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Pollution Prevention

Draft Environmental Risk Assessment for Formaldehyde

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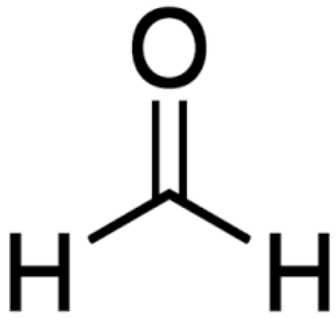

March 2024

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As part of an intra-agency review, the draft Formaldehyde Risk Evaluation was provided to multiple EPA Program Offices for review.

Docket
Supporting information can be found in public docket, Docket ID (EPA-HQ-OPPT-2018-0438).

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Authors: Shawn Shifflett (Assessment Lead), Rochelle Bohaty (Management Lead and Branch Chief), Melody Bernot, Whitney Hollinshead, Giorvanni Merilis, Kevin Vuilleumier

Technical Support: Mark Gibson, Hillary Hollinger.

This draft assessment was reviewed by OPPT, OPP, and OCSPP leadership.

Key Points: Environmental Risk Assessment for Formaldehyde

This assessment considers formaldehyde Toxic Substances Control Act (TSCA) conditions of use (COUs), physical and chemical properties, environmental release data, as well as environmental modeling and monitoring data of formaldehyde and concludes there is

- No risk to aquatic organisms as formaldehyde does not persist in water and exposure is not expected;
- No risk to terrestrial organisms through soil exposure as formaldehyde does not persist in or on land and exposure is not expected;
- No risk to terrestrial mammals through inhalation as air concentrations are at least an order of magnitude lower than the most sensitive toxicity value;
- No risk to other terrestrial taxa, even though no inhalation toxicity data are available for other terrestrial species, as there is at least an order of magnitude difference in the toxicity and exposure for mammals; and
- No risk to plants from formaldehyde exposures in ambient air because air concentrations are 7 times lower than the most sensitive toxicity value.

EXECUTIVE SUMMARY

Formaldehyde is manufactured for a wide variety of commercial and consumer products. It is also a naturally occurring aldehyde produced during combustion, decomposition of organic matter, and as a byproduct of metabolism in living organisms.

EPA reviewed reasonably available information as part of the scope and development of this draft environmental risk assessment for formaldehyde. Specifically, EPA reviewed the environmental fate and transport of formaldehyde (U.S. EPA, 2024b), environmental releases (U.S. EPA, 2024e) and environmental exposures (U.S. EPA, 2024c), as well as reasonably available environmental hazard data (U.S. EPA, 2024d) for aquatic and terrestrial organisms. These evaluations provide the foundation for comparing estimated formaldehyde exposures to environmental hazard data for determining potential risk. Details on each of these topics are provided in the respective modules included as attachments to this draft risk assessment and are summarized below.

EPA assessed formaldehyde in various media (air, water, soil). In some cases, EPA further characterized transformation of formaldehyde to other chemical species to explain how the chemical changes in the environment. EPA does not seek to regulate these transformation products although comparative toxicity data indicate formaldehyde toxicity is protective of transformation product toxicity in aquatic organisms.

Environmental fate and transport data indicate formaldehyde will not persist in water due to its highly reactive nature (U.S. EPA, 2024b, e). Specifically, formaldehyde quickly hydrates in water to methylene glycol and can further transform to other oligomers that are structurally and chemically dissimilar to both formaldehyde and methylene glycol; that is, transformation products do not behave similarly in water (Boyer et al., 2013). Although transformation products were not evaluated for environmental risk, comparative toxicology data for formaldehyde and transformation products are provided in the Environmental Hazard module of this risk assessment (U.S. EPA, 2024d) and demonstrate that formaldehyde toxicity is protective of transformation product toxicity to aquatic organisms. Furthermore, reported releases of formaldehyde waste to water form a smaller component of the total

reported releases to the environment compared to other media such as air and are therefore less common (U.S. EPA, 2024e). Surface water monitoring data indicate formaldehyde is below detection limits in 99 percent of samples (U.S. EPA, 2024c). The single recorded measurement of formaldehyde in water was measured at 0.2 mg/L, which is below the reported detection limit (0.25 mg/L); thus, it is uncertain as a representative measured concentration (U.S. EPA, 2024c). Water monitoring data for formaldehyde may be informative for general context but are not associated either temporally or spatially with known industrial releases to water. Considering these lines of evidence, EPA does not expect formaldehyde will persist in water and therefore concludes there is no risk to aquatic organisms via surface water due to low exposure via the water pathway.

Environmental fate and transport data also indicate formaldehyde will not persist on land (U.S. EPA, 2024b). Specifically, formaldehyde will rapidly react with proton donors on soil particle surfaces and transform to numerous other substances that cannot be effectively characterized. Similar to surface water, formaldehyde will rapidly hydrate in groundwater and can further transform to oligomers of various chain length which will continue to unpredictably react with other chemical substances. These oligomers will generally have different toxicity profiles but are expected to be less toxic than formaldehyde. The predominant environmental release of formaldehyde to land is disposal via underground injection (U.S. EPA, 2024e). Considering these lines of evidence, EPA does not expect formaldehyde will persist in or on land and therefore concludes there is no risk to terrestrial organisms via the land pathway because of low exposures.

Environmental fate and transport data indicate formaldehyde does not bioaccumulate (U.S. EPA, 2024b). Considering the lines of evidence described above regarding the lack of persistence of formaldehyde in water and on land, and because formaldehyde does not bioaccumulate, EPA concludes there is no risk to terrestrial organisms via the dietary pathway.

Environmental fate and transport data indicate formaldehyde can persist in air—although formaldehyde is subject to photolysis or chemical reactions in the presence of free-radicals or other components in the ambient air (including moisture) (U.S. EPA, 2024b). In direct sunlight, the formaldehyde half-life is estimated to be between 1.4 and 4 hours. This persistence can be longer if direct sunlight is not present or if releases are at night. A large portion of reported environmental releases in multiple databases were also identified to the ambient air (U.S. EPA, 2024e). EPA similarly identified ambient monitoring data supporting the persistence of formaldehyde in ambient air, even though the source of monitored formaldehyde may be due to several sources, including industrial releases from TSCA COUs, biogenic[1] sources, or secondary formation from other chemical substances that cannot be determined (U.S. EPA, 2024c). Considering these lines of evidence, EPA expects formaldehyde will be present in ambient air and could result in short, transient exposures to terrestrial organisms. However, attributing these terrestrial exposures to a TSCA-specific COU is difficult due to multiple sources of formaldehyde in ambient air (industrial, biogenic, secondary formation, etc.). EPA evaluated potential environmental exposures of terrestrial organisms to formaldehyde from the ambient air. The Agency's analysis considers the toxicity of formaldehyde exposure to both plants (via air exposure) and terrestrial vertebrates (via inhalation) and compares those to modeled and measured ambient air concentrations. The most sensitive reported toxicity values reported were approximately an order of magnitude higher than the highest measured or modeled formaldehyde concentration in air indicating no risk to both plants and terrestrial vertebrates relative to the most sensitive toxicity endpoints.

[1] Produced by living organisms

1 INTRODUCTION

1.1 Background

Formaldehyde is a gas that is distributed in solution as formalin or in a solid as paraformaldehyde. It is produced industrially and may be used in a wide variety of commercial and consumer products, including textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, construction materials (including insulation and roofing), furniture, toys, and in various adhesives and sealants. Formaldehyde is also a naturally occurring aldehyde produced during combustion, the decomposition of organic matter, and is produced in living things through metabolism. Thus, formaldehyde is ubiquitous in indoor and ambient air environments.

Formaldehyde is a high priority chemical undergoing the TSCA risk evaluation process. There are many COUs for formaldehyde ranging from use in agricultural products to rubber matting. Not all are relevant for this draft risk assessment as it is a TSCA-specific document that serves to support risk management needs by OPPT and is one of many documents comprising the Draft Formaldehyde Risk Evaluation (see Figure 1-1) (Docket ID: EPA-HQ-OPPT-2018-0438).

1.2 Risk Evaluation Scope

The TSCA risk evaluation of formaldehyde comprises several human health and environmental assessment modules and two risk assessment documents—the ecological risk assessment and the human health risk assessment. A basic diagram showing the layout of these assessments and the relationships is provided in Figure 1-1. This OPPT environmental risk assessment is shaded blue. In some cases, modular assessments were completed jointly under TSCA (OPPT) and FIFRA (OPP). These modules are shown in dark gray. This draft assessment relies on the jointly (OPP/OPPT) completed Environmental Hazard Assessment (U.S. EPA, 2024d); the Chemistry, Fate, and Transport Assessment (U.S. EPA, 2024b); and OPPT's Environmental Release Assessment and Environmental Exposure Assessment (U.S. EPA, 2024e) modules.

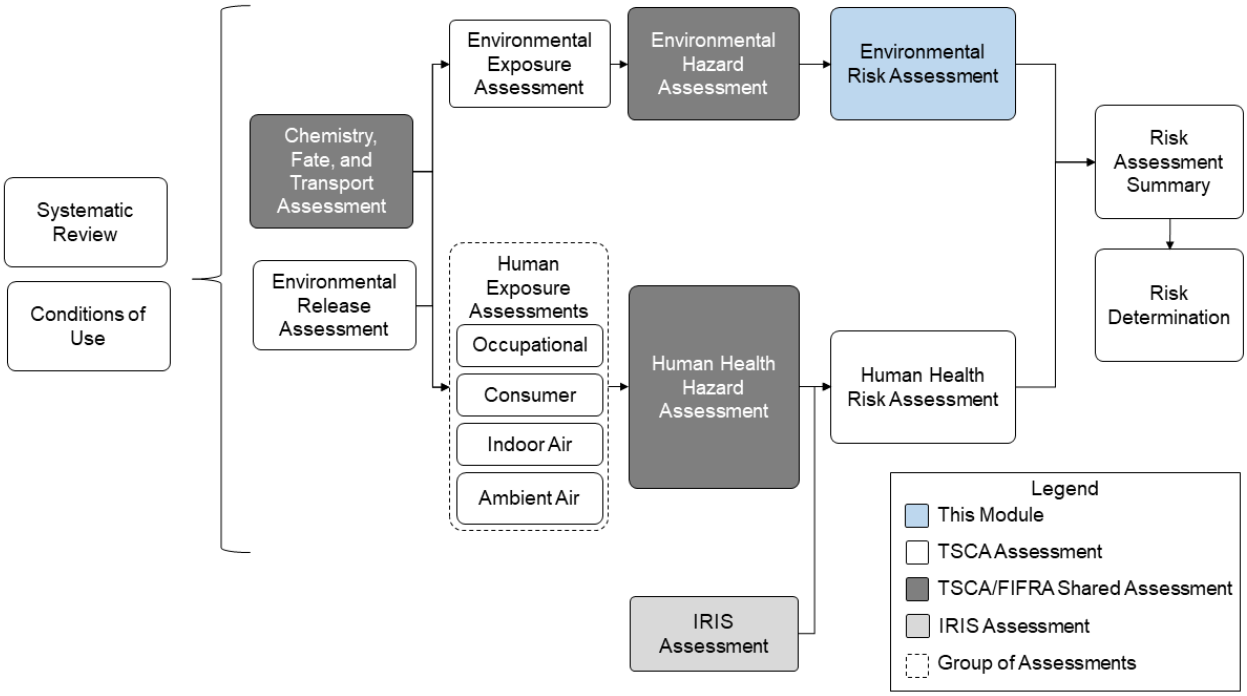

Figure 1-1. Risk Evaluation Document Summary Map

EPA published the *Final Scope for the Risk Evaluation for Formaldehyde 50-0-0* (U.S. EPA, 2020) in August 2020. The published final scope document describes the hazards, exposures, COUs, and other factors EPA expected to consider in its formaldehyde risk evaluation in accordance with the requirements of TSCA section 6(b)(4)(D). Following publication of the final scope document, EPA considered and reviewed reasonably available information[2] in a fit-for-purpose approach to develop this risk evaluation, leveraging existing EPA assessment work, collaborating across offices, relying on best available science, and basing the analyses on the weight of scientific evidence as required by EPA's Risk Evaluation Rule under TSCA (see 82 FR 33726, July 20, 2017). Reasonably available information was reviewed, and the quality evaluated, in accordance with EPA's *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021), which underwent review by EPA's Science Advisory Committee on Chemicals (SACC) in April 2022. A full description of the systematic review protocol for formaldehyde, including chemical-specific protocols, is available in the Systematic Review Supplemental File (U.S. EPA, 2023a).

These modules leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Formaldehyde* (U.S. EPA, 2020). OPPT conducted a comprehensive search for reasonably available information to identify relevant formaldehyde data for use in the risk evaluation. In some modules, data were also located in collaboration with other EPA offices.

1.2.1 Life Cycle and Production

The Life Cycle Diagram (LCD)—which depicts the COUs of use that are within the scope of the risk evaluation during various life cycle stages, including manufacturing, processing, use (industrial,

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

commercial, consumer), distribution, and disposal—is shown below in Figure 1-2. The LCD has been updated since it was included in the *Final Scope for the Risk Evaluation for Formaldehyde 50-00-0* (U.S. EPA, 2020). Agricultural use products (non-pesticidal) have been included; it was inadvertently omitted under the industrial, commercial, and consumer uses lifecycle stage in the diagram in the final scope document.

The current domestic formaldehyde production volume is 453 million to 2.3 billion kg/year. This is based on the Chemical Data Reporting (CDR) Rule under TSCA, which requires U.S. manufacturers (including importers) to provide EPA with information on the chemicals they manufacture or import into the United States every 4 years. For the 2020 CDR cycle, data collected for formaldehyde is further detailed in the *Use Report for Formaldehyde (CAS RN 50-00-0)* (Docket: EPA-HQ-OPPT-2018-0438).

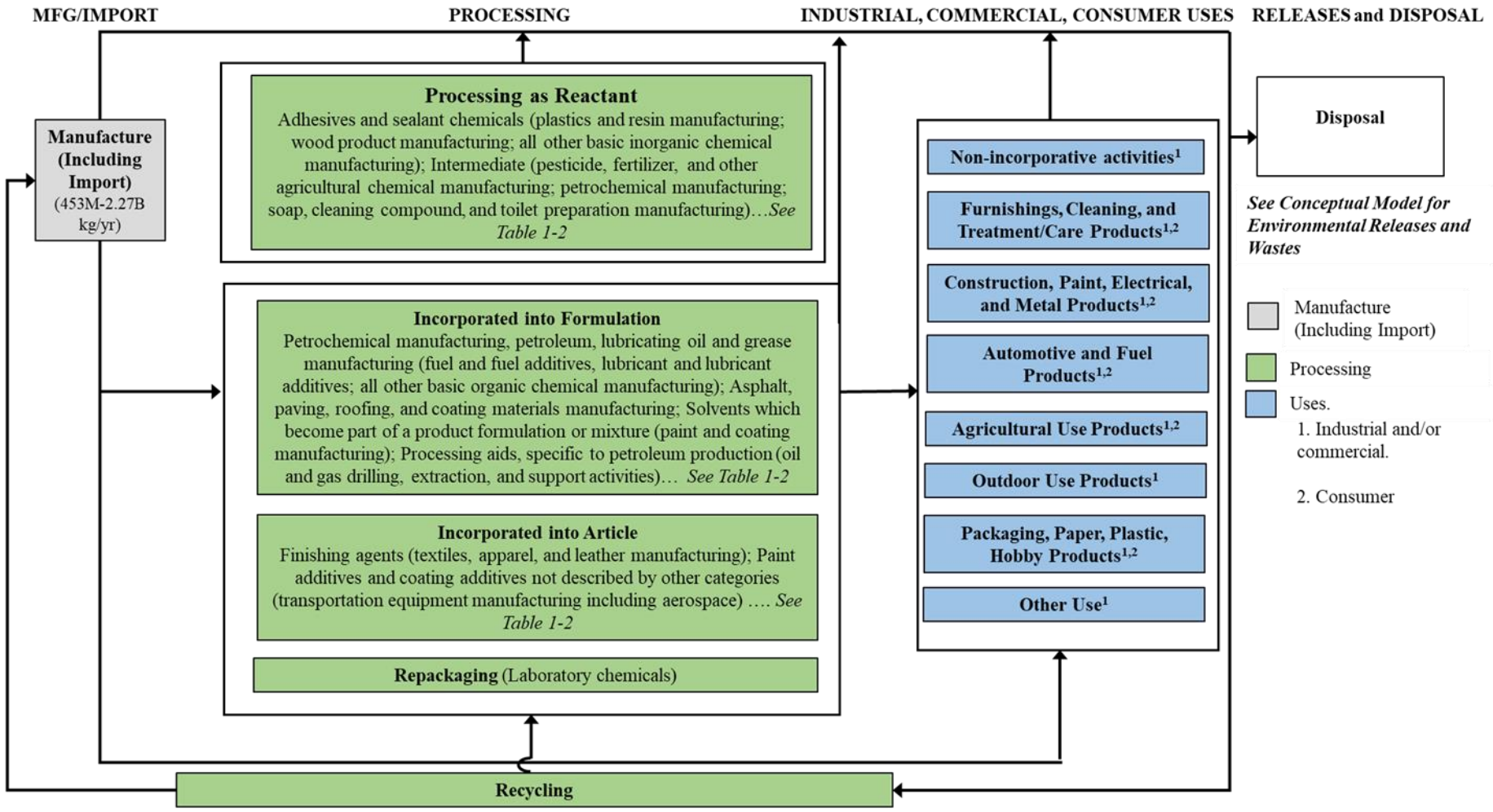

Figure 1-2. Formaldehyde Lifecycle Diagram

1.2.2 Conditions of Use

As part of the TSCA risk evaluation, OPPT is assessing formaldehyde COUs that were included in the final scope document—including industrial, commercial, and consumer applications such as textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, resins, construction materials (including insulation and roofing), furniture, toys, and various adhesives and sealants (see Table 1-1). The COUs were evaluated using the corresponding environmental exposure scenarios for aquatic and terrestrial organisms. A comprehensive description of COUs is available in the *Draft Conditions of Use for the Formaldehyde Risk Evaluation* document (EPA, 2024a).

Table 1-1. Categories and Subcategories of Use and Corresponding Exposure Scenario in the Draft Risk Evaluation for Formaldehyde

Condition(s) of Use		
Life Cycle Stage	**Category**	**Subcategory**
Manufacturing	Domestic manufacturing	Domestic manufacturing
	Importing	Importing
Processing	Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; basic organic chemical manufacturing
Processing	Reactant	Intermediate in: Pesticide, fertilizer, and other agricultural chemical manufacturing; Petrochemical manufacturing; Soap, cleaning compound, and toilet preparation manufacturing; All other basic organic chemical manufacturing; Plastic materials and resin manufacturing; Adhesive manufacturing; chemical product and preparation manufacturing; Paper manufacturing; Paint and coating manufacturing; Plastic products manufacturing; Synthetic rubber manufacturing; Wood product manufacturing; Construction; Agriculture, forestry, fishing, and hunting
Processing	Reactant	Functional fluid in: Oil and gas drilling, extraction, and support activities
Processing	Reactant	Processing aids, specific to petroleum production in all other basic chemical manufacturing
Processing	Reactant	Bleaching agent in wood product manufacturing
Processing	Reactant	Agricultural chemicals in agriculture, forestry, fishing, and hunting
Processing	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing
Processing	Incorporation into an article	Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)
Processing	Incorporation into an article	Additive in rubber product manufacturing
Processing	Incorporation into an article	Adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing
Processing	Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; all other petroleum and coal products manufacturing

Condition(s) of Use		
Life Cycle Stage	**Category**	**Subcategory**
Processing	Incorporation into a formulation, mixture, or reaction product	Asphalt, paving, roofing, and coating materials manufacturing
	Incorporation into a formulation, mixture, or reaction product	Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing
	Incorporation into a formulation, mixture, or reaction product	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing
	Incorporation into a formulation, mixture, or reaction product	Paint additives and coating additives not described by other categories in: Paint and coating manufacturing; Plastic material and resin manufacturing
	Incorporation into a formulation, mixture, or reaction product	Intermediate in: all other basic chemical manufacturing; all other chemical product and preparation manufacturing; plastic material and resin manufacturing; oil and gas drilling, extraction, and support activities; wholesale and retail trade
	Incorporation into a formulation, mixture, or reaction product	Solid separation agents in miscellaneous manufacturing
	Incorporation into a formulation, mixture, or reaction product	Agricultural chemicals (nonpesticidal) in: Agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and other agricultural chemical manufacturing
	Incorporation into a formulation, mixture, or reaction product	Surface active agents in plastic material and resin manufacturing
	Incorporation into a formulation, mixture, or reaction product	Ion exchange agents in adhesive manufacturing and paint and coating manufacturing
	Incorporation into a formulation, mixture, or reaction product	Lubricant and lubricant additive in adhesive manufacturing
	Incorporation into a formulation, mixture, or reaction product	Plating agents and surface treating agents in all other chemical product and preparation manufacturing
	Incorporation into a formulation, mixture, or reaction product	Soap, cleaning compound, and toilet preparation manufacturing
	Incorporation into a formulation, mixture, or reaction product	Laboratory chemicals
	Incorporation into a formulation, mixture, or reaction product	Adhesive and sealant chemical in adhesive manufacturing

Condition(s) of Use		
Life Cycle Stage	**Category**	**Subcategory**
	Incorporation into a formulation, mixture, or reaction product	Bleaching agents in textile, apparel, and leather manufacturing
	Repackaging	Sales to distributors for laboratory chemicals
	Recycling	Recycling
Distribution	Distribution	Distribution in Commerce
Industrial Use	Non-incorporative activities	Process aid in: Oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing
Industrial Use	Non-incorporative activities	Used in: construction
Industrial Use	Non-incorporative activities	Oxidizing/reducing agent; processing aids, not otherwise listed
Industrial Use	Chemical substances in industrial products	Paints and coatings; adhesives and sealants; lubricants
Commercial Uses	Chemical substances in furnishing treatment/care products	Floor coverings; Foam seating and bedding products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; Cleaning and furniture care products; Leather conditioner; Leather tanning, dye, finishing impregnation and care products; Textile (fabric) dyes; Textile finishing and impregnating/ surface treatment products.
	Chemical substances in treatment products	Water treatment products
	Chemical substances in treatment/care products	Laundry and dishwashing products
	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings
	Chemical substances in furnishing treatment/care products	Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles
	Chemical substances in metal products	Construction and building materials covering large surface areas, including metal articles

Condition(s) of Use		
Life Cycle Stage	**Category**	**Subcategory**
Commerical Uses	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products
	Chemical substances in agriculture use products	Lawn and garden products
	Chemical substances in outdoor use products	Explosive materials
	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment
	Chemical substances in packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials
	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; Photographic supplies
	Chemical substances in products not described by other codes	Laboratory Chemicals
Consumer Uses	Chemical substances in furnishing treatment/care products	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles
Consumer Uses	Chemical substances in furnishing treatment/care products	Fabric, textile, and leather products not covered elsewhere (clothing)
Consumer Uses	Chemical substances in treatment products	Water treatment products
Consumer Uses	Chemical substances in treatment/care products	Laundry and dishwashing products
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Consumer Uses	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles

Condition(s) of Use		
Life Cycle Stage	**Category**	**Subcategory**
Consumer Uses	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products
Consumer Uses	Chemical substances in agriculture use products	Lawn and garden products
Consumer Uses	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment
Consumer Uses	Chemical substances in hobby products	Arts, crafts, and hobby materials
Consumer Uses	Chemical substances in packaging, paper, and plastic	Ink, toner, and colorant products; Photographic supplies
Disposal	Disposal	Disposal

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1.3 Chemistry, Fate, and Transport Assessment

EPA considered all reasonably available information identified by the Agency through its systematic review process under TSCA and submissions under FIFRA to characterize the physical and chemical properties as well as the environmental fate and transport of formaldehyde. Physical and chemical properties of formaldehyde, and some known environmental transformation products (methylene glycol, paraformaldehyde) are provided in Table 1-2. Formaldehyde is expected to be a gas under most environmental conditions. Due to the reactivity of formaldehyde, it is not expected to persist in most environmental media but may be abundant due to continual release and formation from secondary sources like combustion or degradation of other organic chemicals.

Table 1-2. Physical and Chemical Properties of Formaldehyde and Select Transformation Products[a]

Chemical Properties	Formaldehyde	Methylene Glycol	Paraformaldehyde
Molecular formula	CH_2O	$CH_2(OH)_2$	$HO(CH_2O)_nH$ (n = 8–100)
CASRN for Chemical Identity	50-00-0	463-57-0	30525-89-4
Molecular weight	30.026 g/mol	48.02 g/mol	$(30.03)_n$ g/mol (varies)
Physical form	Colorless gas	Colorless liquid	White crystalline solid
Melting point	−92.0 to −118.3 °C	−43.8 °C	120 to 170 °C
Boiling point	−19.5 °C	131.6 °C	None identified
Density	0.815 g/cm^3 at 20 °C	1.20 g/cm^3	1.46 g/cm^3 at 15 °C
Vapor pressure	3,890 mmHg at 25 °C	3.11 mmHg at 25°C	1.45 mmHg @ 25 °C
Vapor density	1.067 (air = 1)	None identified	1.03 (air = 1)
Water solubility	<55% 400 to 550 g/L	Miscible	Insoluble
Octanol/water partition coefficient (log K_{OW})	0.35	−0.79	N/A
Henry's Law constant	3.37E−7 atm/m^3·mol at 25 °C	1.65E−7 atm/m^3·mol at 25 °C	N/A

[a] Physical and chemical properties for formaldehyde, methylene glycol, and paraformaldehyde are considered best estimates. Because the chemical substance often exists in a mixture at varying concentrations, these properties can vary based on the equilibration with other chemical substances present. Quality ratings for formaldehyde and select transformation products can be found in the Chemistry, Fate, and Transport Module (U.S. EPA, 2024b).

In water, formaldehyde quickly hydrates in seconds to form methylene glycol which can polymerize to form oligomers of various chain lengths, and paraformaldehyde (U.S. EPA, 2024b) which are all structurally different compounds when compared to formaldehyde (Figure 1-3). Formaldehyde is not expected to be found in aquatic systems for this reason (U.S. EPA, 2024c).

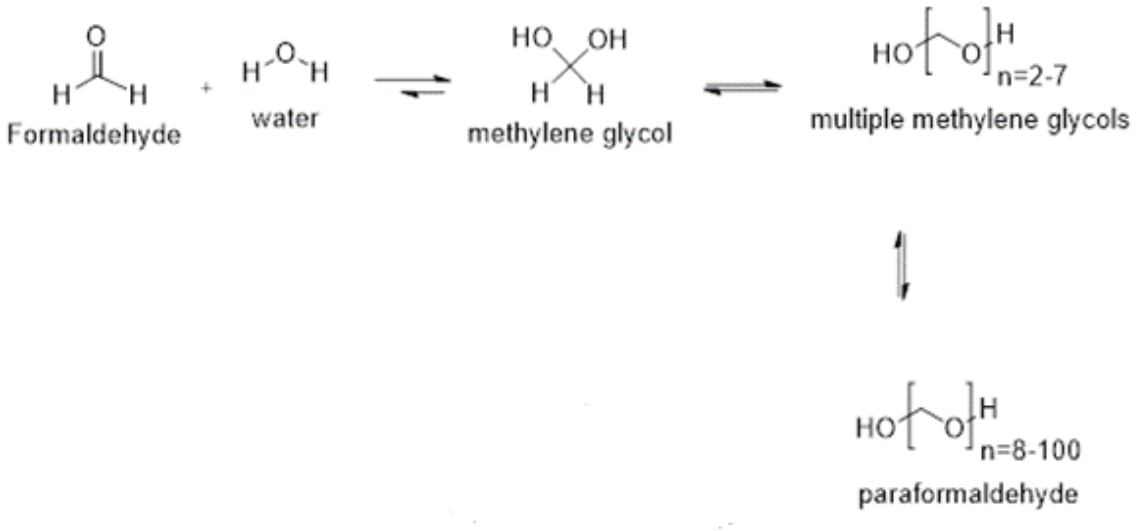

Figure 1-3. Chemical Equilibria for Formaldehyde in Aqueous Solutions
Adapted from (Boyer et al., 2013).

In soil, formaldehyde is also expected to quickly transform to products that are structurally dissimilar to the parent formaldehyde; thus, formaldehyde is not expected to be found in soil (U.S. EPA, 2024b). The transformation products are generally expected to have negligible toxicity; however, not all transformations can be accounted for due to the highly reactive nature of formaldehyde. Formaldehyde can be formed in the early stages of plant residue decomposition in soil and is degraded by bacteria in the soil. Formaldehyde is expected to undergo abiotic (hydration and nucleophilic addition) chemical reactions in soils to form other compounds.

In air, formaldehyde is susceptible to direct and indirect photolysis; however, it may persist in air environments with low or no sunlight (*e.g.*, nighttime). As such, the primary exposure route for formaldehyde is expected to be the air pathway (U.S. EPA, 2024c). More specifically, the half-life of formaldehyde in air depends on the intensity and duration of sunlight and ambient conditions such as temperature and humidity. Under direct sunlight, formaldehyde will undergo photolysis with a half-life up to 4 hours yielding mainly hydroperoxyl radical (HO_2), carbon monoxide (CO), and hydrogen (H_2). In the absence of sunlight, formaldehyde can persist with a half-life up to 114 days.

Bioconcentration and/or bioaccumulation is not expected for formaldehyde due to the physical and chemical properties of the substance (U.S. EPA, 2024b). Furthermore, formaldehyde has a log K_{OW} of 0.35 that similarly confers low potential for bioaccumulation (BAF <1) in both aquatic and terrestrial organisms (U.S. EPA, 2024b). Given the log K_{OW} and associated low BAF, in conjunction with the reactivity of formaldehyde, it is not expected to accumulate in the environment. Therefore, no evaluation of the potential trophic transfer of formaldehyde was conducted.

EPA has high confidence in the overall fate and transport profile of formaldehyde and paraformaldehyde; however, the Agency is less confident in the overall fate and transport of the transformation products methylene glycol and poly(oxy)methylene glycol. Key sources of uncertainty for this assessment are related to formaldehyde equilibrium in various media and subsequent transformation. In cases where there are little fate and transport data, EPA relied on physical and chemical properties to describe the expected fate and transport of the respective chemical. As such, while EPA has some uncertainty in the precision of a specific parameter value, it has confidence in the

overall fate and transport profile of formaldehyde. Additional details can be found in the Draft Chemistry, Fate, and Transport Assessment for Formaldehyde (U.S. EPA, 2024b) document.

1.4 Environmental Release Assessment

Formaldehyde is directly released to all three environmental media (air, land, and water) from TSCA COUs (U.S. EPA, 2024e). It is also released to the environment during regulated non-TSCA uses (*e.g.*, as a pesticide), as a transformation product of different parent chemicals, and from combustion sources.

EPA reviewed release data from the Toxics Release Inventory (TRI; data from 2016 to 2021), Discharge Monitoring Report (DMR; data from 2016 to 2021), and the 2017 National Emissions Inventory (NEI) to identify releases to the environment that are relevant to the formaldehyde COUs, as provided in Table 1-1. From review of these databases, waste streams containing formaldehyde are being directly discharged to surface water, indirectly discharged to publicly owned treatment works (POTW)/wastewater treatment (WWT) plants, disposed of via different land disposal methods (*e.g.*, landfills, underground injection), sent to incineration, and emitted via fugitive and stack releases.

Based on TRI and DMR reporting from 2016 to 2021, less than 150,000 kg each year of formaldehyde are directly discharged to surface water for TSCA-related activities based on reporting from 168 facilities. Approximately 2 million kg each year are indirectly discharged to POTWs or other wastewater WWT plants according to reporting from 168 facilities (U.S. EPA, 2024e). Based on a review of these databases, waste streams containing formaldehyde are transferred to POTW or WWT plants, biological wastewater treatment systems have shown a mean removal efficiency of 99.9 percent for formaldehyde based on literature and 92 percent removal of methylene glycol through biodegredation based on EPISuite™ estimates (U.S. EPA, 2024b). These disposal routes provide additional time for formaldehyde and methylene glycol to further transform to chemically dissimilar products in the presence of water prior to being discharged to surface water.

Based on TRI reporting from 2016 to 2021, most waste of formaldehyde is disposed of via land disposal methods. The most significant method of land disposal of formaldehyde is via underground injection with 22 sites disposing of more than 5 million kg of formaldehyde annually. The amount of waste reported to be disposed of in RCRA Subtitle C landfills and other landfills varies across the reporting years from 200 facilities reporting a total of 423,517 kg per year in 2016 to the most recent year (RY2021) of 127,348 kg per year. Other land disposal methods (*e.g.*, surface impoundments, solidification/stabilization) are also reported at lower levels. Formaldehyde is not expected to persist in water or soils, thus EPA determined that additional analyses of releases to water or land were not needed and targeted its review of release information to fugitive and stack emissions of formaldehyde from TSCA COUs.

EPA identified more than 150,000 point source emission data records (including unit-level estimates) for formaldehyde across the two EPA databases (TRI data from 2016 to 2021 and 2017 NEI). To characterize this amount of data, EPA utilized the self-reported North American Industry Classification System (NAICS) codes to assign sites into CDR industrial sectors. These industrial sectors can be directly correlated with the TSCA COUs, as further discussed in the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024e). Most TSCA COUs indicate one or more industrial sectors, and in some cases an industrial sector can appear in more than one TSCA COU. Therefore, an industrial sector may be associated with multiple formaldehyde TSCA COUs.

For this fit-for-purpose TSCA risk assessment, EPA targeted its review of environmental releases to point sources, and did not review the road, nonroad, and other automotive exhaust information

identified, as formaldehyde produced from combustion sources is not assessed as an independent COU subcategory in this draft risk evaluation. EPA focused its environmental release assessment on total facility emissions which can include emission from both uses of formaldehyde and combustion sources at the same facility or, potentially, only combustion sources from that facility.

EPA categorizes the facilities and corresponding release information by industrial sectors that can be directly correlated to the TSCA industrial COUs. For commercial COUs, EPA used professional judgement to assign the industrial sector to commercial COUs, where applicable. For a few COUs (Commercial use – chemical substances in treatment/care products – laundry and dishwashing products; Commercial use – chemical substances in treatment products – water treatment products; Commercial use – chemical substances in outdoor use products – explosive materials; and Commercial use – chemical substances in products not described by other codes – other: laboratory chemicals), releases were only qualitatively assessed due to limited use information. For the COU Distribution in commerce, formaldehyde released accidently during transit has occurred based on available information, but it was not quantified due to uncertainties in the frequency or volume that may occur in the future. Additional details are provided in the *Draft Environmental Releases for Formaldehyde* (U.S. EPA, 2024e).

In the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024e), EPA identified approximately 800 TRI facilities between 2016 and 2021 and approximately 50,000 NEI facilities in 2017 with reported air releases of formaldehyde (U.S. EPA, 2024e). From these facilities, EPA identified the maximum release reported through TRI was 10,161 kg/year-site (IS: Paper Manufacturing) for a fugitive release reported in 2019 and 158,757 kg/year-site (IS: Wood Product Manufacturing) for a stack release reported in 2017. The NEI program identified sites reporting as high as 138,205 kg/year-site (IS: Wholesale and Retail Trade) for fugitive releases and 1,412,023 kg/year-site (IS: Oil and Gas Drilling, Extraction and Support Activities) for stack releases reporting in 2017, in which the higher releases are associated with sectors not required to report to TRI. The high release sites in NEI were associated with natural gas compressor stations and airport operations, which EPA expects is from combustion sources. EPA analyzed the release information by the industrial sector, providing the minimum, median, 95th percentile, and maximum releases across the entire distribution of reported releases within each industrial sector, as further discussed in the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024e)

In general, EPA has medium to high confidence in environmental releases for industrial COUs[3] and low to medium confidence in commercial COUs[4]. EPA has high data quality ratings for TRI and NEI, which are supported by numerous facility-reported estimates. Some sites that emit formaldehyde may not be included in these databases if the release amount does not meet the reporting threshold for the respective program. EPA used total emissions per site that may combine formaldehyde emissions from multiple COUs if the site's formaldehyde-generating processes are applicable to more than one COU. For example, a facility may manufacture formaldehyde as well as process formaldehyde as a reactant. In some cases, the formaldehyde generating process may also fall outside of scope of the risk evaluation.

1.5 Environmental Exposure Assessment

Although formaldehyde is directly released to water, land, and air, formaldehyde concentrations were not modeled for the water and land pathways because formaldehyde and the corresponding environmental transformation products are not expected to persist in soil and water based on physical-

[3] COUs that are included under the life cycle stage of manufacturing, processing, and industrial use.
[4] COUs that are included under the life cycle stage of commercial uses.

chemical and fate and transport characteristics (see Section 1.3). Formaldehyde air concentrations are estimated and summarized in Section 2.1.

Available environmental formaldehyde monitoring data (*i.e.,* water and ambient air) were reviewed. While the surface water monitoring data for formaldehyde are limited and have many uncertainties, the data are consistent with the conclusion that formaldehyde is not likely to be present in surface water. Formaldehyde concentrations were usually below detection limits. According to the Water Quality Portal (WQP), of 866 formaldehyde monitoring sampling events between 1969 and 2022 (U.S. EPA, 2022b), only 11 percent of samples reported formaldehyde concentrations. However, most formaldehyde concentrations were reported from sampling events before 1975 and the quality of the data could not be verified (U.S. EPA, 2024c). For sampling after 1975, 11 formaldehyde concentrations were detected but were also low quality due to percent recoveries in lab results. Approximately 90 percent of samples had no characterization of the sampling media (*e.g.*, surface vs. groundwater, analytical methodology (*e.g.*, [GC/MS]). Also, for approximately 85 percent of samples, there was no description of the specific forms of formaldehyde measured (*e.g.*, degradants) in water. In addition, replicate sampling was conducted for only 21 samples. Despite formaldehyde's rapid transformation in water, repeat sampling was not conducted over time. The low quality of all detected samples diminished EPA's confidence that the data reasonably represented formaldehyde concentrations in surface water. Agency staff contacted state representatives responsible for those data sets but did not receive a response. Furthermore, monitoring events could not be connected either temporally or spatially with known formaldehyde releases to water resulting from TSCA COUs. Considering these lines of evidence, environmental exposures to formaldehyde are not expected via the water pathway.

Extensive ambient air monitoring data are available for formaldehyde. These data show that formaldehyde is prevalent in ambient air and confirms that air is a major formaldehyde exposure pathway. Although these data represent real formaldehyde concentrations in ambient air, the source is unknown and likely a combination of TSCA and non-TSCA sources (*e.g.*, biogenic, secondary formation of formaldehyde in the environment, etc.). EPA summarizes available formaldehyde ambient air monitoring data in Section 2.1 of this draft assessment. Considering these lines of evidence, EPA expects formaldehyde will be present in air and could result in exposures to terrestrial organisms.

1.6 Transformation Products in Environmental Media

Based on the conclusion of the environmental chemistry, fate, and exposure assessments (U.S. EPA, 2024b, c, e), formaldehyde does not persist in water. It rapidly transforms to methylene glycol and oligomers of various chain length which are similarly reactive and have limited persistence. Data are not reasonably available for assessment of these transformation products and characterizing their downstream effects would result in a highly uncertain risk assessment. Therefore, these transformation products were not further assessed for risk to aquatic or terrestrial organisms, and EPA does not consider formaldehyde or these transformation products a concern in aquatic environments. Likewise, these are out of scope for the Formaldehyde Risk Evaluation. Although transformation products were not evaluated for environmental risk, comparative toxicology data for formaldehyde and transformation products are provided in the Environmental Hazard Module of this risk assessment (U.S. EPA, 2024d) and demonstrate that formaldehyde toxicity is protective of transformation product toxicity to aquatic organisms.

Similarly, rapid transformation of formaldehyde is expected in soil. Data are also not reasonably available for these transformation products and EPA does not consider formaldehyde or these transformation products a concern in soil.

This environmental risk assessment focuses on exposure to formaldehyde (only) in air based on reasonably available data.

1.7 Problem Formulation for Environmental Pathways

Following publication of the final scope document in 2020, EPA considered and reviewed reasonably available information in a fit-for-purpose approach to determine which pathways were relevant for assessments. EPA leveraged existing assessment work, collaborating across offices, relying on best available science, and based on the weight of scientific evidence as required by EPA's Risk Evaluation Rule under TSCA for these risk assessments.

Based on the *Draft Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b), formaldehyde COUs are not expected to result in formaldehyde exposure to aquatic or soil organisms. Therefore, EPA did not pursue assessments of these exposure pathways. In contrast, the Chemistry, Fate, and Transport Assessment Module, as well as ambient monitoring data, indicate that formaldehyde will be present in ambient air and may result in exposure to terrestrial organisms (inhalation, ambient air exposure) based on the continuous release of formaldehyde from various formaldehyde COUs. As such, in this draft environmental risk assessment, EPA focuses on releases to the ambient air and potential exposures resulting from such releases under TSCA COUs to plants and terrestrial organisms. EPA conducted an analysis to evaluate potential environmental exposures of terrestrial organisms to formaldehyde from the ambient air. EPA's analysis compares the toxicity of formaldehyde to plants (via air exposure) and terrestrial vertebrates (via inhalation) to modeled and measured ambient air concentrations.

2 RISK ASSESSMENT APPROACH

EPA used information from all reasonably available sources to characterize exposure, hazard, and risk posed from formaldehyde in air to terrestrial organisms. Modeled or measured environmental concentrations for ambient air reported in the *Draft Environmental Exposure Assessment for Formaldehyde* (U.S. EPA, 2024c) were compared to hazard values for terrestrial organisms reported in the Environmental Hazard Assessment (U.S. EPA, 2024d).

2.1 Ambient Air

The highest measured concentration of formaldehyde in ambient air was 60.1 µg/m^3. The highest modeled concentration of formaldehyde in ambient air for a TSCA COU was 50.5 µg/m^3 (U.S. EPA, 2024c). EPA sought to contextualize these data by modeling all potential sources of formaldehye, including biogenic sources, using AirToxScreen. The sources of these data are summarized below but are described in full in the Ambient Air Exposure Module (U.S. EPA, 2024a).

EPA used the Ambient Monitoring Technology Information Center (AMTIC) (U.S. EPA, 2022a) to determine measured concentrations of formaldehyde in ambient air. It encompasses anthropogenic sources, biogenic sources, secondary formation, mobile sources, combustion sources, and other sources; however, the dataset does not differentiate among the various sources. Samples are submitted to the AMTIC database on a state-by-state basis. Data is provided at the discretion of the submitting program pending approval by AMTIC. Data submitted must meet be collected and quantified using one of the AMTIC pre-approved methodologies (EPA, 2021). Approved sample collection methods included the automated Fluxsense system, pressure vessel collection, or silica cartridge collection followed by quantification by UV absorption, HPLC (high-performance liquid chromatography) photo-diode array, or FTIR (Fourier-transform infrared spectroscopy). Collection durations for Fluxsense systems were set at 5 minutes while pressure vessel and silica cartridge collection durations ranged from 3 hours to 24 hours. All sampling methods were composite samples and concentrations were averaged over the sample collection duration. Monitoring locations and annual summary statistics are provided in the Ambient Air Exposure Module (U.S. EPA, 2024a).

EPA extracted all monitored ambient air concentrations of formaldehyde from the AMTIC ambient air monitoring dataset across 6 years of data (2015 to 2020, n = 233,961 samples, 214 locations). These years were selected to best inform the assessment according to data extracted from TRI for the release assessment. From this dataset, the highest measured formaldehyde air concentration was 60.1 µg/m^3 (U.S. EPA, 2022a). These data are shown in Figure 2-1. These monitoring data are based on multiple monitoring sites (n = 195) from 2015 to 2020. It is worth noting that these data represent different sampling techniques and durations (ranging from 5 minutes to 24 hours sampling periods), but all values shown are above the detection limit. Method detection limits were provided with the concentration data by the submitting agency on a sample-by-sample basis and vary significantly between sampling and quantification methodologies (1×10^{-5} µg/m^3 to 55,900 µg/m^3; median = 4.9 µg/m^3).

EPA used the peer-reviewed Integrated Indoor-Outdoor Air Calculator (IIOAC) to model formaldehyde concentrations in ambient air. The concentrations for all TSCA COUs ranged from 1.1×10^{-4} µg/m^3 to 5.7 µg/m^3 when modeled for distances between 100 and 1,000 m of release facilities and represent annual-averaged modeled concentrations. This range was selected to understand localized impacts from site-ambiguous releasers since formaldehyde will likely undergo complete degradation via photolysis within hours. However, the continuous release of formaldehyde from industrial sources either via fugitive or stack emissions mean that these communities could be continuously exposed to the estimated

concentration. These values are illustrated in Figure 2-1. The highest modeled formaldehyde ambient air concentration was 50.5 µg/m^3 when estimated at 100 m from the release source (not shown). EPA used AirToxScreen to understand the relative contributions of non-TSCA sources to put risks from TSCA sources in context. AirToxScreen uses the chemical transport model (CMAQ) and the dispersion model (AERMOD) to estimate ambient air concentrations across the United States. EPA used data from the 2019 AirToxScreen to understand the relative relationship of formaldehyde concentrations in ambient air resulting from various sources. The tool uses data from the NEI, which is a comprehensive and detailed estimate of air emissions of criteria pollutants, criteria precursors, and hazardous air pollutants from air emissions sources. These data allow EPA to differentiate among modeled emissions from various source categories such as point, nonpoint and mobile sources, biogenic emissions, and fires. In this draft assessment, EPA used data from AirToxScreen to estimate a 95th percentile concentration of formaldehyde from all modeled biogenic sources. This estimate captures concentrations that are reasonably expected to occur without human contributions. The Agency used this estimate for comparison to concentrations from other formaldehyde sources including those that are expected from formaldehyde TSCA COUs. Figure 2-1 shows where TSCA COUs fall in the distribution of all sources of formaldehyde according to AirToxScreen.

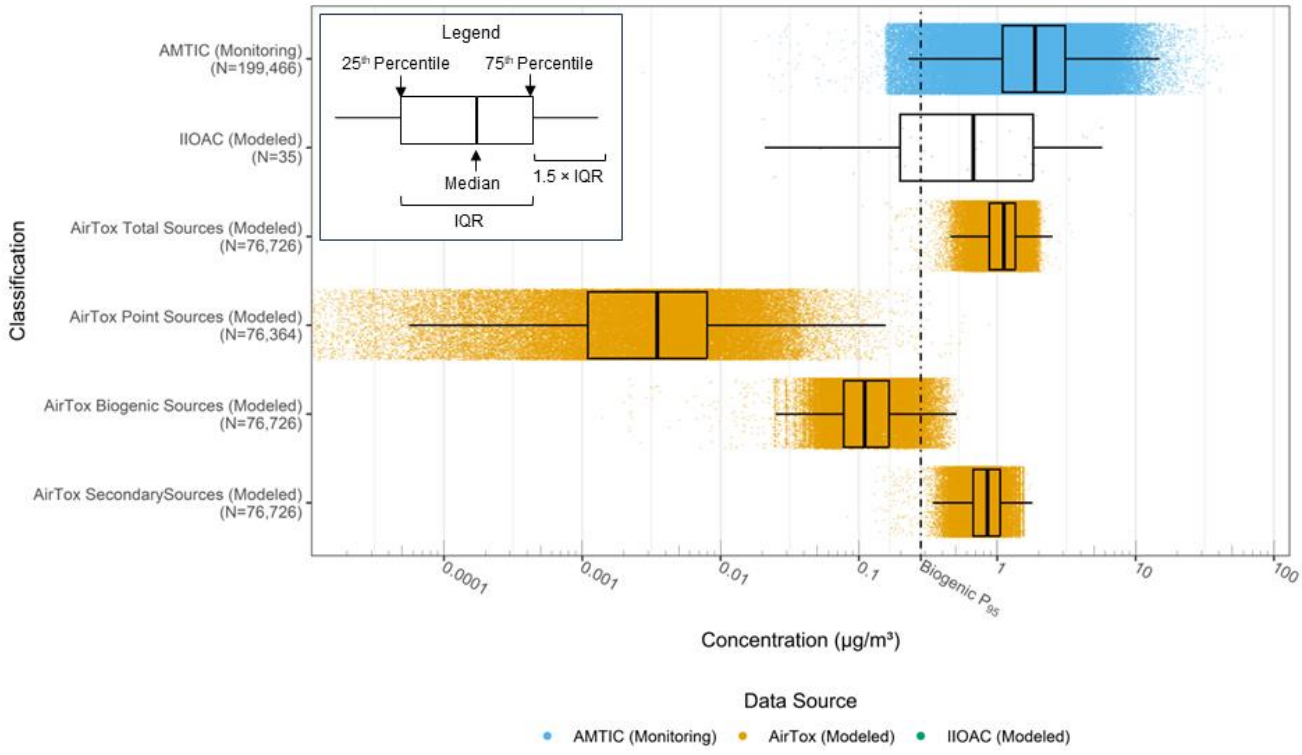

Figure 2-1. Distributions of Ambient Air Formaldehyde Concentration Based on Monitoring Data and Model Data

2.2 Hazard Summary

Several high-quality studies evaluated the toxicity of formaldehyde in ambient air to terrestrial plants though high-quality inhalation toxicity data were limited across terrestrial organisms (U.S. EPA, 2024d). The most sensitive reported endpoint for terrestrial organism exposure to formaldehyde in air was a 4-week exposure in plants (common bean), which yielded a NOAEC of 438 µg/m^3 (Table 2-1) (U.S. EPA, 2024d).

Table 2-1. Summary of the Most Sensitive Toxicity Endpoints for Terrestrial Organisms Exposed to Formaldehyde in Air

Endpoint	Toxicity (µg/m^3)	Exposure Pathway	Exposure Duration	Organism	Citation/MRID
NOAEC	1,230	Inhalation	26 weeks	Terrestrial vertebrate (rat)	MRID 00149755
LOAEC	3,680	Inhalation	26 weeks	Terrestrial vertebrate (rat)	MRID 00149755
NOAEC	438	Air	4 weeks	Terrestrial plant (common bean)	(Mutters et al., 1993)

LOAEC = lowest-observed-adverse-effect-concentration; MRID = Master Record Identification number; NOAEC = no-observed-adverse-effect-concentration
[a] High-ranking studies from OPPT and OPP systematic reviews

2.2.1 Terrestrial Vertebrate Toxicity

While inhalation toxicity studies on formaldehyde are extensive, many do not report apical endpoints which are necessary for ecotoxicity risk evaluation. The most sensitive endpoint that captured effects on an apical endpoint was a 26-week chamber study on adult rats, hamsters, and monkeys exposed to formaldehyde for 22 hours per day for 26 weeks. Decreased body weights were statistically significant in rats at a concentration of 3,680 µg/m^3 from week two (9% decrease) onward (10 to 15% decrease); however, no differences were observed in hamsters or monkeys. Although this study's formaldehyde exposure duration is longer than the shorter-duration intermittent exposures expected in terrestrial environments from OPPT uses, the longer duration exposure toxicity endpoints are expected to be protective of those shorter duration exposures.

The most sensitive reported endpoint for terrestrial vertebrates via inhalation exposure was a 26-week study in rats yielding a LOAEC of 3,680 µg/m^3 and a NOAEC of 1,230 µg/m^3 (Table 2-1) (U.S. EPA, 2024d).

2.2.2 Plant Toxicity

Several high-quality studies were identified for evaluating the effects of formaldehyde on terrestrial plants. No short-term effects were observed in a 4-week fumigation study on the common bean (*Phaseolus vulgaris*) with maximum exposure concentrations of 356 µg/L (438 µg/m^3) NOAEC (Mutters et al., 1993), although there was a linear increase in growth of shoots beginning at 65 µg/L (78 µg/m^3 LOAEC) formaldehyde exposure (Mutters et al., 1993). Reduced growth of pollen tube lengths of lily plants (*Lilium longiflorum*) has also been measured with acute formaldehyde exposure with inhibition of pollen tube growth at 450 µg/m^3 with 5 hours of exposure (72.5% reduction in pollen tube length) and at 1720 µg/m^3 with 1 hour of exposure through fumigation (13.5% reduction in pollen tube length) (Masaru et al., 1976). In *Bromeliaceae* plants (epiphytes), 12 hours of exposure to formaldehyde vapor in chamber experiments at a concentration of 1,000 µg/m^3 reduced chlorophyll content by 17.3 percent (Li et al., 2014).

The most sensitive reported toxicity endpoint for terrestrial plant exposure to formaldehyde in air was a 4-week exposure in the common bean which yielded a NOEAC of 438 µg/m^3 (Table 2-1); (U.S. EPA, 2024d). Overall, plant toxicity endpoints ranged from 438 µg/m^3 (growth effects) in the common bean to 34,188 µg/m^3 in lichen (growth effects).

2.3 Summary of Environmental Risk Assessment

The Agency did not assess risk to aquatic and soil organisms in this risk assessment because exposure is not expected; thus, risk is not expected. The highest measured concentration of formaldehyde in ambient air was 60.1 μg/m^3 and the highest modeled concentration of formaldehyde in ambient air from a TSCA COU was 50.5 μg/m^3 (U.S. EPA, 2024c). Terrestrial organism hazard values are approximately an order of magnitude above the highest measured and modeled concentration of formaldehyde in ambient air (Table 2-2). Thus, no risk to terrestrial organisms is expected relative to the toxicity endpoints.

Table 2-2. Comparison of Formaldehyde Air Concentrations and Terrestrial Organism Toxicity

Receptor	Most Sensitive Toxicity Endpoint (μg/m^3)	Highest Measured Concentration in Ambient Air (μg/m^3)
Terrestrial vertebrates (inhalation)	3,680 LOAEC; 1,230 NOAEC	60.1
Terrestrial plants	438 NOAEC	60.1
LOAEC = lowest-observed-adverse-effect-concentration; NOAEC = no-observed-adverse-effect-concentration		

Hazard data suggest terrestrial plants are the most sensitive terrestrial receptor group to formaldehyde air exposure using apical endpoints. Toxicity endpoints for plants ranged from 438 to 34,188 μg/m^3; thus, the most sensitive endpoint identified is likely protective across taxa. Furthermore, the most sensitive toxicity endpoint identified for mammal inhalation of formaldehyde was only toxic to rats but not toxic to hamsters or monkeys suggesting the most sensitive value is more broadly protective across taxa. The highest concentration of formaldehyde in ambient air (60.1 μg/m^3) is greater than 60 times lower than the lowest concentration that elicited effects on mammal growth (3,680 μg/m^3) with inhalation exposure and greater than 20 times lower than the lowest concentration that did not yield any toxic effect (1,230 μg/m^3). Similarly, the highest concentration is greater than 7 times higher than the lowest concentration that elicited any effect on plant growth (438 μg/m^3).

Although terrestrial organisms may be exposed to formaldehyde in air, EPA did not identify risk to any environmental taxa due to formaldehyde under its conditions of use. The Agency has high confidence in this assessment conclusion.

2.3.1 Terrestrial Vertebrate Risk Assessment

The most sensitive toxicity endpoint for terrestrial vertebrate exposure to formaldehyde via inhalation is at least an order of magnitude higher than the highest measured ambient air concentrations and TSCA COU-modeled formaldehyde concentrations in air; thus, risk to terrestrial vertebrates via formaldehyde inhalation is not expected relative to toxicity endpoints (Table 2-2).

There is uncertainty in potential inhalation exposure durations that are relevant for terrestrial organisms based on formaldehyde use patterns. It is anticipated that most exposures would be short and transient in nature, in the order of minutes to hours, or be intermittent due to the reactive nature of formaldehyde. While formaldehyde exposure duration is longer in the toxicity study than the shorter-duration intermittent exposures expected in terrestrial environments from TSCA uses, the longer duration exposure toxicity endpoints are expected to be protective of those shorter duration exposures because longer term durations are expected to be more toxic.

An additional factor which can impact EPA's ability to attribute exposure for a specific terrestrial organism to a specific TSCA COU is the transient nature of most terrestrial organisms and the absence of specific activity pattern data of such organisms in or around a particular industrial process which could be attributed to a TSCA COU.

2.3.2 Plant Risk Assessment

Modeled and measured concentration data are approximately 7 times below concentrations that would result in adverse effects based on available plant toxicity data. As for terrestrial inhalation exposures, there is uncertainty in the air exposures for plants. The most sensitive reported endpoint for plant air exposure was associated with a 4-week study in the common bean. Given the expected intermittent and short duration exposures expected in the environmental due to TSCA COUs, the study duration is longer than the expected exposure and is assumed to be protective of shorter-term exposures.

2.3.3 Overall Confidence and Remaining Uncertainties in Environmental Risk Assessment

OPPT uses several considerations when weighing the scientific evidence to determine confidence in the draft environmental risk assessment. These considerations include the quality of the database, consistency, strength, and precision, biological gradient/dose response, and relevance. This approach is consistent with the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances (*U.S. EPA, 2021*)*. EPA has high confidence in this environmental risk assessment.

The Agency has high confidence in the conclusion that there is no risk to aquatic organisms relative to toxicity endpoints. Multiple lines of supporting evidence support this conclusion. Environmental fate and transport data indicate formaldehyde rapidly transforms to other forms (chemically dissimilar to formaldehyde) in water and is expected to have negligible persistence in water (as either formaldehyde or its hydrated form methylene glycol). In addition, there are limited releases of formaldehyde directly to surface water. Furthermore, available monitoring data demonstrate formaldehyde has not been detected in water. These qualities support a high confidence conclusion.

EPA has high confidence in the conclusion that there is no risk to terrestrial organisms relative to toxicity endpoints via the land pathway. Multiple lines of evidence support this conclusion. Environmental fate and transport data indicate formaldehyde does not absorb or bind to soil or sediment and has negligible persistence on land (due to volatility and reactivity of formaldehyde) (U.S. EPA, 2024b). Furthermore, formaldehyde is reactive and will volatilize from soils. The predominant environmental release of formaldehyde to land is disposal via underground injection (U.S. EPA, 2024e). These qualities support a high confidence conclusion.

EPA also has high confidence that there is no risk to terrestrial organisms via the dietary pathway. Environmental fate and transport data indicate formaldehyde does not bioaccumulate (U.S. EPA, 2024b). As formaldehyde is also not expected to persist in the water and land pathways, the potential for dietary exposure is limited. These qualities support a high confidence conclusion.

EPA also has high confidence in the conclusion that there is no risk to terrestrial organism via the air pathway as ambient air concentrations are approximately an order of magnitude lower than toxicity values. Both modeled and measured ambient air concentrations support this conclusion and multiple taxa had representative hazard values for evaluation. There is uncertainty in the exposure estimates as formaldehyde exposure is expected to be transient due to its reactive nature. Toxicity endpoints associated with longer exposure durations are expected to be protective of shorter exposures.

Additional details on overall confidence and remaining uncertainties are described in the following modules: Environmental Fate and Transport (U.S. EPA, 2024b), Environmental Hazard (U.S. EPA, 2024d), Environmental Exposure (U.S. EPA, 2024c), and Environmental Release (U.S. EPA, 2024e).

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APPENDICES

Appendix A ABBREVIATIONS AND ACRONYMS

AMTIC	Ambient Monitoring Technology Information Center
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential business information
CDR	Chemical Data Reporting (Rule)
CFR	Code of Federal Regulations
COU	Condition of use (TSCA)
DMR	Discharge Monitoring Report
EPA	Environmental Protection Agency
IIOC	Integrated Indoor-Outdoor Air Calculator (model)
IRIS	Integrated Risk Information System
K_{OC}	Soil organic carbon: water partitioning coefficient
K_{OW}	Octanol: water partition coefficient
LCD	Lifecycle diagram
LOAEC	Lowest-observable-adverse-effect-concentration
LOQ	Limit of quantification
Log K_{OC}	Logarithmic organic carbon: water partition coefficient
Log K_{OW}	Logarithmic octanol: water partition coefficient
MRID	Master Record Identification (number)
NAICS	North American Industry Classification System
NEI	National Emissions Inventory
NOAEC	No-observed-adverse-effect-concentration
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
POTW	Publicly owned treatment works
STORET	STOrage and RETrieval and Water Quality exchange
SVOC	Semi-volatile compound
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
U.S.	United States
UV	Ultraviolet (light)
VP	Vapor pressure
WQP	Water Quality Portal
WWT	Wastewater treatment (plant)

Appendix B LIST OF DOCUMENTS AND SUPPLEMENTAL FILES

List of Documents and Corresponding Supplemental Files

1. Draft Executive Summary for the Formaldehyde Risk Evaluation

2. Draft Conditions of Use for the Formaldehyde Risk Evaluation, (EPA, 2024a)

3. Draft Risk Evaluation for Formaldehyde – Systematic Review Protocol (U.S. EPA, 2023a)
   - *3.1. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties* (U.S. EPA, 2023j)
   - *3.2. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Fate and Transport* (U.S. EPA, 2023d)
   - *3.3. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure* (U.S. EPA, 2023e)
   - *3.4. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure.* (U.S. EPA, 2023f)
   - *3.5. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Extraction Information for General Population, Consumer, and Environmental Exposure* (U.S. EPA, 2023c)
   - *3.6. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Human Health Hazard Epidemiology* (U.S. EPA, 2023i)
   - *3.7. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Human Health Hazard Animal Toxicology* (U.S. EPA, 2023h)
   - *3.8. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Environmental Hazard* (U.S. EPA, 2023g)
   - *3.9. Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology* (U.S. EPA, 2023b)

4. Draft Environmental Risk Assessment for Formaldehyde, (EPA, 2024c)

5. Draft Chemistry, Fate, and Transport Assessment for Formaldehyde, (U.S. EPA, 2024b)

6. Draft Environmental Release Assessment for Formaldehyde, (U.S. EPA, 2024e)
   - *6.1. Supplemental Air Release Summary and Statistics for NEI and TRI for Formaldehyde.xlsx*
   - *6.2. Supplemental Land Release Summary for TRI for Formaldehyde.xlsx*
   - *6.3. Supplemental Water Release Summary for DMR and TRI for Formaldehyde.xlsx*

7. Draft of Environmental Exposure Assessment for Formaldehyde, (U.S. EPA, 2024c)
   - *7.1. Supplemental Water Quality Portal Results for Formaldehyde.xlsx*

8. Draft Environmental Hazard Assessment for Formaldehyde, (U.S. EPA, 2024d)

9. Draft Human Health Risk Assessment for Formaldehyde (EPA, 2024e)

10. Draft Occupational Exposure Assessment for Formaldehyde, (EPA, 2024g)
    - *10.1. Draft Formaldehyde Occupational Exposure Modeling Parameter Summary.xlsx*
    - *10.2. Formaldehyde Draft RE - Occupational Exposure Modeling Parameter Summary - public release - March 2024*
    - *10.3. Formaldehyde Draft RE - Occupational Monitoring Data Summary - public release - March 2024*

11. Draft Consumer Exposure Assessment for Formaldehyde, (EPA, 2024b)
    - *11.1. Formaldehyde Draft RE - Consumer Modeling, Supplement A - public release - March 2024.xlsx*
    - *11.2. Formaldehyde Draft RE - Consumer - Indoor Air Acute and Chronic Inhalation Risk Calculator, Supplement B - public release - March 2024.xlsx*
    - *11.3. Formaldehyde Draft RE - Consumer Acute Dermal Risk Calculator, Supplement B - public release - March 2024.xlsx*

12. Draft Indoor Air Exposure Assessment for Formaldehyde, (EPA, 2024f)
    - *12.1. Formaldehyde Draft RE - Consumer Modeling, Supplement A - public release - March 2024.xlsx*
    - *12.2. Formaldehyde Draft RE - Consumer - Indoor Air Acute and Chronic Inhalation Risk Calculator, Supplement B - public release - March 2024.xlsx*

13. Draft Ambient Air Exposure Assessment for Formaldehyde, (U.S. EPA, 2024a)
    - *13.1. Formaldehyde Draft RE - IIOAC Assessment Results and Risk Calcs Supplement A for Ambient Air - public release - March 2024.xlsx*
    - *13.2. Formaldehyde Draft RE- IIOAC Assessment Results and Risk Calcs Supplement B- public release - March 2024*

14. Draft Human Health Hazard Assessment for Formaldehyde, (EPA, 2024d).

15. Unreasonable Risk Determination of the Draft Risk Determination for Formaldehyde