of Use Reference Stage Manufacture Domestic Domestic manufacture U.S. EPA (2019a) manufacture Import U.S. EPA (2019a) Import Processing Processing -Flame retardant in: U.S. EPA (2019a) incorporating into Electrical equipment, appliance, and formulation, component manufacturing mixture or Plastic material and resin manufacturing Plastics product manufacturing reaction product Computer and electronic product manufacturing Intermediates in transportation equipment U.S. EPA (2019a) manufacturing Processing aids not otherwise listed in plastic U.S. EPA (2019a) material and resin manufacturing Other in miscellaneous manufacturing U.S. EPA (2019a) U.S. EPA (2019a) Processing -Flame retardant in: incorporating into Electrical equipment, appliance, and articles component manufacturing Plastics product manufacturing Processing as a Flame retardant in: U.S. EPA (2019a) reactant Plastic material and resin manufacturing Intermediate in all other chemical product and U.S. EPA (2019a) preparation manufacturing CBI⁶ Recycling U.S. EPA (2019a) Distribution in Distribution commerce ^{a,b} Commercial Us Electrical and Electrical and electronic products U.S. EPA (2019a) electronic es products Industrial U.S. EPA (2019a) Industrial manufacturing manufacturing Building/ Building/construction materials not covered U.S. EPA (2019a) construction elsewhere materials not covered elsewhere

Table 2. 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (CASRN 79-94-7)
Categories and Subcategories of Conditions of Use (2016 CDR reporting cycle) ⁵

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 of Use	Reference	
Consumer Uses	Electrical and electronic products	Electrical and electronic products	<u>U.S. EPA (2019a)</u>	
Disposal ^a	Disposal			
 ^a CDR includes information on the manufacturing, processing, and use of chemicals. 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. 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (CASRN 79-94-7)Categories and Subcategories of Conditions of Use (2012 CDR Reporting Cycle)⁷

Life-Cycle Stage	Category	Subcategory of Use	Reference	
Manufacture	Domestic manufacture	Domestic manufacture	<u>U.S. EPA (2019a)</u>	
	Import	Import	<u>U.S. EPA (2019a)</u>	
Processing	Processing – incorporating into formulation, mixture or reaction product	Flame retardant in: Plastics material and resin manufacturing Computer and electronic product manufacturing	<u>U.S. EPA (2019a)</u>	
	Processing as a reactant	Flame retardant in: All other basic organic chemical manufacturing	<u>U.S. EPA (2019a)</u>	
	Recycling		<u>U.S. EPA (2019a)</u>	
Distribution in commerce ^{a,b}	Distribution			
Commercial Uses	Electrical and electronic products	Electrical and electronic products	<u>U.S. EPA (2019a)</u>	
	Plastic and rubber product s not covered elsewhere	Plastic and rubber products not covered elsewhere	<u>U.S. EPA (2019a)</u>	
Consumer Uses	Electrical and electronic products	Electrical and electronic products	<u>U.S. EPA (2019a)</u>	
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				

⁷ Certain other uses which are excluded from TSCA are not captured in this table.

Life-Cycle Stage	Category	Subcategory of Use	Reference		
(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.					

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 4,4'-(1-Methylethylidene)bis[2, 6dibromophenol] (TBBPA), Reporting Year 2011

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
	Import	Other chemical product and preparation manufacturing	3259
		Semiconductor and other electronic component manufacturing	3344
	Produce or import for on-site use/processing	Semiconductor and other electronic component manufacturing	3344
	Produce or import for	Basic chemical manufacturing	3251
	sale/distribution	Other chemical product and preparation manufacturing	3259
Process	Process as a reactant	Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Other chemical product and preparation manufacturing	3259
		Semiconductor and other electronic component manufacturing	3344
		Aerospace product and parts manufacturing	3364
	Process as an article component	Paint, coating, and adhesive manufacturing	3255
		Plastics product manufacturing	3261
		Semiconductor and other electronic component manufacturing	3344
		Aerospace product and parts manufacturing	3364
	Process as a	Textile and fabric finishing and fabric coating mills	3133
	formulation component	Converted paper product manufacturing	3222
		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
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Computer and peripheral equipment manufacturing	3341
		Semiconductor and other electronic component manufacturing	3344
		Motor vehicle parts manufacturing	3363
		Aerospace product and parts manufacturing	3364
	Process – repackaging	Textile and fabric finishing and fabric coating mills	3133
Otherwise Use	Otherwise use – as a manufacturing aid	Semiconductor and other electronic component manufacturing	3344
	Otherwise use –	Other chemical product and preparation manufacturing	3259
	ancillary or other use	Waste treatment and disposal	5622
Waste	Disposal/releases	Textile and fabric finishing and fabric coating mills	3133
Management		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
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Semiconductor and other electronic component manufacturing	3344
		Motor vehicle parts manufacturing	3363
		Aerospace product and parts manufacturing	3364
		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
		Semiconductor and other electronic component manufacturing	3344

Activity Type	Activity	Industry Group	NAICS Code
		Aerospace product and parts manufacturing	3364
		Waste treatment and disposal	5622
	Recycling	Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Aerospace product and parts manufacturing	3364
	Treatment	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
		Computer and peripheral equipment manufacturing	3341
		Semiconductor and other electronic component manufacturing	3344
		Aerospace product and parts manufacturing	3364
		Waste treatment and disposal	5622

Reference: U.S. EPA 2019c

Table 5. Activities and Uses Reported to TRI for 4,4'-(1-Methylethylidene)bis[2, 6 dibromophenol] (TBBPA), Reporting Year 2015

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
	Import	Semiconductor and other electronic component manufacturing	3344
	Produce or import for on-site use/processing	Semiconductor and other electronic component manufacturing	3344
	Produce or import for sale/distribution	Basic chemical manufacturing	3251
	Produce or import as a byproduct	Basic chemical manufacturing	3251
Process	Process as a reactant	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
		Other electrical equipment and component manufacturing	3359

Activity Type	Activity	Industry Group	NAICS Code
		Aerospace product and parts manufacturing	3364
	Process as an article	Paint, coating, and adhesive manufacturing	3255
	component	Plastics product manufacturing	3261
		Industrial machinery manufacturing	3332
		Semiconductor and other electronic component manufacturing	3344
		Aerospace product and parts manufacturing	3364
	Process as an impurity	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
	Process as a	Textile and fabric finishing and fabric coating mills	3133
	formulation component	Converted paper product manufacturing	3222
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	
		Paint, coating, and adhesive manufacturing	
		Other chemical product and preparation manufacturing	
		Plastics product manufacturing	
		Semiconductor and other electronic component manufacturing	3344
		Motor vehicle parts manufacturing	3363
		Aerospace product and parts manufacturing	3364
		Other miscellaneous manufacturing	3399
	Process – repackaging	Semiconductor and other electronic component manufacturing	3344
Otherwise	Otherwise use – as a	Converted paper product manufacturing	3222
Use	chemical processing aid	Semiconductor and other electronic component manufacturing	
	Otherwise use – as a manufacturing aid	Aerospace product and parts manufacturing	3364
	Otherwise use –	Other chemical product and preparation manufacturing	3259
	ancillary or other use	Waste treatment and disposal	
Waste	Disposal/releases	Textile and fabric finishing and fabric coating mills	
Management		Converted paper product manufacturing	3222

Activity Type			NAICS Code
		Basic chemical manufacturing	3251
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Paint, coating, and adhesive manufacturing	
		Other chemical product and preparation manufacturing	
		Plastics product manufacturing	3261
		Semiconductor and other electronic component manufacturing	3344
		Other electrical equipment and component manufacturing	3359
		Motor vehicle parts manufacturing	3363
		Aerospace product and parts manufacturing	3364
		Other miscellaneous manufacturing Waste treatment and disposal	
	Energy recovery	Textile and fabric finishing and fabric coating mills	3133
		Converted paper product manufacturing	3222
		Basic chemical manufacturing	3251
		Semiconductor and other electronic component manufacturing	
		Aerospace product and parts manufacturing	3364
	Recycling	Converted paper product manufacturing	3222
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Industrial machinery manufacturing	3332
	Treatment	Textile and fabric finishing and fabric coating mills	3133
		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
		Other chemical product and preparation manufacturing	3259

Activity Type	Activity	Industry Group	NAICS Code
	Semiconductor and other electronic compone manufacturing		3344
		Aerospace product and parts manufacturing	3364
		Waste treatment and disposal	5622

Reference: U.S. EPA 2019c

Table 6. Activities and Uses Reported to TRI for 4,4'-(1-Methylethylidene)bis[2, 6 dibromophenol] (TBBPA), Reporting Year 2017

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Basic chemical manufacturing	3251
		Waste treatment and disposal	5622
	Import	Basic chemical manufacturing	3251
		Semiconductor and other electronic component manufacturing	3344
		Waste treatment and disposal	5622
	Produce or import for	Basic chemical manufacturing	3251
	on-site use/processing	Semiconductor and other electronic component manufacturing	3344
	Produce or import for sale/distribution	Basic chemical manufacturing	3251
	Produce or import as a byproduct	Waste treatment and disposal	5622
	Produce or import as an impurity	Waste treatment and disposal	5622
Process	Process as a reactant	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
		Other electrical equipment and component manufacturing	3359
		Aerospace product and parts manufacturing	3364
	Process as an article	Paint, coating, and adhesive manufacturing	3255
	component	Plastics product manufacturing	3261
		Industrial machinery manufacturing	3332

Activity Activity Type		Industry Group	
		Semiconductor and other electronic component manufacturing	3344
		Aerospace product and parts manufacturing	3364
	Process as an impurity	Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
	Process as a	Textile and fabric finishing and fabric coating mills	3133
	formulation component	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
		Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Semiconductor and other electronic component manufacturing	3344
	Aerospace product and parts manufacturing		3364
	Process –	Basic chemical manufacturing	3251
	repackaging	Other chemical product and preparation manufacturing	3259
		Semiconductor and other electronic component manufacturing	3344
Otherwise Use	Otherwise use – as a chemical processing aid	Semiconductor and other electronic component manufacturing	3344
	Otherwise use – as a manufacturing aid	Aerospace product and parts manufacturing	3364
	Otherwise use – ancillary or other use	Waste treatment and disposal	
Waste	Disposal/releases	Textile and fabric finishing and fabric coating mills	
Management		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
		Other chemical product and preparation manufacturing	3259

Activity Type			NAICS Code
		Plastics product manufacturing	3261
		Semiconductor and other electronic component manufacturing	3344
		Other electrical equipment and component manufacturing	3359
		Aerospace product and parts manufacturing	3364
		Waste treatment and disposal	5622
	Energy recovery	Converted paper product manufacturing	3222
		Resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing	3252
		Plastics product manufacturing	3261
		Aerospace product and parts manufacturing	3364
		Waste treatment and disposal	5622
	Recycling	Other chemical product and preparation manufacturing	3259
		Plastics product manufacturing	3261
		Industrial machinery manufacturing	3332
	Treatment	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
		Semiconductor and other electronic component manufacturing	3344
		Aerospace product and parts manufacturing	3364
		Waste treatment and disposal	5622

Reference: U.S. EPA 2019c

CDR and TRI Summary and Additional Information on Conditions of Use

The number of sites reporting use of TBBPA in consumer and commercial electrical and electronic products increased from two to three between 2012 and 2016 from the CDR data. Two sites reported unspecified consumer or commercial use in both 2012 and 2016. One site reported use in plastic or rubber products in 2012 but not 2016. The 2016 CDR reported one site that used TBBPA for building/construction materials and one site that used the chemical in industrial manufacturing, two uses that are not present in the 2012 CDR. The use of TBBPA in industrial computer and electronic product manufacturing as well as plastic and resin manufacturing, is consistent between 2012 and 2016. The 2016 CDR reports additional industrial uses not reported

in 2012: all other chemical product and preparation manufacturing; electrical equipment, appliance, and component manufacturing; transportation equipment manufacturing; and miscellaneous manufacturing. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8).

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 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. Tables 4, 5 and 6 present the activities and uses reported to TRI by industry group for 2011, 2015, and 2017. Waste management activity type includes all industry groups that reported to TRI using each waste management activity for TBBPA.

Public comments received for the proposed designation support the use of TBBPA as a flame retardant. The American Coatings Association states that TBBPA is a flame retardant in adhesives and sealants. Specialty products may have amounts above 10 percent (EPA-HQ-OPPT-2018-0462-0003). The Aerospace Industries Association provides further detail by stating that TBBPA is used as a flame retardant specifically in structural film adhesives, resins for honeycomb core, epoxy pre-impregnated fiberglass or graphite tapes or woven fabrics (EPA-HQ-OPPT-2018-0462-0004). Lastly the American Chemistry Council's North American Flame Retardant Alliance separates the uses of TBBPA as a reactive or additive flame retardant. For instance, TBBPA is identified as a reactive flame retardant in printed circuit boards or laminates. Conversely TBBPA is identified as an additive flame retardant in acrylonitrile-butadiene-styrene plastics, formed into light, rigid, molded products such as electrical housings or piping (EPA-HQ-OPPT-2018-0462-0006).

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 U. These data provide an indication about whether children or other susceptible subpopulation 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 TBBPA.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for TBBPA. Table 7 summarizes the non-CBI CDR information regarding commercial and consumer use and notes whether the chemical substance was identified as used in products intended for children. The 2016 CDR identified use of TBBPA in children's electrical and electronic products (Table 7). Previous EPA assessments also indicated TBBPA has been detected in children's products such as small plastic toys and jewelry (U.S. EPA 2015a).

Chemical	Year	Product Category	Consumer or Commercial	Used in Products Intended for Children
4,4'-(1- Methylethylidene)bis	2012	Electrical and electronic products	Consumer and commercial	No
[2,6-dibromophenol] (TBBPA) (79-94-7)		Plastic and Rubber Products not covered elsewhere	Commercial	No
	2016	Electrical and electronic products	Consumer and commercial	Yes
		Industrial manufacturing	Commercial	No
		Building/construction materials not covered elsewhere	Commercial	No

References: U.S. EPA (2019a)

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

EPA identified studies that observed developmental effects following exposure to TBBPA (Section 7, Table 10). Although no reproductive hazards were identified in the identified studies, 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.

⁸ Certain other uses that are excluded from TSCA are not captured in this table.

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 TBBPA's persistence and bioaccumulation.

Physical and Chemical Properties and Environmental Fate Tables

Table 8 and 9 summarize the physical and chemical properties and the environmental fate characteristics of TBBPA, respectively.

Property or Endpoint	Value ^a	Reference
Molecular Formula	$C_{15}H_{12}Br_4O_2$	HSDB (2018)
Molecular Weight	543.88 g/mole	CRC (2014)
Physical State	Solid	HSDB (2018)
Physical Form	White crystalline	HSDB (2018)
Purity	Purity 98.5%; impurities include 0.1% water, ≤60 mg hydrolysable bromine/kg, and a ≤100 mg ionic bromide/kg.	HSDB (2018) (1995) citing WHO
	<0.01 µg/kg 2,3,7,8-TeBDD; <0.02 µg/kg 1,2,3,7,8- PeBDD; <0.05 µg/kg 1,2,3,4,7,8-HxBDD; <0.05 µg/kg 1,2,3,6,7,8-HxBDD; <0.05 µg/kg 1,2,3,7,8,9- HxBDD; <0.01 µg/kg 2,3,7,8-TeBDF; <0.02 µg/kg 1,2,3,7,8-PeBDF; <0.02 µg/kg 2,3,4,7,8-PeBDF	<u>ECB (2006)</u>
Melting Point	179 °C	Physprop (2012); HSDB (2018)
	181 ℃	HSDB (2018)
Boiling Point	316 °C (decomposes at 200-300 °C)	<u>HSDB (2018)</u>
Density	2.2 kg/L at 4 °C	HSDB (2018) O'Neil (2013)
Vapor Pressure	4.68×10^{-8} mm Hg at 25 °C ^b	HSDB (2018) BRE (2009)
	$< 8.9 \times 10^{-8}$ mm Hg at 20 °C	HSDB (2018); ECHA (2018)
Vapor Density	TBD	TBD
Water Solubility	0.148 mg/L (pH 5); 1.26 mg/L (pH 7) ^b ; 2.34 mg/L (pH 9) at 25 °C	<u>OECD (2005); ECHA</u> (2018)

Table 8. Physical and Chemical Properties of 4,4'-(1-Methylethylidene)bis[2, 6 dibromophenol] (TBBPA)

Property or Endpoint	Value ^a	Reference
	0.171 mg/L (non-ionic form, pH 3.05); 4.15 mg/L (pH 7.56); 30.5 mg/L (pH 7.99); 228 mg/ L (pH 8.48); 1,510 mg/L (pH 8.91) at 25 °C	HSDB (2018) citing Kuramochi (2007)
Log K _{ow}	6.53 (pH 3.05), 4.75 (pH 7.53), 3.00 (pH 8.12), 1.25 (pH 9.18) at 25 °C	OECD (2005); HSDB (2018) citing Kuramochi (2007)
Henry's Law Constant	2.0×10^{-7} atm-m ³ /mol at 25 °C (estimated) ^c	<u>U.S. EPA (2012)</u>
Flash Point	Not relevant/the substance does not have a flash point; the substance is used as a flame retardant	<u>ECB (2006)</u>
рКа	pKa1 = 7.50; pKa2 = 8.5	ECB (2006); HSDB (2018)
	pKa = 9.40 at 20 °C	HSDB (2018); ECHA (2018)
Auto Flammability	The material does not undergo autoignition, but decomposes at elevated temperatures	ECB (2006)
Viscosity	TBD	TBD
Refractive Index	TBD	TBD
Dielectric Constant	TBD	TBD
Surface Tension	TBD	TBD

Notes:

^aMeasured unless otherwise noted;

^bSelected value; ^cEPI SuiteTM SMILES input: Oc(c(cc(c1)C(c(cc(C0)c2Br)Br)c2)(C)C)Br)c1Br).

TBD= to be determined, if reasonably available. **EPA is particularly interested in information from the public on these properties or endpoints.**

Table 9. Environmental Fate Characteristics of 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)

Property or Endpoint	Value ^a	Reference
Direct Photodegradation	$ \begin{array}{l} t_{1/2} = 17 \mbox{ minutes-5.8 hours based on ultraviolet} \\ absorption maximum at 310 nm, a quantum yield of 0.042 and decomposition rates ranging from 3.3 \times 10^{-5} \\ (at \mbox{ pH 5.5}) \mbox{ to } 6.8 \times 10^{-4} \mbox{ (at \mbox{ pH 9}) per second} \end{array} $	HSDB (2018) citing Eriksson (2004)
	2,6-dibromo-p-benzosemiquinone anions and TBBPA were identified as the main photodecomposition byproducts	HSDB (2018) (2016) citing Han

Property or Endpoint				
Indirect Photodegradation	$\begin{array}{l} t_{1/2}=3.615 \text{ days (based on } \cdot OH \text{ rate constant of } 2.96 \times \\ 10^{-12} \text{ cm}^3/\text{mol sec at } 25 \ ^{\text{o}}\text{C} \text{ and } 12\text{-hour day with } 1.5 \times \\ 10^6 \cdot OH/\text{cm}^3\text{; estimated})^b \end{array}$	<u>U.S. EPA (2012)</u>		
Hydrolysis	Not expected to undergo hydrolysis in the environment due to the lack of functional groups that hydrolyze under environmental conditions	HSDB (2018) Lyman (1990)		
Biodegradation (Aerobic)	Water: 0%/14 days (MITI)	<u>HSDB (2018); NITE (2018)</u>		
	Water: $t_{1/2} = 48-84$ days (natural river water)	HSDB (2018) citing U.S. EPA (1989)		
	Soil: t _{1/2} >6 months (18-22% mineralization/6 months); 18–64%/64 days primary degradation	<u>OECD (2005)</u>		
	Sandy soil: $t_{1/2} = 14.7$ days; full degradation after 143 days; primary byproducts are the mono and dimethyl ethers	HSDB (2018) citing Li (2015)		
Biodegradation (Anaerobic)	Soil and sediment: Anaerobic biodegradation of 2,2',6,6'-TBBPA has been shown to occur in soil and sediment studies with primary degradation being complete in 64 days in some; the primary byproduct from anaerobic biodegradation is bisphenol A	HSDB (2018) citing Voordeckers (2002)		
Wastewater Treatment	Wastewater influent containing 2,2',6,6'-TBBPA concentration range of 10-145 ng/L had removal of 76–83% with conventional activated sludge and bioreactor systems	HSDB (2018) (2015) citing Islam		
Bioconcentration Factor	30-341 and $52-485$ for Carp (<i>Cyprinus carpio</i>), which were exposed over an 8-week period to concentrations of 80 and 8 µg/L, respectively	<u>NITE (2018)</u>		
	307 measured in fathead minnow (<i>Pimephales promelas</i>)	HSDB (2018) (2004) citing Hardy		
Bioaccumulation Factor	720 (estimated) ^b	<u>U.S. EPA (2012)</u>		
Soil Organic	5.4 (K _{oc} = 2.7×10^5 MCI method; estimated) ^b	<u>U.S. EPA (2012)</u>		
Carbon:Water Partition Coefficient (Log K _{oc})	Soil column and batch adsorption studies using loam soil and sand found 2,2',6,6'-TBBPA is sorbed extensively by both soil and sand	ECHA (2018)		

Notes: ^aMeasured unless otherwise noted; ^bEPI SuiteTM physical property inputs: SMILES Oc(cc(c(c))C(c(cc(c))Br)c2)(C)C)Br)c1Br)

Results and Discussion

TBBPA is a crystalline solid with moderate water solubility expected under environmental conditions (measured water solubility of 1.26 and 2.34 mg/L at pH 7 and 9 respectively), but lower water solubility in more acidic environments (0.148 mg/L at pH 5). The estimated Henry's Law constant (2.00×10^{-7} atm-m³/mol) and measured vapor pressure (4.68×10^{-8} mm Hg) indicate that this chemical will have negligible volatility and may be persistent in both surface water and soil. TBBPA undergoes direct photodegradation in water with half-lives between 17 minutes and 5.8 hours depending on the pH (where higher pH corresponds to faster degradation). If released to air, TBBPA is estimated to react with photochemically-produced hydroxyl radicals (OH) at a rate corresponding to a half-life of 3.6 days.

TBBPA may undergo some biodegradation under certain conditions. In aerobic natural river water, TBBPA had a half-life of 48–84 days and in aerobic soil, TBBPA displayed 18–64 percent primary degradation in 64 days and 18–22 percent mineralization in 6 months (half-life >6 months). However, in a Japanese MITI test, TBBPA showed 0 percent degradation over 14 days. Under anaerobic conditions in soil and sediment, TBBPA underwent complete primary degradation over 64 days with the main product being bisphenol A. These combined data suggest that TBBPA has slow to negligible biodegradability and is likely to persist in the environment. In *Cyprinus carpio* and *Pimephales promelas*, TBBPA has a bioconcentration factor between 30–485 and 307, respectively, suggesting that TBBPA has low potential for bioaccumulation.

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

TBBPA is subject to reporting requirements under EPCRA (U.S. EPA (2015b). TBBPA is not subject to any of the other regulations described in the previous paragraph.

7. Hazard potential

Approach

EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health and environmental hazards for TBBPA (Tables 10 and 11, respectively

EPA/OPPT 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 for 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 TBBPA, if available, to fill in potential data gaps should there not be when there were no reported observed effects for specific taxa exposed to the TBBPA (Table 11).

Potential Human Health and Environmental Hazard Tables

EPA identified potential human health and environmental hazards based on a review of the reasonably available information for TBBPA (Tables 10 and 11, respectively).

Human Health Hazards	Tested for Specific Effect	Effect Observed	Data Source
Acute Toxicity	Х		<u>U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014),</u> <u>Environment Canada (2013), ECB (2006), NICNAS</u> (2001), <u>IPCS (1995)</u>
Repeated Dose Toxicity	Х	Х	<u>U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014),</u> <u>Environment Canada (2013), ECB (2006), EFSA (2005),</u> <u>NICNAS (2001), IPCS (1995)</u>
Genetic Toxicity	Х		<u>IARC (2018)</u> , <u>U.S. EPA (2015a)</u> , <u>U.S. EPA (2015c)</u> , <u>NTP (2014)</u> , <u>Environment Canada (2013)</u> , <u>ECB (2006)</u> , <u>NICNAS (2001)</u> , <u>IPCS (1995)</u>
Reproductive Toxicity	Х		<u>U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014),</u> Environment Canada (2013), ECB (2006), EFSA (2005)
Developmental Toxicity	Х	Х	<u>U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014),</u> <u>Environment Canada (2013), ECB (2006), NICNAS</u> (2001), IPCS (1995)

Table 10. Potential Human Health Hazards Identified for 4,4'-(1-Methylethylidene)bis[2, 6 dibromophenol] (TBBPA)

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

Human Health Hazards	Tested for Specific Effect	Effect Observed	Data Source
Toxicokinetic	Х	Х	<u>IARC (2018), U.S. EPA (2015a), U.S. EPA (2015c), NTP</u> (2014), Environment Canada (2013), ECB (2006), NICNAS (2001), IPCS (1995)
Irritation/Corrosion	Х	Х	<u>U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014),</u> <u>Environment Canada (2013), ECB (2006), NICNAS</u> (2001), <u>IPCS (1995)</u>
Dermal Sensitization	Х		<u>U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014),</u> <u>Environment Canada (2013), ECB (2006), NICNAS</u> (2001), <u>IPCS (1995)</u>
Respiratory Sensitization	Х		<u>U.S. EPA (2015a)</u> , <u>Environment Canada (2013)</u> , <u>ECB</u> (2006)
Carcinogenicity	Х	Х	<u>IARC (2018)</u> , <u>U.S. EPA (2015a)</u> , <u>U.S. EPA (2015c)</u> , <u>NTP (2014)</u>
Immunotoxicity	Х	X	<u>U.S. EPA (2015c)</u> , <u>NTP (2014)</u> , <u>Environment Canada</u> (2013)
Neurotoxicity	Х	Х	IARC (2018), U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014), Environment Canada (2013), ECB (2006), EFSA (2005)
Epidemiological Studies or Biomonitoring Studies	Х	Х	IARC (2018), U.S. EPA (2015a), U.S. EPA (2015c), NTP (2014), Environment Canada (2013), ECB (2006), IPCS (1995)

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.

Media	Study Duration	Taxa Groups	High Priority Candi 4,4'- Methylethyli 6-dibromo TBB (CAS # ' Number of Studies	date (1- dene)bis[2, ophenol] PA	Isomers of 4,4'-(1- Methylethylidene)bis[2, 6-dibromophenol] TBBPA (CAS # 79947) NONE Number of Observed		Data Sources
Aquatic	Acute	Vegetation	4	X	Studies -	Effects	Debenest et al. (2011); Walsh et al. (1987)
i iquite	exposure	Invertebrate	5	X	-		Anselmo et al. (2011); Brooke (1991); Fabbri et al. (2014); Goodman et al. (1988); Wildlife International Ltd. (2003)
		Fish	10	Х	-		Brooke (1991); Chan and Chan (2012); Chow et al. (2013); Godfrey et al. (2017a); Hu et al. (2009); Kalasekar et al. (2015); McCormick et al. (2010); Ronisz et al. (2004); Thienpont et al. (2011); Wildlife International Ltd. (2003)
		Non-Fish Vertebrates (i.e., amphibians, reptiles, mammals)	2	Х	-		Fini et al. (2007); Fini et al. (2012)
	Chronic	Vegetation	-		-		
	exposure	Invertebrate	1	Х	-		Anselmo et al. (2011)
		Fish	7	Х	-		Feng et al. (2013); Godfrey et al. (2017b); Kuiper et al. (2007); Lower (2008); McCormick et al. (2010); Riu et al. (2014); Ronisz et al. (2004)
		Non-Fish Vertebrates (i.e., amphibians, reptiles, mammals)	2	Х	-		Fini et al. (2012); Zhang et al. (2014)
Terrestrial		Vegetation	-		-		

 Table 11. Potential Environmental Hazards Identified for 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)

Media	Study Duration	Taxa Groups	High Priority Chemical CandidateIsomers of 4,4'-(1-4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol]Methylethylidene)bis[2, 		Data Sources		
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
	Acute	Invertebrate	1	Х	-		Boyd et al. (2016)
	exposure	Vertebrates	1	Х	-		Ma et al. (2015)
	Chronic	Vegetation	-		-		
	exposure	Invertebrate	1	X	-		Shi et al. (2015)
		Vertebrates	-		-		

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 to TBBPA.

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 (POTWs) 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 (<u>CPDat</u>) for TBBPA to inform occupational and consumer exposure potential. The results 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 TBBPA's exposure potential.

Results and Discussion

Release potential for environmental and human health exposure

Aggregated quantities of TBBPA released on-site to air, water, and land, and aggregated quantities of TBBPA transferred off-site to POTW and other wastewater treatment facilities (non-POTW) are presented in Table 12. 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 TBBPA for RY 2011, 2015, and 2017. The TRI data presented were obtained from the TRI dataset following its update in April 2019.

Table 12. The TRI Data on 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)from Reporting Years 2011, 2015, and 2017 and Used in this Document to Assess ExposurePotential

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 POTWs (lbs.)	Total Quantities Transferred to Other (Non- POTWs) Wastewater Treatment Facilities (lbs.)
2011	50	2,111	8	23,694	10	0
2015	55	2,895	11	72,027	10	0
2017	53	2,624	26	8,661	10	4

Note: POTW: publicly owned treatment works Reference: <u>U.S. EPA 2019c</u>

For RY 2017, 53 facilities submitted TRI reports for TBBPA. The total quantities of TBBPA these facilities released on-site to air (as fugitive and stack emissions), surface water, and land are: 2,624 pounds; 26 pounds; and 8,661 pounds, respectfully. These facilities reported 10 pounds of the chemical transferred to POTW and 4 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 TBBPA received by POTW and 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 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 a reactant or an intermediate. 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.

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.

TBBPA does not have an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) 10, a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL)¹¹, or the Threshold Limit Value (TLV) set by American Conference of Governmental Industrial Hygienists (ACGIH).

TBBPA has a vapor pressure of 4.68×10^{-8} mm Hg at 25 °C/77 °F and is solid. Experience has shown that inhalation exposure to vapors generated from solids with vapor pressures below 0.001 mm Hg at ambient room temperature conditions may be negligible. However, some handling activities of TBBPA may generate dust when handled as a dry powder. Workers may be exposed to aerosolized particles.

Consumer exposure

Based on CDR reporting information, TBBPA appears to be widely used in consumer products, specifically electrical and electronic products. TBBPA is intended for and has also been detected in children's products (such as electronics) as well as in small plastic toys and jewelry (<u>U.S. EPA</u> <u>2015a</u>). The NIH Consumer Product Database and the Chemical and Products Database (<u>CPDat</u>) have no reported use of TBBPA in consumer products (Table 13) (<u>U.S. EPA 2019b</u>).

Chemical Identity	Consumer Product Database				
Chemical Identity	Consumer Uses (List).				
4,4'-(1-Methylethylidene)bis [2, 6-dibromophenol] (79-94-7)	Adhesive, automotive, electronics, plastic, sports equipment				

Table 13. Exposure Information for the Consumers

Reference: CPDat

General population exposure

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

¹⁰ OSHA, 2009. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs). <u>https://www.osha.gov/dsg/annotated-pels/tablez-1.html</u>

¹¹ NIOSH, 2005. NIOSH Pocket Guide to Chemical Hazards. <u>https://www.cdc.gov/niosh/npg/npgdcas.html</u>

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

EPA did not find 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 TBBPA 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, children). This is based on the potential hazard and potential exposure of TBBPA under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacturing, processing, distribution, use and disposal of TBBPA may result in presence of the chemical in surface water, inhalation of the chemical from air releases, exposure to workers, exposure to consumers and exposure to the general population, including exposure to children. In addition, EPA identified potential environmental (e.g., aquatic toxicity, terrestrial toxicity), and human health hazards (e.g., repeated dose toxicity, developmental toxicity, toxicokinetics, irritation/corrosion, carcinogenicity, immunotoxicity, neurotoxicity, observations in epidemiological studies or biomonitoring studies).

11. References

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

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