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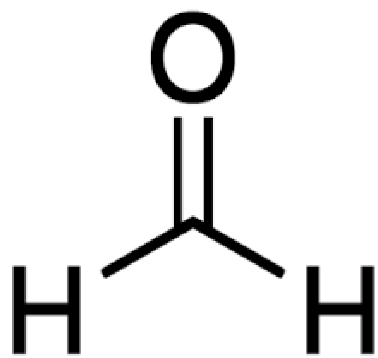
Office of Chemical Safety and Pollution Prevention

United States Environmental Protection Agency

Draft Human Health Risk Assessment for Formaldehyde

CASRN 50-00-0



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. Comments were submitted by ORD, Office of Air and Radiation, and the Office of Children's Health Protection.

Docket

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

Disclaimer

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Formaldehyde – Human Health Risk Characterization - Key Points

Formaldehyde is a highly reactive gas that is ubiquitous in indoor and outdoor environments. It is widely used in a range of industrial applications, consumer products, and building materials (*e.g.*, composite wood products, plastics, rubber, various adhesives and sealants). It also occurs as a product of combustion, a product of normal metabolism in the human body, and is formed naturally through the decomposition of organic matter (*i.e.*, biogenic sources).

Health effects of concern for formaldehyde include cancer and respiratory effects such as increased asthma prevalence, reduced asthma control, and reduced lung function. People may be exposed to formaldehyde at work, through indoor air, through use of consumer products, and through outdoor air near sources of formaldehyde. People are often exposed to many sources of formaldehyde concurrently, some of which are regulated under the Toxic Substances Control Act (TSCA) some of which are regulated under other laws, and some of which are not regulated at all (for example, the decomposition of leaves).

This draft human health risk assessment for formaldehyde evaluates the risks of formaldehyde exposures for workers, consumers, and the general population resulting from TSCA conditions of use (COUs).

Risk estimates include inherent uncertainties and the overall confidence in specific risk estimates varies. The analysis provides support for the Agency to make a determination about whether formaldehyde poses an unreasonable risk to human health and to identify drivers of unreasonable risk among exposures for people (1) with occupational exposure to formaldehyde, (2) with consumer exposure to formaldehyde, (3) with exposure to formaldehyde in indoor air, and (4) who live or work in proximity to locations where formaldehyde is released to air. Concurrent with this draft TSCA Risk Evaluation, EPA is releasing a preliminary risk determination for formaldehyde.

While EPA is making this risk determination, EPA will consider the standard risk benchmarks associated with interpreting margins of exposure and cancer risks. However, EPA cannot solely rely on those risk values. The Agency also will consider naturally occurring sources of formaldehyde (i.e., biogenic, combustion, and secondary formation) and associated risk levels therefrom, and consider contributions from all sources as part of a pragmatic and holistic evaluation of formaldehyde hazard and exposure in making its unreasonable risk determination. If an estimate of risk for a specific exposure scenario exceeds the benchmarks, then the decision of whether those risks are formally unreasonable under TSCA must be both case-by-case and context driven in the case of formaldehyde. EPA is taking the risk estimates of the human health risk assessment (HHRA), in combination with a thoughtful consideration of other sources of formaldehyde, to interpret the risk estimates in the context of making an unreasonable risk determination.

EXECUTIVE SUMMARY

Sixty-two conditions of use of formaldehyde were determined to be within the scope of TSCA and were assessed by OPPT. These conditions of use were identified as part of the *Final Scope for the Risk Evaluation for Formaldehyde 50-00-0* (U.S. EPA, 2020c) and recently updated to better reflect the Agency's understanding of the sources of formaldehyde. Examples of the conditions of use considered in the TSCA risk evaluation are listed below with a comprehensive list provided in the *Draft Conditions of Use for the Formaldehyde Risk Evaluation* (U.S. EPA, 2024c); these include

- manufacturing of formaldehyde,
- processing and manufacturing of articles and products,
- composite wood products,
- plastics used in toys,
- rubber materials, and
- various adhesives and sealants.

Readily available information indicates that formaldhyde is released to air, land, and water from various TSCA conditions of use. Although the draft formaldehyde risk evaluation considered each of these pathways of exposure, some of these releases result in negligible exposure based on the chemistry, fate, and transport properties of formaldehyde. Formaldehyde exposures by those pathways were not assessed further. These include

- sediment and water including drinking water, and
- soils, biosolids, and landfills.

Similarly, some conditions of use were considered for consumer scenarios and result in negligible exposure based on the chemistry, fate, and transport properties of formaldehyde. Other conditions of use could not be assessed due to the limitation of available models and data. These conditions of use are

- water treatment,
- laundry detergent, and
- lawn and garden products.

This Draft Human Health Risk Assessment for Formaldehyde focuses on human exposure to formaldehyde from industrial, occupational, and consumer activities via inhalation of indoor and outdoor air and dermal (skin) routes. Exposure to workers, consumers and people within the general population have been assessed under specific conditions of use. Not all conditions of use result in formaldehyde exposure for all populations. Among the populations assessed are potentially exposed or susceptible subpopulations (PESS), which are people who have higher exposures or are more susceptible so may be at greater risk of adverse health effects from formaldehyde. Example populations (including PESS), routes of exposure, and conditions of use include the following:

- worker inhalation and dermal exposure during manufacturing, processing, distribution, use and disposal of formaldehyde;
- consumer (based on highest expected exposure among all ages) inhalation and dermal exposure from use of paint, laundry detergents, hand and dishwashing soaps, drain and toilet cleaners, textile and leather finishing products, varnishes and floor finishes, rubber mats, adhesives, caulks and sealants, liquid photographic processing solutions, and non-spray lubricants that contain formaldehyde;
- general population (all ages) inhalation exposure to indoor air from products used in new construction of homes and mobile homes (*e.g.,* wood materials, furniture seat covers,); and automobiles with products that contain formaldehyde; and

- general population (all ages) inhalation exposure to outdoor air near industrial facilities that release formaldehyde.

As mentioned, there are many formaldehyde sources. Not all sources are considered in the *Draft TSCA Risk Evaluation*, either because they occur naturally or because they are regulated under other statutes. These include

- forest fires;
- combustion[1];
- tail-pipe emissions from cars, trucks, and other vehicles;
- plastic products used for food storage and distribution;
- animal feed;
- biogenic sources (like trees and wood chips);
- secondary formation[2];
- drugs for fisheries and hatcheries;
- pesticides and other formaldehyde uses regulated by the Food and Drug Administration;
- pacifiers and baby bottles; and,
- embalming or as a preservative from funeral homes and taxidermy.

These other sources can produce substantial amounts of formaldehyde resulting in exposures in the occupational, indoor, and outdoor environments. For example, biogenic concentrations can contribute upwards of 25 percent of the total formaldehyde concentration and secondary formation can account for as much as 80 percent in ambient air, depending on the circumstances.

Hazard Values

Human health hazard data for this draft assessment were obtained through many sources including collaboration with ORD and OPP as well as through the TSCA systematic review process. In addition, OSCPP is relying on the peer reviews provided by the National Academies of Sciences, Engineering, and Medicine and the Human Studies Review Board on certain aspects of the human hazard assessment.

OPPT is using the inhalation unit risk for nasopharyngeal cancer as derived in the draft EPA *IRIS Toxicological Review of Formaldehyde – Inhalation* (U.S. EPA, 2022b). Although inhaled formaldehyde has been associated with multiple types of cancer in humans, including nasopharyngeal and myeloid leukemia, the myeloid leukemia findings are not sufficient to develop quantitative estimates of cancer risk. While there may be uncertainty on the extent to which other mechanisms contribute to the carcinogenicity of formaldehyde, the IRIS assessment concluded that a mutagenic action contributes to risk of nasopharyngeal cancer from inhaled formaldehyde. To account for the potential increased susceptibility that may be associated with early life exposure to formaldehyde, OPPT modified this cancer value using age-dependent adjustment factors for exposure scenarios that include early life.

Formaldehyde exposure is also associated with a range of respiratory and non-respiratory health effects in humans—including reduced pulmonary function, increased asthma prevalence, decreased asthma

[1] Formaldehyde can be emitted from many types of combustion, from naturally occurring wildfires and burning candles to household appliance and industrial combustion turbines. These sources can also include tailpipe emissions (including cars, trucks, and boats); and emissions from fires (including wildfires, accidental fires, and agricultural burning). Some combustion activities could be included in the evaluation of other conditions of use under TSCA such as processing or other similar industrial use. However, given the number of potential sources of formaldehyde production in the home, occupational settings and in the environment, EPA did not consider formaldehyde from the combustion sources independent of other TSCA COUs due to their abundant nature.

[2] Formaldehyde is also largely found in the environment due to secondary formation of the chemical after degradation of other compounds, for example when a chemical undergoes chemical reactions in the air and forms formaldehyde. Some secondary formation may be a result of TSCA conditions of use but these cannot be distinguished from all other secondary formations because they are so abundant.

control, allergy-related conditions, sensory irritation, male and female reproductive toxicity, and developmental effects. OPPT is using a chronic point of departure for pulmonary function in children derived from the draft EPA *IRIS Toxicological Review of Formaldehyde – Inhalation*. Sensory irritation (*e.g.*, eye irritation) observed in adults is the critical effect for non-cancer respiratory effects from breathing formaldehyde for more than 15 minutes. Skin sensitization observed in adults is the critical effect for assessing formaldehyde exposure via the dermal routes.

Oral hazard data are also available for formaldehyde but were not used in the risk assessment because exposure was not expected.

Exposure for Workers and the General Population

Many data sources were used to evaluate exposures to humans (workers; consumers and general population, both including children) from indoor and outdoor air as well as dermal exposures. These include measured and model estimated concentrations data. There are many conditions of use and many different exposure scenarios for each population assessed.

Workers

Worker exposure to formaldehyde via inhalation and dermal are expected to result in the highest formaldehyde exposures among the assessed populations. Workplace concentrations of formaldehyde vary based on activities performed (*i.e.*, manufacturing, processing, industrial, and commercial settings). Individuals in workplaces whose duties are not directly associated with manufacturing, processing, or use of formaldehyde (*i.e.*, occupational non-users [ONUs] such as supervisors] who may be near or within the same workspace (*i.e.*, breathing the same air) are also expected to be exposed to formaldehyde at similar concentrations.

Inhalation exposures were estimated based largely on measured formaldehyde concentrations in occupational settings. Monitoring data were available for many scenarios. However, monitoring data are not available for three conditions of use in commercial settings and were thus modeled. These model estimates generally fell within the range of monitored workplace concentrations. Across all conditions of use, full work shift (8 to 12 hours) inhalation exposure estimates were between 7.5 to 17,353.3 $\mu g/m^3$. Peak inhalation estimates for workers were between 86 to 237,902 $\mu g/m^3$ across all conditions of use. The highest inhalation exposure was based on modeled estimates for use of formulations containing formaldehyde in automotive care products. Occupational exposure concentrations, as expected, are generally higher than modeled and measured outdoor and indoor formaldehyde air concentrations. EPA has an overall medium confidence in the reported exposure estimates because most of the values are based on recent (1992 to 2020) real workplace monitoring data from multiple sources and therefore are expected to be reflective of current industrial practices. The Agency does not have higher overall confidence in the reported exposure estimates because the sources did not always provide supplemental information such as worker activities and associated process conditions. Therefore, EPA made assumptions in integrating monitoring data.

Short-term dermal exposures were estimated based on liquid contact with formulations containing formaldehyde. Dermal exposure estimates ranged from 0.56 to 3,090 $\mu g/cm^2$. The highest dermal exposure was estimated during spray application of products such as paints and automotive care products. EPA has medium confidence in the dermal exposure estimates because the estimates were derived using a standard peer-review model based on measured data on the retention of liquids on the skin surface. EPA does not have higher confidence in the reported values because the Agency did not have monitored formaldehyde dermal exposure data to ground truth these exposure estimates.

General Population – Consumer Exposures in Residential Settings

Frequent users of products containing formaldehyde are anticipated to be the next highest population effected due to its use in products and articles that are available to most people for purchase. Some examples of these consumer products that contain formaldehyde include automotive care products; fabrics, textiles, and leather products; and adhesives or sealants. Exposure estimates for these products varies due to the different durations (or activity) of use along with formaldehyde amount acquired from safety data sheets. This assessment considered concentrations of formaldehyde during and following use of consumer products in residential settings. Specifically, peak (15-minute) and long-term (annual average) inhalation exposures as well as short-term dermal exposures were estimated. For a subset of conditions of use, longer-term or lifetime exposure scenarios were assessed based on known consumer use activities.

Seven conditions of use were evaluated for peak inhalation exposures. Fifteen-minute concentration estimates ranged from 1.72 to 2,500 $\mu g/m^3$. The highest concentrations were for products like floor covering, foam seating, and bedding. Four conditions of use were evaluated for chronic consumer inhalation exposure to formaldehyde. These conditions of use were selected because the uses are expected to be the most substantial contributors to long-term inhalation exposures based on the expected consumer activity profile and formaldehyde concentrations in the product. Annual estimated formaldehyde concentrations ranged from 0.04 to 23.83 $\mu g/m^3$. The highest concentrations were for arts, crafts, and hobby materials. EPA has medium confidence in the inhalation exposure estimates based on the number of monitoring data sources, use of the EPA's *Exposure Factors Handbook* (U.S. EPA, 2011) and survey data on consumer behavior and activities, and chemical amounts report on product-specific safety data sheets. Monitoring data that can be tied to specific consumer conditions are not available. Formaldehyde concentrations from consumer products are expected to be represented in the available indoor air monitoring data as an aggregate concentration with other consumer and indoor air sources.

Dermal short-term exposures for consumers were estimated based on contact with products containing formaldehyde. Nineteen conditions of use were evaluated with estimated short-term formaldehyde dermal loading rates ranging from 1.03 to 3,090 $\mu g/cm^2$. The highest concentrations were estimated to be for exterior car waxes and polishes followed by photographic processing solutions. EPA has medium confidence in these estimates because there are no monitoring data available to ground truth these concentration estimates.

General Population – Indoor Air Exposures in Residential and Vehicular Settings

There are many sources of formaldehyde within residences (homes and mobile homes) and vehicles. As mentioned, these include both TSCA sources such as building materials, finishes such as wood flooring and paint, and foam cushions on furniture, and other sources such as combustion sources like candles, fireplaces, and stoves. Additionally, consumer products containing formaldehyde may also contribute to indoor concentrations of formaldehyde.

The highest formaldehyde concentrations from TSCA sources are expected in newly constructed homes and mobile homes. In these settings, multiple sources of formaldehyde contribute to total indoor air concentrations especially during the peak product emission period when new formaldehyde containing articles and products are introduced. These concentrations substantially diminish within the first two years of the product life based on open literature data. The peak exposure to formaldehyde from these products is expected to occur within one year of use or manufacture. Indoor air concentrations can also be high when new materials like hardwood floors or wallpaper are installed in homes. Similarly, fabric in new furniture may also release formaldehyde in indoor environments after being introduced. Therefore, formaldehyde concentrations in indoor environments are expected to vary over longer time periods (*e.g.*, an individual's lifetime) and are highly dependent on an individual's propensity to move to new homes as well as their purchasing behaviors.

Four conditions of use in both automobiles and homes were evaluated. The estimated average daily concentrations of formaldehyde for these conditions of use ranged from 5.19 to 423 $\mu g/m^3$. The highest concentration comes from construction and building materials that cover large surface areas like hardwood floors. These modeled concentrations represent high-end estimates for each condition of use. Furthermore, many of the products that fall within this condition of use are subject to the new emission standards under TSCA Title VI (15 U.S.C. §2697) which have not been fully implemented.

Monitoring data from the American Healthy Homes Survey II suggests that concentrations of formaldehyde range from 0.27 to 124.2 $\mu g/m^3$ for all homes, with 95 percent of homes having concentrations below 46 $\mu g/m^3$. Thus, indoor exposures to formaldehyde are in general agreement across available data and sources of formaldehyde; however, monitoring values represent all sources of formaldehyde in indoor air (including sources that are not subject to TSCA) and cannot be attributed to a single TSCA condition of use. Similarly, measured concentrations are not expected to reflect full implementation of the TSCA Title VI (15 U.S.C. §2697), which have not been fully implemented as of the time of publication of this draft risk evaluation. Therefore, it is reasonable to expect that less formaldehyde will be released from many wood products in the future than occurred in the past.

EPA has medium confidence in the indoor air concentration estimates because the values are based on product-specific emission rates and product-specific formulations of formaldehyde. However, EPA does not have high confidence in the indoor air concentration estimates because available monitoring data could not corroborate the full range of estimates. In addition, the Agency does not have high confidence because (1) dissipation rates of formaldehyde cannot be determined for indoor air for all types of furniture, wood, or other products; and (2) the available monitoring data cannot be directly tied to specific products (*e.g.*, wood and fabric products) and associated conditions of use.

General Population – Outdoor Air Exposures
As mentioned at the beginning of this summary, formaldehyde exposures in outdoor air (ambient air) come from many sources including biogenic sources, secondary formation, and conditions of use. Outdoor air exposures are lower than those in any other setting. However, TSCA condition of use contributions are highly variable across the United States and only exceed other sources in specific locations. The outdoor air exposure assessment only considered exposures from inhalation for populations living within a half mile of release facilities. This assessment considered short-term (daily average) and long-term (annual average) inhalation exposures. After evaluating all durations, only long-term durations appeared to be substantial and relevant for this Draft TSCA Risk Evaluation. Estimated annual ambient air concentration ranged from 0.0001 to 5.75 $\mu g/m^3$. The highest potential exposures come from operations with nonmetallic mineral product manufacturing as well as textile, apparel, and leather manufacturing.

Monitoring data from Ambient Monitoring Technology Information Center, based on data collected between 2015 to 2020, range from 0 to 60.1 $\mu g/m^3$ with a median of 1.6 $\mu g/m^3$ across more than 300,000 monitored values from 214 sites. Monitoring data could not be linked to specific conditions of use.

Since monitored concentrations represent total aggregated concentrations from all contributing sources, while these values are not directly comparable to IIOAC modeled concentrations alone, by considering multiple data sources (modeled concentrations, biogenic and secondary sources), EPA found considering these three primary contributors together represent a large portion of the total monitored concentrations and does not result in concentrations outside of or well above any monitored concentration.

EPA has high confidence in the outdoor air concentration estimates because the values are based on reported formaldehyde releases from EPA databases, uses standard risk assessment approaches and utilizes more refined models to better understand population and demographics near releasing facilities.

Risk Characterization

People are regularly exposed to formaldehyde in their workplace, in their vehicles, and in their homes. People may also be exposed to formaldehyde due to its natural formation in the environment and as a natural part of human metabolism.

Worker Risk Characterization

Based on available occupational monitoring data and exposure modeling estimates, worker exposure to formaldehyde is expected to be higher than exposures from naturally occuring sources. This assessment does not assume personal protective equipment use to account for a range of possible workplaces. Both high-end and central tendency exposure estimates were used with the available hazard data to calculate worker risk for acute, chronic non-cancer, and cancer inhalation effects along with the potential to cause dermal sensitization.

Results indicate that effects to workers are more likely to be for acute and chronic non-cancer inhalation effects. Workers may experience sensory irritation from short-term exposures and decreased pulmonary function or other respiratory effects from longer-term exposures. The hazard values are largely based on studies in children, but adults may also experience adverse effects at similar concentrations. At high-end exposure scenarios, results indicate workers may also be at increased risk for nasopharyngeal cancer. Cancer effects are based on human studies in occupational settings.

The risk estimates for occupational exposures reflect use of standard risk assessment approaches considering an abundance of high-quality workplace monitoring data that clearly exceed concentrations of formaldehyde from other sources including natural sources and human hazard data. Likewise, risk estimates are generally consistent across central tendency and high-end exposure scenarios for workers. While there are some uncertainties in the assessment, these uncertainties are not expected to change risk estimates enough to shift the overall risk assessment conclusions but may be great enough to change risk estimates for specific conditions of use.

Results indicate that effects to workers from dermal exposure that could lead to sensitization with repeated exposure for all conditions of use except one. All exposure estimates were based on standard modeling approaches including the assumption of the amount of liquid left on the skin after contact which is not specific to formaldehyde. The hazard data for skin sensitization is based on controlled human exposures in adult volunteers and is corroborated by animal and in vitro evidence. The dermal sensitization data are based on controlled human exposures studies in adults.

Consumer Exposure Risk Characterization

Consumer risk estimates were calculated for acute, chronic non-cancer, and cancer inhalation effects, as well as dermal sensitization.

Consumers may experience acute sensory irritation (eye irritation) when inhaling peak concentrations of formaldehyde in their residences when using products that contain high amounts of formaldehyde for short durations. These acute effects are based on a robust dataset of evidence for sensory irritation in humans, including several high-quality controlled exposure studies with relevance for acute exposure scenarios. The risk estimates reflect use of standard risk assessment approaches and best available data.

Consumers inhaling formaldehyde may also experience decreased pulmonary function and other chronic effects when those products are used frequently. These effects are based on data from humans at sensitive lifestages, but it is unclear whether exposure scenarios represent how all people use these products and articles containing formaldehyde. EPA has substantial data on use patterns of these products based on surveys conducted on consumer activities and behaviors. Similarly, EPA's *Exposures Factors Handbook* was used to support consumer exposure analyses. Lastly, safety data sheets were used to identify concentrations of formaldehyde in consumer products. It is worth noting that conservative estimates from these data sources may not represent exposures to all consumers using products and articles containing formaldehyde. The risk estimates reflect use of standard risk assessment approaches considering best available data for consumers who frequently use products containing formaldehyde; but understanding the commonness of these practices has some uncertainty because it is unclear how older data from surveys represents current behaviors and uses.

At high-end exposure scenarios, results indicate consumers may have increased risk for developing nasopharyngeal cancer, but this is expected to be rare in the general population. The data for cancer effects are based on human studies that are corroborated in animal studies. EPA believes these risk estimates are for consumers who frequently use products containing formaldehyde over the course of many years. However, the Agency does not have information on how common it is that consumers would use these products for this length of time, and it is unclear how older data from surveys represents current behaviors and uses.

Consumers using products containing formaldehyde may experience dermal sensitization after acute exposures to their skin. The hazard data for skin sensitization is based on controlled human exposures in adult volunteers and is corroborated by animal and in vitro evidence. Risk estimates for these dermal exposures is based on estimated dermal loading from models. Monitoring data are not available to determine how common these exposures may be for consumers. Thus, EPA has less certainty in how common these exposures result in skin sensitization for consumers in the general population.

Indoor Air Exposure Characterization

Indoor air risk estimates were calculated for chronic non-cancer inhalation effects. People who are living in homes where high concentrations are present may experience decreased pulmonary function and other chronic effects. These effects are based on data from humans at sensitive lifestages. However, the exposure scenarios where these effects are seen are mostly limited to homes where high surface area products like hardwood floors and wallpaper may be introduced. Similarly, these effects may occur in new homes and mobile homes where all new products may be contributing to high concentrations of formaldehyde in air. As previously mentioned, the dissipation rate of formaldehyde from these TSCA conditions of use could not be fully characterized. However, concentrations are anticipated to decrease with time and ventilation. Generally, new products are expected to have substantially reduced formaldehyde emissions within 2 years.

In addition to TSCA sources, other sources of formaldehyde may contribute substantially to indoor air concentrations of formaldehyde. Formaldehyde concentrations from candles, incense, cooking, wood combustion, and air cleaning devices fall within the range of formaldehyde concentrations from TSCA conditions of use. Furthermore, the range of concentrations estimated fall within the range of available monitoring data.

Many of these other sources of formaldehyde represent temporary emission sources, which may affect the overall impact on indoor air quality. Further, qualities such as the frequency and duration of use of these temporary formaldehyde sources (*e.g.*, burning candles or the use of a fireplace), age of the home and formaldehyde-containing home finishes and furnishings, and ventilation rate will impact the total concentration of formaldehyde in indoor air and the relative contribution of TSCA and other sources to the indoor air. Combined, the many factors that may contribute to overall indoor air concentrations and relative concentrations from TSCA and other uses introduce a significant source of uncertainty in the indoor air exposure assessment.

EPA has medium confidence in the conclusion of the inhalation risk assessment for indoor air. This is because the assessment is based on product-specific emission rates, data, and standard methods. While the monitoring data cannot be tied to individual conditions of use, it is expected to represent aggregate exposure to formaldehyde resulting from multiple sources. As such, EPA has confidence it is not underestimating formaldehyde exposure resulting from TSCA conditions of use or across all sources of formaldehyde.

Ambient Air Risk Characterization

Based on modeling estimates, individuals of the general population living within half mile of a releasing facility may be exposed to formaldehyde concentrations greater than naturally occuring sources in the outdoor environment but are generally within the range of concentrations from natural sources like biogenic sources. Acute, chronic non-cancer, and cancer inhalation risk estimates were calculated. Non-cancer risk estimates are based on chronic respiratory effects observed in people at sensitive lifestages and acute sensory irritation observed in controlled human exposures in adults. Cancer risk estimates are based on effects observed in human studies and corroborated in animal studies.

Results indicate that the general population is not likely to experience sensory irritation from short-term exposures or decreased pulmonary function or increased asthma prevalence from longer-term exposures when compared to other formaldehyde exposures; however, in some locations some individuals may be at increased risk for developing nasopharyngeal and other cancer types. However, this is contingent on the assumption that an individual lives within a half mile of a releasing facility their entire life. EPA conducted a higher tier analysis to identify locations where TSCA releases contributed to formaldehyde concentrations exceeding background concentrations of formaldehyde.

EPA has high confidence in the conclusion of the inhalation risk assessment for the general population. EPA has this confidence because the assessment is based on a large amount for formaldehyde reported release data and standard methods. Furthermore, the range of concentrations estimated fall within the range of available monitoring data. Although the monitoring data cannot be tied to individual conditions of use, it is expected to represent aggregate exposure to formaldehyde resulting from multiple sources. As such, EPA has confidence it is not underestimating formaldehyde exposure resulting from TSCA conditions of use or across all sources of formaldehyde.

1 INTRODUCTION

1.1 Background

Formaldehyde is a high priority chemical undergoing the Toxic Substances Control Act (TSCA) risk evaluation process after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016. It is concurrently undergoing a hazard assessment in EPA's Integrated Risk Information System (IRIS) program and a risk assessment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This *Draft Human Health Risk Assessment* is a TSCA-specific assessment that will serve to support risk management needs by the Office of Pollution Prevention and Toxics (OPPT) and is one of many documents comprising the draft formaldehyde risk evaluation.

In April 2022, EPA's IRIS program released a draft *Toxicological Review of Formaldehyde – Inhalation* (U.S. EPA, 2022b) (also called "draft IRIS assessment") for public comment and peer review. OPPT and OPP have relied upon the hazard conclusions and dose-response analysis presented in the draft IRIS assessment for inhalation and have coordinated to evaluate additional information on environmental fate and transport, human health hazard, and environmental hazard consistently across programs.

A list of the regulatory history of formaldehyde can be found in Appendix D of the *Final Scope for the Risk Evaluation for Formaldehyde 50-00-0* (U.S. EPA, 2020c), which includes regulation under the Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, and other EPA regulatory programs and non-EPA programs.

Following publication of the final scope document, EPA considered and reviewed reasonably available information in a systematic and fit-for-purpose approach to develop this draft formaldehyde risk evaluation, leverage existing EPA assessment work, collaborate across offices, rely on best available science, and base it on the weight of the scientific evidence as required by EPA's Risk Evaluation Rule under TSCA. 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, 2021b), which underwent external peer review by the Science Advisory Committee on Chemicals (SACC) in July 2021.

1.2 Risk Evaluation Scope

The draft formaldehyde risk evaluation comprises a series of modular assessments. Each module contains sub-assessments that inform adjacent, "downstream" modules. A basic diagram showing the layout and relationships of these assessments is provided below in Figure 1-1. In some cases, modular assessments were completed jointly under TSCA and FIFRA. These modules are shown in dark gray. This human health risk assessment is shaded blue. High level summaries of each relevant module are presented in this risk assessment. Detailed information for each module can be found in the corresponding documents/modules.

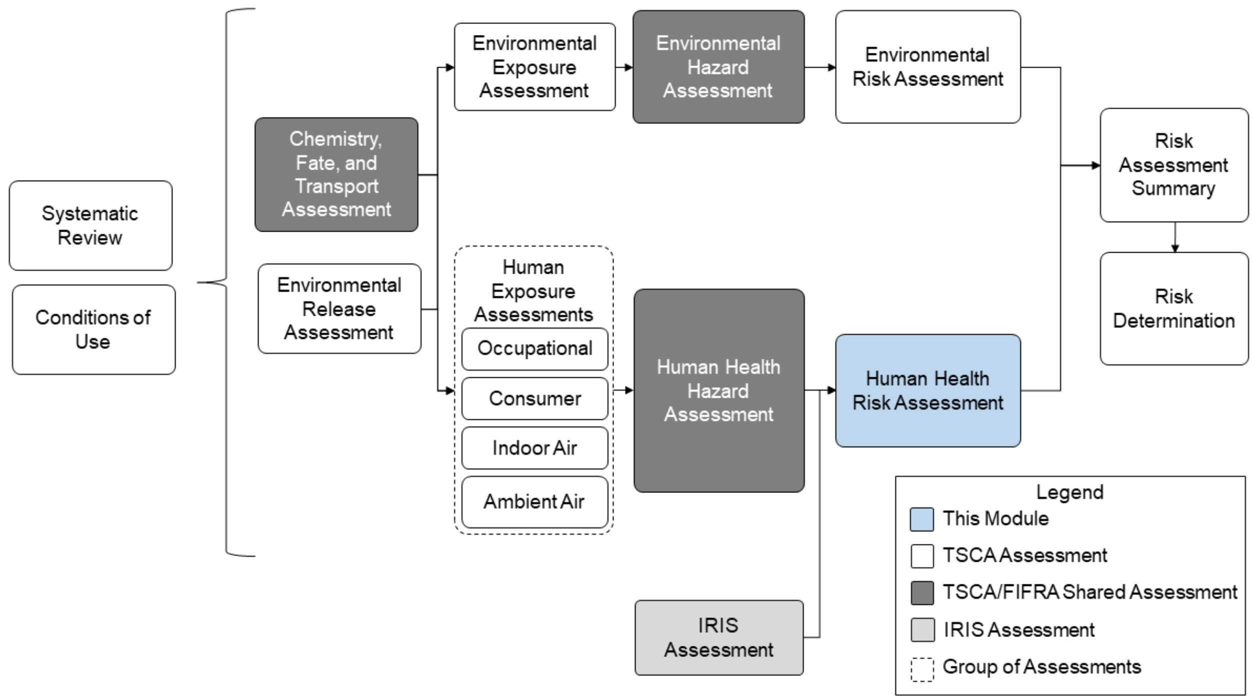

Figure 1-1. Risk Evaluation Document Summary Map

These modules leveraged the data and information sources already identified in the *Final Scope of the Risk Evaluation for Formaldehyde 50-00-0* (U.S. EPA, 2020c). OPPT conducted a comprehensive search for "reasonably available information" to identify relevant formaldehyde data for use in the risk evaluation. In some modules, data utilized were also located in collaboration with other EPA offices. As previously noted, OPPT is relying on the EPA's IRIS draft *Toxicological Review of Formaldehyde – Inhalation* (U.S. EPA, 2022b) in the formaldehyde risk evaluation (shaded light gray in Figure 1-1). The draft IRIS assessment is not part of the TSCA risk evaluation bundle. The approach used to identify specific relevant risk assessment information was discipline-specific and is detailed in *Systematic Review Protocol for the Draft Formaldehyde Risk Evaluation* (U.S. EPA, 2023a), or as otherwise noted in the relevant modules.

1.2.1 Life Cycle and Production Volume

The Life Cycle Diagram (LCD)—which depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages, including manufacturing, processing, use (industrial, 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 of the Risk Evaluation for Formaldehyde CASRN 50-00-0* (U.S. EPA, 2020c). The commercial and consumer uses for 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 (U.S. EPA, 2020c).

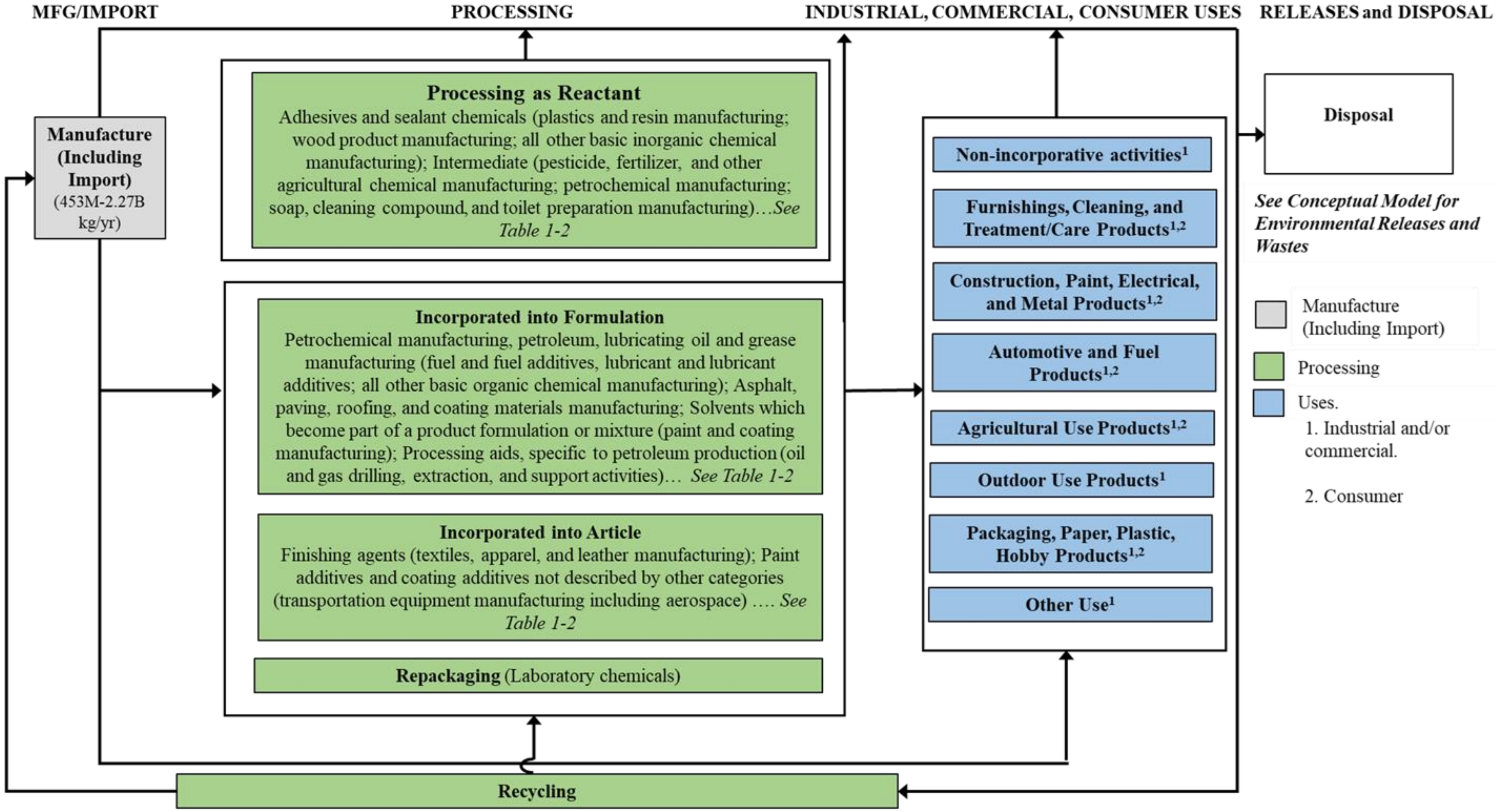

Figure 1-2. Lifecycle Diagram of Formaldehyde

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 (CASRN 50-00-0)* (EPA-HQ-OPPT-2018-0438).

1.2.2 Conditions of Use

The formaldehyde COUs included in the scope of the draft formaldehyde risk evaluation are reflected in Table 1-1 and the LCD (Figure 1-2) and include 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 roofing), furniture, toys, and various adhesives and sealants.

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

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Manufacturing	Domestic manufacturing	Domestic manufacturing	Manufacturing of formaldehyde
Manufacturing	Importing[a]	Importing	Import and/or repackaging of formaldehyde
Processing	Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; basic organic chemical manufacturing	Processing as a reactant
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 as a reactant
Processing	Reactant	Functional fluid in: oil and gas drilling, extraction, and support activities	Processing as a reactant
Processing	Reactant	Processing aids, specific to petroleum production in all other basic chemical manufacturing	Processing as a reactant
Processing	Reactant	Bleaching agent in wood product manufacturing	Processing as a reactant
Processing	Reactant	Agricultural chemicals in agriculture, forestry, fishing, and hunting	Processing as a reactant
Processing	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	Textile finishing
			Leather tanning
Processing	Incorporation into an article	Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)	Use of coatings, paints, adhesives, or sealants (non-spray applications)
			Use of coatings, paints, adhesives, or sealants (spray or unknown applications)

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Processing	Incorporation into an article	Additive in rubber product manufacturing	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	Composite wood product manufacturing Paper manufacturing Plastic product manufacturing Other composite material 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	Processing of formaldehyde into formulations, mixtures, or reaction products
	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	

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Processing	Incorporation into a formulation, mixture, or reaction product	Agricultural chemicals (non-pesticidal) in: agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and other agricultural chemical manufacturing	Processing of formaldehyde into formulations, mixtures, or reaction products
	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	
	Incorporation into a formulation, mixture, or reaction product	Bleaching agents in textile, apparel, and leather manufacturing	
	Repackaging	Sales to distributors for laboratory chemicals	Import and/or repackaging of formaldehyde
	Recycling	Recycling	Recycling
Distribution	Distribution	Distribution in Commerce	Storage and retail stores

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Industrial Use	Non-incorporative activities	Process aid in: oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing	Use of formaldehyde for oilfield well production
Industrial Use	Non-incorporative activities	Used in: construction	Furniture manufacturing
Industrial Use	Non-incorporative activities	Oxidizing/reducing agent; processing aids, not otherwise listed	Processing aid
Industrial Use	Chemical substances in industrial products	Paints and coatings; adhesives and sealants; lubricants	Use of coatings, paints, adhesives, or sealants (non-spray applications)
			Use of coatings, paints, adhesives, or sealants (spray or unknown applications)
			Industrial use of lubricants
			Foundries
Commercial Use	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.	Installation and demolition of formaldehyde-based furnishings and building/construction materials in residential, public, and commercial buildings, and other structures
			Textile finishing
			Leather tanning
	Chemical substances in treatment products	Water treatment products	Use of formulations containing formaldehyde for water treatment
	Chemical substances in treatment/care products	Laundry and dishwashing products	Use of formulations containing formaldehyde in laundry and dishwashing products
	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	Use of coatings, paints, adhesives, or sealants (non-spray applications)
			Use of coatings, paints, adhesives, or sealants (spray or unknown applications)

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
Commercial Use	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	Installation and demolition of formaldehyde-based furnishings and building/construction materials in residential, public and commercial buildings, and other structures
	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles	Use of electronic and metal products
	Chemical substances in metal products	Construction and building materials covering large surface areas, including metal articles	
	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	Use of formulations containing formaldehyde in automotive care products
			Use of automotive lubricants
			Use of formulations containing formaldehyde in fuels
	Chemical substances in agriculture use products	Lawn and garden products	Use of fertilizer containing formaldehyde in outdoors including lawns
	Chemical substances in outdoor use products	Explosive materials	Use of explosive materials
	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Use of paper, plastic, and hobby products
	Chemical substances in packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	Use of craft materials
	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; Photographic supplies	Use of printing ink, toner and colorant products containing formaldehyde
			Photo processing using formulations containing formaldehyde

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
	Chemical substances in products not described by other codes	Laboratory chemicals	General laboratory use
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	Varnishes and floor finishes
			Plastic articles: foam insulation (living room)
			Plastic articles: foam insulation (automobile)
			Drain and toilet cleaners
			Textile and leather finishing products
			Furniture & furnishings – wood articles: furniture
Consumer Uses	Chemical substances in furnishing treatment/care products	Fabric, textile, and leather products not covered elsewhere (clothing)	Fabrics: furniture covers, car seat covers, tablecloth (automobiles)
			Fabrics: furniture covers, car seat covers, tablecloth (living room)
			Fabrics: clothing
Consumer Uses	Chemical substances in treatment products	Water treatment products	Drinking water treatment
Consumer Uses	Chemical substances in treatment/care products	Laundry and dishwashing products	Laundry detergent (liquid)
			Hand Dishwashing Soap/ Liquid detergent
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	Water-based wall paint
			Solvent-based wall paint
			Glues and adhesives, small scale
			Caulk (Sealants)
Consumer Uses	Chemical substances in construction, paint,	Construction and building materials covering large surface areas, including wood articles; Construction and building	Building/construction materials – wood articles: hardwood floors

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	
	electrical, and metal products	materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	Liquid concrete
Consumer Uses	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles	Electronic appliances
Consumer Uses	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	Exterior car wax and polish
			Lubricants (Non-spray)
			Liquid fuels/motor oil
Consumer Uses	Chemical substances in agriculture use products	Lawn and garden products	Fertilizers (garage/outside)
Consumer Uses	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Paper articles: with potential for routine contact (diapers, wipes, newspaper, magazine, paper towels)
			Rubber articles: flooring, rubber mats
			Rubber articles: with potential for routine contact
			Plastic articles: other objects with potential for routine contact
Consumer Uses	Chemical substances in hobby products	Arts, crafts, and hobby materials	Craft paint – generic
Consumer Uses	Chemical substances in packaging, paper, and plastic	Ink, toner, and colorant products; Photographic supplies	Inks applied to skin
			Liquid photographic processing solutions
Disposal[b]	Disposal	Disposal	Worker handling of wastes

Conditions of Use			Occupational/Consumer Exposure Scenario Mapped to COU
Life Cycle Stage	**Category**	**Subcategories**	

[a] The repackaging scenario covers only those sites that purchase formaldehyde or formaldehyde containing products from domestic and/or foreign suppliers and repackage the formaldehyde from bulk containers into smaller containers for resale. Sites that import and directly process/use formaldehyde are assessed in the relevant occupational exposure scenario (OES). Sites that that import and either directly ship to a customer site for processing or use or warehouse the imported formaldehyde and then ship to customers without repackaging are assumed to have no exposures or releases and only the processing/use of formaldehyde at the customer sites are assessed in the relevant OES.
[b] Each of the TSCA COU of formaldehyde may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat, dispose, or directly discharge onsite wastes that they themselves generate are assessed in each COU assessment. This section only assesses wastes of formaldehyde that are generated during a COU and sent to a third-party site for treatment, disposal, or recycling.

1.2.3 Other Sources of Formaldehyde in Air

Formaldehyde is ubiquitous in both indoor and outdoor (ambient) air because it is formed naturally in the environment and from numerous anthropogenic sources, which include both TSCA (Section 1.2.2) and other activities. As a result, people are routinely exposed to formaldehyde in indoor and outdoor air, with indoor air generally having higher concentrations than outdoor air. Robust monitoring data are available to estimate the concentrations of formaldehyde across common outdoor and indoor environments. However, attributing measured concentrations to TSCA versus other sources is complex. This section will provide an overview of these data sources and seeks to differentiate between sources when possible. This section is not intended to be a comprehensive review of the scientific literature on this topic but instead provides context for understanding and interpreting the exposures of formaldehyde from a variety of sources as part of risk characterization and risk determination of COUs under TSCA.

Formaldehyde has been measured in outdoor air across the country. EPA's Ambient Monitoring Technology Information Center (AMTIC) maintains a database of spatially and temporally diverse air quality monitoring data that meet specified collection and quality assurance criteria. The Agency used monitoring data extracted from EPA's AMTIC (U.S. EPA, 2022a) from 2015 through 2021 to contextualize modeled values as well as characterize total aggregate exposures to formaldehyde from all possible contributing sources—including sources associated with TSCA COUs and other sources out of scope for this assessment and not associated with TSCA COUs (*e.g.*, biogenic sources (decay of organic matter), secondary formation, combustion byproduct formation, other byproduct formation, mobile sources, and others).These data are described in detail in Sections 2.4.1 and 3.3.2 of the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a). In addition, satellite data have measured formaldehyde concentrations across the United States, providing insights on temporal and geographic trends that help to characterize ambient formaldehyde concentrations (Wang et al., 2022; Harkey et al., 2021; Zhu et al., 2017).

Comprehensive modeling efforts have been undertaken to characterize formaldehyde concentrations that vary across the county. EPA's AirToxScreen is one example that uses release data with chemical transport and dispersion models to estimate average annual outdoor ambient air concentrations of air toxics across the U.S. and is validated against available monitoring data. For formaldehyde, this model estimates concentrations from different sources contributing to ambient air concentrations including biogenic sources, secondary formation, and point sources. Other sources of formaldehyde are included but may not be relevant to the scope of this draft risk evaluation for formaldehyde. Accordingly, the 2019 AirToxScreen estimates that secondary formation of formaldehyde accounts for 80 percent of formaldehyde in ambient air and direct biogenic sources contribute 15 percent. Based on the 2019 AirToxScreen estimates, the calculated ninety-fifth percentile biogenic concentration of formaldehyde in ambient air was 0.28 µg/m^3 (*e.g.*, Ninety-five percent of estimated concentrations of formaldehyde in ambient air attributable to biogenic sources based on the 2019 AirToxScreen data all biogenic sources of formaldehyde are below 0.28 µg/m^3.).

Much like outdoor air, many efforts have been made to characterize formaldehyde in the indoor environment. Draft data from a recent national survey provides a representative sample of formaldehyde concentrations in indoor air, showing average residential levels an order of magnitude higher than outdoor concentrations. The American Healthy Homes Survey II (AHHS II) survey, sponsored by the U.S. Department of Housing and Urban Development (HUD) along with EPA, was conducted from March 2018 through June 2019 and measured indoor air concentrations of formaldehyde in U.S. homes of various ages, types, conditions, and climates (QuanTech, 2021). Across all housing, the weighted-mean concentration is 23.2 µg/m^3 (95% confidence interval 21.6–25.2 µg/m^3) with 10 percent of homes higher than 41.8 µg/m^3. Formaldehyde is introduced into residential indoor air from numerous TSCA sources (*e.g.*, building materials, finishes such as flooring and paint, and furniture) and other sources (*e.g.*, fireplaces, gas stoves, candles, photocatalytic air purifiers, and tobacco use). The TSCA sources are expected to consistently release formaldehyde over long periods of time, with release rates decreasing over time as the materials age. In contrast, many of the other sources are temporary emission sources and contribute formaldehyde to the indoor air intermittently. Overall, due to differences in the ages of building materials, home finishes, and furnishings and differences in presence and use patterns of other formaldehyde sources in the residence, the relative contributions of formaldehyde from TSCA and other sources to residential indoor air varies both among homes and over time within a single home. Thus, despite the availability of quality monitoring data, it remains difficult to discern source apportionment for the residential environment and there are uncertainties related to assessing exposures tied to specific TSCA COUs based on this monitoring data. OPPT will solicit comment from the SACC and the public on additional sources of information that could inform the attribution of other sources of formaldehyde to support risk characterization.

1.3 Chemistry, Fate, and Transport Assessment Summary

EPA considered 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. This was done as a joint effort with the OPP. Physical and chemical properties of formaldehyde, as well as 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 be present in most environmental media but may be abundant in air due to continual release from multiple sources including from TSCA releases, biogenic sources, and formation from secondary sources.

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	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−07 atm/m^3·mol at 25 °C	1.65E−07 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.

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

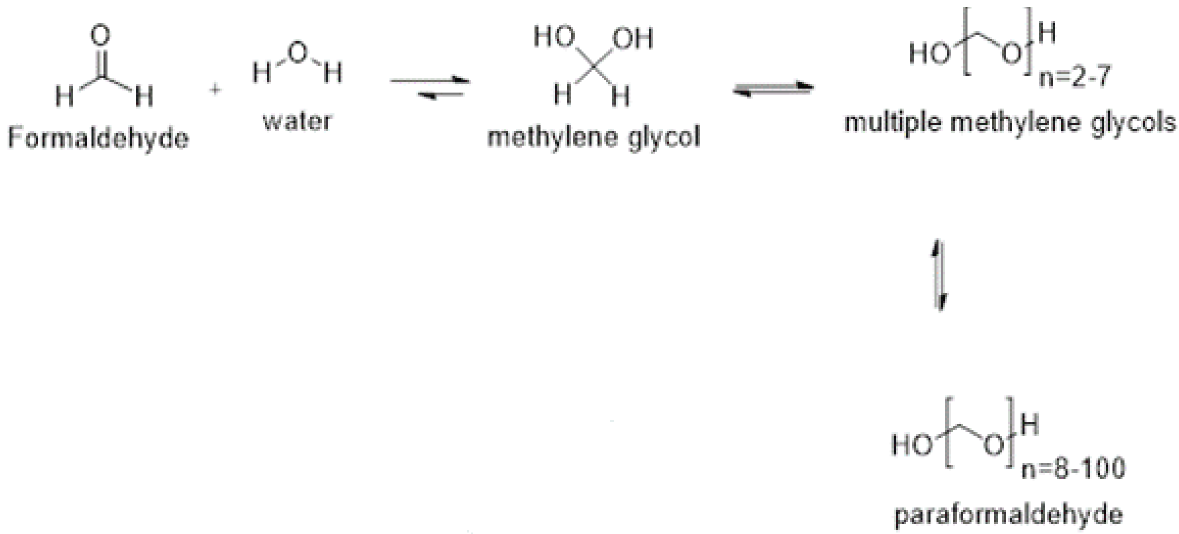

Figure 1-3. Chemical Equilibria for Formaldehyde in Aqueous Solutions
Adapted from (Boyer et al., 2013).

In soil, formaldehyde is also expected to quickly transform to products that are structurally dissimilar to parent formaldehyde; thus, formaldehyde is not expected to be found in soil (U.S. EPA, 2024b). Formaldehyde can be formed in the early stages of plant residue decomposition in soil and is reportedly degraded by bacteria in the soil (U.S. EPA, 2024b). 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 be present in air environments with low or no sunlight (*e.g.*, nighttime, indoor). As such, the primary exposure route for formaldehyde is expected to be the air pathway (U.S. EPA, 2024e). 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.

Due to the physical and chemical properties of formaldehyde including a log K_{OW} (0.35), which is associated with low bioconcentration and bioaccumulation are not expected (U.S. EPA, 2024b). Therefore, human exposure to formaldehyde via consumption of fish was not expected and therefore not assessed.

EPA has high confidence in the overall fate and transport profile of formaldehyde and paraformaldehyde; however, EPA 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, although 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 *Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b).

1.4 Environmental Release Assessment

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

EPA reviewed release data from the Toxics Release Inventory or 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 TSCA COUs, as stated in Table 1-1. Based on a review of these databases, waste streams containing formaldehyde are directly discharged to surface water, indirectly discharged to publicly owned treatment works (POTW) or other 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 transferred to POTW/WWT plants for treatment based on reporting from 168 facilities (U.S. EPA, 2024g). For these wastewater streams 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 methods provide additional time for formaldehyde and methylene glycol to further transform to chemically dissimilar products in the presence of water and chemical, biological, and physical treatment processes 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/year in 2016 to the most recent year (RY2021) of 127,348 kg/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 (includes unit-level estimates) for formaldehyde across the two EPA databases (TRI data from 2016 to 2021and 2017 NEI). To characterize this amount of data, EPA utilized the self-reported NAICS codes to assign sites into CDR industrial sectors (IS). 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, 2024g). 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 TSCA COUs, EPA used professional judgement to assign the industrial sector to commercial TSCA COUs, where applicable. For a few TSCA 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. Additional details are provided in the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g).

In the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g), 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, 2024g). 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 program were associated with natural gas compressor stations and airport operations, which EPA expects is due to formaldehyde produced 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, 2024g)

In general, EPA has medium to high confidence in environmental releases for industrial TSCA COUs[3] and low to medium confidence in commercial TSCA 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 does not meet the reporting criteria for the respective program. EPA used total emissions per site, which may combine formaldehyde emissions from multiple TSCA COUs if the site's formaldehyde-generating processes are applicable to more than one TSCA 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 draft risk evaluation.

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;

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

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 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 Release Assessment for Formaldehyde* (U.S. EPA, 2024g).

1.5 Human Health Assessment Scope

Generally, EPA expects inhalation to be a major route of exposure for occupational, consumer, indoor air, and ambient air based on the volatility and presence of formaldehyde in air. Dermal sensitization from formaldehyde exposure is a rapid effect. Thus, for occupational and consumer COUs where dermal contact to formaldehyde may occur, EPA expects the dermal route to be another significant route of exposure to formaldehyde.

A quantitative assessment of the water pathway was not conducted in this risk assessment given the relatively limited release of formaldehyde directly to surface water, and due to the rapid transformation of formaldehyde in water based on the physical and chemical properties governing the environmental fate of formaldehyde in water. Water monitoring data, while limited, demonstrate formaldehyde is not detected in water as described in more detail in the environmental exposure assessment (U.S. EPA, 2024e). Based on these lines of evidence, EPA does not expect human exposure to formaldehyde will occur via surface water. In addition, formaldehyde is not expected to persist in land or leach to groundwater that may be sourced for drinking water based on the physical and chemical properties governing the environmental fate of formaldehyde in land. Therefore, EPA does not expect human exposure to formaldehyde will occur via soil, land, or groundwater.

1.5.1 Conceptual Exposure Models

1.5.1.1 Industrial and Commercial Activities and Uses

The conceptual model in Figure 1-4 presents the exposure pathways, exposure routes and hazards to people from industrial and commercial activities and uses of formaldehyde. EPA evaluated exposures to workers and occupational non-users (ONU) via inhalation routes and exposures to workers via dermal routes, as shown in Figure 1-4. Oral exposure may occur through wood or textile dust that deposit in the upper respiratory tract that is then ingested; however, formaldehyde will continue to evaporate and there is uncertainty on the amount inhaled that is ingested. For this draft risk evaluation, these exposures were evaluated as an inhalation exposure.

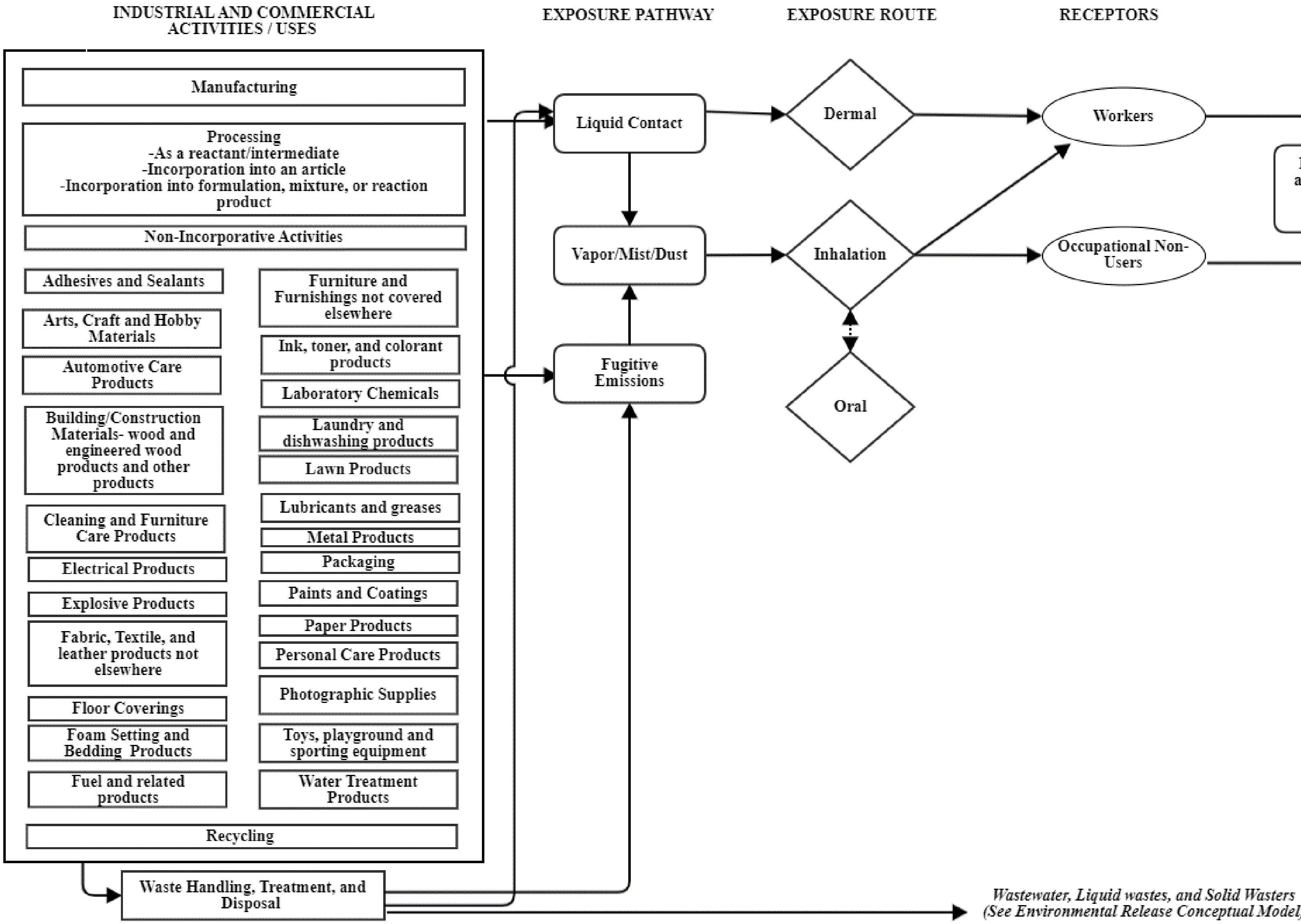

Figure 1-4. Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

Note that fugitive air emissions, as described in Figure 1-4, are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

1.5.1.2 Consumer Activities and Uses

Formaldehyde is found in consumer products and articles that are readily available for public purchase at common retailers and through online shopping venues. Formaldehyde may be either a chemical ingredient in a consumer product or a component in material(s) utilized in the manufacturing of consumer products or articles (adhesives, resins, glues, etc.) or both. Use of such product is expected to result in exposures to both consumers who use a product (consumer user) and bystanders (individuals who are not directly using a product but are exposed while the product is being used by someone else).

Figure 1-5 presents the conceptual model for consumer activities and uses that are in scope for the TSCA formaldehyde risk evaluation. Formaldehyde-containing consumer products include textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, resins, construction materials (including roofing), furniture, toys, and various adhesives and sealants. EPA identified these formaldehyde COUs from information reported to EPA through CDR and TRI reporting, published literature, and consultation with stakeholders for products currently in production or not discontinued.

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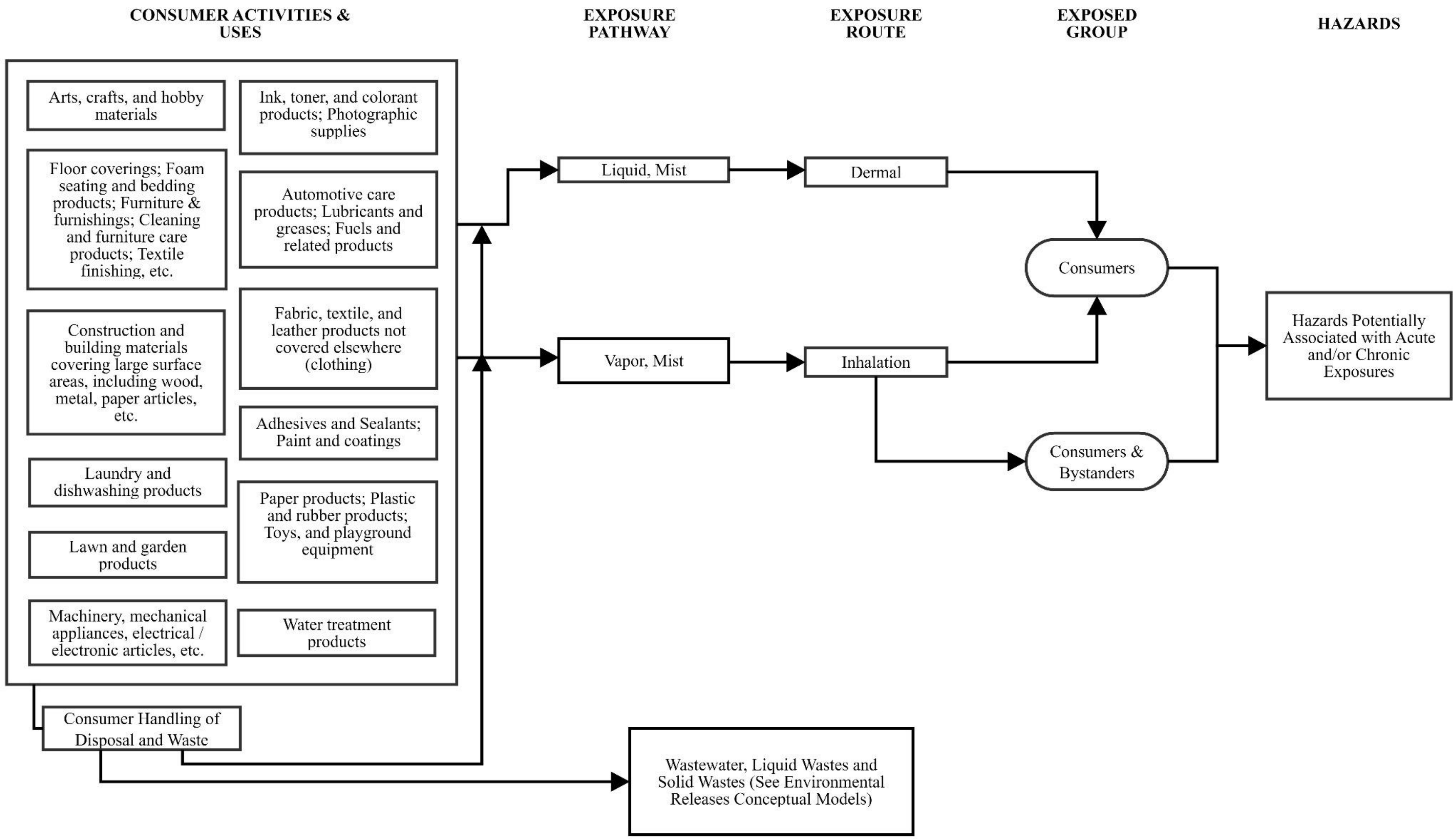

918

919 **Figure 1-5. Formaldehyde Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards**

Some consumer products assessed may also have commercial applications. See Table 1-1 for categories and subcategories of COUs. Inhalation is the primary expected route of exposure for formaldehyde resulting from consumer activities, however, dermal exposures are also expected. EPA considered potential oral exposure pathways associated with TSCA COUs, including lawn and garden products and oral mouthing behaviors in infants and young children. However, because EPA lacks sufficient data to quantify exposures and risks for any of these pathways, oral exposures were qualitatively assessed for relevant COUs (*e.g.*, lawn and garden products). Section 2.2 for the Consumer Exposure Module (U.S. EPA, 2024d) provides more detail about the COUs within the scope of this draft risk evaluation.

1.5.1.3 Indoor Air Exposures

EPA expects formaldehyde exposure to occur in the indoor air environments from several sources via air including from off-gassing of formaldehyde from various consumer articles. The separation of the consumer exposure assessment and the indoor air exposure assessment is intentional; each assessment represents a different context of exposures. The conceptual model in Figure 1-6 presents the exposure pathways, exposure routes and hazards to people from emitters of formaldehyde in indoor air. For example, a passenger may be exposed to formaldehyde through inhalation for the duration of a taxi ride due to formaldehyde off-gassing to air from seat covers within the vehicle.

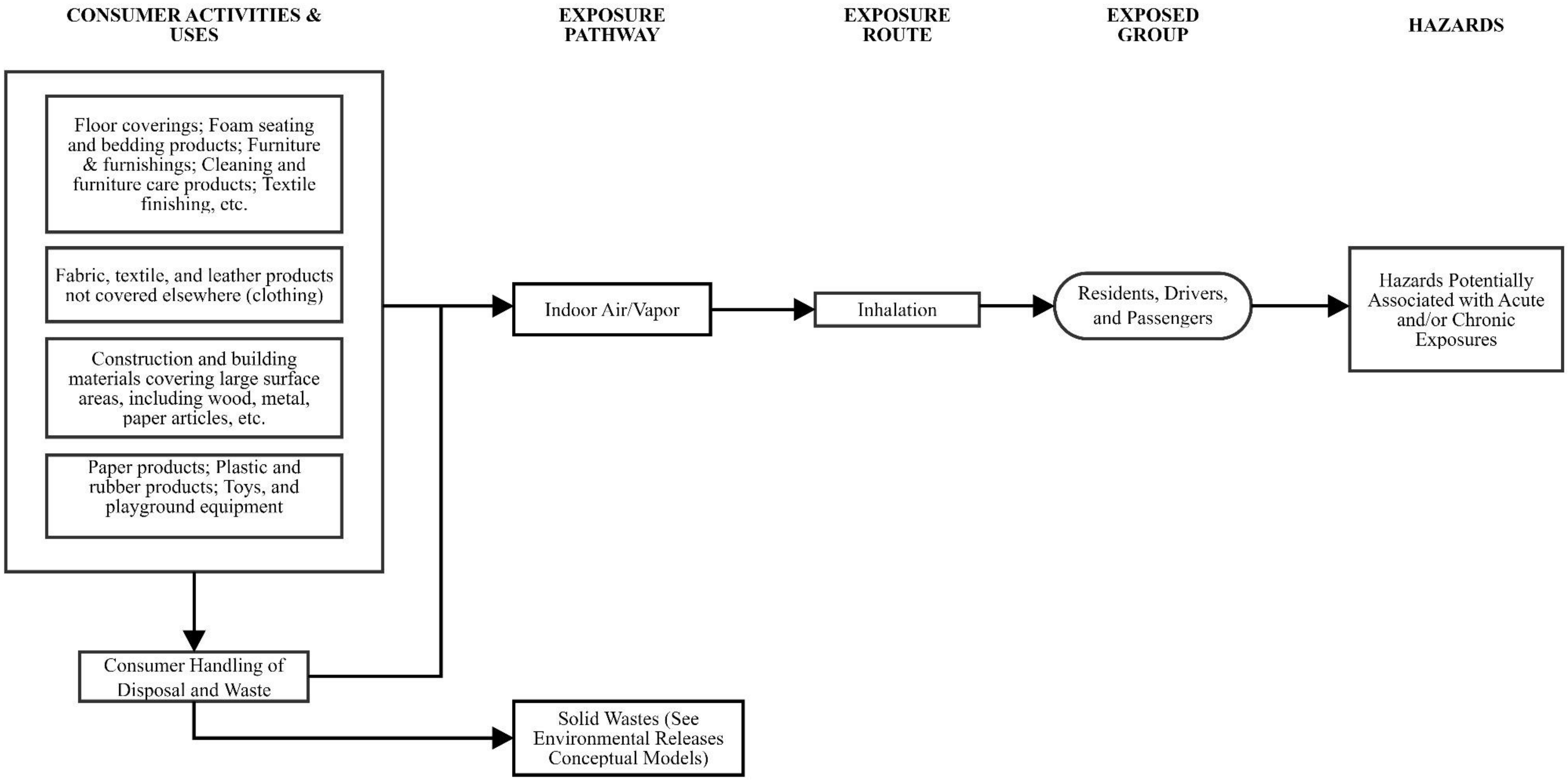

Figure 1-6. Formaldehyde Conceptual Model for Indoor Air: Residential Exposures and Hazards from Article Off-Gassing

1.5.1.4 General Population Exposures from Environmental Releases

Environmental releases of formaldehyde are reported to occur into the ambient air, ambient water, and land environmental media. (U.S. EPA, 2024g). General population exposures to formaldehyde occur when individuals encounter these releases through interaction with one or more of these media (*e.g.*, breathing ambient air into the body (inhalation), incidental skin contact through swimming (dermal), or ingestion of soil (oral)).

Figure 1-7 provides a detailed conceptual model of all pathways and all routes of exposure by which exposures to the general population may occur. While releases are reported to all three environmental media, formaldehyde is not expected to be present in water or land based on the chemical, fate, and transport properties of formaldehyde as described in the *Draft Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b) and discussed in Section 1.2.3. As such, EPA does not expect general population exposure to formaldehyde to occur via either the water or land media and therefore did not quantitatively assess exposures via these media in this draft risk assessment. This is depicted in Figure 1-7 by the dashed lines.

While formaldehyde is susceptible to direct and indirect photolysis, it is expected to be present in the ambient air for at least several hours in direct sunlight (and many more hours in no sunlight) based on the chemical, fate, and transport properties of formaldehyde as described in the *Draft Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b) and Section 1.2.3. Formaldehyde is consistently present in ambient air based on monitoring and testing programs implemented under the Clean Air Act and other EPA programs and statutes. Additional modeling and data from the 2019 AirToxScreen supports the ubiquity and consistent presence of formaldehyde in ambient air from multiple sources (including TSCA and other sources). Considering these multiple lines of evidence, EPA expects general population exposure to formaldehyde from industrial releases to be predominantly via the ambient air pathway. Therefore, EPA quantitatively assessed the ambient air pathway in this risk assessment. This is depicted in Figure 1-7 by a solid line.

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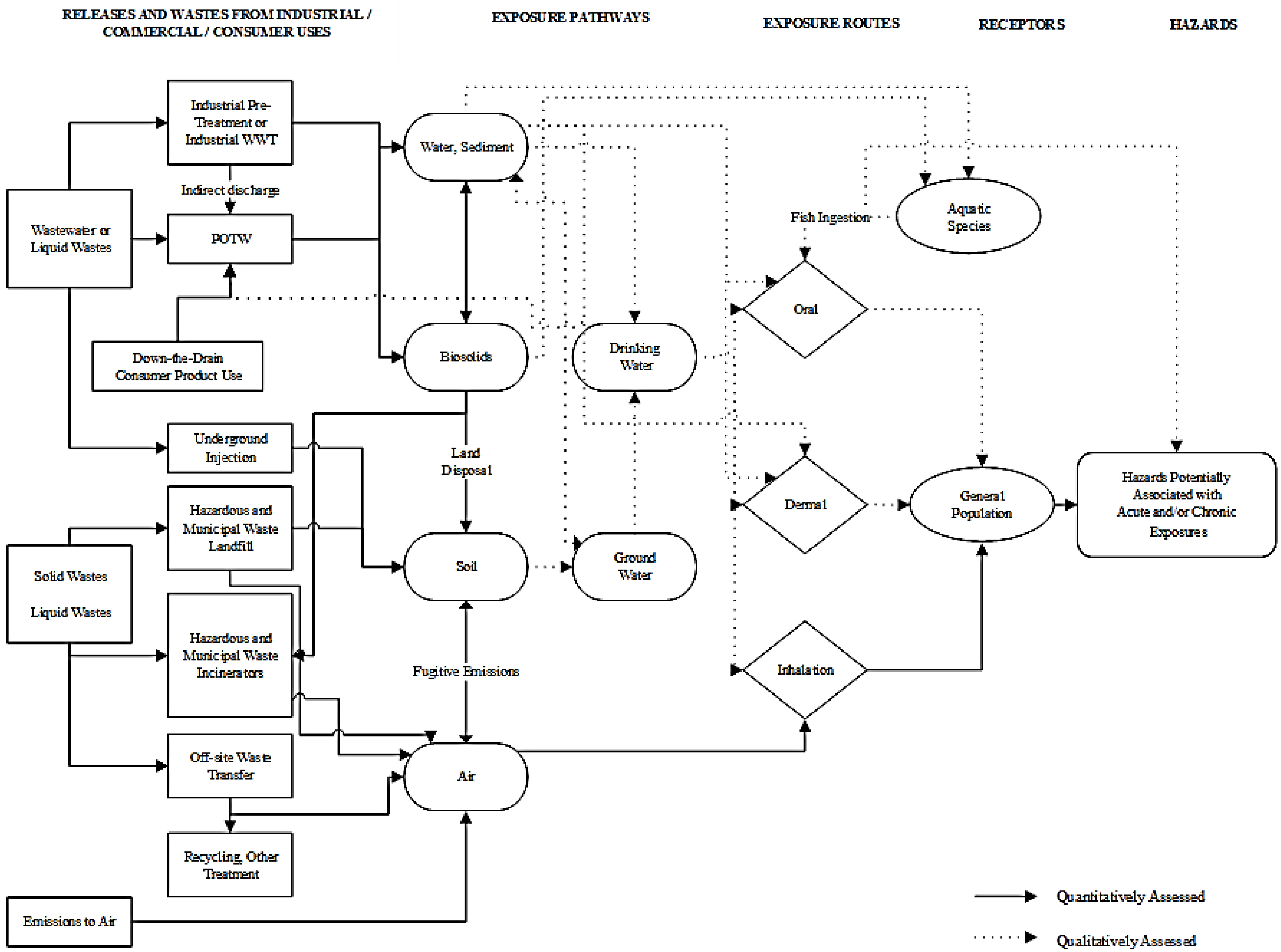

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968 **Figure 1-7. Formaldehyde Conceptual Model for Environmental Releases and Wastes: General Population Exposures and Hazards**

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Figure 1-8 provides a simplified visual representation of industrial releases to ambient air by which exposure to the general population occurs. In general, formaldehyde is released from industrial facilities as uncontrolled fugitive releases (*e.g.*, process equipment leaks, process vents, building windows, building doors, roof vents) and stack releases that may be either uncontrolled (*e.g.*, direct releases out a stack) or controlled with some pollution control device prior to release to the ambient air (*e.g.*, baghouse, scrubber, thermal oxidizer). Once released to the ambient air, the releases move off-site into the surrounding ambient air where exposure to the general population occurs through inhalation. For purposes of this risk assessment, EPA focuses on formaldehyde exposures to individuals living nearby industrial facilities associated with TSCA COUs that are releasing formaldehyde to the ambient air.

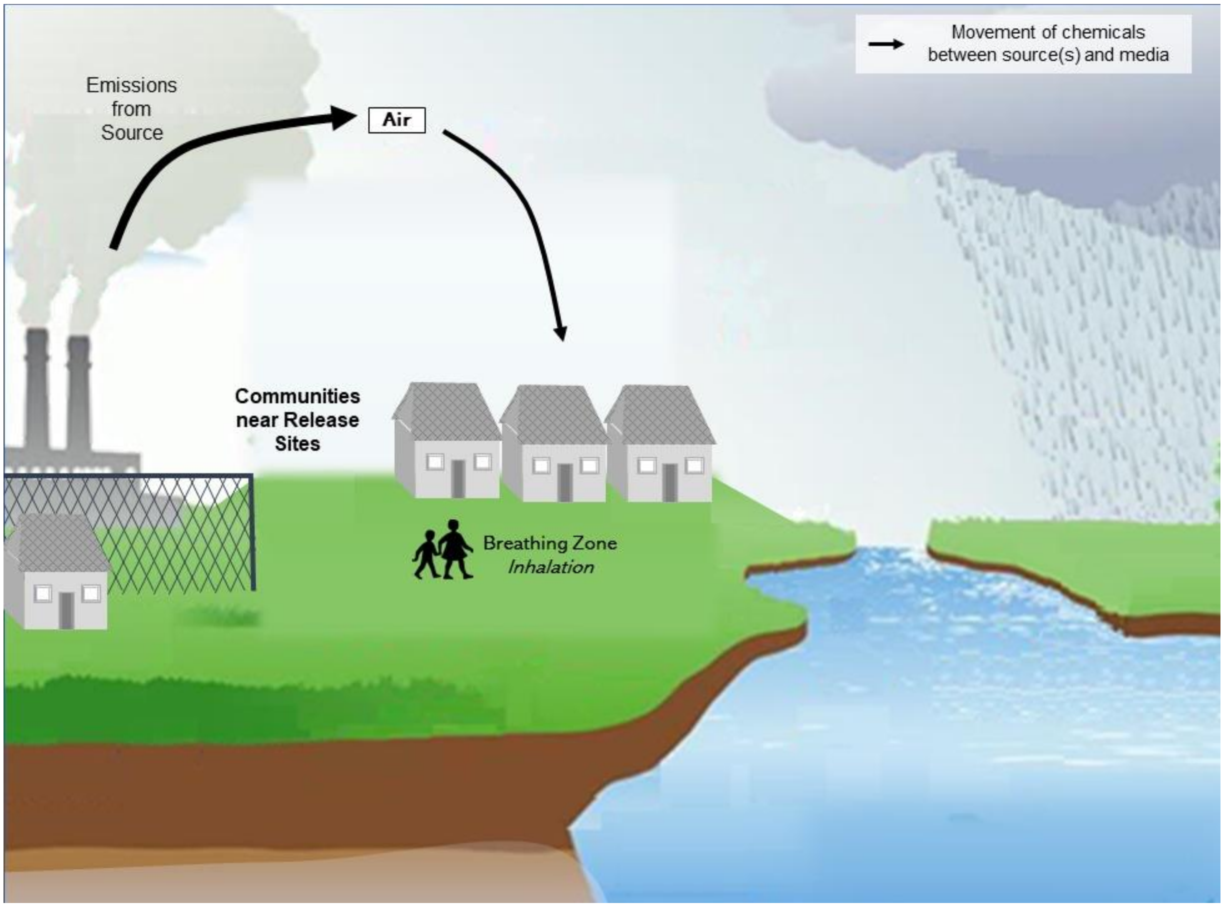


Figure 1-8. Industrial Releases to the Environment and Pathways by Which Exposures to the General Population May Occur

1.5.2 Potentially Exposed or Susceptible Subpopulations

This assessment considers potentially exposed or susceptible subpopulation (PESS), 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. There are many factors that may contribute to increased exposure or biological susceptibility to a chemical, including life stage (*e.g.*, infants, children, pregnant women, elderly), pre-existing disease, lifestyle activities (*e.g.*, smoking, physical activity), occupational and consumer exposures (including workers and ONUs, consumers and bystanders), geographic factors (living in proximity to a large industrial source of formaldehyde), socio-demographic factors, unique activities (*e.g.*, subsistence fishing), aggregate exposures, and other chemical and non-chemical stressors.

Considerations related to PESS may influence the selection of relevant exposure pathways, the sensitivity of derived hazard values, the inclusion of populations, and/or the discussion of uncertainties throughout the assessment.

2 HUMAN EXPOSURE ASSESSMENT SUMMARY

This section summarizes the formaldehyde exposures to occupational workers, ONUs, consumers, bystanders, and general population from both indoor air and ambient air. Detailed information supporting each subsection are available in the associated technical support modules included as supplemental files to this draft human health risk assessment for formaldehyde.

Each exposure assessment considers peak and long-term inhalation exposures. When available, the highest 15-minute average concentrations are used to represent peak exposures while annual average concentrations or 8-hour time-weighted averages (TWA) are used to represent longer-term exposure durations. The long-term exposure duration depends on the exposure scenario being assessed. Specifically, exposure durations for cancer assessment are based on 31 (central tendency) and 40 (high-end) working years for occupational exposure. Exposure durations for cancer assessment are based on 12- or 57-year residency time and 78-year lifetime exposure for consumer and general population. Acute dermal exposures were estimated for workers and consumers and are based on short-term durations, see Appendix G for additional information on the dermal approaches.

Each exposure assessment integrates modeling methodologies previously peer reviewed as well as monitoring data to assess exposures to the respective populations. The exposure assessment also integrates information from the *Draft Chemistry, Fate, and Transport Assessment for Formaldehyde* (U.S. EPA, 2024b) and the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g).

Due to the magnitude of available scientific information on formaldehyde coupled with its complex toxicology and exposure profiles, EPA acknowledges that the evaluation of formaldehyde exposure is challenging. The Agency is at a critical point in the development of the draft risk evaluation where SACC and public input will be essential. For example, OPPT will seek input on its use of inputs and assumptions in the exposure assessments for occupational, consumer, outdoor air, and indoor air scenarios, in part to understand whether its approach may compound one conservative assumption upon another in a manner that leads to unrealistic or un-addressable outcomes. Following SACC and public comments, EPA will revise the draft risk evaluation and issue a final evaluation that will include a determination of whether, under its conditions of use, formaldehyde presents unreasonable risk to health or the environment.

2.1 Occupational Exposure Assessment

EPA identified 49 TSCA COUs under manufacturing, processing, industrial/commercial uses, and disposal. In the *Draft Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024k), EPA evaluated occupational exposure scenarios (OESs) based on the COUs with expected worker activities, inhalation exposure estimates, and dermal exposure estimates for each OES (U.S. EPA, 2024k). Several of the TSCA COU categories and subcategories were grouped and assessed together into a single OES due to similarities in the processes or lack of data to differentiate between them. This grouping minimized repetitive assessments. In other cases, TSCA COU subcategories were further delineated into multiple OESs based on expected differences in processes and associated releases/exposure potentials between facilities. This resulted in assessing 36 OESs for inhalation and dermal exposure. For additional details on the approaches and results, please refer to *Draft Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024k).

2.1.1 Inhalation Exposure Assessment

To assess inhalation exposures from formaldehyde, EPA reviewed workplace inhalation monitoring data from government agencies such as Occupational Safety and Health Administration (OSHA), inhalation monitoring data found in peer-reviewed literature, and other inhalation monitoring data submitted to EPA. Where monitoring data were reasonably available, EPA used these data to characterize central tendency and high-end peak (15-minute) and 8-hour TWA (*i.e.*, full-shift) inhalation exposures for each scenario (OES) to workers and ONUs. In some cases, EPA did not identify 15-minute peak exposure data but identified task-based monitoring data that was used in lieu of 15-minute peak data. The quality of the monitoring data was evaluated using the data quality review evaluation metrics and the categorical ranking criteria described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluation for Chemical Substances* (U.S. EPA, 2021b). Relevant data were assigned an overall quality determination of high, medium, low, or uninformative. For evidence integration, preference was given to monitoring data sampled after the latest update of the OSHA permissible exposure limit (PEL) of formaldehyde in 1992 to 937 μg/m^3 (0.75 ppm) and short-term exposure limit (STEL) to 2,498 μg/m^3 (2.0 ppm). This reduces uncertainties with relying on data that may not reflect current regulatory requirements for TSCA COUs.

For many cases, EPA did not have monitoring data to estimate inhalation exposure for ONUs. In such cases for full-shift exposures, EPA used the central tendency of worker exposure estimates. However, EPA did not quantify peak exposures for ONUs. In general, EPA expects ONU exposures to be less than worker exposures.

For some of the OESs, inhalation monitoring data were not identified. For these cases, EPA utilized models including using a Monte Carlo simulation and Latin Hypercube sampling method to estimate inhalation exposures. Where available, the EPA used generic scenarios or emission scenario documents for relevant exposure points and model input parameters. The Agency then used either monitoring data or modeling results to develop a high-end and central tendency estimates for short-term exposures and 8-hour TWAs for each OES.

Monitoring data were available to support exposure estimates for all COUs except for three COUs that relied on modeled estimates:

- Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products;
- Commercial use – chemical substances in agriculture use products – lawn and garden products; and
- Commercial use – chemical substances in treatment products – water treatment products.

Across TSCA COUs for peak exposure estimates, the central tendency of air concentration estimates ranged from 86 to 2,002 μg/m^3 (0.07 to 1.63 ppm) and high-end of air concentration estimates ranged from 86 to 237,902 μg/m^3 (0.07 to 193.7 ppm). The TSCA COU of Manufacturing showed formaldehyde concentrations above other scenarios, with high-end and central tendency of air concentration results of 237,902 μg/m^3 and 590 μg/m^3, respectively. The underlying scenario was based on monitoring data from manufacturing sites within the United States, which included tasks where the workers wore respiratory protection.

Across TSCA COUs for full-shift estimates, the central tendency of air concentration estimates ranged from 7.5 to 499.3 μg/m^3 (0.01 to 0.40 ppm) and high-end of air concentration estimates ranged from 7.5 to 17,353.3 μg/m^3 (0.01 to 13.9 ppm). The TSCA COU of Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products showed formaldehyde concentrations above other scenarios. The underlying scenario was modeled using a Monte Carlo simulation and assumed that no engineering controls were present. The first modeling approach resulted in a high-end and central tendency of air concentrations results of 17,353.3 μg/m^3 and 499.3 μg/m^3, respectively and assumes that formaldehyde within the automotive care product is completely evaporated during duration of application. This results in a very conservative high-end estimate, well above the current OSHA PEL. EPA also used a second modeling approach using industry monitoring data on total volatile organic compounds to estimate 1,874 μg/m^3 and 371 μg/m^3.

EPA uses peak exposure concentration estimates to calculate acute exposure concentrations (AECs), which is used to estimate acute, non-cancer risks. The full-shift (8- or 12-hour TWA concentrations) are used to calculate average daily concentrations (ADCs) and lifetime average daily concentrations (LADCs). The ADC is used to estimate chronic, non-cancer risks and the LADC is used to estimate chronic, cancer risks. These calculations required additional parameter inputs, such as years of exposure (31 or 40 year worker tenure), exposure duration and frequency (167 or 250 days), and lifetime years (78 years). See Appendix F for more information about parameters and equations used to calculate acute and chronic exposures.

2.1.2 Dermal Exposure Summary

Dermal exposure data were not reasonably available for any of the formaldehyde OESs. Therefore, the EPA modeled dermal exposure to workers using a modified version of the EPA Dermal Exposure to Volatile Liquids Model. As the health effect of concern for formaldehyde is the result of exposure at the point of contact, as opposed to the chemical absorbing into the skin, the absorption factor, body weight, and surface area were not necessary for the calculation of dermal exposure. The calculation reduces to an assumed amount of liquid on the skin during one contact event per day adjusted by the weight fraction of formaldehyde in the liquid to which the worker is exposed.

EPA only evaluated dermal exposures for workers since ONUs are not assumed to directly handle formaldehyde. EPA did not quantify dermal exposure for two COUs: Distribution in commerce and Commercial use – chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment as dermal contact was expected with solid articles that may contain low residual formaldehyde concentrations.

EPA used the maximum formaldehyde concentrations, which is the highest concentration level of formaldehyde that a worker handles throughout the process. EPA used concentration data from published literature and CDR to develop high-end and central tendency dermal exposure estimates.

The dermal exposure estimates ranged from 0.56 to 840 μg/cm^2 for central tendency exposures, and 0.84 to 3,090 μg/cm^2 for high-end exposures. The high-end dermal retained dose for four COUs had a value of 3,090 μg/cm^2, which is well above the other dermal exposure estimates:

- Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products and
- Processing – incorporation into an article – paint additives and coating additives not described by other categories in transportation equipment manufacturing [including aerospace];
- Industrial use – paints and coatings; adhesives and sealants; lubricants; and
- Commercial use – chemical substances in construction, paint, electrical, and metal products – adhesives and sealants; paint and coatings.

For manual spray applications, EPA expects dermal exposures to be higher. Spray applications are expected for the use of automotive care products and coatings, paints, adhesives, or sealants. In addition, during the use of automotive care products, workers may use immerse rags in the detailing products, which could lead to higher dermal loading. For both OESs, EPA assumed an immersive dermal loading (HE: $Q_{\underline{u}}$ of 10.3 mg/cm^2) on the skin during the exposure scenario. For other OESs, EPA calculated dermal exposures assuming lower dermal loadings based on expected worker activities (HE: $Q_{\underline{u}}$ of 2.1 mg/cm^2).

2.2 Consumer Exposure Assessment

To assess consumer exposures, EPA identified 30 exposure scenarios (from 12 formaldehyde TSCA COUs) that may lead to consumer or bystander exposures. EPA's Consumer Exposure Model (CEM) Version 3.0 was used to estimate the 15-minute peak and lifetime average daily concentration for inhalation exposures to consumer users and bystanders, and the dermal loading during relevant product and article use. The key conclusions of the consumer exposure assessment are summarized in the CEM (U.S. EPA, 2024d) and below.

EPA only quantified exposures for plausible exposure pathways, routes, and timespans of exposure and exposure scenarios for which EPA had at least a medium level of confidence. This means that for some COUs (*i.e.*, solid products) a dermal loading estimate was not generated since it was not deemed appropriate (*e.g.*, dermal loading from machinery, mechanical appliances, electrical/electronic articles) given the best available tools and data. This also means that the total number of COUs assessed for acute and chronic inhalation scenarios (*e.g.*, 15-minute peak compared to lifetime average daily concentration estimations) varied according to the relevance of the exposure assessment. However, as presented in Table 1-1 of the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d), EPA quantified exposures for all relevant COUs for at least one route of exposure.

Of note, when potential exposures to the machinery, mechanical appliances, electrical/electronic articles were assessed, CEM did not yield any expected inhalation exposures via estimates of 15-minute peak and average daily concentration. Modeled estimates for adhesives and sealants were used as surrogates for the exposures to electronic products because adhesives and sealants are used in the binding of internal components and especially at the seams of electronic products. Similarly, EPA does not expect dermal (skin loading) or oral exposures from reasonably foreseen use of such products, as these exposures are expected to be negligible.

In addition, EPA did not quantify exposures for COUs in which EPA had a low exposure assessment confidence. EPA did, however, qualitatively assess the following COUs:

- Water treatment products: No supporting products could be identified other than a fish tank cleaning solution and because formaldehyde is highly reactive in water; therefore, these exposures are expected to be negligible.
- Laundry and dish washing products: Formaldehyde is highly reactive in water. EPA believes these preliminary CEM modeling results are implausible.
- Lawn and garden products: The non-pesticidal exposure scenario for this TSCA COU is unclear because when mixed in water, formaldehyde is highly reactive. In addition, EPA's CEM assumes no inhalation exposure from such products. This is likely due to the default assumption that such activities typically occur outdoors where the chemical would be diluted in the ambient air during and after use.
- Foam insulation: Formaldehyde exposures from foam insulation products were not quantified as consumer exposures to these products are expected to be minimal. During the public comment period for the draft high priority designation of formaldehyde, the North American Insulation Manufacturers Association stated "for those insulation products in which formaldehyde is a

> component of the binder, the products are cured at high temperatures during the manufacturing process after the binder has been applied, virtually eliminating the free formaldehyde content. Any free formaldehyde released from the binder during cure is destroyed either during the cure process or by emissions control equipment required by the Maximum Achievable Control Technology (MACT) standard. Therefore, formaldehyde off-gassing from the majority of finished products is highly unlikely" (Docket ID EPA-HQ-OPPT-2019-0131). Given this information, EPA expects formaldehyde exposures to foam insulation to be negligible.

Given that each TSCA COU may comprise multiple exposure scenarios and multiple scenarios may be applicable to multiple COUs, representative scenarios were identified for each TSCA COU per relevant exposure assessment. Representative scenarios were identified according to the highest estimated exposure estimate per assessment. Refer to Appendix B of the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d) for a list of representative consumer exposure scenarios according to TSCA COUs.

CEM uses a two-zone representation of the building of use when predicting indoor air concentrations. Zone 1 represents the room where the consumer product is used; Zone 2 represents the remainder of the building. Each zone is considered well-mixed. CEM allows further division of Zone 1 into a near-field and far-field to accommodate situations where a higher concentration of product is expected very near the product user when the product is used. Zone 1-near-field represents the breathing zone of the user at the location of the product use while Zone 1-far-field represents the remainder of the Zone 1 room.

Inhalation exposure is estimated in CEM based on zones and pre-defined activity patterns. The simulation run by CEM places the product user within Zone 1 for the duration of product use while the bystander is placed in Zone 2 for the duration of product use. Following the duration of product use, the user and bystander follow one of three predefined activity patterns established within CEM, based on modeler selection. The selected activity pattern takes the user and bystander in and out of Zone 1 and Zone 2 for the period of the simulation. The user and bystander inhale airborne concentrations within those zones, which will vary over time, resulting in the overall estimated exposure to the user and bystander.

Modeled formaldehyde concentrations depend upon the room of use, amount of the chemical in the product and consumer use patterns (*e.g.*, amounts used). Consumer users of products and articles generally had higher peak and long-term inhalation exposures, in comparison with bystanders. Across all relevant age groups and exposure scenarios, the highest estimated 15-minute peak TWA formaldehyde air exposure was for consumer users of 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, while the lowest 15-minute peak exposure was for individuals using textiles or clothing that emit formaldehyde (Figure 2-1). Consumer users of adhesives and sealants; paint and coatings were estimated to have the highest estimated average daily air exposure to formaldehyde (Figure 2-2), while consumer users of automotive care products had the lowest average daily exposure.

The highest acute dermal loading for consumer users resulted from use of automotive care products. The lowest acute dermal loading resulted from use of arts, crafts, and hobby materials (Figure 2-3). For the dermal assessment, the estimated dermal loading was based on weight fraction identified in the literature and safety data sheets (SDSs).

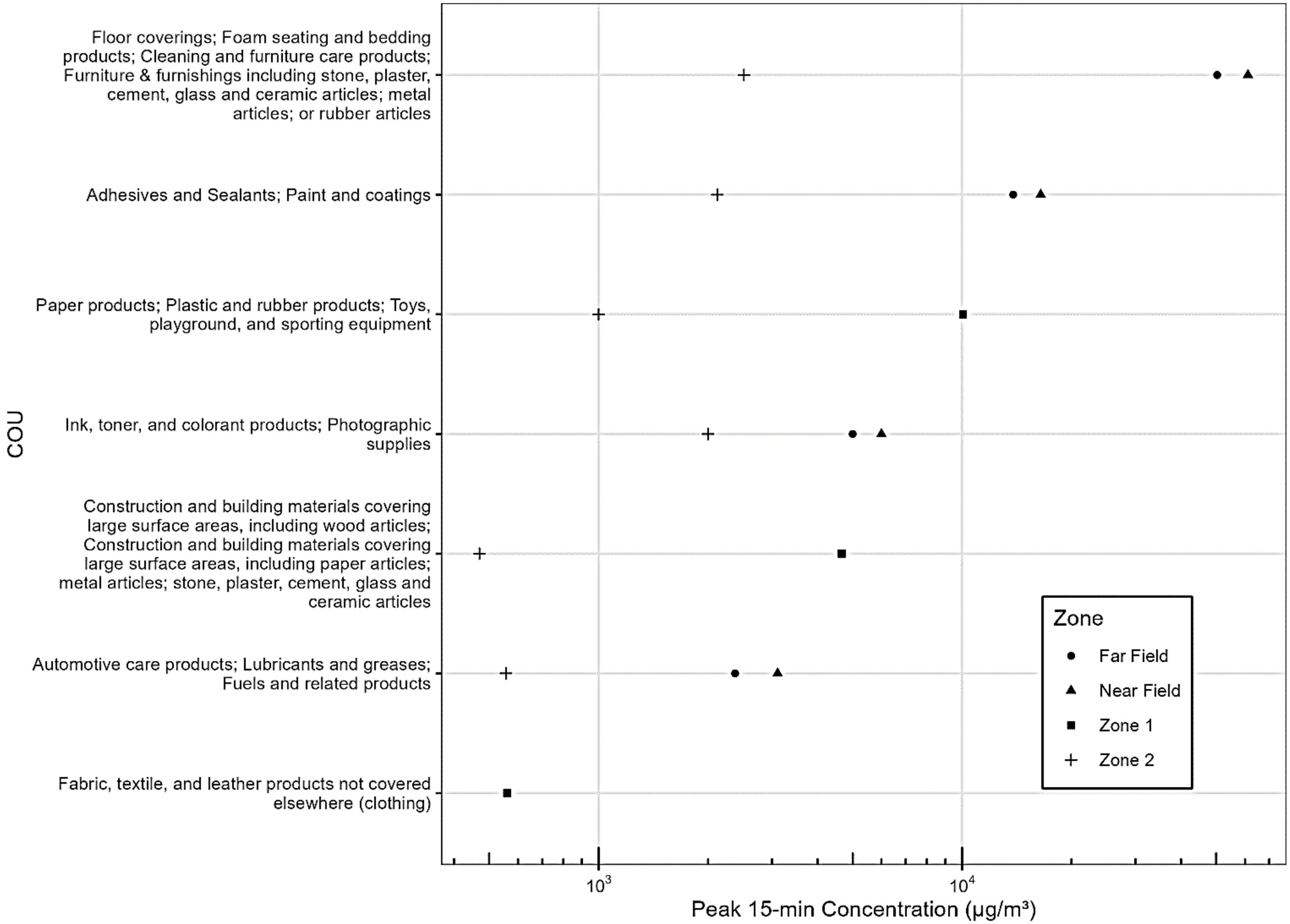
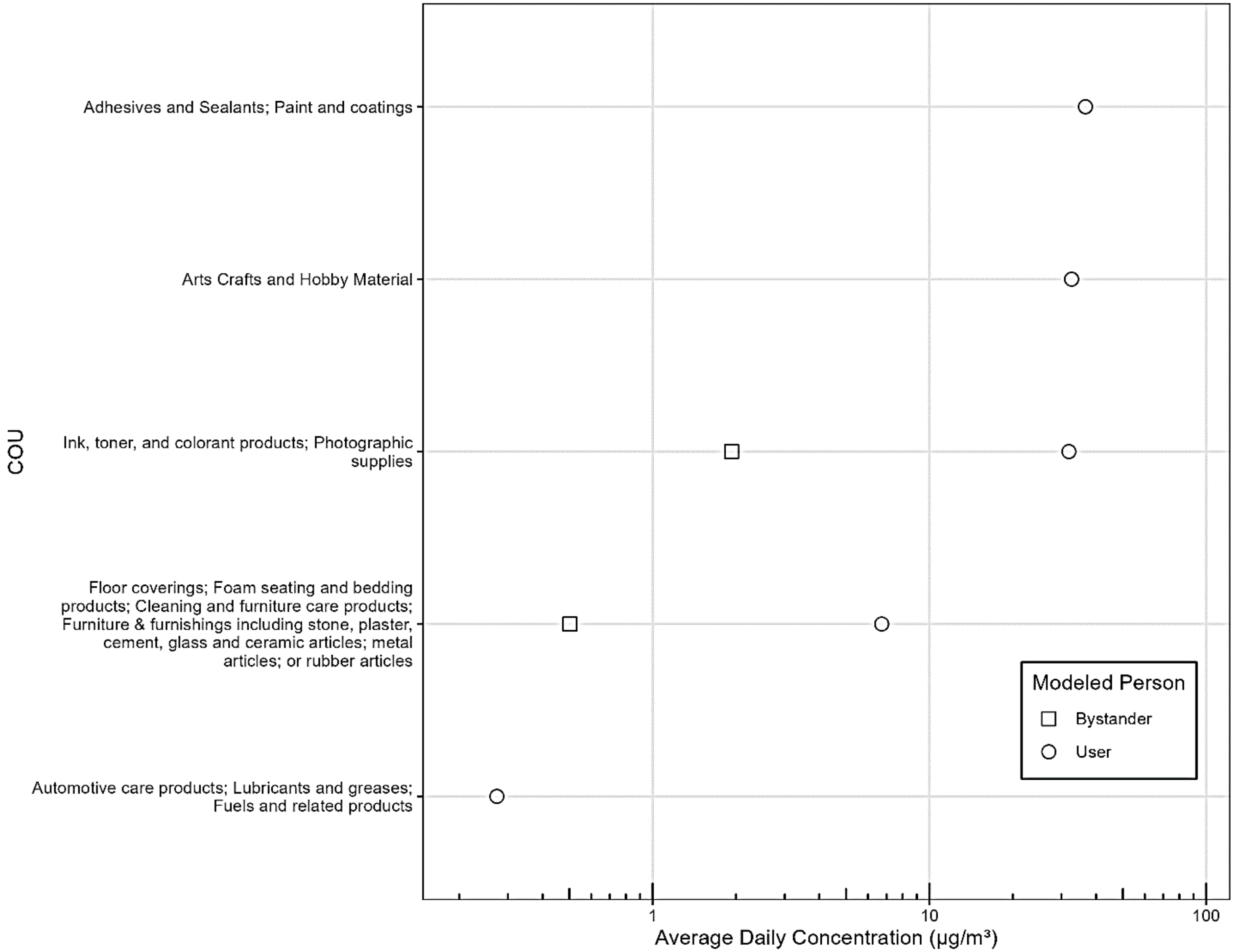


Figure 2-1. Summary of 15-Minute Peak Consumer Inhalation Concentrations (Based on CEM)

For some products, air concentrations were modeled for near-field and far-field (generally describing differences in exposure within the same room), while for other products, concentrations were modeled for zones 1 and 2 (generally describing different rooms). Risks from near-field and zone 1 exposures generally represent risks from direct exposures to consumer users while far-field and zone 2 tend to represent risks to consumer bystanders. The x-axis presents the 15-minute peak inhalation non-cancer concentration and the y-axis presents the modeled TSCA COU.



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1237 **Figure 2-2. Summary of Average Daily Consumer Inhalation Concentrations, per Year (Based on CEM)**
1238 The x-axis presents the chronic inhalation average daily concentration, and the y-axis presents the modeled exposure TSCA COU.

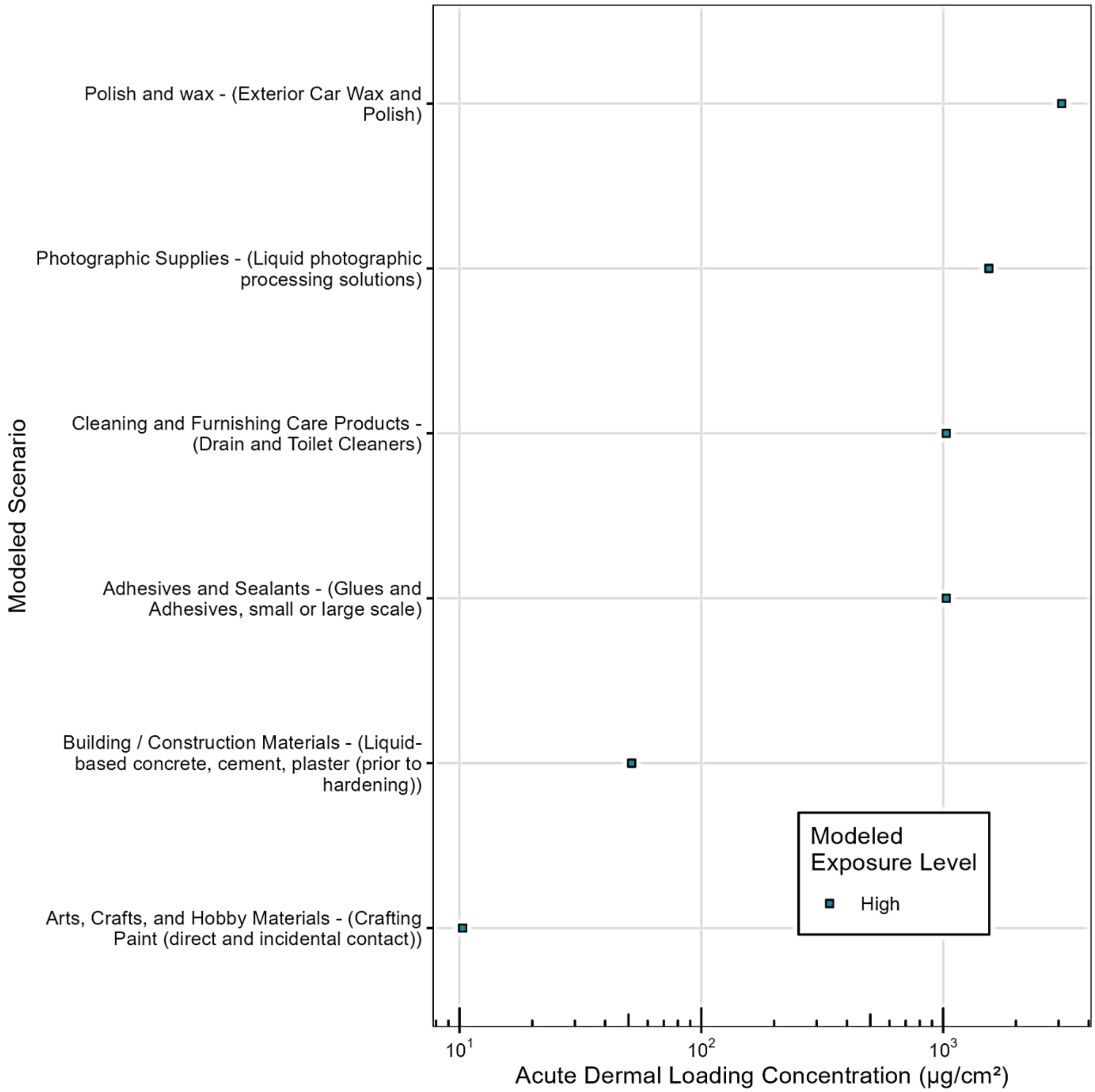


Figure 2-3. Summary of Acute Consumer Dermal Concentrations (Based on Thin Film Model)
The x-axis presents dermal loading concentration, and the y-axis presents the modeled TSCA COUs. The term "High" in the figure refers to high-end scenarios as described above.

2.3 Indoor Air Exposure Assessment

A detailed analysis for indoor air can be found in the *Draft Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j). The separation of the consumer exposure assessment and the indoor air exposure assessment is intentional; each assessment represents a different context of exposures. Generally, exposures to most consumer products occur over a relatively short period of time (minutes to hours per day) and the duration of exposure from those uses within a residence are expected to be short relative to continuous sources of exposure such as flooring or furniture. Thus, the indoor air exposure assessment represents exposures mainly resulting from the presence of articles or materials within a residential household which typically off-gas formaldehyde over an extended period (particularly the first several years after an article or material is manufactured). The indoor air exposure assessment also incorporates aspects of ongoing exposures to populations in office or commercial settings and therefore is more expansive and inclusive than the consumer exposure assessment.

Formaldehyde is a chemical ingredient in many products, which release formaldehyde into the indoor air. Indeed, indoor air studies of formaldehyde (IPCS, 2002; ATSDR, 1999) demonstrate that the indoor environment, including homes and automobiles, can be a major source of formaldehyde exposure. This is because formaldehyde is used ubiquitously for the manufacturing of various consumer products (*e.g.*, wallpaper, hardwood floors, seat covers used in numerous articles) and because formaldehyde is formed as a combustion byproduct from sources such as fireplaces, ovens, stoves, and tobacco smoke.

Given the number of TSCA and other sources contributing to formaldehyde in indoor air, indoor air concentrations reported in monitoring studies are generally considered a reflection of aggregate exposures. Any reported average indoor air monitoring for formaldehyde in American homes is expected to be a result of off-gassing from articles or materials, or long-term emissions (*e.g.*, from fireplaces or stoves), from multiple TSCA COUs and other sources. While intermittent product or article use may briefly contribute to indoor air formaldehyde concentrations, generally EPA assumes that most formaldehyde indoor air exposures occur over an extended period spanning several months to multiple years (U.S. EPA, 2016b).

In the *Draft Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j), EPA considered available monitoring data from commercial, residential, and automobile environments (Section 2.3.10). EPA also used CEM to model chronic indoor air exposure resulting from TSCA COUs that are expected to be the largest contributors of formaldehyde to indoor air primarily due to off-gassing (Section 0). EPA incorporated TSCA COU-specific emission rates extracted from the literature, when available, into its modeling to better approximate real-world conditions. Residential indoor air modeled and measured concentrations of formaldehyde were generally within the same order of magnitude.

2.3.1 Indoor Air Exposure Monitoring Results

EPA identified over 800 monitoring studies, 290 of which are specific to the indoor air environment and associated with the 12 TSCA COUs subject to this risk evaluation (see Appendix A of the *Draft Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j)). As was presented in Section 3.2.2 of the *2016 Formaldehyde Exposure Assessment Report TSCA Title VI Final Rule* (U.S. EPA, 2016b), EPA presents a supplemental summary of formaldehyde concentrations identified from several well-established residential (Table 2-1, Figure 2-4) and commercial (Table 2-2) indoor air monitoring studies to provide additional context to the TSCA formaldehyde indoor air exposure assessment. From a comparison of residential (Table 2-1) and commercial (Table 2-2) indoor air monitoring, residential indoor air exposures to formaldehyde are generally expected to be higher compared to commercial buildings due to expected lower room volumes and air exchange rates in residences relative to commercial buildings.

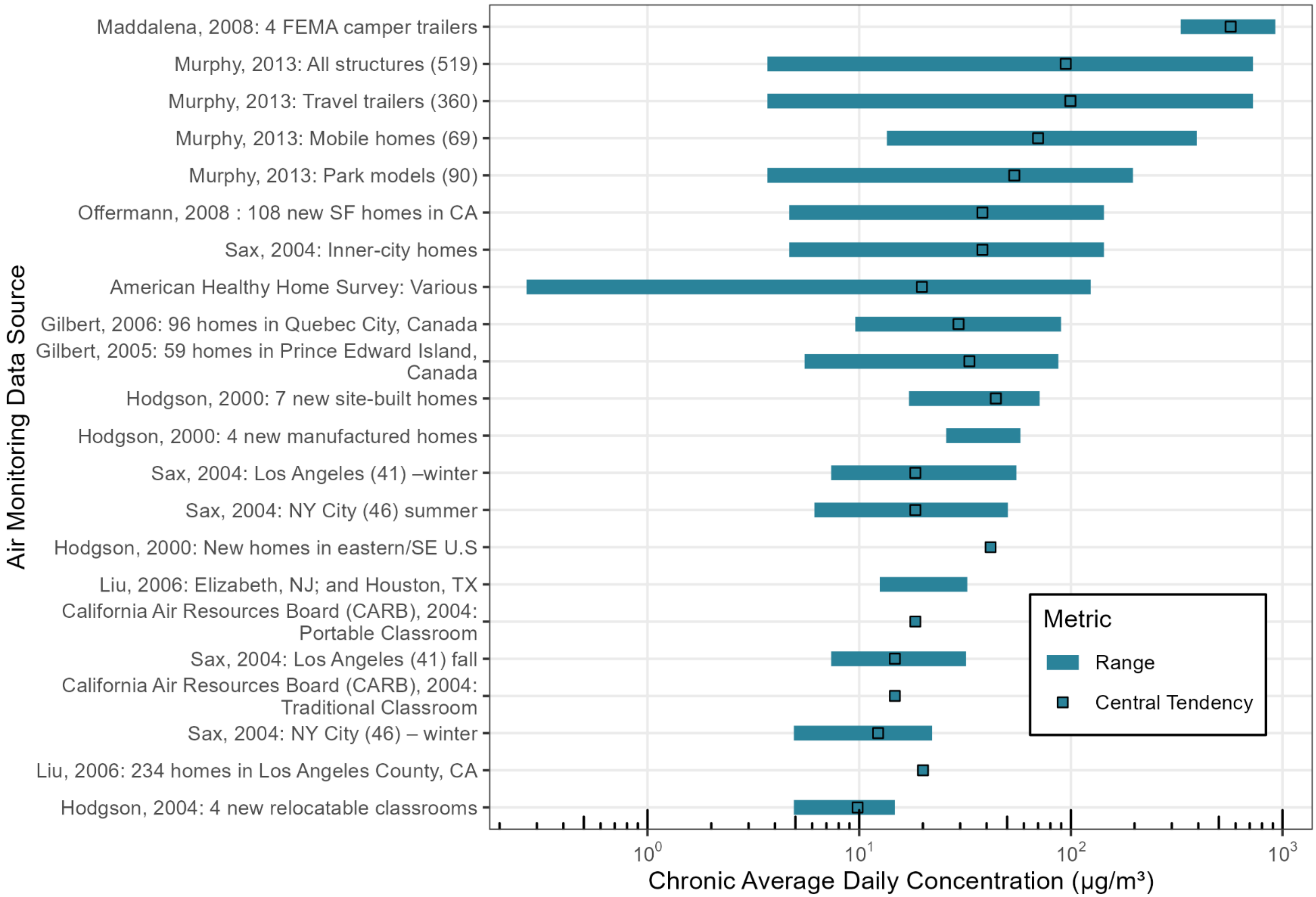
Table 2-1. Indoor Air Monitoring Concentrations for Formaldehyde

Reference	Monitoring Study Description	Formaldehyde Concentrations (µg/m³)	
		Central Value	**Range/Percentiles**
American Healthy Home Survey (QuanTech, 2021)	Nationally representative sample of 688 U.S. homes of various ages, types, conditions, and climates	Mean: 23.2	Range (lower/upper 95% tiles of mean): 21.4–25.0
(CARB, 2004)	Portable and traditional classrooms in 67 California schools (Phase II study)	Arithmetic mean: 18.42 (portable) 14.74 (traditional)	95th Percentile: 31.93 (portable) 27.02 (traditional)
(Gilbert et al., 2005)	59 homes in Prince Edward Island, Canada	Geometric mean: 33.16	Range: 5.53–87.33
(Gilbert et al., 2006)	96 homes in Quebec City, Canada	Geometric mean: 29.48	Range: 9.58–89.91
(Hodgson et al., 2004)	4 new relocatable classrooms	Unspecified mean: 9.83 (indoor-outdoor)	Range: 4.91–14.74 (indoor-outdoor)
(Hodgson et al., 2000)	New homes in eastern/SE U.S.: 4 new manufactured homes 7 new site-built homes	Geometric mean: 41.76 44.22	Range: 25.79–57.73 17.2–71.24
(Liu et al., 2006)	234 homes in Los Angeles County, CA; Elizabeth, NJ; and Houston, TX	Median: 20.02	Range: 12.53–32.43 (5th–95th percentiles)
(LBNL, 2008)	4 FEMA camper trailers	Unspecified mean: 568.67	Range: 330.39–924.85
(Murphy et al., 2013)	Sample: All structures (519) Travel trailers (360) Park models (90) Mobile homes (69)	Geometric mean: 94.57 99.49 54.04 70.01	Range: 3.68–724.65 3.68–724.65 3.68–196.52 13.51–393.03
(Offermann et al., 2008)	108 new SF homes in CA	Median: 38.2	Range: 4.67–143.33
(Sax et al., 2004)	Inner-city homes: NY City (46) – winter (W), summer (S) Los Angeles (41) – winter (W), fall (F)	Median: 12.28 (W), 18.42 (S) 18.42 (W), 14.74 (F)	Range: 4.91–22.11 (W), 6.14–50.36 (S) 7.37–55.27 (W), 7.37–31.93 (F)

Table 2-2. Formaldehyde Monitored in U.S. Commercial Buildings from 2000 to Present

Reference	Monitoring Study Description	Formaldehyde Concentrations (µg/m³)	Descriptor
(Ceballos and Burr, 2012)	Office space indoor air monitoring for formaldehyde in a commercial building	24.56	Average
(U.S. EPA, 2023k)	Indoor air monitoring across 100 randomly selected U.S. commercial buildings	3.68	5th percentile
		14.74	50th percentile
		30.71	95th percentile
(Page and Couch, 2014)	Indoor air U.S. government offices	<61.41	Maximum
(Lukcso et al., 2014)		12.28	Geometric mean
		56.50	Maximum
(Dodson et al., 2007)	Classrooms in school buildings in the United States	17.69	Median

1295



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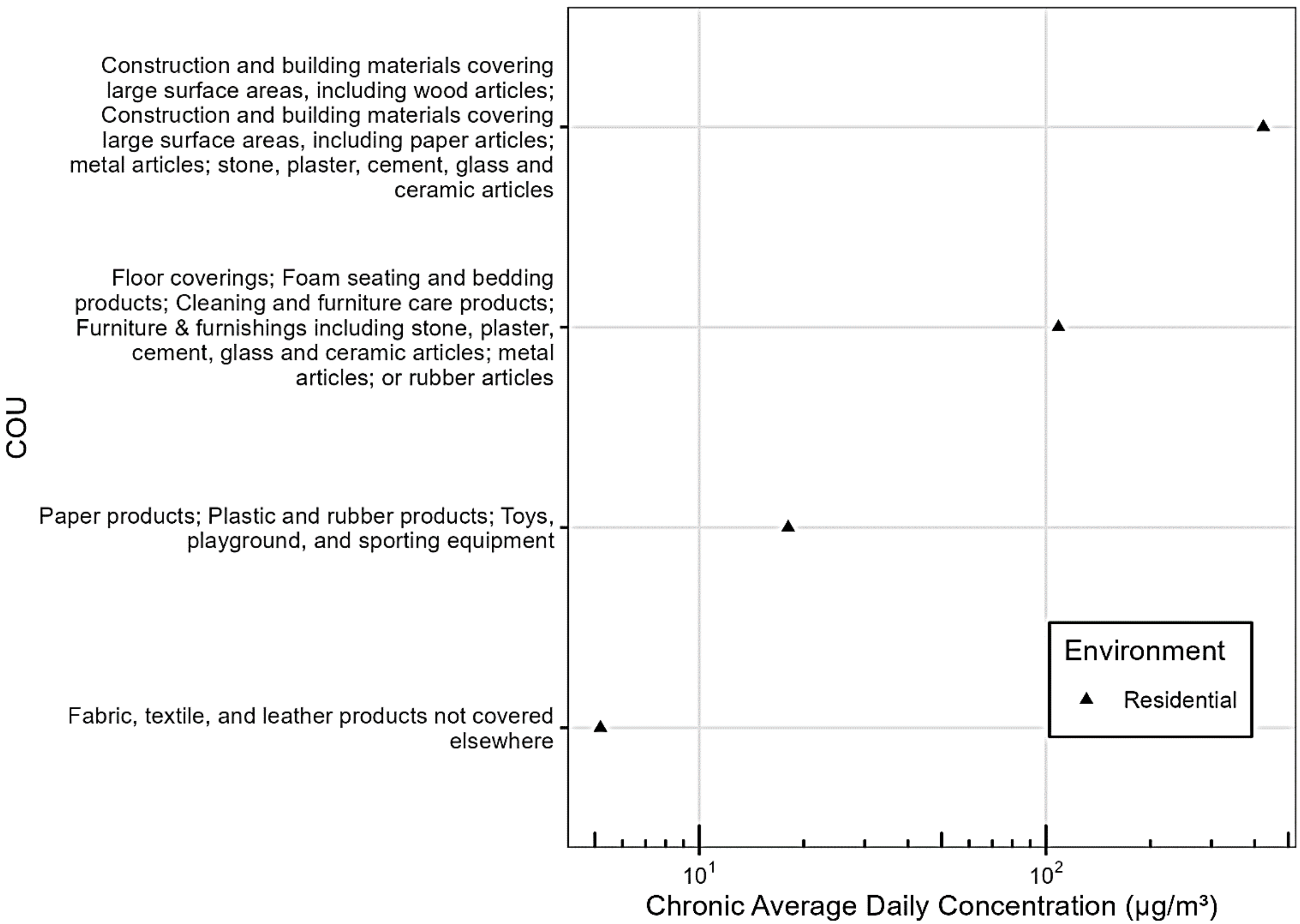
1297 **Figure 2-4. Long-Term Average Daily Concentrations of Formaldehyde According to Air Monitoring Data Source**

Monitoring data from the American Healthy Homes Survey II suggests that concentrations of formaldehyde may range from 0.27 to 124.2 µg/m^3 for all homes (including new homes at the time of survey), with 95 percent of homes having concentrations below 47 µg/m^3 (QuanTech, 2021). Those data include formaldehyde produced from both TSCA sources (Section 3.1.1 of the *Draft Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j) and other sources of formaldehyde such as tobacco smoke or the use of fireplaces, gas-burning appliances, candles, and air purifiers (QuanTech, 2021). These other sources do not contain formaldehyde but rather lead to the formation of formaldehyde during use.

For other sources of formaldehyde in indoor air, simulated 50th percentile room concentrations ranged from 12.3 to 44.2 µg/m^3 individually for candles, incense, cooking, wood combustion, and air cleaning devices, and up to 152.2 µg/m^3 for ethanol fireplaces (ECHA, 2019). Air cleaning devices such as photocatalytic air purifiers can produce formaldehyde from irradiation of air contaminants, leading to increased indoor air concentrations of formaldehyde (Salthammer, 2019). Formaldehyde production associated with cooking depends on many factors, including cooking temperature and type of oil and variety of food being cooked. Select gas-oven cooking tests involving a variety of cooking parameters resulted in formaldehyde concentrations ranging from 36.5 to 417.3 µg/m^3 (Salthammer, 2019). Tobacco smoke is also known to be a contributor to formaldehyde concentrations within all indoor air environments (U.S. EPA, 2016b; Girman et al., 1982), although according to the World Health Organization, tobacco smoke primarily increases formaldehyde concentrations in indoor air environments where the rates of smoking are high with minimal ventilation (IPCS, 2002).

2.3.2 Indoor Air Exposure Modeling Results

EPA used CEM to model indoor air concentrations in American homes and vehicles based on TSCA COU-specific emission rates, providing an estimate of TSCA COU-specific contributions to formaldehyde in indoor air. Central tendency estimates were generated as discussed in Section 2.1.1.1.3 of the Indoor Air Exposure Module (U.S. EPA, 2024j) for comparability with AHHS II monitoring data and to estimate common indoor air concentrations for most American households. For the TSCA COUs identified in Section 1.1 of the Indoor Air Exposure Module (U.S. EPA, 2024j), EPA estimated chronic average daily indoor air exposures. Through a review of key products known to be significant and persistent emitters of formaldehyde, EPA identified four TSCA COUs as potentially significant contributors to residential indoor air environment.

1329 

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1331 **Figure 2-5. Modeled Formaldehyde Average Daily Inhalation Concentrations in Indoor Air (According to CEM)**

1332 The x-axis presents the average daily concentration, and the y-axis presents the modeled TSCA COUs.

EPA generated estimated indoor air exposures using the CEM for four TSCA COUs (see Section 2.1.1 of the Indoor Air Exposure Module (U.S. EPA, 2024j)). The Agency used emission rates and fluxes identified from the literature and compared the estimated indoor air concentrations in homes and vehicles with air monitoring concentrations from the literature (Table 2-3 of the Indoor Air Exposure Module (U.S. EPA, 2024j)). Modeled concentrations of formaldehyde are within the same order of magnitude as reported in monitoring studies, including the American Healthy Homes Survey II (see Section 3.2 of the Indoor Air Exposure Module (U.S. EPA, 2024j)).

The estimated formaldehyde indoor air exposures likely represent exposures from new articles added to a resident (*e.g.*, wood products). Given each COU may comprise multiple exposure scenarios and multiple scenarios may be applicable to multiple COUs, representative exposure scenarios were identified according to the highest estimated exposure estimate per scenario in a room of use, for each COU (Table 2-3).

Table 2-3. Representative Residential Indoor Air Exposure Scenarios According to COUs

Conditions of Use	CEM Exposure Scenarios[a]
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	**Building/Construction Materials – Wood Articles: Hardwood Floors (residential)**
Fabric, textile, and leather products not covered elsewhere	Seat Covers (automobile)
	Furniture Seat Covers (residential)
	Fabrics: Clothing (residential)[b]
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	**Furniture & Furnishings – Wood Articles: Furniture (residential)**
Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	**Paper-Based Wallpaper (residential)**

[a] Representative exposure scenarios, as noted in Section 2.1.1, are bolded as these scenarios had the highest estimated concentrations per COU.
[b] Within this COU, the Clothing (residential) scenario is identified as the representative scenario despite a lower estimated concentration compared to Seat covers (automobile), since residential indoor air environments are of primary interest in this indoor air assessment.

Over the span of a year, the highest TSCA COU contributor to the residential indoor air environment was building wood products. Additionally, while several of the modeled COUs may occur simultaneously, aggregating exposures for all four TSCA COUs may not be reflective of actual exposure scenarios encountered over a lifetime as the combination of these TSCA COU likely differ from home to home and overtime. Additionally, while several of the modeled COUs may occur simultaneously, aggregating exposures for all four TSCA COUs may not be reflective of actual exposure scenarios encountered over a lifetime because the combination of these TSCA COUs likely differ both from home to home and over time.

2.3.2.1 Aggregate Indoor Air Exposure

EPA defines aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33)." Theoretically, the reported formaldehyde concentrations from the monitoring data may represent aggregate formaldehyde indoor air concentrations in vehicles per the Lawryk et al. study (Lawryk and Weisel, 1996; Lawryk et al., 1995) and across U.S. households per the AHHS II study (QuanTech, 2021), assuming at least a 3-hour TWA; or the typical indoor air concentration of formaldehyde in these environments.

EPA considered aggregating modeled air concentrations for plausible combinations of COUs expected to co-occur in specific indoor air environments (*e.g.*, combinations of products likely to be present in mobile homes, new homes or automobiles), but concluded that, due to variability among homes and over time within a given home, uncertainties were too great to support a quantitative aggregate analysis across multiple COUs.

2.4 Ambient Air Exposure Assessment

The ambient air exposure assessment for formaldehyde quantitatively evaluates exposures resulting from industrial releases of formaldehyde to ambient air that are associated with TSCA COUs. This assessment focuses on a subset of the general population who reside near releasing facilities by utilizing both modeling approaches and ambient monitoring data to assess and characterize ambient air concentrations and exposures to formaldehyde. A detailed summary of all the analyses conducted, methodologies used, and all exposure concentration results for formaldehyde are provided in the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) and associated supplemental files.

2.4.1 Monitoring for Ambient Air Concentrations

EPA identified and summarized monitoring data for formaldehyde from EPA's Ambient Monitoring Technology Information Center (AMTIC) (U.S. EPA, 2022a). The Agency also identified and summarized outside monitoring data during EPA's systematic review process (U.S. EPA, 2023a). These results are presented in the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

This assessment summarizes monitoring data from EPA's AMTIC (U.S. EPA, 2022a)to understand aggregate or total formaldehyde concentrations in ambient air. The AMTIC data are also used to characterize modeled concentrations of formaldehyde with recognition of the differences between these information sources. That is, modeled environmental concentrations only include releases that can be associated with TSCA COUs while monitoring data does not differentiate between concentrations associated with TSCA COUs and concentrations from all other sources. These differences can limit direct comparison, although EPA conducted some analyses to inform specific local impacts where both modeled and monitored ambient air concentrations are available based on locations of monitoring sites and industrial facilities releasing formaldehyde to the ambient air.

The AMTIC dataset for formaldehyde includes 195 monitoring sites from 36 different states. Data were extracted across 6 years (2015 through 2020) and include a total of 306,529 observations. EPA calculated summary statistics for all samples, samples by state, samples by census tract, samples by monitoring site, samples by monitoring site and year, and samples by monitoring site and year and quarter. For purposes of this ambient air exposure assessment, EPA used the overall statistics across all samples to characterize exposures and characterize exposures to the general population (Table 2-4). Monitoring locations and annual summary statistics are provided in the ambient air exposure module (U.S. EPA, 2024a).

The last 5 years of available AMTIC data were selected for use in the formaldehyde assessment. (2015 to 2020). This dataset includes a total of 233,961 entries for formaldehyde within the five-year duration from 20 air monitoring programs covering 32 states within the contiguous United States. Any entries with missing key data were omitted from the analysis (*e.g.*, concentrations, concentration units, method detection limits, methodology used). All concentration and method detection limit (MDL) values were converted to micrograms per cubic meter (µg/m^3) for unit uniformity between submitting programs. Method detection limits were provided along with sample concentrations on a submission-by-submission basis by submitting agencies, from 0.000011 to 1.2 µg/m^3, and varied by sample based on the sampling and analysis methodology. Entries with reported concentrations below the method detection limit were substituted with a value of 0 µg/m^3. Concentrations of formaldehyde ranged from below the method detection limit to 60.1 µg/m^3 and a median value of 1.6 µg/m^3. A summary of the statistics extracted from the overall dataset are provided in Table 2-4.

Table 2-4. Overall Monitored Concentrations of Formaldehyde from AMTIC Dataset

Monitored Concentrations (µg/m^3)						
Aggregation	**Count**	**Minimum**	**Minimum (non-zero)**	**Median**	**Mean**	**Maximum**
All Entries	233,961	0	0.002	1.6	2.1 ± 2.2	60
Daily Mean	3,843	0	0.011	2.5	3.0 ± 2.0	18.4
Annual Mean	64	1.4	1.4	2.9	3.0 ± 1.1	6.5

The individual site data collected by AMTIC represents various sampling techniques sample collection duration ranging from 5 minutes to 24 hours. When using these data for comparison to the presented formaldehyde models, the concentrations were converted to daily and annual averages. AMTIC concentration values were used to calculate daily or annual average only when there was greater than 75 percent sample coverage over the averaged timeframe when converting from sub-hour samples to hourly averages and again for hourly samples to daily averages. Each annual quarter required a minimum of seven valid daily averages and each annual mean required a minimum of three valid quarterly averages per year per site. The high standards for coverage resulted in a drastic reduction in the data available for conversion to daily and annual averages. Of the original 233,961 complete entries, there were 64 site-years and 3,843 site-days with sufficient coverage to calculate daily and annual average statistics (Table 2-4). EPA is investigating additional methods under OAR guidance to better estimate daily and annual average statistics to increase the number of available sites and data available for use in model comparison.

2.4.2 Modeling Ambient Air Concentrations

2.4.2.1 Integrated Indoor/Outdoor Air Calculator Model (IIOAC)

EPA used the Integrated Indoor-Outdoor Air Calculator (IIOAC) Model to estimate daily- and annual-averaged formaldehyde concentrations for a suite of exposure scenarios at three predefined distances from a facility releasing formaldehyde to the ambient air. EPA's modeling evaluated industrial releases of formaldehyde that are associated with COUs from two separate databases (TRI and NEI). EPA compared releases and modeled concentrations from the two databases and found results were within the same estimated distribution range. Therefore, to provide a clearer picture of findings, the Agency only presents results from the TRI dataset in this draft human health risk assessment. Nonetheless, results from all exposure scenarios and datasets evaluated are provided in the "Draft Ambient Air Exposure Assessment Results and Risk Calcs Supplement A."

EPA utilized the 95th percentile release value reported to TRI by Industry Sector (mapped to respective TSCA COUs) and the 95th percentile modeled daily-averaged and annual-averaged air concentrations from the IIOAC output file at a distance of 100 to 1,000 m from the release facility to characterize exposures and derive risk estimates (see Section 4.2.4.2). Additionally, the exposure scenario used for this *Draft* Human Health Risk Assessment assumes an industrial facility releasing formaldehyde to the ambient air operates 24 hours/day, 7 days/week, 365 days/year, which is likely a conservative assumption.

The 95th percentile release scenario and modeled concentrations were used to represent a more national level exposure estimate based on actual reported releases. The operating scenario was selected because it is representative of typical operating conditions under which industrial facilities involved with formaldehyde manufacturing, processing, etc. operate. Although this scenario is representative of a high-end exposure scenario that is inclusive of more sensitive and locally impacted populations, it is not a maximum worst-case exposure scenario and thus considered more representative of an overall community or nationally representative exposure scenario.

Because of the exposure scenario used (365 days per year, 24 hrs/day, 7 days per week), the daily-averaged modeled concentration and annual-averaged modeled concentration output values from the IIOAC Model are the same. Results from this exposure scenario are summarily presented independently in the "Draft Ambient Air Exposure Assessment Results and Risk Calcs Supplement B." The reason for the same modeled concentrations is a math exercise based on the way annual-averaged concentrations are calculated as an arithmetic average of all daily-averaged concentrations. If the daily-averaged concentrations are based on 365 days of exposure, then the annual average will be the average of the same values and result in the same modeled concentration. However, EPA also ran 250 days of exposure (although not presented here, modeled concentrations are included in the supplemental files), and for this 250-day exposure scenario, the daily-averaged and annual-averaged concentrations are different. The reason for that is the annual-averaged concentrations will also include zero concentration days, and therefore result in a different arithmetic average of the daily modeled concentrations.

Results for acute and chronic exposures across all industry sectors and associated COUs ranged from 0.0001 to 5.7 $\mu g/m^3$ for the exposure scenario described above. Results are presented for each TSCA COU in Figure 2-6. These results represent the highest exposure concentration across all industry sectors associated with the respective formaldehyde TSCA COU. The presented results also represent both the acute and chronic exposure concentrations, which are the same, as described above. Additional details on these results, including the industry sectors with the highest estimated exposure concentrations and associated TSCA COUs are provided in the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a).

Figure 2-6. Exposure Concentrations by TSCA COU for the 95th Percentile Release Scenario and 95th Percentile Modeled Concentration between 100 and 1,000 m from Industrial Facilities Releasing Formaldehyde to the Ambient Air

2.4.2.2 AirToxScreen

EPA used 2019 AirToxScreen to understand the relative contributions of other sources to overall formaldehyde concentrations in the ambient air. AirToxScreen is an EPA screening tool used to evaluate air toxics from all known sources across the United States and estimates air concentration and associated health risk at the census tract level nationwide using a combination of models and data sources (Scheffe et al., 2016). For formaldehyde specifically, AirToxScreen integrates atmospheric chemistry for predicting the production and decay over larger extents using the Community Multiscale Air Quality (CMAQ) model (Luecken et al., 2019). The 2019 AirToxScreen data are shown in Figure 2-7. The figure shows the range of concentrations across all sources of formaldehyde, as well as contributions from biogenic sources, secondary sources, and point sources.

Secondary production of formaldehyde is the largest contributor of formaldehyde to ambient air with modeled concentrations ranging from 0.085 to 1.8 $\mu g/m^3$ (mean ± 1SD: 0.86 ± 0.25 $\mu g/m^3$) according to the AirToxScreen data. Secondary production is the atmospheric formation of formaldehyde from natural and manmade compounds. This can include the degradation of isoprene (a compound naturally produced by animals and plants) to formaldehyde and other complex air chemistry. AirToxScreen is not able to apportion the relative contributions from different secondary sources (source apportion).

Biogenic sources also have a higher contribution to total concentration with a range of 0.0014 to 0.67 $\mu g/m^3$ (mean ± 1SD: 0.13 ± 0.072 $\mu g/m^3$) based on the AirToxScreen data. Biogenic sources include those emissions from trees, plants, and soil microbes.

It is noteworthy that the AirToxScreen data cannot be attributed to COUs but do show relative distributions of various sources. The point source estimates; however, are expected to include contributions from COUs. Point sources contributions to total formaldehyde concentrations range from 0.0 to 0.88 $\mu g/m^3$ (mean ± 1SD: 0.0070 ± 0.014 $\mu g/m^3$). However, as described above, the AirToxScreen data are averaged across census tracts, which can result in a considerable underestimation of exposures relative to a source-specific contribution to which populations living nearby releasing facilities are exposed and thus not comparable to the modeled concentrations from IIOAC.

Figure 2-7 does not include AirToxScreen data for on-road sources, near-road sources, off-road sources, wildfire sources, etc. However, these sources would be captured in the results shown for all sources.

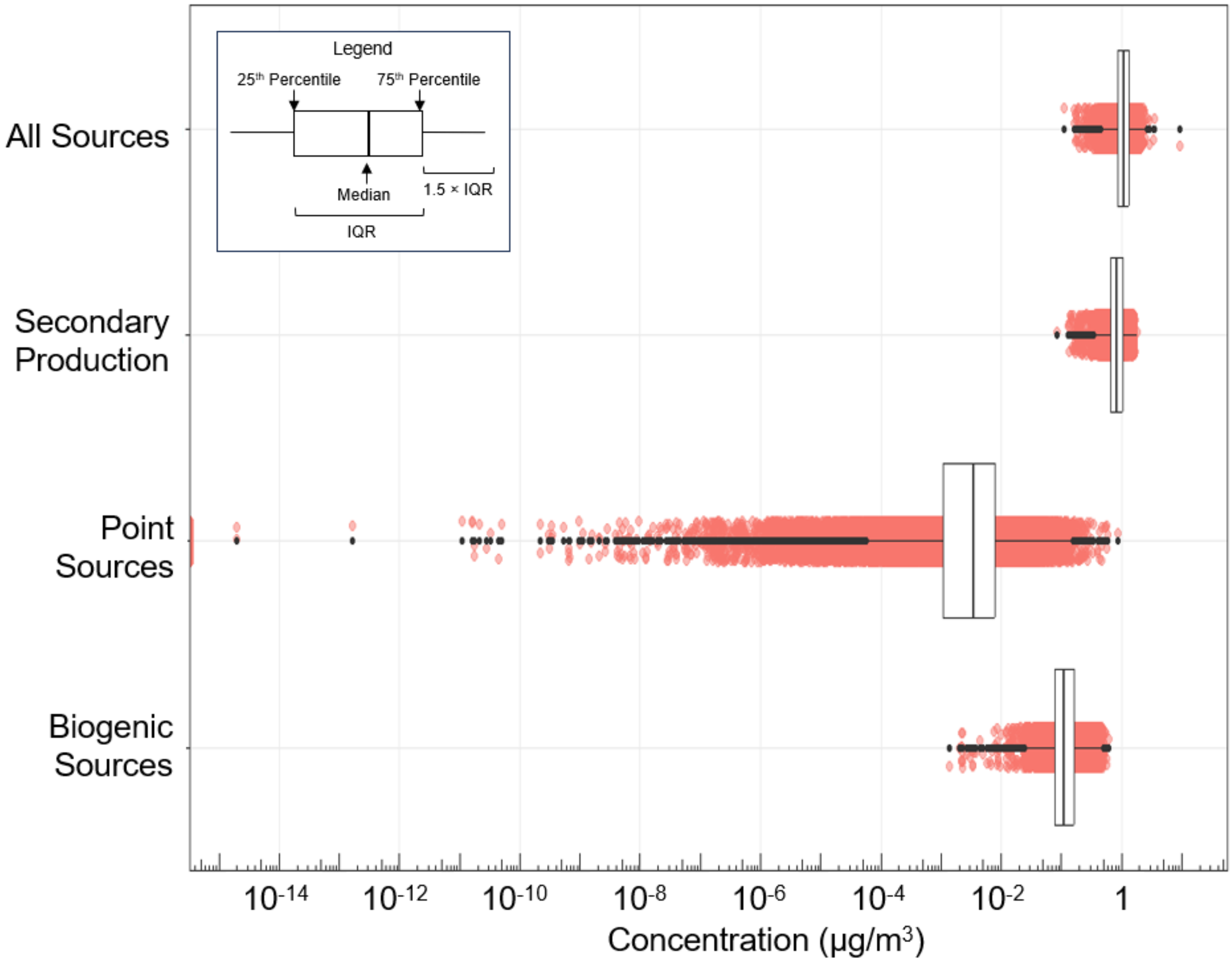


Figure 2-7. Distributions of 2019 AirToxScreen Modeled Data for All Sources, Secondary Production Sources, Point Sources, and Biogenic Sources for the Contiguous United States

2.4.2.3 Human Exposure Model (HEM)

EPA used the Human Exposure Model (HEM 4.2) to estimate formaldehyde concentrations on a site-specific basis at multiple distances from releasing facilities. HEM 4.2 has two components: (1) an atmospheric dispersion model, AERMOD, with included regional meteorological data; and (2) U.S. Census Bureau population data at the Census block level. The current HEM version utilizes 2020 Census data—including all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. AERMOD estimates the magnitude and distribution of chemicals concentrations in ambient air in the vicinity of each releasing facility within a user-defined radial distances out to 50 km (about 30 miles). HEM also provides chemical concentrations in ambient air at the centroid of over 8 million census blocks across the United States. This higher tier model was selected to expand on the IIOAC results by providing more granularity in modeling individual facilities and more discrete distances, geospatial data associated with modeling results for mapping and further analysis, and population data associated with modeled results.

Ambient air concentrations at the census block level were modeled by HEM and are shown in Figure 2-8. These aggregated concentrations are the summed stack and fugitive modeled concentrations, which can include the summation of multiple adjacent facilities, at specific locations. The site-specific concentration results represent the expected annual average ambient air concentration attributable from all modeled TRI releases of TSCA COUs, in some census blocks accounting for concentrations from multiple releasing facilities. Concentrations ranged from 0 to 8.9 µg/m³. Census blocks with modeled total concentrations below the 95th percentile biogenic formaldehyde threshold of 0.28 µg/m³ are presented in grey. Turquoise dots show census blocks with concentrations ranging from 1 to 5 times the biogenic threshold, purple dots show concentrations from 5 to 10 times the biogenic threshold, and pink dots show values greater than 10 times the biogenic threshold. Across the country, a total population of 105,463 people (based on 2020 Census data) live in census blocks shown with ambient air.

Elevated ambient air concentrations of formaldehyde from industrial releases appear most densely concentrated in the southeastern United States. Census blocks with elevated concentrations are found throughout the country, with some regions showing fewer overall TRI facilities, and fewer releases resulting in elevated air concentrations.

Patterns in the relative contribution of stack and fugitive releases, and the distribution of results at varying radial distances from the releasing facility were examined (Figure 2-9). Each vertical bar and median line indicate the shape of the distribution of concentrations by release type for individual facilities. These results indicate that concentrations resulting from fugitive emissions are greater than those from stack emissions closer to the releasing facility, but concentrations from stack emissions tend to become greater at further distances. As many facilities report only a single release type (either fugitive or stack), the total concentration distributions represent a greater number of facilities than the corresponding fugitive and stack distributions and tend to fall somewhere between the fugitive and stack values. Total modeled concentrations tend to reach their maximum within 1,000 m of a facility. Values represented in this analysis are directly modeled at the 16 radial points around each distance ring, rather than census block centroids, and can therefore be located much closer to the releasing facility and represent much higher concentrations. These points are not associated with population estimates, and in some cases the modeled distances may still be within a facility property boundary.

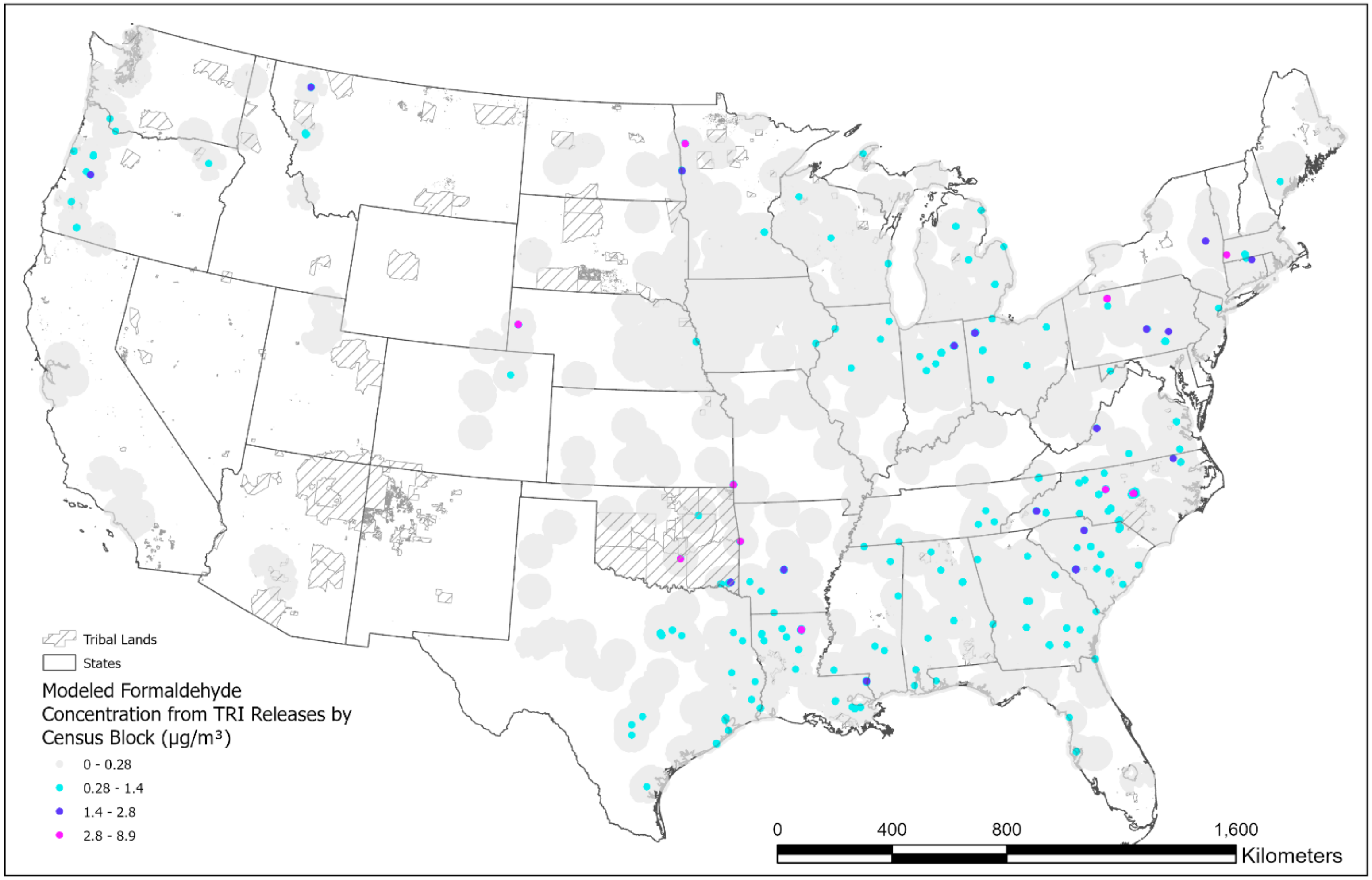


Figure 2-8. Map of Contiguous United States with HEM Model Results for TRI Releases Aggregated and Summarized by Census Block

Census blocks with modeled total concentrations below the 95th percentile biogenic formaldehyde threshold of 0.28 µg/m³ are presented in grey. Turquoise dots show census blocks with concentrations ranging from 1 to 5 times the biogenic threshold, purple dots show concentrations from 5 to 10 times the biogenic threshold, and pink dots show values greater than 10 times the biogenic threshold.

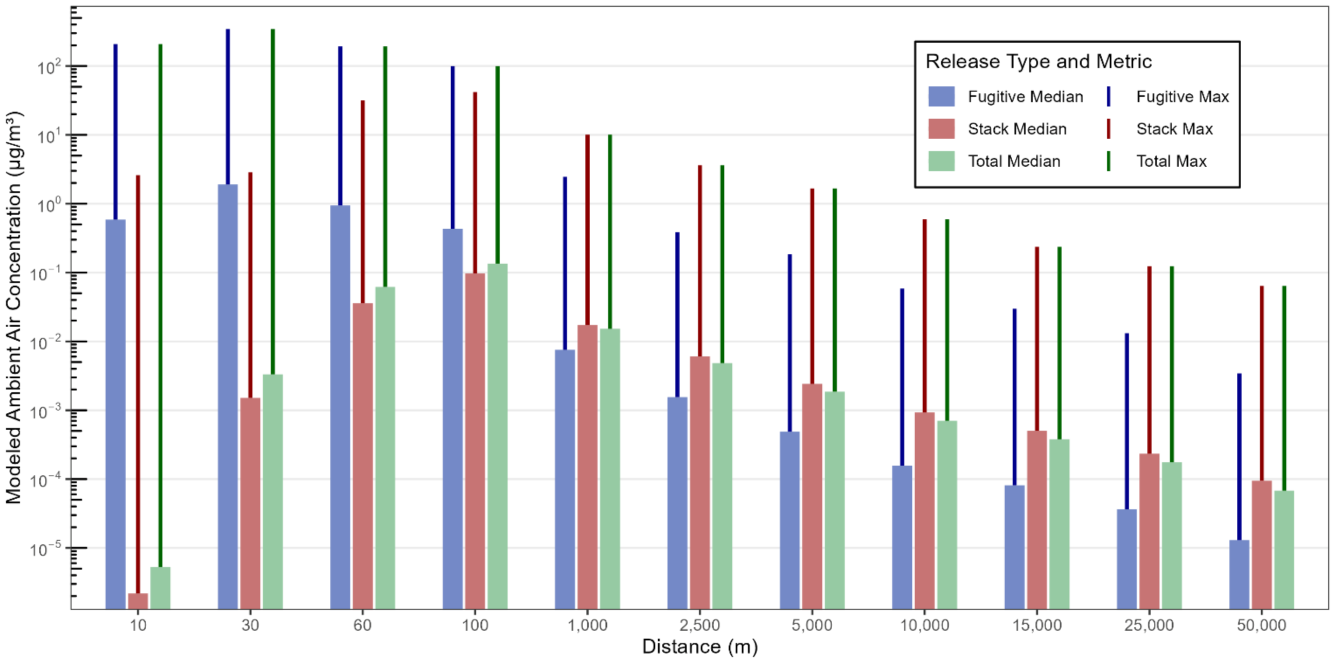


Figure 2-9. Median and Maximum Concentrations (Fugitive, Stack, and Total Emissions) across the 11 Discrete Distance Rings Modeled in HEM

2.4.3 Integrating Various Sources of Formaldehyde Data

Monitoring data from AMTIC, modeled exposures calculated from IIOAC, and modeled data from AirToxScreen were compiled to understand how exposures from COUs fit into the broader context of available information on formaldehyde. Figure 2-10 shows the distributions of data from these datasets. As shown these distributions overlap. At the national scale, populations are exposed to many different sources of formaldehyde (COUs, secondary, biogenic, etc.*)*. Modeled exposure estimates downwind from TSCA COU releases are variable across COUs and locations. In some locations the concentrations from COUs dominate total concentrations of formaldehyde in ambient air. In most of the country however, ambient air concentrations are dominated by other sources (secondary, biogenic, etc.) according to AirToxScreen. All populations are exposed to concentrations between the various sources of formaldehyde.

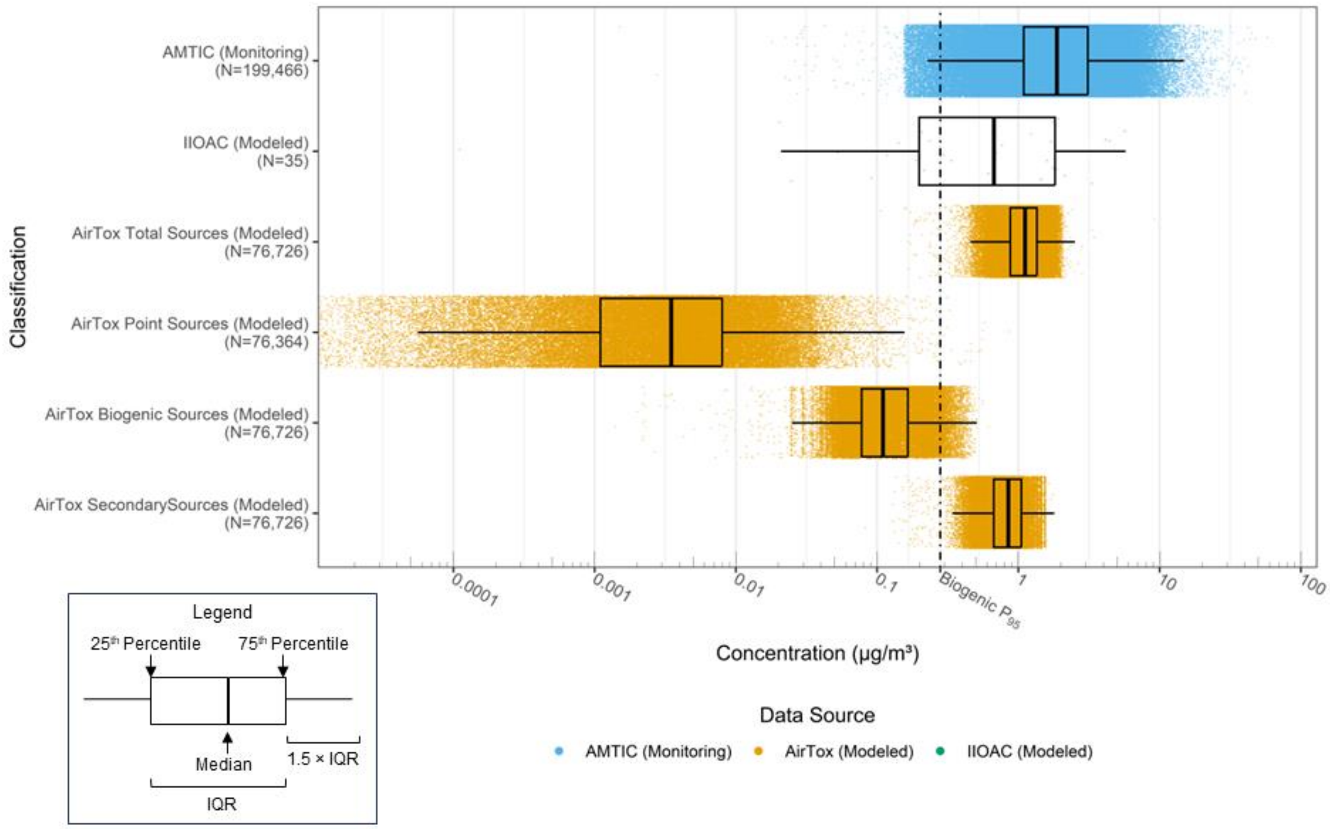


Figure 2-10. Distributions of AMTIC Monitoring Data, IIOAC Modeled Data, and AirToxScreen Modeled Data

EPA recognizes that the different model estimates are not directly comparable. For example, the IIOAC results represent a 95th percentile annual average concentration between 100 to 1,000 m from the release point. In contrast, AirToxScreen concentrations represent annual average concentrations at the census tract scale. Given the spatial scale difference it is expected that AirToxScreen results could underestimate concentrations on a smaller scale (*i.e.*, near facilities) or have lower concentration estimates than IIOAC and this difference can be seen in Figure 2-10. Additionally, only point source data within AirToxScreen may represent a broader set of formaldehyde releases that include releases associated with TSCA COUs.

Furthermore, the AMTIC data represent a range of samples collected at various locations (independent of TSCA releases of formaldehyde) and collection durations are much shorter than a year (5 minutes to 24 hours). Despite these uncertainties, these data suggest that formaldehyde concentrations from TSCA sources are higher than formaldehyde concentrations that are expected to occur due to natural formation. These higher concentrations will be driven by the location of release. These COUs are listed in Section 2.4.2.1 and this conclusion is further supported by the HEM analysis.

2.5 Weight of Scientific Evidence and Overall Confidence in Exposure Assessment

As described in the 2021 Draft Systematic Review Protocol (U.S. EPA, 2021b), the weight of scientific evidence supporting exposure assessments is evaluated based on the availability and strength of exposure scenarios and exposure factors, measured and monitored data, estimation methodology and model input data, and, if appropriate, comparisons of estimated and measured exposures. The strength of each of these evidence streams can be ranked as either robust, moderate, slight, or indeterminate. For each component of this exposure assessment, EPA evaluated the weight of scientific evidence for individual evidence streams and then used that information to evaluate the overall weight of evidence supporting each set of exposure estimates. General considerations for evaluating the strength of evidence for each evidence stream are summarized in Table 7-6 of the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021b). Specific examples of how these considerations can be applied to overall weight of scientific evidence conclusions are provided in Table 7-7 of the Draft Systematic Review Protocol (U.S. EPA, 2021b). The weight of scientific evidence supporting each element of the human health exposure assessment are discussed in the occupational exposure assessment (U.S. EPA, 2024k) consumer exposure assessment (U.S. EPA, 2024d), indoor air assessment (U.S. EPA, 2024j) and ambient air assessment (U.S. EPA, 2024a) modules.

Overall confidence descriptions of high, medium, or low are assigned to the exposure assessment based on the strength of the underlying scientific evidence. When the assessment is supported by robust evidence, overall confidence in the exposure assessment is high; when supported by moderate evidence, overall confidence is medium; when supported by slight evidence, overall confidence is low.

OPPT will seek input on its use of inputs and assumptions in the exposure assessments for occupational, consumer, outdoor air, and indoor air scenarios, in part to understand whether its approach may compound one conservative assumption upon another in a manner that leads to unrealistic or un-addressable outcomes.

2.5.1 Overall Confidence in Occupational Exposure Assessment

The confidence in the occupational exposure assessment varies from low to high, the confidence is based on the strengths, limitations, and uncertainties associated with the exposure estimates for each individual occupational exposure scenario. Most COUs have medium confidence based on moderate to robust and moderate weight of scientific evidence conclusions. The primary strength of most of the inhalation assessments is that it uses monitoring data that is chemical-specific and is directly applicable to the exposure scenario. The use of applicable monitoring data is preferable to other assessment approaches such as modeling or the use of occupational exposure limits. The principal limitation of the monitoring data is the uncertainty in the representativeness of the data due to some scenarios having limited exposure monitoring data in the literature or the available monitoring data lacking additional contextual information. Additionally, different sampling objectives may introduce uncertainty since OSHA and other studies may target workers with the highest expected exposures. For many of the COUs, the EPA received aggregated data from industry; therefore, EPA was unable to distinguish each site’s contribution to the exposure estimates. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous formaldehyde exposure for each working day for a typical worker schedule. It is uncertain whether this captures actual worker schedules and exposures.

Some of the COUs lacked monitoring data; therefore, EPA used models to estimate inhalation exposures. EPA addressed variability in inhalation models by identifying key model parameters to apply a statistical distribution that mathematically defines the parameter’s variability. EPA defined statistical distributions for parameters using documented statistical variations where available. Where the statistical variation was unknown, assumptions were made to estimate the parameter distribution using available literature data, such as General Scenario (GS) and Emission Scenario Document (ESDs). However, there is uncertainty as to the representativeness of the parameter distributions with respect to the modeled scenario because the data are often not specific to sites that use formaldehyde. In general, the effects of these uncertainties on the exposure estimates are unknown, as the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distributions of each of the model input parameters.

As described in the *Draft Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024k), EPA has low confidence in the inhalation estimates for the four COUs below based on a slight weight of scientific evidence:

- Industrial use – non-incorporative activities – process aid in: oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing
- Commercial use – chemical substances in treatment/care products – laundry products and dishwashing products
- Commercial use – chemical substances in outdoor use products – explosives materials
- Commercial use– chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment

This was mainly due to the low number of monitoring samples available, lack of information specific to formaldehyde usage for the given COUS and uncertainties with the representativeness of the monitoring data. However, EPA concluded that the underlying data still provides a plausible estimate of exposures for these OESs.

EPA had moderate weight of scientific evidence conclusions for all dermal scenarios assessed. The primary strength of the dermal assessment is that most of the data that EPA used to inform the modeling parameter distributions have overall data quality determinations of either high or medium from EPA's systematic review process, such as the 2020 CDR (U.S. EPA, 2020b). A limitation of the assessment is that some COUs lacked formaldehyde weight concentration data.

2.5.2 Overall Confidence in the Consumer Exposure Assessment

EPA has medium confidence in the inhalation exposure assessment for consumers. As detailed in Section 3.2 of the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d), the inhalation exposure assessment is supported by a robust monitoring dataset and robust modeling approaches.

Aside from the potential exposures to water treatment, laundry and dish washing, and lawn and garden products, EPA has medium confidence in the consumer inhalation modeling approaches and model input data—including TSCA COU-specific product weight fractions identified from SDS of consumer products currently on the market, the quality and applicability of the CEM for the assessment of realistic consumer exposure scenarios that are representative of COUs, common consumer use patterns (*e.g.*, TSCA COU-specific amount used, duration and frequency of use (U.S. EPA, 2019)) according to the EPA *Exposure Factors Handbook* (U.S. EPA, 2011) and the 1987 Westat survey (Westat, 1987) and applicable to most population groups. EPA also has medium confidence in the quality and representativeness of air monitoring data. This use of TSCA COU-specific monitoring information increases confidence in estimated inhalation exposures.

EPA has medium confidence in the dermal exposure assessment for consumers. As detailed in Section 3.2 of the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d), EPA has medium confidence in the Thin Film Model, which EPA used to estimate dermal loading from spray and liquid consumer products, and in default model input values used in the dermal exposure assessment of realistic consumer exposure scenarios, which are representative of COUs, common consumer use patterns, and applicable to most population groups. EPA has high confidence in the TSCA COU-specific product weight fractions identified from SDSs of consumer products currently on the market and medium confidence in the applied quantity remaining on skin (Q_u) constant. Although a Q_u of 10.3 mg/cm^2 (used to approximate hand immersion and wiping experiments using oil-based products (U.S. EPA, 1992)) is assumed to be realistic and protective of most liquid product consumer dermal exposures to formaldehyde, it is conceivable that a lower Q_u may be applicable for some consumer exposure scenarios (*e.g.*, consumer uses liquid product with personal protective equipment [PPE] that prevents immersion or development of thin film of formaldehyde on the skin). No monitoring data are available on dermal exposures for consumers.

2.5.3 Overall Confidence in the Indoor Air Exposure Assessment

EPA has medium confidence in the overall findings for the indoor air exposure assessment. As detailed in Section 3.2.1 of the *Draft Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j), the exposure assessment is supported by a robust monitoring dataset and robust modeling approaches. EPA has medium confidence that the exposure scenarios evaluated in this assessment are reasonable and representative of people who spend most time indoors. The indoor air exposure scenario assumes continuous exposure to indoor air over a lifetime.

EPA has medium confidence in the quality and representativeness of indoor air monitoring data. The set of 16 studies used as an indication of indoor air concentrations and as a basis for comparison to modeled concentrations were rated high quality. This dataset includes the American Healthy Homes Survey II, a quality nationally representative formaldehyde residential indoor air monitoring study administered by EPA and the U.S. Department of Housing and Urban Development (HUD). EPA also has medium confidence in the indoor air modeling approaches and model input data, including the quality and applicability of the Consumer Exposure Model and the emission rates and fluxes from quality product emission studies used to refine the model. The set of nine studies incorporated into indoor air modeling were, altogether, rated medium quality.

EPA considered concordance between monitored and modeled concentrations. Monitored concentrations are expected to reflect aggregate concentrations resulting from multiple sources of formaldehyde and are therefore not directly comparable to modeled concentrations estimated for specific sources. In addition, CEM does not incorporate chemical half-life. Therefore, it is unclear whether the modeling results are reflective of most indoor air home environments in American residences. However, the fact that modeled concentrations are within the same order of magnitude of monitored concentrations increases confidence in modeled concentrations. The availability of both modeled concentrations and monitoring data provides information about both the aggregate exposures from all sources contributing to indoor air concentrations as well as information about the relative contributions of individual TSCA COUs.

Based on consideration of the weight of scientific evidence, EPA has medium confidence in the overall findings for the indoor air exposure assessment (U.S. EPA, 2024j) due to a high confidence in the CEM used and emission fluxes and rates from quality product emission studies used to refine the model, in comparison with American Healthy Homes Survey II.

2.5.4 Overall Confidence in the Ambient Air Exposure Assessment

EPA has high confidence in the overall characterization of exposures for the ambient air exposure assessment. As described in the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a), exposure estimates rely upon direct reported releases and peer-reviewed models to derive exposure concentrations at distances from releasing facilities where individuals within the general population reside for many years. Furthermore, ambient monitoring data supports the presence of formaldehyde in the ambient air and shows comparable monitored values to EPA's modeled concentrations.

For industrial TSCA COUs, EPA has a moderate to robust weight of scientific evidence as the databases have high data quality scores and are supported by numerous data points. A primary strength of TRI and NEI data is that these programs compile the best readily available release data for large facilities. Limitations are that these programs may not cover some sites that emit formaldehyde as both programs have conditions that must be met prior to being required to report releases. For formaldehyde, the potential contribution of combustion sources is an uncertainty and use of the full facility data complicate singular TSCA COU estimates, such that emissions at one site may include multiple sources under multiple COUs that include combustion sources and non-combustion sources.

In general, for commercial COUs, EPA has a moderate weight of scientific evidence as TRI and NEI have high data quality and generic scenarios that have a medium to high data quality rating. EPA relied upon professional judgement in mapping TRI and NEI industrial sectors to commercial COUs. There is some uncertainty that a commercial TSCA COU may occur across several industrial sectors beyond the industrial sector used for analysis. In addition, some industrial sectors cover both industrial and commercial operations, so they may overestimate air releases occurring in a commercial setting. Four commercial COUs either lacked sufficient data or was supported by a slight weight of evidence:

- 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.

EPA estimated the exposed population to modeled releases to ambient air; however, these estimates are considered an underestimate of total exposed population. EPA limited this modeling to the 810 TRI facilities directly reporting with Form R. As indicated in the TRI reporting, the ambient air releases reported to EPA are from different estimation approaches (*e.g.*, emission factors) and may not be from active stack monitoring. These TRI emissions are a subset of the approximately 49,000 distinct facilities with estimated emissions in NEI but are of greater confidence due to the direct reporting rather than the indirect, state-specific reporting currently used to develop the NEI. Finally, the exposed population estimates from HEM are derived by averaging the modeled annual concentration at the proximate census block centroids across the census block, using site-specific meteorological conditions. EPA did not make facility-specific adjustments to modeling receptor files based on land use analysis to capture the highest proximate populations in this analysis, therefore population estimates are biased against capturing the populations of the most highly exposed residents within rural (and therefore larger) census blocks. Therefore, while EPA has a high confidence in the methods used, based on the expected underestimation of the exposed population estimates, the confidence is medium.

3 HUMAN HEALTH HAZARD SUMMARY

EPA's OPP and OPPT collaborated to develop a joint hazard assessment for formaldehyde (U.S. EPA, 2024i). This joint assessment evaluated available human health hazard and dose-response information for formaldehyde and identified hazard values to support risk assessments in both offices.

For cancer and non-cancer hazards associated with chronic inhalation exposures, the joint hazard assessment relies upon the analysis already completed in the draft IRIS assessment on formaldehyde inhalation (U.S. EPA, 2022b) and peer reviewed by the National Academies of Sciences, Engineering, and Medicine (NASEM) (NASEM, 2023). The systematic review literature searches, data quality review, evidence integration, dose-response analyses, and peer review performed in support of the IRIS assessment reflect the best available science on formaldehyde hazards from chronic inhalation exposures and are consistent with the needs of both OPP and OPPT.

To identify additional available hazard and dose-response information for acute inhalation, dermal, and oral formaldehyde exposures, EPA used a fit-for-purpose systematic review protocol, integrating the needs and approaches of both OPP and OPPT. Details of the fit-for-purpose systematic review protocol used in OPPT's work on this assessment are described in the *Systematic Review Protocol for the Draft Risk Evaluation for Formaldehyde* (U.S. EPA, 2023a). This approach is based in part on the OPPT systematic review approach described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substance*s (U.S. EPA, 2021b).

EPA identified a range of factors that may increase susceptibility to formaldehyde and considered susceptibility throughout the hazard assessment. Descriptions of how EPA incorporated PESS due to greater biological susceptibility into the risk evaluation are provided in Appendix C. Factors that may increase susceptibility to formaldehyde exposures include chronic respiratory disease, lifestage, sex, and co-exposure to chemical and non-chemical stressors that influence the same health outcomes.

3.1 Summary of Hazard Values

The non-cancer and cancer hazard values identified for inhalation, dermal, and oral exposures to formaldehyde in the joint hazard assessment (U.S. EPA, 2024i) are summarized in Table 3-1. Consistent with the recommendations of the Human Studies Review Board (HSRB), OPPT will seek input on its hazard assessment, particularly with regards to the PODs and uncertainty/extrapolation factors for acute and chronic non-cancer assessment and the extent to which the draft hazard assessment for formaldehyde appropriately considered recommendations from other federal advisory committees (*e.g.*, NASEM, HSRB).

Table 3-1. Hazard Values Identified for Formaldehyde

Exposure Scenario	Hazard Value	Uncertainty Factors	Total Uncertainty Factor	Study and Toxicological Effects
Inhalation Acute (15-minute duration)	NOAEC and BMCL = 0.5 ppm (0.62 mg/m^3) as a 15-minute peak exposure	UF_H = 10	Total UF = 10	Kulle et al, (1987); supported by: LOAEC = 1 ppm (mg/m^3) based on eye irritation in adult volunteers Mueller et al. (2013) LOAEC = 0.3 ppm over 4 hours, with 15-minute peaks of 0.6 ppm, based on eye irritation in hypersensitive adult volunteers Lang et al. (2008) LOAEC= 0.5 ppm over 4 hours, with peaks of 1 ppm (0.62/1.23 mg/m^3), based on eye irritation in adult volunteers
Inhalation Chronic non-cancer[a] (Long-term, >6 months)	$BMCL_{10}$ = 0.017 ppm (0.021 mg/m^3)	UF_H = 3	Total UF = 3	POD is derived from the IRIS RfC (U.S. EPA, 2022b). The specific $BMCL_{10}$ value used here is based on reduced pulmonary function in children in Krzyzanowski et al. (1990), but is consistent with the RfC, derived based on, pulmonary function, allergy-related conditions, asthma (prevalence and degree of asthma control) in people, as reported in Annesi-Maesano et al. (2012), Matsunaga et al. (2008), Venn et al. (2003), and Krzyzanowski et al. (1990).
Inhalation Chronic Cancer	Adult-based IUR: 0.0079 ppm^{-1} (6.4 × 10^{-6} (µg/m^3)$^{-1}$) ADAF-adjusted IUR: 0.013 ppm^{-1} (1.1 × 10^{-5} (µg/m^3)$^{-1}$)	N/A	N/A	IUR established by IRIS (U.S. EPA, 2022b) based on data on nasopharyngeal cancer in people reported in Beane-Freeman et al. (2013).
Dermal Acute	Induction: EC_3 = 0.4% (100 µg/cm^2) in 4:1 acetone:olive oil	UF_A = 10 UF_H = 10	Total UF= 100	Basketter et al., (2003) based on induction of dermal sensitization in mice
	Elicitation: $BMDL_{10}$ = 10.5 µg/cm^2 (0.035%)	UF_H = 10	Total UF = 10	Flyvholm et al., (1997) based on threshold for elicitation of dermal sensitization in people
Oral Short-Term/ subchronic (1-30 days),	HED= 6 mg/kg-day	UF_A = 3 UF_H = 10	Total UF = 30	Til (1988) NOAEL= 25 mg/g-day; LOAEL = 125 mg/kg-day based on gastrointestinal histopathology in rats

Exposure Scenario	Hazard Value	Uncertainty Factors	Total Uncertainty Factor	Study and Toxicological Effects
Oral Chronic	HED = 3.6 mg/kg-day	UF_A = 3 UF_H = 10	Total UF = 30	Civo Inst.(1987); Til (1989) NOAEL= 15 mg/g-day; LOAEL = 82 mg/kg-day based on gastrointestinal histopathology in rats

[a] This value is used to estimate risks from both sub-chronic and chronic occupational exposures.
Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures; NOAEL = no-observed adverse-effect level; LOAEL = lowest-observed adverse-effect level; UF = uncertainty factor; UF_A = extrapolation from animal to human (interspecies); UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (*i.e.*, lack of a critical study). IUR= inhalation unit risk; ADAF-adjusted IUR = IUR for calculating cancer risks associated with a full lifetime of exposure

3.2 Weight of Scientific Evidence and Overall Confidence in Hazard Assessment

As described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021b), the weight of scientific evidence supporting hazard assessment and dose response is evaluated based on the quality of the key studies, consistency of effects across studies, the relevance of effects for human health, confidence in the dose-response models, and the coherence and biological plausibility of the effects observed. The weight of evidence and overall confidence in chronic inhalation hazard values derived by IRIS are described in the draft IRIS assessment (U.S. EPA, 2022b). The weight of evidence and sources of confidence and uncertainty in dermal, oral, and acute inhalation hazard values derived by OCSPP are described in the hazard assessment (U.S. EPA, 2024i). This section summarizes overall confidence and sources of uncertainty in the hazard values used to develop risk estimates in this risk characterization.

3.2.1 Overall Confidence in the Acute Inhalation POD

Overall confidence in the acute inhalation POD is medium. As described in the joint hazard assessment (U.S. EPA, 2024i), the acute POD is based on a robust dataset of evidence for sensory irritation in humans, including several high-quality controlled exposure studies with relevance for acute exposure scenarios. Concordance of reported sensory irritation effects and the effect levels reported across acute exposure studies increases confidence in the final POD. Variability across individuals' response contributes to uncertainty around effect levels that are protective across the population. A 10x uncertainty factor is applied to account for uncertainty related to intraindividual variability.

This acute POD focuses on defining peak threshold exposure concentrations rather than average 8- or 24-hour exposure concentrations. There is some uncertainty around the degree to which duration influences effect levels because there are no studies available that provide direct evidence that effect levels following 8- or 24-hour exposures are the same as effects following 2 to 5 hours of exposure.

Immune-mediated respiratory effects like asthma may also have relevance for acute hazard, but available studies do not provide sufficient information to characterize dose-response relationships for acute inhalation exposures. Although this may be a source of uncertainty for the acute POD, dose-response data for these additional respiratory endpoints are used as the basis for the chronic inhalation POD.

3.2.2 Overall Confidence in the Chronic, Non-cancer Inhalation POD

As described in the draft IRIS assessment (U.S. EPA, 2022b), overall confidence in the chronic non-cancer inhalation POD is high. The chronic POD derived by IRIS is supported by a robust database of evidence for a range of endpoints in humans and animals. The overall POD is informed by dose-response information in humans across multiple respiratory endpoints and reflects concordance in effect levels identified across those endpoints. EPA also considered dose-response information for reproductive and developmental effects in selection of the overall POD. While there is more uncertainty around the PODs derived for these endpoints, the overall POD is expected to be protective of these reproductive and developmental effects in humans. Many of the observational epidemiology studies providing the quantitative basis for the chronic POD reflect relevant human exposure scenarios in homes and schools. In addition, several of the studies include children with asthma or other sensitive groups.

3.2.3 Overall Confidence in the Chronic IUR

As described in the draft IRIS assessment (U.S. EPA, 2022b), overall confidence in the preferred unit risk estimate is medium. The IUR derived for nasopharyngeal cancer is informed by a robust dataset of both human and animal data. The availability of human data eliminates the need to extrapolate from animal studies, increasing the confidence in the IUR. In addition, the IUR derived from animal data is similar to the IUR derived from human evidence, further increasing confidence in the IUR. Sources of uncertainty in the IUR include reliance on extrapolation from high doses that occur in occupational settings to lower doses that may occur in the general population, reliance on data from a single high quality occupational cohort study that may not capture the sensitivity of susceptible populations or lifestages, and reliance on mortality data as a surrogate for cancer incidence.

EPA was not able to derive IURs for all tumor sites associated with formaldehyde exposure. This is a source of uncertainty and may lead to an underestimate of risk. Although EPA was able to derive an IUR for myeloid leukemia, the lack of confidence in the dose-response data and IUR for myeloid leukemia is a source of uncertainty. The cancer risk estimates presented in this risk characterization do not include risks for myeloid leukemia and other tumor sites. Based on the IUR estimated for myeloid leukemia in the draft IRIS document, IRIS estimated that consideration of myeloid leukemia may increase the age-dependent adjustment factor (ADAF)-adjusted IUR by as much as four-fold.

3.2.4 Overall Confidence in the Dermal POD

Overall confidence in the dermal POD is medium. As described in the OCSPP joint hazard assessment (U.S. EPA, 2024i), the dermal POD is derived from an extensive dataset on dermal sensitization in human, animal, and *in vitro* studies. Multiple streams of evidence from studies evaluating elicitation thresholds in sensitive people and induction thresholds in animal and in in vitro assays arrive at similar effect levels. While there are some uncertainties associated with the human studies related to lack of clarity in methods and data reporting, concordance in effect levels across multiple streams of evidence increases confidence in the POD. The potential impact of methanol present in available dermal formaldehyde studies is a source of uncertainty in the POD. While there is substantial variation in sensitization responses across individuals, application of a 10× uncertainty factor is used to account for uncertainty related to intraindividual variability.

3.2.5 Overall Confidence in the Subchronic and Chronic Oral PODs

Overall confidence in the subchronic and chronic oral PODs is medium. As described in the OSCPP joint hazard assessment (U.S. EPA, 2024i), the subchronic and chronic oral PODs rely on a limited database of animal studies but are supported by three studies that report consistent patterns of gastrointestinal damage at similar dose levels.

Due to technical challenges around generating pure and stable formaldehyde treatments for oral exposure, most of the available animal studies have major limitations and uncertainties. Among the available studies that are not confounded by the presence of methanol, gastrointestinal effects are the most sensitive endpoint evaluated. Reduced drinking water intake in the high dose groups reduced confidence in each of the chronic studies when considered in isolation. However, when considered in conjunction with the results of the 28-day study that included water-restricted controls, EPA has confidence that the reported effects are attributable to formaldehyde exposure.

There is very limited information on reproductive, developmental, and immune endpoints following oral exposure to formaldehyde. Although there are some studies that suggest effect levels for these endpoints may be more sensitive than those used as the basis for the POD, the only studies that evaluate reproductive, developmental, and immune endpoints are confounded by the presence of methanol.

Evidence of reproductive and developmental effects reported in humans and animals following inhalation exposure to formaldehyde indicates that such effects are possible following formaldehyde exposure. Similarly, the available data do not evaluate factors that may increase susceptibility to oral formaldehyde exposure in sensitive groups or lifestages. The lack of data on these endpoints and sensitive groups and lifestages following oral exposure could be perceived as uncertainty; however, the likelihood of a lower POD being identified based on these outcomes is low given the effect used as the basis of the current PODs (gastrointestinal effects) are close to the portal of entry, first pass metabolism via the oral route, and the reactivity of formaldehyde.

4 HUMAN HEALTH RISK CHARACTERIZATION

4.1 Risk Characterization Approach

The exposure scenarios, populations of interest, and toxicological endpoints used for evaluating risks from acute and chronic exposures are summarized below in Table 4-1. EPA estimated cancer and non-cancer risks from occupational, consumer, and general population exposures as described below.

While EPA will consider the standard risk benchmarks shown in Table 4-1 associated with interpreting margins of exposure and cancer risks, EPA cannot solely rely on those risk values. Risk estimates include inherent uncertainties and the overall confidence in specific risk estimates varies. The analysis provides support for the Agency to make a determination about whether formaldehyde poses an unreasonable risk to human health and to identify drivers of unreasonable risk among exposures for people (1) with occupational exposure to formaldehyde, (2) with consumer exposure to formaldehyde, (3) with exposure to formaldehyde in indoor air, and (4) who live or work in proximity to locations where formaldehyde is released to air. Concurrent with this draft TSCA Risk Evaluation, EPA is releasing a preliminary risk determination for formaldehyde.

The Agency also will consider naturally occurring sources of formaldehyde (*i.e.*, biogenic, combustion, and secondary formation) and associated risk levels from, and consider contributions from all sources as part of a pragmatic and holistic evaluation of formaldehyde hazard and exposure in making its unreasonable risk determination. If an estimate of risk for a specific scenario exceeds the benchmarks, then the decision of whether those risks are unreasonable is both case-by-case and context driven. In the case of formaldehyde, EPA is taking the risk estimates of this draft human health risk assessment (HHRA) in combination with a thoughtful consideration of other sources of formaldehyde, to interpret the risk estimates in the context of an unreasonable risk determination.

Table 4-1. Use Scenarios, Populations of Interest, and Toxicological Endpoints Used for Acute and Chronic Exposures

Populations of Interest and Exposure Scenarios	**Workers** [a] Acute – Adolescent (≥16 years old) and adult workers exposed to formaldehyde in a single workday for 15 min or longer Chronic – Adolescent (≥16 years old) and adult workers exposed to formaldehyde over a full-shift workday for 250 days per year for 40 working years
	Consumers and Bystanders Acute – Consumers across all age groups (depending on the product or article) exposed to formaldehyde result from product or article use. Exposures are estimated to be 15-minute peak concentrations. It should be noted that the 15-minute peak concentration for a given TSCA COU and exposure scenario may occur several hours after product use. Chronic – Consumers across all age groups (depending on the product or article) exposed to formaldehyde result from product or article use up to 78 years.
	General Population Indoor Ambient Air Exposure [b] Chronic – People across all age groups exposed to formaldehyde through ambient air continuously up to 78 years.
	General Population Outdoor Ambient Air Exposure [b] Chronic – People across all age groups exposed to formaldehyde through ambient air near industrial release site continuously up to 78 years.
Health Effects, Hazard	**Non-cancer Acute Hazard Values** Acute inhalation health effect: sensory irritation • Acute inhalation POD (15-minute duration) = 0.5 ppm (0.62 mg/m^3)

Values and Benchmarks	• Uncertainty Factors (Benchmark MOE) = 10 (UF_A = 1; UF_H = 10; UF_L = 1; UF_S=1; UF_D=1) Acute dermal health effect: sensitization (elicitation) • <u>Acute POD</u> = 10.5 µg/cm^2 • Uncertainty factors (Benchmark MOE) = 10 (UF_A = 1; UF_H = 10; UF_L = 1; UF_S=1; UF_D=1) Acute oral health effect: no acute oral PODs identified **Non-cancer Subchronic Hazard Values** Subchronic oral health effects: Gastrointestinal effects • Oral HED = 6 mg/kg-day • Uncertainty Factors (Benchmark MOE) = 30 (UF_A = 3; UF_H = 10; UF_L = 1; UF_S=1; UF_D=1) **Non-cancer Chronic Hazard Values** Chronic inhalation health effects: Respiratory effects, including reduced pulmonary function, allergy-related conditions, asthma (prevalence and degree of asthma control), and sensory irritation • Inhalation HEC = 0.017 ppm (0.021 mg/m^3) • Uncertainty Factors (Benchmark MOE) = 3 (UF_A = 1; UF_H = 3; UF_L = 1; UF_S = 1; UF_D = 1) Chronic oral health effects: Gastrointestinal effects • Oral HED = 3.6 mg/kg-day • Uncertainty Factors (Benchmark MOE) = 30 (UF_A = 3; UF_H = 10; UF_L = 1; UF_S = 1; UF_D = 1) **Cancer Hazard Values** Inhalation cancer hazard for formaldehyde is based on nasopharyngeal cancers • IUR = 0.0079 ppm^{-1} (6.4×10^{-6} (µg/m^3)$^{-1}$) • ADAF applied for early life exposures Oral and dermal cancer hazards are not quantified because there is insufficient data to support derivation of cancer slope factors for these routes of exposure.

[a] Adult workers (≥16 years old) include both female and male workers.
[b] Inhalation exposures are described in terms of air concentrations and do not include lifestage-specific adjustments; risk estimates based on air concentrations are intended to address risks to all lifestages.
MOE = margin of exposure; UF_A = Interspecies uncertainty factor for animal-to-human extrapolation; UF_H = Intraspecies uncertainty factor for human variability; UF_L = LOAEC-to-NOAEC uncertainty factor for reliance on a LOAEC as the POD

4.1.1 Estimation of Non-cancer Risks

EPA used a margin of exposure (MOE) approach to identify potential non-cancer risks. The MOE is the ratio of the non-cancer POD divided by a human exposure dose. Acute and chronic MOEs for non-cancer inhalation and dermal risks were calculated using Equation 4-1:

Equation 4-1.

$$MOE_{acute\ or\ chronic} = \frac{Non - cancer\ Hazard\ value\ (POD)}{Human\ Exposure}$$

Where:

MOE	=	Margin of exposure (unitless)
Hazard value (POD)	=	HEC (ppm) or HED (mg/kg-d)
Human Exposure	=	Exposure estimate (in ppm or mg/kg-d)

MOE risk estimates may be interpreted in relation to benchmark MOEs. Benchmark MOEs are typically the total UF for each non-cancer POD. If the numerical value of the MOE is less than the benchmark

MOE, this relationship is a starting point to determine if there are unreasonable non-cancer risks. On the other hand, if the MOE estimate is equal to or exceeds the benchmark MOE, risk is not indicated. Typically, the larger the MOE, the more unlikely it is that a non-cancer adverse effect occurs relative to the benchmark. When determining whether a chemical substance presents unreasonable risk to human health or the environment, calculated risk estimates are not "bright-line" indicators of unreasonable risk, and EPA has discretion to consider other risk-related factors apart from risks identified in risk characterization.

4.1.2 Estimation of Cancer Risks

Extra cancer risks for repeated inhalations exposures to formaldehyde were estimated using Equation 4-2:

Equation 4-2.

$$Inhalation\ Cancer\ Risk = Human\ Exposure\ \times IUR$$

Where:

Risk	=	Extra cancer risk (unitless)
Human exposure	=	Exposure estimate (LADC in ppm)
IUR	=	Inhalation unit risk

EPA has concluded that "the evidence is sufficient to conclude that a mutagenic mode of action of formaldehyde is operative in formaldehyde-induced nasopharyngeal carcinogenicity" (U.S. EPA, 2022b). To account for increased nasopharyngeal cancer risks from early life exposures to formaldehyde, EPA applies an ADAF.

Estimates of extra cancer risks are interpreted as the incremental probability of an individual developing cancer over a lifetime following exposure (*i.e.*, incremental, or extra individual lifetime cancer risk).

4.2 Risk Estimates

4.2.1 Risk Estimates for Workers

EPA estimated cancer and non-cancer risks for workers exposed to formaldehyde based on the occupational exposure estimates that were described in Section 2.1. For many TSCA COUs, EPA did not identify inhalation exposure data for ONUs, and therefore evaluated chronic risks using the central tendency estimates for workers. EPA did not identify information for potential peak exposures by ONUs and therefore did not quantify acute inhalation risks for ONUs. Risks to ONUs are assumed to be equal to or less than risks to workers who handle materials containing formaldehyde as part of their job.

These risk estimates are based on exposures to workers in the absence of PPE such as gloves or respirators. Section 2.5.1 contains an overall discussion on strengths, limitations, assumptions, and key sources of uncertainty for the occupational exposure assessment. Additionally, the *Draft Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024k) contains a comprehensive weight of scientific evidence summaries, which presents an OES-by-OES discussion of the key factors that contributed to each weight of scientific evidence conclusion.

4.2.1.1 Risk Estimates for Inhalation Exposures

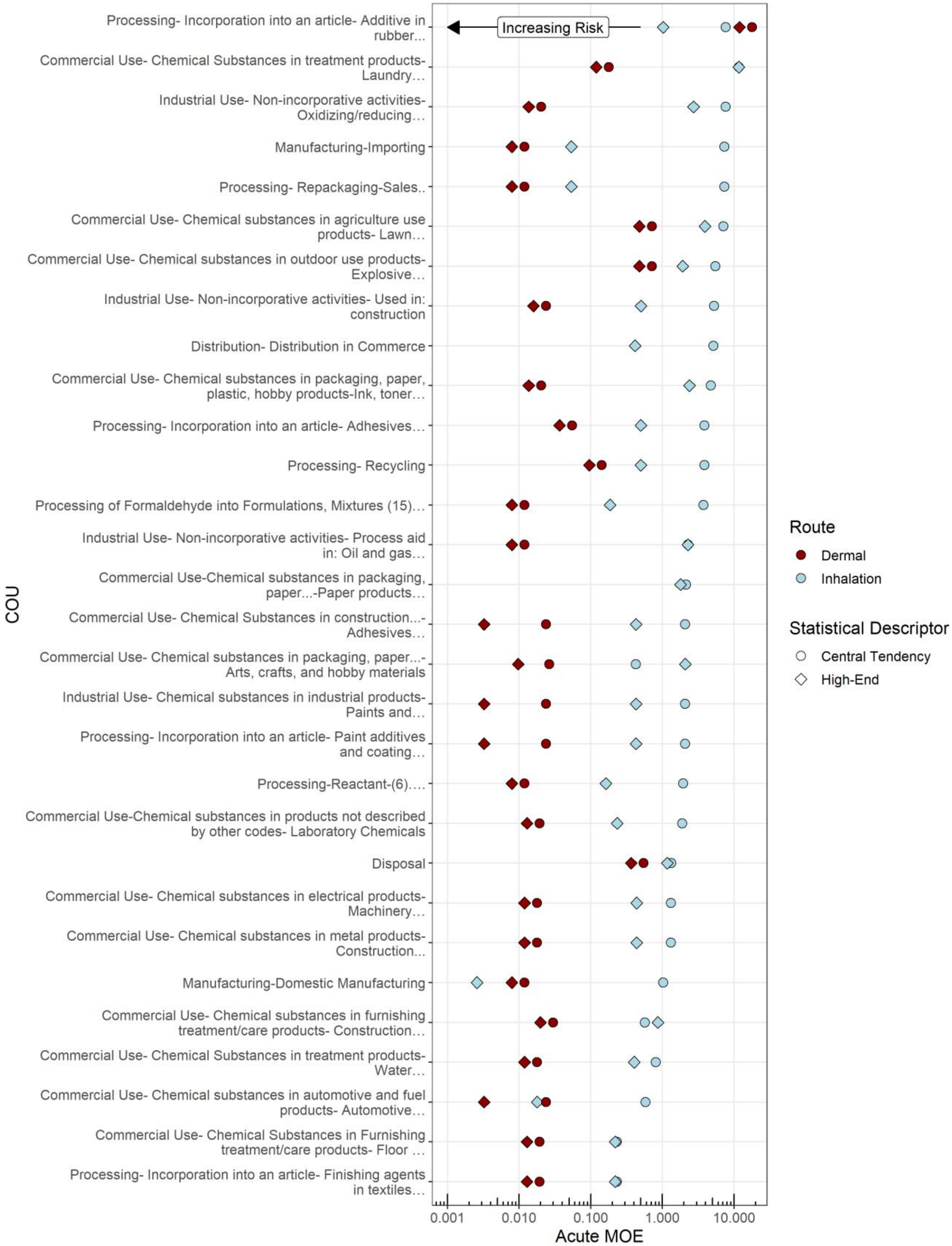
EPA estimated acute, sub-chronic and chronic non-cancer and chronic cancer risks to workers and ONUs from inhalation. Generally, EPA expects workers to be exposed at higher formaldehyde concentrations comparative to other populations. Across occupational exposure scenarios for full-shift estimates, the central tendency of air concentrations estimates ranged from 7.5 to 499.3 µg/m^3 (0.006 to 0.40 ppm) and high-end of air concentrations estimates ranged from 7.5 to 17,353.3 µg/m^3 (0.006 to 13.9 ppm), which is generally higher than the modeled estimates of ambient air (up to 5.7 µg/m^3) and measured indoor air concentrations (~40 µg/m^3 at the 95th percentile of concentrations measured in AHHS II).

Risk estimates vary across OESs/COUs. As shown in Figure 4-1, acute non-cancer risk estimates for worker inhalation exposure range from 2.58×10^{-3} to 11.6 for both high-end and central tendency exposures. For COUs with multiple OESs or estimation approaches, the estimate with the highest high-end value was illustrated. For the formaldehyde risk assessment, acute occupational risks were estimated using 15-minute monitoring data, which in most cases is expected to represent activities with the highest exposure potential for the scenario. Acute risk estimates below indicate that exposure is greater than the hazard POD identified for 15-minute peak exposures based on sensory irritation reported in controlled human exposure studies in healthy adult volunteers. All TSCA COUs except one COU have acute risk estimates below an MOE of 10, and 39 TSCA COUs have acute risk estimates below an MOE of 1.

EPA did not identify inhalation exposure data for peak exposures for the industrial use as process aid in: Oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing. Of note, the Commercial use – laundry and dishwashing products COU only had one identified data point for peak exposures, and therefore one risk value is provided.

As shown in Figure 4-2, chronic non-cancer risk estimates for worker inhalation exposure range from 2.42×10^{-3} to 6.4 for both high-end and central tendency exposures. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated. Chronic non-cancer risk estimates below 1 indicate that exposure is greater than the hazard point of departure based on respiratory effects in children. While some healthy adult workers may be less susceptible to formaldehyde at those concentrations, MOEs below 1 may be a concern for susceptible workers such as those with chronic respiratory disease or those with co-exposures that contribute to similar respiratory effects. Of the 49 TSCA COUs evaluated, 48 TSCA COUs have chronic risk estimates below an MOE of 3, and 47 TSCA COUs have chronic risk estimates below an MOE of 1. Sub-chronic, non-cancer risk estimates follow a similar risk profile and are not separately illustrated.

Worker cancer risk estimates for inhalation exposure range from 4.05×10^{-6} to 1.3×10^{-2} for both high-end and central tendency exposures, as shown in Figure 4-3. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated. The cancer risk estimates calculated for workers do not include risks for myeloid leukemia and other tumor sites because EPA was not able to quantify those risks with confidence. Cancer risk estimates may therefore underestimate risks. Of the 49 TSCA COUs evaluated, 46 TSCA COUs have chronic risk estimates greater than 1 in 10,000. All risk estimates including for all exposure scenarios evaluated are provided in the "Supplemental file: Occupational Risk Calculator."



2053

2054 **Figure 4-1. Acute, Non-cancer Occupational Inhalation and Dermal Risk by TSCA COU**
2055 Acute non-cancer MOE risk estimates based on peak occupational exposure estimates (15-minute) with lower
2056 MOE values indicating greater risks. For COUs with multiple OESs or estimation approaches, the estimate with
2057 the highest high-end value was illustrated.

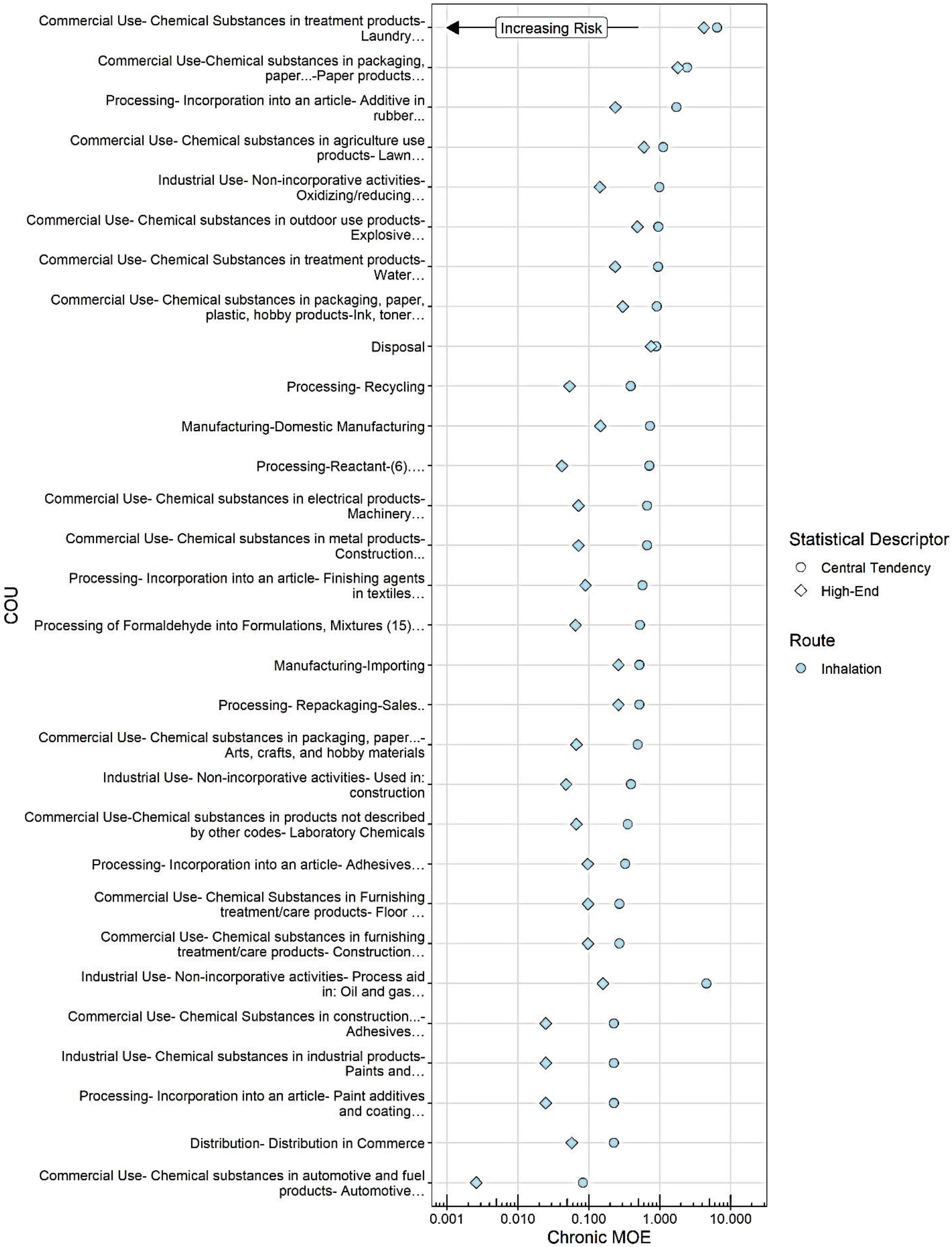


Figure 4-2. Chronic, Non-cancer Occupational Inhalation Risk by TSCA COU
Non-cancer MOE risk estimates based on occupational exposure with lower MOE values indicating greater risks. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated.

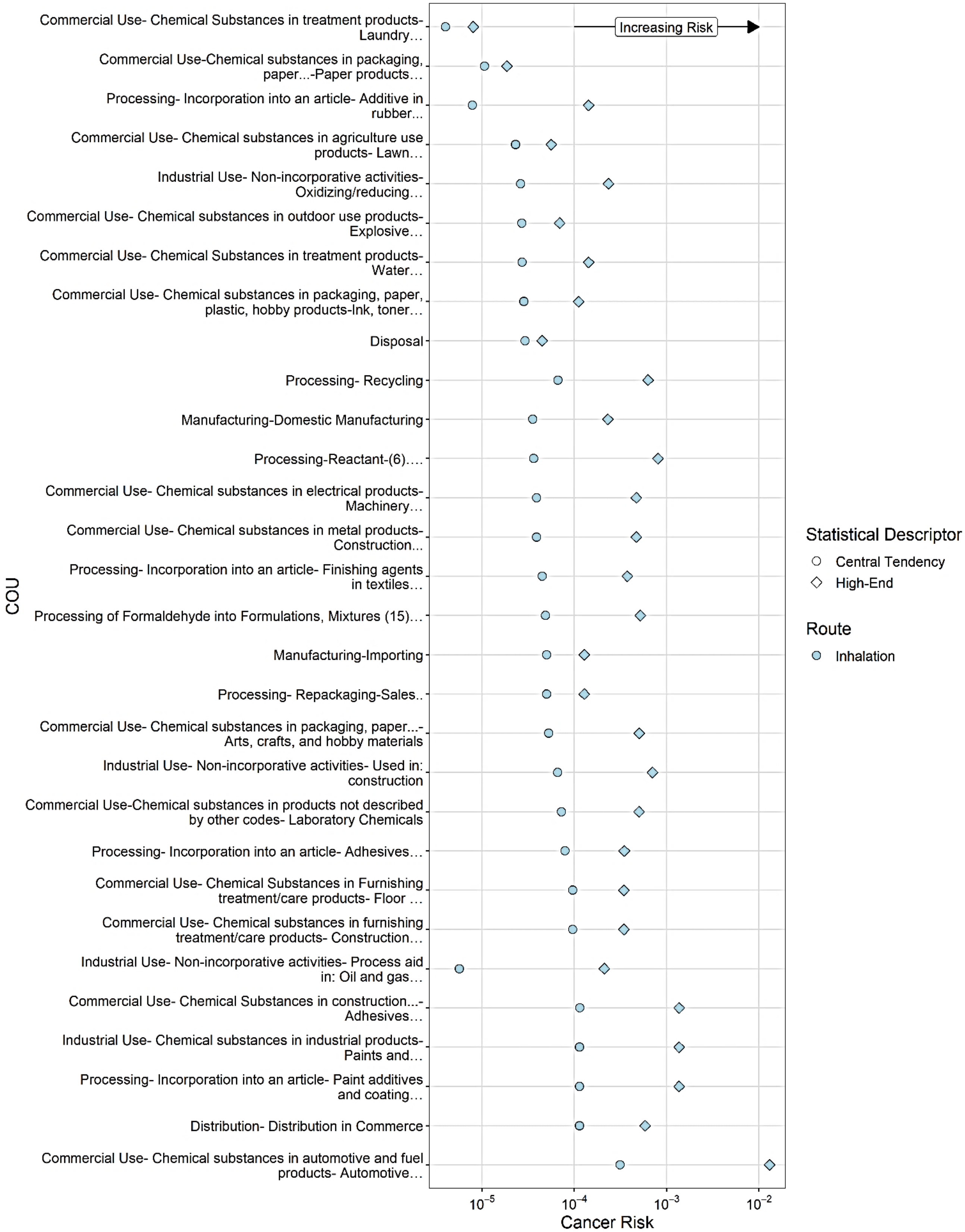


Figure 4-3. Chronic Cancer Occupational Inhalation Risk by TSCA COU

Cancer risk estimates based on occupational exposure with higher values indicating greater risks. For COUs with multiple OESs or estimation approaches, the scenario with the highest central tendency value was illustrated.

4.2.1.2 Overall Confidence in Worker Inhalation Risks

Overall confidence in risk estimates for workers via inhalation exposure varies per COU, depending on the confidence in the hazard and the exposure assessment for each OES as provided in the *Draft Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024k).

EPA's occupational exposure assessment is supported by a large body of workplace monitoring data specific to the exposure scenarios assessed. A limitation of the monitoring data is the uncertainty in the representativeness of the data. Some monitoring data was limited in additional contextual information such as site identification, worker activities and process conditions, such that EPA used other information to assign to the respective exposure scenario. For scenarios based on limited monitoring data, the assessed exposure levels are less likely to be representative of worker exposure across the entire job category or industry. For many exposure scenarios, EPA incorporates OSHA CEHD data. This data source does not provide job titles or worker activities associated with the sample. As the OSHA CEHD data were apportioned to OESs based on their NAICS code, there is an uncertainty in the representativeness of the mapped OSHA CEHD data for the corresponding exposure scenario.

The effects of these uncertainties on the occupational exposure assessment are unknown, as the uncertainties may result in either overestimation or underestimation of exposures depending on the actual distribution of formaldehyde air concentrations and the variability of work practices among different sites. In some scenarios where monitoring data were available, EPA did not find sufficient data to determine complete statistical distributions. Ideally, EPA will present 50th and 95th percentiles for each exposed population. In the absence of percentile data for monitoring, the mean or midpoint of the range may serve as a substitute for the 50th percentile of the actual distributions. Similarly, the highest value of a range may serve as a substitute for the 95th percentile of the actual distribution. However, these substitutes are uncertain. The effects of these substitutes on the occupational exposure assessment are unknown, as the substitutes may result in either overestimation or underestimation of exposures depending on the actual distribution. Although the weight of scientific evidence varies, EPA has concluded that the underlying data still provide plausible estimates of exposures for all OESs.

EPA has medium confidence in the acute inhalation POD. It is based on evidence in healthy adults in controlled exposures. Generally, EPA has medium confidence in the exposure estimates for peak exposures, but it varies from low to high across the OESs assessed. For most exposure scenarios, EPA estimated peak exposures using 15-minute workplace monitoring data from the OSHA CEHD database. However, in some cases, EPA may not have information on the worker activities sampled and whether these activities would be expected to result in peak levels of formaldehyde. For many scenarios, there is a high level of non-detects integrated within exposure estimates, which can bias the exposure estimate. Generally, the limit of detection for the 15-minute samples were higher than the calculated occupational exposure value for acute effects (see Appendix E.1). For example, acute risks are greatest for the below COUs, in which EPA has an overall medium confidence in the individual risk estimates:

- **Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products:** EPA has medium confidence in the risk estimates for this COU. Three occupational exposure scenarios are estimated for this COU, the exposure scenario with the highest central tendency exposure estimate was selected for risk characterization of this condition of use. The automotive care products OES was modeled for the worker activity of applying a detailing product containing formaldehyde. The scenario was modeled using two approaches: an approach that model complete evaporation of the expected formaldehyde contained in the detailing product during application, and an approach using measured VOC data. To account for variability, EPA performed 100,000 Monte Carlo iterations where parameters were varied based on industry defaults such as number of cars detailed per site, amount of product used, and formaldehyde specific information, concentration of formaldehyde in the product. EPA calculated vapor generation using the chemical properties of formalin as well as reported VOC emissions in the automotive detailing industry. A limitation of this modeled estimate is that it does not account for if any engineering controls are used during application.

- **Manufacturing-manufacturing:** EPA has medium confidence in the risk estimates for this COU. Acute inhalation risk estimates were derived using 15 personal breathing zone sample data collected at two U.S. formaldehyde manufacturing facilities in 1992 and one U.S. formaldehyde manufacturing facility in 2020. Due to a limited amount of recent monitoring data, there is some uncertainty in the representativeness of the estimates at current manufacturing facilities.

For chronic inhalation risks, EPA has medium confidence in the cancer inhalation unit risk underlying these risk estimates and high confidence in the chronic, non-cancer hazard POD. The chronic, non-cancer hazard POD is supported by a robust database of evidence in humans and animals that demonstrates concordance in effect levels across multiple endpoints and it includes evidence in children with asthma and other sensitive groups.

Generally, EPA has medium confidence in the exposure estimates for full-shift exposures but confidence for individual scenarios varies from low to high across the OESs assessed. For most exposure scenarios, EPA estimated full-shift exposures by integrating discrete data identified from peer-reviewed literature and other sources. As discussed earlier, OSHA CEHD does not provide all of the meta-data associated with the sampled data. For estimation of full-shift exposures, EPA establish a cut-off total sampling duration of 5.5 hours to reduce uncertainties by using data most expected to represent full-shift exposures. EPA then calculated an 8-hour TWA assuming that unsampled time was zero. This approach may lead to underestimation of full-shift exposures if workers were still exposed to formaldehyde for the unsampled time. A sensitivity analysis on these assumptions were included in the *Draft Occupational Exposure Assessment for Formaldehyde* (U.S. EPA, 2024k).

For calculation of the ADC and LADC, EPA assumes that workers are exposed for 250 days per year for chronic and 22 days per month for sub-chronic risk estimates across all scenarios. For LADC, the assumption of worker tenure is important, in which EPA uses 31 years for central tendency risk estimates and 40 years for high-end risk estimates. These parameters may vary by individual workers. A principal limitation of the ADC and LADC used is that these exposure estimates assume no exposure to formaldehyde outside of the workplaces. In Section 4.3, EPA considers how aggregate exposures to formaldehyde from multiple sources, across multiple routes, or across pathways may increase the overall risk for some people.

Although the weight of scientific evidence varies, EPA has concluded that the underlying data still provide plausible estimates of exposures for all OESs. As examples, chronic risks are greatest for the below COUs, in which EPA has an overall medium confidence in the risk estimates:

- **Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products:** EPA has medium confidence in the risk estimates for this COU. Three occupational exposure scenarios are estimated for this COU, the exposure scenario with the highest central tendency exposure estimate was selected for risk characterization of this condition of use. The automotive care products OES was modeled for the worker activity of applying a detailing product containing formaldehyde. The model assumes that as the detailing product containing formaldehyde is applied, that the formaldehyde evaporates during application. To account for variability, EPA performed 100,000 Monte Carlo iterations where parameters were varied based on industry defaults such as number of cars detailed per site, amount of product used, and formaldehyde specific information, concentration of formaldehyde in the product. A limitation of this modeled estimate is that it does not account for if any engineering controls are used during application. EPA calculated vapor generation both using the chemical properties of formalin as well as reported VOC emissions in a similar industry.

- **Processing – processing as a reactant (COU Group):** EPA has medium to high confidence in the risk estimates for this COU. The underlying occupational exposure scenario covers, in general, processes that use formaldehyde as a reactant for a variety of downstream products. This scenario integrates data from a variety of sources (*e.g.*, industry submissions, OSHA CEHD data) for a total of 192 8-hr TWA samples. Limitations within the monitoring data is a lack of additional details on worker activities for the individual samples. There is some uncertainty on the representativeness of the 50th and 95th percentiles towards the true distribution for the exposed population for this scenario.

4.2.1.3 Risk Estimates for Dermal Exposures

Acute non-cancer risk estimates for dermal exposure range from 3.24×10^{-3} to 18 (benchmark MOE of 10) for central tendency exposures and high-end exposures. Risk estimates are greatest for TSCA COUs: Commercial use – chemical substances in automotive and fuel products – automotive care products; lubricants and greases; fuels and related products; and TSCA COUs: Processing – incorporation into an article – paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace); Industrial use – paints and coatings; adhesives and sealants; lubricants; commercial use – chemical substances in construction, paint, electrical, and metal products – adhesives and sealants; paint and coatings. Both OESs assumed an immersive dermal loading on the skin during the exposure scenario.

Dermal risk estimates were not provided for Distribution in commerce and commercial use – packaging, paper, and hobby products COUs. These COUs involve the handling of solid articles with low concentrations of formaldehyde in which the dermal modeling approaches were not suitable. EPA expects the primary concern for these products is inhalation exposures from formaldehyde off-gassing.

4.2.1.4 Overall Confidence in Worker Dermal Risks

Overall confidence in risk estimates via dermal exposure is medium. As described in Section 3.2, overall confidence in the dermal hazard value is medium. As described in Section 2.5.1, overall confidence in dermal occupational exposures is medium based on a moderate weight of scientific evidence for all scenarios assessed. All scenarios used a modified version of the EPA Dermal Exposure to Volatile Liquids Model, which reduced to two parameters: an activity-based dermal loading and a maximum weight concentration of formaldehyde in the formulations handled. For many scenarios, maximum concentration information from sources such as the 2020 CDR (U.S. EPA, 2020b) have overall data quality determinations of either high or medium from EPA's systematic review process. Some scenarios lacked sufficient information on the maximum concentrations expected and industry-specific or surrogate scenarios were used to inform calculations. There is some uncertainty on the range of concentrations of formaldehyde within certain processes and products whose impact is unknown and may either result in an overestimation or underestimation of exposures.

4.2.2 Risk Estimates for Consumers

EPA estimated cancer and non-cancer risks for exposure to formaldehyde resulting from exposure to formaldehyde in consumer products. For this analysis, EPA relied on the consumer exposure estimates modeled in the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d) and summarized in Section 2.2.

4.2.2.1 Risk Estimates for Inhalation Exposure to Formaldehyde in Consumer Products

EPA estimated cancer and non-cancer risks to consumers and bystanders from inhalation of formaldehyde in consumer products.

Acute inhalation risk estimates range from 4.65×10^{-4} to 1.31 (Figure 4-4). These acute risk estimates are calculated using high-end air concentrations modeled for a 15-minute period based a set of high-end model input assumptions and TSCA COU-specific assumptions about exposure frequency and duration. Acute risk estimates below 1 indicate that exposure is greater than the hazard point of departure identified for 15-minute peak exposures based on sensory irritation reported in controlled human exposure studies in healthy adult volunteers.

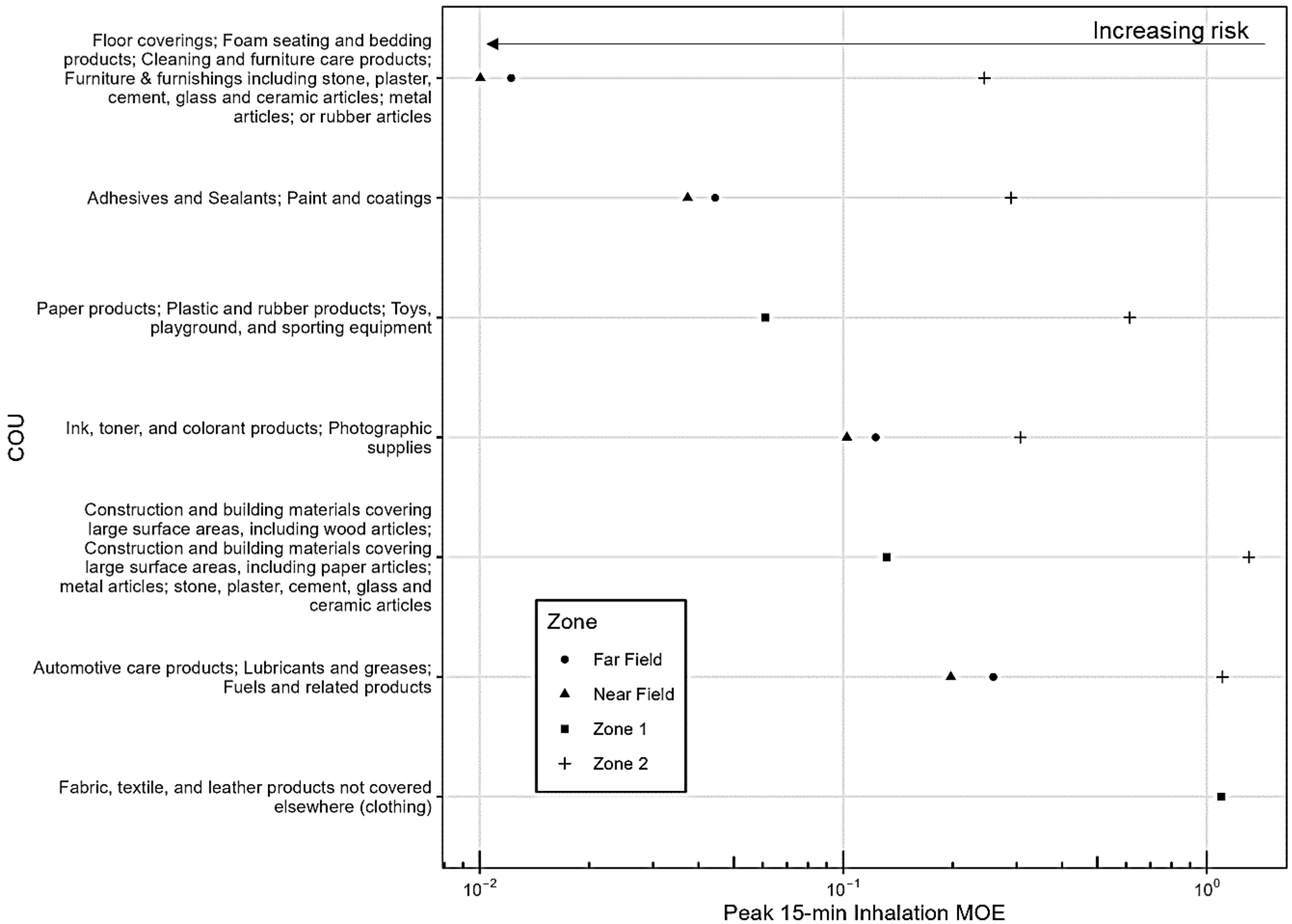


Figure 4-4. Peak 15-Minute Inhalation Risk by COUs in Consumer Products

Acute non-cancer risk estimates are based on high-end consumer and bystander exposure estimates. Acute non-cancer MOEs are based on modeled air exposure estimates and are interpreted relative to a benchmark MOE of 10. Lower MOE values indicate greater risks. For some products, air concentrations were modeled for near-field and far-field (generally describing differences in exposure within the same room) while for other products concentrations were modeled for zones 1 and 2 (generally describing different rooms). Risks from near-field and zone 1 exposures generally represent risks from direct exposures to consumer users while far-field and zone 2 tend to represent risks to consumer bystanders. For instance, an individual applying floor coverings: Varnishes and floor finishes in a living room can be described as a consumer of that product in zone 1 or near-field of the application area. On the other hand, while the product is being applied there may be someone else either also in the room of use and assumed to be away from the immediate application area (or in the far-field), or in a completely different room from where the product is being applied (also known as zone 2). The x-axis presents the 15-minute peak inhalation non-cancer concentration, and the y-axis presents the modeled TSCA COUs.

Chronic non-cancer risk estimates for consumers based on modeled chronic inhalation exposures range from 5.70×10^{-1} to 7.64, with lower values indicating greater risks (Figure 4-5). Non-cancer risk estimates below 1 indicate that exposure is greater than the hazard point of departure based on respiratory effects in sensitive groups, including children. Chronic ADAF-adjusted lifetime cancer risk estimates based on modeled chronic inhalation range from 2.36×10^{-11} to 4.82×10^{-4} (Figure 4-6), with larger numbers indicating increasing risk. The risk estimates for chronic exposures presented here are based on central tendency air concentrations modeled for a set of mid-range model input assumptions and TSCA COU-specific assumptions about exposure frequency and duration. Risk estimates presented here represent risks to consumers who frequently use products containing formaldehyde and are based on the consumer activity and use patterns described in the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d). For example, cancer risk estimates for the arts, crafts, and hobby material COU presented here are not representative of all arts and crafts products. They are based on an assumption of exposure to a specific set of products that contain 0.1 percent formaldehyde used an average of 15 minutes/day, 300 days each year, over a period of 57 years which are standard CEM temporal inputs primarily based upon the 1987 Westat survey of consumer activities and use patterns (U.S. EPA, 2021a, 2019; Westat, 1987).

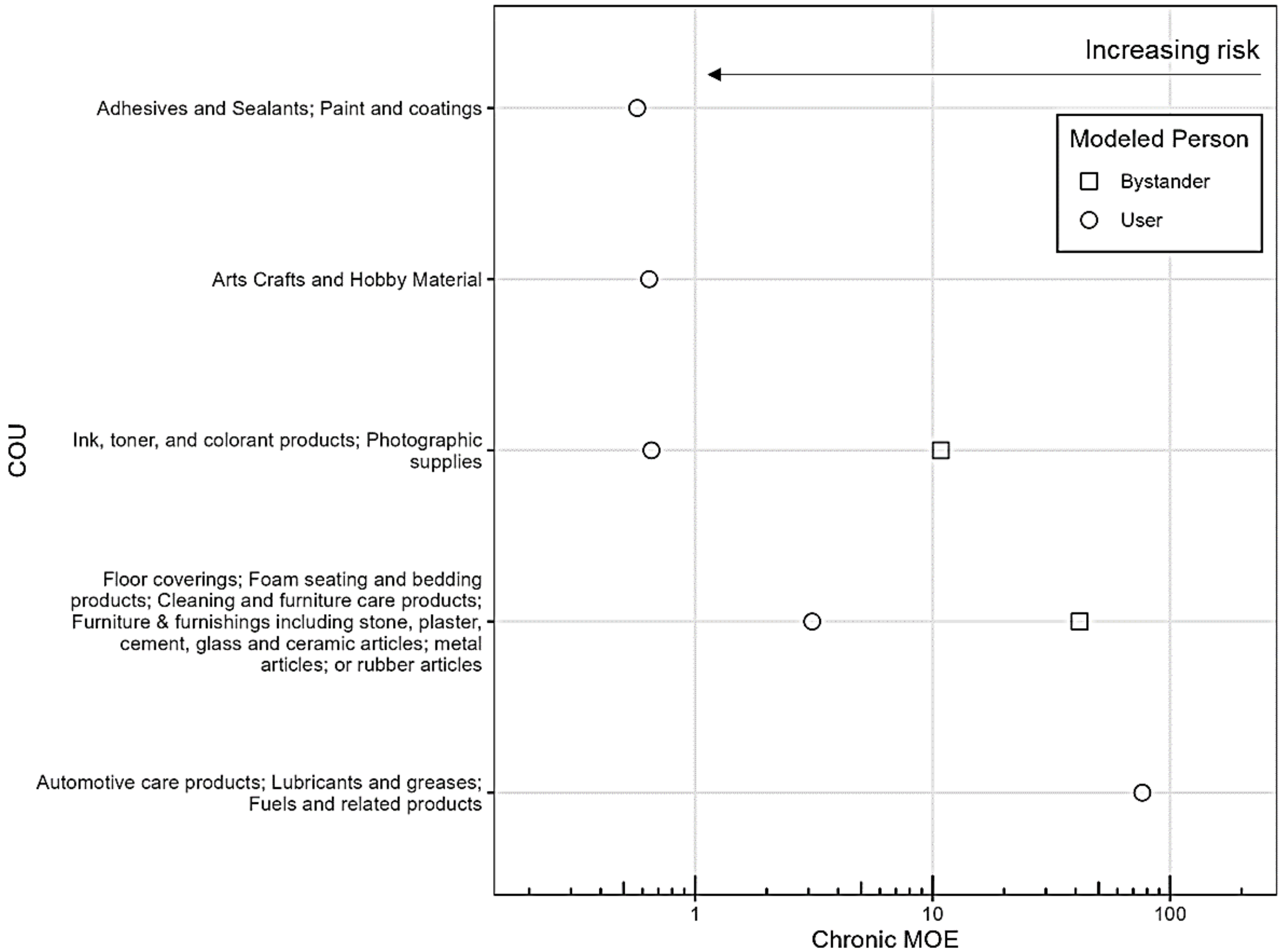


Figure 4-5. Chronic Non-cancer Inhalation Risks for Consumer Products by COU

Chronic risk estimates are based on consumer and bystander exposure estimates that rely on central tendency assumptions about product use duration and frequency. Non-cancer MOEs are based on modeled air exposure estimates and are interpreted relative to a benchmark MOE of 3. Lower MOE values indicate greater risks. The x-axis presents risk estimates for chronic inhalation exposure estimates, and the y-axis presents the modeled TSCA COUs.

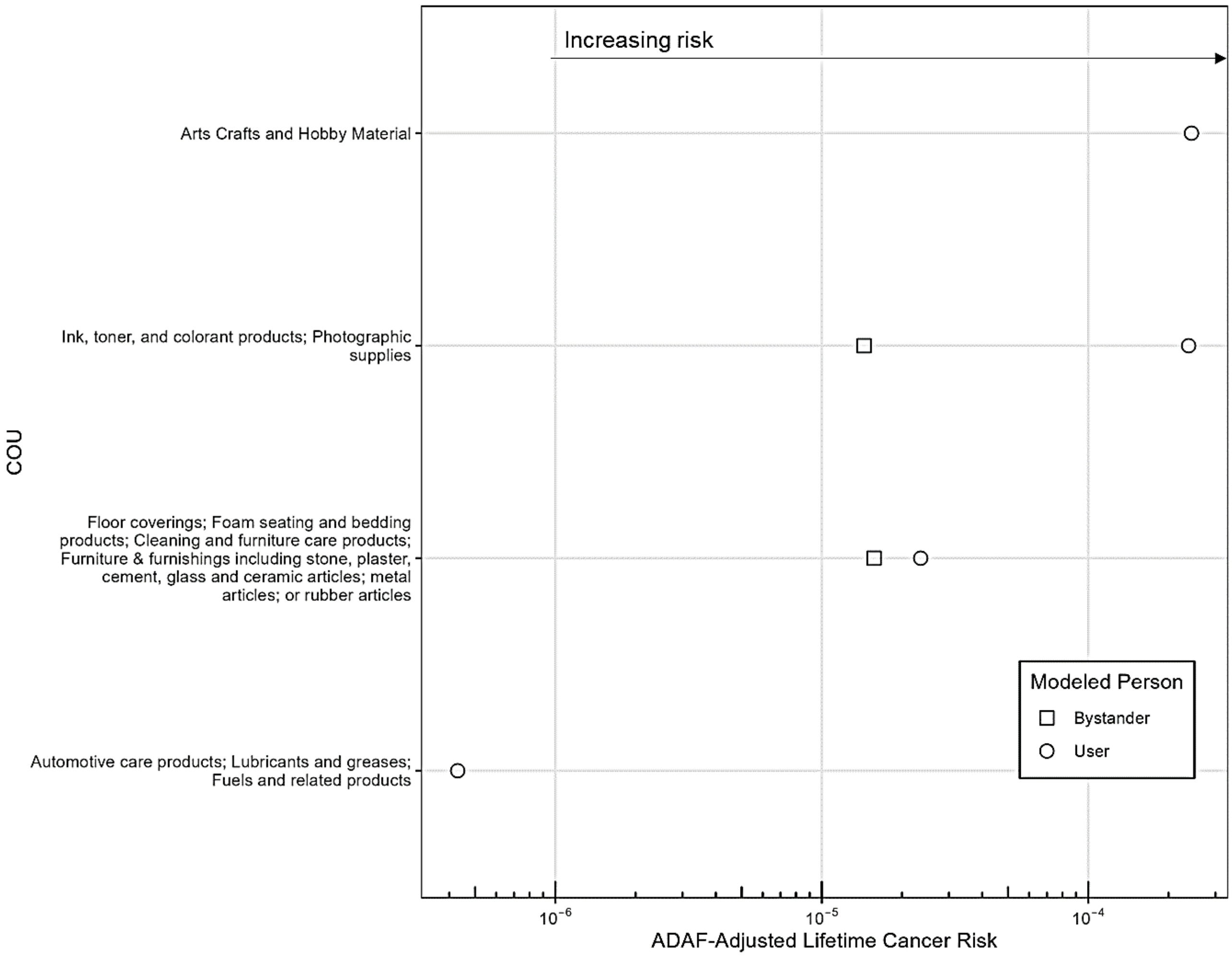


Figure 4-6. ADAF-Adjusted Chronic Inhalation Cancer Risk by COUs in Consumer Products
ADAF-adjusted lifetime cancer risk estimates are based on consumer and bystander central tendency exposure estimates. Higher cancer risk estimates indicate greater risk. The x-axis presents the ADAF-adjusted lifetime cancer risk and the y-axis presents the modeled TSCA COUs.

Overall confidence in inhalation risk estimates for consumer products is medium for chronic non-cancer risks and medium for cancer risk and acute non-cancer risk. As described in Section 3.2.1.1 of the Consumer Exposure Module, the overall confidence in monitoring data used in the indoor air assessment is high due to reliance on 41 high quality formaldehyde air exposure studies relevant to TSCA COUs, and CEM modeling assumptions and inputs, which have been peer reviewed and used in previous existing chemical risk evaluations. While EPA relied on available survey data on product use patterns, there is uncertainty around the applicability of the generic survey data for current use patterns for specific product types. For example, for some inputs relied on the use and activity patterns reported in the Westat survey from 1987 (Westat, 1987). Although this is a robust dataset it may not be reflective of current use patterns for the specific product types assessed. As described in Section 3.2, overall confidence in the chronic, non-cancer hazard POD is high because it is supported by a robust database of evidence in humans and animals that demonstrates concordance in effect levels across multiple endpoints and it includes evidence in children with asthma and other sensitive groups. Overall confidence in the inhalation unit risk for formaldehyde is medium. The cancer risk estimates presented here do not include risks for some of the tumor sites. While the draft IRIS assessment concluded that the evidence demonstrates that formaldehyde inhalation causes myeloid leukemia and sinonasal cancer in humans, EPA was not able to quantify those risks with confidence. The draft IRIS assessment estimated that the IUR used to estimate lifetime cancer risks may underestimate total cancer risk by as much as 4-fold. EPA has medium confidence in the acute inhalation POD based on evidence in healthy adult volunteers in controlled exposure conditions.

4.2.2.2 Risk Estimates for Dermal Exposure to Formaldehyde in Consumer Products

EPA estimated non-cancer risks for acute dermal exposure to formaldehyde in consumer products.

Dermal risk estimates were calculated based on low, central tendency and high-end exposure estimates. The estimated dermal risks based on high-end exposures range from 3.24×10^{-3} to 9.71 and are presented in Figure 4-7. Risk estimates below 1 indicate that exposures are above the POD based on skin sensitization responses observed in adults. There is uncertainty surrounding the assumption of occlusion or immersion of hands using liquid or spray consumer products, which may overestimate exposures and risks for some consumer exposure scenarios.

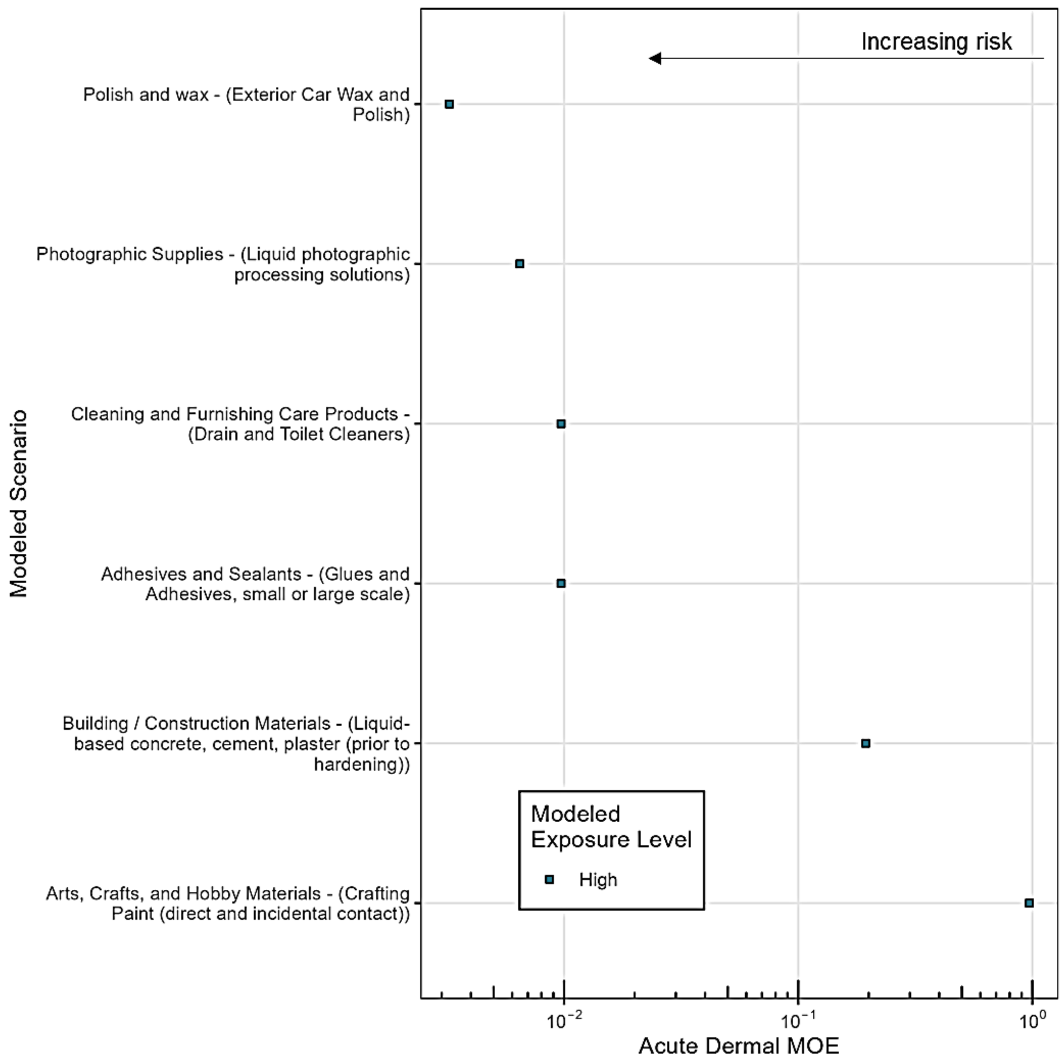


Figure 4-7. Acute Dermal Loading Risk by High-End Exposure Scenarios in Consumer Products

Dermal non-cancer MOE risk estimates are based on consumer exposure estimates and are interpreted relative to a benchmark MOE of 10. Lower MOE values indicate greater risks. The x-axis presents the acute dermal loading MOE, and the y-axis presents the modeled scenarios written as TSCA COU followed by relevant exposure scenario in parentheses.

Overall confidence in risk estimates for dermal exposure is medium. As described in Section 3.2.1.1 of the Consumer Exposure Module, the overall confidence in monitoring data used in the indoor air assessment is medium due to no formaldehyde dermal exposure studies identified through systematic review; though other highly rated supplemental studies were used to identify loading of formaldehyde to skin (U.S. EPA, 2019; Delmaar et al., 2013; IPCS, 2002; ATSDR, 1999) and product specific modeling assumptions and weight fractions identified via safety data sheets reviewed and used in previous existing chemical risk evaluations. As described in Section 3.2, overall confidence in the dermal hazard value is medium.

4.2.3 Risk Estimates for Indoor Air

EPA estimated cancer and non-cancer risks for exposure to formaldehyde in indoor air. For this analysis, EPA considered available indoor air monitoring data as well as air concentrations modeled based on specific TSCA COUs, as described in the *Draft Indoor Air Assessment for Formaldehyde* (U.S. EPA, 2024j). Monitoring data provide an indication of aggregate exposure and risks in a range of indoor environments while modeled air concentrations can provide information about the contributions of specific TSCA COUs to indoor air concentrations.

4.2.3.1 Risk Estimates Based on Indoor Air Monitoring Data

Monitoring data provide information about actual concentrations of total formaldehyde in indoor air, but the data reflect aggregate concentrations from all TSCA and other sources present. Monitoring data are therefore a good indication of aggregate formaldehyde exposures and risks in a range of indoor environments, but do not provide information about the relative contributions of each source.

EPA estimated cancer and non-cancer risks based on levels of formaldehyde detected in indoor air in monitoring studies representing a range of indoor air environments. The American Healthy Home Survey II is a survey published in 2021 that is representative of residential indoor air conditions across a wide range of American households (QuanTech, 2021). It is the most current nationally representative survey of formaldehyde in indoor air in American homes and is likely the best representation of the current range of aggregate exposures and risks from all sources of formaldehyde in indoor air. Other monitoring datasets considered in this analysis generally target indoor environments that typically have higher formaldehyde concentrations, such as trailers and mobile homes. Available indoor air monitoring datasets likely do not represent current conditions in indoor air following Title VI regulation of wood products. Figure 4-8 summarizes ADAF-adjusted lifetime cancer risk estimates based on indoor air monitoring data, relying on the assumption that these monitored concentrations could represent average exposures in indoor air and that exposure to these concentrations may be experienced continuously over a 78-year lifetime. This may be a conservative assumption for high end indoor air exposures, as concentrations in a particular home change over time and people typically live in multiple homes over the course of their lives.

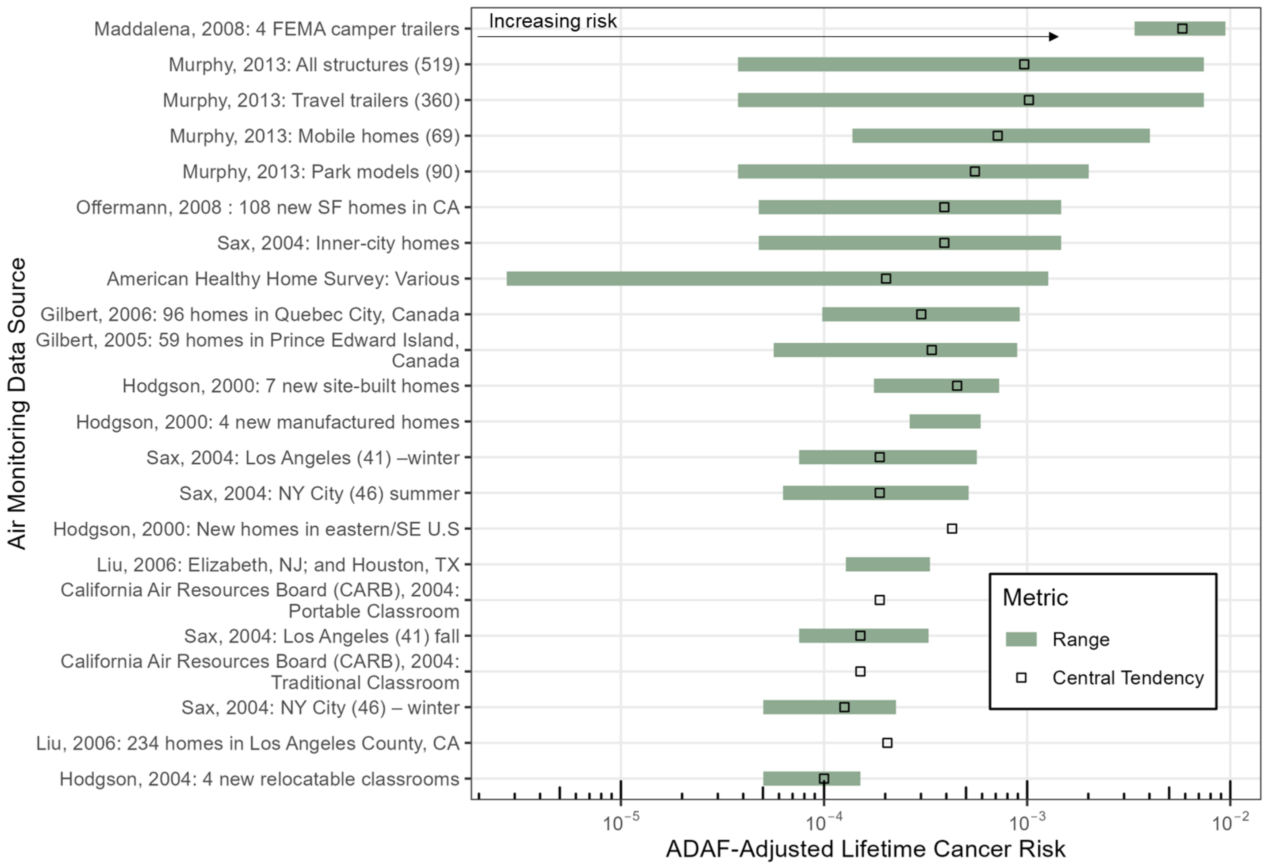


Figure 4-8. ADAF-Adjusted Lifetime Cancer Inhalation Risk by Indoor Air Monitoring Data Source

Cancer risk estimates are based on air concentrations reported in monitoring data and rely on the assumption that individuals may be consistently exposed to these concentrations over a 78-year lifetime. Higher cancer risk estimates indicate greater risk. Air monitoring data sources listed on the y-axis are described in more detail in the *Draft Indoor Air Assessment for Formaldehyde* (U.S. EPA, 2024j).

Among all residence types and commercial environments, lifetime cancer risk estimates based on indoor air monitoring data ranged from 2.74×10^{-6} to 9.46×10^{-3}. These ranges of risk estimates correspond to measured minimum concentrations of 2.18×10^{-4} ppm by the American Healthy Home Survey II (QuanTech, 2021), and a measured maximum concentration of 7.53×10^{-1} ppm from a study of four FEMA camper trailers (LBNL, 2008), respectively. Chronic non-cancer risk estimates based on the same indoor air monitoring data range from 77.8 to 0.02, with lower values indicating greater risk.

4.2.3.2 Risk Estimates Based on Indoor Air Modeling for Specific TSCA COUs

Indoor air concentrations modeled for specific COUs provide an indication of the contributions of individual COUs to formaldehyde exposure and risk. EPA estimated chronic non-cancer risks based on formaldehyde concentrations modeled based on long-term emissions associated with specific COUs, as described in Section 2.3. The modeled air concentrations used as the basis for chronic risk estimates for indoor air were designed to estimate concentrations at the central tendency. As described in the *Draft Indoor Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024j), there is substantial uncertainty related to the degree of dissipation of formaldehyde over time and how exposures from specific products change over the course several years. For this reason, EPA has low confidence in exposure estimates modeled over longer than a year for specific TSCA COUs contributing to formaldehyde in indoor air.

EPA therefore did not calculate cancer risk based on chronic indoor air exposures resulting from specific TSCA COUs.

Non-cancer risk estimates based on indoor air concentrations modeled for specific COUs range from 0.05 to 4. Risk estimates below 1 indicate that exposure is greater than the hazard point of departure based on respiratory effects in sensitive groups, including children. Figure 4-9 summarizes chronic non-cancer risk estimates based on modeled average indoor air concentrations estimated to result from specific TSCA COUs over the course of the first year of product use. These risk estimates account for dissipation that occurs over time due to the depletion of formaldehyde from the article and air exchange but do not account for the half-life of formaldehyde.

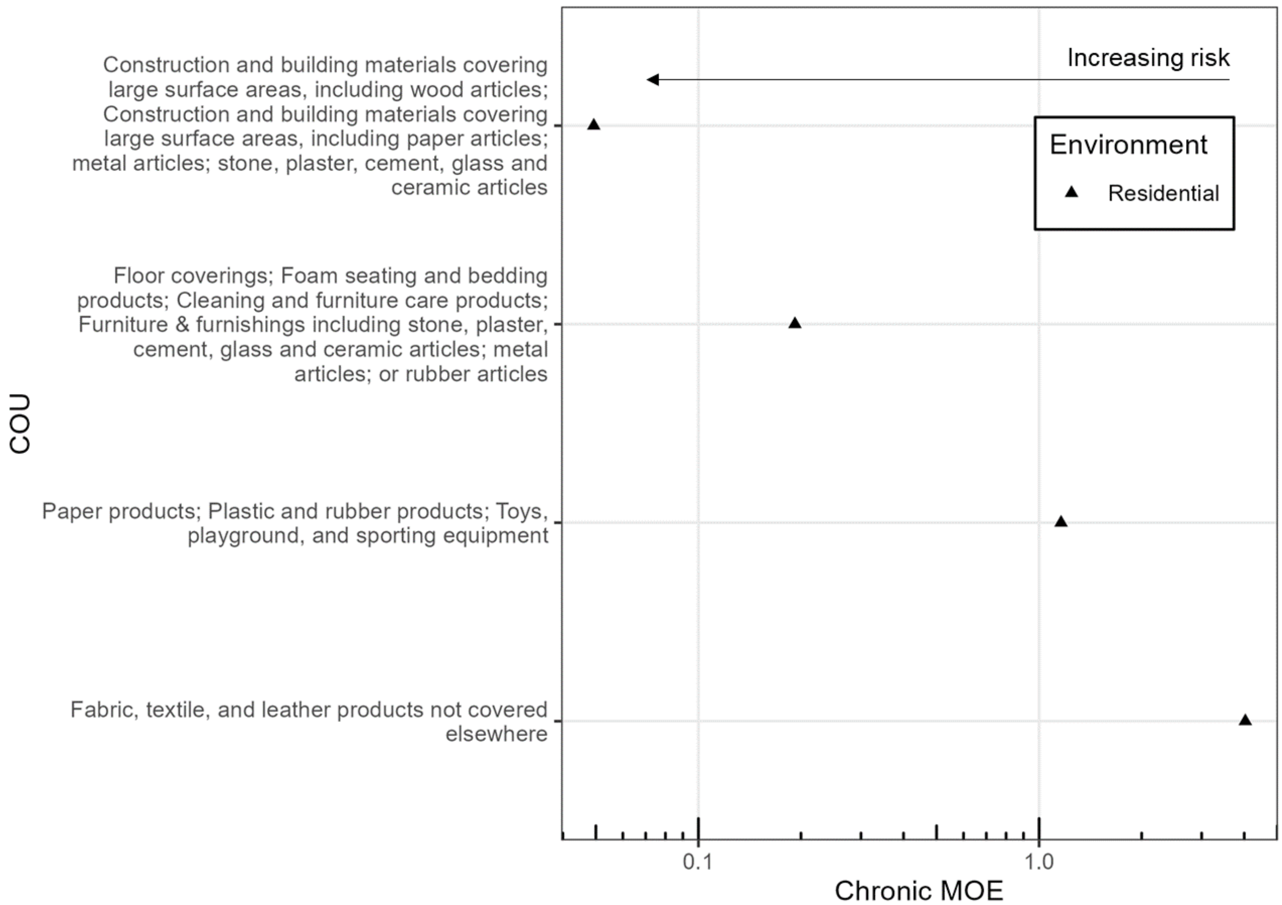


Figure 4-9. Chronic Non-cancer Inhalation Risk Based on Modeled Air Concentrations for Specific TSCA COUs

Chronic non-cancer risk estimates are based on indoor air exposure estimates. Lower MOEs indicate greater risk. The y-axis presents the modeled scenarios written as TSCA COU followed by relevant exposure scenario.

Overall confidence in risk estimates by individual TSCA COU modeling is medium. In general, EPA has medium confidence in CEM's ability to assess formaldehyde exposures in indoor air and the supporting monitoring data. The inability to account for half-life in the model decreases confidence in the exposure estimates. It is unclear whether the modeling results are reflective of most indoor air home environments in American residences. EPA has medium confidence in the applicability of the modeling results used to assess indoor air exposures to formaldehyde. As described in Section 3.2.1.1 of the Draft Indoor Air Exposure Assessment Module, the overall confidence in modeling used in the indoor air assessment is high due to medium quality studies used to incorporate TSCA COU-specific emission rates and due to the use of a high quality CEM modeling inputs and formulas used to generate TSCA COU-specific indoor air concentrations.

Monitoring data reflect total concentrations from a wider range of sources and are therefore not directly comparable to modeled estimates. However, in general, modeled and monitored indoor air formaldehyde concentrations are within the same order of magnitude that increases the confidence in the modeled formaldehyde indoor air exposures underlying these risk estimates.

As described in Section 3.2, overall confidence in the chronic non-cancer hazard POD is high. It is supported by a robust database of evidence in humans and animals that demonstrates concordance in effect levels across multiple endpoints and it includes evidence in children with asthma and other sensitive groups.

4.2.3.3 Integration of Modeling and Monitoring Information and Consideration of Aggregate Risk

Risk estimates based on modeled air concentrations provide information about the contribution of specific COUs to exposures and risks from formaldehyde in indoor air. However, given the ubiquity of formaldehyde in indoor environments, risks from individual sources rarely occur in isolation. EPA has therefore also considered monitoring data as an indication of aggregate exposure and risks from all sources contributing to formaldehyde in indoor air.

While monitoring data does not distinguish between risk contributions from TSCA and other sources, it offers a way to interpret risks from individual COUs in the context of aggregate risks from all co-occurring sources.

As previously noted, the AHHS II is the most current nationally representative survey of formaldehyde in indoor air in American homes. Therefore, among all monitoring sources, it is likely the most appropriate source for the estimation of aggregate risks in American residential indoor air across all households, including old and new homes. Using the maximum estimated monitoring indoor air estimate for formaldehyde in AHHS II (including contributions from both TSCA and other sources), it may be assumed that indoor air aggregate non-cancer MOEs are as low as 1.681×10^{-1} and cancer MOEs are as high as 1.271×10^{-3} in typical U.S. The same can be inferred from mobile home, classroom, and other monitoring indoor air risk estimates.

4.2.4 Risk Estimates for Ambient Air

EPA evaluated cancer risks resulting from human exposure to formaldehyde via the ambient air pathway using previously peer-reviewed methodologies along with multiple lines of evidence including multiple release estimates from two separate databases (TRI and NEI), several peer-reviewed models (IIOAC, HEM, AirToxScreen), and monitoring data (AMTIC) from EPA's ambient monitoring network. When looking at direct analysis of formaldehyde release data from TRI using IIOAC to represent a more localized exposure, 26 of 29 TSCA COUs evaluated have risk estimates greater than 11×10^{-6}, and 19 COUs have risk estimates greater than 11×10^{-5}. Additionally, 21 of the 29 TSCA COUs have risk estimates greater than relative risk estimates for biogenic sources. As expected, modeled concentrations using IIOAC fall within the lower range of monitoring data from AMTIC (although not amortized as annual averages) since AMTIC represents a total formaldehyde concentration from all sources rather than localized impacts near industrial facilities releasing formaldehyde to the ambient air and associated with COUs evaluated with IIOAC. Nonetheless, cancer risk estimates based on monitoring data from AMTIC range from 7.11×10^{-8} to 6.1×10^{-4}. Figure 4-10 shows the ADAF-adjusted cancer risk estimates for all AMTIC monitoring data, IIOAC modeled data, and AirToxScreen modeled data, based on the assumption that these concentrations reflect average exposures that occur continuously over a 78-year lifetime.

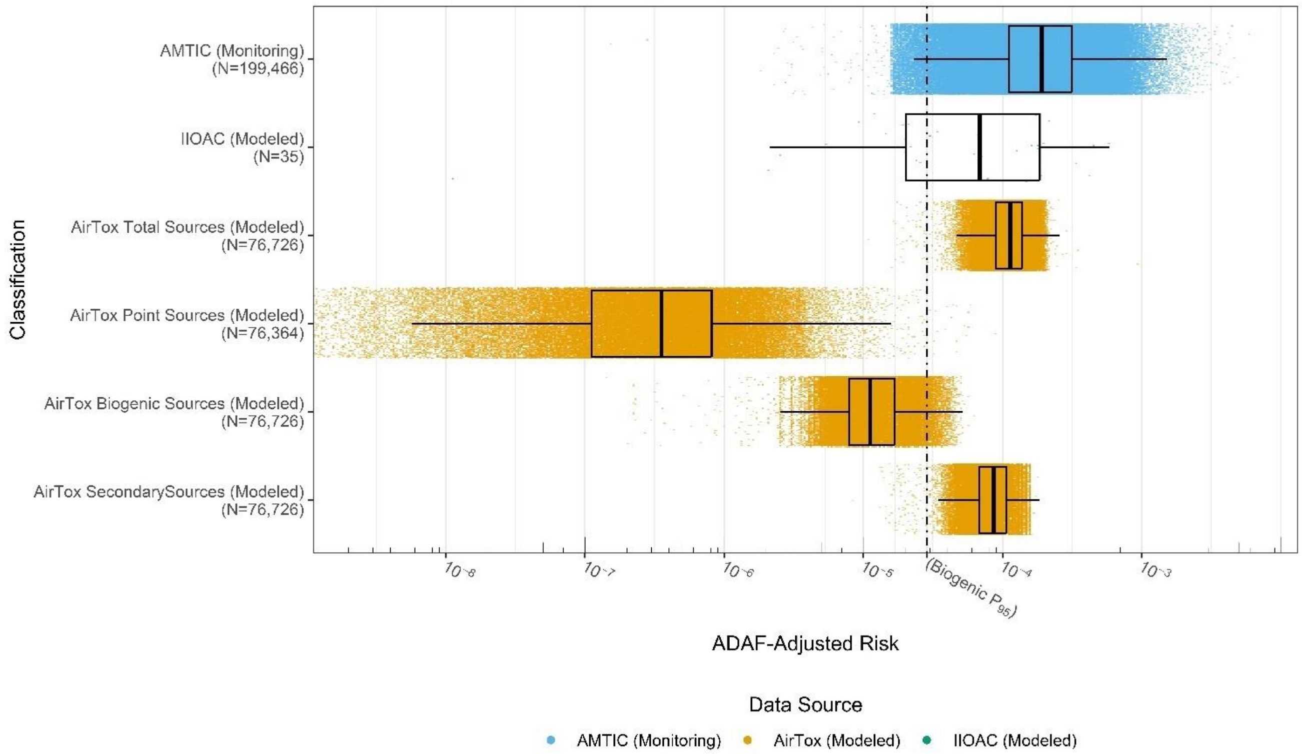


Figure 4-10. ADAF-Adjusted Cancer Risk for Monitoring and Modeling Ambient Air Data

EPA recognizes that the different model estimates are not directly comparable. For example, the IIOAC results represent a risk estimate between 100 to 1,000 m from the release point. In contrast, AirToxScreen concentrations represent risk estimates at the census tract scale; only point source data may represent some releases of formaldehyde from TSCA COUs. Given the spatial scale difference, it is expected that AirToxScreen results could underestimate concentrations on a smaller scale (*i.e.*, near facilities) or have lower concentration estimates than IIOAC and this difference can be seen in Figure 2-10. Additionally, only point source data within AirToxScreen may represent a broader set of formaldehyde releases that include releases associated with TSCA COUs.

4.2.4.1 Risk Estimates Based on Ambient Air Monitoring

There is abundant monitoring data on formaldehyde in ambient air. As described in Section 2.4.1, monitoring data from EPA's AMTIC (U.S. EPA, 2022a) include a range of air monitoring data collected across the country under a range of experimental designs across heterogenous environments. EPA considers the available monitoring data for formaldehyde to reflect the range of aggregate formaldehyde concentrations under a range of outdoor environments from both TSCA and other sources of formaldehyde.

EPA calculated chronic cancer risks based on air concentrations reported in AMTIC, relying on the assumption that monitored concentrations could represent chronic exposure (as shown at the top of Figure 4-10). However, because some monitoring efforts included in the dataset capture a snapshot of air concentrations at a single timepoint, there is uncertainty around the extent to which the available monitoring data are an accurate representation of long-term chronic exposures.

Given the ubiquity of formaldehyde and the diversity of sources, monitoring data does not provide clear information on the contributions of specific TSCA or other sources of formaldehyde. Risk estimates based on the available monitoring data provide an indication of the aggregate risk from all sources contributing to ambient air concentrations of formaldehyde, which may be present in the real world and provide context for risks from individual TSCA COUs.

4.2.4.2 Risk Estimates Based on Modeled Concentrations near Releasing Facilities

EPA estimated risks associated with acute and chronic non-cancer exposure to formaldehyde in the ambient air. EPA utilized the 95th percentile release value reported to TRI by Industry Sector (mapped to respective COUs) and the 95th percentile modeled annual-averaged air concentrations from the IIOAC output file at 100 to 1,000 m from the release point as described in the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) to derive risk estimates. All derived risk estimates for acute and chronic non-cancer effects were above relative MOE benchmarks. Therefore, while all risk estimates are included in the "Draft IIOAC Assessment Results and Risk Calcs Supplement A for Ambient Air," EPA focuses on cancer risk estimates as described below for purposes of risk characterization in this draft human health risk assessment.

EPA estimated cancer risks associated with continuous chronic exposure to formaldehyde in the ambient air over a 78-year lifetime. EPA utilized the 95th percentile release value reported to TRI by Industry Sector (mapped to respective TSCA COUs) and the 95th percentile modeled annual-averaged air concentrations from the IIOAC output file at a distance of 100 to 1,000 m from the release facility described in the *Draft Ambient Air Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a) and in Section 2.4.2.1, to derive cancer risk estimates. Risk estimates are presented by TSCA COU in Figure 4-11. As described in Section 4.1.2, higher cancer risk estimates indicate higher risks.

Figure 4-11. Risk Estimates by TSCA COU for the 95th Percentile Release Scenario and 95th Percentile Modeled Concentration between 100 and 1,000 m from Industrial Facilities Releasing Formaldehyde to the Ambient Air

Across all TSCA COUs, cancer risk estimates ranged from 1.1×10^{-9} to 5.9×10^{-5}. The three highest cancer risk estimates are 5.9×10^{-5}, 4.5×10^{-5}, and 3.4×10^{-5}. These three cancer risk estimates represent three industry sectors and seven TSCA COUs.

The three industry sectors with the highest cancer risk estimates associated with TSCA COUs are:

- Non-metallic mineral product manufacturing (5.9×10^{-5});
- Textiles, apparel, and leather product manufacturing (4.5×10^{-5}); and
- Transportation equipment manufacturing (3.4×10^{-5}).

Together, these three industry sectors are associated with seven formaldehyde TSCA COUs (*i.e.*, individual industry sector results are used to represent multiple formaldehyde TSCA COUs as shown below). Those COUs are:

- Processing – incorporation into an article-adhesives and sealant chemicals (5.9×10−5);
- Processing as a reactant-intermediate (5.9×10^{-5});
- Processing – incorporation into a formulation, mixture, or reaction product-intermediate (5.9×10^{-5});
- Processing – incorporation into article-finishing agent (4.5×10^{-5} µg/m^3);
- Processing – incorporation into a formulation, mixture, or reaction product-bleaching agents (4.5×10^{-5});
- Processing-incorporation into an article-paint additives and coating additives (3.4×10^{-5}); and
- Industrial use-chemical substances in industrial products-paints and coatings; adhesives and sealants, lubricants (3.4×10^{-5}).

In total, 19 of the 29 TSCA COUs (65.5%) have cancer risk estimates within the same order of magnitude greater than 1×10^{-5}. An additional seven TSCA COUs have cancer risk estimates within the same order of magnitude greater than 1×10^{-6} and less than 1×10^{-5}. Two COUs have cancer risk estimates within the same order of magnitude greater than 1×10^{-7} and less than 1×10^{-6}, and one TSCA COU has a cancer risk estimate in the 1×10^{-9} range.

Recognizing the ubiquity of formaldehyde in ambient air occurs from multiple sources including other sources like biogenic/natural sources and secondary formation, EPA compared the calculated risk estimates for modeled concentrations from IIOAC to the calculated risk estimate for the 95th percentile concentration of attributable to biogenic sources. Across all 29 TSCA COUs evaluated, 21 TSCA COUs have risk estimates greater than the risk estimate for biogenic sources (2.85×10^{-6}). Eighteen TSCA COUs have calculated risk estimates greater than 5 times the calculated risk estimate for biogenic sources (1.42×10^{-5}). Seven TSCA COUs have calculated risk estimates greater than 10 times the calculated risk estimate for biogenic sources (2.85×10^{-5}). Eight TSCA COUs have calculated risk estimates less than the risk estimate for biogenic sources.

For the industry sector of Oil and Gas Drilling, Extraction, and Support Activities, results were not available from the TRI program. Although many of the NAICS codes for this industry sector are not covered by the TRI program, the sites are well represented in the NEI database. This industry sector is associated with the following formaldehyde TSCA COUs:

- Processing as a reactant-functional fluid;
- Processing – incorporation into a formulation, mixture, or reaction product – processing aids, specific to petroleum production;
- Processing – incorporation into a formulation, mixture, or reaction product – intermediate; and
- Industrial use – non-incorporative activities – process aid.

Upon further review, the emission source information provided in the NEI database indicated that the majority of emissions within this industry are combustion sources (*e.g.*, reciprocating engines), with a limited number of emission sources related to storage tanks, amine processes, and unclassified units with emission sources typically less than 100 kg/year. These releases are lower than the median for the industry sector, which have cancer risks below the 1×10^{-5}. Therefore, EPA did not include the oil and gas drilling, extraction, and support activities industry sector as the primary emissions are outside of the scope of this draft risk evaluation.

Overall, these results indicate that while releases, exposures, and associated risk estimates may vary across industry sectors and TSCA COUs, the results presented in Figure 4-11 are generally representative of risks to individuals residing near industrial facilities releasing formaldehyde into the ambient air that are associated with TSCA COUs.

Risks estimates calculated by the HEM model at census blocks were also considered to inform EPA's understanding of how modeled results intersected with populated areas and demographic characteristics. Overall, HEM modeling estimated a total population of 1,023,773 people experiencing a lifetime cancer risk of at least one in one million. These cancer risk estimates are based solely on formaldehyde emissions from facilities reporting to TRI, and do represent the aggregation of exposures from multiple nearby facilities. A full breakdown of estimated population by level of risk estimate with stratification by demographics is presented in Table 4-2. At higher levels of estimated risk, 6,935 people were estimated to experience risk greater than 10 in 1 million, and 19 were estimated to experience risk greater than 100 in 1 million. No estimated risks exceeded 200 in 1 million. Across the entire modeling domain, which included census blocks within 50 km of any TRI facility reporting formaldehyde releases, the average risk to the entire population of 232,907,302 people was estimated to be 0.04 in 1 million. This average risk was slightly higher for the African American and Native American demographics included in the modeling, at an estimate of 0.06 in 1 million. While population counts are summarized at the census block level, the demographic information is summarized by census block group, and applied to each block within the block group. In order to avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories presented below: White, African American, Native American, Other and Multiracial, or Hispanic/Latino.

Table 4-2: **Population Summary for Cancer Risk Estimates Derived from HEM Modeling of TRI Releases Formaldehyde to Air**

Range of Lifetime Individual Cancer Risk	Number of People within 50 km of any Facility in Different Ranges for Lifetime Cancer Risk					
	Total Population	White	African American	Native American	Other and Multiracial	Hispanic or Latino
< 1 in 1 million	232,907,302	140,083,682	30,322,675	881,180	21,243,988	40,375,778
1 to <5 in 1 million	1,023,773	665,609	171,444	7,929	54,384	124,408
5 to <10 in 1 million	40,652	26,742	5,429	542	2,884	5,055
10 to <20 in 1 million	6,935	4,430	1,057	21	246	1,181
20 to <30 in 1 million	2,692	1,901	388	8	64	331

Range of Lifetime Individual Cancer Risk	Number of People within 50 km of any Facility in Different Ranges for Lifetime Cancer Risk					
	Total Population	White	African American	Native American	Other and Multiracial	Hispanic or Latino
30 to <40 in 1 million	509	359	70	4	11	65
40 to <50 in 1 million	555	379	117	0	18	41
50 to <100 in 1 million	338	202	101	0	7	27
100 to <200 in 1 million	19	10	6	0	1	2
≥200 in 1 million	0	0	0	0	0	0
Total population within model domain	233,982,775	140,783,315	30,501,287	889,684	21,301,603	40,506,886
Average risk (chance in 1 million)	0.04	0.04	0.06	0.06	0.03	0.03

Further breakdown of relative population demographics compared to national averages is presented in Table 4-3. This summary of results shows that among the population with estimated cancer risk modeled by HEM to be higher than 1 in 1 million, some population groups are disproportionately represented, which would be indicated by a higher percentage of a population group experiencing elevated risk than the overall nationwide percentage of the population representing that group. These groups include white, African American, and Native American demographics, as well as those with income below the poverty level and those aged over 25 years without a high school diploma.

Table 4-3. Demographic Details of Population with Estimated Cancer Risk Higher than or Equal to 1 in 1 Million, Compared with National Proportions

Demographic	Nationwide	Population with Cancer Risk Higher than or Equal to 1 in 1 Million (Estimated by HEM Modeling of TRI Releases)
Total Population	329,824,950	1,075,473
Race and ethnicity by percent		
White	59.5%	65.1%
African American	12.1%	16.6%
Native American	0.6%	0.8%
Other and Multiracial	8.8%	5.4%
Hispanic or Latino	19.0%	12.2%
Income by percent		
Below Poverty Level	12.8%	15.7%
Above Poverty Level	87.2%	84.3%
Below Twice Poverty Level	30.2%	34.9%

Above Twice Poverty Level	69.8%	65.1%
Education by percent		
Over 25 and without a High School Diploma	11.6%	12.3%
Over 25 and with a High School Diploma	88.4%	87.7%
Linguistically isolated by percent		
Linguistically Isolated	5.2%	2.2%

Overall confidence in risk estimates based on modeled air concentrations is high for non-cancer risk estimates and medium for cancer risk estimates. As described in Section 2.4.2, overall confidence in modeling for exposures used to derive risk estimates for ambient air is high because modeling relies upon direct reported releases from multiple years and databases that received a high-quality rating from EPA's systematic review process. Peer-reviewed modeling approaches and methods with IIOAC were used to estimate concentrations to derive risk estimates at distances from releasing facilities where individuals typically reside for many years. Use of additional peer-reviewed models (AirToxScreen and HEM) along with monitoring data (AMTIC) to further contextualize ambient air concentrations of formaldehyde, which also present a consistent picture of exposures when compared to IIOAC results, provide added strength and confidence to the risk estimates.

As described in Section 3.2, overall confidence in the acute and chronic, non-cancer hazard POD is high while overall confidence in the inhalation unit risk for formaldehyde is medium. The cancer risk estimates presented here do not include risks for some of the tumor sites. While the draft IRIS assessment concluded that the evidence demonstrates that formaldehyde inhalation causes myeloid leukemia and sinonasal cancer in humans, EPA was not able to quantify those risks with confidence. The draft IRIS assessment estimated that the IUR used to estimate lifetime cancer risks may underestimate total cancer risk by as much as 4-fold.

4.2.4.3 Integration of Modeling and Monitoring Information

EPA evaluated and characterized exposures and risks to the general population from industrial releases of formaldehyde to the ambient air using actual reported releases and peer reviewed models to estimate exposures at select distances from releasing facilities. EPA also evaluated and characterized exposures and risks to the general population based on ambient monitoring data obtained from AMTIC.

Modeling and monitoring results show comparable exposures and risks to the general population from formaldehyde in the ambient air. However, direct comparisons between modeled and monitored concentrations and associated risks should be made with caution because each approach represents different contributions to the overall exposures and associated risks.

EPA's modeling approaches use actual reported releases of formaldehyde, required to be reported by statute to peer-reviewed databases, as direct inputs to peer-reviewed models. The models are then used to estimate exposures used to derive risk estimates and characterize risks. Because the modeling approaches use actual reported releases from real facilities, each release can be mapped to a representative TSCA COU. This allows EPA to estimate exposures, derive risk estimates, and characterize risks to its TSCA COU as required by statute and is a strength of the modeling approaches used. However, since some modeling inputs require assumptions that may be conservative in nature and retain some uncertainty results from modeling may overestimate exposures to the chemical modeled and thus overestimate risk. While this may be seen as a limitation to the relevance of modeling to estimate exposures and associated risks, the modeling approaches are not overly conservative (based on a series of sensitivity analyses) and provide a more health protective estimate for use in risk characterization, risk determination, and regulatory decisions.

In addition to modeled concentrations of formaldehyde in ambient air, EPA relied upon monitoring data from EPA's ambient air monitoring network. The monitoring network samples on a regular, and sometimes continuous, basis concentrations of a variety of chemicals in the ambient air. The monitoring, sampling, and analysis methods follow EPA reference methods, which have been rigorously peer reviewed and often promulgated in the Code of Federal Regulations (CFR). Monitored concentrations, therefore, represent actual measured concentrations of chemicals in the ambient air that contrasts with modeled concentrations that are estimated based on a series of assumptions and input parameters. However, ambient monitoring also measures the total concentration of the chemical in the ambient air, which can be due to multiple sources (TSCA COUs, secondary formation, biogenic formation, and other sources that cannot readily be mapped to a single TSCA COU). Since monitored concentrations represent a total concentration of a chemical in ambient air, in a given location, at a given period in time, monitoring data may be more representative of a total aggregate exposure of the general population to formaldehyde in the ambient air rather than an independent exposure from a single source over a continuous exposure period.

4.2.4.4 Overall Confidence in Exposures, Risk Estimates, and Risk Characterizations for Ambient Air

Confidence in the characterization of exposures for the general population utilized to derive these risk estimates is high as exposures are based on actual reported releases required by statute to be reported by industry to peer-reviewed databases. Additionally, peer-reviewed models are used to model ambient air concentrations at distances from releasing facilities where individuals within the general population typically reside for many years. Finally, the TRI database undergoes repeatable quality assurance and quality control reviews and is a high-quality database under EPA's systematic review process.

For formaldehyde, the potential contribution of combustion sources is an uncertainty and use of the full facility data complicate singular TSCA COU estimates, such that emissions at one site may include multiple sources under multiple COUs that include combustion sources and non-combustion sources. For industrial COUs, EPA has a moderate to robust weight of scientific evidence as the databases have high data quality scores and are supported by numerous data points. EPA targeted its assessment to industrial COUs as it expects industrial releases to be the largest proportion of TSCA-related releases. For commercial COUs, EPA used TRI and NEI results to inform the potential ranges of ambient air risk estimates in Appendix D. EPA has a moderate weight of scientific evidence for the commercial COUs.

Overall confidence in risk estimates based on air concentrations modeled near release sites is high for non-cancer estimates and moderate for cancer estimates based on the hazard values. As described in Section 3.2, overall confidence in the chronic, non-cancer hazard POD is high, while overall confidence in the inhalation unit risk for formaldehyde is medium. The cancer risk estimates presented here do not include risks for some of the tumor sites. Although the draft IRIS assessment concluded that the evidence demonstrates that formaldehyde inhalation causes myeloid leukemia and sinonasal cancer in humans, EPA was not able to quantify those risks with confidence. The draft IRIS assessment estimated that the IUR used to estimate lifetime cancer risks may underestimate total cancer risk by as much as 4-fold.

4.2.5 Comparison of Non-cancer Effect Levels and Air Concentrations

Hazard and risk assessments often lack human data on the specific concentrations at which an effect occurs in people and risk estimates often incorporate a substantial amount of uncertainty. In the case of formaldehyde, a robust database of epidemiology studies provides information about the air concentrations of formaldehyde that have been associated with respiratory effects in people and supports hazard values with minimal uncertainty.

Figure 4-12 indicates that the respiratory effects of formaldehyde in people can occur within the range of air concentrations reported in monitoring studies. This comparison suggests that chronic exposure to some of the indoor and outdoor air concentrations captured in available monitoring data are at levels that may be expected to result in adverse health effects based on available human evidence.

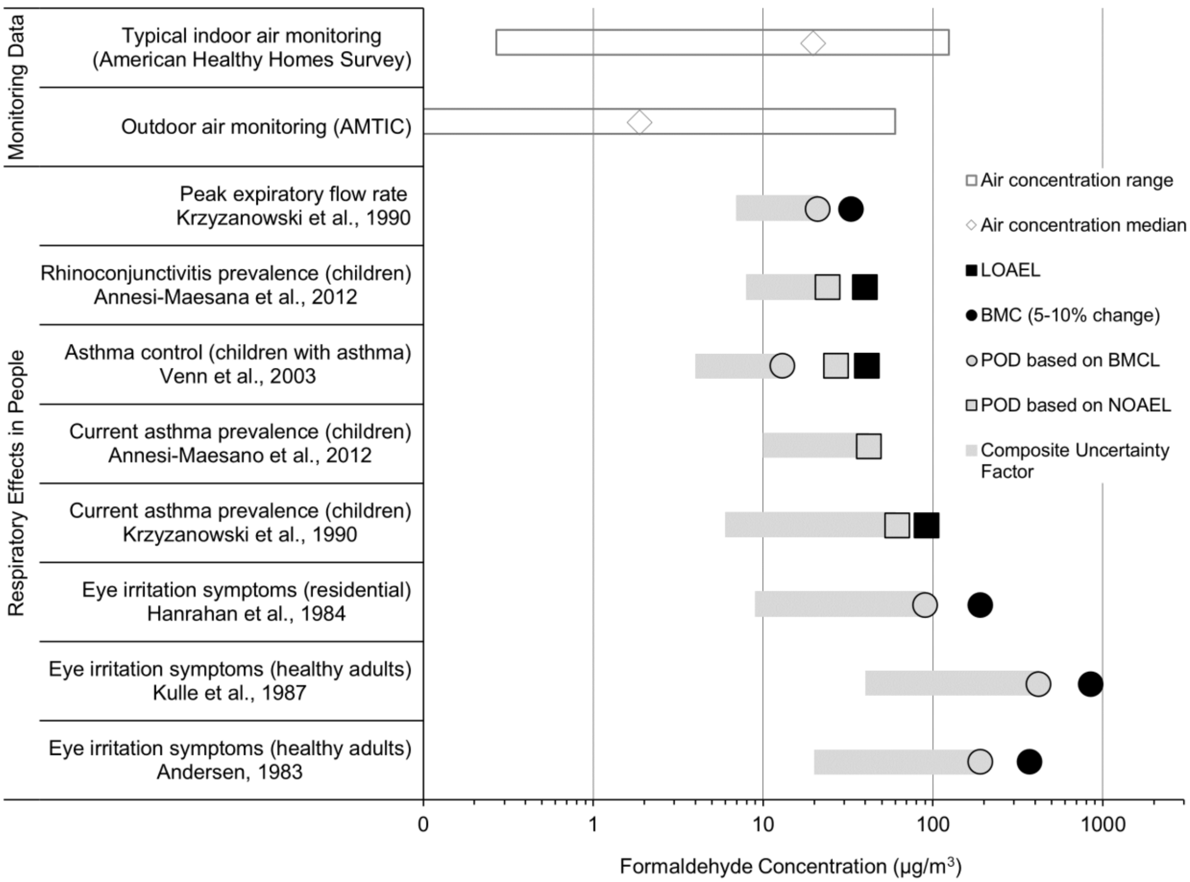


Figure 4-12. Comparison of Non-cancer Health Effect Levels Reported in People and Indoor and Outdoor Air Concentrations

Indoor air monitoring data summarized here are the American Healthy Homes Survey II data described in Section 2.3.1 and reflect the range of typical indoor air concentrations. Outdoor air monitoring data summarized here are the AMTIC dataset and include a diverse range of outdoor air monitoring sources. Black shapes indicate air concentrations at which adverse health effects were reported in epidemiology studies or controlled human exposure studies (LOAEL or BMC), grey circles and squares indicate concentrations at which no significant health effects were reported (NOAEL or BMCL), and grey bars indicate the total uncertainty factors identified for each study. Effect levels (LOAEL, BMC, NOAEL and BMCL) and composite uncertainty factors for each study are presented as reported in the draft IRIS assessment.

4.2.6 Potentially Exposed or Susceptible Subpopulations

EPA considered PESS throughout the exposure and hazard assessments supporting this analysis. Table 4-4 summarizes how PESS were incorporated into the risk evaluation through consideration of increased exposures and/or increased biological susceptibility. The table also summarizes the remaining sources of uncertainty related to consideration of PESS. Appendix C provides additional details on PESS considerations for the formaldehyde risk evaluation.

The available data suggest that some groups or lifestages have greater exposure to formaldehyde. For example, people exposed to formaldehyde at work, those who frequently use consumer products containing high concentrations of formaldehyde, people living or working near facilities that emit formaldehyde, and people living in mobile homes and other indoor environments with high formaldehyde concentrations are expected to have greater exposures. In this assessment, EPA evaluated risks anticipated for a range of scenarios under TSCA COUs where exposures are expected to be greatest. In addition to high exposures associated with COUs, some people will have greater exposure to formaldehyde through sources that are not being assessed under TSCA. For example, those living near major roadways, people living in areas with frequent exposure to wildfire smoke, smokers, and people exposed to second-hand smoke, are expected to have greater exposures to formaldehyde. For these groups, higher exposures from other sources of formaldehyde may increase susceptibility to additional exposures from TSCA sources. As described in Section 4.3, EPA assessed risks from several aggregate exposure scenarios; however, the wide range of possible combinations of aggregate sources are expected to be highly variable across individuals and are a remaining source of uncertainty.

Some groups or lifestages may be more susceptible to the health effects of formaldehyde exposures. For example, children have developing respiratory systems and narrower airways that may make them more susceptible to the respiratory effects of formaldehyde. The chronic inhalation hazard value is derived in part based on dose-response information in children with asthma and is supported by dose-response information on lifestage-specific reproductive and developmental effects in humans and animals. The chronic inhalation hazard value incorporates information on several sensitive groups; therefore, EPA used a value of 3 for the UF_H to account for human variability.

Other factors that may increase susceptibility to formaldehyde include chronic disease, co-exposures, sex, lifestyle, sociodemographic status, and genetic factors. People with chronic respiratory diseases (*e.g.*, asthma) may be more susceptible to the respiratory effects of formaldehyde. Co-exposure to other chemical or non-chemical stressors that increase risk of asthma, reduced pulmonary function, reproductive and/or developmental toxicity, nasopharyngeal cancer or myeloid leukemia, may increase susceptibility to the effects of formaldehyde on the same health outcomes. While these factors are not quantitatively accounted for in the hazard characterization, EPA used values of 3 or 10 for the human variability UF_H to account for increased susceptibility when quantifying risks from exposure to formaldehyde. The Risk Assessment Forum, in *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002), discusses some of the evidence for choosing the default factor of 10 when data are lacking—including toxicokinetic and toxicodynamic factors as well as greater susceptibility of children and elderly populations. U.S. EPA (2002), however, did not discuss many of the factors presented in Appendix C**Error! Reference source not found.**

As described in Section 4.1.2 and in the draft IRIS assessment (U.S. EPA, 2022b), EPA concluded that a mutagenic mode of action is operative in formaldehyde-induced nasopharyngeal carcinogenicity. EPA therefore applied ADAFs to lifetime cancer risk estimates to account for increased susceptibility to nasopharyngeal cancer following inhalation exposure during early life.

Table 4-4. Summary of PESS Considerations Incorporated throughout the Analysis and Remaining Sources of Uncertainty

PESS Categories	Potential Exposures Identified and Incorporated into Exposure Assessment	Potential Sources of Biological Susceptibility Identified and Incorporated into Hazard Assessment
Lifestage	EPA considered several scenarios in which lifestage may influence exposure. For air exposures, the impacts of lifestage differences were not able to be adequately quantified and so the air concentrations are used for all lifestages. Consumer exposure scenarios include lifestage-specific exposure factors for adults, children, and formula-fed infants (U.S. EPA, 2024d). Based on physical chemical properties and a lack of studies evaluating potential for accumulation in human milk following inhalation, dermal or oral exposures, EPA did not quantitatively evaluate the human milk pathway. This is a remaining source of uncertainty. In the consumer exposure assessment, EPA also considered potential oral exposure associated with mouthing behaviors in infants and young children (U.S. EPA, 2024d); however, EPA did not have sufficient information on this exposure route to quantify risks.	EPA identified potential sources of biological susceptibility to formaldehyde due to lifestage differences and developmental toxicity as described in the draft IRIS assessment, the hazard value for chronic inhalation was informed in part by dose-response data on asthma in children, male reproductive toxicity, female reproductive effects and developmental toxicity and is expected to be protective of these endpoints. A 3× UF was applied for human variability. For oral, dermal, and acute inhalation hazard values, EPA did not identify quantitative information on lifestage differences in toxicity and this is a remaining source of uncertainty. A 10× UF was applied for human variability. EPA has concluded that a mutagenic mode of action is operative in formaldehyde-induced nasopharyngeal carcinogenicity. To account for increased cancer risks from early life inhalation exposures to formaldehyde, EPA applied an age dependent adjustment factor (ADAF) to cancer risk estimates to account for increased susceptibility to nasopharyngeal cancer following exposure during early life.
Pre-existing Disease	EPA did not identify health conditions that may influence exposure. The potential for pre-existing disease to influence exposure (due to altered metabolism, behaviors, or treatments related to the condition) is a source of uncertainty.	EPA identified the potential for pre-existing health conditions, such as asthma, allergies, nasal damage, or other respiratory conditions to contribute to susceptibility to formaldhyde. As described in the draft IRIS assessment, EPA considered quantitative dose-response information in children with asthma in derivation of the chronic inhalation hazard value. A 3× UF was applied for human variability. For oral, dermal, and acute inhalation hazard values, the potential influence of pre-existing diseases on susceptibility to formaldehyde remains a source of uncertainty. A 10× UF was applied for human variability.
Lifestyle Activities	EPA identified smoking as an additional other source of exposure to formaldehyde that may increase aggregate exposure for smokers and people exposed to second-hand smoke. To some degree, formaldehyde exposure from	EPA qualitatively described the potential for biological susceptibility resulting from smoking, alcohol consumption and physical activity but did not identify quantitative evidence of increased susceptibility to formaldehyde. This is a remaining source of uncertainty.

PESS Categories	Potential Exposures Identified and Incorporated into Exposure Assessment	Potential Sources of Biological Susceptibility Identified and Incorporated into Hazard Assessment
	smoking is indirectly accounted for in some indoor air monitoring data described in Section 4.2.3.1, but it is not directly quantified.	
Occupational Exposures	EPA evaluated risks for a range of occupational exposure scenarios that increase exposure to formaldehyde, including manufacturing, processing, and use of formulations containing formaldehyde. EPA evaluated risks for central tendency and high-end exposure estimates for each of these scenarios (Section 4.2.1). Firefighters are an occupational group expected to have increased exposure to formaldehyde associated with combustion and burning building materials but those exposures are beyond the scope of this assessment.	EPA did not identify occupational factors that increase biological susceptibility to formaldehyde. This is a remaining source of uncertainty.
Geographic Factors	EPA evaluated risks to communities in proximity to sites where formaldehyde is released to ambient air (Section 4.2.4). In the environmental release assessment, EPA mapped tribal lands in relation to air, surface water and ground water releases of formaldehyde to identify potential for increased exposures for tribes due to geographic proximity (U.S. EPA, 2024g). EPA also identified living near major roadways or in areas with frequent exposure to wildfire smoke as potential sources of increased exposure to formaldehyde for some populations. These other sources of exposure are a source of uncertainty that is not directly incorporated into risk estimates for outdoor air exposures.	EPA did not identify geographic factors that increase biological susceptibility to formaldehyde. This is a remaining source of uncertainty.
Socio-demographic Factors	EPA did not identify specific sociodemographic factors that influence exposure to formaldehyde. Income and other sociodemographic factors may be correlated with some of the exposure scenarios that result in greater exposure from both TSCA and other sources (*e.g.*, living near industrial release sites, or near roadways). This is a remaining source of uncertainty.	EPA qualitatively described the potential for biological susceptibility due to socioeconomic factors, such as race or ethnicity and sex or gender, but did not identify quantitative evidence of increased susceptibility to formaldehyde. This is a remaining source of uncertainty.

PESS Categories	Potential Exposures Identified and Incorporated into Exposure Assessment	Potential Sources of Biological Susceptibility Identified and Incorporated into Hazard Assessment
Nutrition	EPA did not identify nutritional factors influencing exposure to formaldehyde. This is a remaining source of uncertainty.	EPA did not identify nutritional factors that affect biological susceptibility to formaldehyde.
Genetics	EPA did not identify genetic factors influencing exposure to formaldehyde. This is a remaining source of uncertainty.	EPA qualitatively described the potential for biological susceptibility due to genetic variants, which was accounted for applying a 10× UF for human variability. The specific magnitude of the impact of genetic variants is unknown and remains a source of uncertainty.
Unique Activities	EPA did not identify specific exposure scenarios that are unique to tribes or other groups that expected to increase exposure to formaldehyde. Potential sources of increased exposure to formaldehyde due to specific tribal lifeways or other unique activity patterns are a source of uncertainty.	EPA did not identify unique activities that influence susceptibility to formaldehyde. This is a remaining source of uncertainty.
Aggregate Exposures	EPA evaluated risk from multiple sources releasing to indoor or outdoor air and aggregate exposures across multiple exposure pathways or exposure scenarios. While EPA assessed risks from several aggregate exposure scenarios, the wide range of possible combinations of aggregate sources are expected to be highly variable across individuals and are a remaining source of uncertainty.	EPA does not identify ways that aggregate exposures would influence susceptibility to formaldehyde. This remains a source of uncertainty.
Other Chemical and Non-chemical Stressors	EPA did not identify chemical and nonchemical stressors influencing exposure to formaldehyde. This is a remaining source of uncertainty.	EPA qualitatively described the potential for biological susceptibility due to chemical or nonchemical factors such as chemical co exposures but did not identify specific quantitative evidence regarding susceptibility to formaldhyde based on chemical and non-chemical stressors. This remains a source of uncertainty.

4.3 Aggregate and Sentinel Exposures

TSCA section 6(b)(4)(F)(ii) (15 USC 2605(b)(4)(F)(ii)) requires EPA, in conducting a risk evaluation, to describe whether aggregate or sentinel exposures under the COUs were considered and the basis for their consideration.

EPA considered how aggregate exposures to formaldehyde from multiple sources, across multiple routes, across groups of people or across pathways may increase the overall risk for some people.

The relative contributions of each source of formaldehyde to overall exposure and risk varies across individuals, locations, and scenarios. For example, in communities living near industrial facilities with high releases, those point sources may be one of the greatest sources of exposure to formaldehyde in outdoor air. For people living near roadways, formaldehyde emitted from vehicles as a combustion byproduct may be a greater source of exposure. For people living in mobile homes or other indoor environments with high formaldehyde concentrations, indoor air in their homes may be the greatest source of exposure. Some people may be exposed to formaldehyde from multiple sources in indoor and outdoor air and through work or use of consumer products. For example, some people living near release sites may also be exposed at work and through high concentrations of formaldehyde in indoor air at home. Although there are too many possible combinations of exposures to evaluate all iterations, EPA considered a range of scenarios in which aggregate exposures within and across exposure pathways may increase total exposure and risk.

EPA qualitatively considered aggregate exposures and risks across inhalation, oral, and/or dermal routes of exposure. For formaldehyde, cancer risk is only quantified for inhalation exposures and therefore cannot be quantitatively aggregated across multiple routes. Non-cancer risks for formaldehyde are highly route-specific and each route-specific hazard value was based on effects that occur near the portal of entry. Because the non-cancer effects are specific to the route of exposure, EPA concluded that the non-cancer risks are not additive across routes. Similarly, because EPA determined that risks are not additive across routes, EPA did not aggregate exposure and risk across pathways for which exposure routes are not the same (*e.g.,* EPA did not aggregate inhalation exposure through outdoor air with dermal exposure associated through use of consumer products).

EPA considered the combined exposures that may result from multiple sources releasing formaldehyde to air in a particular indoor or outdoor environment. Monitoring data for formaldehyde is the best available indication of aggregate exposures that occur in indoor or outdoor air under a range of conditions. As described in Section 4.2.3 and Section 4.2.4.1, EPA considers the range of risk estimates based on monitoring data to provide an estimate of the range of risks from aggregate exposures in air. However, risk estimates based on monitoring do not provide information about the relative contribution of different sources. EPA therefore also evaluated aggregate risks based on modeled air concentrations for multiple TSCA sources releasing formaldehyde to outdoor air (Section 4.2.4.2 and the *Draft Ambient Exposure Assessment for Formaldehyde* (U.S. EPA, 2024a)). The Agency considered aggregating air concentrations estimated for plausible combinations of COUs expected to co-occur in specific indoor air environments (*e.g.*, combinations of products likely to be present in mobile homes, new homes, or automobiles), but concluded that COU-specific modeled air concentrations are too uncertain to support a quantitative aggregate analysis across multiple COUs.

EPA qualitatively considered the aggregate exposures individuals may experience from multiple exposure scenarios. For example, individuals exposed to formaldehyde through work or through use of consumer products are expected to also have exposure to formaldehyde through outdoor air and/or indoor air. However, EPA concluded that there is too much uncertainty in the individual analyses underlying exposure and risks from individual pathways to support a quantitative aggregate analysis. For example, given uncertainty around modeled indoor air concentrations resulting from individual consumer COUs, EPA concluded that aggregation of exposures resulting from multiple sources would compound uncertainty. Further aggregating those combined indoor air exposures and risks with a set of occupational exposures and risks would further compound those uncertainties. EPA is currently seeking peer review of the methods underlying individual components of this draft analysis with the aim of increasing confidence in exposure and risk estimates for each individual pathway and welcomes input on approaches to improving confidence in an aggregate analysis.

EPA defines sentinel exposure as "the exposure to a single 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)." In this draft risk evaluation, EPA considered sentinel exposures by considering risks to populations who may have upper bound exposures, including workers and ONUs who perform activities with higher exposure potential and communities in proximity to release sites. EPA characterized high-end exposures in evaluating exposure using both monitoring data and modeling approaches. Where statistical data are available, EPA typically uses the 95th percentile value of the available dataset to characterize high-end exposure for a given TSCA COU.

5 NEXT STEPS

EPA's TSCA existing chemical risk evaluations must determine whether a chemical substance does or does not present unreasonable risk under its COUs. The unreasonable risk must be informed by science, but the Agency, in making the finding of "presents unreasonable risk" also considers risk-related factors as described in its risk evaluation framework rule. Risk-related factors beyond exceedance of benchmarks include the toxicological endpoint under consideration, the reversibility of the health effect being evaluated, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or the size of population exposed), and the confidence in the information used to inform the hazard and exposure values. Specifically, while EPA will consider the standard risk benchmarks associated with interpreting margins of exposure and cancer risks, EPA cannot solely rely on those risk values. The Agency also will consider naturally occurring sources of formaldehyde (*i.e.*, biogenic, combustion, and secondary formation) and associated risk levels from, and consider contributions from all sources as part of a pragmatic and holistic evaluation of formaldehyde hazard and exposure in making its unreasonable risk determination. If an estimate of risk for a specific scenario exceeds the benchmarks, then the decision of whether those risks are unreasonable is both case-by-case and context driven. In the case of formaldehyde, EPA is taking the risk estimates of the human health risk assessment (HHRA) in combination with a thoughtful consideration of other sources of formaldehyde, to interpret the risk estimates in the context of an unreasonable risk determination.

With regards to the HHRA, associated technical modules, and supporting documents, and in accordance with the 2017 risk evaluation framework rule, OPPT's draft risk evaluation will be reviewed by the SACC in 2024. OPPT will also be soliciting comments from the public. OPPT will ask for input from the SACC on a variety of scientific issues related to human health hazard, ecological hazard, fate, exposure assessment including its assessment of background sources, and weight of scientific evidence. Due to the magnitude of available scientific information on formaldehyde coupled with its complex toxicology and exposure profiles, EPA acknowledges that the evaluation of formaldehyde hazard and exposure is challenging. EPA is at a critical point in the development of the draft risk evaluation where SACC and public input will be important. For example, OPPT will seek input on its use of inputs and assumptions in the exposure assessments for consumer and indoor air scenarios, in part to understand whether its approach may compound one conservative assumption upon another in a manner that leads to unrealistic or un-addressable outcomes. Following the SACC and public comments, EPA will revise the draft risk evaluation and issue a final evaluation that will include a determination of whether, under its conditions of use, formaldehyde presents unreasonable risk to health and the environment.

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APPENDICES

Appendix A ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ADAF	Age-dependent adjustment factor
ADC	Average daily concentrations
BMD	Benchmark dose
BMR	Benchmark response
CASRN	Chemical Abstracts Service Registry Number
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CNS	Central nervous system
DIY	Do it yourself
DMR	Discharge Monitoring Report
EPA	Environmental Protection Agency
ESD	Emission Scenario Document
FSHA	Federal Hazardous Substance Act
GS	Generic Scenario
HAP	Hazardous Air Pollutant
HEC	Human Equivalent Concentration
HED	Human Equivalent Dose
HEM	Human Exposure Module
HERO	Health and Environmental Research Online (Database)
HUD	(U.S.) Department of Housing and Urban Development
IIOAC	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
LADC	Lifetime average daily concentrations
LC50	Lethal concentration at which 50% of test organisms die
LD50	Lethal dose at which 50% of test organisms die
LOD	Limit of detection
Log K_{OC}	Logarithmic organic carbon: water partition coefficient
Log K_{OW}	Logarithmic octanol: water partition coefficient
MOA	Mode of action
NAICS	North American Industry Classification System
NASEM	National Academies of Sciences, Engineering, and Medicine
ND	Non-detect
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
OCSPP	Office of Chemical Safety and Pollution Prevention
OES	Occupational exposure scenario

ONU	Occupational non-user
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulations
POD	Point of departure
POTW	Publicly owned treatment works
PPE	Personal protective equipment
REL	Recommended Exposure Limit
SACC	Science Advisory Committee on Chemicals
SDS	Safety data sheet
STEL	Short-Term Exposure Limit
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total toxic organics
TWA	Time-weighted average
U.S.	United States
WWT	Wastewater treatment

Appendix B LIST OF DOCUMENTS AND SUPPLEMENTAL FILES

List of Documents and Corresponding Supplemental Files

1. Draft Conditions of Use for the Formaldehyde Risk Evaluation, (U.S. EPA, 2024c).

2. Draft Environmental Risk Assessment for Formaldehyde, (U.S. EPA, 2024h)

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

4. Draft Environmental Release Assessment for Formaldehyde, (U.S. EPA, 2024g).
    - *4.1. Supplemental Air Release Summary and Statistics for NEI and TRI for Formaldehyde.xlsx*
    - *4.2. Supplemental Land Release Summary for TRI for Formaldehyde.xlsx*
    - *4.3. Supplemental Water Release Summary for DMR and TRI for Formaldehyde.xlsx*

5. Draft of Environmental Exposure Assessment for Formaldehyde, (U.S. EPA, 2024e)
    - *5.1. Supplemental Water Quality Portal Results for Formaldehyde.xlsx*

6. Draft Environmental Hazard Assessment of Formaldehyde, (U.S. EPA, 2024f)

7. Draft Occupational Exposure Assessment for Formaldehyde, (U.S. EPA, 2024k)
    - *7.1. Draft Formaldehyde Occupational Exposure Modeling Parameter Summary.xlsx*
    - *7.2. Draft Occupational Supplemental Formaldehyde Risk Calculator.xlsx*
    - *7.3. Draft Supplemental Occupational Monitoring Data Summary.xlsx*

8. Draft Consumer Exposure Assessment for Formaldehyde, (U.S. EPA, 2024d).
    - *8.1. Draft Consumer Modeling, Supplemental A for Formaldehyde.xlsx*
    - *8.2. Draft Consumer Acute Dermal Risk Calculator, Supplemental B for Formaldehyde.xlsm*
    - *8.3. Draft Consumer - Indoor Air Acute and Chronic Inhalation Risk Calculator, Supplemental B for Formaldehyde.xlsm*

9. Draft Indoor Air Exposure Assessment for Formaldehyde, (U.S. EPA, 2024j).
    - *9.1. Draft Indoor Air Modeling, Supplemental A for Formaldehyde.xlsx*
    - *9.2. Draft Consumer - Indoor Air Acute and Chronic Inhalation Risk Calculator, Supplemental B for Formaldehyde.xlsm*

10. Draft Ambient Air Exposure Assessment for Formaldehyde, (U.S. EPA, 2024a)
    - *10.1. Draft IIOAC Assessment Results and Risk Calcs Supplement A for Ambient Air.xlsx*
    - *10.2. Draft IIOAC Assessment Results and Risk Calcs for Formaldehyde Supplement B.xlsx*

11. Draft Human Health Hazard Assessment for Formaldehyde, (U.S. EPA, 2024i).

12. *Draft Risk Evaluation for Formaldehyde – Systematic Review Protocol* (U.S. EPA, 2023a)
    - 12.1. *Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties* (U.S. EPA, 2023f)
    - 12.2. *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)

12.3. *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)

12.4. *Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for General Population, Consumer, and Environmental Exposure.* (U.S. EPA, 2023g)

12.5. *Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Extraction Information for General Population, Consumer, and Environmental Exposure* (U.S. EPA, 2023c)

12.6. *Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Human Health Hazard Epidemiology* (U.S. EPA, 2023i)

12.7. *Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Human Health Hazard Animal Toxicology* (U.S. EPA, 2023h)

12.8. *Draft Risk Evaluation for Formaldehyde – Systematic Review Supplemental File: Data Quality Evaluation Information for Environmental Hazard* (U.S. EPA, 2023j)

12.9. *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)

13. Draft Unreasonable Risk Determination for Formaldehyde

Appendix C DETAILED EVALUATION OF POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS

C.1 PESS Based on Greater Exposure

In this section, EPA addresses potentially exposed populations expected to have greater exposure to formaldehyde. Table_Apx C-1 presents the quantitative data sources that were used in the PESS exposure analysis for incorporating increased background and COU-specific exposures.

3371 **Table_Apx C-1. PESS Based on Greater Exposure**

Category	Subcategory	Increased Exposure from OtherSources	Increased Exposure from TSCA COUs	Quantitative Data Sources
Lifestage	Embryo/fetus	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• EPA did not identify sources of increased TSCACOU exposure anticipated for this lifestage.	• EPA did not quantify exposures specific to this lifestage.
	Pregnant people	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• EPA did not identify sources of increased TSCA COU exposure anticipated for this lifestage.	• EPA did not quantify exposures specific to this lifestage
	Children (infants, toddlers)	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• For air exposures, the impacts of lifestage differences were not able to be adequately quantified and so the air concentrations are used for all lifestages. • Consumer exposure scenarios include lifestage-specific exposure factors for adults, children, and infants (U.S. EPA, 2024d) • Based on pchem properties and a lack of studies evaluating potential for accumulation in human milk following inhalation, dermal or oral exposures, EPA did not quantitatively evaluate the human milk pathway. This is a remaining source of uncertainty. • In the consumer exposure assessment, EPA also considered potential oral exposure associated with mouthing behaviors in infants and young children (U.S. EPA, 2024d), however EPA did not have sufficient information on this exposure route to quantify risks.	• Lifestage specific consumer exposure scenarios for infants, children, and adults are based on information from U.S. EPA (2005a)and U.S. EPA (2011).
	Older Adults	• EPA did not identify other sources of increased exposure anticipated for this lifestage.	• EPA did not identify sources of increased COU or pathway specific exposure for this lifestage.	• EPA did not quantify exposures specific to this lifestage.
Sociodemo-graphic factors	Race/Ethnicity	• EPA did not identify specific data on other sources of increased exposure associated with race/ethnicity.	• EPA did not identify specific data on increased COU or pathway specific exposure associated with race/ethnicity.	• EPA did not quantify exposures associated with race/ethnicity.

Category	Subcategory	Increased Exposure from OtherSources	Increased Exposure from TSCA COUs	Quantitative Data Sources
	Socioeconomic status	• EPA did not identify specific data on other sources of increased exposures associated with socioeconomic status.	• EPA did not identify specific data on increased COU or pathway specific exposure associated with socioeconomic status.	• EPA did not directly quantify exposures associated with socioeconomic status.
Unique Activities	Subsistence Fishing	• EPA did not identify other sources of increased exposure associated with subsistence fishing or other exposure scenarios unique to tribes or other groups.	• EPA did not identify sources of increased COU or pathway specific exposure for subsistence fishing or other exposure pathways unique to tribes or other groups.	• EPA did not quantify exposures associated with subsistence fishing.
Lifestyle	Smoking	• EPA identified smoking as an additional other source of exposure to formaldehyde that may increase aggregate exposure for smokers and people exposed to second-hand smoke. To some degree, formaldehyde exposure from smoking is indirectly accounted for in some indoor air monitoring data described in Section 5.2.3.1, but it is not directly quantified.	• EPA did not identify sources of increased COU or pathway specific exposure for smoking or other lifestyle factors.	• EPA did not directly quantify exposures associated with smoking.
Geography	Living in proximity to sources of formaldehyde releases to outdoor air	• EPA identified living near major roadways or in areas with frequent exposure to wildfire smoke as potential sources of increased exposure to formaldehyde for some populations. To some degree, ambient air monitoring data may indirectly account for some of these sources but they are not directly quantified. These other sources of formaldehyde are a source of uncertainty that is not directly incorporated into risk estimates for outdoor air exposures.	• EPA evaluated risks to communities in proximity to sites where formaldehyde is released to ambient air (Section 5.2.4). In the environmental release assessment, EPA mapped tribal lands in relation to air, surface water and ground water releases of formaldehyde to identify potential for increased exposures for tribes due to geographic proximity (U.S. EPA, 2024g).	• EPA quantified exposures for communities in proximity to release sites using air concentrations modeled based on releases reported to TRI, as described in U.S. EPA (2024g) and Section 5.2.4 • EPA did not directly quantify exposures associated with living near roadways or other sources of formaldehyde in outdoor air.
Other chemical and non-chemical stressors	Built Environment	• EPA identified the built environment (including building materials and other products) as source of increased exposure to formaldehyde associated with other sources. Indoor air concentrations assessed in Section 4.2.3 incorporate both TSCA and other sources of formaldehyde in indoor air.	• EPA identified the built environment (including building materials and other products) as a source of increased exposure to formaldehyde associated with COUs. Indoor air concentrations assessed in Section 4.2.3 incorporate both TSCA and other sources of formaldehyde in indoor air.	• EPA quantified exposures associated with specific TSCA COUs based on 2016 and 2020 Chemical Data Reporting (U.S. EPA, 2020a, 2016a), the Formaldehyde and Paraformaldehyde Use Report (U.S. EPA, 2020d) and product weight fractions and densities reported in

Category	Subcategory	Increased Exposure from OtherSources	Increased Exposure from TSCA COUs	Quantitative Data Sources
				chemical safety data sheets (SDSs) identified through product-specific internet searches; EPA quantified exposures and risks associated with aggregate indoor air based on a range of monitoring data described in the Indoor Air Assessment (U.S. EPA, 2024j). • EPA did not directly quantify indoor air exposures associated with other sources.
Occupational	Workers and occupational non-users	• EPA identified firefighters as an occupational group with increased exposure to formaldehyde associated with combustion containing building materials with high concentrations to formaldehyde. While combustion exposures are beyond the scope of this assessment, this is a remaining source of uncertainty in characterizing aggregate exposures for some groups.	• EPA identified all occupational exposure scenarios as a potential source of exposure to formaldehyde. Those with higher frequency or higher duration exposures are expected to have the greatest exposures and risks. EPA evaluated risks for a range of occupational exposure scenarios that increase exposure to formaldehyde, including manufacturing, processing, and use of formulations containing formaldehyde. EPA evaluated risks for central tendency and high-end exposure estimates for each of these scenarios (Section 5.2.1).	• EPA quantified occupational exposures associated with TSCA COUs based on a range of COU-specific data, including monitoring data from OSHA and NIOSH and modeled air concentrations. Specific data sources are described in detail in the Draft Occupational Exposure Assessment (U.S. EPA, 2024k).
Consumer	High frequency consumers High duration consumers	• EPA identified dietary exposures through food, food packaging, drugs, and personal care products that contain formaldehyde as other sources that may contribute to total formaldehyde exposure. These exposures are beyond the scope of this assessment and are a source of uncertainty in characterizing aggregate exposures.	• Consumer products designed for children (*e.g.*, children's toys) may lead to elevated exposures for children and infants. • EPA identified all consumer exposure scenarios involving TSCA COUs as potential sources of exposure to formaldehyde. Those with higher frequency and/or higher duration exposures are expected to have the greatest exposures and risks.	• EPA quantified consumer exposure (U.S. EPA, 2024d) based on the Formaldehyde and Paraformaldehyde Use Report (U.S. EPA, 2020d) and the Exposure Factors Handbook (U.S. EPA, 2011) (Ch. 17).

C.2 PESS Based on Greater Susceptibility

In this section, EPA addresses subpopulations and lifestages expected to be more susceptible to formaldehyde exposure than others. This discussion draws heavily from the recent summary of susceptible populations and lifestages included in the draft IRIS assessment. Table_Apx C-2. presents the data sources that were used in the PESS analysis evaluating susceptible subpopulations and identifies whether and how the subpopulation was addressed quantitatively in the risk evaluation of formaldehyde.

Table_Apx C-2. Susceptibility Category, factors, and evidence for PESS susceptibility

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	**Key Citations**	**Description of Interaction**	**Key Citations**	
Lifestage	Embryos/ fetuses/infants	Direct quantitative human and animal evidence for developmental toxicity following inhalation exposure (*e.g.*, decreased fertility, increased spontaneous abortions and changes in brain structures).	Taskinen et al. (1999) John et al. (1994) Sarsilmaz et al. (2007) Aslan et al. (2006)	–	–	Hazard value for chronic inhalation is supported in part by dose-response information on female reproductive effects and developmental toxicity and is expected to be protective of these endpoints
	Infants and children	In some studies, children appear to be more susceptible than adults to respiratory effects of formaldehyde. Early life exposures to chemicals with a mutagenic mode of action may increase cancer risk. EPA has concluded that the evidence is sufficient to conclude that a mutagenic mode of action of formaldehyde is operative in formaldehyde-induced nasopharyngeal carcinogenicity.	Bateson and Schwartz (2008) Venn et al. (2003) Annesi-Maesano et al. (2012) Krzyzanowski et al. (1990). U.S. EPA (2005b)	Developing lungs until age 6-8, narrower airways Different expression of enzymes responsible for metabolizing formaldehyde	Bateson and Schwartz (2008) Thompson et al. (2009)	Hazard value for chronic inhalation is based in part on dose-response information on asthma prevalence/asthma control in children. ADAFs are applied to nasopharyngeal cancer risk estimates to account for increased susceptibility to cancer following exposure during early life.
	Pregnant women	No direct evidence identified	–	Pregnant women may have increased sensitivity to the development and exacerbation of atopic eczema following exposure to formaldehyde	Matsunaga et al. (2008)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Males of reproductive age	Direct quantitative evidence in humans and animals evidence for reduced fertility following inhalation exposure	–	Possible contributors to male reproductive effects/infertility (see also factors in other rows): • Enlarged veins of testes • Trauma to testes	CDC (2023b)	Hazard value for chronic inhalation is supported in part by dose-response information on male reproductive toxicity and is expected to be protective of these endpoints

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
Lifestage				• Anabolic steroid or illicit drug use Cancer treatment		
	Older adults	No direct evidence identified	–	Older adults may have reduced metabolism and higher rates of chronic diseases that may increase susceptibility	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
Pre-existing disease or disorder	Health outcome/ target organs	A few epidemiological studies found that individuals with asthma and allergies were more susceptible to the deterioration of respiratory function after being exposed to formaldehyde than those without these conditions. Evidence from human and animal studies indicated that individuals with pre-existing nasal damage or a history of respiratory issues were more susceptible to developing formaldehyde induced nasal cancer.	Krzyzanowski et al. (1990) Kriebel et al. (1993) Woutersen et al. (1989) Appelman et al. (1988) Falk et al. (1994)	Individual variations in nasal anatomy and soluble factors in the upper respiratory tract can potentially influence the uptake of highly reactive gases like formaldehyde. This variability could possibly lead to differences in the distribution of inhaled formaldehyde and susceptibility to its health effects.	ICRP (1994) Santiago et al. (2001) Singh et al. (1998)	Acute inhalation hazard values are based in part on dose-response information in humans already identified as sensitive to formaldehyde in dermal patch test studies. No direct quantitative adjustment to chronic inhalation, oral or dermal hazard values or risk estimates; Use of UF_H
Lifestyle activities	Smoking	No direct evidence identified	–	Heavy smoking may increase susceptibility to formaldehyde toxicity. However, it is unclear if this increased sensitivity is due to additional formaldehyde exposure or other chemicals in cigarette smoke.	Fishbein (1992) CDC (2023a) CDC (2023b)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
Lifestyle activities	Alcohol consumption	No direct evidence identified	–	Chronic alcohol consumption may affect the susceptibility to reproductive and cancer related health outcomes.	CDC (2023a)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Physical activity	Studies observed that prolonged physical activity increased an individual's susceptibility to formaldehyde induced respiratory impairments. These studies demonstrated that those who were exposed to formaldehyde after 15 minutes of exercise experienced more significant declines in lung function compared to those who had shorter exercise sessions or no exercise at all.	Green et al. (1987) Green et al. (1989)	Insufficient activity may increase susceptibility to multiple health outcomes Overly strenuous activity may also increase susceptibility.	CDC (2022)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
Sociodemo-graphic status	Race/ethnicity	An epidemiological study suggests a racial difference in susceptibility to formaldhyde toxicity, as nonwhite individuals were found to have higher mortality rates for nasopharyngeal cancer and multiple myeloma compared to their white counterparts.	Hayes et al. (1990)	–	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Socio-economic status	No direct evidence identified	–	Individuals with lower socioeconomic status may experience adverse health	ODPHP (2023b)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
Sociodemo-graphic status				outcomes due to unmet social needs, environmental factors, and limited access to healthcare services.		
	Sex/gender	A higher prevalence of burning or tearing eyes was observed among women compared to men, suggesting that women may be more sensitive to the irritant properties of formaldehyde on the eyes and upper respiratory tract. Several animal studies showed that males exhibit a higher incidence of lesions in the upper respiratory tract than females. Evidence from epidemiological studies and animal models indicates that formaldehyde exposure can lead to male reproductive impairments, reduced fertility, and increased risk of miscarriage in women	Liu et al. (1991) Woutersen et al. (1987) Zwart et al. (1988) Maronpot et al. (1986) Kerns et al. (1983) Taskinen et al. (1999) John et al. (1994) Wang et al. (2015)	–	–	Both acute and chronic inhalation hazard values are based in part on epidemiological studies include that include both male and female subjects,
Nutrition	Diet	No direct evidence identified	–	An antioxidant deficient diet may exacerbate inflammatory responses, primarily due to formaldehyde's well-known inflammatory properties. Obesity can increase susceptibility to cancer.	CDC (2023a) CDC (2020) CDC (2023c)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Malnutrition	No direct evidence identified	–	Micronutrient malnutrition can result in various	CDC (2021) CDC (2023c)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
Nutrition				conditions, such as birth defects, maternal and infant mortality, preterm birth, low birth weight, poor fetal growth, childhood blindness, and undeveloped cognitive ability. Deficiencies in micronutrients may increase an individual's susceptibility to the adverse health effects of formaldehyde, particularly respiratory impairments. This is due to the critical role of micronutrients in maintaining robust immune function, potent antioxidant defenses, and the structural integrity of the respiratory system.		
Genetics/ epigenetics	Target organs	No direct evidence identified	–-	Genetic disorders, such as Klinefelter's syndrome, Y-chromosome microdeletion, myotonic dystrophy can affect male reproduction/fertility	CDC (2023b)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
	Toxicokinetics	Studies suggested that certain genetic variants could impair the activity of ADH and ALDH enzyme. This	Wu et al. (2007) Hedberg et al. (2001)	–	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
Genetics/ epigenetics		potential impairment could reduce the clearance of formaldehyde, thereby increasing susceptibility to adverse health effects associated with formaldehyde exposure. Studies have demonstrated that genetic variations in ADH3 and ALDH2 genes have been associated to higher susceptibility to asthma and CNS toxicity, while polymorphism in genes related to DNA repair, such as XRCC3, have been shown to impact susceptibility to formaldhyde induced genotoxicity. Studies in experimental animals with genetically modified ALDH2 and ALDH5 genes, responsible for eliminating endogenous formaldhyde, suggested that variations in these genes could potentially increase susceptibility to genotoxicity. Although some studies have suggested that specific genetic variants may influence susceptibility to formaldehyde toxicity, their findings have not been conclusive.	Deltour et al. (1999) Tan et al. (2018) Nakamura et al. (2020) Dingler et al. (2020)			
Other chemical and nonchemical stressors	Built environment	No direct evidence identified	–	Poor quality housing often contains environmental triggers of asthma such as pests, mold, dust, building materials that may exacerbate reduced asthma control associated with	ODPHP (2023a)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	Key Citations	Description of Interaction	Key Citations	
				formaldehyde exposure		
	Social environment	No direct evidence identified	–	Poverty, violence, as well as other social factors may make some populations more susceptible to the health effects associated with formaldehyde exposure.	CDC (2023d) ODPHP (2023c)	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H
Other chemical and nonchemical stressors	Chemical co-exposures	Several studies have demonstrated that co-exposure to formaldehyde and other substances, including environmental pollutants and dietary components, could potentially affect respiratory health, hypersensitivity reactions, or lung function. While studies have indicated that certain dietary components, such as methanol and caffeine can contribute to the endogenous production of formaldehyde in non-respiratory tissues, the extent to which this influences susceptibility to inhaled formaldehyde remains unclear. Environmental tobacco smoke exposure has been associated with an increased likelihood of hypersensitivity responses in individuals concurrently exposed to formaldehyde. Studies suggest that exposure to tobacco smoke may potentiate the effects of formaldehyde or even trigger such responses at lower formaldehyde	Besaratinia et al. 2014 Fang et al. 2004 Gavriliu et al. 2013 Hohnloser et al. (1980) Riess et al. (2010) Summers et al. (2012) Krzyzanowski et al. (1990)	–	–	No direct quantitative adjustment to hazard values or risk estimates; Use of UF_H

Susceptibility Category	Specific Factors	Direct Evidence this Factor Modifies Susceptibility to Formaldehyde		Indirect Evidence of Potential Impact through Target Organs or Biological Pathways Relevant to Formaldehyde		Incorporation of Each Factor into the Risk Evaluation
		Description of Interaction	**Key Citations**	**Description of Interaction**	**Key Citations**	
		concentrations, particularly in children and nonsmoking adults				

Appendix D AMBIENT AIR RISK ESTIMATES – COMMERCIAL USES

The ambient air exposure assessment for formaldehyde quantitatively evaluates exposures resulting from industrial releases of formaldehyde to ambient air. EPA expects that releases resulting from TSCA industrial COUs have larger point source emissions than the air emissions resulting from commercial uses.

As discussed in the Environmental Release Assessment (U.S. EPA, 2024g), where available, EPA used TRI and NEI to inform air releases from commercial COUs. However, facilities are only required to report to TRI if the facility has 10 or more full-time employees; is included in an applicable North American Industry Classification System (NAICS) code; and manufactures, processes, or uses the chemical in quantities greater than a certain threshold. Reporting to NEI depends on submissions voluntarily provided by state, local, and tribal agencies and is supplemented by data from other EPA programs. For NEI, the general threshold for major source is the potential to emit more than 10 tons per year for a single Hazardous Air Pollutant (HAP), or 25 tons/year for any combination of HAPs.

Due to these limitations, commercial sites that use formaldehyde and/or formaldehyde-containing products may not report to TRI or NEI and are therefore not included in these datasets.

EPA did not quantify releases and therefore ambient air risk estimates for the following COUs:

- Distribution in commerce
- 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
- Commercial use – chemical substances in products not described by other codes – other: laboratory chemicals; and
- Commercial use – chemical substances in automotive and fuel products- automotive care products; lubricants and greases; fuels and related products.[5]

EPA discusses the release potential for each COU in in the *Draft Environmental Release Assessment for Formaldehyde* (U.S. EPA, 2024g) based on the available information. In general, EPA expects industrial COUs to be the drivers of risk for ambient air from the TSCA COUs within the scope of this draft risk evaluation.

For the following commercial COUs

- Commercial use – chemical substances in furnishing treatment/care products- floor coverings; foam seating and bedding products; furniture and furnishings not covered elsewhere; cleaning and furniture care products; fabric, textile, and leather products not covered elsewhere-construction
- Commercial Use – chemical substances in construction, paint, electrical, and metal products-adhesives and sealants; paint and coatings

[5] Use of fuels may be associated with petroleum refinery and utilities, however, note formaldehyde from combustion sources is not assessed as an independent COU subcategory in this risk evaluation.

- Commercial Use – chemical substances in furnishing treatment/care products – building/construction materials – wood and engineered wood products; building/ construction materials not covered elsewhere

EPA expects emissions may be similar to the construction sector, which has cancer risk estimate lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount.

For the following commercial COUs

- Commercial use – chemical substances in electrical products – electrical and electronic products
- Commercial use – chemical substances in metal products – metal products not covered elsewhere

EPA expects emissions may be similar to the electrical equipment, appliance, and component manufacturing and fabricated metal product manufacturing sector, which has cancer risk estimate lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount.

For the following commercial COU, Commercial use – chemical substances in agriculture use products – lawn and garden products, EPA expects emissions may be similar to the agriculture, forestry, fishing, and hunting sector, which has risk estimate lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount.

For the following commercial COUs

- Commercial use – chemical substances in packaging, paper, plastic, hobby products – paper products; plastic and rubber products; toys, playground, and sporting equipment
- Commercial use – chemical substances in packaging, paper, plastic, hobby products- arts, crafts, and hobby materials
- Commercial use – chemical substances in packaging, paper, plastic, hobby products- ink, toner, and colorant products; photographic supplies

EPA expects emissions may be similar to the Printing and Related Support Activities & Photographic Film Paper, Plate, and Chemical Manufacturing sector, which have risk estimates lower than 1×10^{-6} based on 100 to 1,000 m from the release site for the 95th percentile annual reported release amount. EPA does, however, note that printing operations that use printing ink, toner, or colorant products containing formaldehyde may occur at industrial sites such as those included in Paper Manufacturing, which has a cancer risk estimate of 1.24×10^{-5}.

Appendix E DRAFT OCCUPATIONAL EXPOSURE VALUE DERIVATION

EPA has calculated a draft 8-hour existing chemical occupational exposure value to summarize the occupational exposure scenario and sensitive health endpoints into a single value. EPA calculated the draft value rounded to 0.011 ppm (14 µg/m^3) for inhalation exposures to formaldehyde as an 8-hour TWA and for consideration in workplace settings (see Appendix E.1) based on the chronic and intermediate non-cancer hazards value for respiratory effects.

TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus this draft occupational exposure value represents a risk-only number. If risk management for formaldehyde follows the final risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. In general, any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes could differ from the draft occupational exposure value presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c), and this is certain to be the case for formaldehyde. The unique challenge associated with this evaluation is that the formaldehyde released from activities and products that are subject to TSCA is mixed in with the formaldehyde released from all sources as described in the executive summary, which could raise a challenge if/when an implementable regulatory occupational exposure limit is designed. More specifically, the draft occupational exposure value of 14 µg/m^3 for formaldehyde is below ~20 - 40 µg/m^3 (50th to 95th percentile of concentrations measured in AHHS II for indoor air in residential settings)for indoor air. EPA must therefore consider this unique challenge if it ultimately designs and proposes a regulatory limit for occupational inhalation exposures to formaldehyde.

This calculated draft value for formaldehyde represents the exposure concentration below which workers and occupational non-users are not expected to exhibit any appreciable risk of adverse toxicological outcomes, accounting for potentially exposed and susceptible populations (PESS). It is derived based on the most sensitive human health effect relative to benchmarks and standard occupational scenario assumptions of 8 hours/day, 5 days/week exposures for a total of 250 days exposure per year, and a 40-year working life.

EPA expects that at the draft occupational exposure value of 0.011 ppm (14 µg/m^3), a worker or ONU also would be protected against respiratory effects resulting from chronic exposures. In addition, this calculated draft value would protect against excess risk of nasopharyngeal cancer above the 1×10^{-4} benchmark value resulting from lifetime exposure if ambient exposures are kept below this draft occupational exposure value. The acute exposure limit is unchanged for all durations of a single exposure and also serves as the short-term exposure limit (STEL) to protect against 15-minute exposures.

Of the identified occupational monitoring data for formaldehyde, there have been measured workplace air concentrations below the calculated draft exposure value. A summary table of available monitoring methods from the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) is included in Appendix E.2. The table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The calculated draft exposure value is above the limit of detection (LOD) and limit of quantification (LOQ) using at least one of the monitoring methods identified.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as an 8-hour TWA for formaldehyde of 0.75 ppm in 1992 (https://www.osha.gov/annotated-pels), with an action level of 0.5 ppm. In addition, OSHA has set a STEL of 2 ppm. OSHA's PEL must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act. EPA's calculated draft exposure value is a lower value and is based on newer information and analysis from this risk evaluation.

There are also recommended exposure limits established for formaldehyde by other governmental agencies and independent groups. The American Conference of Governmental Industrial Hygienists (ACGIH) set a Threshold Limit Value (TLV) at 0.1 ppm TWA and 0.3 ppm STEL in 2017. This chemical also has a NIOSH Recommended Exposure Limit (REL) of 0.016 ppm TWA and 15-minute Ceiling limit of 0.1 ppm (https://www.cdc.gov/niosh/npg/).

E.1 Draft Occupational Exposure Value Calculations

This appendix presents the calculations used to estimate draft occupational exposure values using inputs derived in this draft risk evaluation. Multiple values are presented below for hazard endpoints based on different exposure durations. For formaldehyde, the most sensitive occupational exposure value is based on respiratory effects and the resulting 8-hour TWA is rounded to 14 μg/m^3. The human health hazard values used in these equations are based on the inhalation non-cancer hazard values and the IUR summarized in Table 3-1.

Draft Intermediate Non-cancer Occupational Exposure Value

The draft exposure value was calculated for the occupational non-cancer repeat-dose human equivalent concentration for respiratory effects as the concentration at which the chronic margin of exposure (MOE) would equal the benchmark MOE for 8-hour intermediate occupational exposures with Equation_Apx E-1:

Equation_Apx E-1.

$$EV_{intermediate} = \frac{HEC_{repeat}}{Benchmark\ MOE_{repeat}} * \frac{AT_{HEC\ repeat}}{ED*EF} * \frac{\mathrm{IR_{input}}}{\mathrm{IR_{workers}}}$$

$$= \frac{0.017\ \mathrm{ppm}}{3} * \frac{24h/d * 30d}{8h/d * 22d} * \frac{0.6125\ \mathrm{m}^3/hr}{1.25\ \mathrm{m}^3/hr} = 0.011\ \mathrm{ppm}$$

$$EV\ \left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume} = \frac{0.011\ \mathrm{ppm} * 30.026\frac{g}{mol}}{24.45\frac{L}{mol}} = \ 0.014\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW	=	Molecular weight of formaldehyde (30.026 g/mole)

Draft Acute/Short-Term, Non-cancer Occupational Exposure Value

The acute occupational exposure value (EV_{acute}), equivalent to the 15-minute STEL, was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx E-2:

Equation_Apx E-2.

$$EV_{acute} = \frac{HEC_{acute}}{Benchmark\ MOE_{acute}} = \frac{0.5\ \text{ppm}}{10} = 0.050\ \text{ppm} = 0.061\ \frac{\text{mg}}{\text{m}^3}$$

Draft Chronic, Non-cancer Occupational Exposure Value

The chronic occupational exposure value ($EV_{chronic}$) can be calculated as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures. However, for purposes of risk management, EPA has determined that because the same critical health effect applies to both in both intermediate and chronic exposure contexts, the relevant averaging time should be considered equivalent across both exposure scenarios. Therefore, the resulting $EV_{chronic}$ would be the same as the draft exposure value based on intermediate exposures.

Draft Lifetime Cancer Occupational Exposure Value

The EV_{cancer} is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of $1{\times}10^{-4}$:

$$EV_{cancer} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} * \frac{IR_{input}}{IR_{workers}}$$

$$= \frac{1X10^{-4}}{7.90 \times 10^{-3}\ per\ ppm} * \frac{24\frac{h}{d} * \frac{365d}{y} * 78y}{8\frac{h}{d} * \frac{250d}{y} * 40y} * \frac{1.25\ \text{m}^3/hr}{1.25\ \text{m}^3/hr} =$$

$$= 0.108\ \text{ppm} = 1.33\ \frac{\text{mg}}{\text{m}^3}$$

Where:

$AT_{HECrepeat}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, intermediate and chronic occupational risk, based on study conditions and/or any HEC adjustments (24 hr/day for 30 days) (see Section 4.2.2.1)
$AT_{HECacute}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (24 hr/day) (see Section 4.2.2.1)
AT_{IUR}	=	Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hr/day for 365 days/year) and averaged over a lifetime (78 years) (Supplemental File: Releases and Occupational Exposure Assessment; Appendix B).
$Benchmark\ MOE_{acute}$	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 10 (see Table 3-7)
$Benchmark\ MOE_{repeat}$	=	Short term non-cancer benchmark margin of exposure, based on the total uncertainty factor of 100 (see Table 3-8)
$Benchmark_{Cancer}$	=	Benchmark for excess lifetime cancer risk
EV_{acute}	=	Exposure limit based on acute effects
$EV_{intermediate}$	=	Existing chemical exposure limit (mg/m^3), based on non-cancer effects following repeat exposures
$EV_{chronic}$	=	Existing chemical exposure limit (mg/m^3), based on non-cancer effects following repeat exposures
EV_{cancer}	=	Exposure limit based on excess cancer risk
ED	=	Exposure duration (8 hr/day) (see Table 3-8)
EF	=	Exposure frequency (250 days/yr), (see Section 4.2.2.1)

$HEC_{acute\ or\ repeat}$	=	Human equivalent concentration for acute or intermediate/chronic occupational exposure scenarios, respectively (see Tables 3-7 and 3-8)
IUR	=	Inhalation unit risk (per ppm) (see Table 3-6)
IR	=	Inhalation rate (default is 1.25 m^3/hr for workers and 0.6125 m^3/hr for general population at rest)
WY	=	Working years per lifetime at the 95th percentile (40 years (Supplemental File: Releases and Occupational Exposure Assessment; Appendix B)

Unit conversion:

1 ppm = 1.23 mg/m^3 (based on molecular weight of 30.026 g/mol for formaldehyde)

E.2 Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH and OSHA analytical methods used to monitor for the presence of formaldehyde in air (see Table_Apx E-1). This table covers validated methods from governmental agencies and is not intended to be a comprehensive list of available air monitoring methods for formaldehyde. The sources used for the search included the following:

1. NIOSH Manual of Analytical Methods (NMAM), 5th Edition;
2. NIOSH NMAM 4th Edition; and
3. OSHA Index of Sampling and Analytical Methods.

Table_Apx E-1. Limit of Detection (LOD) and Limit of Quantification (LOQ) Summary for Air Sampling Analytical Methods Identified

Air Sampling Analytical Methods[a]	Year Published	LOD[b]	LOQ	Notes	Source
NIOSH Method 2016	2016	0.012 ppm	N/A	Estimated LOD is 0.07 µg/sample. The working range is 0.012 to 2.0 ppm for a 15-L sample.	NIOSH Manual of Analytical Methods (NMAM 2016)
NIOSH Method 2541[c]	1994	0.24 ppm	N/A	Estimated LOD is 1 µg/sample. The working range is 0.24 to 16 ppm for a 15-L sample.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 2541)
NIOSH Method 3500[d]	1994	0.02 ppm	N/A	Estimated LOD is 0.5 µg/sample. The working range is 0.02 to 4 ppm for an 80-L sample.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 3500)
NIOSH Method 5700[e]	1994	0.0004 mg/m^3 (0.0003 ppm)	N/A	Estimated LOD is 0.08 µg/sample. The working range is 0.0004 to 3.8 mg/m^3 for a 1,050-L sample. Used for determination of formaldehyde in both textile and wood dusts.	NIOSH Manual of Analytical Methods, 4th Edition (NMAM 5700)

Air Sampling Analytical Methods[a]	Year Published	LOD[b]	LOQ	Notes	Source
OSHA Method 52	1989	16 ppb	16 ppb	Detection limit and reliable quantification limit is 482 ng per sample (16 ppb for 24 L)	OSHA Index of Sampling and Analytical Methods (OSHA 52)
OSHA Method 1007[f] https://www.osha.gov/sites/default/files/methods/osha-1007.pdf	2005	0.56, 1.70, or 0.17 ppb (Sampler – ChemDisk-AL, UMEx 100, DSD-DNPH, respectively)	1.88, 5.68, or 0.58 ppb (Sampler – ChemDisk-AL, UMEx 100, DSD-DNPH, respectively)	Method reports LOD/LOQ of overall procedure as 0.56/1.88 ppb for ChemDisk-AL samplers, 1.70/5.68 ppb for UMEx 100 samplers, and 0.17/0.58 for DSD-DNPH samplers	OSHA Index of Sampling and Analytical Methods (OSHA 1007)

ppm = parts per million; ppb = parts per billion; ppt = parts per trillion
[a] EPA has additional air sampling methods targeted for measurement of ambient and indoor air, the methods listed in this table are air sampling for occupational exposures.
[b] These sources cover a range of LOD including both below and above the preliminary occupational exposure value.[c] The method is suitable for the simultaneous determinations of acrolein and formaldehyde.
[d] This is the most sensitive formaldehyde method in the NIOSH Manual of Analytical Methods and is able to measure ceiling levels as low as 0.1 ppm (1 5-L sample). It is best suited for the determination of formaldehyde in area samples.
[e] Results should be considered separately from vapor-phase formaldehyde exposure; Method measures both “released” and formaldehyde equivalents.
[f] Recommends use of OSHA Method 52 when monitoring exposures resulting from the use of formalin solutions.

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Appendix F ACUTE AND CHRONIC (NON-CANCER AND CANCER) OCCUPATIONAL INHALATION EQUATIONS

This assessment provides estimates of 15-minute peak air concentrations, short-term air concentrations, and full-shift (8- or 12-hour) concentrations. For calculation of risk, these exposure estimates are incorporated with additional parameter inputs, such as working years, exposure duration and frequency, and lifetime years.

AC is used to estimate workplace inhalation exposures for acute risks (*i.e.*, risks occurring after less than one day of exposure), per Equation_Apx F-1, Equation_Apx F-2, and Equation_Apx F-3 below.

Equation_Apx F-1.

$$AC = \frac{C \times ED \times BR}{AT_{acute}}$$

Where:

AC = Acute exposure concentration
C = Contaminant concentration in air (TWA)
ED = Exposure duration (hr/day), 0.25 hr/day
BR = Breathing rate ratio (unitless), 1
AT_{acute} = Acute averaging time (hr), 0.25 hr

ADC and LADC are used to estimate workplace exposures for non-cancer and cancer risks, respectively. These exposures are estimated per Equation_Apx F-2, as follows:

Equation_Apx F-2.

$$ADC = \frac{C \times ED \times EF \times WY \times BR}{AT}$$

$$ATSC = WY \times 30\frac{day}{month} \times 24\frac{hr}{day}$$

$$AT = WY \times 365\frac{day}{yr} \times 24\frac{hr}{day}$$

Where:

ADC = Average daily concentration used for chronic non-cancer risk calculations
ED = Exposure duration (hr/day)
EF = Exposure frequency (day/yr)
BR = Breathing rate ratio (unitless),
WY = Working years per lifetime (yr)
AT_{SC} = Averaging time (hr) for sub-chronic, non-cancer risk
AT = Averaging time (hr) for chronic, non-cancer risk

Equation_Apx F-3.

$$LADC = \frac{C \times ED \times EF \times WY \times BR}{AT_c}$$

$$AT_C = LT \times 365\frac{day}{yr} \times 24\frac{hr}{day}$$

Where:

$LADC$	=	Lifetime average daily concentration used for chronic cancer risk calculations
ED	=	Exposure duration (hr/day)
EF	=	Exposure frequency (day/yr)
WY	=	Working years per lifetime (yr),
AT_C	=	Averaging time (hr) for cancer risk
LT	=	Lifetime years (yr) for cancer risk, 78 yr

For exposure duration, frequency, and working years used in this appendix, see Table_Apx F-1.

Table_Apx F-1. Appendix F Formulae – Symbols, Values, and Units

Symbol	Value	Unit
ED	8 or 12	hour/day
EF	250 or 167	day/year
$WY_{(CT)}$	31	years
$WY_{(HE)}$	40	years
$AT_{(CT)}$	271,560	hours
$AT_{(HE)}$	350,400	hours
AT_c	683,280	hours

Worker Years

EPA has developed a triangular distribution for working years. EPA has defined the parameters of the triangular distribution as follows:

- Minimum value: BLS CPS tenure data with current employer as a low-end estimate of the number of lifetime working years: 10.4 years;
- Mode value: The 50th percentile tenure data with all employers from SIPP as a mode value for the number of lifetime working years: 36 years; and
- Maximum value: The maximum average tenure data with all employers from SIPP as a high-end estimate on the number of lifetime working years: 44 years.

This triangular distribution has a 50th percentile value of 31 years and a 95th percentile value of 40 years. EPA uses these values for central tendency and high-end ADC and LADC calculations, respectively.

The BLS (U.S. BLS, 2014) provides information on employee tenure with current employer obtained from the CPS, which is a monthly sample survey of about 60,000 households that provides information on the labor force status of the civilian non-institutional population age 16 and over. CPS data are released every 2 years. The data are available by demographics and by generic industry sectors but are not available by NAICS codes.

The U.S. Census' (U.S. Census Bureau, 2019a) SIPP provides information on lifetime tenure with all employers. SIPP is a household survey that collects data on income, labor force participation, social program participation and eligibility, and general demographic characteristics through a continuous series of national panel surveys of between 14,000 and 52,000 households (U.S. Census Bureau, 2019b). EPA analyzed the 2008 SIPP Panel Wave 1, a panel that began in 2008 and covers the interview months of September 2008 through December 2008 (U.S. Census Bureau, 2019a, b). For this panel, lifetime tenure data are available by Census Industry Codes, which can be cross walked with NAICS codes.

SIPP data include fields for the industry in which each surveyed, employed individual works (TJBIND1), worker age (TAGE), and years of work experience with all employers over the surveyed individual's lifetime. Census household surveys use different industry codes than the NAICS codes used in its firm surveys, so these were converted to NAICS using a published crosswalk (Census Bureau, 2012b). EPA calculated the average tenure for the following age groups: (1) workers aged 50 and older, (2) workers aged 60 and older, and (3) workers of all ages employed at time of survey. EPA used tenure data for age group "50 and older" to determine the high-end lifetime working years, because the sample size in this age group is often substantially higher than the sample size for age group "60 and older." For some industries, the number of workers surveyed, or the sample size, was too small to provide a reliable representation of the worker tenure in that industry. Therefore, EPA excluded data where the sample size is less than five from our analysis.

Table_Apx F-2 summarizes the average tenure for workers aged 50 years and older from SIPP data. Although the tenure may differ for any given industry sector, there is no significant variability between the 50th and 95th percentile values of average tenure across manufacturing and non-manufacturing sectors.

Table_Apx F-2. Overview of Average Worker Tenure from U.S. Census SIPP (Age Group 50+)

Industry Sectors	Working Years			
	Average	50th Percentile	95th Percentile	Maximum
Manufacturing sectors (NAICS 31–33)	35.7	36	39	40
Non-manufacturing sectors (NAICS 42–81)	36.1	36	39	44

Source: (U.S. Census Bureau, 2019a).
Note: Industries where sample size is less than five are excluded from this analysis.

BLS CPS data provides the median years of tenure that wage and salary workers had been with their current employer. Table_Apx F-3 presents CPS data for all demographics (men and women) by age group from 2008 to 2012. To estimate the low-end value on number of working years, EPA uses the most recent (2014) CPS data for workers aged 55 to 64 years, which indicates a median tenure of 10.4 years with their current employer. The use of this low-end value represents a scenario where workers are only exposed to the chemical of interest for a portion of their lifetime working years, as they may change jobs or move from one industry to another throughout their career.

Table_Apx F-3. Median Years of Tenure with Current Employer by Age Group

Age	January 2008	January 2010	January 2012	January 2014
16 years and over	4.1	4.4	4.6	4.6
16 to 17 years	0.7	0.7	0.7	0.7
18 to 19 years	0.8	1.0	0.8	0.8
20 to 24 years	1.3	1.5	1.3	1.3
25 years and over	5.1	5.2	5.4	5.5
25 to 34 years	2.7	3.1	3.2	3.0
35 to 44 years	4.9	5.1	5.3	5.2
45 to 54 years	7.6	7.8	7.8	7.9
55 to 64 years	9.9	10.0	10.3	10.4
65 years and over	10.2	9.9	10.3	10.3

Appendix G DERMAL EXPOSURE APPROACH

The dermal load (Q_u) is the quantity of chemical on the skin after the dermal contact event. This value represents the quantity remaining after the bulk chemical formulation has fallen from the hand that cannot be removed by wiping the skin (*e.g.*, the film that remains on the skin). To estimate the dermal load for formaldehyde for occupational and consumer uses, EPA used dermal loading based on *A Laboratory Method to Determine the Retention of Liquids on the Surface of the Hands* (U.S. EPA, 1992) and formaldehyde weight concentrations relevant to the occupational use or consumer product. In addition, only acute exposures were quantitatively assessed given the identified dermal skin sensitization POD is likely only relevant to acute exposures (U.S. EPA, 2024i). The supporting study measured liquid retention on the surface of hands based on indirect (*i.e.*, contact with saturated object) contact and direct (*i.e.*, immersive) contact.

For consumer exposures, EPA assumes the product used may involve immersion into a liquid and that a pool of a liquid product was formed on the skin, or that a rag was used that reduced the evaporation of formaldehyde during use. A *Qu* of 10.3 mg/cm^2 was used to approximate hand immersion and wiping experiments, using oil-based products expected to have longer residence times on the skin relative to water-based products, as reported in (U.S. EPA, 1992). While this is the most protective value for consumer usage of oil-based products, it may overestimate exposures in some cases including when using water-based liquid products. Dermal exposures are only reasonably foreseen for consumers but not bystanders.

Owing to volatility and expected use patterns, dermal loading of formaldehyde from solid products is unlikely, except for certain textiles including clothing that are treated with formaldehyde in dyeing and wrinkle prevention step in the textile manufacturing process (Herrero et al., 2022). EPA could not identify supporting evidence for dermal loading exposures from the handling or wear of fabrics. The Agency also could not identify a diffusion coefficient of formaldehyde for clothing. Therefore, EPA had a low level of confidence in the estimation of dermal loading from textiles including clothing. Thus, a qualitative assessment is reported for this product type in the *Draft Consumer Exposure Assessment for Formaldehyde* (U.S. EPA, 2024d).

For occupational exposures, EPA uses the guidance in *Updating CEB's Method for Screening-Level Assessments of Dermal Exposure* (U.S. EPA, 2013) on selection of Q_u values. EPA assumes routine and incidental contact with liquids occur for workers during routine maintenance activities, manual cleaning of equipment, filling drums, connecting transfer lines, sampling, and bench-scale liquid transfers. For this event, the memorandum uses values of 0.7 to 2.1 mg/cm^2-event for routine liquid contact. EPA uses the maximum value of the range from the memorandum to estimate high-end dermal loads. EPA also included a central tendency liquid dermal loading values, EPA used the 50th percentile of the dermal loading results from the underlying study (U.S. EPA, 1992). The 50th percentile value was 1.4 mg/cm^2-event for routine/incidental contact with liquids.

EPA assumes routine and immersive contact with liquids occur for workers during manual spray applications or contact with very wet surfaces. For this event, the memorandum uses values of 1.3 to 10.3 mg/cm^2-event for liquid contact. EPA uses the maximum value of the range from the memorandum to estimate high-end dermal loads. EPA also included a central tendency liquid dermal loading values, EPA used the 50th percentile of the dermal loading results from the underlying study (U.S. EPA, 1992). The 50th percentile value was 3.8 mg/cm^2-event for routine/incidental immersive contact with liquids. The dermal exposure estimates do not consider the use of gloves or other protective equipment.