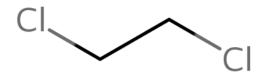


Draft Scope of the Risk Evaluation for 1,2-Dichloroethane

CASRN 107-06-2



April 2020

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Docket

Supporting information can be found in public docket: Docket ID: EPA-HQ-OPPT-2018-0427.

Disclaimer

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States Government.

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Government Industrial Hygienists				
ADME	Absorption, Distribution, Metabolism, and Excretion				
AMTIC	EPA Ambient Monitoring Technology Information Center				
ATSDR	Agency for Toxic Substances and Disease Registry				
AWQC	Ambient Water Quality Criteria				
BAF	Bioaccumulation Factor				
BCF	Bioaccumulation Factor Bioconcentration Factor				
BMF	Biomagnification factor				
BOD	Biochemical Oxygen Demand				
BP	Boiling Point				
BSER	Best System of Emission Reduction				
$BW^{3/4}$	Body Weight ³ / ₄ Extrapolation				
CAA	Clean Air Act				
CAL EPA	California Environmental Protection Agency				
CASRN	Chemical Abstracts Service Registry Number				
CBI	Confidential Business Information				
CDC	Centers for Diseases Control and Prevention				
CDR	Chemical Data Reporting				
CEHD	Chemical Exposure Health Data				
CEHD CEM	-				
CEPA	Consumer Exposure Model				
	Canadian Environmental Protection Act				
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act				
CFR	Code of Federal Regulations				
CHRIP	Chemical Risk Information Platform				
COC	Concentration of Concern				
CSCL	Chemical Substances Control Law				
CWA	Clean Water Act				
DMR	Discharge Monitoring Report				
DOT	Department of Transportation				
EC	Engineering Control(s)				
ECHA	European Chemicals Agency				
DCE	1,2-Dichloroethane				
EPA	Environmental Protection Agency				
EPCRA	Emergency Planning and Community Right-to-Know Act				
ERG	Eastern Research Group				
ESD	Emission Scenario Document				
EU	European Union				
FDA	Food and Drug Administration				
FFDCA	Federal Food, Drug, and Cosmetic Act				
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act				
FR	Federal Register				
FYI	For your information				
GACT	Generally Available Control Technology				
GC	Gas Chromatography				

GESTIS	Substance Database contains information for the safe handling of hazardous substances
	and other chemical substances at work
GDIT	General Dynamics Information Technology
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HERO	Health and Environmental Research Online
HHE	Health Hazard Evaluation
HLC	Henry's Law Constant
HMTA HSDB	Federal Hazardous Materials Transportation Act Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
IBCs	Intermediate Bulk Containers
ICF	ICF is a global consulting services company
IECCU	Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned
шеее	Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
ISHA	Industrial Safety and Health Act
Koc	Organic Carbon: Water Partition Coefficient
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology
Kow	Octanol: Water Partition Coefficient
LC _x	Lethal Concentration
LOAELs	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MFG MITI	Manufacturing Ministry of International Trade and Industry
MOA	Mode of Action
MP	Mode of Action Melting Point
MWCs	Municipal waste combustors
MSW	Municipal Solid Waste
NAICS	North American Industry Classification System
NATA	National-scale Air Toxics Assessment
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NOAELs	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPDWR NPL	National Primary Drinking Water Regulation National Priorities List
NPL	National Phonties List National Pollutant Release Inventory
NSPS	New Source Performance Standards
NTP	National Toxicology Program
1111	

OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OELs	Occupational Exposure Limits
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OW	EPA's Office of Water
P-chem	Physical-chemical
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, and Toxic
PECO	Population, Exposure, Comparator, Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulations
PODs	Points of Departure
POTW PPE	Publicly Owned Treatment Works
RCRA	Personal Protective Equipment Resource Conservation and Recovery Act
RDF	Refuse-derived Fuel
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REL	Recommended Exposure Limit
RIVM	Dutch National Institute for Public Health and the Environment
SARA	Superfund Amendments and Reauthorization Act
SBR	Styrene Butadiene Rubber
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SIDS	Screening Information Dataset
SRC	SRC Inc., formerly Syracuse Research Corporation
STEL	Short-term Exposure Limit
STORET	Storage and Retrieval for Water Quality Data; EPA's repository of water quality
avoc	monitoring data
SVOCs	Semi-Volatile Organic Compounds
TBD TERA	To be determined Toxicology Excellence for Pick Assessment
TG	Toxicology Excellence for Risk Assessment Test Guideline
TIAB	Title and Abstract
TK	Toxicokinetics
TLV	Threshold Limit Value
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total Toxic Organics
TURA	Toxic Use Reduction Act
TWA	Time-weighted average
UCMR	Unregulated Contaminants Monitoring Rule
UIC	Underground Injection Control
USDA	United States Department of Agriculture
USGS	United States Geological Survey

VOC	Volatile Organic Compound
VP	Vapor Pressure
WHO IPCS	World Health Organization International Programme on Chemical Safety
WQX	Water Quality Exchange
WS	Water Solubility
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated 1,2-dichloroethane (CASRN 107-06-2) as a high-priority substance for risk evaluation following the prioritization process as required by Section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0427). The first step of the risk evaluation process is the development of the scope document, and this document fulfills the TSCA requirement to issue a draft scope document as required in 40 CFR 702.41(c)(7). The draft scope for 1,2-dichloroethane includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. 1,2-Dichloroethane occurs as a colorless, oily, heavy liquid that is slightly soluble in water with a total production volume in the United States between 20 and 30 billion pounds. 1,2-Dichloroethane has a pleasant chloroform-like odor. It is a volatile, synthetic hydrocarbon that is used principally in the synthesis of vinyl chloride monomer and other chlorinated solvents.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for 1,2-dichloroethane to inform the development of this draft scope document. To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) and the search and screening results to date are provided in Section 2.1. EPA is seeking public comment on this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. EPA plans is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS and conditions of use that will help inform the risk evaluation for 1,2-dichlorethane.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of 1,2-dichloroethane in the risk evaluation. 1,2-Dichloroethane is manufactured within the U.S. as well as imported into the U.S. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction products, and incorporated into articles. The identified processing activities also include the repackaging and recycling of 1,2-dichloroethane. Several industrial and commercial uses were identified that ranged from use in plastic and rubber products to use in lubricants. The only consumer use reported is in plastic and rubber products. EPA identified these conditions of use from information reported to EPA through CDR and TRI reporting, published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for 1,2-dichloroethane 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 - from manufacturing, processing, distribution in commerce, storage, or use, to release or disposal. EPA plans to focus the risk evaluation for 1,2-dichloroethane on the following exposures, hazards and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

• *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of 1,2-dichloroethane that EPA plans to consider in the risk evaluation. Exposures for 1,2-dichloroethane are discussed in 2.3. EPA identified environmental monitoring data reporting the presence of 1,2-dichloroethane in air, drinking water, ground water, sediment, soil, surface water and biota. 1,2-dichloroethane is subject to reporting to EPA's Toxics Release Inventory (TRI) and EPA plans to use TRI information as reasonably available information to inform 1,2-dichloroethane's environmental release assessment. For the 2018 reporting year, 60 facilities reported to EPA releases of 1,2-dichloroethane to air, water, and via land disposal. Additional information gathered through the results of systematic review searches will also informed expected exposures.

EPA's plan as to environmental exposure pathways considers whether and how other EPAadministered statutes and regulatory programs address the presence of 1,2-dichloroethane in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 1,2-dichloroethane within the scope of the risk evaluation.

Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- Occupational exposure pathways associated with industrial and commercial conditions of use: EPA plans to evaluate exposures to workers and/or occupational non-users via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of 1,2-dichloroethane (Section 2.2.1).
- *Consumer and bystander exposure pathways associated with consumer conditions of use:* EPA plans to evaluate the inhalation and dermal exposure to 1,2-dichloroethane when consumers are handling plastic and rubber products.
- *Receptors and PESS:* EPA plans to include children, women of reproductive age (e.g., pregnant women per TSCA statute), workers and consumers as receptors and PESS in the risk evaluation.
- *Environmental exposures:* EPA plans to evaluate exposure to1,2-dichloroethane for aquatic and terrestrial receptors.
- *Hazards*. Hazards for 1,2-dichloroethane are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for 1,2-dichloroethane as part of the

prioritization process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for 1,2-dichloroethane. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. EPA plans to evaluate all of the potential human health hazards for 1,2-dichloroethane identified in Section 2.4.2. The broad health effect categories include reproductive and developmental, dermal, immunological, neurological and irritation effects. Studies were also identified reporting information on genotoxicity, carcinogenicity, biomonitoring and toxicokinetics. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards in the final scope document of the 1,2-dichloroethane risk evaluation.

Analysis Plan. The analysis plan for 1,2-dichlorethane 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 1,2-dichloroethane to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA will continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

EPA will seek public comments on the systematic review methods supporting the risk evaluation for 1,2-dichloroethane, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for 1,2-dichloroethane will be peer reviewed. Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's <u>Peer Review Handbook</u> and other methods consistent with Section 26 of TSCA (See <u>40</u> <u>CFR 702.45</u>).

1 INTRODUCTION

This document presents for comment the scope of the risk evaluation to be conducted for 1,2dichloroethane under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations 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 (84 FR 71924), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. 1,2-dichloroethane was also one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information¹ to support the development of this draft scope document for 1,2-dichloroethane. EPA leveraged the data and information sources already collected in the documents supporting the high-priority substance designations. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from in the following general categories of sources:

- 1. Databases containing publicly available, peer-reviewed literature;
- 2. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases.
- 3. Data and information submitted under TSCA Sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions

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).

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. The search and screening process was conducted based on EPA's general expectations for the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). EPA plans to publish supplemental documentation on the systematic review methods supporting the 1,2-dichloroethane risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed up to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for 1,2-dichloroethane upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature² and identified 99 search results relevant to EPA's risk assessment needs for 1,2-dichloroethane. Appendix A lists the gray literature sources that yielded 99 discrete data or information sources relevant to 1,2-dichloroethane. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

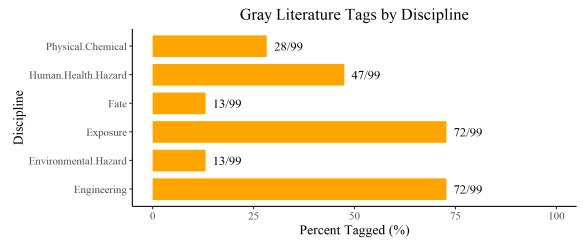


Figure 2-1. Gray Literature Tags by Discipline for 1,2-Dichloroethane

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

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

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

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physicalchemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of 1,2-dichloroethane. Eligibility criteria were applied in the form of PECO (population, exposure, comparator, outcome) statements. Included references met the PECO criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure 2-2 through Figure 2-6. "TIAB" in these figures refers to title and abstract screening. Note that the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various subcategories 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.

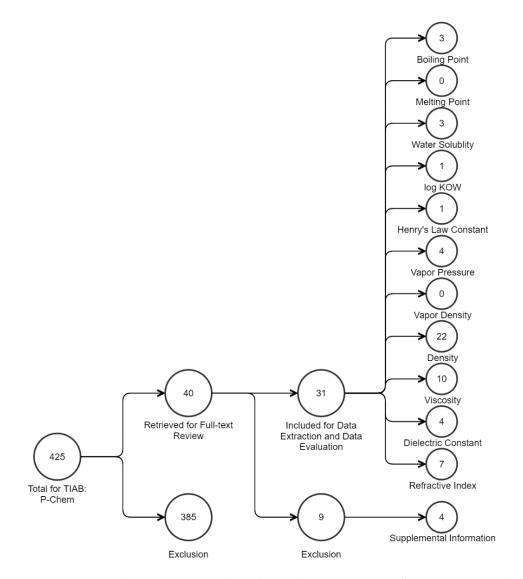


Figure 2-2. Peer-Reviewed Literature - Physical-Chemical Properties Search Results for 1,2-Dichloroethane

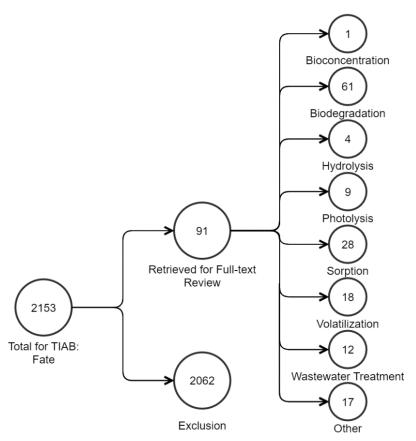


Figure 2-3. Peer-Reviewed Literature - Fate and Transport Search Results for 1,2-Dichloroethane

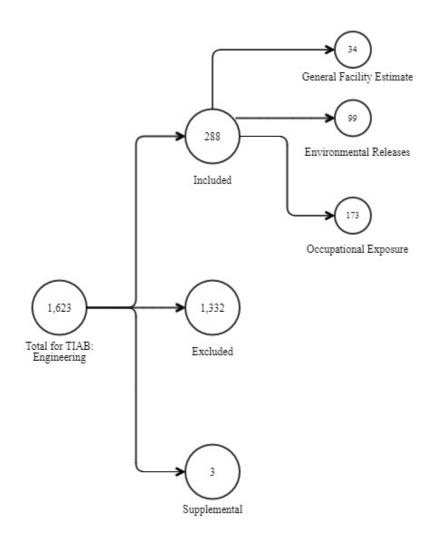


Figure 2-4. Peer Reviewed Literature - Engineering Search Results for 1,2-Dichloroethane

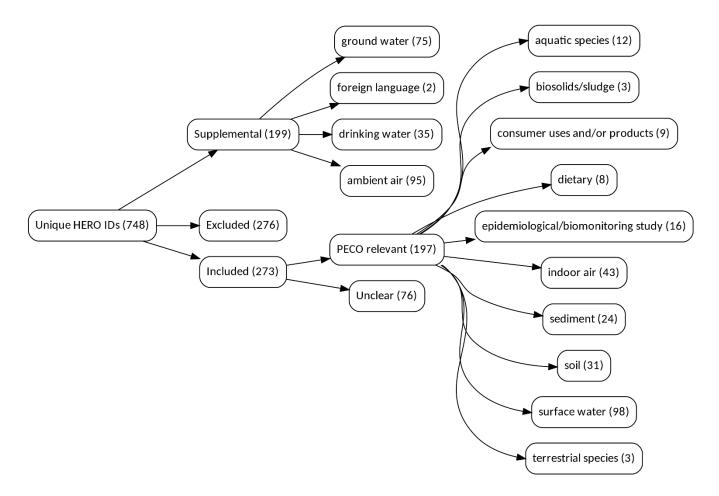


Figure 2-5. Peer-Reviewed Literature - Exposure Search Results for 1,2-Dichloroethane

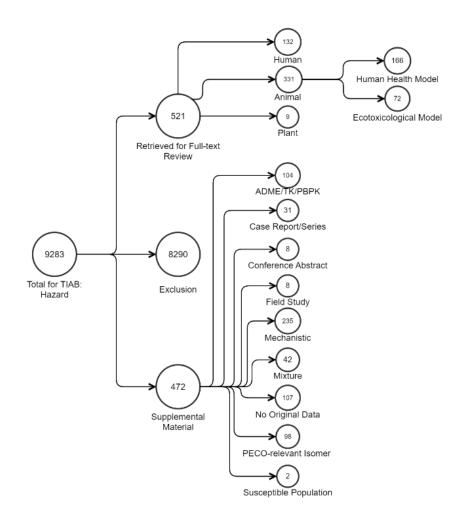


Figure 2-6. Peer-Reviewed Literature - Hazard Search Results for 1,2-Dichloroethane

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, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 235 submissions using inclusion/ exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 206 submissions that met the inclusion criteria in these statements and identified 15 submissions with supplemental data. EPA excluded 14 submissions because the reports were identified as one of the following:

- Published report that would be identified via other peer or gray literature searches
- Draft report of a final available submitted report
- Illegible submission
- Data not relevant to any discipline
- Letter of notification of bioremediation initiation
- Memo regarding meeting
- Submission on a different chemical
- Ranking of chemicals for proposed evaluation

- Letter with no attached report
- Route-to-route extrapolation of human health hazard with no original data

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

Discipline	Included	Supplemental
Physicochemical Properties	0	0
Environmental Fate and Transport	18	0
Environmental and General Population Exposure	114	1
Occupational Exposure/Release Information	70	0
Environmental Hazard	9	1
Human Health Hazard	61	13

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

2.2 Conditions of Use

As described in the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use³ or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of 1,2-dichloroethane, including: published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing 1,2-dichloroethane, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, and when applicable, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

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

After gathering the conditions of use, EPA identified those categories or subcategories of use activities for 1,2-dichloroethane the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.22.1.1.

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 are included in the scope of the risk evaluation. EPA is looking for more information to confirm reports of 1,2-dichloroethane use in cleaning and mechanical cleaning that are not currently included as conditions of use.

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

Life Cycle Stage	Category	Subcategory	References
Manufacturing	Domestic	Domestic manufacture	U.S. EPA (2019)
	manufacture		
	Import	Import ^a	U.S. EPA (2019)
Processing	Processing as a	Intermediate in:	U.S. EPA (2019); EPA-HQ-
	reactant	Petrochemical	OPPT-2018-0427-0006: EPA-
		manufacturing; Plastic	HQ-OPPT-2018-0427-0015
		material and resin	
		manufacturing; All	
		other basic organic	
		chemical manufacturing	
	Processing -	Fuels and fuel	U.S. EPA (2019); <u>EPA-HQ-</u>
	Incorporated into	additives: All other	<u>OPPT-2018-0427-0006; EPA-</u>
	formulation, mixture,	petroleum and coal	HQ-OPPT-2018-0427-0015
	or reaction product	products manufacturing	
		Functional Fluids:	U.S. EPA (2019)
		Pharmaceutical and	
		medicine	
		manufacturing	
		Processing aids:	U.S. EPA (2019)
		specific to petroleum	
	D 1'	production	
	Recycling	Recycling	U.S. EPA (2019)
Distribution in	Distribution in	Distribution in	
commerce	commerce	commerce	EDA 110 ODDT 2010 0427 0010
Industrial Use	Adhesives and sealants	Adhesives and sealants	EPA-HQ-OPPT-2018-0427-0018
	Functional Fluids (closed systems)	Heat transferring agent	Baldwin Filters (2015)
	Lubricants and	Paste lubricants and	EPA-HQ-OPPT-2018-0427-0005
	Greases	greases	
	Oxidizing/ reducing	Oxidation inhibitor in	EPA-HQ-OPPT-2018-0427-0006
	agents	controlled oxidative	
		chemical reactions	
	Solvents (for cleaning	A component of	EPA-HQ-OPPT-2018-0427-0005
	and degreasing)	degreasing and cleaning	
		solvents	
Commercial Use	Plastic and rubber	Products such as:	U.S. EPA (2019)
	products	plastic and rubber	
		products	
	Fuels and related	Fuels and related	U.S. EPA (2019); <u>EPA-HQ-</u>
	products	products	<u>OPPT-2018-0427-0006</u>
	Other use	Laboratory chemical ^b	ThermoFisher (2018)
		(e.g. reagent)	Enigid Eluid Company (2015)
		Embalming agent	Frigid Fluid Company (2015)

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

Life Cycle Stage	Category	Subcategory	References
Consumer Use	Plastic and rubber	Plastic and rubber	U.S. EPA (2019); Doucette, et al.
	products	products ^c	(2010)
Disposal	Disposal	Disposal	

a - The Agency has included information in this draft scope document sourced from the 2012 and 2016 Chemical Data
Reporting (CDR) Rule collections. In instances where particular CDR data elements included in this document were claimed as confidential business information (CBI), the Agency reviewed the claims and secured their declassification.
b- This use covers the reported industrial use of laboratory chemicals as they are used for services and wholesale and retail trade.

c – EPA continues to engage with stakeholders on this condition of use.

Notes:

- 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.

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

As explained in the final rule for *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, TSCA section 6(b)(4)(D) requires EPA to identify "*the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider*" in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). As a result, EPA does not plan to include in this scope or in the risk evaluation the activities that the Agency has concluded do not constitute conditions of use.

Organizations submitted docket comments to EPA regarding the presence of 1,2-dichloroethane in pesticides (EPA-HQ-OPPT-2018-0427-0005; EPA-HQ-OPPT-2018-0427-0006). These activities and releases are not TSCA conditions of use and will not be evaluated during the risk evaluation.

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 1,2-dichloroethane in 2015 was between 20 billion and 30 billion pounds (U.S. EPA 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of 1,2-dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that EPA plans to consider in the risk evaluation for the various life cycle stages. This section provides a brief overview of the industrial, commercial, and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities) for each manufacturing, processing, distribution in commerce, use and disposal category based on preliminary information.

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)⁴, in combination with other data sources (e.g., published literature and consultation with stakeholders) to provide an overview of the conditions of use.

⁴ The descriptions are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions and can be found in EPA's <u>Instructions for Reporting 2016 TSCA Chemical Data Reporting</u>.

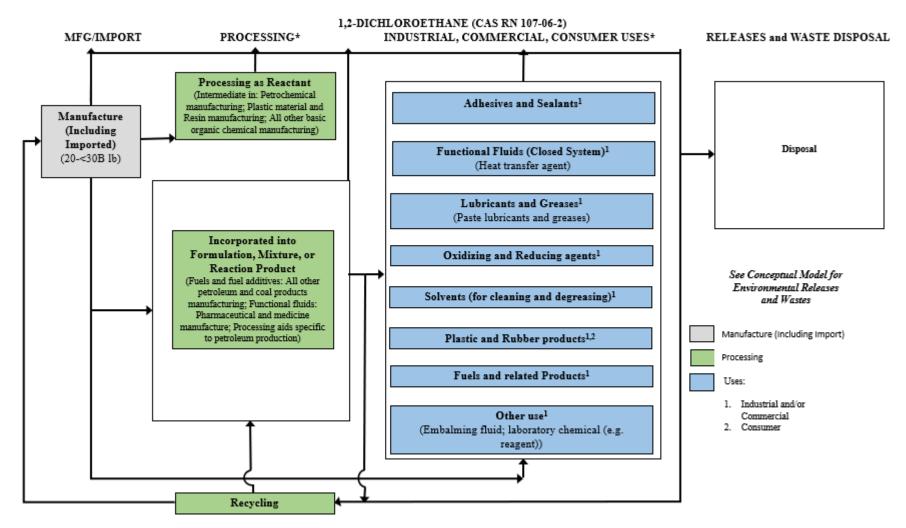


Figure 2-7. 1,2-Dichloroethane Life Cycle Diagram

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

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for 1,2-dichloroethane. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and environmental receptors. EPA plans to take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to 1,2-dichloroethane.

2.3.1 Physical and Chemical Properties

Physical and chemical properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019)) to support the development of the risk evaluation for 1,2-dichloroethane. The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for 1,2-dichloroethane. EPA plans to use the environmental fate characteristics described in the <u>Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a</u> <u>High-Priority Substance for Risk Evaluation</u> (U.S. EPA (2019)) to support the development of the risk evaluation for 1,2-dichloroethane. The values for the environmental fate properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

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

A source of information that EPA plans to consider in the risk evaluation in evaluating exposure is data reported under the Toxics Release Inventory (TRI) program. EPA's TRI database contains information on chemical waste management activities that are disclosed by industrial and federal facilities, including quantities released into the environment (i.e., to air, water, and disposed of to land), treated, burned for energy, recycled, or transferred off-site to other facilities for these purposes.

Under the Emergency Planning and Community Right-to-Know Act (EPCRA) 1,2-dichloroethane is a TRI-reportable substance, under the name 1,2-dichloroethane (or ethylene dichloride), effective January 01, 1987 (40 CFR 372.65). For TRI reporting⁵, facilities in covered sectors in the United States are required to disclose releases and other waste management activity quantities of 1,2-dichloroethane under the CASRN 107-06-2 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

⁵ For TRI reporting criteria see <u>https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting</u>

Table 2-3provides production-related waste management data for 1,2-dichloroethane reported by facilities to the TRI program for reporting year 2018.⁶ As shown in the table, 60 facilities reported a total of approximately 373 million pounds of 1,2-dichloroethane waste managed. Of this total quantity, approximately 69% was reported as recycled and 25% was treated, and for each occurred mostly on site. The quantities of 1,2-dichloroethane waste burned for energy recovery or released to the environmental during 2018 are of much smaller magnitude and were mostly on site.

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released (lbs) ^{a,b,c}	Total Production Related Waste (lbs)	
2018	60	255,728,005	22,317,586	94,383,691	579,621	373,008,902	

Table 2-3. Summary of 1,2-Dichloroethane TRI Production-Related Waste Managed in 2018

Data source: 2018 TRI Data (Updated November 2019)

^a Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points. ^b Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.

^o Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes. ^c Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-4 provides a summary of the quantities of 1,2-dichloroethane released to the environment during 2018.⁶ Of these quantities, 76% was released to air, and roughly 70% of these air emissions originated from fugitive sources, with the remainder from point sources. Land disposal accounted for roughly 7% of the total releases, about half of which was to Class I underground injection wells. "Other Releases" of 1,2-dichloroethane accounted for 16% of all reported total releases, in which transfer quantities for off-site storage and other off-site management comprised the vast majority.

Table 2-4. Summary of Releases of 1,2-Dichloroethane to the Environment During 2018

		Air Releases			Land Disposal				
Year	Number of Facilities	Stack Air Releases (lbs)	Fugitive Air Releases (lbs)	Water Releases (lbs)	Class I Under- ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal (lbs) ^a	Other Releases (lbs) ^a	Total Releases (lbs) ^{b, c}
2018	60	136,759	311,737	3,361.95	21,801	19,665	82	94,113.1	587,519
		448	,496	5,501.95	41,548			5	

Data source: 2018 TRI Data (Updated November 2019)

^a Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.

^b These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.

^c Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While production-related waste managed shown in Table 2-3 excludes any quantities reported as catastrophic or one-time releases (TRI Form R Section 8 data), release quantities shown in Table 2-4 include both production-related and non-production-related quantities for 2018. Approximately 12,500 pounds of 1,2-dichloroethane waste not related to production were reported for 2018. These waste quantities are included in the total releases stated in Table 2-4.

⁶ Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for 1,2-dichloroethane.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of 1,2-dichloroethane can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review available environmental exposure data in biota in the risk evaluation. Monitoring data were identified in EPA's data search for 1,2-dichloroethane and can be used in the exposure assessment. Relevant and reliable monitoring studies provide(s) 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 in the risk evaluation. EPA's Ambient Monitoring Technology Information Center Air Toxics database has identified 1,2-dichloroethane in air (U.S. EPA 1990). In addition, EPA's Unregulated Contaminant Monitoring Rule has identified 1,2dichloroethane in drinking water (U.S. EPA 1996). USGS's Monitoring Data – National Water Quality Monitoring Council has identified 1,2-dichloroethane in air, ground water, sediment, soil, surface water and biota (e.g., fish tissue concentrations) (USGS 1991).

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.1. In addition, EPA plans to analyze exposure to occupational non-users (ONUs), i.e., 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 (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with conditions of use within the scope of the risk evaluation for 1,2dichloroethane will be analyzed, including but not limited to:

- Unloading and transferring 1,2-dichloroethane to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing 1,2-dichloroethane;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing 1,2-dichloroethane for quality control;
- Repackaging chemicals, formulations or products containing 1,2-dichloroethane;

EPA has received comments that manufacturers have identified residual amounts of the chemical in end products, however, formulators are uncertain how much remains in these products from the residuals in raw materials (EPA-HQ-OPPT-2018-0451-0005). Because of this uncertainty; EPA plans to evaluate these conditions of use for potential occupational exposures via inhalation and dermal routes.

1,2-Dichloroethane has a vapor pressure of around 79 mm Hg at 25 °C (see Appendix B). EPA plans to analyze inhalation exposure to vapor for workers and ONUs. Where mist generation is expected (e.g. spray application), EPA also plans to analyze inhalation exposure to mist for workers and ONUs. 1,2-Dichloroethane has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) (<u>OSHA, 2009</u>). The PEL is 50 parts per million (ppm) over an 8-hour work day, time weighted average (TWA), with 100 ppm acceptable Ceiling limit

and 200 ppm acceptable maximum peak above the acceptable ceiling limit for 5 min in any 3 hours period. This chemical also has a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL) of 1 ppm TWA, with short term exposure limit (STEL) of 2 ppm (NIOSH, 2019a).

EPA also plans to evaluate worker exposure to liquids via the dermal route. EPA does not play to evaluate dermal exposure for ONUs because they do not directly handle 1,2-dichloroethane.

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

2.3.6 Consumer Exposures

According to reports to the 2012 and 2016 CDR, plastic and rubber products was identified as consumer products for 1,2-dichloroethane. Consumers using or disposing of plastic or rubber products may be exposed to 1,2-dichloroethane through oral or dermal pathways by using rubber or plastic articles. In addition, consumers may be exposed to 1,2-dichloroethane through vapor emissions which may lead to inhalation exposure, given its volatility at room temperature (79.1 mmHg). Consumers are not expected to routinely handle liquids containing 1,2-dichloroethane, since the conditions of use are in rubber/plastic article form. Bystanders are not expected to routinely come in contact with solid plastic or rubber articles containing 1,2-dichloroethane. In addition, bystanders are not expected to have significant inhalation exposures to vapor emissions from plastic and rubber articles. Based on these potential sources and pathways of exposure, EPA plans to analyze inhalation, oral and dermal routes of exposures to evaluate bystander exposures to 1,2-dichloroethane via the inhalation, oral, and dermal routes as the exposure is not expected.

2.3.7 General Population Exposures

Releases of 1,2-dichloroethane from certain conditions of use, such as manufacturing, processing, or disposal activities, may result in general population exposures. Inhalation of the compound from the air is a source of exposure to the general population. Other routes of exposure include, ingestion of 1,2-dichloroethane form contaminated drinking water or food items and dermal absorption (ATSDR 2001). Populations living near industrial waste sites may have a higher likelihood of exposure to 1,2-dichloroethane. 1,2-dichloroethane is found in more than 570 hazardous waste sites on the National Priorities List (ATSDR 2001). An EPA survey found an average of 0.31 ppm 1,2-dichloroethane in 29 groundwater near hazardous waste sites (NTP 1993).

The OECD monitoring database has identified human biomonitoring data for 1,2-dichloroethane (OECD 2018). However, blood concentrations of 1,2-dichloroethane were below the limit of detection in the 2,876 individuals who participated in the National Health and Nutrition Examination Survey (NHANES) 2015-2016 subsample of the U.S. population (CDC, 2019).

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the <u>Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority</u> <u>Substance for Risk Evaluation (U.S. EPA 2019</u>), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for 1,2dichloroethane. EPA considers all the potential environmental hazards for 1,2-dichloroethane identified during prioritization to be relevant for the risk evaluation and thus they remain within the scope of the evaluation. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with 1,2-dichloroethane exposure. If necessary, EPA plans to update the list of potential hazards in the final scope document for 1,2-dichloroethane. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of 1,2-dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for 1,2dichloroethane. EPA plans to evaluate all of the potential human health hazards for 1,2-dichloroethane identified during prioritization. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME (absorption, distribution, metabolism, and excretion). The broad health effect categories included in scope are reproductive and developmental, dermal, immunological, neurological and irritation effects. Studies were also identified reporting information on genotoxicity, carcinogenicity, biomonitoring and toxicokinetics. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards in the final scope document of the 1,2-dichloroethane risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA 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, 2011).

During the prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: workers and consumers (U.S. EPA 2019). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

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

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 1,2-dichloroethane. 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 environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws are discussed pursuant to other Federal laws, are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of 1,2-dichloroethane that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or ONUs via inhalation routes and exposures to workers via dermal routes. It is expected that inhalation exposure to vapors is the most likely exposure route. In addition, workers at waste management facilities may be exposed via inhalation or dermal routes disposed in wastewater treatment, incineration or via other disposal methods. EPA plans to evaluate activities resulting in exposures associated with distribution in commerce (e.g., loading, unloading) throughout the various lifecycle stages and conditions of use (e.g., manufacturing, processing, industrial use, commercial use, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be further analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in 2.8Appendix F.

EPA does not plan to further analyze exposure to vapor/mist via the dermal route because vapor/mist deposition is not expected to be a significant exposure pathway. In addition, EPA does not plan to further analyze dermal exposure for ONUs because they are not expected to directly handle 1,2-dichloroethane.

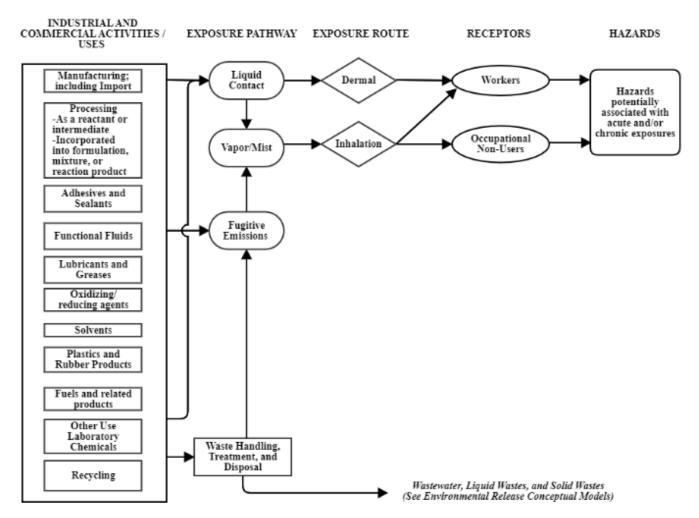


Figure 2-8. 1,2-Dichloroethane Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of 1,2-dichloroethane.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1,2-dichloroethane. EPA expects inhalation to be the primary route of exposure and plans to further analyze inhalation exposures to 1,2-dichloroethane vapor for consumers. There is potential for dermal exposures to 1,2-dichloroethane via direct dermal contact with rubber articles during consumer uses, and inhalation exposure to 1,2-dichloroethane via vapors emitted from rubber consumer products. Direct dermal exposure via liquid is not an expected route of exposure as the conditions of use for 1,2-dichloroethane are plastic and rubber products and no liquid consumer use is expected. Bystanders are not expected to have direct dermal contact or inhalation to 1,2-dichloroethane. The supporting rationale for consumer pathways that are in scope for 1,2-dichloroethane are included in 2.8Appendix G.

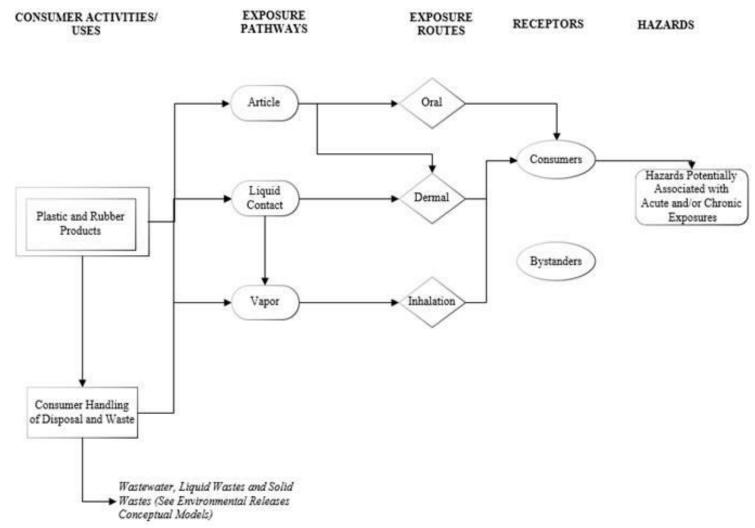


Figure 2-9. 1,2-Dichloroethane Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1,2-dichloroethane. a) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.6.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 1,2-dichloroethane within the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of 1,2-dichloroethane in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial, commercial and consumer uses of 1,2-dichloroethane. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The regulatory programs that cover these environmental release and waste pathways are further described in Section 2.6.3.1 through Section 2.6.3.4.

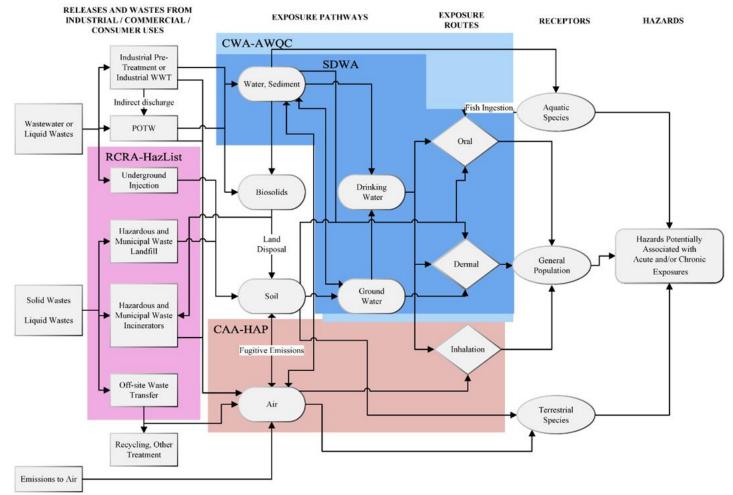


Figure 2-10. 1,2-dichloroethane Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of 1,2-dichloroethane including the environmental statutes covering those pathways. Notes:

- a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering
- b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).
- c) For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

2.6.3.1 Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant.

1,2-Dichloroethane is a HAP. EPA has issued a number of technology-based standards for source categories that emit 1,2-dichloroethane to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks. Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of 1,2-dichloroethane to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.2 Drinking Water Pathway

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the Safe Drinking Water Act for 1,2-dichloroethane. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL, SDWA Section 1412(b)(4)(D), and public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the MCL. The MCL for 1,2-dichloroethane in water is 0.005 mg/L.

The drinking water exposure pathway for 1,2-dichloroethane is currently addressed in the SDWA regulatory analytical process for public water systems. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the SDWA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.3 Ambient Water Pathway

EPA develops recommended water quality criteria under Section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA has developed recommended water quality criteria for protection of human health for 1,2-dichloroethane which are available for possible adoption into state water quality standards and are available for possible use by NPDES permitting authorities in deriving effluent limits to meet state narrative criteria. EPA's OW and OPPT will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA.

For pollutants with recommended human health criteria, EPA regulations require that state criteria contain sufficient parameters and constituents to protect designated uses. Once states adopt criteria as water quality standards, the CWA requires that National Pollutant Discharge Elimination System (NPDES) discharge permits include effluent limits as stringent as necessary to meet standards CWA

Section 301(b)(1)(C). This permit issuance process accounts for risk in accordance with the applicable ambient water exposure pathway (human health or aquatic life as applicable) for the designated water use and, therefore, can the risk from the pathway can be considered assessed and managed.

EPA has not developed CWA Section 304(a) recommended water quality criteria for the protection of aquatic life for 1,2-dichloroethane, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. As a result, this pathway will undergo aquatic life risk evaluation under TSCA. EPA may issue CWA Section 304(a) aquatic life criteria for 1,2-dichloroethane in the future if it is identified as a priority under the CWA.

2.6.3.4 Disposal and Soil Pathways

1,2-Dichloroethane is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U077, D028, K018, K029, K096, F024, F025 lists. The general standard in RCRA Section 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to "*tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.*" Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products from incineration treatment of 1,2-dichloroethane wastes may be subject to regulations, as would 1,2-dichloroethane burned for energy recovery.

TRI reporting in 2018 indicated 21,801 pounds released to underground injection to Class I hazardous waste wells. Environmental disposal of 1,2-dichloroethane injected into Class I well types fall under the jurisdiction of RCRA and SDWA; and the disposal of 1,2-dichloroethane via underground injection to Class I hazardous waste well is not likely to result in environmental and general population exposures.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills. Based on 2018 reporting, the majority of TRI land disposal includes Subtitle C landfills (19,665 pounds) with a much smaller amount transferred to "other landfills" both on-site and off-site (82 pounds reported in 2018). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

1,2-Dichloroethane is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste (MSW) landfills. On-site releases RCRA Subtitle D municipal solid waste landfills leading to exposures of the general population (including susceptible populations) or terrestrial species from such releases are expected to be minimal based on current TRI releases (i.e., 82 lb in 2018) for 1,2-dichloroethane. While permitted and managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lb per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land may occur from industrial non-hazardous and construction/demolition waste landfills. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so.

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

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-11 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of 1,2-dichloroethane that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of 1,2-dichloroethane in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 includes releases from industrial, commercial and/or consumer uses to water/sediment; biosolids and soil, via direct and indirect discharges to water, that may lead to exposure to aquatic and terrestrial receptors. The supporting basis for environmental pathways considered for 1,2-dichloroethane are included in Appendix H.

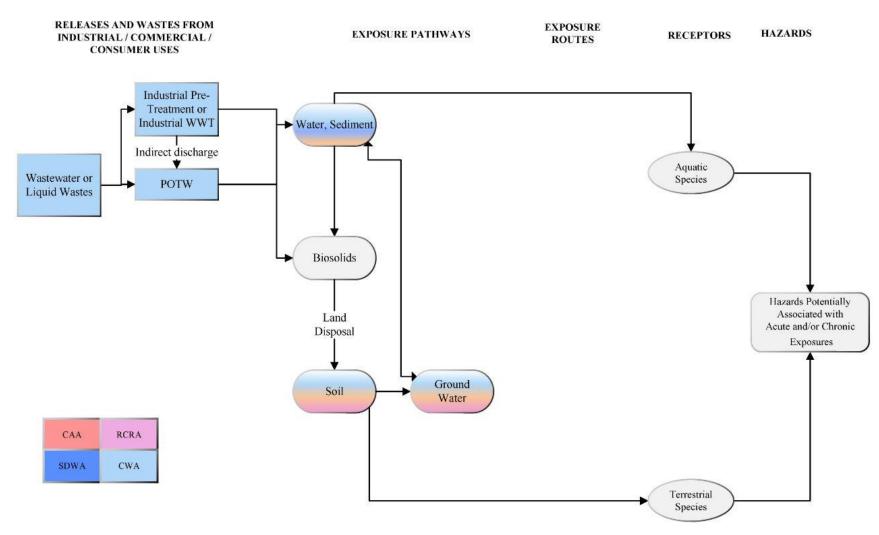


Figure 2-11. 1,2-Dichloroethane Conceptual Model for Environmental Releases and Wastes: Environmental Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to environmental receptors from releases and wastes from industrial, commercial, and consumer uses of 1,2-dichloroethane that EPA plans to consider in the risk evaluation. Notes:

- a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW.
- b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of 1,2-dichloroethane to date which includes a partial, but not complete review of identified 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 for further evaluating conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. Furthermore, EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. EPA will consider new information submitted by the public. Should additional data or approaches become available, EPA may update its analysis plan in the final scope document. As discussed in the <u>Application of Systematic Review in TSCA Risk Evaluations</u> document [EPA Document #740-P1-8001] (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 1,2-dichloroethane.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical-chemical properties and environmental fate and transport of 1,2dichloroethane as follows:

- Review reasonably available measured or estimated physical-chemical properties and environmental fate endpoint data collected using systematic review procedures and, where available, environmental assessments conducted by other regulatory agencies.
 EPA plans to review data and information collected through the systematic review methods and public comments about the physical-chemical properties (Appendix B) and fate endpoints (Appendix C) previously summarized in the *Proposed Designation of 1,2-Dichloroethane* (*CASRN 107-06-2*) as a High-Priority Substance for Risk Evaluation (U.S. EPA, 2019). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.
- 2) Using measured data and/or modeling, determine the influence of physical-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-chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of 1,2dichloroethane 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-evidence evaluation of physical-chemical and environmental fate data, including qualitative and quantitative sources of information.

During risk evaluation, EPA plans to evaluate and integrate the physical-chemical properties and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air, surface water, sediment, soil, aquatic biota, and terrestrial biota associated to exposure to 1,2-dichloroethane. EPA has not yet determined the exposure levels in these media or how they may be used in the risk evaluation. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for 1,2-dichloroethane are presented in Appendix F, Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures.

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

2.7.2.1 **Environmental Releases**

EPA plans to analyze releases to environmental media as follows:

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

EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to continue to review data sources identified in Appendix E during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-7 below:

Table 2.5 Catagonias and Sources of Environmental Delease Data

	Table 2-5. Categories and Sources of Environmental Release Data		
U.S. EPA TRI Data			
	U.S. EPA Generic Scenarios		
	OECD Emission Scenario Documents		
	Discharge Monitoring Report (DMR) surface water discharge data for 1,2-dichloroethane from		
	NPDES-permitted facilities		

2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies). EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.3. EPA plans to continue to review relevant data sources during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

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

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

If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other chlorinated solvents may be considered as surrogates for 1,2-dichloroethane.

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

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

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

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

EPA Generic Scenarios are available at the following: <u>https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.</u>

OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

EPA plans to perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

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

EPA has identified release scenarios and mapped (i.e. grouped) them to relevant conditions of use as shown in Appendix F. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g. recycling, construction and demolition). EPA plans to perform

targeted research to understand those uses, which may inform identification of release scenarios. EPA may further 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 as additional information is identified during risk evaluation.

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

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of 1,2-dichloroethane:

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

For 1,2-dichloroethane, environmental media which will be analyzed are sediment, soil and surface water.

- 2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available environmental exposure models that meet the TSCA Science Standards and that estimate surface water, sediment, and soil concentrations will be analyzed and considered alongside available surface water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into 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) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.

Monitoring data or modeled estimates will be reviewed to determine how use patterns have changed over recent years and will determine how representative environmental concentrations are of ongoing use patterns.

Studies which relate levels of 1,2-dichloroethane in the environment or biota with specific sources or groups of sources will be evaluated.

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

Refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For 1,2-dichloroethane, 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 available monitoring data.
- Generally, consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
- Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
- Weight of scientific evidence of environmental occurrence data and modeled estimates.
- 5) Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2.3 Occupational Exposures

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

1) Review reasonably available exposure monitoring data for specific condition(s) of use.

EPA plans to review exposure data including workplace monitoring data collected by government agencies such as the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

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

EPA plans to evaluate and consider applicable regulatory and non-regulatory limits, such as OSHA PEL, NIOSH REL, and ACGIH TLV.

Table 2-6. Potential Sources of Occupational Exposure Data

2012 ATSDR Toxicological Profile for 1,2-Dichloroethane
U.S. OSHA Chemical Exposure Health Data (CEHD) program data
U.S. NIOSH Health Hazard Evaluation (HHE) Program reports

2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to 1,2-dichloroethane.

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. For several

conditions of use, EPA believes data for other chlorinated solvents may serve as surrogates for 1,2-dichloroethane.

3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.

EPA has identified potentially relevant OECD emission scenario documents (ESDs) and EPA generic scenarios (GSs) corresponding to some conditions of use. For example, the <u>November</u> 2004 Emission Scenario Document on Lubricants and Lubricant Additives (OECD, 2004) may be used to estimate occupational exposures. EPA plans to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use, including the use of 1,2-dichloroethane as an intermediate chemical. EPA plans to perform additional targeted research in order to better understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

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

This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA/OPPT, other government agencies, or 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 ONUs.

5) Consider and incorporate applicable EC and/or PPE into exposure scenarios.

EPA plans to review potentially relevant data sources on EC and PPE as identified in Appendix E to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of EC, 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). EPA was not able to identify occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may further refine the mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.
- 7) Evaluate the weight of the 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 systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

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

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

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

For 1,2-dichloroethane, the following are noteworthy considerations in constructing consumer exposure scenarios:

- Conditions of use including type of consumer product
- 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 available data.

Based on the condition of use in "plastic and rubber products" (see Section 2.2.1), indoor exposure pathways expected to be potentially higher include dust ingestion and mouthing of products. Other indoor exposure pathways include inhalation of indoor air, dermal contact with dust and articles. The data sources associated with these respective pathways have not been comprehensively evaluated, therefore quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) Review existing indoor exposure models that may be applicable in estimating indoor air, indoor dust concentrations, or indoor dust surface loadings.

Indoor exposure models that estimate emissions from consumer products are available. These models generally consider physical-chemical 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.

Indoor exposure models that estimate emission and migration of SVOCs into the indoor environment are available. These models generally consider 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-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 available.

To the extent other organizations have already modeled a 1,2-dichloroethane 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 1,2-dichloroethane 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 1,2-dichloroethane in specific media (e.g., dust or indoor air).

The availability of 1,2-dichloroethane concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air and dust levels and various indoor sources will be analyzed.

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

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

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

2.7.2.5 General Population

EPA does not expect to analyze general population exposures, based on a review of exposure pathways as described in Section 2.3.7. EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of 1,2-dichloroethane 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 1,2-dichlorethane to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g., analogue and read-across data) when characterizing the potential hazards of 1,2-dichloroethane to aquatic and/or terrestrial organisms.

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

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

2) Derive hazard thresholds for aquatic and/or terrestrial organisms.

Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x. LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of 1,2-dichloroethane to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

3) Evaluate the weight of 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 systematic review documentation that EPA plans to publish prior to finalizing the scope document.

4) Consider the route(s) of exposure, based on 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 1,2-dichloroethane conceptual model. These organisms may be exposed to 1,2-dichloroethane via a number of environmental pathways (e.g., surface water, sediment, soil, diet).

5) Conduct an environmental risk characterization of 1,2-dichloroethane.

EPA plans to conduct a risk characterization of 1,2-dichloroethane to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of

1,2-dichloroethane in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of 1,2-Dichloroethane.

EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of 1,2dichloroethane after reviewing relevant physical-chemical properties and exposure pathways. EPA plans to assess the available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of 1,2-dichloroethane. 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 1,2dichloroethane with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

 Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
 EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for 1,2-dichloroethane. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

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

Reasonably available human health hazard data will be evaluated to ascertain whether some PESS may have greater susceptibility than the general population to 1,2-dichloroethane hazard(s). Susceptibility of particular populations or subpopulations to 1,2-dichloroethane 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 1,2-dichloroethane exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

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

Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (e.g., oral, dermal, inhalation) and by cancer and noncancer endpoints.

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

The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to 1,2-dichloroethane, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated. Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

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

5) Evaluate the weight of the scientific evidence of human health hazard data.

During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment. Following systematic review, EPA plans to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure based on the results. This may include using route-to-route extrapolation methods where appropriate. EPA also plans to evaluate any potential human health hazards following dermal and inhalation exposure to 1,2-dichloroethane, which could be important for worker, consumer, and general population risk analysis. 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 toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in the EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

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

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

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's <u>Peer Review Handbook</u> and other methods consistent with Section 26 of TSCA (See <u>40 CFR 702.45</u>). 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 1,2-dichloroethane will be peer reviewed.

1,2-Dichloroethane (2018)

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

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

Table Apx A-1. List of Gray Literature Sources for 1,2-Dichloroethane

Source/Agency	Source Name	Source Type	Source Category
ECHA	ECHA Documents	International Resources	Assessment or Related Document
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document
EPA	Office of Air: TRI	US EPA Resources	Database
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database

Source/Agency	Source Name	Source Type	Source Category
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Water: Drinking Water Standards Health Effects Support Documents	US EPA Resources	Regulatory Document or List
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document
IARC	IARC Monograph	International Resources	Assessment or Related Document
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine's HazMap	Other US Agency Resources	Database

Source/Agency	Source Name	Source Type	Source Category
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD SIDS	International Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document
RIVM	Probit Function Technical Support Document	International Resources	Assessment or Related Document
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF 1,2-DICHLOROETHANE

This appendix provides p-chem information and data found in preliminary data gathering for 1,2dichloroethane. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the <u>Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a</u> <u>High-Priority Substance for Risk Evaluation</u> (U.S. EPA, 2019) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies (EPA-HQ-OPPT-2018-0427).

Property or Endpoint	Value ^a	Reference	Data Quality Rating
Molecular formula	C2H4Cl2	NA	NA
Molecular weight	98.96 g/mol	NA	NA
Physical state	Heavy liquid	O'Neil, 2013	High
Physical properties	Clear, colorless, oily liquid	NLM, 2018	High
Melting point	-35.6°C	Rumble, 2018	High
Boiling point	83.4°C	Rumble, 2018	High
Density	1.2569 g/cm ³ at 20°C relative to water at 4°C	O'Neil, 2013	High
Vapor pressure	78.9 mm Hg at 25°C	NLM, 2018	High
Vapor density	Not available		
Water solubility	8,600 mg/L at 25°C	Rumble, 2018	High
Log Octanol/water partition coefficient (Log Kow)	1.48	NLM, 2018	High
Henry's Law constant	0.00118 atm·m ³ /mol at 25°C	NLM, 2018	High

Table_Apx B-1. Physical and Chemical Properties of 1,2-Dichloroethane

Property or Endpoint	Value ^a	Reference	Data Quality Rating
Flash point	13°C (closed cup)	O'Neil, 2013	High
Auto flammability	413°C	NLM, 2018	High
Viscosity	0.779 cP at 25°C	Rumble, 2018	High
Refractive index	1.4422	Rumble, 2018	High
Dielectric constant	10.43 (time domain reflectometry)	Pawar, 2006	High
^a Measured unless otherwise noted. NA = Not applicable			

Appendix CENVIRONMENTAL FATE AND TRANSPORT
PROPERTIES OF 1,2-DICHLOROETHANE

Property or Endpoint	Value	Reference
Direct Photodegradation	Not expected to be susceptible to direct photolysis by sunlight because 1,2-dichloroethane does not contain chromophores that absorb at wavelengths >290 nm	HSDB (2010) citing Lyman et al. (1990)
Indirect Photodegradation	t $_{1/2} = 65$ days (based on \cdot OH reaction rate constant of 2.48×10^{-13} cm ³ /molecule-second at 25 °C)	HSDB (2010); Physprop (2012) citing Kwok and Atkinson (1994)
	t _{1/2} = 73 days (based on ·OH reaction rate constant of 2.2×10^{-13} cm ³ /molecule·second and an ·OH concentration of 5×10^{5} ·OH/cm ³ at 25 °C)	ATSDR (2001) citing Arnts et al. (1989) and Atkinson (1989)
	Atmospheric degradation products: formyl chloride, chloroacetyl chloride, hydrogen chloride, and chloroethanol	ATSDR (2001) citing U.S. EPA (1993)
Hydrolysis	$t_{1/2} = 65$ and 72 years (based on first order rate constant = 2.1×10^{-8} second ⁻¹ and 1.8×10^{-8} second ⁻¹ , respectively, in neutral conditions at 25 °C)	ATSDR (2001) citing Barbash and Reinhard (1989) and Jeffers et al. (1989)
Biodegradation (Aerobic)	Water: 0%/21 days (modified shake-flask test)	HSDB (2010) citing Mudder and Musterman (1982)
	Water: 20–63%/7 days with 5– 27% from volatilization after an unspecified acclimation period (static-flask method)	WHO IPCS (1995) citing Tabak et al. (1981)
	Water: 1.6%/14 days based on BOD 1.1% after 14 days based on GC (Japanese MITI test)	NITE (2010)
	Water: $t_{1/2} = 100$ days	ATSDR (2001) citing Capel and Larson (1995)
Biodegradation (Anaerobic)	Groundwater: $t_{1/2} = 63-165$ days	NICNAS (2014) citing Lawrence (2006)

Table_Apx C-1. Environmental Fate and Transport Properties of 1,2-Dichloroethane

	Water: t $_{1/2} = 400$ days	ATSDR (2001) citing Capel and Larsen (1995)
	Sediment: $t_{1/2} = 52$ days based on an observed 0.013/day	ATSDR (2001) citing Peijnenburg et al. (1998)
	Sediment: 0%/35 days	WHO IPCS (1995) citing Jafvert and Wolfe (1987)
Wastewater Treatment	45% total removal (16% by biodegradation, 1% by sludge and 28% by volatilization to air; estimated) ^b	U.S. EPA (2012a)
Bioconcentration Factor	2 (<i>Lepomis macrochirus</i>); $t_{1/2} = 2$ days for clearance from tissues	WHO IPCS (1995) citing Barrows (1980)
Bioaccumulation Factor	3.8 (estimated) ^b	U.S. EPA (2012a)
Soil Organic Carbon:Water Partition Coefficient (Log Koc)	1.28–1.62 (Koc = 19–42)	ATSDR (2001) citing Chiou et al. (1980), Sabljić et al. (1995), and Borisover and Graber (1997)

^aMeasured unless otherwise noted

^bEPI SuiteTM (physical property inputs: Log K_{OW} = 1.48, BP = 83.4 °C, MP = -35.6 °C, VP = 78.9 mm Hg, WS = 8600 mg/L, HLC = $1.18 \times 10-3$ atm-m3/mole), BioP = 120, BioA = 30 and BioS = 30 SMILES: ClCCCl, ·OH = hydroxyl radical; BOD = biochemical oxygen demand; OECD = Organisation for Economic Co-operation and Development; TG = test guideline; GC = gas chromatography; MITI = Ministry of International Trade and Industry

Appendix D REGULATORY HISTORY

The chemical substance, 1,2-dichloroethane, is subject to federal and state laws and regulations in the United States (Table_Apx D-1and Table_Apx D-2). Regulatory actions by other governments, tribes and international agreements applicable to 1,2-dichloroethane are listed in Table Apx_D-3.

D.1 Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	1,2-Dichloroethane is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (<u>84 FR 71924</u> , Dec. 30, 2019). Designation of 1,1,2-trichloroethane as a 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.	1,2- Dichloroethane manufacturing (including importing), processing and use information is reported under the CDR rule (<u>76 FR 50816</u> , August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	1,2-Dichloroethane was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA Section 5 (<u>60 FR 16309</u> , March 29, 1995).
Toxic Substances Control Act (TSCA) – Section 8(d)	Provides EPA with authority to issue rules requiring producers, importers, and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies.	Five health and safety studies were received for 1,2- Dichloroethane (2002- 2006) (U.S. EPA, ChemView. Accessed April 25, 2019).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Ten risk reports were received for 1,2-Dichloroethane (years when the submissions were received: 1995-2017) (U.S. EPA, ChemView. Accessed April 2, 2019).

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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.	Six chemical data submissions from test rules and enforceable consent agreements were received for 1,2-Dichloroethane: one acute inhalation toxicity study (2006), four studies on metabolism and pharmacokinetics (2005, 2006, 2009, 2010) and one study on neurological toxicity (2006) (U.S. EPA, ChemView. Accessed April 2, 2019).
Emergency Planning and Community Right-To- Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	1,2-Dichloroethane is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.
Clean Air Act (CAA) – Section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	1,2-Dichloroethane is subject to the NSPS for equipment leaks of volatile organic compounds (VOCs) in the synthetic organic chemicals manufacturing industry for which construction, reconstruction or modification began after January 5, 1981 (40 CFR Part 60, Subparts VV, NNN, and RRR).
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA Section 112(d). CAA Section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance.	1,2-Dichloroethane is listed as a HAP (42 U.S. Code Section 7412).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has established NESHAPs for a number of source categories that emit 1,2- dichloroethane to air. (See <u>https://www.epa.gov/stationary-</u> <u>sources-air-pollution/national-</u> <u>emission-standards-hazardous-</u> <u>air-pollutants-neshap-9</u>).
Clean Water Act (CWA) - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for 1,2- Dichloroethane, including a recommendation of 9.9 (μ g/L) for "Human Health for the consumption of Water + Organism" and 650 (μ g/L) for "Human Health for the consumption of Organism Only" for states and authorized tribes to consider when adopting criteria into their water quality standards (80 FR 36986, June 29, 2015).
Clean Water Act (CWA) – Section 301, 304, 306, 307, and 402	Clean Water Act Section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statue specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see Section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	1,2-Dichloroethane is designated as a toxic pollutant under Section 307(a)(1) of the CWA and as such is subject to effluent limitations. Under CWA Section 304, 1,2- Dichloroethane is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Clean Water Act (CWA) – Section 311(b) (2)(A) and 501(a) of the Federal Water Pollution Control Act.	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	1,2-Dichloroethane is a designated hazardous substance in accordance with Section 311(b) (2)(A) of the Federal Water Pollution Control Act.
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	1,2-Dichloroethane is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.005 mg/L (Section 1412).
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	1,2-Dichloroethane is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: D028 (40 CFR 261.24); U077 (40 CFR 261.33); F024, F025 (40 CFR 261.31); K018, K029, K096 (40 CFR 261.32).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	1,2-Dichloroethane is a hazardous substance under CERCLA. Releases of 1,2- Dichloroethane in excess of 100 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	1,2-Dichloroethane is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
Other Federal Regulatio	ns	
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	The FDA regulates 1,2- Dichloroethane in bottled water. The maximum permissible level of 1,2- Dichloroethane in bottled water is .005 mg/L (21 CFR 165.110). FDA established a limit of 1 ppm on the amount of 1,2-Dichloroethane that can be present as a residual in finished polyethylenimine polymer (21 CFR 173.357). 1,2-Dichloroethane is listed as an optional substance to be used in: adhesives used as components of articles intended for use in packaging, transporting, or holding food
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C Section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	(21 CFR § 175.105). In 1979, OSHA issued occupational safety and health standards for 1,2- Dichloroethane that included a PEL of 50 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Federal Hazardous Materials Transportation Act (HMTA)	 Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce. 	The Department of Transportation (DOT) has designated 1,2- Dichloroethane as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR Part 172).

D.2 State Laws and Regulations

Table	Apx	D-2.	State	Laws and	Regulations
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State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants). Rhode Island (Air Pollution Regulation No. 22)
State Drinking Water Standards and Guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008), California (Cal Code Regs. Title 26, § 22-64444), Delaware (Del. Admin. Code Title 16, § 4462), Connecticut (Conn. Agencies Regs. § 19-13-B102), Florida (Fla. Admin. Code R. Chap. 62-550), Maine (10 144 Me. Code R. Chap. 231), Massachusetts (310 Code Mass. Regs. § 22.00), Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017), Minnesota (Minn R. Chap. 4720), New Jersey (7:10 N.J Admin. Code § 5.2), Pennsylvania (25 Pa. Code § 109.202), Rhode Island (Rules and Regulations Pertaining to Public Drinking Water R46-13-DWQ), Texas (30 Tex. Admin. Code § 290.104).
State PELs	California (PEL of 1 ppm and a STEL of 2 ppm) (Cal Code Regs. Title 8, § 5155) Hawaii PEL: 1 ppm (Hawaii Administrative Rules Section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (N.J.A.C. 7:1G) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing 1,2-Dichloroethane, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407).
Other	California listed 1,2-Dichloroethane on Proposition 65 in October 1, 1987 due to cancer. (Cal Code Regs. Title 27, § 27001). 1,2-Dichloroethane is listed as a Candidate Chemical under California's Safer Consumer Products Program (Health and Safety Code § 25252 and 25253).

State Actions	Description of Action
	California issued a Health Hazard Alert for 1,2-Dichloroethane (Hazard Evaluation System and Information Service, 2016).
	California lists 1,2-Dichloroethane as a designated priority chemical for biomonitoring (California SB 1379).
	1,1,2-trichloroethane is on the MA Toxic Use Reduction Act (TURA) list of 2019 (301 CMR 41.00).

D.3 International Laws and Regulations

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

Country/Tribe/ Organization	Requirements and Restrictions
Canada	 1,2-Dichloroethane is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1) and is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed April 17, 2019). Other regulations include: Canada's National Pollutant Release Inventory (NPRI).
European Union	In May 2016, 1,2-dichloroethane was added to Annex XIV of REACH (Authorisation List) with a sunset date of November 22, 2017. After the sunset date, only persons with approved authorization applications may continue to use the chemical. Twenty applications for authorization have been received and decided, for uses as an industrial solvent, swelling agent, and reaction medium (European Chemicals Agency (ECHA) database. Accessed April 15, 2019).
Australia	1,2-dichloroethane was assessed under both Human Health and Environment Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Uses reported in Australia include as a component of solvents to remove grease, resins, glue and dirt; and as an anti-knock component of leaded petrol (previous use only); as a solvent in the manufacture of polystyrene and styrene butadiene rubber (SBR) latex. International uses include in solvents; in varnish and finish removers, paints, coatings and adhesives for professional use (European product registers contain entries of products with the chemical as an ingredient. The product types are paints and lacquers (concentrations between 1 and 100%), adhesives (concentrations between 10 and 50%) and fertilizers (concentrations below 1%)); as a component in leaded gasoline; as a chemical intermediate in the production of vinyl choride monomer which in turn is used in the manufacture of polymers; and as a chemical intermediate in the manufacture of other chlorinated solvents. (NICNAS, Ethane, 1,2-dichloro-: Human health tier II assessment, 22 March 2013. Accessed April 15, 2019).
Japan	1,2-Dichloroethane 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)

Country/Tribe/ Organization	Requirements and Restrictions
	Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof Industrial Safety and Health Act (ISHA) Air Pollution Control Law Water Pollution Control Law Soil Contamination Countermeasures Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. Accessed April 16, 2019).
Australia, Austria, Belgium, Canada, Denmark, Finland, France, Hungary, Ireland, Japan, Latvia, New Zealand, People's Republic of China, Poland, Romania, Singapor e, South Korea, Spain, Sweden, Switzerland, The Netherlands, United Kingdom	Occupational exposure limits for 1,2-Dichloroethane (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 17, 2019).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for 1,2-dichloroethane.

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 Manufacture

1,2-Dichloroethane is produced by the vapor- or liquid-phase chlorination of ethylene. Most liquidphase processes use small amounts of ferric chloride as the catalyst. Other catalysts claimed in the patent literature include aluminum chloride, antimony pentachloride, and cupric chloride and an ammonium, alkali, or alkaline-earth tetrachloroferrate. The chlorination is carried out at 40–50 degrees C with 5% air or other free-radical inhibitors added to prevent substitution chlorination of the product. Selectivities under these conditions are nearly stoichiometric to the desired product. The exothermic heat of reaction vaporizes the 1,2-dichloroethane product, which is purified by distillation. (Snedecor, et al., 2004)

E.1.1.2 Import

Commodity chemicals such as 1,2-dichloroethane may be imported into the United States in bulk via water, air, land, and intermodal shipments {Tomer, 2015, 5018559}. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. Chemicals shipped in bulk containers may be repackaged into smaller containers for resale, such as drums or bottles. Domestically manufactured commodity chemicals may be shipped within the United States in liquid cargo barges, railcars, tank trucks, tank containers, intermediate bulk containers (IBCs)/totes, and drums. Both imported and domestically manufactured commodity chemicals may be repackaged by wholesalers for resale; for example, repackaging bulk packaging into drums or bottles. The type and size of container will vary depending on customer requirement. In some cases, QC samples may be taken at import and repackaging sites for analyses. Some import facilities may only serve as storage and distribution locations, and repackaging/sampling may not occur at all import facilities.

1,2-Dichloroethane may be imported neat or as a component in a formulation. In the 2016 CDR, 11 companies reported importing 1,2-dichloroethane at mainly >90% concentration. Six additional facilities reported manufacturing/import information (U.S. EPA, 2016).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant or Intermediate

Processing as a reactant or intermediate refers to the use of 1,2-dichloroethane as a feedstock in the production of another chemical via a chemical reaction in which 1,2-dichloroethane is consumed to form the product. In the 2016 CDR, companies reported use of 1,2-dichloroethane as an intermediate in the manufacture of petrochemicals, plastic material and resin, and other basic organic chemicals. EPA has not identified specific process information for the processing of 1,2-dichloroethane as a reactant but will further investigate during the risk evaluation (U.S. EPA, 2016).

E.1.2.2 Incorporation into 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 product or mixture. In the 2016 CDR, companies reported use of 1,2-dichloroethane in fuels and fuel additives, functional fluids for pharmaceutical and medicinal applications, and processing aids for petroleum production. (U.S. EPA, 2016). 1,2-Dichloroethane - specific formulation processes were not identified; however, lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004).

E.1.3 Uses

E.1.3.1 Functional Fluids (Heat Transfer Agent)

EPA identified a safety data sheet for a supplemental coolant additive containing <1 percent of 1,2-Dichloroethane (Baldwin Filters, 2015). However, specific use activities are unknown. EPA plans to further investigate the use of 1,2-Dichloroethane in functional fluids during the risk evaluation.

E.1.3.2 Lubricants and Greases

EPA identified a safety data sheet for a low friction coating containing 5 to 10 percent 1,2dichloroethane (Everlube Products, 2019). According to the associated product Technical Data sheet, this product is a thermally cured lubricant to prevent metal to metal contact when used in the presence of conventional lubricants, with spray application method suggested (Everlube Products, 2003). EPA plans to further investigate the potential use of 1,2-dichloroethane in this type of process and other lubricant/grease applications during the risk evaluation.

E.1.3.3 Degreasing and Cleaning Solvents

EPA identified a safety data sheet for 1,2-Dichloroethane (99 to 100 percent) that identified use as a process cleaner (Occidental Chemical Corporation, 2015). However, specific use activities are unknown. EPA plans to further investigate the use of 1,2-Dichloroethane in degreasing and cleaning (including potential use in vapor degreasing, cold cleaning, aerosol degreasing) during the risk evaluation.

E.1.3.4 Plastic and Rubber Products

EPA has not identified specific process information for the use of 1,2-dichloroethane in plastics and rubber products but will further investigate during the risk evaluation. The 2014 Generic Scenario on Use of Additive in Plastic Compounding and 2014 Generic Scenario on Use of Additives in the Thermoplastic Converting Industry discuss typical worker activities during plastics compounding and converting, including unloading/loading, mixing, processing, and trimming (U.S. EPA, 2014a; U.S. EPA, 2014b).

E.1.3.5 Fuels and Related Products

EPA has not identified specific process information for the use of 1,2-dichloroethane in fuels and related products but will further investigate during the risk evaluation.

E.1.3.6 Laboratory Use

EPA identified a safety data sheet for 1,2-dichloroethane (>95% percent purity) that indicates recommended use as a laboratory chemical (ThermoFisher, 2018). However, specific laboratory use activities are unknown. EPA plans to further investigate the laboratory use of 1,2-dichloroethane during the risk evaluation.

E.1.3.7 Embalming Agent

EPA identified a safety data sheet for a supplemental embalming fluid containing >90 percent 1,2dichloroethane (Frigid, 2015). However, specific use activities are unknown. EPA plans to further investigate the use of 1,2-Dichloroethane in embalming agents during the risk evaluation.

E.1.4 Disposal

Each of the conditions of use of 1,2-dichloroethane may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat or dispose onsite wastes that they themselves generate will be assessed in each condition of use assessment. Wastes of 1,2-dichloroethane that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: 1,2-dichloroethane may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing 1,2-dichloroethane discharged to a POTW may be subject to EPA or authorized NPDES state pretreatment programs.
- Solid Wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

1,2-Dichloroethane is a U-listed hazardous waste under code U077 under RCRA; therefore, discarded, unused pure and commercial grades of 1,2-Dichloroethane are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of 1,2-dichloroethane may generate wastes of 1,2-dichloroethane that are exempted as solid wastes under 40 CFR § 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of 1,2-Dichloroethane may be exempt as a solid waste.
- •

E.2 Sources Containing Potentially Relevant Data or Information

EPA presents below examples of occupational exposure-related information from the preliminary data gathering. EPA plans to consider this information and data in combination of other data and methods for use in the risk evaluation. Note these points are the only data available for the last ten years.

 Table_Apx E-1. Summary of Industry Sectors with 1,2-Dichloroethane Personal Monitoring Air

 Samples Obtained from OSHA Inspections Conducted since 2014

NAICS	NAICS Description	Number of Data Points
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	2 (2016)
339112	Surgical and Medical Instrument Manufacturing	2 (2014)

Table_Apx E-2. Potentially Relevant Data Sources for Exposure Monitoring and Area Monitoring
Data from NIOSH Health Hazard Evaluations

Year of Publication	Report Number	Facility Description
1992	НЕТА 91-251-2218	Manufacture of self lubricating ball bearings
1984	HETA 83-375-1521	USDA Grain Inspection Service (grain fumigants)
1982	HETA 80-186-1149	Plastic Manufacuring
1980	HE 79-80, 81-746	Medical Equipment Manufacturing
1979	HE 77-73-610	Chemical Manufacturing

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

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Manufacturing	Domestic Manufacture		Domestic manufacture	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
	Import I			Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
		nport Import I	Import	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.

 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	Plans to Evaluate	Rationale
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Processing	Processing as a reactant or intermediate	Petrochemical manufacturing	Processing of petrochemicals, plastics, resins, and other basic organic	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
			chemicals	Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
		Plastic material and resin manufacturing Processing of plastics and resins		Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
			Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor	
				Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
	organic	All other basic organic chemical manufacturing	ganic chemical organic chemicals	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
			Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor	
	Incorporated into formulation, mixture or	Fuels and fuel additives: All other petroleum and coal products	Processing of fuels, fuel additives, and/or other products containing	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
	reaction product	eaction manufacturing 1,2-dichloroethan roduct Functional Fluids: Processing of	1,2-dichloroethane	Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
			Processing of liquid products that	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
		and medicine manufacturing	contain 1,2- dichloroethane	Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
		Processing aids, specific to petroleum production	Processing of liquid products that contain 1,2- dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
		F	Vapor	Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
	Recycling	Recycling	Handling of products containing 1,2-dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquid products containing 1, 2-dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Liquid Contact	Dermal	ONU	No	Dermal exposure by ONU is not expected for this condition of use as they are not expected to directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution of bulk shipments of 1,2- dichloroethane and formulated products	Liquid Contact, Vapor	Dermal, Inhalation	Worker, ONU	Yes	EPA plans to analyze activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, commercial use, disposal) rather than as a single distribution scenario.
Industrial Use	Adhesives and Sealants		Application of glues and adhesives containing 1,2- dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Mist	Mist	Worker/ON U	Yes	EPA plans to evaluate the possibility of mist generation and resulting releases and/or exposures that could occur during this condition of use.
Industrial Use	Functional Fluids (closed systems)	Heat Transfer agent	Heat Transfer agent	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Industrial Use	Lubricants and Greases		Application of "solid film lubricant"	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
				Mist	Mist	Worker/ON U	Yes	TDS recommends spray application
Industrial Use	Oxidizing/red ucing agents	Oxidation inhibitor in controlled oxidative	Use of 1,2- dichloroethane as an oxidation inhibitor in controlled oxidative chemical reactions	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Industrial Use	Solvents (for cleaning and degreasing)	A component of degreasing and cleaning solvents	Use of solvents and/or degreasing formulations containing 1,2- dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
	degreasing)			Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Commercial Use	Plastic and rubber products	Products such as: plastic and rubber products	Use of plastic and rubber products containing 1,2- Dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Commercial Use	Fuels and related products	Fuels and related products	Use of fuels, fuel additives, and/or other products containing 1,2- dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Commercial Use	Other Use	Laboratory Chemicals (e.g. reagents)	Use of laboratory products and/or reagents containing 1,2-dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Commercial Use	Other Use	e Embalming agent	Use of embalming products containing 1,2-Dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor
Disposal	Disposal	Waste Handling, Treatment, and Disposal	Handling of wastes containing 1,2- dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 2- dichloroethane

Life Cycle Stage	Category	Subcategory	Release/Exposure Scenario	• •	Exposure Route	Receptor	Plans to Evaluate	Rationale
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 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.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (79.1 mmHg at 25°C), EPA plans to evaluate inhalation exposure to vapor

Appendix G SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer	Plastic and rubber products	Products such as: plastic and rubber products	Use of products containing 1,2- Dichloroethane	Liquid Contact	Dermal	Consumers	No	Consumers are not expected to routinely handle liquids containing 1,2- dichloroethane, since COU are in rubber/plastic article form.
				Vapor	Inhalation	Consumers	Yes	Due to high volatility (79.1 mmHg at 25C) inhalation exposure to vapor should be evaluated
Use; Consumer Reuse and Recycling						Bystanders	No	Bystanders are not expected to routinely come in contact with inhalation of plastic and rubber products.
					Oral Dermal	Consumer	Yes	Consumers can routinely come in contact with solid plastic or rubber articles.
						Bystanders	No	Bystanders are not expected to routinely come in contact with inhalation of plastic and rubber products.

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Appendix H SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate ⁷	Rationale
			Near facility ambient air concentrations	Inhalation	General Population	No	1,2-Dichloroethane is a HAP. Stationary
	Emissions to Air	Emissions to Air	Indirect deposition to	Oral Dermal	General Population	No	source releases of 1,2-dichloroethane to ambient air are under the jurisdiction of the
			nearby bodies of water and soil catchments	TBD	Aquatic and Terrestrial Receptors	No	CAA.
		Industrial pre- treatment and wastewater or Liquid Wastes	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	EPA has developed Ambient Water
All				Oral Dermal	General Population	No	Quality Criteria for protection of human health for 1,2-dichloroethane.
	1		Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	No	The drinking water exposure pathway for 1,2-dichloroethane is currently addressed in the SDWA regulatory analytical process for public water systems.
			Biosolids: application to soil and/or migration to	Oral (e.g. ingestion of soil) Inhalation	General Population	No	Unlikely to be a route to general population since 1,2-dichloroethane is not expected to sorb onto biosolids.
			groundwater and/or surface water	TBD	Aquatic and Terrestrial receptors	Yes	

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

⁷ The exposure pathways, exposure routes and hazards EPA plans to consider are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of 1,2-dichloroethane in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate ⁷	Rationale
		Underground injection	Migration to groundwater, potential surface/drinking	Oral Dermal Inhalation	General Population	No	1,2-Dichloroethane is released to Class I Underground Injection Hazardous Waste Wells which are covered by SDWA and
			water	TBD	Aquatic and Terrestrial Species		RCRA.
	Solid and	Hazardous,	Leachate to soil, ground	Oral Dermal	General Population	No	1,2-Dichloroethane is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
Disposal		Municipal landfill and other land disposal	water and/or mitigation to surface water	TBD	Aquatic and Terrestrial Receptors		