

Office of Chemical Safety and Pollution Prevention

Proposed Designation of Ethylene Dibromide (CASRN 106-93-4) as a High-Priority Substance for Risk Evaluation

August 22, 2019

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Acronyms and Abbreviations

Term	Description
ACGIH	American Conference of Governmental Industrial Hygienists
ATSDR	Agency for Toxic Substances and Disease Registry
Biomon.	Biomonitoring
BOD	Biochemical oxygen demand
BP	Boiling point
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
Concen.	Concentration
CWA	Clean Water Act
CPDat	Chemical and Products Database
ECOTOX	Ecotoxicology Database
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FDA	U.S. Food and Drug Administration
FR	Federal Register
GC	Gas chromatography
HPLC	High performance liquid chromatography
IRIS	Integrated Risk Information System
IUR	Inventory Update Rule
К	Thousand
Koc	Organic carbon-water partition coefficient
K _{OW}	Octanol-water partition coefficient
Μ	Million

Term	Description
MITI	Ministry of International Trade and Industry
MP	Melting point
NAICS	North American Industry Classification System
NIH	National Institute of Health
NIOSH	National Institute for Occupational Safety and Health
NR	Not reported
OECD	Organisation for Economic Co-operation and Development
·OH	Hydroxyl radical
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PPM	Parts per million
RCRA	Resource Conservation and Recovery Act
REL	Recommended Exposure Limit
RY	Reporting Year
SOP	Standard Operating Procedure
SMILES	Simplified Molecular-Input Line-Entry System
T _{1/2}	Half-life
TG	Test guidance
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TWA	Time weighted average
USGS	United States Geological Survey
VP	Vapor pressure
WS	Water solubility

1. Introduction

In section 6(b)(1)(B) of the Toxic Substances Control Act (TSCA), as amended, and in the U.S. Environmental Protection Agency's (EPA) implementing regulations (40 CFR 702.3)¹, a high-priority substance for risk evaluation is defined as a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Before designating prioritization status, under EPA's regulations at 40 CFR 702.9 and pursuant to TSCA section 6(b)(1)(A), EPA will generally use reasonably available information to screen the candidate chemical substance under its conditions of use against the following criteria and considerations:

- the hazard and exposure potential of the chemical substance;
- persistence and bioaccumulation;
- potentially exposed or susceptible subpopulations;
- storage near significant sources of drinking water;
- conditions of use or significant changes in the conditions of use of the chemical substance;
- the chemical substance's production volume or significant changes in production volume; and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

This document presents the review of the candidate chemical substance against the criteria and considerations set forth in 40 CFR 702.9 for a may present risk finding. The information sources used are relevant to the criteria and considerations and consistent with the scientific standards of TSCA section 26(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the *TSCA Work Plan Chemicals: Methods Document* (February 2012) (40 CFR 702.9(b)). EPA uses scientific information that is consistent with the best available science. Final designation of the chemical substance as a high-priority chemical substance would immediately initiate the risk evaluation process as described in the EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (40 CFR 702).

Ethylene dibromide is one of the 40 chemical substances initiated for prioritization as referenced in the March 21, 2019 notice (84 FR 10491)². EPA has determined that ethylene dibromide is a suitable candidate for the proposed designation as a high-priority chemical substance. The proposed designation is based on the results of the review against the aforementioned criteria and considerations as well as review of the reasonably available information on ethylene dibromide, including relevant information received from the public and other information as appropriate.

¹ For all 40 CFR 702 citations, please refer to:

https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol33/xml/CFR-2018-title40-vol33-part702.xml and https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0108

² <u>https://www.federalregister.gov/documents/2019/03/21/2019-05404/initiation-of-prioritization-under-the-toxic-substances-control-act-tsca</u>

EPA will take comment on this proposed designation for 90 days before finalizing its designation of ethylene dibromide. The docket number for providing comments on ethylene dibromide is EPA-HQ-OPPT-2018-0488 and is available at <u>www.regulations.gov</u>.

The information, analysis and basis used for the review of the chemical is organized as follows:

- Section 1 (*Introduction*): This section explains the requirements of the amended TSCA and implementing regulations including the criteria and considerations pertinent to the prioritization and designation of high-priority chemical substances.
- *Section 2 (Production volume or significant changes in production volume)*: This section presents information and analysis on national aggregate production volume of the chemical substance.
- Section 3 (Conditions of use or significant changes in conditions of use): This section presents information and analysis regarding the chemical substance's conditions of use under TSCA.
- Section 4 (Potentially exposed or susceptible subpopulations): This section presents information and analysis regarding potentially exposed or susceptible subpopulations, including children, women of reproductive age, and workers, with respect to the chemical substance.
- *Section 5 (Persistence and bioaccumulation)*: This section presents information and analysis regarding the physical and chemical properties of the chemical substance and the chemical's fate characteristics.
- Section 6 (Storage near significant sources of drinking water): This section presents information and analysis considered regarding the risk from the storage of the chemical substance near significant sources of drinking water.
- *Section 7 (Hazard potential)*: This section presents the hazard information relevant to the chemical substance.
- *Section 8 (Exposure potential)*: This section presents information and analysis regarding the exposures to the chemical substance.
- Section 9 (Other risk-based criteria): This section presents the extent to which EPA identified other risk-based criteria that are relevant to the designation of the chemical substance's priority.
- Section 10 (Proposed designation): Based on the results of the review performed and the information and analysis presented, this section describes the basis used by EPA to support the proposed designation.

2. Production volume or significant changes in production volume

Approach

EPA considered current volume or significant changes in volume of the chemical substance using information reported by manufacturers (including importers). EPA assembled reported information for years 1986 through 2015 on the production volume for ethylene dibromide reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule.³ The national aggregate production volume, which is presented as a range to protect individual site production volumes that are confidential business information (CBI), is presented in Table 1.

Results and Discussion

Production volume of ethylene dibromide in 2015, as reported to EPA during the 2016 CDR reporting period, was withheld. In reporting years (RY) 1986–1994, aggregate production volume of ethylene dibromide declined, from >100–500 million pounds in 1986, to >50–100 million pounds in 1990, and to >10–50 million pounds in 1994. Aggregate production volume stayed between 1 and 10 million pounds for RY 1998–2006. In the RY 2011–2015, aggregate production volume for ethylene dibromide was withheld (Table 1).

 Table 1. 1986-2015 National Aggregate Production Volume Data (Production Volume in Pounds)

Chemical ID	1986	1990	1994	1998	2002	2006	2011	2012	2013	2014	2015
Ethylene Dibromide (106-93-4)	>100 M to 500M	>50M to 100M	>10M to 50M	>1M to 10M	>1M to 10M	1M to <10M	Withheld ⁴	Withheld	Withheld	Withheld	Withheld
Notes: $M = million$, Reference: U.S. EPA (2013) and U.S. EPA (2017)											

³ Over time, the requirements for reporting frequency, production volume thresholds, and chemical substances under the Chemical Data Reporting (CDR) rule have changed. CDR was formerly known as the Inventory Update Rule (IUR). The first IUR collection occurred in 1986 and continued every four years through 2006. As part of two rulemakings in 2003 and 2005, EPA made a variety of changes to the IUR, including to change the reporting frequency to every five years to address burdens associated with new reporting requirements. Additional changes to reporting requirements were made in 2011, including to suspend and replace the 2011 submission period with a 2012 submission period, return to reporting every four years, and require the reporting of all years beginning with 2011 production volumes. The reporting of production volumes for all years was added because of the mounting evidence that many chemical substances, even larger production volume chemical substances, often experience wide fluctuations in production volume from year to year. In addition, also as part of the 2011 IUR Modifications final rule (76 FR 50816, Aug 16, 2011), EPA changed the name of the regulation from IUR to CDR to better reflect the distinction between this data collection (which includes exposure-related data) and the TSCA Inventory itself (which only involves chemical identification information).

⁴ This information is withheld, because EPA is releasing the 2016 CDR data in stages. EPA released the initial 2016 CDR data in May 2017. The initial data included national production volume (released in ranges), other manufacturing information, and processing and use information, except for information claimed by the submitter to be confidential business information (CBI) or information that EPA is withholding to protect claims of CBI. EPA anticipates releasing additional data after completion of an effort to obtain CBI substantiation required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act.

In the past, the largest use of ethylene dibromide in the United States was as a lead scavenger in fuels; the next largest use was as a fumigant and pesticide. In 1977, U.S. production of ethylene dibromide was approximately 300 million pounds with approximately 93 percent used as a lead scavenger and 6.5 percent used as a fumigant. The remainder was used in other uses. In 1974, EPA mandated that lead content of fuels be reduced and by 1996, lead and lead scavengers, including ethylene dibromide, were largely removed from conventional fuels, only remaining in aviation gasoline and certain racing fuels (U.S. EPA, 2008a). In addition, in 1983, EPA issued an immediate suspension of the use of ethylene dibromide as a soil fumigant for agricultural crops. In 1993, the last registered (garment) fumigant product containing ethylene dibromide cancelled production (U.S. EPA, 2006a).

Production volume trends illustrate the effect of the regulation of ethylene dibromide. According to CDR data, since 1986, the production volume of ethylene dibromide has trended downward to remain at 1M to less than 10M through 2006. After that time, CDR data are withheld from the public. However, based on the uses there is no information that would suggest that production volume after 2006 and into the future would increase over the 2006 levels.

3. Conditions of use or significant changes in conditions of use

Approach

EPA assembled information to determine conditions of use or significant changes in conditions of use of the chemical substance. TSCA section 3(4) defines the term "conditions of use" to mean the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

A key source of reasonably available information that EPA considered for determining the conditions of use for ethylene dibromide was submitted by manufacturers (including importers) under the 2012 and 2016 CDR reporting cycles. CDR requires manufacturers (including importers) to report information on the chemical substances they produce domestically or import into the United States greater than 25,000 pounds per site, except if certain TSCA actions apply (in which case the reporting requirement is greater than 2,500 lbs per site). CDR includes information on the manufacturing, processing, and use of chemical substances. Based on the known manufacturing, processing and uses of this chemical substance, EPA assumes distribution in commerce. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). While EPA may be aware of additional uses, CDR submitters are not required to provide information on chemical uses that are not regulated under TSCA.

For chemical substances under review that are included on the Toxics Release Inventory (TRI) chemical list, information disclosed by reporting facilities in Part II Section 3 ("Activities and Uses of the Toxic Chemical at the Facility") of their TRI Form R reports was used to supplement the CDR information on conditions of use (Tables 4, 5, and 6). There is not a one-to-one correlation between conditions of use reported under CDR and information reported in Part II Section 3 of the TRI Form R because facilities are not required to disclose in their Form R submissions the specific uses of TRI chemical substances they manufactured on-site or imported. In addition to the information disclosed in Part II Section 3 of the TRI Form R, the information pertaining to waste management activities (i.e., disposal/releases, energy recovery, recycling, and

treatment) disclosed in other sections of the Form R was also used to supplement the CDR information on conditions of use as shown in Table 4, 5, and 6. For purposes of this proposed prioritization designation, EPA assumed end-of-life pathways that include releases to air, wastewater, and solid and liquid waste based on the conditions of use.

CDR and TRI Tables

Based on the publicly available⁵ manufacturing information, industrial processing and use information, and consumer and commercial use information reported under CDR, EPA developed a list of conditions of use for the 2016 and 2012 reporting cycles (Tables 2 and 3, respectively).

Life-Cycle Stage	Category	Subcategory of Use	Reference
Manufacturing	Domestic manufacturing/import	CBI ⁷	<u>U.S. EPA (2019a)</u>
Processing	Incorporation into formulation, mixture, or reaction product	 Fuels and fuel additives in: Petroleum refineries All other Petroleum and coal products manufacturing 	<u>U.S. EPA (2019a)</u>
Distribution in commerce ^{a, b}	Distribution in commerce	Distribution in commerce	
Commercial Uses	Fuels and related products	Fuels and related products	<u>U.S. EPA (2019a)</u>
Consumer Uses	Fuels and related products	Fuels and related products	<u>U.S. EPA (2019a)</u>
Disposal ^a	Disposal	Disposal	

 Table 2. Ethylene Dibromide (106-93-4) Categories and Subcategories of Conditions of Use

 (2016 CDR Reporting Cycle)⁶

^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage. ^b EPA is particularly interested in information from the public on distribution in commerce.

⁵ Some specific chemical uses may be claimed by CDR submitters as confidential business information (CBI) under section 14 of TSCA. In these cases, EPA has indicated that the information is CBI.

⁶ Certain other uses that are excluded from TSCA are not captured in this table.

⁷ At this time, "CBI" indicates that a data element has been claimed CBI by the information submitter; it does not reflect the result of an EPA substantiation review.

Life-Cycle Stage	Category	Subcategory of Use	Reference
Manufacturing	Domestic manufacturing/import	CBI ⁹	<u>U.S. EPA</u> (2019a)
	Import	Import	<u>U.S. EPA</u> (2019a)
Processing	CBI	CBI	<u>U.S. EPA</u> (2019a)
Distribution in commerce ^{a,b}	Distribution in commerce	Distribution in commerce	
Commercial/Consumer Uses	CBI	СВІ	<u>U.S. EPA</u> (2019a)
Disposal ^a	Disposal	Disposal	

 Table 3. Ethylene Dibromide (106-93-4) Categories and Subcategories of Conditions of Use

 (2012 CDR Reporting Cycle)⁸

^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table row is highlighted in gray to indicate that no information is provided for this life-cycle stage.

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

EPA used TRI data to identify additional conditions of use and to supplement CDR information about conditions of use. In addition, TRI information from 2017 is useful for demonstrating that a condition of use reported to CDR in 2015 is still ongoing.

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
	Import	Basic chemical manufacturing	3251
		Scientific research and development services	5417
	Produce or import for on-site use/processing	Scientific research and development services	5417
	Produce or import for sale/distribution	Basic chemical manufacturing	3251
	Produce or import as a	Petroleum and coal products manufacturing	3241
	byproduct	Basic chemical manufacturing	3251

Table 4. Activities and Uses Reported to TRI for Ethylene Dibromide, Reporting Year 2011			
	Table 4. Activities and Uses Re	ported to I KI for Ethylene	Dibromide, Reporting Year 2011

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

⁹ At this time, "CBI" indicates that a data element has been claimed CBI by the information submitter; it does not reflect the result of an EPA substantiation review.

Activity Type	Activity	Industry Group	NAICS Code	
	Produce or import as an impurity	Scientific research and development services	5417	
Process	Process as a reactant	Basic chemical manufacturing	3251	
	Process as an impurity	Petroleum and coal products manufacturing	3241	
	Process as a formulation	Petroleum and coal products manufacturing	3241	
	component	Basic chemical manufacturing	3251	
	Process – repackaging	Petroleum and coal products manufacturing	3241	
		Basic chemical manufacturing	3251	
Otherwise Use	Otherwise use – ancillary or other use	Other nonmetallic mineral product manufacturing	3279	
		Scientific research and development services	5417	
		Waste treatment and disposal	5622	
Waste	Disposal/releases	Petroleum and coal products manufacturing	3241	
Management		Basic chemical manufacturing	3251	
		Other nonmetallic mineral product manufacturing	3279	
		Waste treatment and disposal	5622	
	Energy recovery	Petroleum and coal products manufacturing	3241	
		Other nonmetallic mineral product manufacturing	3279	
Recycling Treatment		Waste treatment and disposal	5622	
	Recycling	Petroleum and coal products manufacturing	3241	
	Other nonmetallic mineral product manufacturing	3279		
	Treatment	Petroleum and coal products manufacturing	3241	
		Basic chemical manufacturing	3251	
		Other nonmetallic mineral product manufacturing	3279	
		Waste treatment and disposal	5622	

Reference: U.S. EPA, 2019b

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
	Import	Basic chemical manufacturing	3251
	Produce or import for sale/distribution	Basic chemical manufacturing	3251
	Produce or import as a	Petroleum and coal products manufacturing	3241
	byproduct	Basic chemical manufacturing	3251
Process	Process as an article component	Waste treatment and disposal	5622
	Process as a	Petroleum and coal products manufacturing	3241
	formulation component	Basic chemical manufacturing	3251
	Process – repackaging	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
Otherwise Use	Otherwise use – ancillary or other use	Other nonmetallic mineral product manufacturing	3279
		Scientific research and development services	5417
		Waste treatment and disposal	5622
Waste	Disposal/Releases	Petroleum and coal products manufacturing	3241
Management		Basic chemical manufacturing	3251
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622
	Energy recovery	Petroleum and coal products manufacturing	3241
		Other nonmetallic mineral product manufacturing	3279
	Recycling	Petroleum and coal products manufacturing	3241
		Other nonmetallic mineral product manufacturing	3279
	Treatment	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622

Table 5. Activities and Uses Reported to TRI for Ethylene Dibromide, Reporting Year 2015

Reference: U.S. EPA, 2019b

Activity Type	Activity	Industry Group	NAICS Code
Manufacture	Produce	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
	Import	Basic chemical manufacturing	3251
	Produce or import for sale/distribution	Basic chemical manufacturing	3251
	Produce or import as a	Petroleum and coal products manufacturing	3241
	byproduct	Basic chemical manufacturing	3251
Process	Process as a formulation	Petroleum and coal products manufacturing	3241
	component	Basic chemical manufacturing	3251
	Process – repackaging	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
Otherwise Use	Otherwise use – ancillary or other use	Other nonmetallic mineral product manufacturing	3279
		Scientific research and development services	5417
		Waste treatment and disposal	5622
Waste	Disposal/Releases	Petroleum and coal products manufacturing	3241
Management Energy recove Recycling Treatment		Basic chemical manufacturing	3251
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622
	Energy recovery	Petroleum and coal products manufacturing	3241
		Other nonmetallic mineral product manufacturing	3279
	Recycling	Waste treatment and disposal	5622
	Treatment	Petroleum and coal products manufacturing	3241
		Basic chemical manufacturing	3251
		Other nonmetallic mineral product manufacturing	3279
		Waste treatment and disposal	5622

 Table 6. Activities and Uses Reported to TRI for Ethylene Dibromide, Reporting Year 2017

Reference: U.S. EPA, 2019b

CDR and TRI Summary and Additional Information on Conditions of Use

In the reports to 2016 CDR, manufacturing (domestic manufacturing or import) was claimed as CBI. Two sites reported consumer and/or commercial use of ethylene dibromide in fuels and related products.

Reports to the 2016 CDR included processing information of ethylene dibromide was for in all other petroleum and coal products manufacturing (one site) and petroleum refineries (one site). Both uses were reported under the functional category fuels and fuel additives. Commercial and/or consumer use was fuels and related products. Consumer uses were also identified in additional databases, which are included in the Exposure Potential section (Section 8).

In the 2012 CDR, reports of manufacturing (domestic manufacture or import) and processing information was claimed as CBI. Two sites reported commercial and/or consumer use of ethylene dibromide, and the product category was claimed as CBI for one site and not reported for the other site. Due to the lack of information, it is difficult to determine whether there was a significant change in producers or conditions of use.

Data from the ECHA registration dossier for ethylene dibromide provide similar information regarding conditions of use. The dossier lists the use of ethylene dibromide as an anti-knock additive in refineries in production of aviation fuel in European countries. Ethylene dibromide is used in aviation gasoline (Avgas) as a lead scavenger (ECHA 2019).

TRI data reported in Part II Section 3 of the TRI Form R ("Activities and Uses of the Toxic Chemical at the Facility") were compiled for RY 2011, RY 2015, and RY 2017. RY 2011, RY 2015, and RY 2017 reflect the chemical activities at reporting facilities in calendar years 2011, 2015, and 2017, respectively. Each facility filing a TRI Form R discloses activities that apply to the TRI chemical at the facility. The TRI data presented above are from the TRI dataset updated in April 2019. Tables 4, 5 and 6 present the activities and uses reported to TRI by industry group for 2011, 2015, and 2017, respectively. Waste management activity type include all industry groups that reported to TRI using each waste management activity for ethylene dibromide.

Information from public comments confirm that the use of ethylene dibromide is almost exclusively as part of a fuel additive (EPA-HQ-OPPT-2018-0488-0006). According to another public comment, the aerospace industrial uses include use as an additive in aviation gasoline. In addition, the aerospace industry uses ethylene dibromide as an additive in vinyl lacquers (EPA-HQ-OPPT-2018-0488-0008).

Should the Agency decide to make a final decision to designate this chemical substance as a high-priority substance, further characterization of relevant TSCA conditions of use will be undertaken as part of the process of developing the scope of the risk evaluation.

4. Potentially exposed or susceptible subpopulations

Approach

In this review, EPA considered reasonably available information to identify potentially exposed or susceptible subpopulations, such as children, women of reproductive age, workers, consumers or the elderly. EPA analyzed processing and use information included on the CDR Form U. These data provide an indication about whether children may be potentially exposed or other susceptible subpopulations may be exposed. EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.

Results and Discussion

At this stage, EPA identified children, women of reproductive age, consumers and workers as subpopulations who may be potentially exposed or susceptible subpopulations for ethylene dibromide.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for ethylene dibromide. The 2012 and 2016 CDR did not report any use in children's products. In the existing assessments reviewed, there was no discussion on the susceptibility of children to ethylene dibromide. EPA also identified potential developmental hazards that would impact any stage of children's development.

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

EPA identified studies that observed developmental and reproductive toxicity following exposure to ethylene dibromide (Section 7, Table 9). Thus, women of reproductive age were identified as a potentially exposed or susceptible subpopulation.

Consideration of women of reproductive age as a potentially exposed or susceptible subpopulation was also based on exposure because women of reproductive age are potential workers in the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance.

Workers

Please refer to the Exposure Potential section (Section 8) for a summary of potential occupational exposures, which EPA indicates that workers are potentially exposed or susceptible subpopulations based on greater exposure.

Consumers

Please refer to the Exposure Potential section (Section 8) for a summary of potential consumer exposures, which EPA indicates that consumers are potentially exposed or susceptible subpopulations based on greater exposure.

5. Persistence and bioaccumulation

Approach

EPA reviewed reasonably available information, such as physical and chemical properties and environmental fate and characteristics, to understand ethylene dibromide's persistence and bioaccumulation.

Physical and Chemical Properties and Environmental Fate Tables

Tables 7 and 8 summarize the physical and chemical properties, and the environmental fate characteristics of ethylene dibromide, respectively.

Property or Endpoint	Value ^a	Reference	
Molecular Formula	$C_2H_4Br_2$	CRC Handbook (Haneys, 2014)	
Molecular Weight	187.861 g/mole	CRC Handbook (Haneys, 2014)	
Physical State	Liquid	<u>HSDB (2018)</u>	
Physical Form	Colorless liquid or solid below 10 °C	<u>HSDB (2018)</u>	
Purity	>99% and 99% reported in studies	<u>HSDB (2018)</u>	
Melting Point	10 °C ^b	ATSDR (2018) citing NIOSH (1978)	
	9.9 °C	Physprop (2012); OECD (2012)	
	9.8 °C	HSDB (2018) citing CRC Handbook (Haneys, 2014)	
Boiling Point	131.6 °C ^b	Physprop (2012); OECD (2012)	
	131–132 °C	ATSDR (2018) citing Windholz (1983)	
	131.3 °C	HSDB (2018) citing CRC Handbook (Haneys, 2014)	
Density	2.17 g/cm^3	ATSDR (2018) citing Windholz (1983)	
Vapor	11 mm Hg at 25 °C	ATSDR (2018) citing Windholz (1983)	
Pressure	11.2 mm Hg at 25 °C ^b	Physprop (2012); HSDB (2018)	
	8.5 mm Hg at 20 °C	HSDB (2018) citing Ioffe and Frim (2011)	
Vapor Density	6.48 (relative vapor density to air = 1)	HSDB (2018) citing Lewis (2012)	
Water 3,910 mg/L at 25 °C ^b Solubility		Physprop (2012); OECD (2012); HSDB (2018) citing Horvath et al. (1999)	
	4,310 mg/L at 30 °C	HSDB (2018) citing Yalkowsky et al. (2010)	
	4,000 mg/L at 20 °C	ATSDR (2018)	
	4,290 mg/L at 25 °C	ATSDR (2018)	

 Table 7. Physical and Chemical Properties of Ethylene Dibromide

Property or Endpoint	Value ^a	Reference	
Log K _{OW}	1.96	HSDB (2018) citing Hansch et al. (1995); Physprop (2012)	
Henry's Law Constant	$6.5 \times 10^{-4} \text{ atm-m}^3/\text{mol}^{b}$	HSDB (2018) citing Rathbun (2000); Physprop (2012)	
	8.2×10^{-4} atm-m ³ /mol	ATSDR (2018)	
Flash Point	Not flammable	ATSDR (2018) citing Weiss (1986)	
Auto Flammability	Not flammable	ATSDR (2018) citing Weiss (1986)	
Viscosity	1.73 at 20 °C	HSDB (2018) citing CRC Handbook (Haneys, 2014)	
Refractive Index	1.54 at 20 °C	HSDB (2018) citing CRC Handbook (Haneys, 2014)	
Dielectric Constant	4.77 at 20.5 °C	HSDB (2018) citing Ioffe and Frim (2011)	
Surface Tension	38.75 dynes/cm = 0.03875 Newtons/m at 20 °C	HSDB (2018) citing NOAA (2018)	
Notes: ^a Measure	ed unless otherwise noted. ^b Selected value	·	

Property or Endpoint	Value ^a	Reference
Direct Photodegradation	No photolysis was observed when exposed to ultraviolet light between 300 and 400 nm	HSDB (2018) citing Ollis (1985)
	Direct photolysis of ethylene dibromide 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 °C)	HSDB (2018) 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 °C in pure water; rate constant = 2.1×10^{-7} minute ⁻¹)	<u>HSDB (2018)</u>
	$t_{1/2} = 141$ hours at 67 °C and 380 days at 25 °C for test solutions at pH 4	ECHA (2019) citing Sarvari (2010)

Property or Endpoint	Value ^a	Reference
	$T_{1/2} = 114$ hours at 67 °C and 2.3 years at 25 °C for test solutions at pH 9 (OECD 111)	
Biodegradation (Aerobic)	Water: $t_{1/2} = 35-350$ days; shallow aquifer material and groundwater	HSDB (2018) citing Pignatello (1987)
	Water: 21–35%/3 days in a die-away test using Japanese river and seawater	HSDB (2018) citing Kondo et al. (1988)
	Water: 0% after 2 weeks based on BOD (MITI test); degradation effected by volatilization	HSDB (2018) citing Pignatello and Cohen (1990)
	4.2% after 28 days	ECHA (2019) citing Sipos (2010)
Biodegradation	63% degradation after 25 weeks	ECHA (2019) citing Bouwer (1983)
(Anaerobic)	$t_{1/2} = 2$ weeks (17 °C, methanogenic aquifer) Bromoethanol detected as a metabolite	HSDB (2018) citing Verschueren (1996)
	$t_{1/2} = 0.8$ days by reductive dehalogenation (22 °C, anoxic sediment with 6% organic carbon)	HSDB (2018) citing Rathbun (2000)
Wastewater Treatment	$t_{1/2} = 1-16$ days by evaporation from flowing and standing surface waters	<u>ATSDR (2018)</u> citing <u>EPA (1987)</u>
	24% total removal (0.08% by biodegradation, 1.8% by sludge, and 22% by volatilization to air; estimated) ^b	EPI Suite (2012)
Bioconcentration	<3.5–14.9 (carp)	HSDB (2018) citing Kawasaki, 1980
Factor	<1-20	<u>OECD (2012)</u>
Bioaccumulation Factor	8.3 (estimated) ^b	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	HSDB (2018) citing Rathbun (2000); Falta (2004)
50,	1.69 (in peat soil)	HSDB (2018) citing Chiou and Kile (1998)

Notes:

^aMeasured unless otherwise noted

^bEPI SuiteTM physical property inputs: Log K_{OW} = 1.96, BP = 131.60 °C, MP = 9.9 °C, VP = 11.2 mm Hg, WS = 3910 mg/L, Henry LC = 6.5×10^{-4} atm-m³/mol

 \cdot OH = hydroxyl radical; OECD: Organisation for Economic Co-operation and Development; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand; K_{OC} = organic carbon-water partitioning coefficient; K_{OW} = octanol-water partitioning coefficient

Results and Discussion

Ethylene dibromide is a volatile, highly water-soluble liquid (3,910 mg/L). Measured Henry's Law constant $(6.5 \times 10^{-4} \text{ atm-m}^3/\text{mol})$ and vapor pressure (11.2 mm Hg) data indicate that this chemical is not likely to be persistent in surface water or soil as it will volatilize upon release. In the air, ethylene dibromide is expected to exist in the vapor phase where it may react with photochemically-produced hydroxyl radicals at a rate corresponding to a half-life of 64 days. It is not expected to be susceptible to direct photodegradation. Hydrolysis is expected to be negligible under environmental conditions based on half-lives ranging from 2.5 to 13.2 years.

In aerobic aquatic environments ethylene dibromide is not readily biodegradable; however, it may biodegrade slowly under certain conditions. In water, this chemical showed no biodegradation over a 2-week incubation period using the OECD 301C test method in which degradation was affected by volatilization of the test substance. In Japanese river and seawater, this chemical reached 21–35 percent biodegradation after 3 days using the die-away test method. Additionally, half-lives ranging from 35 to 350 days were reported for shallow aquifer material and groundwater.

In anaerobic environments, biodegradation of ethylene dibromide is expected to be moderate. This chemical reached 63% degradation over a 25-week incubation period in an anaerobic biodegradation test and has a reported half-life of 2 weeks in methanogenic aquifer material. In addition, a half-life of 0.8 days in anoxic sediment was reported for reductive debromination of ethylene dibromide. Therefore, ethylene dibromide has the potential to persist in subsurface environments, groundwater, or enclosed pipes when volatilization is not an option. Furthermore, this chemical is expected to have low potential for bioaccumulation based on a measured bioconcentration factor in carp (<3.5–14.9) and a bioaccumulation factor estimate of 8.3.

6. Storage near significant sources of drinking water

Approach

To support the proposed designation, EPA analyzed each chemical substance, under its conditions of use, with respect to the seven criteria in TSCA section 6(b)(1)(A) and 40 CFR 702.9. The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of drinking water, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure.

EPA reviewed reasonably available information, specifically looking to identify certain types of existing regulations or protections for the proposed chemical substances. EPA considered the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, by identifying existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (SDWA; 40 CFR Part 141) and regulations under the Clean Water Act (CWA; 40 CFR 401.15). In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA; Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; Hazardous Substances), and the Clean Air Act (CAA) Section 112(r) (Regulated Chemicals for Accidental Release Prevention). Regulation by

one of these authorities is an indication that the substance is a potential health or environmental hazard which, if released near a significant source of drinking water, could present an unreasonable risk of injury to human health or the environment.

Results and Discussion

Ethylene dibromide is subject to National Primary Drinking Water Regulation (NPDWR) under SDWA with a Maximum Contaminant Level Goal (MCLG) of zero and an enforceable Maximum Contaminant Level (MCL) of 0.00005 mg/L. The chemical has been designated as a hazardous substance under the Federal Water Pollution Control Act. Ethylene dibromide is subject to TRI reporting requirements under EPCRA. Ethylene dibromide is considered a CERCLA hazardous substance and releases of quantities in excess of 1 pound are subject to reporting to the National Response Center under CERCLA.

Ethylene dibromide is also subject to Resource Conservation and Recovery Act (RCRA) and has the hazardous waste code UO67. RCRA 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.

7. Hazard potential

Approach

EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health and environmental hazards for ethylene dibromide (Tables 9 and 10, respectively).

Because there are very few publicly available assessments for ethylene dibromide with cited environmental hazard data, EPA uses the infrastructure of ECOTOXicology knowledgebase (ECOTOX) to identify single chemical toxicity data for aquatic and terrestrial life (U.S. EPA, 2018b). It uses a comprehensive chemical-specific literature search of the open literature that is conducted according to the Standard Operating Procedures (SOPs)¹⁰. The environmental hazard information was populated in ECOTOX and is available to the public. In comparison to the approach used to survey human health hazard data, EPA also used a read-across approach to identify additional environmental hazard data for isomers of ethylene dibromide, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa exposed to the ethylene dibromide (Table 10).

Potential Human Health and Environmental Hazard Tables

EPA identified potential human health and environmental hazards based on a review of the reasonable available information for ethylene dibromide (Tables 9 and 10, respectively).

¹⁰ The ECOTOX Standard Operating Procedures (SOPs) can be found at: <u>https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4</u>

Human Health Hazards	Tested for Specific Effect	Effect Observed	Data Source
Acute Toxicity	Х	Х	ATSDR (2018), NICNAS (2013), Environment Canada (2013), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), OEHHA (2003), IARC (1999)
Repeated Dose Toxicity	Х	Х	ATSDR (2018), NICNAS (2013), NTP (2016), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), U.S. EPA (2004b), OEHHA (2003), OEHHA (1999), IARC (1999), NTP (1982)
Genetic Toxicity	Х	Х	ATSDR (2018), NICNAS (2013), OECD (1999), Environment Canada (2013), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), OEHHA (2003), IARC (1999), NTP (1982)
Reproductive Toxicity	Х	Х	ATSDR (2018), NICNAS (2013), Environment Canada (2013), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), U.S. EPA (2004b), OEHHA (2003), OEHHA (1999), IARC (1999), NTP (1982)
Developmental Toxicity	Х	Х	ATSDR (2018), NICNAS (2013), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), U.S. EPA (2004b), OEHHA (2003), OEHHA (1999), IARC (1999)
Toxicokinetics	Х	Х	ATSDR (2018), NICNAS (2013), U.S. EPA (2008b), U.S. EPA (2004a), OEHHA (2003), OEHHA (1999), IARC (1999)
Irritation/ Corrosion	Х	Х	ATSDR (2018), NICNAS (2013), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), OEHHA (2003)
Dermal Sensitization			
Respiratory Sensitization			
Carcinogenicity	Х	Х	ATSDR (2018), NICNAS (2013), NTP (2016), Environment Canada (2013), U.S. EPA (2009), U.S. EPA (2008b), RIVM (2007), U.S. EPA (2004a), U.S. EPA (2004b), OEHHA (2003), IARC (1999), NTP (1982), OEHHA (2011)
Immunotoxicity			
Neurotoxicity	Х	Х	ATSDR (2018), NICNAS (2013), U.S. EPA (2008b), U.S. EPA (2004a), U.S. EPA (2004b), OEHHA (2003)
Epidemiological Studies or Biomonitoring Studies	Х	Х	CDC (2019), ATSDR (2018), NICNAS (2013), NTP (2016), Environment Canada (2013), U.S. EPA (2009), U.S. EPA (2008b), U.S. EPA (2004a), U.S. EPA (2004b), OEHHA (2003), OEHHA (1999), IARC (1999), OEHHA (2011)

 Table 9. Potential Human Health Hazards Identified for Ethylene Dibromide

Note: The "X" in the "Effect Observed" column indicates when a hazard effect was reported by one or more of the referenced studies. Blank rows indicate when information was not identified during EPA's review of reasonably available information to support the proposed designation.

Media Study Duratior		Taxa Groups	High-Priority Chemical Candidate Ethylene Dibromide (CASRN 106-93-4)		Isomers of Ethylene Dibromide (CASRN 106-93-4) 1,1-Dibromoethane (CASRN 557-91-5) Dibromoethane (CASRN 25620-62-6)		Data Sources
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Acute	Vegetation	_	Х	_		
exposure	exposure	Invertebrate	7	Х	_		Adams and Kennedy (1992); Adams et al. (1988); Herring et al. (1988); Kszos et al. (2003); Rogers et al. (2005)
		Fish	2	Х	_		Holcombe et al. (1995); Kszos et al. (2003)
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	_		_		
	Chronic	Vegetation	_		_		
	exposure	Invertebrate	1	Х	_		Adams and Kennedy (1992)
		Fish	2	Х	—		Hawkins et al. (1998); Holcombe et al. (1995)
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	_		_		
	Acute exposure	Vegetation	14	Х	-		Broadley (1979); Crebelli et al. (1985); Johnson and Leonard (1995); Queneherve et al. (1991); Reddy and Nettles (1955); Saidi et al. (1992); Sholberg et al. (1986)
		Invertebrate	21	Х	_		Adu and Muthu (1985); Bhatia and Bansode (1971); Broadley (1979); Evans and Thomason (1971); Graf et al. (1984); Foureman et al. (1994); Kincaid and Volk (1952); Leesch (1984); Mehta et al. (1984); Minton et al. (1985); Muthu et al. (1970); Queneherve et al.

Table 10. Potential Environmental Hazards Identified for Ethylene Dibromide

Media	Study Duration	Taxa Groups	Chemical Ethylene I	High-Priority Chemical Candidate Ethylene Dibromide (CASRN 106-93-4)		ers of Dibromide 106-93-4) omoethane 557-91-5) oethane 25620-62-6)	Data Sources
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
							(1991); Rajendran and Muthu (1987); Rodriguez-Kabana and King (1985); Rodriguez-Kabana et al. (1981); Saidi et al. (1992); Sholberg et al. (1986); Swaine et al. (1978)
		Vertebrate	4	Х	_		Nachtomi et al. (1968); Sasaki et al. (1998); Schlinke (1970)
	Chronic exposure	Vegetation	65	Х	_		Aycock (1955); Broadley (1979); Ijani and Mmbaga (1988); Kincaid and Volk (1952); Kinloch (1983a); Kinloch (1983b); Kulkarni et al. (1975); Lawn et al. (1988); Madamba et al. (1967); McDonald and De Waele (1987); Meagher and Jenkins (1970); Middleton et al. (1949); Minton and Parker (1979); Minton and Parker (1987); Minton et al. (1985); Niblack and Hussey (1986); Oduor-Owino and Waudo (1994); Onsager (1969); Potter et al. (1956); Reddy and Nettles (1955); Rodriguez-Kabana and King (1985); Rodriguez- Kabana et al. (1987); Schmitt and Nelson (1987); Sholberg et al. (1986); Stanton and Fisher (1985); Stirling and Nikulin (1993); Stirling and Wachtel (1985); Stirling et al. (1989); Stirling (1989); Weaver et al. (1987); Youmans (1985)
		Invertebrate	84	Х	_		Adu and Muthu (1985); Aycock (1955); Bang and Telford (1966); Barker (1976); Bond et al. (1973); Bowry (1985); Broadley (1979); Christie and Perry (1951); Gough and Brown (1988); Ijani and Mmbaga (1988); Johnson and Leonard (1995); Kincaid and Volk (1952); Kinloch (1983a); Kinloch (1983b); Kulkarni et al. (1975); Lawn et al. (1988); Lindgren et al. (1954); Madamba et al. (1967); McDonald and De Waele (1987); McKenry and Thomason (1974); Meagher and Jenkins (1970); Middleton et al. (1949); Minton and Parker (1979); Minton and Parker (1987); Minton et al. (1982);

Media	Study Duration	Taxa Groups	High-P Chemical (Ethylene I (CASRN	Candidate Dibromide	le (CASPN 557-91-5)		Data Sources
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
	Chronic exposure						Minton et al. (1985); Niblack and Hussey (1986); Oduor-Owino and Waudo (1994); Onsager (1969); Philis (1978); Potter et al. (1956); Punj and Verma (1970); Punj (1970); Rajendran and Muthu (1981); Rajendran and Muthu (1987); Rajendran and Muthu (1989); Rajendran and Shivaramaiah (1985); Rajendran (1982); Rodriguez- Kabana et al. (1979); Rodriguez-Kabana et al. (1981); Rodriguez- Kabana et al. (1987); Saidi et al. (1992); Schmitt and Nelson (1987); Sharma and Tara (1986); Shivanandappa and Rajendran (1987); Stanton and Fisher (1985); Stirling and Nikulin (1993); Stirling and Wachtel (1985); Stirling et al. (1989); Stirling et al. (1987);Youmans (1985)
		Vertebrate	2	Х	_		Bernard et al. (1989); Hardin et al. (1981)

Note: The dash indicates that no studies relevant for environmental hazard were identified during the initial review and thus the "Observed Effects" column is left blank. The X in the Observed Effects column indicates when a hazard effect was reported by one or more of the referenced studies. The N/A in the Observed Effects column indicates when a hazard effect was not reported by one of the referenced studies' abstract (full reference review has not been conducted).

8. Exposure potential

Approach

EPA considered reasonably available information to identify potential environmental, worker/ occupational, consumer, and general population exposures to ethylene dibromide.

Release potential for environmental and human health exposure

In addition to other required information, a submission of a TRI Form R report must include the quantities of a TRI chemical the facility released on-site to air, water, or land, and the quantities it transferred off-site to another facility for further waste management. On-site release quantities are reported in Part II Section 5 of the TRI Form R, and off-site transfers are reported in Part II Section 6. Waste management activities include: transfers of a TRI chemical in wastewater to a publicly owned treatment works (POTW) facility or to a non-POTW wastewater treatment facility for the purpose of treatment for destruction or removal; combustion for energy recovery; treatment (treatment includes treatment via incineration for destruction and waste stabilization); recycling; and release, including disposal. During treatment, combustion for energy recovery, or recycling activities, it is possible that some of the quantities of the TRI chemical will be released to the environment.

Worker/Occupational and consumer exposure

EPA's approach for assessing exposure potential was to review the physical and chemical properties, conditions of use reported in CDR, and information from the National Institutes of Health Consumer Product Database and the Chemical and Products Database (CPDat) for ethylene dibromide to inform occupational and consumer exposure potential. The results of this review are detailed in the following tables.

General population exposure

EPA identified environmental concentration and human biomonitoring data to inform ethylene dibromide's exposure potential to the general population (Table 13).

Results and Discussion

Release potential for environmental and human health exposure

Aggregated quantities of ethylene dibromide released on-site to air, water, and land, and aggregated quantities of ethylene dibromide transferred off-site to POTW and other wastewater treatment facilities (non-POTW) are presented in Table 11 for RY 2011, 2015, and 2017. The table does not include any of the reported quantities pertaining to other waste management activities (e.g., recycling, combustion for destruction) that occurred on-site or off-site during RY 2011, 2015, and 2017. The "Number of Facilities" is the count of unique facilities that filed a TRI Form R report for ethylene dibromide for RY 2011, 2015, and 2017. The TRI data presented were obtained from the TRI dataset following its update in April 2019.

 Table 11. The TRI Data on Ethylene Dibromide from Reporting Years 2011, 2015, and

 2017 Used in this Document to Assess Exposure Potential

Year	Number of Facilities That Reported	Total Quantities Released On-Site to Air (lbs.)	Total Quantities Released On- Site to Water (lbs.)	Total Quantities Released (Disposed of) On-Site to Land (lbs.)	Total Quantities Transferred to POTW (lbs.)	Total Quantities Transferred to Other (Non- POTW) Wastewater Treatment Facilities (lbs.)
2011	12	2,279	1	6	0	32
2015	13	836	0	90,000	0	0
2017	11	788	70	0	0	0

Note: POTW = publicly owned treatment works Reference: U.S. EPA, 2019b

For RY 2017, 11 facilities submitted TRI reports for ethylene dibromide. The total quantities of ethylene dibromide these facilities released on-site to air (as fugitive and stack emissions), surface water and land are: 788 pounds; 70 pounds; and 0 pounds, respectively. These facilities reported zero pounds of the chemical transferred to POTW and zero pounds transferred off-site to other non-POTW wastewater treatment facilities for the purpose of wastewater treatment. These transfer categories represent two types of off-site transfers for wastewater treatment that may lead to releases from the receiving facilities. They do not include quantities sent off-site for other types of waste management activities that include, or may lead to, releases of the chemical.

Quantities transferred off-site represent the amount of a toxic chemical a facility sent off-site prior to any waste management (e.g., treatment) at a receiving facility. Some of the quantities of ethylene dibromide received by the non-POTW wastewater treatment facilities may have been released to surface waters or to air during treatment processes at the facilities.

Ethylene dibromide has a vapor pressure of approximately 11 mm Hg at 25 °C. This chemical's vapor pressure indicates potential for air releases from volatilization during manufacturing, processing, and use.

When chemical substances are incorporated into formulations, mixtures, or reaction products, the industrial releases may be a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the production volume is incorporated without significant process losses during its incorporation into a formulation, mixture, or product. The actual percentages, quantities, and media of releases of the reported chemical associated with this processing or use are not known.

Worker/Occupational exposure

Worker exposures to this chemical may be affected by many factors, including but not limited to volume produced, processed, distributed, used, and disposed of; physical form and concentration; processes of manufacture, processing, and use; chemical properties such as vapor pressure, solubility, and water partition coefficient; local temperature and humidity; and

exposure controls such as engineering controls, administrative controls, and the existence of a personal protective equipment (PPE) program.

Ethylene dibromide has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL). The PEL is 20 parts per million (ppm) over an 8-hour work day, time weighted average (TWA), with 30 ppm Ceiling limit (<u>OSHA, 2017</u>). The acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift is 50 ppm for 5-minute duration. This chemical also has a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) of 0.045 ppm TWA, with 0.13 ppm Ceiling limit for 15-minute (<u>NIOSH, 2005</u>).

Ethylene dibromide has a vapor pressure of approximately 11 mm Hg at 25 °C. Ethylene dibromide's vapor pressure indicates the potential for inhalation exposure to vapors generated by the liquid at ambient room temperature conditions. The extent of inhalation exposure could vary from facility to facility depending on many factors including but not limited to engineering controls, type of facility and process design.

Consumer exposure

Based on CDR reporting information, ethylene dibromide is used in fuels and fuel additives for both consumer and commercial use (U.S. EPA 2016). For the 2012 CDR, two sites reported use of ethylene dibromide and the reporting information for these two sites were claimed as CBI. The Chemical and Products Database (CPDat) reported only one specific product a lubricant that could be used by consumers and two undefined consumer products that had detected levels of ethylene dibromide (Table 12). In the most recent assessments reviewed, no uses of ethylene dibromide in consumer products have been identified (Environment Canada 2013).

Chemical Identity	Consumer Product Database
Chemical Identity	Consumer Uses (List)
Ethylene Dibromide (106-93-4)	Lubricant

Reference: CPDat

General population exposure

Releases of ethylene dibromide from certain conditions of use, such as manufacturing and processing activities, may result in general population exposures via inhalation of air near processing facilities or ingestion of contaminated drinking water (ATSDR 2018, NTP 2016, OEHHA 2003). Ethylene dibromide was reported in air, water, soil/sediment environmental concentrations, as well as in human blood/serum samples; it was not reported in ecological biomonitoring matrices (Table 13).

Existing assessments also indicated ethylene dibromide was detected in ambient air, surface water, groundwater, drinking water, soil, diet (U.S. EPA 2004a, IARC 1999, NICNAS 2013, NTP 2016, FDA 2006, Environment Canada 2013, ATSDR 2018). 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 (<u>ATSDR 2018</u>, <u>Environment Canada 2013</u>, <u>NICNAS</u> 2018, <u>U.S. EPA 2009</u>, <u>U.S. EPA 2004a</u>, <u>OEHHA 2003</u>).

Database Name	Env. Concen. ^a Data Present?	Human Biomon. ^b Data Present?	Ecological Biomon. Data Present?	Reference
California Air Resources Board	no	no	no	<u>CARB (2005)</u>
Comparative Toxicogenomics Database	no	no	no	<u>MDI (2002)</u>
EPA Ambient Monitoring Technology Information Center – Air Toxics Data	yes	no	no	<u>U.S. EPA (1990)</u>
EPA Discharge Monitoring Report Data	yes	no	no	U.S. EPA (2007)
EPA Unregulated Contaminant Monitoring Rule	yes	no	no	<u>U.S. EPA (1996)</u>
FDA Total Diet Study	no	no	no	<u>FDA (1991)</u>
Great Lakes Environmental Database	yes	no	no	<u>U.S. EPA</u> (2018a)
Information Platform for Chemical Monitoring Data	yes	no	no	<u>EC (2018)</u>
International Council for the Exploration of the Sea	no	no	no	<u>ICES (2018)</u>
OECD Monitoring Database	no	no	no	OECD (2018)
Targeted National Sewage Sludge Survey	no	no	no	<u>U.S. EPA</u> (2006b)
The National Health and Nutrition Examination Survey	no	yes	no	<u>CDC (2013)</u>
USGS Monitoring Data –National Water Quality Monitoring Council	no	no	no	<u>USGS (1991a)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Air	no	no	no	<u>USGS (1991b)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Ground Water	yes	no	no	<u>USGS (1991c)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Sediment	yes	no	no	<u>USGS (1991d)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Soil	yes	no	no	<u>USGS (1991e)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Surface Water	yes	no	no	<u>USGS (1991f)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Tissue	no	no	no	<u>USGS (1991g)</u>

Table 13. Exposure Information for the Environment and General Population

^a Concen.= concentration

^bBiomon.= biomonitoring

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

EPA did not identify other risk-based criteria relevant to the designation of the chemical substance's priority.

10. Proposed designation and Rationale

Proposed Designation: High-priority substance

Rationale: EPA identified and analyzed reasonably available information for exposure and hazard and is proposing to find that ethylene dibromide may present an unreasonable risk of injury to health and/or the environment, including potentially exposed or susceptible subpopulations, (e.g., workers, consumers, women of reproductive age, children). This is based on the potential hazard and potential exposure of ethylene dibromide under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacturing, processing, distribution, use, and disposal of ethylene dibromide may result in presence of the chemical in surface water and groundwater, ingestion of the chemical in drinking water, inhalation of the chemical from air releases, and exposure to workers and consumers. In addition, EPA identified potential environmental (e.g., aquatic toxicity, terrestrial toxicity) and human health hazards (e.g., acute toxicity, repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, irritation/corrosion, carcinogenicity, neurotoxicity, and observations in epidemiologic and/or biomonitoring studies).

11. References

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

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