Product Stewardship Summary

Formaldehyde

Introduction
This document is intended to provide the general public with a high-level overview of formaldehyde, including its uses, properties, and health and environmental considerations. It is not intended to replace the Safety Data Sheet (SDS), which is available from suppliers. All purchasers and users of this substance should read the SDS carefully to understand the hazards and appropriate precautions and practices for safe use of this substance. It is also not intended to replace or supersede manufacturer’s instructions and warnings for products that may contain this substance. This information is being provided for information only. This information does not constitute a product specification, warranty, or approval for specific uses. This information does not alter or affect Hexion Inc.’s standard terms and conditions of sale. It is the sole responsibility of the purchaser to select a particular Hexion product, determine its suitability for the purchaser’s application, follow appropriate handling and processing procedures, and to comply with all applicable statutory, regulatory, compatibility and industry requirements and standards for testing, safety, efficacy and labeling.

Chemical Identity
Formaldehyde is the simplest aldehyde, with a molecular formula of HCHO (CAS No. 50-00-0). Synonyms include formic anhydride, methyl aldehyde, methylene oxide, oxornethane and oxymethylene.\(^1\)\(^2\)

General Facts about Formaldehyde
Formaldehyde is natural and widespread in nature. You can find it in every living system—from plants to animals to humans. Humans, along with plants and animals, actually produce formaldehyde as a normal part of metabolism. The average person generates about 1.5 ounces a day. Formaldehyde occurs as a by-product of all combustion processes. It’s produced in forest fires, automotive exhaust, tobacco smoke and cooking. Of the total atmospheric formaldehyde in the world, 70 to 90 percent comes from mobile sources (e.g., automobiles), power generation and combustion. Only a very small amount is the result of emissions from wood products. Formaldehyde does not accumulate in the environment or within plants and animals. It metabolizes quickly and breaks down readily in the body and in the atmosphere, making it “greener” than you might think. Formaldehyde is one of the most extensively studied chemicals in use today. Its health and safety properties have been researched in depth, and the evidence is reassuring that current standards and safeguards are protective.

Uses
Formaldehyde is used as a chemical intermediate in the production of plywood and particleboard adhesives, abrasive materials, insulation, foundry binders, brake linings, surface coatings, molding compounds, laminates, wood adhesives made from melamine resins, phenolic thermosts, resin curing agents, urethanes, lubricants, alkyd resins, plumbing components from polyacetal resins, and controlled-release fertilizers made from urea formaldehyde concentrates. In smaller quantities, formaldehyde is used for the preservation and embalming of bodies and biological specimens. It is also used as a biocide to control salmonella and other bacteria and fungus.\(^2\)\(^3\)

Manufacturing Process
Formaldehyde is produced by passing vaporized methanol and air over a catalyst. The formaldehyde vapors are absorbed into water to produce aqueous solutions. All formaldehyde solutions contain some amount of methanol. Low methanol formaldehyde solutions typically contain 0.2% to 1.5% by weight methanol due to the incomplete conversion of methanol. Formaldehyde solutions containing greater than 30% by weight formaldehyde require shipping and storing at elevated temperatures to prevent the formaldehyde polymers in solutions from precipitating out of solution. The more concentrated the formaldehyde solution, the higher the required shipping and storage temperature. The Technical Data Sheets for the specific formaldehyde solution lists the required temperature range. Methanol is sometimes added to aqueous formaldehyde solutions to produce formaldehyde solutions containing varying amounts of formaldehyde, water, and methanol. These solutions are sometimes referred to as Formalin. The addition of methanol to formaldehyde solutions inhibits the formation and precipitation of insoluble formaldehyde polymers but lowers the flash point of the formaldehyde solution.
Physical/Chemical Properties

Formaldehyde is a colorless gas with a distinct pungent odor that can be detected by most people at low levels, with the odor threshold typically ranging from 0.5 to 1 ppm. As with the detection of any odor, some individuals may be more sensitive to the odor of formaldehyde than others.\textsuperscript{1,2,3}

The flash point of formaldehyde solutions depends upon the formaldehyde concentration but even more so upon the amount of methanol it contains. The higher the methanol concentration, the lower the flash point of the formaldehyde solution. The flash point of most formaldehyde solutions Hexion markets ranges from 44°C to 99°C or 110°F to 210°F as determined by the Tag Closed Cup (ASTM D56) or Setaflash point (ASTM D3278) methods.\textsuperscript{1,2,3}

Formaldehyde is very soluble in water, alcohols, ether and acetone. Industrial formaldehyde is sold almost exclusively as aqueous solutions of various strengths. These solutions are characterized as complex mixtures of different molecules, or adducts of formaldehyde and water (methylene glycol and polymers thereof) and hemiformals. Methylene glycol cannot be isolated as a substance, and Hexion Inc. does not manufacture or sell methylene glycol labeled as such. Formaldehyde solutions can release formaldehyde gas, and therefore should be assumed to exhibit the properties and hazards of formaldehyde as regulated by OSHA. Although formaldehyde in water immediately reacts to form methylene glycol and various polymers, because these are equilibrium mixtures, they are not considered eligible for individual listing by TSCA or most other global chemical inventories.

Biological Properties

- Formaldehyde is a naturally occurring compound present in all living organisms—plants, animals and humans. As a one-carbon compound, it is used in numerous metabolic processes for the biosynthesis of more complex molecules.\textsuperscript{1,2,3}
- Formaldehyde is found naturally in numerous foods, with daily intake from these sources in the range of 1.5–14 mg for an average adult (Table 1).\textsuperscript{3}
- In all living systems, greater than 99.9% of the formaldehyde is present in its hydrated form of formaldehyde acetal (methylene glycol). Free formaldehyde does not exist at appreciable levels in tissue. Instead, formaldehyde forms a water addition product, formaldehyde acetal, that reacts with glutathione to form formaldehyde thioacetal. Thioacetal is the major cellular form of formaldehyde under normal conditions.
- Because formaldehyde normally is found in the body, the concentrations in blood, tissues and organs are well known.\textsuperscript{4,5}
- Studies in rats, monkeys and humans show that inhalation exposure to formaldehyde of up to 14 ppm (in monkeys) for up to four weeks does not change the concentrations of formaldehyde normally present in the blood.\textsuperscript{4,5}
- Sophisticated techniques can readily distinguish between naturally occurring formaldehyde in the body and inhaled formaldehyde. Studies in rats and monkeys demonstrate that inhaled formaldehyde, even at concentrations up to 10 ppm, does not move past the nose to enter the body, and cannot be detected in the lung, spleen, liver, thymus, bone marrow or white blood cells. This finding has implications for the likelihood of distant-site toxicity.\textsuperscript{6,7,8,9,10,11,12,13,14,15}
- Because of its presence in tissues of the upper respiratory tract (i.e., nose and throat), formaldehyde is exhaled in the breath at levels of up to about 2 ppb.\textsuperscript{16}
- Formaldehyde, which is a gas, is not absorbed through the skin.\textsuperscript{3}
- Several chronic studies in rats have shown that prolonged exposure to formaldehyde at 6 ppm or greater can cause nasal tumors. The mechanism by which these tumors occur is well known and extensively characterized, and lower concentrations have not shown such effects. No other types of cancer (including leukemia) have been reported in animal studies following inhalation of formaldehyde.\textsuperscript{3,17,18,19,20,37,38}
General Health Effects

The main acute effects of formaldehyde are sensory irritation of the eyes, nose and throat, with eye irritation the most sensitive indicator of exposure. The concentrations of formaldehyde that are required to elicit symptoms of sensory irritation are well established. Individuals have been exposed to known concentrations of formaldehyde in more than 20 controlled human volunteer studies. These studies have included people who are particularly sensitive to the irritant effects of formaldehyde, as well as asthmatics. The lowest concentration of formaldehyde that is unequivocally associated with sensory irritation is 0.5 ppm.  This is credited to studies in which some people were intentionally exposed to air with formaldehyde levels between 0.3 ppm to 1 ppm, while some were exposed to clean air (i.e., formaldehyde-free). The results indicated the most sensitive parameter to be eye irritation with minimal objective eye irritation observed following exposure to 0.5 ppm with peaks of 1 ppm for 4 hours, for 10 consecutive work days. Based on the extensive human database, the recent critical assessments conducted by regulatory bodies from around the world have concluded that a formaldehyde level of 0.08 ppm (0.1mg/m³) is protective for the symptoms of sensory irritation for all individuals, including asthmatics and even those with self-reported sensitivity to formaldehyde. No empirical data have demonstrated that exposure to formaldehyde alone (i.e., not confounded by co-exposures to other chemicals) at concentrations of less than 0.08 ppm (0.1 mg/m³) causes symptoms of sensory irritation.  

Air concentrations of formaldehyde greater than about 5 ppm cause increasing irritation of the eyes, nose and throat, with excessive tearing of the eyes.  Concentrations above 10 ppm quickly become intolerable, and breathing such levels for more than a very short period may result in severe upper respiratory tract irritation, with possible progression to bronchitis, pulmonary edema and pneumonia.  

Direct skin contact with formaldehyde solutions (e.g., formalin) also may cause chemical burns, and skin contact with such solutions can cause allergic skin reactions in some individuals. There is no evidence that dermal exposure to gaseous formaldehyde alone produces effects on the skin or allergic responses.  

Other Health Effects

Other health effects (e.g., reproductive, developmental or neurological) have been reported to be a consequence of exposure to formaldehyde. However, the inability of inhaled formaldehyde to enter the body to reach distant site tissues in the body raises the question as to how such effects might occur.  Controlled human studies with asthmatics show that symptoms are not exacerbated by exposure to formaldehyde at up to 3 ppm. All of the studies suggesting that formaldehyde causes asthma or reproductive effects are confounded by co-exposure to other chemicals. There are no studies demonstrating that exposure to formaldehyde alone causes or exacerbates asthma.  

Carcinogenic Potential

There is controversy regarding the potential for formaldehyde to cause cancer. The International Agency for Research on Cancer (IARC) has classified formaldehyde as “carcinogenic to humans” specifically for nasopharyngeal cancer (NPC) and leukemia. These determinations are based primarily on several epidemiology studies conducted by the National Cancer Institute (NCI) which have been criticized with respect to their methodology and conclusions. However, the decision by IARC concerning an association with leukemia has been seriously questioned because it is unknown how this might occur given that inhaled formaldehyde does not enter the body to get into the blood and therefore cannot reach distant site tissues (e.g., the bone marrow). Other chemicals which are known to cause myeloid leukemia in animals and humans share a number of well-studied biological properties (e.g., bone marrow toxicity). However, formaldehyde does not share any of these properties. The draft determination regarding cancer risks reached by EPA in the Agency’s June 2, 2010 proposed Integrated Risk Information System (IRIS) assessment of formaldehyde has been criticized on numerous grounds by scientists from other government agencies who reviewed this draft document. In particular, available data cannot explain how a chemical such as formaldehyde, which is naturally present in the body and which does not get to distant sites in the body following inhalation, would be capable of causing leukemia.

The draft EPA/IRIS assessment of formaldehyde was critically reviewed by a Committee from the National Academy of Sciences/National Research Council (NAS/NRC 2011) which found numerous methodological and interpretative flaws in the document.  This review concluded that the EPA/IRIS assessment failed to support a causal association between formaldehyde exposure and leukemia or other health problems. The NRC committee concluded that EPA’s claims that formaldehyde causes leukemia or related blood cancers are not supported in the IRIS assessment since it was not described how this conclusion was reached particularly given the inconsistencies in the epidemiology data, the weak animal data, and the inability to explain how this kind of cancer could be caused by formaldehyde. Given the numerous criticisms and methodological issues concerning EPA’s formaldehyde IRIS assessment as identified in the NAS/NRC review, it is expected that the entire document and draft conclusions will be extensively modified and/or rewritten. However, the draft IRIS assessment is still awaiting finalization with currently no status on its release date. Since the availability of the draft formaldehyde IRIS assessment, multiple peer-reviewed articles discussing the need for transparency and reproducibility in the regulatory decision-making process for formaldehyde and summarizing the new science relevant to the potential toxicity and carcinogenicity of formaldehyde have been published.  

The National Toxicology Program (NTP 2011) also evaluated the carcinogenic potential of formaldehyde and suggested that formaldehyde could cause NPC, sinonasal cancer and myeloid leukemia. This evaluation contains many of the same methodological and interpretive flaws that plagued the EPA/IRIS assessment of formaldehyde and its conclusions regarding formaldehyde were not updated with the most recent publication of the 14th RoC in 2016.  

Given the continuing controversy surrounding the data upon which formaldehyde is classified as a human carcinogen (particularly for leukemia), the application and the incorporation of the new science regarding the potential carcinogenicity of formaldehyde into these assessments are crucial.
Environmental Effects

Environmental Fate Information
Formaldehyde is biodegradable and does not persist in the atmosphere, due to sunlight-catalyzed degradation to formic acid with a half-life of a few hours. When released to water, formaldehyde biodegrades to low levels in a few days.\(^1\)

Aquatic and/or Terrestrial Toxicity
Due to the rapid rate that formaldehyde biodegrades in aquatic and soil environments, it has low to moderate toxicity to a variety of fish species. Also, formaldehyde does not bioconcentrate in a variety of fish and shrimp.\(^1\)

Exposure Potential
The principal route of formaldehyde exposure for both the general population and workers is by inhalation of air that contains formaldehyde. Ambient air levels of formaldehyde for the general public are mostly attributable to emissions from industrial activities, building materials, consumer products, vehicle exhaust, and tobacco smoke. Inhalation exposure of workers is due to handling, storing and processing of formaldehyde and formaldehyde-containing polymers. Formaldehyde is found naturally in remote, rural, urban, and indoor air. Formaldehyde levels are typically higher in indoor air than outdoor air due to release of formaldehyde from many home products such as latex paint, fingernail polish, plywood and particleboard, furniture and cabinets, carpets, some permanent-press fabrics, and some paper products. It is also a major contributor to indoor air as a consequence of cooking fish indoors (Table 1).\(^3,4\)

Table 1. Sources of Potential Exposure to Formaldehyde\(^a\)

<table>
<thead>
<tr>
<th>Source</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food</strong></td>
<td></td>
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<tr>
<td>Daily intake for average adult</td>
<td>1.5–14 mg</td>
</tr>
<tr>
<td>Fruits and vegetables</td>
<td>3–60 mg/kg</td>
</tr>
<tr>
<td>Meat and fish</td>
<td>6–20 mg/kg</td>
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<tr>
<td>Shellfish</td>
<td>1–100 mg/kg</td>
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<tr>
<td>Milk and milk products</td>
<td>1–3.3 mg/kg</td>
</tr>
<tr>
<td><strong>Air</strong></td>
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<tr>
<td>Remote air</td>
<td>0.1–1 ppb</td>
</tr>
<tr>
<td>Human breath</td>
<td>Up to 2 ppb</td>
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<tr>
<td>Rural air</td>
<td>0.7–5 ppb</td>
</tr>
<tr>
<td>Urban air</td>
<td>3–50 ppb</td>
</tr>
<tr>
<td>Normal indoor air</td>
<td>20–100 ppb</td>
</tr>
<tr>
<td>WHO guidance</td>
<td>80 ppb</td>
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<tr>
<td>Polluted indoor air</td>
<td>300 ppb</td>
</tr>
<tr>
<td>ACGIH short-term exposure limit</td>
<td>300 ppb</td>
</tr>
<tr>
<td>Buildings with smoking not permitted</td>
<td>Up to 220 ppb</td>
</tr>
<tr>
<td>Buildings with smoking permitted</td>
<td>Up to 600 ppb</td>
</tr>
<tr>
<td>OSHA standard</td>
<td>750 ppb</td>
</tr>
<tr>
<td>Indoor air from cooking fish</td>
<td>480–5,310 ppb</td>
</tr>
</tbody>
</table>

\(^a\): various sources
Risk Management Measures

Levels of formaldehyde in the workplace have declined over the past few decades due to improved manufacturing practices and advances in resin chemistry, resulting in significant reductions of emissions in the workplace, in ambient air and in indoor air. Exposure to formaldehyde in the workplace is subject to a number of established limits. For example, the Occupational Safety and Health Administration (OSHA) established the OSHA Formaldehyde Standard (29CFR 1900.1048) that sets limits on worker exposure. Those limits include 0.75 ppm as a time weighted average (TWA) over an 8-hour workday, and 2 ppm as a short-term exposure limit (STEL). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends an occupational exposure limit of 0.1 ppm TWA and 0.3 ppm as a STEL value. In Europe the Scientific Committee on Occupational Exposure Limits (SCOEL) has established a 0.3 ppm TWA and a 0.6 ppm STEL as formaldehyde OEL values.

Exposure to formaldehyde in the workplace is readily controlled by good engineering and process controls, sufficient ventilation and proper handling and storage techniques. Examples include: local exhaust ventilation systems; proper protective equipment such as eye protection; suitable work clothing which covers arms and legs; formaldehyde-resistant gloves; and NIOSH-approved respirators in situations where exposure exceeds allowable exposure limits and/or ventilation alone is not sufficient.

In the United States, federal, state, and some local governments regulate formaldehyde emissions from certain industrial and commercial facilities. The regulatory emission limits for each regulated facility are typically written into a facility’s operating permit.

The latest formaldehyde risk assessment performed by the German Federal Institute for Risk Assessment (BfR) determined that 0.1 ppm is a safe indoor air concentration with respect to cancer risk for the general population. Two recent reviews, conducted in the framework of the World Health Organization (WHO) Indoor Air Quality Guideline Development on an indoor air guideline value for formaldehyde, concluded that 0.08 ppm would be protective for all cancer and non-cancer effects. The WHO guideline value is sensible, practicable and toxicologically defendable.

There has been a significant decline in contamination of the indoor environment since the 1980’s. The Environmental Protection Agency (EPA) now regulates formaldehyde emissions from composite wood products sold in the United States. The regulation ensures that all products—both domestic and imported composite wood panels and the finished products containing them—meet the world’s most stringent standards for formaldehyde emissions. In partnership with the composite panel industry, resin manufacturers, like Hexion, have developed formaldehyde-based resin technologies that now emit formaldehyde levels at or near the levels that occur naturally from wood itself.

As required in the legislation—the bipartisan “Formaldehyde Standards for Composite Wood Products Act,” which became Title VI of the Toxic Substances Control Act (TSCA)—the EPA regulation is largely consistent with the California Air Resources Board (CARB) Air Toxics Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products. The federal regulation applies the same CARB emissions limits for hardwood plywood (0.05 ppm), MDF (0.11 ppm), thin MDF (0.13 ppm) and particleboard (0.09 ppm). The regulation also puts in place a rigorous third-party certification system. The regulation calls for labeling of panels as “TSCA Title VI Compliant.”

Product Stewardship Commitment

Formaldehyde and derivative resins and adhesives of Hexion Inc. are used in a wide range of industrial applications. The chemistry of formaldehyde continues to make it a versatile and valuable material, with applications that enhance the quality and sustainability of modern life. We continue to develop new technology and manufacturing processes to improve the safety and environmental performance of formaldehyde and derivative products. We are committed to responsible plant operations that protect the health and safety of our associates, neighbors and the environment. As responsible stewards of our products, we are committed to helping our customers with regulatory compliance, safe product use, product enhancements and lower emissions. We continue to support scientific research, compliance awareness and education programs designed to advocate for the safe use and sustainability of formaldehyde-based technologies.
References


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Environmental Protection Agency (EPA). 2015. EPA's integrated risk information system (IRIS) program: Progress report and report to congress November 2015.


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