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United States
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Executive Summary of the Risk Evaluation for Formaldehyde

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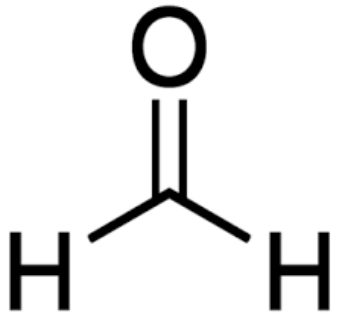

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Introduction

The U.S. Environmental Protection Agency (EPA, or the Agency) evaluated the health and environmental risks of formaldehyde under the Toxic Substances Control Act (TSCA). In this completed risk evaluation, EPA determined that formaldehyde presents an unreasonable risk of injury to human health under the conditions of use. These risks may not apply to everyone, everywhere. The revised risk evaluation points out uncertainties in the precision of risk estimates. However, EPA has high confidence in the overall conclusions of the risk evaluation.

Formaldehyde is found nearly everywhere. Living things—plants, animals, and people—produce and release formaldehyde just through natural life ("biogenic") processes. It is also formed when other chemicals break down in the environment and formaldehyde is released into the air when things burn, such as when automobiles emit exhaust, when furnaces and stoves operate, and through forest fires. Formaldehyde sources focused on in this risk evaluation involve the manufacturing, processing, distribution in commerce, use, and disposal of formaldehyde and formaldehyde-containing products and articles that are subject to TSCA. These may include composite wood articles, plastics, paints, adhesives, and sealants. In addition, other articles and products containing formaldehyde may not be subject to TSCA and may be on the market (*e.g.*, pesticides as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], or use as a food, food additive, drug, cosmetic, or device as defined in the Federal Food, Drug, and Cosmetic Act). The varied sources of formaldehyde exposure, some of which are subject to TSCA and some of which are not, results in a complex exposure profile.

Studies in people demonstrate that exposure to formaldehyde for a short period of time, such as for 15 minutes (called an acute exposure) cause sensory irritation such as eye and respiratory inflammation. Sensory irritation effects go away when exposure stops. Longer-term exposure to formaldehyde in air might cause cancer and respiratory effects such as reduced lung function and asthma. Skin (dermal) contact with formaldehyde has also been shown to cause sensitization—an allergic reaction in exposed humans. Although there are data on the hazards of oral ingestion, such as by drinking water, exposure via ingestion is not likely from conditions of use. Formaldehyde is not expected to persist in water or soils based on its physical and chemical properties; therefore, it is not expected in groundwater or surface water used for drinking water.

EPA assessed human exposure for a total of 63 conditions of use of formaldehyde, using many scenarios, considering multiple human life stages (*e.g.*, childhood, adulthood), and how people might be exposed outdoors in the open air, in their homes or other buildings, and at workplaces that use formaldehyde. In some cases, EPA had data from air monitors; in other cases, the Agency used models to predict air concentrations and exposures. Both measured and modeled information show that people are exposed to formaldehyde at work, indoors, and outdoors. Furthermore, multiple sources of formaldehyde—including sources regulated under TSCA as well as other sources of formaldehyde (including natural sources as well as sources that are regulated under other laws)—contribute to the total amount of formaldehyde that a person breathes outside, inside, and at work, every day.

EPA's TSCA existing chemical risk evaluations must determine whether a chemical substance does or does not present unreasonable risk under its conditions of use. The unreasonable risk determination must be informed by science, but the Agency EPA, in making a finding of "presents unreasonable risk," also considers risk-related factors as described in its TSCA Risk Evaluation Framework Rule. Risk-related factors include the type of health effect under consideration, the reversibility of the health effect being evaluated, exposure-related considerations (*e.g.*, duration, magnitude, frequency of exposure), population exposed (including any susceptible subpopulations), and the confidence in the information used to inform the hazard and exposure values.

TSCA requires EPA to evaluate risks to the environment as well as to people. Formaldehyde does not last long (persist) in water, sediment, or soil, and therefore exposure is less likely to aquatic or terrestrial organisms. For this reason, the Agency focused its risk environmental risk assessment on releases of formaldehyde to air. EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for formaldehyde, because formaldehyde air concentrations are much lower than the concentrations needed to produce adverse effects. **Therefore, the rest of this executive summary focuses on EPA's evaluation of risks to people.**

In March 2024, EPA released the *Draft Risk Evaluation for Formaldehyde* for public comment and for peer review by the Science Advisory Committee on Chemicals (SACC). For the long-term inhalation points of departure (which represent the adverse health effects that occurs at the lowest concentration used to identify risk), the draft TSCA Risk Evaluation relied on hazard values from the draft EPA's Integrated Risk Information System (IRIS) assessment. This is because the final EPA IRIS assessment had not yet been released. The SACC meeting was held May 20–23, 2024, with the minutes and final report released on August 2, 2024. The SACC provided input on a variety of issues associated with formaldehyde exposure, hazard characterization, and hazard identification. SACC input has been incorporated, as appropriate, in the revised risk evaluation for formaldehyde. Multiple federal advisory committees—including the National Academies of Sciences, Engineering, and Medicine (NASEM), TSCA SACC, and the Human Studies Review Board (HSRB)—have provided review of various aspects of the TSCA formaldehyde risk evaluation. EPA recognizes that the NASEM, SACC, and HSRB provided feedback on several overlapping issues; some peer review feedback was consistent across panels whereas some feedback was inconsistent, providing divergent views.

For this risk evaluation, EPA's Office of Chemical Safety and Pollution Prevention developed its own hazard assessment for the acute inhalation, oral, and dermal exposure to formaldehyde. The risk assessment also considers nasopharyngeal cancer and non-cancer hazard values for formaldehyde inhalation presented in the final *IRIS Toxicological Review of Formaldehyde – Inhalation* for those scenarios under TSCA where chronic exposure may be expected. Because TSCA risk evaluations are required to consider risks to potentially exposed or susceptible subpopulations that are identified as relevant to the risk evaluation, such as children, EPA applied age-dependent adjustment factors to inhalation unit risk to account for the possibility of children's increased susceptibility to formaldehyde.

Workers who are in workplaces where formaldehyde is made or is used are at the most risk from formaldehyde exposure.

Workplace air concentrations are generally higher than both ambient outdoor concentrations and residential indoor air concentrations. Workers may be exposed to formaldehyde in air during manufacturing, processing, distribution in commerce or use of formaldehyde and products and articles containing formaldehyde—particularly when personal protective equipment is not used. Workers can also be exposed to formaldehyde by making skin contact with formaldehyde-containing materials, especially when personal protective equipment like gloves are not worn.

Sensory irritation is being used by EPA to evaluate acute air exposure to formaldehyde. Sensory irritation is commonly used as a parameter for setting occupational exposure limits. Although reversible and less serious than cancer, sensory irritation is still a serious effect that can reduce job performance or lead to undesirable outcomes such as falling or reduced visibility in the workplace. EPA is using skin sensitization to evaluate dermal exposure to formaldehyde. Due to its prevalence, persistence, and impact on quality of life, skin sensitization is recognized as an important occupational and general health

issue. Skin sensitization is a known and common occupational illness. EPA also looked at the possibility of people getting formaldehyde on their skin through liquid products that contain formaldehyde. Workers engaged in daily activities like spraying liquids that contain formaldehyde may also have enough dermal contact with formaldehyde, particularly if they are not wearing protective equipment like gloves, to develop skin sensitization.

EPA recognizes that chronic exposure is likely for many workers and has calculated non-cancer and cancer risk estimates for workers. However, the non-cancer chronic effects the Agency used in its calculations are based on effects observed in children, and some SACC peer reviewers indicated concerns with determining risk to workers based on health effects observed in children. Therefore, EPA is basing its unreasonable risk determination for workers on (1) acute, non-cancer effects (sensory irritation) due to peak inhalation exposures; (2) non-cancer effects (skin sensitization) due to dermal contact; and (3) cancer risk due to long-term inhalation.

EPA has determined with high confidence that there is unreasonable risk to workers from inhalation (acute and cancer) and dermal (acute) exposure to formaldehyde. This overall conclusion is based on the magnitude of the difference between the exposure and the hazard values and because most of the inhalation data are based on recent workplace monitoring data from multiple sources for multiple sites. Therefore, these are expected to be reflective of current industrial practices. Although dermal exposures are modeled, based on the magnitude of the difference between the exposure and the hazard values, EPA is confident in the unreasonable risk to workers identified.

At the next-highest risk from formaldehyde are people who frequently use certain consumer products that contain formaldehyde. Like workers, EPA is considering sensory irritation and skin sensitization to evaluate risks to consumers from use of products like automotive-care products like car waxes; crafting supplies such as some glues and sealants; and fabrics, textiles, and leather goods treated with formaldehyde. The Agency does not expect most consumer exposures to be chronic in nature since these products generally tend to be infrequently used and have relatively short durations of use. Therefore, for calculating consumer risk, EPA focused its risk determination on consumer uses that pose acute inhalation and dermal risks.

The highest acute inhalation exposure estimates are for adhesives and sealants as well as for paint and coatings. The highest concentrations of formaldehyde due to acute dermal exposures were estimated for exterior car waxes and polishes followed by photographic processing solutions.

Risks for people in indoor environments were estimated based on exposure to articles that may release formaldehyde over time. EPA is considering sensory irritation, non-cancer, and cancer effects to evaluate risks to the general population from exposure to formaldehyde in indoor air resulting from releases of formaldehyde from articles like furniture and construction materials. There are many sources of formaldehyde within homes, other indoor places where people spend extended periods of time, and inside of vehicles. These include building materials, wood flooring, insulation, and fabrics. Consumer products containing formaldehyde as well as combustion sources like candles, fireplaces, or stoves may also intermittently add to indoor concentrations of formaldehyde; however, emissions from these products are generally not expected to substantially contribute to formaldehyde indoor air concentrations.

The highest formaldehyde concentrations from TSCA sources in indoor environments are expected in newly constructed homes and mobile homes. In these settings, multiple sources of formaldehyde contribute to total indoor air concentrations, which is evident during the peak article emission period

with new formaldehyde-containing articles. These concentrations substantially diminish within the first few months and years of the article life. Peak exposures to formaldehyde from these articles are expected to occur within 1 year of manufacture or use. Indoor air concentrations of formaldehyde 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. Taken together, formaldehyde concentrations in indoor environments are expected to vary greatly over longer time periods (*e.g.*, an individual's lifetime) and are highly dependent on (1) a person's likelihood to move into newly constructed homes, (2) what articles and how often a person introduces new materials into the home, and (3) how soon after manufacture a person brings the articles into their home. Many of the articles that fall within two conditions of use are also subject to EPA's formaldehyde emission standards for composite wood products under TSCA Title VI (15 U.S.C. §2697; see 40 CFR Part 770), which began to go into effect in 2018 but were not fully implemented until 2024. Therefore, it is reasonable to expect that less formaldehyde will be released from many wood articles in the future than occurred in the past.

No acute risk was identified for individual conditions of use in indoor environments. Cancer and chronic non-cancer risks were identified for some conditions of use. However, as discussed above, EPA believes that implementation of Title VI will substantially reduce formaldehyde indoor air concentrations. The Agency has more confidence in the ability to model indoor short-term compared to long-term exposures. Therefore, EPA did not rely on chronic and cancer risk estimates in its risk determination.

EPA has high confidence in the indoor air risk assessment but has some uncertainties in the precise indoor air concentration estimates because the models used are not able to predict precise, long-term concentrations due to model limitations (*e.g.*, changes in emission rates over time). However, the models used were parameterized based on both article-specific emission rates and article-specific formulation data. In addition, EPA has some uncertainty in the precise exposure values because (1) dissipation rates of formaldehyde cannot be determined for all types of furniture, wood, or other articles; and (2) the available monitoring data cannot be directly tied to specific articles (*e.g.,* wood and fabric) and associated conditions of use.

Potential risks for people living near formaldehyde-releasing facilities were estimated. EPA is considering sensory irritation, non-cancer, and cancer effects to evaluate risks to the general population from exposure to formaldehyde resulting from releases of formaldehyde to outdoor air. The Agency used both model estimates and available monitoring data to estimates exposures. Overall, formaldehyde concentrations are highly variable based on location, releases, weather conditions, and other sources of formaldehyde. In addition, modeling does not account for atmospheric degradation of formaldehyde, which may reduce concentrations. Available monitoring data indicates that there were no significant seasonal changes in ambient formaldehyde concentration over time. However, formaldehyde concentrations do experience periodic increases and decreases in concentration throughout the day that largely align with the 24-hour daily cycle.

EPA has medium confidence in the ambient air risk assessment due to uncertainties related to input parameters as well as spatial and temporal differences across the multiple lines of evidence considered. The highest risk is above the 1×10^{-6} cancer benchmark for some communities—particularly those near releasing facilities and especially some facilities with releases attributed to combustion. However, there remain uncertainties with regard to cancer hazard assessment as described in the *Human Health Risk Assessment*. Additional conversative assumptions that reduce EPA's confidence in the realism of its risk calculations include

- that individuals within 100 to 1,000 m are exposed to high-end modeled formaldehyde concentrations in ambient air for the entire duration of their life (*i.e.,* 78 years); and
- that no atmospheric degradation of formaldehyde occurs, which may reduce ambient air concentrations.

Furthermore, additional regulatory measures already promulgated but not yet implemented under the Clean Air Act (*e.g.,* regulations expected to reduce emissions from combustion sources such as vehicles as well as oil, gas, and other facilities), as well as regulatory steps EPA expects to promulgate under TSCA to address the unreasonable risk to workers and consumers would be expected to also reduce ambient exposures to the general population. As such, all of these considerations lead the Agency to find that general population exposures from ambient air emissions under the conditions of use of formaldehyde do not significantly contribute to the unreasonable risk of formaldehyde.

Overall Conclusions

EPA determined that workers and occupational non-users (ONUs)[1] may be exposed to formaldehyde concentrations high enough to result in sensory irritation, thus leading the Agency to make an unreasonable risk determination. Similarly, EPA determined that sensory irritation may be observed due to formaldehyde exposure from use of some consumer products, thus leading the Agency to an unreasonable risk determination.

EPA determined that workers and consumers (*e.g.,* hobbyists) may be exposed to concentrations of formaldehyde high enough to cause skin sensitization, thus leading the Agency to an unreasonable risk determination.

Overall, the unreasonable risk presented by formaldehyde is based on the significant contribution from 58 out of 63 TSCA conditions of use (50 occupational and 8 consumer) due to non-cancer effects. Specifically, air and skin exposure associated with **acute** exposure, meaning that formaldehyde in air can result in eye irritation and/or skin contact that can result in an allergic response for workers (and in some instances also ONUs) as well as consumers (and in some cases also bystanders). In addition, cancer effects to workers, including ONUs, under 43 conditions of use, also support the unreasonable risk determination.

The following TSCA conditions of use significantly contribute to the unreasonable risk:

- Manufacturing (domestic manufacture)
- Manufacturing (import)
- Processing – as a reactant in:
    - adhesives and sealant chemicals in plastic and resin manufacturing; wood product manufacturing; paint and coating manufacturing; and basic organic chemical manufacturing
    - an intermediate in pesticide, fertilizer, and other agricultural chemical manufacturing; petrochemical manufacturing; soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; plastic materials and resin manufacturing; adhesive manufacturing; chemical product and preparation manufacturing; paper manufacturing; paint and coating manufacturing; plastic products

[1] ONUs are workers who do not directly handle formaldehyde but may be indirectly exposed to it through its use in the workplace.

manufacturing; synthetic rubber manufacturing; wood product manufacturing; construction; and agriculture, forestry, fishing, and hunting
    - a functional fluid in oil and gas drilling, extraction, and support activities
    - processing aids specific to petroleum production in all other basic chemical manufacturing
    - bleaching agent in wood product manufacturing
    - agricultural chemicals in agriculture, forestry, fishing, and hunting
- Processing – incorporation into an article, in:
    - finishing agents in textiles, apparel, and leather manufacturing
    - paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)
    - additive in rubber product manufacturing
    - adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); and paper manufacturing
- Processing – incorporation into a formulation, mixture, or reaction product, in:
    - petrochemical manufacturing; petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; petroleum and coal products manufacturing; and basic organic chemical manufacturing
    - asphalt, paving, roofing, and coating materials manufacturing
    - solvents (which become part of a product formulation or mixture) in paint and coating manufacturing
    - processing aids, specific to petroleum production oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing
    - paint additives and coating additives not described by other categories in paint and coating manufacturing and plastic material and resin manufacturing
    - an intermediate in basic chemical manufacturing; chemical product and preparation manufacturing; plastic material and resin manufacturing; oil and gas drilling, extraction, and support activities; and wholesale and retail trade
    - solid separation agents in miscellaneous manufacturing
    - agricultural chemicals (nonpesticidal) in agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and agricultural chemical manufacturing
    - surface active agents in plastic material and resin manufacturing
    - ion exchange agents in adhesive manufacturing and paint and coating manufacturing
    - lubricant and lubricant additive in adhesive manufacturing
    - plating agents and surface treating agents in chemical product and preparation manufacturing
    - soap, cleaning compound, and toilet preparation manufacturing
    - laboratory chemicals
    - adhesive and sealant chemical in adhesive manufacturing
    - bleaching agents in textile, apparel, and leather manufacturing
- Processing – repackaging – sales to distributors for laboratory chemicals
- Processing – recycling
- Distribution – distribution in commerce
- Industrial use (non-incorporative activities)
    - as a process aid in oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing
    - used in: construction

    - oxidizing/ reducing agent; processing aids, not otherwise listed
- Industrial use – chemical substances in industrial products
    - paints and coatings; adhesives and sealants; lubricants
    - aerospace use in: paints and coatings; adhesives and sealants; lubricant; and foam insulation
- Commercial use in:
    - 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
    - water treatment products
    - laundry and dishwashing products
    - adhesives and sealants; paint and coatings
    - 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
    - machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles
    - construction and building materials covering large surface areas, including metal articles
    - automotive care products; lubricants and greases; fuels and related products
    - lawn and garden products
    - explosive materials
    - arts, crafts, and hobby materials
    - ink, toner, and colorant products; photographic supplies
    - laboratory chemicals
- Consumer use in:
    - 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
    - fabric, textile, and leather products (clothing)
    - adhesives and sealant; paint and coatings
    - 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
    - automotive care products; lubricants and greases; fuels and related products
    - paper products; plastic and rubber products; toys, playground, and sporting equipment
    - arts, crafts, and hobby materials
    - ink, toner, and colorant products; photographic supplies
- Disposal

The following conditions of use do *not* significantly contribute to the unreasonable risk:

- Commercial use in paper products; plastic and rubber products; toys, playground, and sporting equipment
- Consumer use in water treatment products
- Consumer use in laundry and dishwashing products
- Consumer use in machinery, mechanical appliances, electrical/electronic articles; other machinery, mechanical appliances, electronic/electronic articles
- Consumer use in lawn and garden product