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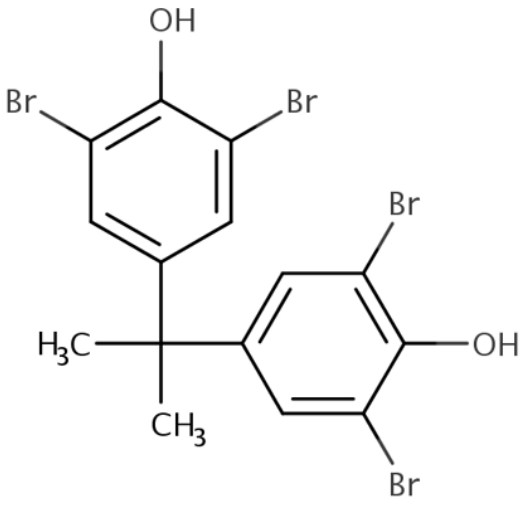
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

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

(TBBPA)

CASRN 79-94-7



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Docket

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

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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
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
CSF	Cancer slope factor
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
IUR	Inhalation unit risk
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
MOE	Margin of exposure
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
OSF	Oral slope factor
OSHA	Occupational Safety and Health Administration
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
PESO	Pathways and Processes, Exposure, Setting or Scenario, and Outcomes
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
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
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] (CASRN 95-50-1), also known as tetrabromobisphenol A (TBBPA), as a high-priority substance for risk evaluation following the prioritization process as required by § 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2019-0131). The first step of the risk evaluation process is the development of the draft scope document. EPA published the *Draft Scope of the Risk Evaluation for 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] CASRN 79-94-7* (EPA Document No. EPA-740-D-20-008) (U.S. EPA, 2020c). EPA published the draft scope and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0462) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for TBBPA. This document fulfills the TSCA requirement to issue a final scope document per TSCA § 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The 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 the risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance.

General Information. 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 *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, 2019e) to inform the development of this scope document. Furthermore, EPA conducted a comprehensive search to identify and screen multiple evidence streams (*i.e.*, chemistry, fate, release and engineering, exposure, hazard), and the search and screening results are provided in Section 2.1. EPA used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for TBBPA. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. EPA will consider additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

Conditions of Use. EPA plans to evaluate manufacturing (including importing), processing, distribution in commerce, industrial, commercial and consumer uses, and disposal of TBBPA in the risk evaluation. TBBPA is manufactured (including imported) in the United States. The chemical is processed as a reactant and incorporated into 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 and laminate for transportation interiors. It is also used as an intermediate to create other flame retardants, building/construction materials, textiles 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 semiconductor packages) 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, laminate for aviation and automobile interiors 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 CDR and Toxics Release Inventory (TRI) reporting, published literature, public comments and consultation with stakeholders. EPA revised the conditions of use in the final scope of the risk evaluation based on additional information and public comments (Docket ID: EPA-HQ-OPPT-2018-0462) on the draft scope document for TBBPA. Section 2.2 provides details regarding 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 considered reasonably available information as well as public comments received on the draft scope document for TBBPA in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for TBBPA on the following exposures, hazards and receptors:

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

  EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether other EPA administered statutes and regulatory programs cover TBBPA in media pathways falling under the jurisdiction of those authorities. TBBPA does not have pathways covered under the jurisdiction of other EPA-administered laws. In Section 2.6.3, EPA presents the conceptual model 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.

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

  - *Occupational exposure:* EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with manufacturing, processing, use or disposal of TBBPA.
  - *Consumer and bystander exposure:* EPA plans to evaluate oral and dermal exposure to TBBPA for consumers, and inhalation exposure to bystanders and consumers from use of electrical and electronic products, batteries, building/construction materials, and fabric, textiles and leather products containing TBBPA; and children's mouthing of products/articles containing TBBPA.
  - *General population exposure:* EPA plans to evaluate general population exposure to TBBPA via the oral route from drinking water, surface water, groundwater, fish

ingestion, human breast milk and soil, via the inhalation route from ambient air and via dermal route from contact with drinking water, surface water, groundwater and soil.
  - *PESS:* EPA plans to include children, women of reproductive age (*e.g.*, pregnant women, breast-feeding women), workers and consumers as PESS in the risk evaluation.
  - *Environmental exposure:* EPA plans to evaluate exposure to TBBPA for aquatic and terrestrial receptors.

- *Hazards.* Hazards for TBBPA are discussed in Section 2.4. EPA completed preliminary reviews of information (*e.g.*, federal and international government chemical assessments) to identify potential environmental and human health hazards for TBBPA as part of the prioritization (U.S. EPA, 2019e) and scoping process **(**U.S. EPA, 2020c**)**. EPA also considered reasonably available information collected through systematic review methods as outlined in Appendix A and public comments received on the draft scope for TBBPA in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for TBBPA.

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

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 review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

Peer Review. The draft risk evaluation for 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, 2015c) and other methods consistent with TSCA § 26 (see 40 CFR 702.45).

1 INTRODUCTION

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

Under TSCA § 6(b), the Environmental Protection Agency (EPA) must designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA to conduct risk evaluations for existing chemicals, to "*determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other 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 PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (Docket ID: EPA-HQ-OPPT-2019-0131) (84 FR 71924, December 30, 2019), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. TBBPA is one of the chemicals designated as a high-priority substance for risk evaluation. On April 9, 2020, EPA published the *Draft Scope of the Risk Evaluation for 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol]* (EPA Document No. 740-D-20-008) (85 FR 19941, April 9, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments (Docket ID: EPA-HQ-OPPT-2018-0462) received on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

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

1. Databases containing publicly available, peer-reviewed literature;
2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases; and

[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 § 14 (40 CFR 702.33).

3. Data and information submitted under TSCA § 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review process.

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

EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 92 search results relevant to EPA's risk evaluation needs for TBBPA. Appendix A.3.4 lists the gray literature sources that yielded 92 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 and chemical properties, environmental fate, environmental hazard, human health hazard, exposure, engineering), and the breakdown is shown in Figure 2-1. EPA will consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

[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.

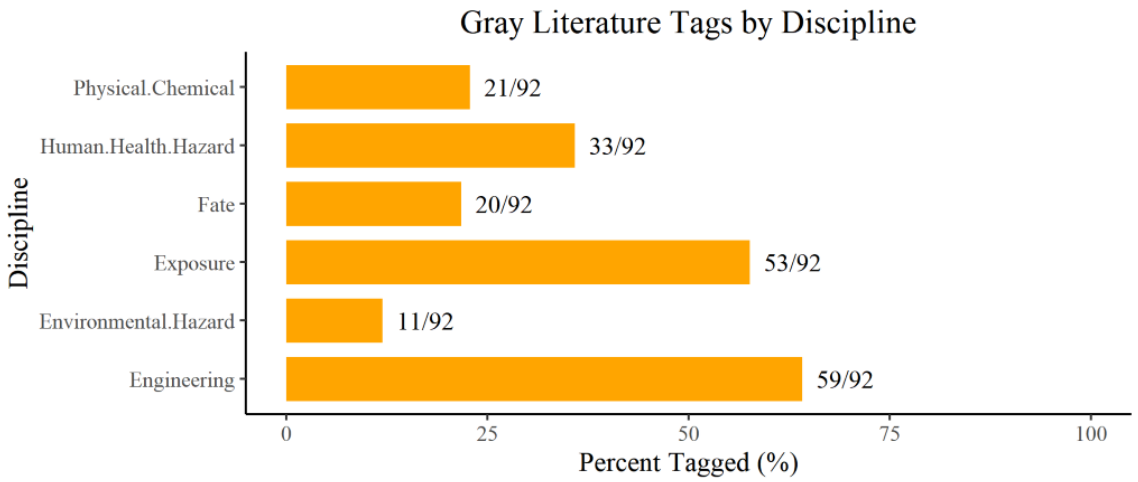

Figure 2-1. Gray Literature Tags by Discipline for TBBPA
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

EPA has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature on physical and chemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of TBBPA. Eligibility criteria were applied in the form of PECO statements (see Appendix A). 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 (see Appendix A.2). EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation.

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

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

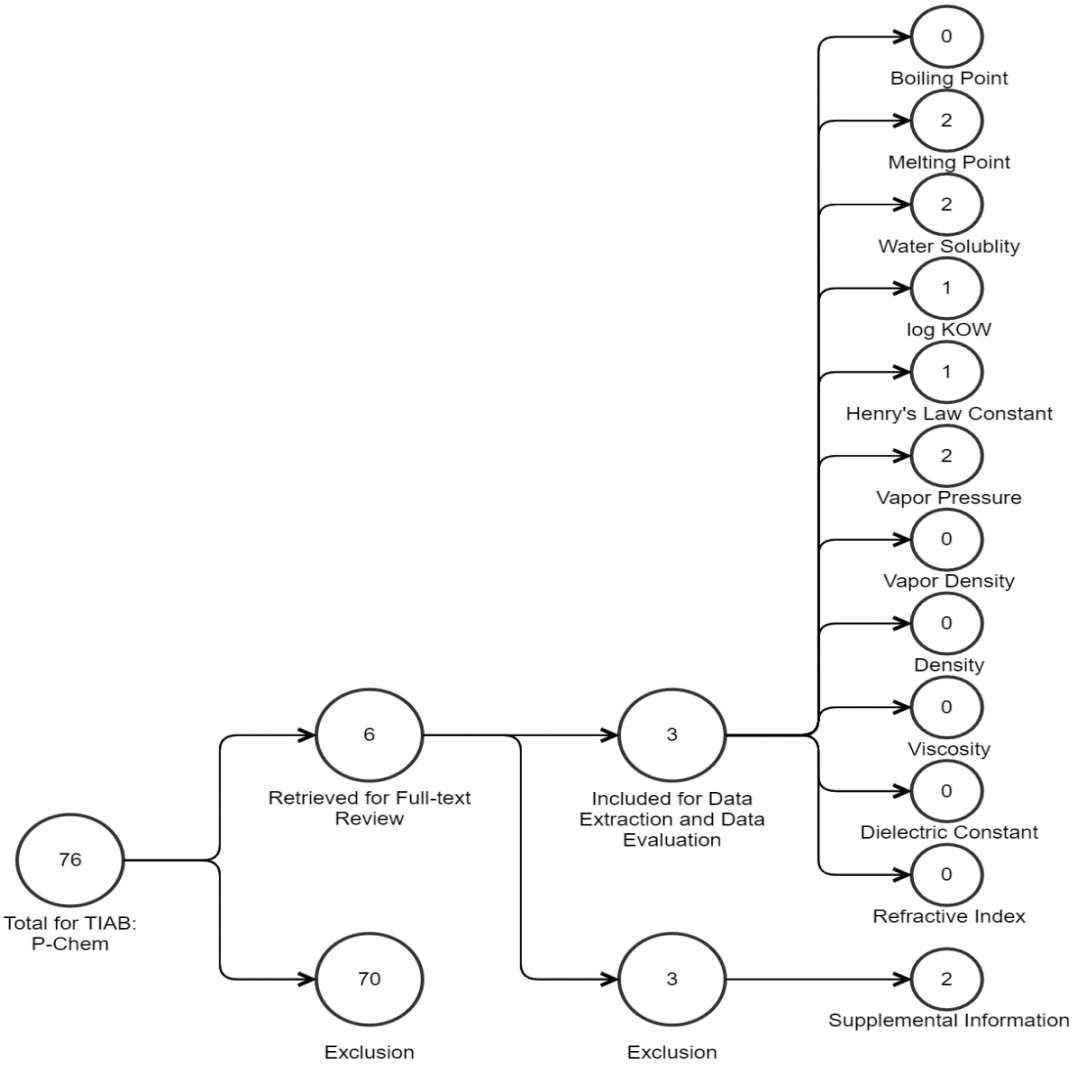

Figure 2-2. Peer-reviewed Literature Inventory Tree – Physical and Chemical Properties Search Results for TBBPA

Data in this static figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. TIAB refers to "title and abstract" screening.

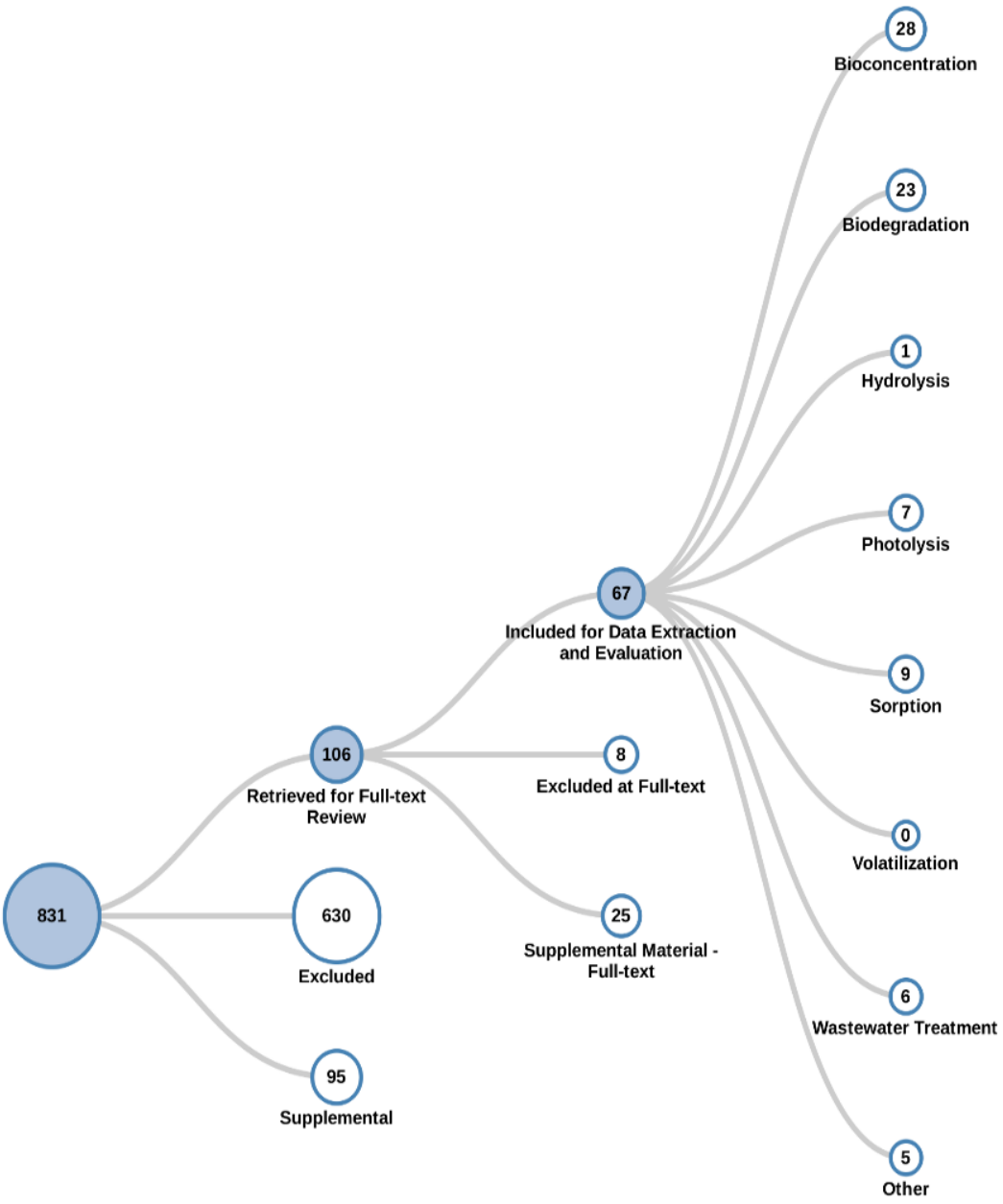

Figure 2-3. Peer-reviewed Literature Inventory Tree – Fate and Transport Search Results for TBBPA

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

	Media					
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total
Bioconcentration	1	16	1	16		28
Biodegradation		18	5	4		23
Hydrolysis				1		1
Photolysis	2	1		5		7
Sorption		9		6		9
Volatilization						
Wastewater Treatment			6	4		6
Other	2	2		1		5
Grand Total	5	37	11	32		67

Figure 2-4. Peer-reviewed Literature Inventory Heat Map – Fate and Transport Search Results for TBBPA

Click here to view the interactive version for additional study details. The column totals, row totals and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by media or endpoint. The darker the color, the more references are available for a given media or endpoint. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

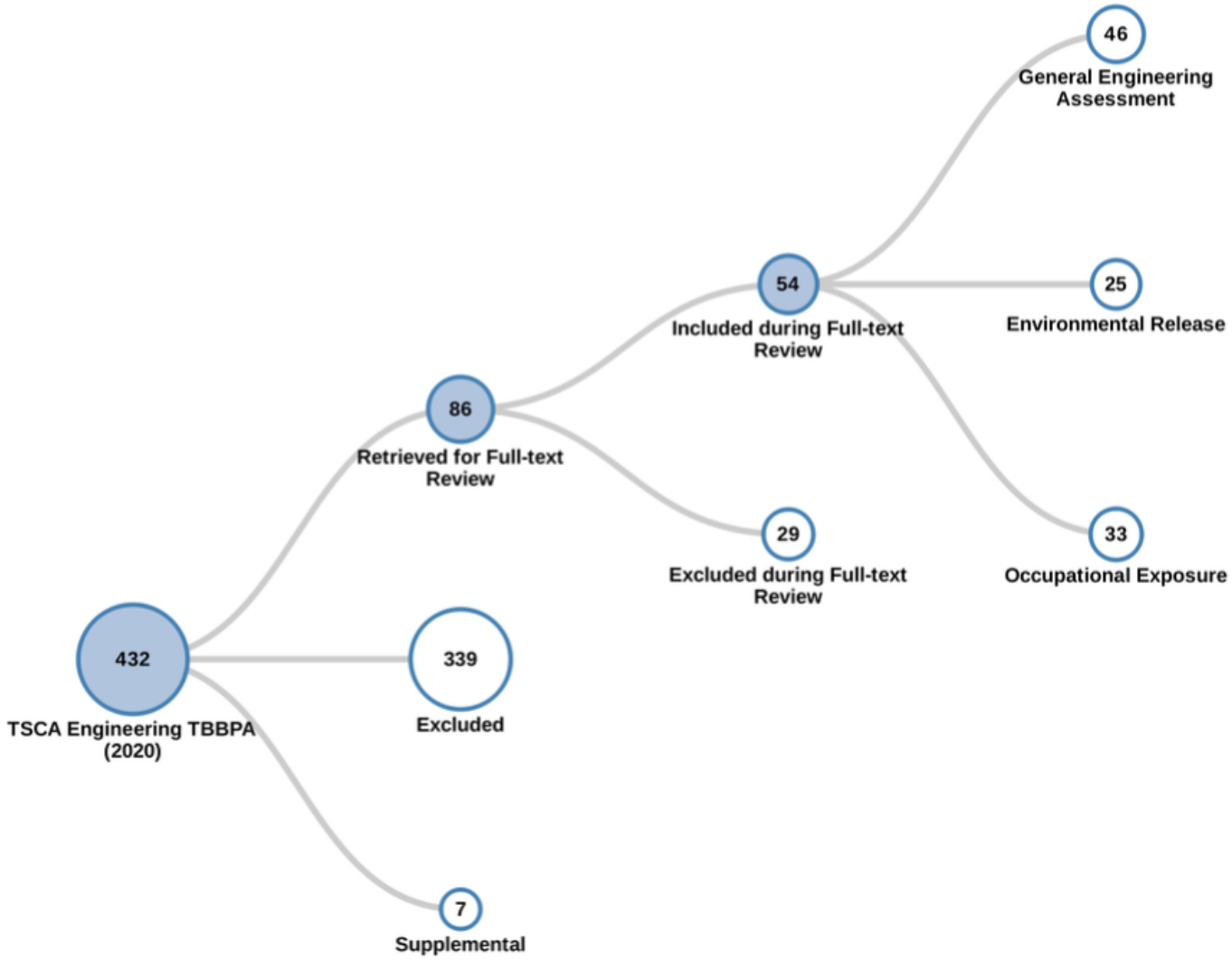

Figure 2-5. Peer-reviewed Literature Inventory Tree – Engineering Search Results for TBBPA
Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	16
	No evidence tag	2
	Release frequency	2
	Release or emission factors	9
	Release quantity	3
	Waste treatment methods and pollution control	14
	Total	25
General Engineering Assessment	Chemical concentration	17
	Life cycle description	19
	No evidence tag	5
	Number of sites	2
	Process description	22
	Production, import, or use volume	22
	Throughput	2
	Total	46
Occupational Exposures	Area sampling data	11
	Dermal exposure data	10
	Engineering control	4
	Exposure duration	4
	Exposure frequency	2
	Exposure route	14
	No evidence tag	6
	Number of workers	6
	Particle size characterization	1
	Personal protective equipment	8
	Personal sampling data	7
	Physical form	10
	Worker activity description	11
	Total	33
Grand Total		54

Figure 2-6. Peer-reviewed Literature Inventory Heat Map – Engineering Search Results for TBBPA

Click here to view the interactive version for additional study details. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

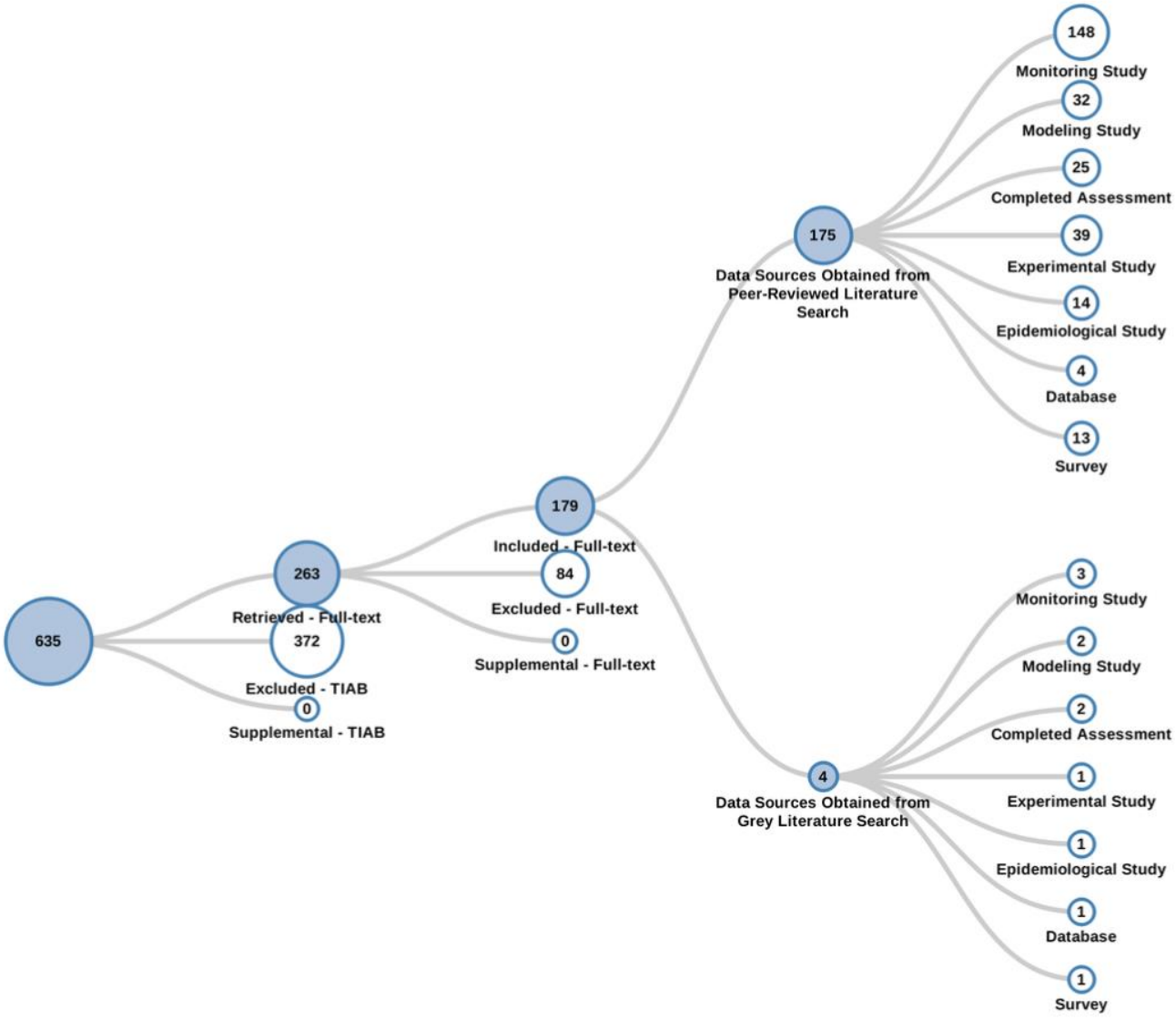

Figure 2-7. Peer-reviewed and Gray Literature Inventory Tree – Exposure Search Results for TBBPA

Click here to view the interactive literature inventory tree. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2) and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

Media (group)	Data Type: Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air	13	5	3	3	1		2	14
Biosolids/Sludge	11	2		1				11
Drinking Water	2		1					2
Groundwater	1			1				2
Land Disposal/ Landfill	1			2				3
Sediment	13	1						13
Soil	10	1	2		1			10
Surface Water	12	1	2		2	1		12
Wastewater	5						1	5
Aquatic Species	18	3	2	1	1			18
Terrestrial Species	5							5
Consumer	26	6	12	34	3		5	48
Dietary	32	9	6	6			2	34
Dust	44	22	15	4	2		6	48
Exposure Factors	16	8	8	3	3		3	19
Exposure Pathway	13	7	2	9			1	22
Human Biomonitoring	66	8	9	4	13	4	6	67
Indoor Air	28	8	7	7	1		2	31
Isomers								
Use Information	3	1		2				3
No Evidence Type		1						1
Grand Total	151	34	27	40	15	5	14	179

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

Click here to view the interactive version for additional study details. The column totals, row totals and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by exposure media or data type. The darker the color, the more references are available for a given exposure media or data type. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

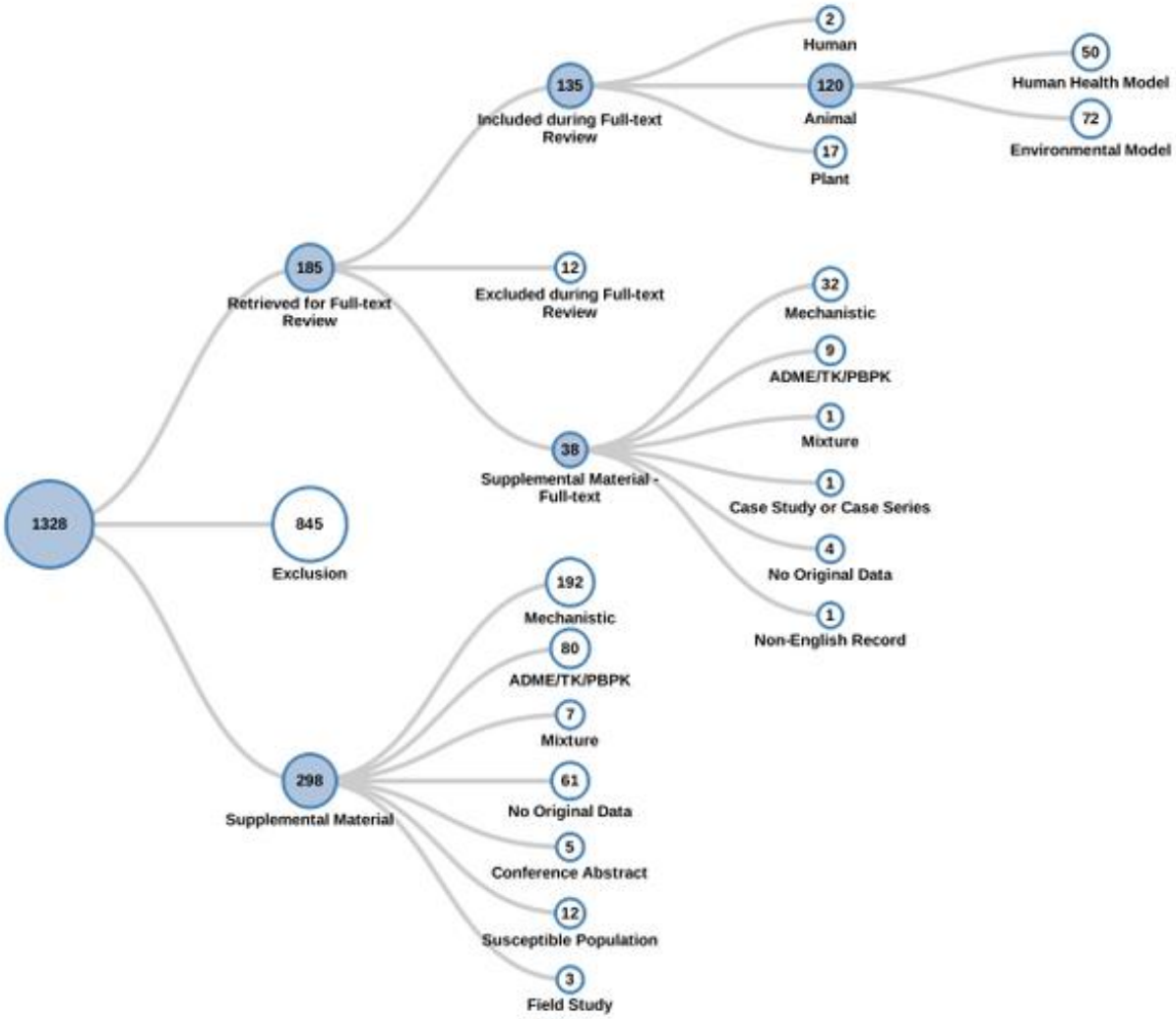

Figure 2-9. Peer-reviewed Literature Inventory Tree – Human Health and Environmental Hazards Search Results for TBBPA

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 9, 2020. Additional data may be added to the interactive version as they become available.

	Evidence Type				
Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	1	14	21	2	36
Cancer		10	3		13
Cardiovascular		1	8		9
Developmental	1	15	34	6	55
Endocrine	2	25	31		56
Gastrointestinal		3	2		5
Hematological and Immune	2	15	8		24
Hepatic		14	5		19
Mortality		11	14		25
Musculoskeletal			15		15
Neurological	1	13	21		35
Nutritional and Metabolic		12	14	2	27
Ocular and Sensory		6	4		10
PBPK			2		2
Renal		5	1		6
Reproductive		20	25		44
Respiratory		4	4		8
Skin and Connective Tissue		4	4		8
No Tag		7	15	8	27
Grand Total	2	50	72	17	135

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

Click here to view the interactive version for additional study details. The numbers indicate the number of studies with TIAB keywords related to a particular health outcome, not the number of studies that observed an association with TBBPA. Evidence types were manually extracted, and health systems were determined via machine learning. Therefore, the studies examining multiple health outcomes and evidence types, connections between health outcome and evidence type may not be accurately represented. If a study evaluated multiple health outcomes or included multiple populations or study designs, it is shown here multiple times. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 9, 2020. Additional data may be added to the interactive version as they become available.

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 96 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are presented in Appendix A.2.1. EPA identified 70 submissions that met the inclusion criteria in these statements and identified 10 submissions with

supplemental data.[3] 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

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

Discipline	Included	Supplemental[b]
Physical and Chemical Properties	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] Individual submissions may be relevant to multiple disciplines.
[b] Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

2.2 Conditions of Use

As described in the *Proposed Designation of 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CASRN 79-94-7) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e), EPA assembled information from the CDR and TRI programs to determine conditions of use[4] or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA will use the most recent CDR information. 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) (U.S. EPA, 2019c) data 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 and public comments to supplement the conditions of use information.

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

[3] EPA may further consider some supplemental or excluded references depending on the reasons for tagging as supplemental or excluded.
[4] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of (TSCA § 3(4)).

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

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

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

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

Life Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
Manufacturing	Domestic manufacturing	Domestic manufacturing	U.S. EPA (2019a)
	Import	Import	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0041
Processing	Processing as a reactant	Flame retardant (*e.g.*, plastic material and resin manufacturing)	U.S. EPA (2019a)
		Intermediate (*e.g.*, all other chemical product and preparation manufacturing)	U.S. EPA (2019a)
	Processing - incorporating into formulation, mixture or reaction product	Flame retardant (*e.g.*, electrical equipment, appliance and component manufacturing)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0017
		Flame retardant (*e.g.*, plastic material and resin manufacturing)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0017
		Flame retardant (*e.g.*, plastics product manufacturing)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016
		Flame retardant (*e.g.*, computer and electronic product manufacturing)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; 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	Reactive flame retardant (*e.g.*, Printed circuit boards and semiconductor packages)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0041; EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-

Life Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
			OPPT-2018-0462-0030; EPA-HQ-OPPT-2018-0462-0036
		Reactive flame retardant [d] (*e.g.*, Interior material for transportation equipment)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0041; EPA-HQ-OPPT-2018-0462-0004; EPA-HQ-OPPT-2018-0462-0045
		Additive flame retardant (*e.g.*, Plastic electronic enclosures)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-OPPT-2018-0462-0030
	Recycling	Recycling (*e.g.*, electronic products)	U.S. EPA (2019a); U.S. EPA (2019f); EPA-HQ-OPPT-2018-0462-0016
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial and Commercial Use	Construction, Paint, Electrical and Metal Products	Electrical and electronic products (*e.g.*, reactive flame retardant)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016; EPA-HQ-OPPT-2018-0462-0041; EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-OPPT-2018-0462-0030; EPA-HQ-OPPT-2018-0462-0036
		Laminate [d] (*e.g.*, reactive flame retardant in prepreg material for automotive and aviation interiors)	EPA-HQ-OPPT-2018-0462-0041; EPA-HQ-OPPT-2018-0462-0004; EPA-HQ-OPPT-2018-0462-0016; EPA-HQ-OPPT-2018-0462-0033
		Electrical and electronic products (*e.g.*, additive flame retardant in plastic enclosures)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016; EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-OPPT-2018-0462-0030
		Building/construction materials not covered elsewhere	U.S. EPA (2019a); NIEHS (2002)
		Batteries (*e.g.*, adhesive in lead-acid battery casings)	Yuasa (2016)
	Furnishing, Cleaning and Treatment/Care Products	Fabric, textile and leather products not covered elsewhere	EPA-HQ-OPPT-2018-0462-0016; NIEHS (2002); IPCS (1995); Government of Canada (2013); Gustafsson and Wallen (1988)
	Other	*E.g.*, Laboratory chemical	Sigma-Aldrich Inc. (2019); EPA-HQ-OPPT-2018-0462-0039
Consumer Use	Construction, Paint, Electrical and Metal Products	Electrical and electronic products (*e.g.*, reactive flame retardant)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0017; EPA-HQ-OPPT-2018-0462-0016; EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-

Life Cycle Stage [a]	Category [b]	Subcategory [c]	Reference
			OPPT-2018-0462-0030; EPA-HQ-OPPT-2018-0462-0036
		Electrical and electronic products (*e.g.*, additive flame retardant in plastic enclosures)	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0462-0006; EPA-HQ-OPPT-2018-0462-0016; EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-OPPT-2018-0462-0030
		Batteries (*e.g.*, adhesive in lead-acid battery casings)	Yuasa (2016)
	Furnishing, Cleaning and Treatment/Care Products	Fabric, textile and leather products not covered elsewhere	EPA-HQ-OPPT-2018-0462-0016; IPCS (1995); NIEHS (2002); Government of Canada (2013); Gustafsson and Wallen (1988)
Disposal	Disposal	Disposal	

a. Life Cycle Stage Use Definitions (40 CFR § 711.3)
- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA § 6(a)(5) to reach both.

b. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of TBBPA in industrial and/or commercial settings and for consumer uses.

c. These subcategories reflect more specific conditions of use of TBBPA.

d. In the final scope, EPA made the following changes to the conditions of use:
- 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, 2019e), a condition of use is included for processing for TBBPA as an intermediate (*e.g.*, transportation equipment manufacturing). After further communication with the industry reporting the use, EPA has concluded that the correct classification of the use of TBBPA is as a *reactive flame retardant (e.g., interior material for transportation equipment) and as industrial and commercial use in laminate (e.g., reactive flame retardant in prepreg material for automotive and aviation interiors)* (EPA-HQ-OPPT-2018-0462-0040; EPA-HQ-OPPT-2018-0462-0041).

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017), TSCA § 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA § 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance.[5] As a result, EPA does not plan to include in this scope or in the risk evaluation

[5] *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or

activities that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA § 6(b)(4)(D).

No activities were excluded for TBBPA.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of TBBPA in 2015 was between 50 million and 100 million pounds (U.S. EPA, 2020a). EPA also uses pre-2015 CDR production volume information, 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, 2019e), and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-11 provides the lifecycle diagram for TBBPA. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial and consumer use categories included within the scope of the risk evaluation. The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). Appendix E contains additional descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

uncombined radical. Chemical substance does not include (1) any mixture; (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product; (4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); (5) any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by Section 4182 or 4221 or any other provision of such Code), and; (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device (TSCA § 3(2)).

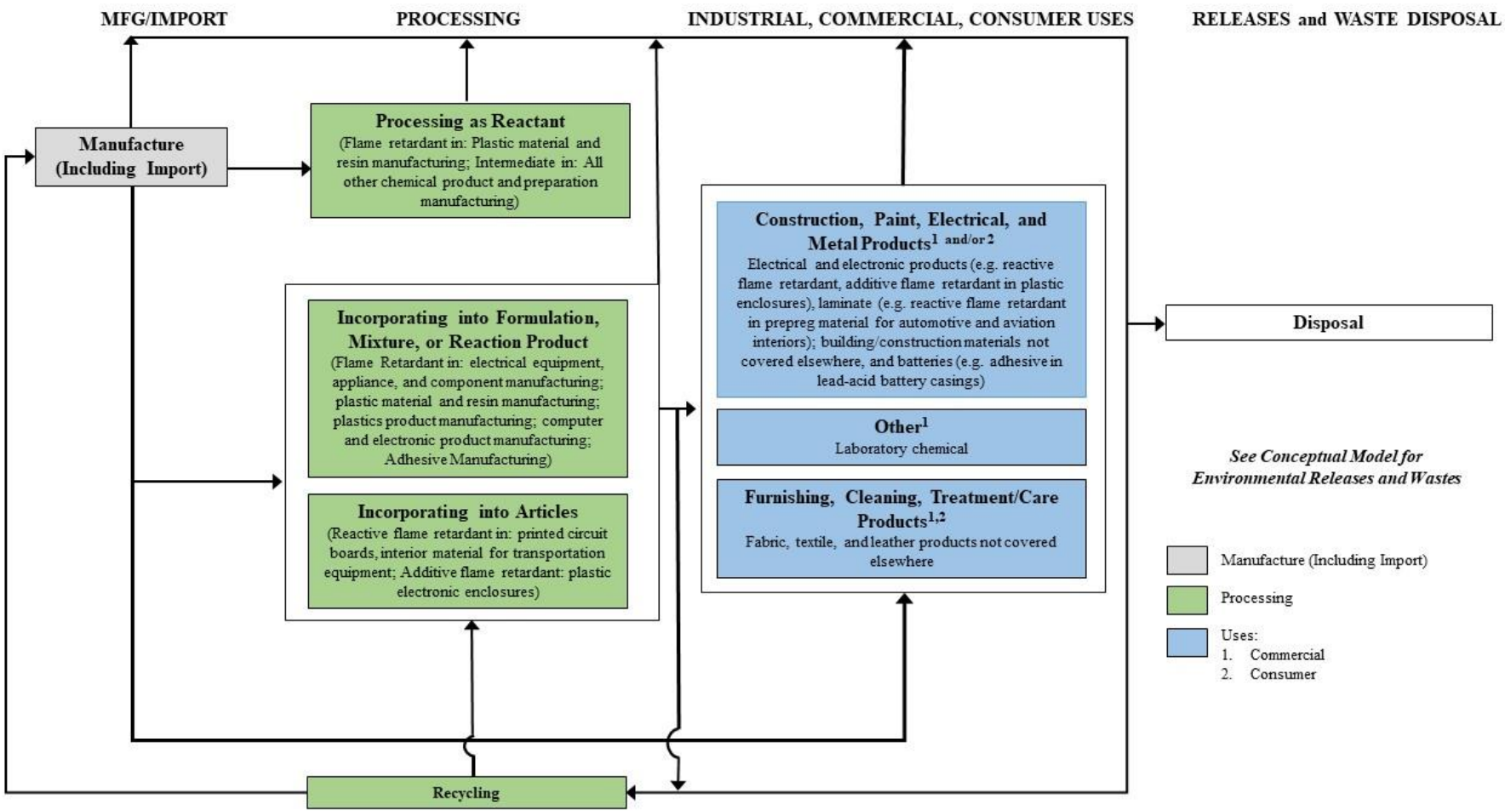

Figure 2-11. TBBPA Life Cycle Diagram

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation of TBBPA. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible or known sources. Release pathways and routes will be described in Section 2.6 to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to 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. It can also inform the hazard assessment. Table 2-3 summarizes the physical and chemical property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 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, 2019e) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-12 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0462).

Table 2-3. Physical and Chemical Properties of TBBPA

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_{15}H_{12}Br_4O_2$	N/A	N/A
Molecular weight	543.88 g/mol	N/A	N/A
Physical state	Solid crystals	O'Neil (2013)	High
Physical properties	Odorless; white	NLM (2018) Elsevier (2019)	High
Melting point	181°C	U.S. EPA (2019b)	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		

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Water solubility	4.15 mg/L at 298 K (pH 7.56)	Kuramochi et al. (2008)	High
Octanol/water partition coefficient (log Kow)	4.75 at 298 K (pH 7.53)	Kuramochi et al. (2008)	High
Henry's Law constant	1.45×10^{-10} atm·m^3/mol at 298 K	Kuramochi et al. (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

Figure 2-12 displays a summary of the data collected as of June 2020 for eight physical and chemical values routinely used in TSCA existing chemical risk evaluations. The box and whisker plots for each endpoint illustrate the mean (average, indicated by the blue diamond) and the 10^{th}, 25^{th}, 50^{th} (median), 75^{th}, and 90^{th} percentiles. All individual data points are indicated by black squares, and value preliminarily selected for use in the risk evaluation is overlaid (indicated by the orange circle) to provide context for where it lies within the distribution of the dataset. The number of unique primary data sources is indicated below each box and whisker plot. If multiple sources presented equivalent values and cited the same primary source, only one of those was included in the statistical calculations. As a result, the number of sources listed in Figure 2-12 may differ from the total number of data sources presented in Figure 2-2. Where no data could be identified through systematic review, text appears to clearly demonstrate the gap for the endpoint.

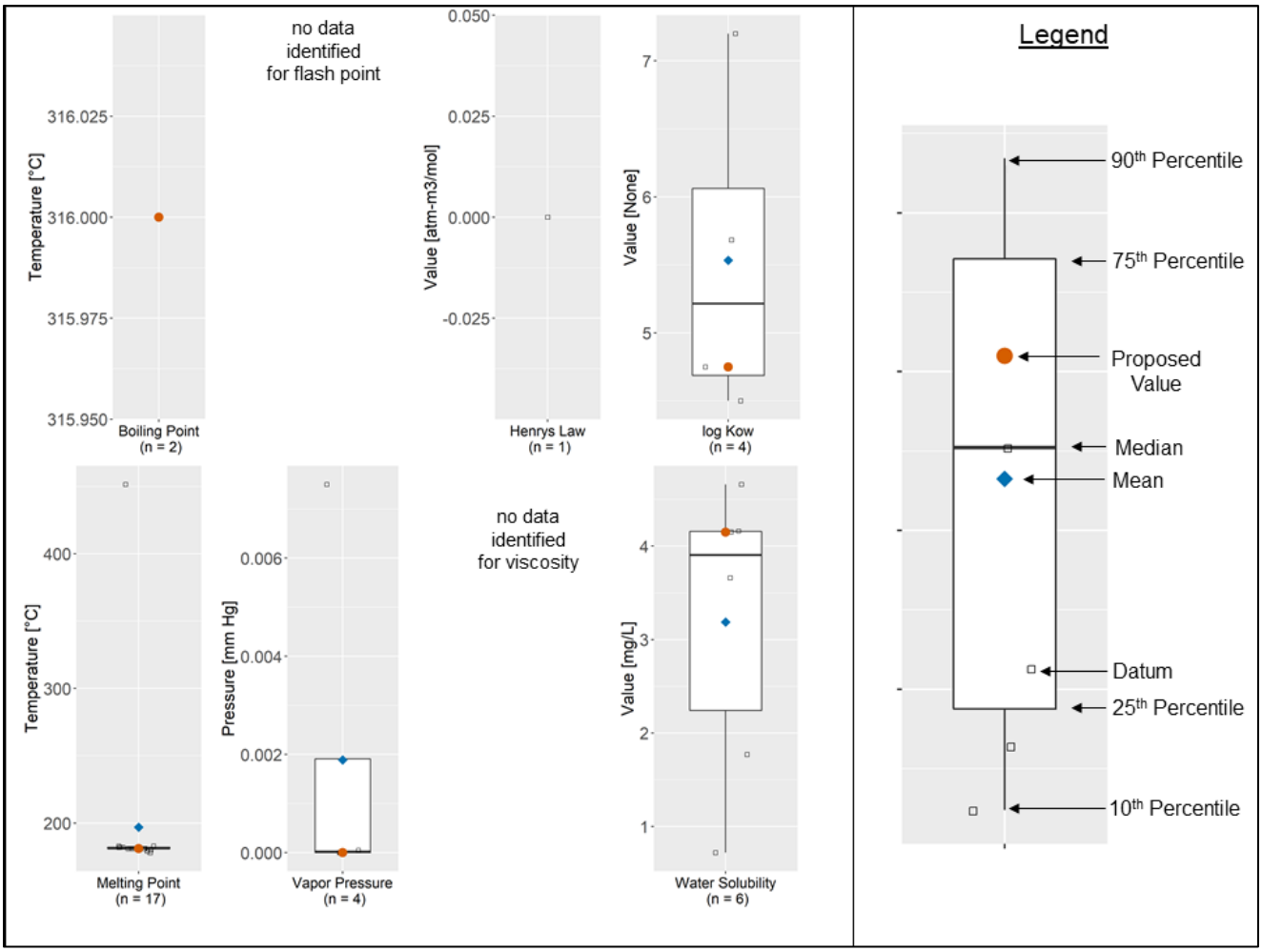

Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for TBBPA. EPA plans to use the environmental fate characteristics described in Appendix C to support the development of the risk evaluation for TBBPA. The values for the environmental fate properties may be updated as EPA evaluates and integrates additional information into the risk evaluation through systematic review methods.

2.3.3 Release to the Environment

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

A source of information that EPA plans to consider in evaluating exposure are data reported to the Toxics Release Inventory (TRI) program. EPA's TRI database contains information on chemical waste management activities that are disclosed 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 [6], facilities in covered sectors in the United States are required to disclose releases 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.

Table 2-4 provides production-related waste management data for TBBPA reported by facilities to the TRI program for reporting year 2018.[7] As shown in the table, 48 facilities reported a total of 138,456 pounds of TBBPA waste for 2018. 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 2-4. 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 (2019f)
[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 2-5 provides a summary of TBBPA released to the environment during 2018 as reported to TRI. 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.

[6] For TRI reporting criteria see (U.S. EPA, 2018b), https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting
[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-4 were queried using TRI Explorer and uses the 2018 national analysis dataset (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

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

Year	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 (2019f)

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

[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.

[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While the production-related waste quantity that is managed, as shown in Table 2-4, excludes any quantities reported as catastrophic or one-time releases (TRI **§** 8 data), release quantities shown in Table 2-5 include both production-related and non-production-related quantities. For TBBPA, the total release quantities shown in each table differ slightly and may reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2019d).

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

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). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation and bioaccumulation within the environment and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available environmental monitoring data for TBBPA.

2.3.5 Occupational Exposures

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

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

- Unloading and transferring TBBPA to and from storage containers to process vessels during manufacturing, processing and use;
- Handling and disposing of waste containing TBBPA during manufacturing, processing (including recycling), and use;
- 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 (U.S. EPA, 2019e). 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).

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

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 ONUs is not expected for the condition of uses as they are not expected to directly handle the chemical.

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.

2.3.6 Consumer Exposures

According to reports of the CDR, 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, 2015d). TBBPA has been detected in children's products (such as electronics) as well as in small plastic toys and jewelry (U.S. EPA, 2015d). 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. Based on these potential sources and pathways of exposure, EPA plans to analyze oral, dermal and inhalation routes of exposure to consumers, and the inhalation route for bystanders that may result from the conditions of use of 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. TBBPA has been found in drinking water, ground water, ambient air, indoor air, fish, human breast milk and dust and soil, which may be mouthed or ingested. The general population pathways in the scope of this evaluation are described in Sections 2.6.3 and 2.7.2.5.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on TBBPA as well as public comments received on 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, 2019e) and draft scope for TBBPA (U.S. EPA, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following potential environmental hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory, skin and connective tissue (Figure 2-10). A summary of the references identified through the systematic review process is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on TBBPA as well as public comments received on 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, 2019e) and draft scope for TBBPA (U.S. EPA, 2020c) to identify potential

human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: immunological, neurological, carcinogenic and developmental effects.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following additional potential human health hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, cardiovascular endocrine, gastrointestinal, hematological, hepatic, mortality, nutritional and metabolic ocular and sensory, renal, reproductive, respiratory and skin and connective tissue (Figure 2-10). A summary of the references identified through the systematic review process is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

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

EPA identified the following PESS based on CDR information, public comment received on the draft scope for TBBPA (Docket ID: EPA-HQ-OPPT-2018-0462), and studies reporting developmental and reproductive effects: women of reproductive age (*e.g.*, pregnant women), lactating females, workers, including ONUs and users, and consumers, including users and bystanders (U.S. EPA, 2019e). 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, 2015d). EPA plans to evaluate these PESS in the risk evaluation. Following further evaluation of the reasonably available information, EPA may evaluate PESS in the general population as they relate to fence line communities.

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

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 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: Potential Exposures and Hazards

Figure 2-13 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 ONUs via inhalation/oral 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, a determination was made as to whether or not EPA plans to evaluate each combination of exposure pathway, route and receptor in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

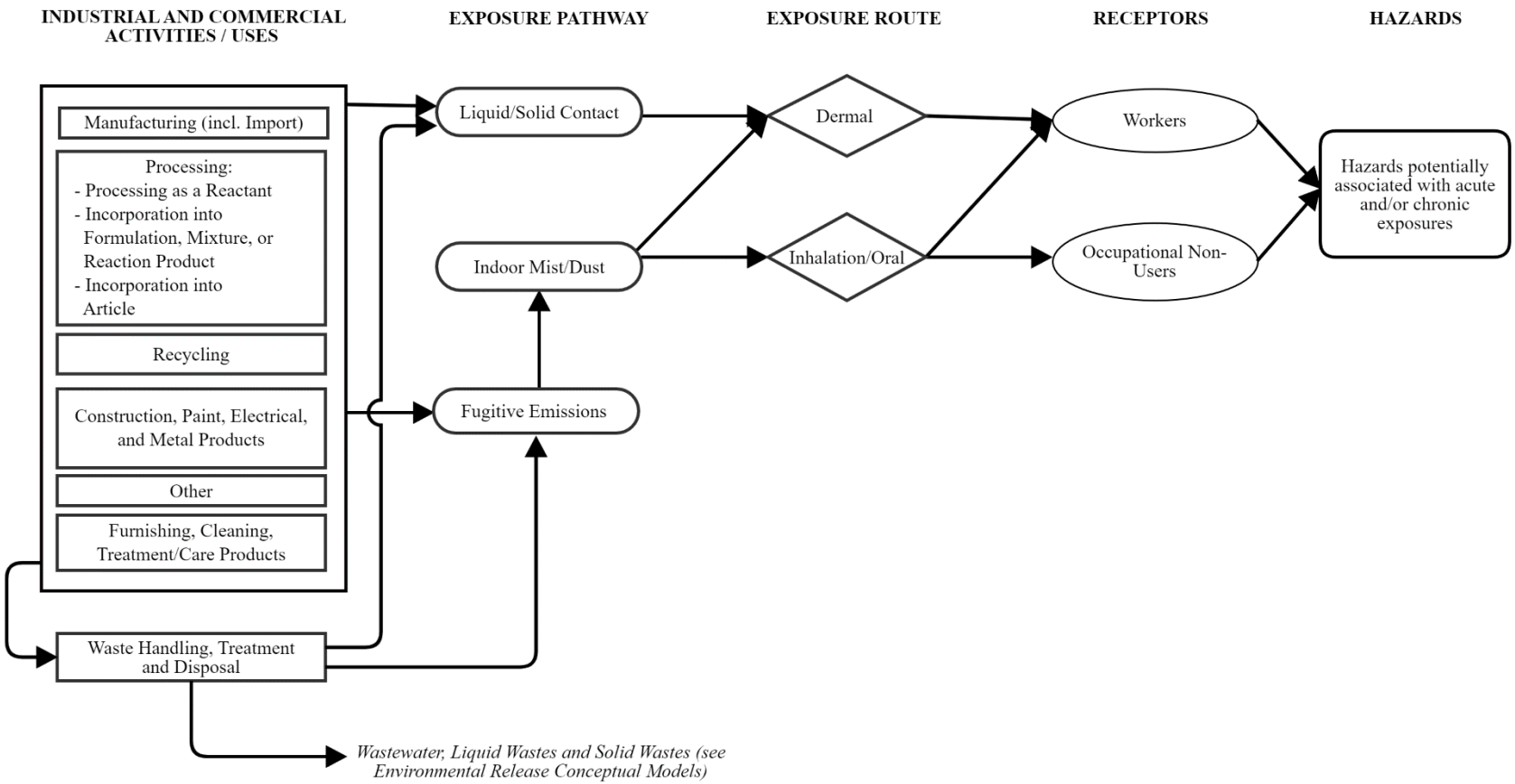

Figure 2-13. TBBPA Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-14 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TBBPA. EPA expects inhalation to be the primary route of exposure and plans to evaluate inhalation exposures to TBBPA in vapor, mist and dust for consumers and bystanders. Consumer oral exposures may also result from direct contact with mist and powders or dust containing TBBPA during use. Dermal exposures may result from liquids and mist containing TBBPA. Bystanders are not expected to have direct dermal or oral contact to TBBPA products. The supporting rationale for consumer pathways considered for TBBPA is included in Appendix G.

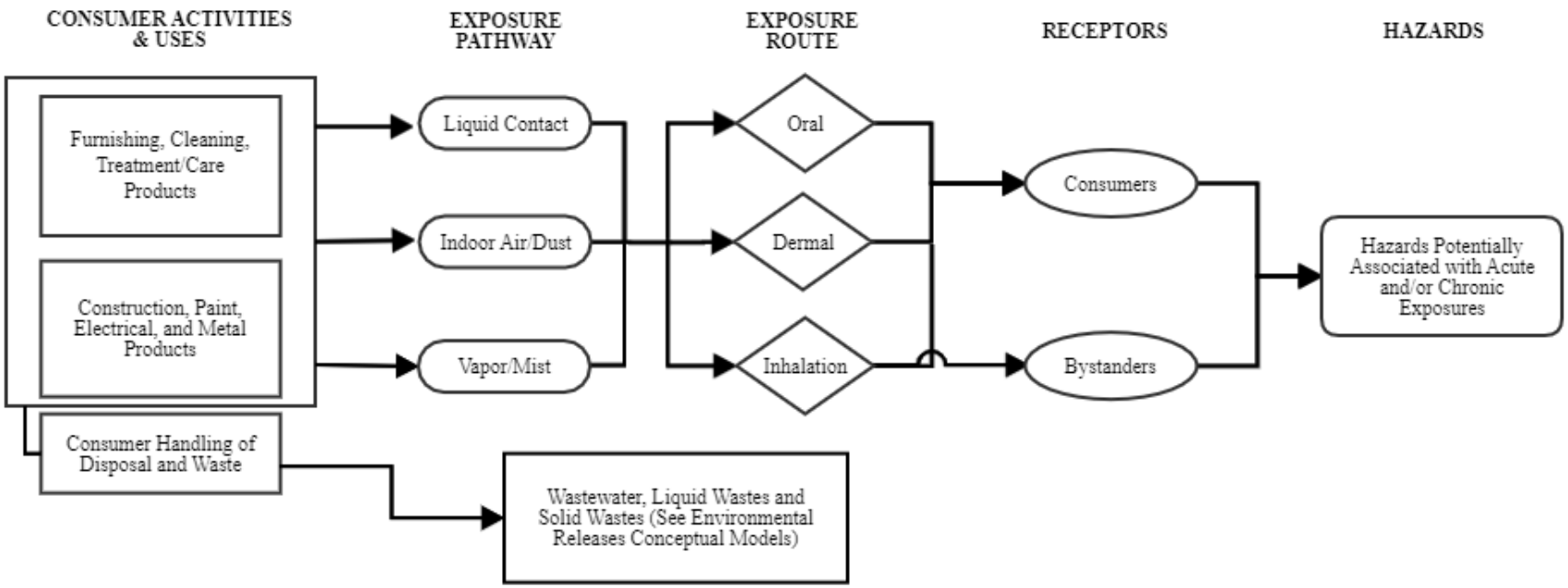

Figure 2-14. TBBPA Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TBBPA.

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

Figure 2-15 presents the exposure pathways, exposure routes, and hazards to general population and environmental receptors for releases and waste streams associated with environmental releases of 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 and orally via drinking water, fish and soil ingestion, and dermally from contact with drinking water, surface water, groundwater and soil. The supporting rationale for general population and environmental pathways considered for TBBPA are included in Appendix H.

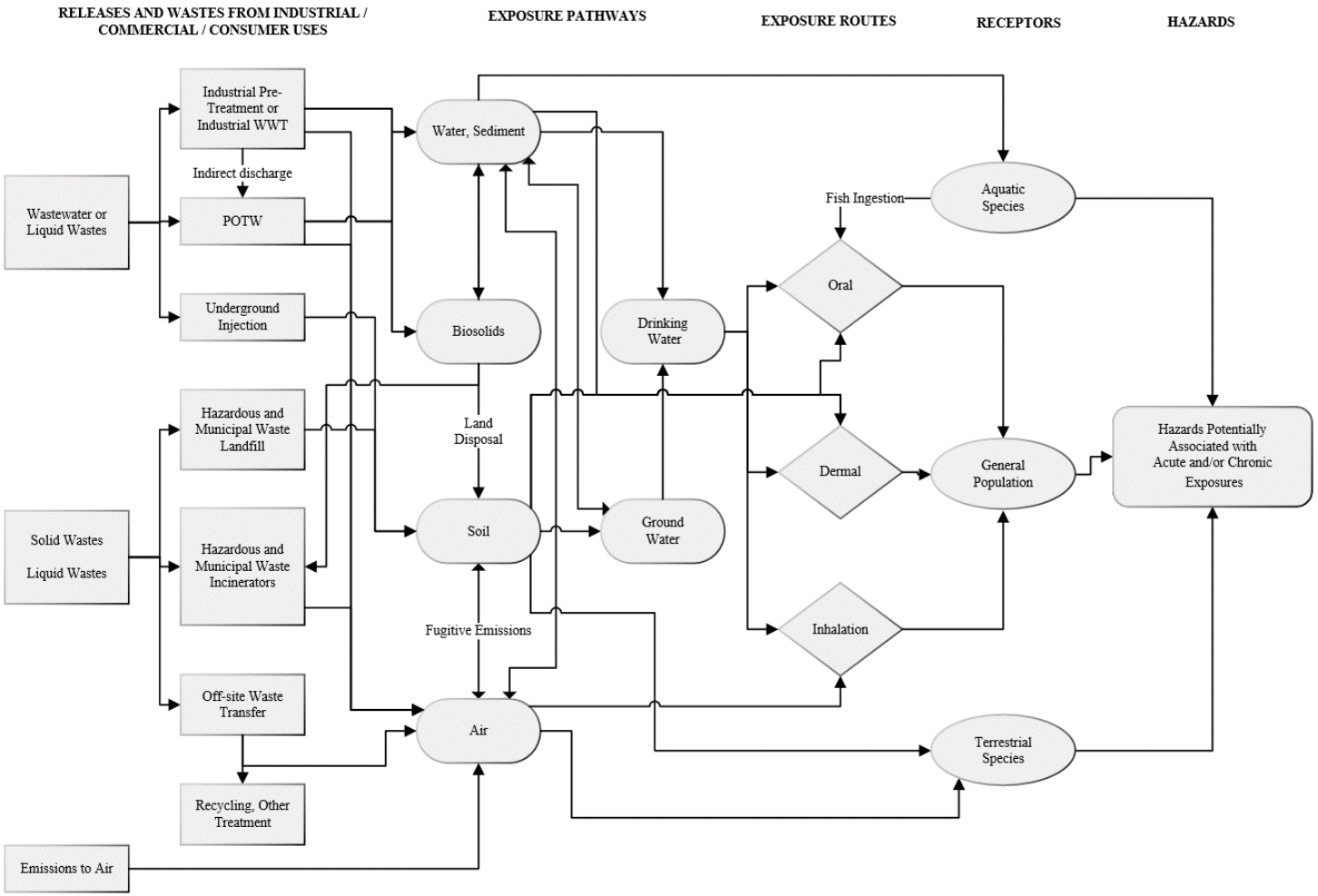

Figure 2-15. TBBPA Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial and consumer uses of TBBPA.

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to 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. Inhalation from drinking water may occur via showering

b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

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

2.7.1 Physical and Chemical Properties and Environmental Fate

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

1) **Review reasonably available measured or estimated physical and chemical and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.** EPA plans to review data and information collected through the systematic review methods and public comments about the physical and chemical properties (Appendix A) and fate endpoints (Appendix C), some of which appeared 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, 2019e). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). Where the systematic review does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA § 4 authority, or values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of physical, chemical and environmental fate endpoints (*e.g.*, persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.** Measured data and, where necessary, model predictions of physical and chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of TBBPA within and across environmental media. The physical and 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 the scientific evidence evaluation of physical and chemical and environmental fate data, including qualitative and quantitative sources of information.** During risk evaluation, EPA plans to evaluate and integrate the environmental fate evidence identified in the literature inventory using the methods described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

2.7.2 Exposure

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

2.7.2.1 Environmental Releases

EPA plans to evaluate 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 sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to review additional identified data sources. Potential sources of environmental release data are summarized in Table 2-6:

Table 2-6. 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 will continue to consider additional reasonably available information and will evaluate it during development of the risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in #3 and #4 below by considering potential surrogate data and models.

Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including release estimation approaches and assumptions in

the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) (U.S. EPA, 2015a)

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.

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

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (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 (OECD, 2009a) and the 2011 ESD (OECD, 2011b) 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 assessed.

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) (U.S. EPA, 2004a);
- EPA's *Spray Coatings in the Furniture Industry - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (April, 2004) (U.S. EPA, 2004c);
- EPA's *Manufacture and Use of Printing Ink - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (September, 2001) (U.S. EPA, 2001)
- EPA's *Leather Dyeing - Generic Scenario for Estimating Occupational Exposures and Environmental Releases* (September 2000) (U.S. EPA, 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) (U.S. EPA, 1994b)

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

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

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

6) **Map or group each condition of use to a release assessment scenario(s).**
EPA has completed an initial mapping of release scenarios to relevant conditions of use as shown in Appendix F. EPA plans to refine the mapping/grouping of release scenarios based on factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use using reasonably available information. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop release scenarios.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental release evidence identified in the literature inventory using the methods described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

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

1) **Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.**
For TBBPA, environmental media which EPA plans to analyze are sediment, biosolids, soil, air and water.

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 and consider reasonably available environmental exposure models that meet the scientific standards under TSCA § 26(h) and that estimate surface water, sediment and soil concentrations alongside reasonably available surface water, sediment and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations consider the following inputs: direct release into surface water, sediment or soil, indirect release into water, sediment or soil (*i.e.*, air deposition), fate and transport (partitioning within media) and characteristics of the environment (*e.g.*, river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
There have been changes to use patterns of TBBPA over the last few years. EPA plans to review and characterize monitoring data or modeled estimates to determine how representative they are of ongoing use patterns.

Any studies that relate levels of TBBPA in the environment or biota with specific sources or groups of sources will be evaluated.

4) **Group each condition(s) of use to environmental assessment scenario(s).**
Refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes and populations exposed. For 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 reasonably 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. Monitoring data 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 reasonably available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

2.7.2.3 Occupational Exposures

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

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
   EPA plans to review reasonably available 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 physical and chemical properties similar to TBBPA.**
   EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.

3) **For conditions of use where data are limited or not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
   EPA has identified potentially relevant OECD ESDs and EPA GSs corresponding to some conditions of use. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use. EPA may conduct industry outreach efforts or perform supplemental targeted searches of peer-reviewed or gray literature to understand those conditions of use, which may inform identification of exposure scenarios. EPA plans to also consider the applicability of exposure models in the ChemSTEER (U.S. EPA, 2015a) tool, which are routinely used for assessing new chemicals, to assess exposures during various conditions of use. EPA may also perform targeted supplemental searches to identify other applicable models that EPA may use to estimate exposures for certain conditions of use.

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

5) **Consider and incorporate applicable ECs and/or PPE into exposure scenarios.**
   EPA plans to review potentially relevant data sources on ECs and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on control technologies and control effectiveness.

For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**
EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). As presented in the fourth column in Table_Apx F-1, EPA has completed an initial mapping of exposure scenarios to condition of use. EPA plans to refine mapping or grouping of occupational exposure scenarios based on factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is reviewed during risk evaluation. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. EPA plans integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

EPA plans to evaluate 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
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the potential of indoor exposure pathways based on reasonably available data.**
Based on physical and chemical properties of TBBPA and the consumer uses identified, inhalation of particles is expected to be an important indoor exposure pathway for consumers. Other pathways include dust ingestion and dermal contact as a result of indoor use of TBBPA consumer products. Inhalation of vapor and mist and oral ingestion of liquid and mist are also possible. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air exposure.**

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

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

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.**
To the extent other organizations have already modeled a 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 dust, indoor air).**
The availability of TBBPA concentration for various conditions of use will be evaluated. This data provides the source term for any subsequent indoor modeling. EPA plans to analyze source attribution between overall indoor air and dust levels and various indoor sources.

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

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**
EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and

quantitative sources of information. EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA plans to evaluate general population exposures as follows:

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

   EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data and survey-based data can all be used to inform exposure scenarios. EPA anticipates that there will be a range in the potential exposures associated with the exposure scenarios identified Section 2.6.

   After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses. The number of scenarios will depend on the conditions of use, exposure pathways and receptors. The number of scenarios is also dependent upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis may be qualitative, semi-quantitative or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and include careful consideration of variability and uncertainty.

2) **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 considered for TBBPA: ingestion of water and food including fish and breast milk as well as dermal contact to TBBPA via water and inhalation of TBBPA via ambient air.

3) **For exposure pathways where empirical data is not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
For TBBPA, media where exposure models will be considered for general population exposure include models that estimate surface water concentrations, sediment concentrations, soil concentrations (including biosolids application), drinking water concentrations (including groundwater), ambient air 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 reasonably 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 and 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 reasonably available monitoring data to determine representativeness.

6) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (*e.g.*, early life and/or puberty as a potential critical window of exposure).**
For TBBPA, exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For example, children will have different intake rates for dust, soil and diet 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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

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 evaluate the hazards of TBBPA to aquatic and 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 terrestrial organisms.

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

   Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **Derive hazard thresholds for aquatic and 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 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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other approaches to integrate exposure and hazard assessments.**
   EPA plans to consider aquatic (*e.g.*, water and sediment exposures) 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) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of TBBPA.**
   EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of TBBPA after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to

bioaccumulation and bioconcentration (*e.g.*, BAF, BCF) of 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).

6) **Conduct an environmental risk estimation and characterization of TBBPA.**
EPA plans to conduct a risk estimation and characterization of TBBPA to identify if there are risks to the aquatic and terrestrial environments from the measured and/or predicted concentrations of TBBPA in environmental media (*e.g.*, 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). Analysis of risk for characterization includes a confidence statement in risk estimation that qualitative judgement describing the certainty of the risk estimate considering the strength evidence scores for hazard and exposure and the limitations, and relevance.

2.7.3.2 Human Health Hazards

EPA plans to evaluate human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from alternative test methods (*e.g.*, computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).**
EPA plans to evaluate human health studies using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a) and updates to the epidemiological data quality criteria released with the first ten risk evaluations. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

   Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to 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 may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

3) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria for inclusion during the screening process that is described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). Hazards identified by studies which meet data quality criteria for inclusion will be grouped by routes of exposure relevant to humans (*e.g.*, oral, dermal, inhalation) and by the cancer and noncancer endpoints identified in Section 2.4.2.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011a, 1994b) developing points of departure (POD) for either margins of exposure (MOEs), cancer slope factors (CSFs), oral slope factors (OSFs) and/or inhalation unit risks (IURs). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not reasonably available or would not alter the analysis.

The cancer mode of action (MOA) analyses determine the relevancy of animal data to human risk and how data can be quantitatively evaluated. If cancer hazard is determined to be applicable to TBBPA, EPA plans to evaluate information on genotoxicity and the MOA for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the *U.S. EPA Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-life Exposures to Carcinogens* (U.S. EPA, 2005b), EPA plans to determine whether age-dependent adjustment factors (ADAFs) are appropriate for TBBPA for specific conditions of use based upon potential exposures to children.

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (*e.g.*, adjust for duration of exposure) to the specific exposure scenarios evaluated.**
Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

EPA plans to evaluate whether the reasonably available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD or for extrapolation of the POD to standard exposure durations (*e.g.*, lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ 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 *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

6) **Consider the route(s) of exposure (*e.g.*, oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient reasonably available data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to 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.

   If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994b). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004b).

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

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

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's Risk Characterization Policy, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision

makers" (U.S. EPA, 2000). Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment and a description of how others have assessed the risk into an integrated picture.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent and reasonable (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use...." The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (*e.g.*, related to nature and magnitude of effects).

EPA plans to also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA plans to also identify: (1) each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the 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 Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for TBBPA will be peer-reviewed.

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APPENDICES

Appendix A ABBREVIATED METHODS FOR SEARCHING AND SCREENING

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

To develop the chemical terms for the subsequent literature search for TBBPA, several online sources were queried.

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

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

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

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

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Sigma – Aldrich website58784 http://www.sigma-aldrich.com	Organic and inorganic Compounds by chemical name, has CAS index and some structure and Physical Property data	Online
STN International (CAS) 1994	***Most complete source of chemical name, synonym and structure information, no physical properties	Online
The Pesticide Manual 10th edition, 1994	Pesticide Compounds by chemical name, synonym, product code, has CAS index and some structure and Physical Property data	ECOTOX
TSCA (Toxic Substances Control Act Chemical Substance Inventory, 1985 ed., 5 vols)	Chemical names, synonyms and CAS numbers	ECOTOX
World Wide Web (misc. web sources) A copy of the verification page is saved to the Attachments tab of the chemical entry. This includes company MSDS sheets or Chemical Labels.	Chemical names, synonyms and CAS numbers	Online
California Department of Pesticide Regulation (http://www.cdpr.ca.gov/dprdatabase.htm)	Multiple databases containing chemicals, pesticides, companies, products, *etc.*	Online
PAN Pesticide Database (http://www.pesticideinfo.org/Search_Chemicals.jsp)	Pesticides searchable by name or CAS #. Includes CAS #, Name, synonyms, targets, toxicity data, related chemicals and regulatory information.	Online
US EPA Office of Pesticide Programs Pesticide Fate Database – No web access available. An electronic copy of the data file is located at the Contractor site: PFATE_37_Tables.mdb.	Multiple databases containing chemicals, pesticides, companies, products, *etc.*	Online

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching occurred during April and May of 2019 by an information specialist and the results were stored in the Health and Environmental Research Online (HERO) database and assigned a HERO reference identification number.[8] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

[8]EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.

After initial deduplication in HERO[9], these studies were imported into SWIFT Review software (Howard et al., 2016) to identify those references most likely to be applicable to each discipline area (*i.e.* consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

A.1.2.1 Query Strings for the Publicly Available Database Searches on TBBPA

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

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

Source	Date of Search	Number of References
Current Contents	06/10/2019	1375
Web of Science	09/13/2019	1631
ProQuest CSA	06/11/2019	1967
Dissertation Abstracts	06/07/2019	7
Science Direct	06/11/2019	1228
Agricola	06/07/2019	417
TOXNET	06/11/2019	784
PubMed	07/02/2019	1070
UNIFY	06/11/2019	134
Totals:		**8613**

GENERAL:

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

"2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane" OR "3,3,5,5-Tetrabromobisphenol A" OR "3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol" OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]" OR "4,4'-Isopropylylidenebis(2,6-dibromophenol)" OR "BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-

[9] Deduplication in HERO involves first determining whether a matching unique ID exists (*e.g.*, PMID, WOSid, or DOI). If one matches one that already exists in HERO, HERO will tag the existing reference instead of adding the reference again. Second, HERO checks if the same journal, volume, issue and page number are already in HERO. Third, HERO matches on the title, year, and first author. Title comparisons ignore punctuation and case.

METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-" OR "Bromdian" OR "CP 2000" OR "FCP 2010" OR "FG 2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P" OR "Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA" OR "Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane"

"Tetrabromodiphenylopropane" OR "UNII-FQI02RFC3A"

CURRENT CONTENTS CONNECT:
Current Contents Connect may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/10/2019
Date Range of Search: 1998 to Present
N = 1375

TS=("2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane" OR "3,3,5,5-Tetrabromobisphenol A" OR "3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol" OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]" OR "4,4'-Isopropylylidenebis(2,6-dibromophenol)" OR "BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-" OR "Bromdian" OR "CP 2000" OR "FCP 2010" OR "FG 2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P" OR "Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA" OR "Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane")
N = 1375

TS=("Tetrabromodiphenylopropane" OR "UNII-FQI02RFC3A")
N = 0

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

Date Searched: 09/13/2019

Date Range of Search: 1970 to Present
N = 1631

TS=("2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane" OR "3,3,5,5-Tetrabromobisphenol A" OR "3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol" OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]" OR "4,4'-Isopropylylidenebis(2,6-dibromophenol)" OR "BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-" OR "Bromdian" OR "CP 2000" OR "FCP 2010" OR "FG 2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P" OR "Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA" OR "Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane")
N = 1631

TS=("Tetrabromodiphenylopropane" OR "UNII-FQI02RFC3A")
N = 0

PROQUEST Agricultural and Environmental Science Database:
ProQuest Agricultural and Environmental Science Database may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/11/2019
Date Range of Search: 1900 to Present
N = 1967

ALL("2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane" OR "3,3,5,5-Tetrabromobisphenol A" OR "3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol" OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]" OR "4,4'-Isopropylylidenebis(2,6-dibromophenol)" OR "BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-" OR "Bromdian" OR "CP 2000" OR "FCP 2010" OR "FG

2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P" OR "Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA" OR "Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 1967

ALL("Tetrabromodiphenylopropane" OR "UNII-FQI02RFC3A") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 0

PROQUEST Dissertations and Theses @ CIC Institutions:
ProQuest Dissertations and Theses may be accessed through the Kathryn A. Martin Library at the University of Minnesota at Duluth (https://libguides.d.umn.edu/az.php).

Date Searched: 06/07/2019
Date Range of Search: 1900 to Present
N = 7
ALL("2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane" OR "3,3,5,5-Tetrabromobisphenol A" OR "3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol" OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]" OR "4,4'-Isopropylylidenebis(2,6-dibromophenol)" OR "BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-") AND LA(ENG)
N = 0

ALL("Bromdian" OR "CP 2000" OR "FCP 2010" OR "FG 2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P" OR "Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA" OR "Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane") AND LA(ENG)
N = 7

SCIENCE DIRECT:
Science Direct may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/11/2019

Date Range of Search: 1823 to Present
N = 1228

Science Direct 01:
"2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane" OR "3,3,5,5-Tetrabromobisphenol A"
N = 0

Science Direct 02:
"3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol" OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]"
N = 0

Science Direct 03:
"4,4'-Isopropylylidenebis(2,6-dibromophenol)" OR "BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-" OR "Bromdian" OR "CP 2000"
N = 0

Science Direct 04:
"FCP 2010" OR "FG 2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P"
N = 0

Science Direct 05:
"Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA"
N = 615

Science Direct 06:
"Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane"
N = 613

Science Direct 07:
"Tetrabromodiphenylopropane" OR "UNII-FQI02RFC3A"
N = 0

AGRICOLA:
Agricola may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) or within the EndNote environment.

Date Searched: 06/07/2019
Date Range of Search: 15th century to the Present
N = 417

Agricola 01:
2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane
2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol
2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
2,2',6,6'-Tetrabromobisphenol A
2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane
2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane
2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane
3,3,5,5-Tetrabromobisphenol A
3,3',5,5'-Tetrabromobisphenol A
N = 0

Agricola 02:
3,5,3',5'-Tetrabromobisphenol A
4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)
4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol
4,4'-(Methylethylidene)bis[2,6-dibromophenol]
4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)
4,4'-Isopropylidenebis(2,6-dibromophenol)
4,4'-Isopropylidenebis[2,6-dibromophenol]
4,4'-Isopropylylidenebis(2,6-dibromophenol)
BA 59
N = 1

Agricola 03:
BA 59BP
BA 59P
BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)
BISPHENOL A, TETRABROMO-
BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-
N = 0

Agricola 04:
Bromdian
CP 2000
FCP 2010
FG 2000

Fire Guard 2000
Firemaster BP 4A
Flame Cut 120G
Flame Cut 120R
FR 1524
FR 1525
N = 0

Agriocola 05:
GLCBA 59P
Great Lakes BA-59P
NSC 59775
PB 100
RB 100
Saytex CP 2000
Saytex RB 100
Saytex RB 100PC
T 0032
TBBPA
N = 341

Agricola 06:
Tetrabromo-4,4'-isopropylidenediphenol
Tetrabromobisphenol A
TETRABROMOBISPHENOL-A
Tetrabromodian
Tetrabromodiphenylolpropane
N = 75

TOXNET/(Toxline):
TOXNET(Toxline) may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched:
Date Range of Search: 1900 to Present
N = 784

TOXNET 01:
79-94-7 OR 107719-55-1 OR 108608-60-2 OR 110670-65-0 OR 121839-52-9
N = 778

TOXNET 02:
124779-54-0 OR 131891-38-8 OR 186673-39-2 OR 224951-26-2 OR 25639-54-7
N = 0

TOXNET 03:

26446-62-8 OR 30496-13-0 OR 51253-31-7 OR 7300-23-4 OR 76341-26-9
N = 6

PubMed:
PubMed may be accessed through the EPA Desktop Library (https://www.ncbi.nlm.nih.gov/pubmed/)

Date Searched: 07/02/2019
Date Range of Search: 1900 to present
N = 1070

"2, 2-Bis (4'-hydroxy-3',-5'-dibromophenyl) propane" OR "2,2',6,6'-Tetrabrom-4,4'-isopropylidendiphenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropilidendifenol" OR "2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol" OR "2,2',6,6'-Tetrabromobisphenol A" OR "2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl) propane" OR "2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane"
N = 5

OR "3,3,5,5-Tetrabromobisphenol A" OR "3,3',5,5'-Tetrabromobisphenol A" OR "3,5,3',5'-Tetrabromobisphenol A" OR "4,4'-(1-Methylethylidene)bis(2,6-dibromophenol)" OR "4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(2,2-propanediyl) bis[2,6-dibromo]phenol"
N = 26

OR "4,4'-(Methylethylidene)bis[2,6-dibromophenol]" OR "4,4'-(Propane-2,2-diyl)bis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis(2,6-dibromophenol)" OR "4,4'-Isopropylidenebis[2,6-dibromophenol]" OR "4,4'-Isopropylylidenebis(2,6-dibromophenol)"
N = 54

"BA 59" OR "BA 59BP" OR "BA 59P" OR "BIS(PHENOL, 2,6-DIBROMO), 4,4'-(1-METHYLETHYLIDENE)" OR "BISPHENOL A, TETRABROMO-" OR "BISPHENOL, 4,4'-(1-METHYLETHYLIDENE)TETRABROMO-" OR "Bromdian" OR "CP 2000" OR "FCP 2010" OR "FG 2000" OR "Fire Guard 2000" OR "Firemaster BP 4A" OR "Flame Cut 120G" OR "Flame Cut 120R" OR "FR 1524" OR "FR 1525" OR "GLCBA 59P" OR "Great Lakes BA-59P" OR "NSC 59775" OR "PB 100" OR "RB 100" OR "Saytex CP 2000" OR "Saytex RB 100" OR "Saytex RB 100PC" OR "T 0032" OR "TBBPA" OR "Tetrabromo-4,4'-isopropylidenediphenol" OR "Tetrabromobisphenol A" OR "TETRABROMOBISPHENOL-A" OR "Tetrabromodian" OR "Tetrabromodiphenylolpropane"
N = 985

"Tetrabromodiphenylopropane" OR "UNII-FQI02RFC3A"
N = 0

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

Date Searched: 06/11/2019
Date Range of Search: all years
N = 134

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

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.*, analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH*)* fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR[10].

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

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

A.2 Peer-Reviewed Screening Process

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

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

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

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

A.2.1 Inclusion/Exclusion Criteria

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

A.2.1.1 PECO for Environmental and Human Health Hazards

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

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

PECO Element	Evidence
P	**Human:** Any population and life stage (*e.g.*, occupational or general population, including children and other sensitive populations). **Animal:** Aquatic and terrestrial species (live, whole organism) from any life stage (*e.g.*, preconception, in utero, lactation, peripubertal, and adult stages). Animal models will be inventoried according to the categorization below: Human health models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicity only) Ecotoxicological models: invertebrates (*e.g.*, insects, spiders, crustaceans, mollusks, and worms) and vertebrates (*e.g.*, mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models. **Plants:** All aquatic and terrestrial species (live), including algal, moss, lichen and fungi species. **Screener note:** To identify human health and environmental hazards, other organisms not listed above in their respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards (*e.g.*, Xenopus, zebrafish), and traditional human health models (*e.g.*,

PECO Element	Evidence
	rodents) can be used to identify potential environmental hazard. Neurotoxicity studies performed in hens (*e.g.*, OECD 418 and 419) are considered relevant to both human and eco hazard. PECO considerations should be directed toward effects on target species only and not on the indirect effects expressed in taxa as a result of chemical treatment (*e.g.*, substance is lethal to a targeted pest species leading to positive effects on plant growth due to diminished presence of the targeted pest species). Tests of the single toxicants in *in vitro* systems or on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially supplemental (mechanistic studies). Bacteria and yeast studies specific for assessing genotoxicity or mutagenicity (*e.g.*, Ames assay) will also be tagged as potentially supplemental (mechanistic studies) but are otherwise excluded. Studies on viruses are excluded.
E	**Relevant forms and isomers:** 3,3',5,5' – Tetrabromobisphenol A (CASRN 79-94-7) For synonyms see the EPA Chemistry Dashboard. No isomers were included for TBBPA. **Human:** Any exposure to 3,3',5,5' – Tetrabromobisphenol A (TBBPA 79-94-7), singularly or in mixture, including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (*i.e.* urine, blood, semen, *etc.*). **Animal:** Any exposure to 3,3',5,5' – Tetrabromobisphenol A (TBBPA 79-94-7) including via water, injection (including environmental aquatic exposures), soil or sediment, gavage, diet, dermal, and inhalation. **Plants:** Exposure to 3,3',5,5' – Tetrabromobisphenol A (TBBPA 79-94-7) including via water, soil, sediment. **Screener note:** Field studies with media concentrations (surface water, interstitial water, soil) and/or body/tissue concentrations of animals or plants are to be identified as ***Supplemental*** if any biological effects are reported. Animal and plant studies involving exposures to mixtures will be included only if they also include exposure to (chemical name(s) and CASRN) alone. Otherwise, animal and plant mixture studies will be tagged as Supplemental. Human mixture studies are included. Controlled outdoor experimental studies (*e.g.*, controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be laboratory studies (not field studies) because there is a known and prescribed exposure dose(s) and an evaluation of hazardous effect(s). Whereas field studies (*e.g.*, biomonitoring) where there is no prescribed exposure dose(s) will be excluded if there is no evaluated hazardous effect, and tagged as supplemental field, if there is an evaluated hazardous effect.
C	**Human:** A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of 3,3',5,5' – Tetrabromobisphenol A (TBBPA 79-94-7), or exposure to 3,3',5,5' – Tetrabromobisphenol A (TBBPA 79-94-7). All case reports and case studies/series describing findings in a sample size of less than 20 people in any setting (*e.g.*, occupation, general population) will be tracked as "potentially relevant supplemental information". **Animal and Plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement). **Screener note:**

PECO Element	Evidence
	If no control group is explicitly stated or implied (*e.g.* by mention of statistical results that could only be obtained if a control group was present), the study will be marked as ***Unclear*** during Title/Abstract Screening. All case series and case studies describing findings in a sample size of less than 20 people in any setting (*e.g.*, occupation, general population) will be tracked as ***Supplemental.*** Case-control, case-crossover, case-referent, case-only, case-specular, case-cohort, case-parent, nested case-control study designs are all ***Included.***
O	**Human**: All health outcomes (cancer and noncancer) at the organ level or higher. **Animal and Plants**: All apical biological effects (effects measured at the organ level or higher) and bioaccumulation from laboratory studies with concurrently measured media and/or tissue concentrations. Apical endpoints include but are not limited to reproduction, survival, and growth. **Screener note:** **Measurable biological effects relevant for humans, animals and plants may include, but are not limited to,** mortality, behavioral, population, physiological, growth, reproduction, systemic, point of contact (irritation and sensitization) effects. Effects measured at the cellular level of biological organization and below are to be tagged as supplemental, mechanistic.

Table_Apx A-4. Major Categories of Potentially Relevant Supplemental Material for TBBPA

Category	Evidence
Mechanistic studies	Studies reporting measurements related to a health outcome that inform the biological or chemical events associated with phenotypic effects, in both mammalian and non-mammalian model systems, including *in vitro, in vivo, ex vivo,* and *in silico* studies.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.
Case reports or case series	Case reports ($n \leq 3$ cases) and case series (non-occupational) will be tracked as potentially relevant supplemental information.
Susceptible populations (no health outcome)	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype. This tag applies during full-text screening.
Mixture studies	Mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest. Human health animal model and eco animal model/plant will be tagged separately for mixture studies.
Non-English records	Non-English records will be tracked as potentially relevant supplemental information.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Field Studies	Field studies where there are accompanying body/tissue concentrations of animals or plants if biological effects reported

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

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

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

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

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Under-ground Disposal	Ground Water
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	--	--	--	--	--	--

[a] "Supplemental pathways" refers to pathways addressed by other EPA administered statutes. Studies tagged under these pathways provide media information that is not prioritized in the screening process.

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

EPA developed a generic RESO statement to guide the screening of engineering and occupational

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

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

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

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

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

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

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

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

Objective Determined during Scoping	Type of Data [a]

[a] These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.
In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis.
Abbreviations:
hr=Hour
kg=Kilogram(s)
lb=Pound(s)
yr=Year
PV=Particle volume
POTW=Publicly owned treatment works
PPE=Personal protection equipment
PSD=Particle size distribution
TWA=Time-weighted average

A.2.1.4 PESO for Fate and Transport

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

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

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

PESO Element	Evidence
Pathways and **P**rocesses	Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.
Exposure	Environmental exposure of environmental receptors (*i.e.*, aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Environmental exposure of human receptors, including any potentially exposed or susceptible subpopulations, to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (*e.g.*, buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (*i.e.*, aquatic and terrestrial organisms) or human receptors (*i.e.*, general population, and potentially exposed or susceptible subpopulation)
Outcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)

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

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

A.2.1.5 Generation of Hazard Heat Maps

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

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

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

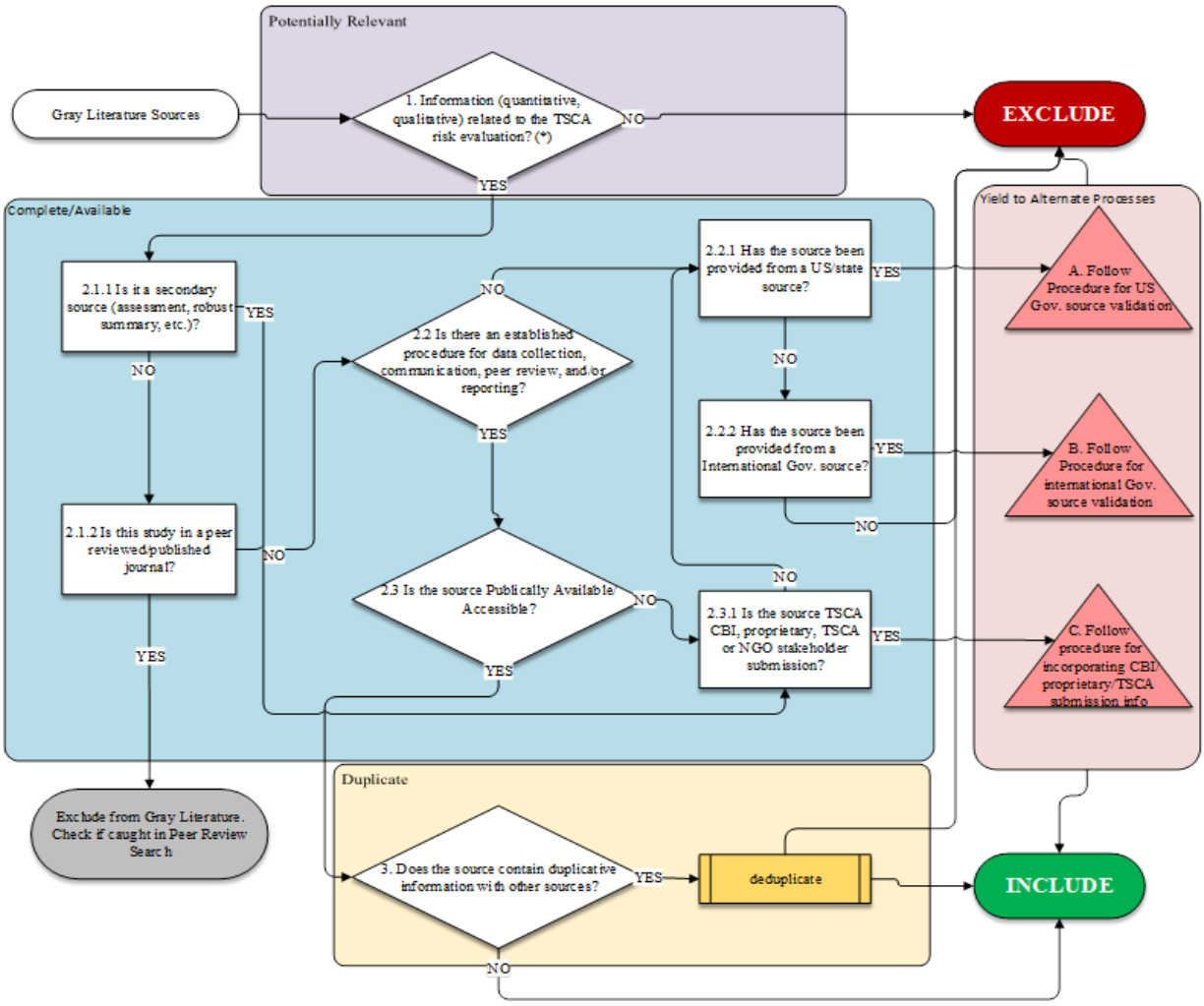
A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. Gray literature is defined as the broad category of data/ information sources not found in standard, peer-reviewed literature databases (*e.g.*, PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases. Given the nature of how gray literature is searched and collected, results may not come with a bibliographic citation or abstract and were therefore processed using a decision tree logic described in Appendix A.3.1 for potential relevance prior to entering full text screening where a discipline-specific PECO is applied.

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

A.3.1 Screening of Gray Literature

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



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

A.3.2 Initial Screening of Sources using Decision Logic Tree

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

Table_Apx A-11. Decision Logic Tree Overview

Step	Metric	Questions to Consider
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations? *Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?

Step	Metric	Questions to Consider
2.1.2		Is the document from a peer reviewed/published journal?
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

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

A.3.3 TSCA Submission Searching and Title Screening

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

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

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

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

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

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

A.3.4 Gray Literature Search Results for TBBPA

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

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

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document	https://www.industrialchemicals.gov.au/chemical-information/search-assessments
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer, Notice	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Research--Statistics/Chemicals
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document	https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance.html
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document	https://www.canada.ca/en.html
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	OPPT: Chemview (TSCA submissions - chemical test rule data and substantial risk reports)	US EPA Resources	Database	https://chemview.epa.gov/chemview
EPA	OPPT: 8e database (CBI) (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata.us/portal/
EPA	Design for the Environment (DfE) Alternatives Assessments	US EPA Resources	Assessment or Related Document	https://www.epa.gov/saferchoice/design-environment-alternatives-assessments
EPA	TSCA Assessments	US EPA Resources	Assessment or Related Document	https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-conducted-tsca-work-plan-chemicals-prior
EPA	Other EPA: Misc sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios
IARC	IARC Monograph	International Resources	Assessment or Related Document	http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php

Source Agency	Source Name	Source Type	Source Category	Source Website
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshtic-2/
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database	https://pubchem.ncbi.nlm.nih.gov/
NLM	NIEHS Tox Review	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/tetrabromobisphenola_508.pdf
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/reports/index.html?type=Technical+Report
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document	http://www.oecdsaatoolbox.org/
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document/46/0,2340,en_2649_201185_2412462_1_1_1_1,00.html
RIVM	RIVM Reports: Dietary Intake	International Resources	Assessment or Related Document	https://www.rivm.nl/en
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	http://www.tera.org/

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

Table_Apx B-1 summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0462).

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	-	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	2	-	NA	NA	NA	NA
Physical properties	4	-	NA	NA	NA	NA
Melting point	17	ºC	196.9	65.6	178	451.5
Boiling point	2	ºC	316	0	316	316
Density	3	g/cm^3	2.04	0.24	1.76	2.2
Vapor pressure	4	mm Hg	0.001887	0.003742	3.54×10^{-11}	0.007501
Vapor density	-	-	-	-	-	-
Water solubility	6	mg/L	3.186667	1.572357	0.72	4.66
Octanol/water partition coefficient (log K_{OW})	4		5.533	1.222193	4.5	7.2
Henry's Law constant	1	$atm \cdot m^3/mol$	1.45×10^{-10}	-	1.45×10^{-10}	1.45×10^{-10}
Flash point	-	ºC	-	-	-	-
Auto flammability	-	ºC	-	-	-	-
Viscosity	-	cP	-	-	-	-
Refractive index	-	-	-	-	-	-
Dielectric constant	-	-	-	-	-	-

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 was 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, 2019e) and may be updated as EPA collects additional information through systematic review methods.

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	NLM (2018), citing Eriksson et al. (2004)
	2,6-dibromo-p-benzosemiquinone anions and TBBPA were identified as the main photodecomposition byproducts	NLM (2018), citing Han et al. (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	NLM (2018), citing Lyman et al. (1990)
Biodegradation (Aerobic)	Water: 0%/14 days (MITI)	NLM (2018) NITE (2018)
	Water: $t_{1/2}$ = 48-84 days (natural river water)	NLM (2018) citing Great Lakes Chem (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	NLM (2018), citing Li et al. (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	NLM (2018), citing Voordeckers et al. (2002)
Wastewater Treatment	Wastewater influent containing 2,2',6,6'-TBBPA concentration range of 10-145 ng/L had removal of 76–83% with conventional activated sludge and bioreactor systems	NLM (2018), citing Islam (2015)

Property or Endpoint	Value[a]	Reference
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*)	NLM (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)

[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 Statutes/Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	TBBPA is one of the first 20 chemical substances designated as high-priority substances for risk evaluation under TSCA (84 FR 71924, December 30, 2019).
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 (85 FR 20122, April 2, 2020).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	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 chemical substance or mixture presents a substantial risk of injury to health or the environment.	11 risk reports received for TBBPA (1992-2005**)** (U.S. EPA, ChemView, Accessed June 25, 2019).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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 was 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).

State Actions	Description of Action
	California issued a Health Hazard Alert for TBBPA (Hazard Evaluation System and Information Service, 2016). California lists TBBPA as a designated priority chemical for biomonitoring (California SB 1379). The Oregon Department of Environmental Quality lists TBBPA as a priority persistent pollutant (Oregon SB 737).

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 recommended 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

Country/Tribe/ Organization	Requirements and Restrictions
	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. http://www.basel.int/Portals/4/Basel%20Convention/docs/text/BaselConventionText-e.pdf
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. https://www.oecd.org/env/waste/guidance-manual-control-transboundary-movements-recoverable-wastes.pdf

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 Manufacturing (Including Importing)

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, 2011).

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 Incorporating 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 Incorporating 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 (U.S. EPA, 2018d). For example, as a reactive flame retardant TBBPA in incorporated into printed circuit boards, semiconductor packages and the interior material for transportation equipment (U.S. EPA, 2019a); EPA-HQ-OPPT-2018-0462-0041; EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-OPPT-2018-0462-0030; EPA-HQ-OPPT-2018-0462-0036; EPA-HQ-OPPT-2018-0462-0020 and EPA-HQ-OPPT-2018-0462-0004. 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 (Borchardt, 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

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.*, all other chemical product and preparation manufacturing)

The Chemtura company, at two sites, reported to CDR (U.S. EPA, 2019a) 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.1.3.3 Building/Construction Materials

One company, Lintech International Inc., reported to CDR (U.S. EPA, 2019a) 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 (Environment Canada, 2013) states that it is used flame-retardant resins containing TBBPA are found in glass-reinforced construction panels.

E.1.3.4 Electrical and Electronic Products (Reactive Flame Retardant)

Three companies reported to CDR (U.S. EPA, 2019a) 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 that use TBBPA as a reactive flame retardant are printed circuit boards and semiconductor packages. 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). Environment Canada (2013) states that TBBPA is used to make rigid epoxy-laminated printed circuit boards and terminal boards and further reports that flame-retarded resins made with TBBPA are used in communications and electronics equipment, appliances and lighting fixtures. Albemarle and the Consumer Technology Association additionally commented that TBBPA reactively incorporated into electronics are internal to the device (EPA-HQ-OPPT-2018-0462-0029 and EPA-HQ-OPPT-2018-0462-0030). According to the American Chemistry Council, Albemarle, the Semiconductor

Industry Association and Huntsman, the quantity of residual TBBPA after it has been reactively incorporated into a matrix is none; although EPA agrees that the quantity is minimal or zero, the Agency does not have data to quantify the amount of TBBPA in the reacted matrix (EPA-HQ-OPPT-2018-0462-0038; EPA-HQ-OPPT-2018-0462-0029; EPA-HQ-OPPT-2018-0462-0036; EPA-HQ-OPPT-2018-0462-0041). During the risk evaluation, EPA will determine how much of the TBBPA is found in electronics after reactive uses. 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.1.3.5 Electrical and Electronic Products (Additive Flame Retardant in Plastic Enclosures)

Three companies reported to CDR (U.S. EPA, 2019a) 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 that incorporated TBBPA additively into products are plastic enclosures. 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). Environment Canada (2013) states that acrylonitrile-butadiene-styrene (ABS) resins containing TBBPA are used in refrigerators and other appliances, business machines and telephones. Additive flame retardants are not chemically bonded to the base material while reactive flame retardants are chemically bonded. Albemarle and the Consumer Technology Association (CTA) offered conflicting comments on the location of the plastic containing TBBPA in electronics. Albemarle suggested that the plastic enclosure forms a barrier from the rest of the appliance and the CTA asked EPA to specify that the plastic enclosure is external to the electronic device; therefore, comes into contact with consumers (EPA-HQ-OPPT-2018-0462-0029 and EPA-HQ-OPPT-2018-0462-0030). During the risk evaluation, EPA will determine the exposure of additive TBBPA in electronic products.

E.1.3.6 Laminate (Reactive Flame Retardant in Prepreg Material for Automotive and Aviation Interiors)

Huntsman described that TBBPA is imported and incorporated reactively into a matrix to create an epoxy resin. This resin then creates laminate or prepreg for use in interior automotive and aviation products. The resin product is called Tactix® 695. End uses of these products have consumer, commercial and military applications. According to Huntsman all TBBPA is reacted when creating the polymer matrixes and epoxy resin; therefore, no remaining (or residual) TBBPA is present in the final products sold (EPA-HQ-OPPT-2018-0462-0041). Environment 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.1.3.7 Plastic Products and Resins

One company, Sabic Innovative Plastics, reported to CDR (U.S. EPA, 2019a) 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 during the risk evaluation 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.1.3.8 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 (Government of Canada, 2013; NIEHS, 2002; IPCS, 1995; Gustafsson and Wallen, 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. While the use of TBBPA in textiles may be a limited use, it is still an ongoing condition of use and the Agency did not receive any comments on the draft scope document that would warrant excluding the condition of use from the final scope document. EPA plans to further investigate 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.1.3.9 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.1.3.10 Other Uses: Laboratory Chemical

A safety data sheet for TBBPA (<=100% percent purity) indicates recommended use as a laboratory chemical (Sigma-Aldrich Inc., 2019). A commenter (EPA-HQ-OPPT-2018-0462-0039) provided description of their use of TBBPA in analytical standards, research, equipment calibration and sample preparation for analysis of terrestrial and extraterrestrial material samples, which the commenter also indicated was critical use, further information EPA's understanding of this condition of use.

E.1.4 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 (U.S. EPA, 2018d, 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
HHEs can be found at https://www.cdc.gov/niosh/hhe/

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
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	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
Manufacturing	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		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	Reactive flame retardant (*e.g.*, printed circuit boards and semiconductor packages, interior material for transportation equipment); additive flame retardant (*e.g.*, plastic electronic enclosures)	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 (*e.g.* electronic products)	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.
		Laminate (*e.g.* reactive flame retardant in prepreg material for automotive and aviation interiors)	Production of laminate (*e.g.* reactive flame retardant in prepreg material for automotive and aviation interiors)	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 ONUs is not expected for this condition of use because ONUs 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
		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.
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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
	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)
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.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
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 (*e.g.*, reactive flame retardant)	Direct contact through use of electrical and electronic products made containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers Bystanders	Yes	Inhalation of air and/or particles from electrical and electronic products containing TBBPA may occur for this condition of use. EPA plans to evaluate 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 evaluate dust exposure via ingestion.
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate dermal exposure.
Consumer Use		Electrical and electronic products (*e.g.*, additive flame retardant in plastic enclosures)	Direct contact through use of electrical and electronic products made containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers Bystanders	Yes	Inhalation of air and/or particles from electrical and electronic products containing TBBPA may occur for this condition of use. EPA plans to evaluate 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 evaluate dust exposure via ingestion.
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate dermal exposure.
		Batteries	Direct contact through use of batteries made containing TBBPA	Air/Particulate/ Vapor/Mist	Inhalation	Consumers Bystanders	Yes	Inhalation of air and/or particles from batteries containing TBBPA may occur for this condition of use. EPA plans to evaluate inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of dust from batteries containing TBBPA may occur for this condition of use. EPA plans to evaluate dust exposure via ingestion.
Consumer Use				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to evaluate dermal exposure.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
	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 Bystanders	Yes	Inhalation via air and/or particulate exposure may occur during product/article use. EPA plans to evaluate inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of TBBPA sorbed onto dust may occur for this condition of use. EPA plans to evaluate dust exposure via ingestion.
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur via use of articles containing TBBPA. EPA plans to evaluate 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 evaluate 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 evaluate dermal exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of TBBPA sorbed onto dust may occur for this condition of use. EPA plans to evaluate 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 evaluate inhalation exposure.
			Long-term emission/mass-transfer through use of products containing TBBPA	Dust	Ingestion	Consumers	Yes	Ingestion of TBBPA sorbed onto dust may occur for this condition of use. EPA plans to evaluate 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 evaluate 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 evaluate 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 evaluate 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 evaluate 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 evaluate the pathway from biosolids to the general population, aquatic and terrestrial species.
				TBD	Aquatic and Terrestrial Receptors	Yes	

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	Yes	TBBPA is released to Class I Underground Injection Wells (U.S. EPA (2019f). EPA will evaluate this pathway.
				TBD	Aquatic and Terrestrial Receptors		
Disposal	Solid and Liquid Wastes	Municipal landfill and other land disposal	Leachate to soil, ground water and/or migration to surface water	Oral Dermal	General Population	Yes	EPA plans to analyze the pathway from municipal landfills and other land disposal to the general population, aquatic and terrestrial receptors.
				TBD	Aquatic and Terrestrial Receptors		