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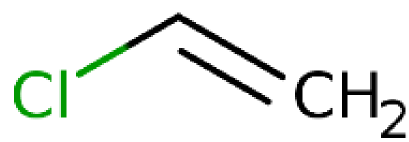
United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for Vinyl Chloride (Ethene, chloro-)

CASRN 75-01-4



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KEY ABBREVIATIONS AND ACRONYMS

ATSDR	Agency for Toxic Substances and Disease Registry
ANSI	American National Standards Institute
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CASRN	Chemical Abstracts Service Registry Number
CDR	Chemical Data Reporting
CEM	Consumer Exposure Model
CFR	Code of Federal Regulations
COU	Condition of use
DMR	Discharge Monitoring Report
EPA	(U.S.) Environmental Protection Agency (or the Agency)
ESD	Emission scenario document
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IRIS	Integrated Risk Information System
K_{OC}	Organic carbon:water partition coefficient

MCL	Maximum contaminant level
MOA	Mode of action
MRL	Minimal risk level
NEI	National Emissions Inventory
NIOSH	National Institute for Occupational Safety and Health
NSF	National Sanitation Foundation
OCSPP	Office of Chemical Safety and Pollution Prevention (EPA)
OECD	Organization for Economic Cooperation and Development
ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics (EPA)
ORD	Office of Research and Development (EPA)
OSHA	Occupational Safety and Health Administration
PCE	Perchloroethylene
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulation
POD	Point of departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
PVC	Polyvinyl chloride
SDWA	Safe Drinking Water Act
SDS	Safety data sheets
TCE	Trichloroethylene
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
U.S.	United States
VOC	Volatile organic compound

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Docket

Supporting information can be found in the public docket, Docket ID: EPA-HQ-OPPT-2018-0448.

Disclaimer

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Authors: Marcy Card (Scope Lead), Kesha Forrest (Management Lead and Branch Supervisor), Lillie Marie Barnett, Albana Bega, Judith Brown, Emily Griffin, Franklyn Hall, Keith Jacobs, Kara Koehrn, Catherine Ngo, Haley Skinner, and Olivia Wrightwood.

Collaborators: Amber Aranda and Bridget Eklund.

Technical Support: Mark Gibson and Hillary Hollinger.

This draft scope document was reviewed and cleared for release by OPPT and OCSPP leadership.

EXECUTIVE SUMMARY

In December 2024, EPA designated vinyl chloride (CASRN 75-01-4)—a colorless gas at room temperature and pressure—as a high-priority substance for risk evaluation following the prioritization process as required by section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0448). The first step of the chemical risk evaluation process is the development of the draft scope document. Following its publication, EPA will provide a 45-day comment period on the draft scope per 40 CFR 702.43(a). The Agency will consider information received during the public comment period to both inform the finalization of the scope document and the subsequent development of the draft risk evaluation for vinyl chloride. This draft scope for vinyl chloride includes the conditions of use (COUs; also called TSCA COUs), potentially exposed or susceptible subpopulations (PESS), hazards, and exposures that EPA expects to consider in the risk evaluation—along with a description of the reasonably available information, conceptual models, analysis plan and science approaches, and plan for peer review.

General Information

Vinyl chloride is listed on the TSCA Inventory with the name "ethene, chloro-." Vinyl chloride has total production volume in the United States of between 10 and less than 20 billion pounds (lb) per year.

Reasonably Available Information

EPA leveraged the data and information sources already described in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c) to inform the development of this draft scope document. As described in the proposed designation document, EPA applied systematic review methods to identify and screen reasonably available information across multiple evidence streams (*i.e.,* chemistry, fate, release and engineering, exposure, and hazard) for consideration in the risk evaluation. This information includes the hazards, exposures, PESS, and TSCA COUs that may help inform the risk evaluation for vinyl chloride. EPA has focused on the data collection phase (consisting of data search and screening) during prioritization and preparation of this draft scope; in contrast, the data extraction, evaluation, and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document. EPA plans to consider additional information identified following release of the draft and final scope, as appropriate, in developing the draft risk evaluation—including Chemical Data Reporting (CDR) information that the Agency received in November 2024.

Conditions of Use

Vinyl chloride COUs are presented in Section 2.2. EPA plans to evaluate manufacturing (including importing); processing; distribution in commerce; industrial, commercial, and consumer uses; and disposal of vinyl chloride in the risk evaluation. Vinyl chloride is manufactured domestically and imported into the United States. The chemical is processed as a reactant; incorporated into a formulation, mixture, or reaction product; incorporated into articles; and used in other industrial and commercial processes. The identified processing activities also include the repackaging and recycling of vinyl chloride. All of the identified industrial, commercial, and consumer uses are related to vinyl chloride serving as a monomer in plastics—primarily polyvinyl chloride (PVC)—and other polymers. EPA identified these COUs from information reported to the Agency through CDR, public comments, and other publicly available data sources, including emissions databases, safety data sheets (SDSs), published literature, and company websites.

Conceptual Model

The conceptual models for vinyl chloride are presented in Section 2.5. These are graphical depictions of the actual or predicted relationships of COUs, exposure pathways (*e.g.,* media), exposure routes (*e.g.,* inhalation, dermal, oral), hazards, and populations throughout the life cycle of the chemical. EPA considered reasonably available information, including public comments, in considering the exposure pathways, exposure routes, and hazards the Agency expects to evaluate in the risk evaluation. Furthermore, EPA's plan for evaluating exposure in the scope of the risk evaluation considers major or minor exposure pathways and routes based on physical and chemical information (Section 2.1), release information (Section 2.3.1), fate and transport properties (Section 2.3.1.1), and other information such as industry standards in PVC production. The Agency expects to focus the risk evaluation for vinyl chloride on the exposures and hazards listed below, with a fit-for-purpose approach determining the level and types of analysis (*i.e.,* quantitative or qualitative) conducted for each exposure route, pathway, and population (40 CFR 702.37(a)(4)):

- *Exposures (Pathways and Routes), Populations, and PESS:* EPA plans to evaluate releases to the environment as well as both human and environmental exposures resulting from vinyl chloride COUs that the Agency expects to consider in the risk evaluation. Exposures to vinyl chloride are discussed in Section 2.3. Vinyl chloride is a gas at room temperature (Section 2.1), more than 98 percent of vinyl chloride releases are to air (Section 2.3.1), and vinyl chloride is not expected to significantly partition from air into other environmental media (Section 2.3.1.1). Thus, EPA plans to quantitatively assess inhalation exposures in occupational settings, to consumers and bystanders, and to the general population. The Agency also plans also to qualitatively assess other exposures to vinyl chloride (Section 2.5). Additional information gathered through systematic review searches will also inform expected exposures.

  EPA considered reasonably available information and comments received on the proposed designation document for vinyl chloride in determining the relevancy of human and environmental exposure pathways, routes, populations, and PESS for inclusion in this draft scope. The Agency expects to evaluate the following human and environmental exposure pathways, routes, populations, and PESS in the scope of the risk evaluation:

  - <u>Occupational Exposure</u>: EPA plans to quantitatively evaluate exposures to workers and occupational non-users (ONUs) via the inhalation route and to qualitatively assess exposures only to workers—not ONUs—via the dermal route associated with the manufacturing, processing, distribution, use, and disposal of vinyl chloride.
  - <u>Consumer and Bystander Exposure</u>: EPA plans to quantitatively evaluate inhalation exposures to vinyl chloride vapor for consumers and bystanders during use of products containing vinyl chloride. The Agency further plans to qualitatively assess oral and dermal exposures to consumer products and articles containing residual vinyl chloride monomer.
  - <u>General Population Exposure</u>: EPA plans to quantitatively evaluate general population exposures to vinyl chloride from inhalation of ambient air and to qualitatively assess exposures via other media.
  - <u>PESS</u>: EPA plans to include children, women of reproductive age (*i.e.,* developmental exposures), workers, populations who live near a facility releasing vinyl chloride, and consumers as PESS in the risk evaluation due to the potential for increased exposure and/or susceptibility to vinyl chloride in these groups.
  - <u>Environmental Exposures</u>: EPA plans to qualitatively evaluate exposure to vinyl chloride for aquatic and terrestrial organisms.

- *Hazards:* Hazards for vinyl chloride are discussed in Section 2.4. EPA completed preliminary reviews of information (*e.g.,* U.S. and international government chemical assessments, databases, and information obtained through systematic review) to identify potential environmental and human health hazards for vinyl chloride as part of the prioritization process

(U.S. EPA, 2024c). The information received through public comments and collected during prioritization informed determination of the broad categories of environmental and human health hazard effects to be evaluated in the draft risk evaluation.

EPA plans to evaluate all potential environmental and human health hazard effects identified for vinyl chloride in Sections 2.4.1 and 2.4.2, respectively. The Agency identified limited environmental hazard information for vinyl chloride during prioritization due to its volatility from water and surfaces (including food), which are the exposure pathways included in most ecological toxicity tests. EPA plans to qualitatively assess hazards and risks to environmental organisms, as described in Sections 2.5.3.2.2 and 2.5.3.2.3. The following human health hazards were identified for vinyl chloride: liver toxicity, neurotoxicity, immunotoxicity, developmental toxicity, genotoxicity and cancer, and other hazards. EPA plans to quantitatively assess human health hazards. As the Agency continues to evaluate reasonably available and relevant hazard information identified through systematic review, EPA may update the potential environmental and human health hazards considered in the risk evaluation. The Agency plans to evaluate PESS due to factors that potentially increase susceptibility to vinyl chloride toxicity—including early-life and prenatal exposures (*e.g.,* infants, children, pregnant women), sex, comorbidities, genetic polymorphisms, and other lifestyle factors (*e.g.,* consuming certain drugs, alcohol, and high-calorie diets).

Analysis Plan

The analysis plan for vinyl chloride is presented in Section 2.6. It outlines the general science approaches that EPA plans to use for the various evidence streams (*i.e.,* releases, fate, engineering, exposure, and hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of vinyl chloride to date that includes a review of identified information as described in Section 1.3. Should additional data or approaches become reasonably available, the Agency plans to consider them for the draft risk evaluation.

Peer Review

The draft risk evaluation for vinyl chloride will be peer reviewed as required by the TSCA Risk Evaluation Rule (89 FR 37028). Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations, including using EPA's *Peer Review Handbook* (U.S. EPA, 2015a) and other methods consistent with section 26 of TSCA (40 CFR 702.41).

1 INTRODUCTION

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

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

TSCA section 6(b)(4)(D) and the implementing regulation (40 CFR 702.43) require EPA to publish the scope of the risk evaluation to be conducted, including the hazards, exposures, COUs, and PESS that the Administrator expects to consider within 6 months after the initiation of a risk evaluation. In addition, a draft scope is to be published pursuant to 40 CFR 702.43(a). In December 2024, EPA published a list of five chemical substances, including vinyl chloride, that have been designated high-priority substances for risk evaluation (see Docket ID: EPA-HQ-OPPT-2018-0448, December 18, 2024), which initiated the risk evaluation process for those chemical substances. The Agency is now releasing this draft scope for the risk evaluation of vinyl chloride.

1.1 Regulatory History

In addition to federal and state laws and regulations, vinyl chloride is also subject to various regulatory actions by other governments, tribes, and international agreements as described in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c).

1.2 Assessment History

The Agency identified previous assessments of vinyl chloride conducted by EPA programs and other organizations (Table_Apx A-1). The Agency may also look to consider these assessments or portions of assessments conducted by other federal, state, or international authoritative bodies. EPA may consider whether these existing assessments or reviews represent the best available science as required under TSCA and use pertinent portions of them to directly inform a risk evaluation. Depending on the source, these assessments may include information on COUs, hazards, exposures, and PESS—information useful to EPA in preparing this draft scope for the risk evaluation of vinyl chloride. In addition to using information from prior assessments, the Agency is reviewing data recently collected through systematic literature review (Section 1.3).

1.3 Reasonably Available Information

As described in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c), EPA's 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 assessing the risks associated with each high-priority substance under its COUs. 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]). The Agency also used the systematic review process described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for*

Chemical Substances, Version 1.0: A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies (also called the "Draft Systematic Review Protocol") (U.S. EPA, 2021), incorporating recommendations from the Scientific Advisory Committee on Chemicals (SACC), to identify relevant information to inform the prioritization considerations set forth in 40 CFR 702.9.

The chemical-specific systematic review process being employed by EPA to identify and screen reasonably available information for vinyl chloride is described in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c); the search of reasonably available information on vinyl chloride, title and abstract screening, and full-text screening were conducted to inform the designation of vinyl chloride as a High-Priority Substance (HPS) during prioritization. Since the designation of vinyl chloride as an HPS, additional PDFs of the identified potentially relevant data sources for vinyl chloride were acquired and underwent full-text screening. During the two 90-day public comment periods, additional data sources were also identified, and if relevant, were considered for inclusion in this draft scope of the risk evaluation for vinyl chloride. EPA is in the process of incorporating all potentially relevant data sources identified for vinyl chloride and respective disciplines into visuals such as the evidence maps, available in Appendix B, which depict discipline-specific data elements identified in data sources that meet screening criteria during full-text screening.

Relevant information submitted with public comments on the draft scope document will be considered for use in the draft risk evaluation of vinyl chloride. EPA has completed data quality evaluation and data extraction of data sources containing physical and chemical property information identified during the prioritization process and is currently evaluating and extracting environmental fate and transport information. The chemistry and fate information collected to date was used to inform the fit-for-purpose analysis described in this draft scope document. During the risk evaluation phase, EPA will conduct data extraction and evaluation for information sources related to the pathways, routes, and populations that will receive quantitative assessment, and will conduct evidence integration for all components that are in scope for vinyl chloride. Chemical-agnostic data extraction, data evaluation, and evidence integration approaches are described in the Draft Systematic Review Protocol (U.S. EPA, 2021). The exposure routes, pathways, and populations that EPA expects to quantitatively assess are described in Sections 2.5 and 2.6. The Agency may update the analysis plan based on additional relevant information received or identified.

2 SCOPE OF THE RISK EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the COUs, hazards, exposures, and PESS that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA included in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c) an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between vinyl chloride and human and ecological populations. This draft scope document additionally presents conceptual models that were revised to illustrate which components of the risk evaluation (*i.e.,* exposure pathways and routes, ecological organisms, and human populations) EPA is proposing to quantitatively assess. An initial analysis plan is also included that identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards), and risks under the TSCA COUs of vinyl chloride.

2.1 Physical and Chemical Properties

EPA reviewed databases and previously conducted assessments to identify information for physical and chemical properties to characterize the potential for vinyl chloride to persist in the environment or bioaccumulate. The physical and chemical property values selected preliminarily and for use in this draft scope are given in Table 2-1. Detailed information on the draft physical and chemical assessment of vinyl chloride is available in the *Draft Chemistry and Fate Technical Support Document: Physical and Chemical Property and Fate and Transport Assessment for Vinyl Chloride* (U.S. EPA, 2025a).

Table 2-1. Physical and Chemical Properties of Vinyl Chloride

Property	Selected Value[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	NLM (2023b); RSC (2023); U.S. EPA (2000b)
Melting point	–153.84 °C	PhysProp (2023); Rumble (2023)
Boiling point	–13.9 °C	NLM (2023b); Reaxys (2023); U.S. EPA (2023a)
Density	0.9106 g/cm^3 at 20 °C	ATSDR (2023); RSC (2023); Rumble (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	ECHA (2023a); Reaxys (2023)
Octanol:water partition coefficient (log K_{OW})	1.38	ATSDR (2023); ECHA (2023b); Rumble (2023)
Octanol:air partition coefficient (log K_{OA})	1.324[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	ATSDR (2023); OECD (2001)

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

2.2 Conditions of Use

TSCA section 3(4) defines COUs as "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."' EPA will not exclude COUs from the scope of the risk evaluation, but a fit-for-purpose approach may result in varying types and levels of analysis and supporting information for certain COUs. The extent to which the Agency will refine its evaluations for one or more COUs in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to human health or the environment.

2.2.1 Data and Information Sources

EPA identified COUs based on Chemical Data Reporting (CDR) provided in 2016 (U.S. EPA, 2016) and 2020 (U.S. EPA, 2020a)—as well as other publicly available data sources such as the Toxics Release Inventory (TRI), Discharge Monitoring Reports (DMRs), National Emissions Inventory (NEI) (U.S. EPA, 2020b), safety data sheets (SDSs), Chemical Exposure Knowledgebase (ChemExpo), EPA Chemical and Product Categories (CPCat) data (U.S. EPA, 2019), and the High Priority Chemicals Data System (HPCDS). 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 (*Use Report for Vinyl Chloride (CASRN 75-01-4)*, (U.S. EPA, 2025b)). The Agency also received public comments that can be found in docket ID numbers EPA-HQ-OPPT-2018-0448 and EPA-HQ-OPPT-2023-0601, which contain potentially relevant information regarding the use of vinyl chloride. COUs determined based on these sources are summarized below in Table 2-2.

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

Most reported COUs in CDR for vinyl chloride have remained unchanged between the 2016 and 2020 reporting periods, although some changes have been identified. Guidance regarding the reporting of categories and subcategory information was updated between the 2016 and 2020 reporting periods for CDR. This makes it difficult to discern whether there were significant changes in vinyl chloride COUs based on reported information to CDR during that period. 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.

In the 2016 reporting period, vinyl chloride was reported as a reactant intermediate in adhesive and industrial gas manufacturing. It was also reported 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 reported 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; however, they are included in Table 2-2. In the 2020 reporting period, vinyl chloride was newly reported 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 reported. These may be new uses for vinyl chloride since the 2016 reporting cycle or uses that increased since the 2016 reporting cycle and therefore meet CDR reporting thresholds or reporting discrepancies. EPA is seeking comment to understand if these uses are ongoing.

Information presented in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation CASRN 75-01-4* (U.S. EPA, 2024c) and in public comments indicates the presence of vinyl chloride in commercial and consumer products and articles as an impurity. Consistent with the *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)* rule (89 FR 37028), EPA expects to conduct risk evaluations in a fit-for-purpose manner, tailoring the level of analysis based on factors such as the substance's physical-chemical properties; environmental fate and transport properties; the likely duration, intensity, frequency, and number of exposures under the COU; reasonably available information about the release to the environment; and other relevant considerations.

Table 2-2. Conditions of Use of Vinyl Chloride

Life Cycle Stage[a]	Category[b]	Subcategory[c]	Reference(s)
Manufacture	Domestic manufacture	Domestic manufacture	U.S. EPA (2020a, 2016)
	Import	Import	U.S. EPA (2020a, 2016)
Processing	Processing as a reactant	Intermediate in: adhesive manufacturing; industrial gas manufacturing; plastic material and resin manufacturing	U.S. EPA (2020a, 2016); EPA-HQ-OPPT-2018-0448-0021
		Intermediate in petrochemical manufacturing	U.S. EPA (2020a)
		Other basic inorganic chemical manufacturing	U.S. EPA (2022b)
		Monomer in plastic material and resin manufacturing	U.S. EPA (2020a); U.S. EPA (2022b)
	Processing –incorporating into formulation, mixture, or reaction product	Intermediate in petrochemical manufacturing	U.S. EPA (2020a, 2016)
		Solvent	U.S. EPA (2020b)
		Cleaning agent	U.S. EPA (2020b)
		Binder in plastics material and resin manufacturing	U.S. EPA (2020a)
	Processing – incorporating into articles	Wire and cable in primary metal manufacturing	U.S. EPA (2020a, 2016)
	Repackaging	Intermediate in plastic material and resin manufacturing	U.S. EPA (2016)
	Other	Industrial process – pulp and paper	(U.S. EPA, 2020b)
		HFC production	EPA-HQ-OPPT-2018-0448-0025
		Industrial process – non-ferrous metals; industrial process – ferrous metals	(U.S. EPA, 2020b)
		Laboratory chemical	2016 CDR; EPA-HQ-OPPT-2018-0448-0025
	Recycling	Recycling	U.S. EPA (2020a, 2016)

Life Cycle Stage[a]	Category[b]	Subcategory[c]	Reference(s)
Distribution in Commerce	Distribution in commerce	Distribution in commerce	
Commercial Use	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Construction and building materials, including roof sheets, drinking water pipes, sewer pipes, cable and wire	U.S. EPA (2020a, 2016); EPA-HQ-OPPT-2018-0448-0018
	Petrochemical manufacturing	Intermediate	U.S. EPA (2020a, 2016); EPA-HQ-OPPT-2018-0448-0018
	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)	Binder	U.S. EPA (2020a, 2016); EPA-HQ-OPPT-2018-0448-0016
		Intermediate	U.S. EPA (2020a, 2016); EPA-HQ-OPPT-2018-0448-0016
	Other	Automotive components, including instrument and door panels, convertible tops, upholstery	EPA-HQ-OPPT-2018-0448-0018
Consumer Use	Furniture & furnishings including plastic articles (soft); leather articles	Furniture & furnishings including plastic articles (soft); leather articles	EPA-HQ-OPPT-2018-0448-0018
	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	Construction and building materials including roof sheets, drinking water pipes, sewer pipes, cable and wire, fabrics, textiles, and apparel	U.S. EPA (2024a); EPA-HQ-OPPT-2018-0448-0014; EPA-HQ-OPPT-2018-0448-0018
	Two-component caulks	Two-component caulks	IC2 (2024); U.S. EPA (2024a)
	Water-based paint	Water-based paint	IC2 (2024); U.S. EPA (2024a)
	Single-component glues and adhesives	Single-component glues and adhesives	https://www.homedepot.com/p/Super-Glue-1-fl-oz-Vinyl-Leather-Mender-12-Pack-T-VL/202806522
	Solvent-based paint	Solvent-based paint	IC2 (2024); U.S. EPA (2024a)
	Other	Textiles, synthetic fibers and blends	IC2 (2024)

Life Cycle Stage[a]	Category[b]	Subcategory[c]	Reference(s)
Consumer Use	Packaging (Excluding rubber articles; plastic articles (hard); plastic articles (soft)	Packaging (Excluding rubber articles; plastic articles (hard); plastic articles (soft)	EPA-HQ-OPPT-2018-0448-0016
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	U.S. EPA (2016)
	Toys intended for children's use (and child dedicated articles), including fabrics, textiles, and apparel; or plastic articles (hard)	Toys intended for children's use (and child dedicated articles), including fabrics, textiles, and apparel; or plastic articles (hard)	EPA-HQ-OPPT-2018-0448-0018; EPA-HQ-OPPT-2018-0448-0021; https://hpcds.theic2.org/Search;
Disposal	Disposal	Disposal	

[a] Life cycle stage use definitions (40 CFR 711.3)
"Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
"Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
"Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.
[b] These categories of COUs 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. For categories of conditions of use reported in CDR where there might be overlaps or misidentification of conditions of use. If those issues arise, EPA plans to address them in the preparation of the draft risk evaluation.
[c] These subcategories reflect CDR codes and represent more specific conditions of use of vinyl chloride. For subcategories of conditions of use reported in the CDR there might be overlaps or misidentification of conditions of use. If those issue arise, EPA plans to address them in the preparation of the draft risk evaluation.
Note: Byproducts can be formed during the manufacture of vinyl chloride, including 1,1-dichloroethane (CASRN 75-34-3); 1,1,2-trichloroethane (79-00-5); *trans*-1,2-dichloroethylene (156-60-5); trichloroethylene (79-01-6); perchloroethylene (127-18-4); methylene chloride (75-09-2); and carbon tetrachloride (56-23-5). Additionally, vinyl chloride may contain residual feedstocks including hydrochloric acid (7647-01-0) and 1,2-dichloroethane (107-06-2). EPA plans to assess byproducts and residual feedstocks of vinyl chloride manufacture during the risk evaluation phase.

2.2.3 Activities Excluded from the Scope of the Risk Evaluation

TSCA section 6(b)(4)(D) requires EPA, during scoping, to identify COUs of a chemical substance the Administrator expects to consider in a risk evaluation.

In accordance with TSCA section 3(4)'s definition of COUs, EPA determines the circumstances appropriately considered to be COUs for a particular chemical substance.[1] TSCA section 3(2) excludes

[1] *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

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 the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide."

Cosmetics

EPA determined that vinyl chloride was historically used in cosmetics, including hair sprays that meet the definition of cosmetics under Section 201 of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. 321. Therefore, these uses are excluded from the definition of "chemical substance" in TSCA section 3(2)(B)(vi) and are not included in Table 2-2. Activities and releases associated with the use of such cosmetics are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA section 3(4)) and will not be evaluated during the risk evaluation of vinyl chloride.

Food Additives

The U.S. Food and Drug Administration lists vinyl chloride as an optional substance to be used in food packaging materials. Food packaging materials meet the definition for a "food additive" described in section 201 of FFDCA, 21 U.S.C. 321. Therefore, use of vinyl chloride in food packaging is excluded from the definition of "chemical substance" in TSCA section 3(2)(B)(vi) and is not included in Table 2-2. Activities and releases associated with the use of such food packaging materials are therefore not "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA section 3(4)) and will not be evaluated during risk evaluation.

Intentional Misuse

EPA will not include within the scope of a risk evaluation any exposures associated with intentional misuse or acts of terror (82 FR 33729-1; 89 FR 37028; S.Rept.114-67, 2015). As expressed by the U.S. Senate, the term "conditions of use" is intended to describe the context in which EPA will assess a chemical substance and apply the TSCA standard in making risk determinations and taking risk management action. Intentional misuse of a chemical substance was one example identified by the Senate as not a condition of use (82 FR 33729-1; 89 FR 37028; S.Rept.114-67, 2015). EPA believes acts of terror are comparable to intentional misuse and thus generally not a condition of use.

Catastrophic Accidents, Extreme Weather Events, and Other Natural Disasters

EPA generally does not include in the scope of the risk evaluation catastrophic accidents, extreme weather events, and other natural disasters if such events do not lead to regular and predictable exposures associated with a given condition of use. However, such a determination requires a fact-specific, chemical-by-chemical analysis (EPA-HQ-OPPT-2023-0496-0431). Thus, EPA would consider including such events (*e.g.,* catastrophic accidents, extreme weather events, and other natural disasters) in the scope of the risk evaluation if the Agency receives information indicating regular and predictable changes in exposures associated with these events (88 FR 74292).

2.2.4 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 CDR rule, formerly known as the Inventory

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)).

Update Rule (IUR) (40 CFR Part 711).

The national aggregate production volume, which is presented as a range to protect individual site production volumes that are confidential business information, is presented in Table 2-3. Since 1986, the national aggregate production volume of vinyl chloride has been consistently over 1 billion lb. In 2011, over 16 billion lb were reported and since 2012 production volume has been reported between 10 and 20 billion lb.

Table 2-3. 1986 to 2019 National Aggregate Production Volume Data for Vinyl Chloride

Year	Production Volume (Billions of lb)
1986	>1
1990	>1
1994	>1
1998	>1
2002	>1
2006	>1
2011	16,713,648,476
2012	10 to <20
2013	10 to <20
2014	10 to <20
2015	10 to <20
2016	10 to <20
2017	10 to <20
2018	10 to <20
2019	10 to <20

2.2.5 Overview of Conditions of Use and Lifecycle Diagram

Figure 2-1 provides the preliminary life cycle diagram for vinyl chloride, which 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. There might be overlaps or misidentification of COUs for categories and subcategories of uses reported in CDR. If those issues arise, EPA plans to address them in the preparation of the draft risk evaluation. Figure 2-1 duplicates and is identical to the preliminary life cycle diagram presented in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c).

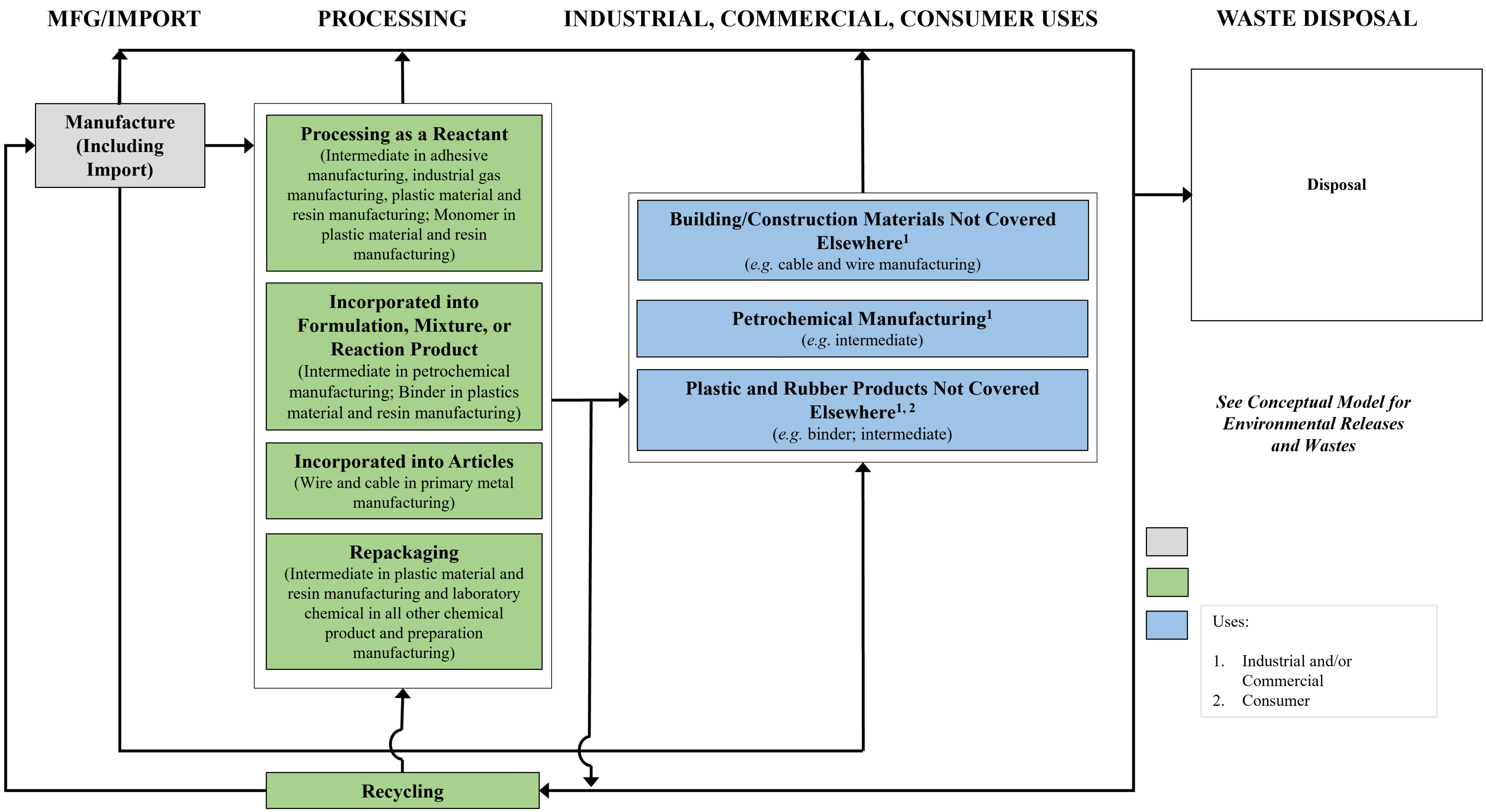


Figure 2-1. Preliminary Life Cycle Diagram for Vinyl Chloride

Distribution in commerce is not explicitly included in the life cycle diagram because its activities are associated with other COUs. Unloading and loading activities are associated with other COUs. 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.

2.3 Exposures

EPA expects to assess human and environmental exposures and releases to the environment resulting from COUs within the scope of the risk evaluation of vinyl chloride. This section describes the physical and chemical properties, environmental fate and transport properties, releases to the environment, and potential human and environmental exposures from COUs and from other possible or known sources. EPA plans to consider, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to vinyl chloride.

2.3.1 Releases to the Environment

Chemical releases to the environment from COUs 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. Preliminary information on releases to the environment, as reported in TRI, NEI, and DMR are presented in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c). In summary, of the more than 5 million lb of vinyl chloride disposed of or otherwise released to the environment during the TRI reporting years 2013 to 2022, more than 98 percent was released onsite to air. Eighty-four percent of NEI-reported air emissions are from industrial processes for chemical manufacturing or waste disposal. The majority of offsite releases reported to TRI were to wastewater treatment facilities other than publicly-owned treatment works (*e.g.,* industrial wastewater treatment). In DMR, less than 20 percent of the facilities with water discharge monitoring requirements reported a vinyl chloride discharge in 2023. Of those discharges, nearly 90 percent were from two industry sectors (516 kg from 5 facilities in total), miscellaneous plastics products and rolling, drawing, and extruding of nonferrous metals.

Appendix B.2 summarizes the types of information used to inform environmental releases of vinyl chloride.

2.3.2 Fate and Transport

EPA reviewed databases and previously conducted assessments (see Section 3.2 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024d)) to identify information on fate endpoints for vinyl chloride that inform the fit-for-purpose analysis plan. Specifically, this information was analyzed to characterize transport and partitioning pathways, identify environmental persistence potential, and assess bioaccumulation potential of vinyl chloride. Appendix B.1 summarizes the types of information identified for environmental fate and transport properties of vinyl chloride. Table_Apx C-1 provides the identified and selected environmental fate properties for vinyl chloride considered in this draft scope. Detailed information on the draft fate and transport assessment of vinyl chloride is available in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a).

2.3.2.1 Intermedia Transport and Partitioning Behavior of Vinyl Chloride

The magnitude of the partitioning coefficients identified for vinyl chloride suggest that vinyl chloride will exist primarily in air and water in the environment. Vinyl chloride has a vapor pressure of 2,550 mmHg at 20 °C (ECHA, 2023a), indicating that vinyl chloride will exist predominantly as a free gas in the atmosphere. Therefore, dry deposition is unlikely to be a common process. This is consistent with the estimated octanol:air partition coefficient of 25.4 (U.S. EPA, 2012c).

Vinyl chloride has a considerable water solubility (9,150 mg/L at 20.5 °C (ECHA, 2023a; Reaxys, 2023)), consistent with its polarity and small molecular size. However, with a Henry's Law constant of 0.0278 atm·m^3/mol at 24.8 °C (PhysProp, 2023), volatilization from surface waters is expected to be rapid and a dominant process for vinyl chloride. (ECHA, 2023a; Reaxys, 2023)Sorption to organics present in sediment and suspended and dissolved solids present in water is unlikely to be a dominant pathway given the range of log K_{OC} values identified to date (Table_Apx C-1). Vinyl chloride's solubility along with its low tendency to sorb to organics present in solids suggest that in soil it will exhibit mobility and might be transported through the vadose zone to groundwater.

2.3.2.2 Preliminary Media Assessments to Inform Fit-for-Purpose Analysis Plan

Preliminary media assessments were conducted to (1) inform the fit-for-purpose analysis plan for the risk evaluation of vinyl chloride, and (2) to identify major and minor media in which vinyl chloride is expected to occur given that its physical and chemical properties drive its ready partitioning to air. Furthermore, because the vast majority (see more below) of vinyl chloride TRI releases are reported to air (Section 2.3.1), the air compartment is expected to be a major compartment of interest. Surface water and soil media are expected to hold minor importance; that is, vinyl chloride that remains in each of these media is expected to show moderate to high persistence moderated by biodegradation that is highly variable and dependent on environmental conditions (*e.g.,* electron donors, oxygen levels, minerality). However, occurrences of vinyl chloride in surface water and soil are expected to be minimal as supported by monitoring and TRI release data, as well as the expected rapid volatilization of vinyl chloride from both wet and dry surfaces. Biosolids, sediments, groundwater, and biota are expected to be minor compartments in the evaluation of vinyl chloride due to negligible releases and/or negligible partitioning to these media. The following subsections summarize the preliminary media assessments for this draft scope.

2.3.2.3 Air and Atmosphere

Based on its release information, physical and chemical properties, as well as fate properties, vinyl chloride in the environment is expected to primarily be present in air. Vinyl chloride is a gas at room temperature and most environmentally relevant temperatures (boiling point −13.9 °C or 7 °F). According to the reporting to TRI, greater than 98 percent of reported vinyl chloride releases are to air. Additionally, it is expected that vinyl chloride released to surface water and wastewater treatment plants will rapidly volatilize to the air compartment. Vinyl chloride reacts with hydroxyl radicals (•OH) with transformation rates reported between 3.95×10^{-12} and 8.40×10^{-12} cm^3/mole-sec (ATSDR, 2024; ECHA, 2023a; NIST, 2023; NLM, 2023a; OECD, 2001). Assuming a •OH concentration of 1.5×10^6 •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 (Sections 3.3.2.1 and 3.4.1.1 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)). Thus, in the atmosphere, vinyl chloride is expected to have low to high persistence (*i.e.,* half-life [$t_{1/2}$] > 2 days; 64 FR 692; January 5, 1999).

In indoor air, vinyl chloride in gas phase is expected to be more persistent as compared to in outdoor environments. Indoor environments have fewer physical transport drivers (*e.g.,* advection by wind and atmospheric flows) as well as less sunlight and subsequently lower concentrations of hydroxyl radicals. Therefore, vinyl chloride transformation rates are expected to be slower in indoor air than in the atmosphere. However, vapor intrusion is not expected to be a dominant pathway introducing vinyl chloride to indoor environments (Section 3.4.1.2 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)).

2.3.2.4 Aquatic Environments

Monitoring data from the Water Quality Portal indicate minimal occurrence of vinyl chloride in surface waters (Section 3.4.2 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* U.S. EPA, 2025a)). Vinyl chloride may enter surface waters through direct release (approximately 0.01% of releases reported to TRI in the period 2013–2022), migration of landfill leachate, and releases from spills and leaks. Vinyl chloride is not expected to undergo wet or dry deposition (Section 3.4.1.1 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)). Vinyl chloride may also form in anaerobic media from the reductive dehalogenation of more highly chlorinated ethylenes such as perchloroethylene (PCE) and trichloroethylene (TCE); Section 3.3.4.5 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)).

Although vinyl chloride present in 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 log K_{OC} values presented in Table_Apx C-1. Of the small amount of vinyl chloride that may remain in surface water, dissolved and sorbed fractions are expected to have moderate to high persistence (characterized by $t_{1/2}$ of 60–179 days, and ≥180 days, respectively). Because hydrolysis of vinyl chloride is unlikely, transformation of vinyl chloride in water is expected to be primarily mediated by biodegradation processes, as discussed below.

One ready biodegradability test (Organization for Economic Cooperation and Development [OECD] test protocol 301D) indicates vinyl chloride is not readily biodegradable, reporting a degradation rate of 16 percent over 28 days (ECHA, 2023a; NITE, 2023; NLM, 2023a). One additional CO_2 evolution study employing a municipal activated sludge inoculum, reported a mineralization rate of 21.5 percent over 5 days (ECHA, 2023a; OECD, 2001). Anaerobic biodegradation rates range from a half-life of 70 days with groundwater inoculum to 10 percent over 106 days in water under methanogenic conditions following a 50-day lag period (ECHA, 2023a; NLM, 2023a; Reaxys, 2023). The degree of vinyl chloride biodegradation in aqueous systems is therefore expected to vary with microbial community and environmental conditions. Despite not being readily biodegradable, vinyl chloride is not widely or frequently detected in aquatic environments, likely due to minimal releases to water and its tendency to volatilize rapidly.

No empirical data on vinyl chloride adsorption to sediment were identified. Based on empirical soil log K_{OC} values, vinyl chloride sorption to organics in particulate matter and sediments might occur. Although is not expected to be a dominant process, vinyl chloride can also 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 natural, non-adapted sediments (Section 3.4.2.2 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)). However, aqueous vinyl chloride concentrations resulting from COUs are expected to be negligible based on water release and discharge information identified to date (see Section 2.3.1 and Section 3.2.2 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)).

2.3.2.5 Terrestrial Environments

Vinyl chloride can enter terrestrial environments via the disposal of industrial processing wastes, the degradation of more highly-chlorinated ethylenes (Section 3.3.4.5 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)), and incidental spills and leaks. Because the majority of reported releases are to air (Section 3.2.2 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a) and releases to soil media are expected to volatilize rapidly, terrestrial environments and processes are not expected to be significant to the evaluation of vinyl chloride. However, understanding the terrestrial fate of vinyl chloride is important to inform exposure potential from incidental releases; for example, by spills and leaks during regular manufacturing, processing, and handling activities.

Vinyl chloride may be subject to several competing processes dictating its fate in soil, including (1) volatilization from both wet and dry soil, (2) migration to groundwater, (3) limited sorption to organic solid fractions, and (4) aerobic and anaerobic biodegradation. Two sources were identified reporting measured 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-organic content, natural clayey till soils from Denmark, reporting log K_{OC} values ranging from 2.38 to 2.95 (mean 2.70) (ATSDR, 2024). 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 alongside low historical releases to land, vinyl chloride is not expected to persist in soil environments.

Vinyl chloride present in groundwater systems is likely to be primarily due to the reductive dehalogenation of chlorinated ethylenes. Vinyl chloride in groundwater may be subject to both anaerobic biodegradation and abiotic reductive dehalogenation. The degree of susceptibility of vinyl chloride to abiotic dehalogenation relies on the minerality of the anaerobic system, with estimated half-lives ranging from 1.25 to 12.6 days (Reaxys, 2023). Despite the short half-lives achieved in laboratory reductive dehalogenation studies, vinyl chloride has been detected in groundwater in several U.S. locations (ATSDR, 2024) and might be fed by the degradation of chloroethylene (CE) plumes.[2]

Volatility of vinyl chloride is expected to drive its removal in wastewater treatment plants (WWTPs). Results from the STPWIN Model of EPI Suite™ v4.11 predict that approximately 89 percent of vinyl chloride will be removed via losses to air stripping assuming negligible removal due to biodegradation (U.S. EPA, 2012c). Negligible amounts of vinyl chloride are expected to partition to sludge during wastewater treatment; therefore, vinyl chloride transport to terrestrial environments from the application of municipal biosolids is not expected to be a significant pathway (Section 3.4.3.1 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)).

Articles containing vinyl chloride-based polymers (namely polyvinyl chloride [PVC]) may be disposed of in municipal landfills. However, information gathered to-date suggests that typical conditions in landfill environments will tend not to drive vinyl chloride monomer release from PVC products. For example, Mersiowsky et al. (2001) performed lysimeter experiments over 4 years to track the release of organics from PVC wiring and flooring under simulated landfill conditions and found no detectable degradation of the PVC polymer (based on molecular weight distribution) and no vinyl chloride monomer in lysimeter biogas. These results are consistent with the low expected concentration of residual vinyl chloride monomer in PVC (Section 2.3.4).

Vinyl chloride may also occur in landfills from the biological reductive dehalogenation of more highly-chlorinated ethylenes (*e.g.,* PCE, TCE), especially in deep anaerobic landfill layers. Kromann et al. (1998) demonstrated that vinyl chloride formed from chlorinated ethylenes can be degraded within the time frame of weeks-to-months in landfill leachate, although is highly dependent on landfill characteristics (*e.g.,* organic content). Vinyl chloride in gas form can also diffuse upwards in landfill soils and might degrade in the presence of methane and oxygen—conditions characteristic of topsoil layers in landfills with methanogenic activity (Scheutz and Kjeldsen, 2005). The fate of vinyl chloride in a landfill was modeled and its removal was found to occur primarily through volatilization/gas flow and biodegradation (contingent upon the presence of appropriate microbial consortia and conditions), with minimal (<1%) remaining in the landfill after 5 years (Kjeldsen and Christensen, 2001). Fractions of

[2] Note that vinyl chloride as a transformation product was addressed by the recently finalized risk management actions for PCE or TCE, or will be addressed in future risk evaluations for other chlorinated ethylenes; see also Section 2.3.2.7).

vinyl chloride that are not degraded in the landfill will likely volatilize and may cause areas of elevated atmospheric concentrations above landfill surfaces (ATSDR, 2024; Molton et al., 1987). Because the majority of the vinyl chloride in landfills is expected to originate from sources outside of scope, and leaching of vinyl chloride from polymers is likely to be minimal, the Agency expects to assess landfill pathways qualitatively in subsequent risk analyses. Section 3.4.3.3 in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a) provides additional detail on the behavior of vinyl chloride in landfills.

2.3.2.6 Bioaccumulation Potential

Vinyl chloride is not expected to significantly bioconcentrate, bioaccumulate, or undergo trophic transfer. Two empirical bioconcentration factors (BCFs) were identified: a BCF of 40 was found in green algae (*Chlorella fusca*) (ATSDR, 2024; ECHA, 2023a; NLM, 2023a; OECD, 2001) and a BCF of less than 10 in golden ide (*Leuciscus idus melanotus*) (ATSDR, 2024; ECHA, 2023a; NLM, 2023a; OECD, 2001). Supporting evidence from empirical BCFs, bioaccumulation factors (BAFs) of 2.59, 2.80, 3.63 L/kg were obtained for lower, middle, and upper trophic levels, respectively, using the Arnot-Gobas method of the BCFBAF model (U.S. EPA, 2012c). EPA identified no bioaccumulation or bioconcentration data for terrestrial organisms from databases or previously conducted assessments.

2.3.2.7 Vinyl Chloride as a Transformation Product

Vinyl chloride has been reported as a transformation product (*i.e.,* resulting from biotic or abiotic degradation of other substances) of other chlorinated organic compounds; therefore, some instances of vinyl chloride in the environment may be due to the uses of those parent chemicals rather than direct uses of vinyl chloride. PCE and TCE are two of the most commonly reported precursors of vinyl chloride; in anaerobic environments, more highly-chlorinated ethylenes can undergo sequential reductive dehalogenation following the pathway:

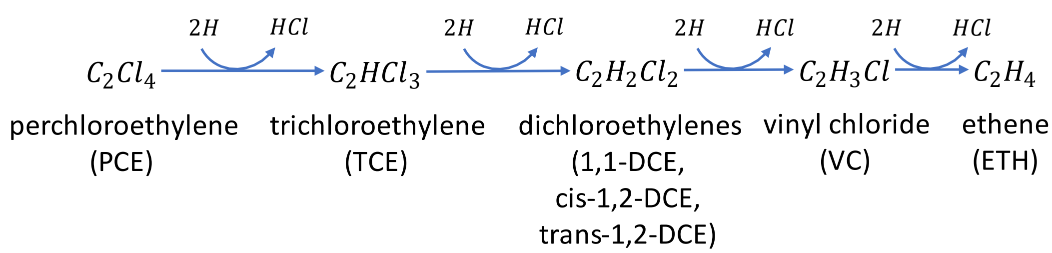


Figure 2-2. Reductive Dechlorination Pathway via Biodegradation in Anaerobic Environments
Adapted from (Eklund et al., 2022; Freedman and Gossett, 1989; Molton et al., 1987).

The relative rates of dechlorination proceed such that the half-lives of PCE and TCE are much shorter than those of 1,1- and 1,2-dichloroethylenes (DCEs) and vinyl chloride. Wood et al. (1985) reported half-lives of 34, 43, and 53 days for PCE, TCE, and 1,1-DCE, respectively, while there was no detectable reduction of 1,2-DCEs and vinyl chloride. Historically, this has led to accumulation and presence of DCEs and vinyl chloride in groundwater where only PCE and/or TCE were known to have been released (Lee et al., 2015; Hunkeler et al., 2011; Milde et al., 1988). This is consistent with observations that the vinyl chloride-to-ethene reduction is the rate-limiting step during complete dechlorination in controlled systems (Freedman and Gossett, 1989).(Freedman and Gossett, 1989). The composition of microbial communities and redox conditions also dictate the kinetics and extent to which the degradation pathway illustrated in Figure 2-2 might proceed (Lee et al., 2015; Hunkeler et al., 2011). Dechlorination of more highly-chlorinated ethylenes yielding vinyl chloride has also been reported as an important source of vinyl chloride in landfills (Molton et al., 1987). While vinyl chloride can accumulate in anaerobic environments (*e.g.,* groundwater or landfills) as a result of anaerobic biodegradation of parent substances, the concentration of vinyl chloride appears generally to be orders of magnitude lower than that of the parent chemical and the relative concentration of vinyl chloride to the parent chemical varies depending on factors such as the age of the plume and local conditions (*e.g.,* Hunkeler et al. (2011), Lee et al. (2015)).

Because of this formation route, environmental concentrations of vinyl chloride from monitoring data—especially in areas of known chloroethylene contamination—may not be reliably attributable to direct sources or uses of vinyl chloride. Related uncertainties will be accounted for when considering the use of monitoring data during the evaluation of environmental concentrations and exposures. Exposures and risks related to vinyl chloride as a transformation product will be assessed in future risk evaluations of parent substances or will be addressed by the recently finalized risk management actions for PCE (Docket ID: EPA-HQ-OPPT-2019-0502) or TCE (Docket ID: EPA-HQ-OPPT-2019-0500). Given these regulations for PCE and TCE have been finalized, EPA will not be re-evaluating these chemicals.

2.3.3 Environmental Exposures

The manufacturing, processing, distribution, use, and disposal of vinyl chloride can result in releases to the environment and exposure to aquatic and terrestrial organisms (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment, as well as partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA expects to consider reasonably available fate information (Section 2.3.1.1; Appendix B.1) and environmental monitoring data for vinyl chloride—including the identified studies monitoring for vinyl chloride in groundwater (68 studies), ambient air (26 studies), soil (13 studies), sediment (5 studies), and other media, and in biota (aquatic species, 1 study; and terrestrial species, 3 studies). These are summarized in Appendix B.3.

2.3.4 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures, and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

All human populations that EPA expects to be assessed in the vinyl chloride risk evaluation may be exposed to vinyl chloride as a residual monomer in plastics made from PVC and related polymers. However, due to regulatory and industry standards, the concentration of residual vinyl chloride monomer in plastic products is expected to be low. In the most common PVC production process, 90 percent of the vinyl chloride monomer is consumed to make PVC resin (small particles that are later melted and mixed with additives to make PVC products), while excess monomer is removed and retained for reuse. PVC resin is stripped of excess vinyl chloride monomer using pressure and steam and then may be dried, depending on the type of PVC resin. Final concentrations of residual vinyl chloride monomer in PVC resin are generally $\leq$ 3 ppm (Borrelli et al., 2005). Due to its boiling point (−13.9 °C), vapor pressure (2,550 mm Hg at 20 °C), and Henry's Law constant (0.0278 atm·m^3/mol at 24.8 °C), vinyl chloride will volatilize from wet or dry surfaces that are exposed to the atmosphere. Thus, the residual vinyl chloride in PVC resin and products is expected to be entrapped within the matrix of PVC polymer but, depending on factors such as the density and porosity of the PVC, might leach out of the material by diffusion over time (*e.g.,* Walter et al. (2011)).

2.3.4.1 Occupational Exposures

EPA plans to evaluate worker activities where there is a potential for exposure under the various COUs (manufacturing, processing, industrial/commercial uses and disposal) described in Section 2.2. The Agency plans to evaluate exposure to both workers (*i.e.,* employees who handle the chemical substance) and occupational non-users (ONUs; *i.e.,* employees who do not directly handle the chemical but perform work in an area where the chemical is present). Although EPA generally does not assume the use of personal protective equipment (PPE), where information is reasonably available, EPA expects to consider the availability of engineering controls and/or PPE as part of the risk evaluation.

Examples of worker activities associated with COUs within the scope of the risk evaluation for vinyl chloride that EPA may analyze include, but are not limited to the following:

- unloading and transferring vinyl chloride to and from storage containers to process vessels;
- handling and disposing of waste containing vinyl chloride;
- cleaning and maintaining equipment;
- sampling chemicals, formulations, or products containing vinyl chloride for quality control;
- repackaging chemicals, formulations, or products containing vinyl chloride; and
- performing other work activities in or near areas where vinyl chloride is used.

Several commercial uses in Section 2.2 are reported to be downstream uses of PVC and other polymers produced using vinyl chloride monomer. According to regulatory and industry standards currently in place (Section 2.3.4), residual vinyl chloride monomer in plastic products is required to be abated through process operations. Subsequently, occupational exposures for the commercial use of these products may be low. Additional key data that EPA expects will inform occupational exposure assessment include Occupational Safety and Health Administration (OSHA), Chemical Exposure Health Data (CEHD), and National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluation (HHE) program data.

Vinyl chloride is a gas with a vapor pressure of 2,550 mmHg at 20 °C (ECHA, 2023a); hence, inhalation exposure is expected to be a significant route of exposure for workers and ONUs. Vinyl chloride has an OSHA standard (29 CFR 1910.1017; established in 1974) Permissible Exposure Limit (PEL) of 1 part per million (ppm) over an 8-hour work day by time-weighted average (TWA), and a Short-Term Exposure Limit (STEL) of 5 ppm over 15 minutes (OSHA, 2019). NIOSH labels vinyl chloride a potential carcinogen and recommends that both exposure to carcinogens be limited to the lowest feasible concentration, and that workers exposed to measurable concentrations of vinyl chloride should wear respirators (assigned protection factor [APF] = 10,000) (NIOSH, 2020; Whittaker, 2017).

EPA generally does not evaluate occupational exposures through the oral route. In some cases, workers and ONUs may inadvertently ingest inhaled particles that deposit in the upper respiratory tract. Additionally, workers may transfer chemicals from their hands to their mouths. However, because vinyl chloride is a gas at room temperature and highly volatile (Section 2.1), these exposures are not expected to be significant for vinyl chloride.

EPA plans to evaluate dermal exposure to workers for particular COUs based on expected handling practices as identified through the Agency's systematic review process. ONUs do not directly handle vinyl chloride; therefore, direct liquid contact with vinyl chloride is not expected.

Appendix B.2 summarizes the types of information identified for occupational exposures to vinyl chloride.

2.3.4.2 Consumer Exposures

Information presented in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation CASRN 75-01-4* (U.S. EPA, 2024c) indicates the potential presence of vinyl chloride in consumer products and articles: plastic and rubber products, adhesives and sealants, paints and coatings, furniture and furnishings, floor coverings, apparel, toys, and fabrics. These products and articles often contain PVC, of which approximately 99 percent of global vinyl chloride is used to produce. Residual vinyl chloride monomer can leach from PVC-containing products, potentially resulting in exposures to consumers, but the concentration of residual vinyl chloride monomer in plastic products is expected to be low due to regulatory and industry standards (Section 2.3.4). EPA plans to review the reported concentrations of residual vinyl chloride monomer in and potential to leach from PVC products during the risk evaluation phase. Appendix B.3 summarizes the types of information identified for consumer exposures to vinyl chloride.

Based on reasonably available information on consumer COUs, inhalation of vinyl chloride may occur through inhalation of vapor during product use. During the risk evaluation phase EPA plans to investigate the plausibility of inhalation exposures to products containing vinyl chloride monomer. Dust- or mist-mediated pathways are not expected because vinyl chloride will predominantly exist as a gas at room temperature and not partition to particulates in air. Thus, exposure pathways that are not expected include inhalation of indoor dust or mist, incidental ingestion of dust or mist containing vinyl chloride, and dermal contact with dust or mist deposition onto the skin. Other potential oral exposure pathways for consumers are ingestion during product use via transfer from hand to mouth or mouthing of articles. Other possible dermal pathways are direct dermal contact with articles containing vinyl chloride.

2.3.4.3 General Population Exposures

Environmental releases of vinyl chloride from certain COUs such as but not limited to manufacturing, processing, distribution, use, and disposal may lead to general population exposure. General population may be exposed via oral, dermal, or inhalation routes. Appendix B.3 summarizes the types of information identified for general population exposures to vinyl chloride.

2.3.4.3.1 Inhalation

There is inhalation exposure potential to vinyl chloride by breathing indoor air and ambient air. Indoor air exposures can occur from infiltration from ambient air, where less sunlight and lower concentrations of hydroxyl radicals retard indirect photolysis (Section 2.3.2.2). Although vapor intrusion is another possible source of vinyl chloride in indoor air, it is not expected to be a significant one because (1) degradation of vinyl chloride in the vadose zone is expected to be faster than its upward diffusion into buildings, and (2) its occurrence in groundwater and soil from COUs is negligible (Sections 2.5.3.2.2 and 2.5.3.2.4).

Ambient air exposures may occur from releases from industrial or commercial sources. More than 98 percent of vinyl chloride disposed of or otherwise released to the environment is released onsite to air according to TRI data for 2013 through 2022 (Section 2.3.1 and (U.S. EPA, 2024c)). As a preliminary screening step, EPA used existing modeled data from the 2020 AirToxScreen Assessment to evaluate the range of vinyl chloride concentrations in ambient air from nonpoint sources, point sources, and all sources (Figure 2-3). The 2020 AirToxScreen uses the Community Multiscale Air Quality (CMAQ) chemical transport model and the AERMOD dispersion model to estimate annual average outdoor ambient air concentrations across the United States using release data from the 2020 NEI database. The maximum vinyl chloride concentration in the AirToxScreen modeling results is approximately 3.2 $\mu g/m^3$ (equivalent to ~0.0012 ppm), which falls below the acute (0.5 ppm) and intermediate Minimal Risk Levels (MRLs; 0.02 ppm) reported by the Agency for Toxic Substances and Disease Registry (ATSDR) (2024). The sources of vinyl chloride included in Figure 2-3 may include non-TSCA uses; during risk evaluation, EPA plans to assess general population inhalation exposures specific to COUs resulting in point and nonpoint sources of vinyl chloride in ambient air.

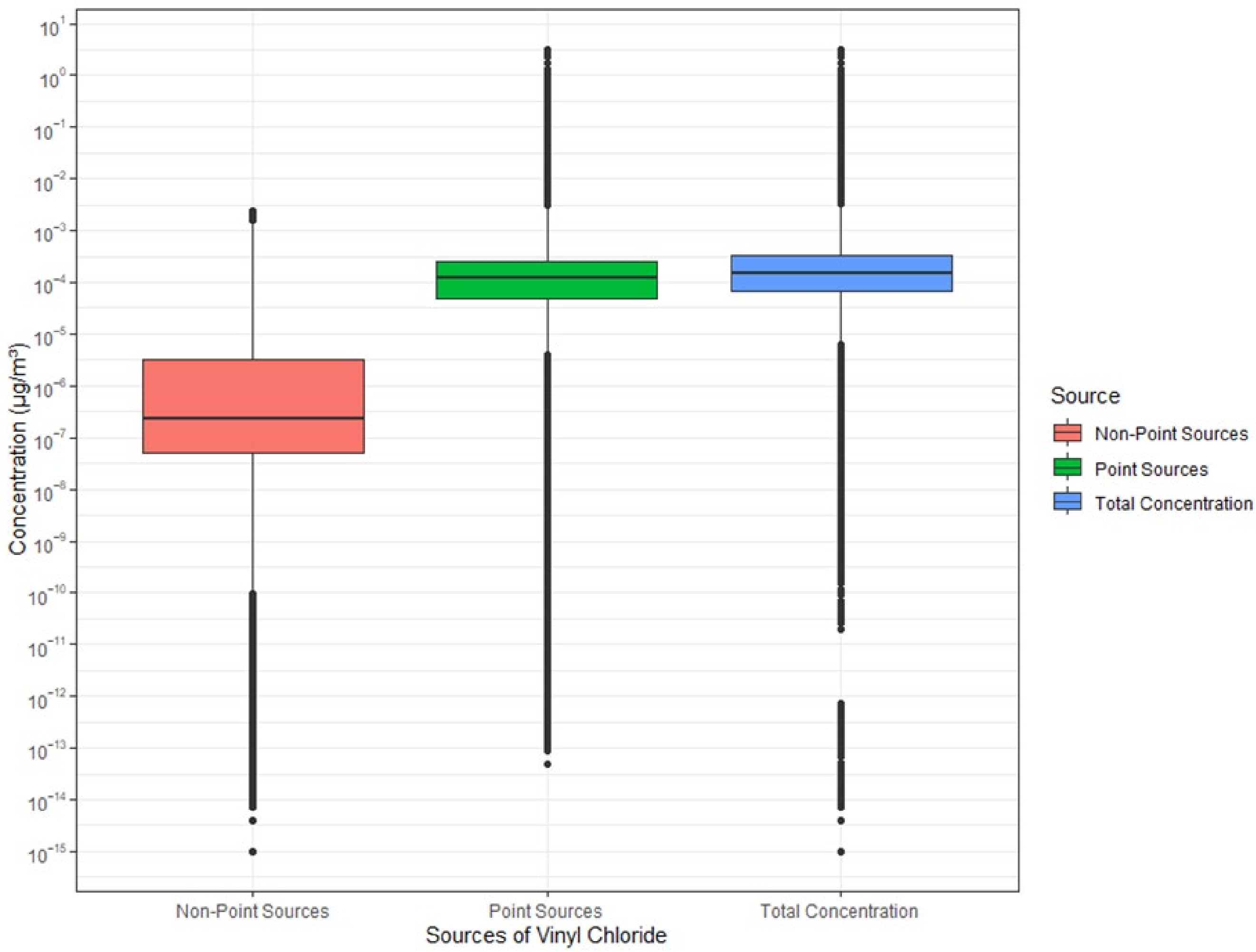


Figure 2-3. AirToxScreen Modeling Results for Vinyl Chloride, Based on 2020 NEI Data

2.3.4.3.2 Oral

The general population may be exposed to chemical substances via processes such as incidental ingestion of surface water during recreational activities like swimming; ingestion of contaminated drinking water, soil, or fish exposed to water or sediment containing the chemical; or incidental ingestion of consumer products containing the chemical. Based on its physical and chemical properties, fate properties, and release patterns, none of these exposure pathways are expected to be significant for vinyl chloride (Section 2.5.3.2).

The fourth cycle (2012–2019) of the Six-Year Review of National Primary Drinking Water Regulations under the Safe Drinking Water Act (SDWA) showed that less than 0.001 percent of drinking water systems (1 system serving 45 people out of 52,021 systems in the United States collectively serving 274.5 million people) exceeded the current maximum contaminant level (MCL) for average vinyl chloride concentrations in drinking water (U.S. EPA, 2024b). ATSDR (2024) also concluded that the majority of U.S. drinking water supplies do not contain detectable levels of vinyl chloride based on their review of existing monitoring data, which includes those collected under previous SDWA 6-Year Reviews.

The majority of PVC produced in the United States is used in the manufacture of pipes such as drinking water distribution pipes and sewer pipes, and there is evidence that residual vinyl chloride monomer can leach into water carried in PVC pipes (*e.g.,* Walter et al. (2011)). State and local authorities establish requirements for plumbing materials via building and plumbing codes. EPA has supported the development of independent, third-party testing standards for plumbing materials under NSF International and American National Standards Institute (ANSI) Standard 61, which has been incorporated into many state and local codes. NSF/ANSI requires analysis of chemicals that leach from a material into drinking water and a toxicological evaluation of leached concentrations to ensure that they are below levels that might cause potential adverse human health effects. The toxicological evaluation criteria are based on lifetime exposure to the concentration of contaminants in drinking water.

Compliance of drinking water system components with NSF/ANSI 61 is required in legislation, regulation, or policies in 49 U.S. states (National Sanitation Foundation, 2019). NSF/ANSI 61 requires that PVC and chlorinated PVC materials be tested for several analytes, including residual vinyl chloride monomer, and that materials meet the standard if residual vinyl chloride monomer concentrations are below 3.2 mg vinyl chloride monomer/kg PVC. NSF set the limit for water distribution pipes at 3.2 mg/kg using a diffusion model and maximum leached vinyl chloride content in water set to 10 percent of the drinking water MCL level of 2 ppb (Borrelli et al., 2005).

Most U.S. drinking water monitoring data are collected at the entry point into the distribution system, before the water may be exposed to PVC pipes. However, one study evaluated the concentration of vinyl chloride in tap water in homes with a variety of types of PVC pipes (Walter et al., 2011). In that study, vinyl chloride concentrations were less than or equal to 25 ng/L after 101 hours of exposure to new PVC and chlorinated PVC (CPVC) pipes, compared to the vinyl chloride drinking water MCL of 2,000 ng/L.

2.3.4.3.3 Dermal

Dermal exposure to a chemical substance can occur through incidental contact with contaminated water during recreation, use of contaminated drinking water for washing or bathing, contact with soil, or contact with products and materials containing the chemical. No measured information related to dermal exposures have yet been identified (Section B.3).

2.3.4.4 Potentially Exposed or Susceptible Subpopulations: Exposure Considerations

TSCA section 6(b)(4) requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." In 40 CFR 702.33 states that "potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA 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, the elderly, or overburdened communities." General population is "the total of individuals inhabiting an area or making up a whole group" and hereafter refers to the U.S. general population (U.S. EPA, 2011a).

EPA identified and plans to evaluate the relevancy of exposure pathways for the following PESS based on CDR information and previous assessments: children; pregnant women and people of reproductive age; workers; ONUs; communities living near industrial facilities where vinyl chloride is manufactured or used; and consumers, including users and bystanders. The Agency plans to review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further defined (*e.g.,* early life and/or puberty as a potential critical window of exposure).

2.4 Hazards

2.4.1 Environmental Hazards

EPA used the Agency's ECOTOXicology Knowledgebase (ECOTOX) and previous assessments to identify reasonably available information that may be relevant for characterizing potential environmental hazard resulting from exposure to vinyl chloride. For scoping purposes, the Agency consulted previous assessments of environmental hazard data for vinyl chloride (NICNAS, 2014a; OECD, 2001; IPCS, 1999). EPA also expects to consider publicly available peer-reviewed literature, gray literature, and other relevant information submitted to the Agency not covered by these assessments using the TSCA systematic review process as described in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation CASRN 75-01-4* (U.S. EPA, 2024c). Appendix B.4 summarizes the types of information identified for environmental hazards of vinyl chloride.

Based on data collected through ECOTOX and previous assessments, exposure to vinyl chloride might cause acute toxicity to aquatic vertebrates (mortality, growth, and behavior) and invertebrates (mortality, reproduction, behavior), chronic toxicity to aquatic vertebrates (mortality) and chronic toxicity to aquatic invertebrates (reproduction and growth/development), and toxicity to algae (growth inhibition). No environmental hazard information for terrestrial organisms were identified in previous assessments. Data gathered within the ECOTOX database identified environmental hazard information for terrestrial invertebrates (mortality, reproduction, and growth/development). As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, the Agency may update the list of potential hazard effects to be analyzed in the risk evaluation. In the case of inhalation, which is a potential exposure route for terrestrial wildlife, the relative contribution to total exposure risk is considered to be negligible in most situations. Inhalation exposure risk results both from inhalation of airborne particulates and from inhalation of volatile organic compounds (VOCs). The fraction of dust that cannot be inhaled is considered non-respirable and is accounted for in published soil ingestion rates. Data to quantify the dust fraction that is respirable to wildlife are species-specific and very limited (U.S. EPA, 1993).

2.4.2 Human Health Hazards

Vinyl chloride has been previously assessed by EPA and other authoritative bodies (ATSDR, 2024; CA DTSC, 2022; NTP, 2021; NICNAS, 2014a, b; Health Canada, 2013; IARC, 2012; NRC, 2012; OEHHA, 2011; OECD, 2001; IRIS, 2000; U.S. EPA, 2000b; IPCS, 1999; CARB, 1990a, b, c; ORD, 1975); thus, many of the hazards of vinyl chloride have been previously compiled and reviewed. EPA plans to use these previous assessments to identify reasonably available epidemiological, animal toxicity, and mechanistic information relevant for characterizing potential human health hazards resulting from exposure to vinyl chloride—with a particular focus on (ATSDR)'s *Toxicological Profile for Vinyl Chloride* (ATSDR, 2024) and EPA's Integrated Risk Information System (IRIS) assessment (IRIS, 2000). In addition to previous assessments, the Agency plans to evaluate publicly available, peer-reviewed literature, gray literature, and other relevant information submitted to EPA and not covered by these assessments using the TSCA systematic review process described in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation CASRN 75-01-4* (U.S. EPA, 2024c). Appendix B.5 shows the human health hazard literature, organized by hazard domain, which EPA identified through systematic review.

2.4.2.1 Non-cancer Hazards

EPA expects to consider all potential hazards associated with vinyl chloride. Based on reasonably available information from ATSDR (2024) and from the Agency's systematic review process, the Agency plans to focus its risk assessment on the non-cancer human health hazards detailed below. As

EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, the Agency may update the potential human health hazards considered in the risk evaluation.

2.4.2.1.1 Liver Toxicity

ATSDR (2024) concluded that hepatic effects are "a presumed health effect for humans" based on evidence of fibrosis, cirrhosis, and steatohepatitis in vinyl chloride workers following chronic-duration inhalation exposures. Evidence of hepatic effects in animals includes increased liver weight and histopathological liver lesions in rats and mice following intermediate- and chronic-duration inhalation and chronic-duration oral exposure. No studies on liver toxicity resulting from dermal exposure were identified, and EPA will determine whether this data gap can be supplemented through systematic review of the available literature.

Previous risk assessments derived quantitative endpoints based on liver effects in rodents. Specifically, ATSDR selected liver toxicity as the endpoint on which it based MRLs for intermediate inhalation and chronic oral exposures (ATSDR, 2024). Additionally, EPA also selected liver toxicity as the endpoint on which it based the Reference Concentration/Dose (RFC/RFD) in its IRIS assessment (IRIS, 2000).

2.4.2.1.2 Neurotoxicity

ATSDR (2024) concluded that neurological effects are "a presumed health effect for humans" based on limited epidemiological and animal evidence. This includes neurological symptom reporting (*e.g.,* dizziness, headache, nausea, ataxia, neurasthenia), peripheral neuropathy, and other peripheral nervous system symptoms in vinyl chloride workers following inhalation exposure and in volunteers after acute and intermediate inhalation exposure. There is a moderate level of evidence in animal studies based on clinical signs in multiple acute-duration inhalation studies in rats, mice, and guinea pigs as well as a chronic-duration oral study in rats. No studies on neurotoxicity resulting from dermal exposure were identified, and EPA will determine whether this data gap can be supplemented through systematic review of the available literature.

2.4.2.1.3 Immunotoxicity

ATSDR (2024) concluded that immunological effects are "a suspected health effect for humans" based on increased circulating immune complexes, immunoglobulins, complement factors, and levels of inflammatory cytokines in vinyl chloride workers. Limited evidence in animal studies includes increases in spleen weight in rats after chronic duration inhalation exposure, increased thymus weight in immunized rabbits, and spontaneous and mitogen-stimulated lymphocyte proliferation in mice and immunized rabbits after intermediate duration inhalation exposure. No studies on immunotoxicity resulting from oral or dermal exposure were identified, and EPA will determine whether this data gap can be supplemented through systematic review of the available literature.

2.4.2.1.4 Developmental Toxicity

ATSDR (2024) concluded that developmental effects are a "suspected health effect for humans" based on evidence from studies in mice and rabbits that were exposed via inhalation during gestation. Human data were limited to a small number of ecological and case-control studies that did not report developmental effects. No studies on developmental toxicity resulting from oral or dermal exposure were identified, and EPA will determine whether this data gap can be supplemented through systematic review of the available literature.

Previous risk assessments derived quantitative endpoints based on developmental toxicity in rodents. Specifically, ATSDR (2024) selected developmental toxicity as the endpoint on which they based an MRL for acute inhalation.

2.4.2.1.5 Other Hazards

EPA identified the following additional potential non-cancer human health hazards and related information that may be considered for the risk evaluation: cardiovascular, gastrointestinal, skin and eye irritation, respiratory, mortality, musculoskeletal, nutritional and metabolic, ocular and sensory, renal, reproductive, sensitization, skin/connective tissue, and thyroid. As EPA continues to evaluate reasonably available and relevant hazard information identified through systematic review, the Agency may update the potential human health hazards considered in the risk evaluation.

2.4.2.2 Genotoxicity and Cancer Hazards

2.4.2.2.1 Cancer

Carcinogenicity classifications for vinyl chloride in previous assessments range from "May Cause Cancer" (NICNAS, 2014b) to "Known Human Carcinogen" (ATSDR, 2024; IRIS, 2000) or "Carcinogenic to Humans" (NTP, 2021; NICNAS, 2014b; Health Canada, 2013; IARC, 2012; IRIS, 2000; CARB, 1990a). EPA previously evaluated the weight of evidence for cancer in humans and animals (IRIS, 2000) and concluded that vinyl chloride is "a known human carcinogen by the inhalation route of exposure, and by analogy, the oral route because of positive animal bioassay data and pharmacokinetic data allowing dose extrapolation across routes." The Agency further concluded that vinyl chloride is also considered "highly likely to be carcinogenic by the dermal route." These findings are based on a large body of epidemiological and animal evidence described below.

Occupational inhalation exposure to vinyl chloride was associated with liver cancer (including angiosarcoma, hepatocellular carcinoma, and cholangiocellular carcinoma) in male workers, and this provides the most compelling evidence of the carcinogenicity of vinyl chloride. Although other cancers were previously reported in vinyl chloride workers—including brain cancer, lung cancer, soft tissue cancers, lymphatic/hematopoietic cancers, and malignant melanoma—more recent follow-up studies and pooled and meta-analysis studies do not demonstrate a consistent association between vinyl chloride exposure and tumor formation in these organs (ATSDR, 2024). Studies in non-occupational settings and in women are limited, with one study associating occupational exposure with leukemia or lymphoma in women, and another associating increased breast cancer risk with exposure to vinyl chloride as a hazardous air pollutant in California (ATSDR, 2024).

Evidence of the carcinogenicity of vinyl chloride in animals is available from inhalation studies in rats, mice, and hamsters and from oral studies in rats. No studies are currently available for dermally exposed animals. Chronic inhalation studies report liver angiosarcomas, mammary gland carcinomas, Zymbal gland carcinomas, neuroblastomas, nephroblastomas, lung tumors, melanomas, acoustical duct epithelial tumors, and leukemias in rats, mice, and hamsters—with species-specific variation in the target organs that developed tumors. Notably, liver angiosarcomas were reported in all tested species. Studies in orally exposed rats found increased neoplastic nodules of the liver, hepatocellular carcinoma, hepatic angiosarcoma, and increased incidence of Zymbal gland tumors.

2.4.2.2.2 Genotoxicity/Mutagenicity and Other Mechanisms of Carcinogenicity

EPA (2000b) previously concluded that vinyl chloride carcinogenicity occurs via a well-understood genotoxic mode of action. Vinyl chloride is metabolized to a reactive metabolite, probably 2-chloroethylene oxide, which is believed to be the ultimate carcinogenic metabolite of vinyl chloride.

This metabolite binds to DNA, forming DNA adducts that, if not repaired, ultimately lead to mutations and tumor formation.

Several lines of evidence indicate that vinyl chloride metabolites are genotoxic; that is, interacting directly with DNA. Occupational exposure to vinyl chloride has resulted in chromosome aberrations, micronuclei, and sister chromatid exchanges (SCEs); response levels were correlated with exposure levels, and reversibility of chromosome damage has been reported following a cessation or reduction of exposure to vinyl chloride. DNA adducts were identified in rats following inhalation exposure to vinyl chloride and have been shown to generate mainly base pair substitution mutations (ATSDR, 2024).

Vinyl chloride is mutagenic in the *Salmonella typhimurium* reverse mutation assay, with the mutagenic activity decreased or eliminated in the absence of exogenous metabolic activation (Bartsch and Montesano, 1975; Rannug et al., 1974). The vinyl chloride metabolites 2-chloroethylene oxide and 2-chloroacetaldehyde are both mutagenic in the *Salmonella* assay; however, 2-chloroethylene oxide was shown to be the more potent mutagen and might be the ultimate carcinogenic metabolite. Mutations in specific genes (*i.e., ras* oncogenes and p53 tumor suppressor gene) have also been identified in vinyl chloride-induced liver tumors in rats and humans (ATSDR, 2024).

2.4.2.3 Potentially Exposed or Susceptible Subpopulations: Hazard Considerations

In developing the hazard assessments, EPA will evaluate available data to ascertain whether some human subpopulations may have greater susceptibility than the general population to the chemical's hazard(s). ATSDR (2024) identified the following factors that might increase susceptibility to adverse health effects from vinyl chloride exposure based on direct evidence in humans and/or animals: early-life and prenatal exposures; sex; comorbidities (obesity, liver disease, irregular heart rhythms, impaired peripheral circulation, and systemic sclerosis); genetic polymorphisms (HLA-DR5, HLA-DR3, and B8 alleles); and other lifestyle factors (exposure to organochlorine pesticides, consuming high-calorie diets, ethanol, Antabuse, and barbiturates).

2.5 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), populations, and hazards associated with COUs of vinyl chloride. Pathways and routes of exposure associated with workers and ONUs are described in Section 2.5.1 and consumers in Section 2.5.2. Pathways and routes of exposure associated with environmental releases and wastes are discussed and depicted in the conceptual model shown in Section 2.5.3.

Except where noted, the pathways, routes, and populations illustrated in these conceptual models are the same as those in the preliminary conceptual models presented in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c). The conceptual models presented in Sections 2.5.1, 2.5.2, and 2.5.3 have been modified to depict those pathways, routes, and populations for which EPA expects to conduct quantitative assessments (bold lines) and those for which EPA expects to conduct qualitative assessments (dashed lines). Pathways, routes, and populations labeled here as not receiving quantitative assessment will be reconsidered for quantitative assessment if additional reasonably available information is identified.

2.5.1 Conceptual Model for Industrial and Commercial Activities and Uses

The conceptual model in Figure 2-4 illustrates the pathways of exposure from industrial and commercial activities and uses of vinyl chloride that EPA expects to include in the draft risk evaluation. There is potential for exposures to workers and ONUs via inhalation routes and exposures to workers via dermal routes. Due to vinyl chloride's high vapor pressure, it is expected that inhalation exposure to vapor is the most likely exposure pathway. In addition, workers at waste management facilities might be exposed via inhalation and dermal routes during waste handling, treatment, and disposal. EPA expects to evaluate activities resulting in exposures associated with distribution in commerce (*e.g.,* loading, unloading) throughout the various lifecycle stages and COUs (*e.g.,* manufacturing, processing, industrial use, commercial use, disposal) rather than a single distribution scenario.

For each COU identified in Table 2-2, a determination was made as to whether EPA plans to evaluate each combination of exposure pathway, route, and populations in the risk evaluation.

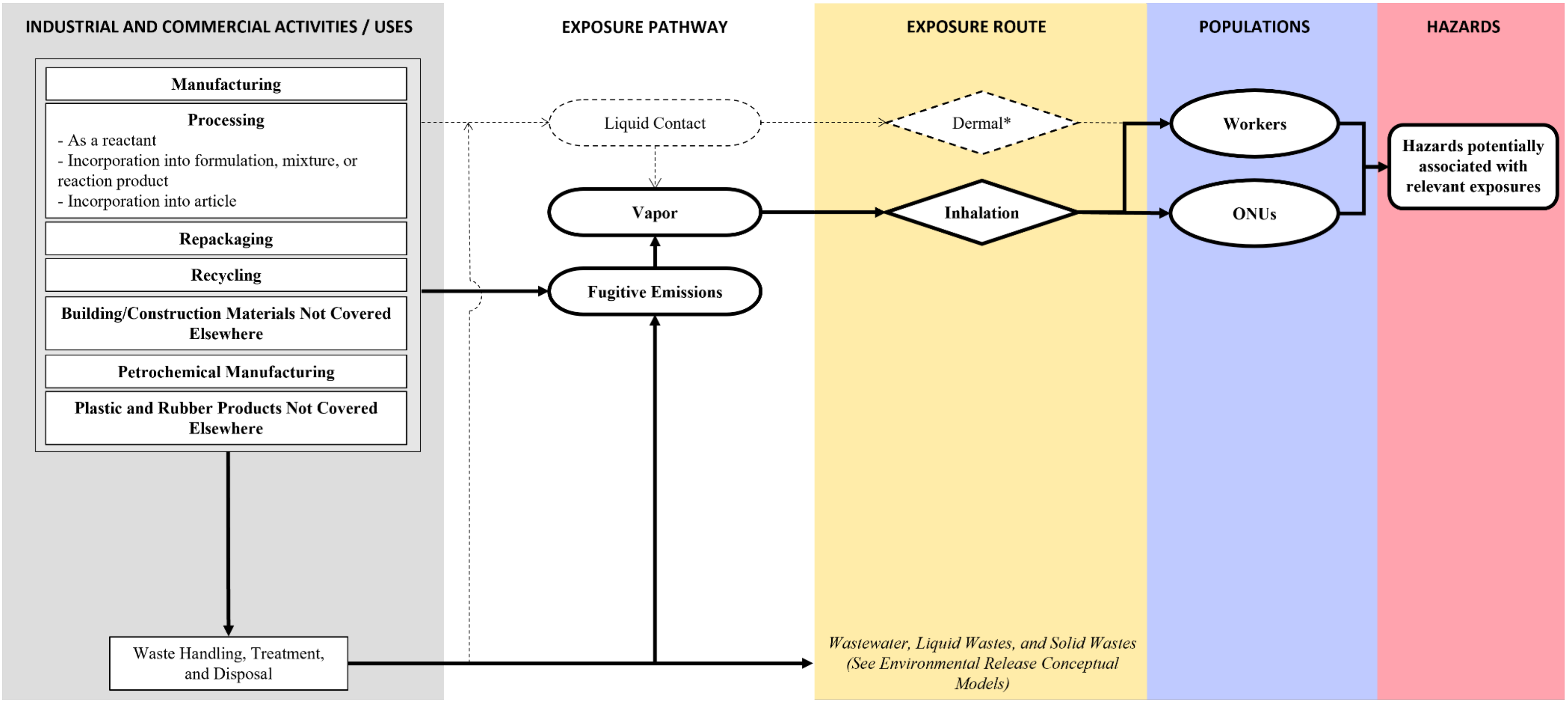


Figure 2-4. Vinyl Chloride Conceptual Model for Industrial and Commercial Activities and Uses: Worker and ONU Exposures and Hazards

This conceptual model presents the exposure pathways, exposure routes, and hazards to humans from industrial and commercial activities and uses of vinyl chloride. Bold lines indicate pathways, routes, populations, and hazards that EPA plans to quantitatively assess (Section 2.5.1.1) while dashed lines indicate those that the Agency plans to include but not quantitatively assess (Section 2.5.1.2).

2.5.1.1 Pathways EPA Plans to Quantitatively Analyze in the Risk Evaluation

As described in Section 2.3.2.2, air is the primary exposure pathway for vinyl chloride. In industrial settings, vinyl chloride is transported and stored as a liquefied compressed gas, but when released to ambient pressure it rapidly expands and converts to gaseous form. Thus, inhalation is expected to be a significant route of occupational exposure for workers and ONUs. EPA plans to quantitatively assess concentration of vinyl chloride vapors in industrial and commercial settings and inhalation exposures of workers and ONUs to those vapors.

2.5.1.2 Pathways EPA Plans to Qualitatively Analyze in the Risk Evaluation

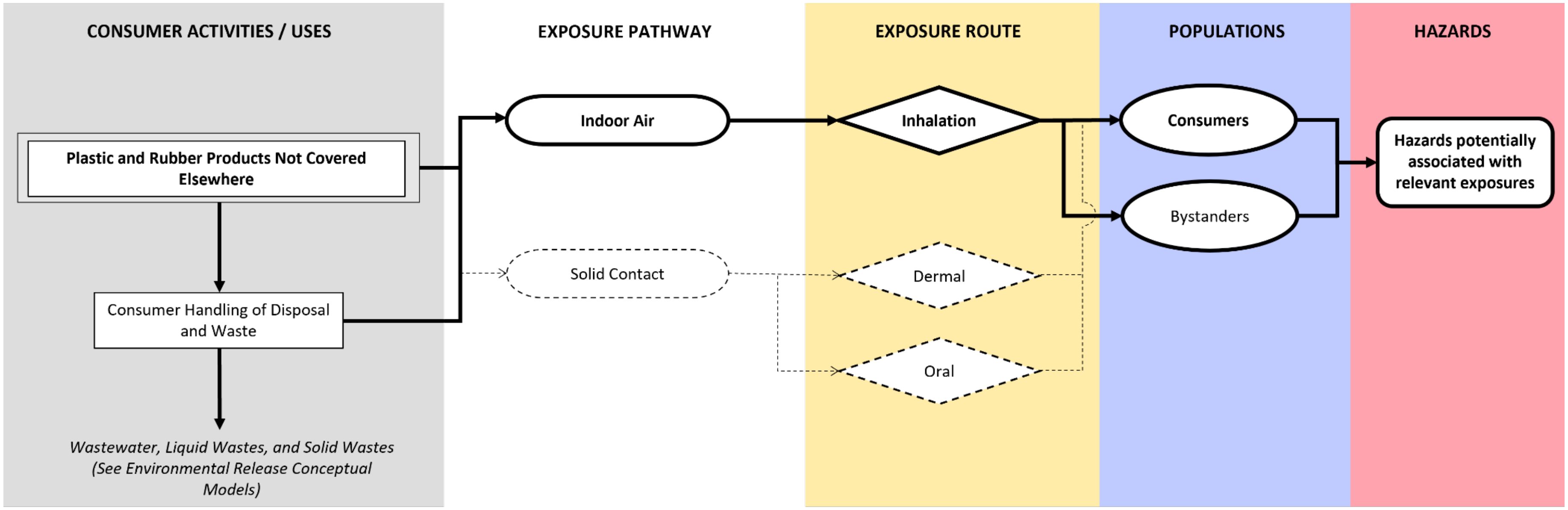
EPA plans to evaluate dermal exposure to workers for particular COUs based on expected handling practices as identified through the Agency's systematic review process. Vinyl chloride is a gas at room temperature and is transported and stored as a liquid under pressure. Because contact with rapidly vaporizing liquid vinyl chloride can cause frostbite, sustained or routine dermal exposure to liquid vinyl chloride is not expected.

Residual vinyl chloride monomer can be present in PVC resin and products, but the concentration of vinyl chloride in PVC is generally low (Section 2.3.4). Workers do not handle PVC resin until it has been stripped of excess vinyl chloride monomer, and in some cases (depending on the type of resin), dried. Overall, because dermal exposure to liquid vinyl chloride and residual vinyl chloride in PVC resin is expected to be low to negligible, workers' dermal exposure to vinyl chloride is expected to be low.

ONUs do not directly handle vinyl chloride; therefore, dermal contact with vinyl chloride is not expected for any COU expected to be assessed. Overall, EPA does not plan to quantitatively assess occupational dermal exposures to vinyl chloride for workers or ONUs. Barring identification of information that indicates that further qualitative or quantitative assessment of occupational dermal exposure to vinyl chloride is warranted, the Agency does not plan to further assess occupational dermal exposure beyond that which is presented in this draft scope document.

2.5.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-5 presents the exposure pathways, exposure routes, and hazards to humans from consumer activities and uses of vinyl chloride. EPA expects inhalation to be the primary route of exposure and plans to quantitatively evaluate inhalation exposures to vinyl chloride vapor for consumers and bystanders during use and disposal of products containing vinyl chloride. Oral exposures were added to this conceptual model following the publication of the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c) based on reports that residual vinyl chloride monomer may be present in plastic consumer products, including toys (U.S. EPA, 2025b).



1235

1236 **Figure 2-5. Vinyl Chloride Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards**
1237 The conceptual model presents the exposure pathways, exposure routes, and hazards to humans from consumer activities and uses of vinyl chloride. Bold
1238 lines indicate pathways, routes, populations, and hazards that EPA plans to quantitatively assess (Section 2.5.2.1) while dashed lines indicate those that the
1239 Agency plans to include but not quantitatively assess (Section 2.5.2.2).

2.5.2.1 Pathways EPA Plans to Quantitatively Analyze in the Risk Evaluation

As described in Section 2.3.2.2, air is the primary exposure pathway for vinyl chloride; thus, EPA expects to quantitatively evaluate all consumer articles and products that could lead to inhalation exposure. Two consumer COUs (Adhesives and sealants, Paints and coatings) include consumer products that can contain vinyl chloride monomer ranging from trace levels to up to 15.4 percent. In addition, many consumer products made with PVC and related polymers may contain residual vinyl chloride monomer, which may volatilize from consumer products and lead to inhalation exposure. These include home and office furnishings, clothing, sporting goods, as well as children's toys and other products (U.S. EPA, 2023b). However, some of the SDSs that indicate the presence of vinyl chloride in consumer products do not report a weight fraction, likely because it is below the 0.1 percent reporting threshold for carcinogens like vinyl chloride.

2.5.2.2 Pathways EPA Plans to Qualitatively Analyze in the Risk Evaluation

EPA does not plan to quantitatively evaluate oral exposure from Adhesives and sealants as well as Paints and coatings—even though these two consumer COUs contain consumer products reporting concentrations up to 15.4 percent. Consumers are unlikely to ingest these products during use. Other COUs that have consumer products containing PVC might lead to oral and dermal exposure. As described in Section 2.3.4, the concentration of residual vinyl chloride monomer in plastic products is expected to be low, and based on that assessment, EPA expects to conduct a qualitative assessment of oral and dermal exposure to vinyl chloride via consumer products that contain PVC or related polymers. Taking all of the above into account, the Agency does not plan to further assess this pathway beyond that which is presented in this draft scope document. However, consideration of reasonably available information on the concentration of vinyl chloride monomer in consumer products is underway and will inform whether further qualitative assessment or a quantitative assessment of consumer exposure to vinyl chloride via ingestion or dermal contact is appropriate for the fit-for-purpose risk assessment.

2.5.3 Conceptual Model for Environmental Releases and Wastes

The conceptual model in Figure 2-6 illustrates the potential exposure pathways, exposure routes, and hazards to general population and environmental organisms from releases and waste streams associated with industrial, commercial, and consumer uses of vinyl chloride.

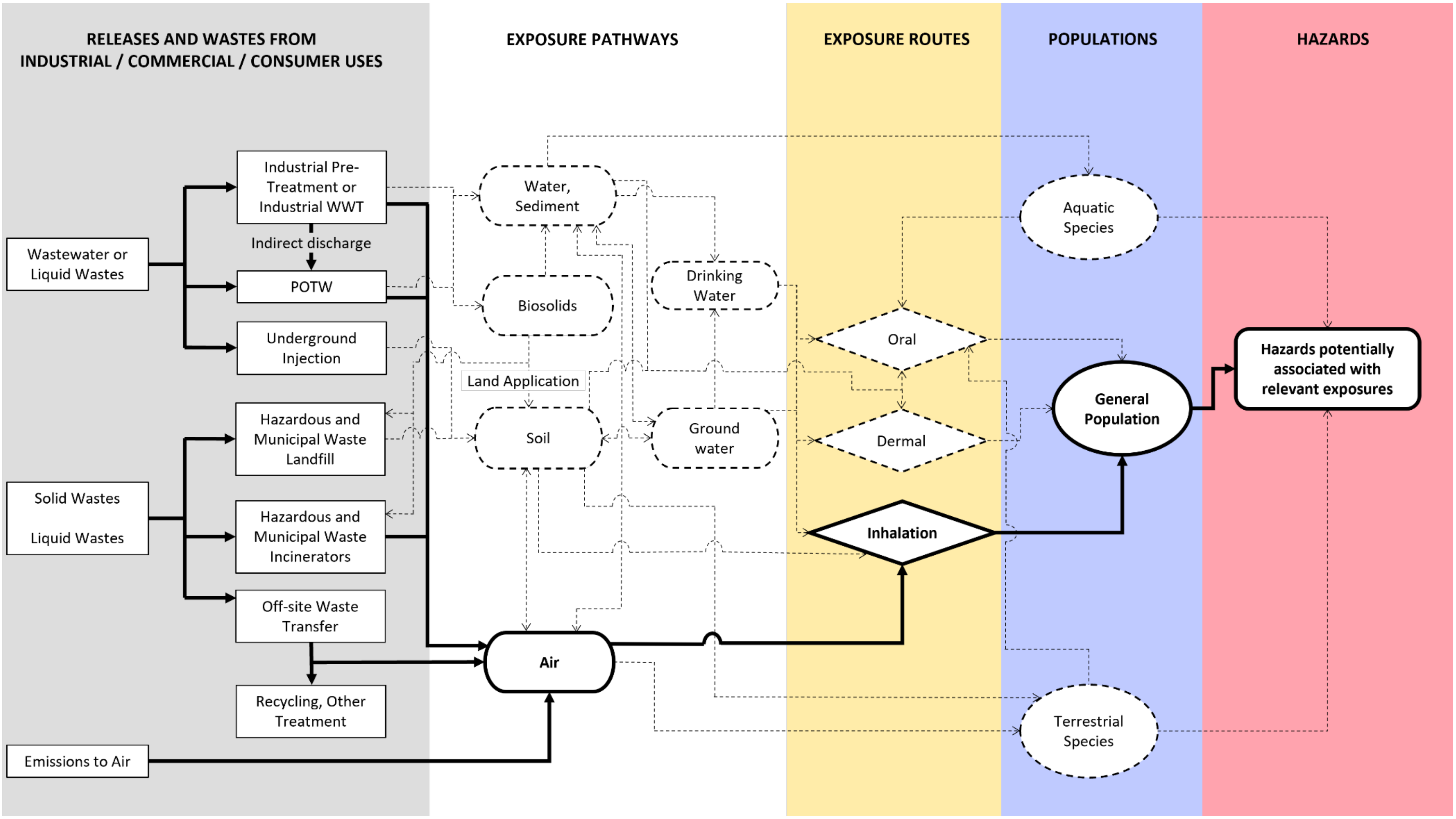


Figure 2-6. Vinyl Chloride Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes, and hazards to humans and ecological species from environmental releases and wastes resulting from uses of vinyl chloride. Bold lines indicate pathways, routes, populations, and hazards that EPA plans to quantitatively assess (Section 2.5.2.1) while dashed lines indicate those that the Agency plans to include but not quantitatively assess (Section 2.5.2.2).

2.5.3.1 Pathways EPA Plans to Quantitatively Analyze in the Risk Evaluation

Air is the primary exposure pathway for vinyl chloride because it is a gas at room temperature (boiling point −13.9 °C; Section 2.1), greater than 98 percent of releases are to air (Section 2.3.1), and vinyl chloride releases to the air are not expected to partition into other media (Section 2.3.2.2). Thus, inhalation is expected to be a significant route of exposure for the general population and ecological species. EPA plans to quantitatively assess concentrations of vinyl chloride in ambient air.

2.5.3.2 Releases, Pathways, Routes, and Populations That EPA Plans to Qualitatively Analyze in the Risk Evaluation

2.5.3.2.1 Surface Water and Sediment

Vinyl chloride in surface water or sediment can occur from direct releases of industrial processes (including leaks and spills) or transport from groundwater through sediment layers at aquifer-fed bodies of water. TRI data for 2013 to 2022 report an average of 0.12 percent of vinyl chloride releases each year going to water on-site and publicly-owned treatment works (POTW) or non-POTW wastewater treatment (U.S. EPA, 2024c). Monitoring data from the Water Quality Portal report minimal occurrence of vinyl chloride in surface waters with most tests results being non-detects, which is expected because most vinyl chloride that does enter surface water will likely volatilize (Section 2.3.2.3). EPA's systematic review process identified about 30 monitoring studies published prior to January 2023 that investigated the presence of vinyl chloride in surface water. A preliminary title and abstract screen of these studies indicate low levels of vinyl chloride in the surface water and co-occurrence of highly chlorinated ethylenes (*e.g.,* TCE) that can degrade into vinyl chloride (Section 2.3.2.7), which may explain the presence of vinyl chloride in the water. Taking the above information into account, barring identification of information that indicates that further qualitative or quantitative assessment of surface water or sediment is warranted, EPA does not plan to further assess this pathway beyond that which is presented in this draft scope document. Potential exposure to vinyl chloride through ingestion of surface water used as a source of drinking water is discussed in Section 2.5.3.2.3.

2.5.3.2.2 Landfill Leachate and Groundwater

Vinyl chloride found in landfill leachate and subsequent groundwater can come from a variety of sources—particularly the transformation of more highly-chlorinated ethylenes (*e.g.,* TCE, PCE; see Sections 2.3.2.7) following their disposal. As of January 2025, EPA's systematic review process has identified 94 monitoring studies published prior to January 2023 that investigated the presence of vinyl chloride in groundwater and 3 studies that assessed vinyl chloride in landfill leachate (Section B.3). A preliminary title and abstract screen indicated that almost all studies reported a co-occurrence of vinyl chloride with more highly chlorinated compounds, which can transform into vinyl chloride in anaerobic environments (Section 2.3.2.7). or investigated groundwater in or near a contaminated site with known use of those compounds.

Multiple waste streams, including consumer, residential, industrial, and municipal waste, can also be a source of vinyl chloride in landfills. They may not be direct sources but rather a result of residual vinyl chloride monomer leaching from PVC-containing products. The release of residual vinyl chloride monomer into landfill leachates might be limited for various reasons. PVC products, such as pipes and plastic materials from consumer products, often contain low concentrations of residual vinyl chloride monomer. During these products' useful lifetimes, residual vinyl chloride is expected to evaporate or leach from the surface prior to disposal. When they are disposed of in landfills, vinyl chloride can be removed through volatilization/gas flow (*e.g.,* diffusion upwards toward landfill soil) or biodegradation (Section 2.3.1.1)—both of which further limit the concentration of vinyl chloride in landfill leachate.

For the reasons discussed above, release of vinyl chloride into landfill leachate is unlikely to occur from TSCA COUs (*i.e.,* vinyl chloride present in landfill leachate is more likely to be present as a transformation product of other substances; see Section 2.3.2.7). Therefore, EPA does not plan to quantitatively evaluate this exposure pathway unless the ongoing review of existing literature or new information that becomes available during the risk evaluation process warrant reconsideration.

Very small quantities of vinyl chloride are expected to be directly released to groundwater. As presented in the *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* U.S. EPA, 2024c), almost all the vinyl chloride released to the environment is released to air (average >99.8% per year since 2019; average 448,000 lb per year released to air). Releases to other media, which includes off-site transfers for treatment or disposal, average 630 lb per year across 10 states, primarily Louisiana (56%) and Texas (27%). Because the vinyl chloride released to air is not expected to be transported to groundwater and vinyl chloride released to water or land is expected to largely partition to air, these relatively small releases to other media represent the upper bound of potential direct releases of vinyl chloride to groundwater.

Overall, concentrations of vinyl chloride in groundwater as a result of releases of vinyl chloride (as opposed to parent compounds that degrade to vinyl chloride in anaerobic environments) are expected to be very low. Considering the information above, EPA does not plan to conduct further assessment of landfill leachate and groundwater beyond that which is presented in this draft scope document unless information is identified that indicates that further qualitative or quantitative assessment is necessary.

2.5.3.2.3 Drinking Water

Vinyl chloride concentrations in drinking water are regulated by SDWA, with an MCL of 2 ppb (2 µg/L) allowed in finished drinking water, measured at the point where the water leaves the drinking water treatment plant and enters the distribution system. Under SDWA, EPA also set a Maximum Contaminant Level Goal (MCLG) of 0 ppb for vinyl chloride. Further, vinyl chloride concentrations are regulated in some drinking water source water (*i.e.,* water that is collected to be routed to drinking water treatment plants) under the Clean Water Act. Under the Clean Water Act section 304(a), EPA recommends that (1) vinyl chloride concentrations be limited to 0.022 µg/L for "Human Health for the consumption of Water + Organism" based on 10^{-6} carcinogenicity risk (U.S. EPA, 2022a); and (2) vinyl chloride be labeled as a toxic contaminant and thus subject to effluent controls (40 CFR 413.02(i)).

Due to standard industry practice that limits residual vinyl chloride monomer concentrations in PVC, widespread building codes that set limits on vinyl chloride monomer concentrations in drinking water-grade PVC pipes, as well as low detected concentrations of vinyl chloride in drinking water at the distribution entry point (Section 2.3.4 and Section 2.3.4.3.2), EPA plans to qualitatively evaluate potential exposure through drinking water—including direct consumption or incidental ingestion during showering. Taking the above information into account, unless information is identified which indicates that further qualitative or quantitative assessment of drinking water is warranted, the Agency does not plan to conduct further assessment beyond that which is presented in this scope document.

2.5.3.2.4 Soil

As described in Section 2.3.2.4, EPA expects that vinyl chloride released to soil will rapidly volatize or leach into groundwater. No on-site releases to land have been reported to TRI since 2018, so off-site transfers for treatment or disposal (0.13% of total vinyl chloride releases) are the only potential releases to land. ATSDR (2024) reports 140 lb of vinyl chloride released to land from 38 manufacturing facilities in 2021, which amounts to 0.03 percent of total environmental releases. Vinyl chloride that is released to air (>98% of TRI releases) is not expected to significantly partition to soil through wet or dry deposition.

Based on low releases to land and limited expected partitioning from other environmental media into soil, EPA expects that vinyl chloride concentrations in soil are negligible and therefore does not plan to quantitatively assess exposures via soil. Considering the information above, barring identification of information that indicates that further qualitative or quantitative assessment of soil is necessary, the Agency does not plan to conduct further assessment beyond that which is presented in this scope document.

2.5.3.2.5 Land-Applied Biosolids Pathway

EPA does not plan to quantitatively analyze vinyl chloride releases to terrestrial environments from biosolids application to soil and subsequent human exposure during risk evaluation. This is not expected to be a significant pathway because stripping of volatile organics in WWTP processes and industrial settings is expected to dominate the removal of vinyl chloride. Vinyl chloride sorbed to solids in biosolids is also expected to desorb readily and not be persistent in receiving areas based on its water solubility and relatively low affinity for organic solids (Section 2.3.1). Therefore, biosolids are generally expected to be a minor compartment due to negligible releases as supported by TRI data and/or negligible partitioning to this media.

Monitoring data, albeit limited, also indicate the negligible occurrence of vinyl chloride in biosolids. EPA identified three studies that investigated the presence of vinyl chloride in biosolids or sludge in its comprehensive search of reasonably available literature published before January 2023. Parrish et al., (1991) evaluated the emissions of metals and organics from four wastewater sludge incineration processes presumably in the United States (*i.e.,* authors did not specify sampling location). Vinyl chloride was not detected in any of the four feed sludges. The authors noted the formation of vinyl chloride due to incomplete combustion of other VOCs but did not describe possible chemical formation routes. Lu et al., (2017) investigated the use of a bacterial biomarker of organohalides' presence in waste streams; however, vinyl chloride was not measured in sludge but in sediment as a transformation product of PCE. The sampling location was not indicated. Lastly, EPA (1982) measured either negligible (<1 µg/L) or non-detectable concentrations of vinyl chloride in sludge collected from a U.S. POTW for 30 consecutive days. Based on physical and chemical properties and monitoring data, EPA does not expect the land application of biosolids leading to incidental soil exposure through dermal uptake or ingestion to be a pathway of concern. Taking the above information into account, EPA does not plan to conduct further assessment of land-applied biosolids beyond that which is presented in this draft scope document unless additional information is identified which indicates that further assessment is warranted.

2.5.3.2.6 Aquatic Species

Vinyl chloride has a low potential for bioconcentration, bioaccumulation, and trophic transfer in aquatic species, as discussed in Section 2.3.1 and previous assessments by ATSDR (2024) and other authoritative sources (NICNAS, 2014a; Health Canada, 2013; OECD, 2001). EPA also did not identify any biomonitoring studies reporting vinyl chloride concentrations in fish tissue in its comprehensive search of reasonably available literature published before January 2023. Taken together with the minimal releases to surface water as supported by TRI data (Section 2.3.1) and its high volatility (Section 2.3.2.3), exposure of aquatic species to vinyl chloride via surface water, sediment, or diet are not expected to be pathways of concern and humans nor are they expected to be exposed via consumption of aquatic species. Considering the information above, barring identification of information that indicates that further qualitative or quantitative assessment of aquatic species is necessary, EPA does not plan to conduct further assessment beyond that which is presented in this scope document.

2.5.3.2.7 Terrestrial Species

Vinyl chloride has low bioaccumulation and trophic transfer potential (Section 2.3.2.6) so (1) terrestrial species are not expected to be exposed to vinyl chloride through their diet, and (2) humans are not expected to be exposed via consumption of terrestrial species. Furthermore, vinyl chloride is not expected to be present in surface water or soil at significant concentrations (Sections 2.5.3.2.1 and 2.5.3.2.4); thus, terrestrial organisms are expected to be exposed to vinyl chloride primarily through the air.

Because at least 95 percent of vinyl chloride is used in production of PVC and related copolymers and vinyl chloride have a low persistence potential in air (Section 2.3.2.2), the ecological organisms most exposed to vinyl chloride are those that live near vinyl chloride and/or PVC manufacturing facilities. However, with few exceptions, environmental risk assessments typically do not quantitatively address inhalation hazards posed by VOCs such as vinyl chloride (Markwiese et al., 2008; Spring et al., 2004; Carlsen, 1996) (Section 2.4.1).

Taking the above information into account, unless information is identified which indicates that further qualitative or quantitative assessment of terrestrial species is warranted, EPA does not plan to conduct further assessment beyond that which is presented in this scope document.

2.5.3.2.8 Oral and Dermal

Vinyl chloride is expected to be present in drinking water at concentrations below the MCL, even after passing through PVC water distribution pipes (Section 2.5.3.2.3). Therefore, oral or dermal (*e.g.,* bathing) exposures via drinking water are expected to be limited. Vinyl chloride also has a low potential for bioconcentration and bioaccumulation (Section 2.3.2.6) and exposure from consumption of aquatic or terrestrial species is expected to be negligible. Considering the information above, barring identification of information that indicates that further qualitative or quantitative assessment of the drinking water or fish ingestion pathways is necessary (*e.g.,* empirical fish tissue data), EPA does not plan to conduct further assessment beyond that which is presented in this scope document.

2.6 Analysis Plan

The analysis plan is based both on EPA's knowledge of vinyl chloride resulting from review of previous assessments and screening of reasonably available information as described in *Proposed Designation of Vinyl Chloride as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2024c). The Agency encourages submission of additional existing data such as full study reports or workplace monitoring from industry sources that may be relevant to EPA's evaluation of COUs, exposures, hazards, and PESS during risk evaluation. As discussed in the Draft Systematic Review Protocol (U.S. EPA, 2021), targeted supplemental searches during the analysis phase may be necessary to identify additional information for the risk evaluation of vinyl chloride. For any additional data needs identified during the risk evaluation, EPA may use the Agency's TSCA authorities under sections 4, 8, or 11, as appropriate.

2.6.1 Exposure

EPA plans to quantitatively analyze exposures via vapors in indoor and outdoor air and to qualitatively assess exposures via other pathways (Section 2.5). Exposures can be characterized through a combination of reasonably available monitoring data and estimated concentrations from modeling approaches. EPA plans to analyze scenario-specific exposures based on sources (uses), exposure pathways, and exposed populations.

2.6.1.1 Releases to the Environment

EPA plans to analyze releases to environmental media as described below.

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

EPA will review reasonably available information as described in the Draft Systematic Review Protocol (U.S. EPA, 2021). EPA plans to continue to review data sources identified, including potential sources such as:

- EPA TRI Data,
- EPA Generic Scenarios,
- EPA National Emissions Inventory,
- OECD Emission Scenario Documents,
- EU Risk Assessment Reports, and
- DMR surface water discharge data for vinyl chloride from National Pollutant Discharge Elimination System (NPDES)-permitted facilities.

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

EPA has reviewed key release data sources including TRI, as summarized in Section 2.3.1. The Agency plans to consider additional reasonably available information and will evaluate it during development of the risk evaluation as well as match identified data to applicable COUs (Section 2.2) and identify COUs where no data are found. EPA also plans to address data gaps identified as described in Steps 3 and 4 below by considering potential surrogate data and models.

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

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

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

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

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

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

EPA will identify potentially relevant OECD ESDs and EPA Generic Scenarios (GSs) that correspond to COUs of vinyl chloride. If ESDs and GSs are not available, other methods may be considered. The

Agency may perform additional supplemental targeted searches of peer-reviewed or gray literature to understand those COUs that may inform identification of release scenarios. The Agency may also need to perform supplemental targeted searches for applicable models and associated parameters that the Agency may subsequently use to estimate releases for certain COUs. Additionally, for COUs where no measured data on releases are available, EPA may use a variety of methods, including the application of default assumptions.

6. **Map or group each COU to a release assessment scenario(s).**

EPA plans to map release scenarios to relevant COUs based on a variety of factors, such as process equipment and handling, magnitude of production volume used, release sources and usage rates of vinyl chloride, polymer products, and formulations containing vinyl chloride, corresponding to COUs using reasonably available information. The Agency may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain COUs to further develop release scenarios.

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

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the Draft Systematic Review Protocol (U.S. EPA, 2021). Based on data quality and relevance (including strengths and limitations) and synthesis and integration of the evidence, EPA will determine the weight of scientific evidence related to environmental releases of vinyl chloride.

2.6.1.2 Fate and Transport

EPA plans to refine the analysis presented in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a) on the physical and chemical properties and environmental fate and transport of vinyl chloride according to the steps below. EPA will consider all reasonably available information on vinyl chloride for inclusion in the risk evaluation.

1. **Review reasonably available measured or estimated physical and chemical properties and environmental fate endpoint data.**

EPA plans to evaluate data and information collected through the systematic review process and public comments about the physical and chemical properties (Table 2-1) and fate endpoints (Table_Apx C-1). The Agency plans to evaluate and integrate identified information according to the procedures and metrics described in EPA's Draft Systematic Review Protocol (U.S. EPA, 2021). Where experimentally measured values for chemical properties are not reasonably available or of sufficiently high-quality, values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality. Newly identified and evaluated data will be used to update and refine the preliminarily identified and selected physical and chemical properties and environmental fate endpoints presented in this draft scope.

2. **Use the updated dataset to revise the influence of physical and chemical properties and environmental fate endpoints (*e.g.,* persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental populations.**

Measured data and, where necessary, model predictions of physical and chemical properties and environmental fate endpoints will be used to update characterizations of the persistence and movement of vinyl chloride within and across environmental media. As discussed in the *Draft Chemistry and Fate*

Assessment for Vinyl Chloride (U.S. EPA, 2025a), fate characteristics of particular importance to vinyl chloride include volatilization, solubility and transport in aqueous phases, atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and abiotic reductive dehalogenation rates. EPA plans to use these finalized endpoint data in exposure calculations.

3. **Using the updated physical and chemical properties, environmental fate endpoints, and associated analyses, refine the identification of major and minor pathways.**

This will likely include rerunning the Level III fugacity model and assessing the long-range transport potential of vinyl chloride—especially in the atmosphere—using finalized endpoint data as model inputs. EPA plans to perform more granular, quantitative analyses on the preliminarily identified major media and pathways highlighted in Section 2.5; media and pathways contributing less to vinyl chloride exposure potential will receive qualitative assessment.

4. **Conduct a weight of scientific evidence evaluation of physical and chemical properties and environmental fate data, including qualitative and quantitative sources of information.**

The Agency plans to evaluate the weight of scientific evidence for fate and transport information as described in the Draft Systematic Review Protocol (U.S. EPA, 2021).

2.6.1.3 Environmental Exposures

EPA does not plan to quantitatively analyze environmental exposures to aquatic or terrestrial environmental species (Sections 2.5.3.2.2 and 2.5.3.2.3). The Agency expects that vinyl chloride concentrations in ambient air, especially close to industrial sites where vinyl chloride is produced or used, may be significant. However, EPA generally does not assess inhalation hazards to environmental species because environmental risk assessments, including those in TSCA risk evaluations, typically do not quantitatively address inhalation hazards posed by VOCs (Markwiese et al., 2008; Spring et al., 2004; Carlsen, 1996). Based on release patterns and chemical and fate properties, vinyl chloride concentrations in all other environmental media are expected to be negligible; therefore, exposure in aquatic organisms and exposure by pathways other than inhalation in terrestrial organisms are expected to be negligible.

2.6.1.4 Occupational Exposures

EPA plans to analyze worker and ONU exposures as described below.

1. **Review reasonably available exposure monitoring data for specific COUs.**

EPA plans to review exposure data including workplace monitoring data collected by government agencies such as OSHA and NIOSH as well as monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

OSHA has established a PEL for vinyl chloride of 1 ppm 8-hour TWA and a STEL of 5 ppm (OSHA, 2019). EPA plans to consider the influence of these regulatory limits on occupational exposures in the occupational exposure assessment.

2. **Review reasonably available exposure data for surrogate chemicals that have uses, volatility, and physical and chemical properties similar to vinyl chloride.**

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

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

EPA plans to conduct mapping or grouping of occupational exposure scenarios based on factors (*e.g.,* process equipment and handling, magnitude of production volume used, exposure/release sources) corresponding to COUs. The Agency may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain COUs to further develop exposure scenarios. The mapping will be completed in accordance with engineering assessment predictability tables that present the assessment approaches used for each COU and occupational exposure scenario combination from past risk evaluations. These tables provide insight into how various uses of a chemical may be assessed and the type of data needed for the assessment.

4. **For COUs where data are limited or not reasonably available, review existing exposure models that may be applicable in estimating exposure levels.**

EPA plans to identify relevant OECD ESDs and EPA GSs corresponding to COUs, and to critically review these ESDs and GSs to determine their applicability to the COUs. If the Agency is not able to identify ESDs or GSs for all COUs, it may conduct industry outreach or perform supplemental targeted searches of peer-reviewed or gray literature to understand those COUs that may inform identification of applicable exposure scenarios. EPA may also need to perform targeted supplemental searches to identify applicable models that the Agency may subsequently use to estimate exposures for certain COUs.

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

Based on information developed during Steps 2 and 3 above, EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific COUs (and corresponding exposure scenarios). The Agency may utilize existing, peer-reviewed exposure models developed by EPA or other government agencies or that are reasonably available in the scientific literature. Alternatively, the Agency may elect to develop additional models to assess specific COUs. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models.

6. **Consider and incorporate applicable engineering controls and/or PPE into exposure scenarios.**

EPA plans to review potentially relevant data sources on engineering controls and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. OSHA recommends employers utilize the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. EPA plans to assess worker exposure pre- and post-implementation of engineering controls using reasonably available information on available control technologies and control effectiveness. For example, the Agency may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

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

During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the Draft Systematic Review Protocol (U.S. EPA, 2021). The Agency plans to rely on the weight of scientific evidence when evaluating and integrating occupational data. EPA also plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance including strengths and limitations, and synthesize and integrate the evidence.

2.6.1.5 Consumer Exposures

EPA plans to analyze exposures for consumers using a consumer product and bystanders to a consumer using the product as described below.

1. **Group COUs to consumer exposure assessment scenarios.**

2. **Review available hazard and exposure information to determine whether oral and dermal exposure routes will be quantitatively assessed.**

EPA currently plans to qualitatively assess oral and dermal exposures via consumer products (Section 2.5.2.2). If information is identified (*e.g.,* as data extraction and evaluation proceed [Section 1.3] or public comments are received) that indicates that these exposure routes should be quantitatively assessed, oral and/or dermal information will be included in subsequent steps of the consumer exposure assessment.

3. **Construct exposure scenarios.**

EPA plans to consider all reasonably available information in developing the relevant exposure pathways and in constructing consumer exposure scenarios. The following are important parameters to construct consumer exposure scenarios:

- COU and type of consumer product specific to the exposed population (*e.g.,* adults, children, infants);
- Duration, frequency, and magnitude of exposure;
- Weight fraction of chemical in products: When weight fractions are not specified, such as several plastic products containing PVC, EPA will assume a concentration equal to the SDS reporting threshold. For carcinogens including vinyl chloride, that weight fraction is 0.1 percent;
- Amount of chemical used; and
- Use patterns of the consumer product.

If oral and dermal exposure routes are to be quantitatively assessed, additional route-specific parameters include mouthing duration for oral exposure or absorption values for dermal exposure. These values will be estimated based on peer-reviewed literature or modeling if no empirical data are available.

4. **Evaluate existing indoor exposure models that may be applicable in estimating indoor air concentrations.**

Vinyl chloride is a VOC that is expected to volatilize readily from the surface of liquid and solid consumer goods to air. Once emitted, partitioning to airborne dust and particulates is likely negligible because it exists predominantly in the gas phase. Two models may be required to estimate exposure to vinyl chloride via inhalation: (1) the Consumer Exposure Model (CEM), and (2) the Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) Model. CEM can estimate exposure during use of liquid and paste products (*e.g.,* paint). However, it was designed to model exposures to semi-volatile organic compounds (SVOCs), and its equations for emissions of chemicals from solid articles contain simplifying assumptions specific to SVOCs that undermines its suitability for use for VOCs. For inhalation exposure to solid articles, the IECCU model may be more appropriate.

Both the CEM and IECCU Models consider physical and chemical properties (*e.g.,* vapor pressure, molecular weight), product-specific properties (*e.g.,* weight fraction of the chemical in the product), use patterns (*e.g.,* duration and frequency of use), user environment (*e.g.,* room of use, ventilation rates), and characteristics of the exposed population (*e.g.,* exposure factors, activity patterns).

Additional methods may be employed if oral and dermal exposures to vinyl chloride from consumer products are to be quantitatively assessed.

5. **Review reasonably available empirical data that may be used in developing, adapting, or applying exposure models to each exposure scenario.**

To the extent that previous assessments have already modeled a vinyl chloride consumer exposure scenario using TSCA-relevant products, EPA plans to evaluate those modeled estimates along with their underlying parameters and assumptions and compare to our modeled consumer exposure results. The Agency also plans to compare its modeled estimates of indoor air concentrations from use of consumer products with monitoring data reporting vinyl chloride in indoor air.

6. **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if PESS need to be further refined.**

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

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

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

2.6.1.6 General Population Exposures

EPA plans to analyze general population exposures to vinyl chloride in ambient air as described below.

1. **Review reasonably available ambient air data collected through systematic review and public comments.**

    a. *Releases from COUs:* EPA will use industry-specific releases from COUs, to be assessed as described in Section 2.6.1.1, as evidence of presence of vinyl chloride in ambient air.

b. *Monitoring data*: EPA will use monitoring data as (1) evidence of presence of vinyl chloride in ambient air, and (2) to determine how modeled estimates of concentrations near industrial point sources compare with reasonably available monitoring data. The monitoring data EPA plans to use are the following:
   i. Ambient Monitoring Technology Information Center (AMTIC) archive
   ii. Literature. Literature data provides context but rarely if ever temporally or spatially aligned with releases from COUs, and
   iii. Other federal (including data collected from industry by other EPA offices), state, or local monitoring data.

b. *Previous assessments:* To the extent other organizations have already modeled a vinyl chloride general population exposure scenario, EPA plans to evaluate their monitored or modeled estimates, along with their underlying parameters and assumptions, and compare published exposure findings to exposure results.

2. **Apply a tiered approach to estimate inhalation exposures from releases to ambient air.**

The first-tier analysis is based on data that is reasonably available without a significant number of additional inputs or assumptions. The results of first-tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative and require careful consideration of variability and uncertainty.

a. *Tier 1*
   i. Use the single highest release value within industries and sectors within the reporting period (*i.e.,* max kg/site-yr) as determined by the process described in Section 2.6.1.1.
   ii. Industry-specific data from TRI will be used in Tier 1.
   iii. Use Integrated Indoor/Outdoor Air Calculator (IIOAC) Model. IIOAC estimates high-end and central tendency (mean) exposures at 100, 100 to 1,000, and 1,000 m from a releasing point. Uses the most conservative (health protective) exposure scenario: a facility that operates year-round (365 days per year, 24 hours per day, 7 days per week), a South Coastal meteorologic region, and a rural topography setting.
   iv. Use provisional inhalation point of departures (PODs) from prior assessments (Section 2.4.2).

If there is no risk above Agency benchmark(s), EPA does not plan to further analyze the ambient air pathway. If there is risk at or above Agency benchmark(s), EPA plans to conduct a Tier 2 analysis.

b. Tier 2
   i. Use highest release for each industry or sector within the reporting period (*i.e.,* max kg/site-yr for each industry/sector) as determined by the process described in Section 2.6.1.1.
   ii. Facility-specific data from TRI will be used in Tier 2.
   iii. Use IIOAC Model.
   iv. Use provisional inhalation PODs from prior assessments (Section 2.4.2).

If there is no risk at or above Agency benchmark(s) for a given industry or sector, EPA does not plan to further analyze the ambient air pathway for that industry or sector. For any industries or sectors for which there is risk at or above Agency benchmark(s), EPA plans to conduct a Tier 3 analysis.

c. *Tier 3*
   i. Use facility-specific releases and NEI data.
   ii. Use Human Exposure Model (HEM).
   iii. Use inhalation PODs as determined in the TSCA risk evaluation for vinyl chloride.

3. **Compare modeled estimates of concentrations near industrial point sources with available monitoring data.**

4. **Evaluate the weight of scientific evidence of ambient air exposure estimates.**

EPA plans to rely on the weight of scientific evidence when evaluating and integrating data related to general population exposures. The weight of scientific evidence may include qualitative and quantitative sources of information. EPA plans to use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance including strengths and limitations, and synthesize and integrate the evidence.

For the non-air pathways, EPA expects to analyze general population exposure as follows:

1. **Review reasonably available monitoring and source information collected through systematic review and public comments.**

The Agency plans to consider all identified information according to the procedures and metrics described in EPA's Draft Systematic Review Protocol (U.S. EPA, 2021). It is not possible to source apportion between TSCA and non-TSCA sources using monitoring data. However, this review will inform assessment of potential vinyl chloride concentrations in these media and determination of whether media other than air will be quantitatively analyzed.

2. **Using the updated data following the completion of systematic review, revise the fit-for-purpose assessment plans for human exposure pathways and routes.**

As discussed in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a), fate characteristics of particular importance to vinyl chloride include volatilization, solubility and transport in aqueous phases, atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and abiotic reductive dehalogenation rates. If the physical and chemical properties and environmental fate endpoints are revised following review of reasonably available data, and further review of monitoring data support the presence of vinyl chloride in other media, EPA plans to consider conducting quantitative analyses for oral and dermal exposure to vinyl chloride from other environmental media (*e.g.,* surface and drinking water).

If these pathways are evaluated quantitatively, EPA plans to follow a similar approach as the ambient air pathway. The Agency also plans to evaluate a variety of data types to determine which types are most appropriate when assessing exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. Not all data types will be relevant to each pathway, although, for example, experimental data will not be applicable to estimating exposure scenarios for drinking water ingestion. After developing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios using a tiered approach. The approaches will vary by the pathway being assessed. For example, the surface water pathway's Tier 1 approach may involve use of a simple dilution-based model known as Exposure and Fate Assessment Screening Tool, version 2014 (E-FAST 2014) (Versar, 2014). A higher-tiered model may not be needed because partitioning of vinyl chloride to sediment and suspended and dissolved solids in water is unlikely given its range of log K_{OC} values identified to date. Modeled estimates of concentrations will be compared with reasonably available monitoring data including the Water Quality Portal, EPA's Safe Drinking Water's Six-Year Review, state databases, or peer-reviewed literature obtained through systematic review. The Agency will plan to reply on the weight of scientific evidence when evaluating and integrating data related to population exposures.

2.6.2 Hazards

2.6.2.1 Environmental Hazards

EPA expects to conduct an environmental hazard assessment as described below.

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

EPA plans to qualitatively consider the hazards of vinyl chloride to aquatic and terrestrial organisms—including vertebrates, invertebrates, and plants and/or algae across exposure durations and conditions if potential environmental hazards are identified through systematic review and public comments. Additional types of environmental hazard information may also be considered (*e.g.,* analog and read-across data) when characterizing the potential hazards of vinyl chloride to aquatic organisms.

EPA also plans to evaluate environmental hazard data using the evaluation strategies laid out in the Draft Systematic Review Protocol (U.S. EPA, 2021). The study evaluation results will be documented in the risk evaluation phase and data from acceptable studies will be extracted and integrated in the risk evaluation process.

2. **Derive hazard thresholds.**

EPA plans to qualitatively consider the hazards of vinyl chloride to aquatic and terrestrial organisms and does not plan to derive quantitative hazard thresholds.

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

During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the Draft Systematic Review Protocol (U.S. EPA, 2021).

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

EPA also plans to qualitatively consider aquatic (*e.g.,* water and sediment exposures) and terrestrial (*e.g.,* soil) pathways in the vinyl chloride conceptual model.

5. **Consider a persistence, bioaccumulation, and toxicity assessment of vinyl chloride.**

Vinyl chloride is not expected to persist in environmental media. EPA plans to consider the reasonably available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (*e.g.,* BAF, BCF) of vinyl chloride. Detailed information on the draft physical and chemical assessment of vinyl chloride, including a discussion of preliminary-available bioconcentration information, is available in the *Draft Chemistry and Fate Assessment for Vinyl Chloride* U.S. EPA, 2025a). Additional bioconcentration data that becomes available through systematic review or through public comment will also be considered. EPA also plans to qualitatively consider environmental hazard endpoint values (*e.g.,* LC50, lowest-observed-effect concentration [LOEC]) if sufficient data is available and exposure concentrations (*e.g.,* surface water concentrations, tissue concentrations) for vinyl chloride with the fate parameters (*e.g.,* BAF, BCF, biomagnification factor, trophic magnification factor) in the environmental risk characterization.

2.6.2.2 Human Health Hazards

EPA expects to evaluate human health hazards as follows. The steps described below are iterative and may not necessarily occur in the prescribed order based on data availability and evolving fit-for-purpose analysis during the evaluation stage.

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

EPA plans to review epidemiological, animal toxicology, and mechanistic studies using the strategies described in the Draft Systematic Review Protocol (U.S. EPA, 2021). During prioritization, the Agency searched and screened publicly available peer-reviewed literature, gray literature including previous assessments from other regulatory agencies, and other relevant information submitted to EPA to identify literature pertinent to understanding the potential human health hazards of vinyl chloride. Next, the Agency will produce literature inventory trees and evidence tables to summarize the extent and nature of the evidence that meets the human health hazard screening criteria. EPA will then evaluate the quality of key studies and extract information containing relevant data for dose-response analysis. In identifying key studies for data evaluation and extraction, the Agency will prioritize studies used to derive hazard values in the ATSDR (2024) and EPA IRIS (2000) assessments, in addition to any other studies identified in EPA's systematic review of the reasonably available literature that were not covered by these assessments. The Agency's review of the literature will additionally focus on identifying data on toxicokinetics, mode of action, and factors that increase biological susceptibility to vinyl chloride to support the PESS analysis.

2. **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and evidence integration (evaluating the evidence supporting those endpoints across all evidence streams) that may include mode of action analysis for target organs/critical effects, especially for cancer.**

To identify human health hazards from acute, intermediate, and chronic exposures, EPA will consider conclusions from previous assessments (discussed in Sections 2.4.2.1 and 2.4.2.2) in addition to epidemiological, animal toxicology, and mechanistic data identified during the TSCA systematic review process (U.S. EPA, 2021). The Agency will integrate these separate bodies of evidence to draw an overall judgement for each potential health effect. The evidence integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data;

evaluate the data for quality and relevance, including strengths and limitations; followed by synthesis and integration of the evidence; and considering principles of Bradford-Hill criteria. The results of evidence integration will inform which endpoints are considered for dose-response analysis. Refer to Section 7 in the Draft Systematic Review Protocol (U.S. EPA, 2021) for more information on the general process for evidence integration.

The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. EPA will evaluate information on genotoxicity and other information informing the MOA for cancer to determine the appropriate dose-response approach for quantitative cancer assessment in accordance with the *U.S. EPA Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). Based on an initial review of the literature, including previous assessments (discussed in Section 2.4.2.2), vinyl chloride appears to have a mutagenic MOA. MOA analysis will also be performed for non-cancer endpoints when appropriate for informing dosimetry, human relevance, or other dose-response considerations.

3. **Conduct dose-response analysis, including selection of key studies and hazard endpoints. Identify what types of hazard values (*e.g.,* inhalation unit risk [IUR], cancer slope factor [CSF], no-observed-adverse-effect concentration or level [NOAEC/NOAEL], benchmark concentration or dose limit [BMCL/BMDL]) are appropriate for the assessment and what adjustments are required. Adjustments may include dosimetry for extrapolating across species or routes, duration adjustments to consistently match a given human exposure scenario, and modeling to refine the precision of hazard values. Determine appropriate uncertainty factors required to account for adjustments that could not be accurately quantified.**

EPA will evaluate whether cancer and non-cancer hazard values need to be updated from prior assessments or derived *de novo*. In cases where the Agency must derive updated/new hazard values, non-cancer dose-response assessment will be performed in accordance with the following EPA guidance to derive hazard values:

- *U.S. EPA Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011a)
- *Recommended Use of Body Weight 3/4 as the Default Method in Derivation of the Oral Reference Dose* (U.S. EPA, 2011b)
- *Benchmark Dose Technical Guidance* (U.S. EPA, 2012b)
- *A Review of the Reference Dose and Reference Concentration Processes (*U.S. EPA, 2002b*)*
- *Advances in Inhalation Gas Dosimetry for Derivation of a Reference Concentration (RfC) and Use in Risk Assessment (*U.S. EPA, 2012a*).*

Consistent with EPA's *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2012b), non-cancer hazard data will be evaluated to determine whether benchmark dose modeling is applicable to derive a benchmark dose lower 95th percentile estimate (BMDL). Where benchmark dose modeling is not feasible, NOAELs and lowest-observed-adverse-effect levels (LOAELs) will be identified.

To derive cancer hazard values, dose-response assessment will be performed in accordance with EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a). The Agency will determine whether a linear or threshold-based approach is appropriate depending on the cancer MOA for vinyl chloride. Based on an initial review of the literature, including previous assessments (discussed in Section 2.4.2.2), vinyl chloride appears to have a mutagenic MOA; therefore, EPA expects to perform linear modeling. In accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposures to Carcinogens* (U.S. EPA, 2005b), and based on the determination in previous assessments that vinyl chloride is carcinogenic through a mutagenic MOA, EPA plans to apply age-dependent adjustment factors when calculating cancer risk for specific COUs that involve potential early life exposure to vinyl chloride.

EPA will evaluate whether the available physiologically-based pharmacokinetic (PBPK) and empirical kinetic models for vinyl chloride are adequate for interspecies extrapolation of hazard values, or for extrapolation of the hazard values to standard exposure durations (*e.g.,* lifetime continuous exposure). If application of the PBPK Model is not possible, oral hazard values may be adjusted by body weight $(BW)^{3/4}$ scaling in accordance with (U.S. EPA, 2011b) and inhalation hazard values may be adjusted by exposure duration and chemical properties in accordance with (U.S. EPA, 2012a, 2002b, 1994).

Studies from all available routes will be considered for hazard values and route-to-route extrapolation will be performed as needed. For vinyl chloride, EPA will consider whether the oral toxicological studies are adequate for use in dose-response due to uncertainties in the method of administration (*e.g.,* entrained in PVC powder). There may be uncertainties both in the accurate quantification of vinyl chloride monomer and additionally whether the PVC powder itself may be inducing any toxicological responses. In such cases where data are either limited or unavailable for a given exposure route, EPA will consider whether route-to-route extrapolation is valid based on portal of entry effects, first pass metabolism, method of exposure administration, and the relevance of that exposure route given vinyl chloride's COUs and physical-chemical properties. Without an adequate PBPK Model, considerations regarding the adequacy of data for route-to-route extrapolation are described in (U.S. EPA, 2012a, 2002b, 1994). EPA may use these considerations when determining whether to extrapolate from the oral to the inhalation route of exposure. Similar approaches for oral-to-dermal route extrapolation are described in EPA's *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual* (Part E, Supplemental Guidance for Dermal Risk Assessment) (U.S. EPA, 2004).

Uncertainty factors (UFs) are used to account for potential uncertainty in estimating a human exposure that will not result in any adverse health effects. EPA will apply UFs in the human health hazard dose-response assessment according to previously published guidance (U.S. EPA, 2002b, 1994). In summary, the Agency will determine whether any of the following UFs is appropriate depending on the uncertainties, variability, or absence of human health hazard data for vinyl chloride: An interspecies UF (UF_A) to account for uncertainty related to extrapolating from experimental animals to humans; an intraspecies UF (UF_H) to account for variation in sensitivity among the human population; a LOAEL-to-NOAEL UF (UF_L) to account for use of a LOAEL rather than a NOAEL or BMDL value; a subchronic-to-chronic UF (UF_S) to account for uncertainty in extrapolating effects observed in a short-term exposure study to potential effects for a longer exposure duration; and a database UF (UF_D) to account for deficiencies in the toxicological database that might lead to a lower POD.

4. **Identify factors that increase biological susceptibility and determine whether these groups were addressed in the risk assessment.**

Reasonably available human health hazard data will be evaluated to ascertain whether some human populations may have greater susceptibility than the general population to vinyl chloride hazard(s). Susceptibility of particular human populations to vinyl chloride will be determined by evaluating information on factors such as life stage, pre-existing diseases or disorders, lifestyle activities, sociodemographic status, nutrition, genetics, and other chemical and nonchemical stressors.

5. **Evaluate the weight of scientific evidence and overall confidence for human health hazard conclusions.**

EPA will evaluate the weight of the scientific evidence supporting the human health hazard assessment. This evaluation may separately consider distinct aspects such as evidence integration, dose-response, and incorporation of PESS. The Agency EPA will then describe overall confidence in human health hazard conclusions based on these considerations.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. The Agency will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000a). More specifically, EPA will consider for each COU and exposure scenario whether risks should be quantified or qualitatively described based on a fit-for-purpose assessment. Risks which are quantified will be compared to various benchmarks. These benchmarks are not "bright-lines" for determination of unreasonable risk but provide context for where a risk concern may exist. EPA expects to only qualitatively describe environmental risk. For human health non-cancer effects, an MOE approach is used where the value of the POD divided by the exposure estimate is compared to a benchmark MOE that incorporates relevant uncertainty factors. Cancer risk will be estimated by multiplying the cancer hazard value by the lifetime average daily dose/concentration (for tumors following a linear model, as is expected for vinyl chloride). For all risk calculations, assumptions, exposure durations, and exposure factors will be coordinated across hazard and exposure considerations. EPA may additionally qualitatively describe some risks through comparative narrative or using pilot examples. Tier-based approaches may also be used, whereby a conservative screening estimate is followed by a more detailed analysis if risk concerns are indicated.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) (U.S. EPA, 2000a). EPA will also present information in this section consistent with approaches described in the *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)* Rule (EPA), 2024). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. The Agency will also be guided by EPA's *Information Quality Guidelines* (U.S. EPA, 2002a) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will also identify (1) each population addressed by an estimate of applicable risk effects; (2) the expected upper end risk or central estimate of risk, including consideration of any potentially exposed or susceptible subpopulations affected; (3) each significant uncertainty identified as part of the risk assessment how these uncertainties might lead to over- or underestimation of risk; and (4) all reasonably available information known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

2.7 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using the *Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA); Final Rule* (May 3, 2024; 89 FR 37028), preamble to the TSCA Risk Evaluation

Rule (89 FR 37041-37042),), EPA's *Peer Review Handbook* (U.S. EPA, 2015a), and other methods consistent with Section 26 of TSCA (40 CFR 702.41). As explained in the TSCA Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for vinyl chloride will be peer reviewed with the appropriate scope and type of peer review consistent with the applicable peer review policies, procedures, and methods in guidance promulgated by the Office of Management and Budget and EPA, and in accordance with 15 U.S.C. 2625(h) and (i).

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2386 # APPENDICES

2388 ## Appendix A ASSESSMENT HISTORY

2389 **Table_Apx A-1. Assessment History**

Authoring Organization	Title or Description	Reference
EPA		
Integrated Risk Information System (IRIS)	*Toxicological Review of Vinyl Chloride*	U.S. EPA (2000b)
IRIS	*IRIS Chemical Assessment Summary: Vinyl Chloride CASRN 75-01-4*	IRIS (2000)
Office of Research and Development (ORD)	*Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride*	ORD (1975)
Office of Water	*Update of Human Health Ambient Water Quality Criteria: Vinyl Chloride 75-01-4*	U.S. EPA (2015b)
Office of Water	*Vinyl Chloride Health Advisory Draft*	U.S. EPA (1987)
Office of Water	*Drinking Water Criteria Document for Vinyl Chloride (Final Draft)*	U.S. EPA (1985)
Other U.S.-Based Organizations		
ATSDR	*Toxicological Profile for Vinyl Chloride: Draft for Public Comment*	ATSDR (2024)
ATSDR	*Interaction Profile for Chloroform, 1,1-Dichloroethylene, Trichloroethylene, and Vinyl Chloride [Draft]*	ATSDR (2007)
ATSDR	*Toxicological Profile for Vinyl Chloride*	ATSDR (2006)
California Air Resources Board (CARB)	*Proposed Identification of Vinyl Chloride as a Toxic Air Contaminant*	CARB (1990a)
CARB	*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*	CARB (1990b)
CARB	*Proposed Identification of Vinyl Chloride as a Toxic Air Contaminant: Technical Support Document, Part B: Health Effects of Airborne Vinyl Chloride*	CARB (1990c)
California Environmental Protection Agency	*Human Health Risk Assessment Note 3 – DTSC-Modified Screening Levels (DTSC-SLs), June 2020, Revised Update*	CA DTSC (2022)

Authoring Organization	Title or Description	Reference
California Environmental Protection Agency	*Technical Support Document for Cancer Potency Values, Appendix B: Chemical-Specific Summaries of the Information Used to Derive Unit Risk and Cancer Potency Values*	OEHHA (2011)
California Environmental Protection Agency	*Technical Support Document for Noncancer RELs, Appendix D2: Acute RELs and Toxicity Summaries Using the Previous Version of the Hot Spots Risk Assessment Guidelines (OEHHA 1999)*	OEHHA (2008)
National Research Council (now the National Academies of Sciences, Engineering, and Medicine)	*Vinyl Chloride: Acute Exposure Guideline Levels, in Acute Exposure Guideline Levels for Selected Airborne Chemicals*	NRC (2012)
National Toxicology Program	*Vinyl Halides (Selected), in Report on Carcinogens*	NTP (2021)
International Organizations		
Australia: National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	*Ethene, Chloro-: Environment Tier II Assessment*	NICNAS (2014a)
Australia: NICNAS	*Ethene, Chloro-: Human Health Tier II Assessment*	NICNAS (2014b)
Canada: Health Canada	*Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Vinyl Chloride*	Health Canada (2013)
International Agency for Research on Cancer	*Vinyl Chloride, in Chemical Agents and Related Occupations: A Review of Human Carcinogens*	IARC (2012)
OECD	*SIDS Initial Assessment Report for SIAM 13: Vinyl Chloride*	OECD (2001)
World Health Organization	*Vinyl Chloride in Drinking-Water. Background Document for Development of Who Guidelines for Drinking-Water Quality*	WHO (2004)
World Health Organization: International Program on Chemical Safety	*Environmental Health Criteria (EHC) 215: Vinyl Chloride*	IPCS (1999)

Appendix B EVIDENCE MAPS OF VINYL CHLORIDE INFORMATION

B.1 Fate and Transport

Distinct count of Hero ID
1 90

Endpoints	Media						
	Air	Sediment	Soil	Wastewater/ biosolids	Water	Other	**Grand Total**
Atmospheric Cycling/Transport	3	1	1		2		**5**
Bioconcentration		1	3	1	5		**5**
Biodegradation	4	29	17	9	90	30	**118**
Drinking Water Treatment			1		3	2	**3**
Hydrolysis		1	2	1	4		**4**
Incineration	1						**1**
Photolysis	10	1	3	2	7	1	**16**
Reductive Dehalogenation	1	7	3		22	5	**27**
Sorption		1	4	1	4	1	**5**
Transformation Products	7	7	2	2	17	9	**31**
Vapor Intrusion	1		1			1	**2**
Volatilization	2	1	3	1	7	2	**8**
Wastewater Treatment	2		1	7	8	1	**11**
Other	3	3	2	1	22	38	**38**
Grand Total	**21**	**32**	**20**	**10**	**101**	**38**	**147**

Figure_Apx B-1. Evidence Map of Environmental Fate and Transport Properties for Vinyl Chloride

View the interactive evidence map in HAWC. 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 December 11, 2024. Additional data may be added to the interactive version as they become available.

B.2 Occupational Exposure and Environmental Release

Distinct count of Hero ID
4 146

Data Type	Evidence Tag	References
COU	Disposal	30
	Distribution in Commerce	5
	Industrial/Commercial Use	37
	Manufacture - Domestic manufacture	101
	Manufacture-Import	7
	Processing - Processing - repackaging	5
	Processing - Processing as a reactant	113
	Processing - Processing incorporation into formulation, mixture, or reaction product	94
	Processing - Processing- incorporation into articles	87
	Processing - Recycling	4
	COU Other	60
	Total	303
Environmental Release	Accidental releases/spills	4
	Description of the release source	66
	Environmental release media	52
	Release frequency	17
	Release or emission factors	56
	Release quantity	42
	Waste treatment and pollution control	44
	Total	85
General Engineering	Chemical Concentration	25
	Life cycle Description	11
	Number of sites	45
	Process description	121
	Production, Import, or Use Volume	50
	Throughput	19
	Total	164
Occupational Exposure	Area sampling data	129
	Dermal exposure data	12
	Engineering control	44
	Exposure duration	82
	Exposure frequency	45
	Exposure route	105
	Number of workers	115
	Particle size characterization	4
	Personal protective equipment	31
	Personal sampling data	108
	Physical form	55
	Sampling and analytical methodology	60
	Worker Activity description	146
	Total	225
Grand Total		**303**

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 B-2. Evidence Map of Occupational Exposure and Environmental Release Information for Vinyl Chloride

View the interactive evidence map in HAWC. 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 December 19, 2024. Additional data may be added to the interactive version as they become available.

B.3 General Population, Consumer, and Environmental Exposure

Distinct count of Hero ID
1 94

Media	Study type						
	Completed Assessment	Database	Experimental	Modeling	Monitoring	Survey	**Grand Total**
Ambient (Outdoor) Air	12	8	1	17	44		72
Aquatic Species	1	2			2		5
Biosolids/Sludge	1				4		5
Building Material			2	1			2
Consumer Product or Article	2	1	8	2	2		12
Dietary/Food	5	1	2	2	7		15
Drinking Water	10	3	3	2	18		33
Dust (Indoor)	1						1
Groundwater	9	3	1	9	94		111
Human Biomonitoring - Blood	1			2	1		3
Human Biomonitoring - Dermal	1						1
Human Biomonitoring - Milk	1						1
Human Biomonitoring - Tissues, Other	1			1	1		2
Human Biomonitoring - Urine	1				1		2
Indoor Air	4	2	6	3	10		22
Leachate	1			2	3		6
Other Media	3	1	5	7	22		33
Personal Inhalation	2			1	3		6
Precipitation				1	1		1
Sediment	3	1		1	8		12
Soil	5	3	1	3	18		27
Surface Water	9	4		2	24		37
Terrestrial Species	1	1			3		5
Wastewater	5	1	1		11		18
Grand Total	21	11	17	34	176	0	238

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 B-3. Evidence Map of Consumer, General Population, and Environmental Exposure Information for Vinyl Chloride

View the interactive evidence map in HAWC. 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 January 6, 2025. Additional data may be added to the interactive version as they become available.

B.4 Environmental Hazard

Distinct count of Hero ID
1 4

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				4			4
Growth	1	1	1				3
Histology							0
Immobilization							0
Morphology		1					1
Mortality		2		3			5
Oxidative stress	1						1
Photosynthesis/Respiration							0
Physiology/organ function							0
Population							0
Receptor binding/regulation of receptor activity							0
Reproduction	1			3			4
Grand Total	2	2	1	5	0	0	9

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 taxonomic group or health outcome tag. The darker the color, the more references are available for a given taxonomic group or health outcome tag...

Figure_Apx B-4. Evidence Map of Environmental Hazard Information for Vinyl Chloride

View the interactive evidence map in HAWC. 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 December 19, 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.

B.5 Human Health Hazard

Distinct count of Hero ID

1 – 91

Health outcome	Exposure type: Animal toxicity – Inhalation	Animal toxicity – Oral	Epidemiology – Dermal	Epidemiology – Drinking water	Epidemiology – Food	Epidemiology – Inhalation	Epidemiology – Ocular/Eye	Epidemiology – Teeth or dental patient	Grand Total
Cancer/Carcinogenesis	28	7	68	4	2	91	31		124
Cardiovascular	20	4	33	2	1	38	17		61
Gastrointestinal	6	4	15		1	19	9		28
Hepatic/Liver	56	8	41	4	2	51	20		113
Immune/Hematological	28	5	28	4	3	37	13	1	69
Irritation(skin, eye)			3			3	3		3
Lung/Respiratory	24	5	30	2	1	38	19		65
Mortality	33	6	26	1	1	32	13		69
Musculoskeletal	5	2	7		1	9	4		16
Neurological/Behavioral	19	6	16	2	1	26	10		48
Nutritional/Metabolic	39	7	7	1	1	9	4		53
Ocular/Sensory	4	2	4			9	3		14
Other	28	7	44		1	64	24		97
Renal/Kidney	25	5	13	1	1	18	8		46
Reproductive/Developmental	25	5	9	1	1	15	4		44
Sensitization	5								5
Skin/Connective Tissue	5	2	10	1	2	14	7	1	20
Thyroid	5	3				1			9
Grand Total	90	9	129	9	4	176	65	1	272

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 B-5. Evidence Map for Human Health Hazard Information for Vinyl Chloride

View the interactive evidence map in HAWC. Data in this figure represent all references obtained from the publicly available databases that were included in systematic review as of December 19, 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.

Appendix C ENVIRONMENTAL FATE PROPERTIES OF VINYL CHLORIDE

Table_Apx C-1. Environmental Fate Properties of Vinyl Chloride

Property or Endpoint	Value[a]	Reference(s)
Direct photodegradation (air) *Section 3.3.2.1[d]*	Does not absorb light at wavelengths >218 nm	ATSDR (2024)
	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) *Section 3.3.2.2[d]*	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) *Section 3.3.2.1[d]*	•OH-mediated: $t_{1/2}$ range = 1.27 to 2.71 days (n = 9; based on •OH rate constants of 3.95E10−12 to 8.40E10−12 cm^3/mole-sec and a 12-hour day with 1.5E6 ·OH/cm^3)	OECD (2001), ECHA (2023a), NLM (2023a), NIST (2023), ATSDR (2024)
	NO_3-mediated: $t_{1/2}$ range = 155 to 478 days (n = 6; based on NO_3 rate constants of 1.40E−16 to 4.30E−16 cm^3/mole-sec and a 12-hour day with 2.40E08 NO_3/cm^3)	ECHA (2023a), NIST (2023)
	O_3-mediated: $t_{1/2}$ range = 91.3 to 93.6 days (n = 2; based on O_3 rate constant of 2.45E−19 to 2.51E-19 cm^3/mole-sec and a 12-hour day with 7.0E11 O_3/cm^3)	ECHA (2023a), NLM (2023a)
Indirect photodegradation (water) *Section 3.3.2.2[d]*	No decomposition over 20 hours at 10 mg/L test substance concentration in unfiltered Oconee River and Okefenokee Swamp water with 20 mg/L commercial humic acid	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 1.0E−04 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) *Section 3.3.1[d]*	$t_{1/2}$ > 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 concentration; saturated with molecular oxygen	ATSDR (2024)

Property or Endpoint	Value[a]	Reference(s)
	<10 years at 25.5 °C and pH 4.3–9.4 (estimated)	OECD (2001), ATSDR (2024)
Abiotic reductive dehalogenation (water, soil) *Section 3.3.3*[d]	<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) *Section 3.3.4.1*[d]	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% over 28 days (OECD 301D) at 2.04 mg/L test substance concentration; with sludge inoculum, adaptation not specified	NITE (2023), ECHA (2023a), NLM (2023a)
Aerobic biodegradation (sediment) *Section 3.3.4.2*[d]	Complete dehalogenation within 28 days in a freshwater river sediment microcosm, following a 7-day lag period; non-adapted	Atashgahi et al. (2013)
Aerobic biodegradation (groundwater microcosms) *Section 3.3.4.4*[d]	22–39% over 84 hours (mineralization) at ~1.13 mg/L test substance concentration in natural aquifer microcosm; some adaptation from chlorinated solvent and vinyl chloride contamination	Reaxys (2023), ATSDR (2024)
	>99% over 57 days, and >99% over 204 days at 330 µg/L test substance concentration, in groundwater/sediment batch microcosms; adaptation likely due to media exposure to vinyl chloride	NLM (2023a)
Aerobic biodegradation (soil) *Section 3.3.4.3*[d]	>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 (2024) ECHA (2023a)
	1.456 µg/g soil/hour biodegradation in gas phase, incubated with soil from a landfill under methane oxidizing conditions, adaptation not specified	NLM (2023a)
Anaerobic biodegradation (water)	10% over 106 days following a 50-day lag at 2.6E−04 mg/L test substance concentration in groundwater containing H_2 and acetate, under	Reaxys (2023)

Property or Endpoint	Value[a]	Reference(s)
Section 3.3.4.1[d]	methanogenic conditions; adaptation likely due to media exposure to vinyl chloride	
	$t_{1/2}$ = 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) *Section 3.3.4.2[d]*	5–44% over 37 days and 8–100% 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 (2024)
	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; vinyl chloride-oxidizing culture inoculum in microcosm with media from contaminated site; adapted	ATSDR (2024)
	98% and 21% over 70 days in Naval Air Station, and Naval Weapons Industrial Reserve Plant sediment microcosms, respectively; under methanogenic conditions; some adaptation with preexposure of media to chlorinated solvents	ECHA (2023a)
	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)
	Complete dehalogenation within 28 days in a freshwater river sediment microcosm, following a 7-day lag period; non-adapted	Atashgahi et al. (2013)
Anaerobic biodegradation (groundwater microcosms) *Section 3.3.4.4[d]*	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 electron donors,[c] respectively, in aquifer microcosm; some adaptation with media from vinyl chloride-contaminated site	Reaxys (2023)
	100% over >100 days at 39 mg/L test substance concentration in groundwater with sediment microcosm under Fe- and SO_4^{-}-reducing conditions; some adaptation with media from contaminated site	Reaxys (2023)

Property or Endpoint	Value[a]	Reference(s)
	15–34% over 84 hours and 2.8–4.6% over 84 hours (mineralization) at ~1.13 mg/L test substance concentration, in natural aquifer microcosm, amended with Fe(III) and unamended, respectively; some adaptation from media exposure to chlorinated solvents and vinyl chloride	Reaxys (2023), ATSDR (2024)
Anaerobic biodegradation (soil) *Section 3.3.4.3*[d]	$t_{1/2}$ = 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 [ww]) *Section 3.6*[d]	BCF <10 in Golden Ide (*Leuciscus idus* melanotus)	OECD (2001), ATSDR (2024), NLM (2023a), ECHA (2023a)
	BCF = 40 in green algae (*Chlorella fusca*)	OECD (2001), ATSDR (2024), NLM (2023a), ECHA (2023a)
	Upper Trophic Level: 3.168 Middle Trophic Level: 2.482 Lower Trophic Level: 2.310	EPI Suite™ (BCFBAF, Arnot-Gobas method) [b]
Bioaccumulation factor (BAF) (L/kg ww, unless noted) *Section 3.6*[d]	Upper Trophic Level: 3.168 Middle Trophic Level: 2.482 Lower Trophic Level: 2.310	EPI Suite™ (BCFBAF, Arnot-Gobas method) [b]
Organic carbon:water partition coefficient (log K_{OC}) (soil) *Section 3.2.1*[d]	2.38–2.95 in seven natural clayey till soil samples	ATSDR (2024)
	1.75	OECD (2001), NLM (2023a)
Removal in wastewater treatment *Section 3.5.3*[d]	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, 2012c).
[c] H_2, formate, acetate, pyruvate, lactate, fumarate, glycerol, glucose, molasses, or whey
[d] Respective accompanying section of the *Draft Chemistry and Fate Assessment for Vinyl Chloride* (U.S. EPA, 2025a)