

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

CASRN 75-07-0



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Docket

Supporting information can be found in public dockets <u>EPA-HQ-OPPT-2023-0601</u> and <u>EPA-HQ-OPPT-2018-0497</u>.

Disclaimer

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

ABBREVIATIONS AND ACRONYMS

ADME	Absorption, distribution, metabolism, and excretion
ACGIH	American Conference of Governmental Industrial Hygienists
AICIS	Australian Industrial Chemicals Introduction Scheme
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CAA	Clean Air Act
CalEPA	California Office of Environmental Health Hazard Assessment
CAP	Criteria Air Pollutants
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CEPA	Canadian Environmental Protection Act
CERCLA	Comprehensive Environmental Response. Compensation, and Liability Act
CFR	Code of Federal Regulations
CPCat	Chemical and Product Categories
CSF	Cancer slope factor
CWA	Clean Water Act
DFG	Deutsche Forschungsgemeinschaft
DMR	Discharge Monitoring Report
БСНА	European Chemicals Agency
ECIA	European Commission
EC	Effective Concentration for x percent of exposed organisms
EC/HC	Environment Canada and Health Canada
EC/IIC ECOTOX	Environment Canada and Treatm Canada ECOTOVicelegy Knowledgebese
ECUIUA	ECOTOAICOlogy Kilowledgebase
	Environmental Protection Agency
EPCKA	Emergency Planning and Community Right-to-Know Act
EU	
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FIFKA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
FYI	For Your Information
GHS	Globally Harmonized System
HAWC	Health Assessment Workplace Collaborative
HERO	Health and Environmental Research Online (database)
Hg	Mercury
HLC	Henry's Law Constant
HPCDS	High Priority Chemicals Data System
NPDES	National Pollutant Discharge Elimination System
HQ	Headquarters
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substance Information System
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IRIS	Integrated Risk Information System
IUR	Inventory Update Rule
Koc	Organic carbon: water partition coefficient
Kow	Octanol: water partition coefficient

LC10	Lethal concentration of 10% test organisms			
LC50	Lethal concentration of 50% test organisms			
LD50	Lethal dose of an ingested substance that kills 50% of test organisms			
LEC	Lowest effective concentration			
LOEC	Lowest observed effect concentration			
NAAQS	National Ambient Air Quality Standard			
NICNAS	National Industrial Chemicals Notification and Assessment Scheme			
NIOSH	National Institute for Occupational Safety and Health			
NIST	National Institute of Standard and Technology			
NITE	National Institute of Technology and Evaluation			
NEI	National Emissions Inventory			
NLM	National Library of Medicine			
NOEC	No observed effect concentration			
NPDES	National Pollutant Discharge Elimination System			
NTP	National Toxicology Program			
OECD	Organisation for Economic Co-operation and Development			
OEHHA	California Office of Environmental Health Hazard Assessment			
OEL	Occupational exposure limit			
ONU	Occupational non-user			
OPPT	Office of Pollution Prevention and Toxics			
OQD	Overall Quality Determination			
OSHA	Occupational Safety and Health Administration			
PECO	Population, exposure, comparator, and outcome			
PESO	Pathways and processes or population, exposure, setting or scenario, and outcomes			
PESS	Potentially exposed or susceptible subpopulation			
POTW	Publicly owned treatment works			
PPE	Personal Protective Equipment			
PPRTV	Provisional Peer Reviewed Toxicity Values			
RCRA	Resource Conservation and Recovery Act			
SDWA	Safe Drinking Water Act			
SDS	Safety Data Sheet			
SWPA	Source Water Protection Area			
TIAB	Title and abstract			
TRI	Toxics Release Inventory			
TSCA	Toxic Substances Control Act			
WWTP	Wastewater Treatment Plant			

Proposed Designation and Rationale

Proposed Designation

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

Production Volume or Significant Changes in Production Volume

The annual national aggregate production volume of acetaldehyde is presented in Table 2-1, which includes the consideration of both confidential business information (CBI) and non-CBI reported production volume information to chemical data reporting (CDR). The screening review of production volume information indicates that since 1986, the annual national aggregate production volume of acetaldehyde has decreased through the 1990s but has remained steadily above 100 million pounds, suggesting a consistent potential source of exposure to acetaldehyde.

Conditions of Use or Significant Changes in Conditions of Use

EPA uses reasonably available information, such as data reported to CDR, to support the TSCA existing chemicals program for chemical prioritization, risk evaluation, and risk management. In addition to CDR, EPA reviewed acetaldehyde uses from other publicly available data sources, including public comments received following initiation. This information allows EPA to develop an understanding of the types, amount, end uses, and possible exposure to chemicals in commerce. The conditions of use of acetaldehyde demonstrate the continued manufacturing, distribution, processing, use (industrial, commercial and consumer) and disposal of acetaldehyde since 2016. While there have been some changes in use information reported to CDR in recent cycles, most reported conditions of use in CDR have remained unchanged between the 2016 and 2020 reporting periods, though some changes have been identified. In the 2016 reporting period, acetaldehyde was identified as being used in plastic and rubber products and paint and coatings manufacturing for commercial and consumer use. It was also identified as used for commercial use in golf and sports turfs. In the 2020 CDR reporting cycle, acetaldehyde was identified in commercial use for construction and building materials covering large surfaces, agricultural non-pesticidal products, and commercial and consumer packaging (excluding food packaging), including paper articles. EPA is seeking additional information from the public on the uses presented in Section 2.3.

Potentially Exposed and Susceptible Subpopulations

EPA is required to account for sensitive subpopulations identified by EPA, referred to by TSCA as potentially exposed or susceptible subpopulation(s) (PESS), when implementing the TSCA existing chemicals program for chemical prioritization, risk evaluation, and risk management. EPA conducted a screening review of reasonably available information on factors that may make certain groups more vulnerable to adverse effects. These factors include lifestage, occupational exposures, certain consumer exposures, nutrition, lifestyle activities, and proximity to facilities that manufacture or process a chemical substance. For prioritization, EPA also reviewed whether children may be exposed to acetaldehyde, and EPA identified acetaldehyde use in several children's products and articles intended for children as a result of the Agency's screening review in Section 2.4. Based on this information, EPA

believes that children, women of reproductive age, consumers, workers, and overburdened communities may be PESS for acetaldehyde.

Persistence and Bioaccumulation

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

Storage Near Significant Sources of Drinking Water

Drinking water is a possible source of chemical exposure and EPA is required to screen whether or not chemicals in the TSCA prioritization process are stored near significant sources of it. EPA identified facilities reporting acetaldehyde to the TRI in 2022 near potential sources of drinking water (Section 2.6) using public water systems data stored in EPA's Safe Drinking Water Information System Federal Data Warehouse (U.S. EPA, 2022). EPA determined whether TRI reporting facilities are located inside defined source water protection areas or within four miles of wellheads to identify potential storage of acetaldehyde near sources of surface water and groundwater, respectively. As shown in Table 2-4, from among 455 total TRI facilities that stored acetaldehyde on-site in 2022, EPA identified 64 facilities that were withing source water protection areas and 377 facilities that were within four miles of wellhead protection points.

Potential Hazard

In the TSCA existing chemicals program, through the prioritization process, EPA determines whether or not a chemical will undergo risk evaluation by making a priority designation. To support this proposed designation for Acetaldehyde, EPA identified potential hazards to humans and ecological receptors, including plants, birds, other wildlife, and aquatic life. Should this chemical undergo risk evaluation, hazard information, along with exposure information, will be used to characterize risk. As described in Section 2.7.1, EPA identified potential environmental hazards for both aquatic and terrestrial organisms, such as mortality, growth, developmental and reproductive effects resulting from acetaldehyde. Additionally, as described in Section 2.7.2, EPA identified potential human health hazards such as eye, skin, and respiratory irritation, acutely toxic and potentially genotoxic and carcinogenic, resulting from exposure to acetaldehyde based on epidemiological and animal toxicity information.

Potential Exposure

EPA has identified potential occupational, consumer, and general population exposure to acetaldehyde (Section 2.8). Due to releases of acetaldehyde to air, water, and land (Table 2-6, Table 2-7 and Table 2-8), the intentional use of acetaldehyde in consumer products (Table 2-3), monitoring information demonstrating the presence of acetaldehyde in surface water, groundwater, soil, and ambient air (Section 2.8.4.1); and the presence of TRI reporting facilities near significant sources of drinking water (Section 2.6), EPA has determined that various human populations (*e.g.*, general population, workers, consumers) and ecological receptors may be exposed to acetaldehyde via various exposure pathways and routes associated with the conditions of use.

Conclusion

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

1 INTRODUCTION

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

On December 18, 2023, EPA issued a public notice (88 FR 87423) initiating the prioritization process for five chemical substances, including acetaldehyde. Acetaldehyde (CASRN 75-07-0) is a colorless liquid with a pungent odor. At room temperature, acetaldehyde is a colorless gas. Acetaldehyde is one of the naturally occuring aldehydes. Acetaldehyde is mainly used as an intermediate in the production of other chemicals. Acetaldehyde is also included in EPA's TSCA Work Plan for Chemical Assessments (U.S. EPA, 2014). Before proposing to designate a chemical substance's prioritization status, under EPA's regulations at 40 CFR 702.9 and pursuant to TSCA section 6(b)(1)(A), EPA will generally use reasonably available information, including relevant information received from the public, to screen the candidate chemical substance under its conditions of use against the following criteria and considerations:

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

The screening review of reasonably available information for acetaldehyde against these criteria and considerations will inform a finding of whether acetaldehyde may present unreasonable risk because of a potential hazard and a potential route of exposure under the conditions of use. That preliminary finding, proposed designation, and associated rationale can be found in the Proposed Designation and Rationale section. Based on the information contained in this proposed designation document, EPA proposes that acetaldehyde be designated as a High-Priority Substance. EPA will take comment on this proposed designation for 90 days before finalizing its designation of acetaldehyde (EPA-HQ-OPPT-2018-0497). Relevant information received from the public and other information as appropriate will be considered for the final designation.

In developing this proposed designation and throughout the prioritization process, EPA has engaged and will continue to engage the public to obtain information relevant to acetaldehyde. On December 18, 2023, EPA initiated a 90-day public comment period, during which EPA received information about conditions of use for received comments pertaining to acetaldehyde, including manufacturing,

processing, and consumer/commercial uses and products; release and exposure information; and potential hazards of acetaldehyde, as well as previously conducted hazard assessments. In February 2024, EPA hosted a public webinar to discuss prioritization efforts and data gathering authorities utilized and considered for identifying potentially relevant information for the five chemical substances currently undergoing prioritization. Following this public webinar, there were follow-up discussions with stakeholders representing different sectors, in which comments and information submitted during the first public comment period were discussed for additional context to help determine potentially relevancy for a respective chemical substance. See docket ID number <u>EPA-HQ-OPPT-2023-0601</u> for additional information on the information presented during the February 2024 public webinar (presentation materials and transcript). Final designation of the chemical substance as a High-Priority Substance would immediately initiate the risk evaluation process as described in EPA's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (40 CFR 702).

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

2 PROPOSED DESIGNATION OF ACETALDEHYDE

2.1 Screening Review of the Reasonably Available Information for Acetaldehyde

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

EPA conducted a comprehensive search for reasonably available information¹ to support the development of this proposed designation document for acetaldehyde. Chemical-specific literature searches and data source screening for relevance were conducted as described in Appendix B and Appendix C, respectively, for all disciplines (*i.e.*, physical and chemical properties, environmental fate and transport properties, occupational exposure and environmental release, general population, consumer and environmental exposure, environmental hazard, and human health hazard) from the following general categories of sources:

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

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

¹*Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use, considering the deadlines specified in TSCA section 6(b) for prioritization and risk evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information that is protected from public disclosure under TSCA section 14 (40 CFR 702.3).

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

2.2 Production Volume or Significant Changes in Production Volume

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

EPA considered both CBI and non-CBI reported production volume information reported to CDR, and the annual national aggregate production volume, which is presented as a range to protect individual site production volumes that are CBI (Table 2-1). The screening review of production volume information indicates that since 1986, the annual national aggregate production volume of acetaldehyde has decreased in production volume through the 1990s but has remained steadily above 100 million pounds, suggesting a consistent potential source of exposure to acetaldehyde.

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Year	Production Volume (lbs)	
1986	> 500M - 1B	
1990	> 500M - 1B	
1994	>100M - 500M	
1998	>100M - 500M	
2002	> 100M - 500M	
2006	100M - < 500M	
2011	284,905,696	
2012	250M - < 500M	
2013	250M - < 500M	
2014	250M - < 500M	
2015	250M - < 500M	
2016	100M - < 1B	
2017	100M - < 1B	
2018	100M - < 1B	
2019	100M - < 1B	
^{<i>a</i>} $\mathbf{M} = $ million; ^{<i>b</i>} $\mathbf{B} = $ billion		

2.3 Conditions of Use or Significant Changes in Conditions of Use

Under TSCA, the conditions of use of a chemical substance are "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" (15 U.S.C. 2602(4); 40 CFR 702.3). The conditions of use or significant changes in conditions of use considered for the proposed

designation of acetaldehyde were assembled from use information from CDR as well as other sources. Reporting requirements for the 2016 and 2020 CDR reporting cycles were different, as the function of the chemical in commercial and consumer uses was required beginning in 2020. Therefore, the category and subcategory descriptions in Table 2-2 combine the use description and chemical function for commercial and consumer uses. EPA consulted a variety of other sources, including published literature, company websites, and government and commercial trade databases and publications to identify additional readily available information regarding the use of acetaldehyde. Such additional information is organized in a separate table due to differences in how information was reported by the various data sources as compared to CDR (Table 2-3).

The categories and subcategories of conditions of use that EPA identified from information reported to CDR for the proposed designation of acetaldehyde are presented in Table 2-2. It is difficult to discern whether there are significant changes in conditions of use for acetaldehyde based on reported information to CDR in 2016 and 2020 because guidance regarding the reporting of categories and subcategory information was updated between these periods. This update may have resulted in the use information being reported differently in 2020 compared to 2016, possibly leading to inaccurate implications that some uses may have commenced or ceased in recent years. Most reported conditions of use in CDR for acetaldehyde have remained unchanged between the 2016 and 2020 reporting periods, though some changes have been identified. In the 2016 reporting period, acetaldehyde was identified as being used for commercial use in golf and sports turfs, as well as in both commercial and consumer use in plastic and rubber products and paint and coatings manufacturing. These uses were not reported during the 2020 CDR reporting cycle. In the 2020 CDR reporting cycle, acetaldehyde was identified in commercial use for construction and building materials covering large surfaces and agricultural nonpesticidal products, as well as commercial and consumer packaging (excluding food packaging), including paper articles. These uses may be new uses for acetaldehyde since the 2016 reporting cycle, uses that have now met the CDR reporting threshold and have, therefore, increased since the 2016 reporting cycle, or are potential reporting discrepancies. EPA is presenting information reported to CDR from both reporting cycles as reported to ensure all conditions of use information is captured and reduce any mischaracterization of the reported information.

In addition to the CDR information, EPA reviewed the uses of acetaldehyde from other publicly available data sources, such as the Toxics Release Inventory (TRI), Discharge Monitoring Reports (DMRs), National Emissions Inventory (NEI), Safety Data Sheets (SDSs), Chemical Exposure Knowledgebase (ChemExpo), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), EPA Chemical and Product Categories (CPCat) (U.S. EPA, 2019b), and the High Priority Chemicals Data System (HPCDS). EPA also received public comments, which can be found in docket ID number EPA-HQ-OPPT-2018-0497 containing potentially relevant information regarding the use of acetaldehyde. The relevant information is summarized in Table 2-3.

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

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Manufacture	Domestic manufacture	Domestic manufacture	2016 CDR; 2020 CDR
	Import	Import	2016 CDR
Processing	As a reactant	Intermediate in – all other basic chemical manufacturing – petrochemical manufacturing	2016 CDR; 2020 CDR
		Intermediate in adhesive manufacturing	2020 CDR
		Fuels and fuel additives in all other basic chemical manufacturing	2016 CDR
	Repackaging	Intermediate in food, beverage, and tobacco product manufacturing	2020 CDR
	Recycling	Recycling	2016 CDR
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Commercial Use	Golf and sports turf	Golf and sports turf	2016 CDR
	Adhesives and sealants	Adhesives and sealants	2016 CDR
	Paints and coatings	Paints and coatings	2016 CDR
	Paper products	Paper products	2016 CDR
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	2016 CDR
	Process intermediates	Process intermediates	2016 CDR
	Intermediate	Intermediate in – single component glues and adhesives – in packaging (excluding food packaging), including paper articles	2020 CDR
	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, and cement, glass and ceramic materials	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, and cement, glass and ceramic materials	2020 CDR
	Agricultural non-pesticidal products	Agricultural non-pesticidal products	2020 CDR
Consumer Use	Adhesives and sealants	Adhesives and sealants	2016 CDR
	Paints and coatings	Paints and coatings	2016 CDR
	Paper products	Paper products	2016 CDR
	Plastic and rubber products not covered elsewhere	Plastic and rubber products not covered elsewhere	2016 CDR
	Intermediate in single component glues and adhesives	Intermediate in single component glues and adhesives	2020 CDR

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

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)		
	Intermediate in packaging (excluding food packaging), including paper articles	Intermediate in packaging (excluding food packaging), including paper articles	2020 CDR		
Disposal	Disposal	Disposal			
^{<i>a</i>} Life cycle stage use definitions (40 CFR 711.3)					

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

^b These categories of conditions of use appear in the preliminary life cycle diagram, reflect CDR codes, and broadly represent conditions of use of acetaldehyde in industrial and/or commercial settings.

^c These subcategories reflect more specific conditions of use of acetaldehyde.

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

Use/Activity	Reference
Processing as a reagent – laboratory chemical	ECHA (2023a), ECHA (2023c)
Intermediate – inks	<u>M&R (2019)</u>
Consumer products – surface cleaners, wood polish, car degreaser and wax, motor oil, adhesives and caulking, surface sealer, paint, drywall, and home insulation	<u>U.S. EPA (2024b)</u>
Consumer products – toys, games, blankets, jewelry, and clothing	<u>IC2 (2024)</u>
Consumer products – leather cleaning products	<u>NICNAS (2019)</u>
Consumer products reported from public comments - epoxy film adhesive, automobile components, imaging products such as cameras and camcorders, displays, projectors, audio equipment, broadcasting systems, harnesses, cables, sheets, rubbers, and films acetic acid used to make polyvinyl acetate ("PVA"), used for glue and adhesives for envelopes and other packaging.	(EPA-HQ-OPPT-2018-0497-0003; EPA-HQ- OPPT-2018-0497-0005; EPA-HQ-OPPT-2018- 0497-0006; EPA-HQ-OPPT-2023-0601-0014)

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

2.3.1 Activities That May Be Excluded

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

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

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

2.3.2 Overview of Conditions of Use and Preliminary Life Cycle Diagram

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

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



Figure 2-1. Preliminary Life Cycle Diagram for Acetaldehyde

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

2.4 Potentially Exposed or Susceptible Subpopulations

Potentially exposed or susceptible subpopulation (PESS) means "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly" (15 U.S.C. 2602(12)). General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

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

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

Children

EPA used data reported to the 2020 CDR to identify uses of acetaldehyde in products and articles intended for children and did not identify products intended for children as reported to 2016 and 2020 CDR for acetaldehyde. However, EPA has identified acetaldehyde uses in several products and articles intended for children from the HPCDS database (IC2, 2024), as described in Table 2-3. Children's exposure to chemicals may differ from exposures among adults due to physiological and behavioral differences (U.S. EPA, 2008). For example, children have a higher ratio of body surface area to volume and higher inhalation rates per unit of body weight compared to adults. Additionally, children consume more of certain foods and water per unit of body weight. Children's behaviors that may increase exposure include oral exploration of their environment, touching the ground, surfaces, and objects, and ingesting human milk. In addition to consumer products, other media types of interest may include drinking water, indoor and outdoor air, soil, dust, human milk, and diet (e.g., food) (U.S. EPA, 2011, 2008). Figure_Apx C-7 displays the media types identified for each data source. Through the implementation of systematic review approaches, as described as described in Section 8 of the Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information (U.S. EPA, 2024c), EPA identified ten data sources documenting reproductive and/or developmental effects following exposure to acetaldehyde (see Figure Apx C-10 in Appendix C.5.4).

Women of Reproductive Age

EPA identified animal toxicity and epidemiology data sources that document reproductive and/or developmental effects following exposure to acetaldehyde (see Figure_Apx C-10 in Appendix C.5.4). This screening review of data sources identified through the systematic review approaches, as described as described in Section 8 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024c), suggests that women of reproductive age may be a PESS.

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

Overburdened Communities

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

Workers

Information about the uses and activities described in Section 2.8.2 was used to identify potential occupational exposure to acetaldehyde, indicating that workers are also likely to be PESS based on potentially greater exposure.

Consumers

Information about the uses and activities described in Section 2.8.3 was used to identify potential consumer exposure to acetaldehyde, indicating that consumers are also likely to be PESS based on potentially greater exposure.

2.5 Persistence and Bioaccumulation

EPA reviewed databases and previously conducted assessments to identify information for physical and chemical properties and fate endpoints to characterize the potential for acetaldehyde to persist in the environment or bioaccumulate. Table_Apx D-1 and Table_Apx E-1 summarize the information identified for physical and chemical properties and environmental fate and transport properties of acetaldehyde, respectively. Through the implementation of systematic review approaches, as described in Sections 4 and 5 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024c), EPA identified 596 data sources containing potentially relevant physical and chemical property information and 1,952 data sources for the environmental fate characterization of acetaldehyde, as shown in Figure_Apx C-1 and Figure_Apx C-2, respectively.

With a boiling point of 20.8 °C (<u>CRC Press, 2023</u>; <u>Reaxys, 2023</u>; <u>U.S. EPA, 2023a</u>), acetaldehyde may exist as a colorless gas or liquid in the ambient environment (<u>CRC Press, 2023</u>; <u>NLM, 2023a</u>, <u>b</u>). Acetaldehyde has a water solubility of 1.0×10^6 mg/L at 20 - 25 °C (<u>CRC Press, 2023</u>; <u>NLM, 2023b</u>;

<u>PhysProp</u>, 2023) and a Henry's Law Constant (HLC) of 6.67×10^{-5} atm·m³/mol at 25 °C (<u>NIST</u>, 2023; <u>PhysProp</u>, 2023), indicating slight to moderate volatility from water.

The octanol:water partition coefficient (log K_{OW}) and organic carbon (OC):water partition coefficient (log K_{OC}) values presented in Table_Apx D-1 and Table_Apx E-1 indicate that acetaldehyde will preferentially partition to water over organic phases in aqueous environments and during wastewater treatment. Two empirical log Kow values, -0.34 and 0.45, were identified from trusted databases (<u>PhysProp, 2023</u>) and (<u>CRC Press, 2023</u>), respectively. While contrasting, both log Kow values demonstrate acetaldehyde's hydrophilicity. No empirical log K_{OC} values for acetaldehyde were identified during screening. Therefore, the range of 0.508 to 0.945 calculated from identified log K_{OW} values with the K_{OW} method of KOCWIN in EPI SuiteTM was used for screening purposes (<u>U.S. EPA</u>, 2012). The identified partition coefficients, water solubility, and HLC values suggest that acetaldehyde released to water will remain predominantly in water. Similarly, acetaldehyde present in soil and sediment is highly likely to partition to pore water and is expected to have rapid migration to groundwater. This is supported by the existence of groundwater monitoring data for acetaldehyde, as highlighted in Section 2.8.4. However, the rate of migration to groundwater may be offset by biodegradation processes, as discussed below.

Hydrolysis of acetaldehyde is unlikely to be an important environmental process based on its chemical structure, as aldehydes are generally resistant to hydrolysis under environmental conditions (NLM, 2023b). Instead, biodegradation of acetaldehyde is expected to mediate its persistence in water, sediment, and soil. One OECD 301C ready biodegradability study employing a non-adapted, domestic sewage sludge inoculum resulted in degradation rates ranging from 80 to 100 percent over 14 days (ECHA, 2023a, b; NITE, 2023; NLM, 2023a). A second die-away test study found acetaldehyde to degrade 75 percent over one hour in seawater (NLM, 2023a). Because of its ready biodegradability, acetaldehyde is therefore expected to have low persistence in surface water. No data was identified on the degradation rate of acetaldehyde in soil. However, considering its expected high mobility and susceptibility to biodegradation, acetaldehyde is likely to have low persistence in soil.

Because acetaldehyde is both readily biodegradable and unlikely to partition to sludge, the majority that enters wastewater treatment plant (WWTP) is expected to be removed via biodegradation. This is supported by results from the STPWIN model of EPI SuiteTM v 4.11 predicting that approximately 91 percent of acetaldehyde will be removed via biodegradation when using BIOWIN/EPA Draft Method for biodegradation half-life estimation (*i.e.*, primary settling tank half-life of 10 hours, aeration tank half-life of 1 hour, and settling tank half-life of 1 hour) (U.S. EPA, 2012).

Limited empirical anaerobic biodegradation data was identified. One report of 97 percent acetaldehyde removal was observed in an anaerobic biological treatment unit operating at a 20-day hydraulic retention time (NLM, 2023a). A second source reported 67 percent degradation of acetaldehyde in an anaerobic lagoon, though without an associated timeframe or other details (NLM, 2023a). When modeled with the BIOWIN models of EPI SuiteTM v 4.11, acetaldehyde was predicted to be biodegraded rapidly, including under anaerobic conditions (BIOWIN 7) (U.S. EPA, 2012). Based on the biodegradation evidence identified to date, it is expected that acetaldehyde will also have low persistence in sediment.

Most acetaldehyde releases reported to TRI are to air via stack and fugitive air releases (see Table 2-6). With a vapor pressure of 900 – 902 mm Hg at 25°C (<u>CRC Press, 2023</u>; <u>PhysProp, 2023</u>), acetaldehyde will likely exhibit volatility from dry surfaces and will not partition appreciably to particles in the atmosphere. The boiling point of acetaldehyde lies within the temperature range of the troposphere (20.8 °C (<u>CRC Press, 2023</u>; <u>Reaxys, 2023</u>; <u>U.S. EPA, 2023a</u>)). Because of this, acetaldehyde may exist as a

gas in lower, warmer tropospheric elevations and will condense to liquid phase at higher, cooler elevations. Given its water solubility, acetaldehyde in either gas or liquid phase may dissolve in water droplets in the troposphere and precipitate via wet deposition.

Acetaldehyde is expected to be susceptible to direct photolysis in the atmosphere, as it readily absorbs wavelengths above 290 nm (NIST, 2023; Reaxys, 2023). Acetaldehyde also reacts with hydroxyl radicals (\cdot OH) in the atmosphere with transformation rates reported between 1.20×10^{-11} to 1.69×10^{-11} cm³/mole-sec. Assuming a \cdot OH concentration of $1.5 \times 10^6 \cdot$ OH/cm³, the half-life of acetaldehyde may range from 6.60 to 10.7 hours, with a mean of 8.37 hours (CRC Press, 2023; NIST, 2023; NLM, 2023a; PhysProp, 2023). With the combination of direct photolysis, indirect photolysis and potential for wet deposition, acetaldehyde is expected to have low persistence in the atmosphere and is unlikely to undergo long-range atmospheric transport.

No empirical BCF or BAF values were identified for acetaldehyde. Due to this, the BCFBAF model of EPI SuiteTM v 4.11 was used to fill aquatic bioaccumulation data gaps for screening purposes. Estimated BCFs and BAFs of 0.964, 0.957, and 0.927 L/kg were obtained for lower, middle, and upper trophic levels using the Arnot-Gobas method of the BCFBAF model, indicating that bioconcentration and bioaccumulation of acetaldehyde are unlikely (U.S. EPA, 2012). Though no terrestrial bioaccumulation or bioconcentration data were identified, acetaldehyde is not expected to accumulate in terrestrial species.

2.6 Storage Near Significant Sources of Drinking Water

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

EPA reviewed reasonably available information, including certain existing regulations or protections in place for the proposed chemical substance. To that end, EPA reviewed acetaldehyde existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (SDWA) (40 CFR Part 141 and regulations under the Clean Water Act (CWA) (40 CFR 401.15). Acetaldehyde is regulated under CWA sections 311(b)(2)(A) and 501(a) as well as SDWA section 1412(b). In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 302 (Extremely Hazardous Substances) and EPCRA section 313 (Toxic Chemicals), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (Hazardous Substances), and the Clean Air Act (CAA) section 111(b) (Volatile Organic Compounds), section 112(b) (Hazardous Air Pollutant), section 112(r) (Regulated Chemicals for Accidental Release Prevention), and section 183(e) (National Volatile Organic Compound Emission Standards for Aerosol Coatings). Acetaldehyde is regulated under EPCRA section 313, CERCLA sections 102(a) and 103, CAA sections 111(b), 112(b) and 183(e) and is not regulated under EPCRA section 302 and the CAA section 112(r) (Appendix A). Regulation by one or more of these authorities is an initial indication that could be used to support a "may present an unreasonable risk of injury to human health or the environment" finding for the chemical the substance, if released near a significant source of drinking water.

EPA identified facilities reporting acetaldehyde activities to the TRI in 2022 near potential sources of drinking water using public water systems data stored in EPA's Safe Drinking Water Information System Federal Data Warehouse (<u>U.S. EPA, 2022</u>). This data warehouse is updated quarterly and

provided by EPA's Office of Ground Water and Drinking Water (OGWDW). Specifically, EPA determined whether TRI reporting facilities are located inside defined Source Water Protection Areas (SWPA) or within four miles of wellheads to identify potential storage of acetaldehyde near sources of surface water and groundwater, respectively. TRI reporting facilities were used as a reasonably available indicator for locations where storage of acetaldehyde is likely to occur. Similarly, while the source water protection areas and wellhead protection points analyzed are not inclusive of all sources of drinking water, for the purposes of this document they were used as a representation of likely drinking water sources.

As shown in Table 2-4, EPA identified 455 TRI reporting facilities that stored acetaldehyde on-site in 2022. Multiple facilities were identified to be within SWPA and/or near wellhead protection points. Should acetaldehyde be designated as a High-Priority Substance, additional information about potential exposure via drinking water identified during this and future public comment periods may be considered to help identify the appropriate pathways included in the scope of the risk evaluation during the scoping process.

Group	Facility Count
All	455
Within source water protection area (surface water)	64
Within 4 miles of wellhead protection (ground water)	377

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

2.7 Hazard Potential

EPA considered reasonably available information from previous assessments and databases, as well as information sources identified in the systematic review approach outlined in Section 2.1 to conduct a screening review of potentially relevant hazard information for acetaldehyde. Furthermore, Section 8 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024c), and Appendix C.5 specifically describe how information sources were identified and screened to characterize potential environmental and human health hazards resulting from exposure to acetaldehyde, respectively. A summary of references for hazards identified for acetaldehyde during the screening step of systematic review is included in the interactive literature inventory tree in Appendix C.5.2. Through the implementation of systematic review approaches EPA identified 9,123 data sources that contain information that may be relevant for the characterization of potential hazard resulting from acetaldehyde exposure (Figure_Apx C-8). The evidence maps depicting a summary of data identified during the full-text screening of data sources considered through systematic review are also available in Appendices C.5.3 and C.5.4 for environmental and human health hazard, respectively.

2.7.1 Potential Environmental Hazard

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

A summary describing the potential environmental hazard resulting from exposure to acetaldehyde is provided below. EPA has preliminarily characterized organisms into aquatic and terrestrial categories to summarize potentially relevant hazards that reflect exposure in these ecosystems. EPA recognizes that some organisms have home ranges or lifestages that span multiple ecosystems, therefore exposure can

occur in a variety of media and pathways. Figure_Apx C-9 presents an evidence map that depicts health outcomes (*e.g.*, development, behavior, growth), categorized by ecosystem and taxonomic group, from data sources identified for ecological receptors cited and reviewed in assessments and ECOTOX, and identified through the systematic review approach. EPA has identified 23 aquatic and 25 terrestrial data sources that may be used to inform the potential environmental hazard resulting from exposure to acetaldehyde. These data sources underwent full-text screening as described in Appendix C.5 and met the screening criteria described in Appendix C.5.1. All the data sources reflected in Figure_Apx C-9 underwent a screening level review.

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

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

Environmental hazard endpoints displayed represent measures of a biological effect in response to exposure to acetaldehyde and focused on the traditionally statistically derived endpoints (*e.g.*, LC₅₀, LOEC, NOEC). Although considered for identifying potential environmental hazard resulting from acetaldehyde exposure, uncommon endpoints (*e.g.*, effective concentration that causes a response that is x percent of the maximum (EC_x) endpoints where x= uncommon percentages in which a statistically significant response was observed in specific studies) or taxa (*e.g.*, bacteria) cited by the previous assessments or available in ECOTOX may not be represented in these visualizations. As seen in the figures below, common endpoints were grouped into categories based on the quantitative nature of the biological effect in the exposed population and included no observed in 10% of the population (*e.g.*, EC10, LC10), 20% of the population (*e.g.*, EC20, LC20), and 50% of the population (*e.g.*, EC50, IC50,

LD50). Definitions of the health outcome terms displayed in these visualizations are located in ECOTOX <u>Appendix S. Effect Groups and Measurements</u>. The "cell(s)" health outcome term refers to either measurements of cell viability, membrane integrity, and/or cytotoxicity. Definitions of endpoint terms displayed in these visualizations are located in ECOTOX <u>Appendix T. Endpoint Terms and</u> <u>Definitions</u>.

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

2.7.1.1 Aquatic Organisms

Information was identified that may be used to identify toxicological effects for aquatic organisms resulting from acetaldehyde exposure via surface water. Figure 2-2 depicts reasonably available environmental hazard information sourced from previous assessments and ECOTOX. Furthermore, 23 data records that underwent full-text screening contain environmental hazard information that may inform potential hazard to aquatic organisms exposed to acetaldehyde (Figure_Apx C-9). Overall, among the full-text screening results, the health outcomes reported most often are mortality in aquatic invertebrates and vertebrates and developmental effects in aquatic vegetation and fungi. Additional information on the health outcomes identified for different taxa groups can be found in Figure_Apx C-9.

Surface Water

As presented in Figure 2-2, environmental hazard information was identified from previous assessments and ECOTOX for aquatic organisms (vertebrates, invertebrates, vegetation and fungi) via surface water exposure. Environmental hazard data reported in ECOTOX span numerous health outcomes (e.g., development, mortality, population) identified for the above taxonomic groups in response to varying acetaldehyde exposure durations at concentrations ranging from 0.003 to 625 mg/L. For example, mortality reported for vertebrates ranged from LC50 values (concentration causing 50 percent mortality of the exposed organisms) of 0.0036 mg/L in the African clawed frog (Xenopus laevis) to 140 mg/L in carp (Leuciscus idus ssp. melanotus) after four- and two-day exposures to acetaldehyde, respectively (Fort et al., 2003; Juhnke and Luedemann, 1978). Similarly, EC₅₀ values (concentration impacting 50 percent of the exposed organisms) reported for vertebrates in ECOTOX ranged from 0.0033 mg/L after 96-hours of exposure (teratogenic developmental effects in African clawed frog (X. laevis) embryos) to 106.6 mg/L after a 24-hour exposure (cellular measurements of membrane integrity in the rainbow trout, Oncorhynchus mykiss) to acetaldehyde (Tanneberger et al., 2013; Fort et al., 2003). In invertebrates, immobilization (intoxication) was reported for the water flea (Daphnia magna) after a 24-hour exposure to 48.25 mg/L of acetaldehyde (Randall and Knopp, 1980). Furthermore, reduced population growth rates were reported for both invertebrates (44 to 625 mg/L; ciliates) and algae (0.02 to 249.1 mg/L) following <4-day exposures to acetaldehyde (Tsai and Chen, 2007; Sauvant et al., 1995; ANSP, 1960).

In addition, data in Figure 2-2 represent empirical hazard values identified in a previous assessment for a variety of aquatic vertebrate (*e.g.*, bluegill sunfish (*Lepomis macrochirus*), guppies (*Poecilia reticulata*)) and invertebrate (*e.g.*, water flea (*D. magna*)) species (IPCS, 1995). Hazard values include endpoints such as lethal concentrations (*e.g.*, LC₅₀) and effect concentrations (*e.g.*, EC₅₀). (IPCS, 1995) reported LC₅₀ and EC₅₀ values for fish (35 to 124 mg/L) and invertebrates (42 mg/L; water flea). As compared to the observed developmental (EC₅₀= 0.0033 mg/L) and mortality (LC₅₀= 0.0036 mg/L) effects for African clawed frog (*X. laevis*) embryos following a four-day exposure to acetaldehyde, the (IPCS, 1995) assessment reported a 4-day LC₅₀ for bluegill sunfish (*Lepomis macrochirus*) of 53 mg/L (IPCS, 1995; von Burg and Stout, 1991). Such data suggest species-specific toxicity differences (*e.g.*,

amphibian versus fish) as well as potential life stage-dependent (*i.e.*, embryo versus juvenile or adult) toxicity differences to acetaldehyde exposure.



Figure 2-2. Summary of Select Environmental Hazard Information for Aquatic Organisms Resulting from Exposure for Acetaldehyde

2.7.1.2 Terrestrial Organisms

Information was identified that may be used to identify toxicological effects for terrestrial organisms resulting from acetaldehyde exposure. Figure 2-3 depicts reasonably available environmental hazard information sourced from previous assessments and ECOTOX. Furthermore, 25 data records that underwent full-text screening contain environmental hazard information that may inform potential hazard to terrestrial organisms resulting from acetaldehyde exposure (Figure_Apx C-9). These data sources contain potential hazards for endpoints including behavior, growth, and mortality for terrestrial invertebrates, vertebrates, and vegetation and fungi. Additional information on health outcomes identified for different taxa groups can be found in Figure_Apx C-9.

Water

As seen in Figure 2-3, through previous assessments and ECOTOX, environmental hazard information was identified for invertebrates and vegetation and fungi via water exposure. In these studies, the experimental designs encompassed multiple types of water exposure, including being dipped or soaked in an aqueous solution or via media agar. Several health outcomes (*e.g.*, genetics, growth, physiology, reproduction) were identified in response to a broad range of acetaldehyde concentrations (0.54 to 7,489 mg/L). A physiology-associated EC₅₀ of 7,489 mg/L resulting in electrolyte leaking following a 24-hour aqueous acetaldehyde exposure to the potato (*Solanum tuberosum*), was the least sensitive endpoint identified in Figure 2-3 (Dent, 1932).

Data identified in two previous assessments suggest that terrestrial invertebrates are potentially less sensitive to acetaldehyde compared to plant and fungal species (EC/HC, 2000; OEHHA, 1993a).

Whereas the lowest observed effect concentration (LOEC) for the reduction of brood size following a two-hour acetaldehyde exposure was 783 mg/L in the invertebrate soil nematode *Caenorhabditis elegans* (<u>OEHHA, 1993a</u>; <u>Greenwald and Horvitz, 1980</u>), the LOEC for growth inhibition following a five-day acetaldehyde exposure was 0.54 mg/L for two molds (*Penicillium italicum, P. digitatum*) (<u>EC/HC, 2000</u>; <u>Yuen et al., 1995</u>).



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

2.7.2 Potential Human Health Hazard

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

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

Table 2-5. Risk Assessment Classifications for Acetaldehyde Based on Human Health Haza	rd
Information	

Risk Classification System	Health Outcome	Classification	Assessment Label ^{<i>a</i>}	Exposure Route ^{b,c,d}	Based on Animal Toxicity Data	Based on Epidemiology Data
Approved Criteria, Hazardous Substance Information System (HSIS)	Acute toxicity	Xn; R22 – harmful if swallowed	NICNAS 2017	Oral, Dermal, Inhalation	X	
Approved Criteria, HSIS	Acute toxicity	Xi; R36 – skin and eye irritation	NICNAS 2017	Ocular, Dermal	Х	
Approved Criteria, HSIS	Acute toxicity	Xi; R37 – irritating to respiratory system	NICNAS 2017	Inhalation	Х	
Approved Criteria, HSIS	Carcinogenicity	Xn; R40 (Category 3) – limited evidence of a carcinogenic effect	NICNAS 2017	NA	Х	
Approved Criteria, HSIS	Genotoxicity	Xn; R68 (Category 3) – possible risk of irreversible effects	NICNAS 2017	In vitro, Intraperitoneal injection	Х	
Globally Harmonized	Acute toxicity	H302 (Category 4) – harmful if swallowed	NICNAS 2017	Oral, Dermal, Inhalation	Х	
System (GHS)			NICNAS 2019	NA	Х	
GHS	Acute toxicity	H319 (Category 2A) – causes serious eye	NICNAS 2017	Ocular, Dermal	Х	
		irritation	NICNAS 2019	NA	Х	
GHS	Acute toxicity	H335 (Category 3) – may cause respiratory irritation	NICNAS 2017	Inhalation	Х	
GHS	Genotoxicity	H341 – Suspected of causing genetic defects	NICNAS 2019	Inhalation, <i>In</i> <i>vitro</i> , Intraperitoneal injection	Х	
			NICNAS 2017	In vitro, Intraperitoneal injection	Х	
GHS	Carcinogenicity	H350 (Category 1B) – may cause cancer	NICNAS 2019	Inhalation	Х	
GHS	Carcinogenicity	H351 (Category 2) – suspected of causing cancer	NICNAS 2017	NA	Х	
International Agency for	Carcinogenicity	Group 2B – possibly carcinogenic to	NICNAS 2017	Inhalation ^{<i>b</i>} , NA ^{<i>c</i>}	X	X
Research on		human	OEHHA 1993	Inhalation, Intratracheal	Х	

Risk Classification System	Health Outcome	Classification	Assessment Label ^a	Exposure Route ^{b,c,d}	Based on Animal Toxicity Data	Based on Epidemiology Data
Cancer (IARC) Classification			ОЕННА 2011	NA	Х	
			NTP 2021	Inhalation, Drinking water	Х	
			US EPA 1991	Inhalation	Х	
			DFG 2023	NA	X	
IARC Classification	Carcinogenicity	Group 1 – carcinogenic to humans (when associated with consumption of alcoholic beverages)	NICNAS 2017	NA		Х
EPA Carcinogenicity Classification	Carcinogenicity	Group B2 – probable human carcinogen	ОЕННА 2011	NA		Х
Canadian Environmental Protection Act (CEPA), section 64	Carcinogenicity, Acute toxicity	"Toxic"	EC/HC 2000	NA ^d	Х	X
^a "Assessment labels" refer to labels associated with previous assessments identified in various figures within Section 2.7.2. These						

are commonly secondary sources citing the risk classification system and outcome listed. Recent risk assessments may cite older outcomes that are still supported by current research.

^b Exposure route is associated with an animal toxicity study.

^c Exposure route is associated with an epidemiological study.

^d Exposure route is associated with both an animal and epidemiological study.

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

described below. Table_Apx C-10 contains all the endpoint values considered from previous assessments based on epidemiological and animal toxicity studies, including the subset depicted in Figure 2-4. All endpoint values shown in the figure are greater than zero. To simplify the figure, endpoint values may occasionally exceed the upper bounds of the Y axis. Although there is only one endpoint for inhalation in the top series of panels within Figure 2-4, the inclusion of three horizontal axis of "5e+06" or 5 x 10^6 ppm only indicates the maximum endpoint value being depicted in this visual.



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

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

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

2.7.2.1 Epidemiological Information

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

As identified in Table 2-5, carcinogenicity descriptions and designations for acetaldehyde by previous assessments range from "possibly or probable carcinogenic to humans"(<u>NICNAS, 2017; OEHHA, 2011</u>), "carcinogenic to humans (primarily when associated with consumption of alcoholic beverages)"(<u>NICNAS, 2017</u>), and "carcinogenicity" (<u>EC/HC, 2000</u>). As presented in Figure 2-5, ten previous assessments described carcinogenic effects, but none were noted to be critical. No additional carcinogenicity qualitative endpoints were described.

No qualitative risk classifications for genotoxic effects for acetaldehyde were described in previous assessments. However, as shown in Figure 2-5, within the "other" health outcome category, four of the previous assessments described genotoxic effect endpoints but none were noted to be critical (<u>DFG</u>, <u>2023</u>; <u>NICNAS</u>, <u>2019</u>, <u>2017</u>; <u>ACGIH</u>, <u>2001</u>).

In addition, epidemiological data identified in previous assessments suggest that acetaldehyde exposure is associated with acute and chronic toxic effects (Figure 2-4). One qualitative acute toxicity effect from exposure to acetaldehyde is described in previous assessments as "toxic" (EC/HC, 2000). EPA found 44.4 percent of assessments described acute toxicity to be critical (Figure 2-5). These findings are based on a variety of observations from epidemiological studies. Observed inhalation endpoints with exposure to acetaldehyde included dermal, ocular, sensory and upper respiratory tract irritation, bronchoconstriction and reduced pulmonary function (NICNAS, 2019; OEHHA, 2014; ACGIH, 2001; EC/HC, 2000; IPCS, 1995). As shown in Figure 2-5, EPA also found 16.7 percent of the previous assessments indicate respiratory toxicity effects are critical for characterizing acetaldehyde toxicity due to acute and chronic exposure. Inhalation exposure endpoints are described by ACGIH (2001), where critical endpoints were based on chronic toxicity. EPA would welcome additional information regarding toxicological effects resulting from exposure to acetaldehyde during this public comment period.



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

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

2.7.2.2 Animal Toxicity Information that Supports Human Health Hazard

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

As seen in Table 2-5, statements on acetaldehyde's carcinogenicity range from "Limited Evidence of Carcinogenic Effect" (NICNAS, 2017), to "Possibly Carcinogenic in Humans" (DFG, 2023; NTP, 2021; NICNAS, 2017; OEHHA, 2011, 1993a; U.S. EPA, 1991). EPA found 54.5 percent of assessments described carcinogenic effects to be critical (Figure 2-6). These findings are based on a variety of observations in animals. Studies in rats resulted in squamous cell carcinomas and adenocarcinomas originating in the nasal passage and larynx (DFG, 2023; NICNAS, 2017; EC/HC, 2000; IPCS, 1995; OEHHA, 1993a, b; U.S. EPA, 1991), while similar studies in hamsters resulted in laryngeal carcinomas (DFG, 2023; NICNAS, 2017; ACGIH, 2001; OEHHA, 1993a, b; U.S. EPA, 1991). Based on these observed effects, human dose approximations were determined by previous risk assessments and are plotted in Figure 2-4. Not visualized in this figure due to design limitations, (NICNAS, 2019) reports a lifetime cancer risk (LCR) of 7x10⁻⁷.

Genotoxicity effects for acetaldehyde outlined on Table 2-5 include "Possible Risk of Irreversible Effects" (NICNAS, 2017) and "Suspected of Causing Genetic Defects" (NICNAS, 2019, 2017). Ten previous risk assessments described genotoxic effects, but none were noted to be critical (Figure 2-6). *In vitro* studies yielded gene mutations in mouse lymphoma cells, chromosome aberrations in primary rat skin fibroblasts and hamster ovary cells, and micronucleus formation in primary rat skin fibroblasts and hamster lung fibroblast (V79) cells (NICNAS, 2017; ACGIH, 2001; EC/HC, 2000; OEHHA, 1993a). These effects observed in animals were not described uniquely as genotoxicity-specific human endpoints (Figure 2-4). Rather, this data was considered with other chronic toxicity findings, and is plotted as such.

Table 2-5 describes a wide variety of qualitative acute toxicity effects of exposure to acetaldehyde including: "Harmful if Swallowed," "Causes Serious Eye Irritation" (NICNAS, 2019, 2017), "Skin and Eye Irritation," "Irritating to the Respiratory System," and "May Cause Respiratory Irritation" (NICNAS, 2017). As stated in previous risk assessments, acute toxicological effects observed in exposed rodents include skin, eye, sensory, and respiratory tract irritation (NICNAS, 2017; OEHHA, 2014; ACGIH, 2001; EC/HC, 2000). Rats experienced increased mortality (OEHHA, 2014; IPCS, 1995), increased blood pressure and tachycardia (ACGIH, 2001; EC/HC, 2000; IPCS, 1995), weight loss, liver damage, keratinized stratified metaplasia and severe hyperplasia of the larynx, labored respiration and mouth breathing (OEHHA, 2014; ACGIH, 2001; IPCS, 1995; OEHHA, 1993a), increased kidney weights, and focal hyperkeratosis of the forestomach (NICNAS, 2017; IPCS, 1995). Based on these observed effects, acute human dose approximations were determined by various previous risk assessments and are plotted in Figure 2-4.

Previous risk assessments did not describe chronic toxicity qualitative risk classifications related to acetaldehyde exposure. Rather, all reported data was quantitatively used by previous assessments. Chronic inhalation studies in rats resulted in disarrangement of nasal and respiratory epithelial cells, as well as loss of microvilli and sensory cells, stratified squamous metaplasia and keratinization, and focal hyperplasia in the respiratory tract (EC/HC, 2000; OEHHA, 1993a). Hamster inhalation studies resulted in increased mortality, increased kidney weight, and hyperplasia, squamous metaplasia and inflammation in the larynx and trachea (ACGIH, 2001; EC/HC, 2000; IPCS, 1995; OEHHA, 1993a). In some rodents, acetaldehyde has been shown to cross the placenta and enter the fetus (OEHHA, 1993a). Based on these observed effects, chronic human dose approximations were determined by various previous risk assessments indicate lung cancer and noncancer effects are critical for characterizing acetaldehyde toxicity. EPA would welcome additional information regarding toxicological effects resulting from acetaldehyde exposure during this public comment period.



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

2.8 Exposure Potential

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

2.8.1 Release Information

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

Toxics Release Inventory

EPA's TRI database contains information on chemical waste management activities reported to EPA by industrial and federal facilities, including quantities released to the environment (*i.e.*, to air, to water, and disposed of to land), treated, burned for energy, recycled, or transferred off-site to other facilities for these purposes.

Under section 313 of EPCRA, acetaldehyde is a TRI-reportable substance effective January 1, 1987 (40 CFR 372.65). For TRI reporting, facilities in covered sectors in the United States are required to disclose
release and other waste management activity quantities of acetaldehyde under the CASRN 75-07-0 if they manufacture, import, or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in the previous calendar year by July 1 of the following year. For more detailed information about how facilities report information to EPA, see the <u>Agency's web page on TRI</u> reporting.

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

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

Year	Number of Facilities that Reported	Total Quantities Released On-Site to Air (lbs)	Total Quantities Released On-site to Water (lbs)	Total Quantities Released (Disposed of) On- Site to Land (lbs)	Total Quantities Transferred to POTW (lbs)	Total Quantities Transferred to Other (Non- POTW) Wastewater Treatment Facilities (lbs)	Total Release Quantity (lbs)
2013	429	9,007,079	327,796	316,443	0	4,220	9,655,538
2014	446	9,312,352	337,340	251,247	31,742	4,559	9,937,240
2015	453	8,919,876	315,911	233,734	42,356	11,919	9,523,796
2016	460	8,249,073	375,370	306,228	41,069	4,519	8,976,259
2017	451	8,221,542	358,830	299,189	38,883	4,734	8,923,178
2018	458	8,360,877	375,366	280,771	88,258	4,544	9,109,816
2019	456	7,760,049	310,551	289,263	66,971	3,709	8,430,543
2020	446	7,357,174	304,768	122,613	106,843	4,821	7,896,219
2021	447	7,646,696	299,270	263,350	93,637	18,755	8,321,708
2022	442	8,098,574	381,859	141,283	151,707	3,597	8,777,021

Of the more than 89 million pounds of acetaldehyde disposed of or otherwise released to the environment during reporting years 2013-2022, less than 1 percent was released or disposed of offsite. The majority of onsite releases were to land. The majority of offsite transfers were to POTWs. Onsite air and water releases have generally trended downward as onsite land releases have fluctuated considerably during the same timeframe. Offsite transfers to POTWs and Non-POTW wastewater treatment facilities also show variability.

National Emissions Inventory (NEI)

The NEI was established to track emissions of Criteria Air Pollutants (CAPs) and CAP precursors and assist with National Ambient Air Quality Standard (NAAQS) compliance under the CAA. Air emissions

data for the NEI are collected at the state, local, and Tribal (SLT) level. SLT air agencies then submit these data to EPA through the Emissions Inventory System (EIS). In addition to CAP data, many SLT air agencies voluntarily submit data for pollutants on EPA's list of hazardous air pollutants (HAPs). EPA uses data collected from SLT air agencies, in conjunction with supplemental HAP data to build the NEI. EPA releases an updated NEI every three years. The most recent version of the NEI was released in 2020 for reporting year 2017.

Table 2-7 presents the 2020 NEI data for acetaldehyde (U.S. EPA, 2020). Nearly 93 percent of NEI reported air emissions are from vegetation on soil, wildfires and prescribed fires, and fuel comb in residential wood. Additionally, over 112,300 lbs (nearly 7 percent of the total emissions) of acetaldehyde is emitted from fuel combustion sources. For point/major sources, NEI reports emissions data at the emission unit-level. Emission units are the individual processes at a facility with the potential to emit a regulated air pollutant.

Sector	Total Emissions (lbs.)
Biogenics - vegetation and soil	806,919,821
Fires - wildfires	285,421,478
Fires - prescribed fires	128,846,042
Fuel comb - residential - wood	103,991,918
Fires - agricultural field burning	12,630,029
Mobile - on-road non-diesel light duty vehicles	11,134,048
Mobile - non-road equipment - diesel	10,355,134
Miscellaneous non-industrial NEC	10,061,574
Industrial processes - oil & gas production	8,471,086
Mobile - non-road equipment - gasoline	7,899,683
Commercial cooking	6,495,218
Mobile - on-road diesel heavy duty vehicles	5,663,636
Fuel comb - industrial boilers, ICEs - natural gas	5,188,704
Industrial processes - pulp & paper	5,056,935
Waste disposal	4,710,062
Agriculture - livestock waste	3,458,676
Mobile - locomotives	3,117,880
Mobile - aircraft	3,043,892
Fuel comb - industrial boilers, ICEs - biomass	1,914,516
Mobile - on-road diesel light duty vehicles	1,844,766
Industrial processes - NEC	1,799,096
Industrial processes - chemical manufacturing	1,492,599
Mobile - on-road non-diesel heavy duty vehicles	479,095
Fuel comb - electric generation - natural gas	413,172
Industrial processes - cement manufacturing	265,465
Fuel comb - industrial boilers, ICEs - coal	242,387
Mobile - commercial marine vessels	184,623
Mobile - non-road equipment - other	169,216

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

Sector	Total Emissions (lbs.)
Fuel comb - comm/institutional - biomass	154,108
Solvent - non-industrial surface coating	123,560
Fuel comb - electric generation - coal	108,557
Fuel comb - comm/institutional - natural gas	79,397
Fuel comb - industrial boilers, ICEs - other	77,426
Industrial processes - petroleum refineries	62,833
Industrial processes - storage and transfer	60,311
Fuel comb - electric generation - biomass	49,553
Fuel comb - industrial boilers, ICEs - oil	39,638
Dust - construction dust	36,580
Fuel comb - electric generation - other	31,611
Fuel comb - comm/institutional - oil	23,953
Fuel comb - comm/institutional - coal	21,676
Industrial processes - non-ferrous metals	21,663
Industrial processes - ferrous metals	18,750
Fuel comb - residential - oil	15,145
Solvent - industrial surface coating & solvent use	8,461
Fuel comb - comm/institutional - other	7,769
Fuel comb - electric generation - Oil	7,752
Solvent - graphic arts	2,658
Bulk gasoline terminals	1,644
Solvent - consumer & commercial solvent use	559
Solvent - degreasing	402
Fuel comb - residential - natural gas	13
Gas stations	2
Industrial processes - mining	2

Discharge Monitoring Reports (DMR)

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

Table 2-8 presents the 2023 industry sector water release information for acetaldehyde. The annual loadings for acetaldehyde are relatively low with two sectors, sanitary services and industrial organic chemicals, accounting for the entire 2023 discharge volume reported from 7 of the 33 permitted facilities. For additional information on the DMR data for acetaldehyde, refer to (U.S. EPA, 2023b).

	Facilities with	Annual Loadings Calculation		
Industry Sector (3-digit SIC)	Monitoring Requirements	Facilities	Discharged Amount in 2023 (kg)	
282 - Plastics materials and synthetic resins, synthetic	4	1	25.39	
229 - Miscellaneous textile goods	1	1	9.80	
Total	5	2	35.19	

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

2.8.2 Industrial and Commercial Activities and Uses

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

Acetaldehyde has an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL)³ since 1993. The PEL is 200 parts per million (ppm) over an 8-hour workday, time-weighted average (TWA), 40 hours work week. It also has an OSHA proposed Short Term Exposure Limit (STEL) of 150 ppm over a 15-minute period, TWA. The National Institute for Occupational Safety and Health (NIOSH) considers acetaldehyde a potential occupational carcinogen and has yet to determine a recommended exposure limit (REL). Furthermore, American Conference of Governmental Industrial Hygienists (ACGIH) has established a Threshold Limit Values (TLV) of 25 ppm over an 8-hour workday, TWA during a 40hours work week. EPA has identified the OSHA PEL, OSHA STEL and ACGIH TLV for acetaldehyde as indicators of potential workplace exposure to acetaldehyde via the inhalation route.

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

³ For more information, see the Occupational Safety and Health Administration's <u>PEL Tables</u>.



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

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

2.8.3 Consumer Activities and Uses

Based on the 2016 CDR reporting information, acetaldehyde was reported for use in adhesives and sealants, paints and coatings, paper products, plastic products, and rubber products not covered elsewhere. In the 2020 CDR cycle, acetaldehyde was reported as an intermediate in single component glues and adhesives and an intermediate in packaging (excluding food packaging), including paper articles (Table 2-2). However, as shown in Table 2-3, databases that report consumer uses have reported acetaldehyde in several other consumer products, including children's products. As described in Section 2.4, use in children's products was not reported to the CDR in 2016 or 2020. In addition, based on EPA's screening review of reasonably available information, 38 studies containing information relevant to consumer use were identified, see Figure_Apx C-7.

Acetaldehyde has been reported in the Chemical Exposure Knowledgebase (ChemExpo), a publicly available web-based data search and visualization tool developed by U.S. EPA, as potentially being present in surface cleaners, wood polish, car degreaser and wax, motor oil, adhesives and caulking, surface sealer, paint, drywall, and home insulation. Chemical weight fractions in products and documentation date are reported in ChemExpo. This information is primarily obtained from documents published by manufacturers, retailers, governments, and NGOs, and is released by EPA as the Chemical and Products database (CPDat). For acetaldehyde, of the 45 consumer products curated in accordance with the product use category (PUC), an identifier assigned to products which indicates the type of product assigned to each data record based on information provided in the original data source, seven were reported with weight fractions ranging from 0.00073 to 1 percent, however, the weight fraction was unavailable for the other 38 products (U.S. EPA, 2024b).

As described in Section 2.4 and Table 2-3, manufacturer testing for acetaldehyde in children's products was identified in the HPCDS. The information presented in HPCDS is reported to the state of Oregon or the state of Washington by manufacturers of children's products through the Interstate Chemicals Clearinghouse (IC2). This information is reported in concentration ranges and includes reports beginning in 2014. For acetaldehyde, of the 920 TSCA relevant entries, 323 were reported as greater than the practical quantitation limit but less than 100 ppm, 541 were reported to be equal to or greater than 100 but less than 500 ppm, 29 were reported to be equal to or greater than 500 but less than 1,000 ppm, with the remainder being reported as greater than 1000 ppm IC2 (2024). Nearly 56 percent of the entries across the different product types reported acetaldehyde as a contaminant.

Additionally, EPA has also received information during the public comment period that indicates that acetaldehyde may be present in consumer products otherwise not listed in Table 2-2, *e.g.*, imaging products and glue. For additional consumer products identified via public comments, see Table 2-3.

Based on the information reported to a previous assessment, studies found at EPA's screening review, HPCDS and ChemExpo and the uncertainty regarding use of acetaldehyde in these categories of consumer products, EPA seeks confirmation, comment or additional information on consumer uses. EPA will consider public comments received regarding the presence of acetaldehyde in consumer products and articles. EPA has not yet determined which pathways and routes would be included in the scope of the risk valuation, should acetaldehyde be designated a High-Priority Substance.

Potential exposure to acetaldehyde may occur via inhalation through indoor air where products and articles containing acetaldehyde are present and through oral exposure and dermal contact to products and articles containing acetaldehyde. Potential pathways and routes of exposure relevant to consumers, based on consumer uses from 2016 and 2020 reporting, are described in Figure 2-8. As part of this

prioritization action, this preliminary conceptual model is presented for public comment. EPA has not yet determined which pathways and routes would be included in the scope of the risk evaluation, should acetaldehyde be designated a High-Priority Substance.



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

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

2.8.4 Environmental and General Population Exposure

The manufacturing, processing, distribution, use, and disposal of acetaldehyde may result in releases to the environment and potential exposure to aquatic and terrestrial ecological receptors (biota), as well as the general human population. Environmental and general population potential exposure are informed by releases to the environment, overall persistence, degradation, and bioaccumulation within the environment, and partitioning across different media. Concentrations of acetaldehyde in biota (*e.g.*, fish, shellfish, and breast milk) may also provide evidence that supports potential exposure.

As described in previous assessments (NTP, 2021; EC/HC, 2000; IPCS, 1995), acetaldehyde may be present in the outdoor environment as a result of releases from multiple industrial and commercial conditions of use identified in Section 2.3. Chemical manufacturing, manufacturing of products containing acetaldehyde and use of acetaldehyde in other chemical manufacturing processes may contribute to releases to different media and to the outdoor environment.

Based on these environmental releases reported in Section 2.8, as well as physical and chemical and environmental fate and transport properties of acetaldehyde discussed in Sections 2.5, Appendix D, and Appendix E, acetaldehyde may be present in ambient air, surface water, and soil (EC/HC, 2000). While data reported to TRI indicate releases of acetaldehyde to air, surface water, land, and wastewater, ongoing presence of acetaldehyde in air, water, and soil may be limited due to the rapid degradation of acetaldehyde via biodegradation. Acetaldehyde is not expected to bioaccumulate in aquatic species (EC/HC, 2000). Acetaldehyde is not expected to adsorb to soil particles and would be considered mobile in the soil (EC/HC, 2000). EPA identified environmental concentration data to inform potential exposure to acetaldehyde. Table 2-9 lists databases EPA had reviewed for potential sources of environmental exposure to acetaldehyde.

Database	Environmental Concentration Data Present?	Human Biomonitoring Data Present?	Ecological Biomonitoring Data Present?	Reference
Air Monitoring Network	Yes	No	No	Washington State Department of Ecology (2008)
Biomonitoring California	No	No	No	<u>CDPH, CalEPA</u> (2006)
Biomonitoring in Washington State	No	No	No	Washington State Department of Health (2009)
Comparative Toxicogenomics Database	Yes	No	No	MDI, NC State University (2002)
Environmental Information Management (EIM) System	Yes	No	No	Washington State Department of Ecology (2019)
EPA AirToxScreen	Yes	No	No	<u>U.S. EPA (2019)</u>
EPA Ambient Monitoring	Yes	No	No	<u>U.S. EPA (1990)</u>

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

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

2.8.4.1 Environmental Exposure

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

Disposal and waste treatment activities associated with acetaldehyde and products containing acetaldehyde are also expected to result in releases to the outdoor environment. Acetaldehyde may be present in surface water, groundwater, wastewater, and soil as a result of these releases. Environmental monitoring information identified in databases and systematic review has indicated that acetaldehyde has been measured in surface water, soil, groundwater, and ambient air (U.S. EPA, 2024a; WA DOE, 2024; U.S. EPA et al., 2023a). Aquatic ecological receptors may be exposed to acetaldehyde as a result of the TRI-reported releases and acetaldehyde measured in surface water (ND–360 µg/L) (U.S. EPA et al.

<u>al., 2023b</u>). Terrestrial ecological receptors may also be exposed to acetaldehyde as a result of TRI-reported releases and acetaldehyde measured in soil and ambient air (0.10–3.81 μ g/m³) (<u>U.S. EPA</u>, <u>2019a</u>).

2.8.4.2 General Population Exposure

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

Releases of acetaldehyde from certain conditions of use, such as manufacturing, disposal, or hazardous waste treatment activities, may result in general population exposures (<u>NTP, 2021; EC/HC, 2000; IPCS, 1995</u>). Smokers and those exposed to secondhand smoke could also be exposed to higher levels of acetaldehyde (<u>IPCS, 1995</u>).

The National Toxicology Program has indicated that ingestion, inhalation, and dermal routes all have a high potential of exposing the general population to acetaldehyde (<u>NTP, 2021</u>). The general population can be exposed indirectly to acetaldehyde emissions from industrial sites at the local and regional scale. Available assessments note the general population can be exposed to acetaldehyde in the air due to acetaldehyde emissions (<u>IPCS, 1995</u>).

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



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

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

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

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

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Appendix A PRELIMINARY REGULATORY HISTORY

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

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
TSCA– section 6(b)	EPA is directed to identify High-Priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 High-Priority Substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Acetaldehyde is one of the High- Priority Substance candidates for which EPA initiated prioritization under TSCA (88 FR 87423, December 18, 2023).
TSCA – section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Acetaldehyde manufacturing (including importing), processing and use information is reported under the CDR rule (40 CFR part 711).
TSCA – section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Six substantial risk reports received for acetaldehyde (1989- 2010) (U.S. EPA, ChemView. Accessed August 23, 2023).
TSCA – section 4	Provides EPA with authority to issue rules, enforceable consent agreements and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Four chemical data submissions from test rules received for acetaldehyde: one acute aquatic plant toxicity study, one acute aquatic toxicity study, one human developmental toxicity study, and one human reproductive toxicity study (2010-2013) (U.S. EPA, ChemView. Accessed August 23, 2023).
EPCRA – section 313	EPCRA section 313 – also known as the Toxic Release Inventory (TRI) – requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical releases and other waste management	Acetaldehyde is a listed substance (or part of a listed chemical category) subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.

Table	Any	A-1	Federal	Laws	and	Regulations
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Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	(<i>e.g.</i> , quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (<i>i.e.</i> , air, land and water).	
CAA – section 111(b)	Requires EPA establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	EPA has established NSPS for a number of source categories to limit emissions to air of volatile organic compounds (VOCs), which are precursors to the formation of ozone. Acetaldehyde is a VOC. (See <u>link</u>).
CAA – section 112(b)	Contains the original list of 189 hazardous air pollutants (HAPs) that Congress added in 1990. Under 112(c) of the CAA, EPA must identify and list source categories that emit listed HAPs and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has both removed HAPs from and added HAPs to the original list.	Acetaldehyde is listed as a HAP (42 U.S. Code section 7412).
CAA – section 112(d)	Directs EPA to establish, by rule, NESHAP for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For areas sources, the standards must require generally achievable control technology (GACT) though may require MACT. Section 112(d)(6) requires EPA to review, and revise, as necessary, (taking into account developments in practices, processes and control technologies) the emission standards every 8 years.	EPA has established NESHAP for a number of source categories that emit acetaldehyde to air. (See <u>link</u>)
CAA – section 112(f)	Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) NESHAP that require maximum achievable control technology (MACT) and to determine if additional standards are needed to reduce remaining risks; this is required within 8 years of promulgating the NESHAP.	EPA has promulgated a number of Risk and Technology Review (RTR) NESHAP and will do so, as required, for the remaining source categories with NESHAP. (See <u>link</u>).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
CAA – section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	Acetaldehyde is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Acetaldehyde has a reactivity factor of 6.84 g O ³ /g VOC.
CWA – section 301, 304, 306, 307, and 402	CWA section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The list of "priority pollutants" lists the individual chemical names within the toxic pollutants and are found in 40 CFR Part 423 Appendix A. These are pollutants (along with non-conventional pollutants) for which best available technology effluent limitations must be established on either a national basis through rules (sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in National Pollutant Discharge Elimination System (NPDES) permits, see section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable (BAT) for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	Acetaldehyde is a non- conventional pollutant under section 301(b)(2)(F) of the CWA and as such is subject to effluent limitations and any associated monitoring requirements of NPDES permits. (Pollutants that are not found on the toxic pollutant list (40 CFR 401.15) or priority pollutant list (40 CFR 423 Appendix A), or conventional pollutant list (40 CFR 401.16) are non-conventional.)
CWA – section 311(b) (2)(A) and 501(a) of the Federal Water Pollution Control Act.	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	Acetaldehyde is a designated hazardous substance in accordance with section 311(b) (2)(A) of the Federal Water Pollution Control Act (40 CFR section 116.4, see 43 FR 10474 (March 13, 1978)).
SDWA – section 1412(b)	Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years	Acetaldehyde was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate List (CCL) (74 FR 51850, October 8, 2009) (81 FR 81099, November 17, 2016).
Resource Conservation and Recovery Act (RCRA) – section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Acetaldehyde is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U001 (40 CFR 261.33)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
CERCLA – sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances, in addition to those referred to in section 101(14) of CERCLA, those elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold. CERCLA Hazardous substances listed under 40 CFR Table 302.4 are subject to EPCRA section 304 notification requirements.	Acetaldehyde is a hazardous substance under CERCLA. Releases of acetaldehyde in excess of 1000 pounds must be reported (40 CFR 302.4).
Other Federal Regulat	tions	
FFDCA – section 408	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics, except residues of pesticides in food are regulated by EPA under FFDCA section 408 (discussed above where applicable).	FDA established acetaldehyde as a substance generally recognized as safe for use in synthetic flavoring substances and adjuvants (21 CFR 182.60). Acetaldehyde is listed as an optional substance to be used in: Components of Articles Intended for Repeated Use (21 CFR 177.2410)
Occupational Safety and Health Act (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	Acetaldehyde appears in OSHA's annotated PEL tables: OSHA PEL: 200 ppm or 360 mg/m ³ (OSHA Permissible Exposure Limits – Annotated Tables website accessed September 21, 2023).
Federal Hazardous Materials Transportation Act (HMTA)	 Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when 	Acetaldehyde is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	 the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce. 	listed hazardous materials (49 CFR 172).

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants): Toxicity Class I, 24-Hr AAL 161 (µg/m ³), Annual AAL ^B 9.0 (µg/m ³), 24-Hr De Minimis 1.9 (lbs/day), Annual De Minimis 147 (lbs/yr) Rhode Island (Air Pollution Regulation No. 22): Annual AAL 0.5 (µg/m ³)
State Drinking Water Standards and Guidelines	Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017) State MCL: 0.95 (Residential) (mg/L), 2.7 (Nonresidential) (mg/L)
State PELs	California (PEL of 25 ppm and a STEL of N/A) (Cal Code Regs. Title 8, 5155) Hawaii PEL: 100 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. 670.000 Appendix A), New Jersey (N.J.A.C. 7:1G) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing acetaldehyde, including Maine (38 MRSA Chapter 16-D, Chemical of Concern)), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A 1776) and Washington State (Wash. Admin. Code 173-334-130).
Volatile Organic Compound (VOC) Regulations for Consumer Products	Many states regulate acetaldehyde as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products and general degreasers among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Connecticut (R.C.S.A sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20- 735, 20-736, 20-737), Illinois (35 Adm Code 223), Indiana (326 IAC 8-15), Maine (Chapter 152 of the Maine Department of Environmental Protection Regulations), Maryland (COMAR 26.11.32.00 to 26.11.32.26), Massachusetts (310 CMR 7.18), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100), New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235), Ohio (Chapter 3725-112), Pennsylvania (Chapter 130, Subchapter B, sections 130.201 through 130.471), Rhode Island (Air Pollution Control Regulation No. 31), Utah (R 307-357) and Virginia (9VAC5 CHAPTER 45) all have VOC regulations or

State Actions	Description of Action
	limits for consumer products. Some of these states also require emissions reporting.
Other	California listed acetaldehyde on Proposition 65 in 1988 due to cancer. (Cal Code Regs. Title 27, 27001). Acetaldehyde is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code 25252 and 25253 (California, Candidate Chemicals List. Accessed September 8, 2023). Acetaldehyde is on the MA Toxic Use Reduction Act (TURA) list of 2023 (301 CMR 41.00).

Table_Apx A-3. International Laws and Regulations

Country/Organization	Requirements and Restrictions	
Canada	Acetaldehyde is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search. Database accessed October 18, 2023). Acetaldehyde is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). Other regulations include: • Canada's National Pollutant Release Inventory (NPRI). • Environmental Emergency Regulations, 2019.	
EU	Acetaldehyde is registered for use in the EU. (European Chemicals Agency (ECHA) database. Accessed November 28, 2023).	
Australia	Acetaldehyde was assessed under Environment Tier I and Human Health Tiers II & III of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed November 29, 2023). These assessments were carried out by NICNAS, but are now accessed through the Australian Industrial Chemicals Introduction Scheme (AICIS). Uses reported include use as an approved active constituent for use in veterinary chemical products (NICNAS, 2019, <i>Human Health Tier III assessment for Acetaldehyde</i> . Accessed November 29, 2023).	
Japan	 Acetaldehyde is regulated in Japan under the following legislation: Chemical Substances Control Law (CSCL) Pollutant Release and Transfer Registers & Safety Data Sheet Law (PRTR-SDS Law) Industrial Safety and Health Act (ISHA) Air Pollution Control Law Food Sanitation Act High Pressure Gas Safety Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed December 1, 2023). 	
Australia, Austria, Belgium, Canada (Ontario & Quebec), Denmark, EU, Finland, France, Germany (AGS & DFG), Hungary, Ireland, Italy, Japan (JSOH), Latvia, New Zealand,	Occupational exposure limits for acetaldehyde (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed December 1, 2023).	

Country/Organization	Requirements and Restrictions
Norway, People's Republic of	
China, Poland, Romania,	
Singapore, South Africa, South	
Africa Mining, South Korea,	
Spain, Sweden, Switzerland, The	
Netherlands, USA (NIOSH &	
OSHA), United Kingdom	

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

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

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

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

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

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

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

The initial extraction step identified instances of the chemical name and synonyms of the chemical name that appeared as part of a separate, unrelated chemical or substance name (*e.g.*, 3,4-dichloroaniline), as well

as generalized keywords relating to concepts falling outside of PECO and PESO criteria. The results of this extraction were then examined for instances where the chemical name or a synonym appeared in conjunction with a chemical of non-interest, and also met at least one criteria point for a discipline. This subset of the extraction pool was then reintegrated into the peer literature pool for discipline-specific binning.

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

Filtering Step	Filtering Queries		
Initial extraction	tiab_punct:("acetaldehyde" OR "ethanal") tiab:("metal complex*" OR "ligand*" OR ("framework*" AND ("DNA" OR "metal")) OR "polymer*" OR "derivative*" OR "catalyst*" OR "photo*" OR "spectr*" OR "DFT" OR "density functional theory" OR "nano*" OR "synthesis" OR "dye-sensitized" OR "functionalized")		
Reintegration	 tiab:("DNA" OR "photodeg*" OR "spectro*") ((tiab:("occupational health" OR "worker exposure" OR "occupational groups" OR "employee" OR "worker" OR "worker exposed" OR "worke* in a factory" OR "worke* in a plant" OR "worke* in a manufacturing plant" OR "hygienist" OR "OSHA" OR "NIOSH") OR tiab:("carcinogen*" OR "cancer" OR "citology" OR "tumor" OR "mortality" OR "mortality rate" OR "mortality ratio" OR "ats" OR "mortality incidence" OR "cancer incidence" OR "hematuria" OR "intravenous" OR "intra-assay" OR "drosophila" OR "catphila" OR "cytology" OR "atypia" OR ("dog" OR "dogs" OR "cats") NOT "human") OR "oral administration" OR "administration" OR "drosophila" OR "cancer" OR "cytotoxicity" OR "mice" OR "gene" OR "genetic" OR "mutagenicity" OR "genotoxicity" OR "cytotoxicity" OR "LD50" OR "LC50" OR "LT50" OR "D50" OR "P450" OR "carcinoma" OR "bioassay" OR "inmunoassay" OR "cholinesterase" OR "inhibitor" OR "in vivo" OR "in vitro" OR "neoplastic" OR "wirat" OR "sindase" OR "bioassay" OR "inmunoassay" OR "cholinesterase" OR "inhibitor" OR "in vivo" OR "malignant" OR "neoplastic" OR "metatases" OR "oxidase" OR "bydrogenase" OR "dehydrogenase" OR "heoplastic" OR "neoplastic" OR "metatases" OR "inhibitor" OR "preneoplastic" OR "neoplastic" OR "metatases" OR "inmunoescular" OR "inmunoescular" OR "intration" OR "sensitization" OR "attophy" OR "attophy" OR "attophy" OR "attophy" OR "attophy" OR "metological" OR "hopetrension" OR "inheredological" OR "hepaticite" OR "inbred Statciar" OR "inbred MC "attophy" OR "inbred ACT" OR "inbred AC		
	AND ("crystal structure" OR "crystalline structure" OR "morphology" OR "color")) OR "melting		

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

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

Public database searches were conducted for all available years at the time of the search. The literature searches encompassed literature from the earliest date for which literature was available to be searched within each database through January 2023. Search strings were constructed using syntax provided in their respective online search manuals. These are the search terms compiled from agency and industry databases for acetaldehyde used in the initial search strategies for each of the following databases:

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

	Table_Apx B-2. Peer-R	eviewed Literature Search Strategy for Acetaldehyde
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Source	Source-Specific Search Strategy	Results
ProQuest	TIAB("Acetaldehyde" OR "75-07-0" OR "ethanal" OR "acetic aldehyde" OR "ethyl aldehyde" OR "acetaldehyd" OR "acetic ethanol" OR "hydroxyethene" OR "MeCHO")	4,607
PubMed	("Acetaldehyde"[tw] OR "75-07-0"[rn] OR "ethanal"[tw] OR "acetic aldehyde"[tw] OR "ethyl aldehyde"[tw] OR "acetaldehyd"[tw] OR "acetic ethanol"[tw] OR "hydroxyethene"[tw] OR "MeCHO"[tw])	7,968
Scopus	TITLE-ABS({Acetaldehyde} OR {75-07-0} OR {ethanal} OR {acetic aldehyde} OR {ethyl aldehyde} OR {acetaldehyde} OR {acetic ethanol} OR {hydroxyethene} OR {MeCHO})	11,509
Web of Science	TS=("Acetaldehyde" OR "75-07-0" OR "ethanal" OR "acetic aldehyde" OR "ethyl aldehyde" OR "acetaldehyd" OR "acetic ethanol" OR "hydroxyethene" OR "MeCHO")	9,805
Deprioritized Literature Categories	Total literature not meeting initial PECO or PESO refinement	9,739
Total Literature	Total literature considered for systematic review	19,419

Following the identification of potentially relevant peer-reviewed literature on acetaldehyde, SWIFT-Review was used to further refine the peer-reviewed literature pool into discipline-relevant categories via positive and negative seed prioritization and/or discipline-specific keyword filtering depending on that discipline's information needs. Discipline-specific filters predict relevance to a respective discipline or topic based on the presence or absence of applicable keywords and phrases in titles and abstracts. Positive and negative seed prioritization priority ranks individual publications against a predetermined set of references containing desired information (positive seeds) and undesired information (negative seeds). For additional information on the strategies implemented to identify discipline-specific peer-reviewed information, see Section 4.1 of the *Updated Search Strategies Used to Identify Potentially Relevant Discipline-Specific Information* (U.S. EPA, 2024c).

B.2 Identification of Potentially Relevant Gray Literature for Acetaldehyde

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

B.2.1 Gray Literature Sources Considered for Identifying Potential Hazard for Acetaldehyde

Table_Apx B-3 outlines the bibliographical information for the previous assessments considered for Section 2.7.1. Information from both aquatic and terrestrial toxicity studies were considered from all listed

assessments. The quantitative endpoints described in these previous assessments are depicted in the figures within Section 2.7.1.

Assessment HERO ID	Reference	Assessment Label ^a
<u>OEHHA (1993a)</u>	California Environmental Protection Agency (CalEPA) Office of Environmental Health Hazard Assessment. (1993). Acetaldehyde as a Toxic Air Contaminant, Part B: Health Assessment. Sacramento, CA: Air Resources Board, Office of Environmental Health Hazard Assessment.	CalEPA 1993-2
<u>EC/HC (2000)</u>	Environment Canada and Health Canada (ECHC). (2000). Priority Substances List Assessment Report: Acetaldehyde. In Canadian Environmental Protection Act. (Cat. no. En40-215/50E). Ottawa, Canada: Health Canada.	ECHC 2000
<u>IPCS (1995)</u>	International Programme on Chemical Safety (IPCS). (1995). Environmental Health Criteria (EHC) 167: Acetaldehyde [WHO EHC]. In Environmental Health Criteria. Geneva, Switzerland: World Health Organization.	IPCS 1995
^{<i>a</i>} The assessment labels refer to labels associated with previous assessments identified in various figures within Sections 2.7.1.1 and 2.7.1.2.		

Table_Apx B-3. Assessments Identified for Environmental Hazard

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

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

HERO ID	Reference	Assessment Label ^a
<u>ACGIH (2001)</u>	American Conference of Governmental Industrial Hygienists (ACGIH). 2001. Acetaldehyde. American Conference of Governmental Industrial Hygienists. Book title: Documentation of the threshold limit values and biological exposure indices, seventh edition. Page numbers A1-A5. TLV/BEI.	ACGIH 2001
<u>DFG (2023)</u>	Deutsche Forschungsgemeinschaft (DFG). 2023. Acetaldehyde as a food flavoring substance: Aspects of risk assessment. German Research Foundation (DFG). Journal Molecular Nutrition and Food Research. ISSN: 1613-4125 EISSN 1613-4133. Volume 67. Issue 23. Page numbers 2200662. DOI 10.1002/mnfr.202200661.	DFG 2023
EC/HC (2000)	Environment Canada and Health Canada (EC/HC). 2000. Priority substances list assessment report: Acetaldehyde. Health Canada. Cat. no. En40-215/50E. Canadian Environmental Protection Act. ISBN 0662286545.	EC/HC 2000

HERO ID	Reference	Assessment Label ^a			
<u>IPCS (1995)</u>	International Programme on Chemical Safety (IPCS). 1995. Environmental health criteria (EHC) 167: Acetaldehyde. World Health Organization. series: Environmental Health Criteria. ISBN 9789241571678. WHO EHC.	IPCS 1995			
<u>NICNAS (2017)</u>	National Industrial Chemicals Notification and Assessment Scheme: NICNAS. 2017. Acetaldehyde: Human health tier II assessment. Australian Industrial Chemicals Introduction Scheme (AICIS).	NICNAS 2017			
<u>NICNAS (2019)</u>	National Industrial Chemicals Notification and Assessment Scheme (NICNAS). 2019. Acetaldehyde: Human health tier III assessment. Australian Industrial Chemicals Introduction Scheme (AICIS).	NICNAS 2019			
<u>NTP (2021)</u>	National Toxicology Program (NTP). 2021. Acetaldehyde: CAS No. 75-07-0. U.S. Department of Health and Human Services. Book title: Report on carcinogens, fifteenth edition.	NTP 2021			
<u>OEHHA (1993b)</u>	California Office of Environmental Health Hazard Assessment (OEHHA). 1993. Acetaldehyde as a toxic air contaminant: Executive summary. California Office of Environmental Health Hazard Assessment (CalEPA).	OEHHA 1993a			
<u>OEHHA (1993a)</u>	California Office of Environmental Health Hazard Assessment (OEHHA). 1993. Acetaldehyde as a Toxic Air Contaminant, Part B: Health assessment. Air Resources Board and Office of Environmental Health Hazard Assessment.	OEHHA 1993b			
<u>OEHHA (2011)</u>	California Office of Environmental Health Hazard Assessment (OEHHA). 2011. Technical support document for cancer potency values, Appendix B: Chemical-specific summaries of the information used to derive unit risk and cancer potency values. California Office of Environmental Health Hazard Assessment (CalEPA).	OEHHA 2011			
<u>OEHHA (2014)</u>	California Office of Environmental Health Hazard Assessment (OEHHA). 2014. Technical support document for noncancer RELs, Appendix D: Individual acute, 8-hour, and chronic Reference Exposure Level summaries. California Office of Environmental Health Hazard Assessment (CalEPA).	ОЕННА 2014			
<u>U.S. EPA (1991)</u>	Integrated Risk Information System (IRIS). 1991. IRIS Chemical Assessment Summary: Acetaldehyde U.S. Environmental Protection Agency (U.S. EPA).	US EPA 1991			
<u>U.S. EPA (2003)</u>	Integrated Risk Information System (IRIS). 2003. Formaldehyde / vinyl acetate / acetaldehyde: Toxicological review and risk characterization based on mode of action. U.S. Environmental Protection Agency (U.S. EPA).	US EPA 2003			
^{<i>a</i>} "Assessment labels" refer to labels associated with previous assessments identified in various figures and tables within Section 2.7.2, Table_Apx B-4, and Table_Apx C-10.					

Appendix C SYSTEMATIC REVIEW APPROACH – SCREENING OF REASONABLY AVAILABLE INFORMATION

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

TIAB screening efforts are conducted manually as well as using the specialized web-based software programs DistillerSR⁴ and SWIFT-Active-Screener⁵⁶; for the screening review of reasonably available information identified for acetaldehyde, TIAB screening efforts were conducted using SWIFT-Active-Screener, where machine learning helped to prioritize reference screening. Additional details on how SWIFT Active-Screener utilizes a machine-learning algorithm to automatically compute which unscreened documents are most likely to be relevant⁷ are available in Section 4.2.5 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021). During TIAB screening, if it was unclear whether a reference met the screening criteria without having the full reference to review, or if a reference was determined to meet the screening criteria, that reference advanced to full-text screening if the full reference could be retrieved and generated into a Portable Document Format (PDF).

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

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

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

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

⁷ Description comes from the <u>SWIFT-Active Screener web page</u>.

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

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

C.1 Physical and Chemical Properties

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

C.1.1 Screening Criteria for Data Sources Reporting Physical and Chemical Properties In order to be considered, a reference should present measured or modeled values on various physical and chemical properties or endpoints as listed in Table_Apx C-1.

Property or Endpoint				
Physical form or state (<i>e.g.</i> , solid, liquid, gas)				
Physical properties (e.g., color, scent)				
Melting point				
Boiling point				
Density				
Vapor pressure				
Vapor density				
Water solubility				
Octanol-water partition coefficient (also reported as log Kow)				
Octanol-air partition coefficient (also reported as log KOA)				
Henry's law constant				
Dissociation constant				

Table_Apx C-1. Screening Criteria for Data Sources Reporting Physical and Chemical Properties for Acetaldehyde (CASRN: 75-07-0)

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



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

Figure_Apx C-1. Literature Inventory Tree for Physical and Chemical Properties for Acetaldehyde Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of April 29, 2024. Additional data may be added to the interactive version as they become available. View the interactive version of the literature inventory tree in <u>HAWC</u>.

C.2 Environmental Fate and Transport Properties

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

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

T	able_	_Apx C-2	. Sci	reening Criteria for Data Sources Reporting Environmental Fate and Transport	
Properties for Acetaldehyde (CASRN: 75-07-0)					
1				· · · · · · · · · · · · · · · · · · ·	

PESO Element Relevance	Evidence		
<u>P</u> athways and <u>P</u> rocesses	 Fate will use transport, partitioning and degradation behavior across media to inform exposure pathways in conceptual models Exposure pathways included in the conceptual models: Surface water Groundwater Wastewater Drinking water Soil Sediment Biosolids Air Processes associated with the target exposure pathways Bioconcentration and bioaccumulation Destruction and removal by incineration 		
<u>E</u> xposure	 Exposures of aquatic and terrestrial organisms to the chemical substance, mixtures including the chemical substance, and/or degradation products and metabolites of the chemical substance Environmental exposure pathways of humans to the chemical substance, mixtures including the chemical substance, and/or degradation products and metabolites of the chemical substance 		
<u>S</u> etting or <u>S</u> cenario	• All aquatic and terrestrial ecological, general population, and susceptible subpopulation exposure scenarios for releases of the chemical substance to the natural or built environment		
<u>O</u> utcomes	 Fate properties which allow assessments of exposure pathways: Abiotic and biotic degradation rates, mechanisms, pathways, and products Bioaccumulation magnitude and metabolism rates Partitioning within and between environmental media (see Pathways) 		

Items listed in the PESO screening criteria guide the selection of possible and required data types used to complete the data needs table (Table_Apx C-3). Primary source literature containing quantitative data were included if that data described the following environmental fate endpoints in the corresponding media in the table.

Fata Data Endnaint	Associated Processos	Associated Media/Exposure Pathways			
Fate Data Enupoint	Associated 110cesses	Surface water	Soil	Ground water	Air
Abiotic reduction rates or half-lives	Abiotic reduction, abiotic dehalogenation	X			
Aerobic biodegradation rates or half- lives	Aerobic biodegradation	Х	Х		
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	Х	Х	X	
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	Х			
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				Х
BCF BAF	Bioconcentration, bioaccumulation	Х	Х		Х
Biomagnification and related information	Trophic magnification	X			
Desorption information	Sorption, Mobility	X	Х	X	
Destruction and removal by incineration	Incineration				Х
Hydrolysis rates or half-lives	Hydrolysis	X	Х	Х	
K _{AW} and other volatilization information (but NOT Henry's Law constant)	Volatilization, vapor intrusion	Х	Х	Х	Х
K _{OC} and other sorption information	Sorption, mobility	X	Х	X	
Wastewater treatment removal information	Wastewater treatment	X	Х		

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

Supplemental information table

Other types of information that may be useful for completing fate assessments are listed in Table_Apx C-4. This is not an exhaustive list of potential supplemental information.
Table_Apx C-4. Examples of Supplemental Data Used in Developing Fate and Transport Assessments

		Associated Media/Exposure Pathways				
Fate Data Endpoint	Associated Process(es)	Surface water, Wastewater, Sediment	Soil, Biosolids	Ground- water	Air	
Abiotic transformation products	Hydrolysis, photolysis, Incineration	Х			Х	
Aerobic biotransformation products	Aerobic biodegradation	X	Х			
Anaerobic biotransformation products	Anaerobic biodegradation	Х	Х	X		
Atmospheric deposition information	Atmospheric deposition				Х	
Coagulation information	Coagulation, mobility	Х		Х		
Suspension/resuspension information	Suspension/resuspension, mobility	Х				

C.2.2 Literature Inventory Tree – Environmental Fate and Transport Properties Search Results for Acetaldehyde



Figure_Apx C-2. Literature Inventory Tree of Environmental Fate and Transport Properties for Acetaldehyde

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

		Dis 1 [stinct count of Hero I			
	Media					
Endpoints	Air	Water	Grand Total			
Atmospheric cycling/transport	2	1	3			
Biodegradation	1	8	8			
Drinking water treatment		9	9			
Incineration	2		2			
Photolysis	9	2	10			
Grand Total	13	17	29			

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

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

Figure_Apx C-3. Evidence Map of Environmental Fate and Transport Properties for Acetaldehyde

Data in this figure represent the references obtained from the publicly available databases and gray literature references searches that were included in systematic review as of May 17, 2024. Additional data may be added to the interactive version as they become available. View the interactive evidence map in <u>HAWC</u>.

C.3 Occupational Exposure and Environmental Release

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

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

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

Table_Apx C-5. Screening Criteria for the Data Sources Reporting Occupational Exposure and
Environmental Release Information for Acetaldehyde (CASRN: 75-07-0)

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

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

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

Objective	Type of Data ^a			
	weight fractions of the chemicals (s) of interest and material flows of all			
	associated primary chemicals (especially water).			
	5. Number of sites that manufacture, process, or use the chemical(s) of interest			
	for each industrial/ commercial life cycle step and site locations.			
	6. Concentration of the chemical of interest			
Occupational	7. Description of worker activities with exposure potential during the			
Exposures	manufacture, processing, or use of the chemical(s) of interest in each			
	industrial/commercial life cycle stage.			
	8. Potential fouries of exposure (e.g., innatation, definial).			
	9. Physical form of the chemical(s) of interest for each exposure route (e.g.,			
	10 Breathing zone (personal sample) measurements of			
	occupational exposures to the chemical(s) of interest measured as time-			
	weighted averages (TWAs), short-term exposures, or peak exposures in			
	each occupational life cycle stage (or in a workplace scenario similar to an			
	occupational life cycle stage).			
	11. Area or stationary measurements of airborne concentrations of the			
	chemical(s) of interest in each occupational setting and life cycle stage (or			
	in a workplace scenario similar to the life cycle stage of interest).			
	12. Sampling and analytical methodology			
	13. For solids, bulk and dust particle size characterization data.			
	14. Dermal exposure data.			
	15. Exposure duration (hr/day).			
	16. Exposure frequency (days/yr).			
	chamical(s) of interest in each occupational life cycle stage			
	18 PPE types employed by the industries within scope			
	19. Engineering controls employed to reduce occupational exposures in each			
	occupational life cycle stage (or in a workplace scenario similar to the life			
	cycle stage of interest), and associated data or estimates of exposure			
	reductions.			
Environmental	20. Description of sources of potential environmental releases, including			
Releases (to relevant	cleaning of residues from process equipment and transport containers,			
environmental media)	involved during the manufacture, processing, or use of the chemical(s) of			
	interest in each life cycle stage.			
	21. Estimated mass (lb or kg) of the chemical(s) of interest released from			
	industrial and commercial sites to each environmental medium (water) and			
	treatment and disposal methods (POTW), including releases per site and			
	aggregated over all sites (annual release rates, daily release rates)			
	22. Release or emission factors.			
	23. Number of release days per year.			
	24. Waste treatment methods and pollution control devices employed by the			
	and ustries within scope and associated data on release/emission reductions.			
d Those one the tage in the	2.3. According to the sequence of the sequence of the second seco			
describe more specific types of data or information				
In addition to the data type	es listed above, EPA may identify additional data needs for mathematical modeling. These			
data needs will be determined	ined on a case-by-case basis.			

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

Figure_Apx C-4 presents the number of references that report general engineering data, environmental release, and occupational exposure data that passed PESO screening criteria at TIAB, and full-text screening for acetaldehyde. Data or information sources that comply with the screening criteria specified in the PESO screening criteria then undergo data quality evaluation and extraction.



Figure_Apx C-4. Literature Inventory Tree of Occupational Exposure and Environmental Release Search Results for Acetaldehyde (CASRN: 75-07-0)

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

C.3.3 Evidence Map of Occupational Exposure and Environmental Release Information for Acetaldehyde (CASRN: 75-07-0)

		Distinct count of Hero ID
Data Type	Evidence Tag	References
COU	Disposal	12
	Distribution in Commerce	5
	Industrial/Commercial Use	188
	Manufacture - Domestic manufacture	14
	Manufacture-Import	2
	Processing - Processing - repackaging	1
	Processing - Processing as a reactant	19
	Processing - Processing incorporation into formulation, mixture, or reaction product	28
	Processing - Processing- incorporation into articles	37
	Processing - Recycling	1
	Total	249
Environmental	Description of the release source	200
Release	Environmental release media	169
	Release frequency	3
	Release or emission factors	198
	Release quantity	56
	Waste treatment and pollution control	11
	Total	218
General	Chemical Concentration	25
Engineering	Life cycle Description	9
	Number of sites	19
	Process description	47
	Production, Import, or Use Volume	14
	Throughput	12
	Total	76
Occupational	Area sampling data	68
Exposure	Dermal exposure data	8
	Engineering control	24
	Exposure duration	32
	Exposure frequency	14
	Exposure route	47
	Number of workers	30
	Particle size characterization	5
	Personal protective equipment	15
	Personal sampling data	42
	Physical form	34
	Sampling and analytical methodology	42
	Worker Activity description	53
	Total	91
Grand Total		308

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

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

C.4 General Population, Consumer, and Environmental Exposure

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

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

 Table_Apx C-7. Screening Criteria for the Data Sources Reporting Exposure Data on General Population, Consumers, and Environmental Receptors for Acetaldehyde (CASRN: 75-07-0)

PECO Element	Evidence
P opulation	Human : General population; consumers; bystanders in the home; near-facility populations (includes industrial and commercial facilities manufacturing, processing, or using the chemical substance); children; susceptible populations (lifestages, preexisting conditions, genetic factors), pregnant women; lactating women, women of childbearing age. Many human population groups may be exposed.
	Environmental : Aquatic species, terrestrial species, terrestrial plants, aquatic plants (field studies only).
<u>E</u> xposure	 Expected Primary Exposure Sources, Pathways, Routes: Pathways: Indoor air/vapor/mist; indoor dust; particles; surface water; groundwater; outdoor/ambient air; drinking water; land disposal; biosolids/sludge; soil; sediment; aquatic species; terrestrial species; human biomonitoring; dietary; consumer product uses in the home (including consumer product containing chemical). Routes of Exposure: Inhalation, Oral, Dermal.
<u>C</u> omparator (Scenario)	Human : Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which human subpopulations are and are not reasonably exposed across the projected exposure scenarios.
	Environmental : Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	 Human: Acute, subchronic, and/or indoor air and water concentration estimates (mg/m³ or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered. Characteristics of consumer products or articles (weight fraction, emission rates, etc.)
	containing chemical. Environmental : A wide range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations, sediment concentrations.

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



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

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

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

						Distinct co	ount of Hero ID 24
	Study type						
Media	Completed Assessment	Database	Experimental	Modeling	Monitoring	Survey	Grand Total
Ambient (Outdoor) Air	4	5	14	27	240	1	258
Aquatic Species					1		1
Biosolids/Sludge			1		1		2
Building Material			20	3	5		21
Consumer Product or Article	1	1	34	3	7		38
Dietary/Food			8		4		12
Drinking Water			6		6		11
Dust (Indoor)					2		2
Groundwater		1					1
Human Biomonitoring - Blood					1		1
Human Biomonitoring - Dermal			1		1		2
Human Biomonitoring - Milk					1		1
Human Biomonitoring - Tissues, Other			1		15		15
Human Biomonitoring - Urine					3		3
Indoor Air	3	2	36	21	159	1	190
Leachate							0
Other Media	1	1	8	2	49		57
Personal Inhalation	1	1	1	6	17		18
Precipitation				1	18		18
Sediment		1			3		4
Soil		1	1		2		4
Surface Water		1		2	24		26
Terrestrial Species					1		1
Wastewater			1		7		7
Grand Total	6	6	73	39	379	2	457

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

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

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

C.5 Environmental and Human Health Hazard

During data screening, EPA followed the process described in Sections 4.2.5 and 4.3.2 of the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021) to conduct TIAB and full-text screening. Specifically for acetaldehyde literature search results, screening was guided by the PECO screening criteria in Table_Apx C-8. The same PECO screening criteria was used during TIAB and full-text screening for references considered for the evaluation of environmental and human health hazard resulting from exposure to acetaldehyde. For TIAB screening, EPA utilized machine learning to help prioritize reference screening in SWIFT-Active-Screener. Full-text screening occurred manually in DistillerSR for references that either met the PECO screening criteria based on the information available in the title and abstract. While the same PECO screening criteria was used during TIAB and full-text screening, an update to the screening decision was made between TIAB and full-text screening to references that reported meta-analyses with epidemiological data in which originally these references met PECO screening criteria at TIAB screening but were later classified as supplemental information for full-text screening. The rationale for this update being that references with meta-analyses use information of individual studies from sources other than generated by the authors in order to perform their meta-analyses. Figure_Apx C-8 presents the number of references that report environmental and human health hazard data that passed PECO screening criteria at TIAB and full-text screening.

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

Table_Apx C-8. Screening Criteria for Populations, Exposures, Comparators, and Outcomes (PECO) Criteria for Acetaldehyde (CASRN: 75-07-0)

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

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

PECO Element Relevance	Evidence
	mutagenicity, or hormone assay; see bullet above) <i>do not meet the PECO screening criteria</i> .
E	Relevant forms and isomers: • acetaldehyde (CASRN 75-07-0) • Common synonyms of acetaldehyde include Ethanal, Acetic aldehyde, Ethyl aldehyde, Acetic ethanol, and MeCHO. For a full list of synonyms, see list of validated synonyms on the EPA CompTox Chemicals Dashboard. • Isomer(s) (these chemicals are included): • No isomers identified
	Other <i>Supplemental</i> relevant structures (these should be tagged as <i>Supplemental, Other Relevant Structures</i> only if they meet the PECO <u>and</u> if exposure to acetaldehyde is not explicitly mentioned).
	 Degradant(s)/Metabolite(s)/Biomarker(s): Degradants: No degradants are considered. Metabolites: No degradants are considered. DNA adducts used as biomarker of exposure: N2-ethylidene-2'-deoxyguanosine (N2-ethylidene-dG) and 2-methylimidazolidin-4-one adducts Hemoglobin adducts used as a biomarker of exposure: Acetaldehyde-Hb adducts
	Human (Epidemiology): Any exposure to acetaldehyde (CASRN 75-07-0) singularly or in mixture (including co-occurrence and mixtures as defined under TSCA), including exposure as measured by internal concentrations of these chemicals or metabolites of these chemicals in a biological matrix (<i>i.e.</i> , urine, blood, semen, etc.) if acetaldehyde or synonyms are mentioned.
	Animal: Any exposure to acetaldehyde (CASRN 75-07-0) via water (including environmental aquatic exposures), soil or sediment, diet, gavage, dermal (<i>i.e.</i> , exposure to skin), eye, and inhalation will <i>meet screening criteria</i> .
	Plants and Fungi: Any exposure to acetaldehyde (CASRN 75-07-0) including via water, soil, sediment.
	 <u>Human Health Animal Hazard, and Environmental Hazard</u>: Exposure routes not listed above are to be identified as <i>Supplemental, Non-prioritized Exposure Routes</i>. Skin sensitization studies (<i>e.g.</i>, the guinea pig maximization protocol) that include an intradermal induction phase (with application onto the skin during the challenge phase) will <i>meet screening criteria</i>.
	• <u>Epidemiology, Human Health Animal Hazard, and Environmental Hazard:</u> Exposure to the target chemical even if specific exposure concentrations are not reported is sufficient to <i>meet the PECO screening criteria</i> .
	• <u>Environmental Hazard</u> : Field studies with media concentrations (<i>e.g.</i> , surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals, plants, and/or fungi are to be identified as <i>Supplemental</i> , <i>Field Studies</i> <u>only if</u> any biological effects are reported.

PECO Element Relevance	Evidence
	 <u>Human Health Animal Hazard and Environmental Hazard:</u> Animal, plant and/or fungi studies involving exposures to mixtures will <i>meet screening criteria</i> only if they also include exposure to acetaldehyde (CASRN 75-07-0) alone or in the presence of no other non-inert chemicals. Otherwise, mixture studies (including chemical co-occurrence/co-exposure as well as mixtures as defined under TSCA) will be tagged as Unclear during Title/Abstract Screening and as Supplemental, Mixtures during Full Text screening.
	• <u>Human Health Animal Hazard and Environmental Hazard:</u> Chemical plus non- chemical stressor co-exposures (<i>i.e.</i> , chemical + temperature and/or pH, DO, nutrition, feeding rate, culture density, physical injury, light/dark cycles, etc.) will be tagged as <i>Unclear</i> during Title/Abstract Screening and as <i>Supplemental, Chemical plus non- chemical stressor</i> during Full Text screening .
	• <u>Environmental Hazard</u> : Controlled outdoor experimental studies (<i>e.g.</i> , controlled crop/greenhouse studies, mesocosm studies, artificial stream studies) are considered to be similar to laboratory studies (not field studies) because there is a known and prescribed exposure dose(s) and an evaluation of hazardous effect(s). On the contrary, field studies (<i>e.g.</i> , biomonitoring) where there is no prescribed exposure dose(s) will be tagged as <i>Supplemental, Field studies</i> <u>only if</u> there is an evaluated hazardous effect.
	• <u>Epidemiology, Human Health Animal Hazard, and Environmental Hazard</u> : Metabolites of acetaldehyde (CASRN 75-07-0) should be tagged as <i>Supplemental, Other relevant chemical structures</i> if the study meets all PECO screening criteria.
	 Epidemiology, Human Health Animal Hazard, and Environmental Hazard: If biomarkers of exposure are used to assess exposure to the chemical of interest, they will <i>meet the PECO screening criteria</i>. Biomarkers of exposure include measurements of exposure, internal dose, and biologically effective dose (including adducts).
С	 Human (Epidemiology): Any study with a comparison group, control group, or referent group, including: A comparison group that does not have the disease or outcome of interest (such as a case-control study); or
	Any study comparing exposed individuals to unexposed or lower-exposed individuals including:
	 A comparison group with no exposure to the chemical of interest or exposure below detection limits, or A comparison group exposed to lower levels of the chemical of interest; or A comparison group exposed to the chemical of interest for shorter periods of time; or Any study assessing the association between a continuous measure of exposure and a health outcome; or
	For studies in which humans are intentionally exposed to the chemical of interest, an individual can serve as their own control.
	Animal, Plants, and Fungi: A concurrent control group exposed to vehicle-only treatment and/or untreated control (control could be a baseline measurement).

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

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

Table_Apx C-9. Major Categories of Potentially Relevant Supplemental Material for Acetaldehyde (CASRN: 75-07-0) – Title and Abstract and Full Text Screening

PECO Element Relevance	Category	Evidence
Р	Deprioritized ecotoxicological organisms	<u>Environmental Hazard</u> : Studies that assess exposure effects on protozoans, microbial fungi (<i>e.g.</i> , microsporidians), and molds fall under this category because an environmental hazard assessment will unlikely be driven by unicellular organisms or microbial organisms which are low in the natural ecosystem hierarchy.
Р	Indirect exposure	 Environmental Hazard: Studies reporting only indirect effects expressed in taxa that are not the target species of the chemical exposure. Examples include but are not limited to: Plant studies: Substance is used as a means to control pests (<i>e.g.</i>, nematodes), but the study does not report data on nematodes (<i>e.g.</i>, mortality) and only reports data on plant health outcomes (<i>e.g.</i>,

PECO Element Relevance	Category	Evidence
		 plant growth) which are an indirect effect because it is a result of the decrease presence of nematodes. Fish studies: Substance is used as a means to control pathogenic microbes and pests (<i>i.e.</i>, treatment of fungal/parasitic/bacterial infections), and the study only reports health outcomes in fish, which are an indirect effect of the improved health of fish due to diminished presence of pathogenic microbes. Avian studies: Studies reporting increased survival and health of chicks following chemical substance treatment on eggs to prevent growth of bacteria on the eggshell fall in this supplemental category. <u>Reminder</u>: Studies on viruses and any pathogenic microbes (unless bacteria or yeast used for assessing genotoxicity, mutagenicity, or hormone assay; see screener notes under P) <i>do not meet PECO screening criteria</i>.
E	Non-prioritized Exposure Routes	Human Health Animal Hazard, and Environmental Hazard: Examples include but not limited to injection (<i>e.g.</i> , intraperitoneal, intravenous, subcutaneous, intradermal), rectal exposures, intratracheal, intracranial, and bladder instilling (<i>i.e.</i> , exposure using a catheter).
E	Mixture studies	Human Health Animal Hazard and Environmental Hazard: Experimental mixture studies that are not considered to meet PECO because they do not contain an exposure or treatment group assessing <i>only</i> the chemical of interest. The category does not apply to chemical mixtures of enantiomers and/or diastereomers, and the exposure in these cases would be marked as <i>meeting PECO screening criteria</i> . Mixture studies include chemical co-occurrence/co-exposure studies as well as mixtures as defined under TSCA.
E	Chemical plus non- chemical stressor	<u>Human Health Animal Hazard and Environmental Hazard</u> : Studies where organisms are exposed to the target chemical plus non-chemical stressor(s); <i>i.e.</i> , target chemical + temperature and/or pH, DO, nutrition, feeding rate, culture density, physical injury, light/dark cycles, etc. In these scenarios, the non-chemical stressor is a singular or a range of animal maintenance conditions that are not normal/standard. However, if a study includes a group exposure to the target chemical in normal/standard conditions, the study will <i>meet PECO screening criteria</i> .
E	Other relevant chemical structures	 Epidemiology, Human Health Animal Hazard, and Environmental Hazard: PECO-relevant studies with other chemical structures such as metabolites may be useful later. Metabolites of acetaldehyde should be tagged as <i>Supplemental, Other relevant chemical structures</i> if the study meets all PECO screening criteria. If exposure to acetaldehyde is not explicitly mentioned, these metabolites and other structures of interest should be put into this supplemental category. Structures of interest currently include: DNA adducts used as biomarker of exposure: N2-ethylidene-2'- deoxyguanosine (N2-ethylidene-dG) and 2-methylimidazolidin- 4-one adducts Hemoglobin adducts as biomarker of exposure: acetaldehyde- Hb adducts

PECO Element Relevance	Category	Evidence
E	Field Studies	Environmental Hazard: Field studies with media concentrations (<i>e.g.</i> , surface water, interstitial water, soil, sediment) and/or body/tissue concentrations of animals or plants <i>only if <u>any</u></i> biological effects (<i>i.e.</i> , apical and mechanistic) are reported.
С	Hazard value without negative control or appropriate vehicle control	 <u>Human Health Animal Hazard and Environmental Hazard:</u> Studies that do not explicitly report the use of a control but report hazard values (EC10, NOEC, LOEC, or Environmental Hazard LC50) can be of value for datapoor chemicals. Human Health Animal Hazard LC50 and LD50 studies completed within an acute timeframe will <i>meet PECO screening criteria</i>. <u>Epidemiology:</u> Study designs such as case reports, case series, and case studies without a comparison group will be tracked as <i>Supplemental</i>.
		cohort, retrospective cohort, etc.), case-control, case-crossover, case- referent, case-cohort, cross-sectional, nested case-control, regression, relative risk, risk ratio, odds ratio, hazard ratio, or standardized mortality ratio (SMR) study designs, which all will <i>meet PECO screening criteria</i>).
O, P	Mechanistic studies	Human Health Animal Hazard and Environmental Hazard: Bacteria and yeast studies specific for assessing genotoxicity, mutagenicity (<i>e.g.</i> , Ames assay), or hormone assay will be tagged as potentially <i>Supplemental</i> , <i>Mechanistic</i> .
		Studies on gametes, embryos, or plant or fungal sections capable of forming whole, new organisms will be tagged as potentially <i>Supplemental, Mechanistic</i> . EXCEPTION: Fish and invertebrate embryo (<i>e.g.</i> , zebrafish, fathead minnow, copepod, bivalve embryos) studies are included if they meet all other PECO criteria.
		Epidemiology, Human Health Animal Hazard, and Environmental Hazard: <i>Ex vivo</i> studies where the live organism was not directly exposed to the chemical of interest are to be tagged as <i>Supplemental, Mechanistic</i> . For all non- <i>in vivo</i> studies, sub-organ level health outcomes are to be tagged as <i>Supplemental, Mechanistic</i> .
		ADME studies: In vitro Environmental Hazard studies investigating ADME are to be tagged as Supplemental, Mechanistic, sub tag: ADME.
		<i>In vitro</i> and <i>in vivo</i> Human Health Animal Hazard and Epidemiology ADME studies designed to capture information regarding transformation (<i>i.e.</i> , ADME) without assessing a health outcome are to be tagged as <i>Supplemental, Mechanistic, sub tag: ADME</i> .
0	Susceptible populations (no health outcome)	Epidemiology and Human Health Animal Hazard: Studies that identify potentially susceptible subgroups but do not report a health outcome.
		Screener note: If biological susceptibility issues are clearly present or <i>strongly</i> implied in the title/abstract, this supplemental tag may be applied

PECO Element Relevance	Category	Evidence
		at the Title/Abstract Screening. If uncertain at title/abstract, do not apply this tag to the reference during the Title/Abstract Screening.
P, E, C, O	Non-English language records	Epidemiology, Human Health Animal Hazard, and Environmental Hazard: Non-English records will be tracked as potentially relevant supplemental information.
P, E, C, O	Other potentially relevant data sources	 Epidemiology, Human Health Animal Hazard, and Environmental Hazard: Records that may not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries and conference proceedings or abstracts. Epidemiology: Meta-analyses will be tagged as Supplemental, Other potentially relevant data sources, sub tag: Meta-analyses.

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



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

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

C.5.3 Evidence Map of Environmental Hazard Information

Distinct count of Hero ID

	Ecosystem / Taxonomic group						
		Aquatic		Terrestrial			
Health outcome	Invertebrate	Vertebrate	Vegetation and Fungi	Invertebrate	Vertebrate	Vegetation and Fungi	Grand Total
Accumulation/ADME				1			1
Behavior		1		6			7
Biochemical/Biochemistry, Enzyme(s), Hormone(s)				1		1	2
Biomarkers							0
Cancer/Carcinogenesis							0
Cell signaling/function							0
Computation toxicology and data integration							0
Cytotoxicity			1			1	2
Development		2	4	1	1		8
Ecosystem processes							0
Enhanced adipogenesis							0
Epigenetics							0
Genotoxicity				3		1	4
Growth			2			4	6
Histology							0
Immobilization	1						1
Morphology		1					1
Mortality	6	9		11	1		25
Oxidative stress							0
Photosynthesis/Respiration			1				1
Physiology/organ function							0
Population							0
Receptor binding/regulation of receptor activity							0
Reproduction				1			1
Grand Total	7	9	7	18	1	6	43

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

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

	Exposure type							
Health outcome	Animal toxicity			Epidemiology				
	Dermal	Inhalation	Oral	Dermal	Food	Inhalation	Ocular/Eye	Grand Total
Cancer/Carcinogenesis		8	1			3		12
Cardiovascular		9	4	1		4		17
Gastrointestinal	2	2	8					10
Hepatic/Liver	2	14	16					30
Immune/Hematological	2	18	9	3	1	4	1	31
Irritation(skin, eye)	6	5	2	3		2	1	15
Lung/Respiratory	2	27	8	6	2	18	4	53
Mortality	3	18	12					30
Musculoskeletal		1	1					2
Neurological/Behavioral	2	14	16	2	1	3	2	33
Nutritional/Metabolic	3	19	12					32
Ocular/Sensory		2	2	4	2	5	3	9
Other	2	20	11	1	1	3	1	33
Renal/Kidney	2	13	7					20
Reproductive/Developmental		5	5					10
Sensitization	1			2				3
Skin/Connective Tissue	1	2	4	5	2	4	2	12
Thyroid		4	3					7
Grand Total	8	41	28	9	2	22	5	97

C.5.4 Evidence Map of Human Health Hazard Information

Distinct count of Hero ID

27

Figure_Apx C-10. Evidence Map of Human Health Hazard Information

Data in this figure represent all references obtained from the publicly available databases that were included in systematic review as of May 15, 2024. Additional data may be added to the interactive version as they become available. These references are reflected in the Hazard Literature Inventory Tree (Figure_Apx C-8). The X-axis lists exposure types: oral/food/drinking water, dermal, inhalation, and ocular (none yet available for animal toxicity references). The Y-axis lists health outcomes described for each appropriate exposure type. The column totals, row totals, and grand totals indicate total numbers of distinct references. The various shades of color visually represent the distinct number of relevant references identified for each health outcome-taxonomic group pair. Darker colors indicate a higher number of references available for a given health outcome-exposure pair. View the interactive human health outcome heatmap in <u>HAWC</u>.

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

Assessment Label ^a	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
EC/HC 2000	Benchmark Dose for 5% Response (BMC05), male	Sub-Chronic toxicity	357 mg/m ³	Inhalation	Х	
EC/HC 2000	Benchmark Dose for 5%	Sub-Chronic toxicity	445 mg/m ³	Inhalation	Х	

Assessment Label ^a	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
	Response (BMC05), female					
EC/HC 2000	Benchmark Dose for 5% Response (BMC05), male	Sub-Chronic toxicity	218 mg/m ³	Inhalation	Х	
EC/HC 2000	Benchmark Dose for 5% Response (BMC05), female	Sub-Chronic toxicity	17 mg/m ³	Inhalation	Х	
EC/HC 2000	Toxicity Characteristic (TC)	Sub-Chronic toxicity	390 μg/m ³ , Uncertainty Factor: 100	Inhalation	Х	
EC/HC 2000	Toxicity Characteristic (TC)	Sub-Chronic toxicity	490 μg/m ³ , Uncertainty Factor: 100	Inhalation	Х	
EC/HC 2000	Tumorigenic Concentration at 5% (TC05)	Carcinogenicity	86 mg/m ³	Inhalation	Х	
EC/HC 2000	Tumorigenic Concentration at 5% (TC05)	Carcinogenicity	112 mg/m ³	Inhalation	Х	
EC/HC 2000	Tumorigenic Concentration at 5%, Lower Confidence Limit (TCL05)	Carcinogenicity	28 mg/m ³	Inhalation	Х	
EC/HC 2000	Tumorigenic Concentration at 5%, Lower Confidence Limit (TCL05)	Carcinogenicity	72 mg/m ³	Inhalation	Х	
US EPA 1991	Reference Concentration (RfC)	Toxicity (Reference)	9 x10 ⁻³ mg/m ³ , Uncertainty Factor: 1000	Inhalation	Х	
US EPA 1991	Cancer Unit Risk	Carcinogenicity	$\frac{2.2 \text{ x} 10^{-6}}{\mu \text{g/m}^3}$	Inhalation	Х	
IPCS 1995	Tolerable Concentration	Acute Toxicity	2 mg/m ³ , Uncertainty Factor: 20	Inhalation		Х
IPCS 1995	Tolerable Concentration	Carcinogenicity	0.3 mg/m^3	Inhalation	Х	

Assessment Label ^a	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
IPCS 1995	Lifetime Cancer Risk (LCR), Low	Carcinogenicity	11 μg/m ³	Inhalation	Х	
IPCS 1995	Lifetime Cancer Risk (LCR), High	Carcinogenicity	65 µg/m ³	Inhalation	Х	
NICNAS 2019	Tolerable Concentration	Acute toxicity	2.25 mg/m ³ , Uncertainty Factor: 20	Inhalation		Х
NICNAS 2019	Reference Concentration (RfC)	Toxicity (Reference)	9 μg/m ³	Inhalation	Х	
NICNAS 2019	Reference Concentration (RfC)	Toxicity (Reference)	810 μg/m ³ , Uncertainty Factor: 30	Inhalation	Х	
NICNAS 2019	Cancer Unit Risk	Carcinogenicity	2.2 x10 ⁻⁶ μg/m ³	Inhalation	Х	
NICNAS 2019	Inhalation Unit Risk (IUR), 1 in 10,000	Carcinogenicity	50 µg/m ³	Inhalation	Х	
NICNAS 2019	Inhalation Unit Risk (IUR), 1 in 100,000	Carcinogenicity	$5 \ \mu g/m^3$	Inhalation	Х	
NICNAS 2019	Inhalation Unit Risk (IUR), 1 in 1,000,000	Carcinogenicity	$0.5 \ \mu g/m^3$	Inhalation	Х	
NICNAS 2019	Tolerable Concentration	Carcinogenicity	275 μg/m ³	Inhalation	Х	
NICNAS 2019	Reference Concentration (RfC), 24-hr	Toxicity (Reference)	280 μg/m ³ , Uncertainty Factor: 75	Inhalation	Х	
NICNAS 2019	Reference Concentration (RfC), 1-hr	Toxicity (Reference)	1420 μg/m ³ , Uncertainty Factor: 100	Inhalation	Х	
NICNAS 2019	Lifetime Cancer Risk (LCR)	Carcinogenicity	2 x10 ⁻⁴ ppm	Inhalation	Х	
NICNAS 2019	Lifetime Cancer Risk (LCR)	Carcinogenicity	7 x10 ⁻⁷ (no units)	Inhalation	Х	
ОЕННА 1993а	Cancer Unit Risk	Carcinogenicity	5.4 x10 ⁻⁷ mg/m ³	Inhalation	Х	
ОЕННА 1993a	Cancer Unit Risk	Carcinogenicity	1.5 x10 ⁻⁵ mg/m ³	Inhalation	Х	
ОЕННА 1993a	Cancer Unit Risk	Carcinogenicity	9.7 x10 ⁻⁷ ppb	Inhalation	X	

Assessment Label ^a	Endpoint Type	Health Outcome	Value	Exposure Type	Based on Animal Toxicity Data	Based on Epidemiology Data
ОЕННА 1993a	Cancer Unit Risk	Carcinogenicity	2.7 x10 ⁻⁵ ppb	Inhalation	Х	
ОЕННА 1993a	Cancer Potency Unit Risk	Carcinogenicity	2.7 x10 ⁻⁶ mg/m ³	Inhalation	Х	
ОЕННА 1993a	Cancer Potency Unit Risk	Carcinogenicity	4.8 x10 ⁻⁶ mg/m ³	Inhalation	Х	
ОЕННА 1993а	Recommended Exposure Limit (REL)	Chronic Toxicity	9 mg/m ³ (5ppb), Uncertainty Factor: 1000	Inhalation	Х	
OEHHA 1993b	Lifetime Cancer Risk (LCR)	Carcinogenicity	5.4 x10 ⁻⁷ mg/m ³	Inhalation	Х	
OEHHA 1993b	Lifetime Cancer Risk (LCR)	Carcinogenicity	1.5 x10 ⁻⁵ mg/m ³	Inhalation	Х	
ОЕННА 1993b	Lifetime Cancer Risk (LCR)	Carcinogenicity	9.7 x10 ⁻⁷ ppm	Inhalation	Х	
ОЕННА 1993b	Lifetime Cancer Risk (LCR)	Carcinogenicity	2.7 x10 ⁻⁵ ppm	Inhalation	Х	
OEHHA 1993b	Cancer Unit Risk	Carcinogenicity	4.8 x10 ⁻⁶ ppb	Inhalation	Х	
OEHHA 2011	Cancer Unit Risk	Carcinogenicity	2.7 x10 ⁻⁶ mg/m ³	Inhalation	Х	
OEHHA 2011	Slope Factor	Carcinogenicity	1 x10 ⁻² mg/kg/day	Oral	Х	
OEHHA 2014	Reference Exposure Level (REL)	Acute toxicity	750 μg/m ³ , Uncertainty Factor: 60	Inhalation		Х
OEHHA 2014	Reference Exposure Level (REL)	Acute toxicity	470 μg/m ³ (260ppb), Uncertainty Factor: 300	Inhalation	Х	Х
OEHHA 2014	Recommended Exposure Limit (REL), 8hrs	Acute toxicity	300 μg/m ³ (160 ppb), Uncertainty Factor: 300	Inhalation	Х	
OEHHA 2014	Recommended Exposure Limit (REL)	Chronic toxicity	140 μg/m ³ (80ppb), Uncertainty Factor: 300	Inhalation	Х	
ACGIH 2001	Threshold Limit Value (TLV) - Ceiling	Chronic toxicity	45 mg/m ³ (25 ppm)	Inhalation		Х
^{<i>a</i>} "Assessment labels" refers to labels associated with previous assessments identified in various figures and tables within Section 2.7.2 and Table_Apx B-4.						

Appendix D PHYSICAL AND CHEMICAL PROPERTIES

Property	Value(s) ^a	Reference(s)
Molecular formula	CH ₃ CHO	<u>NLM (2023b)</u>
Molecular weight	44.052 g/mole	CRC Press (2023)
Physical form	Colorless liquid (or gas above 21 °C/69 °F) Pungent, fruity odor	<u>NLM (2023b), NLM (2023a)</u>
	Volatile liquid or gas	CRC Press (2023)
Melting point	-123.4 °C	<u>CRC Press (2023)</u> , <u>PhysProp (2023)</u>
Boiling point	20.8 °C	<u>CRC Press (2023)</u> , <u>U.S. EPA (2023a)</u> , <u>Reaxys (2023)</u>
Density	0.7834 g/cm ³ at 18 °C	CRC Press (2023), Reaxys (2023)
	0.788 g/cm ³ at 16 °C	<u>RSC (2023)</u> , <u>Reaxys (2023)</u>
Vapor pressure	750 mm Hg at 20 °C 900 mm Hg at 25 °C	CRC Press (2023)
	902 mm Hg at 25 °C	PhysProp (2023)
Vapor density	1.52 (relative to air $=$ 1)	<u>NLM (2023a)</u>
Water solubility	1.0×10^6 mg/L at $20 - 25$ °C	<u>CRC Press (2023), PhysProp (2023), NLM</u> (2023b)
Octanol:water partition	-0.34	PhysProp (2023)
coefficient (log Kow)	0.45 at 25 °C	<u>CRC Press (2023)</u>
Octanol:air partition coefficient (log KOA)	2.224^{b}	EPI Suite™ (KOAWIN)
Henry's law constant	6.67×10^{-5} atm·m ³ /mol at 25 °C	<u>PhysProp (2023)</u> , <u>NIST (2023)</u>
	-40 °C (closed cup)	<u>NLM (2023b)</u>
Flash point	-38.89 °C (closed cup) -40 °C (open cup)	<u>NLM (2023b)</u>
Autoflammability	175 °C	<u>NLM (2023b)</u>
Viscosity	0.253 cP at 9.5 °C 0.21 cP at 20 °C	<u>NLM (2023a)</u>
UV-Vis absorption	Max absorption at ~289 nm	<u>NIST (2023)</u>
	Absorbs wavelengths >290 nm	<u>Reaxys (2023)</u>
^{<i>a</i>} Measured unless otherwis ^{<i>b</i>} Information was estimated	e noted d using EPI Suite™ <u>U.S. EPA (2012)</u> .	

Table_Apx D-1. Physical and Chemical Properties of Acetaldehyde

Appendix E ENVIRONMENTAL FATE AND TRANSPORT **PROPERTIES**

Property or Endpoint		Reference(s)
	Absorbs wavelengths >290 nm, therefore may	NLM (2023a)
Direct photodegradation (air)	be susceptible to direct photodegradation	
Direct photodegradation (water)	No data identified	
	$t_{1/2} = 6.60 - 10.7$ hours (based on •OH rate constant range of $1.20 \times 10^{-11} - 1.69 \times 10^{-11}$ cm ³ /mole-sec with 1.5E06 •OH/cm ³)	<u>NIST (2023), PhysProp</u> (2023), <u>CRC Press</u> (2023), <u>NLM (2023a)</u>
Indirect photodegradation (air)	$t_{1/2} = 28.4 - 99.8$ days (based on NO ₃ rate constant range of 1.34 x10 ⁻¹⁵ - 4.71 x10 ⁻¹⁵ cm ³ /mole-sec and a 12-hour day with 2.40E08 NO ₃ /cm ³)	<u>NIST (2023)</u> , <u>CRC Press</u> (2023), <u>NLM (2023a)</u>
	$t_{\rm 1/2} = >10 \text{ years (based on O_3 rate constant of} < 5.99 \text{ x}10^{-21} \text{ cm}^3/\text{mole-sec and a 12-hour day} \\ \text{with 7.0E11 O_3/cm}^3)$	<u>NIST (2023)</u>
Indirect photodegradation (water)	No data identified	
Hydrolysis half-life (water)	Not expected to hydrolyze	<u>NLM (2023b)</u>
Aerobic biodegradation (water)	80%, 93%, and 100% over 14 days measured by BOD, TOC, and direct GC, respectively (OECD 301C) at 100 mg/L test substance concentration, with predominantly domestic sewage inoculum, non-adapted	<u>NLM (2023a), ECHA</u> (2023b), <u>ECHA (2023a)</u> , <u>NITE (2023)</u>
	75% over 1 hour (Die-Away Test) in seawater, adaptation not specified	<u>NLM (2023a)</u>
Aerobic biodegradation (soil)	No data identified	
Aerobic biodegradation (sediment)	No data identified	
Anaerobic biodegradation (water)	97% over a 20-day hydraulic retention time in anaerobic biological treatment	<u>NLM (2023a)</u>
	67% in anaerobic lagoon	<u>NLM (2023a)</u>
Anaerobic biodegradation (soil)	No data identified	
Anaerobic biodegradation (sediment)	No data identified	
Bioconcentration factor (BCF) (L/kg wet weight, unless noted)	Upper Trophic Level: 0.9265 Middle Trophic Level: 0.9573 Lower Trophic Level: 0.9636	EPI Suite TM (BCFBAF, Arnot-Gobas method) ^{b}
Bioaccumulation factor (BAF) (L/kg wet weight, unless noted)	Upper Trophic Level: 0.9265 Middle Trophic Level: 0.9573 Lower Trophic Level: 0.9636	EPI Suite TM (BCFBAF, Arnot-Gobas method) ^{b}
Organic carbon:water partition coefficient (log K _{oc})	$0.508 - 0.945^{\circ}$	EPI Suite TM (KOCWIN, K_{OW} method) ^b
Removal in wastewater treatment	Total removal: 92.13% Removal due to biodegradation: ~91%	EPI Suite TM (STPWIN, with BIOWIN $t_{1/2}s)^b$
^{<i>a</i>} Measured unless otherwise noted		

Table Any F-1 Environmental Fate and Transnort Properties of Acataldebyde

^b Information was estimated using EPI Suite[™] (U.S. EPA, 2012).

^cRange calculated using the range of reported log K_{OW} values from <u>PhysProp (2023)</u> and <u>CRC Press (2023)</u>.