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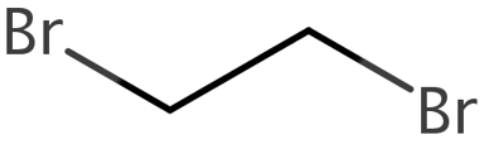
Final Scope of the Risk Evaluation for Ethylene Dibromide

CASRN 106-93-4



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Docket

Supporting information can be found in public docket: [Docket ID: EPA-HQ-OPPT-2018-0488].

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ACC	American Chemistry Council
ACGIH	American Conference of Government Industrial Hygienists
ADME	Absorption, Distribution, Metabolism, and Excretion
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification factor
CAA	Clean Air Act
CARB	California Air Resources Board
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEPA	The Center for European Policy Analysis
CEPA	Canadian Environmental Protection Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CESSD	Chemistry, Economics and Sustainable Strategies Division
CFR	Code of Federal Regulations
COC	Concentration of Concern
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
EC	Engineering Controls
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EDB	Ethylene Dibromide
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
GACT	Generally Available Control Technology
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FDA	Food and Drug Administration
FR	Federal Register
FYI	For Your Information
GDIT	General Dynamics Information Technology
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HAWC	Health Assessment Workplace Collaborative
HERO	Health and Environmental Research Online
HHE	Health Hazard Evaluation
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
ICES	International Council for the Exploration of the Sea
ICF	ICF is a global consulting services company
IDLH	Immediately Dangerous to Life and Health

IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
IPCheM	Information Platform for Chemical Monitoring Data
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
K_{OC}	Organic Carbon: Water Partition Coefficient
K_{OW}	Octanol: Water Partition Coefficient
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MDI	MDI Biological Laboratory
MOA	Mode of Action
MP	Montreal Protocol
MSW	Municipal Solid Waste
NAICS	North American Industry Classification System
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NKRA	Not Known or Reasonably Ascertainable
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
NPRI	National Pollutant Release Inventory
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment (California)
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PEL	Permissible Exposure Limit
PESO	Pathways and Processes, Exposure, Setting or Scenario, and Outcomes
PESS	Potentially Exposed or Susceptible Subpopulations
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
RAD	Risk Assessment Division
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
RESO	Receptors, Exposure, Setting or Scenario, and Outcomes
RIVM	Dutch National Institute for Public Health and the Environment
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SRC	SRC Inc., formerly Syracuse Research Corporation
STEL	Short-term Exposure Limit
TBD	To be determined

TCCR	Transparent, Clear, Consistent and Reasonable
TCSA	Toxic Substances Control Act
TIAB	Title and Abstract
TLV	Threshold Limit Value
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TWA	Time-weighted average
UCM	Unregulated Contaminants Monitoring
USGS	United States Geological Survey
VOC	Volatile Organic Compound
VP	Vapor Pressure
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated ethylene dibromide (CASRN 106-93-4) as a high-priority substance for risk evaluation following the prioritization process as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (Part 40 CFR 702) (Docket ID: EPA-HQ-OPPT-2019-0131). The first step of the risk evaluation process is the development of the scope document. EPA published the *Draft Scope of the Risk Evaluation for Ethylene Dibromide CASRN 106-93-4* (EPA Document No. EPA-740-D-20-012) (U.S. EPA, 2020c) and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0488) 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 ethylene dibromide. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The scope for ethylene dibromide 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. Ethylene dibromide is a volatile, highly water-soluble liquid with a total production volume in the United States between 1 and 20 million pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019e) (Docket ID: EPA-HQ-OPPT-2019-0131) 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 ethylene dibromide. 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 importing, processing, distribution in commerce, commercial and consumer uses, and disposal of ethylene dibromide in the risk evaluation. Ethylene dibromide is imported into the United States. The chemical is processed by incorporation into a formulation, mixture or reaction product for petroleum refineries and all other petroleum and coal products manufacturing. The commercial uses include laboratory chemicals and fuels and related products, such as an additive in aviation and racing fuels. Only one consumer use, fuels and related products, were reported. EPA identified these conditions of use from information reported to EPA through CDR and Toxics Release Inventory (TRI) reporting, published literature, public comments, and consultations with stakeholders for both uses currently in production and uses whose productions may have ceased. EPA did not revise

any conditions of use in the final scope document for ethylene dibromide based on public comments received (Docket ID: EPA-HQ-OPPT-2018-0488) on the draft scope. EPA is aware of information reporting uses of ethylene dibromide in pesticides, however, they are not conditions of use for the chemical substance as defined in TSCA § 3(2) and (4). Section 2.2. provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for ethylene dibromide 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 ethylene dibromide 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 ethylene dibromide 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 ethylene dibromide that EPA plans to consider in the risk evaluation. Exposures for ethylene dibromide are discussed in Section 2.3. Additional information gathered through systematic review searches will also inform expected exposures.

  EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether and how other EPA-administered statutes and regulatory programs cover ethylene dibromide in media pathways falling under the jurisdiction of those authorities. Section 2.6.3.1 discusses pathways under the jurisdiction of other EPA-administered laws. In Section 2.6.3.2, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of ethylene dibromide within the scope of the risk evaluation.

  EPA considered reasonably available information and comments received on the draft scope for ethylene dibromide 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 the manufacturing, processing, use or disposal of ethylene dibromide.
  - *Consumer and bystander exposure:* EPA plans to evaluate inhalation exposures for consumers and bystanders and dermal exposure to ethylene dibromide for consumers from aviation fuel products.
  - *General population exposure:* EPA plans to evaluate general population exposure to ethylene dibromide from ingestion of fish and water and from dermal exposure to surface water.
  - *PESS:* EPA plans to evaluate children, women of reproductive age (*e.g.*, pregnant women), workers, ONUs, consumers, and bystanders as PESS in the risk evaluation.
  - *Environmental exposure:* EPA plans to evaluate exposure to ethylene dibromide for aquatic receptors.

- *Hazards.* Hazards for ethylene dibromide 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 ethylene dibromide as part of the prioritization (U.S. EPA, 2019d) 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 ethylene dibromide 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 ethylene dibromide.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for ethylene dibromide 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, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory, skin and connective tissue for ethylene dibromide. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for ethylene dibromide 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 and skin and connective tissue.

Analysis Plan. The analysis plan for ethylene dibromide 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 ethylene dibromide to date which includes review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

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

1 INTRODUCTION

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

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

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high-priority substances for risk evaluations (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. Ethylene dibromide 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 Ethylene Dibromide* (EPA Document No. 740-D-20-012) (85 FR 19941, April 9, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments received (Docket ID: EPA-HQ-OPPT-2018-0488) on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this final scope document for ethylene dibromide. 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;

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

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

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

Search terms were used to search each of the literature streams and gather ethylene dibromide studies. These terms and the methods used to develop them are listed in Appendix A. The studies resulting from the search process were loaded into the EPA Health and Environmental Research Online (HERO) database and then prioritized to screen first the literature likely relevant for each of the disciplines: fate, physical and chemical properties, engineering, exposure and hazard. The tools and methods used to manage the screening process are also outlined in Appendix A. The studies resulting from the search underwent a title/abstract screening process, which tagged them by topic or category. Following this, a determination was made to move studies forward into full-text screening. The criteria used in the screening process for each discipline are found in the population, exposure, comparator, outcome (PECO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and 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 123 search results relevant to EPA's risk evaluation needs for ethylene dibromide. Appendix A.3.3 lists the gray literature sources that yielded 123 discrete data or information sources relevant to ethylene dibromide. 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, ecological 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.

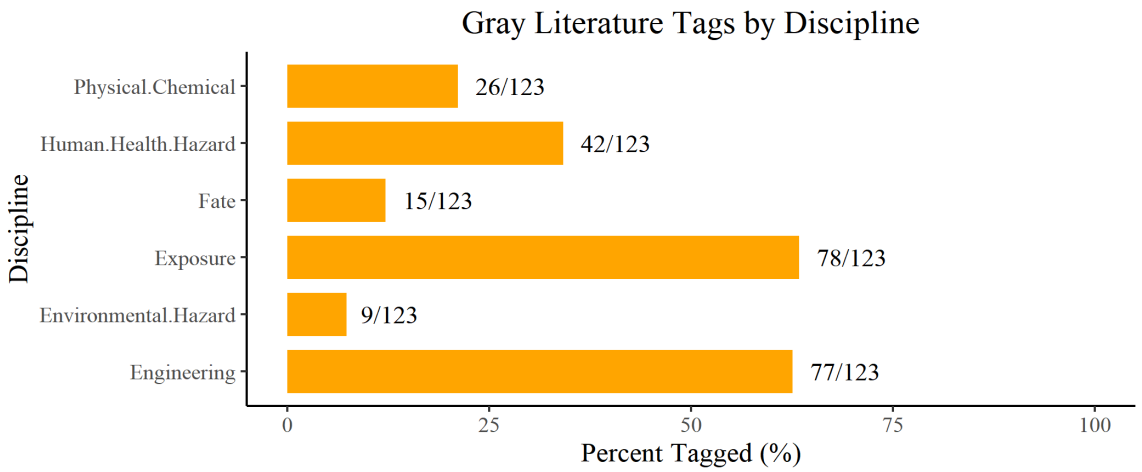

Figure 2-1. Gray Literature Tags by Discipline for Ethylene Dibromide
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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 ethylene dibromide. Eligibility criteria were applied in the form of PECO statements (see Appendix A). Included references met the PECO criteria, whereas excluded references did not meet the criteria (*i.e.*, not relevant), and supplemental material was considered as potentially relevant (see Appendix A.2). EPA plans to evaluate the reasonably available information identified for each discipline during the development of the risk evaluation.

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 and for exposure 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 a literature inventory heat maps for the fate, engineering, exposure, and hazard disciplines (see Figure 2-4, Figure 2-6, Figure 2-8, Figure 2-10). For each of these four disciplines, a static image of the literature inventory heat map is provided, and a link to the interactive version presented in HAWC is included in the caption below each diagram.

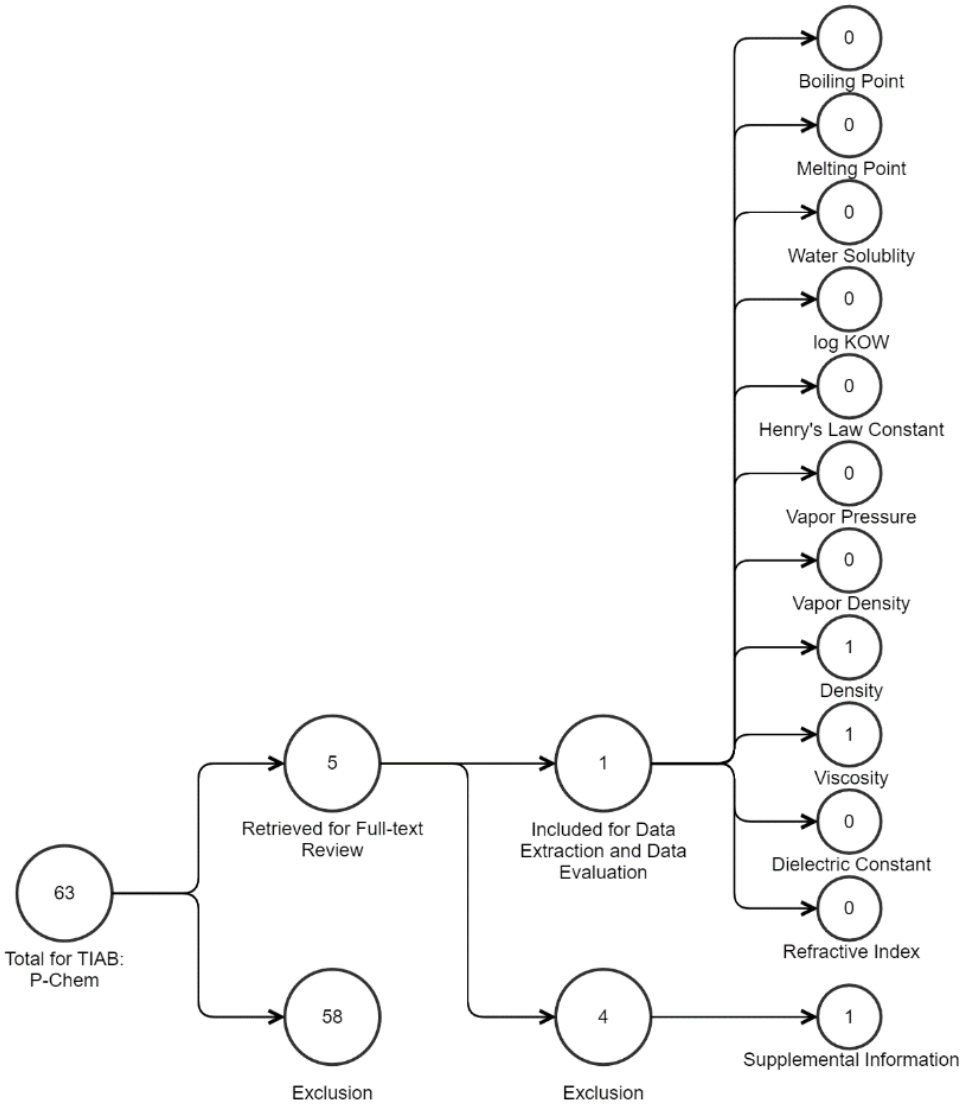

Figure 2-2. Peer-reviewed Literature Inventory Tree – Physical and Chemical Properties Search Results for Ethylene Dibromide

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.

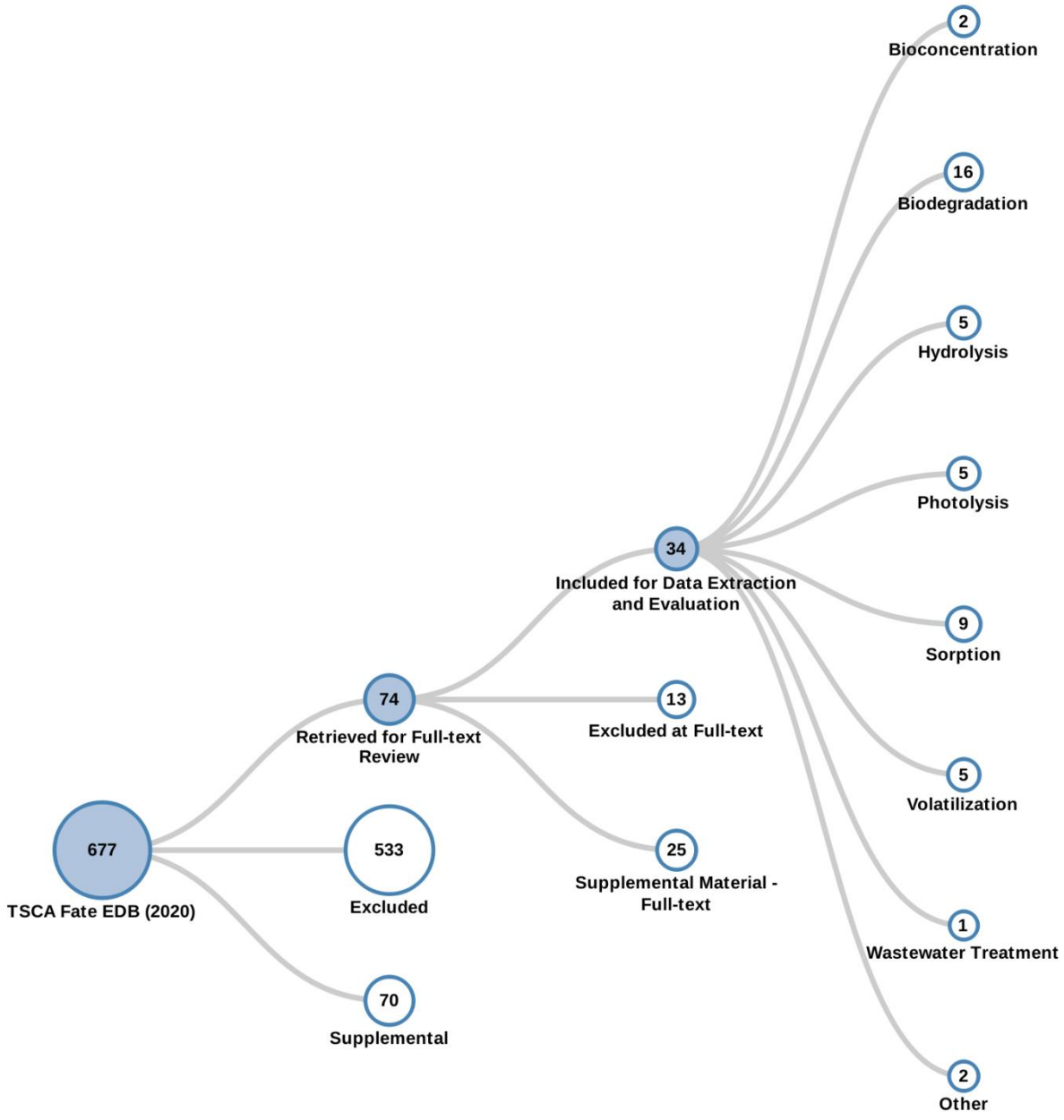

Figure 2-3. Peer-reviewed Literature Inventory Tree – Fate and Transport Search Results for Ethylene Dibromide

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		1		2
Biodegradation	2	14	1	12		16
Hydrolysis	1	2	1	4		5
Photolysis	4	1		2		5
Sorption	1	8	1	3		9
Volatilization	4	3		4		5
Wastewater Treatment			1	1		1
Other	2	1		1		2
Grand Total	7	22	3	22		34

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

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.

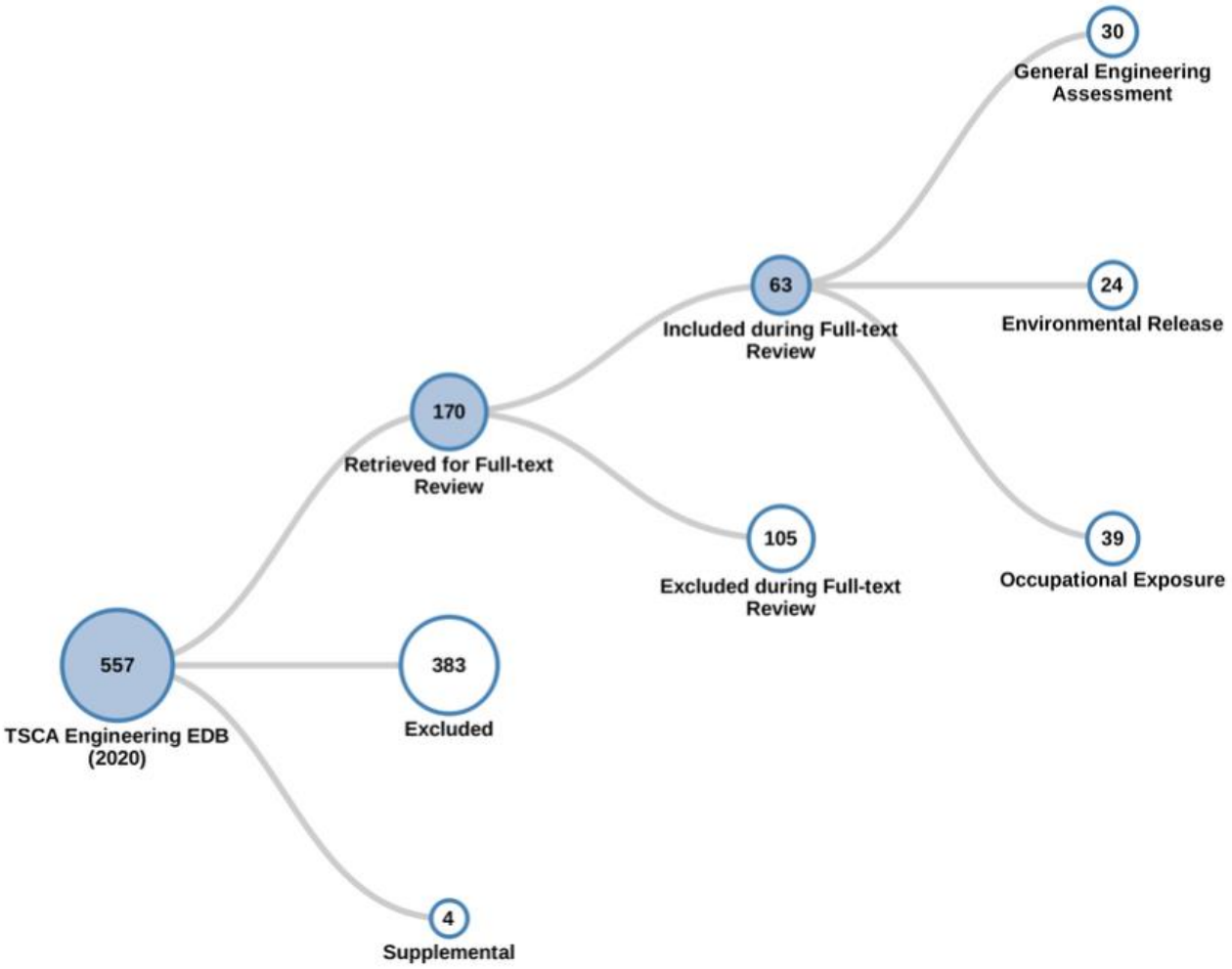

Figure 2-5. Peer-reviewed Literature Inventory Tree – Engineering Search Results for Ethylene Dibromide

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	14
	Release frequency	3
	Release or emission factors	18
	Release quantity	15
	Waste treatment methods and pollution control	5
	Total	24
General Engineering Assessment	Chemical concentration	9
	Life cycle description	10
	Number of sites	6
	Process description	7
	Production, import, or use volume	16
	Throughput	4
	Total	30
Occupational Exposures	Area sampling data	21
	Dermal exposure data	2
	Engineering control	4
	Exposure duration	14
	Exposure frequency	6
	Exposure route	19
	No evidence tag	1
	Number of workers	8
	Particle size characterization	
	Personal protective equipment	6
	Personal sampling data	21
	Physical form	11
	Worker activity description	16
	Total	39
Grand Total		63

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

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.

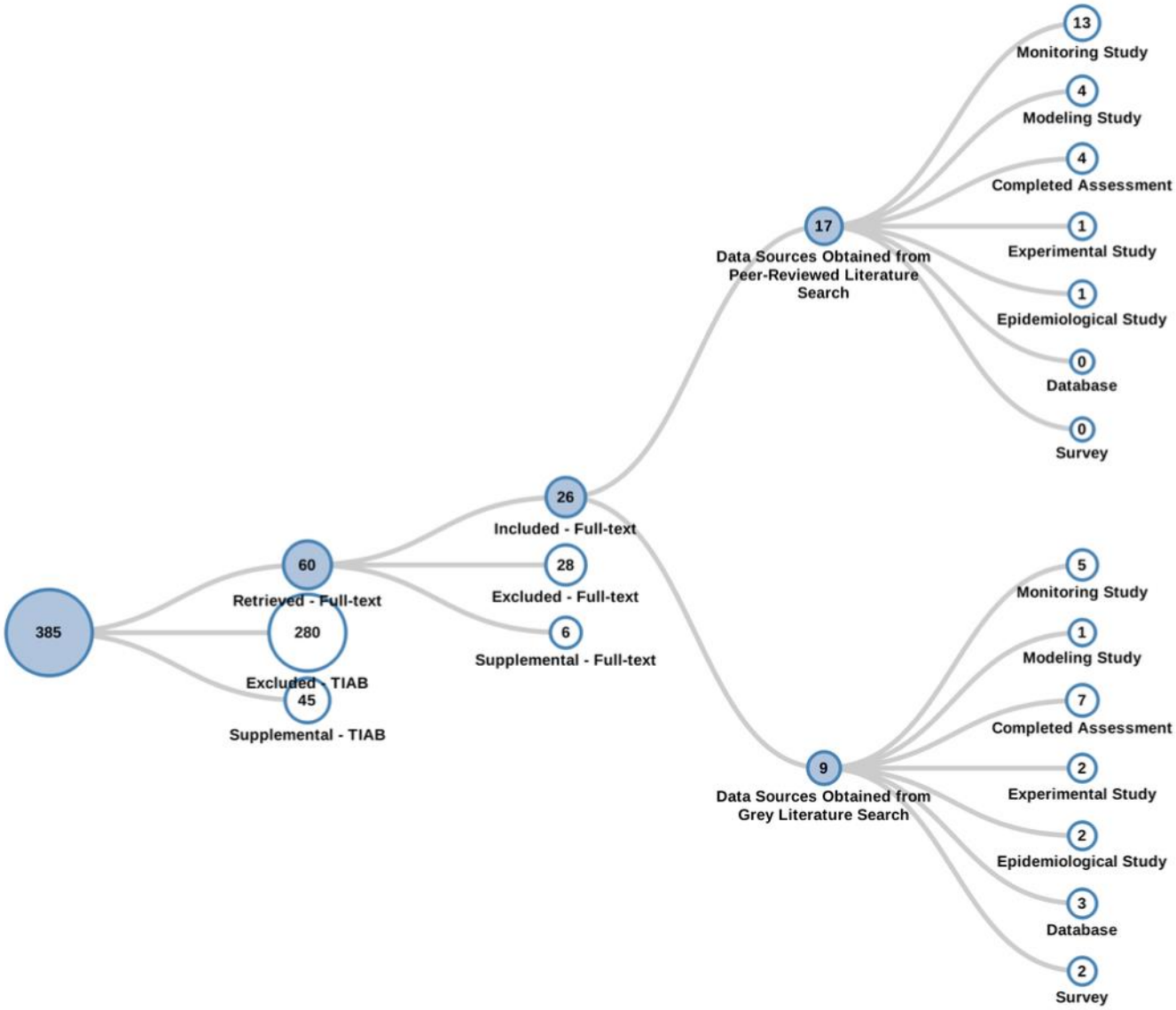

Figure 2-7. Peer-reviewed and Gray Literature Inventory Tree – Exposure Search Results for Ethylene Dibromide

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								
Biosolids/Sludge								
Drinking Water								
Groundwater			2					2
Land Disposal/ Landfill								
Sediment								
Soil			2					2
Surface Water	2	1	2	1		1		3
Wastewater								
Aquatic Species	1	1	1	1				1
Terrestrial Species	3	1	2	3				4
Consumer	1			1				1
Dietary	6	1	5	3		1	1	9
Dust								
Exposure Factors	2	1	2	1		1	1	2
Exposure Pathway	3	2	4	3		1	1	6
Human Biomonitoring	3	1			1	1		3
Indoor Air	9	4	5		1			14
Isomers			1					1
Use Information			4	1				4
No Evidence Type	1		1		1		1	1
Grand Total	18	5	11	3	3	3	2	26

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

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 column totals, row totals, and grand totals indicate total numbers of unique references only, 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.

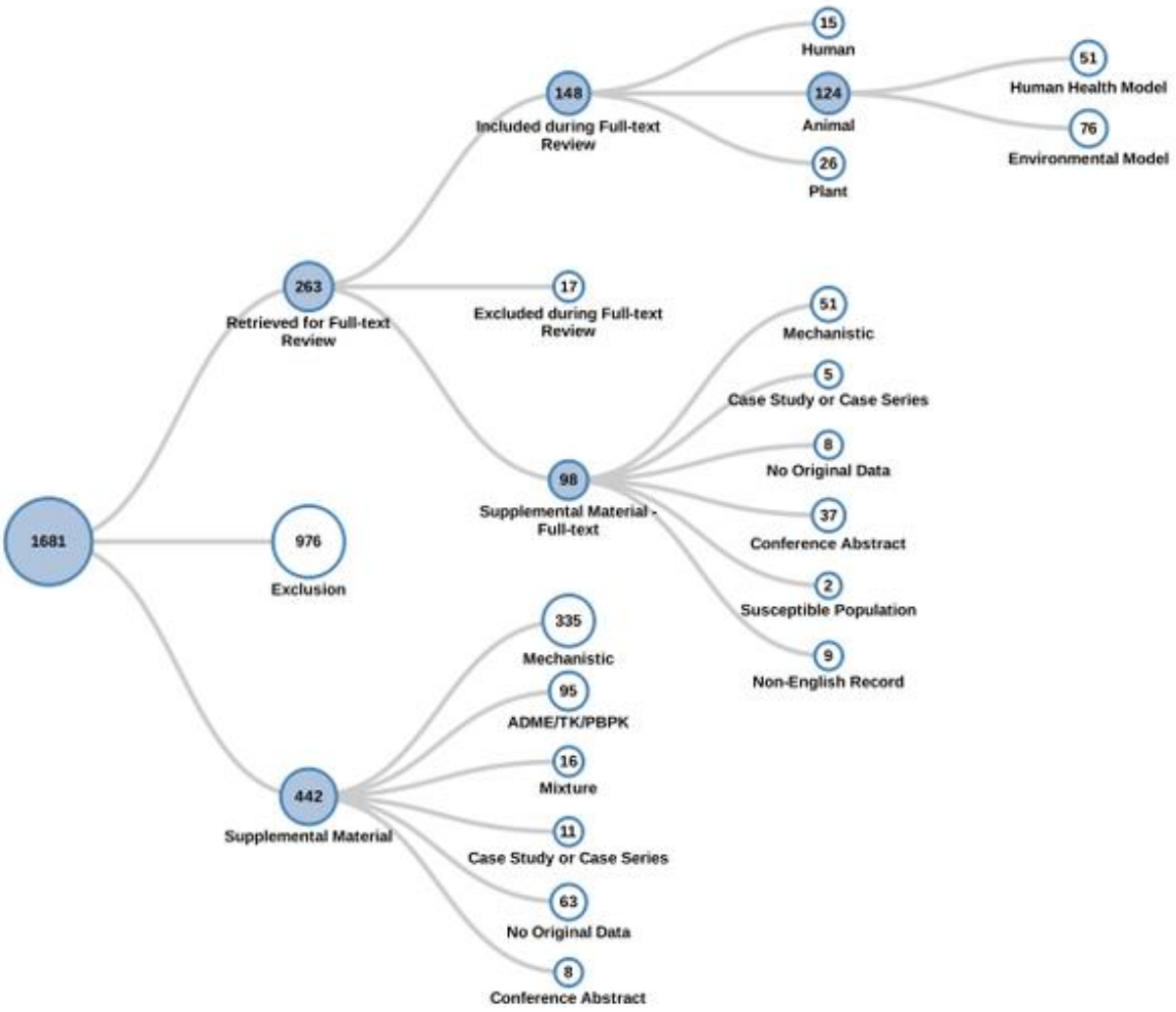

Figure 2-9. Peer-reviewed Literature – Literature Inventory Tree – Human Health and Environmental Hazards Search Results for Ethylene Dibromide

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 July 14, 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	2	24	4	2	32
Cancer	6	21	3		28
Cardiovascular	1	2	1		4
Developmental	7	14	10	11	40
Endocrine	4	17	2		21
Gastrointestinal	2	5	1		6
Hematological and Immune	4	13	7		24
Hepatic	2	24	6		29
Mortality	2	7	14	3	24
Musculoskeletal		1	2		3
Neurological	4	8			12
Nutritional and Metabolic	1	4	3	1	7
Ocular and Sensory	2	5	1		8
PBPK	1				1
Renal	2	10	2		13
Reproductive	8	17	6		29
Respiratory	4	22	1		26
Skin and Connective Tissue	3	3		1	7
No Tag		3	39	9	45
Grand Total	15	51	76	26	148

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

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 ethylene dibromide. 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 July 17, 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 36 submissions using PECO or similar statements that identify inclusion and 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 excluded 7 submissions[3] because the reports were identified as one of the following:

- Published report that would be identified via other peer or gray literature searches
- Summary of other reports
- Preliminary report of a final available submitted report
- Duplicate of another report
- Submission on a different chemical
- List of references with no original data
- Acknowledgment of receipt of request from EPA

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

Discipline	Included	Supplemental [b]
Physical and Chemical Properties	0	0
Environmental Fate and Transport	0	0
Environmental and General Population Exposure	8	1
Occupational Exposure/Release Information	6	0
Environmental Hazard	0	0
Human Health Hazard	6	10

[a] Individual submissions may be relevant to multiple disciplines.
[b] Individual 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 Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d), EPA assembled information from the CDR and TRI programs to determine conditions of use[4] or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA will utilize the most recent CDR information. EPA also consulted a variety of other sources to identify uses of ethylene dibromide, including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing ethylene dibromide, 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 SDS was current. In addition, EPA incorporated communications with companies, industry groups, and public comments to supplement the use information.

[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)

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.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use and disposal of ethylene dibromide, EPA identified those activities for ethylene dibromide 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]	References
Manufacturing	Import	Import	U.S. EPA (2019a)
Processing	Processing - Incorporation into formulation, mixture, or reaction product	Petroleum refineries	U.S. EPA (2019a)
		All other petroleum and coal products manufacturing	U.S. EPA (2019a)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Commercial use	Other use	*E.g.*, Laboratory chemicals	Sigma-Aldrich (2019)
	Fuels and related products	Fuel additive (*e.g.*, in aviation and racing fuels)	U.S. EPA (2019a); Renegade (2014)
Consumer use	Fuels and related products	Fuels and related products	U.S. EPA (2019a)
Disposal	Disposal	Disposal	

[a] Life Cycle Stage Use Definitions
- "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.

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

[c] These subcategories reflect more specific conditions of use of ethylene dibromide.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule for *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017), TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a

particular chemical substance[5]. As a result, EPA does not plan to include in this scope or in the risk evaluation activities described below that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

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

For the pesticidal use of ethylene dibromide, EPA has determined that this use falls outside TSCA's definition of "chemical substance." Under TSCA § 3(2)(B)(ii), the definition of "chemical substance" does not include any pesticide (as the term is defined by EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq. (1996)). Additionally, the last pesticidal products containing ethylene dibromide were cancelled in 1993.Therefore, activities and releases associated with such pesticidal uses are not "conditions of use" (defined as circumstances associated with a "chemical substance" in TSCA § 3(4)) and will not be evaluated during risk evaluation.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of ethylene dibromide in 2015 was between 1 million and 20 million pounds (U.S. EPA, 2020a). EPA also uses pre-2015 CDR, as detailed in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) 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 ethylene dibromide. 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.

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

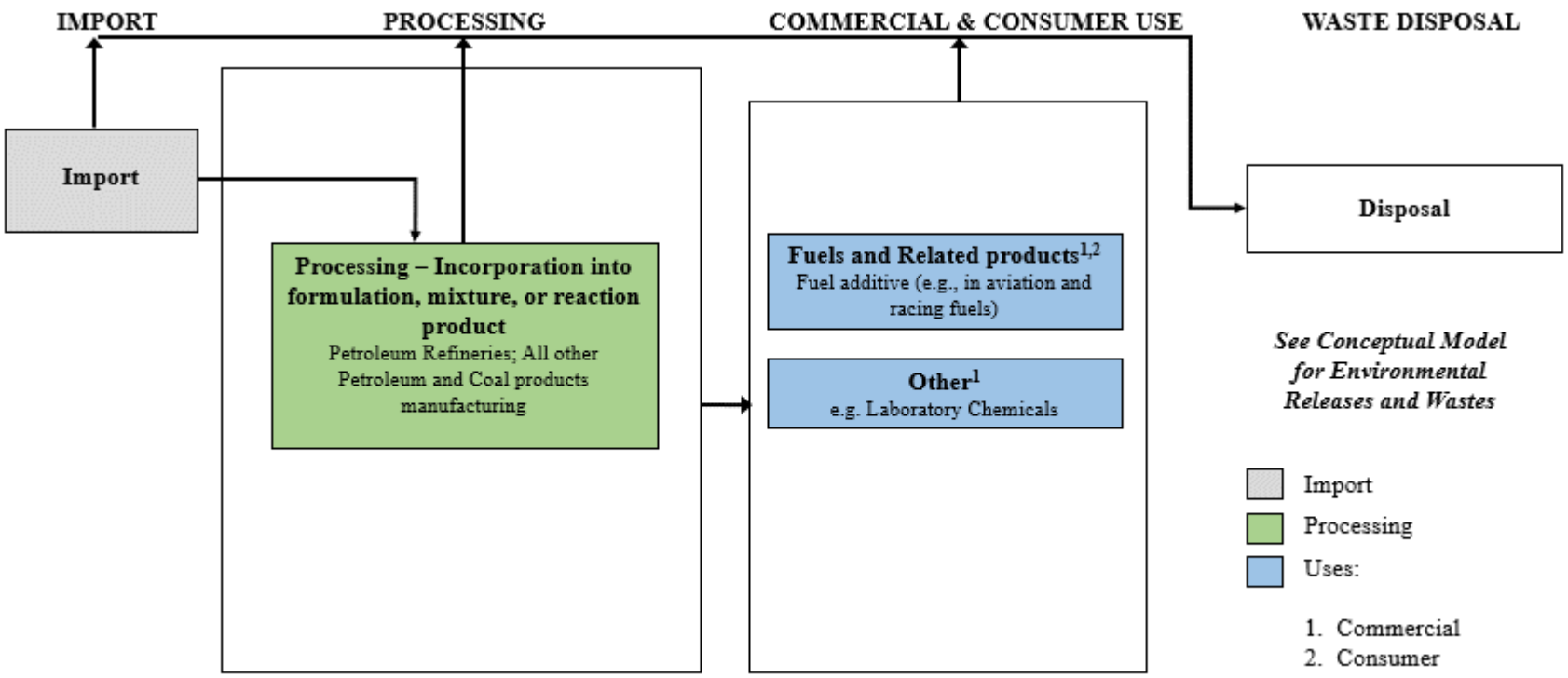

Figure 2-11. Ethylene Dibromide Life Cycle Diagram

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 for ethylene dibromide. 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 ethylene dibromide.

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 Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) 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 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-2018-0488).

Table 2-3. Physical and Chemical Properties of Ethylene Dibromide

Property or Endpoint	Value*	Reference	Data Quality Rating
Molecular formula	$C_2H_4Br_2$	NA	NA
Molecular weight	187.86 g/mol	NA	NA
Physical state	Liquid	Rumble (2018)	High
Physical properties	Colorless with sweet odor	RSC (2020)	High
Melting point	9.8°C	Rumble (2018)	High
Boiling point	131.3°C	Rumble (2018)	High
Density	2.175 g/cm^3 at 25°C relative to water at 25°C	O'Neil (2013)	High
Vapor pressure	11.2 mm Hg at 25°C	NLM (2018)	High
Vapor density	6.48 (air = 1)	NLM (2018)	High

Property or Endpoint	Value*	Reference	Data Quality Rating
Water solubility	4130 mg/L at 20°C	Rumble (2018)	High
Log Octanol/water partition coefficient (Log Kow)	1.96	U.S. EPA (2019b)	High
Henry's Law constant	6.5×10^{-4} atm·m^3/mol at 25°C	U.S. EPA (2019b)	High
Flash point	132°C	RSC (2020)	Medium
Auto flammability	Not available		
Viscosity	1.727 cP at 20°C	NLM (2018)	High
Refractive index	1.5356	NLM (2018)	High
Dielectric constant	4.77	NLM (2018)	High

* Measured unless otherwise noted.
N/A = Not applicable

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

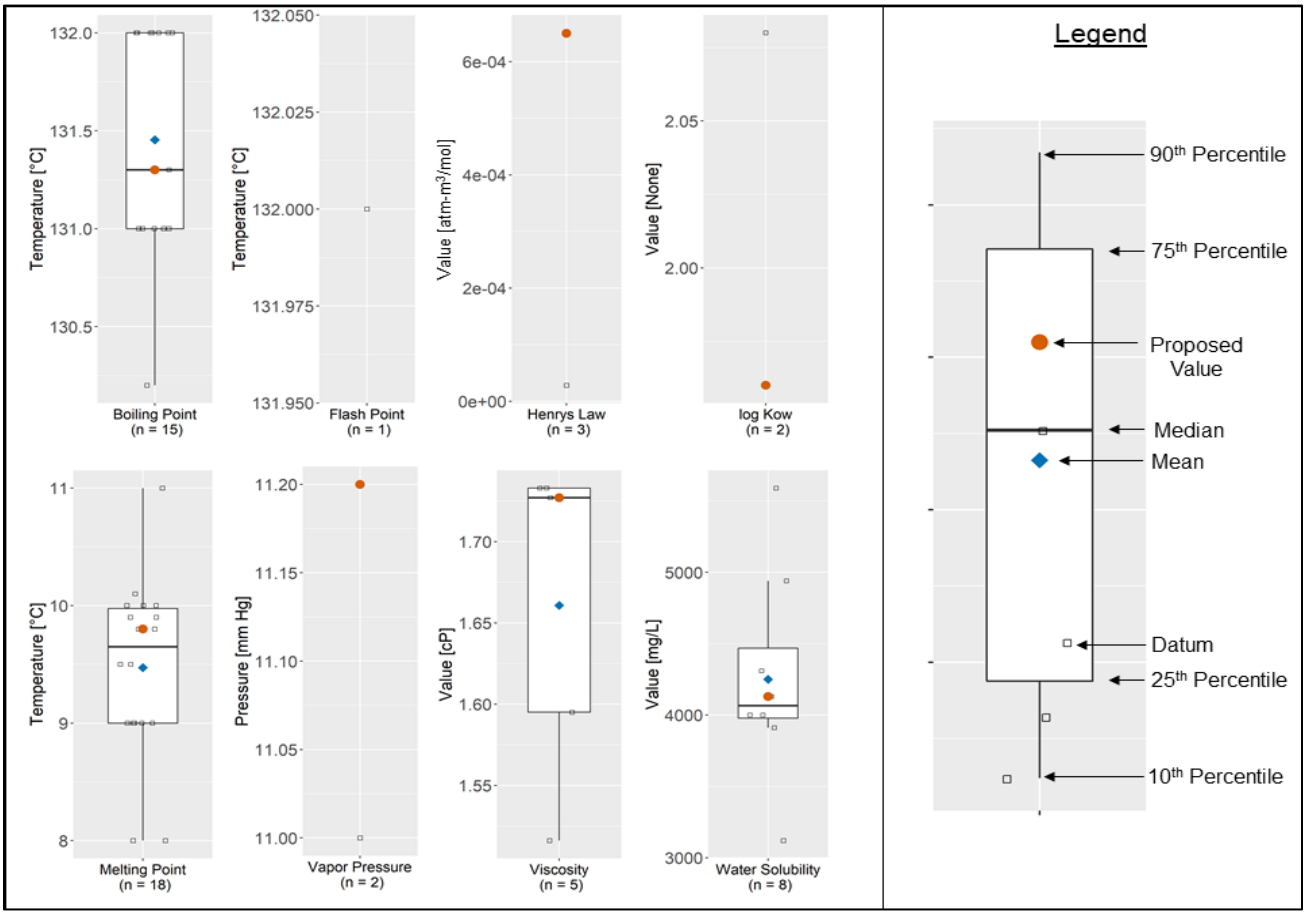

Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for ethylene dibromide. EPA plans to use the environmental fate characteristics described in Appendix C to support the development of the risk evaluation for ethylene dibromide. 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 Releases to the Environment

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

A source of information that EPA plans to consider in evaluating exposure are data reported to the 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), ethylene dibromide is a TRI-reportable substance, under the name 1,2-dibromoethane (or ethylene dibromide), effective January 01, 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 ethylene dibromide under the CASRN 106-43-4 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 ethylene dibromide reported by facilities to the TRI program for reporting year 2018.[7] As shown in the table, 10 facilities reported a total of 33,611 pounds of ethylene dibromide production-related waste managed in 2018. Of this total, approximately 26,500 pounds were treated on site and accounted for nearly 79% of all ethylene dibromide waste management quantities reported for 2018. The next highest portion of ethylene dibromide managed as waste was combustion for energy recovery (approximately 18%), all of which was performed on site. Quantities of ethylene dibromide recycled and released to the environment are of much smaller magnitude, accounting for the remainder of the total production-related waste.

Table 2-4. Summary of Ethylene Dibromide 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	10	35	5,991	26,656	929	33,611

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 a 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 ethylene dibromide released to the environment during 2018 as reported to TRI.[2] Of the 929 pounds of ethylene dibromide that were released to the environment during 2018, 735 pounds (79%) were released to air. Roughly half of these air emissions originated from point sources, with the other half from fugitive sources. Land disposal accounted for roughly 13% of ethylene dibromide release quantities, with the vast majority occurring off site to RCRA Subtitle C landfills. The remaining portion of the total release quantities (70 pounds) were on site and to surface water discharges.

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting
[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

Table 2-5. Summary of Releases of Ethylene Dibromide 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)		
2018	10	386	349	70	0	123	1	0	929
		735			124				

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 managed shown in Table 2-4 excludes any quantities reported as catastrophic or one-time releases (TRI Form R Section 8 data), release quantities shown in Table 2-5 include both production-related and non-production-related quantities. In the case of ethylene dibromide, the total release quantities listed in each table are the same, but for other TRI chemicals the total release quantities in these tables may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017).

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

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of ethylene dibromide 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 ethylene dibromide.

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

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

- Unloading and transferring ethylene dibromide to and from storage containers and process vessels;
- Handling and disposing of waste containing ethylene dibromide;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations, or products containing ethylene dibromide for quality control;
- Repackaging chemicals, formulations, or products containing ethylene dibromide;
- Performing other work activities in or near areas where ethylene dibromide is used.

Ethylene dibromide has a vapor pressure of 11.2 mmHg at 25°C (see Section 2.3.1). Based on the chemical's high volatility, EPA anticipates that both workers and ONUs will be exposed to ethylene dibromide vapors via inhalation. Based on the conditions of use identified in Section 2.2, EPA does not expect that mists will be generated during the conditions of use identified. EPA plans to evaluate dermal exposures for workers, who are expected to have skin contact with ethylene dibromide. ONUs do not directly handle ethylene dibromide; therefore, skin contact with ethylene dibromide is not expected for occupational non-users.

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.

The United States has several regulatory and non-regulatory exposure limits for ethylene dibromide: the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) (29 CFR 1910.1000) of 20 ppm (8-hr time weighted average), a Ceiling of 30 ppm, and a max peak of 50 ppm for 5 minutes during an 8-hour day (OSHA, 2019). This chemical also has a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) of 0.045 ppm TWA and a 0.13 ppm ceiling for 15-minutes during an 8-hour period. NIOSH considers ethylene dibromide to be a potential occupational carcinogen and also set a Immediately Dangerous to Life or Health (IDLH) value of 46 ppm (354 mg/m3)[8] for ethylene dibromide (NIOSH, 2020, 2019).

2.3.6 Consumer Exposures

According to reports to the 2016 CDR, leaded fuel products were identified as consumer products for ethylene dibromide. Consumers using or disposing of leaded fuel products may be exposed to ethylene dibromide through direct liquid contact which may lead to a dermal exposure, or through vapor emissions which may lead to inhalation exposure, given its volatility at room temperature. Bystanders present during the consumer use or disposal of leaded fuel products may also be exposed to ethylene dibromide vapor emissions leading to an inhalation exposure. Based on these potential sources and pathways of exposure, EPA plans to analyze inhalation and dermal routes of exposures to consumers and the inhalation route of exposure to bystanders that may result from the conditions of use of ethylene dibromide. EPA does not plan to evaluate dermal exposures for bystanders, nor oral exposures for

[8] (NIOSH Pub. No. 2020-125).

consumers and bystanders, since these routes of exposure are not expected according to the consumer conditions of use.

2.3.7 General Population Exposures

Environmental monitoring data were identified in EPA's data search for ethylene dibromide and can be used in the exposure assessment. Relevant and reliable monitoring studies provide information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available environmental monitoring data for ethylene dibromide. Based on fate properties, such as vapor pressure, Henry's Law constant, water solubility, and soil organic carbon-water partition coefficient, EPA anticipates possible presence of ethylene dibromide in air, water, and soil, depending on the media of release (ATSDR, 2018; Environment Canada, 2013; U.S. EPA, 2009, 2004b; OEHHA, 2003). EPA's Ambient Monitoring Technology Information Center Air Toxics database has identified ethylene dibromide in air. EPA Discharge Monitoring Report Data has identified ethylene dibromide in surface and ground water. EPA's Unregulated Contaminant Monitoring (UCM) program identified ethylene dibromide in drinking water. USGS's Monitoring Data – National Water Quality Monitoring Council has also identified ethylene dibromide in ground water, surface water, soil, and sediment. In addition, the National Health and Nutrition Examination Survey has identified ethylene dibromide in human biomonitoring samples (CDC, 2013). However, according to a recent ATSDR Toxicological Profile for ethylene dibromide, human blood measurements for this chemical were below the limit of detection (ATSDR, 2018). Ethylene dibromide has not been reported in ecological biomonitoring matrices.

Releases of ethylene dibromide from certain conditions of use, such as manufacturing, processing, distribution, use and disposal activities, may result in general population exposures (OEHHA, 2003). Ethylene dibromide is likely present at low ambient air concentrations in U.S. cities and large suburban areas (OEHHA, 2003). Populations living in areas near oil refineries, chemical manufacturing plants, where ethylene dibromide is manufactured or used, would be expected to have higher exposures (ATSDR, 2018). Recently available assessments note the general population is exposed to low levels of ethylene dibromide in the air due to its presence in gasoline, motor-vehicle exhausts as a product of incomplete combustion of gasoline and diesel oil (NTP, 2016). According to ATSDR, the most common exposure pathway to ethylene dibromide among the general population is ingestion of low levels of the compound in contaminated drinking water. Reasonably available information indicates that daily intake from drinking water may range from 0 to 16 µg/kg/day (ATSDR, 2018). Due to its high water solubility, ethylene dibromide is not expected to bioconcentrate or biomagnify in aquatic food chains (ATSDR, 2018). 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 ethylene dibromide as well as public comments received on the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and draft scope for ethylene dibromide (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, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculo-skeletal, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As 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 ethylene dibromide as well as public comments on the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and draft scope for ethylene dibromide (U.S. EPA, 2020c) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: ADME, PBPK, acute, repeat dose, genetic, reproductive, toxicokinetic, developmental, irritation/corrosion, cancer and neurological effects.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following additional potential human health hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cardiovascular, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, nutritional and metabolic, ocular and sensory, renal, respiratory and skin and connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As 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 and studies reporting developmental and reproductive effects: children, women of reproductive age (*e.g.*, pregnant women), workers, including ONUs and users, and consumers, including users and bystanders. (U.S. EPA, 2019d). EPA plans to evaluate these PESS in the risk evaluation. Following further evaluation of the reasonably available information, EPA may evaluate PESS in the general population as they relate to fence line communities.

In developing exposure scenarios, EPA plans to analyze reasonably available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (*e.g.*, children's crawling, mouthing or hand-to-mouth behaviors) and

whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (*e.g.*, activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006b). Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). Based on these analyses, EPA may update the list of PESS in the risk evaluation.

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of ethylene dibromide. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that are under the jurisdiction of other EPA-administered statutes, are discussed and depicted in the conceptual model shown in Section 2.6.3.1. Pathways and routes of exposure associated with environmental releases and wastes, excluding that are under the jurisdiction of other EPA-administered statutes, are presented in the conceptual model shown in Section 2.6.3.2.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-13 illustrates the conceptual model for the pathways of exposure from commercial activities and uses of ethylene dibromide that EPA plans to include in the risk evaluation. There is potential for exposures to workers and occupational non-users via inhalation routes and exposures to workers via dermal routes. It is expected that inhalation exposure to vapors is the most likely exposure route. In addition, workers at waste management facilities may be exposed via inhalation or dermal routes via wastewater treatment, incineration or via other disposal methods. 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.*, import, processing, 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 will be analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix F.

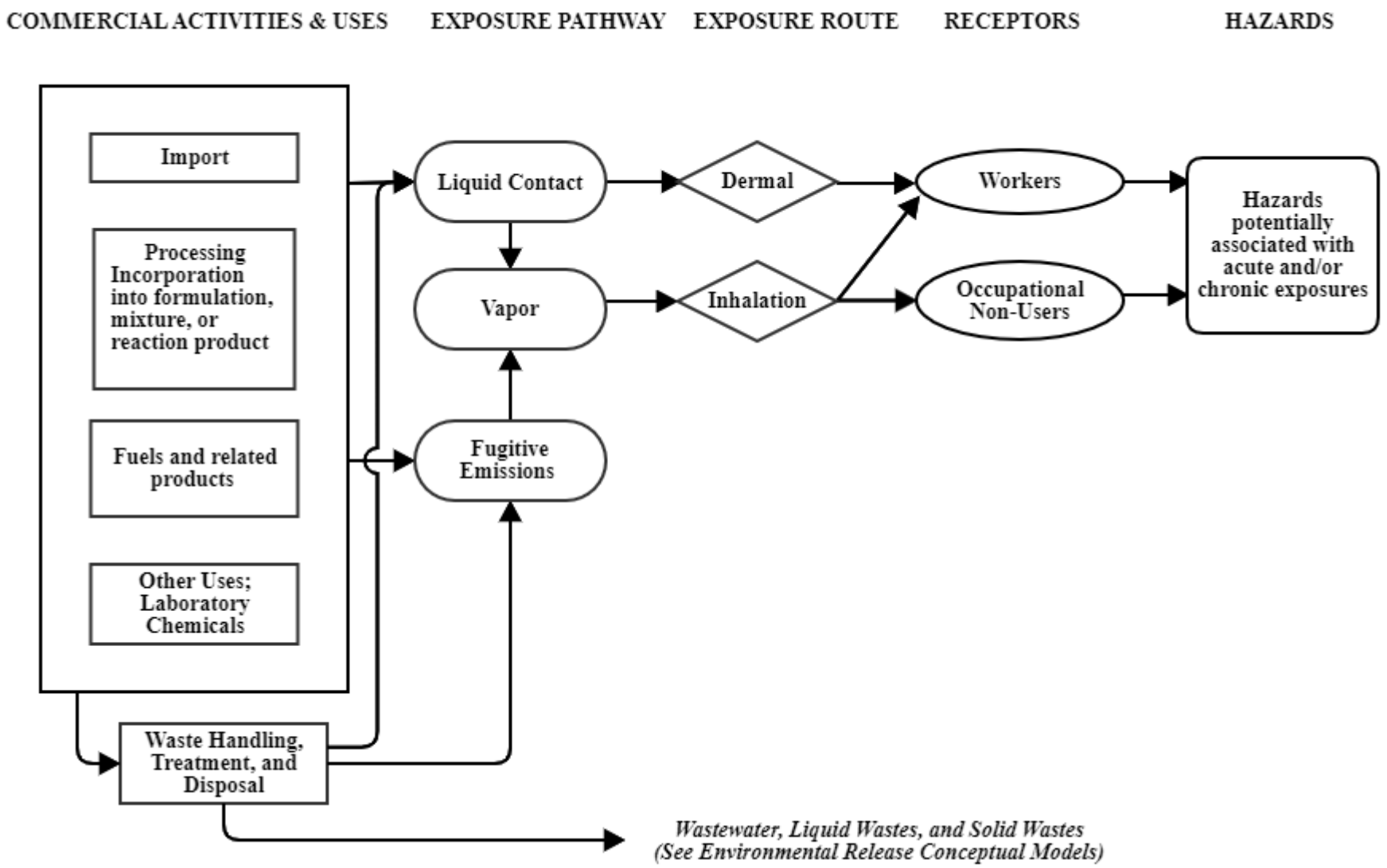

Figure 2-13. Ethylene Dibromide Conceptual Model for Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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

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 ethylene dibromide. EPA expects inhalation to be the primary route of exposure and plans to evaluate inhalation exposures to ethylene dibromide vapor for consumers and bystanders. There is potential for consumer dermal exposures to ethylene dibromide via direct contact during use of leaded fuel products. Bystanders are not expected to have direct dermal contact to ethylene dibromide. Therefore, EPA plans to evaluate dermal exposure to ethylene dibromide for consumers but not for bystanders. In addition, oral exposures to ethylene dibromide are expected to be negligible and, as a result, will not be evaluated for consumers nor bystanders. The supporting rationale for consumer pathways considered for ethylene dibromide are included in Appendix G.

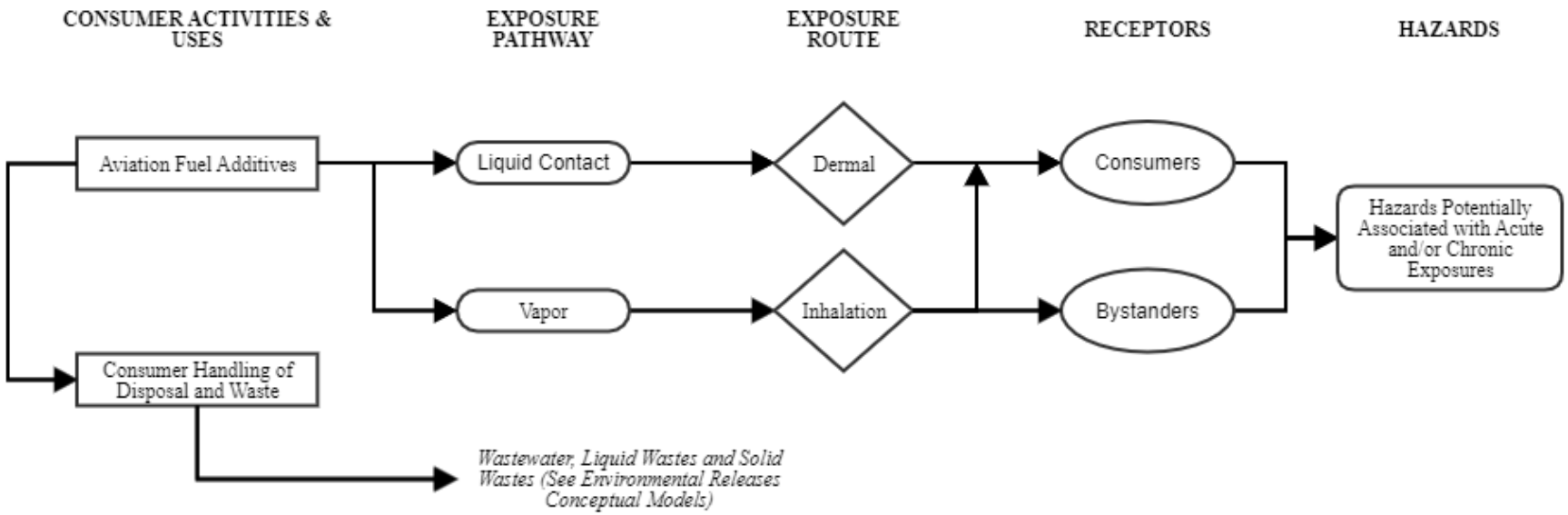

Figure 2-14. Ethylene Dibromide Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of ethylene dibromide.

2.6.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes from environmental releases and wastes) and hazards to general population and environmental receptors and hazards associated with the conditions of use of ethylene dibromide within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

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

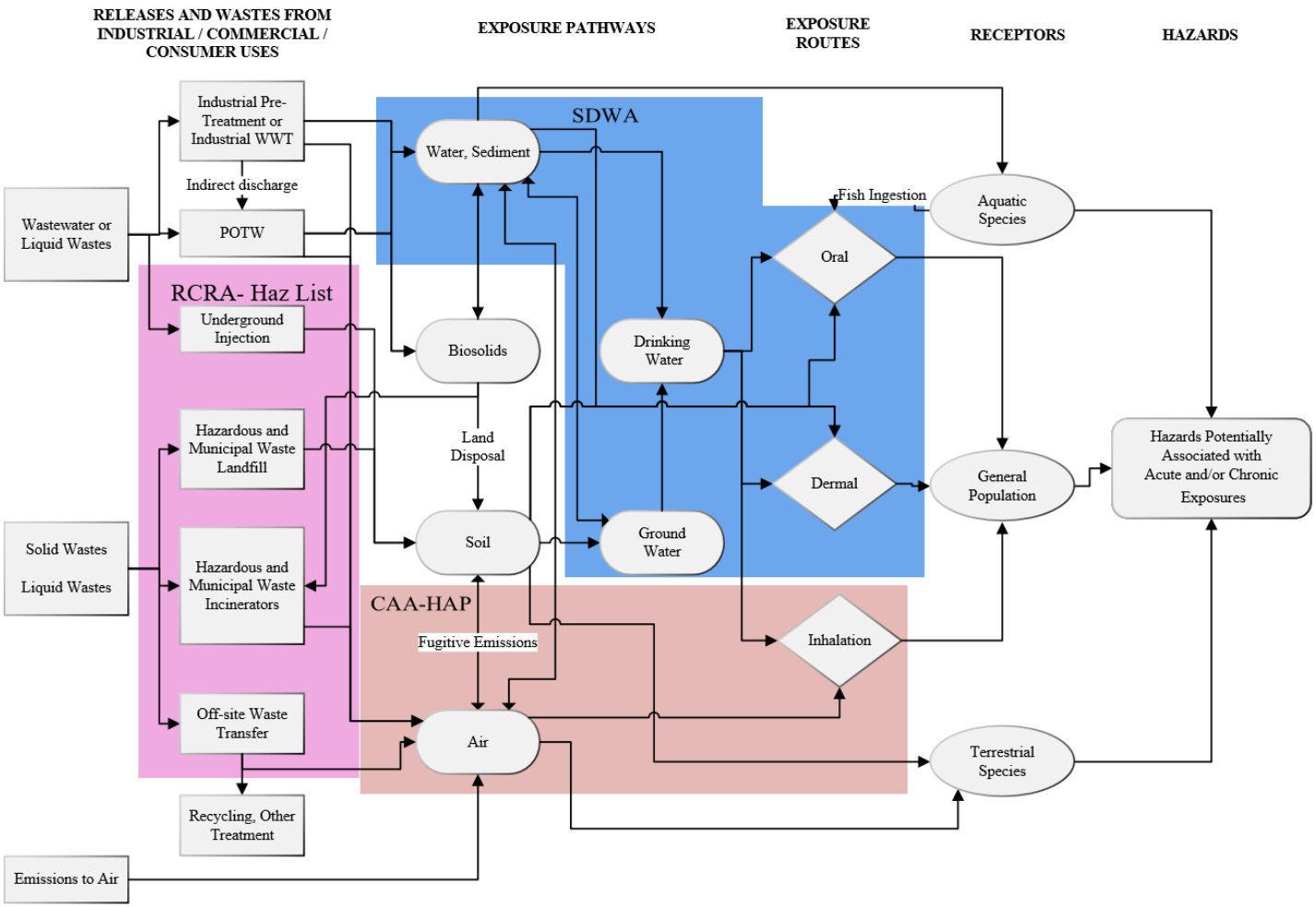

Figure 2-15. Ethylene Dibromide Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of ethylene dibromide showing the regulatory laws that adequately assess and manage those pathways.

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 plants. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering.

b) Receptors include PESS (see Section 2.5).

2.6.3.1 Exposure Pathways and Risks Addressed by Other EPA Administered Statutes

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

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

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

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

TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and PESS the Agency "expects to consider" in a risk evaluation.

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

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

TSCA Section 9(b)(1)

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

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

risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the EPA office(s) responsible for implementing those laws (absent a finding that it is in the public interest to protect against the risk by actions taken under TSCA).

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

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

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

Legislative history also supports a reading of Section 9(b)(1) under which EPA coordinates intra-agency action, including information-sharing under TSCA Section 9(e), and the appropriately positioned EPA office is responsible for the identification of risk and actions to protect against such risks. See, *e.g.*, Senate Report 114-67, 2016 Cong. Rec. S3522 (under TSCA Section 9, "if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information"); H. Rep. No. 114-176 at 28, 2016 Cong. Rec. S3522 (under Section 9, "if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the

Administrator should use those authorities to protect against the risk"). Legislative history on Section 9(b)(1) therefore supports coordination with and referral of action to other EPA offices, especially when statutes and associated regulatory programs administered by those offices could address exposure pathways or risks associated with conditions of use, hazards, and/or exposure pathways that may otherwise be within the scope of TSCA risk evaluations.

TSCA Section 2(c) and 18(d)

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

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

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

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

<u>Ambient Air Pathway</u>
The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive

authority to regulate emissions to ambient air of any hazardous air pollutant. Ethylene dibromide is a HAP. See 42 U.S.C. 7412. EPA has issued a number of technology-based standards for source categories that emit ethylene dibromide to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks. See 40 CFR part 63.

Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of ethylene dibromide to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA. As such, EPA does not plan to evaluate exposures to the general population from ambient air in the risk evaluation under TSCA. This regulatory coverage is represented by the red shading in Figure 2-15.

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate unregulated drinking water contaminants of potential regulatory concern for public water systems under the SDWA. In addition, the SDWA requires EPA to review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the SDWA for ethylene dibromide. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). Public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the MCL. The MCL for ethylene dibromide in water is 0.05 μg/L and the MCLG is 0 mg/L.

The drinking water exposure pathway for ethylene dibromide is currently addressed in the NPDWR. As such, EPA does not plan to evaluate exposures to the general population from drinking water exposure in the risk evaluation. This regulatory coverage is represented by the dark blue shading in Figure 2-15. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the SDWA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

Onsite Releases to Land Pathway

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

CERCLA Section 101(14) defines "hazardous substance" by referencing other environmental statutes, including toxic pollutants listed under CWA Section 307(a); hazardous substances designated pursuant to CWA Section 311(b)(2)(A); hazardous air pollutants listed under CAA Section 112; imminently hazardous substances with respect to which EPA has taken action pursuant to TSCA Section 7; and hazardous wastes having characteristics identified under or listed pursuant to RCRA Section 3001. See

40 CFR 302.4. CERCLA Section 102(a) also authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.

Ethylene Dibromide is a hazardous substance under CERCLA. Releases of ethylene dibromide in excess of 1 pounds within a 24-hour period must be reported (40 CFR 302.4, 302.6). The scope of this EPA TSCA risk evaluation does not include on-site releases to the environment of ethylene dibromide at Superfund sites and subsequent exposure of the general population or non-human species.

Disposal and Soil Pathways

Ethylene dibromide is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (RCRA) 3001 (40 CFR §§ 261.33) as a listed waste on the U list (U070). The general standard in RCRA Section 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the CAA hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the SDWA)[9].

EPA does not plan to evaluate on-site releases to land that go to underground injection or associated exposures to the general population or terrestrial species in its risk evaluation. TRI reporting in 2018 indicated no releases to underground injection to Class I hazardous waste wells. Environmental disposal of ethylene dibromide injected into Underground Injection Control (UIC) Class I hazardous waste well types fall under the jurisdiction of RCRA and SDWA and disposal of ethylene dibromide via underground injection is not likely to result in environmental and general population exposures. See 40 CFR part 144.

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion byproducts from incineration treatment of ethylene dibromide wastes may be subject to regulations, as would ethylene dibromide that is burned for energy recovery.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills. Based on 2018 reporting, TRI land disposal includes Subtitle C landfills (123 pounds) with a much smaller amount transferred to "all other land disposal" both on-site and off-site (1 pounds reported in 2018). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality

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

assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway. See 40 CFR part 264. As a result, EPA is not evaluating on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

Ethylene Dibromide is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste (MSW) landfills. On-site releases to RCRA Subtitle D municipal solid waste landfills leading to exposures of the general population (including susceptible populations) or terrestrial species from such releases are expected to be minimal based on current TRI releases (*i.e.*, 1 lb in 2018) for ethylene dibromide. While permitted and managed by the individual states, municipal solid waste landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills. See 40 CFR part 258. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

On-site releases to land from industrial non-hazardous and construction/demolition waste landfills may occur for ethylene dibromide. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs, but states must implement federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so. See *e.g.*, RCRA Section 3004(c), 4007; 40 CFR part 257. As a result, EPA does not plan to evaluate on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills or associated exposures to the general population. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

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

The diagram shown in Figure 2-16 includes releases from industrial, commercial and/or consumers uses to water/sediment, biosolids and soil via direct and indirect discharges to water that may lead to exposure to aquatic receptors, and to the general population via ingestion of water and fish consumption. The supporting basis for general population and environmental pathways considered for ethylene dibromide are included in Appendix H.

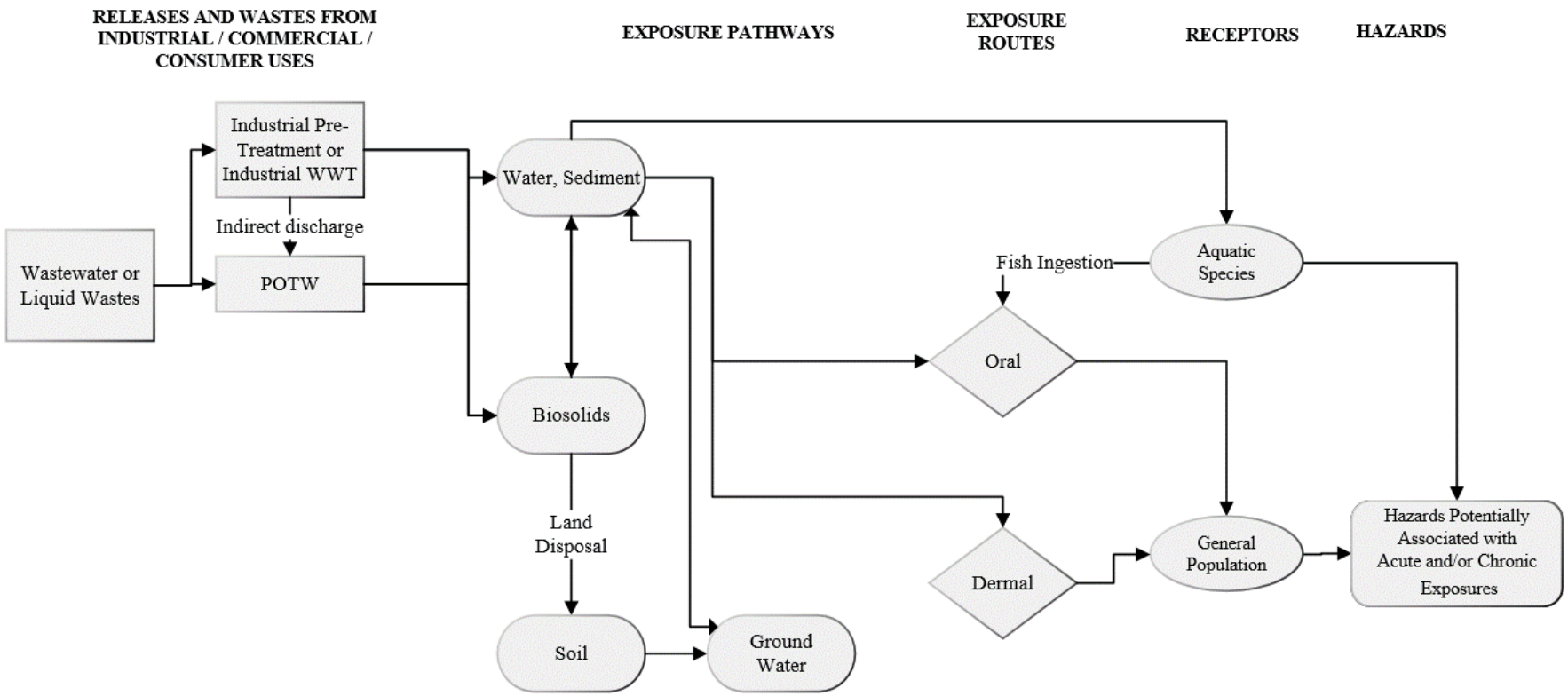

Figure 2-16. Ethylene Dibromide Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

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 Ethylene Dibromide that EPA plans to consider in the risk evaluation.

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW.

b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

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

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical properties and environmental fate and transport of ethylene dibromide 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 evaluate data and information collected through the systematic review methods and public comments about the physical and chemical properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of physical and chemical 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 ethylene dibromide within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight of 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 the *Application of Systematic Review in TSCA Risk Evaluations*(U.S. EPA, 2018).

2.7.2 Exposure

EPA plans to analyze exposure levels in indoor air, ground water, surface water, sediment, and aquatic biota associated with exposure to ethylene dibromide. Based on its physical and chemical properties, expected

sources, and transport and transformation within the outdoor and indoor environment, ethylene dibromide 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 ethylene dibromide are presented in Appendix F, Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to review additional data sources identified. Potential sources of environmental release data are summarized in Table 2-6 below:

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

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
Discharge Monitoring Report (DMR) surface water discharge data for ethylene dibromide from NPDES-permitted facilities

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

   Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Exposures and Environmental Releases (U.S. EPA, 2015a).

3) **Review reasonably available release data for surrogate chemicals that have similar uses and physical and chemical 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 to consider for release estimation and environmental exposures. EPA plans to consider relevant regulatory requirements in estimating releases during risk evaluation.

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the July 2009 ESD on Transport and Storage of Chemicals (OECD, 2009), the September 2011 ESD on The Chemical Industry (OECD, 2011), and the November 2004 ESD on Lubricants and Lubricant Additives (OECD, 2004) may be useful. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed.

   EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

   OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

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

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

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

2.7.2.2 Environmental Exposures

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

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

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards under TSCA Section 26(h) and that estimate surface water, and sediment concentrations will be analyzed and considered alongside reasonably available surface water, and sediment monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations may generally include the following inputs: direct release into surface water, or sediment, and indirect release into surface water, sediment, fate and transport (partitioning within media) and characteristics of the environment (*e.g.*, river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
   There have been changes to use patterns of ethylene dibromide 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 which relate levels of ethylene dibromide 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 ethylene dibromide, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

   - Estimates of surface water concentrations, and sediment concentrations near industrial point sources based on reasonably available monitoring data.
   - Consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
   - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
   - Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic populations.
   - Weight of the scientific evidence of environmental occurrence data and modeled estimates.

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

2.7.2.3 Occupational Exposures

EPA plans to analyze both worker and occupational non-user exposures as follows:

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
EPA plans to review exposure data including workplace monitoring data collected by government agencies such as the OSHA and the 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).

   Ethylene dibromide has an PEL of 20 ppm (8-hr time weighted average), a Ceiling of 30 ppm, and a max peak of 50 ppm for 5 minutes during an 8-hour day. EPA plans to consider the influence of these regulatory limits and recommended exposure guidelines on occupational exposures in the occupational exposure assessment. The following are some potential data sources:

Table 2-7. Potential Sources of Occupational Exposure Data

2018 ATSDR Toxicological Profile for Ethylene Dibromide
U.S. OSHA Chemical Exposure Health Data (CEHD) program data

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to ethylene dibromide.**
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 GS corresponding to some conditions of use. For example, the July 2009 ESD on Transport and Storage of Chemicals (OECD, 2009), the September 2011 ESD on The Chemical Industry (OECD, 2011), and the November 2004 ESD on Lubricants and Lubricant Additives (OECD, 2004) are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use. EPA may conduct industry outreach or perform supplemental targeted searches of peer-reviewed or gray literature to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted supplemental searches to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
This step will be performed after #2 and #3 are completed, and based on information developed from #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA, 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 engineering controls and/or personal protective equipment into exposure scenarios.**
EPA plans to review potentially relevant data sources on EC and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

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

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

2.7.2.4 Consumer Exposures

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

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

For ethylene dibromide, 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 relative potential of indoor exposure pathways based on reasonably available data.**
   Based on the physical and chemical properties of ethylene dibromide and the consumer uses identified, inhalation of vapors is expected to be an important indoor exposure pathway for consumers. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air exposures.**
   Indoor exposure models that estimate emissions from use of consumer products are 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.

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 an ethylene dibromide 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 ethylene dibromide 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 ethylene dibromide in specific media (*e.g.*, indoor air).**
   The availability of ethylene dibromide concentration for various conditions of use will be evaluated. This data provides the source term for any subsequent indoor modeling.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
   For ethylene dibromide 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 different from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

7) **Evaluate the weight of the scientific evidence of consumer exposure estimates based on different approaches.**

EPA plans to rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the scientific evidence may include qualitative and quantitative sources of information. EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering sources conditions of use, exposure pathways and routes.**
   For ethylene dibromide, the following are noteworthy 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).
   - Environmental Exposure pathways regulated by non-TSCA EPA laws and regulations will be excluded from analysis

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

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

2) **For exposure pathways where empirical data is not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**
For ethylene dibromide, media where exposure models will be considered for general population exposure include models that estimate, surface water concentrations, sediment concentrations, and uptake from aquatic environments into aquatic organisms.

3) **Review reasonably available exposure modeled estimates. For example, existing models developed for a previous ethylene dibromide 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 ethylene dibromide general population exposure scenario that is relevant to the OPPT's 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.

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

5) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (*e.g.*, early life and/or puberty as a potential critical window of exposure).**
For ethylene dibromide, exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations.

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

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

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

environmental hazard information will also be considered (*e.g.*, analogue and read-across data) when characterizing the potential hazards of ethylene dibromide to aquatic organisms.

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

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

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

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

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

5) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of ethylene dibromide.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of ethylene dibromide 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 ethylene dibromide. 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 ethylene dibromide with the fate parameters (*e.g.*, BAF, BCF, BMF, TMF).

6) **Conduct an environmental risk estimation and characterization of ethylene dibromide.**
EPA plans to conduct a risk estimation and characterization of ethylene dibromide to identify if there are risks to the aquatic environments from the measured and/or predicted concentrations of ethylene dibromide in environmental media (*e.g.*, water, sediment). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982). Analysis of risk for characterization includes a confidence statement in risk estimation which qualitative judgment describing the certainty of the

risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

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

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

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

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

   Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011a, 1994) 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 ethylene dibromide, 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 ethylene dibromide 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 (1994).

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

6) **Conduct 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 ethylene dibromide, 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, 1994). 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, 2004a).

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, 1994). 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 ethylene dibromide.** 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 PESS affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook (U.S. EPA, 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 ethylene dibromide 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 ethylene dibromide, 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.[10] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

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

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

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

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

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 ethylene dibromide. 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 Ethylene Dibromide

Source	Date of Search	Number of References
Current Contents	05/22/2019	261
Web of Science	09/12/2019	1386
ProQuest CSA	05/22/2019	1502
Dissertation Abstracts	05/23/2019	14
Science Direct	05/22/2019	824
Agricola	05/24/2019	463
TOXNET	05/22/2019	1574
PubMed	07/02/2019	671
UNIFY	06/06/2019	371
Totals:		**7066**

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.

"1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid" OR "alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40" OR "Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90" OR "Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide" OR "Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR "Pestmaster edb-85" OR "Sanhyuum" OR "Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40"

"Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ"

CURRENT CONTENTS CONNECT: (access.webofknowledge.com)
General search terms applied to the search strategy for Current Contents.
Date Searched: 05/22/2019

Date Range of Search: 1998 to Present
N = 261

TS=("1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid" OR "alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40" OR "Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90" OR "Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide" OR "Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR "Pestmaster edb-85" OR "Sanhyuum" OR "Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40")
N = 261

TS=("Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ")
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: 09/12/2019
Date Range of Search: 1970 to Present
N = 1386

TS=("1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid" OR "alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40" OR "Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90" OR "Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide" OR "Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR "Pestmaster edb-85" OR "Sanhyuum" OR "Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40")
N = 1385

TS=("Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ")
N = 1

PROQUEST Agricultural and Scientific Database: (www.csa.com)
General Search Terms applied to the search strategy for ProQuest Agricultural and Scientific Database.
Date Searched: 05/22/2019

Date Range of Search: 1900 to Present
N = 1502

ALL("1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid" OR "alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40" OR "Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90" OR "Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide" OR "Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR OR "Pestmaster edb-85" OR "Sanhyuum" OR "Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 1502

ALL("Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 0

PROQUEST Dissertations and Theses: (search.proquest.com)
General Search Terms applied to the search strategy for ProQuest Dissertations and Theses.
Date Searched: 05/23/2019
Date Range of Search: 1900 to Present
N = 14

ALL("1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid" OR "alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40" OR "Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90" OR "Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide" OR "Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR "Pestmaster edb-85" OR "Sanhyuum" OR "Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40") AND LA(ENG)
N = 14

ALL("Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ") AND LA(ENG)
N = 0

SCIENCE DIRECT: (www.sciencedirect.com)

General Search Terms applied to the search strategy for Science Direct.
Date Searched: 05/22/2019
Date Range of Search: 1823 to Present
N = 824

Science Direct 01:
"1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid"
N = 316

Science Direct 02:
"alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40"
N = 353

Science Direct 03:
"Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90"
N = 1

Science Direct 04:
"Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide"
N = 152

Science Direct 05:
"Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR "NCI-C00522" OR "Pestmaster edb-85" OR "Sanhyuum"
N = 2

Science Direct 06:
"Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40"
N = 0

Science Direct 07:
"Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ"
N = 0

AGRICOLA: (www.nal.usda.gov)
General Search Terms applied to the search strategy for Agricola. The Agricola database contains a significant amount of gray literature including proceedings, symposia, and progress reports from government and educational institutions. Agricola is not used when conducting a search for the Office of Water.
Date Searched: 05/24/2019

Date Range of Search: 15th century to the Present
N = 463

Agricola 01:
1,1-Dibromoethane
1,2-Dibromaethan
1,2-Dibromethan
1,2-dibromoetano
1,2-Dibromoethane
1,2-Dibroomethaan
1,2-Ethylene dibromide
Aadibroom
Aethylenbromid
alpha, beta-Dibromoethane
N = 86

Agricola 02:
alpha, omega-Dibromoethane
BRN 0605266
Bromofume
Caswell No. 439
Celmide
Dayfum W-85
Dibromoethane
11edbDowfume 40
Dowfume EDB
Dowfume W 15
N = 98

Agricola 03:
Dowfume W 8
Dowfume W 85
Dowfume W-100
Dowfume W-40
Dowfume W-8
Dowfume W-85
Dowfume W-90
Dwubromoetan
Edabrom
E-D-Bee
N = 1

Agricola 04:
Ethane, 1,1-dibromo-
Ethane, 1,2-dibromo-
Ethane, dibromo-
Ethylene bromide
Ethylene dibromide

Ethylidene bromide
Ethylidene dibromide
Ethylidine bromide
Fumo-gas
Glycol dibromide
N = 275

Agricola 05:
Iscobrome D
Kopfume
NCI-C00522
Pestmaster edb-85
Sanhyuum
Soilbrom
Soilbrom 85
Soilbrom 90
Soilbrom-100
Soilbrom-40
N = 3

Agricola 06:
Soilbrom-85
Soilbrom-90
Soilbrom-90EC
Soilfume
sym-Dibromoethane
UN 1605
Unifume
UNII-1N41638RNO
UNII-KJ8ZJY72QQ
N = 0

TOXNET: (toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TOXLINE)
General Search Terms applied to the search strategy for TOXNET.
Date Searched: 05/22/2019
Date Range of Search: 1900 to Present
N = 1574

TOXNET 01:
106-93-4 OR 557-91-5 OR 25620-62-6 OR 8003-07-4 OR 56729-21-6
N = 1574

TOXNET 02:
625084-37-9
N = 0

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 = 671

"1,1-Dibromoethane" OR "1,2-Dibromaethan" OR "1,2-Dibromethan" OR "1,2-dibromoetano" OR "1,2-Dibromoethane" OR "1,2-Dibroomethaan" OR "1,2-Ethylene dibromide" OR "Aadibroom" OR "Aethylenbromid" OR "alpha, beta-Dibromoethane" OR "alpha, omega-Dibromoethane" OR "BRN 0605266" OR "Bromofume" OR "Caswell No. 439" OR "Celmide" OR "Dayfum W-85" OR "Dibromoethane" OR "11edbDowfume 40" OR "Dowfume EDB" OR "Dowfume W 15" OR "Dowfume W 8" OR "Dowfume W 85" OR "Dowfume W-100" OR "Dowfume W-40" OR "Dowfume W-8" OR "Dowfume W-85" OR "Dowfume W-90" OR "Dwubromoetan" OR "Edabrom" OR "E-D-Bee" OR "Ethane, 1,1-dibromo-" OR "Ethane, 1,2-dibromo-" OR "Ethane, dibromo-" OR "Ethylene bromide" OR "Ethylene dibromide" OR "Ethylidene bromide" OR "Ethylidene dibromide" OR "Ethylidine bromide" OR "Fumo-gas" OR "Glycol dibromide" OR "Iscobrome D" OR "Kopfume" OR "Pestmaster edb-85" OR "Sanhyuum" OR "Soilbrom" OR "Soilbrom 85" OR "Soilbrom 90" OR "Soilbrom-100" OR "Soilbrom-40"
N = 671

"Soilbrom-85" OR "Soilbrom-90" OR "Soilbrom-90EC" OR "Soilfume" OR "sym-Dibromoethane" OR "UN 1605" OR "Unifume" OR "UNII-1N41638RNO" OR "UNII-KJ8ZJY72QQ"
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: 06/06/2019
Date Range of Search: all years
N = 371

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 SwiftActiveScreener or DistillerSR[12].

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

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 (Section 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 discussion among the primary screeners. For citations with no abstract, the articles are initially screened based on all or some of the following: title relevance (titles that suggest a record is not relevant can be excluded rather than marked as unclear), and page numbers (articles two pages in length or less were assumed to be conference reports, editorials, or letters). During title/abstract or full-text level screening in DistillerSR, studies that did not meet the PECO criteria, but which could provide supporting information were categorized (or "tagged") as supplemental information.

It is important to emphasize that being tagged as supplemental material does not mean the study would necessarily be excluded from consideration in an assessment. The initial screening level distinctions between a study meeting the PECO criteria and a supplemental study are often made for practical reasons and the tagging structures (as seen in the literature inventory trees and heat maps in Section 2.1. of this document) are designed to ensure the supplemental studies are categorized for easy retrieval if needed while conducting the assessment. The impact on the assessment conclusions of individual studies tagged as supporting material is often difficult to assess during the screening phase of the assessment. These studies may emerge as being critically important to the assessment and need to be evaluated and summarized at the individual study level (*e.g.*, cancer MOA mechanistic or non-English-language studies), or be helpful to provide context (*e.g.*, summarize current levels of exposure, provide hazard evidence from routes or durations of exposure not pertinent to the PECO), or not be cited at all in the assessment (*e.g.*, individual studies that contribute to a well-established scientific conclusion). Studies may be tagged as supplemental material during either title and abstract or full-text screening. When tagged as supplemental material during title and abstract screening, it may not be completely clear whether the chemical of interest is reported in the study (*i.e.*, abstracts may not describe all chemicals investigated). In these cases, studies are still tagged with the expectation that if full-text retrieval is pursued, then additional screening would be needed to clarify if the study is pertinent.

A.2.1 Inclusion/Exclusion Criteria

A PECO statement is typically used to focus the research question(s), search terms, and inclusion/exclusion criteria in a systematic review. PECO criteria were developed *a priori* to screening and modified to fit the various discipline areas supporting the TSCA risk evaluations. Variations include the RESO (receptor, exposure, scenario/setting, and outcome) used for the occupational exposure and environmental releases

discipline, and PESO (pathways/processes, exposures, setting/scenario, and outcomes) used by the fate and transport discipline. All PECOs and PECO-equivalent criteria can be found in the following sections.

A.2.1.1 PECO for Environmental and Human Health Hazards

The PECO used in this evidence map to identify literature pertinent to ethylene dibromide 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 Ethylene Dibromide

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.*, 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* and *ex vivo* 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:** Ethylene Dibromide (CASRN 106-93-4) **Isomers** included for Ethylene Dibromide: 1,1-Dibromoethane (CASRN 557-91-5) Dibromoethane (CASRN 25620-62-6)

PECO Element	Evidence
	Synonyms include ethylene dibromide, ethylene bromide, sym-dibromoethane, ethane 1,2 dibromo, alpha beta-dibromoethane, 1,2-dibromaethan, and 1,2-dibroomethaan. For more, see the EPA Chemistry Dashboard. • **Human:** Any exposure to Ethylene Dibromide (CASRN 106-93-4) 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 Ethylene Dibromide (CASRN 106-93-4) including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation. • **Plants:** Any exposure to Ethylene Dibromide (CASRN 106-93-4) including via water, soil, sediment. **Screener notes:** • Field studies with media concentrations (*e.g.*, surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants are to be identified as ***Supplemental*** if any biological effects are reported. • Studies involving exposures to mixtures will be included only if they also include exposure to Ethylene Dibromide (CASRN 106-93-4) 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 Ethylene Dibromide (106-93-4), or exposure to Ethylene Dibromide (106-93-4) for shorter periods of time. • **Animal and Plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement). **Screener note:** • 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.

PECO Element	Evidence
	Screener note: • **Measurable biological effects relevant for humans, animals and plants may include but are not limited to:** mortality, behavioral, population, cellular, 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 Ethylene Dibromide

Category	Evidence
Mechanistic studies	All studies that report results at the cellular level and lower in both mammalian and non-mammalian model systems, including *in vitro*, *in vivo*, *ex vivo*, and *in silico* studies. These studies include assays for genotoxicity or mutagenicity using bacteria or yeast.
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 primarily during full-text screening. **Screener note:** if biological susceptibility issues are clearly present or ***strongly*** implied in the title/abstract, this supplemental tag may be applied at the title abstract level. If uncertain at title/abstract, do not apply this tag to the reference during title/abstract screening.
Mixture studies	Experimental 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 with media concentrations (*e.g.*, surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants if biological effects reported.
Isomer	PECO-relevant studies with an exposure to one of the identified isomers, if any.

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 ethylene dibromide 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 ethylene dibromide.
	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 Ethylene Dibromide[a]

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Ethylene dibromide	X	X	X	X	X	--

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

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

EPA developed a generic RESO statement to guide the screening of engineering and occupational exposure data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria specified in the RESO statement are eligible for inclusion, considered for evaluation,

and possibly included in the environmental release and occupational exposure assessments. On the other hand, data or information sources that fail to meet the criteria in the RESO statement are excluded from further consideration.

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

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

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

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

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).

Objective Determined during Scoping	Type of Data [a]
	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. Personal protective equipment (PPE) types employed by the industries within scope. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental Releases (to relevant environmental media)	Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors. Number of release days per year. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.

[a] These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.
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:
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 PESS to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (*e.g.*, buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (*i.e.*, aquatic and terrestrial organisms) or human receptors (*i.e.*, general population, and PESS)
Outcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)

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

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

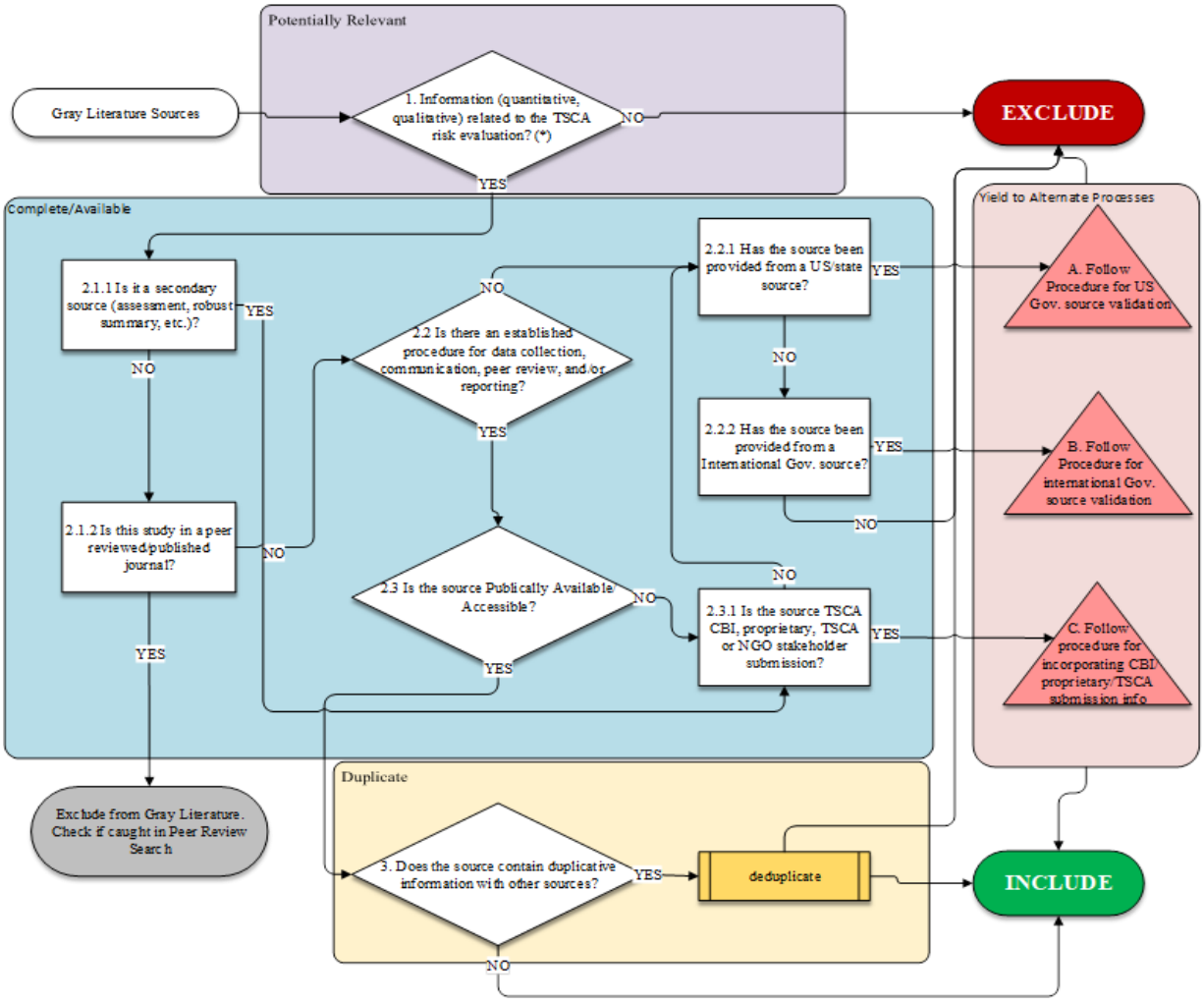
A.3 Gray Literature Search and Screening Strategies

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 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 are provided in Section A.3.3. The criteria for determining the potential relevance of documents identified from gray literature sources is described in the following sections for each discipline.

A.3.1 Screening of Gray Literature

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



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

A.3.2 Initial Screening of Sources using Decision Logic Tree

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

Table_Apx A-11. Decision Logic Tree Overview

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

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

A.3.3 TSCA Submission Searching and Title Screening

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

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

After full texts are obtained, EPA 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 Ethylene Dibromide

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

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

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/profilesaddenda.asp
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.industrialchemicals.gov.au/chemical-information/search-assessments
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: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CDC	CDC Biomonitoring Tables	Other US Agency Resources	Database	www.cdc.gov/exposurereport/index.html/
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals

Source Agency	Source Name	Source Type	Source Category	Source Website
Env Canada	Screening Assessment Report	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	
EPA	OPPT: Chemview (TSCA submissions - chemical test rule data and substantial risk reports)	US EPA Resources	Database	https://chemview.epa.gov/chemview
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document	https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values#chemicals
EPA	Office of Air: AQS, Annual	US EPA Resources	Database	https://aqs.epa.gov/aqsweb/airdata/download_files.html#Annual
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database	https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata.us/portal/
EPA	Support document for AEGLS	US EPA Resources	Assessment or Related Document	https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values
EPA	IRIS Tox Review	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris2/atoz.cfm
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document	https://ofmpub.epa.gov/opptpv/hpv_hc_characterization.get_report_by_cas?doctype=2

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	Other EPA: Misc sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios
FDA	FDA Market Baskets	Other US Agency Resources	Assessment or Related Document	https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document	https://www.fda.gov/
IARC	IARC Monograph	International Resources	Assessment or Related Document	http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments	International Resources	Assessment or Related Document	http://www.env.go.jp/en/chemi/chemicals/profile_erac/index.html
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document	www.cdc.gov/niosh/topics/chemical.html/
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html

Source Agency	Source Name	Source Type	Source Category	Source Website
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/niosh tic-2/
NLM	National Library of Medicine's HazMap	Other US Agency Resources	Database	https://haz-map.com/
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/index.html
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/reports/index.html?type=Technical+Report
OECD	OECD SIDS	International Resources	Assessment or Related Document	https://hpvchemicals.oecd.org/ui/Publications.aspx
OECD	OECD 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
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Database	www.osha.gov/opengov/healthsamples.html/
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	www.tera.org/

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF ETHYLENE DIBROMIDE

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-2018-0488).

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	5	-	NA	NA	NA	NA
Physical properties	4	-	NA	NA	NA	NA
Melting point	18	ºC	9.5	0.8	8	11
Boiling point	15	ºC	131.5	0.6	130	132
Density	8	g/cm^3	2.170	0.050	2.064	2.2484
Vapor pressure	2	mm Hg	11.1	0.14	11	11.2
Vapor density	1		6.48		6.48	6.48
Water solubility	8	mg/L	4250	737	3120	5590
Octanol/water partition coefficient (Log Kow)	2	-	2.02	0.085	1.96	2.08
Henry's Law constant	3	$atm \cdot m^3/mol$	0.000443	0.000359	$2.82x10^{-5}$	0.000651
Flash point	1	ºC	132		132	132
Auto flammability	0	ºC				
Viscosity	5	cP	1.661	0.100	1.516	1.733
Refractive index	7	-	1.5334	0.0372	1.46	1.5865
Dielectric constant	2	-	4.87	0.14	4.77	4.97
NA = Not applicable						

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF ETHYLENE DIBROMIDE

Table Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for ethylene dibromide. This information was presented in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019d) and may be updated as EPA collects additional information through systematic review methods.

Table_Apx C-1. Environmental Fate Characteristics of Ethylene Dibromide

Property or Endpoint	Value [a]	References
Direct Photodegradation	No photolysis was observed when exposed to UV between 300 and 400 nm	NLM (2020) citing Ollis (1985)
	Direct photolysis of 1,2-dibromoethane in the troposphere is not expected to occur	ATSDR (2018) citing Jaber et al. (1984)
Indirect Photodegradation	$t_{1/2}$ = 64 days (based on ·OH reaction rate constant of 2.34×10^{-13} cm^3/mol·second at 25 ºC)	NLM (2020) citing Atkinson (1989)
Hydrolysis	$t_{1/2}$ = 2.5-13.2 years	ATSDR (2018) citing Vogel and Reinhard (1986)
	$t_{1/2}$ = 6.4 years (at 25 ººC in pure water; rate constant = 2.1×10^{-7} $minute^{-1}$)	NLM (2020)
	$t_{1/2}$ = 141 hours at 67 ºC and 380 days at 25 ºC for test solutions at pH 4 $T_{1/2}$ = 114 hours at 67 ºC and 2.3 years at 25 ºC for test solutions at pH 9 (OECD 111)	ECHA (2019)
Biodegradation (Aerobic)	Water: $t_{1/2}$ = 35-350 days; shallow aquifer material and groundwater	NLM (2020) citing Pignatello et al. (1987)
	Water: 21-35%/3 days in a die-away test using Japanese river and seawater	NLM (2020) citing Kondo et al. (1988)
	Water: 0% after 2 weeks based on BOD (MITI test); degradation effected by volatilization	NLM (2020) citing Pignatello and Cohen (1990)
Biodegradation (Anaerobic)	63% degradation after 25 weeks	ECHA (2019) citing Bouwer and McCarty (1983)
	$t_{1/2}$ = 2 weeks (17 ºC, methanogenic aquifer) Bromoethanol detected as a metabolite	NLM (2020) citing Verschueren (1996)
	$t_{1/2}$ = 0.8 days by reductive dehalogenation (22 ºC, anoxic sediment	NLM (2020) citing Rathbun, 1998

Property or Endpoint	Value [a]	References
	with 6% organic carbon)	
Wastewater Treatment	$t_{1/2}$= 1-16 days by evaporation from flowing and standing surface waters	ATSDR (2018) citing U.S. EPA (1987)
	24% total removal (0.08% by biodegradation, 1.8% by sludge, and 22% by volatilization to air; estimated)[b]	U.S. EPA (2012b)
Bioconcentration Factor (BCF)	<3.5-14.9 (carp)	NLM (2020) citing Kawasaki (1980)
	<1-20	OECD (2012)
Bioaccumulation Factor (BAF)	8.3 (estimated)[b]	U.S. EPA (2012b)
Soil Organic Carbon:Water Partition Coefficient (Log K_{oc})	1.82	ATSDR (2018) citing Rogers and Mcfarlane (1981)
	1.1-2.2	NLM (2020) citing Rathbun, 1998 and (Falta, 2004)
	1.69 (in peat soil)	NLM (2020) citing Chiou and Kile (1998)

[a] Measured unless otherwise noted.
[b]EPI Suite Physical Property Inputs: Log Kow = 1.96, BP = 131.60 ºC, MP = 9.9 ºC, VP = 11.2 mm Hg, WS = 3910 mg/L, Henry LC = 6.5×10^{-4} atm-m^3/mol

Appendix D REGULATORY HISTORY

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

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.	Ethylene dibromide is one of the first 20 chemical substances designated as high-priority substances for risk evaluation (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.	Ethylene dibromide 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), processed or imported in the United States.	Ethylene dibromide 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.	Two substantial risk reports received for ethylene dibromide in 1994, (U.S. EPA, ChemView, Accessed March 3, 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	Ethylene dibromide is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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).	
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	Ethylene dibromide was registered as an antimicrobial and a conventional chemical in 1974. Antimicrobial uses were cancelled in 1993. Conventional uses have also been cancelled. (US EPA. Pesticide Chemical Search, Accessed April 25, 2019).
Clean Air Act (CAA) – Section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	Ethylene dibromide is subject to the NSPS for equipment leaks of volatile organic compounds (VOCs) in the synthetic organic chemicals manufacturing industry for which construction, reconstruction, or modification began after November 7, 2006 (40 CFR 60 Subpart VV).
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA Section 112(d). CAA Section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by	Ethylene dibromide is listed as a HAP (42 U.S. Code Section 7412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has established NESHAPs for a number of source categories that emit ethylene dibromide to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9)
Clean Air Act (CAA) – Sections 112(d) and 112(f)	Risk and technology review (RTR) of Section 112(d) national emission standards for hazardous air pollutants (NESHAP). Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to Section 112(d) NESHAP that require maximum achievable control technology (MACT), and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the emission standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP and will do so, as required, for the remaining source categories with NESHAP.
Clean Water Act (CWA) – Section 311(b) (2)(A) and 501(a) of the Federal Water Pollution Control Act.	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	Ethylene dibromide is a designated hazardous substance in accordance with Section 311(b)(2)(A) of the Federal Water Pollution Control Act.(40 FR 116.4, March 13, 1978).
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goal (MCLG) for a contaminant for which EPA makes the determination that the contaminant: 1. may have an adverse effect on the health of persons; 2. is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a	Ethylene dibromide is subject to NPDWR under the SDWA with a MCLG of zero (40 CFR 141.50) and an enforceable MCL of 0.00005 mg/L (Section 1412) (52 FR 25690, January 30, 1991).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Ethylene dibromide is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U067 **(**40 CFR 261.33). EDB is a U-listed hazardous waste under code U067 under RCRA; therefore, discarded, unused pure and commercial grades of EDB are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	Ethylene dibromide is a hazardous substance under CERCLA. Releases of ethylene dibromide in excess of 1 pound must be reported (40 CFR 302.4).
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	Ethylene dibromide is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
Other Federal Statutes/Regulations		
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as PEL, exposure monitoring, engineering and administrative control measures, and respiratory protection.	OSHA occupational exposure limit for ethylene dibromide is 20 ppm TWA, with an acceptable ceiling concentration of 30 ppm and an acceptable maximum peak above the acceptable ceiling concentration for an 8 hour shift of 50 ppm with a maximum duration of 5 min (29 CFR 1910.1000).
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	The Department of Transportation (DOT) has designated ethylene dibromide as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR Part 172.101).

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: New Hampshire - Toxicity class 1; 24-Hr AAL (µg/m3): 0.050; Annual AALB (µg/m3), (Env-A 1400: Regulated Toxic Air Pollutants). Rhode Island - 24 hour: 9, Annual 0.2, (Air Pollution Regulation No. 22)
State Drinking Water Standards and Guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008), California (Cal Code Regs. Title 26, § 22-64444), Connecticut (Conn. Agencies Regs. § 19-13-B102), Delaware (Del. Admin. Code Title 16, § 4462), Maine (10 144 Me. Code R. Chap. 231), Massachusetts (310 Code Mass. Regs. § 22.00), Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017), Minnesota (Minn R. Chap. 4720), New Jersey (7:10 N.J Admin. Code § 5.2), Pennsylvania (25 Pa. Code § 109.202), Rhode Island (Rules and Regulations Pertaining to Public Drinking Water R46-13-DWQ), Texas (30 Tex. Admin. Code § 290.104).
State PELs	California (PEL of 0.13ppm) (Cal Code Regs. Title 8, § 5155) Hawaii PEL: 20 ppm (Hawaii Administrative Rules Section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (8:59 N.J. Admin. Code § 9.1) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing ethylene dibromide, including Maine (38 MRSA Chapter 16-D), and Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407).
Other	California listed ethylene dibromide on Proposition 65 in 1987 due to cancer and in 1998 due to reproductive toxicity (including developmental toxicity and male reproductive toxicity), (Cal Code Regs. Title 27, § 27001). Ethylene dibromide is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). Ethylene dibromide is on the MA Toxic Use Reduction Act (TURA) list of 2019 (301 CMR 41.00).

D.3 International Laws and Regulations

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

Country/ Organization	Requirements and Restrictions
Canada	Ethylene dibromide appears on the Canadian Domestic Substances List. (Government of Canada. Managing substances in the environment. Substances search, Accessed April 23, 2019).
European Union	Ethylene dibromide is registered for use in the EU. (European Chemicals Agency (ECHA) database, Accessed April 23, 2019).

Country/ Organization	Requirements and Restrictions
Australia	Ethylene dibromide was assessed under the Human Health and Environment Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Uses reported include: preparations for dyes and waxes; production of some plastics and latex, manufacture of leaded petro; treatment of logs for pests; fumigant in soils, grains, fruits and vegetables. (NICNAS, 2013, Human Health Tier II assessment for ethylene dibromide. Accessed April 18, 2017).
Japan	Ethylene dibromide is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, *etc.* (Chemical Substances Control Law; CSCL) • Act on Confirmation, *etc.* of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Poisonous and Deleterious Substances Control Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP], Accessed April 18, 2019).
Austria, Canada (Ontario), Denmark, Finland, France, Hungary, Ireland, Israel, New Zealand, Poland, Romania Spain, Switzerland, The Netherlands, United Kingdom	Occupational exposure limits for ethylene dibromide (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs, Accessed April 17, 2017).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

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

E.1 Process Information

The following subsections provide process descriptions based on sources identified from the preliminary literature search for each life cycle stage of ethylene dibromide. Such information may inform potential release sources and worker exposure activities. EPA plans to continue to investigate and further refine the descriptions for each life cycle stage throughout the risk evaluation process.

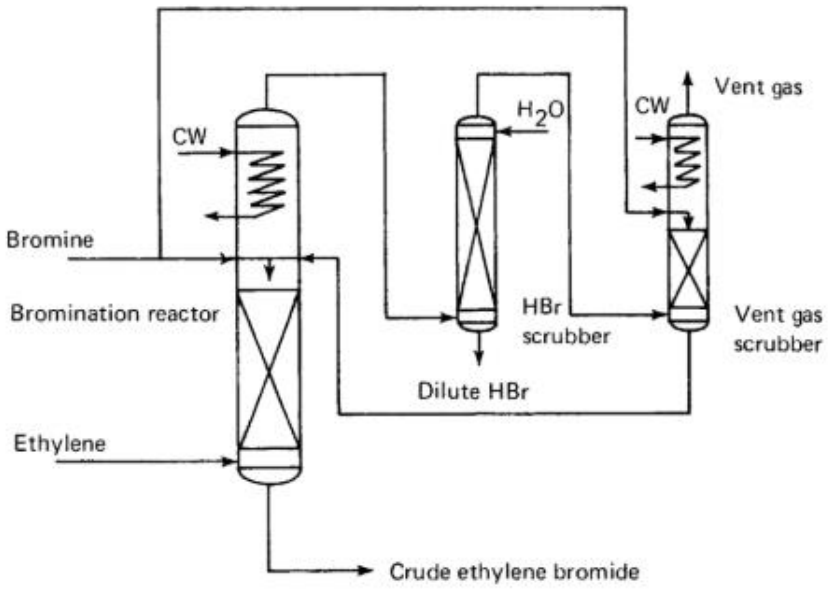
A commenter (EPA-HQ-OPPT-2018-0488-0038) provided descriptions of their use of ethylene dibromide as a laboratory use and a fuel additive including: reference sample for analysis of terrestrial and extraterrestrial material samples, laboratory use including such applications as analytical standards, research, equipment calibration, sample preparation and fuel additive for combustion research, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

E.1.1 Manufacture (Including Import)

Ethylene dibromide imported into the United States, however, the manufacturing process to produce ethylene dibromide is detailed below.

EDB is manufactured via uncatalyzed, liquid-phase bromination of ethylene. Gaseous ethylene is brought into contact with bromine by various methods, allowing for dissipation of the heat of the reaction (Yoffe et al., 2013; Ioffe and Frim, 2011).

The schematic process diagram in Figure_Apx E-1 is an example of a method for manufacturing ethylene dibromide. The main reactor is defined by a lower packed section and an upper reaction zone containing coils for heat removal. Liquid bromine is fed into the reaction zone and ethylene is introduced to the column below the packed section. Heat is removed through the coils to maintain a temperature of less than 100°C. Ethylene Bromide has a normal boiling point of 131.4°C and passes downward through the packed section and is discharged from the bottom of the column (McKetta and John, 1993).



Figure_Apx E-1. Example schematic process diagram of a method to manufacture ethylene dibromide. (**McKetta and John, 1993**)

EPA has not identified specific worker activities related to the manufacture and importation of EDB. However, based on EPA's knowledge of the chemical industry, worker activities at manufacturing and import facilities may involve manually adding raw materials or connecting/disconnecting transfer lines used to unload containers into storage, mixing, and/or reaction vessels, rinsing/cleaning containers and/or process equipment, collecting and analyzing quality control (QC) samples, manually loading EDB product or connecting/disconnecting transfer lines used to load EDB product into containers.
if EPA will proceed with a generic import scenario.

E.1.2 Processing and Distribution

E.1.2.1 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. The primary use of EDB that may require incorporation into a formulation is leaded aviation fuel (avgas) and racing fuel. Leaded fuels may contain from 0.03% to 0.9% EDB, though companies do not report the exact concentrations to protect proprietary formulations (AFD Petroleum, 2014; BP Oil New Zealand Limited, 2011).

The United States produced 208,644,000 gallons of Avgas in 2002 to fuel the 191,000 piston-engine aircraft operating in the United States (U.S. EPA, 2008a; FAA, 2005). There are four different grades of leaded avgas; 80, 100LL, 100/130, and B91/115 with ASTM defined maximum lead concentrations of 0.14, 0.56, 1.12, and 1.60 g/L, respectively. The most common of these four avgas grades is 100LL, or "100 Low Lead" (EPA, 2018). Lead makes up 64.1% of TEL by weight and therefore the concentration of TEL per gallon is about 0.8 g/L. Using the 70%/30% by weight ratio of TEL to EDB, the average concentration of EDB per gallon of avgas is 0.37 g/L (or 1.42 g/gallon). Based on average density of 6 lbs./gallon for 100LL avgas, this equates to 0.05%, the low end of the range provided in the previous paragraph.

EDB specific formulation processes were not identified for avgas or racing fuel, however, the Emission Scenario Document (ESD) on Chemical Additives Used in Automotive Lubricants developed by the

Organization for Economic Co-operation and Development (OECD) provides general process descriptions for similar liquid, petroleum-based products. The formulation of final finished products consists of blending a base stock with additive chemicals, such as EDB, to create a finished product. The three most common blending methods include batch, partial in-line, and continuous in-line blending. In each method, the base stock and additive chemical are unloaded into mixing equipment, blended, and transferred to storage or directly to transport containers (OECD, 2016).

Worker activities are expected to be similar to manufacturing activities and include unloading and loading activities, rinsing/cleaning activities, and collecting and analyzing QC samples (OECD, 2016).

E.1.3 Uses

E.1.3.1 Other Uses (Laboratory chemicals)

EPA identified an SDS that identifies uses of ethylene dibromide as a laboratory chemical and for use in synthesis of substances (Sigma-Aldrich, 2019). EPA did not identify specific process-related information regarding the usage of ethylene dibromide as a laboratory chemical, however, EPA plans to include this condition of use in the risk evaluation. A commenter (EPA-HQ-OPPT-2018-0488-0038) provided descriptions of their use of ethylene dibromide in analytical standards, research, equipment calibration, and sample preparation applications and as a component of common off the shelf fuel additive used in combustion research, as a reference sample for analysis of terrestrial and extraterrestrial material samples, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

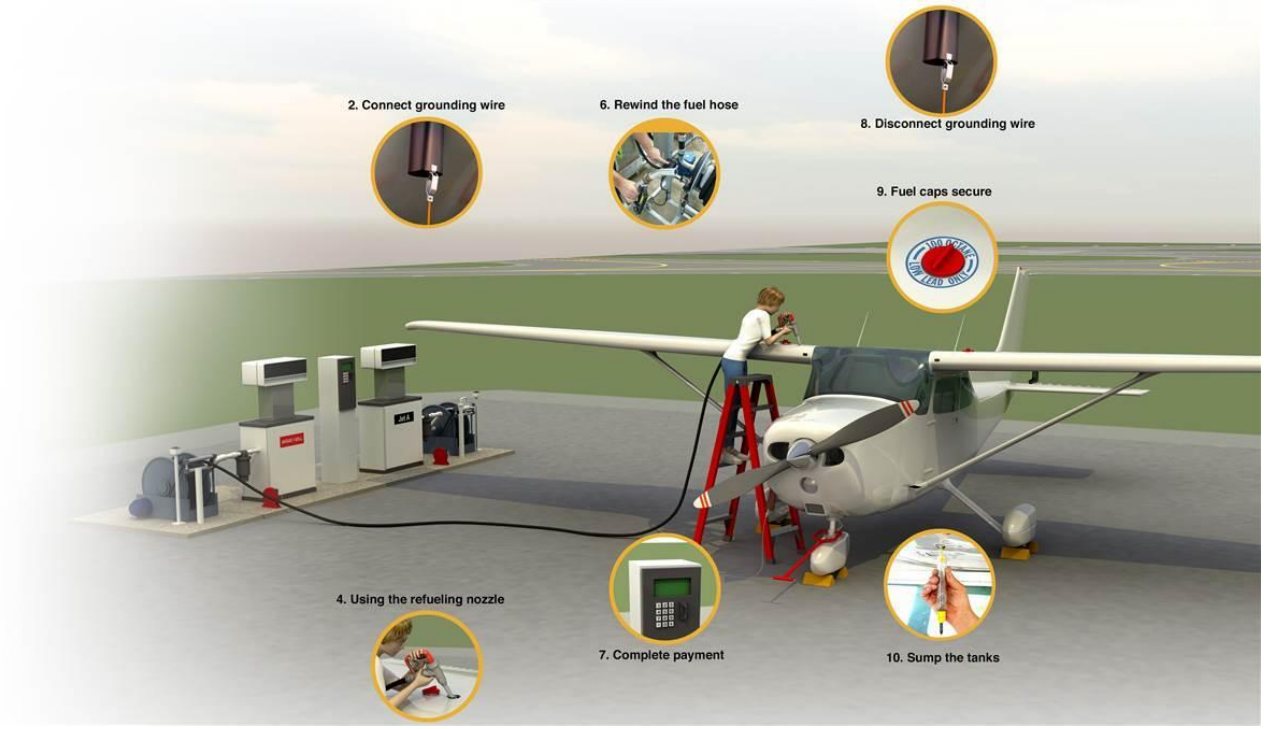
E.1.3.2 Fuel Additive in Aviation and Racing Fuel

Tetra-ethyl lead was widely used in leaded automobile gasoline from 1923 until 1987 to reduce the tendency to knock. Combustion of leaded motor fuel generates lead oxide which accumulated in the engine and causes damage. Lead scavengers, such as EDB, are added to reduce the accumulation of lead deposits by forming higher volatility lead compounds. Lead and lead scavengers were phased out of conventional automobiles gasoline by the end of the 1980s, but aviation gasoline (Avgas) and racing gasoline containing EDB and other lead scavengers are still used (U.S. EPA, 2008b). Avgas comes in a variety of grades for use in high-performance piston engines including fixed wing, rotary wing, multiple engine planes, recreational aircraft, radial warbirds, and "experimental" aircraft as defined by FAA.

Commercial usage consumes most of the US leaded Avgas fuel. Although the population of commercially operated high-performance piston aircraft is low, in comparison to private planes, their fuel consumption, operation frequency, and multiple engines design increase their fuel consumption rate (General Aviation Manufacturers Association, 15 January 2020). Consumers own a far greater number of personal and hobby high-performance piston aircraft, but compared to commercial operations, consumers experience less flight time, consume less Avgas, and release less EDB.

EDB is not sold in small container sales and can only be purchased through the AvGas supply chain. Both commercial and consumer aircraft are expected to be similarly refueled from either fixed tanks or a tanker truck. Small airfields (*e.g.*, a grass strip at a hunting lodge) may keep fuel on-site and refueling is "self-serve" with a gas can.

The figure below, developed by the Aircraft Owners and Pilots Association (AOPA) shows the steps for refueling a small airplane with a piston engine.



Figure_Apx E-2. Refueling a small, piston aircraft. (**Collins, 2019**)

When refueling an airplane, the refueler is required to remain with the refueling nozzle during the entire duration of the refueling, as aviation refueling nozzles do not lock for dispensing. Fuel is generally stored in the wings of most aircraft and some high-winged airplanes may require the person fueling the plane to stand over the plane on a ladder (Collins, 2019).

More information about EDB usage for leaded racing fuel will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

E.1.4 Disposal

One of the modern procedures of disposal is based on the Bromine Recovery Unit (BRU), in which the EDB (or other organic bromide) is incinerated at high temperatures and recovered. In one process ethylene dibromide is reacted in the gas phase with H_2 at 400-500 °C in the presence of a catalyst to prepare HBr (Grinbaum and Freiberg, 2002).

Incineration is the only effective way to get rid of brominated organic wastes without creating an ecological hazard. Recent processes operate at very high temperatures (> 1000°C), to prevent the creation and survival of brominated dioxins (Grinbaum and Freiberg, 2002). Per the EPA meeting with supplying entities, all residual EDB wastes that are produced are disposed of at their own facilities.

E.2 Preliminary Occupational Exposure Data

EPA presents below examples of occupational exposure-related information from the preliminary data gathering. EPA plans to consider this information and data in combination of other data and methods for use in the risk evaluation. Note there are no OSHA Chemical Exposure and Health Data (CEHD) or NIOSH Health Hazard Evaluations for ethylene dibromide within the last ten years.

Table_Apx E-1. Summary of Industry Sectors with Ethylene Dibromide Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted since 1984

SIC Code	SIC Description	Number of Data Points
3089	Plastics Products, Not Elsewhere Classified	9
3479	Coating, Engraving, and Allied Services, Not Elsewhere Classified	1
3711	Motor Vehicles and Passenger Car Bodies	5
3861	Photographic Equipment and Supplies	3
5199	Nondurable Goods, Not Elsewhere Classified	1
8734	Testing Laboratories	6
9221	Police Protection	3
9512	Land, Mineral, Wildlife, and Forest Conservation	10

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

Appendix F SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR COMMERCIAL ACTIVITIES AND USES

Table_Apx F-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release/ Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Manufacture	Import	Import	Import	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing EDB
				Vapor	Inhalation	Worker	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
				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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
Processing	Processing - Incorporation into formulation, mixture, or reaction product	Petroleum Refineries	Manufacture of petroleum and coal products	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing EDB
				Vapor	Inhalation	Worker	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
	Processing – incorporation into formulation, mixture or reaction product	All other petroleum and coal products manufacturing		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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution of bulk shipments of EDB and formulated products	Liquid Contact, Vapor	Dermal, Inhalation	Worker, ONU	Yes	EPA plans to analyze 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,

Life Cycle Stage	Category	Subcategory	Release/ Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
								processing, industrial use, commercial use, disposal) rather than as a single distribution scenario.
Commercial use	Other use	Laboratory chemicals	Use in laboratory and for the synthesis of substances	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing EDB
				Vapor	Inhalation	Worker	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
				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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
Commercial use	Fuel and related products	Fuel additive, such as anti-knock additive in aviation fuels	Exposure to fuel containing EDB, and exhaust containing EDB	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing EDB
				Vapor	Inhalation	Worker	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
				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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.
Disposal	Disposal	Emissions to air Wastewater Liquid Wastes Solid Wastes	Worker handling of waste streams	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle waste streams containing EDB.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.

Life Cycle Stage	Category	Subcategory	Release/ Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (11 mmHG at 25ºC), EPA plans to evaluate inhalation exposure to vapor.

Appendix G SUPPORTING INFORMATION – CONCEPTUAL 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	Leaded Fuel Products; Aviation Fuel Additive	Aviation Fuel Additive	Direct contact through application or use of products using ethylene dibromide	Liquid Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use and should be in scope.
			Long-term emission/mass-transfer through application or use of products using ethylene dibromide	Vapor	Inhalation	Consumers and Bystanders	Yes	Ethylene dibromide is volatile at room temperature; inhalation exposure should be in scope.
Consumer Handling of Disposal and Waste	Wastewater, Liquid wastes and solid wastes	Wastewater, Liquid wastes and solid wastes	Direct contact through application or use of products using ethylene dibromide	Liquid Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use and should be in scope.
			Long-term emission/mass-transfer through application or use of products using ethylene dibromide	Vapor	Inhalation	Consumers and Bystanders	Yes	Ethylene dibromide is volatile at room temperature; inhalation exposure should be in scope.

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

Table Apx H-1. Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	Ethylene dibromide is a HAP. Stationary source releases of ethylene dibromide to ambient air are under the jurisdiction of the CAA.
			Indirect deposition to nearby bodies of water and soil catchments	Oral; Dermal	General Population	No	
				TBD	Aquatic and Terrestrial Receptors	No	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic Receptors	Yes	This chemical is expected to be released to surface water; therefore, EPA plans to evaluate these pathways.
			Direct release into surface water and partitioning to sediment and bioaccumulation into edible aquatic species	Oral Inhalation	General Population	Yes	

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (*e.g.*, showering)	General Population	No	The drinking water exposure pathway for ethylene dibromide is currently addressed in the NPDWR.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral Inhalation	General Population	Yes	Although ethylene dibromide is a volatile chemical and not expected to sorb onto biosolids, EPA plans to analyze this pathway. However, it is expected to be a minor pathway of exposure to the general population and aquatic species.
				TBD	Aquatic Receptors	Yes	
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	Ethylene dibromide is released to Class I Underground Injection Hazardous Waste Wells which are covered by SDWA and RCRA.
				TBD	Aquatic and Terrestrial Receptors	No	
	Solid and Liquid Wastes	Hazardous, Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral (*e.g.*, ingestion) Dermal Inhalation	General Population	No	Ethylene dibromide is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
				TBD	Aquatic and Terrestrial Receptors	No	