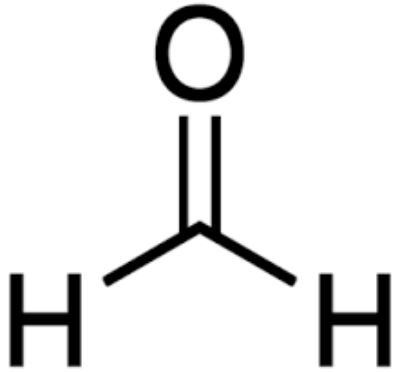
United States
Environmental Protection Agency

December 2024
Office of Chemical Safety and
Pollution Prevention

Environmental Exposure Assessment for Formaldehyde

CASRN 50-00-0



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Key Points: Environmental Exposure Assessment for Formaldehyde

This assessment considers (1) physical and chemical properties as well as fate and transport characteristics, (2) measured formaldehyde concentrations in different media, and (3) modeled formaldehyde concentrations in air. The following bullets summarize the key points of this environmental exposure assessment:

- Environmental exposures to formaldehyde in the aquatic environment are not expected due to fate and transport characteristics as well as a lack of quality monitoring data identifying formaldehyde in water.
- Environmental exposures to formaldehyde in soils and other land media are also not expected for terrestrial populations due to fate and transport characteristics (*e.g.*, inability to sorb, bind to, or persist in soil or organic matter based on the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (EPA, 2024b)) as well as no monitoring data identifying formaldehyde in soil.
- Exposures to formaldehyde in air are expected for terrestrial populations.
    - Modeled formaldehyde concentrations in ambient air associated with a specific Toxic Substances Control Act (TSCA) condition of use (COU) range from 0.0001 to 662 µg/m^3.
        - The highest modeled concentration was 662 µg/m^3 based on reported releases from airports and compressor stations in the wholesale and retail trade industry. This estimated concentration is likely from combustion-sourced formaldehyde.
        - The highest estimated concentration from TSCA sources not related to combustion is from the wood product manufacturing industry and is 66.4 µg/m^3.
        - The lowest modeled concentrations were derived from the rubber product manufacturing industry, mining (except oil and gas) and supporting activities, and industrial gas manufacturing.
    - Monitored formaldehyde concentrations in ambient air have ranged from 0.00012 to 60.1 µg/m^3.

EXECUTIVE SUMMARY

Formaldehyde can be found in the environment for a variety of reasons. It occurs naturally through the decomposition of leaves and brush fires. It can also occur due to the degradation of other organic chemicals resulting in secondary formation. Lastly, formaldehyde can be found in the environment due to anthropogenic activities like stack releases from industrial activities or the burning of fossil fuels. This Environmental Exposure Assessment Module considers environmental concentrations of formaldehyde resulting from environmental releases from TSCA facilities and related activities.

EPA utilized the peer-reviewed Integrated Indoor-Outdoor Air Calculator Model (IIOAC) to estimate formaldehyde concentrations for outdoor air. The modeled estimates are compared to monitoring data from EPA's Ambient Monitoring Technology Information Center from 2015 to 2020 and are presented in the *Ambient Air Exposure Assessment for Formaldehyde* (EPA, 2024a). In brief, the highest modeled formaldehyde outdoor air concentration was 662 µg/m^3 from sites primarily releasing formaldehyde due to combustion of fossil fuels (*e.g.*, airports). The highest modeled outdoor air concentration that does not include combustion sources of formaldehyde (66.4 µg/m^3) came from wood product manufacturing. All of these concentrations exceed the highest monitored value of 60.1 µg/m^3 (EPA, 2024a).

Surface water is not expected to be a significant media for formaldehyde exposures. Based on the available evidence on formaldehyde's physical and chemical properties and lack of supporting monitoring concentrations in surface water, a quantitative assessment could not be performed. Lastly, formaldehyde is highly unlikely to undergo trophic transfers as it is not bioaccumulative. Thus, EPA did not carry any concentrations for surface water or fish tissue into the *Environmental Risk Assessment for Formaldehyde* (EPA, 2024e).

1 INTRODUCTION

1.1 Risk Evaluation Scope

The Toxic Substances Control Act (TSCA) risk evaluation of formaldehyde comprises several human health and environmental assessment modules and two risk assessment documents—the environmental risk assessment and the human health risk assessment. A basic diagram showing the layout of these modular assessments and their relationships is provided in Figure 1-1. This environmental exposure assessment is shaded blue. In some cases, modular assessments were completed jointly under TSCA and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These modules are shown in dark gray.

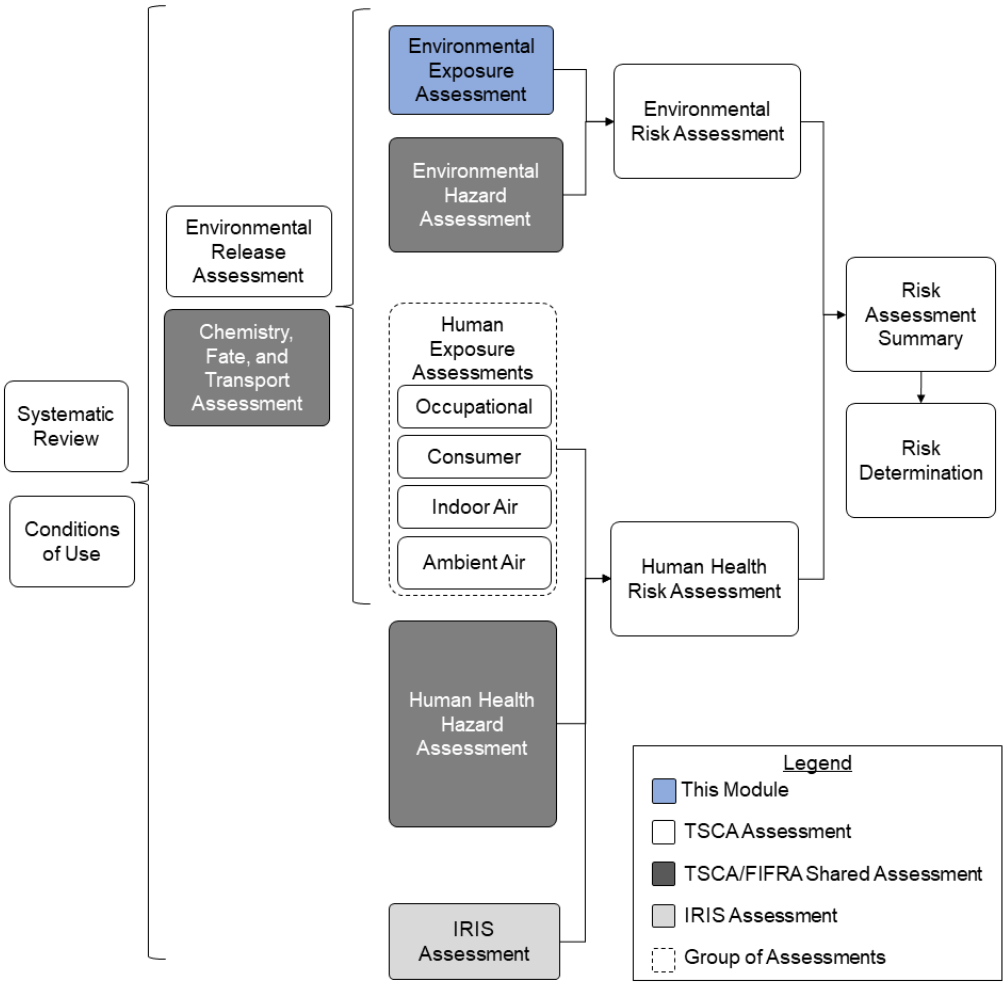

Figure 1-1. Risk Evaluation Document Summary Map

1.2 Changes between Draft and Final Assessment

Key updates to this technical support document from the document that was published with the draft risk evaluation are summarized below:

- EPA has amended language in the ambient air modeling section to be more succinct and references the ambient air module for more detail (see Section 2.1.3).
- EPA has made a clarification in weight of scientific evidence section (2.4).

1.3 Sources Releasing Formaldehyde into the Environment

Formaldehyde is found in the environment for many reasons (IPCS, 2002; ATSDR, 1999). It is produced naturally from the decomposition of leaves, brush fires, and human breath. It is also produced through the breakdown of other organic chemicals in the atmosphere and by combusting organic materials like wood or gasoline. Finally, it may be present due to direct release of formaldehyde from industrial and manufacturing processes.

Environmental releases of formaldehyde from TSCA sources are summarized in the *Environmental Release Assessment for Formaldehyde* (environmental release assessment module) (EPA, 2024d) from multiple databases. Per the environmental release assessment, formaldehyde is released directly to air as reported to the Toxics Release Inventory (TRI) (U.S. EPA, 2024) and National Emissions Inventory (NEI) (EPA, 2019); to land as reported to the TRI; and to water as reported to TRI and the Discharge Monitoring Report (DMR) (EPA, 2020). Environmental releases are categorized by industry sector and mapped to TSCA conditions of use (TSCA COUs) in the environmental release assessment module (EPA, 2024d).

2 EXPOSURES TO ENVIRONMENTAL POPULATIONS

2.1 Terrestrial Exposure

Terrestrial and avian organisms have a wide potential for exposure to formaldehyde in the environment. These exposures may be from natural sources or anthropogenic sources. Terrestrial mammals can be exposed by naturally occuring formaldehyde resulting from the breakdown of organic materials. They can also be transiently exposed after lingering in zones with high industrial releases of formaldehyde. Terrestrial plants are more stationary and might be exposed for longer durations in contrast. Birds can have a more complex exposure profile based on their habitat and migratory behaviors. Because of all the wide potential for exposures, EPA focused this environmental exposure assessment based on the readily available information on ambient air releases, monitoring, and modeling incorporated into the risk evaluation.

EPA considered ambient air releases reported by industry (Section 2.1.1), ambient air monitoring (Section 2.1.2), and performed air modeling of the reported air releases (Section 2.1.3) to qualitatively assess terrestrial population exposures to formaldehyde in ambient air.

2.1.1 Ambient Air Releases

For purposes of this assessment, "ambient air," also commonly referred as "outdoor air," refers to that portion of the atmosphere, external to buildings, to which the environmental populations have access. Although "ambient air" often refers to the general public, it also includes the atmosphere to which animal and plant species have access.

EPA identified more than 150,000 reported releases of formaldehyde from stationary sources to the ambient air across both databases (TRI and NEI) considered in this assessment (environmental release assessment (EPA, 2024d)). Releases are reported to TRI annually (U.S. EPA, 2024) and releases are reported to NEI approximately every 3 years (EPA, 2019). Releases to the ambient air in both databases are reported for two release types: stack and fugitive.

EPA used 6 years of TRI reported releases for this assessment (2016–2021). The Agency also relied upon releases reported via TRI Form R in this assessment as those are actual reported releases. Total reported fugitive releases of formaldehyde from all reporting sites in TRI ranged from 150,467 to 183,133 kg per year (kg/yr) across the years considered and total reported stack releases from all reporting facilities in TRI ranged from 1,939,308 to 2,222,605 kg/yr (U.S. EPA, 2024).
EPA considered 1 year of NEI reported releases (2017) for this assessment. NEI captured more formaldehyde releasing facilities than TRI based on different reporting threshold requirements and additional industry sectors not captured by TRI. Based on the 2017 NEI, total reported fugitive releases of formaldehyde were 7,568,972 kg/yr and total reported stack releases from all reporting facilities were 17,869,243 kg/yr (EPA, 2019).

2.1.2 Ambient Air Monitoring

EPA considered a total of 306,529 samples from the Ambient Monitoring Technology Information Center (AMTIC) database (EPA, 2024a). The Agency computed summary statistics for all samples, as well as samples by state, census tract, monitoring site, monitoring site and year, and monitoring site and year and quarter. Sample collection durations ranged from 5 minutes to 24 hours using one of five approved collection methods. No data were omitted based on collection duration or method. Entries with concentrations reported below the self-reported limit of detection or contained invalid concentration data (*i.e.*, NULL, NA) were omitted from the final dataset. Formaldehyde concentrations were converted to

µg/m^3 for consistency across sample analysis methods but were not otherwise normalized by sample collection duration or methodology. EPA used the overall statistics across all samples to characterize exposures, derive risk estimates, and characterize risks (see Table 2-1). Histograms and summary statistics of annual data are shown in Figure 2-1.

Table 2-1. Overall Monitored Method Detection Limits (MDL) of Formaldehyde from AMTIC Dataset (2015–2020)

Monitored Concentration Statistics (µg/m^3)							
Group	**Entry Count**	**Minimum**	**Non-zero Minimum**	**Median**	**Mean**	**Standard Deviation**	**Maximum**
Grouped by: all samples							
All	233,961	0	0.00012	1.6	2.1	2.2	60
Grouped by: collection duration description							
12 Hours	340	0.50	0.50	3.6	3.8	1.7	9.0
24 Hours	39,288	0	0.0015	2.3	2.8	2.1	60
3 Hours	5,870	0	0.0083	3.7	4.4	3.3	45
5 Minutes	184,307	0	0.00012	1.3	1.8	2.0	49
6 Hours	1	3.4	3.4	3.4	3.4	–	3.4
8 Hours	4,155	0.0055	0.0055	3.6	4.1	2.8	24
Grouped by: collection method description							
6-L Pressurized Canister	67	3.5	3.5	11	14	7.9	42
Cartridge DNPH on Silica, Heated O3 Denuder	6,671	0	0.020	2.3	2.7	1.8	46
Cartridge DNPH On Silica	10,115	0	0.024	3.1	3.7	2.6	60
Fluxsense	184,307	0	0.00012	1.3	1.8	2.0	49
Silica-DNPH-Cart-Ki O3 Scrub	32,801	0	0.0015	2.5	3.0	2.3	45

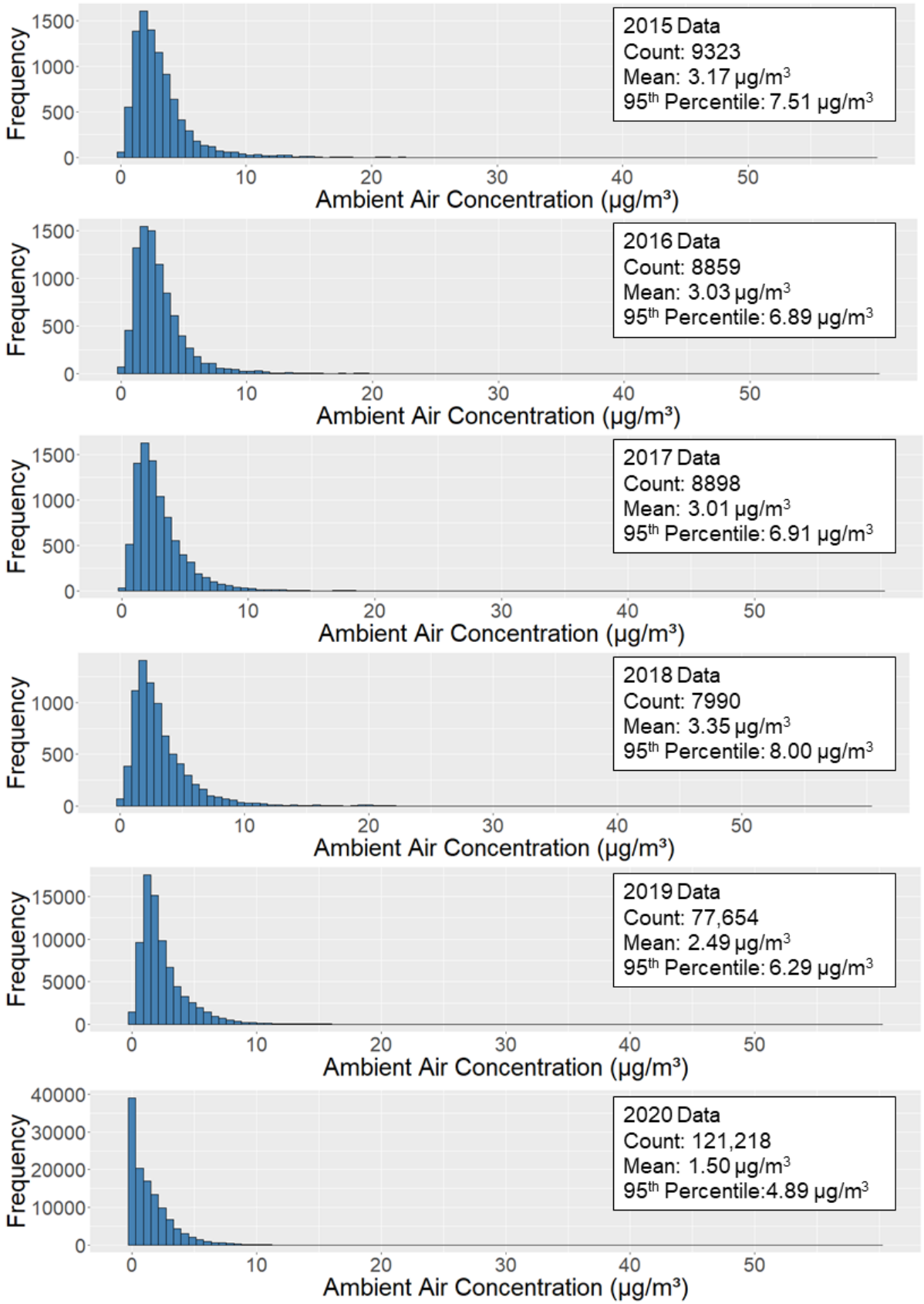

Figure 2-1. Histograms of Ambient Air Concentrations (µg/m^3) of Formaldehyde across Contiguous United States from 2015 to 2020

From the overall AMTIC dataset, samples were collected from June 1, 2015, through December 31, 2020. Within this dataset, EPA found 24 percent of entries lacked standardized concentration data. The Agency also found 15 percent of samples fall below the standard method detection limit (MDL) with a mean standardized formaldehyde concentration of 2.1 ± 2.2 µg/m^3. The overall monitoring dataset had concentrations ranging from 0 to 60 µg/m^3 with a median value of 1.6 µg/m^3. Figure 2-2 shows the location and relative concentration of formaldehyde at each formaldehyde monitoring site.

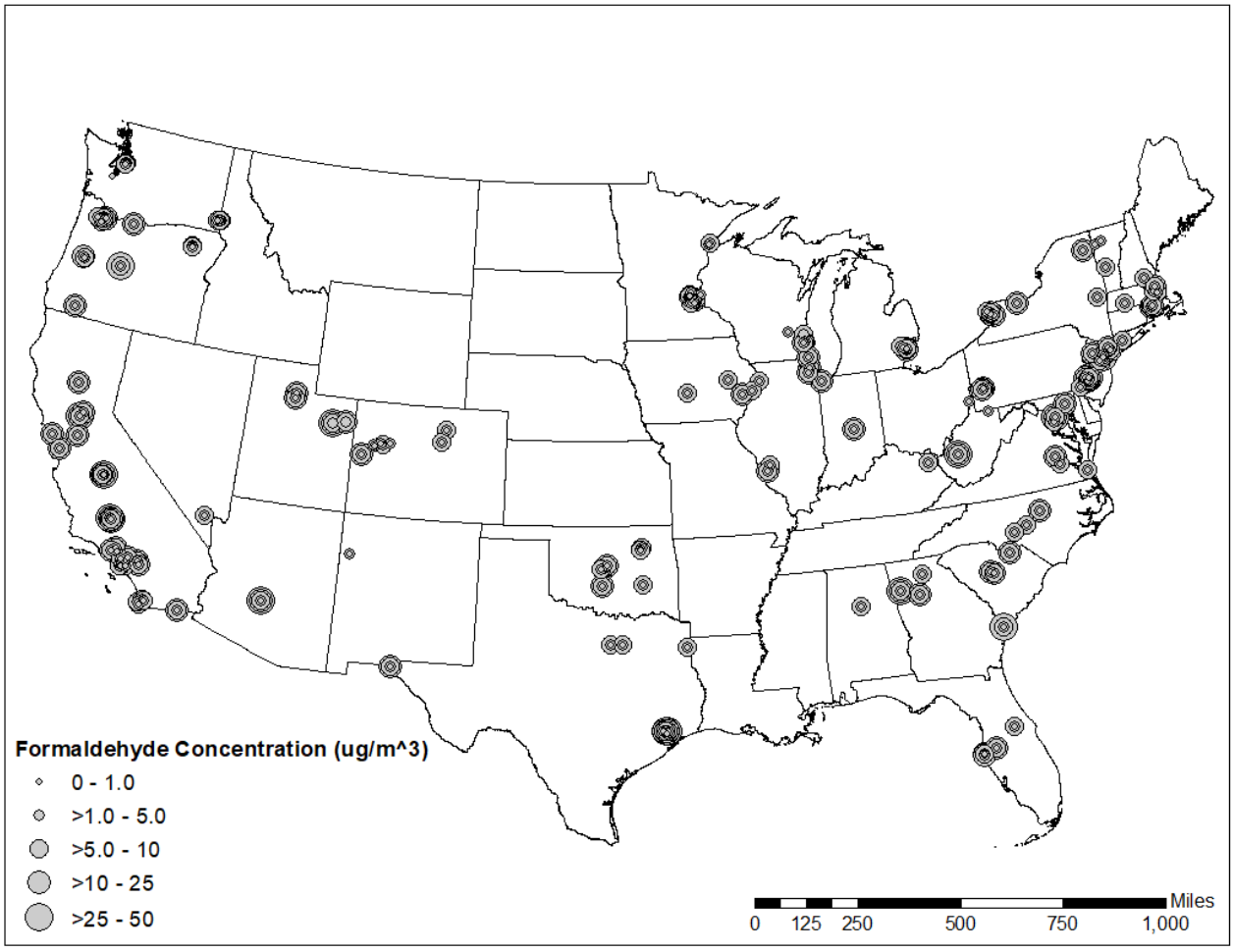

Figure 2-2. Map of Monitoring Sites for Formaldehyde across the Contiguous United States

2.1.3 Ambient Air Modeling

EPA modeled a suite of exposure scenarios with the Integrated Indoor-Outdoor Air Calculator (IIOAC), including releases from two separate datasets (TRI and NEI). These results are provided in the *Ambient Air Exposure Assessment Results and Risk Calcs Supplement A* to the *Ambient Air Exposure Assessment for Formaldehyde* (EPA, 2024a).

Modeled daily average exposure concentrations based on the maximum release and 95th percentile modeled concentrations at 100 m from a releasing facility that are primarily attributable to TSCA COUs range from 0.0004 to 66 µg/m^3. Modeled daily average exposure concentrations based on the maximum release and 95th percentile modeled concentration at 100 m from a releasing facility that are primarily attributable to other sources (combustion)—including airplanes, on-site vehicles, process heaters, turbines, and reciprocating internal combustion engines, range from 2 to 662 µg/m^3. Modeled annual

average exposure concentrations based on the 95th percentile releases and 95th percentile modeled concentration at within the 100 to 1,000 m area distance range 0.0001 to 5.75 µg/m^3.

2.1.4 Conclusion: Terrestrial Exposures

EPA estimated potential concentrations in air that terrestrial organisms may be exposed. Similarly, the Agency considered measured concentrations of formaldehyde in the environment. Based on the available information, EPA determined formaldehyde exposure from TSCA COUs are expected to be negligible for terrestrial populations in ambient air primarily due to formaldehyde's high volatility in air and an inability to sorb, bind to, or persist in soil or organic matter based on the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (EPA, 2024b). These concentrations were carried to the *Environmental Risk Assessment for Formaldehyde* (EPA, 2024e) to understand if and when they cause risk.

2.2 Aquatic Exposure

Aquatic organisms are much less likely to be exposed to naturally-occuring formaldehyde when compared to terrestrial organisms. These exposures are more likely to come from industrial effluents and runoffs. Due to the highly reactive nature of formaldehyde in water and its rapid transformation to oligomers of various chain length however, it is unlikely formaldehyde would remain in its native or hydrated state in water long enough to lead to significant formaldehyde exposures for aquatic organisms. Furthermore, formaldehyde does not bioaccumulate (EPA, 2024b) and therefore is not expected to be in fish that may be consumed by aquatic or terrestrial populations via the dietary pathway.

EPA considered surface water releases of formaldehyde (Section 2.2.1), surface water monitoring (Section 2.2.2), and potential modeling based on the available tools (Section 2.2.3), to qualitatively assess formaldehyde exposure to aquatic organisms. This qualitative approach is consistent with the International Programme on Chemical Safety's Concise International Chemical Assessment Document 40: Formaldehyde (IPCS, 2002).

2.2.1 Surface Water Releases

Based on TRI and DMR reporting, less than 150,000 kg/yr of formaldehyde are released directly to surface water from TSCA-related activities, and approximately 2 million kg/yr are directed to wastewater treatment facilities (see Appendix D.2 of the Environmental Release Assessment). However, current wastewater treatment technologies have been shown to remove up to 99 percent of formaldehyde prior to releasing into a discharge stream (EPA, 2024b). Combined, these findings suggest that releases to surface water are low to negligible.

2.2.2 Surface Water Monitoring

In surface water, formaldehyde is rarely detected and is usually below method detection limits. According to the Water Quality Portal (WQP) (See *Supplemental Water Quality Portal Results for Formaldehyde* to the *Environmental Exposure Assessment for Formaldehyde* (EPA, 2024c)), 866 formaldehyde monitoring activities were conducted between 1969 and 2022. Eighty-nine percent of monitoring samples reported no detectable formaldehyde. The remaining 11 percent of samples reported formaldehyde concentrations were mostly from sampling events before 1975 and their quality could not be verified. For sampling events after 1975, 11 formaldehyde concentrations were detected out of more than 770 sampling events (see *Supplemental Water Quality Portal Results for Formaldehyde* to the *Environmental Exposure Assessment for Formaldehyde* (EPA, 2024c)). However, these were also low quality results due to poor percent recoveries in lab results, lack of available information around the form of formaldehyde evaluated, and because it is unclear whether the surface water sampling and analytical methodologies applied for the monitoring activities were designed to effectively measure the

chemical in surface water. Furthermore, the 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. Due to these uncertainties, EPA considers these samples to be of low quality which diminished the Agency's confidence that they reasonably represented concentrations of formaldehyde in surface water. Although EPA reached out to state representatives responsible for those data sets, the Agency did not receive responses.

2.2.3 Surface Water Modeling

The Exposure and Fate Assessment Screening Tool (E-FAST) is typically used to estimate surface water concentrations resulting from chemical environmental releases. However, E-FAST does not consider post-release fate or downstream transport such as aerobic degradation, hydrolysis, volatilization, etc.(Versar, 2014). Likewise, E-FAST is not well parameterized for chemicals like formaldehyde that are highly reactive and undergo rapid transformation in surface water. Therefore, EPA did not use E-FAST to estimate surface water concentrations of formaldehyde resulting from a water release.

2.2.4 Conclusion: Aquatic Exposures

Based on the evidence presented above, EPA concludes that concentrations of formaldehyde in aquatic systems are expected to be negligible and is not providing estimated concentration in the *Environmental Risk Assessment for Formaldehyde* (EPA, 2024e).

2.3 Trophic Transfer Exposure

Formaldehyde exposures are not expected to occur to aquatic populations. According to the Agency for Toxic Substances and Disease Registry, experiments with various fish and shrimp showed no evidence of the bioaccumulation of formaldehyde (ATSDR, 1999). Therefore, EPA does not expect any trophic transfer of formaldehyde.

2.4 Weight of Scientific Evidence Analysis: Environmental Exposures

Based on the exposure systematic review standard operating procedures (EPA, 2021), only studies and datasets with data deemed useful in generating a quantitative assessment (*e.g.,* via modeling) were extracted after being evaluated. Because a full quantitative assessment was not performed, monitoring data were mainly incorporated as key references used to qualitatively support the environmental exposure assessment of formaldehyde. However, as presented in Section 2.1, EPA (1) performed a semi-quantitative screening assessment of terrestrial ambient air exposures to formaldehyde, (2) utilized the peer-reviewed IIOAC model to estimate formaldehyde concentrations at three predefined distances from releasing facilities, and (3) used reported release data from both TRI and NEI datasets.

The lines of evidence used in the weight of scientific analysis for the environmental exposure assessment of formaldehyde is primarily dependent upon (1) federally curated monitoring studies and datasets (*e.g.,* AMTIC, TRI, NEI datasets (U.S. EPA, 2024; EPA, 2022, 2019), though such data are not specific to TSCA COUs; (2) completed assessments from U.S. agencies (IPCS, 2002; ATSDR, 1999) and (3) EPA guidance documents (Versar, 2014; EPA, 1993) and other formaldehyde modules in the formaldehyde risk evaluation (EPA, 2024a, b, d). Altogether, EPA has high confidence in this environmental exposure assessment and the conclusions reached based on available data for formaldehyde.

2.4.1 Key Limitations and Uncertainties for the Environmental Exposure Assessment

EPA qualitatively evaluated exposures to terrestrial populations in this environmental exposure assessment. IIOAC was used to estimate formaldehyde air concentrations from air releases related to a specific TSCA COU at three predefined distances from releasing facilities. Estimated concentrations at

these predefined distances can be relied upon to estimate exposures to species residing within those distances. Although, on a national scale, there significant uncertainties as to what species may be located within these distances from releasing facilities and how long they might be exposed. Based on the available information, EPA determined formaldehyde exposure from TSCA COUs are expected to be negligible for terrestrial populations in ambient air primarily due to formaldehyde's high volatility in air and an inability to sorb, bind to, or persist in soil or organic matter based on the *Chemistry, Fate, and Transport Assessment for Formaldehyde* (EPA, 2024b).

Formaldehyde does not persist in water as formaldehyde or its hydrated form (methylene glycol), as described above and in the chemistry, fate, and transport assessment module. As such, EPA has not further evaluated the water pathway. The decision to not further assess the water pathway is supported by several lines of evidence identified via the Agency's systematic review process (EPA, 2021), published literature, monitoring data, and professional knowledge around analytical methods used to measure formaldehyde in water. These are summarized below.

- Even if formaldehyde is present in wastewater prior to treatment, current treatment technologies remove up to 99 percent of formaldehyde prior to release into a discharge stream.
- Formaldehyde immediately (within 8 seconds) transforms to its hydrated form (methylene glycol).
- Methylene glycol rapidly transforms to one of several different chemical forms, many of which are structurally dissimilar to either formaldehyde or methylene glycol (Boyer et al., 2013).
- Formaldehyde and methylene glycol are not readily discernable from one another in the analytic outputs for the sampling events conducted.
- Currently available tools, such as EFAST, are not appropriate for an aquatic assessment of formaldehyde because they do not account for formaldehyde's rapid transformation in water.

Although there are uncertainties noted throughout the environmental exposure assessment, none are expected to meaningfully impact the overall risk assessment conclusions.

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APPENDICES

Appendix A LIST OF ENVIRONMENTAL EXPOSURE ASSOCIATED SUPPLEMENTAL FILES

The following environmental exposure associated supplemental information files provide all supplemental data utilized for the revised assessment. See Docket EPA-HQ-OPPT-2018-0438 for all publicly released files associated with this risk evaluation package.

1. File Name: *Supplemental Water Quality Portal Results for Formaldehyde*
2. File Name: *Ambient Air Exposure Assessment Results and Risk Calcs Supplement A*