

Office of Chemical Safety and Pollution Prevention

Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation

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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
Κ	Thousand
K _{OC}	Organic carbon-water partition coefficient
K _{OW}	Octanol-water partition coefficient
М	Million
MITI	Ministry of International Trade and Industry

Term	Description
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 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).

Tris(2-chloroethyl) phosphate (TCEP) 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 TCEP 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: <u>https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol33/xml/CFR-2018-title40-vol33-part702.xml</u> 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 TCEP, 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 TCEP. The docket number for providing comments on TCEP is EPA-HQ-OPPT-2018-0476-0002 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 children, pregnant women, and workers, who could be potentially exposed or susceptible subpopulations for 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 TCEP 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 in order to protect individual site production volumes that are confidential business information (CBI), is presented in Table 1.

Results and Discussion

Production volume of TCEP in 2015, as reported to EPA during the 2016 CDR reporting period, was 25,000 to 100,000 pounds. Though the data are limited to ranges, the production volume for TCEP has been generally decreasing over the time. Production volume of TCEP as reported to EPA remained did not change from 1986-2002 and decreased between 2006 and 2013. The production volume then increased in 2014 and decreased, again, in 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).

 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
Tris(2-chloro ethyl) phosphate (TCEP) (115- 96-8)	>1M to 10M	500K to <1M	CBI ⁴	25K to 100K	25K to 100K	100K to 500K	25K to 100K				
K = thousand, M = million, CBI = confidential business information Reference: <u>U.S. EPA (2013)</u> and <u>U.S. EPA (2017)</u>											

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 TCEP 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 lbs 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. 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. TCEP is not included

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.

on the TRI chemical list. For purposes of this proposed 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 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 (For purposes of this proposed designation, EPA assumed end-of-life pathways that include releases to air, wastewater, and solid and liquid waste based on the conditions of use. Table 2 and 3, respectively).

 Table 2. Tris(2-chloroethyl) phosphate (CASRN 115-96-8) Categories and Subcategories of Conditions of Use⁶ (2016 CDR Reporting Cycle)

Life-Cycle Stage	Category	Subcategory of Use	Reference		
Manufacture	Import	Import	<u>U.S. EPA (2019)</u>		
		-			
Distribution in commerce ^{a,b}	Distribution in commerce	Distribution in			
2 10010 00001 11 000000000		commerce			
Processing/Industrial uses	Processing/Industrial uses	Processing/Industrial	<u>U.S. EPA (2019)</u>		
		uses			
Disposal ^a	Disposal	Disposal			
^a CDR includes information on the manufacturing, processing, and use of chemicals. 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.

Life-Cycle Stage	Category	Subcategory of Use	Reference		
Manufacture	Import	Import	<u>U.S. EPA (2019)</u>		
Processing	Incorporation into formulation, mixture, or reaction product	Flame retardant in paint and coating manufacturing	<u>U.S. EPA (2019)</u>		
Processing	Recycling	Recycling U.S. EPA (2019)			
Distribution in commerce ^{a,b}	Distribution in commerce	Distribution in			
		commerce			
Commercial uses	Paints and coatings	Paints and coatings	<u>U.S. EPA (2019)</u>		
Consumer uses	Paints and coatings	Paints and coatings	<u>U.S. EPA (2019)</u>		
Disposal ^a	sposal ^a Disposal Disposal				
Disposal Disposal a CDR includes information on the manufacturing, processing, and use of chemicals. CDR may not provide information on other life-cycle phases such as distribution or chemical end-of-life after use in products (i.e.,					

Table 3. Tris(2-chloroethyl) phosphate (CASRN 115-96-8) Categories and Subcategories of Conditions of Use⁷ (2012 CDR reporting cycle)

^a CDR includes information on the manufacturing, processing, and use of chemicals. 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.

CDR Summary and Additional Information on Conditions of Use

Production and/or import of TCEP was reported by one site, Aceto Corporation, to the 2012 and 2016 CDR. In the 2016 CDR, industrial use information was reported as not known or reasonably ascertainable and consumer use was not reported. In addition, recycling was reported as not known or reasonably ascertainable. In the 2012 CDR, consumer and/or commercial use of TCEP in paints and coatings was reported. Consumer uses were identified in additional databases, which are included in the Exposure Potential section (Section 8).

Also, in the 2012 CDR, industrial processing (incorporation into formulation, mixture or reaction product) as a flame retardant in the paint and coating manufacturing sector was reported. Due to the limited reported information, it is difficult to determine whether significant changes in conditions of use occurred.

In a public comment, the Aerospace Industries Association indicated that the aerospace industry uses TCEP as a as a constituent within products or formulations for the manufacture, operation and maintenance of aerospace products. This substance can be used as an additive plasticizer and viscosity regulator with flame-retarding properties for polyurethane, polyesters, polyvinyl chloride and other polymers. TCEP is also used in the production of unsaturated polyester resins and in acrylic resins, adhesives and coatings. Specific aerospace industrial uses include, but may not be limited to, resins and elastomeric coatings, polyurethane casting for aircraft interiors and as a flame retardant (EPA-HQ-OPPT-2018-0476-0006).

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

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, consumers, workers, or the elderly. EPA analyzed processing and use information included on the CDR Form U that indicates whether the chemical substance is used in products and articles subject to TSCA and are intended for children. These data provide an indication about whether children or other susceptible subpopulation may be potentially exposed (e.g., workers, women of reproductive age). EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.

Results and Discussion

There were no reports to the 2016 CDR for TCEP in products intended for children, while the 2012 CDR reported the use of TCEP in children's products as not known or reasonably ascertainable (Table 4). Previous EPA assessments indicated that TCEP was reported as used in children's products, based on information from other databases. Due to potential developmental and reproductive hazards, women of reproductive age are included as a potentially exposed or susceptible subpopulation with respect to TCEP. At this stage, EPA identified children, women of reproductive age, workers and consumers as subpopulations who may be potentially exposed or susceptible subpopulations for TCEP.

Children

EPA used data reported to the 2012 and 2016 CDR to identify uses in products and articles intended for children over time for TCEP. Table 4 summarizes the non-CBI CDR information regarding commercial and consumer use and notes whether the chemical substance was identified as used in products intended for children. Previous EPA assessments indicated that TCEP was reported as used in children's products in the Washington State Children's Safe Product Act Database (U.S. EPA 2015a) and the chemical has been measured in infant and toddler products such as car seats, changing table pads, and nursing pillows (U.S. EPA 2015a).

Chemical	Year	Product Category (Product Concentration, Number of Workers)	Consumer or Commercial	Used in Products Intended for Children
Tris(2-chloroethyl) phosphate (TCEP)	2012	Paints and coatings	NKRA	NKRA
(115-96-8)	2016	CDR did not include any rep children	orts as used in pro	oducts intended for
Note(s): NKRA = Not Known or Reasonably Ascertainable. Reference: <u>U.S. EPA (2019)</u>				

Table 4. Uses in Children's Products Information⁸

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

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

EPA identified studies that observed developmental and reproductive effects following exposure to TCEP (Section 7, Table 7). 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 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 on TCEP's persistence and bioaccumulation. Table 5 and 6 summarize the physical and chemical properties and the environmental fate characteristics, of TCEP, respectively.

Property or Endpoint	Value ^a	Reference
Molecular Formula	$C_6H_{12}Cl_3O_4P$	CRC Handbook (Haynes, 2014)
Molecular Weight	285.489 g/mole	CRC Handbook (Haynes, 2014)
Physical State	Liquid	HSDB (2015) citing Lewis (2007)
Melting Point	-55 °C ^b	HSDB (2015); ATSDR (2012); Toscano and Colman (2012); Mackay et al. (2006)
	-58 °C (pour point DIN 51583, ASTM D 97-66 method)	EC (2000); PhysProp Database (U.S. EPA, 2012b)
	-60 °C (approximate pour point)	EC (2000)
	Less than -70 °C (pour point)	<u>EC (2009);</u> EC (2000)
Boiling Point	330 °C at 760 mm Hg ^b	CRC Handbook (Haynes, 2014); <u>ATSDR (2012)</u> ; Mackay et al. (2006); <u>HSDB (2015)</u>
	320 °C decomposes	<u>EC (2009)</u>

Table 5. Physical and Chemical Properties of Tris(2-chloroethyl) Phosphate

Property or Endpoint	Value ^a	Reference		
	Test substance purity: 99.5%			
	351 °C at 760 mm Hg decomposes rapidly at >220 °C; thermal decomposition products: carbon monoxide, hydrogen chloride, 2-chloroethane, and dichloroethane	<u>IPCS (1998)</u>		
	214 °C at 25 mm Hg	Mackay et al. (2006); Larranaga et al. (2016) citing Muir (1984)		
	202 °C at 10 mm Hg (ASTM D1160 method)	EC (2000)		
	145 °C at 0.5 mm Hg 180 °C at 3.75 mm Hg decomposes	EC (2000)		
Density	1.39 g/cm ³ at 25 °C	CRC Handbook (Haynes, 2014); HSDB (2015)		
	1.425 g/cm ³ at 20 °C	<u>ATSDR (2012); IPCS (1998)</u>		
	1.42 g/cm ³ at 20 °C (DIN 51757 method)	EC (2000)		
	1.369 g/cm ³	Mackay et al. (2006)		
Vapor Pressure	1.6×10^{-5} mm Hg at 25 °C ^b Extrapolation from measured values: 0.43 hPa at 136.9 °C, 0.99 hPa at 143.5 °C, 2.03 hPa at 158.6 °C, 5.00 hPa at 174.1 °C, 15.03 hPa at 196.2 °C (dynamic method)	PhysProp Database (U.S. EPA, 2012b); ECHA (2018b)		
	8.6×10^{-6} mm Hg at 20 °C (extrapolated)	<u>OECD (2006); EC (2009)</u>		
	0.06125 mm Hg at 25 °C	ATSDR (2012); HSDB (2015); ECHA (2018b) citing Dobry and Keller (1957); Mackay et al. (2006)		
	0.5 mm Hg at 145 °C	Toscano and Colman (2012)		
	<10 mm Hg at 25 °C	<u>IPCS (1998)</u>		
Vapor Density	9.8 (relative vapor density to air = 1)	<u>IPCS (2007)</u>		
Water Solubility	7,820 mg/L at 20 °C and pH 4.7-6.1 ^b (Directive 84/449/EEC A.6)	<u>HSDB (2015); OECD (2006);</u> EC (2000)		
	7,940 mg/L at 20 °C	PhysProp Database (U.S. EPA, 2012b); ECHA (2018b)		
	7,000 mg/L temperature not specified	HSDB (2015); ATSDR (2012); ECHA (2018b) citing Muir (1984); Mackay et al. (2006)		
Log K _{OW}	1.78 at 20 °C ^b (directive 84/449/EEC A.8)	<u>OECD (2006); HSDB (2015)</u>		

Property or Endpoint	Value ^a	Reference
	1.7 at 20 °C (shake-flask method)	ECHA (2018b); PhysProp Database (U.S. EPA, 2012b)
	1.47 (OECD 107)	EC (2000)
	1.43; 1.48	HSDB (2015); Mackay et al. (2006)
	1.44	ATSDR (2012); ECHA (2018b); MITI (1992)
Henry's Law Constant	$<1 \times 10^{-8}$ atm-m ³ /mole (estimated)	<u>U.S. EPA (2012a)</u>
Flash Point	216 °C (Cleveland open cup)	ATSDR (2012); ECHA (2018b); Larranaga et al. (2016)
	252 °C (open cup)	EC (2000)
	232 °C	Toscano and Colman (2012); ECHA (2018b)
	225 °C (closed cup DIN 51758)	EC (2000)
	202 °C (Pensky Martin closed cup)	<u>IPCS (1998)</u>
	200 °C (ASTM D93)	EC (2000)
Auto Flammability	480 °C (autoignition temperature)	EC (2000); <u>IPCS (1998)</u>
Viscosity	1.4721 at 20 °C	<u>IPCS (1998)</u>
Refractive Index	34 cP at 25 °C	<u>IPCS (1998)</u>
Dielectric Constant	TBD	TBD

Notes:

^aMeasured unless otherwise noted;

^bSelected value

TBD = to be determined, if reasonably available. **EPA is particularly interested in information from the public on these properties or endpoints.**

Property or Endpoint	Value ^a	References
Direct Photodegradation	Not expected to be susceptible to direct photolysis by sunlight because the chemical structure of TCEP does not contain chromophores that absorb at wavelengths >290 nm	<u>HSDB (2015)</u>
Indirect Photodegradation	$t_{1/2} = 5.8$ hours (based on ·OH rate constant of 2.2×10^{-11} cm ³ /molecule-sec at 25 °C and 12-hour day with 1.5×10^{6} ·OH/cm ³ ; estimated) ^b	<u>U.S. EPA (2012a)</u>
Hydrolysis	$t_{1/2}$ = stable at pH 3 $t_{1/2}$ = 3,980 days at pH 7 $t_{1/2}$ = 101 days at pH 10	EnvCanada (2009) citing Brown et al. (1975)

Value ^a	References		
Water: 4%/28 days based on BOD 0%/28 days based on TOC 1%/28 days based on HPLC Test substance concentration 100 ppm (MITI test)	<u>NITE (2010); ECHA</u> (2018b)		
Water: 10%/27 days (OECD 302B) 15%/21 days (OECD 302B) in activated non- adapted industrial sludge 4 and 13%/28 days (OECD 301B) at 20 and 10 mg/L test substance concentration in activated domestic sludge_adaption not specified	EnvCanada (2009); EC (2000)		
70–90%/48 days (OECD 301B) at 20 mg/L test substance concentration in activated domestic sludge, adaption not specified			
Soil: $DT_{50} = 167$ days, $DT_{90} >> 100$ days based on test substance concentration 5 mg/kg in standard soil laboratory test	<u>EnvCanada (2009)</u>		
Soil: 0%/58 days at 80 mg/L test substance concentration related to DOC (ISO DIS 11734)	EC (2000) citing Noack (1993)		
9.2% total removal (7.3% by biodegradation, 1.9 by sludge and 0% by volatilization to air; estimated) ^b	<u>U.S. EPA (2012a)</u>		
0.6–0.8 and $\leq 1.2-5.1$ at test substance concentrations of 0.1 and 1.0 ppm (w/v), respectively (<i>Cyprinus carpio</i>)	<u>NITE (2010)</u>		
6.3 (estimated) ^b	<u>U.S. EPA (2012a)</u>		
2.6 (K_{OC} = 388; MCI method); 2 (K_{OC} = 103; K_{OW} method) (estimated) ^b	<u>U.S. EPA (2012a)</u>		
	Water: 4%/28 days based on BOD 0%/28 days based on TOC 1%/28 days based on HPLC Test substance concentration 100 ppm (MITI test) Water: 10%/27 days (OECD 302B) 15%/21 days (OECD 302B) in activated non- adapted industrial sludge 4 and 13%/28 days (OECD 301B) at 20 and 10 mg/L test substance concentration in activated domestic sludge, adaption not specified 70–90%/48 days (OECD 301B) at 20 mg/L test substance concentration in activated domestic sludge, adaption not specified Soil: DT ₅₀ = 167 days, DT ₉₀ >>100 days based on test substance concentration 5 mg/kg in standard soil laboratory test Soil: 0%/58 days at 80 mg/L test substance concentration related to DOC (ISO DIS 11734) 9.2% total removal (7.3% by biodegradation, 1.9 by sludge and 0% by volatilization to air; estimated) ^b 0.6–0.8 and ≤1.2–5.1 at test substance concentrations of 0.1 and 1.0 ppm (w/v), respectively (<i>Cyprinus carpio</i>) 6.3 (estimated) ^b		

Notes: ^aMeasured unless otherwise noted; ^bEPI SuiteTM physical property inputs: Log $K_{OW} = 1.78$, BP = 330 °C, MP = -55 °C, VP = 1.6×10^{-5} mm Hg, WS = 7,820 mg/L, SMILES O=P(OCCCl)(OCCCl)OCCCl TOC = total organic carbon; HPLC = High-Performance Liquid Chromatography; DOC = dissolved organic carbon; ·OH = hydroxyl radical; OECD = Organization for Economic Cooperation and Development; TG = test guideline; GC = gas chromatography; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand

Persistence and Bioaccumulation Summary

TCEP is a liquid with low volatility and high water solubility (7,820 mg/L at 20 °C). Estimated Henry's Law constant ($<1 \times 10-8$ atm-m³/mol) and vapor pressure ($1.6 \times 10-5$ mm Hg) data indicate that this chemical will be moderately persistent in surface water and soil. In the air, TCEP is expected to exist in the vapor phase where it may react with photochemically-produced hydroxyl radicals at an estimated rate corresponding to a half-life of 5.8 hours.

In aerobic aquatic environments, TCEP is not readily biodegradable. It achieved only 4% of its theoretical biological oxygen demand (BOD) over a 28-day incubation period using a sewage sludge inoculum and the MITI test method. In a standard soil laboratory test, TCEP had a half-

life of 167 days in aerobic soil; in anaerobic soil, it achieved 0% degradation after 58 days. These data indicate that this chemical may persist in subsurface environments, groundwater, or enclosed pipes when volatilization is not an option.

TCEP displayed low bioaccumulation potential with measured bioconcentration factor values of 0.6-0.8 and $\leq 1.2-5.1$ in carp at concentrations of 0.1 and 1.0 ppm, respectively. The estimated bioaccumulation factor (BAF) of 6.3 and log K_{OW} of 1.78 also indicate low bioaccumulation potential.

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

TCEP is not subject to any of the regulations listed in the previous paragraph.

7. Hazard potential

Approach

EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential hazards for TCEP (Tables 7 and 8, respectively).

Because there are very few publicly available assessments for TCEP 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>U.S. EPA, 2018a</u>). It uses a comprehensive chemical-specific literature search of the open literature that is conducted

according to the Standard Operating Procedures (SOPs)⁹. 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 TCEP, if available, to fill in potential data gaps when there were no reported observed effects for specific taxa exposed to TCEP (Table 8).

Potential Human Health and Environmental Hazard Tables

EPA identified human health and environmental hazards based on a review of the reasonable available information for TCEP (Tables 7 and 8, respectively).

⁹ 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
Acute Toxicity	X	Х	ECHA (2018a), ECHA (2018b), U.S. EPA (2015a), U.S. EPA (2015b), CPSC (2015), CPSC (2013), U.S. EPA (2009), EC (2009), IPCS (1998), NTP (1991)
Repeated Dose Toxicity	X	Х	NICNAS (2016), U.S. EPA (2015a), U.S. EPA (2015b), CPSC (2015), CPSC (2013), U.S. EPA (2009), EnvCanada (2009), EC (2009), IPCS (1998)
Genetic Toxicity	Х	Х	ECHA (2018b), NICNAS (2016), U.S. EPA (2015b), CPSC (2013), U.S. EPA (2009), EnvCanada (2009), EC (2009), IARC (1999), IPCS (1998), NTP (1991)
Reproductive Toxicity	X	Х	ECHA (2018a), NICNAS (2016), U.S. EPA (2015a), U.S. EPA (2015b), CPSC (2013), U.S. EPA (2009), EnvCanada (2009), EC (2009), IPCS (1998)
Developmental Toxicity	X	Х	<u>U.S. EPA (2015a), U.S. EPA (2015b), CPSC</u> (2013), <u>U.S. EPA (2009)</u> , <u>EnvCanada (2009)</u> , <u>EC</u> (2009)
Toxicokinetic	X	Х	ECHA (2018a), U.S. EPA (2015a), U.S. EPA (2015b), CPSC (2015), CPSC (2013), EC (2009), IPCS (1998)
Irritation/Corrosion	X		ECHA (2018b), U.S. EPA (2015b), CPSC (2013), EC (2009), IPCS (1998)
Dermal Sensitization	X		<u>U.S. EPA (2015b), EC (2009)</u>
Respiratory Sensitization			
Carcinogenicity	X	Х	ECHA (2018a), NICNAS (2016), U.S. EPA (2015a), U.S. EPA (2015b), CPSC (2013), U.S. EPA (2009), EnvCanada (2009), EC (2009), IARC (1999), IPCS (1998), NTP (1991)
Immunotoxicity			
Neurotoxicity	X	Х	ECHA (2018a), U.S. EPA (2015a), U.S. EPA (2015b), CPSC (2013), EnvCanada (2009), IARC (1999), IPCS (1998)
Epidemiological Studies or Biomonitoring Studies	X	Х	<u>U.S. EPA (2015a), NICNAS (2016), U.S. EPA</u> (2015b), CPSC (2015), IPCS (1998)

 Table 7. Potential Human Health Hazards Identified for Tris(2-chloroethyl) Phosphate

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 Groups	High Priority Chemical Candidate Tris(2-chloroethyl) phosphate (TCEP) (CASRN 115-96-8)		Isomers of Tris(2-chloroethyl) phosphate (TCEP) (CASRN 115-96-8) NONE		Data Sources
			Number of Studies	Observed Effects	Number of Studies	Observed Effects	
Aquatic	Acute	Vegetation	-		-		
	exposure	Invertebrate	-		-		
		Fish	1	Х	-		McGee et al. (2012)
		Non-Fish Vertebrates (i.e., amphibians, reptiles, mammals)	-		-		
	Chronic	Vegetation	-		-		
exposure	exposure	Invertebrate	-		-		
		Fish	-		-		
		Non-Fish Vertebrates (i.e., amphibians, reptiles, mammals)	-		-		
Terrestrial	Acute	Vegetation	-		-		
exposure Chronic exposure	exposure	Invertebrate	1	Х	-		Boyd et al. (2016)
		Vertebrates	-		-		
	Chronic	Vegetation	-		-		
	exposure	Invertebrate	-		-		
		Vertebrates	3		-		Chapin et al. (1998); Hardin et al. (1987); Fernie et al. (2015)

 Table 8. Potential Environmental Hazards Identified for Tris(2-chloroethyl) Phosphate

The dash indicates that no studies relevant for environmental hazard were identified during this 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 exposures and general population to TCEP.

Release potential for environmental and human health exposure

TCEP 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 TCEP.

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 TCEP 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 data to inform TCEP's exposure potential to the general population.

Results and Discussion

Release potential for environmental and human health exposure

TCEP's reported vapor pressure varies widely: 8.6×10^{-6} mm Hg at 20 °C and ranging between 1.6×10^{-5} mm Hg at 25 °C and <10 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 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 and used; 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.

TCEP does not have an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL)¹⁰, a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL)¹¹, or the Threshold Limit Value (TLV) set by American Conference of Governmental Industrial Hygienists (ACGIH).

TCEP's reported vapor pressure varies widely: 8.6×10^{-6} mm Hg at 20 °C and ranging between 1.6×10^{-5} mm Hg at 25 °C and <10 mm Hg at 25 °C, and TCEP can exist as a liquid and a wet solid. This 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.

TCEP is indicated as being used in paints and coatings. Products used as paints and coatings may be applied via spray or roll application methods. These methods may generate mists to which workers may be exposed.

Consumer exposure

Based on CDR reporting information, TCEP appears to be used as a flame retardant in the paint and coating manufacturing sector in 2012. In the 2016 CDR, all consumer and industrial use information were either not reported or reported as not known or reasonably ascertainable. The NIH Consumer Product Database and the Chemical and Products Database (<u>CPDat</u>) reported use of TCEP in consumer products such as adhesives, automotive products, building materials, fragrances, insulation, paint, textiles and toys (Table 9). In addition, TCEP was reported as used in children's products in the Washington State Children's Safe Product Act Database (<u>U.S. EPA</u> <u>2015a</u>). Existing assessments reported that TCEP may be present as an impurity in other commercial flame retardants (<u>ECHA 2018a</u>, <u>CPSC 2015</u>) or possibly in imported articles (<u>ECHA</u> <u>2018a</u>). Despite the decline in production and use of TCEP, as of 2016, the chemical has been measured in several consumer products such as car seats, changing table pads, and nursing pillows (<u>NICNAS 2016</u>, <u>U.S. EPA 2015a</u>).

Chemical Identity	Consumer Product Database			
Chemical Identity	Consumer Uses (List)			
Tris(2-chloroethyl) Phosphate (115-96-8)	Adhesive, automotive, building material, electrical insulation, fragrance, insulation, paint, textile, toys			

Table 9. Exposure Information for Consumers

Reference: <u>CPDat</u>

General population exposure

Releases of TCEP during certain conditions of use, such as industrial processing as a flame retardant and consumer and commercial use, may result in general population exposures via

¹⁰ OSHA, 2009. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs). <u>https://www.osha.gov/dsg/annotated-pels/tablez-1.html</u>

¹¹ NIOSH, 2005. NIOSH Pocket Guide to Chemical Hazards. <u>https://www.cdc.gov/niosh/npg/npgdcas.html</u>

ingestion of indoor dust or through diet (via drinking water and fish ingestion), and dermal or inhalation routes (<u>NICNAS 2016</u>, <u>U.S. EPA 2015a</u>, <u>CPSC 2015</u>, <u>CPSC 2013</u>). TCEP was also reported in water, soil, sediment, vegetation/diet, and other environmental media; it was not reported in human or ecological biomonitoring matrices (Table 10).

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	no	no	no	<u>U.S. EPA (1996)</u>
FDA Total Diet Study	yes	no	no	<u>FDA (1991)</u>
Great Lakes Environmental Database	no	no	no	<u>U.S. EPA (2018b)</u>
Information Platform for Chemical Monitoring Data	no	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	<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	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	no	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 10. Exposure Information for the Environment and General Population

^aConcen.= concentration ^bBiomon.= biomonitoring

Existing assessments also indicated TCEP was detected in ambient air, indoor air, indoor dust, landfill sludge, sewage sludge, drinking water, groundwater, surface water, and wastewater (NICNAS 2016, U.S. EPA 2015a, U.S. EPA 2015b, CPSC 2015, CPSC 2013, EnvCanada 2009, EC 2009, IARC 1999, IPCS 1998), as well as in human breast milk, hair, and nails (U.S. EPA 2015a, NICNAS 2016, CPSC 2015) and in the following biota: avian, fish, aquatic animals (including shellfish), mammalian species (U.S. EPA 2015a, U.S. EPA 2015b, IPCS 1998). Metabolites of TCEP were detected in human urine (NICNAS 2016, U.S. EPA 2015a, CPSC 2015). Based on fate properties, such as water solubility, Henry's Law constant, and soil organic carbon-water partition coefficient, EPA anticipates possible presence of TCEP in water and soil (EnvCanada 2009, EC 2009, IPCS 1998, U.S. EPA 2015a). The primary route of exposure for very young children is via ingestion of indoor dust; mouthing of articles, and hand-to-mouth behavior (ECHA 2018a, NICNAS 2016, CPSC 2015, CPSC 2013, EC 2009).

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 TCEP 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 TCEP 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 TCEP 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, and exposure to the general population, including 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, reproductive toxicity, developmental toxicity, toxicokinetics, carcinogenicity, neurotoxicity, and observations in epidemiological studies and biomonitoring studies).

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