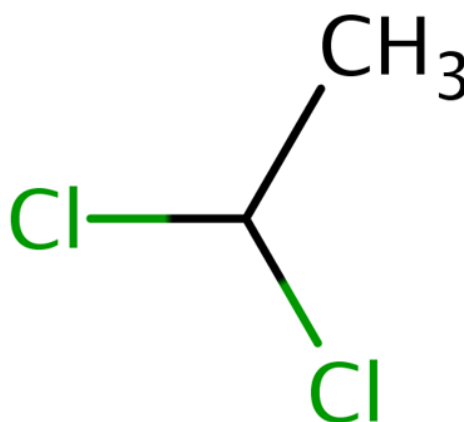




Draft Scope of the Risk Evaluation for 1,1-Dichloroethane

CASRN 75-34-3



April 2020

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Docket

Supporting information can be found in public docket: [EPA-HQ-OPPT-2018-0426](https://www.epa.gov/epaosopr/odsp/odspdocs/epa-hq-oppt-2018-0426).

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Government Industrial Hygienists
ADME	Absorption, Distribution, Metabolism, and Excretion
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
BW ^{3/4}	Body Weight ³ / ₄ Extrapolation
CAA	Clean Air Act
CalEPA	California Environmental Protection Agency
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CDC	Centers for Diseases Control and Prevention
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
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
CPCat	Chemical and Product Categories
CRC	Coordinating Research Council
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DMR	Discharge Monitoring Report
EC	Engineering Control(s)
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FR	Federal Register
FYI	For your information
GACT	Generally Available Control Technology
GC	Gas Chromatography
GDIT	General Dynamics Information Technology
GESTIS	Substance Database contains information for the safe handling of hazardous substances and other chemical substances at work
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HERO	Health and Environmental Research Online
HHE	Health Hazard Evaluation

HMTA	Federal Hazardous Materials Transportation Act
HPLC	High Performance Liquid Chromatography
HSDB	Hazardous Substances Data Bank
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)
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
K _{oc}	Organic Carbon: Water Partition Coefficient
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
MFG	Manufacturing
MITI	Ministry of International Trade and Industry
MOA	Mode of Action
MP	Montreal Protocol
MWCs	Municipal waste combustors
NATA	National-scale Air Toxics Assessment
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NFPA	National Fire Protection Association
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NLM	National Library of Medicine
NOAA	National Oceanic and Atmospheric Administration
NOAELs	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPL	National Priorities List
NTP	National Toxicology Program
OCSP	Office of Chemical Safety and Pollution Prevention
OELs	Occupational Exposure Limits
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment (California)
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
P-chem	Physical-chemical
PAC	Protective Action Criteria
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent, Bioaccumulative, and Toxic

PECO	Population, Exposure, Comparator, Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulations
PODs	Points of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
PV	Production Volume
PWSs	Public Water Systems
RegDet	Regulatory Determinations
RCRA	Resource Conservation and Recovery Act
RDF	Refuse-derived Fuel
REL	Recommended Exposure Limit
RIVM	Dutch National Institute for Public Health and the Environment
RQs	Risk Quotients
SACC	Science Advisory Committee on Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SIC	Standard Industrial Classification
SRC	SRC Inc., formerly Syracuse Research Corporation
STORET	Storage and Retrieval for Water Quality Data; EPA's repository of water quality monitoring data
TBD	To be determined
TG	Test Guideline
TERA	Toxicology Excellence for Risk Assessment
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
UIC	Underground Injection Control
UCMR	Unregulated Contaminants Monitoring Rule
USGS	United States Geological Survey
VP	Vapor Pressure
WQX	Water Quality Exchange

EXECUTIVE SUMMARY

In December 2019, EPA designated 1,1-dichloroethane (CASRN 75-34-3) as a high-priority substance for risk evaluation following the prioritization process as required by section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations ([40 CFR Part 702](#)) (Docket ID: [EPA-HQ-OPPT-2018-0426](#)). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA requirement to issue a draft scope document as described in 40 CFR 702.41(c)(7). The draft scope for 1,1-dichloroethane includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, conceptual model, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. 1,1-Dichloroethane is a colorless oily liquid with characteristic (chloroform-like) odor. This chlorinated hydrocarbon is slightly soluble in water and slightly denser than water, but miscible with most organic solvents.

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

Conditions of Use. EPA plans to evaluate industrial and commercial uses of 1,1-dichloroethane in the risk evaluation. 1,1-Dichloroethane is manufactured within the U.S. The chemical is processed as a reactant. The identified processing activities also include recycling. Industrial and commercial uses identified were non-incorporative activities, use as a processing aid, and in laboratory chemicals. No consumer uses were identified. EPA identified these conditions of use from information reported to EPA through CDR and TRI reporting, published literature, and consultation with stakeholders for both uses currently in production and uses whose production may have ceased. Section 2.2 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Model. The conceptual models for 1,1-dichloroethane are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposures pathways (e.g. media), exposure routes (e.g., inhalation, dermal, oral), hazards and receptors throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal. EPA plans to focus the risk evaluation for 1,1-dichloroethane on the following exposures, hazards, and receptors with the understanding that updates

may happen in the final scope document after consideration of public comments and completion of the systematic review data collection phase.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of 1,1-dichloroethane that EPA plans to consider in the risk evaluation. Exposures for 1,1-dichloroethane are discussed in Section 2.3. EPA identified environmental monitoring data reporting the presence of 1,1-dichloroethane in air, drinking water, ground water, sediment, soil, surface water, and ecological tissue. 1,1-Dichloroethane is subject to reporting to EPA's Toxics Release Inventory (TRI) and EPA plans to use TRI information as reasonably available information to inform 1,1-dichloroethane's environmental release assessment. For the 2018 reporting year, 15 facilities reported to EPA releases of 1,1-dichloroethane to water. Additional information gathered through systematic review searches will also inform expected exposures.

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

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

- *Occupational exposure pathways associated with industrial and commercial conditions of use:* EPA plans to evaluate exposures to workers and/or occupational non-users via the inhalation route and exposures to workers via the dermal route associated with the manufacturing, processing, use or disposal of 1,1-dichloroethane (Section 2.2.1).
- *General population exposures:* EPA plans to evaluate exposure to 1,1-dichloroethane via groundwater and fish ingestion for the general population.
- *Receptors and PESS:* EPA plans to include children, women of reproductive age (e.g., pregnant women per TSCA statute), workers and consumers as receptors and PESS in the risk evaluation.
- *Environmental exposures:* EPA plans to evaluate exposure to 1,1-dichloroethane for aquatic and terrestrial receptors.

Hazards. Hazards for 1,1-dichloroethane are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for 1,1-dichloroethane as part of the prioritization process. Environmental hazard effects were identified for aquatic and terrestrial organisms. Information collected through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment of the risk evaluation.

EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for 1,1-dichloroethane. Relevant mechanistic evidence will also be considered, if reasonably available,

to inform the interpretation of findings related to potential human health effects and the dose-repose assessment. EPA plans to evaluate all of the potential human health hazards for 1,1-dichloroethane identified in Section 2.4.2. The broad health effect categories include reproductive and developmental, immunological, nervous system, and irritation effects. Studies were identified reporting information on genotoxicity, carcinogenicity and absorption, distribution, metabolism, and excretion (ADME).

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

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

Peer Review. The draft risk evaluation for 1,1-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](#) and other methods consistent with Section 26 of TSCA (See [40 CFR 702.45](#)).

1 INTRODUCTION

This document presents for comment the scope of the risk evaluation to be conducted for 1,1-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 Toxic Substances Control Act (TSCA) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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

TSCA § 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations ([84 FR 71924](#)) as required by TSCA § 6(b)(2)(B). 1,1-dichloroethane is one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

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

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

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

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review process. The search and screening process was conducted based on EPA’s general expectations for the planning, execution and assessment activities outlined in the [Application of Systematic Review in TSCA Risk Evaluations](#) document (U.S. EPA, 2018a). EPA will publish supplemental documentation on the systematic review methods supporting the 1,1-dichloroethane risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

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

2.1.1 Search of Gray Literature for All Disciplines

EPA surveyed the gray literature² and identified 58 search results relevant to EPA's risk assessment needs for 1,1-dichloroethane. Appendix A lists the gray literature sources that yielded 58 discrete data or information sources relevant to 1,1-dichloroethane. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

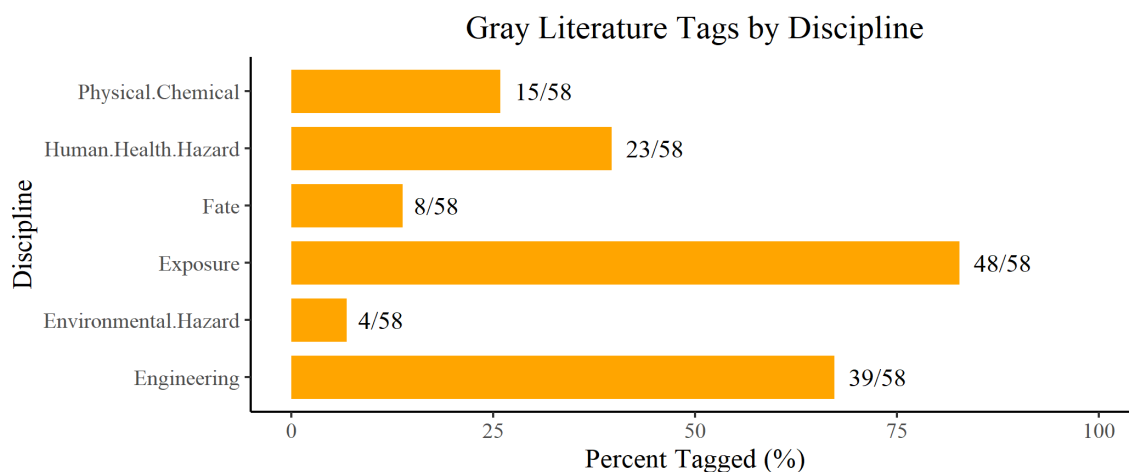


Figure 2-1. Gray Literature Tags by Discipline for 1,1-Dichloroethane

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

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

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

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

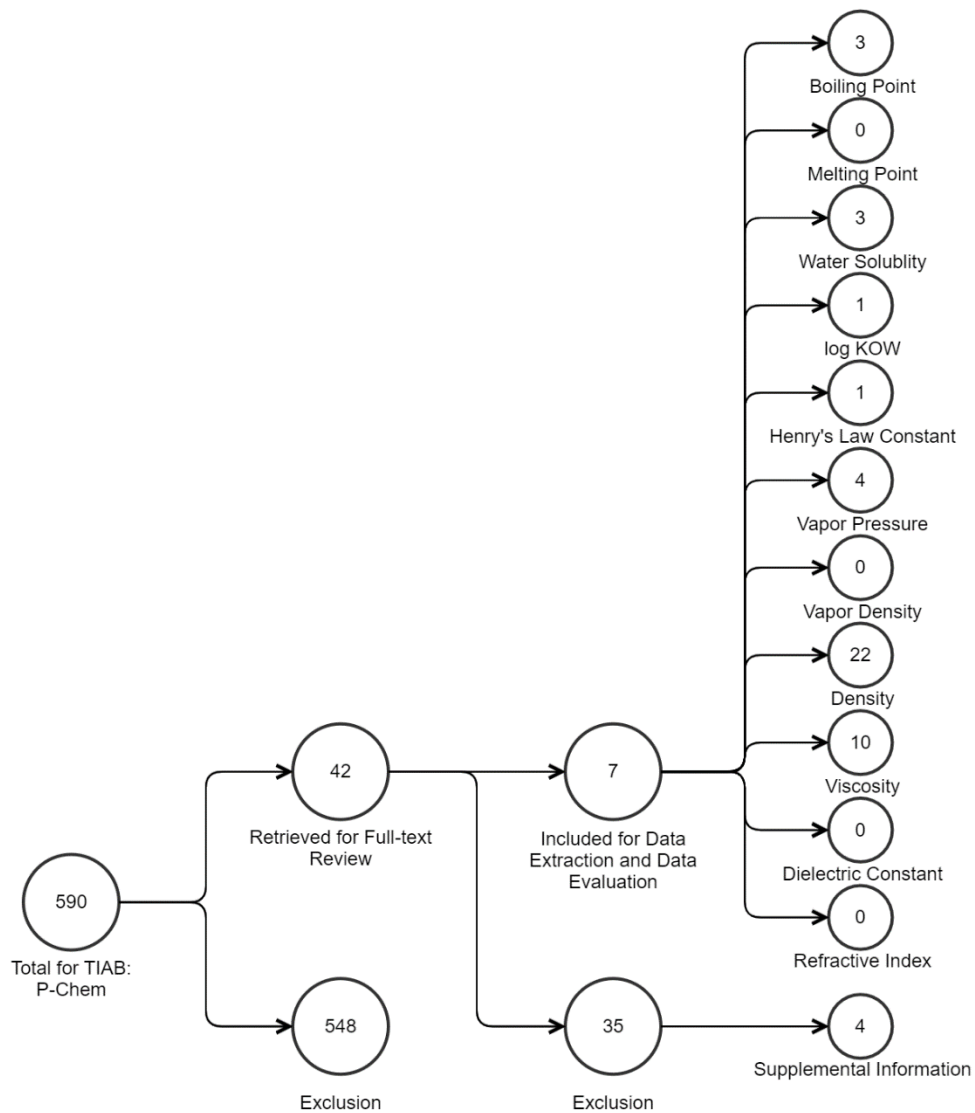


Figure 2-2. Peer-Reviewed Literature - Physical-Chemical Properties Search Results for 1,1-Dichloroethane

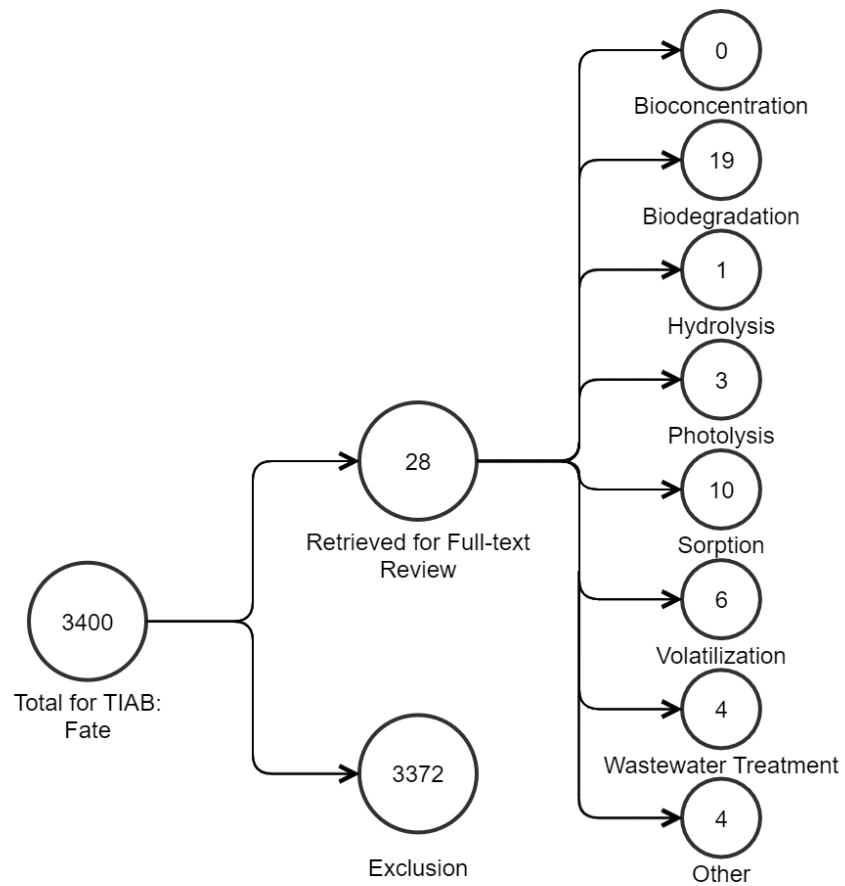


Figure 2-3. Peer-Reviewed Literature – Fate and Transport Search Results for 1,1-Dichloroethane

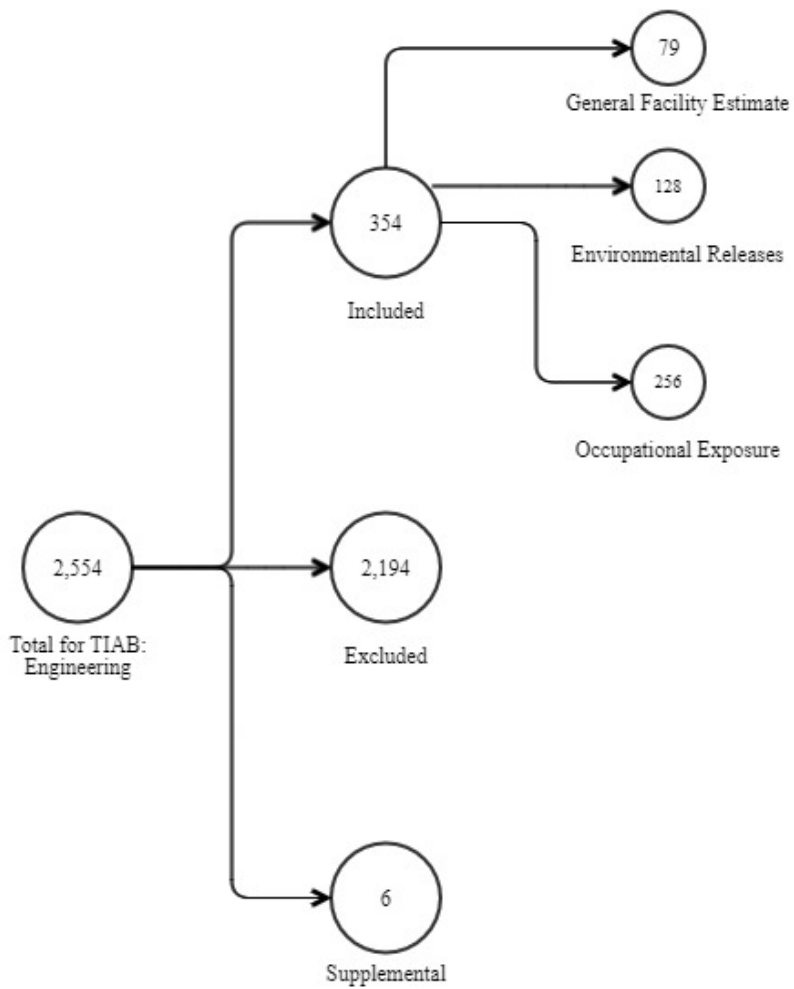


Figure 2-4. Peer-Reviewed Literature - Engineering Search Results for 1,1-Dichloroethane

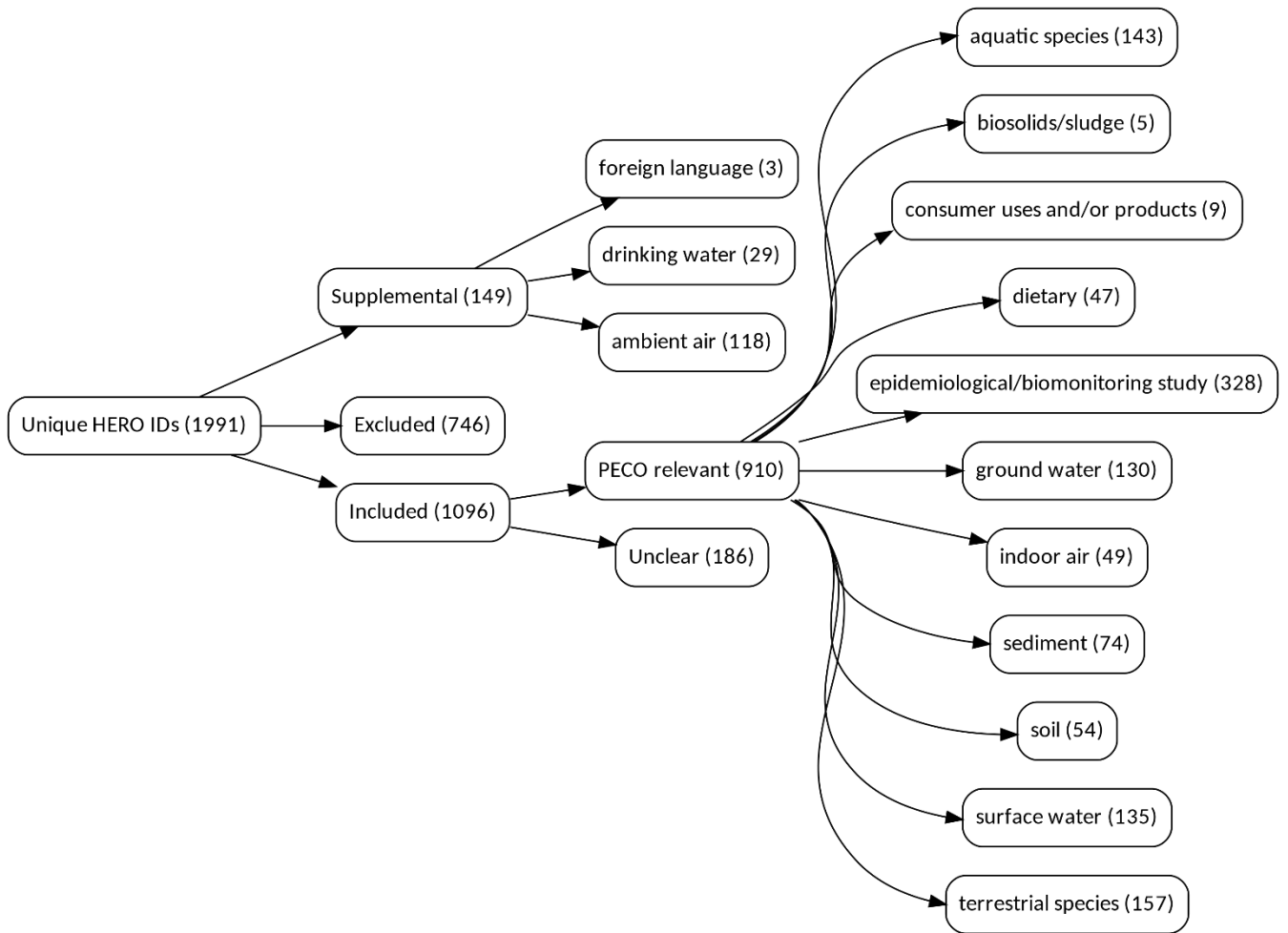


Figure 2-5. Peer-Reviewed Literature - Exposure Search Results for 1,1-Dichloroethane

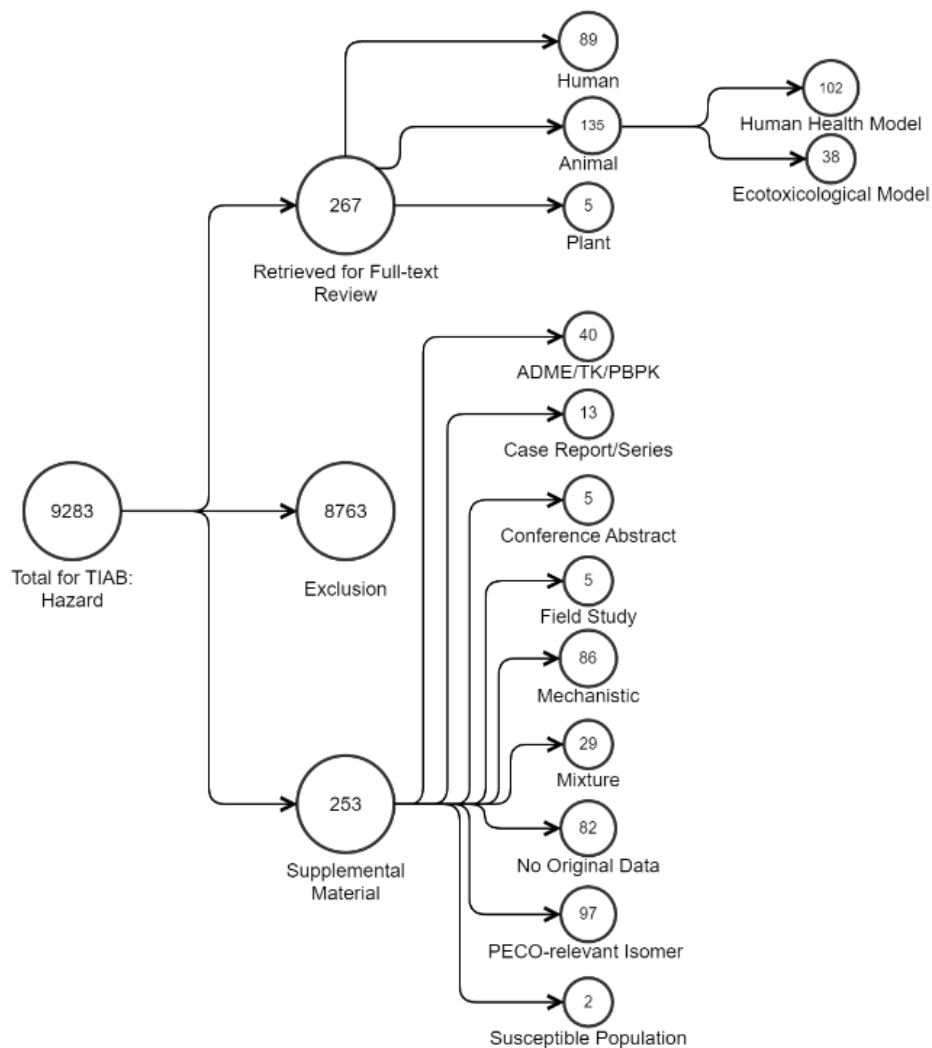


Figure 2-6. Peer-Reviewed Literature - Hazard Search Results for 1,1-Dichloroethane

2.1.3 Search Results for TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 152 submissions using inclusion/exclusion criteria specific to individual disciplines (see Table 2-1 for the list of disciplines). The details about the criteria are not part of this document but will be provided in a supplemental document that EPA anticipates releasing prior to the finalization of the scope document. EPA identified 137 submissions that met the inclusion criteria in these statements and identified 5 submissions with supplemental data. EPA excluded 10 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
- Letter with no attached report

- Submission on a different chemical
- Ranking of chemicals for proposed evaluation
- Protocol for human health hazard testing
- Progress report
- Economic impact analysis
- Environmental impact statement for proposed equipment

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

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

Discipline	Included	Supplemental
Physicochemical Properties	5	0
Environmental Fate and Transport	14	0
Environmental and General Population Exposure	109	1
Occupational Exposure/Release Information	12	0
Environmental Hazard	0	1
Human Health Hazard	9	3

2.2 Conditions of Use

As described in the [Proposed Designation of 1,1-dichloroethane \(CASRN 75-34-3\) as a High-Priority Substance for Risk Evaluation](#) (U.S. EPA 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use³ or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of 1,1-dichloroethane, including: published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing 1,1-dichloroethane, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, and when applicable, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

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

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

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

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. Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category	Subcategory	References
Manufacturing	Domestic Manufacturing	Domestic Manufacturing	U.S. EPA (2019b)
Processing	As a reactant	Intermediate in all other basic organic chemical manufacturing	U.S. EPA (2019b)
	As a reactant	Intermediate in all other chemical product and preparation manufacturing	U.S. EPA (2019b)
	Recycling	Recycling ⁴	U.S. EPA (2019b)
Distribution in Commerce	Distribution in Commerce	Distribution in Commerce	
Industrial Use	Non-incorporative activities	Other in all other chemical product and preparation manufacturing	U.S. EPA (2019b) EPA-HQ-OPPT-2018-0421-0015 .
	Processing aids, specific to petroleum production	Hydraulic fracturing	U.S. EPA (2016)
Commercial use	Other use	Laboratory chemicals	Restek (2019)
Disposal	Disposal	Disposal	
<ul style="list-style-type: none"> Life Cycle Stage Use Definitions (40 CFR § 711.3) <ul style="list-style-type: none"> “Industrial use” means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. “Commercial use” means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use 			

2.2.2 Activities Excluded from the Scope of the Risk Evaluation

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

No activities were excluded for 1,1-dichloroethane.

⁴The Agency has included information in this draft scope document sourced from the 2012 and 2016 Chemical Data Reporting (CDR) Rule collections. In instances where particular CDR data elements included in this document were claimed as confidential business information (CBI), the Agency reviewed the claims and secured their declassification.

2.2.3 Production Volume

EPA is withholding⁵ production volume of 1,1-dichloroethane in 2015, as reported to EPA during the 2016 CDR reporting period, to protect CBI (U.S. EPA 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the [Proposed Designation of 1,1-Dichloroethane \(CASRN 75-34-3\) as a High-Priority Substance for Risk Evaluation](#) (U.S. EPA 2019a) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

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

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses)⁶

⁵ The initial CDR data included national production volume (released in ranges), other manufacturing information, and processing and use information, except for information claimed by the submitter to be confidential business information (CBI) or information that EPA is withholding to protect claims of CBI.

⁶ The descriptions are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions and can be found in EPA's [Instructions for Reporting 2016 TSCA Chemical Data Reporting](#).

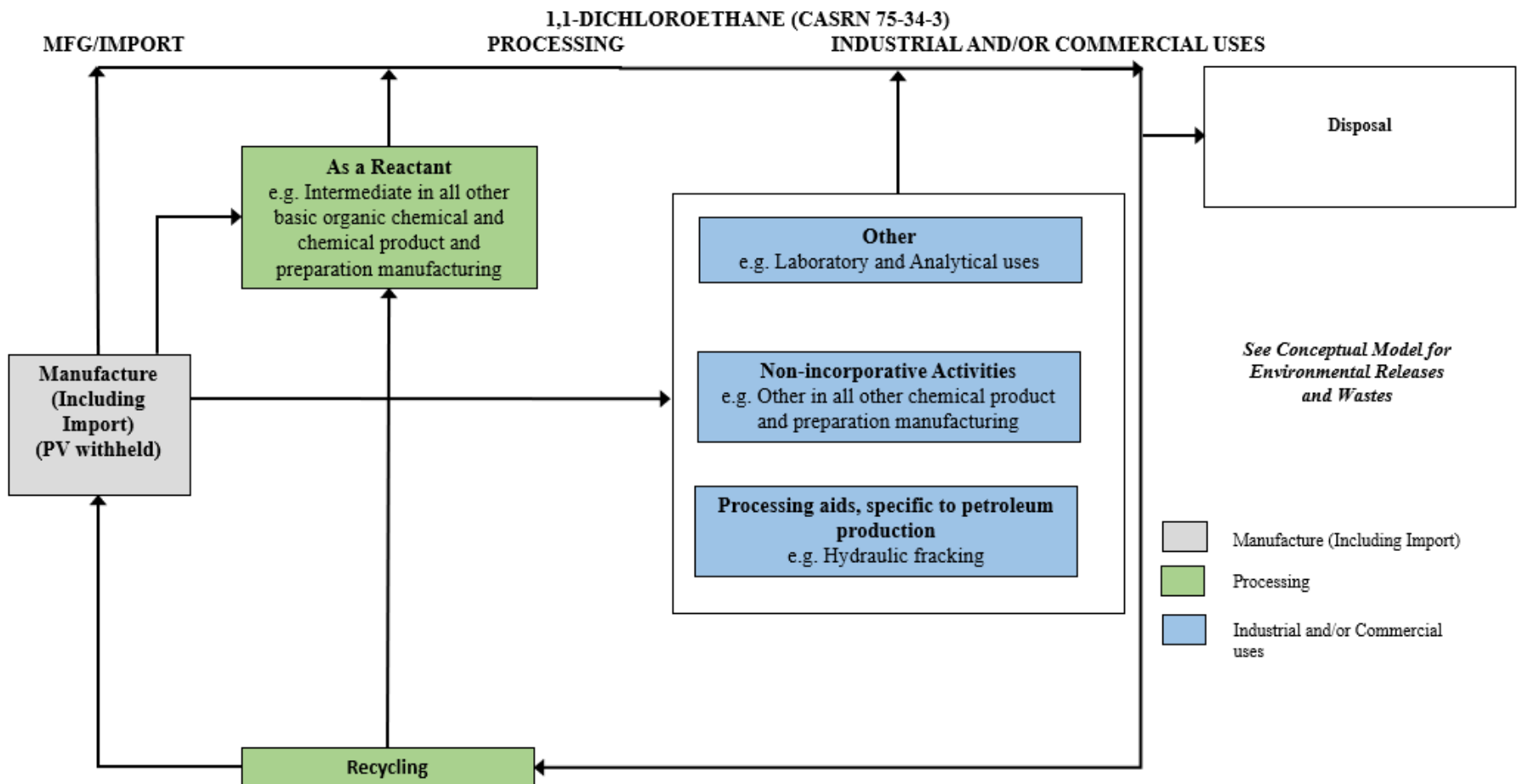


Figure 2-7. 1,1-Dichloroethane Life Cycle Diagram

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

2.3 Exposures

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

2.3.1 Physical and Chemical Properties

Physical and chemical properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of 1,1-Dichloroethane (CASRN 75-34-3) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019a)) to support the development of the risk evaluation for 1,1-dichloroethane. EPA plans to use the physical and chemical properties described in the *Proposed Designation of 1,1-Dichloroethane (CASRN 75-34-3) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019a)) to support the development of the risk evaluation for 1,1-dichloroethane (Appendix B). The values for the physical and chemical properties (Appendix B) may be updated as EPA collects additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for 1,1-dichloroethane. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of 1,1-Dichloroethane (CASRN 75-34-3) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019a)) to support the development of the risk evaluation for 1,1-dichloroethane. The values for the environmental fate properties (Appendix C) may be updated as EPA collects additional information through systematic review methods.

2.3.3 Releases to the Environment

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

A source of information that EPA plans to consider in evaluating exposure are data reported to 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 Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 1,1-dichloroethane is a TRI-reportable substance, under the name ethylidene dichloride, effective January 01, 1994 (40 CFR 372.65). For TRI reporting⁷, facilities in covered sectors in the United States are required to disclose releases and other waste management activity quantities of 1,1-dichloroethane under

⁷ For TRI reporting criteria see <https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting>

the CASRN 75-34-3 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 2-3 provides production-related waste management data for 1,1-dichloroethane reported by facilities to the TRI program for reporting year 2018.⁸ As shown in the table, 15 facilities reported a total of nearly 15 million pounds of 1,1-dichloroethane waste managed. Of this total, over 10.5 million pounds were treated, nearly three million pounds were combusted for energy recovery, nearly 1.4 million pounds were recycled, and over nine thousand pounds were disposed of or otherwise released into the environment.

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

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released Released ^{a,b,c} (lbs) ^{a,b,c}	Total Production Related Waste (lbs)
2018	15	1,394,654	2,999,941	10,575,018	9,151	14,978,743

Data source: (U.S. EPA, 2018b) (Updated November 2019)

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

^b Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.

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

Table 2-4 provides a summary of the quantities of 1,1-dichloroethane released to the environment during 2018.⁸ All of the quantities reported as released to the environment occurred on site and to air, mostly as fugitive emissions.

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

	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases (lbs) ^a Releases ^a (lbs)	Total Releases (lbs) ^b Releases ^{b,c} (lbs)
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal ^a (lbs)		
Totals	15	3,283	5,868	0	0	0	0	0	9,151
		9,151			0				

Data source: (U.S. EPA, 2018b) (Updated November 2019)

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

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

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

While production-related waste managed shown in Table 2-3 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-4 include both production-related and non-production-related quantities. For 1,1-dichloroethane, the total release quantities shown in the two tables are the same, but for other TRI chemicals they may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017d).

⁸ Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

2.3.4 Environmental Exposures

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

Based on fate properties, such as vapor pressure, Henry's Law constant, soil mobility and water solubility, EPA anticipates possible presence of 1,1-dichloroethane in ambient air, and to a lesser extent in surface water, groundwater, and soil ([ATSDR 2015](#), [RIVM 2007](#)). Existing assessments reported 1,1-dichloroethane in ambient air, waste gas from garbage dumps, surface water, groundwater, drinking water, and other environmental media ([ATSDR 2015](#), [CalEPA 2003](#)).

2.3.5 Occupational Exposure

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.1. In addition, EPA plans to analyze exposure to occupational non-users (ONUs), i.e., workers, who do not directly handle the chemical but perform work in an area where the chemical is present. EPA also plans to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

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

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

1,1-Dichloroethane has a vapor pressure of approximately 230 mmHg at 25°C (Appendix B). Based on the chemical's high volatility, EPA anticipates that workers and ONUs will be exposed to vapor via the inhalation route. EPA plans to analyze inhalation exposure to vapor in occupational exposure scenarios where 1,1-dichloroethane is used and handled; the extent of exposure could vary from facility to facility depending on many factors including but not limited to EC, type of facility, and facility design. Based on the conditions of use presented in Section 2.2.1, EPA has not yet identified scenarios where there is inhalation exposure to mist.

1,1-Dichloroethane has an Occupational Safety and Health Administration ([OSHA, 2009](#)) Permissible Exposure Limit (PEL)⁹ of 100 ppm or 400 mg/m³ over an 8-hour work day, time weighted average (TWA). This chemical also has a National Institute for Occupational Safety and Health ([NIOSH, 2005](#)) Recommended Exposure Limit (REL)¹⁰ of 100 ppm (400 mg/m³) TWA. The American Conference of Governmental Industrial Hygienists (ACGIH) sets the Threshold Limit Value (TLV) at 100 ppm TWA.

Based on the conditions of use, EPA also plans to analyze worker exposure to liquids via the dermal route. EPA does not plan on analyzing dermal exposure for ONUs because they do not directly handle 1,1-dichloroethane.

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

2.3.6 Consumer Exposure

No consumer conditions of use were found for 1,1-dichloroethane. The 2012 CDR, 2016 CDR, and the National Institutes of Health Consumer Product Database did not report on the use of 1,1-dichloroethane in consumer products.

2.3.7 General Population Exposures

Releases of 1,1-dichloroethane from certain conditions of use, such as manufacturing, processing, disposal, or hazardous waste treatment activities, may result in general population exposures, mostly via inhalation of ambient air and ingestion of contaminated drinking water near emission sources, whereas presence in food sources is considered very unlikely ([ATSDR 2015](#), [CalEPA 2003](#)). Populations living near source areas, such as petrochemical factories, where 1,1-dichloroethane is manufactured or used, are expected to have higher exposures via inhalation. Low levels (<0.49 ppb) of 1,1-dichloroethane were found in personal air monitoring samples near petrochemical factories (ATSDR 2015). 1,1-Dichloroethane has been found at levels ranging from 0.51 ppb to 30 ppb in drinking water ([CalEPA 2003](#)). Exposure to 1,1-dichloroethane may occur via drinking water ingestion, dermal contact, and inhalation from air releases.

Blood concentrations of 1,1-dichloroethane were below the level of detection (0.01 ng/mL) in 2,736 individuals who participated in the National Health and Nutrition Examination Survey (NHANES) 2011-2012 subsample of the U.S. population (CDC, 2019).

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the [Proposed Designation of 1,1-Dichloroethane \(CASRN 75-34-3\) as a High-Priority Substance for Risk Evaluation](#) (U.S. EPA 2019a), EPA considers all the potential environmental hazards for 1,1-dichloroethane identified during prioritization. EPA is in the process of identifying additional

⁹ OSHA, 2009. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs). <https://www.osha.gov/dsg/annotated-pels/tablez-1.html>

¹⁰ NIOSH, 2005. NIOSH Pocket Guide to Chemical Hazards. <https://www.cdc.gov/niosh/npg/npgdcas.html>

reasonably available information through systematic review methods and public comments, which may update the list of potential environmental hazards associated with 1,1-dichloroethane exposure. If necessary, EPA will update the list of potential hazards in the final scope document of 1,1-dichloroethane. Based on information identified during prioritization, environmental hazard effects were identified for aquatic and terrestrial organisms.

2.4.2 Human Health Hazards

As described in the [*Proposed Designation of 1,1-Dichloroethane \(CASRN 75-34-3\) as a High-Priority Substance for Risk Evaluation*](#) (U.S. EPA 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for 1,1-dichloroethane. EPA plans to evaluate all of the potential human health hazards for 1,1-dichloroethane identified during prioritization. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and ADME. The broad health effect categories include developmental, dermal, and other irritation effects. Studies were also identified reporting information on genotoxicity, carcinogenicity and toxicokinetics. EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA will update the list of potential hazards in the final scope document of the 1,1-dichloroethane risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA requires EPA to determine whether a chemical substance presents an unreasonable risk to “*a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation.*” TSCA §3(12) states that “*the term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.*” General population is “*the total of individuals inhabiting an area or making up a whole group*” and refers here to the U.S. general population ([U.S. EPA, 2011](#)).

During the Prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: children, women of reproductive age (e.g., pregnant women per TSCA statute), workers and consumers (U.S. EPA 2019a). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

In developing exposure scenarios, EPA plans to analyze available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children’s crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population ([U.S. EPA, 2006a](#)). Likewise, EPA plans to evaluate available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical’s hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of 1,1-dichloroethane. Pathways and routes of exposure associated with workers and occupational non-users are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted in the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws, are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

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

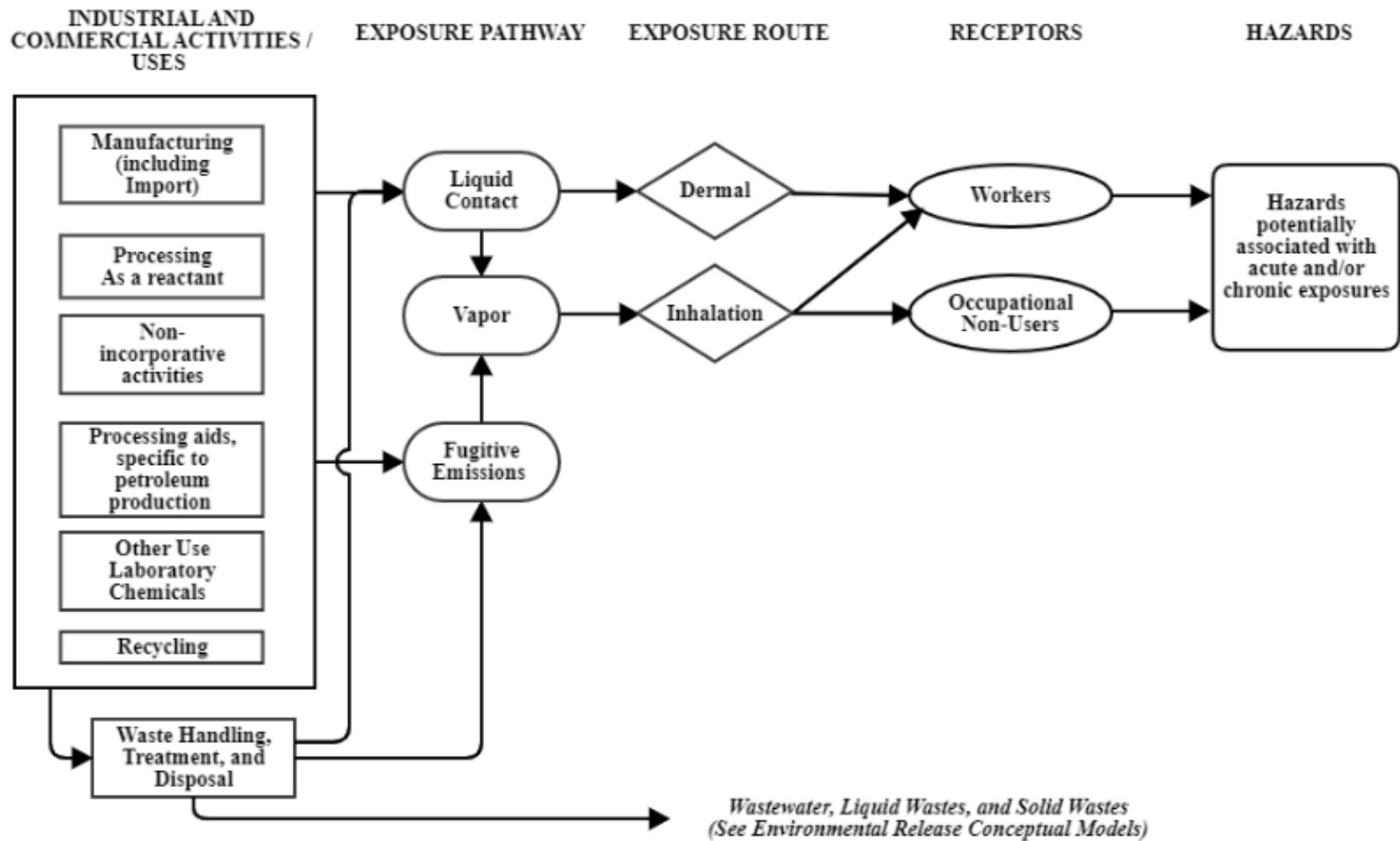


Figure 2-8. 1,1-Dichloroethane Occupational Exposure Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards.

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

2.6.2 Conceptual Model for Consumer Activities and Uses

EPA does not expect consumer exposures as no consumer conditions of use were found for 1,1-dichloroethane, therefore, no conceptual model is presented.

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

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

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

The conceptual model in Figure 2-9 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial and commercial uses of 1,1-dichloroethane. This figure includes overlays, labeled and shaded to depict the regulatory programs (e.g., CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 through Section 2.6.3.4.

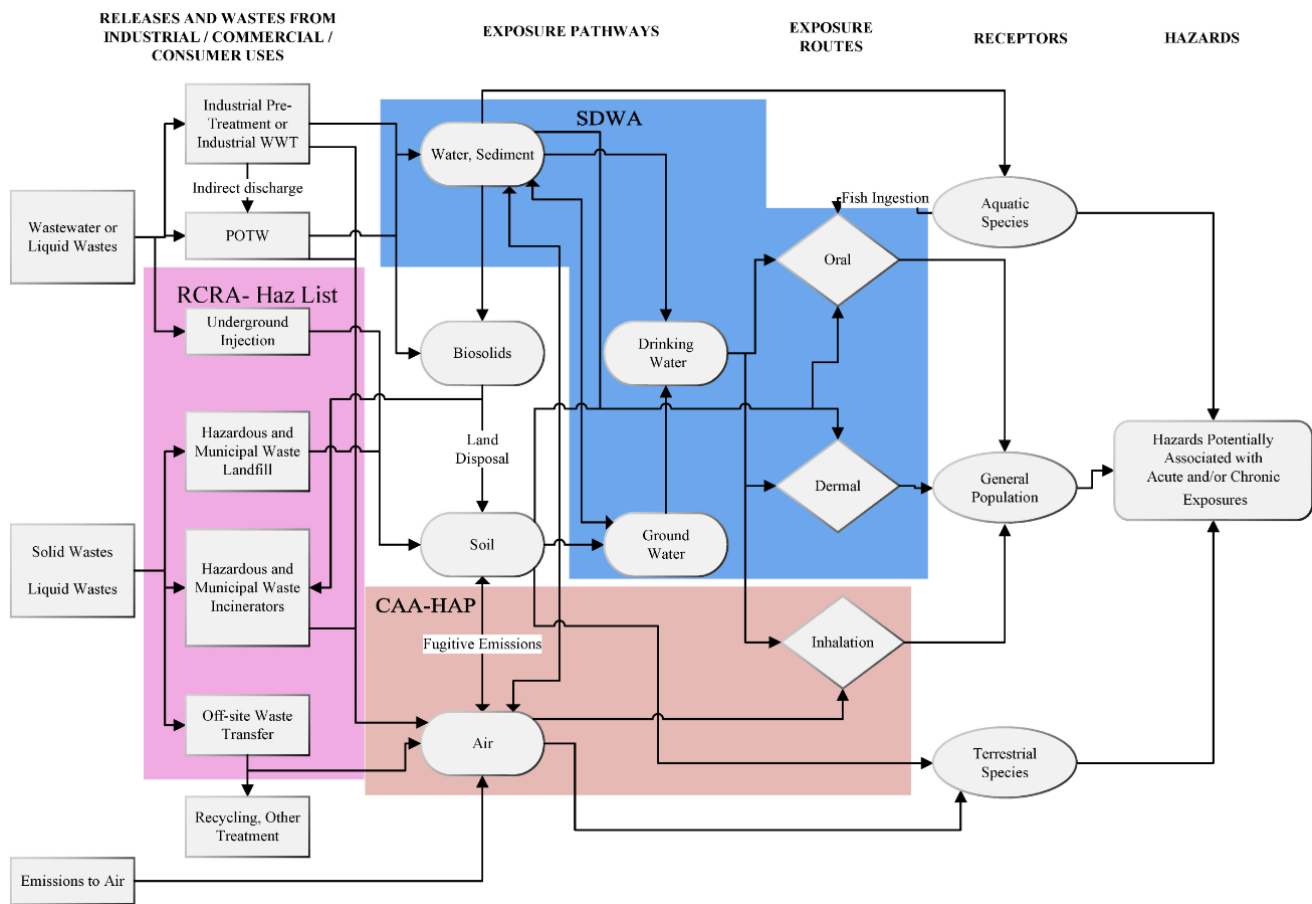


Figure 2-9. 1,1-Dichloroethane Conceptual Model for Environmental Releases and Wastes: Environmental Exposures and Hazards (Regulatory Overlay)

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

- 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). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.
- Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).
- For regulation of hazardous and municipal waste incinerators and municipal waste landfills CAA and RCRA may have shared regulatory authority.

2.6.3.1 Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant. 1,1-Dichloroethane is a HAP. EPA has issued a number of technology-based standards for source categories that emit 1,1-dichloroethane to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks.

Emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation from stationary source releases of 1,1-dichloroethane to ambient air are covered under the jurisdiction of the CAA. EPA's Office of Air and Radiation and Office of Pollution Prevention and Toxics will continue to work together to provide an understanding and analysis of the CAA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

2.6.3.2 Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA). Under SDWA EPA must also review and revise "as appropriate" existing drinking water regulations every 6 years.

The Contaminant Candidate List (CCL) is a list of unregulated contaminants that are known or anticipated to occur in public water systems and that may require regulation. EPA must publish a CCL every 5 years and make Regulatory Determinations (RegDet) to regulate (or not) at least five CCL contaminants every 5 years. To regulate a contaminant EPA must conclude the contaminant may have adverse health effects, occurs or is substantially likely to occur in public water systems at a level of concern and that regulation, in the sole judgement of the Administrator, presents a meaningful opportunity for health risk reduction.

Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including gaps in occurrence data for evaluation under Regulatory Determination; if sufficient occurrence data is lacking, the contaminant may be considered for monitoring under the Unregulated Contaminant Monitoring Rule.

1,1-Dichloroethane is also currently listed on EPA's Fourth Contaminant Candidate List (CCL 4) and was subject to occurrence monitoring in public water systems under the third Unregulated Contaminants Monitoring Rule (UMCR 3). Under UMCR 3, water systems were monitored for 1,1-dichloroethane during 2013-2015. Of the 4,916 water systems monitored, 244 systems had detections of 1,1-dichloroethane in at least one sample. In accordance with EPA-OW's process, a Preliminary Regulatory Determination to not regulate (i.e. develop a drinking water standard) for 1,1-dichloroethane process under SDWA was published in February 2020.

2.6.3.3 Ambient Water Pathway

EPA develops recommended water quality criteria under section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses.

EPA has developed 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 1,1-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.

EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of human or aquatic life for 1,1-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. EPA may publish CWA section 304(a) ambient water quality criteria and/or aquatic life criteria for 1,1-Dichloroethane in the future if it is identified as a priority under the CWA.

2.6.3.4 Disposal and Soil Pathways

1,1-Dichloroethane is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U076 lists. The general standard in section RCRA 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those “*necessary to protect human health and the environment,*” RCRA 3004(a). The regulatory criteria for identifying “characteristic” hazardous wastes and for “listing” a waste as hazardous also relate solely to the potential risks to human health or the environment (40 CFR §§ 261.11, 261.21-261.24). RCRA statutory criteria for identifying hazardous wastes require EPA to “*tak[e] into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.*” Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

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

EPA has not identified releases to land that go to RCRA Subtitle C hazardous waste landfills. Based on 2018 reporting, TRI land disposal includes Subtitle C landfills (0 pounds) and nothing reported as transferred to “other landfills” both on-site and off-site (0 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. Given these controls, general population exposure in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

1,1-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., 0 lb in 2018) for 1,1-dichloroethane. While permitted and managed by the individual states, municipal solid waste landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land from industrial non-hazardous and construction/demolition waste landfills may occur for 1,1-dichloroethane. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized state regulatory programs, but states must implement federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so.

2.6.4 Conceptual Model for Environmental Releases and Wastes

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-10 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial and commercial uses of 1,1-dichloroethane that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of 1,1-dichloroethane in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-10 includes releases from industrial, commercial and/or consumers uses to water/sediment, biosolids and soil via direct and indirect discharges to water that may lead to exposure to aquatic and terrestrial receptors, and to the general population via ingestion of water and fish consumption. The supporting basis for general population and environmental pathways considered for 1,1-dichloroethane are included in Appendix G.

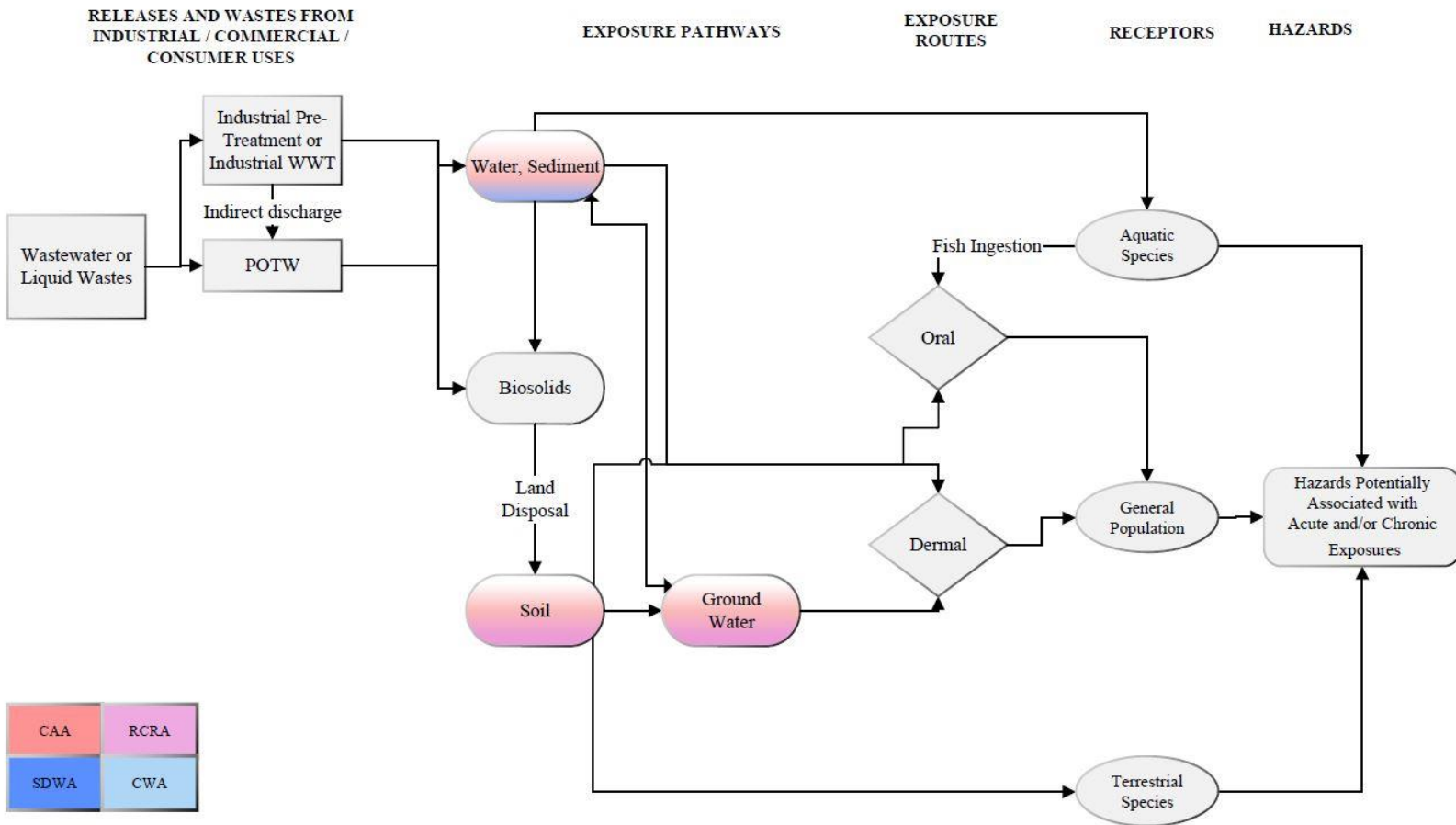


Figure 2-10. 1,1-Dichloroethane Conceptual Model for Environmental Releases and Wastes: Environmental Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and ecological receptors from releases and wastes from industrial and commercial uses of 1,1-dichloroethane with regulatory overlay pathways removed.

- 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).
- Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of 1,1-dichloroethane to date which includes a partial, but not complete review of identified information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for further evaluating conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. Further, EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue considering new information submitted by the public. Should additional data or approaches become available, EPA may update its analysis plan in the final scope document. As discussed in the [Application of Systematic Review in TSCA Risk Evaluations](#) document [EPA Document #740-P1-8001], targeted supplemental searches during the analysis phase may be necessary to identify additional information (e.g., commercial mixtures) for the risk evaluation of 1,1-dichloroethane.

2.7.1 Physical and Chemical Properties and Environmental Fate

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

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

EPA plans to review data and information collected through the systematic review methods and public comments about the physical-chemical properties (Appendix B) and fate endpoints (Appendix C) previously summarized in the [Proposed Designation of 1,1-Dichloroethane \(CASRN 75-34-3\) as a High-Priority Substance for Risk Evaluation](#) (U.S. EPA (2019a)). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

- 2) Using measured data and/or modeling, determine the influence of physical-chemical properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**

Measured data and, where necessary, model predictions of physical-chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of 1,1-dichloroethane within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

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

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

2.7.2 Exposure

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

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

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

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

EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix E. EPA plans to continue reviewing data sources identified in Appendix E during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-5 below:

Table 2-5. Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Risk Assessment Reports
Discharge Monitoring Report (DMR) surface water discharge data for 1,1-dichloroethane from NPDES-permitted facilities

2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).

EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.3. EPA plans to continue reviewing relevant data sources as identified in 2.8E.2 during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for

particular conditions of use. EPA plans to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

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

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

If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other chlorinated solvents and/or chemicals with similar physical properties (e.g. vapor pressure) may be considered as surrogates for 1,1-dichloroethane.

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

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

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

EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the [July 2009 ESD on Plastics Additives](#) (OECD, 2009) and the [September 2011 ESD on 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>

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

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

EPA has identified release scenarios and mapped (i.e. grouped) them to relevant conditions of use as shown in Appendix F. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g. recycling, construction and demolition). EPA plans to perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping/grouping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

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

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

2.7.2.2 Environmental Exposures

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

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

For 1,1-dichloroethane, environmental media which will be analyzed include aquatic and terrestrial species, sediment, soil, and surface water.

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

Available environmental exposure models that meet the TSCA Science Standards and that estimate surface water, sediment, and soil concentrations will be analyzed and considered alongside available surface water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into surface water, sediment, or soil, indirect release into surface water, sediment, or soil (i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

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

There have been changes to use patterns of 1,1-dichloroethane over the last few years. Monitoring data or modeled estimates will be reviewed to determine how representative they are of ongoing use patterns.

Any studies which relate levels of 1,1-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 1,1-dichloroethane, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

- Estimates of surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on available monitoring data.
- Generally, consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
- Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates

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

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

2.7.2.3 Occupational Exposures

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

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

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

EPA has preliminarily reviewed available monitoring data collected by OSHA and NIOSH and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources (identified in Table 2-6) and extract relevant data for consideration and analysis during risk evaluation.

OSHA has established a permissible exposure limit (PEL) of 100 ppm 8-hour time-weighted average (TWA) ([OSHA 2019](#)). EPA will consider the influence of these regulatory limits and recommended exposure guidelines on occupational exposures in the occupational exposure assessment. The following are some data sources identified thus far:

Table 2-6. Potential Sources of Occupational Exposure Data

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

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

If surrogate data are identified, these data will be matched with the applicable conditions of use for potentially filling data gaps.

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

EPA has identified potentially relevant OECD emission scenario documents (ESDs). For example, [September 2011 ESD on the Chemical Industry](#) (OECD, 2011) may be used to estimate occupational exposures. EPA plans to critically review these ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GSs corresponding to the use of 1,1-dichloroethane as a laboratory chemical. EPA plans to perform additional targeted research in order to better understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

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

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

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

EPA plans to review potentially relevant data sources on EC and personal protective equipment as identified in Appendix E to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) Map or group each condition of use to occupational exposure assessment scenario(s).

EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). EPA was not able to identify occupational scenarios corresponding to some conditions of use. EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may further refine the

mapping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.

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

2.7.2.4 Consumer Exposures

EPA does not plan on analyzing consumer exposures to 1,1-dichloroethane because no consumer conditions of use were identified.

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) Refine and finalize exposure scenarios for general population by considering sources and uses, exposure pathways including routes, and exposed populations.

For 1,1-dichloroethane, the following are noteworthy considerations in constructing exposure scenarios for the general population:

- Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
- For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
- Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
- Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
- Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
- Evaluate the weight of the scientific evidence of general population exposure data.
- Map or group each condition of use to general population exposure assessment scenario(s).
- Environmental exposure pathways regulated by non-TSCA EPA laws and regulations will be excluded from analysis

EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix G. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups. If available, EPA plans to compare multiple scenario-specific and background exposure doses estimated from media-specific concentrations and exposure factors with available biomonitoring data. The forward-calculated and back-calculated exposures could be compared to characterize the relative contribution from defined exposure scenarios.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) For exposure pathways where empirical data is not available, review existing exposure models that may be applicable in estimating exposure levels.

For 1,1-dichloroethane, media where exposure models will be considered for general population exposure include models that estimate surface water concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) Review available exposure modeled estimates. For example, existing models developed for a previous 1,1-dichloroethane chemical assessment may be applicable to the EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are available.

To the extent other organizations have already modeled 1,1-dichloroethane general population exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical

chemical properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

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

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

5) Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).

For 1,1-dichloroethane, exposure scenarios that involve potentially exposed or susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for soil than adults.

6) Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.

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

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

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

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

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

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

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

3) Evaluate the weight of scientific evidence of environmental hazard data.

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

4) Consider the route(s) of exposure, based on available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments.

EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the 1,1-dichloroethane conceptual model. These organisms may be exposed to 1,1-dichloroethane via a number of environmental pathways (e.g., surface water, sediment, soil, diet).

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

EPA plans to conduct a risk characterization of 1,1-dichloroethane to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of 1,1-dichloroethane in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk ([U.S. EPA, 1998](#); [Barnthouse et al., 1982](#)).

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

EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of 1,1-dichloroethane after reviewing relevant physical-chemical properties and exposure pathways. EPA plans to assess the available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of 1,1-dichloroethane. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC₅₀, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for 1,1-dichloroethane with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

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 will use systematic review methods to evaluate the epidemiological and toxicological literature for 1,1-dichloroethane. EPA will publish the systematic review documentation prior to finalizing the scope document.

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

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

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

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

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

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

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

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

Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with The EPA's *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the 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 \(2011\)](#), 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 systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

Following systematic review, EPA plans to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure based on the results. This may include using route-to-route extrapolation methods where appropriate. EPA also intends to evaluate any potential human health hazards following dermal and inhalation exposure to 1,1-dichloroethane, which could be important for worker, consumer, and general population risk analysis. Available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes.

If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in The EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* ([U.S. EPA, 2004](#)) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with The EPA's *Risk Characterization Handbook* ([U.S. EPA, 2000](#)). As defined in The 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](#)). For instance, in the risk characterization summary, the EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review.

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

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA’s [Peer Review Handbook](#) and other methods consistent with section 26 of TSCA (See [40 CFR 702.45](#)). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for 1,1-dichloroethane will be peer reviewed.

REFERENCES

- ATSDR (Agency for Toxic Substances and Disease Registry). (2015). Toxicological profile for 1,1-dichloroethane. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. <https://www.atsdr.cdc.gov/ToxProfiles/tp133.pdf>. HERO ID: 5160114
- CDC (Centers for Disease Control and Prevention). (2019). National Health and Nutrition Examination Survey data (NHANES). Atlanta, Georgia: Centers for Disease Control, National Center for Health Statistics. <https://www.cdc.gov/nchs/nhanes/index.htm>. HERO ID: 6124532
- CDPH (California Department of Public Health). (2015). Biomonitoring California. Priority chemicals. December 2015. <http://www.biomonitoring.ca.gov/chemicals/priority-chemicals>. HERO ID: 3859897
- CDTSC (California Department of Toxic Substances Control). (2017). Informational list of candidate chemicals and chemical groups. <https://calsafes.dtsc.ca.gov/chemical/search.aspx>. HERO ID: 4491939
- Dreher, EL;Beutel, KK;Myers, JD;Lübbe, T;Krieger, S;Pottenger, LH. (2014). Chloroethanes and chloroethylenes. In B Elvers (Ed.), *Ullmann's Encyclopedia of Industrial Chemistry* (6th ed., pp. 1-81). Hoboken, NJ: Wiley-VCH Verlag GmbH & Co. http://dx.doi.org/10.1002/14356007.o06_o01.pub2. HERO ID: 4293766
- Environmental Technology Council Hazardous Waste Resources, C. (2018). High Temperature Incineration. Washington D.C.: Environmental Technology Council Hazardous Waste Resources Center. <http://etc.org/advanced-technologies/high-temperature-incineration.aspx>. HERO ID: 5071451
- HSDB (Hazardous Substances Data Bank). (2018). 1,1-Dichloroethane (CASRN: 75-34-3) [Website]. National Library of Medicine. <http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@DOCNO+64>. HERO ID: 5332607
- Jeffers, PM;Ward, LM;Woytowitch, LM;Wolfe, NL. (1989). Homogeneous hydrolysis rate constants for selected chlorinated methanes, ethanes, ethenes, and propanes. *Environ Sci Technol* 23: 965-969. <http://dx.doi.org/10.1021/es00066a006>. HERO ID: 661098
- Kwok, ESC;Atkinson, R. (1994). Estimation of hydroxyl radical reaction rate constants for gas-phase organic compounds using a structure-reactivity relationship: An update. (CMA Contract No. ARC-8.0-OR). Riverside, CA: University of California. HERO ID: 5185218
- Lewis, RJ, Sr;Sax, NI. (2004). *Sax's Dangerous Properties of Industrial Materials* (11th ed.). Hoboken, NJ: John Wiley & Sons. HERO ID: 699583
- Lyman, WJ;Reehl, WF;Rosenblatt, DH. (1990). *Handbook of Chemical Property Estimation Methods* (pp. 8-3). Washington, DC: American Chemical Society. HERO ID: 5352577
- NFPA (National Fire Protection Association). (2010). *Fire protection guide to hazardous materials* (14th ed.). Quincy, MA. HERO ID: 2991057
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme). (2015). Ethane, 1,1-dichloro-: Human health tier II assessment. Sydney, Australia: Australian Department of Health, National Industrial Chemicals Notification and Assessment Scheme. https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1338#cas-A_75-34-3. HERO ID: 5155547

NOAA (National Oceanic and Atmospheric Administration). (2018). CAMEO chemicals. Database of hazardous materials. 1,1-Dichloroethane (75-34-3). Available online at <http://cameochemicals.noaa.gov/> HERO ID: 5185289

OEHHA (California Office of Environmental Health Hazard Assessment). (2020). Cal Code Regs. Title 27, § 27001: Chemicals known to the state to cause cancer or reproductive toxicity. (California Code of Regulations Title 27 Section 27001).

<https://govt.westlaw.com/calregs/Document/I54B9D2B0D45011DEA95CA4428EC25FA0?contextData=%28sc.Default%29&transitionType=Default>. HERO ID: 6305878

Restek Corporation. (2019). 1,1-Dichloroethane.

https://www.restek.com/documentation/msds/30276_useng.pdf. HERO ID: 6305891

RIVM (National Institute for Public Health and the Environment (Netherlands)). (2007).

Ecotoxicologically based environmental risk limits for several volatile aliphatic hydrocarbons (pp. 217). (601782002/2007). Bilthoven, Netherlands: National Institute for Public Health and the Environment (RIVM). <https://www.rivm.nl/bibliotheek/rapporten/601782002.pdf>. HERO ID: 5159900

Sabljić, A;Güsten, H;Verhaar, H;Hermens, J. (1995). QSAR modelling of soil sorption. Improvements and systematics of log KOC vs. log KOW correlations. *Chemosphere* 31: 4489-4514.

<http://www.sciencedirect.com/science/article/pii/0045653595003275>. HERO ID: 5185273

Tabak, HH;Quave, SA;Mashni, CI;Barth, EF. (1981). Biodegradability studies with organic priority pollutant compounds. *Journal of Water Pollution Control Federation* 53: 1503-1518. HERO ID: 9861

Tomer, A;Kane, J. (2015). The great port mismatch. U.S. goods trade and international transportation. The Global Cities Initiative. A joint project of Brookings and JPMorgon Chase.

<https://www.brookings.edu/wp-content/uploads/2015/06/brgkssrvygcifreightnetworks.pdf>. HERO ID: 5018559

U.S. EPA (U.S. Environmental Protection Agency). (1996). EPA Unregulated Contaminant Monitoring Rule (UCMR). <https://www.epa.gov/dwucmr>. HERO ID: 6126665

U.S. EPA. (U.S. Environmental Protection Agency). (2006). A framework for assessing health risk of environmental exposures to children (pp. 1-145). (EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363>. HERO ID: 194567

U.S. EPA. (U.S. Environmental Protection Agency). (2011). Exposure Factors Handbook: 2011 edition [EPA Report]. (EPA/600/R-090/052F). Washington, DC.

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252>. HERO ID: 786546

U.S. EPA. (U.S. Environmental Protection Agency). (2012a). Benchmark dose technical guidance. (EPA/100/R-12/001). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. <https://www.epa.gov/risk/benchmark-dose-technical-guidance>. HERO ID: 1239433

U.S. EPA (U.S. Environmental Protection Agency). (2012b). Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11. Washington, DC. <https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface>. HERO ID: 2347246

U.S. EPA (U.S. Environmental Protection Agency). (2013). 1986-2002 inventory update reporting rule data (non-confidential production volume in pounds). Washington, DC: Washington, DC. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. HERO ID: 6114854

U.S. EPA. (U.S. Environmental Protection Agency). (2018a). Application of systematic review in TSCA risk evaluations. (740-P1-8001). Washington, DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf. HERO ID: 4532281

U.S. EPA (U.S. Environmental Protection Agency). (2018b). Basics of TRI reporting. <https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting>. HERO ID: 6181671

U.S. EPA (U.S. Environmental Protection Agency). (2018c). Hazardous Waste Management Facilities and Units. <https://www.epa.gov/hwpermitting/hazardous-waste-management-facilities-and-units>. HERO ID: 5080427

U.S. EPA (U.S. Environmental Protection Agency). (2019a). Proposed designation of 1,1-dichloroethane (CASRN 75-34-3) as a high-priority substance for risk evaluation. Washington, DC. https://www.epa.gov/sites/production/files/2019-08/documents/11-dichloroethane_75-34-3_high-priority_proposeddesignation_082319.pdf. HERO ID: 6305890

U.S. EPA (U.S. Environmental Protection Agency). (2019b). Chemical data reporting (2012 and 2016 non-CBI CDR database). Washington, DC.: Office of Pollution Prevention and Toxics. HERO ID: 6296234

USGS (U.S. Geological Survey). (1991a). USGS Monitoring Data: National Water Quality Monitoring Council [Database]. <http://www.waterqualitydata.us/portal/>. HERO ID: 4571753

USGS (U.S. Geological Survey). (1991b). USGS Monitoring Data: National Water Quality Monitoring Council - Air. <https://www.waterqualitydata.us/portal/#siteType=f%20groundwater%20use&sampleMedia=Water&imeType=csv&dataProfile=activityAll>. HERO ID: 6120444

USGS (U.S. Geological Survey). (1991c). USGS Monitoring Data: National Water Quality Monitoring Council - Groundwater. <https://www.waterqualitydata.us/portal/#siteType=Aggregate%20groundwater%20use&sampleMedia=Water&imeType=csv&dataProfile=activityAll>. HERO ID: 6120028

USGS (U.S. Geological Survey). (1991d). USGS Monitoring Data: National Water Quality Monitoring Council - Sediment. <https://www.waterqualitydata.us/portal/#sampleMedia=Sediment&imeType=csv>. HERO ID: 6120597

USGS (U.S. Geological Survey). (1991e). USGS Monitoring Data: National Water Quality Monitoring Council - Soil. <https://www.waterqualitydata.us/portal/#sampleMedia=Soil&imeType=csv>. HERO ID: 6120844

USGS (U.S. Geological Survey). (1991f). USGS Monitoring Data: National Water Quality Monitoring Council - Surface Water. <https://www.waterqualitydata.us/portal/#siteType=Aggregate%20surface-water-use&sampleMedia=Water&imeType=csv>. HERO ID: 6120448

USGS (U.S. Geological Survey). (1991g). USGS Monitoring Data: National Water Quality Monitoring Council - Tissue. <https://www.waterqualitydata.us/portal/#sampleMedia=Tissue&mimeType=csv>.
HERO ID: 6120843

Wood, PR;Lang, RF;Payan, IL. (1985). Anaerobic transformation, transport, and removal of volatile chlorinated organics in ground water. In *Ground Water Quality*. New York, NY: John Wiley and Sons.
HERO ID: 4140343

APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1. List of Gray Literature Sources for 1,1-Dichloroethane

Source/Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
Australian Government, Department of Health.	NICNAS Assessments (human health, Tier I, II or III)	International Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Cancer Potency Information	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Proposition 65, Cancer	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document
CDC	CDC Biomonitoring Tables	Other US Agency Resources	Database
ECHA	European Union Risk Assessment Report	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	Office of Air: AQS, Annual	US EPA Resources	Database

EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document
EPA	Included in 2011 NATA	US EPA Resources	Assessment or Related Document
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Occupational Health Guideline Documents	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Pocket Guides	Other US Agency Resources	Database
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document

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

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

This appendix provides p-chem information and data found in preliminary data gathering for 1,1-dichloroethane. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the [Proposed Designation of 1,1-Dichloroethane \(CASRN 75-34-3\) as a High-Priority Substance for Risk Evaluation](#) (U.S. EPA (2019) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* ([EPA-HQ-OPPT-2018-0426](#)).

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

Property or Endpoint	Value ^a	Reference	Data Quality Rating
Molecular formula	C ₂ H ₄ Cl ₂	NA	NA
Molecular weight	98.95 g/mol	NA	NA
Physical state	Liquid	NLM, 2018	High
Physical properties	Colorless, oily liquid, ether-like odor	NLM, 2018	High
Melting point	-96.93°C	Rumble, 2018	High
Boiling point	57.4°C	NLM, 2018	High
Density	1.1680 g/cm ³ at 25°C	O'Neil, 2013	High
Vapor pressure	227 mm Hg at 25°C	NLM, 2018	High
Vapor density	3.44 (Air = 1)	NLM, 2018	High
Water solubility	5040 mg/L at 25°C	NLM, 2018	High
Log Octanol/water partition coefficient (Log Kow)	1.79	NLM, 2018	High
Henry's Law constant	0.00562 atm·m ³ /mol	NLM, 2018	High
Flash point	-8.33°C (closed cup); 14°C (open cup)	NLM, 2018	High

Property or Endpoint	Value^a	Reference	Data Quality Rating
Auto flammability	458°C	NLM, 2018	High
Viscosity	0.464 cP at 25°C	Rumble, 2018	High
Refractive index	1.4164	Rumble, 2018	High
Dielectric constant	10.9	NLM, 2018	High

^a Measured unless otherwise noted.

NA = Not applicable

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

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

Property or Endpoint	Value	Reference
Direct Photodegradation	Not expected to be susceptible to direct photolysis by sunlight because 1,1-dichloroethane does not contain chromophores that absorb at wavelengths >290 nm	HSDB (2018) citing Lyman et al. (1990)
Indirect Photodegradation	$t_{1/2} = 39$ days (based on 12-hour day; 1.5×10^6 $\cdot\text{OH}/\text{cm}^3$ from $\cdot\text{OH}$ rate constant of 2.74×10^{-13} $\text{cm}^3/\text{molecule}\cdot\text{second}$ at 25 °C)	PhysProp Database (U.S. EPA 2012c) citing Kwok and Atkinson (1994)
Hydrolysis	$t_{1/2} = 61.3$ years at 25 °C and pH 7	HSDB (2018) citing Jeffers et al. (1989)
Biodegradation	31.1%/25 days reductive dechlorination to mainly chloroethane (14.5%) in sludge (anaerobic water)	ATSDR (2015)
	$t_{1/2} >30$ –60 days (anaerobic soil)	ATSDR (2015); Wood et al. (1985)
	50%/7 days degradation and 19%/7 days evaporation at 5 ppm 1,1-dichloroethane and 29%/7 days degradation and 4%/7 days evaporation at 10 ppm (aerobic static- screening-flask test method with a municipal wastewater sewage inoculum)	HSDB (2018) citing Tabak et al. (1981)
Wastewater Treatment	72% total removal (9% by biodegradation, 62% by volatilization to air, 1% to sludge; estimated) ^b	U.S. EPA (2012b)
Bioconcentration Factor	7 (estimated) ^b	U.S. EPA (2012b)
Bioaccumulation Factor	6.8 (estimated) ^b	U.S. EPA (2012b)
Soil Organic Carbon:Water Partition Coefficient (Log Koc)	1.48	HSDB (2018) citing Sabljic et al. (1995)

Notes: ^aMeasured unless otherwise noted; ^bEPI Suite™ physical property inputs: Log Kow = 1.79, BP = 57.4 °C, MP = -96.9 °C, VP = 227 mm Hg, WS = 5,040 mg/L, BioP = 120, BioA = 30 and BioS = 30, SMILES C(Cl)(Cl)C

$\cdot\text{OH}$ = hydroxyl radical; OECD: Organisation for Economic Co-operation and Development; TG = test guideline; GC = gas chromatography; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand; HPLC = high performance liquid chromatography

Appendix D REGULATORY HISTORY

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

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	1,1-Dichloroethane is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924 , December 30, 2019). Designation of 1,1-Dichloroethane as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	1,1-Dichloroethane manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
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.	One risk report was received for 1,1-Dichloroethane (1993) (U.S. EPA, ChemView. Accessed April 3, 2019).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	One chemical data submission from test rules was received for 1,1-Dichloroethane: Hydrolysis Study. (Chemical Test Rule Data – 1988) (U.S. EPA, ChemView. Accessed April 11, 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	1,1-Dichloroethane (Ethylidene Dichloride) is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of 1/1/1994.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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).	
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 pollutants from the original list leaving 187 at present.	1,1-Dichloroethane is listed as a HAP (42 U.S. Code section 7412).
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 1,1-Dichloroethane to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9)
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 statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The “priority pollutants” specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national	1,1-Dichloroethane is designated as a priority pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations. Under CWA section 304, 1,1-Dichloroethane is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	<p>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.</p>	
<p>Safe Drinking Water Act (SDWA) – Section 1412(b)</p>	<p>Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.</p>	<p>1, 1-Dichloroethane was identified on CCL1 (1998), CCL2 (2005), CCL3 (2016), and CCL4 (2016). Contaminant Candidate List (CCL) 63 FR 10274, March 2, 1998, 70 FR 9071, February 24, 2005, 81 FR 1, January 4, 2016, 81 FR 81099, November 17, 2016.</p>
<p>Safe Drinking Water Act (SDWA) – Section 1445(a)</p>	<p>Every 5 years, EPA must issue a new list of no more than 30 unregulated contaminants to be monitored by PWSs. The data obtained must be entered into the National Drinking Water Contaminant Occurrence Database.</p>	<p>1,1-Dichloroethane was identified in the third Unregulated Contaminant Monitoring Rule (UCMR3), issued in 2012 (77 FR 26071, May 2, 2012).</p>
<p>Resource Conservation and Recovery Act (RCRA) – Section 3001</p>	<p>Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.</p>	<p>1,1-Dichloroethane is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U076 (40 CFR 261.33).</p>
<p>Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103</p>	<p>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.</p>	<p>1,1-Dichloroethane is a hazardous substance under CERCLA. Releases of 1,1-Dichloroethane in excess of 1000 pounds must be reported (40 CFR 302.4).</p>

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	
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.	1,1-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 Regulations		
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 1993, OSHA issued occupational safety and health standards for 1,1-Dichloroethane that included a PEL of 100 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000). OSHA Annotated Table Z-1, Accessed April 16, 2019.
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: <ul style="list-style-type: none"> • 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. 	1,1-Dichloroethane is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials (70 FR 34381, June 14 2005).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Department of Energy	Protective Action Criteria	PAC listed for 1,1-Dichloroethane.

D.1 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 2037 24-Hr AAL ($\mu\text{g}/\text{m}^3$) 1358 Annual AALB ($\mu\text{g}/\text{m}^3$) (Env-A 1400: Regulated Toxic Air Pollutants). Rhode Island 0.6 Annual ($\mu\text{g}/\text{m}^3$) (Air Pollution Regulation No. 22).
State Drinking Water Standards and Guidelines	California (Cal Code Regs. Title 26, § 22-64444), Connecticut - **A MCL has not been established for this chemical (Conn. Agencies Regs. § 19-13-B102), Florida (Fla. Admin. Code R. Chap. 62-550), 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).
State Water Pollution Discharge Programs	Illinois has adopted water pollution discharge programs which categorize 1,1-dichloroethane as an “halogenated organic chemical,” as applicable to the process wastewater discharges resulting from the manufacture of bulk organic chemicals (35 Ill. Adm. Code 307-2406).
State PELs	California (PEL of 110 ppm (Cal Code Regs. Title 8, § 5155) Hawaii PEL: 100 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 1,1-Dichloroethane, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407).
Other	California listed 1,1-Dichloroethane on Proposition 65 in 1990 due to cancer risk (Cal Code Regs. Title 27, § 27001). 1,1-Dichloroethane is listed as a Candidate Chemical under California’s Safer Consumer Products Program established under Health and Safety Code § 25252 and 25253 (California, Candidate Chemicals List. Accessed April 18, 2019) (CDTSC, 2017). California lists 1,1-Dichloroethane as a designated priority chemical for biomonitoring under criteria established by California SB 1379 (CDPH, 2015) (Accessed February 2019). 1,1-Dichloroethane is on the MA Toxic Use Reduction Act (TURA) list of 1994 (301 Code Mass. Regs. § 41.03).

D.2 International Laws and Regulations

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

Country/Tribe/ Organization	Requirements and Restrictions
Canada	Canada requires notification for 1,1-Dichloroethane under the New Substances Notification Regulations (Chemicals and Polymers) so that health and ecological risks can be assessed before the substance is manufactured or imported into Canada above threshold quantities, however they are subject to fewer information requirements. Canada Gazette Part I, Vol. 142, No. 25, June 21, 2008.
European Union	Not registered in the EU Accessed April 17, 2019.
Australia	<p>1,1-Dichloroethane can be manufactured or imported into Australia for commercial purposes without notifying the Australian government, provided that the Australian importer/manufacturer is currently registered with the Australian government.</p> <p>1,1-Dichloroethane was assessed under Human Health Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). No specific Australian use, import, or manufacturing information has been identified. (NICNAS, 2017, Ethane, 1,1-dichloro-: Human health tier II assessment Accessed April 17, 2019).</p>
Japan	<p>1,1-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) Industrial Safety and Health Act (ISHA) (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]). (Accessed April 17, 2019).</p>
Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Germany, Hungary, Ireland, Italy, Japan, Latvia New Zealand, Poland, Romania, Singapore, South Korea, Spain, Sweden, Switzerland, The Netherlands, Turkey, United Kingdom	Occupational exposure limits for 1,1-Dichloroethane (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database). (Accessed April 18, 2019).

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

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

Various methods for manufacture of 1,1-Dichloroethane are discussed in the literature. 1,1-Dichloroethane may be produced by chlorination of ethane or chloroethane, via thermal chlorination, photochlorination, or oxychlorination. Alternatively, 1,1-Dichloroethane can be produced by adding hydrogen chloride to acetylene (Dreher, et al., 2014). In the 2016 CDR, one company reported manufacturing 1,1-Dichloroethane (U.S. EPA, 2016).

E.1.1.2 Import

Commodity chemicals such as 1,1-Dichloroethane may be imported into the United States in bulk via water, air, land, and intermodal shipments (Tomer, 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.

1,1-Dichloroethane may be imported neat or as a component in a formulation. In the 2016 CDR, no companies reported importing 1,1-Dichloroethane.

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant or Intermediate

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

E.1.2.2 Recycling

EPA did not identify 1,1-dichloroethane specific information for recycling; however, a general description of waste solvent recovery processes was identified. Waste solvents are generated when the solvent stream becomes contaminated with suspended and dissolved solids, organics, water or other substance. Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling (U.S. EPA, 1980a).

E.1.3 Uses

E.1.3.1 Laboratory Use

Sources indicate 1,1-Dichloroethane use as laboratory reference standard (SigmaAldrich, undated; Restek, 2020). EPA plans to further investigate the specific laboratory use activities of 1,1-Dichloroethane during the risk evaluation.

E.1.4 Disposal

Each of the conditions of use of 1,1-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 1,1-dichloroethane that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

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

1,1-Dichloroethane is a U-listed hazardous waste under code U076 under RCRA; therefore, discarded, unused pure and commercial grades of 1,1-dichloroethane are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)).

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

E.2 Sources Containing Potentially Relevant Data or Information

EPA presents below examples of occupational exposure-related information from the preliminary data gathering. EPA plans to consider this information and data in combination of other data and methods for use in the risk evaluation. Note there are no OSHA Chemical Exposure and Health Data (CEHD) or NIOSH Health Hazard Evaluations for 1,1-dichloroethane within the last ten years.

Table_Apx E-1. Summary of Industry Sectors with 1,1-Dichloroethane Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted since 1984

SIC Code	SIC Description	Number of Data Points
1731	Electrical Work	4
3559	Special Industry Machinery, Not Elsewhere Classified	1
3842	Orthopedic, Prosthetic, and Surgical Appliances and Supplies	3
4212	Local Trucking Without Storage	15
8351	Child Day Care Services	1

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

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 manufacturing	Domestic manufacturing	Manufacture of 1,1-Dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 1-dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (230 mmHg at 25C), 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 (230 mmHg at 25C), 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	
Processing	As a reactant	Intermediate in all other basic organic chemical manufacturing	Processing of organic and other chemical products	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 1-dichloroethane	
				Vapor	Inhalation	Worker	Yes	Due to high volatility (230 mmHg at 25C), 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 (230 mmHg at 25C), EPA plans to evaluate inhalation exposure to vapor.		
	Recycling	Recycling		Recycling 1,1-dichloroethane	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 1-dichloroethane
					Vapor	Inhalation	Worker	Yes	Due to high volatility (230 mmHg at 25C), 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 (230 mmHg at 25C), 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
Distribution in Commerce	Distribution in commerce	Distribution in commerce	Distribution of bulk shipments of 1,1-dichloroethane and formulated products	Liquid Contact, Vapor	Dermal, Inhalation	Worker, ONU	Yes	EPA plans to analyze activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, commercial use, disposal) rather than as a single distribution scenario.
Commercial Use	Other use	Laboratory and Analytical Uses	Exposures occurring during; Laboratory and Analytical Uses	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 1-dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (230 mmHg at 25C), 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 (230 mmHg at 25C), 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
Disposal	Disposal	Waste Handling, Treatment, and Disposal	Exposures occurring during; disposal	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing 1, 1-dichloroethane
				Vapor	Inhalation	Worker	Yes	Due to high volatility (230 mmHg at 25C), 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 (230 mmHg at 25C), EPA plans to evaluate inhalation exposure to vapor.

Appendix G SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR ENVIRONMENTAL RELEASES AND WASTES

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

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate ¹¹	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	No	1,1-Dichloroethane is a HAP. Because stationary source releases of 1,1-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 and Terrestrial Receptors	Yes	This chemical is expected to be released to surface water
Direct release into surface water and partitioning to sediment and bioaccumulation into edible aquatic species			Oral Inhalation	General Population	Yes		

¹¹ The exposure pathways, exposure routes and hazards plans to evaluate are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of 1,1-dichloroethane in exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Categories	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate ¹¹	Rationale
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	No	The drinking water exposure pathway for 1,1-dichloroethane is currently addressed in the SDWA regulatory analytical process for public water systems.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	Yes	Although 1,1-dichloroethane is a volatile chemical and not expected to sorb onto biosolids, EPA plans to analyze this pathway. However, it is expected to be a minor pathway of exposure to the general population and terrestrial species.
				TBD	Terrestrial receptors	Yes	
			Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No
	TBD	Aquatic and Terrestrial Receptors			No		
	Solid and Liquid Wastes	Hazardous, Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral (e.g., ingestion) Dermal Inhalation	General Population	No	1,1-dichloroethane is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
				TBD	Aquatic and Terrestrial Receptors	No	