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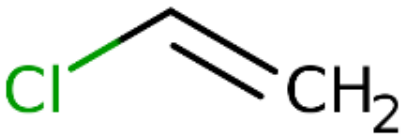
Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation

CASRN 75-01-4



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Supporting information can be found in public dockets EPA-HQ-OPPT-2023-0601 and EPA-HQ-OPPT-2018-0448.

Disclaimer

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ABBREVIATIONS AND ACRONYMS

ADME	Absorption, distribution, metabolism, and excretion
AEGL	Acute Exposure Guideline Level
AICIS	Australian Industrial Chemicals Introduction Scheme
ATSDR	Agency for Toxic Substances and Disease Registry
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CAA	Clean Air Act
CADTSK	California Department of Toxic Substances Control
CalEPA	California Office of Environmental Health Hazard Assessment
CARB	California Air Resources Board
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential business information
CDR	Chemical Data Reporting
CFR	Code of Federal Regulations
CSF	Cancer slope factor
CWA	Clean Water Act
ECHA	European Chemicals Agency
EC	European Commission
EC_x	Effective Concentration for x percent of exposed organisms
ECOSAR	Ecological Structure Activity Relationships
EHC	Environmental health criteria
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FR	Federal Register
GHS	Globally Harmonized System
HAWC	Health Assessment Workplace Collaborative
HBV	Health Based Value
HERO	Health and Environmental Research Online (database)
Hg	Mercury
HHS	U.S. Department of Health and Human Services
HQ	Headquarters
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IRIS	Integrated Risk Information System
IUR	Inhalation Unit Risk
K_{OC}	Organic carbon: water partition coefficient
K_{OW}	Octanol: water partition coefficient
LC_{10}	Lethal concentration of 10% test organisms
LC_{50}	Lethal concentration of 50% test organisms
LD_{50}	Lethal dose of an ingested substance that kills 50% of test organisms
LEC	Lowest effective concentration
LOEC	Lowest observed effect concentration
MAC	Maximum Acceptable Concentration
MCL	Maximum Contaminant Level

MLE	Maximum Likelihood Estimate
MRL	Minimum Risk Level
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standard and Technology
NITE	National Institute of Technology and Evaluation
NLM	National Library of Medicine
NOEC	No observed effect concentration
NPDES	National Pollutant Discharge Elimination System
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRC	National Research Council
NTP	National Toxicology Program
OECD	Organization for Economic Co-operation and Development
OEHHA	California Office of Environmental Health Hazard Assessment
OEL	Occupational exposure limit
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OQD	Overall Quality Determination
OSHA	Occupational Safety and Health Administration
PECO	Population, exposure, comparator, and outcome
PESO	Pathways and processes or population, exposure, setting or scenario, and outcomes
PESS	Potentially exposed or susceptible subpopulation(s)
PHG	Public Health Goal
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PPRTV	Provisional Peer Reviewed Toxicity Values
RCRA	Resource Conservation and Recovery Act
RfC	Reference Concentration
RfD	Reference Dose
SDS	Safety data sheet
SIDS	Screening Information Data Set
TIAB	Title and abstract
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UCL	Upper Confidence Limit
URF	Unit Risk Factor

Proposed Designation and Rationale

Proposed Designation

EPA proposes to designate vinyl chloride as a High-Priority Substance, under the Toxic Substances Control Act (TSCA) section 6(b)(2)(B) and implementing regulations (40 CFR 702.9). The basis for this proposed designation is the result of EPA's screening level review of vinyl chloride against the prioritization considerations identified in TSCA section 6(b)(1)(A) and implementing regulations cited above: the chemical substance's exposure and hazard potential, the chemical substance's persistence and bioaccumulation, potentially exposed or susceptible subpopulations (PESS), storage near significant sources of drinking water, the conditions of use or significant changes in the conditions of use of the chemical substance, the volume or significant changes in the volume of the chemical substance manufactured or processed, and other risk-based criteria that EPA determines to be relevant.

Production Volume or Significant Changes in Production Volume

The annual national aggregate production volume of vinyl chloride is presented in Table 2-1, which includes the consideration of both confidential business information (CBI) and non-CBI reported production volume information to chemical data reporting (CDR). Since 1986, the annual national aggregate production volume of vinyl chloride has been over 1 billion pounds. Since 2011, annual production volume has been reported above 10 billion pounds. These data suggest that, given the relatively steady amount of vinyl chloride produced in the last decade, there is potential for people and the environment to be exposed to vinyl chloride.

Conditions of Use or Significant Changes in Conditions of Use

EPA uses reasonably available information, such as data reported to CDR, to support the TSCA existing chemicals program for chemical prioritization, risk evaluation, and risk management. In addition to CDR, EPA reviewed vinyl chloride uses from other publicly available data sources, including public comments received following initiation. This information allows EPA to develop an understanding of the types, amount, end uses, and possible exposure to chemicals in commerce. The conditions of use of vinyl chloride demonstrate the continued manufacturing, distribution, processing, use (industrial, commercial and consumer) and disposal of vinyl chloride since 2016. While there have been some changes in use information reported to CDR in recent cycles, most reported conditions of use have remained unchanged between the 2016 and 2020 reporting periods. In the 2016 reporting period, vinyl chloride was identified as a reactant intermediate in adhesive and industrial gas manufacturing. It was also identified as used in repackaging as an intermediate in plastic material and resin manufacturing, as well as a laboratory chemical in chemical product and preparation manufacturing. In the 2020 reporting period, vinyl chloride was identified as a reactant as an intermediate in petrochemical manufacturing, as a monomer in plastic material and resin manufacturing and as being incorporated into formulation, mixture, or reaction product as a binder in plastics material and resin manufacturing. Commercial uses as a binder and intermediate in plastic and rubber products were also identified. EPA is seeking additional information from the public on the uses presented in Section 2.3.

Potentially Exposed and Susceptible Subpopulations

EPA is required to account for sensitive subpopulations identified by EPA, referred to by TSCA as potentially exposed or susceptible subpopulation(s) (PESS), when implementing the TSCA existing chemicals program for chemical prioritization, risk evaluation, and risk management. EPA conducted a screening review of reasonably available information on factors that may make certain groups more vulnerable to adverse effects. These factors include lifestage, occupational exposures, certain consumer exposures, nutrition, lifestyle activities, and proximity to facilities that manufacture or process a chemical substance. For prioritization, EPA also reviewed whether children may be exposed to vinyl

chloride, and EPA identified vinyl chloride use in several children's products and articles intended for children as a result of the Agency's screening review in Section 2.4. Based on this information, EPA believes children, women of reproductive age, consumers, workers, and overburdened communities may be PESS for vinyl chloride.

Persistence and Bioaccumulation

EPA determines the characteristics of a chemical to help understand how it behaves in the environment. A chemical's properties dictate its environmental fate- whether it is likely to be found in the air, the water, or the soil and how long it will stay there. These properties also help EPA predict how people and biota are likely to be exposed and whether or not the chemical will accumulate in the bodies of different species. EPA reviewed databases and previously conducted assessments to identify information for physical and chemical properties and environmental fate endpoints to characterize the potential for vinyl chloride to persist in the environment or bioaccumulate (Section 2.5). Based on this information, vinyl chloride is likely to be persistent in water and sediment and is not expected to bioaccumulate or bioconcentrate in aquatic organisms.

Storage Near Significant Sources of Drinking Water

Drinking water is a possible source of chemical exposure and EPA is required to screen whether or not chemicals in the TSCA prioritization process are stored near significant sources of it. EPA identified facilities reporting vinyl chloride to the TRI in 2022 near potential sources of drinking water (Section 2.6) using public water systems data stored in EPA's Safe Drinking Water Information System Federal Data Warehouse (U.S. EPA, 2022a). EPA determined whether TRI reporting facilities are located inside defined source water protection areas or within four miles of wellheads to identify potential storage of benzenamine near sources of surface water and groundwater, respectively. As shown in Table 2-4, from among 33 total TRI facilities that stored vinyl chloride on-site in 2022, EPA identified three facilities within source water protection areas and 28 facilities that were within four miles of wellhead protection points.

Potential Hazard

In the TSCA existing chemicals program, through the prioritization process, EPA determines whether or not a chemical will undergo risk evaluation by making a priority designation. To support this proposed designation for vinyl chloride, EPA identified potential hazards to humans and ecological receptors, including plants, birds, other wildlife, and aquatic life. Should this chemical undergo risk evaluation, hazard information, along with exposure information, will be used to characterize risk. As described in Section 2.7.1, EPA identified potential environmental hazards, such as mortality, growth, and developmental effects for aquatic and terrestrial organisms, resulting from vinyl chloride exposure. Additionally, as described in Section 2.7.2, EPA identified potential human health hazards, such as carcinogenic and genotoxic effects, resulting from exposure to vinyl chloride based on epidemiological and animal toxicological information. Previous risk assessments did not describe acute toxicity qualitative risk classifications related to vinyl chloride exposure. Rather, all reported data was quantitative, however EPA would welcome additional information regarding toxicological effects resulting from chronic exposure to vinyl chloride during the upcoming public comment period.

Potential Exposure

EPA has identified potential occupational, consumer, and general population exposure to vinyl chloride (Section 2.8). Due to annual releases of vinyl chloride to air, water, and land (Table 2-6, Table 2-7 and Table 2-8), the presence of vinyl chloride in consumer products (Table 2-3), and monitoring information demonstrating the presence of vinyl chloride in surface water, soil, groundwater, leachate, wastewater, ambient air (Section 2.8.4.1), EPA has identified that various human populations (*e.g.*, general

population, workers, consumers) and ecological receptors may be exposed to vinyl chloride via various exposure pathways and routes associated with the conditions of use.

Conclusion

Therefore, after screening the reasonably available information for vinyl chloride against the prioritization considerations, EPA preliminarily finds that vinyl chloride may present an unreasonable risk of injury to health and/or the environment, including PESS, because of the potential hazards and potential routes of exposure under the condition of use. Should vinyl chloride be designated as a High-Priority Substance, additional information may be identified and considered for use in the risk evaluation during the scoping process. TSCA section 6(b)(4)(D) and implementing regulations require that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and PESS that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. In addition, a draft scope document is to be published pursuant to 40 CFR 702.41.

1 INTRODUCTION

Under TSCA section 6(b), after initiating prioritization for a chemical substance, the U.S. Environmental Protection Agency (EPA) must designate the chemical substance as a High-Priority Substance for risk evaluation or a Low-Priority Substance for which risk evaluation is not warranted at the time. In TSCA section 6(b)(1)(B) and EPA's implementing regulations (40 CFR 702.3), a High-Priority Substance for risk evaluation is defined as a chemical substance EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as relevant by EPA. A Low-Priority Substance is defined as a chemical substance EPA concludes, based on sufficient information and without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

On December 18, 2023, EPA issued a public notice (88 FR 87423) initiating the prioritization process for five chemical substances, including vinyl chloride. Vinyl chloride (CASRN 75-01-4), also commonly referred to by its chemical synonym, chloroethene, is a colorless gas used almost exclusively to manufacture polyvinyl chloride (PVC) (ATSDR, 2023; Pampell, 2023). Vinyl chloride is included in EPA's TSCA Work Plan for Chemical Assessments (U.S. EPA, 2014). Before proposing to designate a chemical substance's prioritization status, under EPA's regulations at 40 CFR 702.9 and pursuant to TSCA section 6(b)(1)(A), EPA will generally use reasonably available information, including relevant information received from the public, to screen the candidate chemical substance under its conditions of use against the following criteria and considerations:

- the chemical substance's production volume or significant changes in production volume (Section 2.2);
- conditions of use or significant changes in the conditions of use of the chemical substance (Section 2.3);
- PESS (Section 2.4);
- persistence and bioaccumulation (Section 2.5);
- storage near significant sources of drinking water (Section 2.6);
- the potential hazard (Section 2.7) and potential exposure (Section 2.8) of the chemical substance; and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority (Section 2.9).

The screening review of reasonably available information for vinyl chloride against these criteria and considerations will inform a finding of whether vinyl chloride may present unreasonable risk because of a potential hazard and a potential route of exposure under the conditions of use. That preliminary finding, proposed designation, and associated rationale can be found in the Proposed Designation and Rationale section. Based on the information in this proposed designation document, EPA proposes that vinyl chloride be designated as a High-Priority Substance. EPA will take comment on this proposed designation for 90 days before finalizing its designation of vinyl chloride (EPA-HQ-OPPT-2018-0448). Relevant information received from the public and other information as appropriate will be considered for the final designation. As per the Evidence Maps in 2.9Appendix C, EPA particularly welcomes information regarding potential hazards to terrestrial vertebrates and fungi, as well as human biomonitoring exposure information.

In developing this proposed designation and throughout the prioritization process, EPA has engaged and will continue to engage the public to obtain information relevant to vinyl chloride. On December 18,

2023, EPA initiated a 90-day public comment period, during which EPA received information about conditions of use for vinyl chloride, including manufacturing, processing, and consumer/commercial uses and products; release and exposure information; and potential hazards of vinyl chloride, as well as previously conducted hazard assessments. In February 2024, EPA hosted a public webinar to discuss prioritization efforts and data gathering authorities utilized to identify potentially relevant information for the five chemical substances currently undergoing prioritization. Following this webinar, there were follow-up discussions with stakeholders representing different sectors. During these meetings, comments and information submitted during the first public comment period were discussed to further EPA's understanding of the provided information and its relevance to this action. See docket ID number EPA-HQ-OPPT-2023-0601 for additional information on the information presented during the February 2024 public webinar (presentation materials and transcript). Final designation of the chemical substance as a High-Priority Substance would immediately initiate the risk evaluation process described in EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (40 CFR 702).

This proposed designation document also contains additional information EPA believes will help inform the scope of the risk evaluation for vinyl chloride if it is designated as a High-Priority Substance. These additional data elements are considered preliminary draft products and are not intended to meet the requirements for scoping pursuant to 40 CFR 702.39(b). EPA expects to use information gained from public comments on these data elements to better inform and refine a draft scope of the risk evaluation if vinyl chloride is designated as a High-Priority Substance. For example, draft preliminary conceptual models for vinyl chloride are included in Section 2.8, Section 2.8.3, and Section 2.8.4. A draft preliminary regulatory history for vinyl chloride is included in Appendix A. Appendix B and Appendix C include a preliminary description of the reasonably available information used to perform the screening review for this proposed designation and that would also help inform the draft scope of the risk evaluation for vinyl chloride, if it is designated as a High-Priority Substance. These two appendices include a description of the searching methods (Appendix B) and the screening methods (Appendix C) EPA employed for vinyl chloride. Additional information regarding the process used to identify potentially relevant discipline-specific information for vinyl chloride is available in the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b). The proposed designation also includes a preliminary lifecycle diagram (Section 2.3.2), additional information about the physical and chemical properties (Appendix D), and environmental fate and transport information (Appendix E) for vinyl chloride.

2 PROPOSED DESIGNATION OF VINYL CHLORIDE

2.1 Screening Review of the Reasonably Available Information for Vinyl Chloride

EPA's Office of Pollution Prevention and Toxics (OPPT) applies systematic review methods in the identification and review of reasonably available information in a manner that is objective, unbiased, and transparent for the purpose of screening the candidate chemical substance under its conditions of use against criteria and considerations listed in Section 1. EPA uses scientific information that is consistent with the best available science as required by the scientific standards in TSCA section 26(h) (15 U.S.C. 2625[h])). EPA used the TSCA systematic review process described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) (hereinafter referred to as "2021 Draft Systematic Review Protocol") to identify relevant information that informed the prioritization considerations set forth in 40 CFR 702.9. Based upon recommendations by the Scientific Advisory Committee on Chemicals regarding the 2021 Draft Systematic Review Protocol, EPA implemented improvements to its systematic review approaches and data gathering during the prioritization process. Specifically, EPA has incorporated additional data sources such as assessments published by other government agencies to identify potential hazards and exposures; clarified terminology to increase transparency in the systematic review process; and is presenting interactive literature inventory trees and evidence maps to better depict data sources containing potentially relevant information.

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this proposed designation document for vinyl chloride. Chemical-specific literature searches and data source screening for relevance were conducted as described in Appendix B and Appendix C, respectively, for all disciplines (*i.e.*, physical and chemical properties, environmental fate and transport properties, occupational exposure and environmental release, general population, consumer and environmental exposure, environmental hazard, and human health hazard) (U.S. EPA, 2021) from the following general categories of sources:

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

While conducting a screening review of previous assessments identified to be potentially relevant for vinyl chloride, EPA identified additional primary data sources that were considered using the systematic review approach described in 2.9Appendix B. Public comments received during the public comment period following the initiation of prioritization were also considered for the proposed designation status of vinyl chloride. Note that information described in this document is as reported by the authors of the identified potentially relevant data sources, therefore some data sources may have different or conflicting conclusions for a given topic area. For the final designation status of vinyl chloride, EPA will

[1] *Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use, considering the deadlines specified in TSCA section 6(b) for prioritization and risk 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 702.3).

consider additional relevant information received through public comments on this proposed designation document as well as data call-in authorities (*e.g.*, TSCA section 8(d)), when applicable. Potentially relevant chemical-specific information received during the public comment period of data call-in authorities may also undergo systematic review approaches described in Appendix B and Appendix C.

2.2 Production Volume or Significant Changes in Production Volume

EPA considered current volume or significant changes in volume of vinyl chloride using information reported by manufacturers (including importers). EPA assembled reported information for years 1986 through 2019 on the production volume reported under the Chemical Data Reporting (CDR) rule, formerly known as the Inventory Update Rule (IUR) (40 CFR Part 711).

EPA considered both CBI and non-CBI reported production volume information reported to CDR and the annual national aggregate production volume, which is presented as a range to protect individual site production volumes that are CBI (Table 2-1). The screening review of production volume information indicates that since 1986, the annual national aggregate production volume of vinyl chloride has remained above 1 billion pounds. Since 2011, production volume has been reported above 10 billion pounds, suggesting a consistent source of potential exposure to vinyl chloride.

Table 2-1. 1986-2019 National Aggregate Production Volume Data for Vinyl Chloride

Year	Production Volume (lbs)
1986	> 1B[a]
1990	> 1B
1994	> 1B
1998	> 1B
2002	> 1B
2006	> 1B
2011	16,713,648,476
2012	10B - <20B
2013	10B - <20B
2014	10B - <20B
2015	10B - <20B
2016	10B - <20B
2017	10B - <20B
2018	10B - <20B
2019	10B - <20B
[a] B = billion	

2.3 Conditions of Use or Significant Changes in Conditions of Use

Under TSCA, the conditions of use of a chemical substance are “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” (15 U.S.C. 2602(4); 40 CFR 702.3). The conditions of use or significant changes in conditions of use considered for the proposed designation of vinyl chloride were assembled from use information from CDR as well as other sources. Reporting requirements for the 2016 and 2020 CDR reporting cycles were different, as the function of the chemical in specific commercial and consumer uses were required beginning in 2020. Therefore, the category and subcategory descriptions in Table 2-2 combine the use description and chemical function

for commercial and consumer uses. EPA consulted a variety of other sources, including published literature, company websites, and government and commercial trade databases and publications, to identify additional readily available information regarding the use of vinyl chloride. Such additional information is organized in a separate table due to differences in how information was reported by the various data sources as compared to CDR (Table 2-3).

The categories and subcategories of conditions of use EPA identified from information reported to CDR for the proposed designation of vinyl chloride are presented in Table 2-2. It is difficult to discern whether there are significant changes in conditions of use for vinyl chloride based on reported information to CDR in 2016 and 2020 because guidance regarding the reporting of categories and subcategory information was updated between these periods. This update may have resulted in the use information being reported differently in 2020 compared to 2016, possibly leading to inaccurate implications that some uses may have commenced or ceased in recent years. Most reported conditions of use in CDR for vinyl chloride have remained unchanged between the 2016 and 2020 reporting periods, though some changes have been identified. In the 2016 reporting period, vinyl chloride was identified as a reactant intermediate in adhesive and industrial gas manufacturing. It was also identified as used in repackaging as an intermediate in plastic material and resin manufacturing, as well as a laboratory chemical in chemical product and preparation manufacturing. One consumer use was identified in plastic and rubber products not covered elsewhere. None of these uses were reported again in 2020, so they may no longer be occurring or are not occurring at a threshold requiring CDR reporting. In the 2020 reporting period, vinyl chloride was identified as a reactant as an intermediate in petrochemical manufacturing, as a monomer in plastic material and resin manufacturing, and as being incorporated into formulation, mixture, or reaction product as a binder in plastics material and resin manufacturing. Commercial uses as a binder and intermediate in plastic and rubber products were also identified. These all may be new uses for vinyl chloride since the 2016 reporting cycle, uses that increased since the 2016 reporting cycle and so meet CDR reporting thresholds, or reporting discrepancies. EPA is presenting information reported to CDR from both reporting cycles *as reported* to ensure all conditions of use information is captured and reduce any mischaracterization of the reported information.

In addition to the CDR information, EPA reviewed the uses of vinyl chloride from other publicly available data sources, such as the Toxics Release Inventory (TRI), Discharge Monitoring Reports (DMRs), National Emissions Inventory (NEI), and Safety Data Sheets (SDS), Chemical Exposure Knowledgebase (ChemExpo), EPA Chemical and Product Categories (CPCat) data (U.S. EPA, 2019), and the High Priority Chemicals Data System (HPCDS). EPA also received public comments which can be found in docket ID number EPA-HQ-OPPT-2023-0601 containing potentially relevant information regarding the use of vinyl chloride. The relevant information is summarized in Table 2-3.

Table 2-2 and Table 2-3 represent the initial information EPA has collected regarding the conditions of use based on CDR reporting and other sources for the purpose of prioritization. EPA plans to review and incorporate additional information on conditions of use, as relevant, received during the public comment period into the scope of the risk evaluation, should vinyl chloride be designated as a High-Priority Substance. As a result, EPA is seeking additional relevant information from the public during this second public comment period to clarify any inconsistencies regarding the condition of use information identified by EPA thus far.

Table 2-2. Information Reported to CDR Regarding Conditions of Use of Vinyl Chloride

Life Cycle Stage[a]	Category[b]	Subcategory[c]	Reference(s)
Manufacture	Domestic manufacture	Domestic manufacture	2016 CDR; 2020 CDR
	Import	Import	2016 CDR; 2020 CDR
Processing	As a reactant	Intermediate in – adhesive manufacturing – industrial gas manufacturing – plastic material and resin manufacturing	2016 CDR; 2020 CDR
		Intermediate in petrochemical manufacturing	2020 CDR
		Monomer in plastic material and resin manufacturing	2020 CDR
	Incorporating into formulation, mixture or reaction product	Intermediate in petrochemical manufacturing	2016 CDR; 2020 CDR
		Binder in plastics material and resin manufacturing	2020 CDR
	Incorporating into articles	Wire and cable in primary metal manufacturing	2016 CDR; 2020 CDR
	Repackaging	Intermediate in plastic material and resin manufacturing	2016 CDR
		Laboratory chemical in all other chemical product and preparation manufacturing	2016 CDR
	Recycling	Recycling	2016 CDR; 2020 CDR
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Commercial use	Building/construction materials not covered elsewhere	Cable and wire manufacturing	2016 CDR; 2020 CDR
	Petrochemical manufacturing	Intermediate	2016 CDR; 2020 CDR
	Plastic and rubber products not covered elsewhere	Binder	2016 CDR; 2020 CDR
		Intermediate	
Consumer use	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	2016 CDR
Disposal	Disposal	Disposal	

[a] Life cycle stage use definitions (40 CFR 711.3)

- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.

Life Cycle Stage[a]	Category[b]	Subcategory[c]	Reference(s)

- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.

[b] These categories of conditions of use appear in the preliminary life cycle diagram, reflect CDR codes, and broadly represent conditions of use of vinyl chloride in industrial and/or commercial settings.
[c] These subcategories reflect more specific conditions of use of vinyl chloride.

Table 2-3. Information Reported by Other Sources Regarding Conditions of Use of Vinyl Chloride

Use/Activity	Reference
Other basic inorganic chemical manufacturing	U.S. EPA (2022b)
Unlaminated plastics film and sheet (except packaging) manufacturing	U.S. EPA (2022b)
Processing as a reagent – synthetic/analytical chemistry and laboratory chemical	AirGas (2022), LGC Limited (2019a), LGC Limited (2019b), Linde Inc (2022), ECHA (2023c), Restek Corp (2023), Supelco (2024a), Supelco (2024b).
Solvent – industrial surface coating and solvent use	U.S. EPA (2020)
Industrial process – non-ferrous metals	U.S. EPA (2020)
Industrial process – pulp and paper	U.S. EPA (2020)
Solvent – degreasing	U.S. EPA (2020)
Industrial process – ferrous metals	U.S. EPA (2020)
Consumer products – adhesives and sealants, paints and coatings, furniture and furnishings, floor coverings	U.S. EPA (2024a)
Consumer products – apparel, toys, fabric, furniture and furnishings, and paints and coatings	IC2 (2024)
Consumer products reported from public comments – next generation climate-friendly refrigerants and blowing agents; vinyl wallcovering, PVC; agricultural and food packaging, and medical devices; medical products, vinyl roofing, automotive upholstery, instrument and door panels, convertible tops, swimming pool and industrial liners, upholstery for furniture – contract, home, juvenile, home décor, sporting goods, luggage, briefcases, and accessories, commercial and residential wallcovering, garments and footwear; wet-applied coatings, including adhesives, glues, and inks; childrens products	(EPA-HQ-OPPT-2018-0448-0014; EPA-HQ-OPPT-2018-0448-0016; EPA-HQ-OPPT-2018-0448-0018; EPA-HQ-OPPT-2018-0448-0021; EPA-HQ-OPPT-2018-0448-0025)

The categories and subcategories of conditions of use from Table 2-2 are reflected in the preliminary life cycle diagram (Figure 2-1) and conceptual models shown in Section 2.8. In general, information

reported to CDR are initially used to identify conditions of use due to EPA's ability to discern reporting entity-specific information and historical knowledge of connecting this information to conditions of use. However, information from public comments, stakeholder engagement and additional sources of publicly available relevant information are also routinely considered for determining conditions of use (Table 2-3). EPA plans to integrate the information in in Table 2-3 with the categories and subcategories of conditions of use in Table 2-2 and plans to incorporate these activities, as relevant, into the life cycle diagram (Figure 2-1) and conceptual models (Section 2.8) during the scoping process should vinyl chloride be designated as a High-Priority Substance.

2.3.1 Activities That May Be Excluded

TSCA section 6(b)(4)(D) requires EPA, during scoping, to identify the conditions of use of a chemical substance the Administrator expects to consider in a risk evaluation. In accordance with TSCA section 3(4)'s definition of conditions of use, EPA determines the circumstances appropriately considered to be conditions of use for a particular chemical substance.[2]

TSCA section 3(2) excludes from the definition of "chemical substance," among other things, "any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [FFDCA] [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" as well as "any pesticide (as defined in FIFRA [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide."

If vinyl chloride is designated as a High-Priority Substance, EPA plans to conduct a jurisdictional analysis during scoping on specific activities to determine if they are excluded from the definition of a chemical substance under TSCA section 3(2).

2.3.2 Overview of Conditions of Use and Preliminary Life Cycle Diagram

Figure 2-1 provides the preliminary life cycle diagram for vinyl chloride. The life cycle diagram is a graphical representation of the various life stages of the industrial, commercial, and consumer use categories of vinyl chloride. The preliminary life cycle diagram includes functional use codes for industrial uses and product categories for commercial and consumer uses.

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

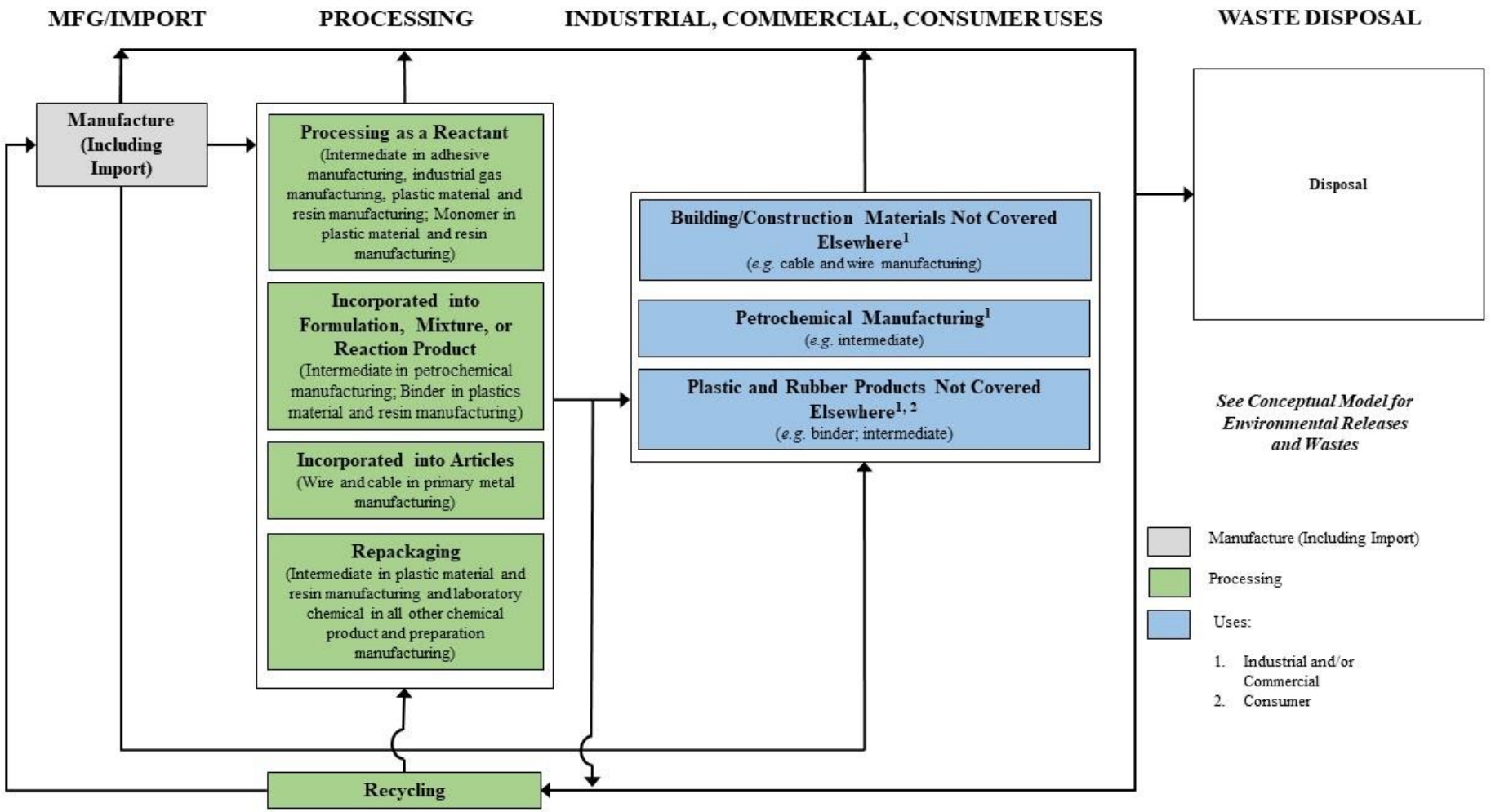


Figure 2-1. Preliminary Life Cycle Diagram for Vinyl Chloride

Distribution in commerce is not explicitly included in the life cycle diagram because its activities are associated with other conditions of use. Unloading and loading activities are associated with other conditions of use. The information in the preliminary life cycle diagram is grouped according to the 2016 and 2020 CDR processing codes and use categories from Table 2-2.

2.4 Potentially Exposed or Susceptible Subpopulations

Potentially exposed or susceptible subpopulation (PESS) 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" (15 U.S.C. 2602(12)). 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).

EPA conducted a screening review of reasonably available information on factors that may make population groups of concern more vulnerable to adverse effects (*e.g.*, unique pathways; behavioral, biological, or environmental factors that increase susceptibility), identifying unique considerations for subsistence populations when relevant and following best practices from the Agency's *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (U.S. EPA, 2016). EPA has preliminarily identified a list of specific PESS factors that may contribute to a group having increased exposure or biological susceptibility. These factors include lifestage, occupational exposures, certain consumer exposures, nutrition, lifestyle activities, and proximity to facilities that manufacture or process a chemical substance.

For the proposed designation, EPA analyzed processing and use information included on CDR Form U. These data provide an indication of whether children or other PESS may be exposed. EPA also used human health hazard information to screen against the PESS criterion for prioritization. During the screening review of data sources identified using the systematic review approaches described in Appendix C, information was identified that may be used to inform potential PESS considerations such as: lifestage (*e.g.*, children and women of reproductive age), and site-related information (*i.e.*, information regarding either a specific site or the surrounding area near a site) associated with vinyl chloride. Based on this information, EPA believes children, women of reproductive age, consumers, workers, and overburdened communities may be PESS for vinyl chloride. If vinyl chloride is designated as a High-Priority Substance, EPA will continue to use the reasonably available information during the scoping process to identify those PESS the Agency plans to assess in the risk evaluation.

Children

EPA used multiple sources to identify uses in products and articles intended for children for vinyl chloride. EPA did not identify products intended for children as reported to 2016 and 2020 CDR for vinyl chloride. However, EPA has identified vinyl chloride uses in several children's products and articles intended for children from the HPCDS database (IC2, 2024) and ChemExpo (U.S. EPA, 2024a) (see Table 2-3). Children's exposure to chemicals may differ from exposures among adults due to physiological and behavioral differences (U.S. EPA, 2008). For example, children have a higher ratio of body surface area to volume and higher inhalation rates per unit of body weight compared to adults. Additionally, children consume more of certain foods and water per unit of body weight. Children's behaviors that may increase exposure include oral exploration of their environment, touching the ground, surfaces, and objects, and ingesting human milk. In addition to consumer products, other media types of interest may include drinking water, indoor and outdoor air, soil, dust, human milk, and diet (*e.g.*, food) (U.S. EPA, 2011, 2008). Figure_Apx C-7 displays the media types identified for each data source. Through the implementation of systematic review approaches, as described in Section 8 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b), EPA also identified 23 data sources that document reproductive and/or developmental effects following exposure to vinyl chloride (see Figure_Apx C-10 in Appendix C.5.3).

Women of Reproductive Age
EPA identified animal toxicity and epidemiology data sources that document reproductive and/or developmental effects following exposure to vinyl chloride (see Figure_Apx C-10 in Appendix C.5.3). This screening review of data sources identified through the systematic review approaches, as described in Section 8 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b), suggests that women of reproductive age may be a PESS.

Consideration of women of reproductive age as a PESS was also based on exposure because women of reproductive age can be workers in the manufacturing, processing, distribution in commerce, use, or disposal of vinyl chloride.

Overburdened Communities
EPA recognizes that some communities such as Tribal populations and fenceline communities (*i.e.*, communities in close proximity to facilities emitting air pollutants or living near effluent releases to water) may experience disproportionate environmental harms, risks, or multiple burdens from chemical exposure. Considerations that may be important for assessing chemical risks to such overburdened communities include aggregate exposure and sentinel exposures. EPA defines aggregate exposure as "the combined exposures to an individual from a chemical substance across multiple routes and across multiple pathways" (40 CFR 702.33). Additionally, EPA defines sentinel exposure as "the exposure from a chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures" (40 CFR 702.33). Environmental and socioeconomic stressors may also impact the health of these communities and their environment. In developing this proposed designation and throughout the prioritization process, EPA has engaged and will continue to engage the public to obtain information relevant to vinyl chloride.

Workers
Information about the uses and activities described in Sections 2.8.2 was used to identify potential occupational exposure to vinyl chloride, indicating that these groups are also likely to be PESS based on potentially greater exposure.

Consumers
Information about the uses and activities described in Sections 2.8.3 was used to identify potential consumer exposure to vinyl chloride, indicating that these groups are also likely to be PESS based on potentially greater exposure.

2.5 Persistence and Bioaccumulation

EPA reviewed databases and previously conducted assessments to identify information for physical and chemical properties and fate endpoints to characterize the potential for vinyl chloride to persist in the environment or bioaccumulate. Table_Apx D-1 and Table_Apx E-1 summarize the information identified for physical and chemical properties and environmental fate and transport properties of vinyl chloride, respectively. Through implementation of systematic review approaches as described in Sections 4 and 5 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b), EPA identified 225 data sources that contain potentially relevant physical and chemical property information and 1,682 data sources for the environmental fate characterization of vinyl chloride, as shown in Figure_Apx C-1 and Figure_Apx C-2, respectively.

Vinyl chloride is a colorless gas at room temperature and pressure (NLM, 2023b; RSC, 2023; U.S. EPA, 2000b) and has a boiling point of -13.9 °C (NLM, 2023b; Reaxys, 2023; U.S. EPA, 2023a). Vinyl chloride has a water solubility of 9,150 mg/L at 20.5 °C (ECHA, 2023a; Reaxys, 2023), a vapor pressure

of 2,550 mmHg at 20 °C (ECHA, 2023a), and a Henry's Law Constant (HLC) of 0.0278 atm·m^3/mol at 24.8 °C (PhysProp, 2023).

Given the magnitude of the above-listed physical and chemical properties along with preliminarily identified octanol:air (logK_{OA}) and air:water (logK_{AW}) partitioning coefficients (see Table_Apx D-1), vinyl chloride is expected to volatilize from both dry and wet surfaces and remain largely in gas phase in the atmosphere. Additionally, the volatility of vinyl chloride is expected to drive its removal in wastewater treatment plants (WWTPs): results from the STPWIN model of EPI Suite™ v 4.11 predict that approximately 89 percent of vinyl chloride will be removed via losses to air stripping assuming negligible removal due to biodegradation (*i.e.*, biodegradation half-life default of 10,000 hours; loss to stripping may be lower when competing with removal by biodegradation) (U.S. EPA, 2012b).

As presented in Table 2-6, a large proportion of reported vinyl chloride releases are to air. In the atmosphere, vinyl chloride is expected to have low to moderate persistence. Vinyl chloride reacts with hydroxyl radicals (•OH) with transformation rates reported between 3.95 x 10^{-12} and 8.40 x 10^{-12} cm^3/mole-sec (ATSDR, 2023; ECHA, 2023a; NIST, 2023; NLM, 2023a; OECD, 2001). Assuming a •OH concentration of 1.5 x 10^6 •OH/cm^3 and 12 hours of sunlight, the half-life of vinyl chloride may range from 1.27 to 2.71 days, with a mean of 1.84 days.

While vinyl chloride released to surface water is expected to volatilize appreciably, some fractions may remain dissolved in the aqueous phase and to a lesser extent adsorbed to organics found in suspended solids, as indicated by the organic carbon (OC):water partition coefficient (logK_{OC}) values presented in Table_Apx E-1. In surface water, vinyl chloride is expected to have moderate to high persistence. Because hydrolysis of vinyl chloride is unlikely (reported half-lives of greater than 9.91 to greater than 107 years at pH 7, and 25 °C and 10 °C, respectively (NLM, 2023a); greater than 1 year at pH levels of 4 and 6.1 (OECD, 2001)), its fate in water is expected to be primarily mediated by biodegradation processes.

One ready biodegradability test (OECD 301D) indicates vinyl chloride is not readily biodegradable, reporting degradation rates ranging from 3 to 16 percent over 28 days (ECHA, 2023a; NITE, 2023; NLM, 2023a). Two additional CO_2 evolution studies, each employing municipal activated sludge inoculums, reported mineralization rates of 21.5 percent over 5 days (ECHA, 2023a; OECD, 2001) and 22 percent over 28 days (ECHA, 2023b). Biodegradation of vinyl chloride in experiments using natural environmental media show a much greater variance in degradation rates. Anaerobic biodegradation rates range from 10 percent over 106 days in water under methanogenic conditions following a 50-day lag, to 50 percent over 28 days in a sand/water microcosm (ECHA, 2023a; NLM, 2023a; Reaxys, 2023). An aerobic degradation rate of greater than99 percent over 108 days (transformation) was reported for an aerobic soil/groundwater microcosm (ATSDR, 2023; ECHA, 2023a; OECD, 2001). The degree of vinyl chloride biodegradation is therefore expected to vary with microbial community and environmental conditions. Note that while Table_Apx E-1 includes biodegradation values determined experimentally with added electron donors and/or inoculums adapted to vinyl chloride-contaminated sites, those were excluded from consideration when conducting preliminary environmental persistence screening.

No empirical data on vinyl chloride adsorption to sediment were identified. Based on empirical soil logK_{OC} values, however, vinyl chloride in the water column is not expected to partition significantly to organics in sediment, though it may be transported by diffusion and advection processes to sediment pore water. Given the range of anaerobic biodegradation rates identified in water, vinyl chloride is expected to have high persistence in sediment.

Vinyl chloride may be subject to several competing processes dictating its fate in soil, including: 1) volatilization from both wet and dry soil; 2) moderate to rapid migration to groundwater; 3) limited sorption to organic solid fractions; and 4) limited aerobic and anaerobic biodegradation. Two sources were identified reporting $\log K_{OC}$ values for vinyl chloride. The first reported a $\log K_{OC}$ value of 1.75, but without additional detail on materials or methods (NLM, 2023a; OECD, 2001). The second is an empirical study following OECD 106 guidelines that investigated seven low-OC, natural clayey till soils from Denmark, reporting $\log K_{OC}$ values ranging from 2.38–2.95 (mean 2.70) (ATSDR, 2023). The authors highlighted that in addition to the organic carbon content of the soil, the clay content and specific surface area of the soil particles influenced the adsorption coefficient values obtained for vinyl chloride, especially on low-OC soils (Lu et al., 2011). Because of vinyl chloride's tendency to volatilize from soil and to have moderate to rapid migration to groundwater, only a small portion of vinyl chloride is likely to be subject to biodegradation in soil. As discussed above, biodegradation rates can vary greatly depending on the conditions and microbial species present. Given the anticipated transport and biodegradation in soil systems, vinyl chloride is expected to have low to moderate persistence in soil.

Vinyl chloride fractions that migrate to groundwater systems may be subject to both anaerobic biodegradation (rates discussed above) and abiotic reductive dehalogenation. The degree of susceptibility of vinyl chloride to abiotic dehalogenation relies on the minerality of the anaerobic system: of those determined only with minerals characteristic of soil and aquifer systems, rates of 0.055 - 0.15 d^{-1}, 0.247 - 0.323 d^{-1}, 0.355 - 0.537 d^{-1}, and 0.358 - 0.555 d^{-1} were determined with Silawa loamy sand, montmorillonite, vermiculite, and biotite, respectively (Reaxys, 2023). Assuming first order kinetics, these equate to half-lives ranging from 1.25 to 12.6 days. Despite the short half-lives achieved in laboratory reductive dehalogenation studies, vinyl chloride has been observed in groundwater in several U.S. locations (ATSDR, 2023).

Vinyl chloride is not expected to bioconcentrate or bioaccumulate in aquatic organisms. Two empirical bioconcentration factors (BCF) were identified: a BCF of 40 was found in green algae (*Chlorella fusca*) (ATSDR, 2023; ECHA, 2023a; NLM, 2023a; OECD, 2001), and BCF less than 10 in golden ide (*Leuciscus idus melanotus*) (ATSDR, 2023; ECHA, 2023a; NLM, 2023a; OECD, 2001). No empirical bioaccumulation factor (BAF) values were identified. Because few BCF studies and no BAF studies were identified (see Table_Apx E-1), the BCFBAF model of EPI Suite™ v 4.11 was leveraged to fill aquatic bioaccumulation data gaps for screening purposes. Supporting evidence from empirical BCFs, BAFs of 2.59, 2.80, 3.63 L/kg were obtained for lower, middle, and upper trophic levels using the Arnot-Gobas method of the BCFBAF model (U.S. EPA, 2012b). EPA identified no bioaccumulation or bioconcentration data for terrestrial organisms from databases or previously conducted assessments.

2.6 Storage Near Significant Sources of Drinking Water

To support the proposed designation, EPA screened vinyl chloride under its conditions of use with respect to the seven criteria in TSCA section 6(b)(1)(A) and 40 CFR 702.9. The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of drinking water, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure.

EPA reviewed reasonably available information, including certain existing regulations or protections in place for the proposed chemical substance (Appendix A). To that end, EPA reviewed vinyl chloride's existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (SDWA) (40 CFR Part 141 and regulations under the Clean Water Act (CWA) (40 CFR 401.15). Vinyl chloride is regulated under both SDWA and CWA. In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under the Emergency Planning and Community Right-to-

Know Act (EPCRA) section 302 (Extremely Hazardous Substances) and EPCRA section 313 (Toxic Chemicals), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; Hazardous Substances), and the Clean Air Act (CAA) section 111(b) (Volatile Organic Compounds), section 112(b) (Hazardous Air Pollutant), section 112(r) (Regulated Chemicals for Accidental Release Prevention) and section 183(e) (National Volatile Organic Compound Emission Standards for Aerosol Coatings). Vinyl chloride is regulated under EPCRA section 302, CERCLA sections 102(a) and 103, CAA sections 111(b), 112(b) and 183(e) but is not regulated under section 112(r) of the CAA. Regulation by one or more of these authorities is an indication that could be used to support a "may present an unreasonable risk of injury to human health or the environment" finding for the chemical substance, if released near a significant source of drinking water.

EPA identified facilities reporting vinyl chloride to the TRI in 2022 near potential sources of drinking water using public water systems data stored in EPA's Safe Drinking Water Information System Federal Data Warehouse (U.S. EPA, 2022a). This data warehouse is updated quarterly and provided by EPA's Office of Ground Water and Drinking Water (OGWDW). Specifically, EPA determined whether TRI reporting facilities are located inside defined Source Water Protection Areas or within 4 miles of wellheads to identify potential storage of vinyl chloride near sources of surface water and groundwater, respectively. TRI reporting facilities were used as a reasonably available indicator for locations where storage of vinyl chloride is likely to occur. Similarly, while the source water protection areas and wellhead protection points analyzed are not inclusive of all sources of drinking water, for the purposes of this document, they were used as a representation of likely drinking water sources.

As shown in Table 2-4, EPA identified 33 TRI reporting facilities that stored vinyl chloride on-site in 2022. Multiple facilities were identified to be within source water protection areas and/or near wellhead protection points. Should vinyl chloride be designated as a High-Priority Substance, additional information about potential exposure via drinking water identified during this and future public comment periods may be considered to help identify the appropriate pathways included in the scope of the risk evaluation during the scoping process.

Table 2-4. Summary of Vinyl Chloride TRI Facility Proximity to Drinking Water Sources

Group	Facility Count
All	33
Within source water protection area (surface water)	3
Within 4 miles of wellhead protection (ground water)	28

2.7 Hazard Potential

EPA considered reasonably available information from previous assessments, databases, and information sources identified in the systematic review approach outlined in Section 2.1 to conduct a screening review of potentially relevant hazard information for vinyl chloride. Furthermore, Section 8 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b) and Appendix C.5 specifically describe how information sources were identified and screened to characterize potential environmental and human health hazards resulting from exposure to vinyl chloride, respectively. A summary of references for hazards identified for vinyl chloride during the screening step of systematic review is included in the interactive literature inventory tree in Appendix C.5.2. Through implementation of systematic review approaches, EPA identified 2,275 data sources containing information that may be relevant for the characterization of potential hazard resulting from vinyl chloride exposure (Figure_Apx C-8). The evidence maps depicting a summary of data identified

during the full-text screening of data sources considered through systematic review are also available in Appendices C.5.3 and C.5.3 for environmental and human health hazard, respectively.

2.7.1 Potential Environmental Hazard

EPA used the Agency's ECOTOXicology Knowledgebase (ECOTOX), previous assessments, and search results from chemical specific data sources using systematic review approaches to identify reasonably available information that may be relevant for characterizing potential environmental hazard resulting from exposure to vinyl chloride. Table_Apx B-3 lists the previous assessments used to identify potential environmental hazard information for vinyl chloride.

A summary describing the potential environmental hazard resulting from exposure to vinyl chloride is provided below. EPA has preliminarily characterized organisms into aquatic and terrestrial categories to summarize potentially relevant hazards reflecting exposure in these ecosystems. EPA recognizes that some organisms have home ranges or lifestages that span multiple ecosystems and therefore exposure can occur in a variety of media and pathways. Figure_Apx C-9 presents an evidence map depicting health outcomes (*e.g.*, reproduction, mortality, development), categorized by ecosystem and taxonomic group, from data sources identified for ecological receptors cited and reviewed in assessments and ECOTOX, and identified through the systematic review approach. EPA has identified five aquatic and four terrestrial data sources that may be used to inform the potential environmental hazard resulting from exposure to vinyl chloride. These data sources underwent full-text screening as described in Appendix C.5 and met the screening criteria described in Appendix C.5.1. All the data sources reflected in Figure_Apx C-9 underwent a screening level review.

The search of reasonably available and relevant information by using systematic review approaches outlined in Appendix C.5.1 identified additional data sources that have not yet been characterized or extracted to the extent accomplished by previous assessments or ECOTOX. To identify quantitatively characterized environmental hazard endpoints resulting from vinyl chloride exposure, EPA identified reasonably available environmental hazard information cited by assessments and extracted in ECOTOX. Specifically, Figure 2-2 and Figure 2-3 present visualizations of environmental hazard endpoint categories organized by health outcomes identified using those data sources.

Separate visualizations depict endpoints observed in taxa inhabiting different ecosystems and various types of exposure media. Generally, EPA has plotted endpoints as reported by previous assessments and ECOTOX, but some data processing (*e.g.*, de-duplication of endpoints reported by the same primary data source, standardization of effect concentration units) was conducted to ensure uniformity in the presentation of hazard information. ECOTOX standardized effect concentration units for aquatic data were used where available. Additionally, where possible, author-reported effect concentration units were converted to mg/L (*e.g.*, ug/L values were divided by 1000, mol/L values were multiplied by the molecular weight and 1000, ppm values were re-coded to mg/L as they are equivalent) and mg/kg (*e.g.*, mmol/kg values were multiplied by the molecular weight, ug/g values were re-coded to mg/kg as they are equivalent) to maximize the amount of data that could be included in the visualizations. The visuals summarize hazard endpoints resulting from vinyl chloride exposure concentrations (*e.g.*, mg/L) in various environmental media (*e.g.*, surface water, water). The shape of points represents the category of endpoint (*i.e.*, measurement of a biological effect in response to vinyl chloride exposure) characterizing a respective hazard value. The color of points represents the data source from which hazard value came (*i.e.*, ECOTOX or the specific previous assessment name and publication year). Individual plot panels are presented for three general taxonomic groups: vertebrates, invertebrates, and vegetation and fungi. In situations in which endpoints have been identified in both previous assessments and ECOTOX, EPA

elected to attribute and label those endpoints as being associated with ECOTOX to reduce duplication in representing reasonably available environmental hazard information.

Environmental hazard endpoints displayed represent measures of a biological effect in response to exposure to vinyl chloride and focus on traditionally statistically derived endpoints (*e.g.*, LC_{50}, LOEC, NOEC). Although considered for identifying potential environmental hazard resulting from vinyl chloride exposure, uncommon endpoints (*e.g.*, effective concentration that causes a response that is x percent of the maximum (EC_x) endpoints where x= uncommon percentages in which a statistically significant response was observed in specific studies) or taxa (*e.g.*, bacteria) cited by the previous assessments or available in ECOTOX may not be represented in the visualizations. As seen in the figures below, common endpoints were grouped into categories based on the quantitative nature of the biological effect in the exposed population and included no observed effect (*e.g.*, NO(A)EC[L], LC0, EC0), lowest observed effect (*e.g.*, LO(A)EC[L]), and effect observed in 10% of the population (*e.g.*, EC10, LC10), 20% of the population (*e.g.*, EC20, LC20), and 50% of the population (*e.g.*, EC50, IC50, LD50). Definitions of the health outcome terms displayed in the visualizations are located in ECOTOX *Appendix S. Effect Groups and Measurements*. Definitions of endpoint terms displayed in these visualizations are located in ECOTOX *Appendix T. Endpoint Terms and Definitions*.

The health outcomes and endpoints selected for these visuals do not represent the entire data landscape of environmental hazard information. The visualizations mainly serve the purpose of depicting the results from a screening review of environmental hazard information resulting from exposure to vinyl chloride via various environmental media types and exposure routes.

2.7.1.1 Aquatic Organisms

Information was identified that may be used to identify toxicological effects for aquatic organisms resulting from vinyl chloride exposure via surface water. Figure 2-2 depicts reasonably available environmental hazard information sourced from previous assessments and ECOTOX. Furthermore, five data sources that underwent full-text screening contain environmental hazard information that may inform potential hazard to aquatic organisms exposed to vinyl chloride (Figure_Apx C-9). Growth effects were identified across all aquatic taxonomic groups and behavior effects for aquatic vertebrates and invertebrates. In addition, mortality and morphological effects were found for aquatic vertebrates. A greater number of health outcomes were identified for invertebrates compared to other taxa groups. More detailed information can be found in Appendix C.5.3.

Surface Water

As presented in Figure 2-2, environmental hazard information was identified from previous assessments and ECOTOX for aquatic organisms (vertebrates, invertebrates, vegetation and fungi) via surface water exposure. Specifically, environmental hazard data that span numerous health outcomes (*e.g.*, mortality, growth, population) were identified for these three taxonomic groups in response to vinyl chloride exposure (0.0001 to 1,220 mg/L).

Reported endpoints such as lethal concentration (*e.g.*, LC_{50}; concentration impacting 50 percent of the exposed organisms) and effect concentration (*e.g.*, EC_{50}; concentration impacting 50 percent of the exposed organisms) values in both ECOTOX and previous assessments for vinyl chloride shown in Figure 2-2 describes effects on vertebrates (*e.g.*, bluegill sunfish (*Lepomis macrochirus*), largemouth bass (*Micropterus salmoides*)), invertebrates (*e.g.*, crustaceans (*Daphnia magna*)), and plant and fungal species (*e.g.*, green algae (*Scenedesmus quadricauda*)) (NICNAS, 2014a; OECD, 2001; IPCS, 1999). Aqueous exposure to vinyl chloride resulted in a four-day LC_{50} of 210, 1,220, and 1,060 mg/L for zebrafish (*Danio rerio*), bluegill sunfish, and largemouth bass, respectively (OECD, 2001; IPCS, 1999).

Observed differences in toxicity values across fish species (*i.e.*, zebrafish versus bluegill sunfish or largemouth bass) for vinyl chloride could potentially be attributed to species-specific differences or broader taxonomic differences, since while zebrafish belong to the Cyprinidae family, bluegill sunfish, and largemouth bass belong to the Centrarchidae family. In addition to empirical data, predicted toxicity values for *D. magna* and green algae based on modeled data calculated using the Ecological Structure Activity Relationships (ECOSAR) Class Program (v. 1.11; (U.S. EPA, 2012a)) were reported as a 48-hour LC_{50} of 61.4 mg/L and a 96-h EC_{50} of 39.6 mg/L, respectively (NICNAS, 2014a). In comparison to the modeled green algae endpoint cited in (NICNAS, 2014a), significant reductions in population growth of the green algae *Raphidocelis subcapitata* were observed after a 48-hour exposure to vinyl chloride (LOEC of 5 mg/L) (Nam and An, 2010).

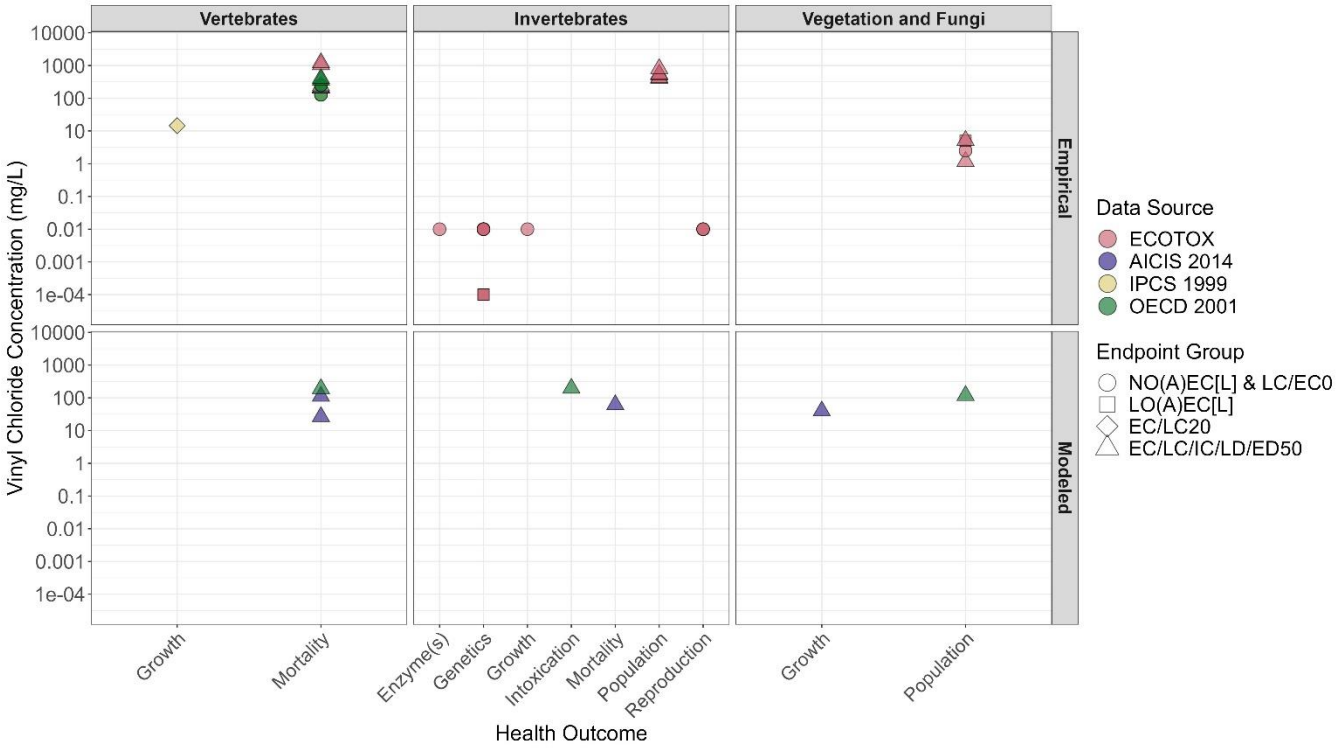


Figure 2-2. Summary of Select Environmental Hazard Information for Aquatic Organisms Resulting from Surface Water Exposure for Vinyl Chloride

2.7.1.2 Terrestrial Organisms

Information was identified that may be used to identify toxicological effects for terrestrial organisms resulting from vinyl chloride exposure via water. Figure 2-3 depicts reasonably available environmental hazard information sourced from ECOTOX. No environmental hazard information for terrestrial organisms was identified from previous assessments. Furthermore, four data sources that underwent full-text screening contain environmental hazard information that may inform potential hazard to terrestrial organisms resulting from vinyl chloride exposure (Figure_Apx C-9). Additional information on the health outcomes identified for different taxa groups can be found in in Figure_Apx C-9.

Water

As seen in Figure 2-3, data gathered within the ECOTOX database identified environmental hazard information for invertebrates via water exposure. In these studies, the experimental designs encompassed multiple types of water exposure, including via culture media and fumigation. Two health outcomes (*e.g.*, development, genetics) were identified in response to a broad range of vinyl chloride

exposure concentrations (0.0006 to 200,000 mg/L). For example, one study identified a lowest observed effect concentration (LOEC) of 0.0006 mg/L for effects on development in a four-day exposure of the nematode *Panagrellus redivivus* (Carlson and Caple, 1977).

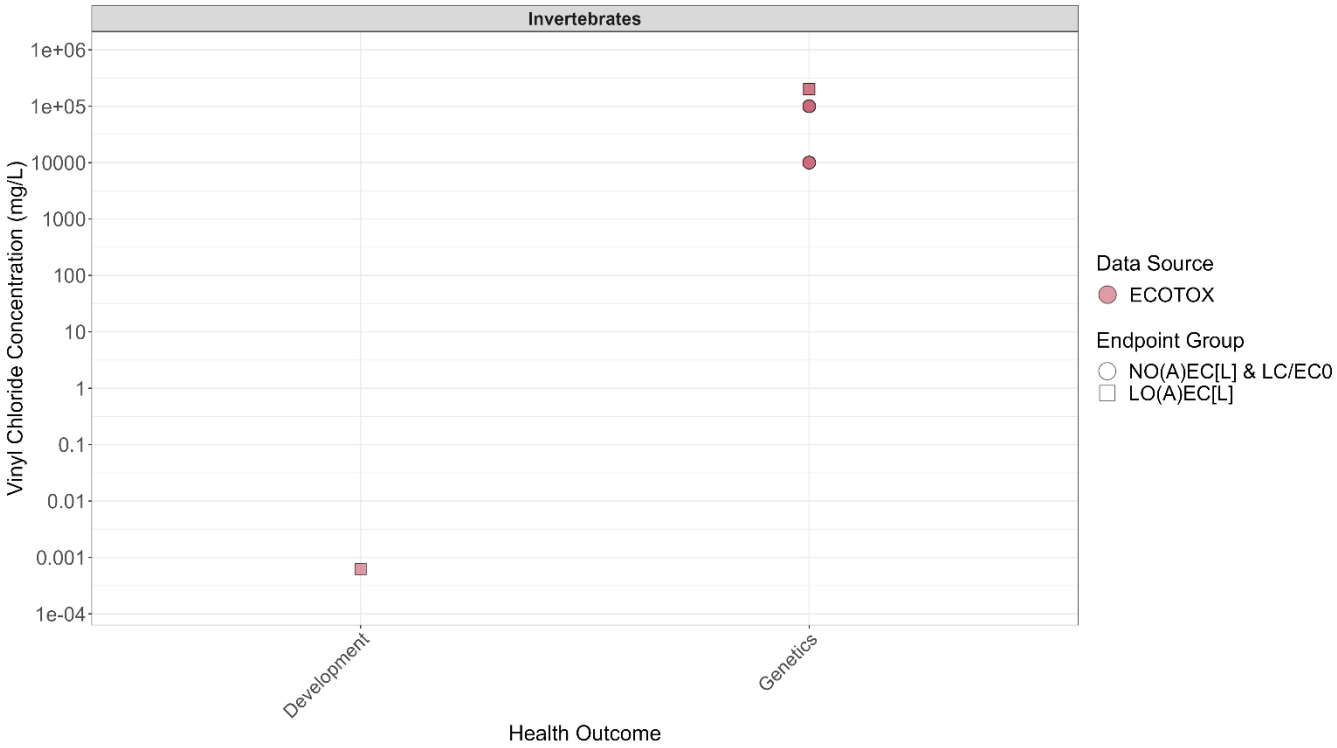


Figure 2-3. Summary of Select Environmental Hazard Information for Terrestrial Organisms Resulting from Water Exposure for Vinyl Chloride

2.7.2 Potential Human Health Hazard

EPA used previous assessments and search results from EPA's identification of chemical-specific data sources using systematic review approaches to identify reasonably available information relevant for characterizing potential human health hazard resulting from exposure to vinyl chloride, based on both epidemiological and animal toxicity information.

Table_Apx B-4 lists the previous assessments used to identify potential human health hazards for vinyl chloride. Table 2-5 presents classifications assigned by various organizations associated with vinyl chloride exposure based on epidemiological and/or animal toxicity information (indicated by the "X" in the "Based on Epidemiology" and/or "Based on Animal Toxicity" columns). If the evidence (animal toxicity and/or epidemiological data) supporting the classification for a respective assessment is only based on either animal toxicity or epidemiological data, no table note was used to indicate the type of evidence in the "Exposure Route" column.

Table 2-5. Risk Assessment Classifications for Vinyl Chloride Based on Human Health Hazard Information

Risk Classification System	Health Outcome	Classification	Assessment Label[a]	Exposure Route[b,c,d]	Based on Animal Toxicity Data	Based on Epidemiology Data
International Agency for Research on Cancer (IARC) Classification	Carcinogenicity	Group 1 – carcinogenic to humans	CARB 1990a	Oral[b], inhalation[d]	X	X
			CARB 1990b	Oral, inhalation	X	
			CARB 1990c	Oral, inhalation	X	
			US EPA 2000b	Oral, inhalation	X	
			IARC 2012	NA	X	X
			Health Canada 2013	Inhalation[b], oral[d], drinking water[d]	X	X
			NICNAS 2014a	Oral, inhalation	X	
			NICNAS 2014b	Oral[b], NA[c]	X	X
			NTP 2021			X
Approved Criteria, Hazardous Substances Information System (HSIS)	Carcinogenicity	R45 (Category 1) – may cause cancer)	NICNAS 2014b	Oral[b], NA[c]	X	X
Approved Criteria, HSIS	Genotoxicity	R68 (Category 3) – possible risk of irreversible effects)	NICNAS 2014b	NA	X	
Approved Criteria, HSIS	Chronic toxicity	R48 – danger of serious damage to health by prolonged exposure	NICNAS 2014b	NA	X	

Risk Classification System	Health Outcome	Classification	Assessment Label[a]	Exposure Route[b,c,d]	Based on Animal Toxicity Data	Based on Epidemiology Data
Globally Harmonized System	Carcinogenicity	H 350 (Category 1A) – may cause cancer	NICNAS 2014b	NA[d]	X	X
Globally Harmonized System	Genotoxicity	H341 (Category 2) – suspected of causing genetic defects)	NICNAS 2014b	NA[d]	X	X
Globally Harmonized System	Chronic toxicity	H372 – causes damage to organs through prolonged or repeated exposure)	NICNAS 2014b	NA[d]	X	X
US EPA Carcinogenicity Classification	Carcinogenicity	Weight-of-evidence category "A" – known human carcinogens	CARB 1990a	Oral[b], inhalation[d]	X	X
			US EPA 2000a	Oral, inhalation	X	
			US EPA 2000b	Oral[b], inhalation[d]	X	X
US EPA Carcinogenicity Classification	Carcinogenicity	Known/Likely human carcinogen	ATSDR 2023	Oral, inhalation	X	
Organization for Economic Cooperation and Development (OECD) Screening Information DataSet (SIDS)	Carcinogenicity	The data collected for SIDS elements were considered adequate for hazard identification.	OECD 2001	Oral, inhalation	X	
U.S. Department of Health and Human Services (HHS)	Carcinogenicity	Known to be a human carcinogen	ATSDR 2023	Oral, inhalation	X	

Risk Classification System	Health Outcome	Classification	Assessment Label[a]	Exposure Route[b,c,d]	Based on Animal Toxicity Data	Based on Epidemiology Data

[a] "Assessment labels" refer to labels associated with previous assessments identified in various figures within Section 2.7.2. These are commonly secondary sources citing the risk classification system and outcome listed. Recent risk assessments may cite older outcomes that are still supported by current research.
[b] Exposure route is associated with an animal toxicity study.
[c] Exposure route is associated with an epidemiological study.
[d] Exposure route is associated with both an animal toxicity and epidemiological study.

Figure 2-4 presents quantitative endpoints identified by various organizations in the respective previous assessments of vinyl chloride (listed in Table_Apx B-4) based on epidemiological and animal toxicity studies, respectively. The Y-axis represents endpoint values (no units). The X-axis specifies exposure type and units (top), while also specifying health outcome type for each exposure type (bottom). As indicated by the key, circles specify an animal toxicity study outcome, triangles specify an epidemiology outcome, and squares denote an outcome that considered both animal data and epidemiology data in its determination. Each outcome specifies the assigning risk assessment by color (see key). Values listed as a range are depicted as two points – the minimum and maximum. Health outcome types have been generalized here so the range of values for a particular category can be visualized (*i.e.*, "cancer index" includes cancer slope factor (CSF), health-based value (HBV), unit risk factor (URF), and other cancer-related endpoints). The range of endpoint values (EV) required that they be represented within ranges to allow for better clarify of individual points. The ranges can be seen in the grey boxes on the right of each row of dot plots. When the EV range is ≥ 1 the software (R, version 4.2.2, Tidyverse package) does not plot the "0" on the y-axis. Some assessments identified endpoint values that are not depicted in Figure 2-4 due to various reasons specific to how previous assessments reported hazard information from epidemiological and/or animal toxicity studies (*e.g.*, lack or use of units cited by previous assessments that do not represent the majority of information identified for a respective exposure route, observational endpoints without quantitative values), further described below. Table_Apx C-10 contains all the endpoint values considered from previous assessments based on epidemiological and animal toxicity studies, including the subset depicted in Figure 2-4. All endpoint values shown in the figure are greater than zero. To simplify the figure, endpoint values may occasionally exceed the upper bounds of the Y axis.

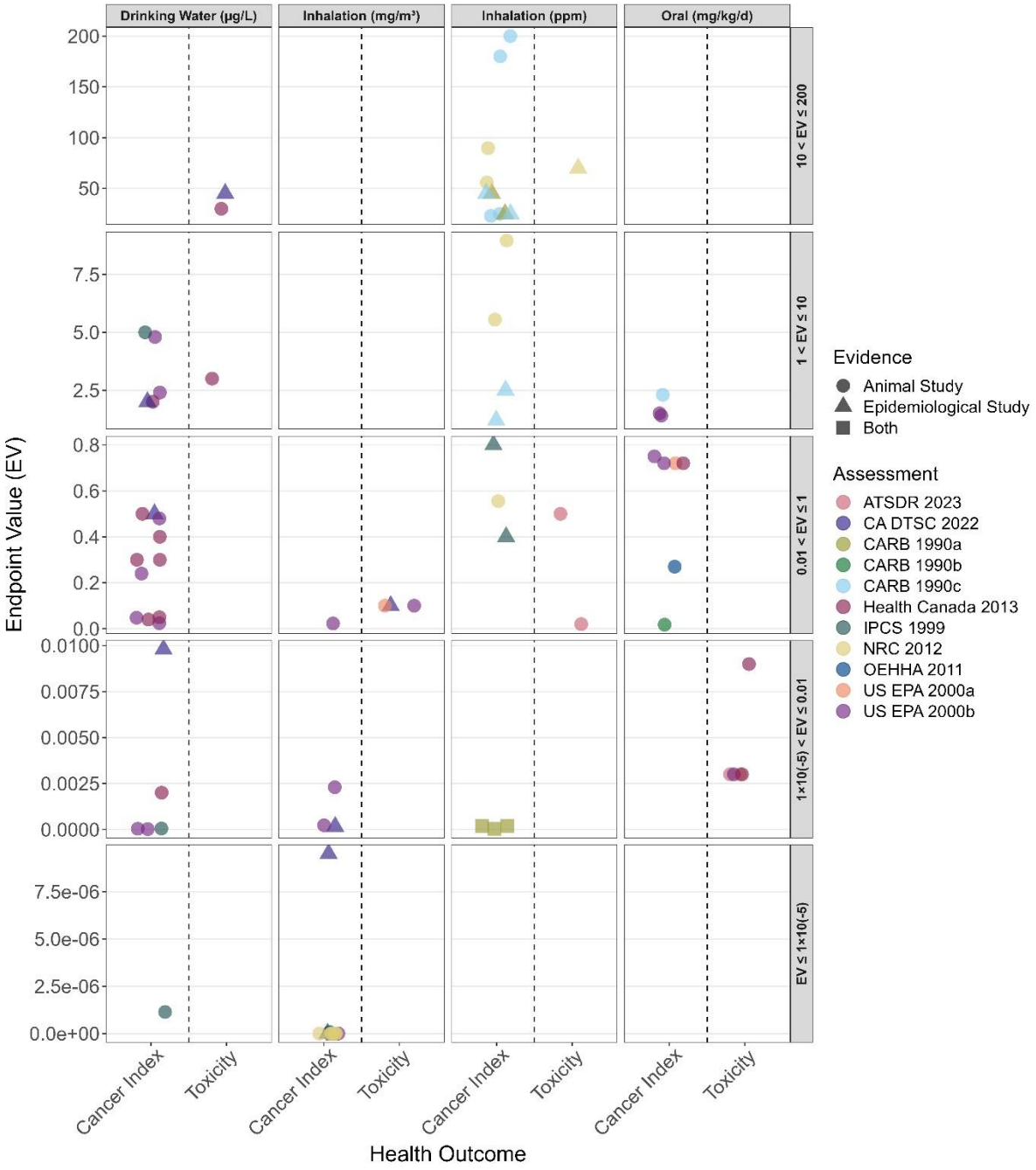


Figure 2-4. Summary of Quantitative Endpoints from Previous Assessments for Health Outcomes by Exposure Type for Animal Toxicity and Epidemiological Information

Figure 2-5 and Figure 2-6 present health outcomes associated with vinyl chloride exposure identified in previous risk assessments based on epidemiological or animal toxicity evidence. The Y-axis lists health outcomes associated with endpoints identified in previous assessments, which are listed in Table_Apx B-4. The X-axis serves to count the number of previous risk assessments that consider the corresponding health outcome. Blue segments denote counts of all the reported health outcomes considered and identified by various assessments. Red segments denote health outcomes utilized to characterize assessment-specific determinations: “primary outcomes” for epidemiological studies and “critical outcomes” for animal toxicology studies due to differences in discipline terminology. Designation as a primary or critical endpoint is otherwise equivalent.

Sections 2.7.2.1 and 2.7.2.2 summarize epidemiological and animal toxicity evidence that characterizes the potential human health hazard resulting from exposure to vinyl chloride, that supports the designation of vinyl chloride as a High-Priority Substance. Figure_Apx C-10 presents an evidence map depicting health outcomes categorized by exposure route from data sources identified using systematic review approaches.

2.7.2.1 Epidemiological Information

During prioritization, hazard information was identified for humans resulting from epidemiological studies, with exposure to vinyl chloride via teeth/dental procedures, drinking water, food, ocular/eye contact, dermal/skin contact, and/or inhalation (see Figure_Apx C-10). Health outcomes considered include carcinogenicity, genotoxicity, and acute and chronic toxicity. This information is organized here according to endpoint descriptive type. Table 2-5 lists qualitative classifications reported by previous risk assessments. Meanwhile, Figure 2-4 contains quantitative endpoints identified by various organizations. Figure 2-5 hallmarks the health outcomes described in these risk assessments by organ system, noting critical epidemiological findings that were considered in the development of assessment-wide endpoints.

As identified in Table 2-5, carcinogenicity descriptions and designations for vinyl chloride by previous assessments range from "may cause cancer" (NICNAS, 2014b) to "a human carcinogen" (NTP, 2021; NICNAS, 2014b; Health Canada, 2013; IARC, 2012; U.S. EPA, 2000a; CARB, 1990a). EPA found 35.7 percent of assessments that described carcinogenic effects noted these endpoints to be critical, as seen in (Figure 2-5). These findings are based on a variety of observations from epidemiological studies. Specifically, observed inhalation exposure to vinyl chloride among workers resulted in liver, brain and lung cancer, and liver angiosarcoma and hepatocellular carcinoma (IARC, 2012; U.S. EPA, 2000a; CARB, 1990c). CADTSC (2022) also reported that drinking water exposure resulted in both cancer and non-cancer effects.

Although NICNAS (2014b) only determined that vinyl chloride is "suspected of causing genetic defects" (Table 2-5), as presented in Figure 2-5 within the "other" health outcome category, one of the previous assessments identified genotoxic effects as being critical for characterizing vinyl chloride toxicity (NRC, 2012).

In addition, epidemiological data identified in previous assessments suggest that vinyl chloride exposure is associated with acute and chronic toxic effects (Figure 2-4). Chronic exposure to vinyl chloride may also cause organ damage (NICNAS, 2014b) and other non-cancer effects (CA DTSC, 2022). EPA found 30 percent of assessments that described neurological or behavioral effects noted these endpoints to be critical, as shown in (Figure 2-5). Acute toxic effects observed in epidemiological studies included dizziness, lightheadedness, nausea, and visual and auditory dulling (NRC, 2012; U.S. EPA, 1985). Not visualized (due to non-specified units for cancer index and high critical exposure values), as described by CARB (1990c) and NRC (2012) are cancer and non-cancer endpoints observed for inhalation exposure to vinyl chloride. CADTSC (2022) also associated cancer and non-cancer endpoints with exposure to vinyl chloride from soil exposure.

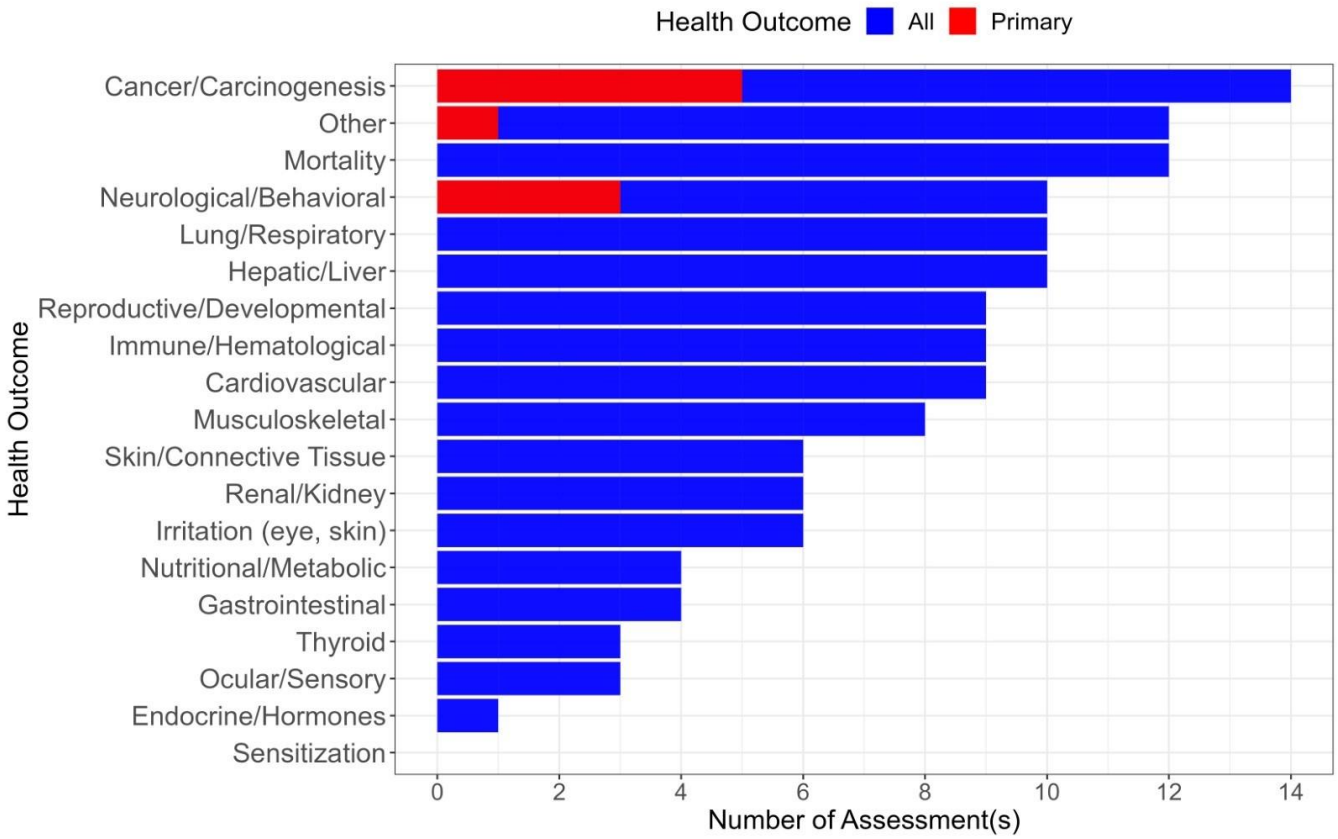


Figure 2-5. Summary of Epidemiological Data Cited by Previous Assessments

The "other" health outcome category in Figure 2-5 refers to outcomes (*e.g.*, absorption, distribution, metabolism, and excretion [ADME], genotoxicity and clinical signs) not explicitly listed as either a primary health outcome(s) or all health outcomes.

2.7.2.2 Animal Toxicity Information that Supports Human Health Hazard

EPA identified animal toxicity information resulting from vinyl chloride exposure via diet, oral gavage, dermal, eye, and/or inhalation, that may be relevant for characterizing human health hazard (Table_Apx C-10). Health outcomes considered include carcinogenicity, genotoxicity, and acute and chronic toxicity. This information is organized here according to endpoint descriptive type. Table 2-5 lists qualitative classifications reported by previous risk assessments. Meanwhile, Figure 2-4 contains quantitative endpoints identified by these various organizations. Figure 2-6 summarizes the health outcomes described in these risk assessments by organ system, noting critical animal findings that were considered in the development of assessment-wide endpoints.

As seen in Table 2-5, carcinogenicity descriptions and designations for vinyl chloride by previous assessments range from "May Cause Cancer" (NICNAS, 2014b), to "Known Human Carcinogen" (ATSDR, 2023; U.S. EPA, 2000a, b) or "Carcinogenic to Humans" (NTP, 2021; NICNAS, 2014a, b; Health Canada, 2013; IARC, 2012; U.S. EPA, 2000a; CARB, 1990a, b, c). EPA found 64.3 percent of assessments described carcinogenic effects to be critical (Figure 2-6). These findings are based on a variety of observations in animals. A variety of cancer types are referenced in rat oral studies including hepatic, pulmonary, abdominal angiosarcoma, hepatocellular carcinoma, neuroblastoma, Zymbal gland tumours (ATSDR, 2023; NICNAS, 2014b; Health Canada, 2013; OEHHA, 2011; U.S. EPA, 2000a, b; IPCS, 1999; CARB, 1990a, b, c), and liver hemangiosarcoma, abdominal mesotheliomas, and mammary adenoma, adenocarcinoma, or anaplastic carcinoma (ATSDR, 2023; Health Canada, 2013; OEHHA, 2011; U.S. EPA, 2000a; CARB, 1990c). Based on these observed effects, human dose approximations

were determined by previous risk assessments and are plotted in Figure 2-4. Not visualized in this figure due to design limitations, Health Canada (2013) reports a Maximum Allowable Carryover (MAC) for lifetime cancer risk in drinking water of 5.0×10^{-5}, CARB (1990c) reports a Cancer Potency Slope of 2.95×10^{-1} ppb, and NRC (2012) reports a Cancer Unit Risk for 1 in 10,000 for 30 minutes exposure as 2990 ppm.

Genotoxicity effects for vinyl chloride outlined on Table 2-5 include "Possible Risk of Irreversible Effects" and "Suspected of Causing Genetic Defects" (NICNAS, 2014b). In Figure 2-6, 12 previous risk assessments described genotoxic effects, but none were noted to be critical. Studies in bacteria, yeast cells and mammalian cells identified metabolic activation, including single strand breaks and unscheduled DNA synthesis in rat hepatocytes, and base-pair substitutions in the Ha-ras and p53 genes in rat liver tumors (OECD, 2001; U.S. EPA, 2000b; IPCS, 1999; CARB, 1990c). Evidence suggests that activation of metabolites by vinyl chloride results in binding to DNA, leading to mutations in proto-oncogenes and tumor-suppressor genes (Health Canada, 2013; IARC, 2012). These effects observed in animals were not described uniquely as genotoxicity-specific human endpoints for Figure 2-4. Rather, this data was considered with other chronic toxicity findings, and is plotted as such.

Previous risk assessments did not describe acute toxicity qualitative risk classifications related to vinyl chloride exposure. Rather, all reported data was quantitative, however EPA would welcome additional information regarding toxicological effects resulting from chronic exposure to vinyl chloride during the upcoming public comment period. Acute toxicity in rats, guinea pigs, and rabbits included eye and skin irritation (NICNAS, 2014b; U.S. EPA, 1975). In rats, mice, and hamsters, inhalation of vinyl chloride resulted in increased motor activity, ataxia and convulsions, followed by narcosis and respiratory failure (ATSDR, 2023; NTP, 2021; Health Canada, 2013; NRC, 2012; IPCS, 1999; CARB, 1990c; U.S. EPA, 1975). Inhalation studies in dogs resulted in severe cardiac arrythmia (ATSDR, 2023; IPCS, 1999; U.S. EPA, 1975). Inhalation of vinyl chloride by guinea pigs resulted in impaired blood clotting (ATSDR, 2023). Congestion of the liver, kidney, and lung, as well as pulmonary edema, was identified in rat inhalation studies (ATSDR, 2023; IPCS, 1999). Based on these observed effects, acute human dose approximations were determined by various risk assessments and are plotted in Figure 2-4. Not visualized in this figure due to design limitations, OECD (2001) reports an AEGL3 as 31,000 mg/m^3 at 10 minutes and 8,800 mg/m^3 at 8 hours, based on cardiac sensitization in dogs. NRC (2012) reports the following cardiac sensitization AEGL3s: 12,000 ppm at 10 minutes, 6,800 ppm at 30 minutes, 4,800 ppm at 1 hour, 3,400 ppm at 4 hours, and 3,400 ppm at 8 hours.

Table 2-5 also describes qualitative determinations based on observed toxicity effects resulting from chronic exposure to vinyl chloride including: "Danger or Serious Damage to Health by Prolonged Exposure" and "Causes Damage to Organs Through Prolonged or Repeated Exposure" (NICNAS, 2014b). Specifically, chronic toxicity in rats resulted in increased mortality (NICNAS, 2014a, b; OECD, 2001; U.S. EPA, 2000a, b; IPCS, 1999), increased liver weights, decreased body weights (NICNAS, 2014b; Health Canada, 2013; U.S. EPA, 2000b; IPCS, 1999), and liver cell polymorphism and lesions (ATSDR, 2023; Health Canada, 2013; OECD, 2001; U.S. EPA, 2000b; IPCS, 1999) including necrosis, mitochondrial damage, and centrilobular degeneration in the hepatic parenchyma (OEHHA, 2011). Within the chronic toxicity category, reproductive/developmental endpoints for rats were included (*e.g.*, increased liver weight, increased kidney/bone and liver/bone ratios, reabsorptions, decreased litter size, increased pup lethality) (Health Canada, 2013; NRC, 2012; OECD, 2001; IPCS, 1999). Also seen in rats was damage to spermatogenic epithelium, contributing to reduced male fertility (U.S. EPA, 2000a; IPCS, 1999). Based on these observed effects, chronic human dose approximations were determined by previous risk assessments and are plotted in Figure 2-4. As seen in Figure 2-6, 63.6 percent of these risk assessments indicate liver cancer and noncancer effects are critical for characterizing vinyl chloride

toxicity. EPA would welcome additional information regarding toxicological effects resulting from vinyl chloride exposure during this public comment period.

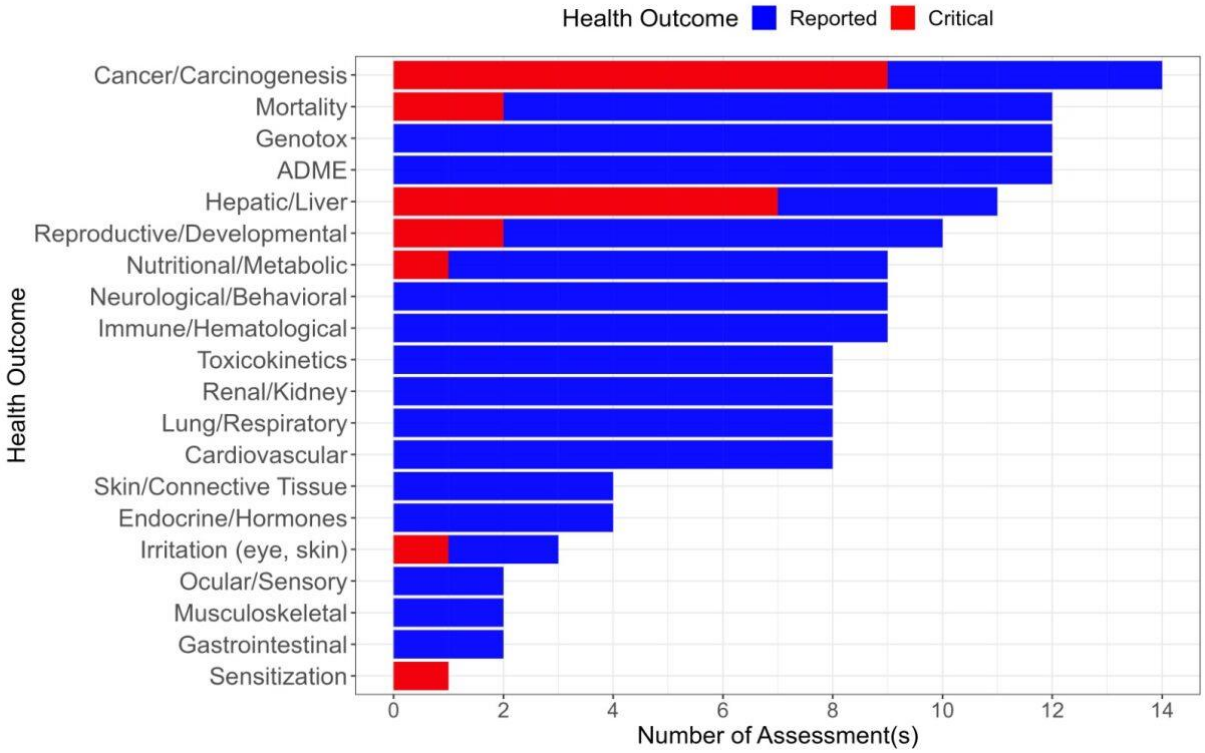


Figure 2-6. Summary of Human Health Animal Toxicity Data Cited by Previous Assessments

2.8 Exposure Potential

EPA considered reasonably available information from previous assessments, databases (*e.g.,* TRI, Water Quality Portal, National Emissions Inventory), and information sources identified in the systematic review approach outlined in Section 2.1 to conduct a screening review of relevant information for vinyl chloride. Section 7 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b), and Appendices, C.3, and C.4 describe how information sources were identified and screened, respectively, to characterize potential exposure to vinyl chloride. Interactive literature inventory tree diagrams available in Appendices C.3.2 and 2.9C.4.2 summarize information identified during the screening step of systematic review that inform the exposure potential of vinyl chloride for different populations. Evidence maps depicting a summary of data identified through the full-text screening of data sources considered through systematic review are available in Appendices C.3.3 and C.4.3 for occupational exposure and environmental release and general population, consumer and environmental exposure, respectively.

2.8.1 Release Information

Chemical releases to the environment from conditions of use are considered in identifying potential exposure and may be derived from reported data obtained through direct measurement, calculations based on empirical data, or assumptions and models.

Toxics Release Inventory

EPA's TRI database contains information on chemical waste management activities reported to EPA 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 EPCRA, vinyl chloride is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting, facilities in covered sectors in the United States are required to disclose release and other waste management activity quantities of vinyl chloride under CASRN 75-01-4 if they manufacture, import, or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in the previous calendar year by July 1 of the following year. For more detailed information about how facilities report information to EPA, see the Agency's web page on TRI reporting.

Table 2-6 provides total quantities of vinyl chloride released onsite to air, water, and land, and aggregated quantities of vinyl chloride transferred off-site to publicly owned treatment works (POTWs) and other wastewater treatment facilities (non-POTW). The table does not include any reported quantities pertaining to other waste management activities (*e.g.*, recycling, combustion for destruction) that occurred on- or off-site during reporting years 2013-2022. The "Number of Facilities" is the count of unique facilities that filed a TRI Form R report for vinyl chloride for reporting years 2013-2022. The TRI data presented in Table 2-6 reflect updates made to the publicly available TRI dataset in October 2023 regarding the addition of TRI information reported to EPA in 2022.

Table 2-6. Summary of TRI Data on Vinyl Chloride from Reporting Years 2013 through 2022 to Assess Exposure Potential

Year	Number of Facilities that Reported	Total Quantities Released On-Site to Air (lbs)	Total Quantities Released On-site to Water (lbs)	Total Quantities Released (Disposed of) On-Site to Land (lbs)	Total Quantities Transferred to POTW (lbs)	Total Quantities Transferred to Other (Non-POTW) Wastewater Treatment Facilities (lbs)	Total Release Quantity (lbs)
2013	43	446,905	71	1	0	132	447,110
2014	41	573,315	46	27	1	371	573,760
2015	44	540,574	42	14,194	3	1,699	556,512
2016	40	573,956	53	29,122	3	393	603,527
2017	43	500,952	48	21,601	0	434	523,036
2018	38	537,841	96	13,627	1	52	551,616
2019	34	420,929	41	0	1	433	421,403
2020	40	471,043	71	0	0	1495	472,609
2021	38	428,185	49	0	1	288	428,522
2022	33	469,074	23	0	3	114	469,215

Of the more than 5 million pounds of vinyl chloride disposed of or otherwise released to the environment during the reporting years 2013-2022, more than 98 percent was released onsite to air. The

majority of offsite releases were to non-POTW facilities. Total releases peaked in 2016 and have varied considerably since that reporting year.

National Emissions Inventory (NEI)

The NEI was established to track emissions of Criteria Air Pollutants (CAPs) and CAP precursors and to assist with National Ambient Air Quality Standard (NAAQS) compliance under the CAA. Air emissions data for the NEI are collected at the state, local, and Tribal (SLT) level. SLT air agencies then submit these data to EPA through the Emissions Inventory System (EIS). In addition to CAP data, many SLT air agencies voluntarily submit data for pollutants on EPA's list of hazardous air pollutants (HAPs). EPA uses data collected from SLT air agencies in conjunction with supplemental HAP data to build the NEI. EPA releases an updated NEI every three years. The most recent version of the NEI was released in 2020 for reporting year 2017.

Table 2-7 presents the 2020 NEI data for vinyl chloride (U.S. EPA, 2020). Over 90 percent of NEI reported air emissions are from industrial processes for chemical manufacturing, waste disposal, and industrial processes not elsewhere classified (NEC) indicating they could not be assigned to any specific industrial sector. Additionally, over 21,000 lbs (less than 3 percent of the total emissions) of vinyl chloride is emitted from fuel combustion sources. For point/major sources, NEI reports emissions data at the emission unit-level. Emission units are the individual processes at a facility with the potential to emit a regulated air pollutant.

Table 2-7. Summary of 2020 NEI Air Emissions Data on Vinyl Chloride

Sector	Total Emissions (lbs)
Industrial processes - chemical manufacturing	395,667
Waste disposal	261,177
Industrial processes - NEC	59,754
Industrial processes - oil & gas production	14,645
Fuel comb - industrial boilers, ICEs - natural gas	10,200
Fuel comb - industrial boilers, ICEs - biomass	7,230
Solvent - industrial surface coating & solvent use	7,126
Industrial processes - storage and transfer	4,883
Industrial processes - non-ferrous metals	4,329
Industrial processes - pulp & paper	3,768
Industrial processes - cement manufacturing	2,725
Fuel comb - electric generation - other	1,816
Fuel comb - electric generation - biomass	1,057
Solvent - degreasing	558
Fuel comb - comm/institutional - other	423
Fuel comb - electric generation - coal	393
Fuel comb - comm/institutional - biomass	359
Fuel comb - electric generation - natural gas	194
Fuel comb - industrial boilers, ICEs - coal	149

Sector	Total Emissions (lbs)
Industrial processes - petroleum refineries	118
Fuel Comb - comm/institutional - natural gas	67
Fuel Comb - industrial boilers, ICEs - oil	50
Fuel Comb - industrial boilers, ICEs - other	46
Industrial processes - ferrous metals	28
Bulk gasoline terminals	8
Fuel comb - electric generation - oil	1

Discharge Monitoring Reports (DMR)

Under the CWA, EPA regulates the discharge of pollutants into receiving waters through the National Pollutant Discharge Elimination System (NPDES). A NPDES permit authorizes discharging facilities to discharge pollutants to specified limits. There are 2 types of effluent limits: (1) technology-based and (2) water quality-based. NPDES permits may also authorize facilities to process, incinerate, landfill, or beneficially use sewage sludge. Under the CWA, EPA may authorize state, Tribal, and territorial governments to write, administer, and enforce NPDES permits. NPDES permits apply pollutant discharge limits to each outfall at a facility. The permits require facilities to monitor their discharges and report the results to EPA and the state regulatory agency. Facilities report these results in DMR.

Table 2-8 presents the 2023 industry sector water release information for vinyl chloride. Less than 20 percent of the facilities with monitoring requirements reported a vinyl chloride discharge in 2023. Of those discharges, nearly 90 percent were from two industry sectors (five facilities in total), miscellaneous plastics products and rolling, drawing, and extruding of nonferrous. Twenty-two of the reporting facilities did not provide an industry sector code. Their releases accounted for less than one percent of the total annual loading for 2023. For additional information on the DMR data for vinyl chloride, refer to (U.S. EPA, 2023b).

Table 2-8. Summary of 2023 DMR Water Release Data on Vinyl Chloride

Industry Sector (3-digit SIC)	Facilities with Monitoring Requirements	Annual Loadings Calculation	
		Facilities	Discharged Amount in 2023 (kg)
281 - Industrial inorganic chemicals	19	9	24.69
282 - Plastics materials and synthetic resins, synthetic	68	22	7.48
286 - Industrial organic chemicals	107	27	0.82
287 - Agricultural chemicals	3	0	0
308 - Miscellaneous plastics products	5	2	270.72
335 - Rolling, drawing, and extruding of nonferrous	3	3	245.31
349 - Miscellaneous fabricated metal products	4	3	0.22
354 - Metalworking machinery and equipment	2	1	3.19

Industry Sector (3-digit SIC)	Facilities with Monitoring Requirements	Annual Loadings Calculation	
		Facilities	Discharged Amount in 2023 (kg)
422 - Public warehousing and storage	43	2	0.04
449 - Services incidental to water transportation	2	1	0.0002
495 - Sanitary services	393	29	28.85
679 - Miscellaneous investing	1	1	0.003
951 - Administration of environmental quality	23	14	0.001
999 - No classifiable establishments	31	9	0.58
No SIC code provided	142	22	1.53
Total	**846**	**22**	**583.43**

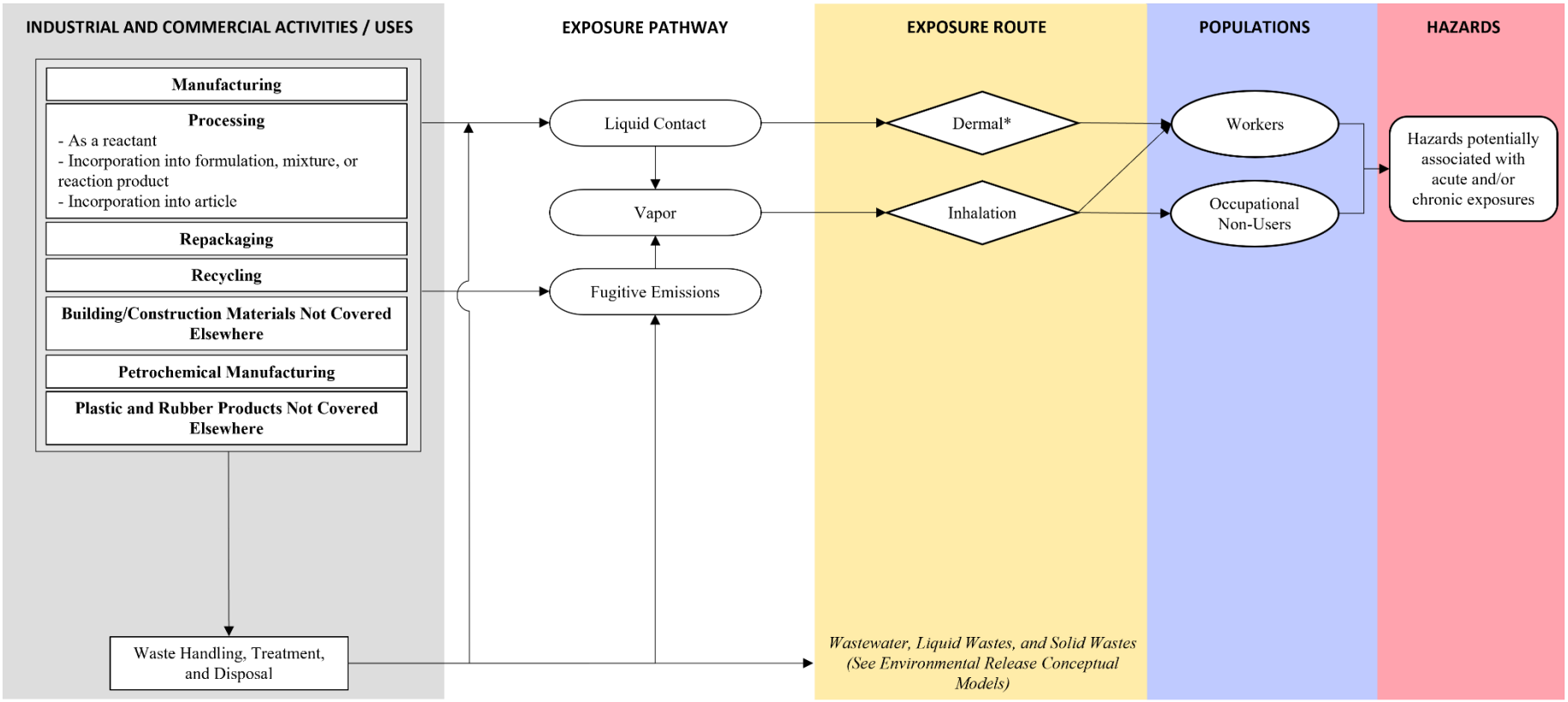
2.8.2 Industrial and Commercial Activities and Uses

Worker exposure to this chemical may be affected by many factors, including but not limited to volume produced, processed, distributed, used, and disposed of; physical form and concentration; processes of manufacture, processing, and use; chemical properties such as vapor pressure; and exposure controls such as engineering controls, administrative controls, and use of a personal protective equipment (PPE) program.

Vinyl chloride has had an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL)[3] since 1974. The PEL is 1 part per million (ppm) over an 8-hour workday, time-weighted average (TWA). The OSHA Short-Term Exposure Limit (STEL) for vinyl chloride is 5 ppm averaged over any period not exceeding 15 minutes. The American Conference of Governmental Industrial Hygienists (ACGIH) set the Threshold Limit Value (TLV) at 1 PPM TWA. EPA has identified these occupational exposure limits for vinyl chloride as indicators of potential workplace exposure to vinyl chloride via the inhalation route.

The pathways and routes of exposure EPA believes may be relevant to workers and occupational non-users (ONUs) are presented in Figure 2-7. This preliminary conceptual model is presented for public comment as part of this prioritization action. EPA has not yet determined which pathways and routes would be included in the scope of the risk evaluation, should vinyl chloride be designated a High-Priority Substance.

[3] For more information, see the Occupational Safety and Health Administration's PEL Tables.



*Vinyl chloride is a gas at room temperature and transported as a liquid under pressure. EPA will evaluate potential for dermal exposure; however, routine dermal contact is not expected.

Figure 2-7. Preliminary Conceptual Model for Industrial and Commercial Activities and Uses: Potential Worker and ONU Exposures and Hazards for Vinyl Chloride

The preliminary conceptual model presents the potential exposure pathways, exposure routes, and hazards to the population from industrial and commercial activities and uses of vinyl chloride. Populations include PESS (see Section 2.4). The information in the preliminary conceptual model is grouped according to the 2016 and 2020 CDR processing codes and use categories from Table 2-2.

2.8.3 Consumer Activities and Uses

Based on 2016 CDR information, vinyl chloride was reported for consumer use in plastics and rubber products not covered elsewhere; in 2020, consumer uses were not reported (Table 2-2). Use in children's products was not reported to the CDR in 2016 or 2020. However, as shown in Table 2-3, databases that report consumer uses have reported vinyl chloride in several categories of consumer products, including children's products. Although the specific consumer products described in Table 2-3 were not reported to CDR, it is possible that vinyl chloride uses in plastics and rubber products like the consumer products described in Table 2-3. In addition, based on EPA's screening review of reasonably available information, 7 studies containing information relevant to consumer use were identified, see Figure_Apx C-7.

Vinyl chloride has been reported in the Chemical Exposure Knowledgebase (ChemExpo), a publicly available web-based data search and visualization tool developed by EPA, as potentially being present in caulk/sealant, paint, primer, furniture and flooring materials. Chemical weight fractions in products and documentation date are reported in ChemExpo. This information is primarily obtained from documents published by manufacturers, retailers, governments, and NGOs, and is released by EPA as the Chemical and Products database (CPDat). For vinyl chloride, of the 15 consumer products curated in accordance with the product use category (PUC), an identifier assigned to products which indicates the type of product assigned to each data record based on information provided in the original data source, 9 were reported with weight fractions ranging from 0.1 to 15.4 percent, however, the weight fraction was unavailable for the other 6 products (U.S. EPA, 2024a).

As described in Section 2.4 and Table 2-3, manufacturer testing for vinyl chloride in children's products was identified in the HPCDS. The information presented in HPCDS is reported to the state of Oregon or the state of Washington by manufacturers of children's products through the Interstate Chemicals Clearinghouse (IC2). This information is reported in concentration ranges and includes reports beginning in 2014. For vinyl chloride, of the 387 entries, 291 were reported as greater than the practical quantitation limit but less than 100 ppm, 14 were reported to be equal to or greater than 100 but less than 500 ppm, 40 entries were reported as greater than 10000 ppm (IC2, 2024). Nearly 6 percent of the entries across the different product types reported vinyl chloride as a contaminant.

Additionally, EPA has also received information during the public comment period that indicates that vinyl chloride may be present in consumer products otherwise not listed in Table 2-2, *e.g.*, wall coverings, garments, and pool liners.

Based on the information reported to the HPCDS, ChemExpo, studies found during EPA's screening review and public comment, there is uncertainty regarding use of vinyl chloride in these categories of consumer products. EPA seeks confirmation, comment or additional information on consumer uses. EPA will consider public comments received regarding the presence of vinyl chloride in consumer products and articles.

Potential exposure to vinyl chloride may occur through dermal contact to products and articles containing vinyl chloride and inhalation through indoor air where products and articles containing vinyl chloride are present. Potential pathways and routes of exposure relevant to consumers, based on consumer uses from 2016 CDR reporting, are shown in Figure 2-8. As part of this prioritization action, this preliminary conceptual model is presented for public comment. EPA has not yet determined which pathways and routes would be included in the scope of the risk evaluation, should vinyl chloride be designated a High-Priority Substance.

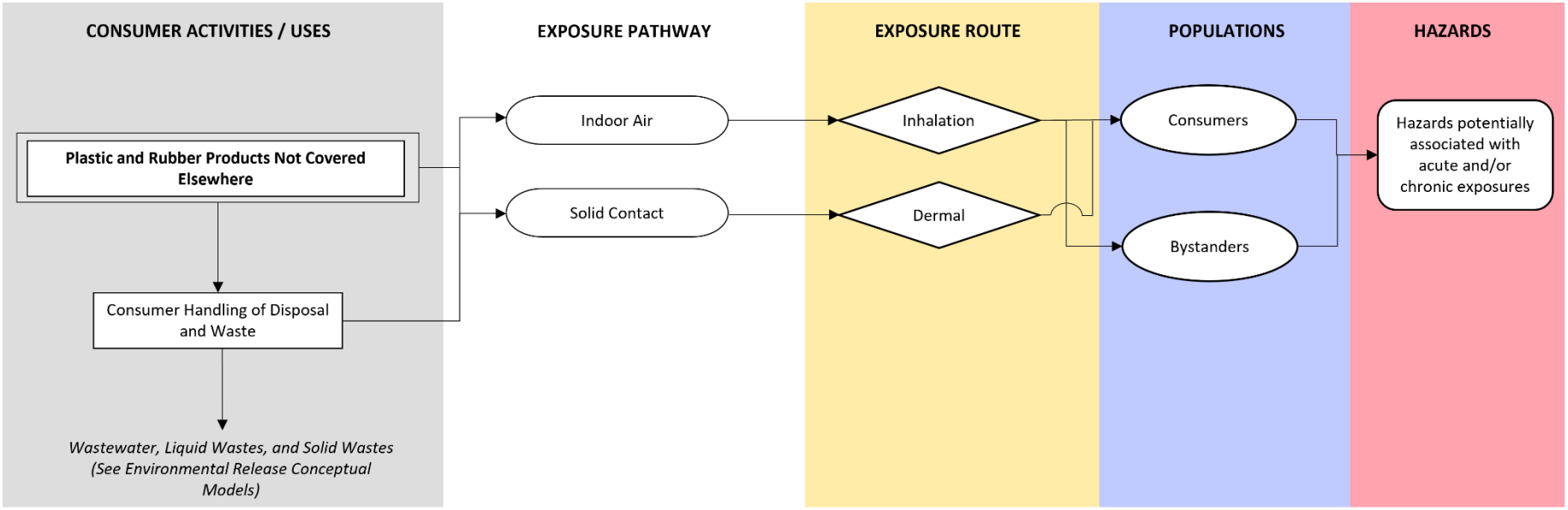


Figure 2-8. Preliminary Conceptual Model for Consumer Activities and Uses: Potential Consumer Exposures and Hazards of Vinyl Chloride

This preliminary conceptual model presents the potential exposure pathways, exposure routes, and hazards to human subpopulations from consumer activities and uses of vinyl chloride. Populations include PESS (see Section 2.4). The information in the preliminary conceptual model is grouped according to the 2016 and 2020 CDR processing codes and use categories from Table 2-2.

2.8.4 Environmental and General Population Exposure

The manufacturing, processing, distribution, use, and disposal of vinyl chloride may result in releases to the environment and potential exposure to aquatic and terrestrial ecological receptors (biota), as well as the general human population. Environmental and general population potential exposure are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment and partitioning across various media. Concentrations of vinyl chloride in contaminated air, food, and drinking water or from dermal contact with consumer products supports potential exposure.

As described in previous assessments (ATSDR, 2023; NTP, 2021; IARC, 2012), vinyl chloride may be present in the outdoor environment as a result of releases from multiple industrial and commercial conditions of use identified in Section 2.3. Chemical manufacturing, manufacturing of products containing vinyl chloride, and use of vinyl chloride in other chemical manufacturing processes could cause releases to various media and to the outdoor environment with ambient air being the primary media.

Based on the environmental releases reported in Section 2.8, as well as physical and chemical properties and the environmental fate of vinyl chloride discussed in Section 2.5, Appendix D, and Appendix E, vinyl chloride may be present in ambient air, surface water, groundwater, wastewater, soil, and sediment. While data reported to TRI indicate releases of vinyl chloride to air, surface water, land, and wastewater, ongoing presence of vinyl chloride in water and soil may be limited due to the rapid volatility of vinyl chloride upon release (ATSDR, 2023). Vinyl chloride is not expected to bioaccumulate in aquatic species (ATSDR, 2023). Additionally, bioaccumulation of vinyl chloride in sediment and soil dwelling organisms is expected to be low (ATSDR, 2023; NICNAS, 2014a). The high vapor pressure of vinyl chloride means it will exist predominantly as a gas in the atmosphere. This combined with its partitioning behavior suggests vinyl chloride to be mobile in soils due to high potential for leaching and evaporative losses (ATSDR, 2023; NICNAS, 2014a). EPA identified environmental concentration data to inform potential exposure to vinyl chloride in Table 2-9.

Table 2-9. Exposure Information for Potential Environment and General Population Exposure

Database	Environmental Concentration Data Present?	Human Biomonitoring Data Present?	Ecological Biomonitoring Data Present?	Reference
Air Monitoring Network	No	No	No	Washington State Department of Ecology (2008)
Biomonitoring California	No	No	No	CDPH, CalEPA (2006)
Biomonitoring in Washington State	No	No	No	Washington State Department of Health (2009)
Comparative Toxicogenomics Database	Yes	Yes	No	MDI, NC State University (2002)
Environmental Information Management (EIM) System	Yes	No	Yes	Washington State Department of Ecology (2019)
EPA AirToxScreen	Yes	No	No	U.S. EPA (2019)

Database	Environmental Concentration Data Present?	Human Biomonitoring Data Present?	Ecological Biomonitoring Data Present?	Reference
EPA Ambient Monitoring Technology Information Center (AMTIC) – Air Toxics Data	Yes	No	No	U.S. EPA (1990)
EPA Air Quality System (AQS)	Yes	No	No	U.S. EPA (1980)
EPA Fish Tissue Studies	No	No	No	U.S. EPA (2006)
EPA Six-year Review	Yes	No	No	U.S. EPA (2003)
EPA Unregulated Contaminant Monitoring Rule	No	No	No	U.S. EPA (1996)
Food and Drug Administration (FDA) Total Diet Study	No	No	No	FDA (1991)
Great Lakes Environmental Database	No	No	No	U.S. EPA (2018b)
International Council for the Exploration of the Sea	No	No	No	ICES (2018)
Targeted National Sewage Sludge Survey	No	No	No	U.S. EPA (2006)
The National Health and Nutrition Examination Survey	No	No	No	CDC (2013)
NWQMC, USGS, and EPA Water Quality Portal (WQP)	Yes	No	Yes	NWQMC, USGS, U.S. EPA (2021)

2.8.4.1 Environmental Exposure

Potentially relevant and reliable environmental monitoring data for vinyl chloride were considered from previous assessments, databases (*e.g.*, DMR) and Water Quality Portal (WQP)) as well as peer-reviewed and gray literature data sources identified in the search of reasonably available information described in Section 7 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b). Table 2-9 identifies data sources containing environmental concentration data that may be used to inform potential exposure to vinyl chloride for ecological receptors.

Disposal and waste treatment activities associated with vinyl chloride and products containing vinyl chloride are also expected to result in releases to the outdoor environment. Vinyl chloride may be present in surface water, groundwater, wastewater, soil, and sediment as a result of these releases. Environmental monitoring information identified in databases and through systematic review indicates

that vinyl chloride has been measured in surface water, soil, groundwater, leachate, wastewater, and ambient air (IARC, 2012). Aquatic ecological receptors may be exposed to vinyl chloride due to the TRI-reported releases and from vinyl chloride measured in surface water (<0.02–5.0 ppb) and sediment (0.5 -1000 ppb) (ATSDR, 2023). Terrestrial ecological receptors may also be exposed to vinyl chloride due to TRI-reported releases and vinyl chloride measured in soil (2.4 -9.5 ppb) and ambient air (0.039 - 0.052 ppb) (ATSDR, 2023). EPA did not identify any monitoring information for biota.

2.8.4.2 General Population Exposure

Environmental releases of vinyl chloride from certain conditions of use identified in Section 2.3, such as manufacturing, processing, distribution, use and disposal may lead to general population exposure. Table 2-9 identifies data sources containing environmental concentration data that may be used to inform general population exposure to vinyl chloride.

Releases of vinyl chloride from certain conditions of use such as manufacturing, disposal, or hazardous waste treatment activities may result in general population exposures (ATSDR, 2023; NTP, 2021; IARC, 2012). Elevated concentrations of vinyl chloride have been measured in the vicinity of chemical manufacturing plants, plastic industries, and landfills (ATSDR, 2023). Populations living near plastic production plants and PVC manufacturing plants (where vinyl chloride is processed to a series of compounds being used) would be expected to have higher exposures to vinyl chloride in outdoor air (IARC, 2012).

Inhalation has been identified by the National Toxicology Program (NTP) as the primary route of exposure to vinyl chloride for the general population (NTP, 2021). The general population can be exposed indirectly to vinyl chloride emissions from industrial sites at the local and regional scale with increased exposure at the local scale (IARC, 2012). Deposition of these emissions onto soil has the potential to increase vinyl chloride concentrations in the impacted soil area. However, most vinyl chloride in soil will volatize into the atmosphere or become susceptible to leaching into groundwater. Vinyl chloride present in groundwater could result in potential dermal exposure from activities such as showering or oral exposure if the groundwater is used a source of drinking water. Previous assessments note the general population can be exposed to vinyl chloride in the ambient air due to vinyl chloride emissions of cigarettes and cigars (NTP, 2021).

The pathways and routes of environmental and general population exposure EPA believes may be associated with environmental releases and wastes are depicted in the preliminary conceptual model shown in Figure 2-9. This preliminary conceptual model is presented for public comment as part of this prioritization action. EPA has not yet determined which pathways and routes would be included in the scope of the risk evaluation, should vinyl chloride be designated a High-Priority Substance.

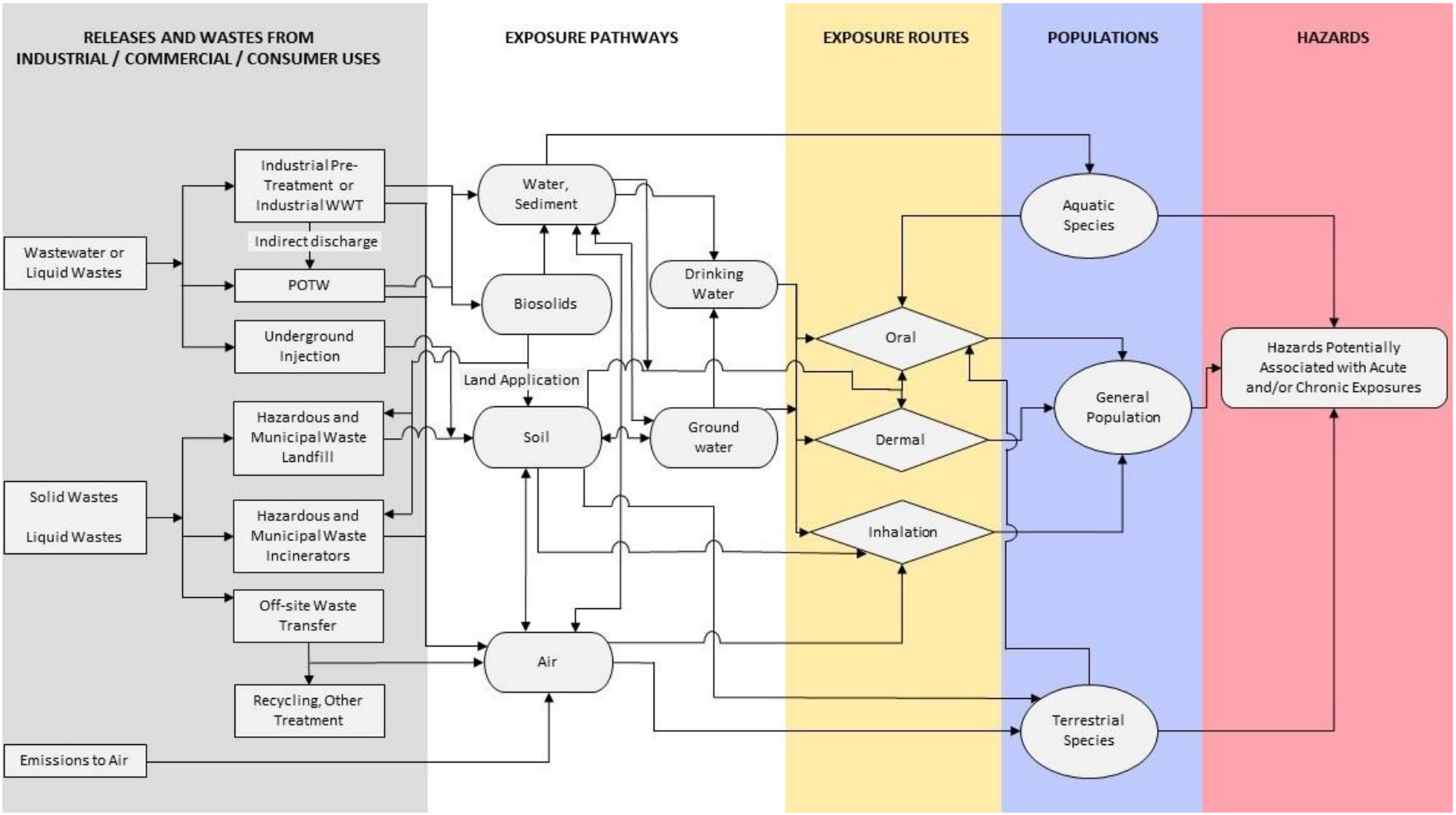


Figure 2-9. Preliminary Conceptual Model for Environmental Releases and Wastes: Potential Environmental and General Population Exposures and Hazards for Vinyl Chloride

Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTWs (indirect discharge). For consumer uses, such wastes may be released directly to POTWs. Drinking water will undergo further treatment in drinking water treatment plant. Groundwater may also be a source of drinking water. Inhalation from drinking water may occur via showering. Populations include PESS (see Section 2.4). The information in the preliminary conceptual model is grouped according to the 2016 and 2020 CDR processing codes and use categories from Table 2-2.

2.9 Other Risk-based Criteria Relevant to the Proposed Designation of Vinyl Chloride

EPA did not identify other risk-based criteria relevant to the proposed designation of vinyl chloride under TSCA.

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APPENDICES

Appendix A PRELIMINARY REGULATORY HISTORY

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

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
TSCA – section 6(b)	EPA is directed to identify High-Priority chemical substances for risk evaluation.	Vinyl chloride is one of the High-Priority Substance candidates for which EPA initiated prioritization under TSCA (88 FR 87423, December 18, 2023).
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.	Vinyl chloride manufacturing (including importing), processing and use information is reported under the CDR rule (40 CFR part 711).
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.	Twenty substantial risk reports received for vinyl chloride (1991-2016). (U.S. EPA, ChemView. Accessed August 9, 2023.)
TSCA – section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	One chemical data submission from test rules received for vinyl chloride: one environmental monitoring report. (1980) (U.S. EPA, ChemView. Accessed August 9, 2023.)
EPCRA – section 313	EPCRA Section 313 – also known as the Toxic Release Inventory (TRI) – 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	Vinyl chloride is a listed substance (or part of a listed chemical category) subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (*e.g.*, quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (*i.e.*, air, land and water).	
CAA – section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	EPA has established NSPS for a number of source categories to limit emissions to air of volatile organic compounds (VOCs), which are precursors to ozone. Vinyl chloride is a VOC. (See link).
CAA – section 112(b)	Contains the original list of 189 hazardous air pollutants (HAPs) that Congress added in 1990. Under 112(c) of the CAA, EPA must identify and list source categories that emit listed HAPs 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 both removed HAPs from and added HAPs to the original list.	Vinyl chloride is listed as a HAP (42 U.S. Code section 7412).
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, NESHAP for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the	EPA has established NESHAP for a number of source categories that emit vinyl chloride to air. (See link).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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 areas sources, the standards must require generally achievable control technology (GACT) though may require MACT. Section 112(d)(6) requires EPA to review, and revise, as necessary, (taking into account developments in practices, processes and control technologies) the emission standards every 8 years.	
Clean Air Act (CAA) – Section 112(f)	Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) NESHAP that require maximum achievable control technology (MACT) and to determine if additional standards are needed to reduce remaining risks; this is required within 8 years of promulgating the NESHAP.	EPA has promulgated a number of Risk and Technology Review (RTR) NESHAP and will do so, as required, for the remaining source categories with NESHAP. (See link).
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	Vinyl chloride is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Vinyl chloride has a reactivity factor of 2.92 g O3/g VOC.
Clean Water Act (CWA) - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA issued an updated AWQC for vinyl chloride, including a recommendation of 0.022 (µg/L) for "Human Health for the consumption of Water + Organism" and 1.6 (µg/L) for "Human Health for the consumption of Organism Only" that states and authorized tribes may consider when

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		adopting criteria into their water quality standards (40 CFR 414).
Clean Water Act (CWA) – Section 301, 304, 306, 307, and 402	CWA Section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statue specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The list of "priority pollutants" lists the individual chemical names within the toxic pollutants and are found in 40 CFR Part 423 Appendix A. These are pollutants (along with non-conventional pollutants) for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in National Pollutant Discharge Elimination System (NPDES) permits, see Section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable (BAT) for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	Vinyl chloride is designated as a toxic pollutant under section 307(a)(1) of the CWA (33 U.S.C. 1317(a)(1)) and as such is subject to effluent limitations and any associated monitoring requirements of NPDES permits (40 CFR 401.15; 40 CFR Part 423 Appendix A). Under CWA section 304, vinyl chloride is included in the list of total toxic organics (TTO) for at least one point source category (Electroplating (40 CFR 413.02(i)); Metal Finishing (40 CFR 433.11(e)).
SDWA – Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goal (MCLG) for a contaminant for which EPA makes the determination that the contaminant: 1. may have an adverse effect on the health of persons; 2. is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a	Vinyl chloride is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.002 mg/L (Section 1412) (40 CFR Part 141).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	required treatment technique. Public water systems are required to comply with NPDWRs.	
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Vinyl chloride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U043 (40 CFR 261.33). Vinyl chloride also exhibits the characteristic of toxicity leading it to be assigned Hazardous Waste Number D043 with a corresponding regulatory level of 0.2 mg/L (40 CFR 261.24). Vinyl chloride is also listed as part of various groups of chemicals in Appendix VII to Part 261 – Basis for Listing Hazardous Waste as K019, K020, K028, K029 (40 CFR Appendix VII to Part 261).
CERCLA – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances, in addition to those referred to in section 101(14) of CERCLA, those elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold. CERCLA Hazardous substances listed under 40 CFR Table 302.4 are subject to EPCRA Section 304 notification requirements.	Vinyl chloride is a hazardous substance under CERCLA. Releases of vinyl chloride in excess of 1 pound must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Superfund Amendments and Reauthorization Act (SARA)	Amendments made several important changes to CERCLA, for example: 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.	Vinyl chloride is listed in 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		
FFDCA – section 408	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics, except residues of pesticides in food are regulated by EPA under FFDCA section 408 (discussed above where applicable).	Vinyl chloride is prohibited by the FDA as an ingredient in aerosol products (21 CFR 700.14). The FDA regulates vinyl chloride in bottled water. The maximum permissible level of vinyl chloride in bottled water is 0.002 mg/L (21 CFR 165.110). Vinyl chloride is listed as an optional substance to be used in a number of food contact substances. (See link)
Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA)	CPSA authorizes the Consumer Product Safety Commission (CPSC) to develop standards and bans, as well as pursue recalls and to ban products under certain circumstances. In 2008, CPSIA provided CPSC with significant new regulatory and enforcement tools. CPSIA addresses, among other things, lead, phthalates, toy safety, third-party testing and certification, and imports.	Self-pressurized products intended or suitable for household use that contain vinyl chloride monomer as an ingredient or in the propellant manufactured or imported on or after October 7, 1974, are banned in interstate commerce. (16 CFR 1500.17)
Occupational Safety and Health Act (OSH Act)	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	In 1974, OSHA issued occupational health and safety standards for vinyl chloride that included a PEL of 1 ppm (8 hour TWA) and 5 ppm (15 minutes); exposure monitoring; control measures and respiratory protection; medical surveillance; and hazard

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	communication (29 CFR 1910.1017(c)(3)). No employee may be exposed to vinyl chloride by direct contact with liquid vinyl chloride. OSHA and the National Institute for Occupational Safety and Health (NIOSH) have issued a Hazard Alert regarding vinyl chloride as a carcinogen (Ca) and recommend reducing exposure to the lowest feasible concentration. (See Appendix A, NIOSH Potential Occupational Carcinogens).
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	Vinyl chloride 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 (49 CFR 172).

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants): Toxicity Class I, 24-Hr AAL 9.3 (µg/m3), Annual AALB 6.2 (µg/m3), 24-Hr De Minimis 0.11 (lbs/day), Annual De Minimis 40 (lbs/yr) Rhode Island (Air Pollution Regulation No. 22): 1-Hr AAL: 1,000 (µg/m3), 24-Hr AAL: 100 (µg/m3), Annual AAL 0.2 (µg/m3)

State Actions	Description of Action
State Drinking Water Standards and Guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008) MCL: 0.002 (mg/L) MCLG: 0 (mg/L) California (Cal Code Regs. Title 26, 22-64444) State MCL: 0.0005 (mg/L) Delaware (Del. Admin. Code Title 16, 4462) State MCL: 0.001 (mg/L) MCLG: 0 (mg/L) Connecticut (Conn. Agencies Regs. 19-13-B102) State MCL: 0.002 (mg/L) Florida (Fla. Admin. Code R. Chap. 62-550) State MCL: 0.001 (mg/L) Maine (10 144 Me. Code R. Chap. 231) State MCL: 0.002 (mg/L) Massachusetts (310 Code Mass. Regs. 22.00) State MCL: 0.002 (mg/L) Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017) State MCL: 0.002 (mg/L) Minnesota (Minn R. Chap. 4720) State MCL: 0.002 (mg/L) New Jersey (7:10 N.J Admin. Code 5.2) State MCL: 0.002 (mg/L) Pennsylvania (25 Pa. Code 109.202) State MCL: 0.002 (mg/L) Rhode Island (Rules and Regulations Pertaining to Public Drinking Water R46-13-DWQ) State MCL: 0.002 (mg/L) Texas (30 Tex. Admin. Code 290.104) State MCL: 0.002 (mg/L)
State PELs	California (PEL of 1 ppm and a STEL of N/A) (Cal Code Regs. Title 8, 5155) Hawaii PEL: 1 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. 670.000 Appendix A), New Jersey (N.J.A.C. 7:1G) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing vinyl chloride, including Maine (38 MRSA Chapter 16-D, Chemical of High Concern)), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, ORS 431A.253-431A.280), Vermont (18 V.S.A 1776) and Washington State (Wash. Admin. Code 173-334-130).
Volatile Organic Compound (VOC) Regulations for Consumer Products	Many states regulate vinyl chloride as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include PVC pipes, contact and aerosol adhesives, aerosols, wire coatings, vehicle upholstery, and plastic kitchen ware among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Delaware (Adm. Code Title 7, 1141), Illinois (35 Adm Code 223), Indiana (326 IAC 8-15),

State Actions	Description of Action
	Maryland (COMAR 26.11.32.00 to 26.11.32.26), Massachusetts (310 CMR 7.18), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100), New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235), Ohio (Chapter 3725-112), Pennsylvania (Chapter 130, Subchapter B, Sections 130.201 through 130.471), Rhode Island (Air Pollution Control Regulation No. 31), Utah (R 307-357) and Virginia (9VAC5 CHAPTER 45) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting.
Other	California listed vinyl chloride on Proposition 65 in 1987 due to cancer (Cal Code Regs. Title 27, 27001). Vinyl chloride 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 August 8, 2023). Vinyl chloride is on the MA Toxic Use Reduction Act (TURA) list of 2023 (301 CMR 41.00).

Table_Apx A-3. International Laws and Regulations

Country/Organization	Requirements and Restrictions
Canada	Vinyl chloride is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed September 8, 2023). Vinyl chloride is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). Other regulations include: • Environmental Emergency Regulations, 2019. • Canada's National Pollutant Release Inventory (NPRI).
European Union	Vinyl chloride is registered for use in the EU. (European Chemicals Agency (ECHA) database). Accessed August 9, 2023. In 2016, a restriction on the sale and all use of Vinyl chloride in aerosols for was added to Annex XVII of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). (European Chemicals Agency (ECHA) database. Accessed November 28, 2023).
Australia	Vinyl chloride was assessed under Human Health and Environment Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed November 29, 2023). These assessments were carried out by NICNAS but are now accessed through the Australian Industrial Chemicals Introduction Scheme (AICIS).

Country/Organization	Requirements and Restrictions
	Uses reported include the production of polyvinyl chloride (PVC), which in turn is used for various plastic products. It was also reported that this chemical was previously used as a refrigerant. (NICNAS, 2014, Human Health Tier II assessment for Ethene, chloro-. Accessed November 29, 2023).
Japan	Vinyl chloride is regulated in Japan under the following legislation: • Chemical Substances Control Law (CSCL) • Pollutant Release and Transfer Registers & Safety Data Sheet Law (PRTR-SDS Law) • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law • Soil Contamination Countermeasures Act • Act on the Control of Household Products Containing Harmful Substances • Food Sanitation Act • High Pressure Gas Safety Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. (Accessed December 1, 2023).
Basel Convention	Vinyl chloride is listed under A3: Wastes containing principally organic constituents, which may contain metals and inorganic materials, a category of waste under the Basel Convention. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters. Parties to the Basel Convention cannot trade Basel-covered waste with nonparties (such as the U.S.) in the absence of a pre-determined agreement between countries.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	Vinyl chloride is listed under A3: Wastes containing principally organic constituents, which may contain metals and inorganic materials, a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.
Australia, Austria, Belgium, Canada (Ontario & Quebec), Denmark, European Union, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan (MHLW & JSOH), Latvia New Zealand, Norway, People's Republic of China, Poland, Romania, Singapore, South Africa, South Africa Mining, South Korea, Spain, Sweden, Switzerland, The Netherlands, Turkey, USA (OSHA), United Kingdom	Occupational exposure limits for Vinyl chloride (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed August 9, 2023).

Appendix B IDENTIFICATION OF PUBLICLY AVAILABLE PEER-REVIEWED AND GRAY LITERATURE FOR VINYL CHLORIDE

As stated above, EPA conducted a comprehensive search for reasonably available information to support the proposed designation of vinyl chloride as a High-Priority Substance. This search included the general categories of sources identified in Section 2 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b), which include publicly available peer-reviewed literature, gray literature, and other relevant information submitted to EPA (*e.g.,* public comments). There was no limit set on the search for reasonably available information on vinyl chloride regarding when or where the data in a respective data source were published, therefore there may be some data that are potentially more relevant than others.

Appendices B.1 and B.2 describe how EPA identifies, potentially relevant peer-reviewed information and gray literature for each chemical, respectively was identified for each discipline from peer-reviewed literature using software applications. As compared to the 2021 Draft Systematic Review Protocol, some updates have been made regarding how EPA identified discipline-specific information from the peer-reviewed literature search, and the gray literature sources considered for each chemical. These updates are described in the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b).

B.1 Identification of Potentially Relevant Peer-Reviewed Information for Vinyl Chloride

Section 4.2.1 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021) provides an overview of how peer-reviewed literature was identified by an information specialist. The chemical-specific literature searches are broad and focus only on the chemical name (including synonyms and trade names) with no additional search limits. Using this approach and searching multiple databases, the search is designed to be comprehensive, using validated chemical descriptors to generate a wide capture of information and yield diverse information for all disciplines. Appendix B.1.2 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021) provides additional information regarding search term genesis for chemical-specific peer-reviewed literature searches implemented under TSCA section 6 for the identification of peer-reviewed vinyl chloride data sources, whereas this section provides chemical verification for the identification of peer-reviewed vinyl chloride data sources.

After the broad search is completed, additional filtering steps are applied in SWIFT-Review (Sciome product) to narrow the literature pool to references that are potentially discipline-relevant. As described by Howard et al. (2016), SWIFT-Review uses the Apache Lucene open-source software to provide a search engine and query language that can be used to interactively explore and filter references using both custom and built-in searches. The software identifies relevant references by automatically scanning for search terms characteristic of each of these disciplines in the title and abstract fields of each reference.

Broad searches are over-inclusive by nature and may lead to a literature pool of overwhelming size, as is the case with vinyl chloride. Additionally, discipline-specific keywords pertaining to desired information categories often overlap with information categories known to be off-topic for all disciplines. This additional filtering process identifies literature that is not expected to meet population, exposure, comparator, and outcome (PECO) or pathways and processes or population, exposure, setting or scenario, and outcomes (PESO) criteria (*e.g.*, chemical derivatives, nanotechnology, etc.), with the resulting subset of literature being deprioritized for later consideration.

The initial extraction step identified instances of the chemical name and synonyms of the chemical name that appeared as part of a separate, unrelated chemical or substance name (*e.g.*, polyvinyl chloride), as well as generalized keywords relating to concepts falling outside of PECO and PESO criteria. The results of this extraction were then examined for instances where the chemical name or a synonym appeared in conjunction with a chemical of non-interest, and also met at least one criteria point for a discipline. This subset of the extraction pool was then reintegrated into the peer literature pool for discipline-specific binning.

Table_Apx B-1. Filtering Strategies for Identifying Peer Literature Not Meeting PECO or PESO Criteria

Filtering Step	Filtering Queries
Initial extraction	tiab_punct:("polyvinyl chloride" OR "poly vinyl chloride" OR "poly-vinyl chloride" OR "PVC") tiab_punct:("vinyl chloride" AND ("polyvinyl chloride" OR "poly vinyl chloride" OR "poly-vinyl chloride" OR "PVC")) tiab:("metal complex*" OR "ligand*" OR ("framework*" AND ("DNA" OR "metal")) OR "polymer*" OR "derivative*" OR "catalyst*" OR "photo*" OR "spectr*" OR "DFT" OR "density functional theory" OR "nano*" OR "synthesis" OR "dye-sensitized" OR "functionalized")
Reintegration	tiab_punct:("polyvinyl chloride" OR "poly vinyl chloride" OR "poly-vinyl chloride" OR "PVC") tiab_punct:("vinyl chloride" AND ("polyvinyl chloride" OR "poly vinyl chloride" OR "poly-vinyl chloride" OR "PVC")) AND (tiab:("occupational health" OR "worker exposure" OR "occupational groups" OR "employee" OR "worker*" OR "worker exposed" OR "work* in a factory" OR "work* in a plant" OR "work* in a manufacturing plant" OR "hygienist" OR "OSHA" OR "NIOSH") OR tiab:("carcinogen*" OR "cancer" OR "etiology" OR "tumor" OR "mortality" OR "mortality rate" OR "mortality ratio" OR "rats" OR "mortality incidence" OR "cancer incidence" OR "hematuria" OR "intravenous" OR "intra-assay" OR "drosophila" OR "daphnia" OR "cytology" OR "atypia" OR (("dog" OR "dogs" OR "cats") NOT "human") OR "oral administration" OR "administration" OR "administered" OR "carcinoma" OR "Sprague-Dawley" OR "mice" OR "gene" OR "genetic" OR "mutagenicity" OR "genotoxicity" OR "cytotoxicity" OR "LD50" OR "LC50" OR "LT50" OR "TD50" OR "P450" OR "cytochrome" OR "bioassay" OR "immunoassay" OR "cholinesterase" OR "inhibitor" OR "*in vivo*" OR "*in vitro*" OR "enzyme" OR "transferase" OR "oxidase" OR "hydrogenase" OR "dehydrogenase" OR "bacteria*" OR "virus" OR "viral" OR "agar" OR "mutation*" OR "nucleotide" OR "malignant" OR "neoplasm" OR "tumor*" OR "tumour*" OR "benign" OR "neoplasia" OR "preneoplastic" OR "neoplastic" OR "metastases" OR "proliferative lesion" OR "hypertension" OR "neurological" OR "behavioral" OR "cardiovascular" OR "endocrine" OR "reproductive" OR "developmental" OR "gastrointestinal" OR "immune" OR "hematological" OR "hepatic" OR "musculoskeletal" OR "ocular" OR "sensory" OR "renal" OR "irritation" OR "sensitization" OR "gene therapy" OR "gavage" OR "radioactivity" OR "hypertrophy" OR "atrophy" OR "inbred strain" OR "congenic" OR "inbred A" OR "inbred AKR" OR "inbred BALB C" OR "inbred C3H" OR "inbred C57BL" OR "inbred mdx" OR "inbred CBA" OR "inbred CFTR" OR "inbred DBA" OR "inbred ICR" OR "inbred MRL Ipr" OR "inbred NOD" OR "inbred NZB" OR "inbred SENCAR" OR "inbred ACI" OR "inbred BB" OR "inbred BN" OR "inbred BUF" OR "inbred Dahl" OR "inbred F344" OR "inbred LEC" OR "inbred Lew" OR "inbred OLETF" OR "inbred SHR" OR "inbred WF" OR "inbred WKY" OR "transgenic" OR "founder animal" OR "GMO animal" OR "genetically engineered animal" OR "genetically modified animal" OR "knockout mice" OR "ApoE" OR "rabbit*" OR "goldfish") OR tiab:("biodegradability" OR "biodegradation" OR "bioisomerization" OR "biomagnification" OR "biotransformation" OR "dechlorination" OR "degradation" OR "dehalogenation" OR "fate" OR "food web" OR "hydrolysis" OR "photodegradation" OR "photolysis" OR "phototransformation" OR "trophic magnification" OR "evaporation rates" OR "reaction" OR "bioremediation" OR

Filtering Step	Filtering Queries
	"bioaugmentation" OR "reverse osmosis" OR "sterilization" OR "kinetic*" OR "ultraviolet irradiation") OR tiab:(("physical form" OR "physical state" OR "physical chemistry" OR "physical properties" AND ("crystal structure" OR "crystalline structure" OR "morphology" OR "color")) OR "melting point" OR "boiling point" OR "density" OR "vapor pressure" OR "vapour pressure" OR "vapor density" OR "vapour density" OR "water solubility" OR "aqueous solubility" OR "aqueous saturation point" OR "water saturation point" OR "octanol:water partition coefficient" OR "octanol-water partition coefficient" OR "octanol/water partition coefficient" OR "octanol water partition coefficient" OR "Kow" OR "Henry's Law constant" OR "heat of Henry" OR "Kaw" OR "air water partition" OR "pKa" OR "acid dissociation constant" OR "dissociation constant" OR "flash point" OR "autoflammability" OR "viscosity" OR "enthalpy of phase change" OR "enthalpy of vaporization" OR "heat of vaporization" OR "photoabsorption" OR "absorption spectra" OR "absorption spectrum" OR "transition state" OR "zeta potential" OR "individual fiber diameter" OR "average fiber outer diameter" OR "particle dimension" OR "decomposition temperature" OR "KOA" OR "K(OA)" OR "log KOA" OR "octanol-air partition coefficient" OR "1-octanol-air partition coefficient" OR "octanol/air partition coefficient" OR "n-octanol/air partition coefficient" OR "Kd" OR "association constant" OR "λmax" OR "absorption wavelength" OR "extinction coefficient" OR "molar absorptivity" OR "absorption maxima" OR "ε" OR "kOH" OR "kOC" OR "Langmuir isotherm" OR "isotherm" OR "thermodynamics") OR tiab:("direct product concentration" OR "direct article concentration" OR "direct weight fraction" OR "product emission*" OR "product test*" OR "article emission*" OR "chamber test*" OR "product migration" OR "article migration" OR "controlled human study" OR "simulated" OR "simulation" OR "test house" OR "test field" OR "building material" OR "consumer product" OR "emission rate" OR "emission factor" OR "migration rate" OR "emission*" OR "emission rate" OR "emission flux" OR "flux" OR "consumer product" OR ("concentration*" AND ("air*" OR "indoor" OR "outdoor" OR "product" OR "article")) OR "chamber" OR "chamber system" OR "exhaust system" OR "ventilation system" OR "air exchange rate" OR "release*" OR "release rate") OR tiab:("modeled indoor concentration*" OR "modeled outdoor concentration*" OR "modeled concentration*" OR "modeled dose*" OR "modeled intake*" OR "dust ingestion" OR "dermal absorption" OR "sensitivity analysis" OR ("exposure" AND "modeling")) OR tiab:(("contaminant*" OR "contaminat*" OR "media" OR "medias" OR "medium" OR "pollutant*" OR "pollution" OR "quality" OR "source*" OR "environment*" OR "monitor" OR "monitoring" OR "occurrence" OR "measured" OR "measurable" OR "measurements" OR "sample*" OR "compound" OR "compounds" OR "detected" OR "accumulate*" OR "analys*" OR "analyz*" OR "collected" OR "estimate" OR "estimated" OR "manufacture" OR "matrices" OR "matrix" OR "micropollutant" OR "microenvironment" OR "quantification" OR "quantified" OR "quantify" OR "quantitation" OR "residue" OR "ubiquitous" OR "trace" OR "monitoring well" OR "wells") AND ("bioconcentrat*" OR "concentrat*" OR "level" OR "levels" OR "mg/L" OR "ug/L")))) NOT tiab:("metal complex*" OR "ligand*" OR ("framework*" AND "metal") OR "polymer*" OR "*polymer*" OR "copolymer*" OR "derivative*" OR "catalyst*" OR "DFT" OR "density functional theory" OR "nano*" OR "synthesis" OR "dye-sensitized" OR "functionalized"))

B.1.1 Query Strings for Peer-Reviewed Literature Database Searches on Vinyl chloride

Public database searches were conducted for all available years at the time of the search. The literature searches encompassed literature from the earliest date for which literature was available to be searched within each database through January 2023. Search strings were constructed using syntax provided in their respective online search manuals.

These are the search terms compiled from agency and industry databases for vinyl chloride used in the initial search strategies for each of the databases below.

- ProQuest: Includes Agricultural & Environmental collection, Agricola, Dissertations & Abstracts, and Toxline
- PubMed
- Scopus
- Web of Science: Includes WoS Core Collection and Current Contents Connect

Table_Apx B-2. Peer-Reviewed Literature Search Strategy for Vinyl Chloride

Source	Source-Specific Search Strategy	Results
ProQuest	TIAB("vinyl chloride" OR "75-01-4" OR "Vinyl chloride monomer" OR "chloroethylene" OR "chloroethene" OR "chloride, vinyl" OR "Ultron" OR "1-chloroethylene" OR "monochloroethylene" OR "monochloroethene" OR "chlorethylene" OR "1-chloroethene" OR "ethene, chloro-" OR "Trovidur" OR "vinyl chlorine" OR "vinylchloride" OR "chlorethene")	3,037
PubMed	("vinyl chloride"[tw] OR "75-01-4"[rn] OR "Vinyl chloride monomer"[tw] OR "chloroethylene"[tw] OR "chloroethene"[tw] OR "chloride, vinyl"[tw] OR "Ultron"[tw] OR "1-chloroethylene"[tw] OR "monochloroethylene"[tw] OR "monochloroethene"[tw] OR "chlorethylene"[tw] OR "1-chloroethene"[tw] OR "ethene, chloro-"[tw] OR "Trovidur"[tw] OR "vinyl chlorine"[tw] OR "vinylchloride"[tw] OR "chlorethene"[tw])	4,120
Scopus	TITLE-ABS({vinyl chloride} OR {75-01-4} OR {Vinyl chloride monomer} OR {chloroethylene} OR {chloroethene} OR {chloride, vinyl} OR {Ultron} OR {1-chloroethylene} OR {monochloroethylene} OR {monochloroethene} OR {chlorethylene} OR {1-chloroethene} OR {ethene, chloro-} OR {Trovidur} OR {vinyl chlorine} OR {vinylchloride} OR {chlorethene})	14,664
Web of Science	TS=("vinyl chloride" OR "75-01-4" OR "Vinyl chloride monomer" OR "chloroethylene" OR "chloroethene" OR "chloride, vinyl" OR "Ultron" OR "1-chloroethylene" OR "monochloroethylene" OR "monochloroethene" OR "chlorethylene" OR "1-chloroethene" OR "ethene, chloro-" OR "Trovidur" OR "vinyl chlorine" OR "vinylchloride" OR "chlorethene")	15,774
Deprioritized Literature Categories	Total literature not meeting initial PECO or PESO refinement	15,156
Total Literature	Total literature considered for systematic review	6,734

Following the identification of potentially relevant peer-reviewed literature on vinyl chloride, SWIFT-Review was used to further refine the peer-reviewed literature pool into discipline-relevant categories via positive and negative seed prioritization and/or discipline-specific keyword filtering depending on that discipline's information needs. Discipline-specific filters predict relevance to a respective discipline or topic based on the presence or absence of applicable keywords and phrases in titles and abstracts. Positive and negative seed prioritization priority ranks individual publications against a predetermined set of references containing desired information (positive seeds) and undesired information (negative seeds). For

additional information on the strategies implemented to identify discipline-specific peer-reviewed information, see Section 4.1 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b).

B.2 Identification of Potentially Relevant Gray Literature for Vinyl Chloride

Gray literature generally contains data sources that do not contain abstracts, such as TSCA and FIFRA submissions, databases containing secondary information, and previous assessments, therefore making it difficult to ascertain chemical- or discipline-specific relevance. The publicly available data sources used to identify discipline-specific gray literature are identified in Section 3.2 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024b).

B.2.1 Gray Literature Sources Considered for Identifying Potential Hazard for Vinyl Chloride

Table_Apx B-3 outlines the bibliographical information for the previous assessments considered for Section 2.7.1. Information from both aquatic and terrestrial toxicity studies was considered from all listed assessments. The quantitative endpoints described in these previous risk assessments are visualized in Figure 2-2 and Figure 2-3.

Table_Apx B-3. Assessments Identified for Environmental Hazard

HERO ID	Reference	Assessment Label[a]
NICNAS (2014a)	NICNAS. (2014). Ethene, Chloro-: Environment Tier II Assessment. Sydney, Australia: Australian Industrial Chemicals Introduction Scheme (AICIS).	AICIS 2014
IPCS (1999)	IPCS. (1999). Environmental Health Criteria (EHC) 215: Vinyl Chloride. Geneva, Switzerland: World Health Organization (WHO).	IPCS 1999
OECD (2001)	OECD. (2001). SIDS Initial Assessment Report for SIAM 13: Vinyl Chloride. Geneva, Switzerland: UNEP Chemicals Publications.	OECD 2001

[a] "Assessment labels" refer to labels associated with previous assessments identified in various figures within Sections 2.7.1.1 and 2.7.1.2.

Table_Apx B-4 outlines the bibliographical information for the previous assessments considered for Section 2.7.2. Both animal toxicity studies and epidemiological information was considered from all listed assessments. The quantitative and qualitative endpoints described in these risk assessments are in the following table and figures: Table 2-5, Figure 2-4, Figure 2-5, and Figure 2-6. Table_Apx C-10 lists the quantitative endpoint values reported in these previous risk assessments.

Table_Apx B-4. Assessments Identified for Human Health Hazard (Animal Toxicity and Epidemiology)

HERO ID	Reference	Assessment Label[a]
ATSDR (2023)	Agency for Toxic Substances and Disease Registry (ATSDR). 2023. Toxicological profile for vinyl chloride (draft for public comment). U.S. Department of Health and Human Services.	ATSDR 2023
CA DTSC (2022)	California Department of Toxic Substances Control (CA DTSC). 2022. Human Health Risk Assessment Note 3 – DTSC-Modified Screening Levels (DTSC-SLs), June 2020, revised update. California Office of Environmental Health Hazard Assessment (CalEPA).	CA DTSC 2022
CARB (1990a)	California Air Resources Board (CARB). 1990. Proposed identification of vinyl chloride as a Toxic Air Contaminant. California Office of Environmental Health Hazard Assessment (CalEPA).	CARB 1990a
CARB (1990b)	California Air Resources Board (CARB). 1990. Proposed identification of vinyl chloride as a Toxic Air Contaminant: Technical support document, Part A: Public exposure to, sources, and emissions of vinyl chloride in California. California Office of Environmental Health Hazard Assessment (CalEPA).	CARB 1990b
CARB (1990c)	California Air Resources Board (CARB). 1990. Proposed identification of vinyl chloride as a Toxic Air Contaminant: Technical support document, Part B: Health effects of airborne vinyl chloride. California Office of Environmental Health Hazard Assessment (CalEPA).	CARB1990c
Health Canada (2013)	Health Canada. 2013. Guidelines for Canadian drinking water quality: Guideline technical document –Vinyl chloride. Water and Air Quality Bureau, Healthy Environments and Consumer Safety Branch, Health Canada. ISBN 978-1-100-23003-0.	Health Canada 2013
IARC (2012)	International Agency for Research on Cancer (IARC). 2012. Chemical agents and related occupations: A review of human carcinogens. International Agency for Research on Cancer. ISBN 9789283201380. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, vol. 100F.	IARC 2012
IPCS (1999)	International Programme on Chemical Safety (IPCS). 1999. Environmental health criteria (EHC) 215: Vinyl chloride. World Health Organization.	IPCS 1999
NICNAS (2014a)	National Industrial Chemicals Notification and Assessment Scheme (NICNAS). 2014. Ethene, chloro-: Environment tier II assessment. Australian Industrial Chemicals Introduction Scheme (AICIS).	NICNAS 2014a
NICNAS (2014b)	National Industrial Chemicals Notification and Assessment Scheme (NICNAS). 2014. Ethene, chloro-: Human health tier II assessment. Australian Industrial Chemicals Introduction Scheme (AICIS).	NICNAS 2014b

HERO ID	Reference	Assessment Label[a]
NRC (2012)	National Research Council (NRC). 2012. Vinyl chloride: Acute exposure guideline levels. National Academies Press volume 11. ISBN 9780309254816.	NRC 2012
NTP (2021)	National Toxicology Program (NTP). 2021. Vinyl halides (selected) U.S. Department of Health and Human Services edition 15th Book title: Report on carcinogens.	NTP 2021
OECD (2001)	Organization for Economic Co-operation and Development (OECD). 2001. SIDS initial assessment report for SIAM 13: Vinyl chloride UNEP Chemicals Publications.	OECD 2001
OEHHA (2011)	California Office of Environmental Health Hazard Assessment (OEHHA). 2011. Technical support document for cancer potency values, Appendix B: Chemical-specific summaries of the information used to derive unit risk and cancer potency values. California Office of Environmental Health Hazard Assessment (CalEPA).	OEHHA 2011
U.S. EPA (1975)	U.S. Environmental Protection Agency. Office of Research and Development (ORD). 1975. Scientific and technical assessment report on vinyl chloride and polyvinyl chloride. U.S. Environmental Protection Agency. EPA-600/6-75-004.	ORD 1975
U.S. EPA (2000b)	U.S. Environmental Protection Agency (U.S. EPA) 2000 Toxicological review of vinyl chloride. U.S. Environmental Protection Agency. EPA635R00004.	US EPA 2000a
U.S. EPA (2000a)	Integrated Risk Information System (IRIS). 2000. IRIS Chemical Assessment Summary: Vinyl chloride CASRN 75-01-4. U.S. Environmental Protection Agency (U.S. EPA).	US EPA 2000b

[a] "Assessment labels" refer to labels associated with previous assessments identified in Table 2-5 and various figures within Section 2.7.2 and Table_Apx C-10.

Appendix C SYSTEMATIC REVIEW APPROACH – SCREENING OF REASONABLY AVAILABLE INFORMATION

Sections 4.2.5 and 4.3.2 of the 2021 Draft Systematic Review Protocol describe how TIAB and full-text screening respectively, are conducted to identify references that may contain relevant information for use in risk evaluations under TSCA using discipline-specific screening criteria (U.S. EPA, 2021). The manual screening process is similar for both TIAB and full-text screening phases, which starts with a calibration exercise for a set of references that are screened by all screeners. Differences in screening decisions during the calibration exercise are discussed, and clarification and refinements are provided for chemical-specific attributes as well as clarification on individual PECO or PESO screening criteria including which supplemental tags might be needed. Once the calibration exercise has concluded, screening proceeds for the remaining references identified during screening.

TIAB screening efforts are conducted manually as well as using the specialized web-based software programs DistillerSR[4] and SWIFT-Active-Screener[5] [6]; for the screening review of reasonably available information identified for vinyl chloride, TIAB screening efforts were conducted using SWIFT-Active-Screener, where machine learning helped to prioritize reference screening. Additional details on how SWIFT Active-Screener utilizes a machine-learning algorithm to automatically compute which unscreened documents are most likely to be relevant[7] are available in Section 4.2.5 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021). During TIAB screening, if it was unclear whether a reference met the screening criteria without having the full reference to review, or if a reference was determined to meet the screening criteria, that reference advanced to full-text screening if the full reference could be retrieved and generated into a Portable Document Format (PDF).

Full-text screening is manually conducted in DistillerSR using the same discipline-specific screening criteria as those used in TIAB screening and consisted of independent screening being conducted by two individuals trained to identify potentially relevant discipline-specific information within the various types of data sources. As mentioned in Appendix B.2, gray literature identified in public sources as well as TSCA and FIFRA submissions undergo a pre-screening step to determine whether there is potentially relevant information for a respective discipline; those that are deemed potentially relevant undergo full-text screening using the same screening criteria used for the TIAB and full-text screening of peer-reviewed literature. The discipline-specific subsections below describe the methodology used to screen data sources identified for a respective discipline, as well as screening results. Specifically, the literature inventory trees convey TIAB and/or full-text screening results for the data sources identified and considered using the systematic review approach. For data sources that meet screening criteria during full-text screening, the evidence maps indicate data elements or characteristics relevant for a respective discipline and chemical. Interactive literature inventory trees and evidence maps are available in chemical- and discipline-specific

[4] As noted on the DistillerSR web page, this systematic review software "automates the management of literature collection, triage, and assessment using AI and intelligent workflows...to produce transparent, audit ready, and compliant literature reviews." EPA uses DistillerSR to manage the workflow related to screening and evaluating references; the literature search is conducted external to DistillerSR.

[5] SWIFT-Active Screener is another systematic review software that EPA is adopting in the TSCA systematic review process. From Sciome's SWIFT-Active Screener web page: "As screening proceeds, reviewers include or exclude articles while an underlying statistical model in SWIFT-Active Screener automatically computes which of the remaining unscreened documents are most likely to be relevant. This 'Active Learning' model is continuously updated during screening, improving its performance with each reference reviewed. Meanwhile, a separate statistical model estimates the number of relevant articles remaining in the unscreened document list."

[6] SWIFT is an acronym for "Sciome Workbench for Interactive Computer-Facilitated Text-mining." SWIFT-Active Screener uses machine learning approaches to save screeners' time and effort.

[7] Description comes from the SWIFT-Active Screener web page.

Health Assessment Workplace Collaborative (HAWC) projects that enable users to identify specific data sources pertaining to elements in either figure via the Health and Environmental Research Online (HERO) database. The links to those HAWC project pages are available for each respective static image of the literature inventory trees and evidence maps. As indicated below, as additional relevant information is identified, the interactive versions of these figures may change.

As described in the discipline-specific sub-sections, EPA is interested in information that may help with the final designation of vinyl chloride as a High- or Low-Priority Substance. EPA is seeking information from the public on the various data elements described in this appendix. As additional information becomes available, EPA will continue to use the discipline-specific screening criteria during TIAB and/or full-text screening. Should this chemical be designated as a High-Priority Substance, screening decisions and data elements characterized in literature inventory trees and evidence maps presented in Appendices C.1, C.2, C.3, C.4, C.5 for discipline-specific interactive visualizations may be updated for future actions.

C.1 Physical and Chemical Properties

During data screening, EPA followed the process described in Appendix H-1 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021), to conduct TIAB and full-text screening for vinyl chloride guided by the data or information needs on various physical and chemical properties or endpoints as listed in the table in Appendix C.1.1. The same screening criteria was used during TIAB and full-text screening for references considered for the evaluation of physical and chemical properties of vinyl chloride. TIAB screening was performed used SWIFT Active Screener. Upon meeting the screening criteria during full-text screening, data or information sources may undergo data quality evaluation and data extraction. Figure_Apx C-1 represents the number of references that report general physical and chemical property information that fulfilled the data needs for vinyl chloride and passed these criteria for TIAB and full-text screening.

C.1.1 Screening Criteria for Data Sources Reporting Physical and Chemical Properties

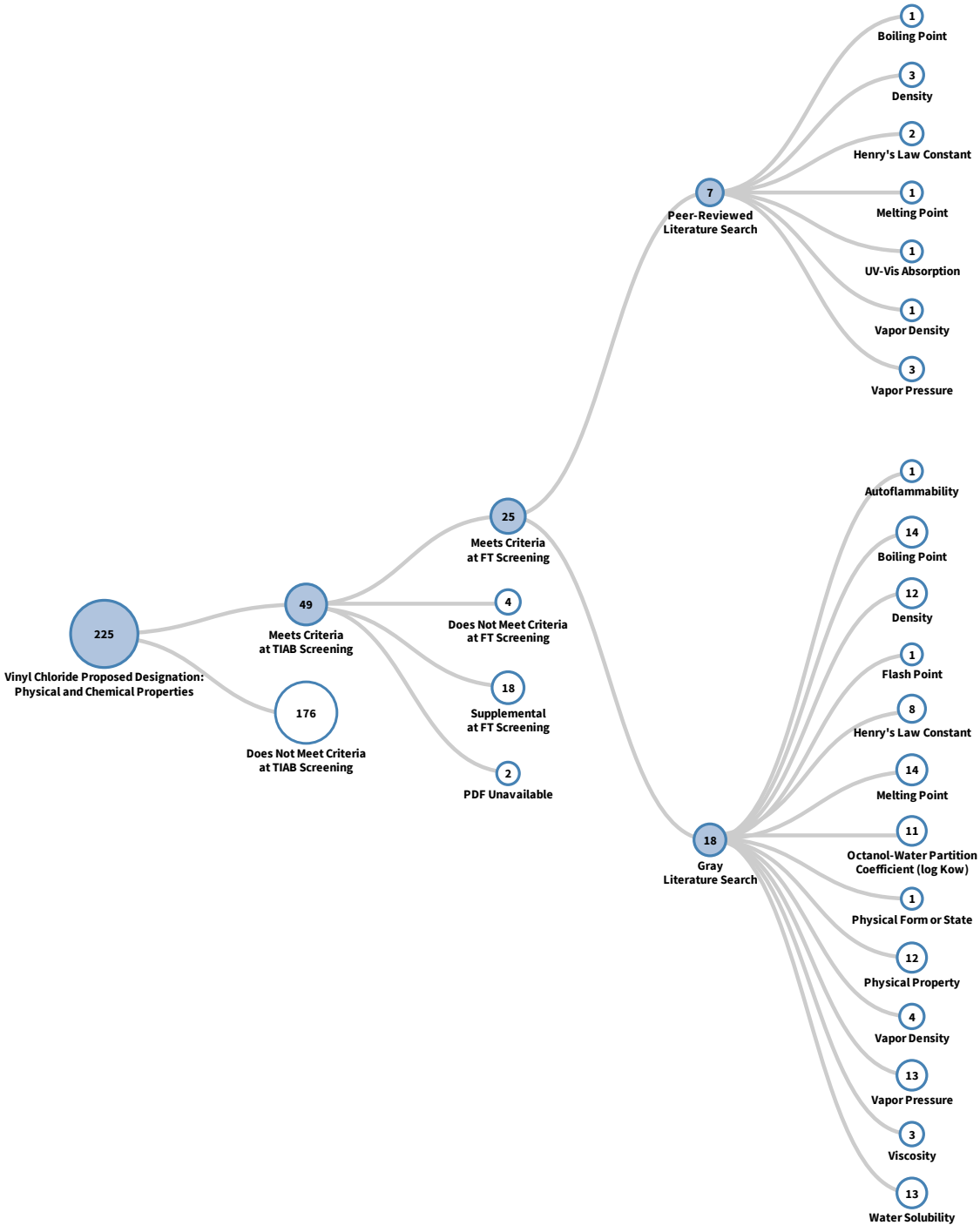
In order to be considered, a reference should present measured or modeled values on various physical and chemical properties or endpoints as listed in Table_Apx C-1.

Table_Apx C-1. Screening Criteria for Data Sources Reporting Physical and Chemical Properties for Vinyl Chloride (CASRN: 75-01-4)

Property or Endpoint
Physical form or state (*e.g.*, solid, liquid, gas)
Physical properties (*e.g.*, color, scent)
Melting point
Boiling point
Density
Vapor pressure
Vapor density
Water solubility
Octanol-water partition coefficient (also reported as log K_{OW})
Octanol-air partition coefficient (also reported as log K_{OA})
Henry's law constant
Dissociation constant
Flash point

Property or Endpoint
Auto-flammability (or flammability)
Viscosity
Decomposition temperature
UV-Vis absorption

C.1.2 Literature Inventory Tree – Physical and Chemical Property Search Results for Vinyl Chloride



Figure_Apx C-1. Literature Inventory Tree for Physical and Chemical Properties for Vinyl Chloride
Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of April 22, 2024. Additional data may be added to the interactive version as they become available. View the interactive version of the literature inventory tree in HAWC.

C.2 Environmental Fate and Transport Properties

During screening of reasonably available information, EPA followed the process described in Appendix H-2 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021) to conduct TIAB and full-text screening for vinyl chloride guided by the data or information needs on various environmental fate and transport properties or endpoints. Specifically, EPA used the PESO statement in Table_Apx C-2 along with the information in Table_Apx C-3. During screening, EPA ensured that data and information provided a complete coverage of the processes, pathways and data or information relevant to the environmental fate and transport of vinyl chloride. Quantitative data for the endpoints in Table_Apx C-2 were included in the literature screening when data come from a primary source and are reported in the environmental media of interest.

C.2.1 Screening Criteria for Data Sources Reporting Environmental Fate and Transport Properties

Table_Apx C-2. Screening Criteria for Data Sources Reporting Environmental Fate and Transport Properties for Vinyl Chloride (CASRN: 75-01-4)

PESO Element Relevance	Evidence

Pathways and **P**rocesses	• Fate will use transport, partitioning and degradation behavior across media to inform exposure pathways in conceptual models
	• Exposure pathways included in the conceptual models:
	  o Surface water
	  o Groundwater
	  o Wastewater
	  o Drinking water
	  o Soil
	  o Sediment
	  o Biosolids
	  o Air
	• Processes associated with the target exposure pathways
	• Bioconcentration and bioaccumulation
	• Destruction and removal by incineration

Exposure	• Exposures of aquatic and terrestrial organisms to the chemical substance, mixtures including the chemical substance, and/or degradation products and metabolites of the chemical substance • Environmental exposure pathways of humans to the chemical substance, mixtures including the chemical substance, and/or degradation products and metabolites of the chemical substance
Setting or **S**cenario	• All aquatic and terrestrial ecological, general population, and susceptible subpopulation exposure scenarios for releases of the chemical substance to the natural or built environment

Outcomes	• Fate properties which allow assessments of exposure pathways:
	  o Abiotic and biotic degradation rates, mechanisms, pathways, and products
	  o Bioaccumulation magnitude and metabolism rates
	  o Partitioning within and between environmental media (see Pathways)

Items listed in the PESO statement guide the selection of possible and required data types used to complete the data needs table (Table_Apx C-2). Primary source literature containing quantitative data were included if that data described the following environmental fate endpoints in the corresponding media in the table.

Table_Apx C-3. Data Categories Included in Developing Fate and Transport Assessments

Fate Data Endpoint	Associated Processes	Associated Media/Exposure Pathways			
		Surface water, Wastewater, Sediment	Soil, Biosolid	Groundwater	Air
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X			
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X			
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X
BCF BAF	Bioconcentration, bioaccumulation	X	X		X
Biomagnification and related information	Trophic magnification	X			
Desorption information	Sorption, mobility	X	X	X	
Destruction and removal by incineration	Incineration				X
Hydrolysis rates or half-lives	Hydrolysis	X	X	X	
K_{AW} and other volatilization information (but NOT Henry's Law constant)	Volatilization, vapor intrusion	X	X	X	X
K_{OC} and other sorption information	Sorption, mobility	X	X	X	
Wastewater treatment removal information	Wastewater treatment	X	X		

Supplemental information table

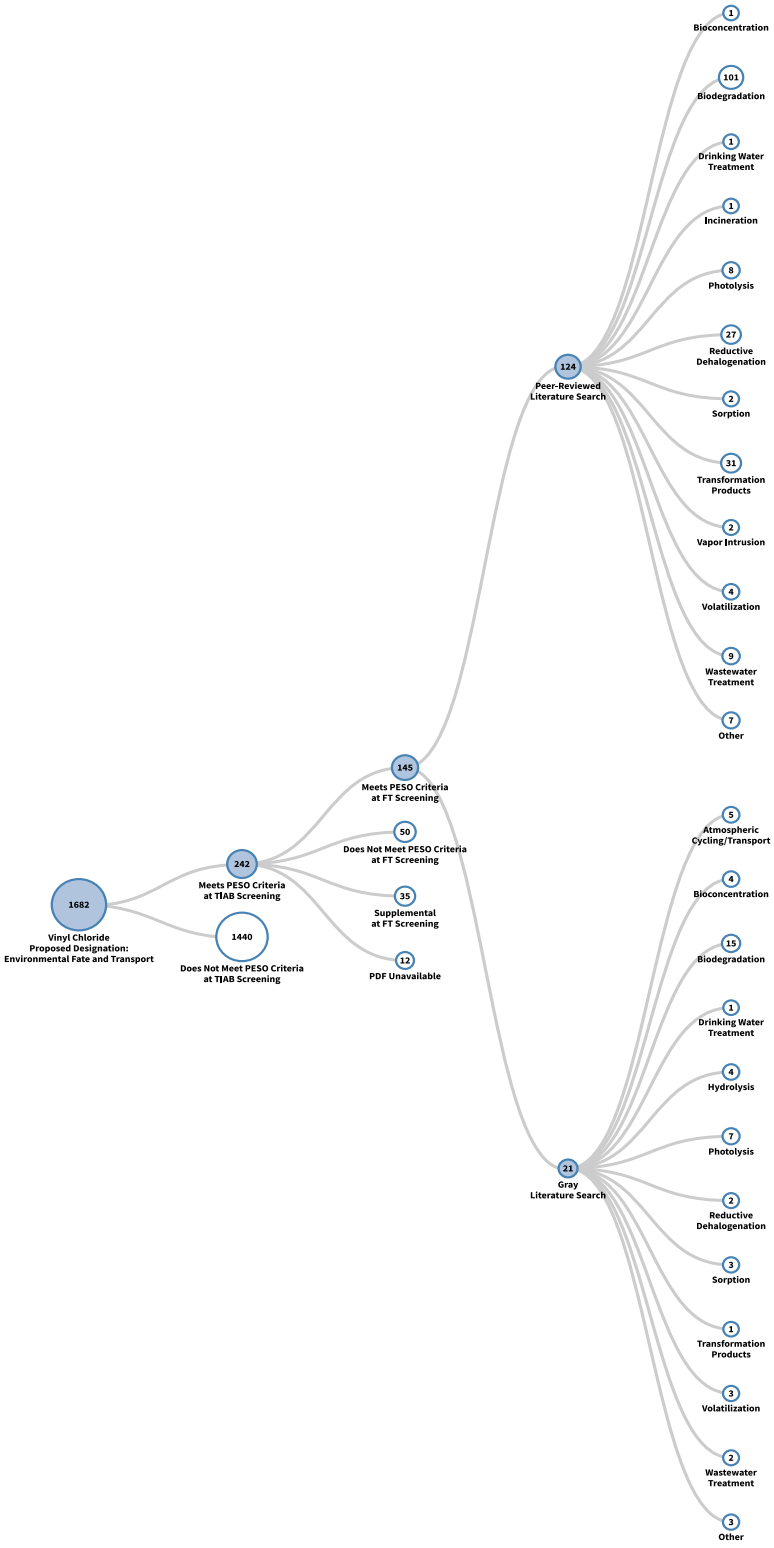
Other types of information that may be useful for completing fate assessments are listed in Table_Apx C-4. This is not an exhaustive list of potential supplemental information.

Table_Apx C-4. Examples of Supplemental Data Used in Developing Fate and Transport Assessments

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Abiotic transformation products	Hydrolysis, photolysis, incineration	X			X
Aerobic biotransformation products	Aerobic biodegradation	X	X		

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways			
		Surface water, Wastewater, Sediment	Soil, Biosolids	Groundwater	Air
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X	
Atmospheric deposition information	Atmospheric deposition				X
Coagulation information	Coagulation, mobility	X		X	
Suspension/resuspension information	Suspension/resuspension, mobility	X			

C.2.2 Literature Inventory Tree – Environmental Fate and Transport Property Search



Figure_Apx C-2. Literature Inventory Tree for Environmental Fate and Transport for Vinyl Chloride

Data in this figure represent all references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. View the interactive version of the literature inventory tree in HAWC.

C.2.3 Evidence Map of Environmental Fate and Transport Property Information for Vinyl Chloride

Distinct count of Hero ID
1 89

Endpoints	Media						
	Air	Sediment	Soil	Wastewater/ biosolids	Water	Other	**Grand Total**
Atmospheric cycling/transport	3	1	1		2		**5**
Bioconcentration, Biomagnification, etc.		1	3	1	5		**5**
Biodegradation	4	27	18	8	89	29	**118**
Degradation products/ transformation pathways	6	7	2	2	18	8	**32**
Drinking water treatment			1		2	1	**2**
Hydrolysis		1	2	1	4		**4**
Incineration	1						**1**
Misc Fate/ Other	3	1	2		8	3	**10**
Photolysis	9	1	3	2	7	1	**15**
Reductive dehalogenation	1	7	3		23	6	**29**
Sorption to soil, sediment, or land-applied biosolids (Koc)		1	4	1	4	1	**5**
Vapor intrusion	1		1			1	**2**
Volatilization (not Henrys law constant)	2	1	3	1	7	1	**8**
Wastewater treatment	2		1	9	8		**13**
Grand Total	**20**	**30**	**22**	**11**	**99**	**34**	**149**

The column totals, row totals, and grand totals indicate total numbers of distinct references. The various shades of color visually represent the distinct number of relevant references identified by data type or engineering evidence tag. The darker the color, the more references are available for a given medium or endpoint.

Figure_Apx C-3. Evidence Map of Environmental Fate and Transport Properties for Vinyl Chloride
Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. View the interactive evidence map in HAWC.

C.3 Occupational Exposure and Environmental Releases

During data screening, EPA followed the process described in Appendix H-3 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021), to conduct TIAB and full-text screening for vinyl chloride literature search results, as guided by the screening criteria in the PESO (pathways/processes, exposure, setting/scenario, and outcomes) statement (Table_Apx C-5). TIAB was performed using SWIFT Active-Screener. Full text screening occurred in DistillerSR for references that met the PESO screening criteria during TIAB.

EPA used the PESO statement along with the information in Table_Apx C-5 when screening the occupational exposure and environmental release data.

C.3.1 Screening Criteria for Data Sources Reporting Occupational Exposure and Environmental Release Information

Table_Apx C-5. Screening Criteria for the Data Sources Reporting Occupational Exposure and Environmental Release Information for Vinyl Chloride (CASRN: 75-01-4)

PESO Element Relevance	Evidence
Population	• **Humans:** Workers, including ONUs • **Environment:** All ecological receptors (relevant release estimates input to Exposure) Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant environmental releases of the chemical substance from occupational scenarios: o Dermal and inhalation exposure routes (as indicated in the conceptual model) o Oral route (as indicated in the conceptual model) Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal indicated in Table 2-2..
Outcomes	• Quantitative estimates[a] of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*
[a] Metrics (*e.g.*, mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; Table_Apx C-6 provides a list of related and relevant general information.	

Table_Apx C-6. Engineering, Environmental Release, and Occupational Exposure Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

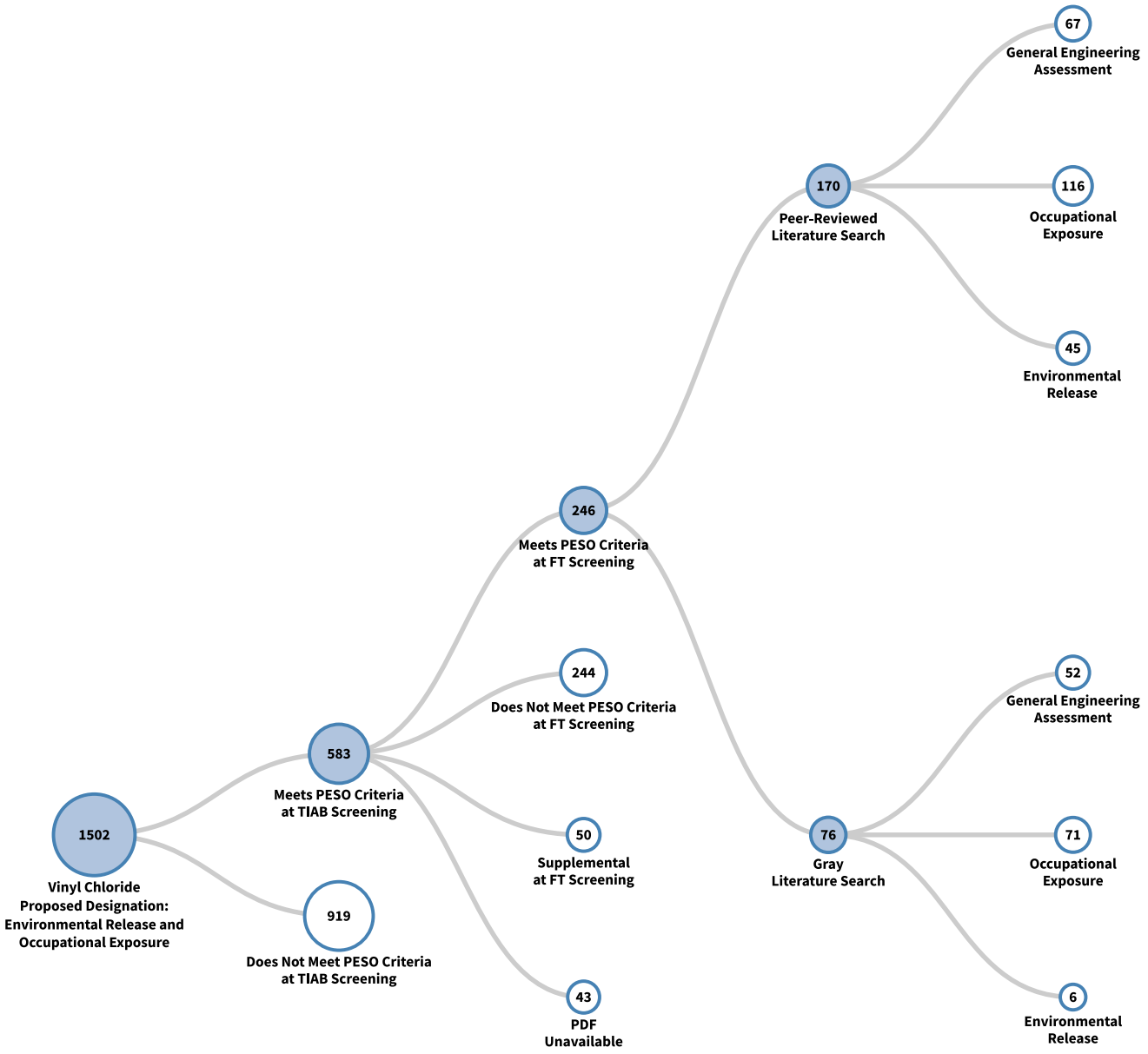
Objective	Type of Data[a]
General Engineering Assessment (may apply to Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (*e.g.*, each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. 3. Description of processes, equipment, and unit operations during each industrial/ commercial life cycle step. 4. Material flows, use rates, and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the

Objective	Type of Data[a]
	chemicals (s) of interest and material flows of all associated primary chemicals (especially water). 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. 6. Concentration of the chemical of interest
Occupational Exposures	7. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. 8. Potential routes of exposure (*e.g.*, inhalation, dermal). 9. Physical form of the chemical(s) of interest for each exposure route (*e.g.*, liquid, vapor, mist) and activity. 10. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). 11. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). 12. Sampling and analytical methodology 13. For solids, bulk and dust particle size characterization data. 14. Dermal exposure data. 15. Exposure duration (hr/day). 16. Exposure frequency (days/yr). 17. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. 18. PPE types employed by the industries within scope. 19. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions.
Environmental Releases (to relevant environmental media)	20. Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. 21. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (water) and treatment and disposal methods (POTW), including releases per site and aggregated over all sites (annual release rates, daily release rates) 22. Release or emission factors. 23. Number of release days per year. 24. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions. 25. Accidental releases/spills
[a] These are the tags included in the full text screening form. The screener selects from these specific tags, which describe more specific types of data or information. In addition to the data types listed above, EPA may identify additional data needs for mathematical modeling. These data needs will be determined on a case-by-case basis.	

C.3.2 Literature Inventory Tree – Occupational Exposure and Environmental Release Information for Vinyl Chloride

Figure_Apx C-4 presents the number of references that report general engineering data, environmental release, and occupational exposure data that passed PESO screening criteria at TIAB, and full-text

screening for vinyl chloride. Data or information sources that comply with the screening criteria specified in the PESO statement then undergo data quality evaluation and extraction.



Figure_Apx C-4. Literature Inventory Tree of Occupational Exposure and Environmental Release Search Results for Vinyl Chloride

Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 14, 2024. Additional data may be added to the interactive version as they become available. View the interactive literature inventory tree in HAWC.

C.3.3 Evidence Map of Occupational Exposure and Environmental Release Information for Vinyl Chloride (CASRN: 75-01-4)

Distinct count of Hero ID
1 118

Data Type	Evidence Tag	References
COU	Disposal	37
	Distribution in Commerce	6
	Industrial/Commercial Use	36
	Manufacture - Domestic manufacture	78
	Manufacture-Import	4
	Processing - Processing - repackaging	5
	Processing - Processing as a reactant	105
	Processing - Processing incorporation into formulation, mixture, or reaction product	75
	Processing - Processing- incorporation into articles	78
	Processing - Recycling	5
	Total	259
Environmental Release	Accidental releases/spills	1
	Description of the release source	46
	Environmental release media	52
	Release frequency	7
	Release or emission factors	54
	Release quantity	31
	Waste treatment and pollution control	25
	Total	76
General Engineering	Chemical Concentration	15
	Life cycle Description	12
	Number of sites	27
	Process description	87
	Production, Import, or Use Volume	28
	Throughput	11
	Total	125
Occupational Exposure	Area sampling data	117
	Dermal exposure data	8
	Engineering control	35
	Exposure duration	67
	Exposure frequency	31
	Exposure route	91
	Number of workers	98
	Particle size characterization	3
	Personal protective equipment	21
	Personal sampling data	100
	Physical form	46
	Sampling and analytical methodology	59
	Worker Activity description	118
	Total	199
Grand Total		**286**

The column totals, row totals, and grand totals indicate total numbers of distinct references. The various shades of color visually represent the distinct number of relevant references identified by data type or engineering evidence tag. The darker the color, the more references are available for a given data type or engineering evidence tag.

Figure_Apx C-5. Evidence Map of Occupational Exposure and Environmental Release Information for Vinyl Chloride

Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 14, 2024. Additional data may be added to the interactive version as they become available. View the interactive evidence map in HAWC.

C.4 General Population, Consumer, and Environmental Exposure

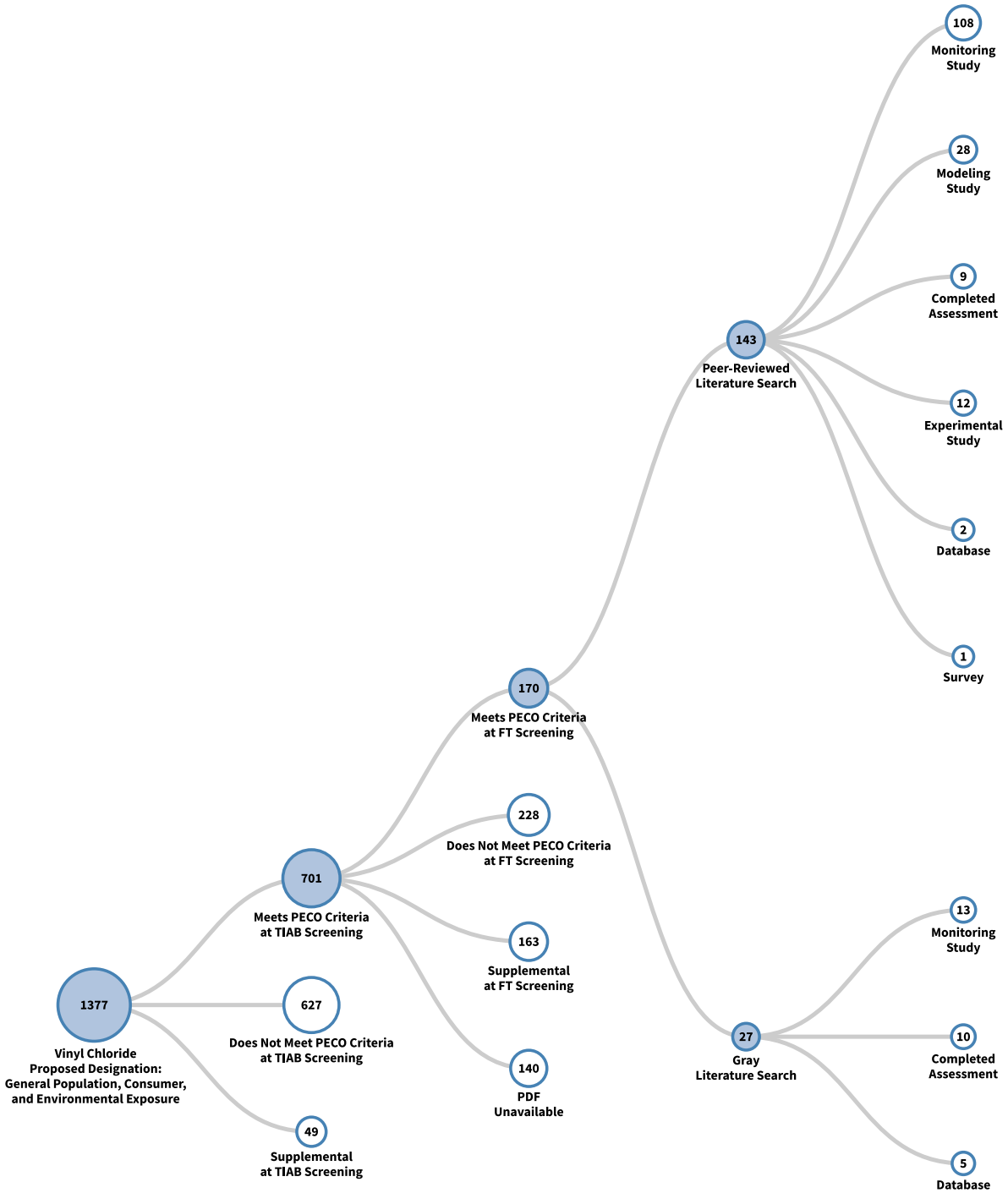
During data screening, EPA followed the process described in Appendix H-4 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021) to conduct TIAB and full-text screening for vinyl chloride literature search results, as guided by the PECO screening criteria (Table_Apx C-7). The same PECO screening criteria was used during TIAB and full-text screening for references considered for the evaluation of general population, consumer, and environmental exposure information for vinyl chloride. TIAB screening was performed using SWIFT Active-Screener. Figure_Apx C-6 presents the number of references that report general population, consumer, and environmental exposure data that passed PECO screening criteria at TIAB and full-text screening.

C.4.1 Screening Criteria for Data Sources Reporting General Population, Consumer, and Environmental Exposure Information

Table_Apx C-7. Screening Criteria for the Data Sources Reporting Exposure Data on General Population, Consumers, and Environmental Receptors for Vinyl Chloride (CASRN: 75-01-4)

PECO Element	Evidence
Population	**Human**: General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (lifestages, preexisting conditions, genetic factors), pregnant women; lactating women, women of childbearing age. Many human population groups may be exposed.
	Environmental: Aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only).
Exposure	**Expected Primary Exposure Sources, Pathways, Routes**: **Pathways**: Indoor air/vapor/mist; indoor dust; particles; surface water; groundwater; outdoor/ambient air; drinking water; land disposal; biosolids/sludge; soil; sediment; aquatic species; terrestrial species; human biomonitoring; dietary; consumer product uses in the home (including consumer product containing chemical). **Routes of Exposure**: Inhalation, Oral, Dermal.
Comparator (Scenario)	**Human**: Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Environmental: Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human**: Acute, subchronic, and/or indoor air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc.) containing chemical.
	Environmental: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

C.4.2 Literature Inventory Tree - General Population, Consumer, and Environmental Exposure Search Results



Figure_Apx C-6. Literature Inventory Tree of Consumer, General Population, and Environmental Exposure Search Results for Vinyl Chloride

Data in this figure represent all references obtained from the publicly available databases and gray literature reference searches that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. View the interactive literature inventory tree in HAWC.

C.4.3 Evidence Map of General Population, Consumer, and Environmental Exposure Information

Distinct count of Hero ID
1 68

Media	Study type						
	Completed Assessment	Database	Experimental	Modeling	Monitoring	Survey	**Grand Total**
Ambient (Outdoor) Air	11	4	2	13	26		47
Aquatic Species		2			1		3
Biosolids/Sludge					2		2
Building Material			1				1
Consumer Product or Article	2		4	1	1		7
Dietary/Food	4	1	1	1	3		9
Drinking Water	9	2	1	1	8		20
Dust (Indoor)							0
Groundwater	7	2	1	6	68	1	81
Human Biomonitoring - Blood				2	1		2
Human Biomonitoring - Dermal							0
Human Biomonitoring - Milk							0
Human Biomonitoring - Tissues, Other				1	1		1
Human Biomonitoring - Urine					1		1
Indoor Air	3	2	3	2	4		13
Leachate				2	1		3
Other Media	2	1	2	6	12		20
Personal Inhalation	1			1	1		3
Precipitation							0
Sediment	2	1		1	5		8
Soil	4	2	1	2	13		20
Surface Water	7	3		1	12		22
Terrestrial Species		1			3		4
Wastewater	4	1	1		3		9
Grand Total	19	7	11	27	118	1	166

The column totals, row totals, and grand totals indicate total numbers of distinct references. The various shades of color visually represent the distinct number of relevant references identified by study type or media tag. The darker the color, the more references are available for a given study type or media tag.

Figure_Apx C-7. Evidence Map of Consumer, General Population, and Environmental Exposure Information for Vinyl Chloride

Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. View the interactive evidence map in HAWC.

C.5 Environmental and Human Health Hazard

During data screening, EPA followed the process described in Sections 4.2.5 and 4.3.2 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021) to conduct TIAB and full-text screening. Specifically for vinyl chloride literature search results, screening was guided by the PECO screening criteria in Table_Apx C-8. The same PECO screening criteria was used during TIAB and full-text screening for references considered for the evaluation of environmental and human health hazard resulting from exposure to vinyl chloride. For TIAB screening, EPA utilized machine learning to help prioritize reference screening in SWIFT-Active-Screener. Full-text screening occurred manually in DistillerSR for references that either met the PECO screening criteria during TIAB screening or if it was unclear to EPA whether the reference would meet the PECO screening criteria based on the information available in the title and abstract. While the

same PECO screening criteria was used during TIAB and full-text screening, an update to the screening decision was made between TIAB and full-text screening to references that reported meta-analyses with epidemiological data in which originally these references met PECO screening criteria at TIAB screening but were later classified as supplemental information for full-text screening. The rationale for this update being that references with meta-analyses use information of individual studies from sources other than generated by the authors in order to perform their meta-analyses. Figure_Apx C-8 presents the number of references that report environmental and human health hazard data that passed PECO screening criteria at TIAB and full-text screening.

C.5.1 Screening Criteria for Data Sources Reporting Environmental and Human Health Hazard Information

Table_Apx C-8. Screening Criteria for the Data Sources Reporting Environmental and Human Health Hazard Information for Vinyl Chloride (CASRN: 75-01-4)

PECO Element Relevance	Evidence
P	**Human (Epidemiology):** Any population and lifestage (*e.g.*, occupational, or general population, including children and other sensitive populations). **Animal:** Aquatic and terrestrial species (live, whole organism) of any life stage (*e.g.*, preconception, *in utero*, lactation, peripubertal, and adult stages). Animal models will be inventoried according to the categorization below: - Human health animal models: rat, mouse, rabbit, dog, hamster, guinea pig, cat, non-human primate, and pig. - Ecotoxicological animal models: All animal studies (invertebrates and vertebrates) excluding the models listed above as a human health model. All hen studies (including neurotoxicity studies) will ***meet screening criteria*** as ecotoxicological animal models. **Plants and Fungi:** All aquatic and terrestrial species (live) (vascular and non-vascular plants), including but not limited to algal species, diatoms, cyanobacteria, moss, lichen and macro fungi (*e.g.*, mushrooms (Phylum: Basidiomycota)) species. **Note on Yeast and Bacteria:** Any genotoxicity, mutagenicity, or hormone assay data utilizing yeast or bacteria are sorted under ***Yeast/Bacteria*** receptor, and tagged ***Supplemental, Mechanistic***. **Screener notes:** • Human Health Animal Hazard and Environmental Hazard: To identify human health and ecological hazards, other organisms not listed above each of these two respective categories can also be used. Non-mammalian model systems are increasingly used to identify potential human health hazards *(e.g.*, *Xenopus*, zebrafish), and traditional human health models (*e.g.*, rodents) can be used to identify potential ecological hazard. For SR screening and data evaluation and extraction purposes, the human health models listed above will be tagged or identified as human health models and all other animal studies will be tagged as ecotoxicological animal models, unless stated otherwise based on existing chemical-specific information. Neurotoxicity studies performed in hens (*e.g.*, OECD 418 and 419) are considered relevant to both human health and environmental hazard, but all hen studies will be tagged only as ecotoxicological animal models for SR screening and data evaluation and extraction purposes. • Environmental Hazard: Ecotoxicological studies that assess exposure effects on organisms such as protozoan, microbial fungi (*e.g.*, microsporidians), and molds will be

PECO Element Relevance	Evidence

	tagged as ***Supplemental, Deprioritized environmental organisms*** because an environmental hazard assessment will unlikely be driven by unicellular organisms or microbial organisms which are low in the natural ecosystem hierarchy.
	
	• Environmental Hazard: The Population (PECO) consideration should be directed toward direct effects on the **target species only** regardless of the type of effect or health outcome. Studies reporting only indirect effects expressed in taxa that are **not** the target species of the chemical exposure do not meet the PECO criteria and thus are ***Supplemental, Indirect exposure***. Examples of target species with direct effects *versus* not the target species with indirect effects include but are not limited to:
	  • *Plant studies*: Several studies conducted with plants investigate the chemical's ability to control pests. Substance is lethal to a **targeted** pest species leading to positive effects on plant growth due to diminished presence of the **targeted** pest species (*e.g.*, nematodes). In these scenarios: The **direct effects** are those on the **targeted** pest species (*e.g.*, increased mortality in nematodes); **indirect effects** are those on the plants that experience an effect (*e.g.*, increased yield) but only as a result of the effects of exposure on the **targeted** pest species. Thus, studies that use the substance to control pest species but only report the plant growth are tagged as ***Supplemental, Indirect exposure***.
	  • *Fish studies*: Substance is used to treat fungal/parasitic/bacterial infections, so increased survival or growth is an indirect effect of the improved health of fish due to diminished presence of pathogenic microbes. Thus, studies that use the substance to control pest species but only report fish health outcomes are tagged as ***Supplemental, Indirect exposure***.
	  • *Avian studies*: Substance is used to treat poultry eggs to prevent growth of bacteria on the eggshell which indirectly can increase the survival and health of chicks. Thus, studies that use the substance to control growth of bacteria on the eggshell and report chick health outcomes are tagged as ***Supplemental, Indirect exposure***.
	  • *Livestock studies*: Substance is used to treat fungal/parasitic/bacterial infections which indirectly results in positive effects of survival, growth of livestock. Thus, studies that use the substance to only control pathogenic microbes but only report livestock health outcomes are tagged as ***Supplemental, Indirect exposure***.
	
	• Human Health Animal Hazard and Environmental Hazard: Studies on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially ***Supplemental, Mechanistic***. **EXCEPTION**: Embryos for environmental hazard studies (*e.g.*, zebrafish, fathead minnow, copepod, bivalve embryos) are included if they meet all other PECO criteria.
	
	• Yeast and Bacteria: Bacteria and yeast studies specific for assessing genotoxicity, mutagenicity (*e.g.*, Ames assay), or hormone assay will be tagged as potentially ***Supplemental, Mechanistic.*** Otherwise, bacteria and yeast studies that are **not** used for assessing genotoxicity, mutagenicity, or hormone assays ***do not meet the PECO criteria***.
	
	• Human Health Animal Hazard and Environmental Hazard: Studies on viruses and any pathogenic microbes (unless bacteria or yeast used for assessing genotoxicity,

PECO Element Relevance	Evidence
	mutagenicity, or hormone assay; see bullet above) ***do not meet the PECO screening criteria***.
E	**Relevant forms and isomers:** • Vinyl chloride (CASRN 75-01-4) • Common synonyms of vinyl chloride include vinyl chloride monomer (VCM), chloroethylene/chloroethene, ultron, 1-chloroethylene/1-chloroethene, monochloroethylene/monochloroethene, Trovidur, and vinyl chlorine. For a full list of synonyms, see list of validated synonyms on the EPA CompTox Chemicals Dashboard. ○ Isomer(s) (these chemicals are included): ▪ No isomers identified Other ***Supplemental*** relevant structures (these should be tagged as ***Supplemental, Other Relevant Structures*** only if they meet the PECO and if exposure to vinyl chloride is not explicitly mentioned). • Degradant(s)/Metabolite(s)/Biomarker(s): ▪ Degradants: Chloroacetylchloranil (monochloroacetyl chloride), chloroethylene epoxide, and 2-chloroacetaldehyde ▪ Metabolites: Thiodiglycolic acid, N-acetyl-vinylcysteine, and S-(formylmethyl)cysteine ▪ DNA adducts used as biomarker of exposure: Cyclic etheno-adducts (1,N^6-ethenoadenine, 3,N^4-ethenocytosine, 3,N^2-ethenoguanine, and 1,N^2-ethenoguanine) **Human (Epidemiology):** Any exposure to vinyl chloride (CASRN 75-01-4) singularly or in mixture (including co-occurrence and mixtures as defined under TSCA), including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (*i.e.*, urine, blood, semen, etc.) if vinyl chloride or synonyms are mentioned. **Animal:** Any exposure to vinyl chloride (CASRN 75-01-4) via water (including environmental aquatic exposures), soil or sediment, diet, gavage, dermal (*i.e.*, exposure to skin), eye, and inhalation will ***meet screening criteria***. **Plants and Fungi:** Any exposure to vinyl chloride (CASRN 75-01-4) including via water, soil, sediment. **Screener notes:** • Human Health Animal Hazard, and Environmental Hazard: Exposure routes not listed above are to be identified as ***Supplemental, Non-prioritized Exposure Routes***. Skin sensitization studies (*e.g.*, the guinea pig maximization protocol) that include an intradermal induction phase (with application onto the skin during the challenge phase) will ***meet screening criteria***. • Epidemiology, Human Health Animal Hazard, and Environmental Hazard: Exposure to the target chemical even if specific exposure concentrations are not reported is sufficient to meet the PECO criteria.

PECO Element Relevance	Evidence
	• Environmental Hazard: Field studies with media concentrations (*e.g.*, surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals, plants, and/or fungi are to be identified as ***Supplemental, Field Studies*** only if any biological effects are reported. • Human Health Animal Hazard and Environmental Hazard: Animal, plant and/or fungi studies involving exposures to mixtures will ***meet screening criteria*** only if they also include exposure to vinyl chloride (CASRN 75-01-4) **alone or in the presence of no other non-inert chemicals**. Otherwise, mixture studies (including chemical co-occurrence/co-exposure as well as mixtures as defined under TSCA) will be tagged as ***Unclear*** during **Title/Abstract Screening** and as ***Supplemental, Mixtures*** during **Full Text screening.** • Human Health Animal Hazard and Environmental Hazard: Chemical plus non-chemical stressor co-exposures (*i.e.*, chemical + temperature and/or pH, DO, nutrition, feeding rate, culture density, physical injury, light/dark cycles, etc.) will be tagged as ***Unclear*** during **Title/Abstract Screening** and as ***Supplemental, Chemical plus non-chemical stressor*** during **Full Text screening.** • Environmental Hazard: Controlled outdoor experimental studies (*e.g.*, controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be similar to laboratory studies (**not field studies**) because there is a known and prescribed exposure dose(s) and an evaluation of hazardous effect(s). On the contrary, field studies (*e.g.*, biomonitoring) where there is no prescribed exposure dose(s) will be tagged as ***Supplemental, Field studies*** only if there is an evaluated hazardous effect. • Epidemiology, Human Health Animal Hazard, and Environmental Hazard: Metabolites of vinyl chloride should be tagged as ***Supplemental, Other relevant chemical structures*** if the study meets all PECO screening criteria. • Epidemiology, Human Health Animal Hazard, and Environmental Hazard: If biomarkers of **exposure** are used to assess exposure to the chemical of interest, they will ***meet screening criteria***. • Biomarkers of **exposure** include measurements of exposure, internal dose, and biologically effective dose (including adducts).
C	**Human (Epidemiology):** Any study with a comparison group, control group, or referent group, including: • A comparison group that does not have the disease or outcome of interest (such as a case-control study); or Any study comparing exposed individuals to unexposed or lower-exposed individuals including: • A comparison group with no exposure to the chemical of interest or exposure below detection limits, or • A comparison group exposed to lower levels of the chemical of interest; or • A comparison group exposed to the chemical of interest for shorter periods of time; or Any study assessing the association between a continuous measure of exposure and a health outcome; or For studies in which humans are intentionally exposed to the chemical of interest, an individual can serve as their own control.

PECO Element Relevance	Evidence
	Animal, Plants, and Fungi: A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement). **<u>Screener notes:</u>** • <u>Epidemiology:</u> All epidemiology studies with a comparison group, control group, or referent group ***meet PECO screening criteria:*** o Studies that mention that they used any of the following common study designs or methods listed (but not limited to): cohort (prospective cohort, retrospective cohort, etc.), case-control, case-crossover, case-referent, case-cohort, cross-sectional, nested case-control, regression, relative risk, risk ratio, odds ratio, hazard ratio, and standardized mortality ratio (SMR) will ***meet screening criteria***. These are not the only included designs but all epidemiology studies that use these designs will ***meet screening criteria*** – other designs may also ***meet screening criteria***. Intentional dosing epidemiology studies (controlled exposure studies or studies in which people are intentionally exposed to the chemical) with an individual serving as their own control will ***meet screening criteria***. (Ethics review will occur later). Otherwise, studies without a comparison group are ***Supplemental***: o All study designs such as case reports, case series, and case studies without a comparison group in any setting (*e.g.*, occupational, general population), will be tracked as ***Supplemental, Hazard value without negative control or appropriate vehicle control***. • <u>Human Health Hazard (Animal Hazard and Epidemiology)</u>: For studies in which humans or human health animal models are intentionally exposed to a chemical, the control could be a baseline measurement of the same individual (*i.e.*, the individual is assessed pre- and post-exposure), and these studies will ***meet screening criteria***. Also, for studies in which humans or human health animal models are intentionally exposed to a chemical, references that contain experimental designs that do not require a negative or vehicle control group (*i.e.*, skin sensitization (such as LLNA), LC50 and LD50 completed within an acute timeframe, or dermal irritation studies in which the experimental individual serves as their own control) will ***meet screening criteria***. • <u>Human Health Animal Hazard and Environmental Hazard</u>: If no control group is explicitly stated, the study will be marked as ***Unclear*** during **Title/Abstract Screening.** But if the study reports these specific hazard values of interest (EC10, NOEC, LOEC, or Environmental Hazard LC50) even if it does not explicitly report the use of a control, it will be tagged as ***Supplemental, Hazard value without negative control or appropriate vehicle control*** during **Full Text screening** because the data can be of value for data-poor chemicals. Otherwise, if no control group is explicitly stated AND the specific hazard values of interest listed in this paragraph are not reported, then the study ***does not meet PECO screening criteria*.**
O	**Human (Epidemiology), Animal, Plants, and Fungi:** For *in vivo* studies, any health outcome measured at any level of biological organization (*e.g.*, DNA damage, apoptosis, organ damage, mortality) will meet screening criteria. For *ex vivo* studies, only health outcomes measured at the organ level or higher, where exposure occurred in a live animal, will ***meet screening criteria***. *Ex vivo* studies where the live organism was not directly exposed to the chemical of interest are to be tagged as ***Supplemental, Mechanistic.*** For all non-*in vivo* studies, sub-organ level health outcomes are to be tagged as ***Supplemental, Mechanistic***.

PECO Element Relevance	Evidence
	Screener notes: • Environmental Hazard: *In vivo* ADME studies designed to capture information regarding transformation (*i.e.*, ADME) will ***meet screening criteria***. • Human Health Animal Hazard and Epidemiology: *In vivo* and *in vitro* ADME studies designed to capture information regarding transformation (*i.e.*, absorption, distribution, metabolism, and excretion) without assessing a health outcome are to be tagged as ***Supplemental, Mechanistic, subtag: ADME.*** • Epidemiology and Human Health Animal Hazard: Studies that identify potentially susceptible subgroups but do not report a health outcome need to be tagged as ***Supplemental, Susceptible Population (no health outcome).*** • Epidemiology and Human Health Animal Hazard: Biomarkers of **effect** are to be considered outcomes. However, if the *only* outcomes assessed are biomarkers of exposure, with no health outcomes assessed, then it is ***Supplemental, Mechanistic***. o Biomarkers of **effect** include measurements of early biological effect (including altered enzymatic activities), altered structure/function, and disease. o Biomarkers of **exposure** include measurements of exposure, internal dose, and biologically effective dose (including adducts). o Biomarkers of **susceptibility** are relevant for potentially exposed or susceptible subpopulations (PESS) considerations. If a reference doesn't meet the O of the PECO but includes biomarkers of susceptibility, then the reference should be tagged as ***Supplemental, Susceptible Populations (no health outcome)***.
P, E, C, O	Meta-analyses are ***Supplemental.*** **Screener notes:** • Epidemiology: Meta-analyses (quantitative, formal, epidemiological study design used to systematically assess the results of previous research addressing a similar research question) may be advantageous when deriving a dose-response relationship and potentially offer improvement in the precision of effect estimates because the individual studies alone included in the meta-analysis may not offer study details (*e.g.*, more appropriate analytical methods, different model fit and more appropriate data inclusion/exclusion rules). Therefore, meta-analyses should be tagged as ***Supplemental, Other potentially relevant data sources, subtag: Meta-analyses***.

Table_Apx C-9. Major Categories of Potentially Relevant Supplemental Material for Vinyl Chloride (CASRN: 75-01-4) – Title and Abstract and Full Text Screening

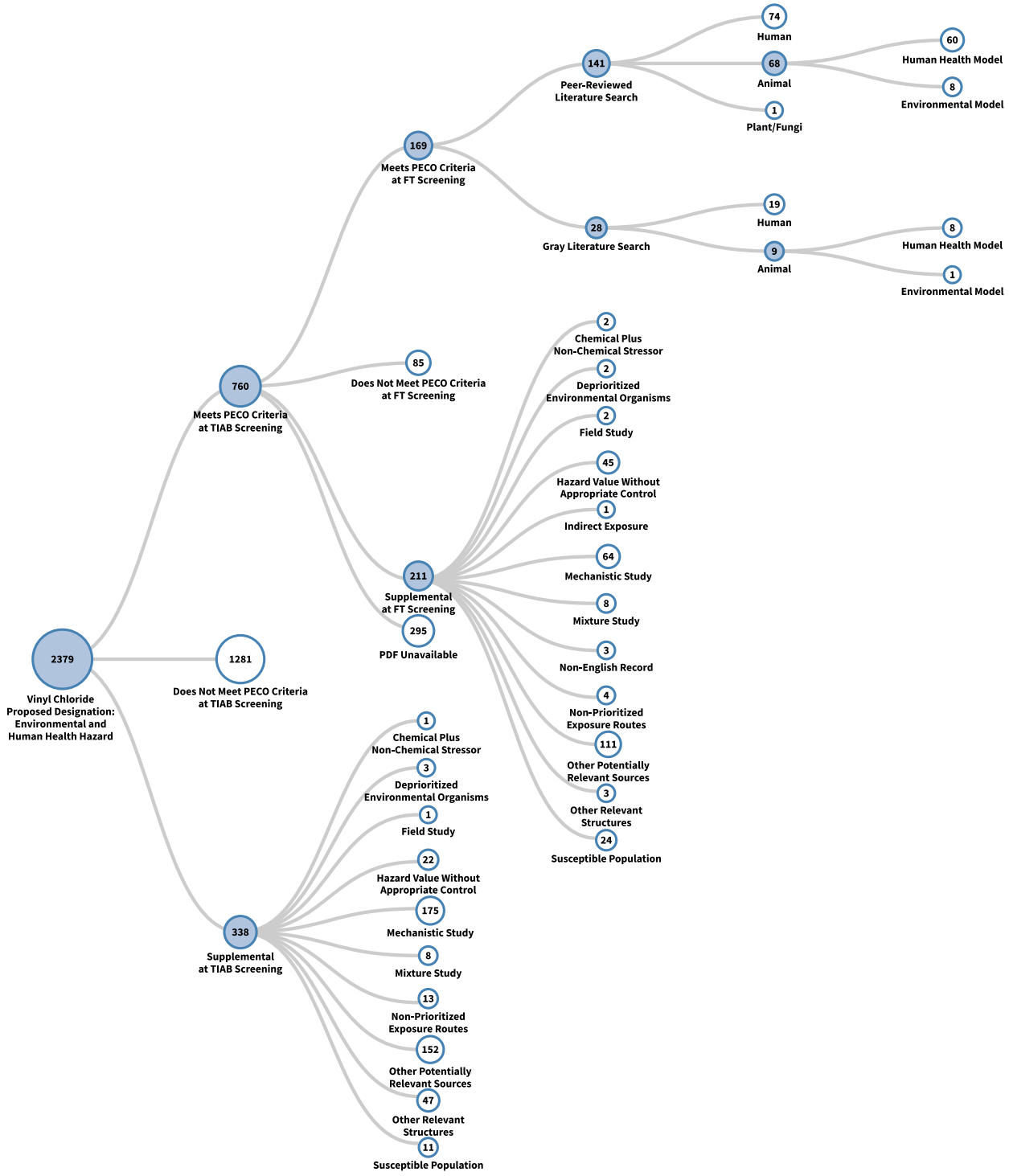
PECO Element Relevance	Category	Evidence
P	Deprioritized environmental organisms	Environmental Hazard: Studies that assess exposure effects on protozoans, microbial fungi (*e.g.*, microsporidians), and molds fall under this category because an environmental hazard assessment will unlikely be driven by unicellular organisms or microbial organisms which are low in the natural ecosystem hierarchy.

PECO Element Relevance	Category	Evidence
P	Indirect exposure	Environmental Hazard: Studies reporting only indirect effects expressed in taxa that are **not** the target species of the chemical exposure. Examples include but are not limited to: • Plant studies: Substance is used as a means to control pests (*e.g.*, nematodes), but the study does **not** report data on nematodes (*e.g.*, mortality) and **only** reports data on plant health outcomes (*e.g.*, plant growth) which are an indirect effect because it is a result of the decrease presence of nematodes. • Fish studies: Substance is used as a means to control pathogenic microbes and pests (*i.e.*, treatment of fungal/parasitic/bacterial infections), and the study only reports health outcomes in fish, which are an indirect effect of the improved health of fish due to diminished presence of pathogenic microbes. • Avian studies: Studies reporting increased survival and health of chicks following chemical substance treatment on eggs to prevent growth of bacteria on the eggshell fall in this supplemental category. Reminder: Studies on viruses and any pathogenic microbes (unless bacteria or yeast used for assessing genotoxicity, mutagenicity, or hormone assay; see screener notes under P) ***do not meet PECO screening criteria***.
E	Non-prioritized Exposure Routes	Human Health Animal Hazard, and Environmental Hazard: Examples include but not limited to injection (*e.g.*, intraperitoneal, intravenous, subcutaneous, intradermal), rectal exposures, intratracheal, intracranial, and bladder instilling (*i.e.*, exposure using a catheter).
E	Mixture studies	Human Health Animal Hazard and Environmental Hazard: Experimental mixture studies that are not considered to meet the PECO because they do not contain an exposure or treatment group assessing *only* the chemical of interest. The category does not apply to chemical mixtures of enantiomers and/or diastereomers, and the exposure in these cases would be marked as meeting the PECO. Mixture studies include chemical co-occurrence/co-exposure studies as well as mixtures as defined under TSCA.
E	Chemical plus non-chemical stressor	Human Health Animal Hazard and Environmental Hazard: Studies where organisms are exposed to the target chemical plus non-chemical stressor(s); *i.e.*, target chemical + temperature and/or pH, DO, nutrition, feeding rate, culture density, physical injury, light/dark cycles, etc. In these scenarios, the non-chemical stressor is a singular or a range of animal maintenance conditions that are **not** normal/standard. However, if a study includes a group exposure to the target chemical in normal/standard conditions, the study is ***included***.
E	Other relevant chemical structures	**Epidemiology, Human Health Animal Hazard, and Environmental Hazard:** Studies that meet the PECO with other chemical structures such as metabolites may be useful later. Metabolites of vinyl chloride should be tagged as ***Supplemental, Other relevant chemical structures*** if the study meets all PECO screening criteria. If exposure to vinyl chloride is not explicitly mentioned, these metabolites and other structures of interest should be put into this supplemental category.

PECO Element Relevance	Category	Evidence
		Structures of interest currently include: - Degradants: Chloroacetylchloranil (monochloroacetyl chloride), Chloroethylene epoxide, and 2-chloroacetaldehyde - Metabolites: Thiodiglycolic acid, N-acetyl-vinylcysteine, and S-(formylmethyl)cysteine - DNA adducts used as biomarker of exposure: cyclic etheno-adducts (1,N^6-ethenoadenine, 3,N^4-ethenocytosine, 3,N^2-ethenoguanine, and 1,N^2-ethenoguanine)
E	Field Studies	Environmental Hazard: Field studies with media concentrations (*e.g.*, surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants ***only if any*** biological effects (*i.e.*, apical and mechanistic) are reported.
C	Hazard value without negative control or appropriate vehicle control	Human Health Animal Hazard and Environmental Hazard: Studies that do not explicitly report the use of a control but report hazard values (EC10, NOEC, LOEC, or Environmental Hazard LC50) can be of value for data-poor chemicals. Human Health Animal Hazard LC50 and LD50 studies completed within an acute timeframe meet the PECO. Epidemiology: Study designs such as case reports, case series, and case studies without a comparison group will be tracked as ***Supplemental***. (This Supplemental category does NOT include cohort (prospective cohort, retrospective cohort, etc.), case-control, case-crossover, case-referent, case-cohort, cross-sectional, nested case-control, regression, relative risk, risk ratio, odds ratio, hazard ratio, or standardized mortality ratio (SMR) study designs, which meet the PECO).
O, P	Mechanistic studies	Human Health Animal Hazard and Environmental Hazard: Bacteria and yeast studies specific for assessing genotoxicity, mutagenicity (*e.g.*, Ames assay), or hormone assay will be tagged as potentially ***Supplemental, Mechanistic***. Studies on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially ***Supplemental, Mechanistic***. EXCEPTION: Fish and invertebrate embryo (*e.g.*, zebrafish, fathead minnow, copepod, bivalve embryos) studies are included if they meet all other PECO criteria. Epidemiology, Human Health Animal Hazard, and Environmental Hazard: *Ex vivo* studies where the live organism was not directly exposed to the chemical of interest are to be tagged as ***Supplemental, Mechanistic***. For all non-*in vivo* studies, sub-organ level health outcomes are to be tagged as ***Supplemental, Mechanistic***. **ADME studies:** *In vitro* Environmental Hazard studies investigating ADME are to be tagged as ***Supplemental, Mechanistic, subtag: ADME***.

PECO Element Relevance	Category	Evidence
		In vitro and *in vivo* Human Health Animal Hazard and Epidemiology ADME studies designed to capture information regarding transformation (*i.e.*, ADME) without assessing a health outcome are to be tagged as ***Supplemental, Mechanistic, subtag: ADME***.
O	Susceptible populations (no health outcome)	Epidemiology and Human Health Animal Hazard: Studies that identify potentially susceptible subgroups but do not report a health outcome. **Screener note:** If biological susceptibility issues are clearly present or *strongly* implied in the title/abstract, this supplemental tag may be applied at the Title/Abstract Screening. If uncertain at title/abstract, do not apply this tag to the reference during the Title/Abstract Screening.
P, E, C, O	Non-English language records	Epidemiology, Human Health Animal Hazard, and Environmental Hazard: Non-English records will be tracked as potentially relevant supplemental information.
P, E, C, O	Other potentially relevant data sources	Epidemiology, Human Health Animal Hazard, and Environmental Hazard: Records that may not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries and conference proceedings or abstracts. Epidemiology: Meta-analyses will be tagged as ***Supplemental, Other potentially relevant data sources, subtag: Meta-analyses***.

C.5.2 Literature Inventory Tree – Environmental and Human Health Hazard Search Results



Figure_Apx C-8. Literature Inventory Tree of Environmental and Human Health Hazard Search Results for Vinyl Chloride

Data in this figure represent all references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. View the interactive literature inventory tree in HAWC.

C.5.3 Evidence Map of Environmental Hazard Information

Distinct count of Hero ID
1 3

Health outcome	Ecosystem / Taxonomic group						Grand Total
	Aquatic			Terrestrial			
	Invertebrate	Vertebrate	Vegetation and Fungi	Invertebrate	Vertebrate	Vegetation and Fungi	
Accumulation/ADME							0
Behavior	1	1					2
Biochemical/Biochemistry, Enzyme(s), Hormone(s)	1						1
Biomarkers	1			1			2
Cancer/Carcinogenesis							0
Cell signaling/function	1						1
Computation toxicology and data integration							0
Cytotoxicity							0
Development	1			1			2
Ecosystem processes							0
Enhanced adipogenesis							0
Epigenetics							0
Genotoxicity				3			3
Growth	1	1	1				3
Histology							0
Immobilization							0
Morphology		1					1
Mortality		2		2			4
Oxidative stress	1						1
Photosynthesis/Respiration							0
Physiology/organ function							0
Population							0
Receptor binding/regulation of receptor activity							0
Reproduction	1			2			3
Grand Total	2	2	1	4	0	0	8

Figure_Apx C-9. Evidence Map of Environmental Hazard Information for Vinyl Chloride

Data in this figure represent all references obtained from the publicly available databases and gray literature reference searches that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. The left side of the evidence map depicts references obtained for aquatic ecosystems, while the right side depicts references obtained for terrestrial ecosystems. The column and row grand totals indicate total number of distinct references. The various shades of color represent the number of relevant references identified for each health outcome-taxonomic group pair. Darker colors indicate a higher number of references available for a given health outcome-taxonomic group pair. In cases where a given reference reported the same health outcome for multiple taxonomic groups and/or multiple health outcomes for a single taxonomic group, the number of references within the table may appear higher than the grand totals. View the interactive evidence map for environmental hazard in HAWC.

C.5.4 Evidence Map of Human Health Hazard Information

Distinct count of Hero ID
1 41

Health outcome	Exposure type								Grand Total
	Animal toxicity		Epidemiology						
	Inhalation	Oral	Dermal	Drinking water	Food	Inhalation	Ocular/Eye	Teeth or dental patient	
Cancer/Carcinogenesis	21	5	27	2	1	41	12		65
Cardiovascular	15	2	11	1		12	6		29
Gastrointestinal	6	3	6			8	4		16
Hepatic/Liver	37	6	13	2		20	6		62
Immune/Hematological	20	4	10	2	1	14	7	1	37
Irritation(skin, eye)			2			2	2		2
Lung/Respiratory	19	3	8	2		13	6		34
Mortality	23	4	7	1		11	4		37
Musculoskeletal	4	1	3			5	3		10
Neurological/Behavioral	12	4	7	2		12	5		26
Nutritional/Metabolic	25	5	2			3	2		32
Ocular/Sensory	4	1	2			6	2		10
Other	15	5	12			28	9		47
Renal/Kidney	16	3	6	1		9	4		27
Reproductive/Developmental	18	3	2			3	2		23
Sensitization	5								5
Skin/Connective Tissue	3		3			5	3		8
Thyroid	4	2							6
Grand Total	59	7	47	5	2	78	24	1	141

The column totals, row totals, and grand totals indicate total numbers of distinct references. The various shades of color visually represent the distinct number of relevant references identified by exposure type or health outcome tag. The darker the color, the more references are available for a given expos..

Figure_Apx C-10. Evidence Map for Human Health Hazard Information for Vinyl Chloride
Data in this figure represent all references obtained from the publicly available databases that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. The X-axis lists exposure types: oral/food/drinking water, dermal, inhalation, and ocular. The Y-axis lists health outcomes described for each appropriate exposure type. The column totals, row totals, and grand totals indicate total numbers of distinct references. The various shades of color visually represent the distinct number of relevant references identified for each health outcome-taxonomic group pair. Darker colors indicate a higher number of references available for a given health outcome-exposure pair. View the interactive human health outcome heatmap in HAWC.

Table_Apx C-10 lists the quantitative endpoint data as reported in the previous assessments considered for Section 2.7.2, potential human health hazard. Each endpoint was determined based on animal toxicity study data, epidemiology data, or both, per the two right-most columns. The data values in this table are visualized in Figure 2-4.

Table_Apx C-10. Human Health Quantitative Endpoints from Previous Assessments

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
ATSDR 2023	Provisional Minimum Risk Level (MRL)	Acute toxicity	0.5 ppm	Inhalation	X	
ATSDR 2023	Provisional Minimum Risk Level (MRL)	Chronic toxicity	0.02 ppm	Inhalation	X	
ATSDR 2023	Minimum Risk Level (MRL)	Chronic toxicity	0.003 mg/kg/day	Oral	X	
CARB 1990a	Cancer Unit Risk - Upper Confidence Limits (UCL)	Cancer	3.7×10^{-5} ppb^{-1} to 20×10^{-5} ppb^{-1}	Inhalation	X	X
CARB 1990a	Cancer Unit Risk	Cancer	20×10^{-5} ppb^{-1}	Inhalation	X	X
CARB 1990a	Lifetime Unit Risk for Workers	Cancer	2.5×10^{-5} ppb^{-1} to 4.5×10^{-5} ppb^{-1}	Inhalation		X
CARB 1990b	Cancer Potency Slope	Cancer	1.75×10^{-2} mg/kg/day	Oral	X	
CARB 1990c	Upper Confidence Limit (UCL) on Cancer Unit Risk (q1*)	Cancer	20×10^{5} ppb	Inhalation	X	
CARB 1990c	Upper Confidence Limit (UCL) on Lifetime Risk	Cancer	2.5×10^{-5} ppb	Inhalation	X	
CARB 1990c	Cancer Potency Slope	Cancer	2.95×10^{-1} ppb	Inhalation	X	
CARB 1990c	Upper Confidence Limit (UCL) on Lifetime Risk	Cancer	2.3×10^{-5} ppb	Inhalation	X	
CARB 1990c	Cancer Risk	Cancer	18×10^{-5} ppb	Inhalation	X	
CARB 1990c	Oral Potency Factor	Cancer	2.3 mg/kg/day	Oral	X	
CARB 1990c	Upper Confidence Limit (UCL) on Unit Risk	Cancer	2.5×10^{-5} ppb^{-1}	Inhalation		X
CARB 1990c	Upper Confidence	Cancer	4.5×10^{-5} ppb^{-1}	Inhalation		X

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
	Limit (UCL) on Unit Risk					
CARB 1990c	Maximum Likelihood Estimate (MLE) Unit Risk	Cancer	1.2×10^{-6} ppb	Inhalation		X
CARB 1990c	Maximum Likelihood Estimate (MLE) Unit Risk	Cancer	2.5×10^{-6} ppb	Inhalation		X
CARB 1990c	Maximum Likelihood Estimate (MLE) Unit Risk Coefficient	Cancer	1.1×10^{-5} (no units)	Inhalation		X
CARB 1990c	Maximum Likelihood Estimate (MLE) Unit Risk Coefficient	Cancer	1.4×10^{-5} (no units)	Inhalation		X
CARB 1990c	Maximum Likelihood Estimate (MLE) Unit Risk Coefficient	Cancer	2.2×10^{-5} (no units)	Inhalation		X
OEHHA 2011	Unit Risk Factor (URF)	Cancer	7.8×10^{-5} $(\mu g/m^3)^{-1}$	Inhalation	X	
OEHHA 2011	Cancer Slope Factor	Cancer	2.7×10^{-1} $(mg/kg/day)^{-1}$	Oral	X	
CA DTSC 2022	Screening Level for Residential Air	Cancer	0.0095 $\mu g/m^3$	Inhalation		X
CA DTSC 2022	Screening Level for Residential Air	Non-cancer endpoint toxicity	100 $\mu g/m^3$	Inhalation		X
CA DTSC 2022	Screening Level for Commercial/Industrial Air	Cancer	0.16 $\mu g/m^3$	Inhalation		X
CA DTSC 2022	Screening Level for Commercial/Industrial Air	Non-cancer endpoint toxicity	440 $\mu g/m^3$	Inhalation		X
CA DTSC 2022	Screening Level for Residential Soil	Cancer	0.0082 mg/kg	Levels in Soil (potentially		X

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
				multiple exposure types)		
CA DTSC 2022	Screening Level for Residential Soil	Non-cancer endpoint toxicity	70 mg/kg	Levels in Soil (potentially multiple exposure route types)		X
CA DTSC 2022	Screening Level for Commercial/Industrial Soil	Cancer	0.15 mg/kg	Levels in Soil (potentially multiple exposure route types)		X
CA DTSC 2022	Screening Level for Commercial/Industrial Soil	Non-cancer endpoint toxicity	370 mg/kg	Levels in Soil (potentially multiple exposure route types)		X
CA DTSC 2022	Screening Level for Tap Water	Cancer	0.0098 µg/L	Drinking Water		X
CA DTSC 2022	Screening Level for Tap Water	Non-cancer endpoint toxicity	45 µg/L	Drinking Water		X
CA DTSC 2022	California Maximum Contaminant Level (MCL)	Cancer/Non-cancer endpoint toxicity	0.5 µg/L	Drinking Water		X
CA DTSC 2022	US Environmental Protection Agency Maximum Contaminant Level (MCL)	Cancer	2 µg/L	Drinking Water		X
US EPA 2000a	Reference Concentration (RfC)	Toxicity (Reference)	1×10^{-1} mg/m^3, Uncertainty Factor: 30	Inhalation	X	
US EPA 2000a	Reference Dose (RfD)	Toxicity (Reference)	3×10^{-3} per mg/kg/day, Uncertainty Factor: 30	Oral	X	
US EPA 2000a	Cancer Risk - Lifetime	Cancer	7.2×10^{-1} per mg/kg/day	Oral	X	
US EPA 2000b	Cancer Slope Factor - Lifetime Exposure	Cancer	2.1×10^{-5} per µg/L	Drinking Water	X	

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
	During Adulthood					
US EPA 2000b	Cancer Slope Factor - Lifetime Exposure from Birth	Cancer	4.2×10^{-5} per µg/L	Drinking Water	X	
US EPA 2000b	Drinking Water Risk - 1 in 10,000, Adult Exposure	Cancer	4.8 µg/L	Drinking Water	X	
US EPA 2000b	Drinking Water Risk - 1 in 10,000, Exposure from Birth	Cancer	2.4 µg/L	Drinking Water	X	
US EPA 2000b	Drinking Water Risk - 1 in 100,000, Adult Exposure	Cancer	4.8×10^{-1} µg/L	Drinking Water	X	
US EPA 2000b	Drinking Water Risk - 1 in 100,000, Exposure from Birth	Cancer	2.4×10^{-1} µg/L	Drinking Water	X	
US EPA 2000b	Drinking Water Risk - 1 in 1,000,000, Adult Exposure	Cancer	4.8×10^{-2} µg/L	Drinking Water	X	
US EPA 2000b	Drinking Water Risk - 1 in 1,000,000, Exposure from Birth	Cancer	2.4×10^{-2} µg/L	Drinking Water	X	
US EPA 2000b	Inhalation Unit Risk (IUR) - Lifetime Exposure During Adulthood	Cancer	4.4×10^{-6} per µg/m3	Inhalation	X	
US EPA 2000b	Inhalation Unit Risk (IUR) - Lifetime Exposure from Birth	Cancer	8.8×10^{-6} per µg/m3	Inhalation	X	
US EPA 2000b	Risk In Air - 1 in 10,000	Cancer	23 µg/m3	Inhalation	X	

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
US EPA 2000b	Risk In Air - 1 in 100,000	Cancer	2.3 µg/m3	Inhalation	X	
US EPA 2000b	Risk In Air - 1 in 1,000,000	Cancer	2.3×10^{-1} µg/m3	Inhalation	X	
US EPA 2000b	Cancer Slope Factor - Lifetime Exposure During Adulthood	Cancer	7.2×10^{-1}; 7.5×10^{-1} per mg/kg/day	Oral	X	
US EPA 2000b	Cancer Slope Factor - Lifetime Exposure from Birth	Cancer	1.4 or 1.5 per mg/kg/day	Oral	X	
Health Canada 2013	Maximum Acceptable Concentration (MAC)	Cancer	0.002 mg/L	Drinking Water	X	
Health Canada 2013	Maximum Contaminant Level (MCL)	Cancer	0.002 mg/L	Drinking Water	X	
Health Canada 2013	Health Based Value	Chronic Toxicity	0.03 mg/L	Drinking Water	X	
Health Canada 2013	Health Based Value	Cancer	0.04 µg/L	Drinking Water	X	
Health Canada 2013	Health Based Value	Cancer	0.4 µg/L	Drinking Water	X	
Health Canada 2013	Cancer Risk	Cancer	0.3 µg/L	Drinking Water	X	
Health Canada 2013	Public Health Goal (PHG)	Cancer	0.05 µg/L	Drinking Water	X	
Health Canada 2013	Public Health Goal (PHG)	Chronic Toxicity	3 µg/L	Drinking Water	X	
Health Canada 2013	Cancer Risk	Cancer	0.3 µg/L	Drinking Water	X	
Health Canada 2013	Maximum Contaminant Level	Cancer	0.5 µg/L	Drinking Water	X	
Health Canada 2013	Maximum Allowable Carryover (MAC) - Lifetime Risk	Cancer	5.0×10^{-5} (no units)	Drinking Water	X	
Health Canada 2013	Oral Slope Factor	Cancer	0.72 mg/kg/day	Oral	X	

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
Health Canada 2013	Reference Dose (RfD)	Toxicity (Reference)	0.003 mg/kg/day	Oral	X	
Health Canada 2013	Tolerable Daily Intake	Chronic toxicity	0.009 mg/kg/day	Oral	X	
IPCS 1999	Cancer Risk Estimate	Cancer	1.14×10^{-6} ug/L	Drinking Water	X	
IPCS 1999	Cancer Risk Estimate	Cancer	5.4×10^{-5} µg/L	Drinking Water	X	
IPCS 1999	Cancer Slope Factor	Cancer	0.005 mg/L	Drinking Water	X	
IPCS 1999	Inhalation Unit Risk - Continuous Lifetime	Cancer	5.7×10^{-7} µg/m^3	Inhalation	X	X
IPCS 1999	95% Upper Confidence Limit (UCL) on Cancer Unit Risk	Cancer	0.4×10^{-6} per ppb to 0.8×10^{-6} per ppb	Inhalation		X
IPCS 1999	Cancer Unit Risk	Cancer	8.4×10^{-6} (µg/m^3)$^{-1}$	Inhalation		X
NRC 2012	Acute Exposure Guideline Levels (AEGL1) - 10 min to 8 hr	Acute toxicity	450 ppm to 70 ppm; Uncertainty Factor: 3	Inhalation		X
NRC 2012	Acute Exposure Guideline Levels (AEGL2) - 10 min to 8 hr	Acute toxicity	2,800 ppm to 820 ppm; Uncertainty Factor: 3	Inhalation		X
NRC 2012	Acute Exposure Guideline Levels (AEGL3) - 10min	Acute toxicity	12000 ppm	Inhalation	X	
NRC 2012	Acute Exposure Guideline Levels (AEGL3) - 30min	Acute toxicity	6800 ppm	Inhalation	X	
NRC 2012	Acute Exposure Guideline Levels (AEGL3) - 1hr	Acute toxicity	4800 ppm	Inhalation	X	
NRC 2012	Acute Exposure Guideline	Acute toxicity	3400 ppm	Inhalation	X	

Assessment Label	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
	Levels (AEGL3) - 4hr					
NRC 2012	Acute Exposure Guideline Levels (AEGL3) - 8hr	Acute toxicity	3400 ppm	Inhalation	X	
NRC 2012	Cancer Unit Risk - 1 in 10,000, 30 min to 8h	Cancer	2990 ppm to 55.9 ppm	Inhalation	X	
NRC 2012	Cancer Unit Risk - 1 in 100,000, 30 min to 8h	Cancer	89.7 ppm to 5.55 ppm	Inhalation	X	
NRC 2012	Cancer Unit Risk - 1 in 1000,000, 30 min to 8h	Cancer	8.97 ppm to 0.555 ppm	Inhalation	X	
NRC 2012	Cancer Potency Slope	Cancer	6.5×10^{-7} μg/m^3 to 1.4×10^{-6} μg/m^3	Inhalation	X	
NRC 2012	Cancer Potency Slope	Cancer	8.8×10^{-6} μg/m^3	Inhalation	X	
NRC 2012	Cancer Potency Slope	Cancer	6×10^{-7} to 2×10^{-6} μg/m^3	Inhalation	X	
NRC 2012	Cancer Potency Slope	Cancer	1.1×10^{-6} μg/m^3	Inhalation	X	
NRC 2012	Cancer Potency Slope	Cancer	5.7×10^{-7} μg/m^3	Inhalation	X	
OECD 2001	Acute Exposure Guideline Levels (AEGL3) - 8 hr. to 10 min	Acute toxicity	8800 mg/m^3 to 31000 mg/m^3	Inhalation	X	

Appendix D PHYSICAL AND CHEMICAL PROPERTIES

Table_Apx D-1. Physical and Chemical Properties of Vinyl Chloride

Property	Value(s)[a]	Reference(s)
Molecular formula	C_2H_3Cl	NLM (2023b)
Molecular weight	62.498 g/mole	Rumble (2023)
Physical form	Colorless gas at room temperature and pressure; mild, sweet odor	RSC (2023), U.S. EPA (2000b), NLM (2023b)
Melting point	-153.84 °C	PhysProp (2023), Rumble (2023)
Boiling point	-13.9 °C	NLM (2023b), U.S. EPA (2023a), Reaxys (2023)
Density	0.9106 g/cm^3 at 20 °C	Rumble (2023), RSC (2023), ATSDR (2023), OECD (2001)
Vapor pressure	2,550 mm Hg at 20 °C	ECHA (2023a)
Vapor density	2.21 (relative to air = 1)	NLM (2023b)
Water solubility	9,150 mg/L at 20.5 °C	Reaxys (2023), ECHA (2023a)
Octanol:water partition coefficient (log K_{OW})	1.38	Rumble (2023), ATSDR (2023), ECHA (2023b)
Octanol:air partition coefficient (log K_{OA})	1.404[b]	EPI Suite™ (KOAWIN)
Henry's law constant	0.0278 atm·m^3/mol at 24.8 °C	PhysProp (2023)
Flash point	-78 °C (closed cup)	NLM (2023b), RSC (2023)
Autoflammability	472 °C	NLM (2023b)
Viscosity	0.01072 cP at 20 °C	NLM (2023b)
UV-Vis absorption	Chemical is a gas that does not absorb wavelengths >218 nm	OECD (2001)

[a] Measured unless otherwise noted
[b] Information was estimated using EPI Suite™ U.S. EPA (2012b).

Appendix E ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES

Table_Apx E-1. Environmental Fate and Transport Properties of Vinyl Chloride

Property or Endpoint	Value[a]	Reference(s)
Direct photodegradation (air)	Does not absorb light at wavelengths > 220 nm	ATSDR (2023)
	0.09 s^{-1} determined in static system, xenon lamp irradiation at 2.7 kW; 0.047 s^{-1} determined from flow experiments with 16-second residence time, xenon lamps at 3.7 kW	Reaxys (2023)
Direct photodegradation (water)	0% over 90 hours in water at 10 mg/L test substance concentration irradiated with >300 nm; absorption in water was <218 nm	OECD (2001)
Indirect photodegradation (air)	$t_{1/2}$ range = 1.27 to 2.71 days (n = 9; based on •OH rate constants of 3.95x 10^{-12} to 8.40x 10^{-12} cm^3/mole-sec and a 12-hour day with 1.5 x 10^6 •OH/cm^3)	OECD (2001), ECHA (2023a), NLM (2023a), NIST (2023), ATSDR (2023)
	$t_{1/2}$ range = 155 to 478 days (n = 6; based on NO_3 rate constants of 1.40 x 10^{-16} to 4.30 x 10^{-16} cm^3/mole-sec and a 12-hour day with 2.40 x 10^8 NO_3/cm^3)	ECHA (2023a), NIST (2023)
	$t_{1/2}$ = 93.6 days (based on O_3 rate constant of 2.45 x 10^{-19} cm^3/mole-sec and a 12-hour day with 7.0 x 10^{11} O_3/cm^3)	ECHA (2023a)
	$t_{1/2}$ = 91.3 days (based on O_3 rate constant of 2.51 x 10^{-19} cm^3/mole-sec and a 12-hour day with 7.0 x 10^{11} O_3/cm^3)	NLM (2023a)
Indirect photodegradation (water)	No decomposition at 10 mg/L test substance concentration in unfiltered Oconee River and Okefenokee Swamp water with	OECD (2001)
	80% over 3 hours at 10 mg/L test substance concentration, and H_2O_2 as a photosensitizer	OECD (2001)
	Not readily degraded at 10 mg/L test substance concentration, with 1.0 x 10^{-4} M methylene blue (singlet) and irradiation at 578 nm	OECD (2001)
	Rapid decomposition at 10 mg/L test substance concentration, with 10% vol. acetone and UV irradiation at 313 nm	OECD (2001)
Hydrolysis half-life (water)	$t_{1/2}$ > 9.91 years at 25 °C and pH 7 $t_{1/2}$ > 107 years at 10 °C and pH 7	NLM (2023a)
	$t_{1/2}$ > 1 year at both pH 4 and 6.1	OECD (2001)
	No degradation observed in water after 12 hours at 85 °C, at 20 mg/L test substance	ATSDR (2023)

Property or Endpoint	Value[a]	Reference(s)
	concentration; saturated with molecular oxygen	
	<10 years at 25.5 °C and pH 4.3-9.4 (estimated)	OECD (2001), ATSDR (2023)
Abiotic reductive dehalogenation (water)	<0.002 d^{-1} with zero-valent FeH_2, and 0.59 to 0.76 d^{-1} with zero-valent FeBH	Reaxys (2023)
	0.055, 0.323, 0.537, and 0.555 d^{-1} with Silawa loamy sand, montmorillonite, vermiculite and biotite, respectively, in the presence of Fe (II) at 22 °C and pH 7 - 7.2	Reaxys (2023)
	0.247, 0.355, and 0.358 d^{-1} with montmorillonite, vermiculite, and biotite, respectively, at 22°C and pH 7	Reaxys (2023)
	0.15 d^{-1} with Silawa loamy sand and dithionite at pH 7.2	Reaxys (2023)
	0.94 d^{-1} with green rust sulfate in Tris buffer at 22 °C and pH 8.1	Reaxys (2023)
Aerobic biodegradation (water)	21.5% over 5 days (CO_2 Evolution) at 0.05 mg/L test substance concentration, with municipal activated sludge inoculum, adaptation not specified	OECD (2001), ECHA (2023a)
	16% and 3%/28 days (OECD 301D) at 2.04 and 10.2 mg/L test substance concentration, respectively; with sludge inoculum, adaptation not specified	NITE (2023), ECHA (2023a), NLM (2023a)
	22% over 28 days (CO_2 Evolution), with municipal activated sludge inoculum; some adaptation	ECHA (2023b)
Aerobic biodegradation (sediment)	22% to 39% over 84 hours (mineralization) at approx. 1.13 mg/L test substance concentration in natural aquifer microcosm; some adaptation from chlorinated solvent and vinyl chloride contamination	Reaxys (2023), ATSDR (2023)
	>99% over 57 days, and >99% over 204 days at 330 µg/L test substance concentration, in groundwater/sediment batch microcosms; media from VC-contaminated sites	NLM (2023a)
Aerobic biodegradation (soil)	>99% over 108 days (transformation) and 65% over 108 days (mineralization) at 1 mg/L test substance concentration in a natural shallow aquifer soil/groundwater microcosm, adaptation not specified	OECD (2001), ATSDR (2023) ECHA (2023a)
	1.456 µg/g soil/hour biodegradation in gas phase, incubated with soil from a landfill under methane oxidizing conditions	NLM (2023a)
Anaerobic biodegradation (water)	10% over 106 days following a 50-day lag at 2.6×10^{-4} mg/L test substance concentration in groundwater containing H_2 and acetate, under	Reaxys (2023)

Property or Endpoint	Value[a]	Reference(s)
	methanogenic conditions; media from VC-contaminated site	
	$t_{1/2}$ = 70 days at 0.4 mg/L test substance concentration, with groundwater bacteria inoculum, adaptation not specified	ECHA (2023a), NLM (2023a)
	$t_{1/2}$ = 110 days; study details not specified	NLM (2023a)
Anaerobic biodegradation (sediment)	15% to 34% over 84 hours, and 2.8% to 4.6% over 84 hours (mineralization) at approx. 1.13 mg/L test substance concentration, in natural aquifer microcosm, amended with Fe(III) and unamended, respectively; some adaptation from chlorinated solvent and vinyl chloride contamination	Reaxys (2023), ATSDR (2023)
	5% to 44% over 37 days, and 8% to 100% over 37 days (mineralization) at 0.013 to 3.79 mg/L test substance concentration, in natural creek bed microcosm under methanogenic and Fe (III)-reducing conditions, respectively; some adaptation from former drum disposal area	Reaxys (2023), ATSDR (2023)
	50% over 25 days and 100% over 19 days with 0.02 and 0.1 mg/L dissolved oxygen, respectively, at 0.65 mg test substance; VC-oxidizing culture inoculum in microcosm with media from contaminated site; adapted	ATSDR (2023)
	98% and 21% over 70 days in Naval Air Station, and Naval Weapons Industrial Reserve Plant sediment microcosms, respectively; under methanogenic conditions; preexposure of media likely	ECHA (2023a)
	100% over >100 days at 39 mg/L test substance concentration in groundwater with sediment microcosm under Fe- and SO_4-reducing conditions; media from contaminated site	Reaxys (2023)
	40% over 20 hours at 31.2 mg/L test substance concentration, in brackish sediment microcosm supplemented with methanol; adaptation not specified	Reaxys (2023)
	40% over 20 hours at 28.7 mg/L test substance concentration, in brackish sediment microcosm supplemented with H_2; adaptation not specified	Reaxys (2023)
	100% over 15 days in aquifer microcosm supplemented with methanol and C_2Cl_4; adaptation not specified	Reaxys (2023)
	100% over 14 weeks, and <20% over 14 weeks with and without supplemented e-donors, respectively, in aquifer microcosm;	Reaxys (2023)

Property or Endpoint	Value[a]	Reference(s)
	media from a site contaminated with vinyl chloride	
Anaerobic biodegradation (soil)	$t_{1/2}$ = 4 weeks at 0.4 mg/L test substance concentration, in sand/water microcosm; adaptation not specified	ECHA (2023a), NLM (2023a)
Bioconcentration factor (BCF) (L/kg wet weight, unless noted)	BCF < 10 in Golden Ide (*Leuciscus idus* melanotus)	OECD (2001), ATSDR (2023), NLM (2023a), ECHA (2023a)
	BCF = 40 in green algae (*Chlorella fusca*)	OECD (2001), ATSDR (2023), NLM (2023a), ECHA (2023a)
	Upper Trophic Level: 3.633 Middle Trophic Level: 2.797 Lower Trophic Level: 2.588	EPI Suite™ (BCFBAF, Arnot-Gobas method)[b]
Bioaccumulation factor (BAF) (L/kg wet weight, unless noted)	Upper Trophic Level: 3.633 Middle Trophic Level: 2.798 Lower Trophic Level: 2.589	EPI Suite™ (BCFBAF, Arnot-Gobas method)[b]
Organic carbon:water partition coefficient (log K_{OC}) (soil)	2.38 to 2.95 in seven natural clayey till soil samples	ATSDR (2023)
	1.75	OECD (2001), NLM (2023a)
Removal in wastewater treatment	Total removal: 91.54% Losses to stripping: ~89%	EPI Suite™ (STPWIN, with default biodegradation $t_{1/2}$s = 10,000 h)[b]

[a] Measured unless otherwise noted
[b] Information was estimated using EPI Suite™ U.S. EPA (2012b).