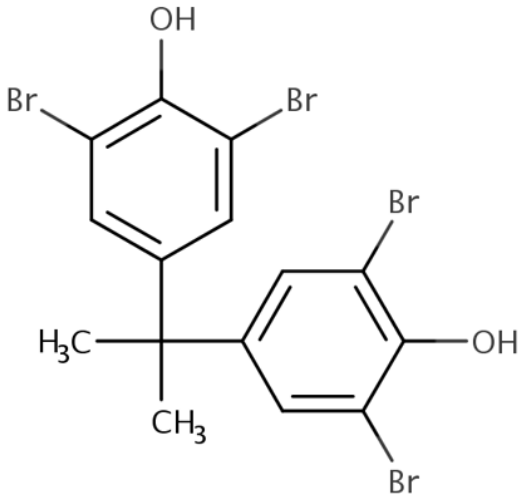
EPA Document # 740-D-20-008
April 2020
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for 4,4′-(1-Methylethylidene)bis[2, 6-dibromophenol]

CASRN 79-94-7



April 2020

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ACKNOWLEDGEMENTS

This report was developed by the United States Environmental Protection Agency (U.S. EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT).

Acknowledgements

The OPPT Assessment Team gratefully acknowledges participation or input from intra-agency reviewers that included multiple offices within EPA, inter-agency reviewers that included multiple federal agencies, and assistance from EPA contractors GDIT (Contract No. HHSN316201200013W), ERG (Contract No. EP-W-12-006), Versar (Contract No. EP-W-17-006), ICF (Contract No.68HERC19D0003), Abt Associates (Contract No. EP-W-16-009) and SRC (Contract No. 68HERH19F0213). EPA also acknowledges the contributions of technical experts from EPA's Office of Research and Development.

Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2018-0462

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ACA	The American Coatings Association
ACGIH	American Conference of Government Industrial Hygienists
AIA	The Aerospace Industry Association
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
BMF	Biomagnification factor
$BW^{3/4}$	Body weight scaling to the 3/4 power
C&D	Construction and demolition
CAA	Clean Air Act
CBI	Confidential business information
CDR	Chemical Data Reporting
ChemSTEER	Chemical Screening Tool for Exposure and Environmental Releases
CHRIP	Chemical Risk Information Platform
COC	Concentration of concern
CoRAP	Community Rolling Action Plan
CPCat	Chemical and Product Categories
CSCL	Chemical Substances Control Law
ECHA	European Chemicals Agency
EC	Engineering controls
EC_x	Concentration that causes a response that is x% of the maximum
EPCRA	Emergency Planning and Community Right-to-Know Act
ESD	Emission Scenario Document
FYI	For Your Information
GS	Generic Scenario
HAP	Hazardous air pollutant
HAWC	Health Assessment Workspace Collaborative
HHE	Health hazard evaluation
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
K_{oc}	Organic carbon: water partition coefficient
LC_{50}	Lethal concentration of 50% of test organisms
LC_x	Lethal concentration that is x% of the maximum
LOAEL	Lowest observed adverse effect level
LOEC	Lowest observed effect concentration
MCI	Molecular conductivity index
MITI	Ministry of International Trade and Industry
mm Hg	Millimeter(s) of mercury
MOA	Mode of action
MSWLF	Municipal Solid Waste Landfill(s)
NAMs	New approach methods
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration

NTP	National Toxicology Program
OH	Hydroxide
OECD	Organisation for Economic Cooperation and Development
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
P-chem	Physical-chemical
PBB	Polybrominated biphenyls
PBPK	Physiologically based pharmacokinetic
PBB	Polybrominated biphenyl
PBT	Persistent, bioaccumulative, toxic
PCB	Polychlorinated biphenyls
PCN	Polychlorinated naphthalene
PCT	Polychlorinated terphenyl
PECO	Population, exposure, comparator, outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulation
PNOR	Particulates Not Otherwise Regulated
POD	Point of departure
PPE	Personal protective equipment
POTW	Publicly Owned Treatment Works
RCRA	Resource Conservation and Recovery Act
RoHS	Restriction of Hazardous Substances
RQ	Risk quotient
SDS	Safety data sheet
SMILES	Simplified molecular-input line-entry system
SVOC	Semi-volatile organic compound
TBBPA	Tetrabromobisphenol A or 4,4′-(1-Methylethylidene)bis[2, 6-dibromophenol]
TIAB	Title and abstract
TMF	Trophic magnification factor
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
VP	Vapor pressure
WEEE	Waste electrical and electronic equipment
WWT	Wastewater treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated 4,4′-(1-methylethylidene)bis[2, 6-dibromophenol], also known as tetrabromobisphenol A (TBBPA) (CASRN 79-94-7), as a high-priority substance for risk evaluation following the prioritization process required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0462). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA regulatory requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft scope for TBBPA includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

***General Information*.** TBBPA is a crystalline solid with a total production volume in the United States between 50 million and 100 million pounds.

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

Conditions of Use. EPA plans to evaluate manufacturing (including import), processing, distribution in commerce, industrial, commercial and consumer uses, and disposal of TBBPA in the risk evaluation. TBBPA is manufactured within the U.S. as well as imported into the U.S. The chemical is processed as a reactant, incorporated into a formulation, mixture or reaction products and incorporated into articles. The identified processing activities also include the recycling of TBBPA and TBBPA containing products. TBBPA is primarily used as a flame retardant in electrical and electronic products, adhesives, transportation equipment, building/construction materials and textiles. It is also used as an intermediate to create other flame retardants and as a laboratory chemical. The predominate uses for TBBPA are as a reactive flame retardant in electrical and electronic products (e.g., printed circuit boards) and as an additive flame retardant in electrical and electronic products (e.g., plastic enclosures). The epoxy resin containing TBBPA can also be used in adhesives, transportation equipment and building/construction materials. The information on the use in textiles is limited in detail and the public is invited to submit information on this use. EPA identified these conditions of use from information reported to EPA through Chemical Data Reporting (CDR) and Toxics Release Inventory (TRI) reporting, published literature and consultation with stakeholders. Section 2.2 details about the conditions of use within the scope of the risk evaluation.

Conceptual Models. The conceptual models for TBBPA are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards, and receptors throughout the life cycle of the chemical substance. EPA plans to focus the risk evaluation for TBBPA on the following exposures, hazards, and receptors with the understanding that updates may be made in the final scope document after consideration of public comments and completion of the systematic review data collection phase.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of TBBPA that EPA plans to consider in the risk evaluation. Exposures for TBBPA are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of TBBPA in surface water, groundwater, biosolids and sediment. Additional information gathered through systematic review searches will also inform expected exposures.

  In Section 2.6.3, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of TBBPA within the scope of the risk evaluation.

  Preliminarily, EPA plans to include the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with manufacturing (including import), processing, industrial and commercial use, and disposal:* EPA plans to evaluate exposures to workers and/or occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of TBBPA (Section 2.2.1).
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate inhalation and dermal exposure to TBBPA when consumers are handling electrical and electronic products, batteries, building/construction materials, and fabric, textiles and leather products containing TBBPA, and children's mouthing or products/articles containing TBBPA.
  - *General population exposures:* EPA plans to evaluate exposure via the oral route to TBBPA via drinking water, groundwater, fish ingestion, human breast milk and soil for the general population and via the inhalation route for ambient air.
  - *Environmental exposures:* EPA plans to evaluate exposure to TBBPA for aquatic and terrestrial receptors via various pathways including surface water, sediment and soil.
  - *Receptors and PESS:* EPA plans to include children, women of reproductive age (including, but not limited to, pregnant women), workers and consumers as receptors and PESS in the risk evaluation.

  Hazards. Hazards for TBBPA are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for TBBPA as part of the prioritization process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for TBBPA. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. EPA plans to evaluate all potential human health hazards for TBBPA identified in Section 2.4.2. The broad health effect categories include immunological, neurological, carcinogenic, developmental and reproductive effects. Effects were seen in epidemiological and biomonitoring human studies.

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

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

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

1 INTRODUCTION

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

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

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

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

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

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

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

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening process was conducted based on EPA's general expectations for the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). EPA will publish supplemental documentation on the systematic review methods supporting the TBBPA risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

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

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 99 search results relevant to EPA's risk assessment needs for TBBPA. 0 lists the gray literature sources that yielded 99 discrete data or information sources relevant to TBBPA. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

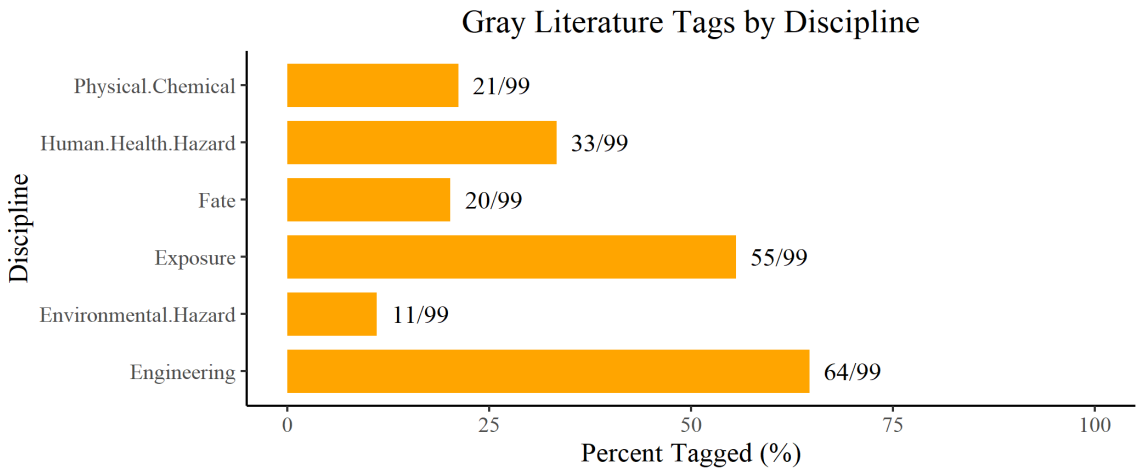

Figure 2-1 Gray Literature Search Results for TBBPA

The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

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

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-chemical (p-chem) properties, environmental fate and transport, engineering (environmental release and occupational ex**posure), exposure (environmental, general population and consumer) and environmental and human health hazards of TBBPA. Eligibility criteria were applied in the form of population, exposure, comparator, outcome (PECO) or similar statements. Included references met the PECO or similar criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure** 2-2 **through Figure 2-6. "TIAB" in these figures refers to title and abstract screening. Note that in some figures the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.**

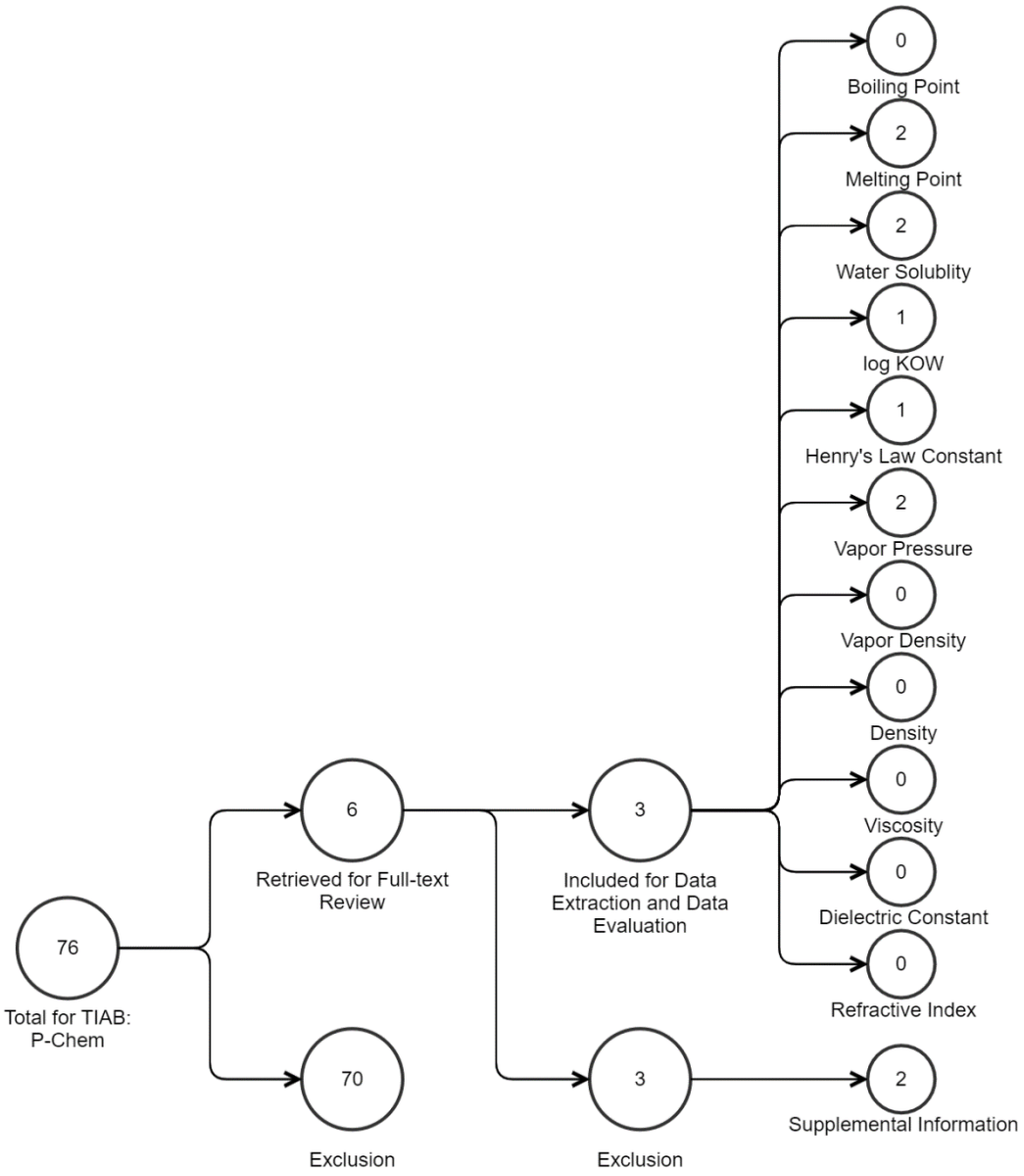

Figure 2-2 Peer-reviewed Literature – Physical-Chemical Properties Search Results for TBBPA

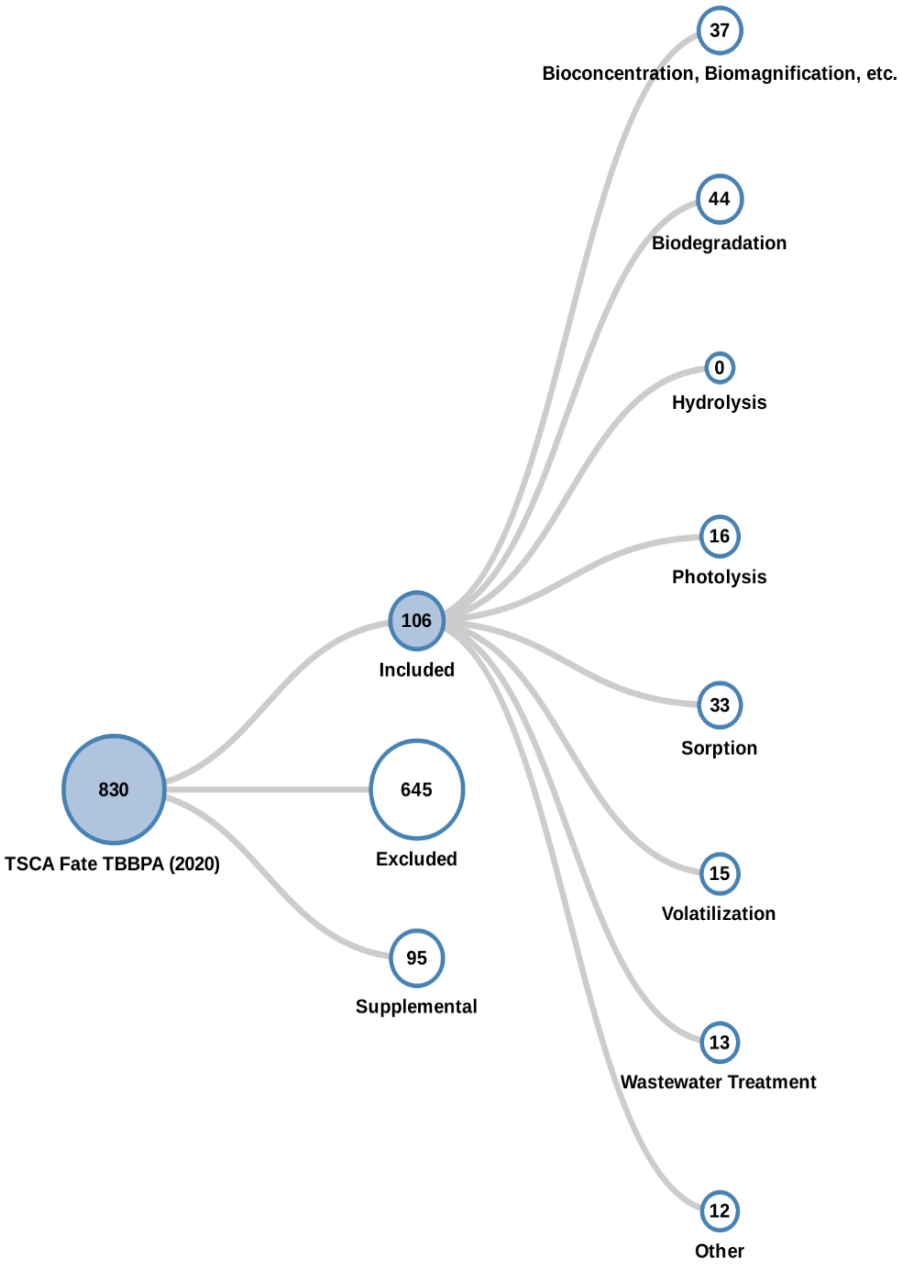

Figure 2-3 Peer-reviewed Literature – Fate and Transport Search Results for TBBPA
Click here for interactive Health Assessment Workspace Collaborative (HAWC) Diagram.

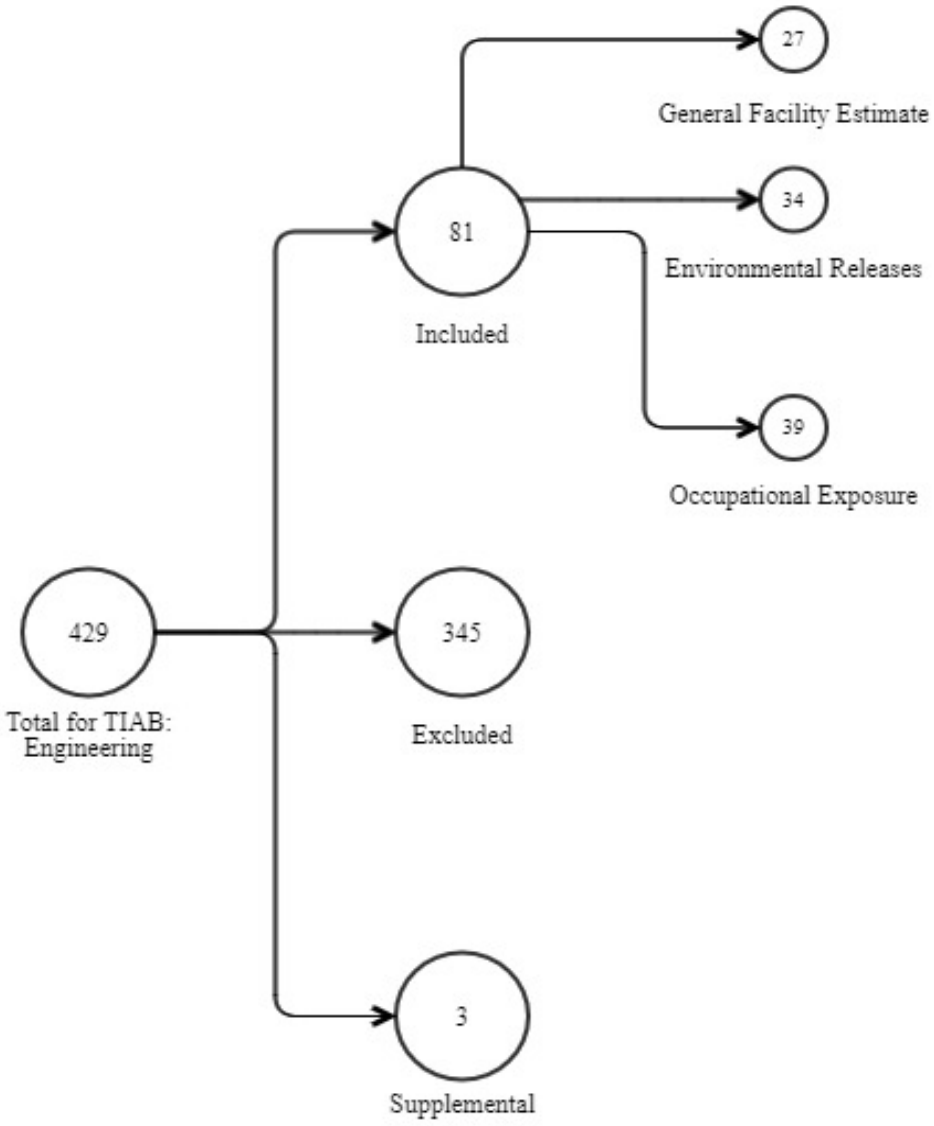

Figure 2-4 Peer-reviewed Literature – Engineering Search Results for TBBPA

Figure 2-5 Peer-reviewed Literature – Exposure Search Results for TBBPA

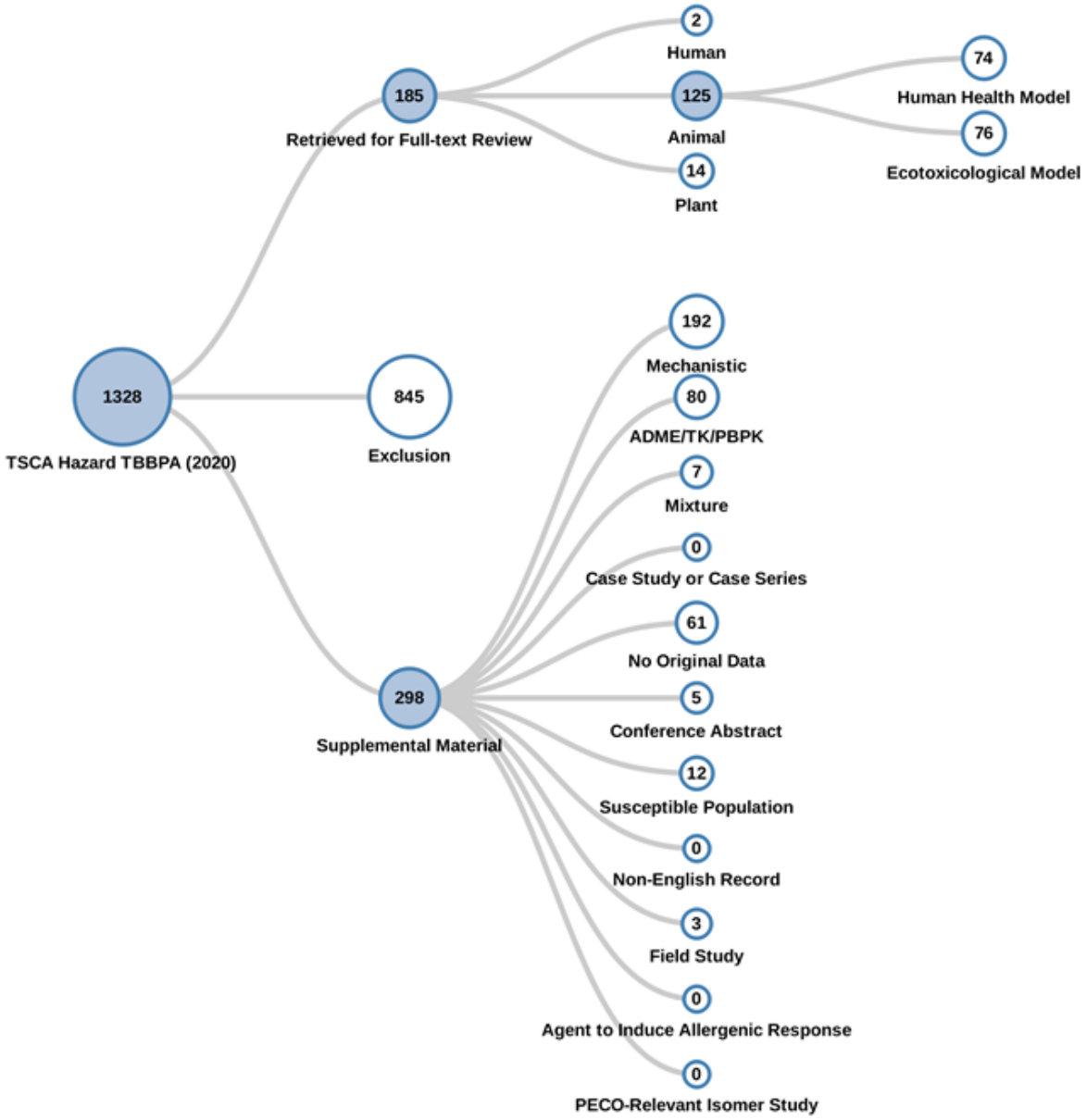

Figure 2-6 Peer-reviewed Literature – Hazard Search Results for TBBPA
Click here for interactive HAWC Diagram.

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 96 submissions using inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 70 submissions that met the inclusion criteria in these statements and identified 10 submissions with supplemental data. EPA excluded 16 submissions because the reports were identified as one of the following:

- Preliminary, interim or draft report of a final available submitted report
- Status report
- Data not relevant to any discipline
- Letter with no data
- Material safety data sheet

EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full text screening), when more information regarding the reports is available.

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

Discipline	Included [a]	Supplemental [a]
Physicochemical Properties	5	0
Environmental Fate and Transport	13	0
Environmental and General Population Exposure	1	0
Occupational Exposure/Release Information	1	0
Environmental Hazard	28	1
Human Health Hazard	35	9

[a]A given submission may have information on multiple disciplines; therefore, the sum of submissions in each column may be greater than the total number of included or supplemental submissions.

2.2 Conditions of Use

As described in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of TBBPA including: published literature, company websites, government and commercial trade databases and publications. To identify formulated products containing TBBPA, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data (U.S. EPA, 2019b) and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product's SDS was current. In addition, EPA incorporated communications with companies, industry groups, environmental organizations and public comments to supplement the conditions of use information.

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

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of TBBPA, EPA identified those categories or subcategories of use activities

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

for TBBPA the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

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

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

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

Life Cycle Stage	Category	Subcategory	References
Manufacturing	Domestic manufacture	Domestic manufacture	U.S. EPA, 2019c
	Import	Import	U.S. EPA, 2019c
Processing	Processing as a reactant	Flame retardant (e.g., plastic material and resin manufacturing)	U.S. EPA, 2019c
		Intermediate (e.g., all other chemical product and preparation manufacturing)	U.S. EPA, 2019c
	Processing - incorporating into formulation, mixture or reaction product	Flame retardant (e.g., electrical equipment, appliance and component manufacturing)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0017
		Flame retardant (e.g., plastic material and resin manufacturing)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0017
		Flame retardant (e.g., plastics product manufacturing)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016
		Flame retardant (e.g., computer and electronic product manufacturing)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016
		Intermediate (e.g., transportation equipment manufacturing)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0004; EPA-HQ-OPPT-2018-0462-0016
		Adhesive Manufacturing	EPA-HQ-OPPT-2018-0462-0003; NIEHS (2002); CPSC (2015); EPA-HQ-OPPT-2018-0462-0004; EPA-HQ-OPPT-2018-0462-0016
	Processing - incorporating into articles	Flame retardant (e.g., Electrical equipment, appliance and component manufacturing)	U.S. EPA, 2019c
		Flame retardant (e.g., Plastics product manufacturing)	U.S. EPA, 2019c

Life Cycle Stage	Category	Subcategory	References
	Recycling	Recycling	U.S. EPA, 2019c; U.S. EPA, 2019d; EPA-HQ-OPPT-2018-0462-0016
Distribution in commerce [a,b]	Distribution in commerce	Distribution in commerce	
Industrial and Commercial[c]	Construction, Paint, Electrical and Metal Products	Electrical and electronic products (e.g., reactive flame retardant)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016
		Electrical and electronic products (e.g., additive flame retardant in plastic enclosures)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016
		Building/construction materials not covered elsewhere	U.S. EPA, 2019c; NIEHS, 2002
		Batteries (e.g., adhesive in lead-acid battery casings)	Yuasa, 2015
	Furnishing, Cleaning and Treatment/Care Products	Fabric, textile and leather products not covered elsewhere	EPA-HQ-OPPT-2018-0462-0016; NIEHS (2002); IPCS, 1995; Gain, 1997; Gustafsson, 1988
	Other	E.g. Laboratory chemical	Sigma-Aldrich, 2019
Consumer	Construction, Paint, Electrical and Metal Products	Electrical and electronic products (e.g., reactive flame retardant)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0017; EPA-HQ-OPPT-2018-0462-0016
		Electrical and electronic products (e.g., additive flame retardant in plastic enclosures)	U.S. EPA, 2019c; EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016
		Batteries (e.g., adhesive in lead-acid battery casings)	Yuasa, 2015
	Furnishing, Cleaning and Treatment/Care Products	Fabric, textile and leather products not covered elsewhere	EPA-HQ-OPPT-2018-0462-0016; NIEHS, 2002; IPCS, 1995; Gain, 1997; Gustafsson, 1988
Disposal [a]	Disposal	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 rows are highlighted in gray to indicate that no CDR information is provided for this life-cycle stage.

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

[c] For the purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both commercial and industrial uses.

[d] Use definitions also applicable to the life cycle diagram:

- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.

Life Cycle Stage	Category	Subcategory	References
– "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. – "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.			

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, TSCA section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA section 3(4) also grants EPA the authority to determine what constitutes a condition of use for a particular chemical substance. EPA does not plan to include in this scope or in the risk evaluation activities that the Agency has concluded do not constitute conditions of use. No conditions of use were excluded for TBBPA.

2.2.3 Production Volume

Total production volume of TBBPA in 2015 was between 50 million and 100 million pounds, as reported to EPA in the 2016 CDR reporting period (U.S. EPA, 2017). EPA also plans to use CDR production volume information prior to 2015, as detailed in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

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

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). The production volume of TBBPA in 2015 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period, as a range between 50 million and 100 million pounds (Figure 2-7) (U.S. EPA, 2017).

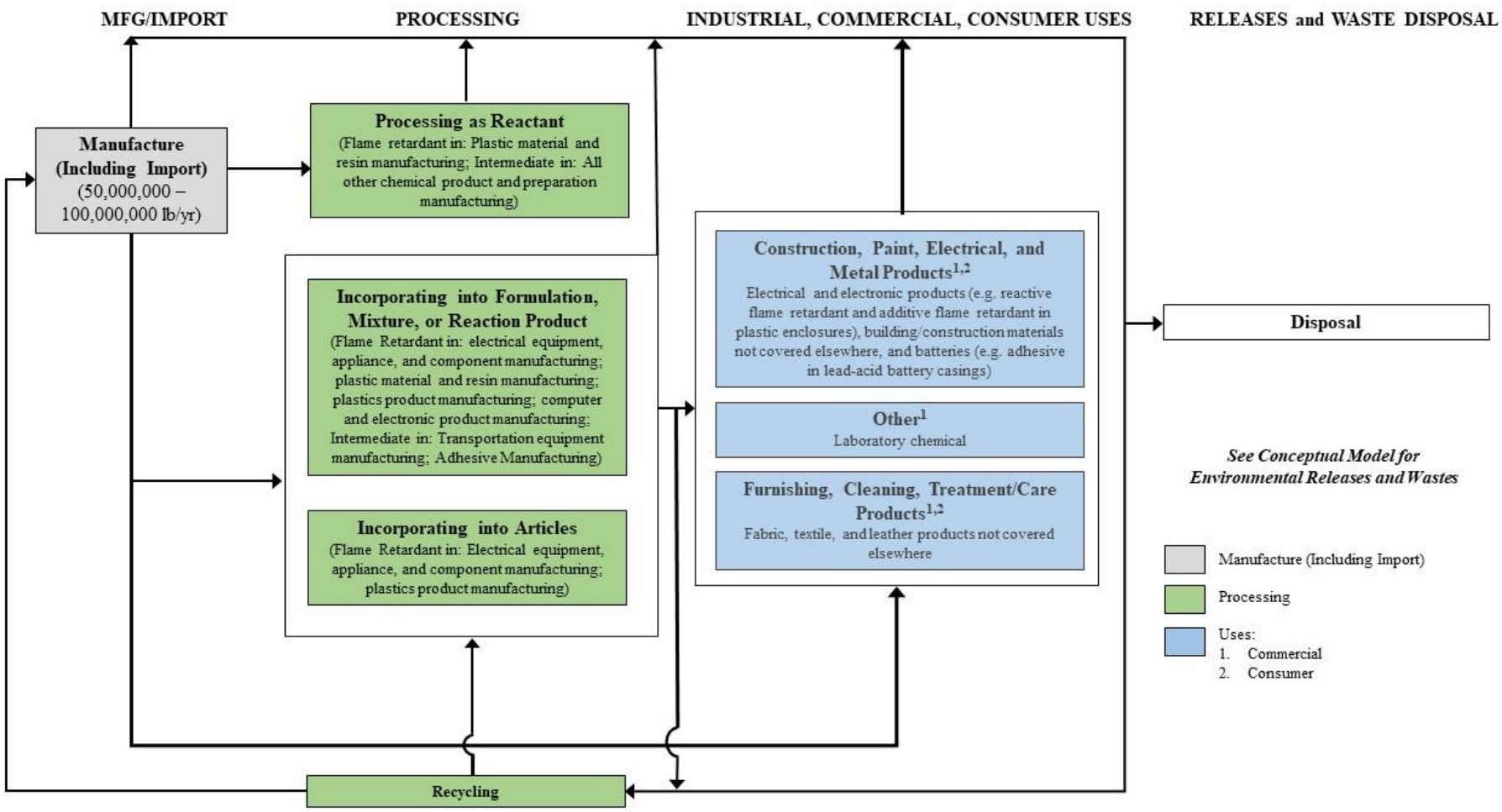

Figure 2-7 TBBPA Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and some commercial and consumer uses as specific production volume from the 2016 CDR is claimed confidential business information (CBI), withheld pursuant to TSCA Section § 14 or unknown.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for TBBPA. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency, and number of exposures in characterizing exposures to TBBPA.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) to support the development of the risk evaluation for TBBPA. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for TBBPA. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a) to support the development of the risk evaluation for TBBPA. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

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

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

Under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), TBBPA is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting [4], facilities in covered sectors in the United States are required to disclose release and other waste management activity quantities of TBBPA under the CASRN 79-94-7 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

[4] For TRI reporting criteria see U.S. EPA (2018b): https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

Table 2-3 provides production-related waste management data for TBBPA reported by facilities to the TRI program for reporting year 2018. As shown in the table, 48 facilities reported a total of 138,456 pounds of TBBPA waste managed. Of the total waste managed, 8,170 pounds were treated, 8,274 pounds were recycled, and 15,252 pounds were combusted for energy recovery. Most TBBPA production-related waste was released to the environment, accounting for 106,760 pounds.

Table 2-3 Summary of TBBPA TRI Production-Related Waste Managed in 2018

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released[a,b,c] (lbs)	Total Production Related Waste (lbs)
2018	48	8,274	15,252	8,170	106,760	138,456

Data source: 2018 TRI Data (U.S. EPA, 2019d)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-4 provides a summary to the environment for the reporting year 2018. Facilities released TBBPA to air (in the form of stack and fugitive emissions), water and land (via underground injection to Class I wells, Resource Conservation and Recovery Act (RCRA) Subtitle C landfills and other land disposal methods). The 99,595 pounds of TBBPA released to land comprised the majority of all TBBPA releases from facilities, accounting for 93% of the total releases. Land disposal methods such as Class I underground injection and RCRA Subtitle C landfills accounted for a relatively small proportion of land releases, whereas "all other land disposal" accounted for 85% of land disposal. Of the 5,887 pounds of TBBPA released to air, on-site stack air releases account for 90% of the total (5,275 pounds). During 2018, 133 pounds of TBBPA were discharged to surface waters on site.

Of the total 106,059 pounds of TBBPA disposed of or otherwise released by TRI facilities during 2018, 65,309 pounds were disposed of or otherwise released on site. Disposal in non-RCRA Subtitle C landfills accounted for 72% (46,742 pounds) of all waste disposed of on site, with on-site disposal in RCRA Subtitle C landfills accounting for the next largest amount at 19% (12,497 pounds). Off-site disposal or other releases of TBBPA comprised 40,750 pounds, with 98% of this waste sent to non-RCRA Subtitle C landfills.

Table 2-4 Summary of Releases of TBBPA to the Environment During 2018

	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal [a] (lbs)		
Totals 2018	48	5,275	612	133	50	12,497	87,048	444	106,059
		5,887			99,595				

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

The total production-related waste managed quantity shown in Table 2-3 does not include any quantities reported as catastrophic or one-time release (TRI Form R Section 8 data). It does include quantities transferred off site to receiving facilities for release or disposal and these same quantities are included in the aggregate as on-site releases by the receiving facilities. This is referred to as "double counting," because the quantities are counted twice. That is, when a facility transfers a quantity of a chemical off site for disposal to another facility, the facility reports the quantity as transferred off site for disposal and the receiving facility reports the same quantity of the chemical as disposed of on site. In processing the data, the TRI program recognizes that this is the same quantity of the chemical and includes it only once in the total releases value, such as in Table 2-3. The production-related waste value in the TRI database, however, considers all instances where the waste is managed (first as a quantity sent off site for disposal and next as a quantity disposed of on-site), and reflects both the off-site transfer and the on-site disposal. As a result, the total release quantities shown in the two tables differ slightly. EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for TBBPA. EPA will use reasonably available information to address potential gaps in TRI reporting.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of TBBPA can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota) via surface water, sediment, soil and ambient air. Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, bioaccumulation and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review available environmental exposure data in biota in the risk evaluation. Monitoring data were identified in EPA's search for reasonably available information and can be used in the exposure assessment. Relevant and reliable monitoring studies provide information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

EPA plans to review available environmental monitoring data found in the literature for TBBPA found in surface water, sediment and soil near and far from point sources. EPA plans to review available monitoring data found in the literature on the presence of TBBPA in various wildlife species such as marine mammals, aquatic invertebrates, fish, and avian species.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.1. In addition, EPA plans analyze exposure to occupational non-users (ONUs), workers who do not directly handle the chemical but perform work in an area where the chemical is present. EPA also plans to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

EPA plans to evaluate potential exposures from the processing of the chemical as it is incorporated into formulations and products. TBBPA can be used as both a reactive and additive flame retardant. EPA plans to evaluate the potential for occupational exposure when TBBPA is used as an additive flame retardant. In general, EPA plans to evaluate the potential for exposure from additive flame retardants due to blooming and release from article components during their manufacture, industrial/commercial use, recycling and disposal.

EPA plans to evaluate the potential for exposure to unreacted TBBPA during the manufacture and industrial/commercial use of article components when it is used as a reactive flame retardant.

EPA also expects to consider potential worker and ONU exposure via the oral route such as from incidental ingestion of TBBPA particulates that deposit in the upper respiratory tract from inhalation exposure.

Worker activities associated with the conditions of use within the scope of the risk evaluation for TBBPA that will be analyzed, include, but are not limited to:

- Unloading and transferring TBBPA to and from storage containers to process vessels during manufacturing, processing and use;
- Handling, transporting and disposing of waste containing TBBPA during manufacturing, processing (including recycling), and use and recycling;
- Cleaning and maintaining equipment; during manufacturing, processing, use and recycling;
- Sampling chemicals, formulations or products containing TBBPA for quality control during manufacturing, processing, and use and recycling;
- Performing other work activities in or near areas where TBBPA is used.

TBBPA is a solid with a vapor pressure of 4.68×10^{-8} mm Hg at 25 ºC/77 ºF (See 2.8Appendix B). EPA anticipates inhalation of dust and other respirable particles as an exposure pathway for workers and ONUs during the manufacture and processing of various articles containing TBBPA (e.g., particulate generated during handling of plastic resins, finishing operations associated with the manufacture and finishing of plastics and plastic articles and incorporation of plastics and other article components into finished products). Occupational exposure limits for TBBPA have not been established by the Occupational Safety and Health Administration (OSHA), the American Conference of Government Industrial Hygienists (ACGIH) or the National Institute for Occupational Safety and Health (NIOSH). However, the OSHA Permissible Exposure Limit (PEL) for Particulates Not Otherwise Regulated (PNOR) (15 mg/m^3) (29 CFR 1910.1000) may be applicable if particulate matter is generated during industrial operations.

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

Based on the conditions of use, EPA plans to evaluate worker dermal exposure from contact with solid during the manufacture of TBBPA, packaging operations and formulation of plastic resins. Dermal exposures for workers are possible during the conditions of uses within the scope of the risk evaluation for TBBPA. Dermal exposure by ONU is not expected for the condition of uses as they are not expected to directly handle the chemical.

2.3.6 Consumer Exposures

Based on CDR reporting information, TBBPA appears to be widely used in consumer products used in indoor environments, specifically fabric, textile, and leather products, electrical and electronic products, building/construction materials and batteries (U.S. EPA, 2019c). TBBPA has been detected in children's products (such as electronics) as well as in small plastic toys and jewelry (U.S. EPA 2015a). Several of

these products have the potential to be mouthed by children. In addition, consumer handling TBBPA containing materials during disposal can lead to consumer and bystander exposures. The main exposure routes where consumers interact with products and articles containing TBBPA are dermal, inhalation and dust ingestion, including children's mouthing of articles (e.g., plastics, textiles, wood products) containing TBBPA.

2.3.7 General Population Exposure

Releases of TBBPA from certain conditions of use, such as manufacturing, processing or disposal activities, may result in general population exposures. EPA plans to evaluate the reasonably available literature for the presence of TBBPA in drinking water, ground water, ambient air, indoor air, fish, human breast milk, and dust and soil, which may be mouthed or ingested.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for TBBPA. EPA considers all the potential environmental hazards for TBBPA identified during prioritization (U.S. EPA 2019) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with TBBPA. If necessary, EPA plans to update the list of potential hazards in the final scope document of TBBPA. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for TBBPA. EPA considers all potential human health hazards for TBBPA identified during prioritization (U.S. EPA 2019a) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME (absorption, distribution, metabolism, and excretion). The broad health effect categories include immunological, neurological, carcinogenic and developmental effects. Genetic toxicity studies were conducted as were respiratory and dermal sensitization tests; however, no effects were observed. Effects were seen in epidemiological and biomonitoring human studies.

Although the high priority designation dossier for TBBPA did not identify reproductive effects, The National Toxicology Program (NTP, 2014) did actually identify atypical endometrium hyperplasia in the uterus as well as uterine tumors. Thus, EPA plans to consider reproductive effects in addition to the other effects identified in U.S. EPA (2019a).

In addition, EPA will also consider new approach methods (NAMs) such as high-throughput assays when evaluating hazards and risks during risk evaluation.

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

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population for adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

During the prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: women of reproductive age (e.g., pregnant women per TSCA statute), workers and consumers (U.S. EPA 2019a). EPA has also added children as a potentially exposed as well as a susceptible subpopulation based on distinct exposure pathways (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and a toxicity study that identified kidney lesions in newborns exposed to TBBPA (Fukuda et al., 2004) briefly discussed in the *TSCA Work Plan Chemical Problem Formulation and Initial Assessment* document for TBBPA (U.S. EPA, 2015a). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

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

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of TBBPA. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.6.1 and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes are shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of TBBPA that EPA plans to include in the risk evaluation. There is potential for exposure to workers and/or ONUs via inhalation routes and exposures to workers via dermal routes. Dermal exposure to TBBPA in both liquid and solid form is expected, as TBBPA can be used/transported as a solid powder or suspended in solution. Inhalation exposure to dust is expected to be a significant exposure pathway. Additionally, potential inhalation exposure to TBBPA in mist form is expected for

certain conditions of use. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not each combination of exposure pathway, route and receptor will be assessed in the risk evaluation. The supporting rationale is presented in Appendix F.

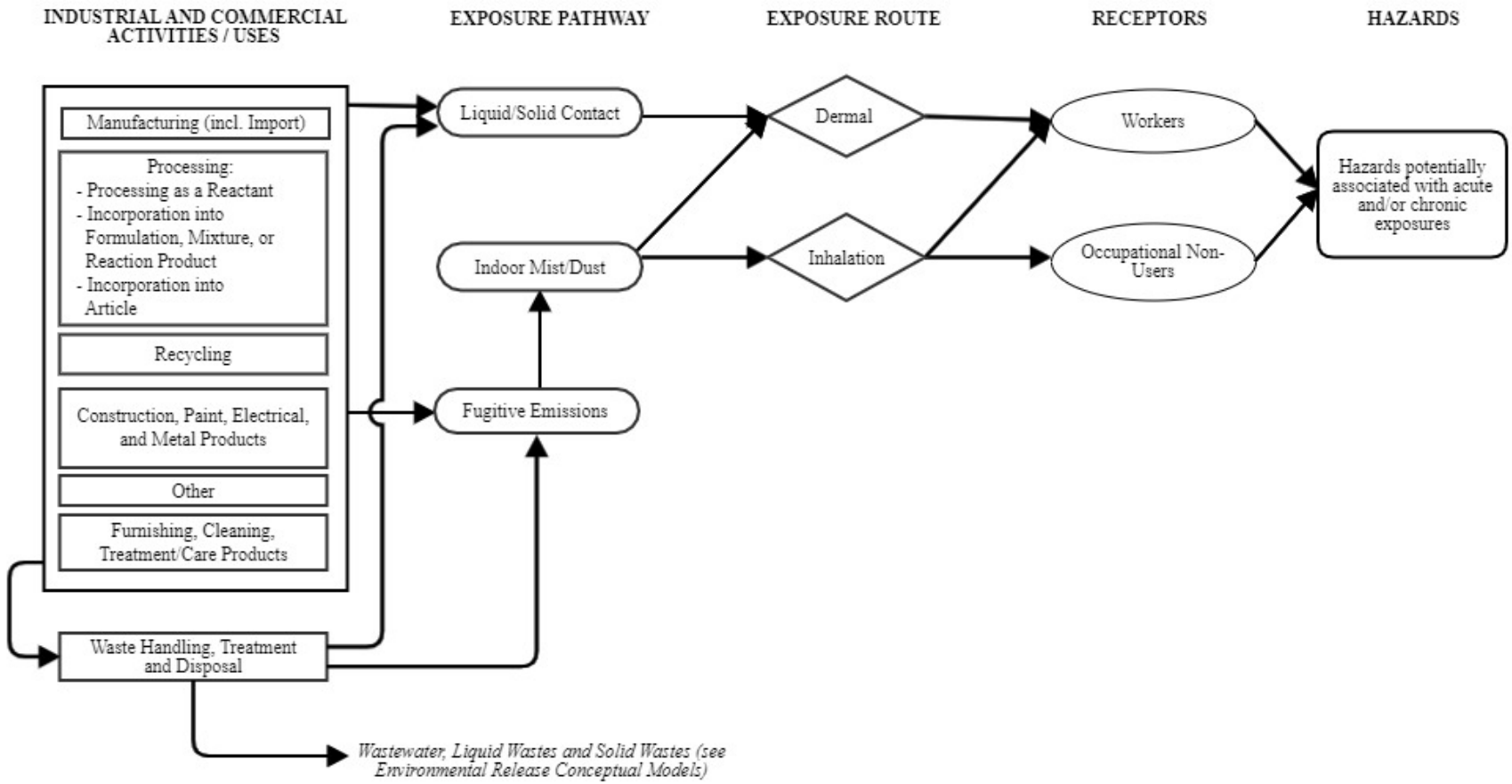

Figure 2-8 TBBPA Conceptual Model for Industrial and Commercial Activities and Uses: Worker and ONU Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of TBBPA.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TBBPA that EPA plans to include in the risk evaluation. Inhalation is expected to be a route of exposure for consumers and EPA plans to evaluate inhalation exposures to TBBPA vapors, mists and dusts for consumers and bystanders. Consumer oral exposures may also result from direct contact with mists and powders or dust containing TBBPA during use. Dermal exposures may result from liquids and mists containing TBBPA. Bystanders are not expected to have significant direct dermal or oral contact to TBBPA products. The supporting rationale for consumer pathways considered for TBBPA are included in Appendix G.

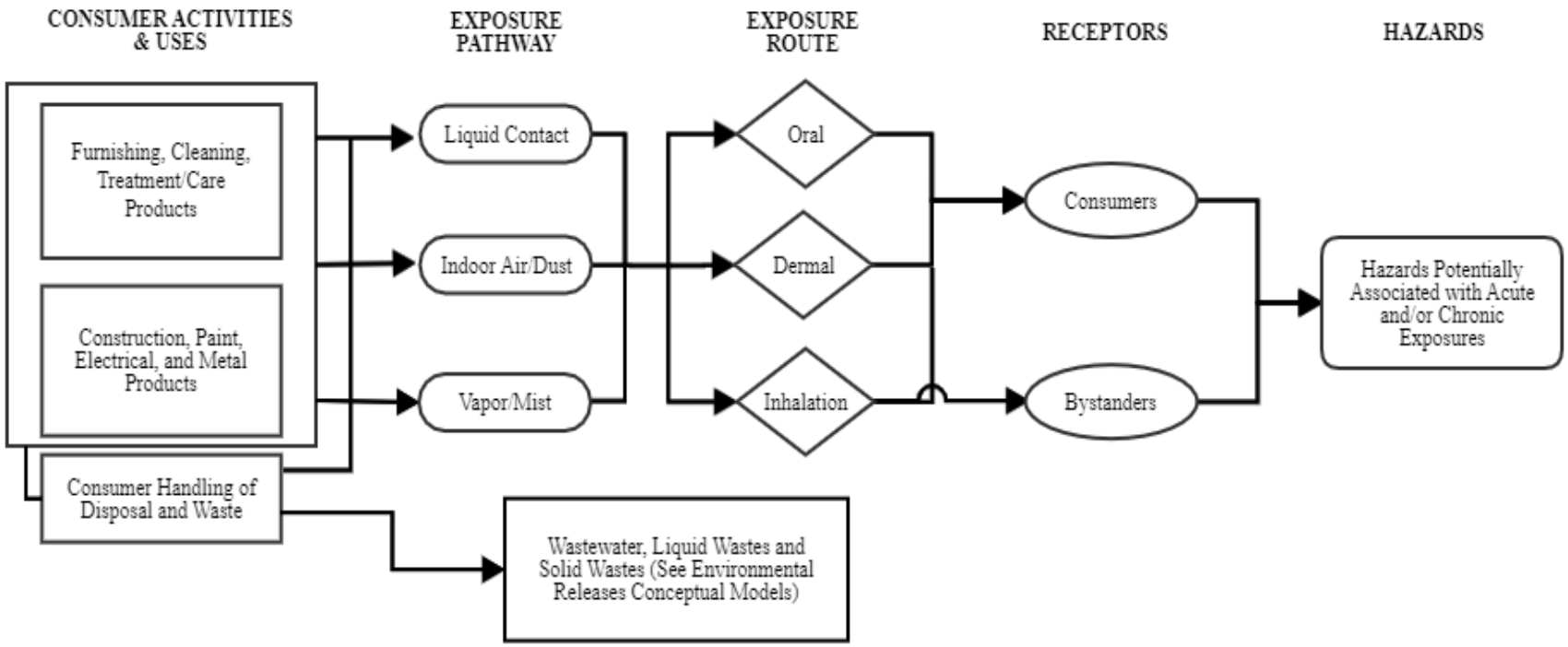

Figure 2-9 TBBPA Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

2.6.3 Conceptual Model for Environmental Releases and Waste: Potential Exposures and Hazards

Figure 2-10 presents the exposure pathways, exposure routes and hazards to human and environmental receptors, respectively, for releases and waste streams associated with environmental releases of and waste from TBBPA. EPA plans to evaluate pathways and routes of exposures to receptors (e.g., general population, aquatic, terrestrial species) that may occur from industrial and/or commercial uses, releases to air, water or land, including biosolids and soil and other conditions of use. EPA expects humans to be exposed to TBBPA from air emissions via inhalation as well as from water, liquid, and solid waste releases; orally via drinking water, fish and soil ingestion; and dermally from contact with groundwater and soil. The supporting rationale for general population and environmental pathways considered for TBBPA are included in Appendix H.

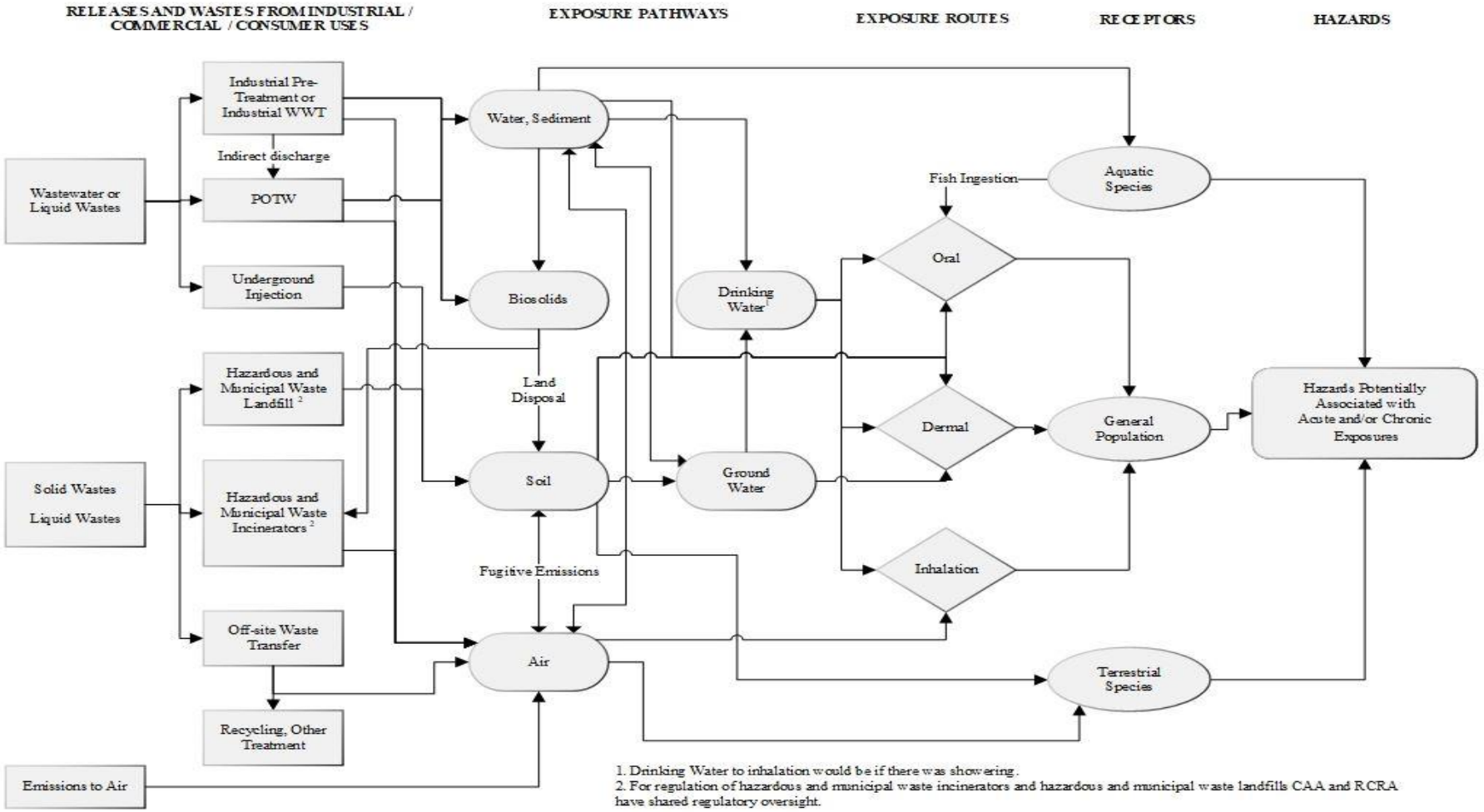

Figure 2-10 TBBPA Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of TBBPA. Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge) or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of TBBPA to date which includes a partial, but not complete review of reasonably available information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources that may be relevant EPA's evaluation of conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. Further, EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document. As discussed in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a), targeted supplemental searches during the analysis phase may be necessary to identify additional reasonably available information (e.g., commercial mixtures) for the risk evaluation of TBBPA.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical properties and environmental fate and transport of TBBPA as follows:

1) **Review reasonably available measured or estimated physical chemical and environmental fate endpoint data collected using systematic review procedures and, where available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the p-chem properties (Appendix B) and fate endpoints (Appendix C) previously summarized in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a). All sources cited in EPA's analysis will be reviewed according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

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

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

2.7.2 Exposure

EPA plans to analyze exposure levels to TBBPA via indoor air, ambient air, surface water, ground water, drinking water, sediment, soil, aquatic biota and terrestrial biota. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios are combinations of sources (uses), exposure pathways and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for TBBPA are presented in Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures.

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

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

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

Table 2-5 Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios (GSs)
OECD Emission Scenario Documents (ESDs)
Canada Screening Assessment Report
EU Risk Assessment Report

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).**
EPA has reviewed key release data sources including TRI, and the data from this source is summarized in Section 2.3.3. EPA plans to continue to review relevant data sources during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases (ChemSTEER, EPA, 2016)

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
EPA has not yet identified surrogate chemicals and data that can be used to estimate releases from uses of TBBPA. EPA plans to review release data for surrogate chemicals that have uses and chemical and physical properties similar to TBBPA as it is identified. EPA may conduct targeted searches for surrogate data.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**
This item will be performed after completion of steps 2 and 3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios).

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GSs) to estimation of environmental releases.**
EPA has identified potentially relevant OECD ESDs and EPA GSs that correspond to some conditions of use; for example, the 2009 ESD on Plastics Additives and the 2011 ESD on the chemical industry may be useful. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

EPA GSs are available at the following: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

GSs that contain information that may be related to the potential uses of TBBPA include, but are not limited to:

- EPA's *Additives in Plastics Processing (Compounding) – Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (May 2004);
- EPA's *Spray Coatings in the Furniture Industry - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (April 2004);
- EPA's *Manufacture and Use of Printing Ink - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (September 2001);
- EPA's *Leather Dyeing - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (September 2000);
- EPA's *Fabric Finishing – Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases (September 1994)* (U.S. EPA, 1994a)*; and,*
- EPA's *Material Fabrication Process for Manufacture of Printed Circuit Boards - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (1994).

OECD ESDs are available at the following: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

ESDs that contain information that may be related to the potential uses of TBBPA include, but are not limited to:

- OECD's *Complementing Document to the ESD On Plastic Additives: Plastic Additives During the Use of End Products* (May 2019);
- OECD's *ESD on the Use of Textile Dyes* (February 2017);
- OECD's *Complementing Document for ESD on Coating Industry: Application of Paint Solvents for Industrial Coating* (December 2015);
- OECD's *ESD on the Chemical Industry* (September 2011);
- OECD's *ESD on Radiation Curable Coating, Inks, and Adhesives* (July 2011);
- OECD's *ESD on Plastic Additives* (July 2009); and
- OECD's *ESD on Coating Industry (Paints, Lacquers and Varnishes)* (July 2009).

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g., recycling, building/construction materials not covered elsewhere). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping/grouping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

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

2.7.2.2 Environmental Exposures

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

1) **Review available environmental and biological monitoring data for all media relevant to environmental exposure.**
For TBBPA, environmental media which will be analyzed are sediment, biosolids, soil, air and water. The environmental exposure pathways which have been identified in the literature include aquatic and terrestrial.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**
EPA plans to analyze reasonably available environmental exposure models that meet the TSCA section 26(h) and (i) Science Standards and that estimate water, sediment and soil concentrations alongside reasonably available water, sediment and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into water, sediment or soil, indirect release into water, sediment or soil (i.e., air deposition), fate and

transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

3) **Review reasonably available biomonitoring data for vegetation, invertebrates, fish, non-fish vertebrates (i.e., amphibians, reptiles, mammals). Plan to consider whether these data could be used to compare with comparable species or taxa-specific toxicological benchmarks.**
EPA plans to analyze predatory bird species that consume fish with elevated levels of TBBPA will be analyzed. If species-specific biomonitoring data matches toxicity studies, direct comparisons can be made. EPA plans to consider refining data for other species by using body weight of the birds, fish ingestion rate of birds and typical fish species consumed.

4) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
There have been changes to use patterns of TBBPA over the last few years. Monitoring data or modeled estimates will be reviewed to determine how representative they are of applicable use patterns.

   EPA plans to evaluate any studies that relate levels of TBBPA in the environment or biota with specific sources or groups of sources.

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

6) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using systematic review methods.

2.7.2.3 Occupational Exposures

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

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

2) **Review reasonably available exposure data for surrogate chemicals that have uses and chemical and physical properties similar to TBBPA.**
   EPA plans to review exposure data for surrogate chemicals that have uses and chemical and physical properties similar to TBBPA.

3) **For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.**
   For conditions of use where data are not available, EPA plans to review existing exposure models that may be applicable in estimating exposure levels of TBBPA.

   EPA has identified potentially relevant OECD ESDs and EPA GSs corresponding to some conditions of use. EPA plans to critically review these GSs and ESDs to determine their applicability to the conditions of use assessed. EPA may conduct industry outreach efforts or perform supplemental, targeted literature searches to better understand the process steps involved in conditions of use. EPA plans to also consider the applicability of exposure models in ChemSTEER (U.S. EPA, 2016)) tool that are routinely used for assessing new chemicals to assess exposures during various conditions of use. EPA may also perform targeted research to identify other models that EPA could use to estimate exposures for certain conditions of use.

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

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

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use. As presented in Appendix F, EPA has grouped the scenarios into representative release/exposure scenarios, all of which will be analyzed. EPA was not able to identify occupational scenarios corresponding to some conditions of use (e.g., recycling, construction and demolition). EPA may further refine the mapping/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

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

2.7.2.4 Consumer Exposures

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

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

For TBBPA, the following are noteworthy considerations in constructing consumer exposure scenarios:
- Conditions of use and type of consumer product
- Duration, frequency and magnitude of exposure
- Weight fraction of chemical in products
- Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
Indoor exposure pathways expected to be relatively higher include particle inhalation, dust ingestion, and dermal contact as a result of indoor use of TBBPA consumer products. Indoor exposure pathways expected to be relatively lower include inhalation of vapor and mist and liquid and mist oral ingestion. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air, indoor dust concentrations, or indoor dust surface loadings.**

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

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

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

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

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

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering sources and uses, exposure pathways including routes and exposed populations.**
For TBBPA, the following are noteworthy considerations in constructing exposure scenarios for the general population: routes of exposure, releases to air, water or land resulting from industrial, commercial, and other conditions of use, in addition to:
    - Review of reasonably available environmental and biological monitoring data for media to which general population exposures are expected;
    - For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels;
    - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling;
    - Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available;
    - Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data;
    - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined;
    - Evaluate the weight of the evidence of general population exposure data; and
    - Mapping or grouping each condition of use to general population exposure assessment scenario(s).

    EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix H. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative or quantitative and is dependent upon reasonably available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with reasonably available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups. If available, EPA plans to compare multiple scenario-specific and background exposure doses estimated from media-specific concentrations and exposure factors with available biomonitoring data. The forward-calculated and back-calculated exposures could be compared to characterize the relative contribution from defined exposure scenarios.

    After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways and receptors are characterized. The number of scenarios is also dependent upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is

reasonably available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **Review reasonably available environmental and biological monitoring data for exposure pathways and media to which general population exposures are expected.**
   General population exposure pathways expected to be relatively higher include: ingestion of water and food including fish, root crops, and mother's milk. General population exposure pathways expected to be relatively lower include: dermal contact to TBBPA via liquids, and inhalation of TBBPA via vapors, mists and dusts. The data sources associated with these respective pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **For exposure pathways where empirical data is not available, review exposure models that may be applicable in estimating exposure levels.**
   For TBBPA, EPA plans to consider exposure models for general population exposure, including models that estimate surface water concentrations, sediment concentrations, soil concentrations and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

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

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

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

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

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

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

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

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

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

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

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

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments.**
EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the TBBPA conceptual model. These organisms may be exposed to TBBPA via a number of environmental pathways (e.g., surface water, sediment, soil, diet).

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

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

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

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

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

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

   EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for TBBPA exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

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

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

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

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

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

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

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

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

2.7.4 Summary of Risk Approaches for Characterization

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

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

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

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook (U.S. EPA, 2015b) and other methods consistent with section 26 of TSCA (See 40 CFR 702.45). As explained in the preamble to the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment (see 82 Fed. Reg. 33726, 33744 (July 12, 2017). Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment and risk characterization.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1 Gray Literature Sources That Yielded Results for TBBPA

Source/ Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Australian Government Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer, Notice	Other US Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	Design for the Environment (DfE) Alternatives Assessments	US EPA Resources	Assessment or Related Document
EPA	TSCA Assessments	US EPA Resources	Assessment or Related Document
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List

EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
IARC	IARC Monograph	International Resources	Assessment or Related Document
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine’s Hazardous Substance Databank	Other US Agency Resources	Database
NLM	NIEHS Tox Review	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine’s PubChem	Other US Agency Resources	Database

NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Dietary Intake	International Resources	Assessment or Related Document
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

This appendix provides p-chem information and data found in preliminary data gathering for TBBPA. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019a) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0462).

Table_Apx B-1 Physical and Chemical Properties of TBBPA

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{15}H_{12}Br_4O_2$	NA	NA
Molecular weight	543.88 g/mol	NA	NA
Physical state	Solid crystals	O'Neil, 2013	High
Physical properties	Odorless	NLM, 2018	High
	White	Elsevier, 2019	High
Melting point	181°C	U.S. EPA, 2019	High
Boiling point	316°C	NLM, 2018	High
Density	2.158 g/cm^3 at 19.85°C	Elsevier, 2019	High
Vapor pressure	4.68×10^{-9} mm Hg at 25°C	NLM, 2018	High
Vapor density	Not available		
Water solubility	4.15 mg/L at 298 K (pH 7.56)	Kuramochi, 2008	High
Log Octanol/water partition coefficient (Log Kow)	4.75 at 298 K (pH 7.53	Kuramochi, 2008	High
Henry's Law constant	1.45×10^{-10} atm·m^3/mol at 298 K	Kuramochi, 2008	Medium
Flash point	Not available		

Auto flammability	Not available		
Viscosity	Not available		
Refractive index	Not available		
Dielectric constant	Not available		

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

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for TBBPA. This information has not changed from that provided in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a).

Table_Apx C-1 Environmental Fate Characteristics of TBBPA

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	$t_{1/2}$ = 17 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 × 10^{-5} (at pH 5.5) to 6.8 × 10^{-4} (at pH 9) per second	HSDB (2018) citing Eriksson (2004)
	2,6-dibromo-p-benzosemiquinone anions and TBBPA were identified as the main photodecomposition byproducts	HSDB (2018) citing Han (2016)
Indirect Photodegradation	$t_{1/2}$ = 3.615 days (based on ·OH rate constant of 2.96 × 10^{-12} cm^3/mol sec at 25 ºC and 12-hour day with 1.5 × 10^6 ·OH/cm^3; estimated)[b]	U.S. EPA (2012b)
Hydrolysis	Not expected to undergo hydrolysis in the environment due to the lack of functional groups that hydrolyze under environmental conditions	HSDB (2018) citing Lyman (1990)
Biodegradation (Aerobic)	Water: 0%/14 days (MITI)	HSDB (2018); NITE (2018)
	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	OECD (2005)
	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	HSDB (2018) citing Islam (2015)

	of 76–83% with conventional activated sludge and bioreactor systems	
Bioconcentration Factor	30–341 and 52–485 for Carp (*Cyprinus carpio*), which were exposed over an 8-week period to concentrations of 80 and 8 µg/L, respectively	NITE (2018)
	307 measured in fathead minnow (*Pimephales promelas*)	HSDB (2018) citing Hardy (2004)
Bioaccumulation Factor	720 (estimated)[b]	U.S. EPA (2012b)
Soil Organic Carbon:Water Partition Coefficient (Log K_{oc})	5.4 (K_{oc} = 2.7 × 10^5 MCI method; estimated)[b]	U.S. EPA (2012b)
	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: [a]Measured unless otherwise noted;

[b]EPI SuiteTM physical property inputs: SMILES Oc(c(cc(c1)C(c(cc(c(O)c2Br)Br)c2)(C)C)Br)c1Br)

Appendix D REGULATORY HISTORY

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

TBBPA is regulated in the United States within EPA, in multiple states and internationally. Primarily TBBPA is regulated by TSCA, but it also included in the Emergency Planning and Community Right-To-Know Act (EPCRA); therefore, listed on the Toxics Release Inventory. Several states list TBBPA as a chemical of concern or a chemical of high concern for children. California regulates TBBPA through multiple processes such as Proposition 65, California's Safer Consumer Products Program, a Health Hazard Alert and TBBPA is designated for biomonitoring. Internationally, TBBPA is either listed as a domestically used chemical, assessed or regulated in Canada, the European Union, Australia, Japan, the Basel Convention and OECD's Control of Transboundary Movements of Wastes Destined for Recovery Operations.

D.1 Federal Laws and Regulations

Table_Apx D-1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	TBBPA is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of TBBPA as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	TBBPA manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	TBBPA was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a	11 risk reports received for TBBPA (1992-2005**)** (U.S.

	chemical substance or mixture presents a substantial risk of injury to health or the environment.	EPA, ChemView. Accessed June 25, 2019).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	14 chemical data submissions from test rules received for TBBPA: eight ecotoxicity reports and six environmental fate reports (1986-1994) (U.S. EPA, ChemView. Accessed April 2, 2019).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	TBBPA is a listed substance subject to reporting requirements (40 CFR 372.65, effective January 1, 2000).

D.2 State Laws and Regulations

Table_Apx D-2 State Laws and Regulations

State Actions	Description of Action
State Prohibitions	California adopted a prohibition on the selling and distribution in commerce of new, not previously owned juvenile products, mattresses, or upholstered furniture that contains, or a constituent component of which contains, covered flame retardant chemicals at levels above 1,000 parts per million (A.B. 2998, Legislative Council, Sess. 2017-2018, C.A. 2018).
State Right-to-Know Acts	New Jersey lists TBBPA as a chemical of concern: persistent, bioaccumulative, toxic (PBT) substance on the Environmental Hazardous Substance List, (N.J.A.C. 7:1G-2).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing TBBPA, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).
Other	California listed TBBPA on Proposition 65 in 2017 due to cancer. (Cal Code Regs. Title 27, § 27001). TBBPA is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253).

	California issued a Health Hazard Alert for TBBPA (Hazard Evaluation System and Information Service, 2016). https://oehha.ca.gov/chemicals/tetrabromobisphenol California lists TBBPA as a designated priority chemical for biomonitoring (California SB 1379). http://www.biomonitoring.ca.gov/chemicals/chemicals-biomonitored-california The Oregon Department of Environmental Quality lists TBBPA as a priority persistent pollutant (Oregon SB 737). 2009. page 39 https://digital.osl.state.or.us/islandora/object/osl%3A20601/datastream/OBJ/view

D.3 International Laws and Regulations

Table_Apx D-3 Regulatory Actions by other Governments, Tribes, and International Agreements

Country/Tribe/ Organization	Requirements and Restrictions
Canada	TBBPA is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed April 16, 2019).
European Union	TBBPA is registered for use in the EU. (European Chemicals Agency (ECHA database. Accessed April 16, 2017). The Waste Electrical and Electronic Equipment (WEEE) directive 2012/19/EU requires the separation of plastics containing brominated flame retardants prior to recycling (European Commission WEEE). TBBPA was evaluated under the 2015 Community rolling action plan (CoRAP) under regulation (European Commission [EC]) No 1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). Additional information was requested and is due January 2021. (ECHA database. Accessed April 16, 2019). TBBPA is being evaluated and considered by the European Commission for addition to the Restriction of Hazardous Substances Directive, which currently restricts the use of ten hazardous substances at more than 0.1% by weight at the 'homogeneous material' level in electrical and electronic equipment. (European Commission RoHS).
Australia	In 2001, TBBPA was assessed. (Polybrominated Flame Retardants. Priority Existing Chemical Assessment Report No. 20 (2001)).
Japan	TBBPA is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Water Pollution Control Law (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. Accessed April 9, 2019).
Basel Convention	Waste substances and articles containing or contaminated with polychlorinated biphenyls (PCBs) and/or polychlorinated

	terphenyls (PCTs) and/or polybrominated biphenyls (PBBs) and wastes, substances and articles containing, consisting of or contaminated with polychlorinated biphenyl (PCB), polychlorinated terphenyl (PCT), polychlorinated naphthalene (PCN) or polybrominated biphenyl (PBB), or any other polybrominated analogues of these compounds, at a concentration level of 50 mg/kg or more are listed as a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	Wastes, substances and articles containing, consisting of or contaminated with polychlorinated biphenyl (PCB), polychlorinated terphenyl (PCT), polychlorinated naphthalene (PCN) or polybrominated biphenyl (PBB), or any other polybrominated analogues of these compounds, at a concentration level of 50 mg/kg or more are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

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

E.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities.

E.1.1 Manufacture (Including Import)

E.1.1.1 Domestic Manufacturing

TBBPA is produced by the bromination of bisphenol-A in the presence of a solvent. This reaction may be conducted in the presence of a hydrocarbon solvent only or with water, 50% hydrobromic acid or aqueous alkyl mono ethers. When methanol is used as the solvent, methyl bromide is formed as a by-product. The production process is largely conducted in closed systems. (EFSA, 2018)

E.1.1.2 Import

EPA expects that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and quality control samples may be taken for analyses (U. S. EPA, 2018c).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant

Processing as a reactant or intermediate is the use of TBBPA as a feedstock in the production of another chemical product via a chemical reaction in which TBBPA is consumed to form the product (U.S. EPA, 2018c).

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

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. TBBPA may undergo several processing steps and the processing is dependent on its downstream incorporation into articles.

E.1.2.3 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of TBBPA-containing formulations or reaction products are dependent on the article (EPA, 2018d). For example, TBBPA may be incorporated into electrical equipment, appliance and component and plastics products as a flame retardant (U.S. EPA, 2019c). EPA plans to further investigate the use of TBBPA being incorporated into articles during risk evaluation.

E.1.2.4 Recycling

EPA did not identify TBBPA-specific information for recycling at this time; however, this chemical has been identified in articles that are commonly recycled such as plastics and electronic materials which indicates that recycling may occur for waste plastics and for electronics wastes. The processes for

recycling these materials may include grinding, washing, and rinsing the recycled material and incorporating it into new formulations and articles. Electronics waste recycling may include recovery of plastics through similar recycling processes, which are described more generally in Kirk Othmer (Kirk-Othmer, 2006). EPA has not identified specific worker activities related to the recycling TBBPA-containing products. Based on EPA's knowledge, worker activities are anticipated to be exposed to TBBPA from reclamation activities such as sorting, materials grinding steps and loading recovered materials into transport containers.

E.1.3 Uses Included in Scope

E.1.3.1 Adhesive Manufacturing

The American Coatings Association (ACA) informed EPA that TBBPA is used as a flame retardant in adhesives and sealants and that specialty products may have amounts above 10% (EPA-HQ-OPPT-2018-0462-0003). The Aerospace Industry Association (AIA) informed EPA that TBBPA is used as an adhesive (films and epoxy) used by the aerospace industry (EPA-HQ-OPPT-2018-0462-0004). The National Institute of Environmental Health Sciences (NIEHS) identified the use of TBBPA in adhesives and coatings (NIEHS, 2002). Four facilities in the "Adhesive Manufacturing" sector reported to TRI in 2017 for TBBPA.

E.1.3.2 Intermediate (e.g., transportation equipment manufacturing)

One company, Huntsman Corporation – The Woodlands Corporate Site, reported to CDR (U.S. EPA, 2019c) that TBBPA is used as an intermediate in transportation equipment manufacturing, for industrial manufacturing. The Government of Canada's Screening Assessment Report (Canada, 2013) states that TBBPA is used to make motor housings, and that ABS resins containing are used in automotive parts. An ABS product was identified as containing TBBPA and used in automobile interior housing. Furthermore, the Aerospace Industry Association (AIA) informed EPA that TBBPA is used as an adhesive (films and epoxy) and in prepreg used by the aerospace industry (EPA-HQ-OPPT-2018-0462-0004). Specifically, AIA noted that TBBPA is used for its flame retardance and temperature stability properties on structural film adhesives, resins for honeycomb core, and in epoxy pre-impregnated fiberglass or graphite tapes or woven fabrics. According to AIA, TBBPA-containing materials are qualified for use in company proprietary specifications and are certified/approved by civil aviation airworthiness authorities and DOD customers used by the aerospace industry. Six facilities in the "Other Aircraft Parts and Auxiliary Equipment Manufacturing" sector and three facilities in the "Aircraft Manufacturing" sector reported to TRI in 2017 for TBBPA.

E.1.3.3 Intermediate (e.g., all other chemical product and preparation manufacturing)

The Chemtura company, at two sites, reported to CDR (U.S. EPA, 2019c) that TBBPA is used as an intermediate in chemical product and preparation manufacturing. Two facilities in the "Other Basic Inorganic Chemical Manufacturing" sector reported to TRI in 2017 for TBBPA.

E.1.3.4 Building/Construction Materials

One company, Lintech International Inc., reported to CDR (U.S. EPA, 2019c) that it is used as a processing aid in plastic material and resins manufacturing, to make building/construction materials. The Government of Canada's Screening Assessment Report for TBBPA (Canada, 2013) states that it is used flame-retardant resins containing TBBPA are found in glass-reinforced construction panels.

E.1.3.5 Electrical and Electronic Products

Three companies reported to CDR (U.S. EPA, 2019c) that TBBPA is used as a flame retardant in electrical equipment, appliance and component manufacturing and in computer and electronic product

manufacturing. Electrical and electronics are divided into two groups those that use TBBPA as an additive flame retardant in plastic enclosures and those that use TBBPA as a reactive flame retardant such as in printed circuit boards. Additive flame retardants are not chemically bonded to the base material while reactive flame retardants are chemically bonded. The American Chemistry Council in its public comments noted that the main application of TBBPA is in printed circuit boards or laminates (EPA-HQ-OPPT-2018-0462-0003). The National Institute of Environmental Health Sciences identifies the use of TBBPA in electronic enclosures made of polycarbonate-acrylonitrile-butadiene-styrene and in integrated circuit chips (NIEHS, 2002). The Government of Canada's Screening Assessment Report (2013) states that TBBPA is used to make rigid epoxy-laminated printed circuit boards and terminal boards. Canada (2013) further reports that flame-retarded resins made with TBBPA are used in communications and electronics equipment, appliances and lighting fixtures, while acrylonitrile-butadiene-styrene (ABS) resins containing TBBPA are used in refrigerators and other appliances, business machines and telephones. One facility in the "Semiconductor and Related Device Manufacturing" sector, one facility in the "Current-Carrying Wiring Device Manufacturing" sector and one facility in the "Other Electronic Component Manufacturing" sector reported to TRI in 2017 for TBBPA.

E.1.3.6 Plastic Products and Resins

One company, Sabic Innovatice Plastics, reported to CDR (U.S. EPA, 2019c) that TBBPA is used as a flame retardant in plastics product manufacturing. According to Canada (2013), TBBPA is incorporated into polymers as a reactive or additive flame retardant for use in flame-retarded epoxy and polycarbonate resins and, to a lesser extent, in acrylonitrile-butadiene-styrene (ABS) resins and phenolic resins. Applications of flame-retarded polycarbonate resins include communications and electronics equipment, appliances, transportation devices, sports and recreation equipment, lighting fixtures and signs. ABS resins containing TBBPA are used in automotive parts, pipes and fittings, refrigerators and other appliances, business machines and telephones. The ECHA registration dossier for TBBPA (ECHA, 2019) identifies the use of TBBPA as a reactive intermediate in the manufacture of polymer resins, and in the manufacture of polymer resins/articles containing additive flame retardant, in European countries. Ten facilities in the "Plastics Material and Resin Manufacturing" sector and five facilities in the "All Other Plastics Product Manufacturing" reported to TRI in 2017 for TBBPA. One facility in the "Other Industrial Machinery Manufacturing" sector also reported to TRI in 2017 for TBBPA; this company, LMR Plastics, is a thermoplastic injection molding company. The plastic products and resins condition of use overlaps with the electrical and electronic products conditions of use. Further research and stakeholder outreach will be conducted to increase understanding and reduce overlap. EPA does not believe that TBBPA is used in plastics other than those which are electronics unless electronic plastic is recycled and reformed into a plastic product with no electronic component.

E.1.3.7 Fabric, Textiles and Leather Products not Covered Elsewhere

The National Institute of Environmental Health Sciences identifies the use of TBBPA as a flame retardant in textiles, and further states that TBBPA is applied to carpeting and office furniture (NIEHS, 2002). Two facilities in the "Fabric Coating Mills" sector reported to TRI in 2017 for TBBPA. There also provides evidence that TBBPA was once used in textiles (NIEHS, 2002; IPCS, 1995; Gain, 1997; Gustafsson, 1988). However, specific uses of TBBPA in textiles are unknown. Based on Washington State data it is believed that presence of TBBPA in textiles for children's clothing is only at contaminant levels. EPA plans to further investigate if there is any evidence of TBBPA in textiles as an ongoing use during this risk evaluation and encourages the public to submit information pertaining to this use.

E.1.3.8 Batteries

Based on SDS information provided by the State of California, TBBPA may be used as an adhesive in lead acid battery casings. EPA did not identify TBBPA-specific process information for adhesive and sealant use within batteries; however, the OECD ESD for Use of Adhesives provides general process descriptions and worker activities for industrial adhesive uses. Liquid adhesives are unloaded from containers into the coating reservoir, applied to a flat or three-dimensional substrate and the substrates are then joined and allowed to cure (OECD, 2013). The majority of adhesive applications include spray, roll, curtain, syringe or bead application (OECD, 2013). For solvent-based adhesives, the volatile solvent evaporates during the curing stage (OECD, 2013). Based on EPA's knowledge of the industry, overlap in process descriptions, worker activities and application methods are expected for sealant products.

E.1.3.9 Laboratory Chemical

A safety data sheet for TBBPA (<=100% percent purity) indicates recommended use as a laboratory chemical (Sigma-Aldrich, 2020). However, specific laboratory use activities are unknown. EPA plans to further investigate the laboratory use of TBBPA during the risk evaluation.

E.1.3.10 Disposal

Disposal of a chemical should take into consideration the chemical's potential impact on air quality, migration to groundwater, effect on biological species, and disposal regulations (ATSDR, 2017). Currently, TBBPA is not regulated under federal regulations as a hazardous waste (HAP List/RCRA Hazardous Waste Lists). However, TBBPA may be disposed of as a hazardous waste if it is present in or co-mingled with solvent mixtures that are RCRA regulated substances (U.S. EPA, 2018c).

Demolished building materials are classified as Construction and Demolition (C&D) waste, which may be disposed in municipal solid waste landfills (MSWLFs) or C&D landfills (EPA, 2018d; EPA, 2014).

E.2 Preliminary Occupational Exposure Data

EPA plans to consider reasonably available data and information related to worker exposure and environmental releases as they are identified during systematic review. Based on a preliminary data gathering, there are no OSHA Chemical Exposure and Health Data (CEHD) specific to TBBPA. However, EPA identified three NIOSH health hazard evaluations, which may have relevant monitoring data.

Table_Apx E-1 Potentially Relevant Data Sources for Exposure Monitoring and Area Monitoring Data from NIOSH Health Hazard Evaluations for TBBPA[a]

Year of Publication	Report Number	Facility Description
2018	HHE-2015-0050-3308	Electronics recycling company
2017	HETA-2014-0131-3308	Gymnastics studios
2016	HHE-2013-0075-3264	Production of automotive parts

[a] Table includes HHEs identified to date

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

Table_Apx F-1 Worker and ONU Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture of TBBPA via bromination of bisphenol-A in the presence of solvent	Liquid Contact	Dermal	Workers	Yes	Due to the presence of solvent in the manufacturing process, exposure to TBBPA suspended in liquid will occur during equipment cleaning and transfer/loading/packaging operations.
				Solid Contact	Dermal	Workers	Yes	According to CDR, all domestically manufactured TBBPA is in the form of a dry powder. Dermal exposure will occur when the material is packaged.
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10 -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during the manufacturing process.
				Dust	Inhalation	Workers, ONU	Yes	According to CDR, all domestically manufactured TBBPA is in the form of a dry powder. Inhalation exposure to TBBPA via fugitive dust will occur when the material is packaged.
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacture	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	According to CDR, one submitter indicated that they import TBBPA in liquid form (30-60% concentration). EPA interprets this as solid TBBPA suspended in solution. Exposure will occur if the imported material is repackaged
				Solid Contact	Dermal	Workers	Yes	According to CDR, multiple submitters indicated that they imported TBBPA in solid form. Exposure will occur if the imported material is repackaged.
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during the import (i.e. repackaging) process.
				Dust	Dermal	Workers	Yes	According to CDR, multiple submitters indicated that they imported TBBPA in the form of dry powder. Exposure will occur if the imported material is repackaged.
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	As a reactant	Flame retardant in plastic material and resin manufacturing	Unloading	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as TBBPA can be used/transported suspended in solution (according to CDR data).
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as TBBPA is in solid form, including dust.
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during the manufacturing of other chemicals.
				Dust	Inhalation	Workers ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during the manufacturing of other chemicals (e.g., unloading TBBPA powder).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Processing	As a reactant	Intermediate in all other chemical product and preparation manufacturing	Unloading	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as TBBPA can be used/transported while suspended in solution (according to CDR data).
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during manufacturing of other chemicals, as TBBPA is in solid form, including dust.
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during the manufacturing of other chemicals.
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during the manufacturing of other chemicals (e.g., unloading TBBPA powder).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporated into Formulation, Mixture, or Reaction Product	Flame retardant in electrical equipment, appliance, and component manufacturing; plastic material and resin manufacturing; plastics product manufacturing; computer and electronic product manufacturing	Unloading	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations for incorporation into formulation, mixture, or reaction product, as TBBPA can be used/transported while suspended in solution (according to CDR data).
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations for incorporation into formulation, mixture, or reaction product,, as TBBPA is in solid form.
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product).
				Dust	Dermal	Workers	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during unloading operations for incorporation into formulation, mixture, or reaction product.
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Processing		Intermediate in transportation equipment manufacturing; adhesive manufacturing	Unloading	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations, as TBBPA can be used/transported while suspended in solution (according to CDR data).
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations, as TBBPA is in solid form.
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during unloading operations.
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during unloading operations.
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Incorporated into article	Flame retardant in Electrical equipment, appliance, and component manufacturing; plastics product manufacturing	Unloading	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations, as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during loading operations, as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during loading operations.
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during loading operations.
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Processing	Recycling	Recycling	Recycling	Liquid Contact	Dermal	Workers	No	The potential for exposures to workers does not exist during processing (recycling), as recycled materials containing TBBPA are primarily solid.
				Solid Contact	Dermal	Workers	Yes	Potential for exposure during recycling of articles containing residual (unreacted) TBBPA .
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during recycling operations).
				Dust	Inhalation	Workers, ONU	Yes	Potential for exposure during recycling of articles containing residual (unreacted) TBBPA
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Industrial and Commercial Use	Construction, Paint, Electrical, and Metal Products	Electrical and Electronic Products (e.g., reactive flame retardant)	Production of electrical and electronic products	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Electrical and Electronic Products), as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Electrical and Electronic Products), as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during this use (Electrical and Electronic Products).
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during this use (Electrical and Electronic Products).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial and Commercial Use	Construction, Paint, Electrical, and Metal Products	Electrical and Electronic Products (e.g., additive flame retardant in plastic enclosures)	Production of electrical and electronic products	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Electrical and Electronic Products), as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Electrical and Electronic Products), as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during this use (Electrical and Electronic Products).
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during this use (Electrical and Electronic Products).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
		Building/ construction materials not covered elsewhere	Use of construction panels and other materials	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Building/Construction Materials), as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Building/Construction Materials), as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	Yes	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during this use (Building/Construction Materials).
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder and in articles that could be cut and sawed during construction processes, thus exposure to dust is likely during this use (Building/Construction Materials).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial and Commercial Use	Construction, Paint, Electrical, and Metal Products	Batteries (e.g., adhesive in lead acid battery casings)	Battery production	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Batteries, adhesives in lead acid battery casings), as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Batteries, adhesives in lead acid battery casings), as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during this use (Batteries, adhesives in lead acid battery casings).
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during this use (Batteries, adhesives in lead acid battery casings).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
	Other	Laboratory chemical	Use of laboratory chemicals	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Laboratory Chemical), as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Laboratory Chemical), as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during this use (Laboratory Chemical).
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during this use (Laboratory Chemical).
				Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Laboratory Chemical), as TBBPA can be used/transported while suspended in solution (according to CDR data)

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial and Commercial Use	Furnishing, Cleaning, Treatment/ Care Products	Fabric, textile, and leather products not covered elsewhere	Textile finishing	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Fabric, textile and leather products not covered elsewhere), as TBBPA can be used/transported while suspended in solution (according to CDR data)
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Fabric, textile and leather products not covered elsewhere), as TBBPA is in solid form
				Vapor, Mist	Inhalation	Workers, ONU	No	Due to the volatility of TBBPA (VP =4.68*10^ -8 Torr) at room temperature, inhalation exposure to TBBPA in the vapor phase is not expected. Mist generation is not expected during this use (fabric, textile and leather products not covered elsewhere)).
				Dust	Inhalation	Workers, ONU	Yes	TBBPA is often used/transported as a solid powder, thus exposure to dust is likely during this use (Fabric, textile and leather products not covered elsewhere).
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Disposal	Waste Handling, Treatment and Disposal	Disposal of TBBPA containing wastes	Worker handling of wastes	Solid Contact	Dermal	Worker	Yes	Dermal exposure is expected for this condition of use
				Dust	Inhalation	Worker	Yes	TBBPA is solid at room temperature, EPA plans to evaluate the inhalation pathway.
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Dust	Inhalation	ONU	Yes	TBBPA is solid at room temperature, EPA plans to evaluate the inhalation pathway.

Appendix G SUPPORTING INFORMATION - CONCECPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Table_Apx G-1 Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use	Construction, Paint, Electrical, and Metal Products	Electrical and electronic products	Direct contact through use of electrical and electronic products made containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers	Yes	Inhalation of air and/or particles from electrical and electronic products containing TBBPA may occur for this condition of use. EPA plans to analyze inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of dust from electrical and electronic products containing TBBPA may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure.
		Building/ construction materials not covered elsewhere	Direct contact through use of building/ construction materials made containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers	Yes	Inhalation of air and/or particles from building/construction materials containing TBBPA may occur for this condition of use. EPA plans to analyze inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of dust from building/construction materials containing TBBPA may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure.
		Batteries	Direct contact through use of batteries made containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers	Yes	Inhalation of air and/or particles from batteries containing TBBPA may occur for this condition of use. EPA plans to analyze inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of dust from batteries containing TBBPA may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure.
Consumer Use	Furnishing, Cleaning, Treatment/ Care Products	Fabric, textile, and leather products not covered elsewhere	Direct contact through use of products/articles containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers	Yes	Inhalation via air and/or particulate exposure may occur during product/article use. EPA plans to analyze inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of TBBPA sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur via use of articles containing TBBPA. EPA plans to analyze dermal exposure.
				Article/Product Mouthing	Ingestion	Consumers	Yes	Ingestion via object to mouth or subsequent hand to mouth from product dermal contact. EPA plans to analyze mouthing via ingestion.
Consumer Handling of Disposal and Waste	Wastewater, liquid wastes and solid wastes	Wastewater, liquid wastes and solid wastes	Direct contact through use of products/articles containing TBBPA	Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use, dermal exposure will be analyzed. TBBPA is semi-volatile at room temperature. EPA plans to analyze dermal exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of TBBPA sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
				Air/Particulate/ Vapor/Mist	Inhalation	Consumers and Bystanders	Yes	Inhalation of air and/or particles from articles/products containing TBBPA may occur for this condition of use. EPA plans to analyze inhalation exposure.
			Long-term emission/mass-transfer through use of products containing TBBPA	Dust	Ingestion	Consumers and Bystanders	Yes	Ingestion of TBBPA sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
				Air/Particulate/ Vapor/Mist	Inhalation	Consumers and Bystanders	Yes	Inhalation of air and/or particles from articles/products containing TBBPA may occur for this condition of use. EPA plans to analyze inhalation exposure.

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

Table_Apx H-1 Environmental Releases and Wastes Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	Yes	TBBPA deposition to nearby bodies of water and soil are expected exposure pathways, not covered under other EPA regulations, and, therefore in scope.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	Yes	
				TBD	Aquatic and Terrestrial Receptors	Yes	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	EPA plans to analyze the release of TBBPA into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors.
				Oral Dermal	General Population	Yes	EPA plans to analyze the release of TBBPA into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population.
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	Yes	EPA plans to analyze the release of TBBPA into surface water and indirect partitioning to drinking water.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to the general population and terrestrial species.
				TBD	Terrestrial receptors	Yes	
		Underground injection	Migration to groundwater, potential	Oral Dermal Inhalation	General Population	No	TBBPA is released to Class I Underground Injection Wells which are covered by SDWA and RCRA.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			surface/drinking water	TBD	Aquatic and Terrestrial Species		EPA does not plan to evaluate this pathway.
Disposal	Waste Handling, Treatment and Disposal	Worker handling of wastes	Solid Contact	Dermal	Worker	Yes	Dermal exposure is expected for this condition of use.
			Dust	Inhalation	Worker	Yes	TBBPA is solid at room temperature. EPA plans to evaluate the inhalation pathway.
			Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
			Dust	Inhalation	ONU	Yes	TBBPA is solid at room temperature. EPA plans to evaluate the inhalation pathway.