

Office of Chemical Safety and Pollution Prevention

Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation

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Acronyms and Abbreviations

Term	Definition
AEGL	Acute exposure guideline level
ATSDR	Agency for Toxic Substances and Disease Registry
Biomon.	Biomonitoring
BOD	Biological oxygen demand
BP	Boiling point
CAA	Clean Air Act
CalEPA	California Environmental Protection Agency
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
CPDat	Chemical and Products Database
CWA	Clean Water Act
ECHA	European Chemicals Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
IRIS	Integrated Risk Information System
IUR	Inventory Update Reporting
Κ	Thousand
K _{OC}	Organic carbon-water partition coefficient
K _{OW}	Octanol-water partition coefficient
М	Million
MAC	Minimum alveolar concentrations
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
MEG	Military exposure guideline

MITI	Ministry of International Trade and Industry
MP	Melting point
MRL	Maximum reference levels
NAICS	North American Industry Classification System
NIH	National Institutes of Health
NKRA	Not Known or Reasonably Ascertainable
NR	Not reported
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
·OH	Hydroxyl radical
RfC	Reference concentration
RfD	Reference dose
RY	Reporting Year
SARA	Superfund Amendments and Reauthorization Act of 1986
SARA	Superfund Amendments and Reauthorization Act of 1986
SARA SIDS	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set
SARA SIDS SMILES	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set Simplified Molecular-Input Line-Entry System
SARA SIDS SMILES SOP	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set Simplified Molecular-Input Line-Entry System Standard Operating Procedure
SARA SIDS SMILES SOP T _{1/2}	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set Simplified Molecular-Input Line-Entry System Standard Operating Procedure Half-life
SARA SIDS SMILES SOP T _{1/2} TG	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set Simplified Molecular-Input Line-Entry System Standard Operating Procedure Half-life Test guidance
SARA SIDS SMILES SOP T _{1/2} TG TLV	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set Simplified Molecular-Input Line-Entry System Standard Operating Procedure Half-life Test guidance Threshold Limit Value
SARA SIDS SMILES SOP T _{1/2} TG TLV TRI	Superfund Amendments and Reauthorization Act of 1986 Screening Information Data Set Simplified Molecular-Input Line-Entry System Standard Operating Procedure Half-life Test guidance Threshold Limit Value Toxics Release Inventory

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 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)). 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).

trans-1,2-Dichloroethylene 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 *trans*-1,2-dichloroethylene 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

¹ NOTE: 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>

information on *trans*-1,2-dichloroethylene, including relevant information received from the public and other information as appropriate.

EPA will take comment on this proposed designation for 90 days before finalizing its designation of *trans*-1,2-dichloroethylene. The docket number for providing comments on *trans*-1,2-dichloroethylene is EPA-HQ-OPPT-2018-0465 and is available at <u>www.regulations.gov</u>.

The information, analysis and basis 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 *trans*-1,2-dichloroethylene reported under the Inventory Update Reporting (IUR) rule and Chemical Data Reporting (CDR) rule.³

Results and Discussion

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.

 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
<i>trans</i> -1,2- dichloroethylene (156-60-5)	10 to 500 K	1 to 10M	1 to 10 M	1 to 10M	1 to 10M	1 to 10M					

Note: K = thousand; M = million Reference: <u>U.S. EPA (2013)</u> and <u>U.S. EPA (2017)</u>

Production volume of *trans*-1,2-dichloroethylene in 2015, as reported to CDR, was between 1 and 10 million pounds. The range of production volume of *trans*-1,2-dichloroethylene as reported to EPA has not changed from 1990-2015 (Table 1).

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).

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 *trans*-1,2-dichloroethylene 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 U.S. above 25,000 pounds per site, except of certain TSCA actions apply (in which case the reporting requirement is greater than 2,500 pounds 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. 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.

1,2-Dichloroethylene is included on the TRI chemical list as a mixture of its *cis*- and *trans*geometric isomers (CASRN 540-59-0). For reporting year 2017, seventeen facilities filed a TRI report for 1,2-dichloroethylene, and the release quantities they reported total 8,728 pounds. When facilities file TRI reports for 1,2-dichloroethylene, they are not required to disclose the specific activities and uses of each geometric isomer in Part II Section 3 ("Activities and Uses of the Toxic Chemical at the Facility"). Likewise, TRI reporting facilities are also not required to disclose the quantities of each geometric isomer they disposed of or otherwise released to the environment or otherwise managed as waste (i.e., energy recovery, recycling, and treatment), but rather the waste management quantities for the mixture. Since there is no way to discern from a TRI report for 1,2-dichloroethylene the activities, uses, and quantities of *trans*-1,2dichloroethylene a facility released to the environment or otherwise managed as waste, TRI data for 1,2-dichloroethylene are not used in this report. EPA assumed end-of-life pathways that include releases to air, wastewater, and solid and liquid waste based on the conditions of use.

CDR Tables

Based on the publicly available⁴ 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	Reference
Manufacture	Domestic manufacture	Domestic manufacture	<u>U.S. EPA (2019)</u>
Manufacture	Import	Import	<u>U.S. EPA (2019)</u>
Processing	Processing as a reactant	Plating agents and surface treating agents in soap, cleaning compound, and toilet preparation manufacturing	<u>U.S. EPA (2019)</u>
Processing	Processing – incorporating into formulation, mixture or reaction product	CBI ⁶ in: – Miscellaneous manufacturing – Wholesale and retail trade – CBI	<u>U.S. EPA (2019)</u>
Processing	Processing – incorporating into formulation, mixture or reaction product	 Solvents (for cleaning and degreasing) in: All other basic organic chemical manufacturing Soap, cleaning compound, and toilet preparation manufacturing 	<u>U.S. EPA (2019)</u>
Processing	Processing – incorporating into articles	Propellant and blowing agent in plastics product manufacturing	<u>U.S. EPA (2019)</u>
Processing	Recycling	СВІ	<u>U.S. EPA (2019)</u>
Distribution in Commerce ^{a,b}	Distribution in commerce	Distribution in commerce	
Commercial Uses	Cleaning and furnishing care products	Cleaning and furnishing care products	<u>U.S. EPA (2019)</u>
Commercial Uses	Metal products not elsewhere covered	Metal products not elsewhere covered	<u>U.S. EPA (2019)</u>
Commercial Uses	Cleaning solvents	Cleaning solvents	<u>U.S. EPA (2019)</u>
Commercial Uses	CBI		<u>U.S. EPA (2019)</u>
Disposal ^a	Disposal	Disposal	

 Table 2. trans-1,2-Dichloroethylene (156-60-5) Categories and Subcategories of Conditions of Use⁵ (2016 CDR Reporting Cycle)

⁴ 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.

⁵ Certain other uses that are excluded from TSCA are not captured in this table.

⁶ 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	Reference

^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.

Note: CBI = confidential business information

Table 3. *trans*-1,2-Dichloroethylene (156-60-5) Categories and Subcategories of Conditions of Use⁷ (2012 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacture	Domestic manufacture	Domestic manufacture	<u>U.S. EPA (2019)</u>
Manufacture	Import	Import	<u>U.S. EPA (2019)</u>
Processing	Processing – incorporating into formulation, mixture or reaction product	Solvent (for cleaning and degreasing) in all other basic organic chemical manufacturing	<u>U.S. EPA (2019)</u>
Processing	Processing – incorporating into formulation, mixture or reaction product	CBI ⁸ in: – Miscellaneous manufacturing – Wholesale and retail trade – CBI	<u>U.S. EPA (2019)</u>
Processing	Processing – incorporating into articles	Propellant and blowing agent in plastics product manufacturing	<u>U.S. EPA (2019)</u>
Processing	Recycling	СВІ	<u>U.S. EPA (2019)</u>
Distribution in Commerce ^{a,b}	Distribution in commerce	Distribution in commerce	
Commercial Uses	CBI		<u>U.S. EPA (2019)</u>
Disposal ^a	Disposal	Disposal	

^a CDR includes information on the manufacturing, processing, and use of chemical substances. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e., disposal). The table 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.

Note: CBI = confidential business information

⁷ Certain other uses which are excluded from TSCA are not captured in this table.

⁸ 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.

Summary

For the 2016 CDR reports, *trans*-1,2-dichloroethylene was manufactured in U.S. and imported. *trans*-1,2-dichloroethylene is processed in several ways: it is incorporated into formulation, mixture or reaction products, and is incorporated into articles. Due to CBI⁹ claims, EPA cannot state if *trans*-1,2-dichloroethylene is recycled.

Between 2012 and 2016, the functional use of *trans*-1,2-dichloroethylene included both solvent for cleaning and degreasing, as well as propellant and blowing agent (Tables 2 and 3), in several industrial sectors. In 2016, an additional function, plating agents and surface treating agents, was reported. This function was described in a new industrial sector: soap, cleaning compound, and toilet preparation manufacturing. The chemical was also noted to be used as a solvent for cleaning and degreasing in this industry. According to CDR, *trans*-1,2-dichloroethylene was used in more types of processing in 2016.

The 2016 CDR includes several reports of commercial uses that do not appear in 2012: cleaning and furnishing care products, metal products not elsewhere covered, and cleaning solvents. Other commercial uses are claimed CBI. Refer to the Exposure Potential section (Section 8) for a discussion of consumer uses that were identified.

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 or other susceptible subpopulation may be potentially exposed. EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.

Results and Discussion

At this stage, EPA identified workers as a subpopulation who may be potentially exposed or susceptible subpopulations for *trans*-1,2-dichloroethylene assessment.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for *trans*-1,2-dichloroethylene. The 2012 and 2016 CDR did not report any use in children's products.

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.

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

EPA did not identify any studies that observed developmental or reproductive effects following exposure to *trans*-1,2-dichloroethylene (Section 7, Table 6). Women of reproductive age are therefore not considered a susceptible subpopulation with respect to *trans*-1,2-dichloroethylene at this time. During the scoping and risk evaluation process, the issue of potentially exposed or susceptible subpopulations will be considered again after a full systematic review of the literature.

Consideration of women of reproductive age as a potentially exposed or susceptible subpopulation was 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 characteristics, to understand *trans*-1,2-dichloroethylene persistence and bioaccumulation.

Physical and Chemical Properties and Environmental Fate Tables

Tables 4 and 5 summarize the physical and chemical properties and the environmental fate characteristics of *trans*-1,2-dichloroethylene, respectively.

Property or Endpoint	Value ^a	Reference
Molecular Formula	$C_2H_2Cl_2$	CRC Handbook (Rumble, 2018)
Molecular Weight	96.943 g/mole	CRC Handbook (Rumble, 2018)
Physical State	Liquid	CRC Handbook (Rumble, 2018); <u>HSDB (2018)</u> ; <u>ATSDR</u> (1996)
Physical Form	Colorless, light liquid	HSDB (2018) citing Dreher (2014)
Purity	98%	Sigma-Aldrich (2018)
Melting Point	−49.8 °C ^b	CRC Handbook (Rumble, 2018); PhysProp Database (U.S. EPA, 2012b); Mackay et al. (2006)

Table 4. Physical and Chemical Properties of trans-1,2-Dichloroethylene

Property or Endpoint	Value ^a	Reference		
	−49.4 °C	HSDB (2018) citing O'Neil (2013); ATSDR (1996)		
	−50 °C	ATSDR (1996)		
Boiling Point	48.7 °C ^b	PhysProp Database (<u>U.S. EPA, 2012b</u>); Mackay et al. (2006) citing CRC (1977)		
	47.64 °C	CRC Handbook (Rumble, 2018); HSDB (2018)		
	47.2 °C at 745 mm Hg	HSDB (2018) citing O'Neil (2013); ATSDR (1996)		
Density	1.2565 g/cm ³ at 20 °C	CRC Handbook (Rumble, 2018); <u>HSDB (2018)</u> ; <u>ATSDR</u> (1996)		
Vapor Pressure	331 mm Hg at 25 °C (extrapolated) ^b	HSDB (2018) citing Boublik et al. (1984)		
	265 mm Hg at 20 °C	HSDB, 2018 citing Mertens (2000); ATSDR (1996)		
	395 mm Hg at 30 °C	HSDB (2018) citing Flick (1991); ATSDR (1996)		
	410 mm Hg at 30 °C	ATSDR (1996) citing Stevens (1979)		
Vapor Density	3.67 g/L at 760 mm Hg (relative vapor density to air = 1)	HSDB (2018)_citing Flick, 1991		
Water Solubility	4,520 mg/L at 25 °C ^b	HSDB (2018) citing Horvath et al. (1999); PhysProp Database (U.S. EPA, 2012b)		
	6.3 g/L at 25 °C	HSDB (2018) citing Flick (1991); ATSDR (1996); Mackay et al. (2006)		
Log K _{OW}	2.09 ^b	HSDB (2018) citing Hansch et al. (1995); ATSDR (1996); Mackay et al. (2006)		
	2.06	Mackay et al. (2006), citing Hansch et al. (1985)		
	1.92 at 24±1 °C pH 6.4–6.6 (OECD 107 Shake-Flask Method) test substance analytical purity ≥99%	<u>NITE (2018)</u>		
Henry's Law Constant	9.38×10^{-3} atm-m ³ /mol at 24 °C	PhysProp Database (U.S. EPA, 2012b); HSDB (2018) citing Gossett (1987); ATSDR (1996)		
Flash Point	6.0 °C (closed cup)	HSDB (2018) citing Sigma-Aldrich (2018)		
	2–4 °C	ATSDR (1996) citing Stevens (1979)		
Auto Flammability	460 °C (autoignition temperature)	HSDB (2018) citing Lewis, 2004; ATSDR (1996) citing Lewis (2004)		
Viscosity	0.41 cP at 20 °C	HSDB (2018) citing Flick (1991)		
Refractive Index	1.4454 at 20 °C	CRC Handbook (Rumble, 2018); HSDB (2018)		
Dielectric Constant	NA	NA		
Surface Tension	25×10-3 N/m at 20 °C	HSDB (2018) citing Dreher (2014)		

Notes:

^aMeasured unless otherwise noted;

^bSelected value; NA = not available

Property or Endpoint	Value ^a	Reference
Direct Photodegradation	UV absorption at <240 nm with minor absorption between 290 and 380 nm; direct photolysis is not expected to be an important fate process	<u>ATSDR (1996); HSDB (2018)</u>
Indirect Photodegradation	$t_{1/2} = 5$ days (based on ·OH reaction rate constant of 4.5×10^{-12} cm ³ /mol·second at 25 °C)	ATSDR (1996) citing Goodman et al. (1986)
	$t_{1/2} = 44$ days (based on ozone reaction rate)	ATSDR (1996) citing Tuazon et al. (1984)
	$t_{1/2} = 6.9 \text{ hours}$ (based on ·OH reaction rate constant of 2.34 × 10 ⁻¹² cm ³ /mol·second at 25 °C and 5 × 10 ⁵ ·OH radicals/cm ³)	HSDB (2018) citing Kwok and Atkinson (1994)
	$ \begin{array}{l} t_{1/2} = 57 \text{ days (based on ozone reaction rate} \\ \text{of } 2.0 \times 10^{-19} \text{ cm}^3/\text{mol} \cdot \text{second and } 7 \times 10^{11} \\ \text{ozone molecules/cm}^3 \text{ at } 25 \ ^\circ\text{C}) \end{array} $	HSDB (2018) citing Kwok and Atkinson (1994)
	$t_{1/2} = 310 \text{ days (based on nitrate reaction rate of } 1.07 \times 10^{-16} \text{ cm}^3/\text{mol} \cdot \text{second at } 25 ^\circ\text{C} \text{ and } 2.4 \times 10^8 \text{ nitrate radicals/cm}^3)$	HSDB (2018) citing Kwok and Atkinson, 1994
Hydrolysis	Stable; <i>trans</i> -1,2-dichloroethylene is not expected to undergo hydrolysis based on its chemical structure, which lacks functional groups known to undergo hydrolysis under environmental conditions	HSDB (2018) citing Callahan (1979)
Biodegradation (Aerobic)	Water: 0% after 28 days based on BOD (Japanese MITI test)	NITE (2018); HSDB (2018)
	Water: 0%/time not specified (river die- away test and shake-flask test)	HSDB (2018) citing Mudder (1981), Mudder and Musterman (1982)
	Water: 67%/7 days with 33% loss due to volatilization in 10 days (enrichment biodegradability screening test with wastewater inoculum; test substance concentration of 5 ppm)	HSDB (2018) citing Fogel et al. (1986)
	Soil and water: Durban, KwaZulu-Natal, South Africa $t_{1/2} = 21$ days in soil A (52% sand, 26.5% clay, 21.5% silt, microbial concentration 6.5×10^5 cfu/g)	HSDB (2018) citing Olaniran et al. (2006)

Table 5. Environmental Fate Characteristics of *trans*-1,2-Dichloroethylene

Property or Endpoint	Value ^a	Reference
	$\begin{array}{l} t_{1/2} = 23 \mbox{ days in soil B (80.25\% \mbox{ sand, 8.25\% } \\ \mbox{clay, 11.5\% \mbox{ silt, microbial concentration} \\ 3.0 \times 10^5 \mbox{ cfu/g)} \end{array}$	
	$t_{1/2} = 27$ days in water A (pH 6.98, microbial concentration 13.25×10^5 cfu/g)	
	$t_{1/2} = 26$ days in water B (pH 6.94, microbial concentration 3.4×10^5 cfu/g)	
Biodegradation (Anaerobic)	18%/40 weeks (serum bottle) vinyl chloride was the primary degradation product	HSDB (2018) citing Wilson (1986)
	73%/6 months (microcosms with uncontaminated organic sediment from the Everglades); vinyl chloride was the degradation product	HSDB (2018) citing Barrio- Lage (1986)
Wastewater Treatment	t $_{1/2}$ = 24 minutes by evaporation from water (1 ppm aqueous solution with still air, an average depth of 6.5 cm, at 25 °C)	HSDB (2018) citing Verschueren (2001)
	90% evaporation after 83 minutes (1 ppm solution at 25 °C)	
	79% total removal (0.04% by biodegradation, 0.90% by sludge and 78% by volatilization to air; estimated) ^b	<u>U.S. EPA (2012a)</u>
Bioconcentration Factor	11 (estimated) ^b	<u>U.S. EPA (2012a)</u>
Bioaccumulation Factor	13 (estimated) ^b	<u>U.S. EPA (2012a)</u>
Soil Organic Carbon:Water Partition Coefficient (Log Koc)	1.77 (K _{oc} = 59)	HSDB (2018) citing Chu and Chan (2000); Mackay et al. (2006)

Notes:

^a Measured unless otherwise noted

^b EPI SuiteTM physical property inputs: Log $K_{OW} = 2.09$, BP = 48.7 °C, MP = -49.8 °C, VP = 331 mm Hg, WS = 4,520 mg/L, SMILES C(=CCl)Cl.

·OH = hydroxyl radical; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand

Results and Discussion

trans-1,2-Dichloroethylene is a volatile, highly water-soluble liquid (4,520 mg/L). Measured Henry's Law constant (9.38×10^{-3} atm-m³/mol) and vapor pressure (331 mm Hg) data indicate that this chemical will not be persistent in surface water and soil as it will likely volatilize upon release. In the air, *trans*-1,2-dichloroethlyene exists in the vapor phase where it may react with photochemically produced hydroxyl radicals, nitrate radicals, and ozone at rates corresponding with half-lives of 6.9, 310, and 57 days, respectively.

In aerobic aquatic environments, *trans*-1,2-dichloroethylene is not readily biodegradable. It achieved 0 percent of its theoretical biological oxygen demand (BOD) over a 28-day incubation period using a sewage sludge inoculum and the modified Ministry of International Trade and Industry (MITI) test method. Therefore, this chemical may persist in subsurface environments, groundwater, or enclosed pipes when volatilization is not an option. This chemical has low bioaccumulation potential based on bioconcentration factor and bioaccumulation factor estimates of 11 and 13, respectively, and its measured log Kow of 2.09.

6. Storage near significant sources of drinking water

Approach

To support the proposed designation, EPA screened 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 (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

EPA has established a Maximum Contaminant Level Goal (MCLG) and Maximum Contaminant Level (MCL) for *trans*-1,2-dichloroethylene at 100 ppb due to potential health effects from long-term exposure above the MCL that result in liver problems. It is also a Priority Pollutant under the CWA.

Dichloroethylene (540-59-0; *trans* and *cis* mixture) is subject to reporting requirements under the EPCRA. *trans*-1,2-Dichloroethylene is also considered a CERCLA hazardous substance and releases in quantities equal to or greater than 1,000 pounds are subject to reporting to the National Response Center under CERCLA.

trans-1,2-Dichloroethylene is also subject to the Resource Conservation and Recovery Act (RCRA; hazardous waste number U079) for storage near significant sources of drinking water. 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 *trans*-1,2-dichloroethylene (Tables 6 and 7, respectively).

Because, there are very few publicly available assessments for *trans*-1,2-dichloroethylene with cited environmental hazard data, EPA used the infrastructure of ECOTOXicology knowledgebase (ECOTOX) to identify single chemical toxicity data for aquatic and terrestrial life (U.S. EPA, 2018a). 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 *trans*-1,2-dichloroethylene, if available, to fill in potential data gaps when no reported observed effects for the specific taxa exposed to *trans*-1,2-dichloroethylene (Table 7).

Potential Human Health and Environmental Hazard Tables

EPA identified potential human health and environmental hazards based on a review of the reasonably available information on *trans*-1,2-dichloroethylene (Tables 6 and 7, respectively).

Human Health Hazards	Tested for Specific Effect	Effect Observed	Data Source			
Acute Toxicity	X	Х	<u>U.S. EPA (2015), U.S. EPA (2008), NTP (2002),</u> <u>ATSDR (1996)</u>			
Repeated Dose Toxicity	Х	Х	U.S. EPA (2015), U.S. EPA (2010b), U.S. EPA (2010a), U.S. EPA (2008), NTP (2002), RIVM (2001), ATSDR (1996)			
Genetic Toxicity	X	Х	U.S. EPA (2008), U.S. EPA (2010a), U.S. EPA (2010b), NTP (2002), RIVM (2001), ATSDR (1996)			
Reproductive Toxicity						
Developmental Toxicity						
Toxicokinetic	X	Х	U.S. EPA (2010b), RIVM (2001), ATSDR (1996)			
Irritation/Corrosion	Х	Х	U.S. EPA (2008), RIVM (2001), ATSDR (1996)			
Dermal Sensitization						

 Table 6. Potential Human Health Hazards Identified for trans-1,2-Dichloroethylene

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

Human Health Hazards	Tested for Specific Effect	Effect Observed	Data Source
Respiratory Sensitization			
Carcinogenicity			
Immunotoxicity	X	Х	U.S. EPA (2010a), U.S. EPA (2010b), ATSDR (1996)
Neurotoxicity			
Epidemiological Studies or Biomonitoring Studies			

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 Duration Taxa Gro		Taxa Groups	High-Priority Chemical Candidate <i>trans</i> -1,2-Dichloroethylene (CASRN 156-60-5)		Isomers of trans-1,2-Dichloroethylene (CASRN 156-60-5) 1,2-Dichloroethylene (CASRN 540-59-0) cis-1,2-Dichloroethylene (CASRN 156-59-2)		Data Sources	
			Number of Studies	Observed Effects	Number of StudiesObserved Effects			
Aquatic	Acute	Vegetation	1	Х	1	Х	Tsai and Chen (2007)	
		Invertebrate	1	Х	1	Х	LeBlanc (1980); Sanchez-Fortun et al. (1997)	
		Fish	1	Х	1	Х	Buccafusco et al. (1981); Great Lakes Environment Center (2005)	
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	_		1	Х	McDaniel et al. (2004)	
	Chronic	Vegetation	_		_			
		Invertebrate	_		_			
		Fish	_		_			
		Non-fish vertebrate (i.e., amphibians, reptiles, mammals)	_		_			

 Table 7. Potential Environmental Hazards Identified for trans-1,2-Dichloroethylene

Media	Study Duration	Taxa Groups	Cano trans-1,2-Dic	ity Chemical didate hloroethylene 156-60-5)	Isomers of trans-1,2-Dichloroethylene (CASRN 156-60-5) 1,2-Dichloroethylene (CASRN 540-59-0) cis-1,2-Dichloroethylene (CASRN 156-59-2)		Data Sources	
			Number of Studies	Observed Effects	Number of Studies	Observed Effects		
Terrestrial	Acute	Vegetation	1	Х	1	Х	Dietz and Schnoor (2001)	
		Invertebrate	1	Х	_		Neuhauser et al. (1985)	
		Vertebrates	-		2	Х	Crebelli et al. (1999); Crebelli et al (1995)	
	Chronic	Vegetation	-		_			
		Invertebrate	-		_			
		Vertebrate	_		_			

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 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 *trans*-1,2-dichloroethylene.

Release potential for environmental and human health exposure

trans-1,2-Dichloroethylene is not included on the TRI chemical list. EPA considered conditions of use reported in CDR and the physical and chemical properties to inform the release potential of *trans*-1,2-dichloroethylene.

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 *trans*-1,2-dichloroethylene 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, human and environmental biomonitoring data to inform *trans*-1,2-dichloroethylene's exposure potential to the general population (Table 9).

Results and Discussion

Release potential for environmental and human health exposure

EPA anticipates releases of *trans*-1,2-dichloroethylene into the environment in accordance with the conditions of use for *trans*-1,2-dichloroethylene, particularly activities associated with the chemical's manufacturing. A review of monitoring data collected under EPA rules and statutes (e.g., CAA, CWA, Safe Drinking Water Act, National Pollutant Discharge Elimination System) indicates that *trans*-1,2-dichloroethylene is detected in air, water, soil, and other matrices. Based on fate properties, such as water solubility, EPA anticipates possible presence of *trans*-1,2-dichloroethylene in surface water and particularly groundwater. In the United States, the California Environmental Protection Agency (CalEPA) has measured *trans*-1,2-dichloroethylene in surface water at levels of 0.43–1,307 ppb and in groundwater at levels of 0.25–500,000 ppb (CalEPA 2006). A source of *trans*-1,2-dichloroethylene is anaerobic biodegradation of chlorinated solvents, and these are present at detectable levels in landfill gases (ATSDR 1996). Thus, the high levels of *trans*-1,2-dichloroethylene found in groundwater are thought to be released into soil and sediment from the disposal and leaching of chlorinated solvent waste. A review of the available literature suggests aquatic, non-mammal ecological biomonitoring data are available (Table 9).

trans-1,2-Dichloroethylene (CAS RN 156-60-5) has a vapor pressure of above 300 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 used as a reactant, industrial releases may be a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the chemical reacts without excess loss during its use as an intermediate. The actual

percentages, quantities, and media of releases of the reported chemical associated with this processing or use are not known.

When chemical substances are incorporated into formulations, mixtures, or reaction products, industrial releases may be a relatively low percentage of the production volume. Lower percentage releases occur when a high percentage of the 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.

When chemical substances have industrial use as aerosol propellants, industrial and/or end use releases may be a relatively high percentage of the production volume. Higher percentage releases occur when the chemical's intended use is to propel other chemicals into air and the chemical itself is dispersed into the atmosphere. In some cases, some engineering controls may reduce these losses. The actual percentage and quantity of release of the reported chemical associated with this category are not known but could be high.

When chemical substances have industrial use as solvents for cleaning or degreasing, industrial and/or end use releases may be a relatively high percentage of the production volume. Higher percentage releases occur when the chemical's intended use is as a solvent that may evaporate into the atmosphere or may be collected and disposed to aqueous media. In some cases, some engineering controls or capture for recycle or reclamation may reduce these losses. The actual percentage and quantity of release of the reported chemical associated with this category are not known but could be high.

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.

trans-1,2-Dichloroethylene has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL)¹¹. The PEL is 200 parts per million (ppm) or 790 milligrams (mg)/cubic meter (m³) over an 8-hour work day, time weighted average (TWA). This chemical also has a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL)¹² of 200 ppm (790 mg/m³) TWA. The American Conference of Governmental Industrial Hygienists (ACGIH) set the Threshold Limit Value (TLV) at 200 ppm TWA.

¹¹ OSHA, 2009. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs). <u>https://www.osha.gov/dsg/annotated-pels/tablez-1.html</u>

¹² NIOSH, 2005. NIOSH Pocket Guide to Chemical Hazards. <u>https://www.cdc.gov/niosh/npg/npgdcas.html</u>

trans-1,2-Dichloroethylene has a vapor pressure of above 300 mm Hg at 25 °C/77 °F. *trans*-1,2-Dichloroethylene'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 control, type of facility and design.

Consumer exposure

CDR reporting and information from the National Institutes of Health (NIH) Consumer Product Database do not list *trans*-1,2-dichloroethylene in consumer products. However, the Chemical and Products Database (<u>CPDat</u>) indicates that *trans*-1,2-dichloroethylene appears to be used in several types of consumer products such as cleaners, propellants, and solvents (Table 8).

Table 8. Exposure Information for Consumers					
				Consum	

	Consumer Product Database		
Chemical Identity	Consumer Uses (List)		
<i>trans</i> -1,2-Dichloroethylene (156-60-5)	Cleaner, propellant, solvent		

Reference: CPDat

General population exposure

trans-1,2-Dichloroethylene was reported in air, water, and soil/sediment environmental concentrations, as well as in human blood and aquatic, non-mammalian ecological biomonitoring data.

Releases of *trans*-1,2-dichloroethylene from certain conditions of use, such as manufacturing, disposal, or waste treatment activities, may result in general population exposures via drinking water ingestion, dermal contact, and inhalation from air releases.

Database Name	Env. Concen. Data Present?	Human Biomon. 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	no	no	no	<u>U.S. EPA (1990)</u>
EPA Discharge Monitoring Report Data	yes	no	no	<u>U.S. EPA (2007)</u>
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	no	no	no	<u>U.S. EPA (2018b)</u>

Table 9. Exposure information for the Environment and General Population

Database Name	Env. Concen. Data Present?	Human Biomon. Data Present?	Ecological Biomon. Data Present?	Reference
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	yes	no	<u>OECD (2018)</u>
Targeted National Sewage Sludge Survey	no	no	no	<u>U.S. EPA (2006)</u>
The National Health and Nutrition Examination Survey	no	no	no	<u>CDC (2013)</u>
USGS Monitoring Data –National Water Quality Monitoring Council	yes	no	no	<u>USGS (1991a)</u>
USGS Monitoring Data –National Water Quality Monitoring Council, Air	yes	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	yes	<u>USGS (1991g)</u>

^a Concen.= concentration

^b Biomon.= biomonitoring

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

EPA did not find 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 *trans*-1,2-dichloroethylene may present an unreasonable risk of injury to health and/or the environment, including potentially exposed or susceptible subpopulations, (e.g., workers including women of reproductive age and consumers). This is based on the potential hazard and potential exposure of *trans*-1,2-dichloroethylene under the conditions of use described in this document to support the prioritization designation. Specifically, EPA expects that the manufacture, processing, distribution, use, and disposal of *trans*-1,2-dichloroethylene 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, exposure to workers, exposure to consumers and exposure to the general population, including exposure to children. 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, toxicokinetics, irritation/corrosion, and immunotoxicity).

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

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