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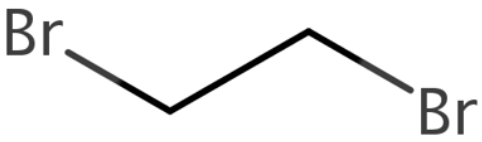
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for Ethylene Dibromide

CASRN 106-93-4



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ACKNOWLEDGEMENTS

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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
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)
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
UMCR	Unregulated Contaminants Monitoring Rule
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-2018-0488). The first step of the risk evaluation process is the development of the scope document and this document fulfills the regulatory requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft 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 this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. Ethylene dibromide is a colorless gas with a total production volume in the United States between 1 and 10 million pounds (2006).

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

Conditions of Use. EPA plans to evaluate industrial, commercial and consumer, distribution, and disposal uses of ethylene dibromide in the risk evaluation. Ethylene dibromide production volumes were reported as imported to the Chemical Data Reporting (CDR) in 2016. 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. Several industrial and commercial uses were identified that ranged from use as laboratory chemicals to fuel additives, such as an additive in aviation fuels. Only one consumer use was reported in fuels and related products to CDR.

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 plans to focus the risk evaluation for ethylene dibromide on the following exposures, hazards, and receptors with the understanding that updates may

be made in the final scope document after consideration of public comments and completion of the systematic review data collection phase.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of ethylene dibromide that EPA plans to consider in the risk evaluation. Exposures for ethylene dibromide are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of ethylene dibromide in air, drinking water, and groundwater. Ethylene dibromide is subject to reporting to the TRI which is reasonably available information that EPA anticipates using to inform ethylene dibromide's environmental release assessment. For the 2018 reporting year, 10 facilities reported to EPA releases of ethylene dibromide to air, water, and via land disposal. Additional information gathered through systematic review searches will also inform expected exposures.

  EPA's plan as to evaluating environmental exposure pathways in the draft scope document considers whether and how other EPA-administered statutes and regulatory programs address the presence of ethylene dibromide in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, 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.

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.
  - *Occupational exposures associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and/or occupational non-users via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of ethylene dibromide (2.2.1).
  - *Consumer and bystander exposures associated with consumer conditions of use:* EPA plans to evaluate the inhalation and dermal exposure to ethylene dibromide when consumers and bystanders are handling leaded fuel products and plastic and rubber products.
  - *General population exposures:* EPA plans to evaluate exposure to ethylene dibromide via fish ingestion for the general population.
  - *Environmental exposures:* EPA plans to evaluate exposure to ethylene dibromide for aquatic and terrestrial receptors.
  - *Receptors and PESS:* EPA plans to evaluate children, women of reproductive age, pregnant women, workers and consumers as receptors and PESS in the risk evaluation.

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

identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for ethylene dibromide. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. EPA plans to evaluate all of the potential human health hazards for ethylene dibromide identified in Section 2.4.2. The broad health effect categories identified in the prioritization document include reproductive and developmental, immunological, nervous system, genotoxicity, carcinogenicity, ADME (absorption, distribution, metabolism, and excretion), and irritation effects.

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 a partial, but ongoing, review of identified information as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

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

Peer Review. The draft risk evaluation for 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 and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for 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 the Toxic Substances Control Act (TSCA) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, to "*determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.*"

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and 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-2018-0451), as required by TSCA § 6(b)(2)(B). Ethylene dibromide is one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

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

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

[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.

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

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

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 128 search results relevant to EPA's risk assessment needs for ethylene dibromide. Appendix A lists the gray literature sources that yielded 128 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 chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. Gray Literature Search Results for Ethylene Dibromide. EPA is currently identifying additional reasonably available information through systematic review methods and public comments, and the reported numbers in Figure 2-1. Gray Literature Search Results for Ethylene Dibromide may change.

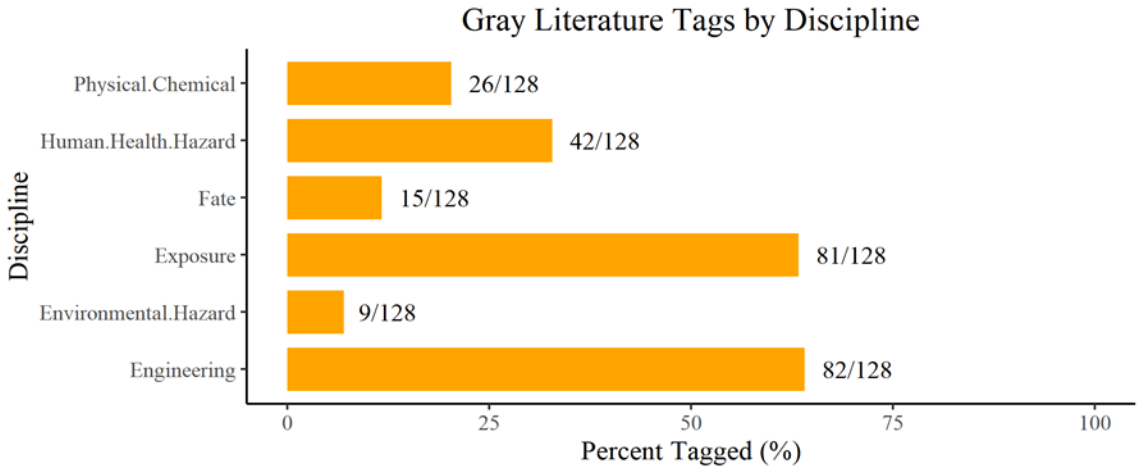
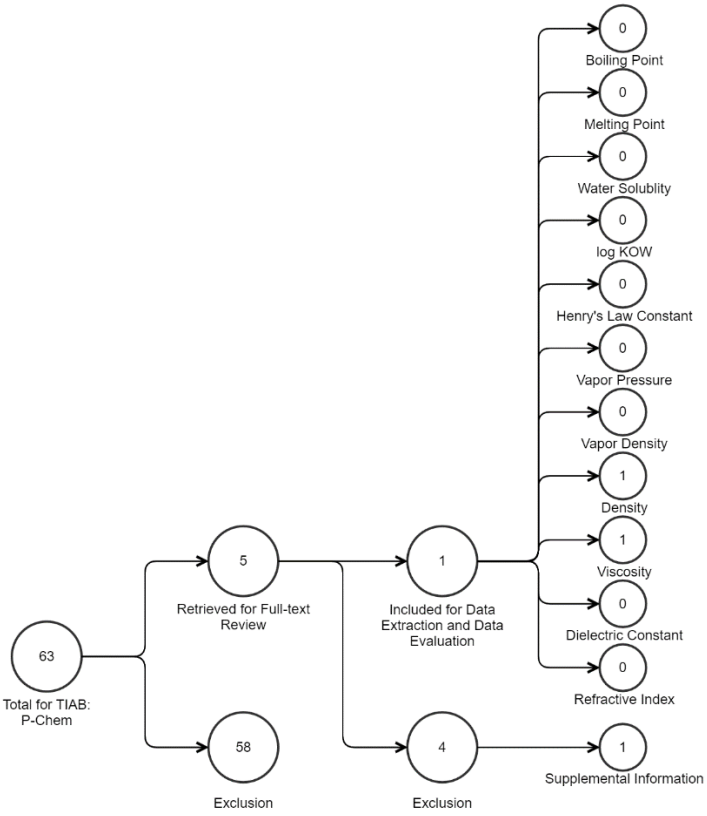


Figure 2-1. Gray Literature Search Results for Ethylene Dibromide
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

2.1.2 Search of Peer-Reviewed Literature

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-chemical 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 (population, exposure, comparator, outcome) statements. 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. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Note that 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.



through Figure 2-6. Peer-reviewed Literature - Hazard Search Results for Ethylene Dibromide. "TIAB" in these figures refer to "title and abstract" screening. Note that the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

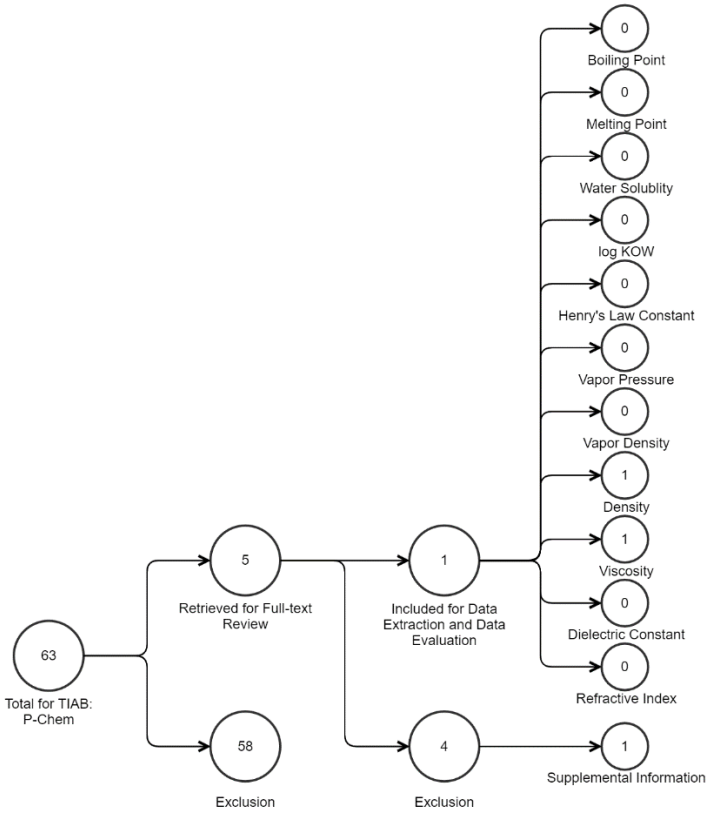


Figure 2-2. **Peer-reviewed Literature - Physical-Chemical Search Results for Ethylene Dibromide**

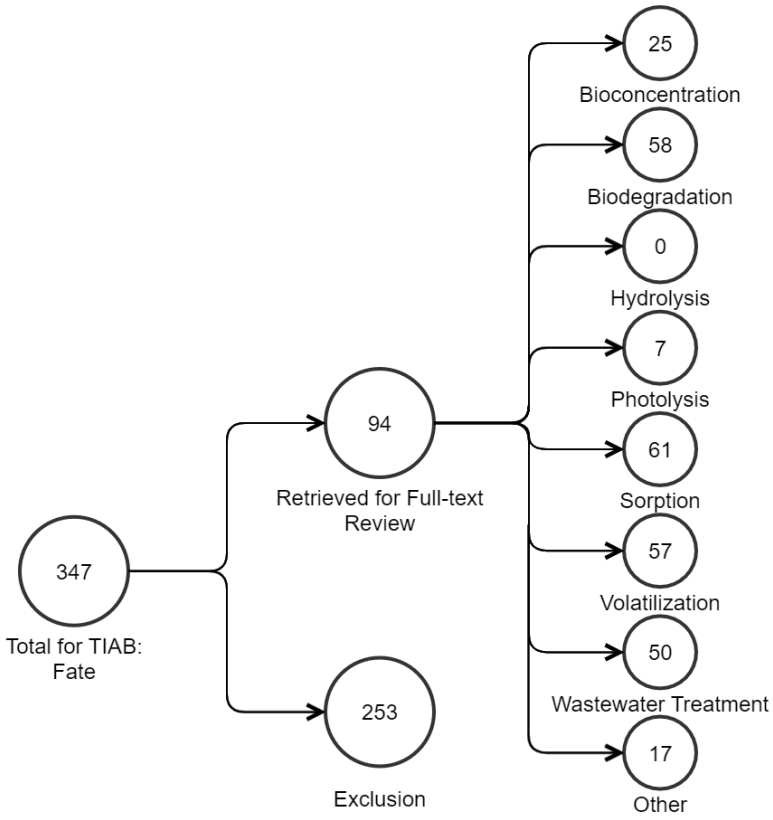


Figure 2-3. Peer-reviewed Literature – Fate and Transport Search Results for Ethylene Dibromide

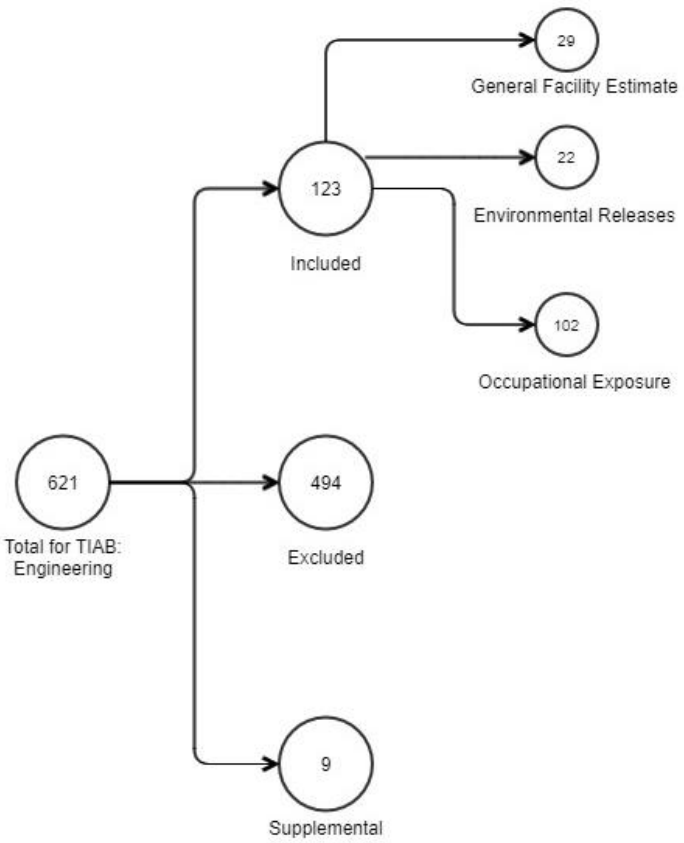


Figure 2-4. Peer-reviewed Literature - Engineering Search Results for Ethylene Dibromide

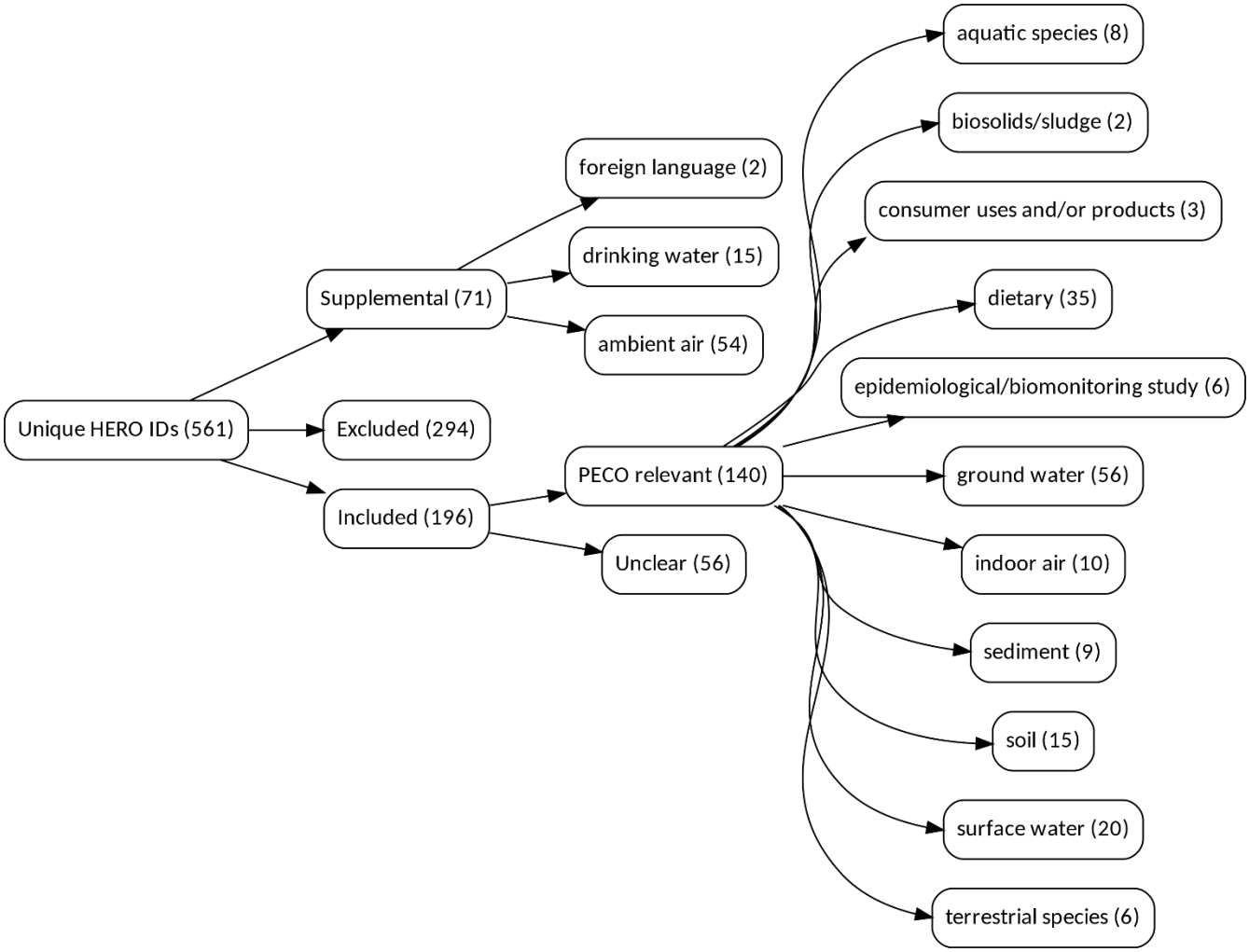


Figure 2-5. Peer-reviewed Literature – Exposure Search Results for Ethylene Dibromide

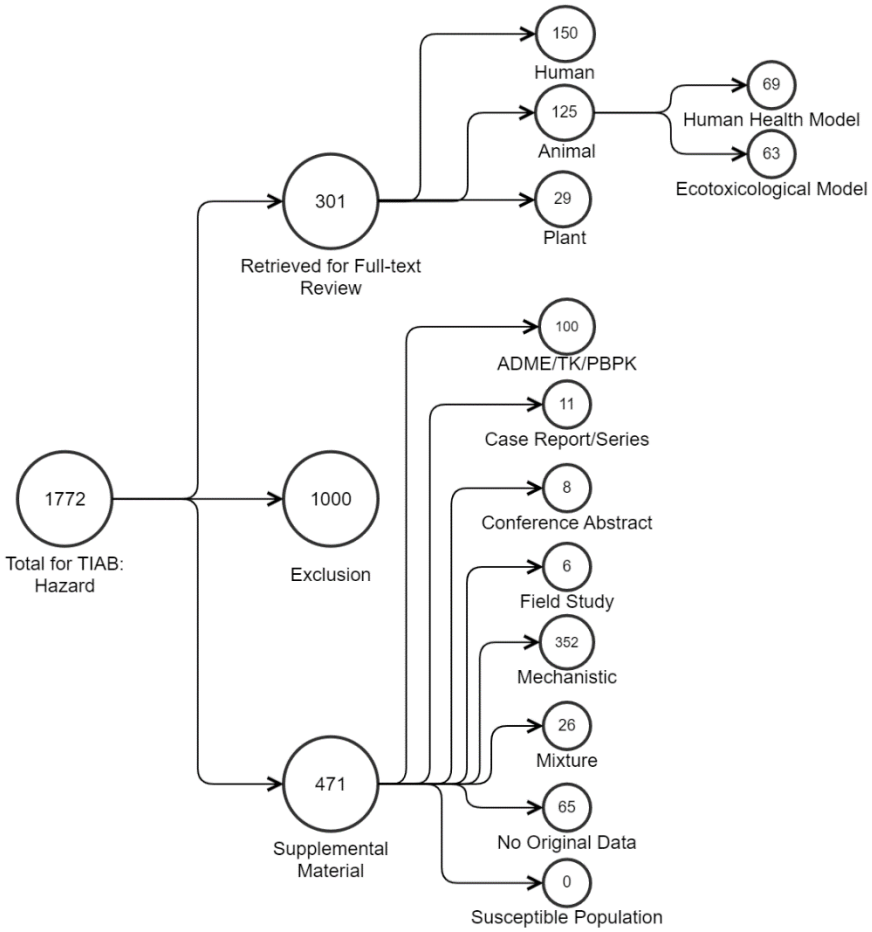


Figure 2-6. Peer-reviewed Literature - Hazard Search Results for Ethylene Dibromide

2.1.3 Search of TSCA Submissions

Table 2-1. Results of Title Screening of Submissions to EPA under Various Sections of TSCA 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 inclusion and exclusion criteria specific to individual disciplines (see Table 2-1. Results of Title Screening of Submissions to EPA under Various Sections of TSCA for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 18 submissions that met the inclusion criteria in these statements and identified 11 submissions with supplemental data. EPA excluded 7 submissions 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

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

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

Discipline	Included	Supplemental
Physicochemical 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

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 2019), EPA assembled information from the CDR and TRI programs to determine conditions of use[3] or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of 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) 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, environmental organizations, and public comments to supplement the condition of use information.

EPA identified and described the categories and subcategories of conditions of use that EPA plans to include in the scope of the risk evaluation (Section 2.2.1; Table 2-2. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation). The conditions of use that EPA plans to include in the scope are those reflected in the life cycle diagrams and conceptual models.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of ethylene bromide, EPA identified those categories or subcategories of use activities for ethylene dibromide the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

[3] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. TSCA § 3(4)

2.2.1 Categories and Subcategories of Conditions of Use 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 lists the conditions of use that are included in the scope of the risk evaluation. EPA is looking for more information to confirm the reports of ethylene dibromide for mechanical cleaning that is not currently included as conditions of use.

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

Life Cycle Stage[a]	Category	Subcategory	References
Manufacturing	Import	Import	U.S. EPA (2019)
Processing	Processing - Incorporation into formulation, mixture, or reaction product	Petroleum refineries	U.S. EPA (2019)
		All other petroleum and coal products manufacturing	U.S. EPA (2019)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Commercial use	Other use	E.g. Laboratory chemicals	Sigma Aldrich (2017)
	Fuels and related products	Fuel additive (e.g. in aviation and racing fuels)	U.S. EPA (2019); Renegade (2014)
Consumer use	Fuels and related products	Fuels and related products	U.S. EPA (2019)
Disposal	Disposal	Disposal	

- Life Cycle Stage Use Definitions
  - "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
  - "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
  - "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- The Agency has included information in this draft scope document sourced from the 2012 and 2016 Chemical Data Reporting (CDR) Rule collections. In instances where particular CDR data elements included in this document were claimed as confidential business information (CBI), the Agency reviewed the claims and secured their declassification.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA the authority to determine what constitutes a condition of use for a particular chemical substance. As a result, EPA does not plan to include in this scope or in the risk evaluation the activities that the Agency has concluded do not constitute conditions of use.

No conditions of use were excluded for ethylene dibromide.

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 10 million pounds (U.S. EPA 2017). 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 2019) and will include future production volume information as it becomes reasonably available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in
Figure 2-5. Peer-reviewed Literature – Exposure Search Results for Ethylene Dibromide depicts the conditions of use that EPA plans to consider in the risk evaluation for the various life cycle stages as presented in Section 2.2.1. Section 2.2.1 provides a brief overview of the industrial, commercial and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams) for each manufacturing, processing, distribution in commerce, use and disposal category.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses).

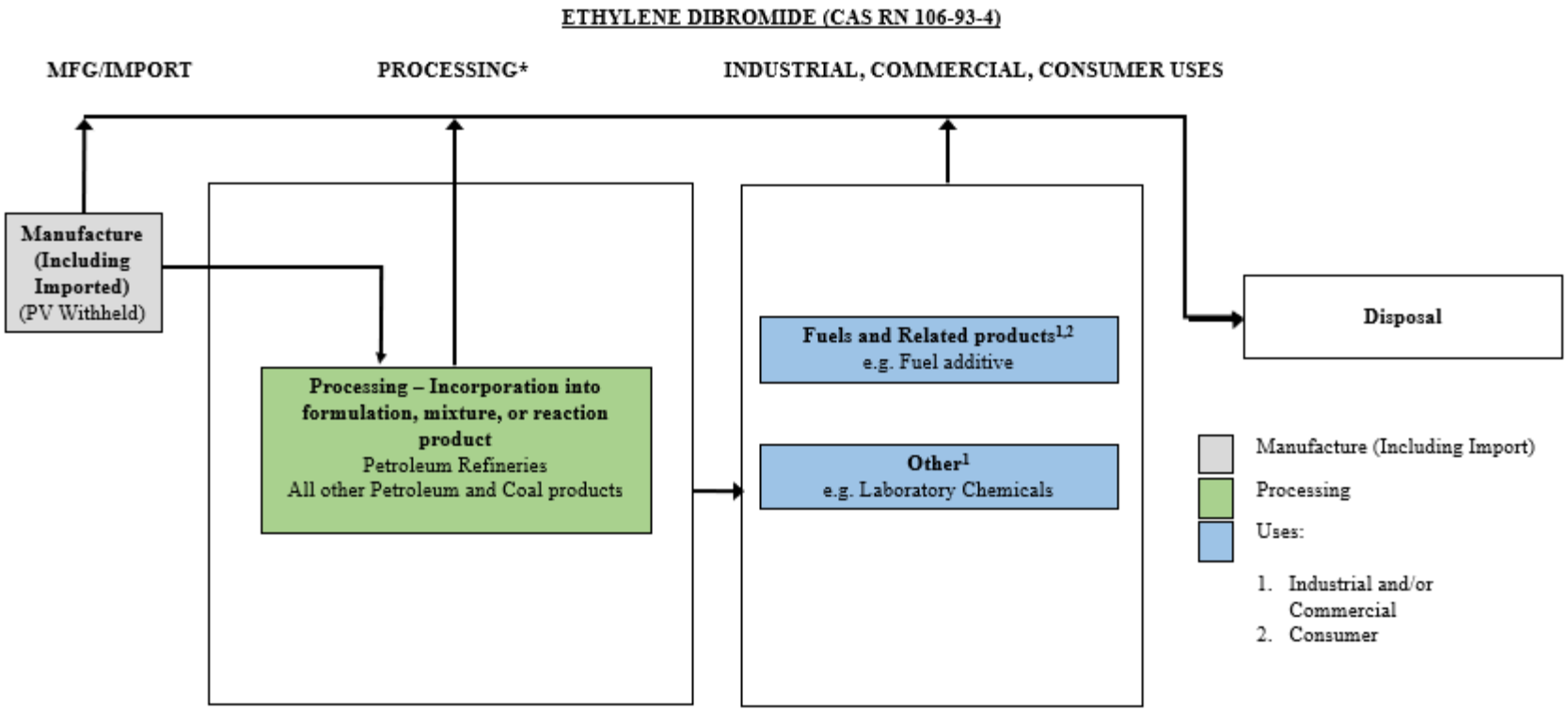


Figure 2-7. Ethylene Dibromide Life Cycle Diagram

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

2.3 Exposures

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

2.3.1 Physical and Chemical Properties

Physical and chemical properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019) to support the development of the risk evaluation for ethylene dibromide. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for ethylene dibromide. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019) to support the development of the risk evaluation for ethylene dibromide. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

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

A source of information that EPA plans to consider in evaluating exposure are data reported to the 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,[4] 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.

[4] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

Table 2-3. Summary of Ethylene Dibromide TRI Production-Related Waste Managed in 2018 provides production-related waste management data for ethylene dibromide reported by facilities to the TRI program for reporting year 2018.[5] 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 2-3. 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 (Updated November 2019)
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-4. Summary of Releases of Ethylene Dibromide to the Environment During 2018 provides a summary of the quantities 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.

Table 2-4. Summary of Releases of Ethylene Dibromide to the Environment During 2018

	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases [a] (lbs)	Total Releases [b, c] (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal [a] (lbs)		
Totals	10	386	349	70	0	123	1	0	929
		735			124				

Data source: 2018 TRI Data (Updated November 2019)

[5] 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.

	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)		

[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 2-3. Summary of Ethylene Dibromide TRI Production-Related Waste Managed in 2018 excludes any quantities reported as catastrophic or one-time releases (TRI Form R Section 8 data), release quantities shown in Table 2-4 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, 2017c).

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, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review reasonably available information on environmental exposures in biota to inform development of the environmental exposure assessment for ethylene dibromide.

2.3.5 Occupational Exposures

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

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

- Unloading and transferring ethylene dibromide to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing ethylene dibromide;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing ethylene dibromide for quality control;

Ethylene Dibromide has a vapor pressure of 11 mmHg at 25°C (Appendix B). Based on the chemical's high volatility, EPA anticipates that both workers and ONUs will be exposed to EDB 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.

Ethylene dibromide has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL)[1] 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 2019b). 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 also has an Immediately Dangerous to Life or Health (IDLH) value of 100 ppm (NIOSH 2019).

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

Based on the conditions of use, EPA also plans to analyze dermal exposure to liquids containing EDB for workers. EPA does not expect to analyze dermal exposure for occupational non-users because they are not expected to directly handle ethylene dibromide.

2.3.6 Consumer Exposures

According to reports to the 2016 CDR, leaded fuel products, and plastic and rubber products including synthetic rubbers, 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. In addition, consumers using or disposing of plastic and rubber products may be exposed to ethylene dibromide through vapor emissions which may lead to inhalation exposure, given its volatility at room temperature. Bystanders present during the consumer use of leaded fuel products, plastic, rubber products, or disposal of ethylene dibromide may also be exposed to 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 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, NICNAS 2018, U.S. EPA 2009, U.S. EPA 2004a, 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 Unregulated Contaminant Monitoring Rule has 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 (U.S. EPA, 2019). 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, and plastic and rubber factories where ethylene dibromide is manufactured or used would be expected to have higher exposures (ATSDR 2012). 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, and thermal breakdown of plastics (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). Thus, the general population is not expected to receive significant exposure to ethylene dibromide via fish ingestion.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for ethylene dibromide. EPA considers all the potential environmental hazards for ethylene dibromide identified during prioritization (U.S. EPA 2019) to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with ethylene dibromide. If necessary, EPA plans to update the list of potential hazards in the final scope document of ethylene dibromide. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for ethylene dibromide. EPA plans to evaluate all of the potential human health hazards for ethylene dibromide identified during prioritization. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME. The health effect categories identified during prioritization included reproductive and developmental, nervous system,

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

2.5 Potentially Exposed or Susceptible Subpopulations

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

During the Prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (including, but not limited to, pregnant women), workers and consumers (U.S. EPA 2019). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

In developing exposure scenarios, EPA plans to analyze reasonably available information 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, 2006a). Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of ethylene dibromide. Pathways and routes of exposure associated with workers and occupational non-users 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 may be addressed pursuant to other Federal laws are discussed and depicted in the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws, are presented in the conceptual model shown in Section Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-6. Peer-reviewed Literature - Hazard Search Results for Ethylene Dibromide illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of ethylene dibromide that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or 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 disposed in 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., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation, a determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be assessed in the risk evaluation. The supporting rationale is presented in SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES.

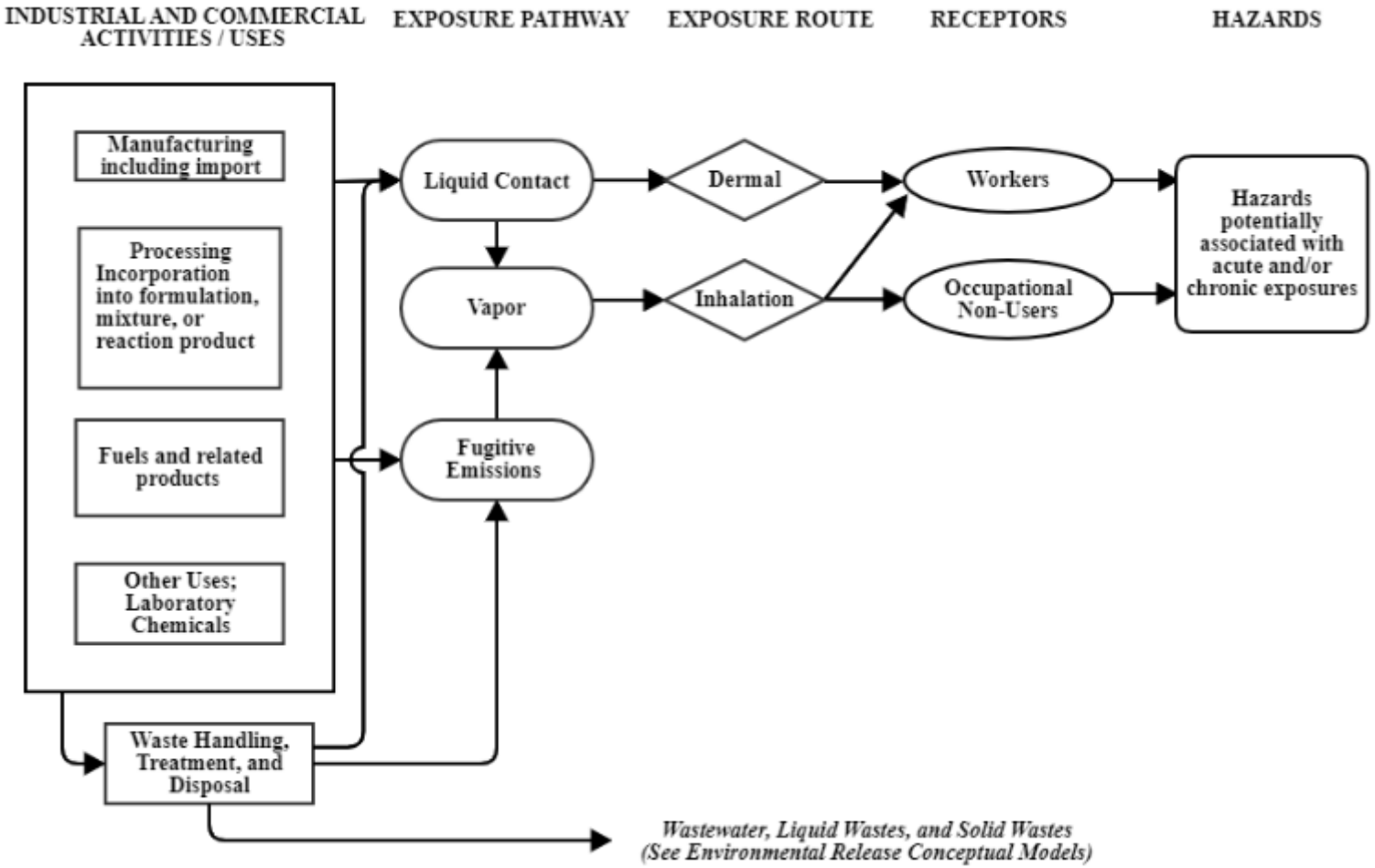


Figure 2-8. Ethylene Dibromide Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-7. Ethylene Dibromide Life Cycle Diagram presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of ethylene dibromide that EPA plans to include in the risk evaluation. 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 2.9Appendix G.

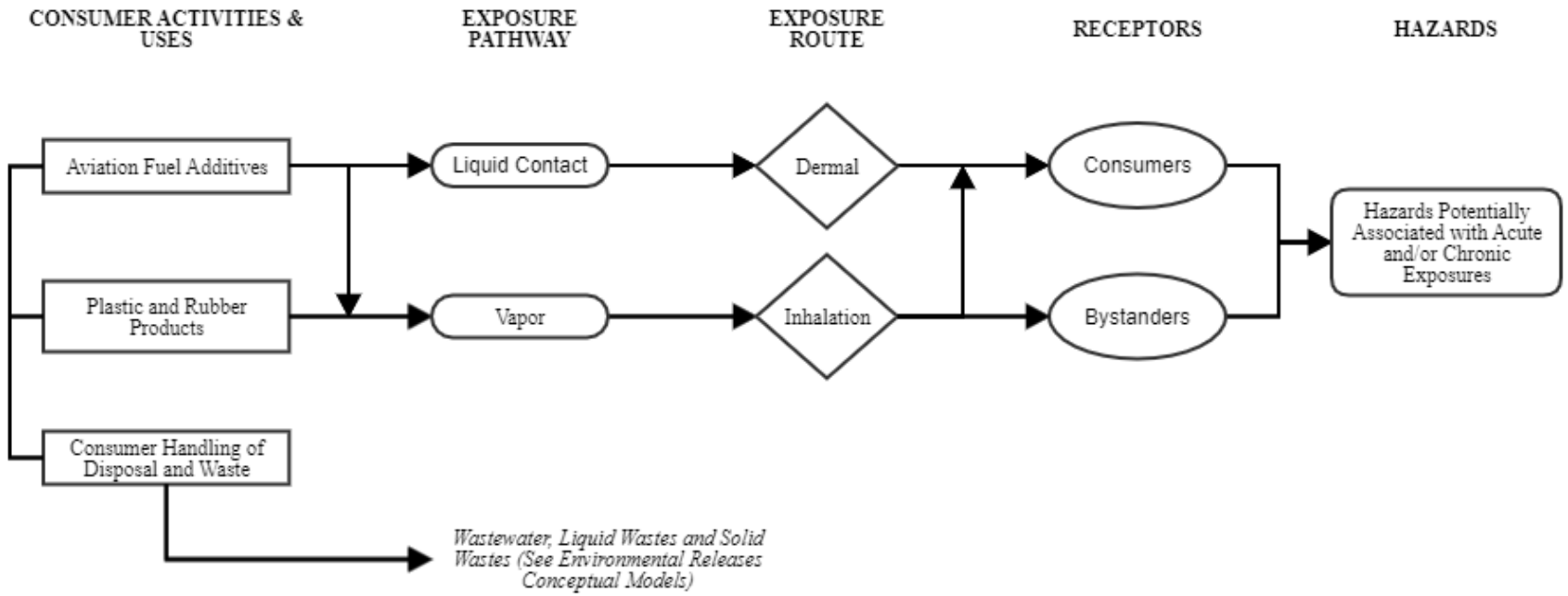


Figure 2-9. Ethylene Dibromide Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes, and hazards to human receptors from consumer activities and uses of ethylene dibromide

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), 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.

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of ethylene dibromide in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-8 presents the potential exposure pathways, exposure routes and hazards to human 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 (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The regulatory programs that cover these environmental release and waste pathways are further described in Section 2.6.3.1 through Section 2.6.3.4.

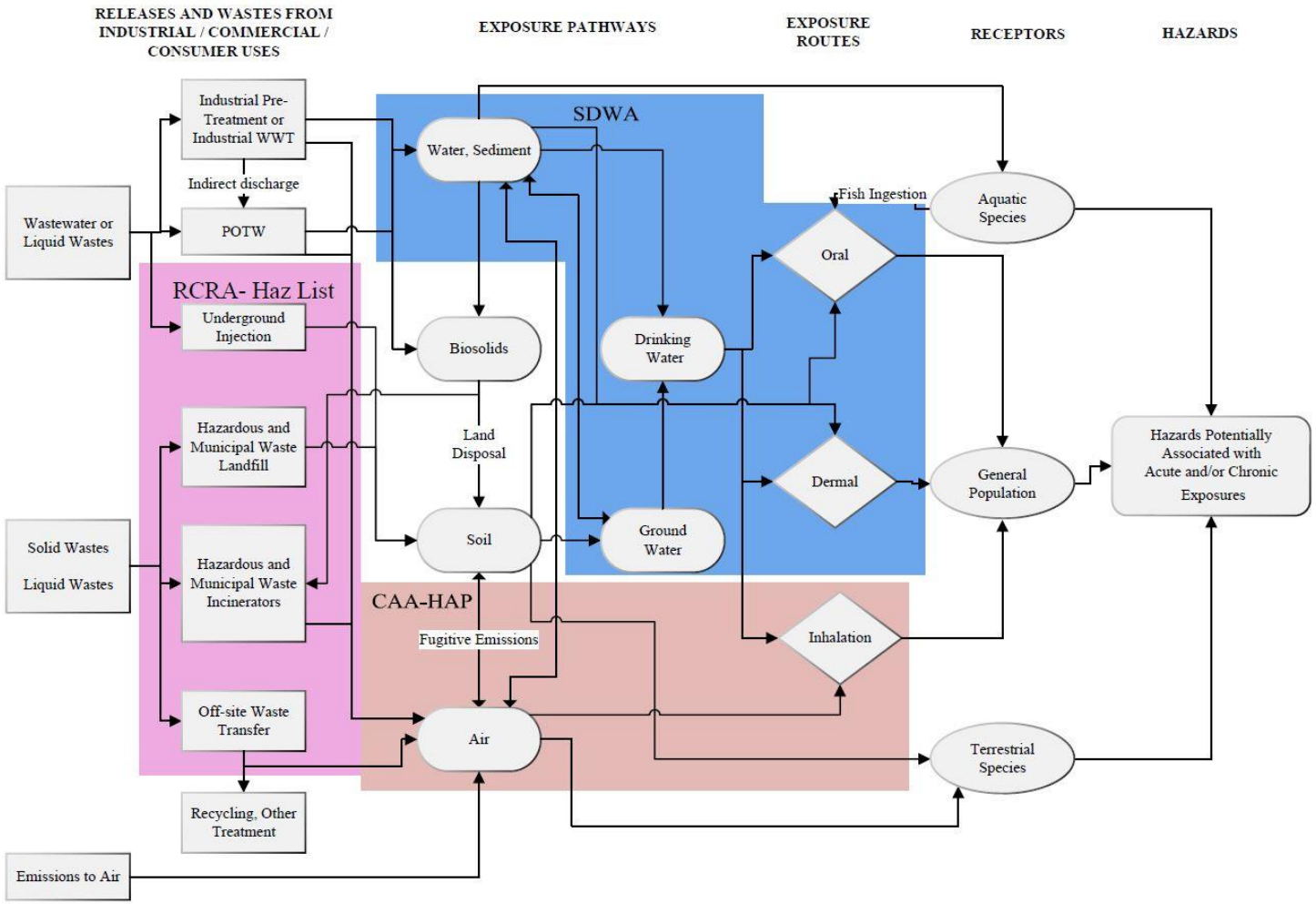


Figure 2-10. Ethylene Dibromide Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

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 including the environmental statutes covering those pathways. Notes:

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

c) For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

2.6.3.1 Ambient Air Pathway

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 HAPs, 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. 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.

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 provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.1 Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA). Under SDWA EPA must also review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the Safe Drinking Water Act 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). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL, SDWA Section 1412(b)(4)(D), and 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.

The drinking water exposure pathway for ethylene dibromide is currently addressed in the SDWA regulatory analytical process for public water systems. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together to provide an 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.

2.6.3.2 Ambient Water Pathway

EPA develops recommended water quality criteria under Section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of human or aquatic life for ethylene dibromide, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. EPA may publish CWA Section 304(a) ambient water quality criteria and/or aquatic life criteria for ethylene dibromide in the future if it is identified as a priority under the CWA.

2.6.3.3 Disposal and Soil Pathways

Ethylene dibromide is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U067 list. 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 Clean Air Act (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 Safe Drinking Water Act (SDWA)).

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.

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products 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 "other landfills" 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 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.

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 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.

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.

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

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-11 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. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of ethylene dibromide in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 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 and terrestrial 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.

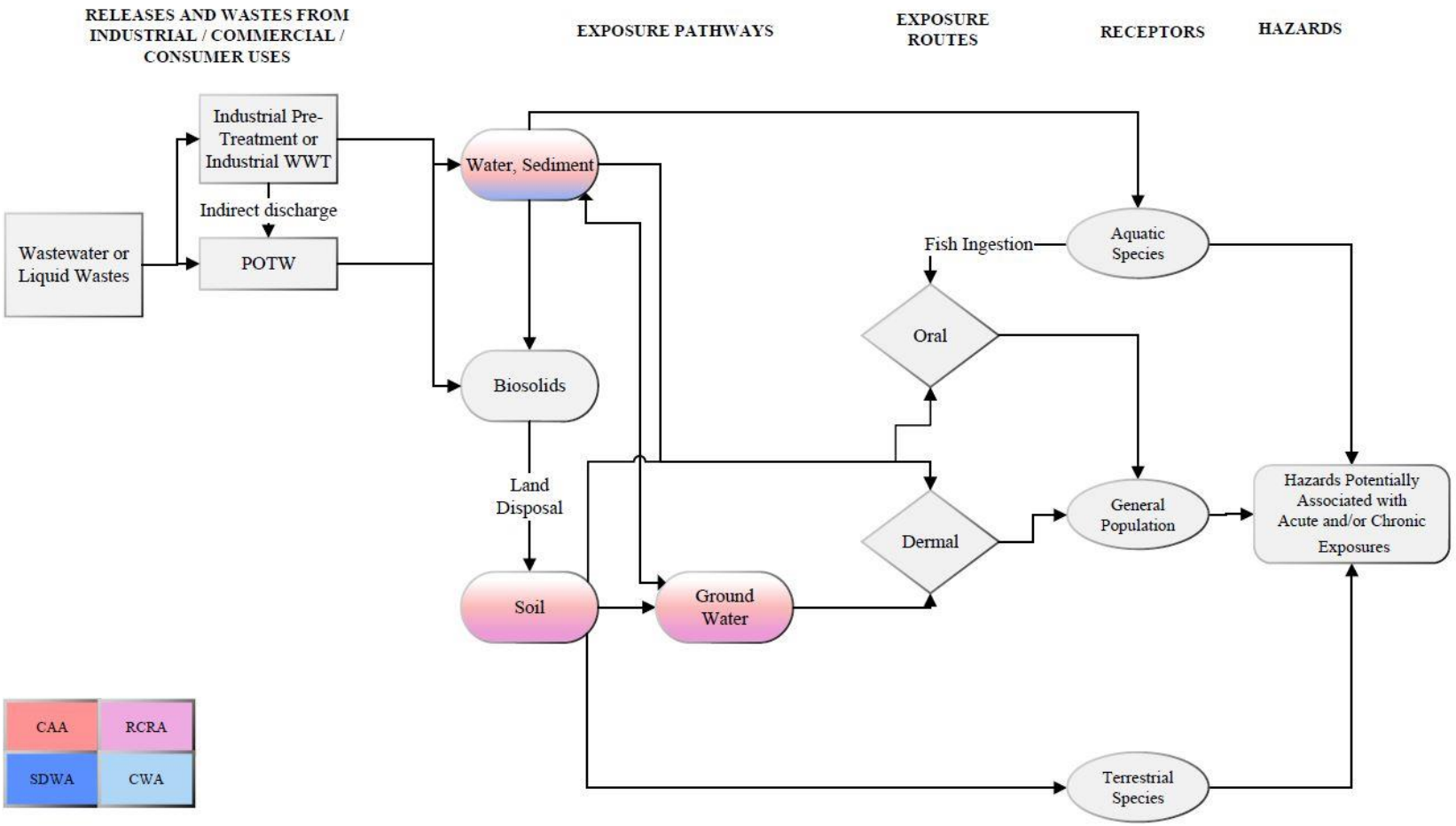


Figure 2-11. Ethylene Dibromide Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

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. Notes:

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 potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of ethylene dibromide to date which includes a partial, but not complete review of reasonably available information as described in Section 2.1. EPA encourages submission of additional data, such as full study reports or workplace monitoring from industry sources, that may be relevant for EPA's evaluation of conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. Further, EPA may consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical (p-chem) properties and environmental fate and transport of ethylene dibromide as follows:

1) **Review reasonably available measured or estimated p-chem and environmental fate endpoint data collected using systematic review procedures and, where available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the physical-chemical properties (Appendix B) and fate endpoints (Appendix C) previously summarized in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of p-chem properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**
   EPA plans to use measured data and, where necessary, model predictions of p-chem 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 soil and 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-the-scientific-evidence evaluation of p-chem and environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ground water, surface water, sediment, soil, aquatic biota, and terrestrial biota associated with exposure to ethylene dibromide. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios include

sources (uses), exposure pathways, and exposed receptors. EPA plans to analyze scenario-specific exposures.

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

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to continue to review data sources during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-7 below:

Table 2-5. 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 2.3.2.1. EPA plans to continue to review relevant data sources during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical chemical properties.**
   If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**

This item will be performed after completion of #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 (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. EPA plans to further 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 to assess potential releases. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

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

EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including use of ethylene dibromide in aviation fuel additives. EPA plans to perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. 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 identified release scenarios and mapped (i.e., grouped) them to relevant conditions of use as shown in Appendix F. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g., use as Aviation Fuel additive). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and release sources and usage rates of ethylene dibromide and formulations containing ethylene dibromide, or professional judgment) corresponding to conditions of use as additional information is identified during risk evaluation.

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

evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of 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 evaluate are sediment, biosolids, soil, and water.

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

3) **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. Monitoring data or modeled estimates will be reviewed to determine how representative they are of applicable 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).**
   EPA plans to 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, sediment concentrations and soil concentrations near industrial point sources based on reasonably available monitoring data.
   - Generally, 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 available, and characterize exposed aquatic and terrestrial populations.

- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

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

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 Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (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).

   EPA has preliminarily reviewed reasonably available monitoring data collected by OSHA and NIOSH and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources (identified in Table 2-2 and in Table Apx-B-3.3) and extract relevant data for consideration and analysis during risk evaluation.

   Ethylene dibromide has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL)[1] 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 data sources identified thus far:

Table 2-6. Potential Sources of Occupational Exposure Data

2012 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 available, review existing exposure models that may be applicable in estimating exposure levels.**
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 to estimate occupational exposures. EPA plans to need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

EPA was not able to identify ESDs or GS's corresponding to some conditions of use, including use of ethylene dibromide as a leaded aviation fuel additive. EPA plans to perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research 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 Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA, or 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 occupational non-users.

5) **Consider and incorporate applicable EC and/or PPE 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. EPA plans to assess worker exposure pre- and post-implementation of engineering controls, 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 Appendix F, EPA has grouped the scenarios into representative release/exposure scenarios that will be evaluated. EPA was not able to identify occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may further refine the mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

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

2.7.2.4 Consumer Exposures

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

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

   For ethylene dibromide, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use
   - Duration of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on reasonably available data.**
   Indoor exposure pathways expected to be relatively higher include inhalation of vapors from indoor air during ethylene dibromide use and disposal. Indoor exposure pathways expected to be relatively lower include dermal contact to liquid dermal contact to liquid. The data sources associated with these respective pathways have not yet been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air.**
   Indoor exposure models that estimate emissions from consumer products are available. These models generally consider p-chem 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 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 ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air levels and various indoor sources will be analyzed.

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

7) **Evaluate the weight of the 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 evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:
While the primary route of exposure to ethylene dibromide is inhalation, the general population may be exposed via the oral route (i.e., fish ingestion). Dermal exposures to the general population are expected to be negligible. However, depending on information identified and evaluated through EPA's systematic review process, exposure through dermal routes may be considered in the risk evaluation of ethylene dibromide (NTP 2016, ATSDR 2012).

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**
   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 models that may be applicable in estimating exposure levels.
   - Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
   - Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
   - Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
   - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
   - Evaluate the weight of the scientific evidence of general population exposure data.

- Map or group each condition of use to general population exposure assessment scenario(s).

EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon reasonably available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with reasonably available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the reasonably available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **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, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial 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 available.**
To the extent other organizations have already modeled ethylene dibromide general population exposure scenario that is relevant to this assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

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 potentially exposed or susceptible subpopulations need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).**
For ethylene dibromide, exposure scenarios that involve potentially exposed or susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for soil than adults.

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

2.7.3 Hazards (Effects)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 and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g., analogue and read-across data) when characterizing the potential hazards of ethylene dibromide to aquatic and/or terrestrial organisms.

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

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

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

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

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

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

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of ethylene dibromide.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of ethylene dibromide after reviewing relevant physical-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).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).**

   EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for ethylene dibromide. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

   Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. 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 plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

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

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

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

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the 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*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

EPA plans to evaluate whether the available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not

possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011), 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 systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, reasonably available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient 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 the worker, consumer, and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes. This may include using route-to-route extrapolation methods where appropriate, and depending on the nature of reasonably available data.

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

2.7.4 Summary of Risk Approaches for Characterization

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

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

were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

EPA plans to also be guided by EPA's Information Quality Guidelines (U.S, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, EPA plans to identify in the risk characterization the following: (1) Each population addressed by an estimate of applicable risk effects; (2) The expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) Each appropriate upper-bound or lower-bound estimate of risk; (4) Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) Peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.8 Peer Review

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

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table Apx A-1 provides a list of gray literature sources that yielded results for ethylene dibromide.

Table_Apx A-1. Gray Literature Sources for Ethylene Dibromide

Source/Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Australian Government Dept of Health	NICNAS Assessments (human health Tier)	International Resources	Assessment or Related Document
Australian Government Dept of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document
Australian Government Dept of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer, Notice	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Reproductive Toxicity	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Soil Screening	Other US Agency Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
Canada Gov	Government of Canada - Factsheet: Prohibition of Certain Toxic Substances Regulations	International Resources	Factsheet
Canada Gov	Government of Canada - Substances Search	International Resources	General Search
CARB	Report to the California Legislature Indoor Air Pollution in California.	Other US Agency Resources	Technical Report
CDC	CDC Biomonitoring Tables	Other US Agency Resources	Data
CDC	NHANES data	Other US Agency Resources	Data
CPSC	Chronic Hazard Advisory Panel Reports	Other US Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document
CPSC	Technical Reports: Toxicity Review	Other US Agency Resources	Assessment or Related Document
EC	European Commission	International Resources	Assessment or Related Document
EC	IPCheM: Information Platform for Chemical Monitoring Data	International Resources	Database
ECHA	Annex XIV Restriction Report	International Resources	Assessment or Related Document
ECHA	Annex XV Restriction Report	International Resources	Assessment or Related Document
ECHA	Annex XVII Restriction Reports	International Resources	Assessment or Related Document
ECHA	Annex XVII To REACH - Conditions of Use	International Resources	Assessment or Related Document
ECHA	Annex XV Transitional Report	International Resources	Assessment or Related Document
ECHA	ECHA Documents	International Resources	Assessment or Related Document
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
EFSA	EFSA reports	International Resources	Assessment or Related Document
Environment Canada	CEPA Environmental Registry - Draft assessments currently available	International Resources	Assessment or Related Document
Environment Canada	CEPA Environmental Registry - Final Assessments	International Resources	Assessment or Related Document
Environment Canada	Canada Substance Grouping Pages	International Resources	Assessment or Related Document
Environment Canada	Screening Assessment Report	International Resources	Assessment or Related Document
Environment Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
Environment Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
Environment Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document
Environment Canada	Screening Assessment for the Challenge	International Resources	Assessment or Related Document
Environment Canada	Government of Canada - Toxic substances list: schedule 1	International Resources	Assessment or Related Document
Env UK	Environmental risk evaluation report	International Resources	Assessment or Related Document
EPA	Design for the Environment (DfE) Alternatives Assessments	US EPA Resources	Assessment or Related Document
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document
EPA	EPA Pesticide Chemical Search (docket)	US EPA Resources	Assessment or Related Document
EPA	EPA Pesticide Chemical Search (assessment)	US EPA Resources	Assessment or Related Document
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document
EPA	IRIS Tox Review	US EPA Resources	Assessment or Related Document
EPA	PPRTV Derivation Support Document	US EPA Resources	Assessment or Related Document
EPA	Support document for AEGLS	US EPA Resources	Assessment or Related Document
EPA	TSCA Assessments	US EPA Resources	Assessment or Related Document
EPA	TSCA Data Needs Assessments or Problem Formulation	US EPA Resources	Assessment or Related Document
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document
EPA	Office of Air: Air Emission Factors	US EPA Resources	Data
EPA	Office of Air: AQS, Annual	US EPA Resources	Data
EPA	Office of Air: NATA 2011	US EPA Resources	Data
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Data
EPA	Office of Air: National Emissions Inventory (NEI) - Additional Documents	US EPA Resources	Data
EPA	Office of Air: TRI	US EPA Resources	Data
EPA	Office of Water: STORET and WQX	US EPA Resources	Data
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA - ECOTOX Database	US EPA Resources	Database
EPA	CPDAT	US EPA Resources	Database

Source/Agency	Source Name	Source Type	Source Category
EPA	EPA Ambient Monitoring Technology Information Center – Air Toxics Data	US EPA Resources	Database
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	enam	US EPA Resources	Database
EPA	EPA: ICIS	US EPA Resources	Database
EPA	Great Lakes Environmental Database	US EPA Resources	Database
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	TSCATS	US EPA Resources	Database
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	EPA Office of Air NESHAP list	US EPA Resources	Regulatory Document or List
EPA	Clean Air Act Hazardous Air Pollutants (HAPs)	US EPA Resources	Regulatory Document or List
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Water: Drinking Water Standards Health Effects Support Documents	US EPA Resources	Regulatory Document or List
EPA	Office of Water: Drinking water Chemical contaminant lists	US EPA Resources	Regulatory Document or List
EPA	EPA: Generic Scenario	US EPA Resources	Technical Report
EPA	EPA OECA Sector Notebooks	US EPA Resources	Technical Report
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document
FDA	FDA Cumulative Estimated Daily Intake	Other US Agency Resources	Data

Source/Agency	Source Name	Source Type	Source Category
FDA	FDA Total Diet Study	Other US Agency Resources	Database
FDA	FDA Market Baskets	Other US Agency Resources	Technical Report
IARC	IARC Monograph	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Assessment or Related Document
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology	Encyclopedia	Encyclopedia
MDI	Comparative Toxicogenomics Database	Other Resource	Database
Misc	Consumer Products Information Database (CPID)	Other Resources	Data
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Technical Report
NIOSH	CDC NIOSH - Workplace Survey Reports	Other US Agency Resources	Technical Report
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Technical Report
NLM	NIEHS Tox Review	Other US Agency Resources	Database
NLM	National Library of Medicine’s HazMap	Other US Agency Resources	Database
NLM	National Library of Medicine’s PubChem	Other US Agency Resources	Database

Source/Agency	Source Name	Source Type	Source Category
NLM	National Library of Medicine's Hazardous Substance Databank	Other US Agency Resources	Database
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document
NTP	OHAT Monographs	Other US Agency Resources	Assessment or Related Document
NTP	RoC Monographs	Other US Agency Resources	Assessment or Related Document
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document
OECD	OECD SIDS	International Resources	Assessment or Related Document
OECD	OECD: eChem Portal	International Resources	Database
OECD	OECD: General Site	International Resources	General Search
OSHA	OSHA Chemical Exposure Health Data	Other US Agency Resources	Data
OSHA	OSHA [data from ERG]	Other US Agency Resources	Data
RIVM	Integrated Critera Documents	International Resources	Assessment or Related Document
RIVM	Probit Function Technical Support Document	International Resources	Assessment or Related Document
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document
RIVM	RIVM Reports: Dietary Intake	International Resources	Assessment or Related Document
SRI	SRI data (proprietary)	Other Resource	Database
State of North Carolina	NC Division of Environmental Assistance and Customer Service	Other US Agency Resources	General Search
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
U.S. Census Bureau	North American Industry Classification System (NAICS)	Other US Agency Resources	Database
UNEP	Risk Profile / Stockholm Convention	International Resources	Assessment or Related Document
US BLS	Bureau of Labor Statistics	Other US Agency Resources	Database
USGS	USGS Monitoring Data – National Water Quality Monitoring Council	Other US Agency Resources	Database

Appendix B PHYSICAL AND CHEMICAL PROPERITES OF ETHYLENE DIBROMIDE

This appendix provides p-chem information and data found in preliminary data gathering for ethylene dibromide. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0488).

Table_Apx B-1. Physical and Chemical Properties of Ethylene Dibromide

Property or Endpoint	Value[a]	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
Water solubility	4130 mg/L at 20°C	Rumble, 2018	High
Log Octanol/water partition coefficient (Log Kow)	1.96	U.S. EPA, 2019	High
Henry's Law constant	6.5×10^{-4} atm·m^3/mol at 25°C	U.S. EPA, 2019	High
Flash point	132°C	RSC, 2020	Medium

Property or Endpoint	Value[a]	Reference	Data Quality Rating
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

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

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF ETHYLENE DIBROMIDE

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	PubChem, 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)	PubChem, 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} $minute^{-1}$)	PubChem, 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, 2019a citing Sárvári, 2010
Biodegradation (Aerobic)	Water: $t_{1/2}$ = 35-350 days; shallow aquifer material and groundwater	PubChem, 2020 citing Pignatello, 1987
	Water: 21-35%/3 days in a die-away test using Japanese river and seawater	PubChem, 2020 citing Kondo et al., 1988
	Water: 0% after 2 weeks based on BOD (MITI test); degradation effected by volatilization	PubChem, 2020 citing Pignatello and Cohen, 1990
Biodegradation (Anaerobic)	63% degradation after 25 weeks	ECHA, 2019a citing Bouwer, 1983
	$t_{1/2}$ = 2 weeks (17 ºC, methanogenic aquifer) Bromoethanol detected as a metabolite	PubChem, 2020 citing Verschueren, 1996
	$t_{1/2}$ = 0.8 days by reductive dehalogenation (22 ºC, anoxic sediment with 6% organic carbon)	PubChem, 2020 citing Rathbun, 1998
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	EPI Suite, 2012

Property or Endpoint	Value[a]	References
	biodegradation, 1.8% by sludge, and 22% by volatilization to air; estimated)[b]	
Bioconcentration Factor (BCF)	<3.5-14.9 (carp)	PubChem, 2020 citing Kawasaki, 1980
	<1-20	OECD, 2012
Bioaccumulation Factor (BAF)	8.3 (estimated)[b]	U.S. EPA (EPI Suite™), 2012
Soil Organic Carbon:Water Partition Coefficient (Log K_{oc})	1.82	ATSDR, 2018 citing Rogers and McFarlane, 1981
	1.1-2.2	PubChem, 2020 citing Rathbun, 1998 and Falta, 2004
	1.69 (in peat soil)	PubChem, 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 D-2). Regulatory actions by other governments, tribes and international agreements applicable to Ethylene Dibromide are listed in Table Apx D-1.

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Ethylene dibromide is one of the 20 high priority candidate chemical substances for which EPA initiated prioritization under TSCA (84 FR 10491, March 21, 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 (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, 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 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.,	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
	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. Database 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 standards of performance for equipment leaks of VOC in the synthetic organic chemicals manufacturing industry for which construction, reconstruction, or modification commenced after November 7, 2006 (40 CFR 60 Subpart VV-VVa).
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 adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	Ethylene dibromide is listed as a HAP (42 U.S. Code Section 7412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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)). 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).	There are a number of source-specific NESHAPs for ethylene dibromide including: • Chemical manufacturing industry (area sources) (40 CFR 63 Subpart VVVVVV (6V)) • Miscellaneous coating manufacturing (40 CFR Part 63, Subpart HHHHH) • Organic liquids distribution (non-gasoline) (40 CFR Part 63, Subpart EEEE) • Pharmaceutical production (40 CFR 63 subpart GGG) • Rubber tire manufacturing (40 CFR 63 Subpart) • Site Remediation (40 CFR Part 63, Subpart GGGGG). • Wood furniture surface coating (40 CFR 63 Subpart JJ)
Clean Air Act (CAA) – Section 112(k)	Section 112(k) requires EPA to identify 30 hazardous air pollutants (HAPS) that pose the greatest potential health threat in urban areas. These HAPs are referred to as the 30 urban air toxics.	Not an urban air toxic. EPA also identified an additional three HAPs, but these HAPs are not generally emitted by area sources and, as such, were not included as part of the 30 urban air toxics. One of the three additional HAPs include ethylene dibromide. (US EPA, Urban Air Toxics. Accessed April 25, 2019).
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.
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the	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
	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 302.4).
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 National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Other Federal 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 Permissible Exposure Limits (PELs), 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).

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), Delaware (Del. Admin. Code Title 16, § 4462), Connecticut (Conn. Agencies Regs. § 19-13-B102), 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 Actions	Description of Action
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

Table D-3. Regulatory Actions by other Governments and Tribes

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. Database accessed April 23, 2019).
European Union	Ethylene dibromide is registered for use in the EU. (European Chemicals Agency (ECHA) database. Accessed April 23, 2019).
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).

Country/ Organization	Requirements and Restrictions
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) database. [Accessed April 17, 2017].

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

E.1 Process Information

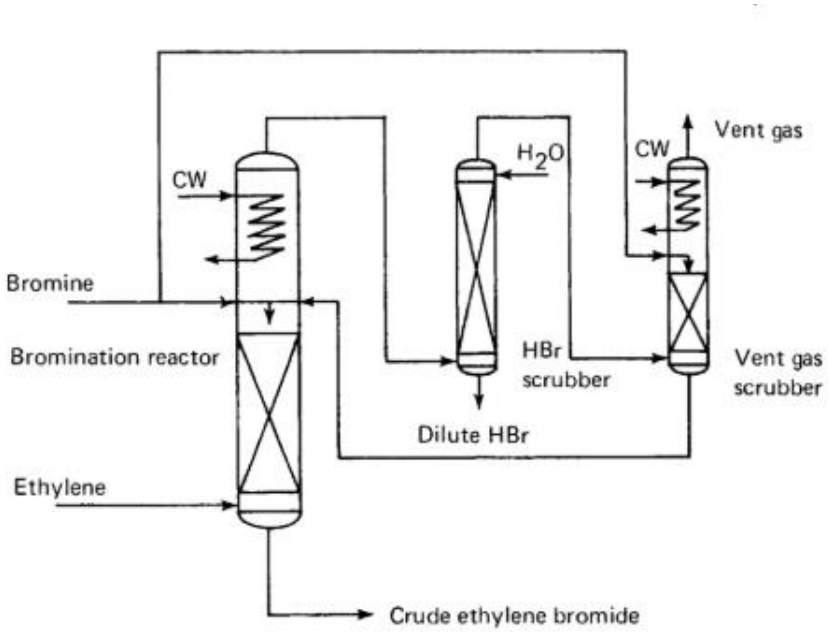
The following subsections provide process descriptions based on sources identified from the preliminary literature search for each life cycle stage of Ethylene Dibromide. Such information may inform potential release sources and worker exposure activities. EPA plans to continue to investigate and further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

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 Ioffe et al., (2011) Yoffe et al., (2013).

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 Jr., (1993)



Figure_Apx E-1. Example schematic process diagram of a method to manufacture ethylene dibromide. (McKetta Jr, 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 (BP Oil New Zealand Limited, 2011), (AFD Petroleum, 2014).

The U.S. produced 208,644,000 gallons of Avgas in 2002 to fuel the 191,000 piston-engine aircraft operating in the U.S. (EPA, 2008) (FAA, 2006). 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 Fuel Additive in Aviation and Racing Fuel

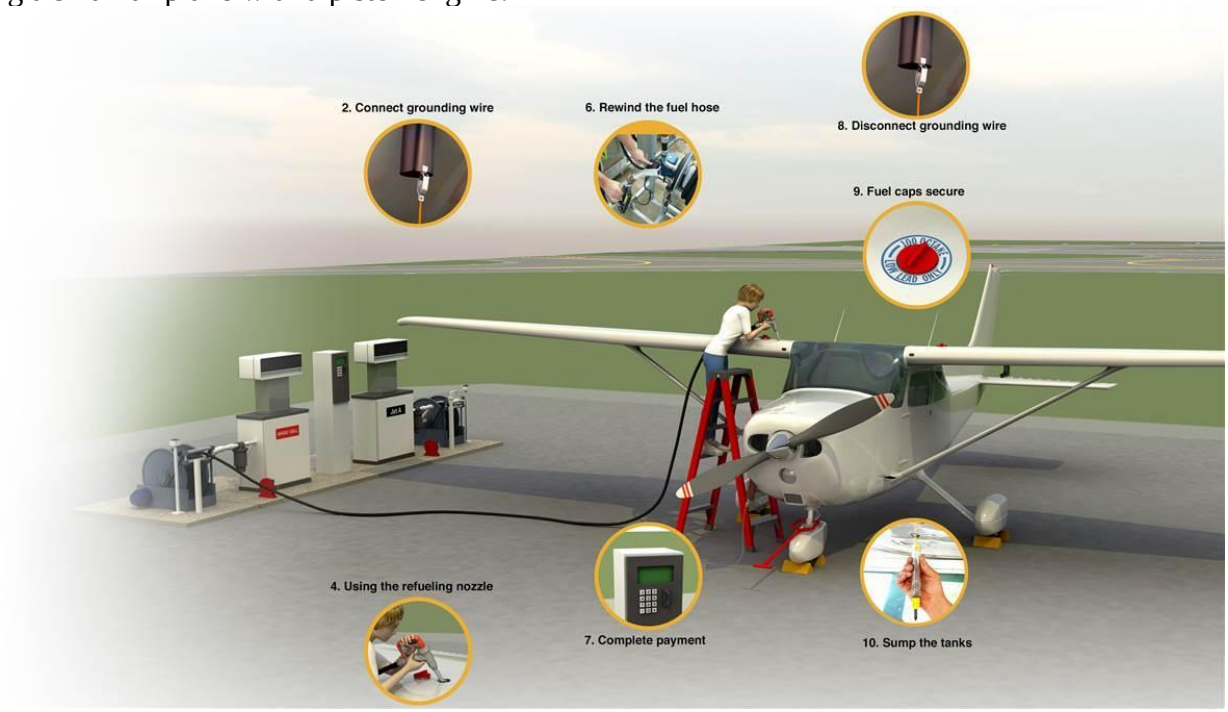
Tetra-ethyl lead was widely used in leaded automobile gasoline from 1923 until 1987 to reduce the tendency to knock. Combustion of leaded motor fuel generates lead oxide which accumulated in the engine and causes damage. Lead scavengers, such as EDB, are added to reduce the accumulation of lead deposits 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 (EPA, 2008). 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

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)). 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 et al, 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 et al, 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

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

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

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Manufacturing	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 25C), 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 25C), 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 25C), 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 25C), 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, processing, industrial use, commercial use,

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
								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 25C), 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 25C), 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 25C), 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 25C), EPA plans to evaluate inhalation exposure to vapor.
Consumer use	Fuels and related products	Fuels and related products	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 25C), 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 25C), 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 25C), 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 25C), 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 Use	Plastic and Rubber Products	Plastic and rubber products not covered elsewhere, including rubber tires	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.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			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. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[6]	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 and Terrestrial Receptors	Yes	This chemical is expected to be released to surface water; therefore, EPA plans to evaluate these pathways.

[6] The exposure pathways, exposure routes and hazards EPA plans to evaluate are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of ethylene dibromide in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[6]	Rationale
			Direct release into surface water and partitioning to sediment and bioaccumulation into edible aquatic species	Oral Inhalation	General Population	Yes	
			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 SDWA regulatory analytical process for public water systems.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) 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 terrestrial species.
				TBD	Terrestrial 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	Leachate to soil, ground water and/or	Oral (e.g., ingestion) Dermal Inhalation	General Population	No	Ethylene dibromide is included on the list of hazardous wastes pursuant

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[6]	Rationale
		and other land disposal	mitigation to surface water	TBD	Aquatic and Terrestrial Receptors	No	to RCRA 3001 (40 CFR §§ 261.33).