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

CASRN 107-06-2

August 2020

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Docket

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

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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	Bioconcentration Factor
BMF	Biomagnification factor
BOD	Biochemical Oxygen Demand
BP	Boiling Point
BSER	Best System of Emission Reduction
$BW^{3/4}$	Body Weight ¾ 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
CEM	Consumer Exposure Model
CEPA	Canadian Environmental Protection Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
ChemSTEER	Chemical Screening Tool for Occupational Exposures and Releases
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	Federal Hazardous Materials Transportation Act
HSDB	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 Zones
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
ISHA	Industrial Safety and Health Act
K_{OC}	Organic Carbon: Water Partition Coefficient
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology
K_{OW}	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	Manufacturing
MITI	Ministry of International Trade and Industry
MOA	Mode of Action
MP	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	National Primary Drinking Water Regulation
NPL	National Priorities List
NPRI	National Pollutant Release Inventory
NSPS	New Source Performance Standards
NTP	National Toxicology Program

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
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, and Toxic
PECO	Population, Exposure, Comparator, Outcome
PEL	Permissible Exposure Limit
PESO	Pathways and Processes, Exposure, Setting or Scenario and Outcomes
PESS	Potentially Exposed or Susceptible Subpopulations
PODs	Points of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
RCRA	Resource Conservation and Recovery Act
RDF	Refuse-derived Fuel
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REL	Recommended Exposure Limit
RESO	Receptors, Exposure, Setting or Scenario and Outcomes
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 monitoring data
SVOCs	Semi-Volatile Organic Compounds
TBD	To be determined
TERA	Toxicology Excellence for Risk Assessment
TG	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-2019-0131). The first step of the risk evaluation process is the development of the scope document. EPA published the *Draft Scope of the Risk Evaluation for 1,2-Dichloroethane CASRN 107-06-2* (EPA Document No. EPA-740-D-20-005) (U.S. EPA, 2020c) and provided a 45-day comment period on the draft scope per 40 CFR 702.41(c)(7). EPA has considered comments received (Docket ID: EPA-HQ-OPPT-2018-0427) during the public comment period to inform the development of this final scope document, and public comments received will continue to inform the development of the risk evaluation for 1,2-dichlorothane. This document fulfills the TSCA requirement to issue a final scope document per TSCA Section 6(b)(4)(D) and as described in 40 CFR 702.41(c)(8). The scope for 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 the risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance.

General Information. 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 *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) to inform the development of this scope document. Furthermore, EPA conducted a comprehensive search to identify and screen multiple evidence streams (*i.e.*, chemistry, fate, release and engineering, exposure, hazard) and the search and screening results are provided in Section 2.1. EPA used the systematic review process described in Appendix A to search for and screen reasonably available information, including information already in EPA's possession, for inclusion in the risk evaluation. This information includes the hazards, exposures, PESS, and conditions of use that may help inform the risk evaluation for 1,2-dichloroethane. EPA has focused on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the scope document, whereas the data evaluation and integration stages will occur during the development of the risk evaluation and thus are not part of the scoping activities described in this document. EPA will consider additional information identified following publication of this scope document, as appropriate, in developing the risk evaluation, including the Chemical Data Reporting (CDR) information that the Agency will receive by the end of November 2020.

Conditions of Use. EPA plans to evaluate manufacturing (including importing), processing, distribution in commerce, industrial, commercial and consumer uses, and disposal of 1,2-dichloroethane in the risk evaluation. 1,2-Dichloroethane is manufactured (including imported) in the United States. During the manufacture of 1,2-dichloroethane, the byproducts 1,1-dichloroethane (75-34-3), 1,1,2-trichloroethane (79-00-5), trans-1,2-dichloroethylene (156-60-5), trichloroethylene (79-01-6), perchloroethylene (127-18-4), methylene dichloride (75-09-2), and carbon tetrachloride (56-23-5) are formed, and will be assessed during the risk evaluation of 1,2-dichloroethane. 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 Toxics Release Inventory (TRI) reporting, published literature, public comments, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. EPA revised the conditions of use in the final scope of the risk evaluation based on additional information and public comments (Docket ID: EPA-HQ-OPPT-2018-0427) on the draft scope document for 1,2-dichloroethane. EPA is aware of information reporting use of 1,2-dichloroethane in "food packaging" and "medical devices"; however, these are not conditions of use for the chemical substance as defined in TSCA § 3(2) and (4). 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. EPA considered reasonably available information as well as public comments received on the draft scope document for 1,2-dichloroethane in finalizing the exposure pathways, exposure routes, and hazards EPA plans to evaluate in the risk evaluation. As a result, EPA plans to focus the risk evaluation for 1,2-dichloroethane on the following exposures, hazards and receptors:

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to evaluate releases to the environment as well as human and environmental exposures resulting from the conditions of use of 1,2-dichloroethane that EPA plans to consider in the risk evaluation. Exposures for 1,2-dichloroethane are discussed in Section 2.3. Additional information gathered through the results of systematic review searches will inform expected exposures.

  EPA's plan for evaluating environmental exposure pathways in the scope of the risk evaluation considers whether and how other EPA-administered statutes and regulatory programs cover 1,2-dichloroethane in media pathways falling under the jurisdiction of those authorities. Section 2.6.3.1 discusses pathways under the jurisdiction of other EPA-administered laws. In Section 2.6.3.2, 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. Based on pathways under the jurisdiction of other EPA-administered laws, EPA does not plan to evaluate the general population as a receptor in the scope of the risk evaluation (see Figure 2-16).

  EPA considered reasonably available information and comments received on the draft scope for 1,2-dichlorethane in determining the human and environmental exposure pathways, routes, receptors and PESS for inclusion in the final scope. EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation:
  - *Occupational exposure:* EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of 1,2-dichloroethane.
  - *Consumer and bystander exposure:* EPA plans to evaluate the oral and dermal exposure to 1,2-dichloroethane for consumers, and inhalation exposure for consumers and bystanders during use of plastic and rubber products.

- *PESS:* EPA plans to include children, women of reproductive age (*e.g.*, pregnant women), workers and consumers as PESS in the risk evaluation.
- *Environmental exposure:* EPA plans to evaluate exposure to 1,2-dichloroethane for aquatic receptors.

- *Hazards.* Hazards for 1,2-dichloroethane are discussed in Section 2.4. EPA completed preliminary reviews of information (*e.g.*, federal and international government chemical assessments) to identify potential environmental and human health hazards for 1,2-dichloroethane as part of the prioritization (U.S. EPA, 2019c) and scoping process (U.S. EPA, 2020c). EPA also considered reasonably available information collected through systematic review methods as outlined in Appendix A and public comments received on the draft scope for 1,2-dichloroethane in determining the broad categories of environmental and human health hazard effects to be evaluated in the risk evaluation. EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for 1,2-dichloroethane.

  EPA plans to evaluate all potential environmental and human health hazard effects identified for 1,2-dichloroethane in Sections 2.4.1 and 2.4.2, respectively. Identified through the data screening phase of systematic review, the potential environmental hazard effects and related information that EPA plans to consider for the risk evaluation include: ADME, cancer, developmental, hematological and immune, hepatic, mortality, musculoskeletal, nutritional and metabolic, ocular and sensory, reproductive, respiratory and skin and connective tissue for 1,2-dichloroethane. Similarly, the potential human health hazard effects and related information identified through prioritization and the data screening phase of systematic review for 1,2-dichloroethane that EPA plans to consider for the risk evaluation include: ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic, ocular and sensory, renal, reproductive, respiratory and skin and connective tissue.

Analysis Plan. The analysis plan for 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 review of identified information as described in Section 2.1. Should additional data or approaches become reasonably available, EPA may consider them for the risk evaluation.

Peer Review. The draft risk evaluation for 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 Peer Review Handbook (U.S. EPA, 2015) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45).

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for 1,2-dichloroethane 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 TSCA on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high-priority substances for risk evaluations (Docket ID: EPA-HQ-OPPT-2019-0131 (84 FR 71924, December 30, 2019), as required by TSCA § 6(b)(2)(B), which initiated the risk evaluation process for those chemical substances. 1,2-dichloroethane is one of the chemicals designated as a high priority substance for risk evaluation. On April 9, 2020, EPA published the *Draft Scope of the Risk Evaluation for 1,2-Dichloroethane CASRN 107-06-2* (EPA Document No. EPA-740-D-20-005) (85 FR 19941) (U.S. EPA, 2020c) for a 45-day public comment period. After reviewing and considering the public comments (Docket ID: EPA-HQ-OPPT-2018-0427) received on the draft scope document, EPA is now publishing this final scope document pursuant to 40 CFR 702.41(c)(8).

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this scope document for 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;

[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).

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.

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

Search terms were used to search each of the literature streams and gather 1,2-dichloroethane studies. These terms and the methods used to develop them are listed in Appendix A. The studies resulting from the search process were loaded into the EPA Health and Environmental Research Online (HERO) database and then prioritized to screen first the literature likely relevant for each of the disciplines: fate, physical and chemical properties, engineering, exposure and hazard. The tools and methods used to manage the screening process are also outlined in Appendix A. The studies resulting from the search underwent a title/abstract screening process, which tagged them by topic or category. Following this, a determination was made to move studies forward into full-text screening. The criteria used in the screening process for each discipline are found in the population, exposure, comparator, outcome (PECO) statements listed in Appendix A. The screening process results are presented in the form of literature inventory trees and heat maps in Section 2.1.2. The screening process was conducted based on EPA's planning, execution and assessment activities outlined in Appendix A.

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

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

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 92 search results relevant to EPA's risk evaluation needs for 1,2-dichloroethane. Appendix A.3.4 lists the gray literature sources that yielded 92 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 will consider additional reasonably available information from gray literature if it becomes available during the risk evaluation phase.

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

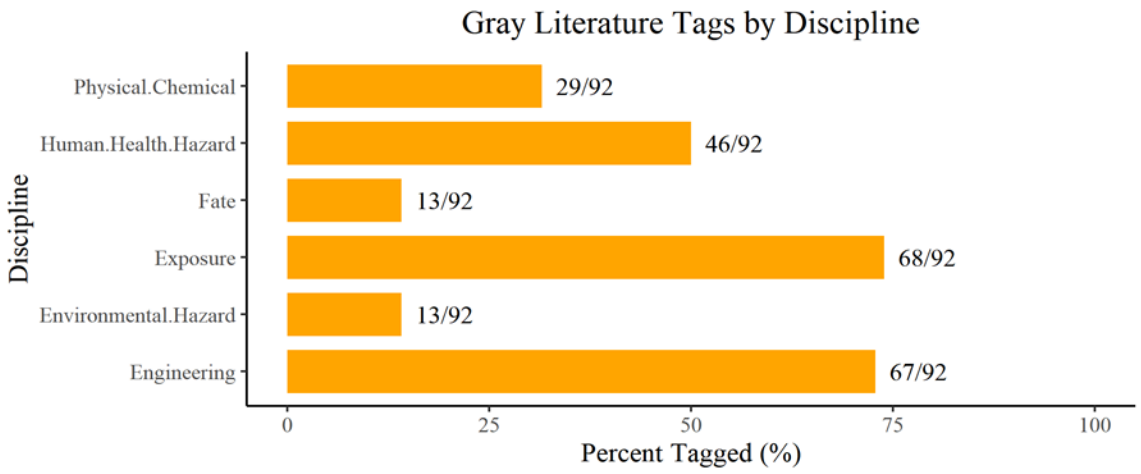

Figure 2-1. Gray Literature Tags by Discipline for 1,2-Dichloroethane
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines).

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

EPA has begun the systematic review process and has conducted searching and screening of the reasonably available literature using the process outlined in Appendix A. This includes performing a comprehensive search of the reasonably available peer review literature on physical and chemical properties, environmental fate and transport, engineering (environmental release and occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of 1,2-dichloroethane. Eligibility criteria were applied in the form of PECO statements (see Appendix A). 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 (see Appendix A.2). EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation.

EPA created literature inventory trees to graphically illustrate the flow of data and information sources following full-text screening (see Figure 2-2, Figure 2-3, Figure 2-5, Figure 2-7, and Figure 2-9). For the physical and chemical, fate, engineering and hazard literature, EPA used the Health Assessment Workplace Collaborative (HAWC) tool to develop web-based literature inventory trees illustrating, through interactive links, studies that were included or excluded. These literature inventory trees enhance the transparency of the decisions resulting from the screening process described in Appendix A. For each of the corresponding disciplines, the literature was tagged to be included for evaluation during the risk evaluation. Literature inventory trees for physical and chemical properties are provided as static diagrams (Figure 2-2). For all other disciplines, static screen captures are provided in addition to links to the interactive trees. The links show individual studies that were tagged as included, excluded, or supplemental. Supplemental studies did not meet all inclusion criteria but may be considered during the risk evaluation as supporting information (see Appendix A). These studies can be accessed through the hyperlink provided in the associated caption. In some figures the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

In addition, EPA tabulated the number and characteristics of the data and information sources included in the full-text screening process in the form of a literature heat map for the fate, engineering, exposure and hazard information (see Figure 2-4, Figure 2-6, Figure 2-8, Figure 2-10). For each of these four disciplines, a static image of the literature inventory heat map is provided, and a link to the interactive version presented in HAWC is included in the caption below each diagram.

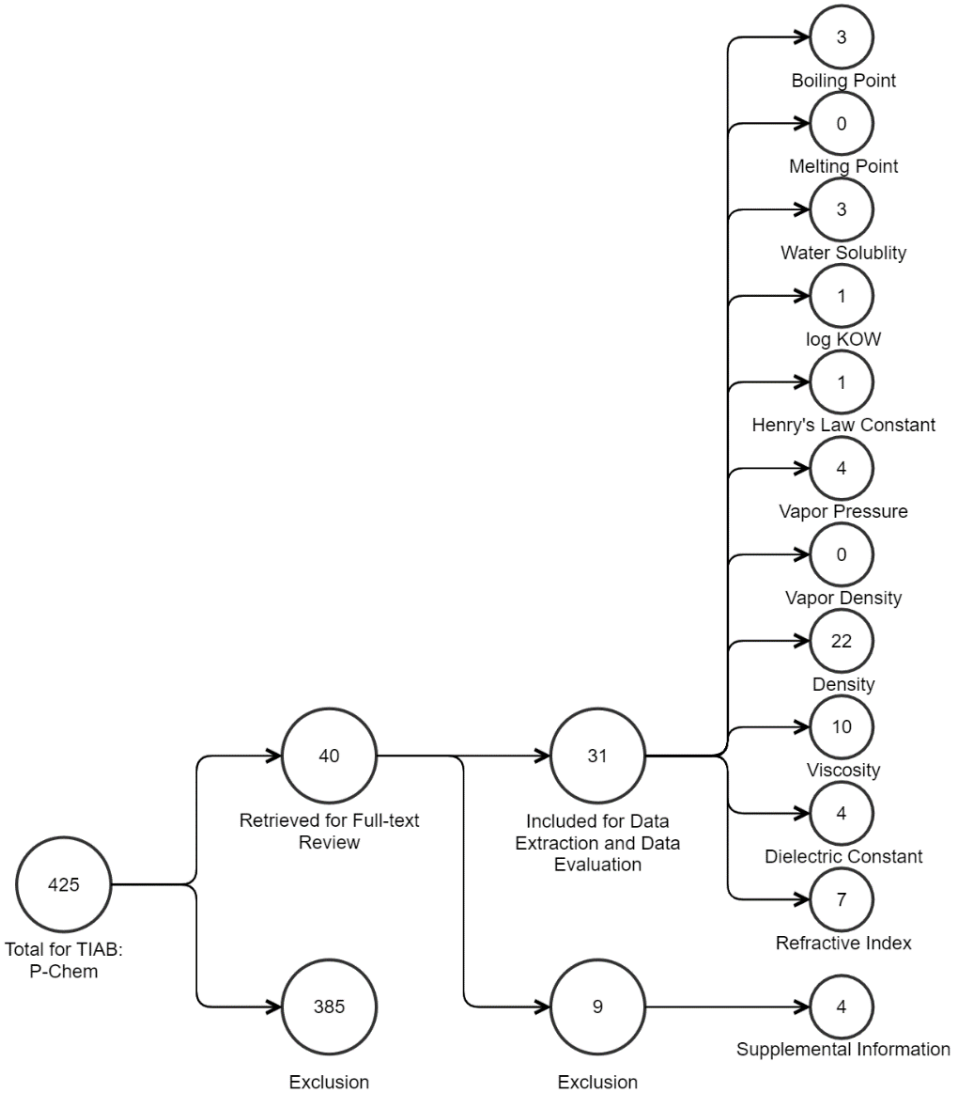

Figure 2-2. Peer-reviewed Literature Inventory Tree - Physical and chemical Properties Search Results for 1,2-Dichloroethane

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

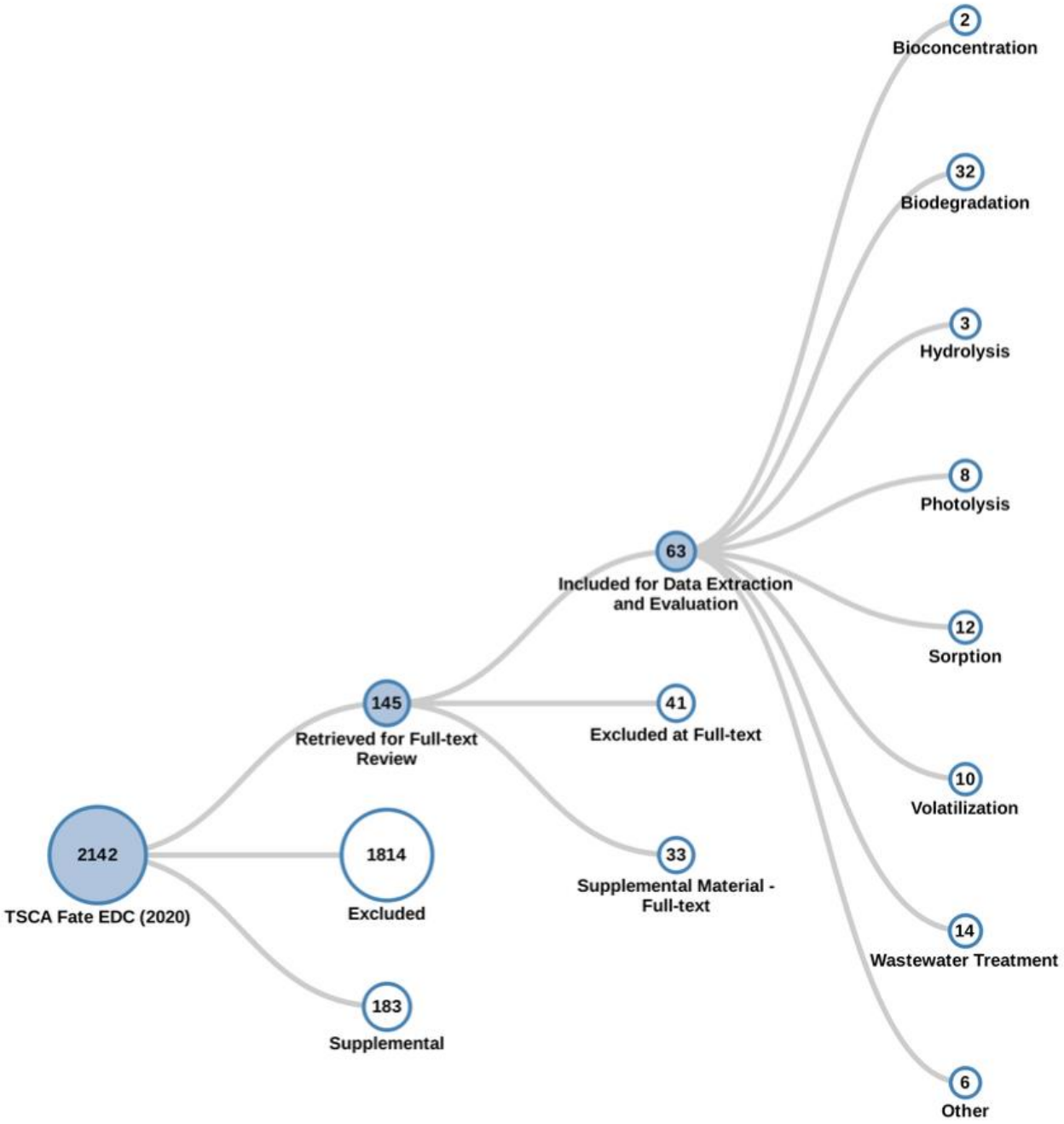

Figure 2-3. Peer-reviewed Literature Inventory Tree – Fate and Transport Search Results for 1,2-Dichloroethane

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

	Media					
Endpoint	Air	Soil, Sediment	Wastewater, Biosolids	Water	Other	Grand Total
Bioconcentration			1	1		2
Biodegradation	1	18	8	17		31
Hydrolysis		1		3		3
Photolysis	6	1	1	2		8
Sorption	1	11		9		12
Volatilization	6	3	3	7		10
Wastewater Treatment	2	1	12	8		14
Other	2	2	3	2		6
Grand Total	11	29	19	36		64

Figure 2-4. Peer-reviewed Literature Inventory Heat Map – Fate and Transport Search Results for 1,2-Dichloroethane

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

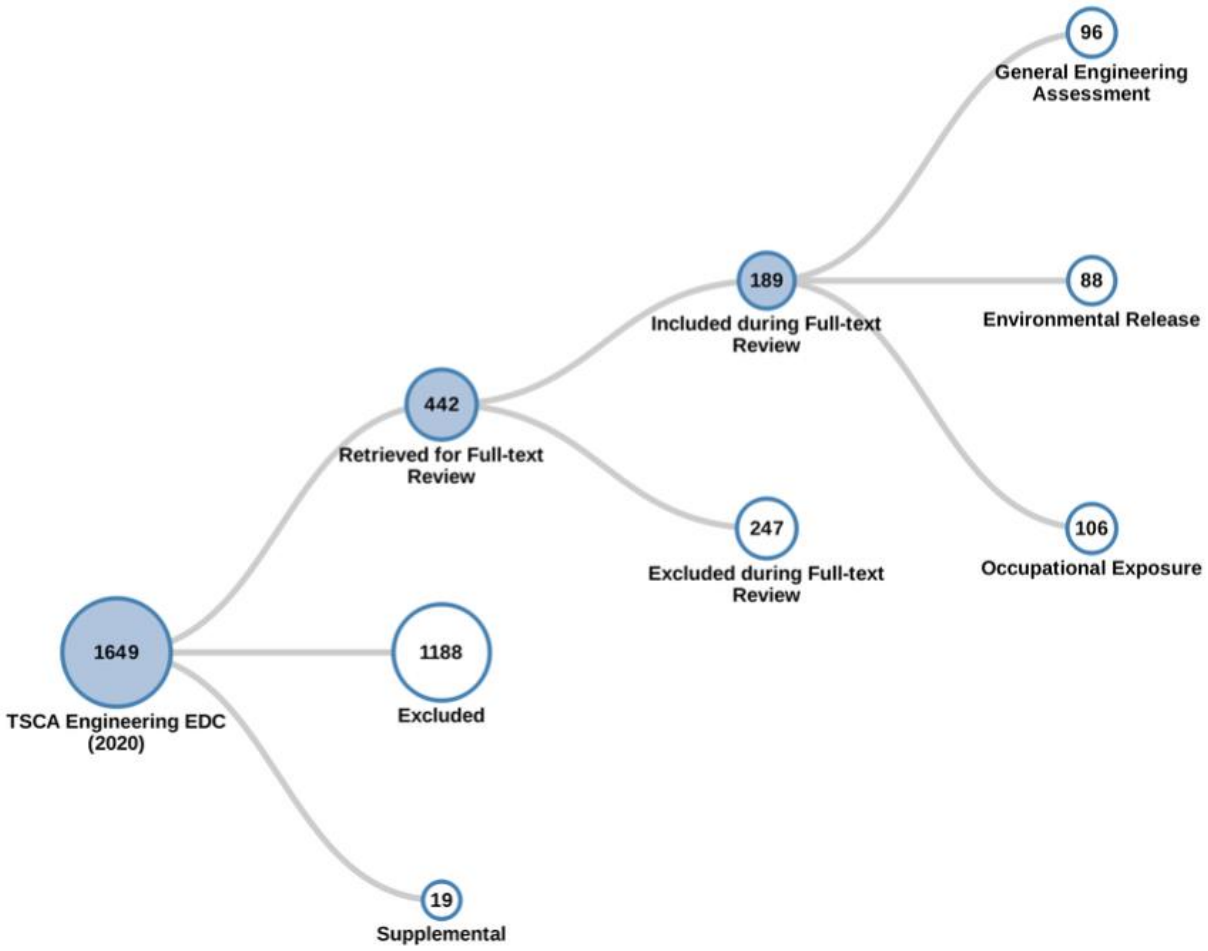

Figure 2-5 Peer-reviewed Literature Inventory Tree - Engineering Search Results for 1,2-Dichloroethane

Click here to view the interactive literature inventory tree. Data in this figure represent references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 10, 2020. Additional data may be added to the interactive version as they become available.

Data Type	Evidence Tags	
Environmental Releases	Description of release source	53
	No evidence tag	1
	Release frequency	8
	Release or emission factors	50
	Release quantity	50
	Waste treatment methods and pollution control	23
	Total	89
General Engineering Assessment	Chemical concentration	23
	Life cycle description	13
	No evidence tag	7
	Number of sites	17
	Process description	36
	Production, import, or use volume	57
	Throughput	14
	Total	97
Occupational Exposures	Area sampling data	64
	Dermal exposure data	10
	Engineering control	12
	Exposure duration	37
	Exposure frequency	16
	Exposure route	58
	No evidence tag	5
	Number of workers	34
	Particle size characterization	
	Personal protective equipment	18
	Personal sampling data	36
	Physical form	30
	Worker activity description	43
	Total	107
Grand Total		190

Figure 2-6. Peer-reviewed Literature Inventory Heat Map - Engineering Search Results for 1,2-Dichloroethane

Click here to view the interactive version for additional study details. Data in this figure represent references obtained from the publicly available databases search (See Appendix A.1.2) that were included during full-text screening as of August 5, 2020. Additional data may be added to the interactive version as they become available.

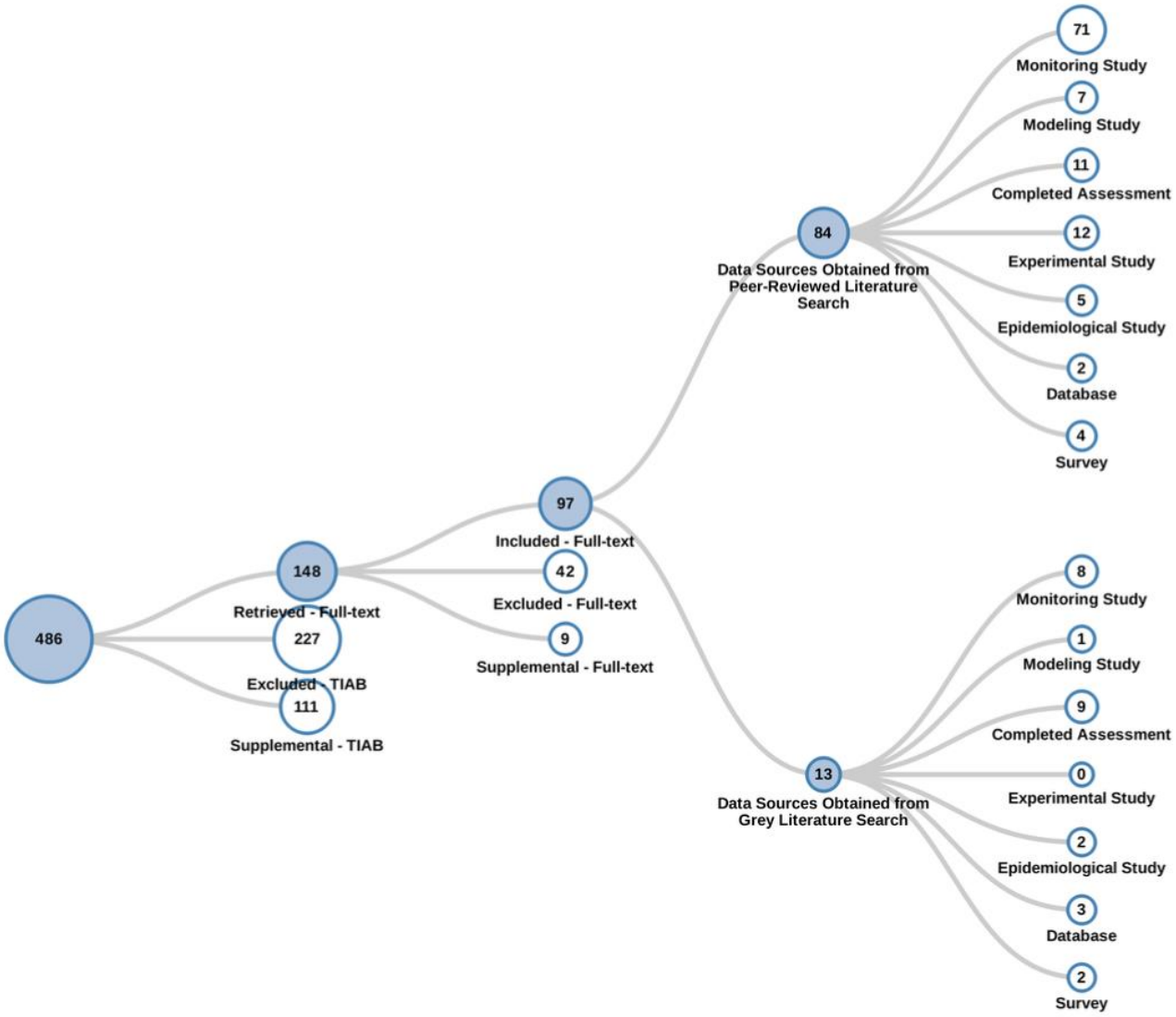

Figure 2-7. Peer-Reviewed and Gray Literature Inventory Tree - Exposure Search Results for 1,2-Dichloroethane

Click here to view the interactive literature inventory tree. Data in this figure represent all references obtained from the publicly available databases search (see Appendix A.1.2), and gray literature references search (see Appendix A.3) that were included during full-text screening as of July 31, 2020. Additional data may be added to the interactive version as they become available.

Media (group)	Data Type: Monitoring Study	Modeling Study	Completed Assessment	Experimental Study	Epidemiological Study	Database	Survey	Grand Total
Ambient Air								
Biosolids/Sludge								
Drinking Water								
Groundwater								
Land Disposal/ Landfill								
Sediment	1							1
Soil	5		2					6
Surface Water	4		2			1		6
Wastewater	1							1
Aquatic Species								
Terrestrial Species			1					1
Consumer	9	3	2	9				18
Dietary	4	1	1	1		1	1	5
Dust								
Exposure Factors	2	1	1	1	1	1	1	4
Exposure Pathway	4	1	3					6
Human Biomonitoring	17	1	4	2	2	3	1	19
Indoor Air	66	6	13	9	4	1	4	77
Isomers	1		1					1
Use Information	1	1	6	1				7
No Evidence Type								
Grand Total	80	8	20	12	7	5	6	98

Figure 2-8 Peer-reviewed and Gray Literature Inventory Heat Map –Exposure Search Results for 1,2-Dichloroethane

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

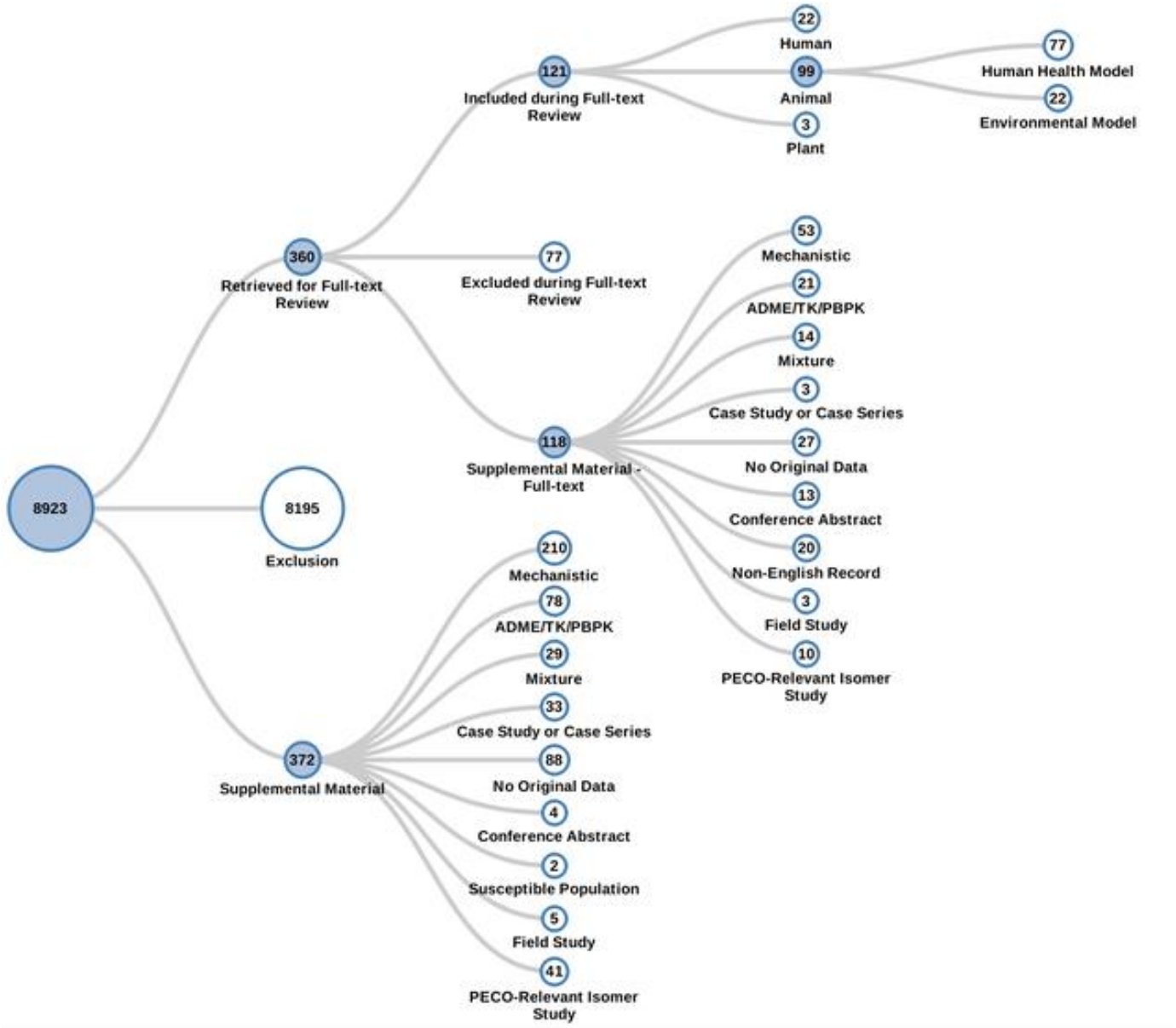

Figure 2-9. Peer-reviewed Literature Inventory Tree - Human Health and Environmental Hazards Search Results for 1,2-Dichloroethane

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

	Evidence Type				
Health Outcomes	Human	Animal - Human Health Model	Animal - Environmental Model	Plant	Grand Total
ADME	7	43	1	1	50
Cancer	12	25	2		38
Cardiovascular	1	4			5
Developmental	7	21	6	1	34
Endocrine	4	25			28
Gastrointestinal	3	6			9
Hematological and Immune	6	20	1		26
Hepatic	4	35	1		39
Mortality	2	8	4		14
Musculoskeletal	1	1	1		3
Neurological	5	16			20
Nutritional and Metabolic	3	18	1		21
Ocular and Sensory	1	4	1		6
PBPK	1	1			2
Renal	2	15			17
Reproductive	2	22	3		27
Respiratory	9	40	1		49
Skin and Connective Tissue	3	6	2		11
No Tag	1	6	11	2	19
Grand Total	22	77	22	3	121

Figure 2-10. Peer-reviewed Literature Inventory Heat Map – Human Health and Environmental Hazards Search Results for 1,2-Dichloroethane

Click here to view the interactive version for additional study details. The numbers indicate the number of studies with TIAB keywords related to a particular health outcome, not the number of studies that observed an association with 1,2-dichloroethane. Evidence types were manually extracted, and Health Systems were determined via machine learning. Therefore, the studies examining multiple Health Outcomes and Evidence types, connections between health outcome, and evidence type may not be accurately represented. If a study evaluated multiple health outcomes or included multiple populations or study designs, it is shown here multiple times. Data in this figure represents references obtained from the publicly available databases search (see Appendix A.1.2) that were included during full-text screening as of June 2, 2020. Additional data may be added to the interactive version as they become available.

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA. EPA screened a total of 235 submissions using PECO or similar statements that identify inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are presented in Appendix A.2.1. EPA identified 206

submissions that met the inclusion criteria in these statements and identified 15 submissions with supplemental data.[3]

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

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

Discipline	Included	Supplemental[b]
Physical and Chemical Properties	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

[a]Individual submissions may be relevant to multiple disciplines.
[b]Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

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, 2019c), EPA assembled information from the CDR and TRI programs to determine conditions of use[4] or significant changes in conditions of use of the chemical substance. Once the 2020 CDR reporting period ends in November 2020, EPA will utilize the most recent CDR information. EPA also consulted a variety of other sources to identify uses of 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) (U.S. EPA, 2019b) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, EPA

[3] EPA may further consider some supplemental or excluded references depending on the reasons for tagging as supplemental or excluded.
[4] *Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of (TSCA § 3(4)).

incorporated communications with companies, industry groups, and public comments to supplement the use information.

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

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of 1,2-dichloroethane, EPA identified those activities for 1,2-dichloroethane the Agency determined not to be conditions of use or are otherwise excluded from the scope of the risk evaluation. These excluded activities are described in Section 2.2.2.

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.

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

Life Cycle Stage[a]	Category[b]	Subcategory[c]	References
Manufacturing	Domestic manufacture	Domestic manufacture	U.S. EPA (2019a)
	Import	Import	U.S. EPA (2019a)
Processing	Processing as a reactant	Intermediate in: Petrochemical manufacturing; Plastic material and resin manufacturing; All other basic organic chemical manufacturing	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0427-0006: EPA-HQ-OPPT-2018-0427-0015
	Processing - Incorporated into formulation, mixture, or reaction product	Fuels and fuel additives: All other petroleum and coal products manufacturing	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0427-0006; EPA-HQ-OPPT-2018-0427-0015
		Processing aids: specific to petroleum production	U.S. EPA (2019a)
	Recycling	Recycling	U.S. EPA (2019a)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial Use	Adhesives and sealants	Adhesives and sealants	EPA-HQ-OPPT-2018-0427-0018
	Functional Fluids (closed systems)	Heat transferring agent	Baldwin Filters (2015)

Life Cycle Stage[a]	Category[b]	Subcategory[c]	References
	Lubricants and Greases	Paste lubricants and greases	EPA-HQ-OPPT-2018-0427-0005
	Oxidizing/ reducing agents	Oxidation inhibitor in controlled oxidative chemical reactions	EPA-HQ-OPPT-2018-0427-0006
	Solvents (for cleaning and degreasing)	A component of degreasing and cleaning solvents	EPA-HQ-OPPT-2018-0427-0005
Commercial Use	Plastic and rubber products	Products such as: plastic and rubber products	U.S. EPA (2019a)
	Fuels and related products	Fuels and related products	U.S. EPA (2019a); EPA-HQ-OPPT-2018-0427-0006
	Other use	Laboratory chemical (*e.g.*, reagent)	Thermo Fisher (2018)
		Embalming agent	Frigid Fluid Company (2015)
Consumer Use	Plastic and rubber products	Plastic and rubber products	EPA-HQ-OAR-2002-0037-0203; EPA-HQ-OPPT-2018-0427-0040; Doucette et al. (2010)
Disposal	Disposal	Disposal	

a. Life Cycle Stage Use Definitions (40 CFR § 711.3)
– "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
– "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
– "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
– Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA Section 6(a)(5) to reach both.
b. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of 1,2-dichloroethane in industrial and/or commercial settings and for consumer uses.
c. These subcategories reflect more specific conditions of use of 1,2-dichloroethane.
- During the manufacture of 1,2-dichloroethane, the byproducts 1,1-dichloroethane (75-34-3), 1,1,2—trichloroethane (79-00-5), trans-1,2-dichloroethylene (156-60-5), trichloroethylene (79-01-6), perchloroethylene (127-18-4), methylene chloride (75-09-2), and carbon tetrachloride (56-23-5) are formed, and will be assessed during the risk evaluation of 1,2-dichloroethane (EPA-HQ-OPPT-2018-0421-0027, EPA-HQ-OPPT-2019-0500-0101).

In the final scope, EPA made the following changes to the conditions of use:
- In the draft scope of the risk evaluation, a condition of use was included for processing use reported for 1,2-dichloroethane as a functional fluid in pharmaceutical and medicine manufacturing. EPA has found that the reported use of 1,2-dichloroethane as a functional fluid during pharmaceutical manufacturing is instead a use as a laboratory chemical to produce vinyl chloride, and has concluded that this use falls within the commercial laboratory chemical condition of use.
- EPA has determined that the CDR reported industrial use of laboratory chemicals, as they are used for services and wholesale and retail trade, falls within the commercial laboratory chemical condition of use.
- EPA engaged with stakeholders and received public comment on the commercial and consumer plastic and rubber product condition of use (EPA-HQ-OPPT-2018-0427-0040). The risk evaluation will be guided by the systematic review of the information regarding the residual level of 1,2-dichloroethane in those products.

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* (82 FR 33726, July 20, 2017), TSCA Section 6(b)(4)(D) requires EPA to identify the hazards, exposures, conditions of use, and the PESS the Administrator expects to consider in a risk evaluation, suggesting that EPA may exclude certain activities that it determines to be conditions of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). TSCA Section 3(4) also grants EPA discretion to determine the circumstances that are appropriately considered to be conditions of use for a particular chemical substance[5]. As a result, EPA does not plan to include in this scope or in the risk evaluation activities that the Agency does not consider conditions of use or for which EPA is exercising discretionary authority provided by TSCA Section 6(b)(4)(D).

TSCA Section 3(2) also excludes from the definition of "chemical substance" "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" as well as "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." EPA has determined that the following uses of 1,2-dichloroethane are non-TSCA uses:

One commenter (EPA-HQ-OPPT-2018-0427-0015) indicated that polyvinyl chloride (PVC) resins, used to make plastic and rubber products, are used in food packaging and medical devices such as blood bags. EPA has determined that these uses fall outside TSCA's definition of "chemical substance." FDA regulates "medical devices" intended for collection and processing of blood (21 CFR 864.9100) as well as "food additives", which would include indirect food additives intended for use in food packaging (21 CFR 174). Additionally, any other use of 1,2-dichloroethane as a PVC resin in "medical devices" would be regulated under FDA. Under TSCA § 3(2)(B)(vi), the definition of "chemical substance" does not include any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. Activities and releases associated with such food packaging and medical applications uses are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA § 3(4)) and will not be evaluated during risk evaluation.

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

2.2.3 Production Volume

As reported to EPA during the 2016 CDR submission 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, 2020a). 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, 2019c) and will include future production volume information from the 2020 CDR reporting period to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-11 provides the lifecycle diagram for 1,2-dichloroethane. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial and consumer use categories included within the scope of the risk evaluation. The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). Appendix E contains additional descriptions (*e.g.*, process descriptions, worker activities, process flow diagrams) for each manufacture, processing, distribution in commerce, use, and disposal category.

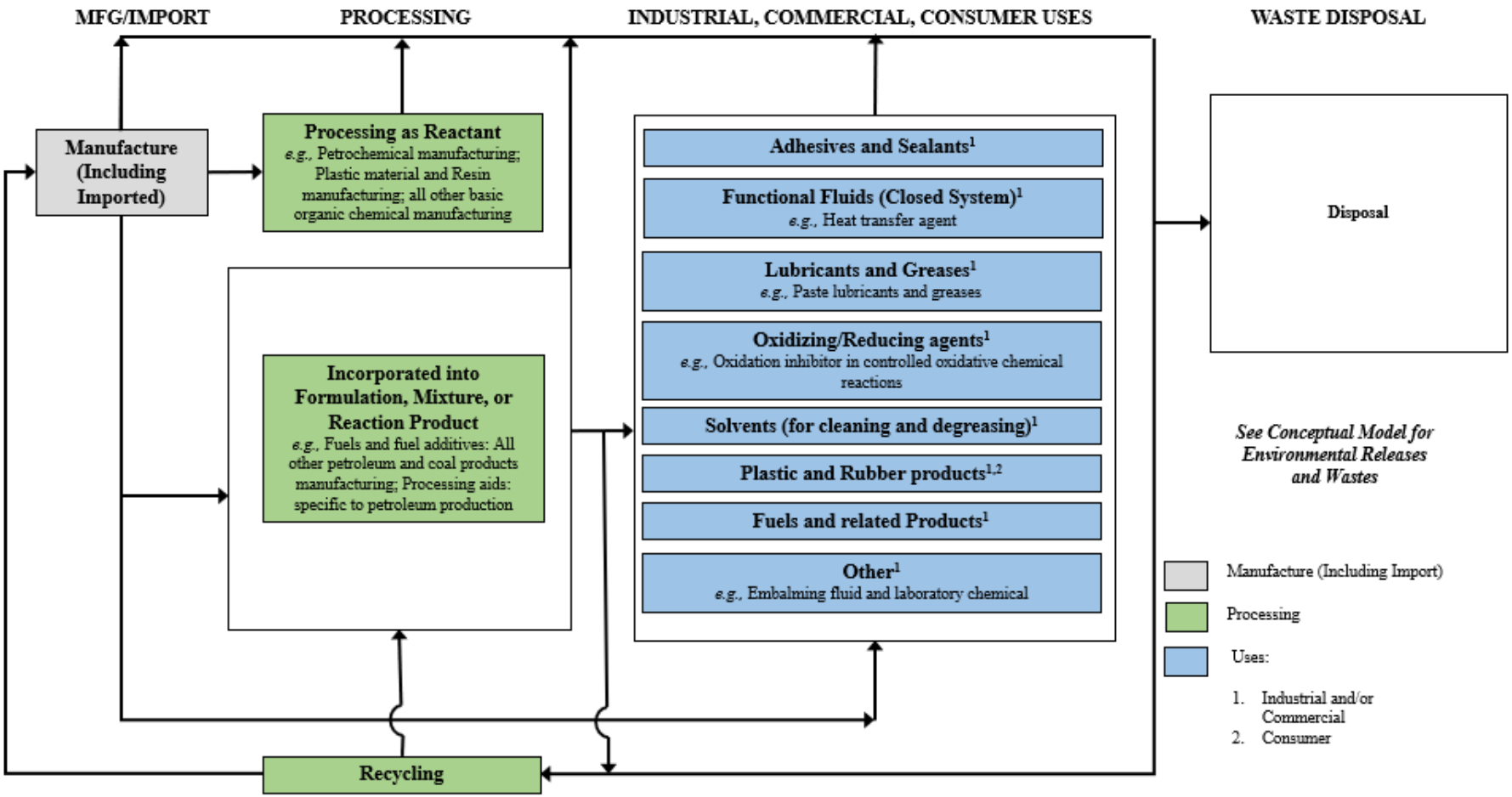

Figure 2-11. 1,2-Dichloroethane Life Cycle Diagram

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze human and environmental exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for 1,2-dichloroethane. In this section, the physical and chemical properties, environmental fate and transport properties and releases to the environment are described in addition to potential human and environmental exposures from TSCA conditions of use and from other possible or known sources. Release pathways and routes will be described in Section 2.6 to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including PESS, and environmental receptors. EPA plans to consider, 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

Consideration of physical and chemical properties is essential for a thorough understanding or prediction of environmental fate (*i.e.*, transport and transformation) and the eventual environmental concentrations. It can also inform the hazard assessment. Table 2-3. summarizes the physical and chemical property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of June 2020. This information differs from that presented in the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and may be updated as EPA continues to evaluate and integrate additional information through systematic review methods. Figure 2-12 summarizes the distribution of reported values for eight physical and chemical properties routinely used in existing chemical risk evaluations. Appendix B presents summary statistics for reported physical and chemical property values. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0427).

Table 2-3. Physical and Chemical Properties of 1,2-Dichloroethane

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_2H_4Cl_2$	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

Property or Endpoint	Value[a]	Reference	Data Quality Rating
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
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

Figure 2-12 displays a summary of the data collected as of June 2020 for eight physical and chemical values routinely used in TSCA existing chemical risk evaluations. The box and whisker plots for each endpoint illustrate the mean (average, indicated by the blue diamond) and the 10th, 25th, 50th (median), 75th, and 90th percentiles. All individual data points are indicated by black squares, and value preliminarily selected for use in the risk evaluation is overlaid (indicated by the orange circle) to provide context for where it lies within the distribution of the dataset. The number of unique primary data sources is indicated below each box and whisker plot. If multiple sources presented equivalent values and cited the same primary source, only one of those was included in the statistical calculations. As a result, the number of sources listed in Figure 2-12 may differ from the total number of data sources presented in Figure 2-2.

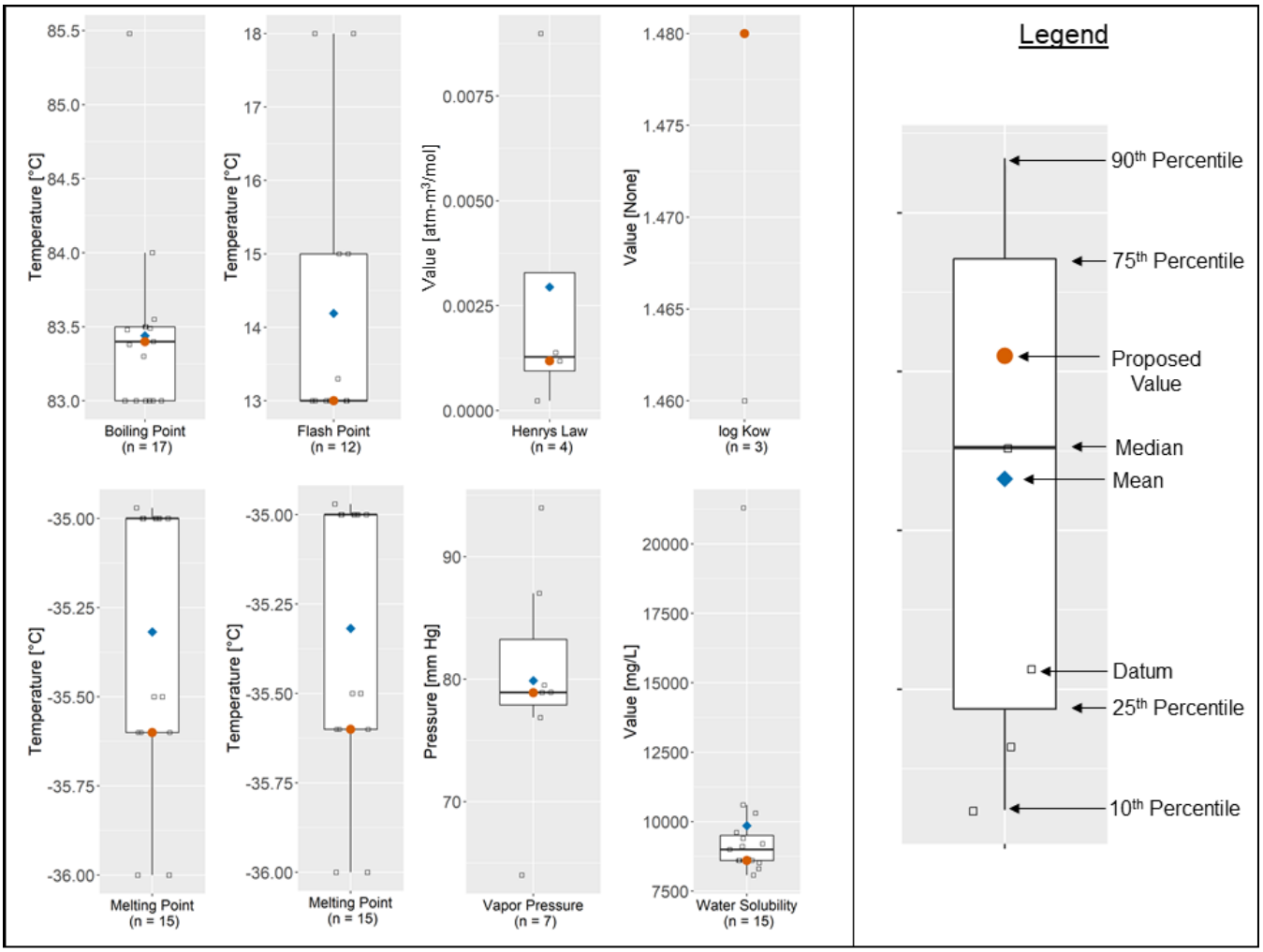

Figure 2-12. Box and Whisker Plots of Reported Physical and Chemical Property Values

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for 1,2-dichloroethane. EPA plans to use the environmental fate characteristics described in Appendix C to support the development of the risk evaluation for 1,2-dichloroethane. The values for the environmental fate properties may be updated as EPA evaluates and integrates additional information into the risk evaluation through systematic review methods.

2.3.3 Releases to the Environment

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

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 reporting[6], 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.

Table 2-4 provides production-related waste management data for 1,2-dichloroethane reported by facilities to the TRI program for reporting year 2018.[7] As shown in Table 2-4, 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 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.

Table 2-4. Summary of 1,2-Dichloroethane TRI Production-Related Waste Managed in 2018

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

Data source: 2018 TRI Data (Updated November 2019) U.S. EPA (2019d)

[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.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-5 provides a summary of the quantities of 1,2-dichloroethane released to the environment during 2018 as reported to TRI. 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 2-5. Summary of Releases of 1,2-Dichloroethane to the Environment During 2018

Year	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases (lbs) [a]	Total Releases (lbs) [b, c]
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal (lbs)[a]		
2018	60	136,759	311,737	3,362	21,801	19,665	82	94,113	587,519
		448,496			41,548				

[6] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

[7] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-4 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.

Year	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases (lbs) [a]	Total Releases (lbs) [b, c]
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal (lbs)[a]		

Data source: 2018 TRI Data (Updated November 2019) U.S. EPA (2019d)

[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 2-4 excludes any quantities reported as catastrophic or one-time releases (TRI Form R Section 8 data), release quantities shown in Table 2-5 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 2-5.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. 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 1,2-dichloroethane 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, 1991a, b, c, d, e, f, g).

2.3.5 Occupational Exposures

EPA plans to evaluate worker activities where there is a potential for exposure under the various conditions of use (manufacturing, processing, industrial/commercial uses, and disposal) described in Section 2.2. In addition, EPA plans to evaluate 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 risk evaluation.

Examples of worker activities associated with the conditions of use within the scope of the risk evaluation for 1,2-dichloroethane that EPA may analyze include, but are not limited to:

- Unloading and transferring 1,2-dichloroethane to and from storage containers and process vessels;
- Handling 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;
- Performing other work activities in or near areas where 1,2-dichloroethane is used.

1,2-Dichloroethane has a vapor pressure of around 79 mm Hg at 25 ºC based on the chemical's volatility, EPA plans to analyze inhalation exposure to vapor for workers and ONUs. EPA also plans to evaluate inhalation exposure to mists for workers and ONUs where products containing 1,2-dichloroethane may be spray-applied. EPA plans to evaluate dermal exposures for workers, who are expected to have skin contact with 1,2-dichloroethane. Occupational non-users do not directly handle 1,2-dichloroethane; therefore, skin contact with 1,2-dichloroethane is not expected for occupational non-users.

In addition, EPA has received comments that manufacturers have identified residual amounts of 1,2-dichloroethane in some commercial plastic and rubber products, however, formulators are uncertain how much remains in these products from the residuals in raw materials (EPA-HQ-OPPT-2018-0427). Because 1,2-dichloroethane may be present as a component of solid products; EPA plans to consider inhalation exposure to dust/particulates (*e.g.*, particulate generated during handling of plastic resins, finishing operations associated with the manufacture and finishing of plastics and plastic articles and incorporation of plastics and other article components into finished products) for workers and ONUs.

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

1,2-Dichloroethane has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) (OSHA, 2019). The PEL is 50 parts per million (ppm) over an 8-hour workday, 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, 2019). NIOSH considers 1,2-dichloroethane to be a potential occupational carcinogen with an Immediately Dangerous to Life or Health (IDLH) value of 50 ppm (NIOSH, 2020, 2016)

2.3.6 Consumer Exposures

According to reports to the 2012 and 2016 CDR, plastic and rubber products were 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 dermal contact with solid plastic or rubber articles containing 1,2-dichloroethane. Based on these potential sources and pathways of exposure, EPA plans to analyze inhalation, oral and dermal routes of exposures to consumers that may result from the conditions of use of 1,2-dichloroethane. EPA does not plan 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). The general population pathways in the scope of this evaluation are described in Sections 2.6.3 and 2.7.2.5.

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

EPA considered reasonably available information (*e.g.,* federal and international government chemical assessments) on 1,2-dichloroethane as well as public comments received on the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and draft scope for 1,2-dichloroethane (U.S. EPA, 2020c) to identify potential environmental hazards. During prioritization, EPA identified environmental hazard effects for aquatic and terrestrial organisms.

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

2.4.2 Human Health Hazards

EPA considered reasonably available information (*e.g.,* federal and international government chemical assessments) on 1,2-dichloroethane as well as public comments received on the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c) and draft scope for 1,2-dichloroethane (U.S. EPA, 2020c) to identify potential human health hazards. During prioritization, EPA identified the following potential human health hazards and related information: acute, repeat dose, genetic, toxicokinetic, irritation/corrosion, cancer, immune and neurological effects.

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

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "[t]he term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011a).

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

In developing exposure scenarios, EPA plans to analyze 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, 2006b). 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). Based on these analyses, EPA may update the list of PESS in the risk evaluation.

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 1,2-dichloroethane. Pathways and

routes of exposure associated with workers and ONUs are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that are under the jurisdiction of other EPA-administered, are discussed and depicted in the conceptual model shown in Section 2.6.3.1. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that are under the jurisdiction of other EPA-administered laws, are presented in the conceptual model shown in Section 2.6.3.2.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-13 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of 1,2-dichloroethane that EPA plans to include in the risk evaluation. There is potential for exposures to workers and ONUs to vapor via the inhalation route 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 during 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. EPA has identified conditions of use where the generation of mists (*e.g.*, spray application of products containing 1,2-dichloroethane) could occur. For these conditions of use EPA plans to analyze the potential of exposure to mist via the inhalation routes for workers. EPA does not plan to further analyze dermal exposure for ONUs because they are not expected to directly handle 1,2-dichloroethane.

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

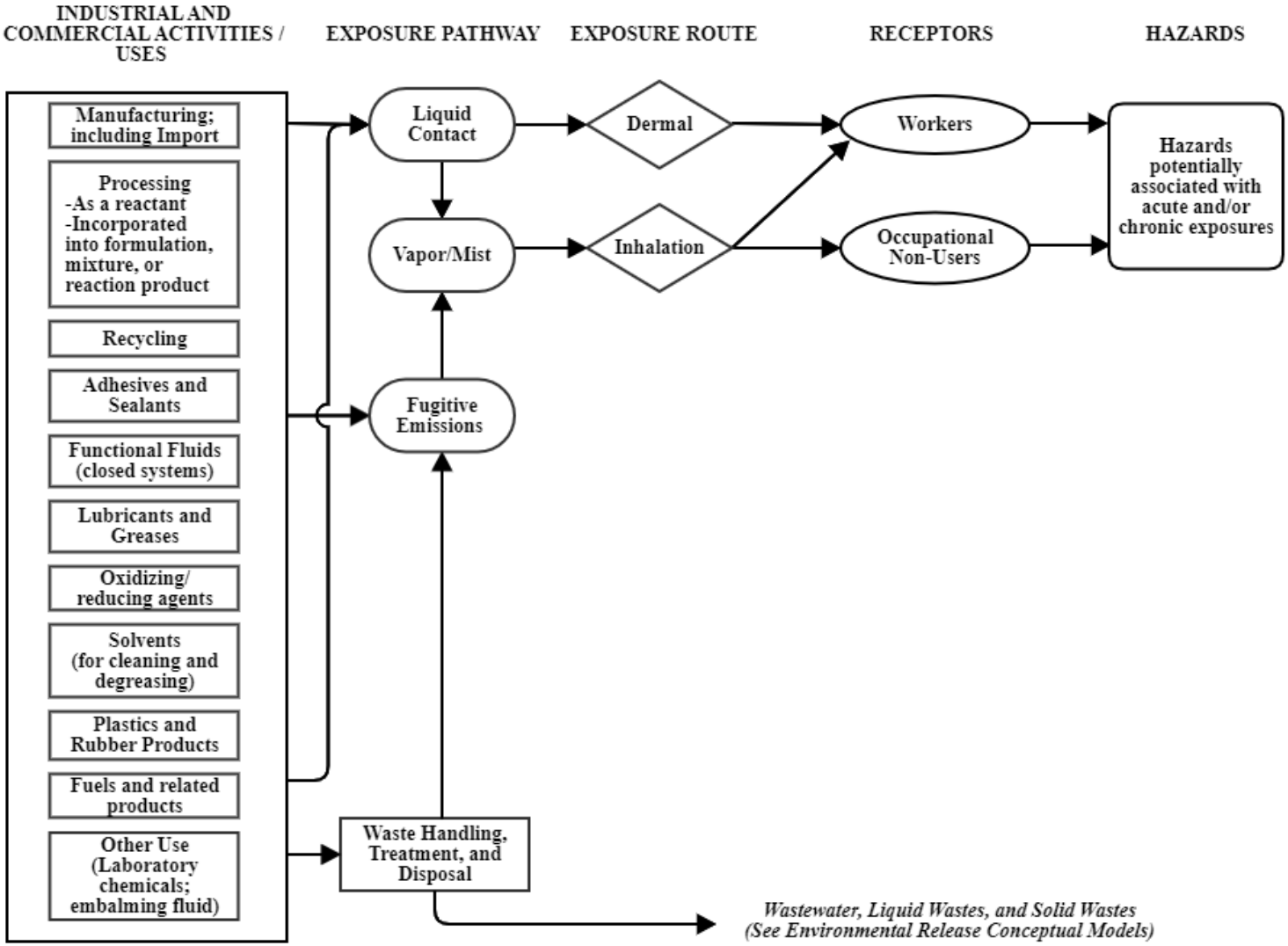

Figure 2-13. 1,2-Dichloroethane Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

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 2-14 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1,2-dichloroethane. There is potential for dermal exposures to 1,2-dichloroethane via direct dermal contact with rubber articles during consumer uses. In addition, consumers and bystanders may have inhalation exposures 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 oral exposure to 1,2-dichloroethane. The supporting rationale for consumer pathways that are in scope for 1,2-dichloroethane are included in Appendix G.

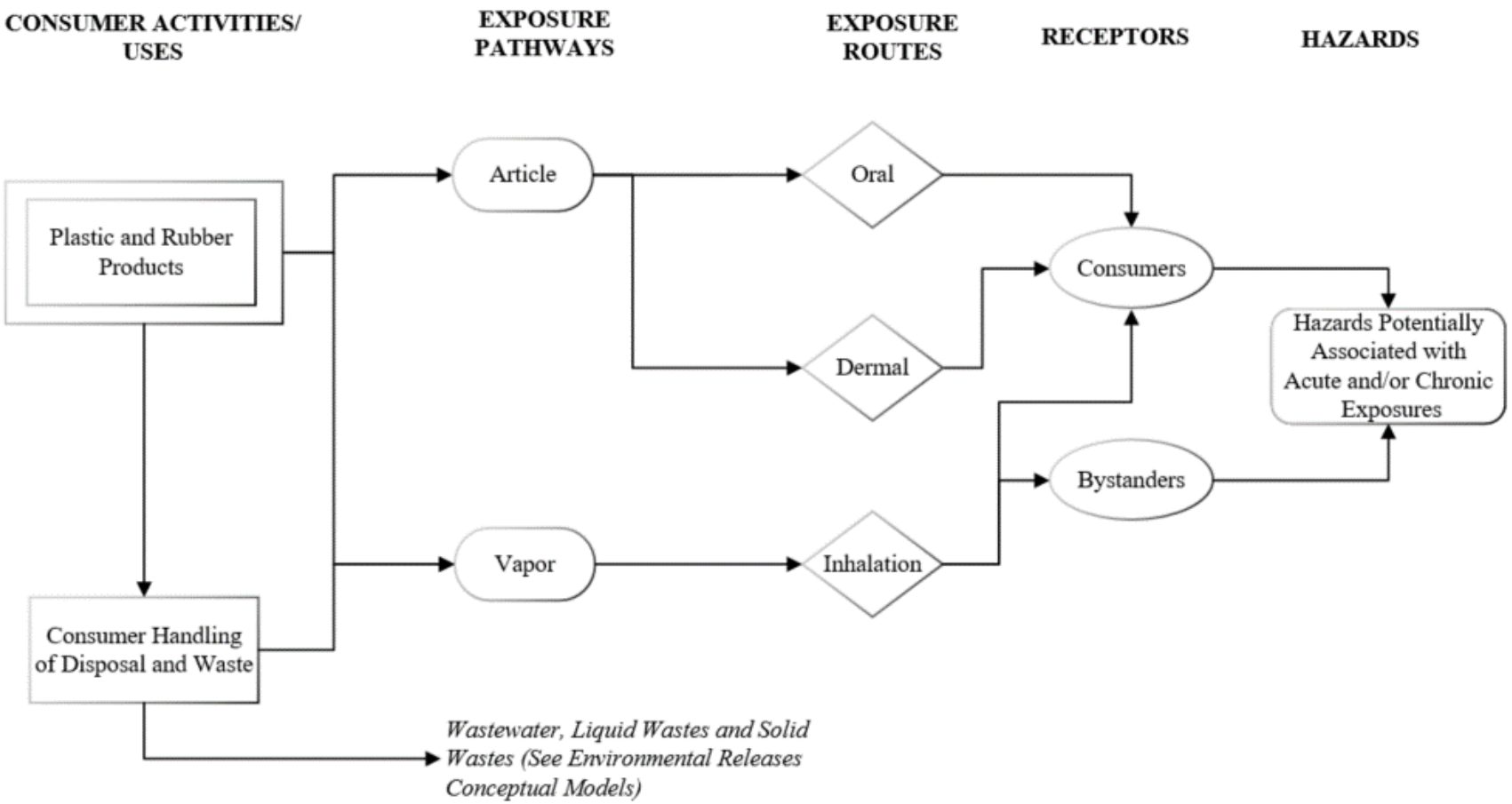

Figure 2-14. 1,2-Dichloroethane Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1,2-dichloroethane.

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 from environmental releases and wastes) and hazards to general population and environmental receptors associated with the conditions of use of 1,2-dichloroethane within the scope of the risk evaluation. This section also discusses those pathways that may be addressed pursuant to other EPA-administered laws.

The conceptual model in Figure 2-15 presents the potential exposure pathways, exposure routes and hazards to general population and environmental receptors from releases and waste streams associated with industrial, commercial and consumer uses of 1,2-dichloroethane. The conceptual model shows the overlays, labeled and shaded to depict the regulatory programs under EPA-administered statutes and associated pathways that EPA considered for the scope of the risk evaluation. The regulatory programs that cover these environmental release and waste pathways are further described in Section 2.6.3.1.

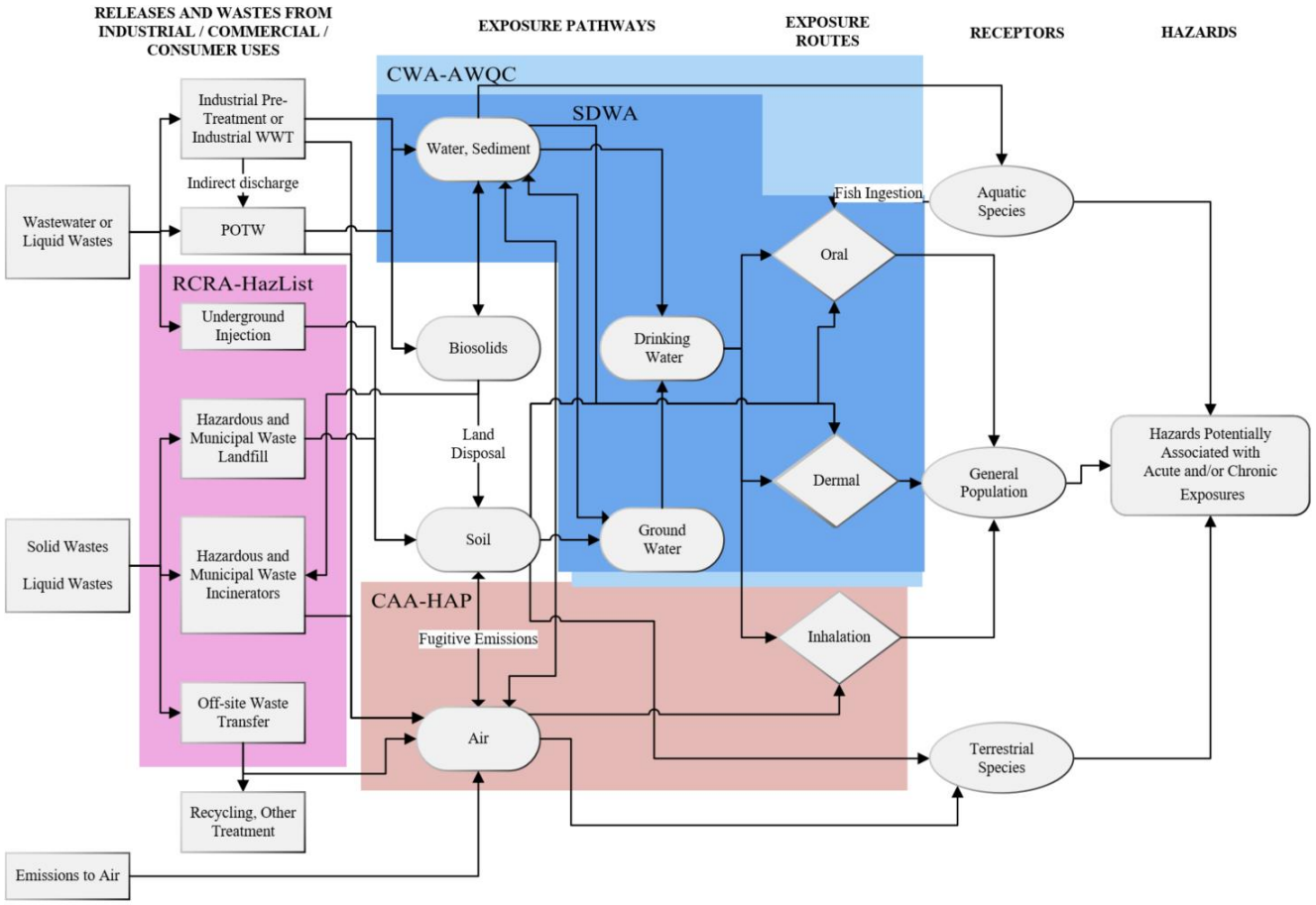

Figure 2-15. 1,2-Dichloroethane Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

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.

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 plants. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering.

b) Receptors include PESS (see Section 2.5).

2.6.3.1 Exposure Pathways and Risks Addressed by Other EPA Administered Statutes

In its TSCA Section 6(b) risk evaluations, EPA is coordinating action on certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. More specifically, EPA is exercising its TSCA authorities to tailor the scope of its risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs or risks that could be eliminated or reduced to a sufficient extent by actions taken under other EPA-administered laws. EPA considers this approach to be a reasonable exercise of the Agency's TSCA authorities, which include:

- TSCA Section 6(b)(4)(D): "The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider…"
- TSCA Section 9(b)(1): "The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter."
- TSCA Section 9(e): "…[I]f the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency."
- TSCA Section 2(c): "It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter."
- TSCA Section 18(d)(1): "Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that— (i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law…"

These TSCA authorities supporting tailored risk evaluations and intra-agency referrals are described in more detail below:

TSCA Section 6(b)(4)(D)

TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a risk evaluation, to identify the hazards, exposures, conditions of use, and PESS the Agency "expects to consider" in a risk evaluation. This language suggests that EPA is not required to consider all conditions of use, hazards, or exposure

pathways in risk evaluations. As EPA explained in the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017) ("Risk Evaluation Rule"), "EPA may, on a case-by-case basis, tailor the scope of the risk evaluation "…in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33729 (July 20, 2017).

In the problem formulation documents for many of the first 10 chemicals undergoing risk evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes." This is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the risk evaluation on areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520. Consistent with the approach articulated in the problem formulation documents, and as described in more detail below, EPA is exercising its authority under TSCA to tailor the scope of exposures evaluated in TSCA risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered, media-specific statutes and regulatory programs.

TSCA Section 9(b)(1)

In addition to TSCA Section 6(b)(4)(D), the Agency also has discretionary authority under the first sentence of TSCA Section 9(b)(1) to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator." This broad, freestanding authority provides for intra-agency coordination and cooperation on a range of "actions." In EPA's view, the phrase "actions taken under [TSCA]" in the first sentence of Section 9(b)(1) is reasonably read to encompass more than just risk management actions, and to include actions taken during risk evaluation as well. More specifically, the authority to coordinate intra-agency actions exists regardless of whether the Administrator has first made a definitive finding of risk, formally determined that such risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered Federal laws, and/or made any associated finding as to whether it is in the public interest to protect against such risk by actions taken under TSCA. TSCA Section 9(b)(1) therefore provides EPA authority to coordinate actions with other EPA offices without ever making a risk finding, or following an identification of risk. This includes coordination on tailoring the scope of TSCA risk evaluations to focus on areas of greatest concern rather than exposure pathways addressed by other EPA-administered statutes and regulatory programs, which does not involve a risk determination or public interest finding under TSCA Section 9(b)(2).

In a narrower application of the broad authority provided by the first sentence of TSCA Section 9(b)(1), the remaining provisions of Section 9(b)(1) provide EPA authority to identify risks and refer certain of those risks for action by other EPA offices. Under the second sentence of Section 9(b)(1), "[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under [TSCA]." Coordination of intra-agency action on risks under TSCA Section 9(b)(1) therefore entails both an identification of risk, and a referral of any risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the

EPA office(s) responsible for implementing those laws (absent a finding that it is in the public interest to protect against the risk by actions taken under TSCA).

Risk may be identified by OPPT or another EPA office, and the form of the identification may vary. For instance, OPPT may find that one or more conditions of use for a chemical substance present(s) a risk to human or ecological receptors through specific exposure routes and/or pathways. This could involve a quantitative or qualitative assessment of risk based on reasonably available information (which might include, *e.g.*, findings or statements by other EPA offices or other federal agencies). Alternatively, risk could be identified by another EPA office. For example, another EPA office administering non-TSCA authorities may have sufficient monitoring or modeling data to indicate that a particular condition of use presents risk to certain human or ecological receptors, based on expected hazards and exposures. This risk finding could be informed by information made available to the relevant office under TSCA Section 9(e), which supports cooperative actions through coordinated information-sharing.

Following an identification of risk, EPA would determine if that risk could be eliminated or reduced to a sufficient extent by actions taken under authorities in other EPA-administered laws. If so, TSCA requires EPA to "use such authorities to protect against such risk," unless EPA determines that it is in the public interest to protect against that risk by actions taken under TSCA. In some instances, EPA may find that a risk could be sufficiently reduced or eliminated by future action taken under non-TSCA authority. This might include, *e.g.*, action taken under the authority of the Safe Drinking Water Act (SDWA) to address risk to the general population from a chemical substance in drinking water, particularly if the Office of Water has taken preliminary steps such as listing the subject chemical substance on the Contaminant Candidate List (CCL). This sort of risk finding and referral could occur during the risk evaluation process, thereby enabling EPA to use a more ~~a~~ relevant and appropriate authority administered by another EPA office to protect against hazards or exposures to affected receptors.

Legislative history on TSCA Section 9(b)(1) supports both broad coordination on current intra-agency actions, and narrower coordination when risk is identified and referred to another EPA office for action. A Conference Report from the time of TSCA's passage explained that Section 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84. See also H. Rep. No. 114-176 at 28 (stating that the 2016 TSCA amendments "reinforce TSCA's original purpose of filling gaps in Federal law," and citing new language in Section 9(b)(2) intended "to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication"). Exercising TSCA Section 9(b)(1) authority to coordinate on tailoring TSCA risk evaluations is consistent with this expression of Congressional intent.

Legislative history also supports a reading of Section 9(b)(1) under which EPA coordinates intra-agency action, including information-sharing under TSCA Section 9(e), and the appropriately positioned EPA office is responsible for the identification of risk and actions to protect against such risks. See, *e.g.*, Senate Report 114-67, 2016 Cong. Rec. S3522 (under TSCA Section 9, "if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information"); H. Rep. No. 114-176 at 28, 2016 Cong. Rec. S3522 (under Section 9, "if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk"). Legislative history on Section

9(b)(1) therefore supports coordination with and referral of action to other EPA offices, especially when statutes and associated regulatory programs administered by those offices could address exposure pathways or risks associated with conditions of use, hazards, and/or exposure pathways that may otherwise be within the scope of TSCA risk evaluations.

TSCA Sections 2(c) and 18(d)

Finally, TSCA Section 2(c) supports coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs. Section 2(c) directs EPA to carry out TSCA in a "reasonable and prudent manner" and to consider "the environmental, economic, and social impact" of its actions under TSCA. Legislative history from around the time of TSCA's passage indicates that Congress intended EPA to consider the context and take into account the impacts of each action under TSCA. S. Rep. No. 94-698 at 14 ("the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill").

Section 18(d)(1) specifies that state actions adopted or authorized under any Federal law are not preempted by an order of no unreasonable risk issued pursuant to TSCA Section 6(i)(1) or a rule to address unreasonable risk issued under TSCA Section 6(a). Thus, even if a risk evaluation were to address exposures or risks that are otherwise addressed by other federal laws and, for example, implemented by states, the state laws implementing those federal requirements would not be preempted. In such a case, both the other federal and state laws, as well as any TSCA Section 6(i)(1) order or TSCA Section 6(a) rule, would apply to the same issue area. See also TSCA Section 18(d)(1)(A)(iii). In legislative history on amended TSCA pertaining to Section 18(d), Congress opined that "[t]his approach is appropriate for the considerable body of law regulating chemical releases to the environment, such as air and water quality, where the states have traditionally had a significant regulatory role and often have a uniquely local concern." Sen. Rep. 114-67 at 26.

EPA's careful consideration of whether other EPA-administered authorities are available, and more appropriate, for addressing certain exposures and risks is consistent with Congress' intent to maintain existing federal requirements and the state actions adopted to locally and more specifically implement those federal requirements, and to carry out TSCA in a reasonable and prudent manner. EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. This approach furthers Congressional direction and EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations.

EPA-administered statutes and regulatory programs that address specific exposure pathways and/or risks are listed as follows:

<u>Ambient Air Pathway</u>
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. See 42 U.S.C. 7412. 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. See 40 CFR part 63.

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 exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA. As such, EPA does not plan to evaluate exposures to the general population from ambient air in the risk evaluation under TSCA. This regulatory coverage is represented by the red shading in Figure 2-15.

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate unregulated drinking water contaminants of potential regulatory concern for public water systems under the SDWA. In addition, the SDWA requires EPA to review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the SDWA 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). 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 and the MCLG is zero mg/L.

The drinking water exposure pathway for 1,2-dichloroethane is currently addressed in the SDWA regulatory analytical process for public water systems. As such, EPA does not plan to evaluate exposures to the general population from drinking water exposure in the risk evaluation. This regulatory coverage is represented by the dark blue shading in Figure 2-15. 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.

Ambient Water Pathway

EPA has developed Clean Water Act (CWA) Section 304(a) recommended human health criteria for 122 chemicals and aquatic life criteria for 47 chemicals. A subset of these chemicals is identified as "priority pollutants" (103 human health and 27 aquatic life), including 1,2-dichloroethane. The CWA requires that states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under Section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted the state. 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.

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. See, *e.g.*, 40 CFR part 423, Appendix A; 40 CFR 131.11(b)(1); 40 CFR 122.44(d)(1)(vi). As such, EPA does not plan to evaluate exposures to the general population from surface water in the risk evaluation under TSCA. This regulatory coverage is represented by the light blue shading in Figure 2-15. EPA's OW and OPPT will continue to work together to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA. EPA may update its CWA Section 304(a) water quality criteria for 1,2-dichloroethane in the future under the CWA.

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.

Onsite Releases to Land Pathway

The Comprehensive Environmental Response, Compensation, and Liability Act, otherwise known as CERCLA, provides broad authority under the statute (generally referred to as Superfund) to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other releases of hazardous substances, pollutants and contaminants into the environment. Through CERCLA, EPA was given authority to seek out those parties potentially responsible for the release of hazardous substances and either have them clean up the release or compensate the Federal government for undertaking the response action.

CERCLA Section 101(14) defines "hazardous substance" by referencing other environmental statutes, including toxic pollutants listed under CWA Section 307(a); hazardous substances designated pursuant to CWA Section 311(b)(2)(A); hazardous air pollutants listed under CAA Section 112; imminently hazardous substances with respect to which EPA has taken action pursuant to TSCA Section 7; and hazardous wastes having characteristics identified under or listed pursuant to RCRA Section 3001. See 40 CFR 302.4. CERCLA Section 102(a) also 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 within 24-hours must be reported (40 CFR 302.4, 302.6). The scope of this EPA TSCA risk evaluation does not include on-site releases to the environment of 1,2-dichloroethane at Superfund sites and subsequent exposure of the general population or non-human species.

Disposal and Soil Pathways

1,2-Dichloroethane is included on the list of hazardous wastes pursuant to the Resource Conservation and Recovery Act (RCRA) Section 3001 (40 CFR §§ 261.33) as a listed waste on the U, D, K, and F list

(U077, D028, K018, K029, K096, F024, F025). 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 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 SDWA)[8].

EPA does not plan to evaluate on-site releases to land that go to underground injection or associated exposures to the general population or terrestrial species in its risk evaluation. 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 wells is not likely to result in environmental and general population exposures. See 40 CFR part 144.

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 "all other land disposal" 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 removal system until leachate is no longer detected, maintaining and monitoring the leak detection 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. See 40 CFR part 264. As a result, EPA does not plan to evaluate on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

[8] This is not an exclusive list of Subtitle C authority, as it also covers, for example, disposal to surface impoundments, waste piles, and land treatment.

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. See 40 CFR part 258. As a result, EPA is does not plan to evaluate on-site releases to land from RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population or terrestrial species from such releases in the TSCA evaluation. This regulatory coverage is represented by the pink shading in Figure 2-15.

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. See *e.g.*, RCRA Section 3004(c), 4007; 40 CFR part 257. As a result, EPA does not plan evaluate on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills or associated exposures to the general population. This regulatory coverage is represented by the pink shading in Figure 2-15.

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

As described in Section 2.6.3.1, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-16 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 evaluate.

The diagram shown in Figure 2-16 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 receptors. The supporting basis for environmental pathways considered for 1,2-dichloroethane are included in Appendix H.

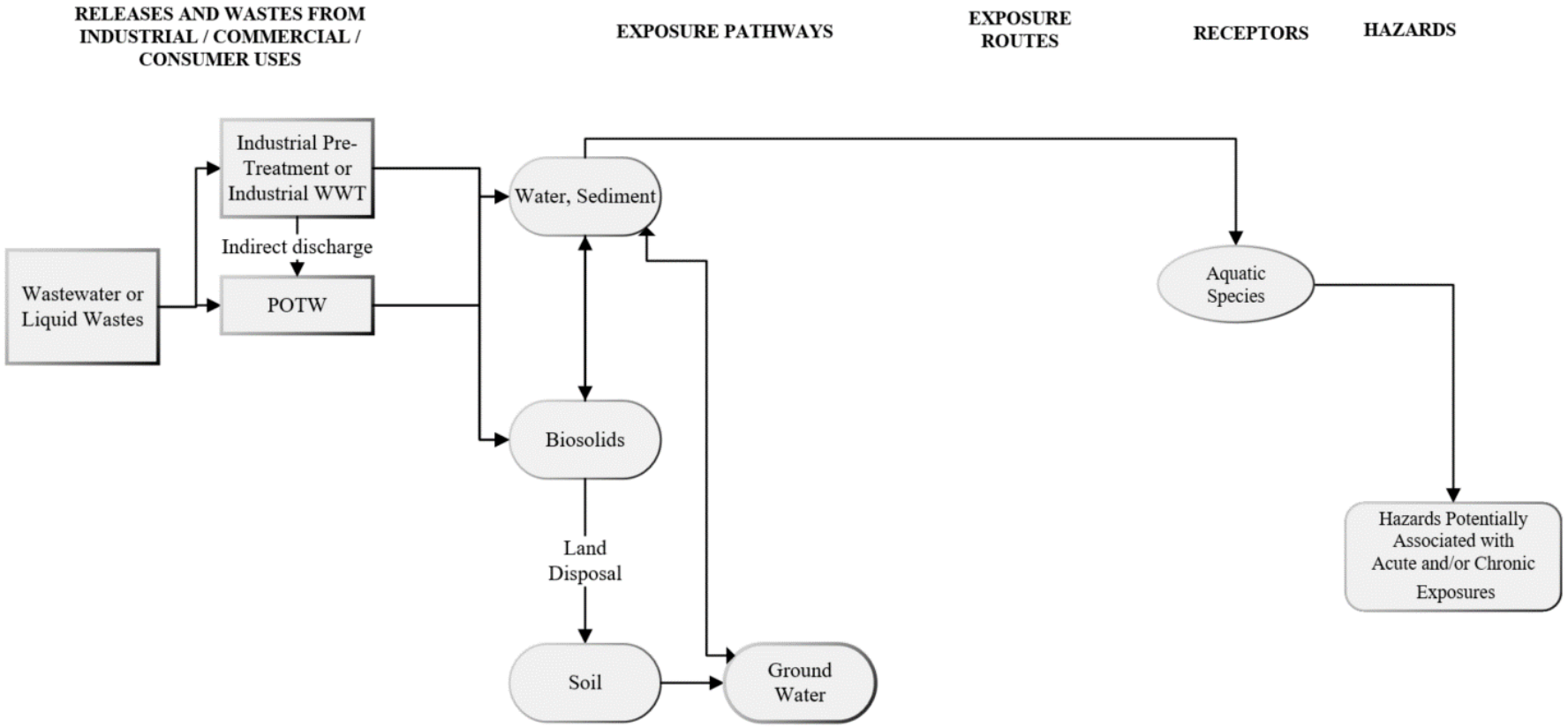

Figure 2-16. 1,2-Dichloroethane Conceptual Model for Environmental Releases and Wastes: Environmental Exposures and Hazards

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.

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.

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of 1,2-dichloroethane resulting from the full-text screening of reasonably available information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant to EPA's evaluation of conditions of use, exposures, hazards and PESS during risk evaluation. As discussed in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018), 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. For any additional data needs identified during the risk evaluation, EPA may use the Agency's TSCA authorities under Sections 4, 8 or 11, as appropriate.

2.7.1 Physical and Chemical Properties and Environmental Fate

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

1) **Review reasonably available measured or estimated physical and chemical properties and environmental fate endpoint data collected using systematic review procedures and, where reasonably available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to evaluate data and information collected through the systematic review methods and public comments about the physical and chemical properties (Appendix B) and fate endpoints (Appendix C), some of which appeared in the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c). All sources cited in EPA's analysis will be evaluated according to the procedures and metrics described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Where the systematic review process does not identify experimentally measured chemical property values of sufficiently high quality, testing will be requested under the TSCA Section 4 authority, or values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of physical and chemical properties and environmental fate endpoints (*e.g.*, persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**
   Measured data and, where necessary, model predictions of physical and chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of 1,2-dichloroethane within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight of the scientific evidence evaluation of physical and chemical and environmental fate data, including qualitative and quantitative sources of information.**
   During risk evaluation, EPA plans to evaluate and integrate the physical and chemical properties and environmental fate evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2.7.2 Exposure

EPA plans to analyze exposure levels for indoor air, ambient air, surface water, sediment and aquatic biota associated to exposure to 1,2-dichloroethane. Based on its physical and chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment, 1,2-dichloroethane is more likely to be present in some of these media and less likely to be present in others. EPA has not yet determined the exposure levels in these media. Exposure level(s) can be characterized through a combination of reasonably available monitoring data and estimated exposure levels from modeling approaches. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft exposure scenarios corresponding to various conditions of use for 1,2-dichloroethane are presented in Appendix F, Appendix G and Appendix H. EPA plans to analyze scenario-specific exposures.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**
   EPA has reviewed some sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to continue to review data sources identified. Potential sources of environmental release data are summarized in Table 2-6 below:

   Table 2-6. 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 will continue to consider additional reasonably available information and will evaluate it during development of the risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in #3 and #4 below by considering potential surrogate data and models.

   Additionally, for conditions of use where no measured data on releases are reasonably available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) (U.S. EPA, 2016).

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

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

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**
This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios). EPA has identified information from various EPA statutes and sources (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to consider for release estimation and environmental exposures. EPA plans to 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 July 2009 ESD on Plastics Additives (OECD, 2009) and the September 2011 ESD on The Chemical Industry (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: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

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

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

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

7) **Evaluate the weight of the scientific evidence of environmental release data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental release evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and

relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of 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 EPA plans to analyze are sediment and surface water.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data.**
   EPA plans to analyze and consider reasonably available environmental exposure models that meet the scientific standards under TSCA *Section 26(h)*. and that estimate surface water, and sediment concentrations will be analyzed and considered alongside available surface water, and sediment monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations may generally include the following inputs: direct release into surface water, or sediment, and indirect release into surface water, sediment, 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 applicable 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, and sediment concentrations near industrial point sources based on reasonably 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 reasonably available, and characterize exposed aquatic 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 *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

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 OSHA and NIOSH, and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

   OSHA has established a permissible exposure limit (PEL) for 1,2-dichloroethane. EPA plans to consider the influence of such limits on occupational exposures in the occupational exposure assessment. The following are some data sources identified thus far:

Table 2-7. Potential Sources of Occupational Exposure Data

2001 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 physical and chemical 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 reasonably 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 November 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 assessed. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including the use of 1,2-dichloroethane as an intermediate chemical. EPA may conduct industry outreach efforts or perform supplemental targeted searches of peer-reviewed or gray literature to understand those conditions of use, which may inform identification of exposure scenarios. EPA may perform targeted supplemental searches to identify applicable models that EPA may use to estimate exposures for certain conditions of use. EPA plans to also consider the applicability of exposure

models in the ChemSTEER (U.S. EPA, 2013) tool that are routinely used for assessing new chemicals to assess exposures during various conditions of use.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
This will be performed after #2 and #3 are completed, and based on information developed from #2 and #3, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA, other government agencies, or reasonably available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to 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 to determine their applicability and incorporation into exposure scenarios during risk evaluation. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly personal protective equipment (PPE). EPA plans to assess worker exposure pre- and post-implementation of 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 has completed an initial mapping of exposure scenarios to conditions of use. EPA plans to refine mapping or grouping of occupational exposure scenarios based on factors (*e.g.*, process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is reviewed during risk evaluation. EPA may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018). EPA plans to rely on the weight of the scientific evidence when evaluating and integrating occupational data. EPA plans to integrate the data using systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.7.2.4 Consumer Exposures

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

1) **Group each condition of use to consumer exposure assessment scenario(s).**
   Refine and finalize exposure scenarios for consumers by considering combinations of sources exposure pathways including routes, and exposed populations.

   For 1,2-dichloroethane, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the potential of indoor exposure pathways based on reasonably available data.**
   Based on the physical and chemical properties of 1,2-dichloroethane and the consumer uses identified in Section 2.2.1 ("plastic and rubber products"), dust ingestion and mouthing of products are important indoor exposure pathways for consumers. Other indoor exposure pathways include inhalation of indoor air, dermal contact with dust and articles. EPA plans to review all reasonably available information in developing the consumer exposure scenarios and evaluating the exposure pathways in indoor environments.

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

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are reasonably available.**
   To the extent other organizations have already modeled a 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.*, indoor air).**

The availability of 1,2-dichloroethane concentration for various conditions of use will be evaluated. This data provides the source term for any subsequent indoor modeling.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**
For 1,2-dichloroethane EPA plans to evaluate exposure scenarios that involve PESS and plans to consider age-specific behaviors, activity patterns and exposure factors unique to those subpopulations. For some exposure scenarios related to consumer uses, EPA plans to consider whether exposures for adults may different from those of children due to different activities (*e.g.*, children may mouth certain products) or exposure factors (*e.g.*, inhalation rates).

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

2.7.2.5 General Population

EPA does not plan to analyze general population exposures, based on a review of exposure pathways as described in Section 2.6.3.1. EPA does not plan to include in the risk evaluation pathways under programs of other environmental statutes administered by EPA.

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 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 organisms.

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

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

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

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

3) **Evaluate the weight of the scientific evidence of environmental hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the *Application of Systematic Review in TSCA Risk Evaluation* (U.S. EPA, 2018).

4) **Consider the route(s) of exposure, based on reasonably available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments.**
EPA plans to consider aquatic (*e.g.*, water and sediment exposures) 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, diet).

5) **Consider a persistent, bioaccumulative, and toxic (PBT) assessment of 1,2-dichloroethane.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of 1,2-dichloroethane after reviewing relevant physical and chemical properties and exposure pathways. EPA plans to assess the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.*, BAF, BCF) of 1,2-dichloroethane. In addition, EPA plans to integrate traditional environmental hazard endpoint values (*e.g.*, LC_{50}, LOEC) and exposure concentrations (*e.g.*, surface water concentrations, tissue concentrations) for 1,2-dichloroethane with the fate parameters (*e.g.*, BAF, BCF, BMF, TMF).

6) **Conduct an environmental risk estimation and characterization of 1,2-dichloroethane.**
EPA plans to conduct a risk estimation and characterization of 1,2-dichloroethane to identify if there are risks to the aquatic environments from the measured and/or predicted concentrations of 1,2-dichloroethane in environmental media (*e.g.*, water, sediment). 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). Analysis of risk for characterization includes a confidence statement in risk estimation which qualitative judgment describing the certainty of the risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

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

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

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

2) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**
Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to 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 may quantify these differences in the risk evaluation following further evaluation of the reasonably available data and information.

3) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**
Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). 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 identified in Section 2.4.2.

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

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

In accordance with EPA's Supplemental Guidance for Assessing Susceptibility from Early-life Exposures to Carcinogens (U.S. EPA, 2005b), EPA plans to determine whether age-dependent adjustment factors (ADAFs) are appropriate for 1,2-dichloroethane for specific conditions of use based upon potential exposures to children.

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the reasonably available data. Adjust the PODs as appropriate to conform (*e.g.*, adjust for duration of exposure) to the specific exposure scenarios evaluated.**
Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with EPA's *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012a). Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of 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.S. EPA (2011b), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

5) **Evaluate the weight of the scientific evidence of human health hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

6) **Consider the route(s) of exposure (*e.g.*, oral, inhalation, dermal), reasonably available route-to-route extrapolation approaches; biomonitoring data; and approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**
At this stage of review, EPA believes there will be sufficient reasonably available data to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to 1,2-dichloroethane, which could be important for worker, consumer and general population risk analysis. Reasonably available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes.

   If sufficient reasonably available toxicity studies are not identified through the systematic review process to assess risks from inhalation or dermal exposure, then a route-to-route extrapolation may be needed. The preferred approach is to use a PBPK model (U.S. EPA, 2006a). Without an adequate PBPK model, considerations regarding the adequacy of data for route-to-route extrapolation are described in *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure.

Similar approaches for oral-to-dermal route extrapolation are described in EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004).

If there are acceptable inhalation data after completion of systematic review, EPA may also consider extrapolating from the inhalation to the dermal route if first-pass metabolism through the liver via the oral route is expected because in that case, use of data from the oral route is not recommended (U.S. EPA, 1994). EPA may also consider inhalation-to-dermal route extrapolation if an inhalation toxicity study with a sensitive hazard endpoint is used to evaluate risks. Based on these considerations, EPA extrapolated from the inhalation to the dermal route for several of the first ten risk evaluations under amended TSCA, including methylene chloride (U.S. EPA, 2020d) and carbon tetrachloride (U.S. EPA, 2020b).

7) **Conduct a human health risk estimation and characterization of 1,2-dichloroethane.** Analysis of risk for characterization includes a confidence statement in risk estimation. This confidence statement is based on qualitative judgment describing the certainty of the risk estimate considering the strength of the evidence scores for hazard and exposure along with their limitations and relevance. The lowest confidence evaluation for either hazard or exposure will drive the overall confidence estimate.

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's Risk Characterization Policy, "*the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers*." 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, July 20, 2017). As discussed in 40 CFR 702.43, risk characterization has a number of considerations. This is the step where EPA integrates the hazard and exposure assessments into risk estimates for the identified populations (including any PESS) and ecological characteristics and weighs the scientific evidence for the identified hazards and exposures. The risk characterization does not consider costs or other nonrisk factors, and takes into account, "where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use …." The risk characterization also summarizes the following considerations: (1) uncertainty and variability in each step of the risk evaluation; (2) data quality, and any applicable assumptions used; (3) alternative interpretations of data and analyses, where appropriate; and (4) any considerations for environmental risk evaluations, if necessary (*e.g.*, related to nature and magnitude of effects).

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook (U.S. EPA, 2015) and other methods consistent with Section 26 of TSCA (see 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment (see 82 Fed. Reg. 33726, 33744; July 12, 2017). 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.

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USGS (U.S. Geological Survey). (1991c). USGS Monitoring Data: National Water Quality Monitoring Council - Sediment [Database]. https://www.waterqualitydata.us/portal/#sampleMedia=Sediment&mimeType=csv

USGS (U.S. Geological Survey). (1991d). USGS Monitoring Data: National Water Quality Monitoring Council - Soil [Database]. https://www.waterqualitydata.us/portal/#sampleMedia=Soil&mimeType=csv

USGS (U.S. Geological Survey). (1991e). USGS Monitoring Data: National Water Quality Monitoring Council - Surface Water [Database]. https://www.waterqualitydata.us/portal/#siteType=Aggregate%20surface-water-use&sampleMedia=Water&mimeType=csv

USGS (U.S. Geological Survey). (1991f). USGS Monitoring Data: National Water Quality Monitoring Council - Tissue [Database]. https://www.waterqualitydata.us/portal/#sampleMedia=Tissue&mimeType=csv

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

A.1 Literature Search of Publicly Available Databases

A.1.1 Search Term Genesis and Chemical Verification

To develop the chemical terms for the subsequent literature search for 1,2-dichloroethane, several online sources were queried.

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

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

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

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

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

A.1.2 Publicly Available Database Searches

The databases listed below were searched for literature containing the chemical search terms. Database searching occurred during April and May of 2019 by an information specialist and the results were stored in the Health and Environmental Research Online (HERO) database and assigned a HERO reference identification number.[9] The present literature search focused only on the chemical name (including synonyms and trade names) with no additional limits. Full details of the search strategy for each database are presented in Appendix A.1.2.1.

After initial deduplication in HERO[10], these studies were imported into SWIFT Review software (Howard et al., 2016b, a) to identify those references most likely to be applicable to each discipline area (*i.e.*, consumer, environmental, and general population exposure, occupational exposure and environmental releases, environmental hazards, human health hazards, and fate and physical chemistry).

A.1.2.1 Query Strings for the Publicly-Available Database Searches on 1,2-Dichloroethane

Table_Apx A-2 presents a list of the data sources, the search dates and number of peer-reviewed references resulting from the searches for 1,2-dichloroethane. The sources are found as online databases

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

and the resulting references were gathered and uploaded into the EPA Health and Environmental Research Online (HERO) database for literature screening.

Table_Apx A-2. Summary of Data Sources, Search Dates and Number of Peer-Reviewed Literature Search Results for 1,2-Dichloroethane

Source	Date of Search	Number of References
Current Contents	4/24/2019	3569
Web of Science	09/10/2019	5112
ProQuest CSA	4/24/2019	2247
Dissertation Abstracts	4/26/2019	47
Science Direct	4/24/2019	1989
Agricola	4/26/2019	371
TOXNET	4/24/2019	1841
PubMed	07/02/2019	1360
UNIFY	04/26/2019	184
Totals:		**16,720**

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

"1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane" OR "1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol" OR "Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion" OR "Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine" OR "Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184"

CURRENT CONTENTS CONNECT: (access.webofknowledge.com)
General Search Terms applied to the search strategy for Current Contents.

Date Searched: 04/24/2019
Date Range of Search: 1970 to Present
N = 3,569

TS=("1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane" OR "1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene

dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol" OR "Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion" OR "Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine" OR "Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184")
N = 3,569

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

Date Searched: 09/10/2019
Date Range of Search: 1970 to Present
N = 2809

TS=("1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane" OR "1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol" OR "Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion" OR "Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine" OR "Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184")
N = 5112

PROQUEST Agricultural and Scientific Database: (www.csa.com)
General Search Terms applied to the search strategy for ProQuest Agricultural and Scientific Database.

Date Searched: 04/24/2019
Date Range of Search: 1900 to Present
N = 2,247

ALL("1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane" OR "1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol" OR "Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion" OR "Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-

1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine" OR "Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184") AND STYPE("Scholarly Journals" OR Reports OR Thesis OR "Government Documents") AND LA(ENG)
N = 2,247

PROQUEST Dissertations and Theses: (search.proquest.com)
General Search Terms applied to the search strategy for ProQuest Dissertations and Theses.

Date Searched: 04/26/2019
Date Range of Search: 1900 to Present
N = 47

ALL("1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane" OR "1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol" OR "Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion" OR "Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine" OR "Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184") AND LA(ENG)

SCIENCE DIRECT: (www.sciencedirect.com)
General Search Terms applied to the search strategy for Science Direct

Date Searched: 04/24/2019
Date Range of Search: 1823 to Present
N = 1989

Science Direct 01:
"1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane"
N = 1,849

Science Direct 02:
"1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol"
N = 1

Science Direct 03:

"Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion"
N = 0

Science Direct 04:
"Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine"
N = 132

Science Direct 05:
"Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184"
N = 7

AGRICOLA: (www.nal.usda.gov)
General Search Terms applied to the search strategy for Agricola. The Agricola database contains a significant amount of gray literature including proceedings, symposia, and progress reports from government and educational institutions. Agricola is not used when conducting a search for the Office of Water.

Date Searched: 04/26/2019
Date Range of Search: 15th century to the Present
N = 371

Agricola 01:
1,2-Ethylidene dichloride
1, 2-Dichloroethan
1,2-Bichloroethane
1,2-DCA
1,2-DCE
1,2-Dichlorethane
1,2-dichloroetan
1,2-Dichloroethane
1,2-Dichloroethane
1,2-Ethylene dichloride
N = 317

Agricola 02:
1,2-Ethylene dichloride
1,2-Ethylidene dichloride
Aethylendichlorid
alpha, beta-dichloride
alpha, beta-dichloroethane
alpha,beta-dichloroethane
alpha,beta-Dichloroethane
Borer sol
Brocide

Caswell No. 440
N = 0

Agricola 03:
CCRIS 225
Destruxol borer-sol
dichlor-1,2-ethane
Dichloremulsion
Dichloretan
Dichlor-Mulsion
Di-chlor-mulsion
Dichloroethane, 1,2-
Dutch liquid
Dutch oil
N = 48

Agricola 04:
ENT 1,656
ENT 1656
ENT-1656
Ethane dichloride
Ethylene chloride
Ethylene Dichlorine
Ethylenedichloride
Freon 150
Glycol dichloride
HCC 150
N = 6

Agricola 05:
HSDB 65
NCI-C00511
RY Dichloro-1,2-ethane
sym-Dichloroethane
UN 1184
N = 0

TOXNET: (toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?TOXLINE)
General Search Terms applied to the search strategy for TOXNET.

Date Searched: 04/24/2019
Date Range of Search: 1900 to Present
N = 1,841

TOXNET 01:
107-06-2 OR 52399-93-6

Search	Database	Query	Time	Result
# 2	toxline	(("ethylene dichloride" OR "1 2 dichloroethane" OR "glycol dichloride" OR "ethylene chloride" OR "ethyleendichloride dutch " OR "ethane dichloride" OR "dutch oil" OR "dutch liquid" OR dichloremulsion OR "destruxol borer sol" OR brocide OR "borer sol" OR "aethylenchlorid german " OR "1 2 ethylene dichloride" OR "1 2 dicloroetano italian " OR "1 2 dichlorethane" OR "1 2 dichlor aethan german " OR "1 2 dichloorethaan dutch " OR 107-06-2 [rn]) OR 52399-93-6 [rn]) AND 1900:2018 [yr] AND (eng [la]) AND (BIOSIS [org] OR NTIS [org] OR PESTAB [org] OR PubMed [org] OR TSCATS [org])	13:10:33	1841

N = 1,841

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

Date Searched: 07/02/2019
Date Range of Search: 1900 to present
N = 1360

."1,2-Ethylidene dichloride" OR "1, 2-Dichloroethan" OR "1,2-Bichloroethane" OR "1,2-DCA" OR "1,2-DCE" OR "1,2-Dichlorethane" OR "1,2-dichloroetan" OR "1,2-Dichloroethane" OR "1,2-Dichloroethane" OR "1,2-Ethylene dichloride" OR "1,2-Ethylene dichloride" OR "1,2-Ethylidene dichloride" OR "Aethylendichlorid" OR "alpha, beta-dichloride" OR "alpha, beta-dichloroethane" OR "alpha,beta-dichloroethane" OR "alpha,beta-Dichloroethane" OR "Borer sol" OR "Brocide" OR "Caswell No. 440" OR "CCRIS 225" OR "Destruxol borer-sol" OR "dichlor-1,2-ethane" OR "Dichloremulsion" OR "Dichloretan" OR "Dichlor-Mulsion" OR "Di-chlor-mulsion" OR "Dichloroethane, 1,2-" OR "Dutch liquid" OR "Dutch oil" OR "ENT 1,656" OR "ENT 1656" OR "ENT-1656" OR "Ethane dichloride" OR "Ethylene chloride" OR "Ethylene Dichlorine" OR "Ethylenedichloride" OR "Freon 150" OR "Glycol dichloride" OR "HCC 150" OR "HSDB 65" OR "NCI-C00511" OR "RY Dichloro-1,2-ethane" OR "sym-Dichloroethane" OR "UN 1184"
N = 1360

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

Date Searched: 04/26/2019
Date Range of Search: all years
N = 184

12DCE,11DCE,DCET

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

In brief, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content from those that likely do not (*e.g.*, analytical methods). The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or medical subject headings (MeSH*)* fields content. The applied SWIFT Review filters focused on lines of evidence: human, animal models for human health, ecological taxa (which includes ecotoxicological animal models, plants, and other taxa), and *in vitro* studies. The details of the search strategies that underlie the filters are available online. Studies not retrieved using these filters were not considered further. Studies that included one or more of the search terms in the title, abstract, keyword, or MeSH fields were exported as a RIS file for screening in Swift-ActiveScreener or DistillerSR[11].

A.1.2.3 Data Prioritization for Occupational Exposures and Environmental Releases and Gen Pop, Consumer and Environmental Exposures

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

A.2 Peer-Reviewed Screening Process

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

It is important to emphasize that being tagged as supplemental material does not mean the study would necessarily be excluded from consideration in an assessment. The initial screening level distinctions between a study meeting the PECO criteria and a supplemental study are often made for practical

[11] DistillerSR is a web-based systematic review software used to screen studies available at https://www.evidencepartners.com/products/distillersr-systematic-review-software.

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

A.2.1 Inclusion/Exclusion Criteria

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

A.2.1.1 PECO for Environmental and Human Health Hazards

The PECO used in this evidence map to identify literature pertinent to 1,2-dichloroethane effects on human health and environmental hazard is presented in Table_Apx A-3. In addition to the PECO criteria, studies containing potentially relevant supplemental material were tracked and categorized during the literature screening process as outlined in Table_Apx A-4.

Table_Apx A-3. Hazards Title and Abstract and Full-text PECO Criteria for 1,2-Dichloroethane

PECO Element	Evidence
P	• **Human:** Any population and life stage (*e.g.*, occupational or general population, including children and other sensitive populations). • **Animal:** Aquatic and terrestrial species (live, whole organism) from any life stage (*e.g.*, preconception, in utero, lactation, peripubertal, and adult stages). Tests of the single toxicants in *in vitro* systems or on live, whole, taxonomically verifiable organisms (*e.g.*, gametes, embryos, or plant or fungal sections capable of forming whole, new organisms) that are not bacteria, humans, monkeys, viruses, or yeast. In most cases, transgenic animal models will get screened as "yes" or "unclear" at the Title and Abstract (TIAB) screening level. Although certain non-mammalian model systems are increasing used to identify potential human health hazards (*e.g.*, *Xenopus* and zebrafish), for simplicity animal models will be further inventoried according to the categorization below: – Human health models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, pig, hen (neurotoxicity only) – Environmental models: invertebrates (*e.g.*, insects, spiders, crustaceans, mollusks, and worms) and vertebrates (*e.g.*, mammals and all amphibians, birds, fish, and reptiles). All hen studies (including neurotoxicity studies) will be included for ecotoxicological models. • **Plants:** All aquatic and terrestrial species (live), including algal, moss, lichen and fungi species.

PECO Element	Evidence
	Screener note: • To identify human health and environmental hazards, other organisms not listed above in their respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards (*e.g.*, Xenopus, zebrafish), and traditional human health models (*e.g.*, rodents) can be used to identify potential environmental hazard. Neurotoxicity studies performed in hens (*e.g.*, OECD 418 and 419) are considered relevant to both human and eco hazard. • PECO considerations should be directed toward effects on target species only and not on the indirect effects expressed in taxa as a result of chemical treatment (*e.g.*, substance is lethal to a targeted pest species leading to positive effects on plant growth due to diminished presence of the targeted pest species).
E	**Relevant forms and isomers** • 1,2-Dichloroethane (CASRN 107-06-2) For synonyms see the EPA Chemistry Dashboard. • **Human:** Any exposure to 1,2-dichloroethane. • **Animal:** Any exposure to 1,2-dichloroethane, including via water, soil or sediment, injection (*i.e.*, oral or topical), gavage, diet, dermal, and inhalation. • **Plants:** Exposure to 1,2-dichloroethane via water and/or soil, with reported concentration and duration. Studies involving exposures to mixtures will be included only if they also include exposure to one of these solvents alone. Screener note: Field studies with media concentrations (surface water, interstitial water, soil) and/or body/tissue concentrations of animals or plants are to be identified as ***Supplemental*** if any biological effects are reported.
C	• **Human:** A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of 1,2-dichloroethane, or exposure to one of these solvents for shorter periods of time. case-crossover, case-referent, case-only, case-specular, case-cohort, case-parent, nested case-control study designs are all included. • **Animal and Plants:** A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement). **Screener note:** • If no control group is explicitly stated or implied (*e.g.*, by mention of statistical results that could only be obtained if a control group was present), the study will be marked as **unclear** during Title/Abstract Screening. • All case reports and case studies/series describing findings in a sample size of less than 20 people in any setting (*e.g.*, occupation, general population) will be tracked as "potentially relevant supplemental information".
O	• **Human**: All health outcomes (cancer and noncancer). • **Animal and Plants**: All biological effects (including bioaccumulation from laboratory studies with concurrently measured water and tissue concentrations). **Screener note:** • **Measurable biological effects relevant for humans, animals and plants may include but are not limited to:** mortality, behavioral, population, cellular, physiological, growth, reproduction of an acceptable organism to a chemical toxicant.

Table_Apx A-4. Major Categories of Potentially Relevant Supplemental Materials for 1,2-Dichloroethane

Category	Evidence
Mechanistic studies	Studies reporting measurements related to a health outcome that inform the biological or chemical events associated with phenotypic effects, in both mammalian and non-mammalian model systems, including *in vitro*, *in vivo* (by various non-inhalation routes of exposure), *ex vivo*, and *in silico* studies.
ADME, PBPK, and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion (ADME), toxicokinetic studies, or physiologically based pharmacokinetic (PBPK) models.
Susceptible populations (no health outcome)	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, life stage, or genotype.
Mixture studies	Mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest.
Case reports or case series	Case reports ($n \leq 3$ cases) and case series/studies (<20 cases) will be tracked as potentially relevant supplemental information.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.
Field Studies	Field studies where there are accompanying body/tissue concentrations of animals without any biological effects reported

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

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

PECO Element	Evidence
Population	**Human:** General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (life stages, preexisting conditions, genetic factors), pregnant women; lactating women, women of childbearing age. Many human population groups may be exposed. No chemical-specific exclusions are suggested at this time.
	Environmental: aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only)
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** Pathways: indoor air/vapor/mist; indoor dust; particles; outdoor/ambient air; surface water; biosolids; sediment; breastmilk; food items containing 1,2-dichloroethane including fish; consumer product uses in the home (including consumer product containing chemical); Routes of Exposure: Inhalation, Oral, Dermal
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.

PECO Element	Evidence
	Environmental Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or indoor air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc) containing 1,2-dichloroethane
	Environmental: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

Table_Apx A-6. Pathways Identified as Supplemental for 1,2-Dichloroethane[a]

Chemical	Drinking Water	Ambient Air	Air Disposal	Land Disposal	Underground Disposal	Ground Water
1,2-Dichloroethane	X	X	X	X	X	X

[a] "Supplemental pathways" refer to pathways addressed by other EPA administered statutes (see Section 2.6.3.1). Studies tagged under these pathways provide media information that is not prioritized in the screening process.

A.2.1.3 RESO for Occupational Exposure and Environmental Releases

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

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

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

RESO Element	Evidence
Receptors	• Humans: Workers, including occupational non-users • Environment: All environmental receptors (relevant release estimates input to Exposure)

RESO Element	Evidence
	Please refer to the conceptual models for more information about the environmental and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant environmental releases of the chemical substance from occupational scenarios: Dermal and inhalation exposure routes (as indicated in the conceptual model) Oral route (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal.
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (*e.g.*, mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release and Occupational Exposure Data Needs (Table_Apx A-8) provides a list of related and relevant general information.
TSCA=Toxic Substances Control Act

Table_Apx A-8. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data [a]
General Engineering Assessment (may apply to Occupational Exposures and / or Environmental Releases)	Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (*e.g.*, each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. Concentration of the chemical of interest
Occupational Exposures	Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Potential routes of exposure (*e.g.*, inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (*e.g.*, liquid, vapor, mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest).

Objective Determined during Scoping	Type of Data [a]
	For solids, bulk and dust particle size characterization data. Dermal exposure data. Exposure duration (hrs/day). Exposure frequency (days/yr). Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. PPE types employed by the industries within scope. EC employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental Releases (to relevant environmental media)	Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) Release or emission factors. Number of release days per year. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.

[a] These are the tags included in the full-text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.
In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis.

Abbreviations:
hrs=Hours
kg=Kilogram(s)
lb=Pound(s)
yr=Year
PV=Particle volume
POTW=Publicly owned treatment works
PPE=Personal protection equipment
PSD=Particle size distribution
TWA=Time-weighted average

A.2.1.4 PESO for Fate and Transport

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

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

A.2.1.5 Generation of Hazard Heat Maps

As stated in Appendix A.1.2.2, SWIFT Review has pre-set literature search strategies ("filters") developed by information specialists that can be applied to identify studies that are more likely to be useful for identifying human health and ecotoxicity content. The filters function like a typical search strategy where studies are tagged as belonging to a certain filter if the terms in the filter literature search strategy appear in title, abstract, keyword or MeSH fields content.

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

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

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

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

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

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface Water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Required Environmental Fate Data					
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X			
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X			

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

A.3 Gray Literature Search and Screening Strategies

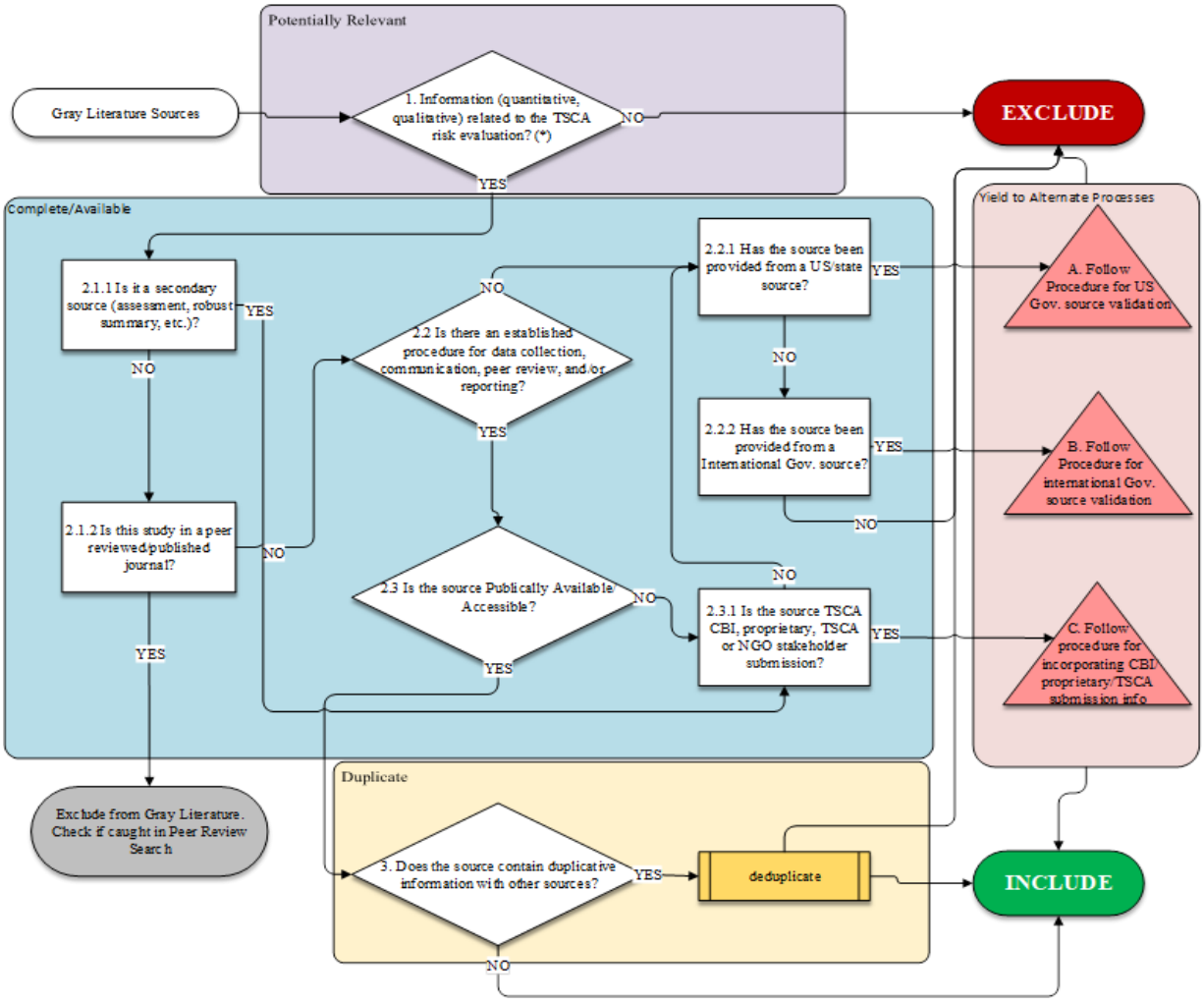
EPA conducted a gray literature search for available information to support the TSCA risk evaluations for the next twenty TSCA risk evaluations. Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (*e.g.*, PubMed and Web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

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

the following sections for each discipline.

A.3.1 Screening of Gray Literature

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



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

A.3.2 Initial Screening of Sources using Decision Logic Tree

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

Table_Apx A-11. Decision Logic Tree Overview

Step	Metric	Questions to Consider
1	Potential Relevance	Does the result have information (qualitative or quantitative) related to TSCA risk evaluations? *Apply Discipline relevancy metric
2.1.1	Complete / Available	Is it a secondary data source (assessment, robust summary, TSCA submission databases, etc.)?
2.1.2		Is the document from a peer reviewed/published journal?
2.2		Is there an established procedure for data collection, communication, peer review, and/or reporting?
2.2.1		Has the data been provided by a US governmental/state source?
2.2.2		Has the data been provided by an international governmental source?
2.3		Are these data publicly available/accessible?
2.3.1		Is the source TSCA CBI, proprietary, TSCA or NGO stakeholder submission?
3	Duplicate	Does the result contain any duplicative information found in other sources?

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

A.3.3 TSCA Submission Searching and Title Screening

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

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

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

EPA may decide to initiate a backwards search on sources that are deemed to have secondary data. In situations where parameters such as procedures for peer review and data collection are unclear, EPA may reach out to the authors to retrieve information to gauge whether the source should be included or

excluded. Studies that are not publicly available (such as proprietary or CBI sources) may undergo additional screening steps.

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

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

A.3.4 Gray Literature Search Results for 1,2-Dichloroethane

Table_Apx A-12 provides a list of gray literature sources that yielded results for 1,2-dichloroethane.

Table_Apx A-12. Gray Literature Sources that Yielded Results for 1,2-Dichloroethane

Source Agency	Source Name	Source Type	Source Category	Source Website
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/profilesaddenda.asp
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document	https://www.atsdr.cdc.gov/toxprofiles/index.asp
Australian Government, Department of Health	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document	https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments
Australian Government, Department of Health	NICNAS Assessments (eco)	International Resources	Assessment or Related Document	https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Reference Exposure Levels (RELs)	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CAL EPA	Technical Support Documents for regulations: Soil Screening	Other US Agency Resources	Assessment or Related Document	https://oehha.ca.gov/chemicals
CDC	CDC Biomonitoring Tables	Other US Agency Resources	Database	cdc.gov/exposurereport/index.html/
ECHA	ECHA Documents	International Resources	Assessment or Related Document	https://echa.europa.eu/information-on-chemicals

Source Agency	Source Name	Source Type	Source Category	Source Website
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document	https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/priority-list.html
Env Canada	Guidelines, Risk Management, Regulations	International Resources	Assessment or Related Document	https://www.canada.ca/en.html
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document	https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/chemicals-glance.html
EPA	OPPT: TSCATS database maintained at SRC (TSCA submissions)	US EPA Resources	Database	http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp
EPA	OPPT: Chemview (TSCA submissions - chemical test rule data and substantial risk reports)	US EPA Resources	Database	https://chemview.epa.gov/chemview
EPA	OPPT: 8e database (CBI) (TSCA submissions)	US EPA Resources	Database	Confidential Business Information
EPA	OPPT: CIS (CBI LAN) (TSCA submissions)	US EPA Resources	Database	Confidential Business Information
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database	https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data
EPA	Office of Water: STORET and WQX	US EPA Resources	Database	https://www.waterqualitydata.us/portal/
EPA	PPRTV Derivation Support Document	US EPA Resources	Assessment or Related Document	https://hhpprtv.ornl.gov/quickview/pprtv_papers.php
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document	epa.gov/wqc/
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document	https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha
EPA	Office of Air: TRI	US EPA Resources	Database	https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools

Source Agency	Source Name	Source Type	Source Category	Source Website
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List	https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors
EPA	Other EPA: Misc sources	US EPA Resources	General Search	https://www.epa.gov/
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List	https://www.epa.gov/eg
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List	https://www.epa.gov/stationary-sources-air-pollution
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document	https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios
FDA	FDA technical support documents for regulations	Other US Agency Resources	Assessment or Related Document	https://www.fda.gov/
IARC	IARC Monograph	International Resources	Assessment or Related Document	http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php
ILO	International Chemical Safety Cards (ICSCs)	International Resources	Database	https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List	https://www.env.go.jp/en/chemi/prtr/substances/
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia	https://onlinelibrary.wiley.com/doi/book/10.1002/0471238961
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document	https://www.cdc.gov/niosh/topics/chemical.html/
NIOSH	CDC NIOSH - Pocket Guide	Other US Agency Resources	Database	https://www.cdc.gov/niosh/npg/default.html

Source Agency	Source Name	Source Type	Source Category	Source Website
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/hhe/search.asp
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document	https://www2a.cdc.gov/nioshtic-2/
NLM	National Library of Medicine's PubChem	Other US Agency Resources	Database	https://pubchem.ncbi.nlm.nih.gov/
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/index.html
NTP	Technical Reports	Other US Agency Resources	Assessment or Related Document	https://ntp.niehs.nih.gov/publications/reports/index.html?type=Technical+Report
OECD	OECD SIDS	International Resources	Assessment or Related Document	https://hpvchemicals.oecd.org/ui/Publications.aspx
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document	http://www.oecd.org/document/46/0,2340,en_2649_201185_2412462_1_1_1_1,00.html
OECD	OECD: General Site	International Resources	General Search	https://www.oecd.org/
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document	https://www.rivm.nl/en
RIVM	Probit Function Technical Support Document	International Resources	Assessment or Related Document	https://www.rivm.nl/en/probit-functions/probit-function-status-overview
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document	https://www.tera.org/

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

Table_Apx B-1 summarizes statistics for the physical and chemical property values identified through systematic review as of June 2020. The "N" column indicates the number of unique primary sources of data for that endpoint. That is, if multiple sources presented equivalent values and cited the same primary source, only one of those was included in these statistics and included in the statistical calculations. All physical and chemical property values that were extracted and evaluated as of June 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical and Chemical Property Studies* (EPA-HQ-OPPT-2018-0427).

Table_Apx B-1. Summary Statistics for Reviewed Physical Properties

Property or Endpoint	N	Unit	Mean	Standard Deviation	Min	Max
Molecular formula	-	-	NA	NA	NA	NA
Molecular weight	-	g/mol	NA	NA	NA	NA
Physical state	3	-	NA	NA	NA	NA
Physical properties	2	-	NA	NA	NA	NA
Melting point	16	ºC	-35.3	0.4	-36	-34.97
Boiling point	17	ºC	83.44	0.596165	83	85.48
Density	30	g/cm^3	1.251	0.015	1.235	1.325
Vapor pressure	7	mm Hg	79.88	9.25	64.00	93.98
Vapor density	0	-	-	-	-	-
Water solubility	15	mg/L	9856	3244	8073	21300
Octanol/water partition coefficient (log Kow)	3	-	1.47	0.01	1.46	1.48
Henry's Law constant	4	$atm \cdot m^3/mol$	0.002945	0.004061	0.00023	0.00899
Flash point	12	ºC	14.2	1.9	13.0	18.0
Auto flammability	1	ºC	413	-	413	413
Viscosity	13	cP	0.7875	0.0444	0.7239	0.8710
Refractive index	13	-	1.4453	0.0179	1.4196	1.5002
Dielectric constant	9	-	10.49	0.36	9.82	10.95

NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF 1,2-DICHLOROETHANE

Table_Apx C-1 provides the environmental fate characteristics that EPA identified and considered in developing the scope for 1,2-dichloroethane. This information was presented in the *Proposed Designation of 1,2-Dichloroethane (CASRN 107-06-2) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019c), and may be updated as EPA collects additional information through systematic review methods.

Table_Apx C-1. Environmental Fate 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 (2018) citing Lyman et al. (1990)
Indirect Photodegradation	$t_{1/2}$ = 65 days (based on ·OH reaction rate constant of 2.48×10^{-13} cm^3/molecule-second at 25 ºC)	HSDB (2018); U.S. EPA (2012c) 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 ºC)	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 ºC)	ATSDR (2001) citing Barbash and Reinhard (1989) and Jeffers et al. (1989)
Biodegradation (Aerobic)	Water: 0%/21 days (modified shake-flask test)	(HSDB, 2018) 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)

Property or Endpoint	Value	Reference
	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 USGS (2006)
	Water: $t_{1/2}$ = 400 days	ATSDR (2001) citing Capel and Larson (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 Lee Wolfe (1987)
Wastewater Treatment	45% total removal (16% by biodegradation, 1% by sludge and 28% by volatilization to air; estimated)[b]	U.S. EPA (2012b)
Bioconcentration Factor	2 (*Lepomis macrochirus)*; $t_{1/2}$ = 2 days for clearance from tissues	WHO IPCS (1995) citing Barrows et al. (1980)
Bioaccumulation Factor	3.8 (estimated)[b]	U.S. EPA (2012b)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	1.28–1.62 (K_{OC} = 19–42)	ATSDR (2001) citing Chiou et al. (1980), Sabljić et al. (1995), and Borisover and Graber (1997)

[a]Measured unless otherwise noted
[b]EPI Suite™ (physical property inputs: Log K_{OW} = 1.48, BP = 83.4 °C, MP = -35.6 ºC, VP = 78.9 mm Hg, WS = 8600 mg/L, HLC = 1.18 × 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

Table_Apx D-1. Federal Laws and Regulations

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
EPA Statutes/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 (84 FR 71924, Dec. 30, 2019). Designation of 1,2-dichloroethane 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 (85 FR 20122, April 2, 2020).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	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 (60 FR 16309, 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, 2019a).
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).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules, enforceable consent agreements and	Six chemical data submissions from test rules and

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
	orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	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. Since 1990, EPA has removed two	1,2-Dichloroethane is listed as a HAP (42 U.S. Code Section 7412).

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
	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.
Clean Air Act (CAA) – Sections 112(d) and 112(f)	Risk and technology review (RTR) of Section 112(d) national emission standards for hazardous air pollutants (NESHAP). Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to Section 112(d) NESHAP that require maximum achievable control technology (MACT), and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the emission standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP and will do so, as required, for the remaining source categories with NESHAP.
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 (µg/L) for "Human Health for the consumption of Water + Organism" and 650 (µg/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.	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

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
	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.	304, 1,2-dichloroethane is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).
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 (40 FR 116.4, March 13, 1978).
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goal (MCLG) for a contaminant for which EPA makes the determination that the contaminant: 1. may have an adverse effect on the health of persons; 2. is 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,	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,

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
	corrosiveness, and other hazardous characteristics.	K019, K020, K029, K030 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).
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 Statutes/Regulations		
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

Statutes/ Regulations	Description of Authority/Regulation	Description of Regulation
		components of articles intended for use in packaging, transporting, or holding food (21 CFR § 175.105).
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.	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).
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 (U.S. DOT 49 CFR Part 172.101)

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

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

State Actions	Description of Action
	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). 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). 1,2-Dichloroethane is on the MA Toxic Use Reduction Act (TURA) list of 2019 (301 CMR 41.03).

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,

Country/Tribe/ Organization	Requirements and Restrictions
	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) 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, Singapore, 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 liquid-phase 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 40–50ºC 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 and Kane, 2015). 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, 2019a).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant

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, 2019a).

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 and also as a processing aids for petroleum production (U.S. EPA, 2019a). 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 Adhesives and Sealants

EPA has identified that some industrial adhesives and sealants contain 1,2-dichloroethane (EPA-HQ-OPPT-2018-0427-0018). Specific process information regarding the manner in which these products are used is unknown at this time, however, adhesives and sealants can be applied via many methods (including spray applications). EPA plans to further investigate the use of 1,2-Dichloroethane in adhesives and sealants during the risk evaluation.

E.1.3.2 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). EPA plans to further investigate the use of 1,2-Dichloroethane in functional fluids during the risk evaluation.

E.1.3.3 Lubricants and Greases

EPA identified a safety data sheet for a low friction coating, also known as a solid film lubricant, containing 5 to 10 percent 1,2-dichloroethane (Everlube Products, 2019). According to the associated product Technical Data sheet, this product is a spray applied thermally cured lubricant used to prevent metal to metal contact when used in the presence of conventional lubricants (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.1.3.4 Oxidizing/Reducing Agents

EPA has learned that 1,2-dichloroethane is used as an oxidation inhibitor in some large scale controlled oxidative chemical reactions (EPA-HQ-OPPT-2018-0427-0006). EPA plans to further investigate this condition of use during the risk evaluation.

E.1.3.5 Solvents (for Cleaning and Degreasing)

EPA identified a safety data sheet for 1,2-Dichloroethane (99 to 100 percent) that identified use as a process cleaner (Occidental Chemical Corp, 2015). EPA plans to further investigate the use of 1,2-Dichloroethane in degreasing and cleaning (including, but not limited to, potential use in vapor degreasing, cold cleaning, aerosol degreasing, and mechanical cleaning) during the risk evaluation.

E.1.3.6 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, b).

E.1.3.7 Fuels and Related Products

A commenter (EPA-HQ-OPPT-2018-0131-0042) provided descriptions of their use of 1,2-dichloroethane as a fuel additive for combustion research, further informing EPA's understanding of this condition of use. 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.1.3.8 Laboratory Use

EPA identified a safety data sheet for 1,2-dichloroethane (>95% percent purity) that indicates recommended use as a laboratory chemical (Thermo Fisher, 2018). EPA plans to further investigate the laboratory use of 1,2-dichloroethane during the risk evaluation. A commenter (EPA-HQ-OPPT-2018-0131-0042) provided descriptions of their use of 1,2-dichloroethane in analytical standards, research, equipment calibration, and sample preparation applications, including as a reference sample for analysis of terrestrial and extraterrestrial material samples, which the commenter also indicated was a critical use, further informing EPA's understanding of this condition of use.

E.1.3.9 Embalming Agent

EPA identified a safety data sheet for a supplemental embalming fluid containing >90 percent 1,2-dichloroethane (Frigid Fluid Company, 2015). 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 wastewater and solid waste.

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 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).

E.2 Preliminary Occupational Exposure Data

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)

Number of data points in Table_Apx E-2 was populated from data found at https://www.osha.gov/opengov/healthsamples.html

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	HETA 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 Manufacturing
1980	HE 79-80, 81-746	Medical Equipment Manufacturing
1979	HE 77-73-610	Chemical Manufacturing

HHEs can be found at https://www.cdc.gov/niosh/hhe/

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

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

Life Cycle Stage	Category	Subcategory	Release/ Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
Manufacturing	Domestic Manufacture	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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
	Import	Import	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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
Processing	Processing as a reactant	Petrochemical manufacturing	Processing of petrochemicals, plastics, resins, and other basic 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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
		Plastic material and resin manufacturing	Processing of plastics and resins	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 25ºC), 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 25ºC), 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
		All other basic organic chemical manufacturing	Processing of organic chemicals 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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
	Incorporated into formulation, mixture or reaction product	Fuels and fuel additives: All other petroleum and coal products manufacturing	Processing 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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
		Processing aids, specific to	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
		petroleum production	contain 1,2-dichloroethane	Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25ºC), 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 25ºC), 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 25ºC), 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 25ºC), 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,

Life Cycle Stage	Category	Subcategory	Release/ Exposure Scenario	Exposure Pathway	Exposure Route	Receptor	Plans to Evaluate	Rationale
								disposal) rather than as a single distribution scenario.
Industrial Use	Adhesives and Sealants	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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
				Mist	Inhalation	Worker	Yes	Method of application for this type of adhesive is not known. If the adhesive is spray applied, there is potential for mist generation and associated exposure.
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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
Industrial Use	Lubricants and Greases	Paste 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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
				Mist	Inhalation	Worker	Yes	The Technical Data Sheet for a product containing 1,2-dichloroethane recommends spray application, therefore, EPA plans to evaluate worker exposure to mist
Industrial Use	Oxidizing/reducing agents	Oxidation inhibitor in controlled	Use of 1,2-dichloroethane as an oxidation	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
		oxidative chemical reactions	inhibitor in controlled oxidative chemical reactions	Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25ºC), 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 25ºC), 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
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25ºC), 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 25ºC), 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 25ºC), 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 25ºC), 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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
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 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor
Commercial Use	Other Use	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 25ºC), 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 25ºC), 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
				Vapor	Inhalation	Worker	Yes	Due to high volatility (79.1 mmHg at 25ºC), 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 25ºC), EPA plans to evaluate inhalation exposure to vapor

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

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use; Consumer Reuse and Recycling	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) EPA plans to evaluate inhalation exposure to vapor
						Bystanders	Yes	Due to high volatility (79.1 mmHg at 25C) EPA plans to evaluate inhalation exposure to vapor
				Article	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.

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

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

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	1,2-Dichloroethane is a HAP. Stationary source releases of 1,2-dichloroethane to ambient air are under the jurisdiction of the CAA.
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	No	
				TBD	Aquatic and Terrestrial Receptors	No	
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic Receptors	Yes	EPA has developed Ambient Water Quality Criteria for protection of human health for 1,2-dichloroethane.
				Oral Dermal	General Population	No	
			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 NPDWR.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (*e.g.*, ingestion of soil) Inhalation	General Population	No	Unlikely to be a route to general population.
				TBD	Aquatic Receptors	Yes	

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