

Final Scope of the Risk Evaluation for Tris(2-chloroethyl) Phosphate

(TCEP)

CASRN 115-96-8

August 2020

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Docket

Supporting information can be found in public docket: <u>EPA-HQ-OPPT-2018-0476</u>.

Disclaimer

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ABBREVIATIONS AND ACRONYMS

ADME Absorption, Distribution, Metabolism, and Excretion

BAF Bioaccumulation factor
BCF Bioconcentration factor
BMF Biomagnification factor

CBI Confidential Business Information

CDR Chemical Data Reporting

ChemSTEER Chemical Screening Tool for Exposure and Environmental Releases

CHRIP Chemical Risk Information Platform

COC Concentration of concern

CPCat Chemical and Product Categories
CSCL Chemical Substances Control Law

CSF Cancer Slope Factor EC Engineering control

ECHA European Chemical Agency

 EC_x Concentration that causes a response that is x% of the maximum

ESD Emission Scenario Document

FYI For Your Information
GS Generic Scenario

HAP Hazardous Air Pollutant IUR Inhalation Unit Risk

LC₅₀ Lethal concentration of 50% of the test organisms LC_x Lethal concentration that is x% of the maximum

LOAEL Lowest observed adverse effect level LOEC Lowest observed effect concentration

lw Lipid Weight

mm Hg Millimeter(s) of Mercury MOE Margins Of Exposure

NIOSH National Institute for Occupational Safety and Health

NOAEL No observed adverse effect level NOEC No observed effect concentration

ONU Occupational Non-User

OPPT Office of Pollution Prevention and Toxics

OSF Oral Slope Factor

OSHA Occupational Safety and Health Administration

PBT Persistent, bioaccumulative, toxic

PECO Population, exposure, comparator, outcome

PEL Permissible Exposure Limit

PESO Pathways and processes, exposure, setting or scenario, and outcomes

PESS Potentially Exposed or Susceptible Subpopulation

PNOR Particulates Not Otherwise Regulated

POD Point of Departure

POTW Publicly Owned Treatment Works
PPE Personal Protective Equipment

RCRA Resource Conservation and Recovery Act

RESO Receptors, exposure, setting or scenario, and outcomes

SDS Safety Data Sheet

TCEP Tris(2-chloroethyl) Phosphate

TIAB Title and abstract

TRI Toxics Release Inventory

ww Wet Weight

WWTP Wastewater Treatment Plant

EXECUTIVE SUMMARY

In December 2019, EPA designated tris(2-chloroethyl) phosphate (TCEP) (CASRN 115-96-8) as a high-priority substance for risk evaluation following the prioritization process required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2019-0131). The first step of the risk evaluation process is the development of the draft scope document. EPA published the *Draft Scope of the Risk Evaluation for Tris*(2-chloroethyl) *Phosphate CASRN 115-96-8* (U.S. EPA, 2020c) and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0476) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for TCEP. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The scope for TCEP includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in the risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance.

General Information. TCEP is a liquid and primarily used as a flame retardant with a total production volume in the United States of 39,682 pounds.

Reasonably Available Information. EPA leveraged the data and information sources already described in the *Proposed Designation of Tris*(2-chloroethyl) *Phosphate* (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation (U.S. EPA, 2019c) to inform the development of this scope document. Furthermore, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard), and the search and screening results are provided in Section 2.1. EPA used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for TCEP. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. EPA will consider additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

Conditions of Use. EPA plans to evaluate manufacturing (including importing), processing, distribution in commerce, industrial, commercial and consumer uses, and disposal of TCEP in the risk evaluation. TCEP is imported into the United States and is primarily used as a flame retardant in paint and coating manufacturing, polymers including polyester resin, and articles, such as aircraft interiors. In addition, TCEP is used as a laboratory chemical. TCEP is incorporated into fabric and textiles, foam seating and bedding products, and paints and coatings. In the past, TCEP was incorporated into building and construction materials, such as roofing insulation and wood resin composites. Some of these products may still be present in consumers' homes and commercial infrastructure. EPA identified these conditions of use from information reported to EPA through CDR, published literature, and consultation with stakeholders for both uses currently in production and uses for which production may have ceased.

EPA did not revise any conditions of use in the final scope document for TCEP based on public comments received (Docket ID: <u>EPA-HQ-OPPT-2018-0476</u>) on the draft scope. Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for TCEP are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards, and receptors throughout the life cycle of the chemical substance. EPA considered reasonably available information as well as public comments received on the draft scope document for TCEP in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for TCEP on the following exposures, hazards, and receptors.

• Exposures (Pathways and Routes), Receptors and PESS. EPA plans to evaluate releases to the environment as well as human and environmental exposures resulting from the conditions of use of TCEP that EPA plans to consider in the risk evaluation. Exposures for TCEP are discussed in Section 2.3. Additional information gathered through systematic review searches will also inform expected exposures.

EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether other EPA administered statutes and regulatory programs cover TCEP in media pathways falling under the jurisdiction of those authorities. TCEP does not have pathways covered under the jurisdiction of other EPA-administered laws. In Section 2.6, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of TCEP within the scope of the risk evaluation.

EPA considered reasonably available information and comments received on the draft scope for TCEP in determining the human and environmental exposure pathways, routes, receptors and PESS for inclusion in the final scope. EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation:

- Occupational exposure: EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use, or disposal of TCEP.
- Consumer and bystander exposure: EPA plans to evaluate oral and dermal exposure to TCEP for consumers, and inhalation exposure for consumers and bystanders from use of paints and coatings, fabric, textiles and leather products, foam setting and bedding products, building/construction materials, wood and engineered wood products containing TCEP; and children's mouthing of products/articles containing TCEP.
- General population exposure: EPA plans to evaluate general population exposure to TCEP via the oral route from drinking water, surface water, groundwater, fish ingestion, human breast milk and soil, via the inhalation route from ambient air and via dermal route from contact with drinking water, surface water, groundwater and soil.
- PESS: EPA plans to evaluate children, women of reproductive age (e.g., pregnant women, breast-feeding women), workers, and consumers as receptors and PESS in the risk evaluation.
- Environmental exposure: EPA plans to evaluate exposure to TCEP for aquatic and terrestrial receptors.

• *Hazards*. Hazards for TCEP are discussed in Section 2.4. EPA completed preliminary reviews of information (*e.g.*, federal and international government chemical assessments) to identify potential environmental and human health hazards for TCEP as part of the prioritization (<u>U.S. EPA, 2019c</u>) and scoping process (<u>U.S. EPA, 2020c</u>). EPA also considered reasonably available information collected through systematic review methods as outlined in Appendix A and public comments received on the draft scope for TCEP in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for TCEP.

EPA plans to evaluate all potential environmental and human health hazard effects identified for TCEP in Sections 2.4.1 and 2.4.2, respectively. Identified through the data screening phase of systematic review, the potential environmental hazard effects and related information that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal and reproductive for TCEP. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for TCEP that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue.

Analysis Plan. The analysis plan for TCEP is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various information streams (*i.e.*, chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of TCEP to date which includes a review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

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

1 INTRODUCTION

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

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

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high-priority substances for risk evaluations (Docket ID: EPA-HQ-OPPT-2019-0131) (84 FR 71924, December 30, 2019), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. TCEP is one of the chemicals designated as a high priority substance for risk evaluation. On April 9, 2020, EPA published the *Draft Scope of the Risk Evaluation for Tris*(2-chloroethyl) Phosphate CASRN 115-96-8 (85 FR 19941, April 9, 2020) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments received (Docket ID: EPA-HQ-OPPT-2018-0476) on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information ¹ to support the development of this scope document for TCEP. EPA leveraged the data and information sources already collected in the documents supporting the chemical substance's high-priority substance designation. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

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

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

3. Data and information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

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

Search terms were used to search each of the literature streams and gather TCEP studies. These terms and the methods used to develop them are listed in Appendix A. The studies resulting from the search process were loaded into the EPA Health and Environmental Research Online (HERO) database and then prioritized to screen first the literature likely relevant for each of the disciplines: fate, physical and chemical properties, engineering, exposure and hazard. The tools and methods used to manage the screening process are also outlined in Appendix A. The studies resulting from the search underwent a title/abstract screening process, which tagged them by topic or category. Following this, a determination was made to move studies forward into full-text screening. The criteria used in the screening process for each discipline are found in the population, exposure, comparator, outcome (PECO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and heat maps in Section 2.1.3. The screening process was conducted based on EPA's planning, execution and assessment activities outlined in Appendix A.

EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods.

2.1.1 Search of Gray Literature for All Disciplines

EPA surveyed the gray literature² and identified 95 search results relevant to EPA's risk evaluation needs for TCEP. Appendix A.3.4 lists the gray literature sources that yielded 95 discrete data or information sources relevant to TCEP. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (*e.g.*, physical and chemical properties, environmental fate, environmental hazard, human health hazard, exposure, engineering), and the breakdown is shown in Figure 2-1. EPA will consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

6

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

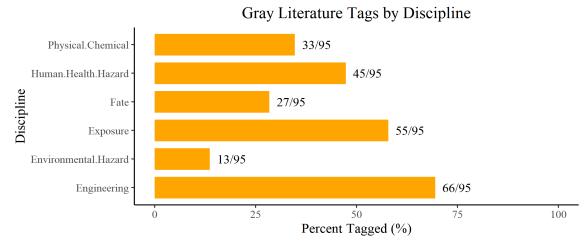


Figure 2-1. Gray Literature Tags by Discipline for TCEP

The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

2.1.2 Search of Literature from Publicly Available Databases (Peer-Reviewed Literature)

EPA has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature physical and chemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of TCEP. Eligibility criteria were applied in the form of PECO statements. Included references met the PECO or similar criteria, whereas excluded references did not meet the criteria (*i.e.*, not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation.

EPA created literature inventory trees to graphically illustrate the flow of data and information sources following full-text screening (see Figure 2-2, Figure 2-3, Figure 2-5,

Figure 2-7, and Figure 2-9). EPA used the Health Assessment Workplace Collaborative (HAWC) tool to develop web-based literature inventory trees illustrating, through interactive links, studies that were included or excluded. These literature inventory trees enhance the transparency of the decisions resulting from the screening process described in Appendix A. For each of the corresponding disciplines, the literature was tagged to be included for evaluation during the risk evaluation. The literature inventory tree for physical and chemical properties are provided as a static diagram (Figure 2-2). For all other disciplines, static screen captures are provided in addition to links within each figure's caption to the interactive trees. The links show individual studies that were tagged as included, excluded, or supplemental. Supplemental studies did not meet all inclusion criteria but may be considered during the risk evaluation as supporting information (see Appendix A). The citations for these studies can be accessed through the hyperlink provided in the associated caption below each figure. In some figures, the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-

categories may be smaller than the main category because some studies may not be depicted in the subcategories if their relevance to the risk evaluation was unclear.

In addition, EPA tabulated the number and characteristics of the data and information sources included in the full-text screening process in the form of a literature inventory heat map for the fate, engineering, exposure and hazard information (see

Figure 2-4,

Figure 2-8, Figure 2-10). For each of these four disciplines, a static image of the literature inventory heat map is provided, and a link to the interactive version presented in HAWC is included in the caption below each diagram.

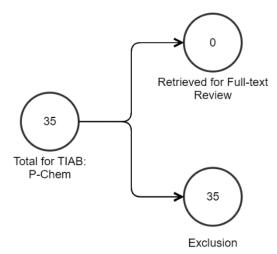


Figure 2-2. Peer-reviewed Literature Inventory Tree – Physical and Chemical Properties Search Results for TCEP

Data in this static figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. TIAB refers to "title and abstract" screening.

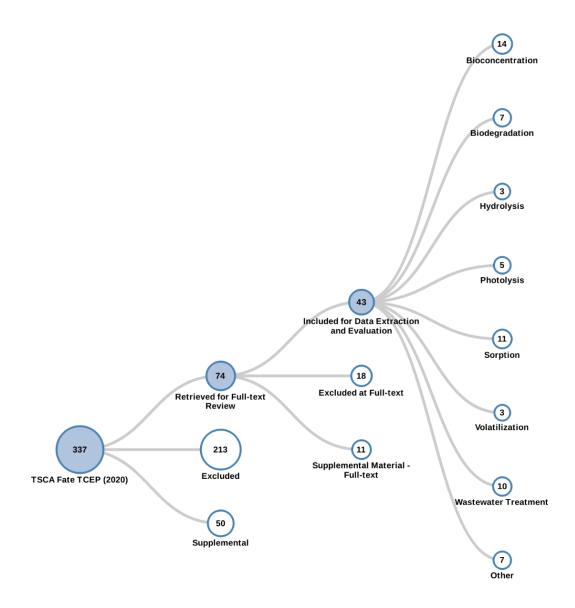


Figure 2-3. Peer-reviewed Literature Inventory Tree – Fate and Transport Search Results for TCEP

Click <u>here</u> for interactive literature inventory tree. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

	Wedia						
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total	
Bioconcentration	1	7	1	8		14	
Biodegradation	1	4	1	6		7	
Hydrolysis				3		3	
Photolysis				5		5	
Sorption		9	3	7		11	
Volatilization	2	2		1		3	
Wastewater Treatment		1	10	8		10	
Other	3	4		5		7	
Grand Total	4	16	12	30		43	

Media

Figure 2-4. Peer-reviewed Literature Inventory Heat Map – Fate Search Results for TCEP Click here to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate the total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by media or endpoint. The darker the color, the more references are available for a given media or endpoint. Data in this figure represents all references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

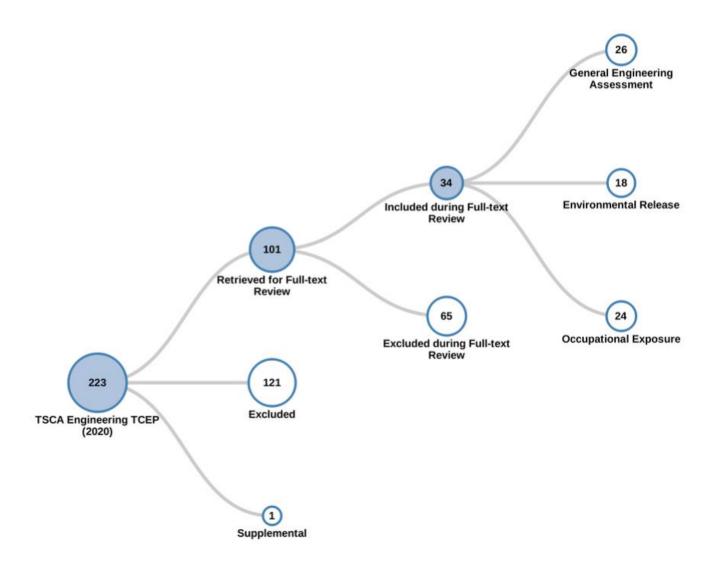


Figure 2-5. Peer-reviewed Literature Inventory Tree – Engineering Search Results for TCEP Click here to view the interactive literature inventory tree. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

Data Type 2	Evidence Tags	
	Description of release source	14
	No evidence tag	1
Environmental	Release frequency	3
Releases	Release or emission factors	8
Releases	Release quantity	6
	Waste treatment methods and pollution control	7
	Total	18
	Chemical concentration	11
	Life cycle description	7
General	No evidence tag	2
	Number of sites	5
Engineering Assessment	Process description	17
Assessment	Production, import, or use volume	11
	Throughput	3
	Total	26
	Area sampling data	9
	Dermal exposure data	10
	Engineering control	4
	Exposure duration	5
	Exposure frequency	3
	Exposure route	15
Occupational	No evidence tag	2
Exposures	Number of workers	6
	Particle size characterization	
	Personal protective equipment	10
	Personal sampling data	7
	Physical form	10
	Worker activity description	12
	Total	24
Grand Total		34

Figure 2-6. Peer-reviewed Literature Inventory Heat Map – Engineering Search Results for TCEP Click here to view the interactive version for additional study details. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

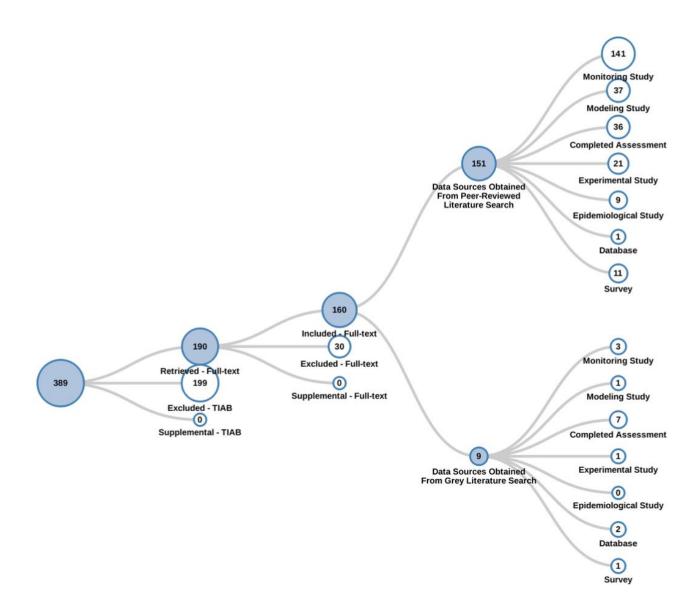


Figure 2-7. Peer-reviewed Literature Inventory Tree – Exposure Search Results for TCEP Click here to view the interactive literature inventory tree. Data in this static figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

				Data	а Туре			
Media (group)	Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Tota
Ambient Air	14	4	9	5				20
Biosolids/Sludge								
Drinking Water	3		3	1				6
Groundwater	2		3	1				5
Land Disposal/Landfill			1					1
Sediment	5		2	1				8
Soil	5	2	4					8
Surface Water	7	1	4	1		1	1	11
Wastewater	1		3				1	4
Aquatic Species	3	1	3					6
Terrestrial Species	3							6
Consumer	23	9	10	18	1		2	35
Dietary	12	3	6	1		1	2	15
Dust	73	24	29	2	5		7	78
Exposure Factors	7	3	6	2		1	1	10
Exposure Pathway	12	5	9	3		2	1	19
Human Biomonitoring	38	5	10		4	1	4	41
Indoor Air	49	12	16	9	3		3	57
Isomers	1		1		1			1
Use Information	3	1	6	2				8
No Evidence Type	3	1		1				3
Grand Total	144	38	43	22	9	3	12	161

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

Click <u>here</u> to view the interactive version for additional study details. The column totals, row totals, and grand totals indicate total numbers of unique references, as some references may be included in multiple cells. The various shades of color visually represent the number of relevant references identified by exposure media or data type. The darker the color, the more references are available for a given exposure media or data type. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

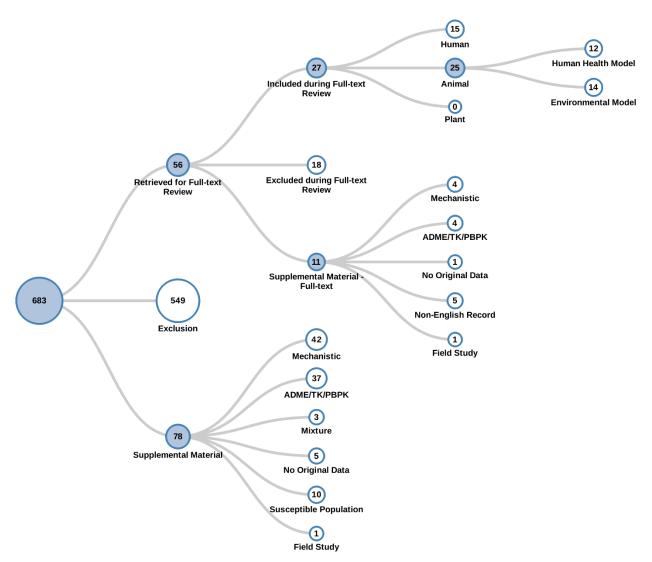


Figure 2-9. Peer-reviewed Literature Inventory Tree – Human Health and Environmental Hazard Search Results for TCEP

Click <u>here</u> to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of May 18, 2020. Additional data may be added to the interactive version as they become available.

			Evidence Type		
Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	7	5	5		10
Cancer	6	5	1		7
Cardiovascular	1	1	3		3
Developmental	1	1	5		6
Endocrine	8	6	3		10
Gastrointestinal	1	1	1		2
Hematological and Immune	4	3	2		4
Hepatic	4	3	1		4
Mortality	3	3	3		5
Musculoskeletal	1	1	6		6
Neurological	9	8	9		17
Nutritional and Metabolic	3	2	3		5
Ocular and Sensory	1	1	4		5
PBPK	1	1	2		2
Renal	7	5	1		7
Reproductive	3	3	4		6
Respiratory	1	1			1
Skin and Connective Tissue	1	1			1
No Tag					
Grand Total	15	12	14		27

Evidence Type

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

Click <u>here</u> to view the interactive version for additional study details. The numbers indicate the number of studies with TIAB keywords related to a particular health outcome, not the number of studies that observed an association with TCEP. Evidence types were manually extracted, and Health Systems were determined via machine learning. Therefore, the studies examining multiple Health Outcomes and Evidence types, connections between health outcome, and evidence type may not be accurately represented. If a study evaluated multiple health outcomes or included multiple populations or study designs, it is shown here multiple times. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of May 18, 2020. Additional data may be added to the interactive version as they become available.

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 15 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are presented in Appendix A.2.1. EPA identified 13

submissions that met the inclusion criteria in these statements and identified 2 submissions with supplemental data.³ EPA excluded zero submissions.

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

Discipline	Included	Supplemental ^b
Physical and Chemical Properties	1	0
Environmental Fate and Transport	2	0
Environmental and General Population Exposure	4	0
Occupational Exposure/Release Information	1	0
Environmental Hazard	4	0
Human Health Hazard	6	2

^a Individual submissions may be relevant to multiple disciplines.

2.2 Conditions of Use

As described in the *Proposed Designation of Tris*(2-chloroethyl) *Phosphate* (*CASRN 115-96-8*) *as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c), EPA assembled information from the CDR program to determine conditions of use⁴ or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA will utilize the most recent CDR information. EPA also consulted a variety of other sources to identify uses of TCEP, including published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing TCEP, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) (U.S. EPA, 2019b) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, EPA incorporated communications with companies, industry groups, and public comments to supplement the use information.

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

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

^b Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

³ EPA may further consider some supplemental references, depending on the reasons for tagging, as supplemental or excluded.

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

2.2.1 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Table 2-2 lists the conditions of use that EPA plans to include in the scope of the risk evaluation.

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

Life Cycle Stage a	Category ^b	Subcategory ^c	References
Manufacturing	Import	Import	<u>U.S. EPA (2019a)</u>
Processing	Processing – incorporation into formulation, mixture or reaction product	Flame retardant in: Paint and coating manufacturing	U.S. EPA (2019a); Duratec Surfacing Technology (2018)
	Processing – incorporation into formulation, mixture or reaction product	Flame retardant in: Polymers (e.g. polyester resin)	EPA-HQ-OPPT-2018-0476- 0015; EPA-HQ-OPPT-2018- 0476-0012; BJB Enterprises (2018)
	Processing – incorporation into article	Flame retardant (e.g., aircraft interiors)	EPA-HQ-OPPT-2018-0476- 0006
	Recycling	Recycling	<u>U.S. EPA (2019a)</u>
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial Use	Other use	Aircraft interiors and aerospace products	EPA-HQ-OPPT-2018-0476- 0006
Commercial Use	Other use	Aircraft interiors and aerospace products	EPA-HQ-OPPT-2018-0476- 0006
Commercial	Paints and coatings	Paints and coatings	<u>U.S. EPA (2019a)</u>
Use	Other use	e.g., Laboratory chemicals	TCI America (2018)
	Furnishing, Cleaning, Treatment/Care Products	Fabric, textile, and leather products not covered elsewhere	EPA-HQ-OPPT-2018-0476- 0015
	Construction, Paint, Electrical, and Metal Products	Building/construction materials not covered elsewhere (e.g., roofing insulation)	EPA-HQ-OPPT-2018-0476- 0015; Environment Canada (2009), cites Plastics Technology (2003)
	Furnishing, Cleaning, Treatment/Care Products	Foam Seating and Bedding Products	Stapleton et al. (2011)

Life Cycle Stage ^a	Category ^b	Subcategory ^c	References
	Construction, Paint, Electrical, and Metal Products	Building/construction materials - wood and engineered wood products (e.g., composites)	Environment Canada (2009), cites IARC (1990), OECD (2006); IPCS (1998)
Consumer Use	Paints and coatings	Paints and coatings	<u>U.S. EPA (2019a)</u>
	Furnishing, Cleaning, Treatment/Care Products	Fabric, textile, and leather products not covered elsewhere	EPA-HQ-OPPT-2018-0476- 0015
	Construction, Paint, Electrical, and Metal Products	Building/construction materials not covered elsewhere (e.g., roofing insulation)	EPA-HQ-OPPT-2018-0476- 0015; (Environment Canada, 2009)), cites <u>Plastics</u> Technology (2003)
	Furnishing, Cleaning, Treatment/Care Products	Foam Seating and Bedding Products	Stapleton et al. (2011)
	Construction, Paint, Electrical, and Metal Products	Building/construction materials - wood and engineered wood products (e.g., wood resin composites)	Environment Canada (2009), cites <u>IARC</u> (1990), <u>IPCS</u> (1998), <u>OECD</u> (2006)
Disposal	Disposal	Disposal	

- ^a Life Cycle Stage Use Definitions (40 CFR § 711.3)
- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA Section 6(a)(5) to reach both.
- b These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of TCEP in industrial and/or commercial settings and for consumer uses.
- ^c These subcategories reflect more specific conditions of use of TCEP.

In the final scope, EPA made the following changes to the conditions of use:

EPA combined "processing – incorporation into formulation, mixture or reaction product – flame retardant in: polyester resin" and "processing – incorporation into formulation, mixture or reaction product – flame retardant in: thermoplastics" under "processing – incorporation into formulation, mixture or reaction product – flame retardant in: polymers (*e.g.*, polyester resin)" to cover all types of polymers using TCEP.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017), TSCA Section 6(b)(4)(D) requires EPA to

identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33726, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance⁵. As a result, EPA does not plan to include in this scope or in the risk evaluation activities described below that the Agency does not consider to be conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

No activities were excluded for TCEP.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of TCEP in 2015 was 39,682 pounds (<u>U.S. EPA, 2020a</u>). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of Tris*(2-chloroethyl) *Phosphate* (*CASRN 115-96-8*) as a *High-Priority Substance for Risk Evaluation* (EPA-HQ-OPPT-2018-0476-0007) (<u>U.S. EPA, 2019c</u>), and will include more recent production volume information from the 2020 CDR reporting period in the risk evaluation to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-11. TCEP Life Cycle Diagram provides the lifecycle diagram for TCEP. The life cycle diagram is a graphical representation of the various life stages of the categories included within the scope of the risk evaluation. The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). Appendix E contains additional descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use and disposal category.

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

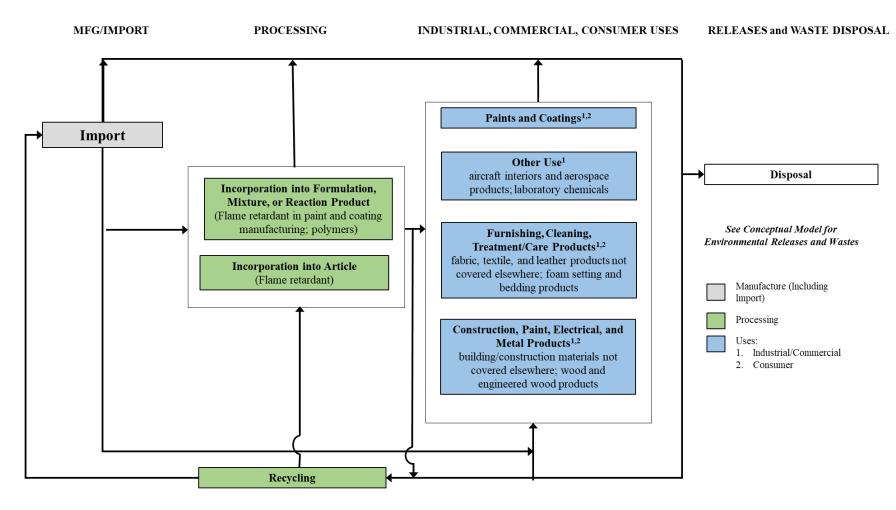


Figure 2-11. TCEP Life Cycle Diagram

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for TCEP. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible or known sources. Release pathways and routes will be described in Section 2.6. to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and environmental receptors. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to TCEP.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (*i.e.*, transport and transformation) and the eventual environmental concentrations. It can also inform the hazard assessment. Table 2-3 summarizes the physical and chemical property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 2020. This table differs from that presented in the *Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-12 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0476).

Table 2-3. Physical and Chemical Properties of TCEP

Property or Endpoint	Value ^a	Reference	Data Quality Rating
Molecular formula	C ₆ H ₁₂ Cl ₃ O ₄ P	NA	NA
Molecular weight	285.49 g/mol	NA	NA
Physical state	Liquid	NLM (2015)	High
Physical properties	Clear, transparent liquid	NLM (2015)	High
Melting point	-55°C	NLM (2015)	High
Boiling point	330°C	NLM (2015)	High
Density	1.39 g/cm ³ at 25°C	Haynes (2014)	High
Vapor pressure	0.0613 mm Hg at 25°C	NLM (2015)	High
Vapor density	Not available		

Property or Endpoint	Value ^a	Reference	Data Quality Rating
Water solubility	7820 mg/L at 20°C	NLM (2015)	High
Octanol/water partition coefficient (log Kow)	1.78	NLM (2015)	High
Henry's Law constant	2.55×10 ⁻⁸ atm·m ³ /mole at 25°C (Bond method)	<u>U.S. EPA (2012b)</u>	
Flash point	222°C	RSC (2019)	Medium
Auto flammability	Not available		
Viscosity	45 cP at 20°C	U.S. EPA (2012b)	High
Refractive index	1.4721	Haynes (2014)	High
Dielectric constant	Not available		

^a Measured unless otherwise noted.

NA = Not applicable

Figure 2-12 displays a summary of the data collected as of June 2020 for eight physical and chemical values routinely used in TSCA existing chemical risk evaluations. The box and whisker plots for each endpoint illustrate the mean (average, indicated by the blue diamond) and the 10th, 25th, 50th (median), 75th, and 90th percentiles. All individual data points are indicated by black squares, and value preliminarily selected for use in the risk evaluation is overlaid (indicated by the orange circle) to provide context for where it lies within the distribution of the dataset. The number of unique primary data sources is indicated below each box and whisker plot. If multiple sources presented equivalent values and cited the same primary source, only one of those was included in the statistical calculations. As a result, the number of sources listed in Figure 2-12 may differ from the total number of data sources presented in Figure 2-12. Where no data could be identified through systematic review, text appears to clearly demonstrate the gap for the endpoint.

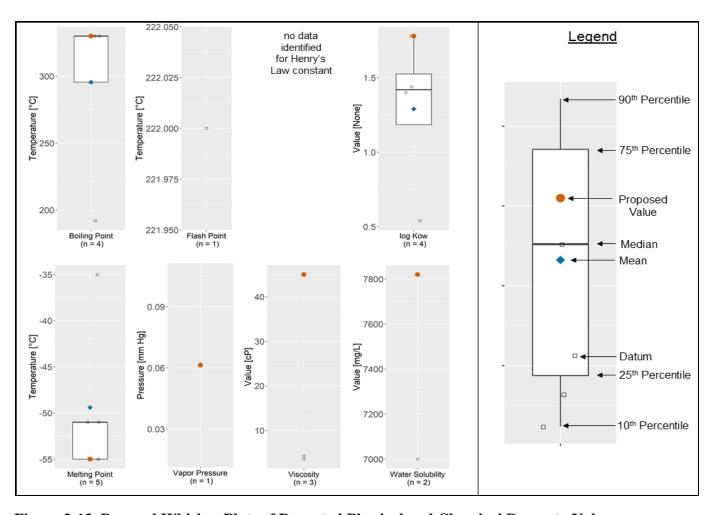


Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for TCEP. EPA plans to use the environmental fate characteristics described in Appendix C to support the development of the risk evaluation for TCEP. The values for the environmental fate properties may be updated as EPA evaluates and integrates additional information into the risk evaluation through systematic review methods.

2.3.3 Releases to the Environment

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

TCEP is not reported to the Toxics Release Inventory (TRI). There may be releases of TCEP from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill. Articles that contain TCEP may release TCEP to the environment during use or through recycling and disposal. EPA plans to review reasonably available data in conducting the exposure assessment component of the risk evaluation for TCEP.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of TCEP can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota) via surface water, sediment, soil and ambient air. Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, bioaccumulation and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review available environmental exposure data in biota in the risk evaluation. Monitoring data were identified in EPA's search for reasonably available information on environmental exposures in biota to inform development of the environmental exposure assessment for TCEP. Relevant and reliable monitoring studies provide information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

EPA plans to review available environmental monitoring data for TCEP. USGS's Monitoring Data – National Water Quality Monitoring Council has identified TCEP in surface water, ground water and sediment. In the screening study from the Norwegian Arctic (Hallanger et al., 2015) TCEP were detected in the fish samples (< 0.6 - 59 ng/g lw) and TCEP was detected in the seabird samples (< 0.5 - 4.7 ng/g ww). TCEP in herring gull eggs from the Lake Huron area in the US have been measured (Chen et al., 2012).

In (<u>Sengupta et al., 2014</u>), water samples were collected during two low-flow events at locations above and below the discharge points of water reclamation plants in Southern California. TCEP was quantified found in aggregate with other chlorinated chemicals.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA plans analyze exposure to occupational non-users (ONUs), workers who do not directly handle the chemical but perform work in an area where the chemical is present. EPA also plans to consider the effect(s) that engineering controls (ECs) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the risk evaluation.

EPA plans to evaluate potential exposures from the processing of the chemical as it is incorporated into formulations and products. TCEP is used as an additive flame retardant. In general, EPA plans to evaluate the potential for exposure from additive flame retardants due to blooming and release from article components during their manufacture and industrial/commercial use.

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

- Unloading and transferring TCEP to and from storage containers to process vessels during manufacturing, processing and use;
- Handling and disposing of waste containing TCEP during manufacturing, processing, use and recycling;
- Cleaning and maintaining equipment during manufacturing, processing, uses and recycling;
- Sampling chemicals, formulations or products containing TCEP for quality control during manufacturing, processing, use and recycling;
- Performing other work activities in or near areas where TCEP is used.

 Repackaging chemicals, formulations or products containing TCEP during manufacturing, processing, use and recycling.

TCEP can exist as a liquid and a wet solid and reported vapor pressure of 0.0613 mm Hg at 25°C (see Section 2.3.1). EPA anticipates inhalation of vapor, mist, dust and/or other respirable particles as an exposure pathway for workers and occupational non-users during the manufacture, processing, and commercial/industrial use of various products containing TCEP (for example, particulate generated during manufacture and handling of foam and incorporation of foam other article components into finished products, and mist generated during application to textiles and application of paints and coatings). Occupational exposure limits for TCEP have not been established by the Occupational Safety and Health Administration (OSHA), the American Conference of Government Industrial Hygienists (ACGIH), or the National Institute for Occupational Safety and Health (NIOSH). However, the OSHA Permissible Exposure Limit (PEL) for Particulates Not Otherwise Regulated (PNOR) (15 mg/m³) (29 CFR 1910.1000) may be applicable if particulate matter containing TCEP is generated during industrial operations.

EPA generally does not evaluate occupational exposures through the oral route. Workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. In addition, workers may transfer chemicals from their hands to their mouths. The frequency and significance of this exposure route are dependent on several factors including the physical and chemical properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace training and practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). EPA will consider the relevance of this exposure route on a case-by-case basis, taking into consideration the aforementioned factors and any reasonably available information, and may assess oral exposure for workers for certain COUs and worker activities where warranted. For certain conditions of use of TCEP, EPA plans to consider inhalation exposure to dust/particulates for workers and ONUs. As inhalation exposure to dust/particulates may occur, EPA plans to consider potential exposure for particulates that deposit in the upper respiratory tract from inhalation exposure and may be ingested via the oral route.

EPA plans to evaluate dermal exposure to workers from contact with liquids during packaging and repackaging operations at import sites when TCEP is handled as a liquid. EPA also plans to evaluate dermal exposure to solids during these operations if TCEP is formulated with solid chemicals and handled as a solid. Dermal exposure by ONUs is not expected for the condition of uses as they are not expected to directly handle the chemical.

2.3.6 Consumer Exposures

TCEP appears to be widely used in consumer products, specifically paints and coatings, electrical and electronic products, building/construction materials, and batteries. The main exposure routes for these uses where consumers interact with products and articles containing TCEP are dermal, inhalation, and dust ingestion, including children's mouthing of articles (*e.g.*, plastics, textiles, wood products) containing TCEP. Based on these potential sources and pathways of exposure, EPA plans to analyze oral, dermal and inhalation routes of exposure to consumers and the inhalation route for bystanders that may result from the conditions of use of TCEP.

2.3.7 General Population Exposures

Releases of TCEP from certain conditions of use, such as manufacturing, processing or disposal activities, may result in general population exposures. EPA plans to evaluate the reasonably available

literature for the presence of TCEP in drinking water, ground water, ambient air, indoor air, fish, human breast milk, and dust and soil, which may be mouthed or ingested.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on TCEP as well as public comments received on the *Proposed Designation of Tris*(2-chloroethyl) *Phosphate* (*CASRN 115-96-8*) as a *High-Priority Substance for Risk Evaluation* (<u>U.S. EPA</u>, 2019c) and draft scope for TCEP (<u>U.S. EPA</u>, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following potential environmental hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic ocular and sensory, renal, and reproductive (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.*, federal and international government chemical assessments) on TCEP as well as public comments on the *Proposed Designation of Tris*(2-chloroethyl) *Phosphate* (*CASRN 115-96-8*) as a *High-Priority Substance for Risk Evaluation* (<u>U.S. EPA, 2019c</u>) and draft scope for TCEP (<u>U.S. EPA, 2020c</u>) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: acute, repeated dose, genetic, reproductive, developmental, toxicokinetic, cancer and neurological effects.

Since prioritization, EPA applied automated techniques during the data screening phase of systematic review to identify the following additional potential human health hazards and related information that may be considered for the risk evaluation (as explained in Appendix A): ADME, PBPK, cardiovascular, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, nutritional and metabolic, ocular and sensory, renal, respiratory and skin and connective tissue (Figure 2-10). A summary of references identified during the screening step of systematic review is included in the interactive literature inventory trees (Figure 2-9). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the list of potential hazard effects to be analyzed in the risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA§ 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women,

workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

EPA identified the following potentially exposed or susceptible subpopulations (PESS) based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (*e.g.*, pregnant women), lactating females, workers, including ONUs and users, and consumers, including users and bystanders (<u>U.S. EPA, 2019c</u>). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation. Following further evaluation of the reasonably available information, EPA may evaluate PESS in the general population as they relate to fence line communities.

In developing exposure scenarios, EPA plans to analyze reasonably available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (*e.g.*, children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (*e.g.*, activities, duration or location of exposure) when compared with the general population (<u>U.S. EPA, 2006b</u>). Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). Based on these analyses, EPA may update the list of PESS in the risk evaluation.

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of TCEP. Pathways and routes of exposure associated with workers and occupational non-users are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes are discussed and depicted the conceptual model shown in Section 2.6.3.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-13 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of TCEP that EPA plans to include in the risk evaluation. There is potential for exposure to workers and ONUs via inhalation/oral routes and exposures to workers via dermal routes. Dermal exposure to TCEP in both liquid and solid form is expected, as TCEP can be used/transported in liquid or wet solid form. Additionally, potential inhalation exposures to TCEP in mist or dust form are expected for certain conditions of use. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (*e.g.*, loading, unloading) throughout the various lifecycle stages and conditions of use (*e.g.*, manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario.

For each condition of use identified in Table 2-2, a determination was made as to whether or not EPA plans to evaluate each combination of exposure pathway, route, and receptor in the risk evaluation. The supporting rationale are presented in Appendix F.

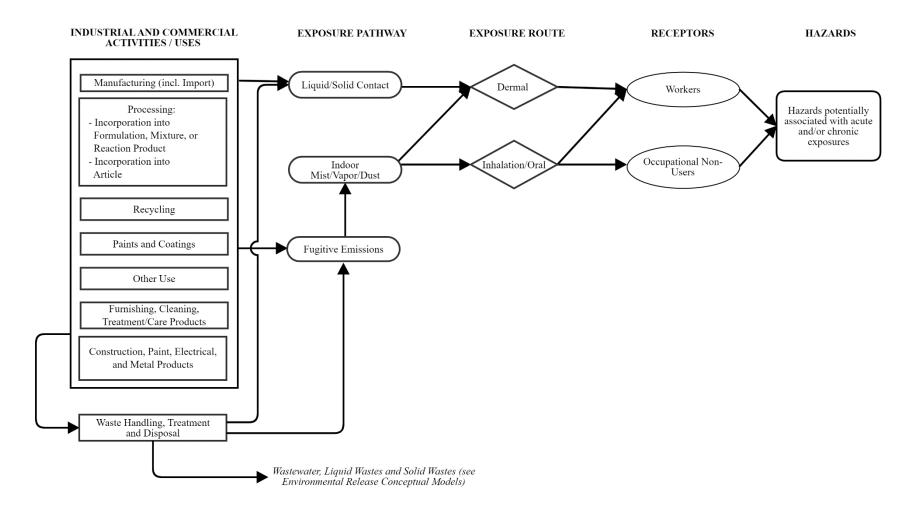


Figure 2-13. Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-14 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TCEP that EPA plans to include in the risk evaluation. EPA expects inhalation and dermal to be the primary routes of exposure and plans to evaluate inhalation exposures to TCEP in vapor or dust for consumers and bystanders. There is potential for dermal exposures to TCEP via direct contact with liquid or solid products or articles containing TCEP during consumer uses, and inhalation exposures to TCEP via dust, vapor or mist generated from use of consumer products. There is also potential for oral ingestion of dust containing TCEP, for example, via children's hand-to-mouth behavior. The supporting rationale for consumer pathways that are in scope for TCEP are included in Appendix G.

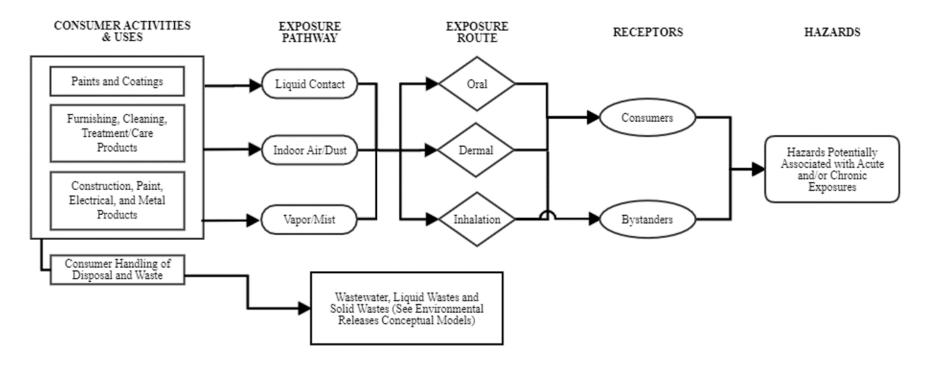


Figure 2-14. TCEP Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TCEP.

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

Figure 2-15 presents the exposure pathways, exposure routes, and hazards to general population and environmental receptors for releases and waste streams associated with environmental releases of TCEP. EPA plans to evaluate pathways and routes of exposures to receptors (*e.g.*, general population, aquatic, terrestrial species) that may occur from industrial and/or commercial uses, releases to air, water or land, including biosolids and soil, and other conditions of use. EPA expects humans to be exposed to TCEP from air emissions via inhalation as well as from water, liquid, and solid waste releases and orally via drinking water, fish and soil ingestion, and dermally from contact with groundwater and soil. The supporting rationale for general population and environmental pathways considered for TCEP are included in Appendix H.

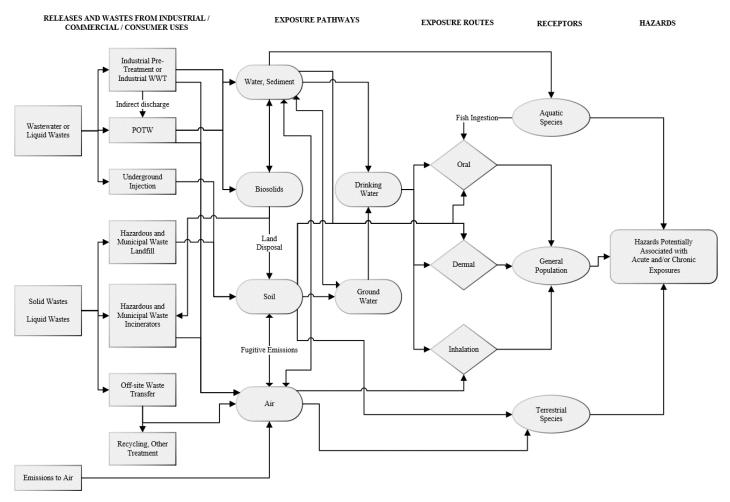


Figure 2-15. TCEP Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of TCEP.

- a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering.
- b) Receptors include PESS (see Section 2.5).

2.7 Analysis Plan

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

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical properties and environmental fate and transport of TCEP as follows:

- 1) Review reasonably available measured or estimated physical and chemical properties and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.

 EPA plans to review data and information collected through the systematic review methods and public comments about the physical and chemical properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of Tris*(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation (U.S. EPA, 2019c). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018a). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.
- 2) Using measured data and/or modeling, determine the influence of physical and chemical properties and environmental fate endpoints (*e.g.*, persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.

Measured data and, where necessary, model predictions of physical and chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of TCEP within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) Conduct a weight of the scientific evidence evaluation of physical and chemical and environmental fate data, including qualitative and quantitative sources of information.

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

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air, surface water, sediment, soil, ground water, aquatic biota, and terrestrial biota associated to exposure to TCEP. Based on its physical and chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment, TCEP is more likely to be present in some of these media and less likely to be present in others. EPA has not yet determined the exposure levels in these media. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and estimated exposure levels from modeling approaches. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft exposure scenarios corresponding to various conditions of use for TCEP are presented in Appendix F, Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.

EPA has reviewed some sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to review additional sources identified. Potential sources of environmental release data are summarized in Table 2-4:

Table 2-4. Categories and Sources of Environmental Release Data

- 0.00 - 0 - 0.00	
	U.S. EPA Generic Scenarios
	OECD Emission Scenario Documents
EU Risk Assessment Report	
	Discharge Monitoring Report (DMR) surface water discharge data for TCEP from NPDES-
	permitted facilities.

EPA plans to consider using the manufacture and import volume identified in CDR to estimate releases resulting from repackaging of imported TCEP and subsequent processing.

Furthermore, EPA plans to consider whether scrap articles and used finished products containing TCEP are recycled. If EPA proceeds with the evaluation of any of the recycling processes, then EPA may perform supplemental targeted searches of peer-reviewed or gray literature as needed.

2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies). EPA plans to continue to review relevant data sources during risk evaluation. EPA will continue to consider additional reasonably available information and will evaluate it during development of the risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt

to address data gaps identified as described in # 3 and #4 below by considering potential surrogate data and models.

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

3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.

EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.

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

This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes and sources (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to consider for release estimation and environmental exposures. EPA plans to consider relevant regulatory requirements in estimating releases during risk evaluation.

5) Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.

EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the July 2009 ESD on Plastics Additives (OECD, 2009) and the September 2011 ESD on Chemical Industry (OECD, 2011) may be useful. EPA plans to need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use.

EPA Generic Scenarios are available at the following (<u>U.S. EPA, 2016</u>): https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

Generic Scenarios that contain information that may be related to the potential uses of TCEP include, but are not limited to:

- EPA's <u>Additives in Plastics Processing (Compounding) Draft Generic Scenario for</u> Estimating Occupational Exposures and Environmental Releases (May 2004);
- EPA's <u>Spray Coatings in the Furniture Industry Generic Scenario for Estimating Occupational Exposures and Environmental Releases</u> (April 2004;
- EPA's <u>Leather Dyeing Generic Scenario for Estimating Occupational Exposures and Environmental Releases</u> (September 2000);
- EPA's <u>Fabric Finishing Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases</u> (September 1994);
- EPA's <u>Application of Spray Polyurethane Foam Insulation Generic Scenario for Estimating Occupational Exposures and Environmental Releases</u> (March 2019;

- EPA's <u>Industry Profile for the Flexible Polyurethane Foam Industry- Generic Scenario</u> <u>for Estimating Occupational Exposures and Environmental Releases</u> (February 2004); and.
- EPA's <u>Industry Profile for the Rigid Polyurethane Foam Industry Draft Generic Scenario for Estimating Occupational Exposures and Environmental Releases</u> (September 2004).

OECD Emission Scenario Documents are available at the following: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

ESDs that contain information that may be related to the potential uses of TCEP include, but are not limited to:

- OECD's Complementing Document to the ESD On Plastic Additives: Plastic Additives During the Use of End Products (May 2019);
- OECD's Complementing Document for ESD on Coating Industry: Application of Paint Solvents for Industrial Coating (December 2015);
- OECD's ESD on the Chemical Industry (September 2011);
- OECD's ESD on Radiation Curable Coating, Inks, and Adhesives (July 2011);
- OECD's ESD on Plastic Additives (July 2009); and
- OECD's ESD on Coating Industry (Paints, Lacquers and Varnishes) (July 2009).

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

6) Map or group each condition of use to a release assessment scenario(s).

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

7) Evaluate the weight of the scientific evidence of environmental release data.

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

2.7.2.2 Environmental Exposures

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

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.

For TCEP, environmental media which EPA plans to analyze are sediment, biosolids, soil, air, and water. The environmental exposure pathways which have been identified in the literature include aquatic and terrestrial.

2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.

EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards under TSCA Section 26(h) and that estimate surface water, sediment, and soil concentrations alongside reasonably available surface water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations, and soil concentrations consider the following inputs: direct release into surface water, sediment, or soil, indirect release into surface water, sediment, or soil (*i.e.*, air deposition), fate and transport (partitioning within media) and characteristics of the environment (*e.g.*, river flow, volume of lake, meteorological data).

3) Review reasonably available environmental monitoring data for vegetation, invertebrates, fish, non-fish vertebrates (*i.e.*, amphibians, reptiles, mammals). Plan to consider whether these data could be used to compare with comparable species or taxa-specific toxicological benchmarks.

EPA plans to analyze predatory bird species that consume fish with elevated levels of TCEP. If species-specific environmental monitoring data matches toxicity studies, direct comparisons can be made. EPA plans to consider refining data for other species by using body weight of the birds, fish ingestion rate of birds, and typical fish species consumed.

4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.

There have been changes to use patterns of TCEP over the last few years. Review and characterize monitoring data or modeled estimates to determine how representative they are of applicable use patterns.

EPA plans to evaluate any studies which relate levels of TCEP in the environment or biota with specific sources or groups of sources.

5) Group each condition(s) of use to environmental assessment scenario(s).

EPA plans to refine and finalize exposure scenarios for environmental receptors by considering combinations of sources, exposure pathways including routes and populations exposed. For TCEP, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

- Estimates of surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on reasonably available monitoring data.

- Modeling inputs such as releases into the media of interest, fate and transport and characteristics of the environment.
- Reasonably available biomonitoring data, which could be used to compare with species or taxa-specific toxicological benchmarks.
- Applicability of existing additional contextual information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are reasonably available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates.

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

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

2.7.2.3 Occupational Exposures

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

- 1) Review reasonably available exposure monitoring data for specific condition(s) of use. EPA plans to review reasonably available exposure data including workplace monitoring data collected by government agencies such as OSHA and NIOSH, and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).
- 2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and physical and chemical properties similar to TCEP.
 EPA plans to review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.
- 3) For conditions of use where data are limited or not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.

 For conditions of use where data are not available, EPA plans to review existing exposure models that may be applicable in estimating exposure levels of TCEP.
 - EPA has identified potentially relevant OECD ESDs and EPA Generic Scenarios corresponding to some conditions of use. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA may conduct industry outreach efforts or perform supplemental targeted searches of peer-reviewed or gray literature to better understand the process steps involved in conditions of use. EPA plans to also consider the applicability of exposure models in ChemSTEER (U.S. EPA, 2015a) tool that are routinely used for assessing new chemicals to assess exposures during various conditions of use. EPA may also perform supplemental targeted searches of peer-reviewed or gray literature to identify other models that EPA could use to estimate exposures for certain conditions of use.
- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.

This will be performed after #2 and #3 are completed and based on information developed from #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA or other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to occupational non-users.

- 5) Consider and incorporate applicable ECs and/or PPE into exposure scenarios.
 - EPA plans to review potentially relevant data sources on ECs and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). EPA plans to assess worker exposure pre- and post-implementation of ECs, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.
- 6) Map or group each condition of use to occupational exposure assessment scenario(s). EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). As presented in the fourth column in Table_Apx F-1, EPA has completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine mapping or grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional is reviewed during risk evaluation. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.
- 7) Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a). EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

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

1) Group each condition of use to consumer exposure assessment scenario(s).

Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes and exposed populations.

For TCEP, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use
- Duration, frequency and magnitude of exposure
- Weight fraction of chemical in products
- Amount of chemical used

2) Evaluate the relative potential of indoor exposure pathways based on reasonably available data.

Based on physical and chemical properties of TCEP and the consumer uses identified, inhalation of particles is expected to be an important indoor exposure pathway for consumers. Other pathways include dust ingestion and dermal contact as a result of indoor use of TCEP consumer products. Inhalation of vapor and mist and oral ingestion of liquid and mist are also possible. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.

3) Review existing indoor exposure models that may be applicable in estimating indoor air exposures.

Indoor exposure models that estimate emissions from use of consumer products are available. These models generally consider p-chem properties (*e.g.*, vapor pressure, molecular weight), product specific properties (*e.g.*, weight fraction of the chemical in the product), use patterns (*e.g.*, duration and frequency of use), user environment (*e.g.*, room of use, ventilation rates), and receptor characteristics (*e.g.*, exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

Models that estimate emission and migration of semi-volatile organic compounds (SVOCs) into the indoor environment models generally consider indoor fate and transport properties such as mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient, and the material-air partition coefficient. In addition, direct transfer to surface dust or physical abrasion may influence emissions over time. These properties vary based on physical and chemical properties and properties of the material. The OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

4) Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.

To the extent other organizations have already modeled a TCEP consumer exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to TCEP have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting TCEP in specific media (e.g., dust or indoor air).

The availability of TCEP concentration for various conditions of use will be evaluated. This data provides the source term for any subsequent indoor modeling. EPA plans to analyze source attribution between overall indoor air and dust levels and various indoor sources.

6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.

For TCEP, EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults may different from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

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

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

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) Refine and finalize exposure scenarios for the general population by considering sources, conditions of use, exposure pathways and routes.

For TCEP, the following are noteworthy considerations in constructing exposure scenarios for the general population: routes of exposure, releases to air, water or land resulting from industrial, commercial, and other conditions of use, in addition to:

- Review of reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
- For exposure pathways where data are not reasonably available, review existing exposure modelling approaches that may be applicable in estimating exposure levels.
- Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
- Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available and relevant.
- Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.

- Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
- Evaluate the weight of the scientific evidence of general population exposure data.
- Map or group each condition of use to general population exposure assessment scenario(s).

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

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

- 2) Review reasonably available environmental and biological monitoring data for exposure pathways and media to which general population exposures are expected.

 General population exposure pathways expected to be considered for TCEP: ingestion of water and food including fish and breast milk as well as dermal contact to TCEP via water and inhalation of TCEP via ambient air.
- 3) For exposure pathways where empirical data is not available, review existing exposure models that may be applicable in estimating exposure levels.
 For TCEP, media where exposure models will be considered for general population exposure include models that estimate, surface water concentrations, sediment concentrations, soil concentrations and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.
- 4) Review reasonably available exposure modeled estimates. For example, existing models developed for a previous TCEP chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are reasonably available.

 To the extent other organizations have already modeled TCEP general population exposure
 - scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical and chemical properties and similar uses are reasonably available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.
- 5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.

The expected releases from industrial facilities are changing over time. Any modeled concentrations based on recent release estimates will be carefully compared with reasonably available monitoring data to determine representativeness.

- 6) Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).
 - For TCEP, exposure scenarios that involve PESS will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for dust, soil, and diet than adults.
- 7) Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.

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

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

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

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

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

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

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

2) Derive hazard thresholds for aquatic and terrestrial organisms.

Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x. LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of TCEP to aquatic and terrestrial species.

Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

- 3) Evaluate the weight of the scientific evidence of environmental hazard data. During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018a).
- 4) Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments. EPA plans to consider aquatic (*e.g.*, water and sediment exposures) and terrestrial pathways in the TCEP conceptual model. These organisms may be exposed to TCEP via a number of environmental pathways (*e.g.*, surface water, sediment, soil, diet).
- 5) Consider a persistent, bioaccumulative, and toxic (PBT) assessment of TCEP. EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of TCEP after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.*, BAF, BCF) of TCEP. In addition, EPA plans to integrate traditional environmental hazard endpoint values (*e.g.*, LC50, LOEC) and exposure concentrations (*e.g.*, surface water concentrations, tissue concentrations) for TCEP with the fate parameters (*e.g.*, BAF, BCF, BMF, TMF).
- 6) Conduct an environmental risk estimation and characterization of TCEP.

 EPA plans to conduct a risk estimation and characterization of TCEP to identify if there are risks to the aquatic and terrestrial environments from the measured and/or predicted concentrations of TCEP in environmental media (*e.g.*, water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (<u>U.S. EPA, 1998</u>; <u>Barnthouse et al., 1982</u>). Analysis of risk for characterization includes a confidence statement in risk estimation which qualitative judgment describing the certainty of the risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

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

EPA plans to evaluate human health studies using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018a) and updates to the epidemiological data quality criteria released with the first ten risk evaluations. The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to

the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.

Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to TCEP hazard(s). Susceptibility of particular human receptor groups to TCEP will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (*i.e.*, gestation) and childhood are potential susceptible lifestages for TCEP exposure. EPA may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.

Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (*e.g.*, oral, dermal, inhalation) and by the cancer and noncancer endpoints identified in Section 2.4.2.

Dose-response assessment will be performed in accordance with EPA guidance (<u>U.S. EPA</u>, <u>2012a</u>, <u>2011a</u>, <u>1994</u>) developing points of departure (POD) for either margins of exposure (MOEs), cancer slope factors (CSFs), oral slope factors (OSFs), and/or inhalation unit risks (IURs). Dose-response analyses may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not reasonably available or would not alter the analysis

The cancer mode of action (MOA) analyses determine the relevancy of animal data to human risk and how data can be quantitatively evaluated. If cancer hazard is determined to be applicable to TCEP, EPA plans to evaluate information on genotoxicity and the MOA for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the *U.S. EPA Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposures to Carcinogens* (U.S. EPA, 2005b), EPA plans to determine whether age-dependent adjustment factors (ADAFs) are appropriate for TCEP for specific conditions of use based upon potential exposures to children.

4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.

Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

EPA plans to evaluate whether the reasonably available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD or for extrapolation of the POD to standard exposure durations (*e.g.*, lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by BW^{3/4} scaling in accordance with U.S. EPA (2011b), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

- 5) Evaluate the weight of the scientific evidence of human health hazard data. During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).
- 6) Consider the route(s) of exposure (e.g., oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

 At this stage of review, EPA believes there will be sufficient reasonably available data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to TCEP, which could be important for worker, consumer and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes.

If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004b).

If there are acceptable inhalation data after completion of systematic review, EPA may also consider extrapolating from the inhalation to the dermal route if first-pass metabolism through the liver via the oral route is expected because in that case, use of data from the oral route is not recommended (U.S. EPA, 1994). EPA may also consider inhalation-to-dermal route

extrapolation if an inhalation toxicity study with a sensitive hazard endpoint is used to evaluate risks. Based on these considerations, EPA extrapolated from the inhalation to the dermal route for several of the first ten risk evaluations under amended TSCA, including methylene chloride (U.S. EPA, 2020d) and carbon tetrachloride (U.S. EPA, 2020b).

7) Conduct a human health risk estimation and characterization of TCEP.

Analysis of risk for characterization includes a confidence statement in risk estimation. This confidence statement is based on qualitative judgment describing the certainty of the risk estimate considering the strength of the evidence scores for hazard and exposure along with their limitations and relevance. The lowest confidence evaluation for either hazard or exposure will drive the overall confidence estimate.

2.7.4 Summary of Risk Approaches for Characterization

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

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (U.S. EPA, 2000) and consistent with the requirements of the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, September 18, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use" The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (e.g., related to nature and magnitude of effects).

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook (<u>U.S. EPA, 2015b</u>) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for TCEP will be peer reviewed.

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- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2018a). Application of systematic review in TSCA risk evaluations. (740-P1-8001). Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
 https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2018b). Problem formulation of the risk evaluation for 1-bromopropane. (EPA-740-R1-7019). Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
 https://www.epa.gov/sites/production/files/2018-06/documents/1bp_problem_formulation_05-31-18.pdf

- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2018c). Problem formulation of the risk evaluation for cyclic aliphatic bromides cluster (HBCD). (EPA-740-R1-7012). Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/production/files/2018-06/documents/hbcd_problem_formulation_05-31-18.pdf
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2019a). Chemical Data Reporting (2012 and 2016 CBI CDR database). Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics.
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2019b). CPCat (Chemical and Product Categories). <u>https://actor.epa.gov/cpcat/faces/home.xhtml</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2019c). Proposed Designation of Tris(2-chloroethyl) Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation. Washington, DC: Office of Pollution Prevention and Toxics.
 https://www.epa.gov/sites/production/files/2019-08/documents/tris2-chloroethylphosphate_115-96-8_high-priority_proposeddesignation_082319.pdf
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2020a). Chemical Data Reporting (2012 and 2016 Public CDR database) [Database]. Washington, DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. ChemView: July 2020. https://chemview.epa.gov/chemview
- U.S. EPA. (U.S. Environmental Protection Agency). (2020b). Draft risk evaluation for carbon tetrachloride (methane, tetrachloro-); CASRN: 56-23-5 (pp. 1-301). (EPA-740-R1-8014). Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency. https://nepis.epa.gov/Exe/ZyPDF.cgi/P100YHUW.PDF?Dockey=P100YHUW.PDF
- U.S. EPA. (U.S. Environmental Protection Agency). (2020c). Draft Scope of the Risk Evaluation for Tris(2-chloroethyl) Phosphate CASRN 115-96-8 [EPA Report]. (EPA-740-D-20-009).
 Washington, DC. https://www.epa.gov/sites/production/files/2020-04/documents/casrn-115-96-8 tris2-chloroethyl phosphatetcep draft scope.pdf
- U.S. EPA. (U.S. Environmental Protection Agency). (2020d). Risk evaluation for methylene chloride (dichloromethane, dcm); CASRN: 75-09-2 (pp. 1-753). (EPA-740-R1-8010). Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency.
 https://www.epa.gov/sites/production/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf

Appendix A ABBREVIATED METHODS FOR SEARCHING AND SCREENING

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

To develop the chemical terms for the subsequent literature search for TCEP, several online sources were queried.

- California Department of Pesticide Regulation: https://www.cdpr.ca.gov/docs/chemical/monster2.htm
- USEPA Chemistry Dashboard: https://comptox.epa.gov/dashboard
- University of Hertfordshire PPDB: Pesticide Properties DataBase: https://sitem.herts.ac.uk/aeru/ppdb/en/search.htm
- USEPA Reregistration Eligibility Decision (RED) documents: https://archive.epa.gov/pesticides/reregistration/web/html/status.html
- Office of Pesticide Programs Pesticide Chemical Search: https://ofmpub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1
- Food and Agriculture Organization of the United Nations: http://www.fao.org/home/en/
- PAN Pesticides Database: http://www.pesticideinfo.org/Search_Chemicals.jsp

Prior to inclusion in the search term string, all forms of chemical names were subjected to verification from several potential sources (*e.g.*, US EPA Chemistry Dashboard, STN International-CAS; see complete list of sources for chemical verification in Table_Apx A-1). From these sources, all chemical names, synonyms, CAS number(s), trade names, etc. were documented and used to generate terms for database searches.

Table_Apx A-1. Sources of Verification for Chemical Names and Structures

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
Chemistry Dashboard	CAS Numbers, Synonyms, Structures, Properties,	Online
(https://comptox.epa.gov/dashboard)	Environmental Fate and Transport.	
Dictionary of Chemical Names and	Wide assortment of chemical compounds by chemical	ECOTOX
Synonyms	name and synonym, has CAS index and some structure	
	data	
Farm Chemicals Handbook-1992	Pesticide information, CAS numbers and synonyms, some	ECOTOX
	structure data	
	***Sometimes CAS number presented for a compound is	
	for the main constituent only	
OPPT SMILES Verification Source	Structure Data	Electronic
		verification
RTECS (Registry of Toxic Effects of	Chemical names, synonyms and CAS numbers	ECOTOX
chemical substance, 1983-84 ed., 2		
vols)		
Sigma – Aldrich website58784	Organic and inorganic Compounds by chemical name, has	Online
http://www.sigma-aldrich.com	CAS index and some structure and Physical Property data	

CHEMICAL SOURCE	CONTENTS	DOCUMENT LOCATION
STN International (CAS) 1994	***Most complete source of chemical name, synonym and structure information, no physical properties	Online
The Pesticide Manual 10th edition, 1994	Pesticide Compounds by chemical name, synonym, product code, has CAS index and some structure and Physical Property data	ECOTOX
TSCA (Toxic Substances Control Act Chemical Substance Inventory, 1985 ed., 5 vols)	Chemical names, synonyms and CAS numbers	ECOTOX
World Wide Web (misc. web sources) A copy of the verification page is saved to the Attachments tab of the chemical entry. This includes company MSDS sheets or Chemical Labels.	Chemical names, synonyms and CAS numbers	Online
California Department of Pesticide Regulation (http://www.cdpr.ca.gov/dprdatabase .htm)	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online
PAN Pesticide Database (http://www.pesticideinfo.org/Search Chemicals.jsp)	Pesticides searchable by name or CAS #. Includes CAS #, Name, synonyms, targets, toxicity data, related chemicals and regulatory information.	Online
US EPA Office of Pesticide Programs Pesticide Fate Database – No web access available. An electronic copy of the data file is located at the Contractor site: PFATE_37_Tables.mdb.	Multiple databases containing chemicals, pesticides, companies, products, etc.	Online

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching occurred during April and May of 2019 by an information specialist and the results were stored in the Health and Environmental Research Online (HERO) database and assigned a HERO reference identification number. The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

After initial deduplication in HERO⁷, these studies were imported into <u>SWIFT Review</u> software (<u>Howard et al., 2016</u>) to identify those references most likely to be applicable to each discipline area (*i.e.* consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

⁶EPA's HERO database provides access to the scientific literature behind EPA science assessments. The database includes more than 600,000 scientific references and data from the peer-reviewed literature used by EPA to develop its regulations.
⁷ Deduplication in HERO involves first determining whether a matching unique ID exists (*e.g.*, PMID, WOSid, or DOI). If one matches one that already exists in HERO, HERO will tag the existing reference instead of adding the reference again. Second, HERO checks if the same journal, volume, issue and page number are already in HERO. Third, HERO matches on the title, year, and first author. Title comparisons ignore punctuation and case.

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

Table_Apx A-2 presents a list of the data sources, the search dates and number of peer-reviewed references resulting from the searches for TCEP. The sources are found as online databases and the resulting references were gathered and uploaded into the EPA Health and Environmental Research Online (HERO) database for literature screening.

Table_Apx A-2. Summary of Data Sources, Search Dates and Number of Peer-Reviewed Literature Search Results for TCEP

Source	Date of Search	Number of References
Current Contents	06/11/2019	313
Web of Science	09/13/2019	361
ProQuest CSA	06/11/2019	599
Dissertation Abstracts	06/11/2019	0
Science Direct	06/11/2019	960
Agricola	06/11/2019	244
TOXNET	06/11/2019	632
PubMed	07/03/2019	274
UNIFY	06/11/2019	32
Totals:		3415

GENERAL:

General search terms were compiled and used in the search strategies for each of the databases/sources listed below. Based upon the online search manuals for the respective databases/sources, it was necessary to construct searches as noted for each of the sources. The search terms are listed below in full for each source and noted if the general search terms or other search terms were used.

"2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE" OR "Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester" OR "Phosphoric acid, tris(2-chloroethyl) ester" OR "Roflam E" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(chloroethyl) phosphate" OR "Tri-beta-chloroethyl phosphate" OR "Tris (2-chloroethyl) phosphate" OR "TRIS-(2-CHLORAETHYL)-PHOSPHAT" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) orthophosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate "OR "Tris(beta-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate" OR "UNII-32IVO568BO"

CURRENT CONTENTS CONNECT:

Current Contents Connect may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/11/2019

Date Range of Search: 1998 to Present

N = 313

TS=("2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE" OR "Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester" OR "Phosphoric acid, tris(2-chloroethyl) ester" OR "Roflam E" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(chloroethyl) phosphate" OR "Tri-beta-chloroethyl phosphate" OR "Tris (2-chloroethyl) phosphate" OR "TRIS-(2-CHLORAETHYL)-PHOSPHAT" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate (TCEP)" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate" OR "Tris(chloroethyl)

WOS Core Collection:

Web of Science Core Collection may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) by clicking on the Web of Science Link or copying and pasting (https://apps.webofknowledge.com).

Date Searched: 09/13/2019

Date Range of Search: 1970 to Present

N = 361

TS=("2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE" OR "Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester" OR "Phosphoric acid, tris(2-chloroethyl)ester" OR "Roflam E" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl)phosphate" OR "Tri(chloroethyl) phosphate" OR "Tri-beta-chloroethyl phosphate" OR "Tris (2-chloroethyl) phosphate" OR "TRIS-(2-CHLORAETHYL)-PHOSPHAT" OR "Tris(2-chloroethyl)phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl)phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate" OR "Tris(chloroethyl)phosphate" OR

PROQUEST Agricultural and Environmental Science Database:

ProQuest Agricultural and Environmental Science Database may be accessed through EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/11/2019

Date Range of Search: 1900 to Present

N = 599

ALL("2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE" OR "Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester" OR "Phosphoric acid, tris(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) orthophosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate" OR "T

PROOUEST Dissertations and Theses:

ProQuest Dissertations and Theses may be accessed through the Kathryn A. Martin Library at the University of Minnesota at Duluth (https://libguides.d.umn.edu/az.php).

Date Searched: 06/11/2019

Date Range of Search: 1900 to Present

N = 0

ALL("2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE" OR "Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester" OR "Phosphoric acid, tris(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "TRIS-(2-CHLORAETHYL)-PHOSPHAT" OR "Tris(2-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate" OR "T

SCIENCE DIRECT:

Science Direct may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/11/2019

Date Range of Search: 1823 to Present

N = 805

Science Direct 01:

"2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE"

N = 0

Science Direct 02:

"Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester"

N = 1

Search string returned 0 results, searching on the highlighted returned N = 1

Science Direct 03:

"Phosphoric acid, tris(2-chloroethyl)ester" OR "Roflam E" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(chloroethyl) phosphate" OR "Tri-beta-chloroethyl phosphate" OR "Tris (2-chloroethyl) phosphate" OR "TRIS-(2-CHLORAETHYL)-PHOSPHAT"

N = 200

Search string returned 0 results, searching on the highlighted returned N = 200

Science Direct 04:

"Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) orthophosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate"

N = 355

Search string returned 0 results, searching on the highlighted returned N = 355

Science Direct 05:

"Tris(chloroethyl)phosphate" OR "Tris-2-chloroethyl phosphate" OR "UNII-32IVO568B0" N=404

AGRICOLA:

Agricola may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm) or within the EndNote environment.

Date Searched: 06/11/2019

Date Range of Search: 15th century to the Present

N = 244

Agricola 01:

2-Chloroethanol phosphate

Amgard TCEP

Antiblaze 100

BRN 1710938

Celluflex

Celluflex CEF

Disflamoll TCA

Ethanol, 2-chloro-, 1,1',1"-phosphate

ETHANOL, 2-CHLORO-, PHOSPHATE

Ethanol, 2-chloro-, phosphate (3:1)

N = 1

Agricola 02:

Fyrol CEF

Fyrol CF

Genomoll P

NCI-C60128

Niax 3CF

Niax Flame Retardant 3CF

NSC 3213

Phosphoric acid tris(2-chloroethyl) ester

Phosphoric acid, tris(2-chloroethyl)ester

Roflam E

N = 0

Agricola 03:

Tri(2-chloroethyl) phosphate

Tri(2-chloroethyl)phosphate

Tri(beta-chloroethyl) phosphate

Tri(chloroethyl) phosphate

Tri-beta-chloroethyl phosphate

Tris (2-chloroethyl) phosphate

TRIS-(2-CHLORAETHYL)-PHOSPHAT

Tris(2-chlorethyl)phosphat

Tris(2-chloroethyl) orthophosphate

Tris(2-chloroethyl) phosphate

N = 129

Agricola 04:

Tris(2-chloroethyl) phosphate (TCEP)

Tris(2-chloroethyl)phosphate

Tris(beta-chloroethyl) phosphate

Tris(beta-chloroethyl) phosphate

Tris(beta-chloroethylphosphate)

Tris(chloroethyl) phosphate

Tris(chloroethyl)phosphate

Tris-2-chloroethyl phosphate

UNII-32IVO568B0

N = 114

TOXNET/(Toxline):

TOXNET(Toxline) may be accessed through the EPA Desktop Library (https://intranet.epa.gov/desktop/databases.htm).

Date Searched: 06/11/2019

Date Range of Search: 1900 to Present

N = 632

TOXNET 01:

115-86-6 OR 21343-84-0

N = 632

PubMed:

PubMed may be accessed through the EPA Desktop Library (https://www.ncbi.nlm.nih.gov/pubmed/)

Date Searched: 07/03/2019

Date Range of Search: 1900 to present

N = 274

"2-Chloroethanol phosphate" OR "Amgard TCEP" OR "Antiblaze 100" OR "BRN 1710938" OR "Celluflex" OR "Celluflex CEF" OR "Disflamoll TCA" OR "Ethanol, 2-chloro-, 1,1',1"-phosphate" OR "ETHANOL, 2-CHLORO-, PHOSPHATE" OR "Ethanol, 2-chloro-, phosphate (3:1)" OR "Fyrol CEF" OR "Fyrol CF" OR "Genomoll P" OR "NCI-C60128" OR "Niax 3CF" OR "Niax Flame Retardant 3CF" OR "NSC 3213" OR "Phosphoric acid tris(2-chloroethyl) ester" OR "Phosphoric acid, tris(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(2-chloroethyl) phosphate" OR "Tri(chloroethyl) phosphate" OR "Tri-beta-chloroethyl phosphate" OR "Tris (2-chloroethyl) phosphate" OR "TRIS-(2-CHLORAETHYL)-PHOSPHAT" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate (TCEP)" OR "Tris(2-chloroethyl) phosphate" OR "Tris(2-chloroethyl) phosphate" OR "Tris(beta-chloroethyl) phosphate" OR "Tris(chloroethyl) phosphate" OR

ECOTOX UNIFY:

This is an internal EPA database that is not accessible to the public. Results from the ECOTOX Unify search strategy.

Date Searched: 06/11/2019 Date Range of Search: all years

N = 32

A.1.2.2 Data Prioritization for Environmental Hazard, Human Health Hazard, Fate and Physical Chemistry

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.*, analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH) fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or

more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR⁸.

A.1.2.3 Data Prioritization for Occupational Exposures and Environmental Releases and General Population, Consumer and Environmental Exposures

To prioritize references related to occupational exposure, environmental release, general population exposure, consumer exposure, and environmental exposure, EPA used positive and negative seed studies to build a classification model in SWIFT Review. The positive seeds were identified using relevant literature pool for the first ten TSCA risk evaluations, while the negative seeds were identified from a subset of literature for the current high-priority substances. The model was then applied to the unclassified literature to generate a classification score for each reference. Scores above a certain threshold value were then prioritized for further review in SWIFT-ActiveScreener.

A.2 Peer-Reviewed Screening Process

The studies identified from publicly available database searches and SWIFT-Review filtering/prioritization were housed in HERO system and imported into SWIFT-ActiveScreener or DistillerSR for title/abstract and full-text screening. Both title/abstract and full-text screening were conducted by two independent reviewers. Screening is initiated with a pilot phase of screening (between 10 and 50) studies to identify areas where clarification in screening criteria might be needed or chemical-specific supplemental material tags might be identified. Records that met PECO (or equivalent criteria (Appendix A.2.1) during title and abstract screening were considered for full-text screening. At both the title/abstract and full-text review levels, screening conflicts were resolved by topic-specific experts and/or discussion among the primary screeners. For citations with no abstract, the articles are initially screened based on all or some of the following: title relevance (titles that suggest a record is not relevant can be excluded rather than marked as unclear), and page numbers (articles two pages in length or less were assumed to be conference reports, editorials, or letters). During title/abstract or full-text level screening in DistillerSR, studies that did not meet the PECO criteria, but which could provide supporting information were categorized (or "tagged") as supplemental information.

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

⁸<u>DistillerSR</u> is a web-based systematic review software used to screen studies available at https://www.evidencepartners.com/products/distillersr-systematic-review-software.

A.2.1 Inclusion/Exclusion Criteria

A PECO statement is typically used to focus the research question(s), search terms, and inclusion/exclusion criteria in a systematic review. PECO criteria were developed *a priori* to screening and modified to fit the various discipline areas supporting the TSCA risk evaluations. Variations include the RESO (receptor, exposure, scenario/setting, and outcome) used for the occupational exposure and environmental releases discipline, and PESO (pathways/ processes, exposures, setting/scenario, and outcomes) used by the fate and transport discipline. All PECOs and PECO-equivalent criteria can be found in the following sections.

A.2.1.1 PECO for Environmental and Human Health Hazards

The PECO used in this evidence map to identify literature pertinent to TCEP effects on human health and environmental hazard is presented in Table_Apx A-3. In addition to the PECO criteria, studies containing potentially relevant supplemental material were tracked and categorized during the literature screening process as outlined in Table_Apx A-4.

Table_Apx A-3. Hazards Title and Abstract and Full-Text PECO Criteria for TCEP

PECO	px A-3. Hazarus Title and Abstract and Fun-Text I ECO Citteria for TCEI		
Element	Evidence		
P	Human: Any population and life stage (<i>e.g.</i> , occupational or general population, including children and other sensitive populations). Animal: Aquatic and terrestrial species (live, whole organism) from any life stage (<i>e.g.</i> , preconception, in utero, lactation, peripubertal, and adult stages). Animal models will be inventoried according to the categorization below: Human health models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicity only) Ecotoxicological models: invertebrates (<i>e.g.</i> , insects, spiders, crustaceans, mollusks, and worms) and vertebrates (<i>e.g.</i> , mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models. Plants: All aquatic and terrestrial species (live), including algal, moss, lichen and fungi species. Screener note: To identify human health and environmental hazards, other organisms not listed above in their		
P	respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards (<i>e.g.</i> , Xenopus, zebrafish), and traditional human health models (<i>e.g.</i> , rodents) can be used to identify potential environmental hazard. Neurotoxicity studies performed in hens (<i>e.g.</i> , OECD 418 and 419) are considered relevant to both human and eco hazard. PECO considerations should be directed toward effects on target species only and not on the indirect effects expressed in taxa as a result of chemical treatment (<i>e.g.</i> , substance is lethal to a targeted pest species leading to positive effects on plant growth due to diminished presence of the targeted pest species). Tests of the single toxicants in <i>in vitro</i> and <i>ex vitro</i> systems or on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially supplemental (mechanistic studies). Bacteria and yeast studies specific for assessing genotoxicity or mutagenicity (<i>e.g.</i> , Ames assay) will also be tagged as potentially supplemental (mechanistic studies) but are otherwise excluded. Studies on viruses are excluded.		
E	Relevant forms and isomers: Tris(2-chloroethyl) phosphate (CASRN 115-96-8) For synonyms see the EPA Chemistry Dashboard.		

PECO Element	Evidence
	No isomers were included for TCEP.
	 Human: Any exposure to Tris(2-chloroethyl) phosphate (TCEP 115-96-8) singularly or in mixture, including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (<i>i.e.</i> urine, blood, semen, etc.). Animal: Any exposure to Tris(2-chloroethyl) phosphate (TCEP 115-96-8) including via water (including environmental aquatic exposures), soil or sediment, diet, gavage, injection, dermal, and inhalation.
	Plants: Exposure to Tris(2-chloroethyl) phosphate (TCEP 115-96-8) via water, soil, or sediment.
	Screener note: Field studies with media concentrations (surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants are to be identified as <i>Supplemental</i> if any biological effects are reported. Animal and plant studies involving exposures to mixtures will be included only if they also include exposure to Tris(2-chloroethyl) phosphate) (TCEP 115-96-8) alone. Otherwise, animal and
	plant mixture studies will be tagged as Supplemental. Human mixture studies are included. Controlled outdoor experimental studies (<i>e.g.</i> , controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be laboratory studies (not field studies) because there is a known and prescribed exposure dose(s) and an evaluation of hazardous effect(s). Whereas field studies (<i>e.g.</i> , biomonitoring) where there is no prescribed exposure dose(s) will be excluded if there is no evaluated hazardous effect, and tagged as supplemental field, if there is an evaluated hazardous effect.
	 Human: A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of Tris(2-chloroethyl) phosphate (TCEP 115-96-8), or exposure to Tris(2-chloroethyl) phosphate (TCEP 115-96-8) for shorter periods of time. Animal and Plants: A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement).
С	 Screener note: If no control group is explicitly stated or implied (<i>e.g.</i> by mention of statistical results that could only be obtained if a control group was present), the study will be marked as <i>Unclear</i> during Title/Abstract Screening. All case series and case studies describing findings in a sample size of less than 20 people in any setting (<i>e.g.</i>, occupation, general population) will be tracked as <i>Supplemental</i>. Case-control, case-crossover, case-referent, case-only, case-specular, case-cohort, case-parent, nested case-control study designs are all <i>Included</i>.
О	Human: All health outcomes (cancer and noncancer) at the organ level or higher. Animal and Plants: All apical biological effects (effects measured at the organ level or higher) and bioaccumulation from laboratory studies with concurrently measured media and/or tissue concentrations. Apical endpoints include but are not limited to reproduction, survival, and growth. Screener note: Measurable biological effects relevant for humans, animals and plants may include but are not limited to: mortality, behavioral, population, cellular, physiological, growth, reproduction, systemic, point of contact effects. Effects measured at the cellular level of biological organization and below are to be tagged as supplemental, mechanistic.

Table_Apx A-4. Major categories of Potentially Relevant Supplemental Material for TCEP

Category	Evidence
Mechanistic studies	All studies that report results at the cellular level and lower in both mammalian and non-mammalian model systems, including <i>in vitro</i> , <i>in vivo</i> , <i>ex vivo</i> , and <i>in silico</i> studies. These studies include assays for genotoxicity or mutagenicity using bacteria or yeast.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.
Case reports or case series	Case reports ($n \le 3$ cases) and case series (non-occupational) will be tracked as potentially relevant supplemental information.
Susceptible populations (no health outcome)	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype. This tag applies primarily during full-text screening. Screener note: if biological susceptibility issues are clearly present or strongly implied in the title/abstract, this supplemental tag may be applied at the title abstract level. If uncertain at title/abstract, do not apply this tag to the reference during title/abstract screening.
Mixture studies	Experimental mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest. Human health animal model and eco animal model/plant will be tagged separately for mixture studies.
Non-English records	Non-English records will be tracked as potentially relevant supplemental information.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Field Studies	Field studies with media concentrations (<i>e.g.</i> , surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants if biological effects reported.

A.2.1.2 PECO for Consumer, Environmental, and General Population Exposures.

Table_Apx A-5. Generic Inclusion Criteria for the Data Sources Reporting Exposure Data on General Population, Consumers and Environmental Receptors

PECO Element	Evidence			
P opulation	Human: General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (life stages, preexisting conditions, genetic factors), pregnant women; lactating women, women of childbearing age. Many human population groups may be exposed. No chemical-specific exclusions are suggested at this time. Environmental: aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only)			

PECO Element	Evidence			
<u>E</u> xposure	Expected Primary Exposure Sources, Pathways, Routes: Pathways: indoor air/vapor/mist; indoor dust; particles; outdoor/ambient air; surface water; biosolids; sediment; breastmilk; food items containing TCEP including fish; consumer product uses in the home (including consumer product containing chemical); Routes of Exposure: Inhalation, Oral, Dermal			
Comparator	<u>Human</u> : Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.			
Comparator (Scenario)	Environmental Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.			
Outcomes for Exposure Concentration or	Human: Acute, subchronic, and/or indoor air and water concentration estimates (mg/m³ or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc) containing TCEP.			
Dose	Environmental: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.			

Table_Apx A-6. Pathways Identified as Supplemental for TCEP^a

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
Tris(2-chloroethyl) phosphate (TCEP)						

^a "Supplemental pathways" refer to pathways addressed by other EPA administered statutes.

Studies tagged under these pathways provide media information that is not prioritized in the screening process

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

EPA developed a generic RESO statement to guide the screening of engineering and occupational exposure data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria specified in the RESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments. On the other hand, data or information sources that fail to meet the criteria in the RESO statement are excluded from further consideration.

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

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

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

^{*} Metrics (*e.g.*, mg/kg/day or mg/m³ for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8) provides a list of related and relevant general information.

TSCA=Toxic Substances Control Act

Table_Apx A-8. Engineering, Environmental Release and Occupational Data Necessary to

Develop the Environmental Release and Occupational Exposure Assessments

Objective	Vironmental Release and Occupational Exposure Assessments				
Determined	Type of Data ^a				
during Scoping	Type of Data				
during beoping	Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each				
	manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages.				
General Engineering	The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step.				
Assessment (may apply to	Description of processes, equipment, and unit operations during each industrial/commercial life cycle step.				
Occupational Exposures and / or Environmental Releases)	Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/				
	commercial life cycle step and site locations. Concentration of the chemical of interest				
	Description of worker activities with exposure potential during the manufacture, processing, or use of				
	the chemical(s) of interest in each industrial/commercial life cycle stage.				
	Potential routes of exposure (<i>e.g.</i> , inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (<i>e.g.</i> , liquid, vapor, mist) and				
	activity.				
	Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage).				
Occupational Exposures	Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest).				
1	For solids, bulk and dust particle size characterization data.				
	Dermal exposure data.				
	Exposure duration (hr/day).				
	Exposure frequency (days/yr).				
	Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage.				
	PPE types employed by the industries within scope.				
	ECs employed to reduce occupational exposures in each occupational life cycle stage (or in a				
	workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.				
	Description of sources of potential environmental releases, including cleaning of residues from process				
	equipment and transport containers, involved during the manufacture, processing, or use of the				
Environmental	chemical(s) of interest in each life cycle stage.				
Releases (to	Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to				
relevant	each environmental medium (water) and treatment and disposal methods (POTW), including releases				
environmental	per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors.				
media)	Number of release days per year.				
	Waste treatment methods and pollution control devices employed by the industries within scope and				
	associated data on release/emission reductions.				

Objective	
Determined	Type of Data ^a
during Scoping	

^a These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.

In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis.

Abbreviations:

hr=Hour

kg=Kilogram(s)

lb=Pound(s)

yr=Year

PV=Particle volume

POTW=Publicly owned treatment works

PPE=Personal protection equipment

PSD=Particle size distribution

TWA=Time-weighted average

A.2.1.4 PESO for Fate and Transport

EPA developed a generic PESO statement to guide the screening of environmental fate data or information sources for the TSCA risk evaluations. Data or information sources that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data or information sources that fail to meet the criteria in the PESO statement are excluded from further consideration.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment for each risk evaluation. EPA uses the PESO statement (Table_Apx A-9) along with the information in Table_Apx A-10 when screening the fate data or information sources to ensure complete coverage of the processes, pathways and data or information relevant to the environmental fate and transport of the chemical substance undergoing risk evaluation.

Table_Apx A-9. Inclusion Criteria for Data or Information Sources Reporting Environmental Fate and Transport Data

PESO Element	Evidence			
Pathways and Processes	Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest Exposure pathways included in the conceptual models: air, surface water, groundwater, wastewater, soil, sediment and biosolids. Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.			
<u>E</u> xposure	Environmental exposure of environmental receptors (<i>i.e.</i> , aquatic and terrestrial organisms) to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Environmental exposure of human receptors, including any potentially exposed or susceptible subpopulations, to the chemical substance of interest, mixtures including the chemical substance, and/or its degradation products and metabolites Please refer to the conceptual models for more information about the environmental and human receptors included in each TSCA risk evaluation.			
<u>Setting</u> or <u>S</u> cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (<i>e.g.</i> , buildings including homes or workplaces, or wastewater treatment facilities) that would expose environmental (<i>i.e.</i> , aquatic and terrestrial organisms) or human receptors (<i>i.e.</i> , general population, and potentially exposed or susceptible subpopulation)			
<u>O</u> utcomes	Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways and Processes)			

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

Considered in the Develo	phient of the Environme	Associated Media/Exposure Pathways			
Fate Data Endpoint	Associated Process(es)	Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Required Environmental Fa	te Data				
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X			
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X			
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X	X		X
Biomagnification and related information	Trophic magnification	X			
Desorption information	Sorption, Mobility	X	X	X	
Destruction and removal by incineration	Incineration				X
Hydrolysis rates or half-lives	Hydrolysis	X	X	X	
K_{OC} and other sorption information	Sorption, Mobility	X	X	X	
Wastewater treatment removal information	Wastewater treatment	X	X		
Supplemental (or Optional)	Environmental Fate Data	T	ı	1	
Abiotic transformation products	Hydrolysis, Photolysis, Incineration	X			X
Aerobic biotransformation products	Aerobic biodegradation	X	X		
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X	
Atmospheric deposition information	Atmospheric deposition				X
Coagulation information	Coagulation, Mobility	X		X	
Incineration removal information	Incineration				X

A.2.1.5 Generation of Hazard Heat Maps

As stated in Appendix A.1.2.1, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content. The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or MeSH fields content.

After the completion of full-text screening for hazard data, all references tagged as included (or "PECO-relevant) were uploaded to the SWIFT Review tool for further filtering. The SWIFT Review filters applied at this phase focused on types of health outcomes included: "ADME", "PBPK", "cancer", "cardiovascular", "developmental", "endocrine", "gastrointestinal", "hematological and immune", "hepatic", "mortality", "musculoskeletal", "neurological", "nutritional and metabolic", "ocular and sensory", "renal", "reproductive", "respiratory", and "skin and connective tissue". The details of these health outcome search strategies that underlie the filters are available online. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported and used to populate the Hazard Heat Map (Figure 2-10). Studies that were not retrieved using these filters were tagged as "No Tag". The evidence type listed in the heat map (*e.g.*, human, animal-human health model, animal- environmental model, and plant) was manually assigned to each reference by screeners during the full-text screening.

The health outcome tags were originally designed for vertebrate systems, and as such, did not conform well to plant evidence. Therefore, any plant studies tagged for: "cancer", "cardiovascular", "gastrointestinal", "hematological and immune", "hepatic", "musculoskeletal", "neurological", "ocular and sensory" and "renal and respiratory" were manually reviewed and re-tagged to more appropriate health outcomes.

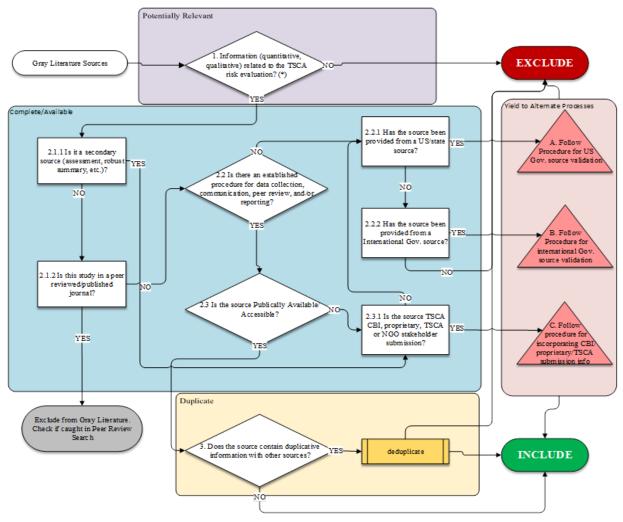
A.3 Gray Literature Search and Screening Strategies

EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (*e.g.*, PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases. Given the nature of how gray literature is searched and collected, results may not come with a bibliographic citation or abstract and were therefore processed using a decision tree logic described in Appendix A.3.1 for potential relevance prior to entering full text screening where a discipline-specific PECO is applied.

Search terms were variable dependent on source and based on knowledge of a given source to provide discipline-specific information. A summary of sources is provided in Appendix A.3.4. The criteria for determining the potential relevance of documents identified from gray literature sources is described in the following sections for each discipline.

A.3.1 Screening of Gray Literature

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



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

A.3.2 Initial Screening of Sources using Decision Logic Tree

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

Table Apx A-11. Decision Logic Tree Overview

Step	Metric	Questions to Consider
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations?
		*Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer reviewed/published journal?

2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

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

A.3.3 TSCA Submission Searching and Title Screening

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

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

After full texts are obtained, EPA reviewed some sources (prior to full-text screening) based on whether they have several factors; primary data, an established procedure for peer review, data collection, communication and/or reporting and are publicly available. Sources that have these factors will move on to full text screening. Other sources will go straight to full text screening using PECO-type criteria without going through this extra step.

EPA may decide to initiate a backwards search on sources that are deemed to have secondary data. In situations where parameters such as procedures for peer review and data collection are unclear, EPA may reach out to the authors to retrieve information to gauge whether the source should be included or excluded. Studies that are not publicly available (such as proprietary or CBI sources) may undergo additional screening steps.

During the full-text screening step, two individuals screen each source according to the PECOs, PESOs and RESOs (Appendix A.2.1).

Results of the TSCA submission search and decision tree process are included in Appendix A.3.4.

A.3.4 Gray Literature Search Results for TCEP

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

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

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/tox profiles/profilesaddenda.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.industrialchemic als.gov.au/chemical- information/search- assessments
CPSC	Technical Reports: Exposure/Risk Assessment	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Resear chStatistics/Chemicals
CPSC	Technical Reports: Toxicity Review	Other US Agency Resources	Assessment or Related Document	https://www.cpsc.gov/Resear chStatistics/Chemicals
ЕСНА	Annex XIV Restriction Report	International Resources	Assessment or Related Document	https://echa.europa.eu/- /guidance-on-inclusion-of- substances-in-annex-xiv
ЕСНА	Annex XV Restriction Report	International Resources	Assessment or Related Document	https://echa.europa.eu/current -activities-on-restrictions
ЕСНА	European Union Risk Assessment Report	International Resources	Assessment or Related Document	https://echa.europa.eu/inform ation-on- chemicals/information-from- existing-substances- regulation
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document	https://www.canada.ca/en/hea lth-canada/services/chemical- substances/fact- sheets/chemicals-glance.html
Env Canada	Screening Assessment for the Challenge	International Resources	Assessment or Related Document	https://www.canada.ca/en/hea lth-canada/services/chemical- substances/challenge/list.html
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	
EPA	OPPT: Chemview (TSCA submissions - chemical test rule data and substantial risk reports)	US EPA Resources	Database	https://chemview.epa.gov/chemview

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata .us/portal/
EPA	PPRTV Derivation Support Document	US EPA Resources	Assessment or Related Document	https://hhpprtv.ornl.gov/quick view/pprtv_papers.php
EPA	Design for the Environment (DfE) Alternatives Assessments	US EPA Resources	Assessment or Related Document	https://www.epa.gov/safercho ice/design-environment- alternatives-assessments
EPA	TSCA Data Needs Assessments or Problem Formulation	US EPA Resources	Assessment or Related Document	https://hhpprtv.ornl.gov/quick view/pprtv.php
EPA	Other EPA: Misc sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air- emissions-factors-and- quantification/ap-42- compilation-air-emissions- factors
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database	https://www.epa.gov/air- emissions-inventories/2014- national-emissions-inventory- nei-data
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationar y-sources-air-pollution
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios
IARC	IARC Monograph	International Resources	Assessment or Related Document	http://monographs.iarc.fr/EN G/Monographs/PDFs/index.p hp
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/ info/publications/WCMS_11 3134/langen/index.htm

Source Agency	Source Name	Source Type	Source Category	Source Website
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List	https://www.env.go.jp/en/che mi/prtr/substances/
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article Other Resource Encyclopedia		Encyclopedia	https://onlinelibrary.wiley.co m/doi/book/10.1002/0471238 961
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/s earch.asp
NIOSH	CDC NIOSH - Workplace Survey Reports	Other US Agency Resources	Assessment or Related Document	https://www.cdc.gov/niosh/surveyreports/allreports.html
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/reports/index.html?type=Technical+Report
OECD	OECD Substitution and Alternatives Assessment	International Resources	Assessment or Related Document	http://www.oecdsaatoolbox.o
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/docume nt/46/0,2340,en_2649_20118 5_2412462_1_1_1_1,00.html
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	https://www.tera.org/

Appendix B PHYSICAL AND CHEMICAL PROPERTIES

Table_Apx B-1 summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0476).

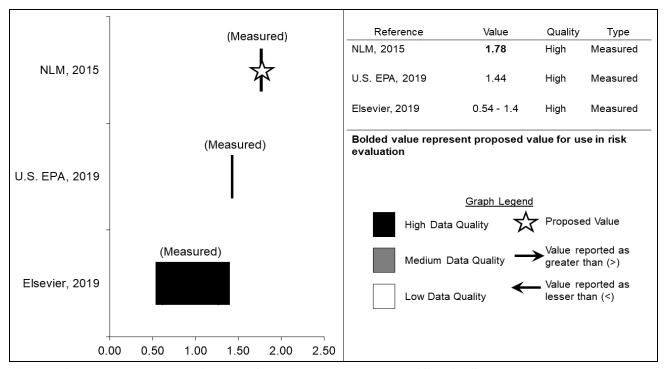
Table Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	_	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	1	-	NA	NA	NA	NA
Physical properties	2	-	NA	NA	NA	NA
Melting point	5	°C	-49	8.3	-55	-35
Boiling point	4	°C	296	69.0	192	330
Density	4	g/cm ³	1.407	0.020	1.39	1.4289
Vapor pressure	1	mm Hg	0.0613	-	0.0613	0.0613
Vapor density	0	-	-	-	-	-
Water solubility	2	mg/L	7410	579.8	7000	7820
Octanol/water partition coefficient (log Kow)	4	-	1.29	0.53	0.54	1.78
Henry's Law constant	0	atm·m³/m ol	-	-	-	-
Flash point	1	°C	222	-	222	222
Auto flammability	0	°C	-	-	-	-
Viscosity	3	cР	17.62	23.71	3.57	45
Refractive index	5	-	1.4731	0.0031	1.4707	1.4786
Dielectric constant	0	-	-	-	-	-

NA = Not applicable

The preliminarily selected value for the log K_{OW} lies outside the 95% confidence interval, defined as ± 2 standard deviations from the mean under the assumption that the data are normally distributed (see Figure 2-12). All of the log K_{OW} values were reported in secondary sources, and EPA will attempt to obtain and review the primary data sources before identifying the final selected log K_{OW} value.

Information about all reported log Kow values are summarized in Figure_Apx B-1 and presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0476).



Figure_Apx B-1. Tornado Diagram for Viscosity Data Identified in Systematic Review

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for tris(2-chloroethyl) phosphate. This information was presented in the *Proposed Designation of Tris*(2-chloroethyl) *Phosphate (CASRN 115-96-8) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and may be updated as EPA collects additional information through systematic review methods.

Table Apx C-1. Environmental Fate Characteristics of TCEP

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	HSDB (2015)
Indirect Photodegradation	$t_{1/2} = 5.8$ hours (based on ·OH rate constant of $2.2 \times 10\text{-}11 \text{ cm}^3\text{/molecule-sec}$ at 25 °C and 12-hour day with $1.5 \times 10^6 \cdot \text{OH/cm}^3$; estimated) ^b	U.S. EPA (2012b)
Hydrolysis	$t_{1/2} = \text{stable at pH 3}$ $t_{1/2} = 3,980 \text{ days at pH 7}$ $t_{1/2} = 101 \text{ days at pH 10}$	Environment Canada (2009), citing Brown et al. (1975)
Biodegradation (Aerobic)	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)	NITE (2010), ECHA (2019)
	Water: 10%/27 days (OECD 302B) 15%/21 days (OECD 302B) in activated non- adapted industrial sludge	Environment Canada (2009), EC (2000)
	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: DT50 = 167 days, DT90 >>100 days based on test substance concentration 5 mg/kg in standard soil laboratory test	Environment Canada (2009)
Biodegradation (Anaerobic)	Soil: 0%/58 days at 80 mg/L test substance concentration related to DOC (ISO DIS 11734)	EC (2000), citing Noack (1993)

Wastewater Treatment	9.2% total removal (7.3% by biodegradation, 1.9 by sludge and 0% by volatilization to air; estimated) ^b	<u>U.S. EPA (2012b)</u>
Bioconcentration Factor	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>)	NITE (2010), ECHA (2019)
Bioaccumulation Factor	6.3 (estimated) ^b	<u>U.S. EPA (2012b)</u>
Soil Organic Carbon: Water Partition Coefficient (Log Koc)	2.6 (K _{OC} = 388; MCI method); 2 (K _{OC} = 103; KOW method) (estimated) ^b	U.S. EPA (2012b)

^a Measured unless otherwise noted;

Abbreviations and acronyms: 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

 $[^]b$ EPI Suite TM physical property inputs: Log KOW = 1.78, BP = 330 °C, MP = -55 °C, VP = 1.6 \times 10-5 mm Hg, WS = 7,820 mg/L, SMILES O=P(OCCCl)(OCCCl)OCCCl

Appendix D REGULATORY HISTORY

D.1 Federal Laws and Regulations

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Statutes/Regulation	s	
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	TCEP is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of TCEP as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA Section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	TCEP manufacturing (including importing), processing and use information is reported under the CDR rule (85 FR 20122, April 2, 2020).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	TCEP was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA Section 5 (60 FR 16309, March 29, 1995). The chemical is on the active inventory.
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Three chemical data submissions from test rules received for TCEP: all three were monitoring reports (1978, 1980, and 1981) (U.S. EPA, ChemView, Accessed April 3, 2019).

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Prohibitions	Three states have adopted prohibitions for the use of TCEP in children's products, including Maryland (MD Health Gen § 24-306), New York (TRIS-free Children and Babies Act (NY Envir Conser § 37-0701 et seq.)), Minnesota (Four flame Retardants in Furniture Foam and Children's Products (Minn. Stat. § 325F.071)). California adopted a prohibition, effective on January 1, 2020, on the selling and distribution in commerce of new, not previously owned juvenile products, mattresses, or upholstered furniture that contains, or a constituent component of which contains, covered flame retardant chemicals at levels above 1,000 parts per million (A.B. 2998, Legislative Council, Sess. 2017-2018, C.A. 2018).
State Drinking Water Standards and Guidelines	Minnesota developed a health-based guidance value for TCEP in drinking water (Minn R. Chap. 4720).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing TCEP, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).
Other	California listed TCEP on Proposition 65 in 1992 due to cancer (Cal Code Regs. Title 27, § 27001). California issued a Health Hazard Alert for TCEP (Hazard Evaluation System and Information Service, 2016). California lists TCEP as a designated priority chemical for biomonitoring (California SB 1379). TCEP is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). The regulation for Children's Foam-Padded Sleeping Products containing TCEP as a Priority Product went into effect on July 1, 2017: Manufacturers' of this product must notify the Department by September 1, 2017 (California Department of Toxic Substances Control, Accessed April 12, 2019).

D.3 International Laws and Regulations

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

Agreements	
Country/ Organization	Requirements and Restrictions
Canada	TCEP (Ethanol, 2-chloro-, phosphate (3:1)) is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1).
	TCEP was added to Schedule 2 of the <i>Canada Consumer Product Safety Act (CCPSA)</i> , based on concerns for carcinogenicity and impaired fertility. (Government Canada Chemical Safety portal. Accessed April 10, 2019).
	In January 2013, a Significant New Activity was adopted for TCEP (<i>Canada Gazette</i> , April 3, 2014; Vol. 148, No. 9).
European Union	In June 2017, TCEP was added to Annex XIV of REACH (Authorisation List) with a sunset date of August 21, 2015 (European Chemicals Agency (ECHA, 2019) database, Accessed April 10, 2019).
	In 2010, TCEP was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 57C)).
Australia	Ethanol, 2-chloro-, phosphate (3:1) (TCEP) was assessed under Human Health Tier II and III of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Uses reported include commercial: (NICNAS, 2016, Ethanol, 2-chloro-, phosphate (3:1): Human health tier II assessment, Accessed April 8, 2019) (NICNAS, 2017, Ethanol, 2-chloro-, phosphate (3:1): Human health tier III assessment, Accessed April 8, 2019).
Japan	 TCEP is regulated in Japan under the following legislation: Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL), Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof, Air Pollution Control Law (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP], April 8, 2019).
Basel Convention	Waste substances and articles containing or contaminated with polychlorinated biphenyls (PCBs) and/or polychlorinated terphenyls (PCTs) and/or polybrominated biphenyls (PBBs) are listed as a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters. http://www.basel.int/Portals/4/Basel%20Convention/docs/text/BaselConventionText-e.pdf .

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

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

E.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities.

E.1.1 Manufacture (Including Import)

E.1.1.1 Import

EPA expects that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and QC samples may be taken for analyses (U.S. EPA, 2018b).

E.1.2 Processing and Distribution

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

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. TCEP may undergo several processing steps and the processing is dependent on its downstream incorporation into articles, which is discussed in the next subsection (U.S. EPA, 2018c).

E.1.2.2 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of TCEP-containing formulations or reaction products are dependent on the article (<u>U.S. EPA, 2018c</u>). For example, TCEP may be incorporated into aircraft interiors as a flame retardant (<u>EPA-HQ-OPPT-2018-0476-0006</u>). EPA plans to further investigate the use of TCEP being incorporated into articles during risk evaluation.

E.1.2.3 Recycling

EPA did not identify TCEP-specific information for recycling at this time; however, this chemical has been identified in articles that are commonly recycled such as insulation, plastics and foam. The processes for recycling these materials may include grinding, washing, and rinsing the recycled material and incorporating it into new formulations and articles as described more generally in Kirk Othmer (Borchardt, 2006). EPA has not identified specific worker activities related to the recycling TCEP-containing products. Based on EPA's knowledge, worker activities are anticipated to be exposed to TCEP from reclamation activities such as sorting, materials grinding steps and loading recovered materials into transport containers.

E.1.3 Uses Included in Scope

E.1.3.1 Aircraft Interiors and Aerospace Products

The Aerospace Industries Association (AIA, 2019) informed EPA that TCEP is used as a constituent within products or formulations for the manufacture, operation and maintenance of aerospace products: it is 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, and coatings. Specific aerospace industrial uses include resins and elastomeric coatings, polyurethane casting for aircraft interiors and as a flame retardant (AIA, 2019). Aceto US, LLC, a former importer of TCEP, has indicated to EPA that TCEP is used as a flame retardant for aircraft furniture (EPA-HQ-OPPT-2018-0476-0015).

E.1.3.2 Building / Construction Materials

Aceto US, LLC, a former importer of TCEP, informed EPA that the building industry (roof insulation) is one potential field of application of the chemical (as used as a flame-retardant plasticizer in unsaturated polyester resins) (EPA-HQ-OPPT-2018-0476-0015). The European Commission (2012) stated that TCEP is used in the building industry, where roofing insulation accounted for more than 80% uses in the EU. Substances in Preparations in Nordic Countries (SPIN, 2019) reported TCEP for use in construction materials (up to 2003) and insulating materials (up to 2010). The World Health Organization's IARC Monographs on the Evaluation of Carcinogenic Risks to Humans identifies the use of TCEP as a flame retardant in rigid foams used for building insulation (IARC, 1999). NLM's PubChem states that TCEP is used in cast acrylic sheet and wood-resin composites such as particle board, citing a 2001 posting of Environment Canada's screening assessment report states that polymer products containing TCEP are used in the building industry, specifically roofing insulation (Environment Canada, 2009). TCEP has been identified in currently available foam products used in structural panels and insulation.

E.1.3.3 Foam Seating and Bedding Products

Aceto US, LLC, a former importer of TCEP, informed EPA that TCEP is sold into the furniture industry, and that the furniture industry uses TCEP as a flame-retardant plasticizer in unsaturated polyester resins (EPA-HQ-OPPT-2018-0476-0015). Polyester fibers are processed into yarns and fabrics in the same manner as other fibers, thus bedding products may contain polyester in the yarns and threads used in bed sheets and blankets (EPA, 1994). NLM's Hazardous Substance Databank (HSDB) identifies the use of TCEP with melamine in flexible urethane cushions and institutional mattresses (Kirk-Othmer Encyclopedia of Chemical Technology, as cited in (HSDB, 2015). Flexible urethane cushions have many applications in furniture and automotive products. Specific uses include furniture foam padding, automotive seat cushions and padding, flooring (carpet underlay), pillows and mattress foam padding (U.S. EPA, 2004a). According to Substances in Preparations in Nordic Countries (SPIN, 2019) TCEP was reported for use in manufacture of furniture, until 2007.

E.1.3.4 Other: Uses (e.g., Laboratory Use)

TCEP is used as a laboratory chemical, such as in a chemical standard mixture. A commenter (EPA-HQ-OPPT-2018-0476-0032) provided descriptions of their use of TCEP in analytical standard, research, equipment calibration and sample preparation applications, including reference sample for analysis of terrestrial and extraterrestrial material samples, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

E.1.3.5 Paints and Coatings

For the 2012 CDR, Aceto US, LLC reported the use of TCEP as a flame retardant for processing (incorporation into formulation, mixture, or reaction product) in the paint and coating manufacturing sector (<u>U.S. EPA, 2014</u>). Aceto US, LLC was a former importer and manufacturer and they did not provide use information in the 2016 CDR. However, Aceto US, LLC did inform EPA that coatings is one potential field of application of the chemical (<u>EPA-HQ-OPPT-2018-0476-0015</u>).

E.1.3.6 Fabric, Textile, and Leather Products

Aceto US, LLC, a former importer of TCEP, informed EPA that TCEP is sold into the textile industry,

and that the textile industry uses TCEP as a flame-retardant plasticizer in unsaturated polyester resins (EPA-HQ-OPPT-2018-0476-0015). Fabric and textile products using polyester resins include polyester yarns and fabrics, in the same manner as other fibers (EPA, 1994). Polyester yarns and fabrics can be found in clothing, bed sheets, blankets, and upholstered furniture while industrial polyester fibers, yarns, and ropes are used in car tire reinforcements, fabrics for conveyor and safety belts, and coated fabric and plastic reinforcements with high-energy absorption. Rudolf-Venture Chemical Inc., an importer of TCEP as of 2015, is a supplier of chemicals specifically for the textile industry. The European Chemicals Agency (ECHA) registration dossier reports the use of TCEP in coatings at industrial and professional sites (ECHA, 2019). Environment Canada's screening assessment reports that TCEP is used in polymer products that are used in the textile industry, including back-coatings for carpets and upholstery (Environment Canada, 2009). The European Commission also lists the textile industry (e.g., back-coatings for carpets and upholstery) as a use in the EU (EC, 2012).

E.1.4 Disposal

Disposal of a chemical should take into consideration the chemical's potential impact on air quality, migration to groundwater, effect on biological species, and disposal regulations (if any) (ATSDR, 2017). Currently, TCEP is not regulated under federal regulations as a hazardous waste. However, TCEP may be disposed of as a hazardous waste if it is present in or co-mingled with solvent mixtures that are Resource Conservation and Recovery Act (RCRA) regulated substances

Demolished building materials are classified as Construction and Demolition (C&D) waste, which may be disposed in municipal solid waste landfills (MSWLFs) or C&D landfills (U.S. EPA, 2018c, 2014).

E.2 Preliminary Occupational Exposure Data

EPA plans to consider reasonably available data and information related to worker exposure and environmental releases as they are identified during systematic review. Based on a preliminary data gathering, there are no OSHA Chemical Exposure and Health Data (CEHD) specific to TCEP.

Table_Apx E-1 summarizes NIOSH Health Hazard Evaluations identified during EPA's preliminary data gathering. HHEs can be found at https://www.cdc.gov/niosh/hhe/.

Table_Apx E-1. Potentially Relevant Data Sources for Exposure Monitoring and Area Monitoring Data from NIOSH Health Hazard Evaluations for TCEP^a

Data Ironi 110011 Iteatin Itazara Dianations for Tolli										
Year of Publication Report Number		Facility Description								
2019	HHE-2016-0257-3333	Elect	ronics recycling company							
2018	HHE-2015-0050-3308	Electronics recycling company								
2017	HHE-2014-0131-3268	Gym	nastics studios							
1977	HHE-77-39-400	Prod	uction of automobile upholstery							

^a Table includes HHEs identified to date

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

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

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	Workers	Yes	According to CDR, one submitter indicated that they import TCEP in liquid form. Exposure will occur if the imported material is repackaged
			ort Repackaging	Solid Contact	Dermal	Workers	Yes	According to CDR, one submitter indicated that they imported TCEP in wet solid form. Exposure will occur if the imported material is repackaged
Manufacture	Import	Import		Mist, Dust	Inhalation	Workers, ONU	No	Mist generation is not expected during the import (<i>i.e.</i> , repackaging) process. Because TCEP is imported as a liquid or wet solid, dust generation is not expected during the import (<i>i.e.</i> , repackaging) process
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
Processing	Incorporation into Formulation, Mixture, or Reaction product	Flame retardant in Paint and coating manufacturing; polymers		Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations as TCEP is in liquid form.
K				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations as TCEP can be used/transported in wet solid form (according to one importer reporting to CDR).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale	
				Mist, Dust	Inhalation	Workers, ONU	No	Mist generation is not expected during processing (incorporation into formulation, mixture, or reaction product). TCEP is in liquid form (or wet solid form according to one importer reporting to CDR), so dust generation is not expected during unloading operations.	
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.	
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.	
				Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations, as TCEP is in liquid form.	
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during unloading operations, as TCEP can be used/transported in wet solid form (according to one importer reporting to CDR)	
	Incorporation into article	I Blame retardant	Flame retardant Unloading	Unloading	Mist, Dust	Inhalation	Workers, ONU	No	Mist generation is not expected during processing (incorporation into articles). TCEP is in liquid form (or wet solid form according to one importer reporting to CDR), so dust generation is not expected during unloading operations.
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.	
				Liquid, Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.	

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during recycling, as TCEP can be incorporated in different liquid products
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during recycling, as TCEP can be incorporated in different solid products.
	Recycling	Recycling		Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during recycling
			Reclamation Activities	Dust	Inhalation	Workers, ONU	Yes	Dust exposure is expected during recycling, as particulates from solid products containing TCEP can be generated
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
			Unloading; Spray Coating	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (Paints and Coatings), as paints and coatings containing TCEP are in liquid form.
				Solid Contact	Dermal	Workers	No	Paints and coatings containing TCEP are not expected to be handled or used in solid form.
Industrial, Commercial, Consumer Use	Paints and Coatings			Mist	Inhalation	Workers, ONU	Yes	The potential for exposure to TCEP suspended in mist exists during spray coating applications (Paints and Coatings)
			Applications	Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
				Dust	Inhalation	Workers, ONU	No	TCEP and paints containing TCEP are in liquid form so dust generation is not expected during this use (paints and coatings)

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Liquid Contact	Dermal	Workers	No	TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form.
			Use/Installati on of	Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during the handling and manufacture of aircraft interiors and aerospace products containing article components with TCEP.
	Aircraft interiors and aerospace products	materials in aircraft interiors and	Mist, Dust	Inhalation	Workers, ONU	No	Mist and dust generation is not expected during this use (aircraft interiors and aerospace products).	
			aerospace products	Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
	Other Use	Other Use Laboratory chemicals		Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
			Use of laboratory chemicals	Liquid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (laboratory chemicals), as TCEP is in liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (laboratory chemicals), as TCEP can be used/transported in wet solid form (according to one importer reporting to CDR)
				Mist, Dust	Inhalation	Workers, ONU	No	Mist generation is not expected during this use (laboratory chemicals). TCEP is in liquid form (or wet solid form according to one importer reporting to CDR), so dust generation is not expected during this use (laboratory chemicals).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Liquid Contact	Dermal	Workers	No	TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form.
			Use of other textile products	Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (fabric, textile, and leather products not covered elsewhere) during the handling of textiles and manufacture of products.
		Fabric, textile, and leather products not		Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during this use (fabric, textile, and leather products not covered elsewhere).
	Furnishing,	covered elsewhere		Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
	Cleaning, Treatment Care Products			Dust	Inhalation	Workers, ONU	Yes	Dust generation may occur as textiles are cut and incorporated into finished products.
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
			Unloading	Liquid Contact	Dermal	Workers	No	TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form.
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (foam seating and bedding products) during the handling of foam and manufacture of products.
				Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during this use (foam seating and bedding products).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale	
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.	
				Dust	Inhalation	Workers, ONU	No	Dust generation is expected during this use (Foam Seating and Bedding Products), as TCEP-containing articles may need to be cut during finishing operations.	
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.	
			aterials not public and	Liquid Contact	Dermal	Workers	No	TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form.	
				Solid Contact	Dermal	Workers	Yes	The potential for exposure to workers from articles and article components containing TCEP exists during this use (building/construction materials not covered elsewhere).	
		Building/constructi on materials not		euse/Demolit ion of materials in residential, public and commercial buildings, and other	Mist	Inhalation	Workers, ONU	No	Mist generation is not expected during this use (building/construction materials not covered elsewhere).
	Construction, Paint, Electrical, and Metal Products	covered elsewhere			commercial buildings, and other	Vapor	Inhalation	Workers, ONU	Yes
				Dust	Inhalation	Worker, ONU	Yes	Dust generation is expected during this use (building/construction materials not covered elsewhere).	
				Liquid/Solid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.	
		Wood and engineered wood products		Liquid Contact	Dermal	Workers	No	TCEP and TCEP-containing article components are not expected to be handled or used in the liquid form	

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
				Solid Contact	Dermal	Workers	Yes	The potential for exposures to workers exists during this use (wood and engineering wood products) during the handling and manufacture of wood and engineered wood products.
			Use of wood and engineering wood products	Mist, Dust	Inhalation	Workers, ONU	No	Mist generation is not expected during this use (wood and engineering wood products). Dust generation is not expected during this use (wood and engineering wood products).
				Vapor	Inhalation	Workers, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.
				Liquid/Solid Contact	Dermal	ONU	NO	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Liquid Contact	Dermal	Worker	Yes	Dermal exposure is expected for this condition of use
				Dust	Inhalation	Worker	Yes	TCEP may be present in solid material. EPA plans to evaluate the inhalation pathway.
Disposal	Disposal Waste Handling. Treatment and Disposal Disposal of TCEP containing wastes	Worker handling of wastes	Vapor	Inhalation	Worker, ONU	Yes	Due to high volatility of TCEP (0.06 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor.	
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
			Dust	Inhalation	ONU	Yes	TCEP may be present in solid material. EPA plans to evaluate the inhalation pathway	

Appendix G SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USE

Table_Apx G-1 Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
			Direct contact via application of paints and coatings	Liquid Contact	Dermal	Consumers	Yes	The potential for exposures exists during this use (Paints and Coatings), as paints and coatings containing TCEP are in liquid form.
Consumer Use	Paints and Coatings	Paints and Coatings		Vapor	Inhalation	Consumers/ Bystanders	Yes	Due to the volatility of TCEP (VP = 0.06 mmHg) at room temperature, inhalation exposure to TCEP in the vapor phase is possible.
			containing TCEP	Mist	Inhalation	Consumers/ Bystanders	Yes	The potential for exposure to TCEP suspended in mist exists during spray coating applications (Paints and Coatings)
		int, cal, and	Direct contact through use of electrical and electronic products made containing TCEP	Air/Particulate	Inhalation	Consumers/ Bystanders	Yes	Inhalation of air and/or particles from electrical and electronic products containing TCEP may occur for this condition of use. EPA plans to analyze inhalation exposure.
				Dust	Ingestion	Consumers	Yes	Ingestion of dust from electrical and electronic products containing TCEP may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
Consumer Use	Construction, Paint, Electrical, and Metal Products			Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure.
Wetai Floduci	wictar i roddets	Building/ construction	Direct contact through use of	Air/Particulate	Inhalation	Consumers/ Bystanders	Yes	Inhalation of air and/or particles from building/construction materials containing TCEP may occur for this condition of use. EPA plans to analyze inhalation exposure.
		materials not covered elsewhere	building/ construction materials made containing TCEP	Dust	Ingestion	Consumers	Yes	Ingestion of dust from building/construction materials containing TCEP may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
				Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure.
				Air/Particulate	Inhalation	Consumers/ Bystanders	Yes	Inhalation via air and/or particulate exposure may occur during product/article use. EPA plans to analyze inhalation exposure.
Consumer Use	Furnishing, Cleaning,	Fabric, textile, and leather products not	Direct contact through use of	Dust	Ingestion	Consumers	Yes	Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
	Treatment/ Care Products	covered elsewhere	products/articles containing TCEP	Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur via use of articles containing TCEP. EPA plans to analyze dermal exposure.
				Article/Product Mouthing	Ingestion	Consumers	Yes	Ingestion via object to mouth or subsequent hand to mouth from product dermal contact. EPA plans to analyze mouthing via ingestion.
			Direct contact through use of	Air/Particulate	Inhalation	Consumers/ Bystanders	Yes	Inhalation via air and/or particulate exposure may occur during product/article use. EPA plans to analyze inhalation exposure.
Consumer Use	Furnishing, Cleaning,	Foam setting and		Dust	Ingestion	Consumers	Yes	Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
	Treatment/ Care Products	bedding products	products/articles containing TCEP	Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur via use of articles containing TCEP. EPA plans to analyze dermal exposure.
				Article/Product Mouthing	Ingestion	Consumers	Yes	Ingestion via object to mouth or subsequent hand to mouth from product dermal contact. EPA plans to analyze mouthing via ingestion.
Consumer Handling of	Wastewater, Liquid wastes	Wastewater, Liquid wastes	Direct contact through use of	Article/Product Contact	Dermal	Consumers	Yes	Dermal exposure may occur for this condition of use. EPA plans to analyze dermal exposure.
Disposal and Waste	and solid wastes	and solid wastes	products/articles containing TCEP	Dust	Ingestion	Consumers	Yes	Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
				Air/Particulate	Inhalation	Consumers and Bystanders	Yes	Inhalation of air and/or particles from articles/products containing TCEP may occur for this condition of use. EPA plans to analyze inhalation exposure.
			Long-term emission/mass- transfer through	Dust	Ingestion	Consumers	Yes	Ingestion of TCEP sorbed onto dust may occur for this condition of use. EPA plans to analyze dust exposure via ingestion.
			use of products containing TCEP	Air/Particulate	Inhalation	Consumers and Bystanders	Yes	Inhalation of air and/or particles from articles/products containing TCEP may occur for this condition of use, EPA plans to analyze inhalation exposure

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

Table Apx H-1 General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale		
			Near facility ambient air concentrations	Inhalation	General Population	Yes			
	Emissions to Air	Emissions to Air	Indirect deposition to	Oral Dermal	General Population	Yes	TCEP deposition to nearby bodies of water and soil are expected exposure pathways, not covered under		
	to Air		nearby bodies of water and soil catchments	TBD	Aquatic and Terrestrial Receptors	Yes	other EPA regulations, and, therefore in scope.		
			Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	EPA plans to analyze the release of TCEP into surface water and indirect partitioning to sediment exposure pathways to aquatic and terrestrial receptors.		
All		iquid wastewater		Oral Dermal	General Population	Yes	EPA plans to analyze the release of TCEP into surface water and indirect partitioning to sediment and bioaccumulation exposure pathways to the general population.		
			treatment and wastewater treatment, or	treatment and wastewater treatment, or	Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	Yes	EPA plans to analyze the release of TCEP into surface water and indirect partitioning to drinking water.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	EPA plans to analyze the pathway from biosolids to		
				TBD	Aquatic and Terrestrial Receptors	Yes	the general population, aquatic and terrestrial species.		

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
	Solid and		Leachate to soil,	Oral Dermal	General Population	Yes	EPA plans to analyze the pathway from municipal
Disposal	Liquid Wastes	Municipal landfill and other land disposal	ground water and/or mitigation to surface water	TBD	Aquatic and Terrestrial Receptors	163	landfills and other land disposal to the general population, aquatic and terrestrial receptors.