

Frequently Asked Questions

Overview

What is formaldehyde?

Formaldehyde is a *simple* but ubiquitous chemical compound made of hydrogen, oxygen and carbon, with the formula CH₂O. All organic life forms – bacteria, plants, fish, animals and humans – naturally produce formaldehyde as a consequence of the processes in cell metabolism.¹

Formaldehyde is naturally present in fruits, vegetables, meats, fish, coffee, and alcoholic beverages. Most formaldehyde inhaled by humans is quickly exhaled. The relatively small amounts of formaldehyde that remain in the nose and upper respiratory tract are swiftly metabolized into harmless products.² Thus, formaldehyde does not accumulate in animals or people because it is quickly broken down in the nose by the body's natural metabolic processes. In the environment, formaldehyde is quickly broken down by sunlight in the air³ or by bacteria present in soil or water.

How does formaldehyde make our lives better?

Without formaldehyde, many products that consumers use every day would not exist or not perform as well. There are four major economic sectors that depend on formaldehyde, all of which have a major impact on our standard of living and economic vitality.

Residential construction: Formaldehyde is used to make products such as plywood, sheathing and cladding, asphalt shingles, cabinets, floors, furniture and paneling, insulation, laminated countertops and flooring systems, and paints and varnishes.

Automobiles: Formaldehyde is used to make interior molded components and under-the-hood components needing to withstand high temperatures. It is also used in the production of highly durable exterior primers, clear coat paints, tire cord adhesives, brake pads, and fuel system components.

Civilian and military aircraft: Formaldehyde is used in the production of landing gear components, lubricants for extreme hot and cold temperatures, brake pads, and door and window insulation.

Health care applications: Formaldehyde is a key component in the manufacturing of vaccines, anti-infective drugs, and hard-gel capsules. It is an essential ingredient in the design of many drugs, such as codeine, cough suppressants, some antidepressants and cancer treatments, enabling their absorption and clinical action.

What would society miss if formaldehyde were eliminated from products?

Formaldehyde is used to manufacture many products that consumers use every day. In certain commercial applications and consumer products, formaldehyde is a building-block molecule, and few compounds can replace it as a raw material without reducing performance and making the final products more expensive. Whether it is used in plywood for home construction, fuel system components for automobiles, or door and window insulation for modern airliners, formaldehyde provides greater utility for consumers in the form of extended use, consistent quality and improved performance.

Formaldehyde and the Economy

How does formaldehyde contribute to the U.S. economy and jobs?

In the U.S., formaldehyde is responsible for employing 600,000 people in the U.S. directly and three million people indirectly. It is responsible, both directly and indirectly, for \$112 billion in U.S. wages and \$77.4 billion in U.S. business investments.

Because formaldehyde is a significant part of the U.S. economy, it is estimated that consumers would have to spend an additional \$17 billion per year if formaldehyde-based products were replaced by substitute materials.⁴ In most instances, because there are no perfect substitutes for formaldehyde, consumers would lose product performance advantages by using alternative materials, and large new capital investments would be required to produce and use substitutes.

Health & Safety

Is inhaled formaldehyde safe?

Formaldehyde is produced naturally by our bodies,⁵ is found in all cells and is a normal component of human blood. In fact, formaldehyde is an essential chemical in the body and serves as a building block for the biosynthesis of more complicated molecules.⁶ Formaldehyde is one of the most studied chemicals in use today. Studies in rats, monkeys, and humans show that inhaled formaldehyde does not change the levels of formaldehyde normally present in the blood.⁷

Does formaldehyde cause leukemia?

Based on the most recent science, there does not appear to be credible evidence that inhaled formaldehyde is capable of triggering the mechanisms in the body that are necessary to cause leukemia.⁸

The notion that there is a link between leukemia and formaldehyde is based primarily on one epidemiology study conducted by the National Cancer Institute⁹ of 25,000 workers at 10 different plants where formaldehyde was either manufactured or used. This study was highly questioned by other scientists. The overall leukemia rates in the study were no different from the general U.S. population.¹⁰ By using the most appropriate ways to measure exposures, there was no association between formaldehyde and leukemia.

Does formaldehyde cause or exacerbate asthma?

Current scientific evidence does not support a link between exposure to inhaled formaldehyde alone as either causing or exacerbating asthma. When people with known asthma conditions have been intentionally exposed in clinical chamber studies to formaldehyde, they have not experienced asthma attacks.¹¹ While some studies conducted in residential housing have reported a link with formaldehyde, other studies conducted by the same investigators on the same populations have reported associations with volatile organic compounds (VOCs) and fungal spores. The World Health Organization (WHO) concludes: "In summary, consistent cause-effect and dose-response relationships between formaldehyde and measurable lung effects have not been found in controlled human exposure studies and epidemiological studies below 1 mg/m³ [80 ppb].¹² In general, associations between formaldehyde and lung effects or sensitization in children in homes and schools have not been convincing owing to confounding factors and chance effects."^{13,14}

Does formaldehyde cause nasopharyngeal cancer (NPC)?

EPA reports that Salthammer *et al.*, 2010, reviewed studies from 2005 or later and concluded that the typical (average) indoor level is between 16 to 32 parts per billion.¹⁵ WHO reports that formaldehyde does not cause the rare NPC in humans exposed to inhaled formaldehyde at or below levels less than 1,020 ppb [1.25 mg/m³] in indoor air and with peak exposures below 4,070 ppb (5.0 mg/m³).¹⁶ In making this conclusion, WHO acknowledges that there is one study of workers by the National Cancer Institute (NCI) that reported cases of NPC where workers were exposed to formaldehyde at higher levels. While government agencies have focused on this one worker study to support their assertion, the study also reported that the majority of these NPC cases were from one plant out of the ten plants studied, with most of the workers with this cancer reportedly employed a year or less at that plant and reported to have previously worked at plants in a different manufacturing sector with exposure to other chemicals known to cause nasal cancer.¹⁷ Scientists have raised significant questions about whether these worker exposures might have caused or contributed to the NPC cases seen.¹⁸

What happens to inhaled formaldehyde in the body?

Inhaled formaldehyde rapidly breaks down in the body from a gas into the soluble form of formaldehyde (methanediol) and then is changed into formate in the nose and upper respiratory tract. Formate is either used as a building block chemical for the body to make more complicated, larger chemical molecules or broken down into carbon dioxide,¹⁹ which is exhaled in breath.^{20,21} Thus, there is essentially no free formaldehyde available to interact with tissues, since the inhaled formaldehyde is broken down into the soluble methanediol (>99.9%) or gaseous formaldehyde (<0.1 %).²² The tiny fraction (*i.e.*, < 0.1 %) of formaldehyde in the body that can exist in a gaseous form in small amounts (< 0.8 ppb to 8 ppb; that is 0.001 – 0.01 mg/m³)²³ is exhaled in the breath. Consequently, formaldehyde levels in the blood do not increase as a result of inhaled formaldehyde.²⁴

Formaldehyde and Government Regulations

Is formaldehyde regulated?

Formaldehyde is an extensively regulated material. Mandatory government regulations set standards to protect human health and the environment. These requirements allow for the safe production, storage, handling and use of this important building block chemical. Based on the extensive amount of data, there is widespread recognition that when formaldehyde is handled and used properly and in accordance with government and industry guidelines, standards and regulations, formaldehyde is safe for its intended uses, and consumers and workers are appropriately protected.

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) has standards for workplace exposures to formaldehyde. These comprehensive health standards include limits on permissible exposures, requirements for monitoring employee exposures in the workplace, protective measures – including engineering controls, medical surveillance and communication – and training about hazards.

The U.S. Department of Housing and Urban Development (HUD) has standards that limit formaldehyde emissions from wood products for use in manufactured housing. Three agencies – U.S. Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), and U.S. Department of Housing and Urban Development (HUD) – have addressed indoor air exposure to formaldehyde. Since industry voluntarily adopted product emission standards and low-emitting resins were developed, indoor formaldehyde emissions have declined significantly. CPSC determined that independent CPSC action

was superfluous given the voluntary actions and low levels of formaldehyde. In 2010, Congress enacted legislation mandating a national emission standard for composite wood products.

Which authoritative bodies and government agencies are evaluating formaldehyde?

Formaldehyde is the subject of ongoing governmental assessments to determine if there is a connection between formaldehyde and certain health effects. Since many of the following actions were initiated, additional, more definitive research has come out that most likely would have led to different classifications for formaldehyde. Nonetheless, the following list represents the agencies currently evaluating formaldehyde and where they are in the evaluative process.

- The International Agency for Research on Cancer (IARC) classified formaldehyde as carcinogenic to humans (Group 1) based upon the epidemiological evidence for nasopharyngeal cancers in the one NCI cohort. In its most recent discussions, IARC accepted that there is sufficient evidence that formaldehyde may cause myeloid leukemia in humans.²⁵ Since this meeting, however, several peer-reviewed studies have clarified the biological mechanism for formaldehyde, questioning formaldehyde's ability to enter the blood stream and bone marrow.²⁶
- The National Toxicology Program (NTP) may revise its carcinogenic classification of formaldehyde in its *12th Report on Carcinogens* (12th RoC) anticipated in 2011.
- EPA, through its Draft Integrated Risk Information System (IRIS) Assessment, is reviewing the potential human health hazards of formaldehyde by inhalation. Because of the intense debate over whether inhaled formaldehyde poses risks of NPC, leukemia or asthma, the EPA commissioned the National Academy of Sciences (NAS) to peer review its Draft IRIS Assessment. The NAS report is anticipated in early 2011.
- The WHO Guidelines for Indoor Air Quality recommend a level of 80 ppb (0.1 mg/m³) to prevent both short-term (30 minute) and long-term health effects, including cancer.²⁷

Endnotes:

- ¹ Neuberger A. 2005. The metabolism of glycine and serine. In Neuberger A., van Deenen LLM, eds. *Comprehensive biochemistry*, Vol. 19A. Amino acid metabolism and sulphur metabolism. Amsterdam, Elsevier. 1981:254-303. as cited in WHO. 2010. at pg. 108.
- ² Garcia GJM, *et al.*, 2009. Dosimetry of nasal uptake of water-soluble and reactive gases: a first study on interhuman variability. *Inhalation Toxicology*. 21:21:607-618. as reported in WHO. 2010. at pg. 111.
- ³ WHO. (World Health Organization). 2010. WHO Guidelines for Indoor Air Quality: Selected Pollutants. At pg. 103; United Nations Environment Programme, International Programme on Chemical Safety. 1991. Health and Safety Guide No. 57. <http://www.inchem.org/documents/hsg/hsg/hsg057.htm>.
- ⁴ Global Insight. 2005. The Economic Benefits of Formaldehyde to the United States and Canadian Economies. WHO. 2010. at pg. 122.
- ⁵ WHO. 2010. at pg. 122.
- ⁶ Neuberger A. 2005. The metabolism of glycine and serine. In Neuberger A., van Deenen LLM, eds. *Comprehensive biochemistry*, Vol. 19A. Amino acid metabolism and sulphur metabolism. Amsterdam, Elsevier. 1981:254-303. as cited in WHO. 2010. at pg. 108.
- ⁷ WHO, 2010. At pg. 108; United Nations Environment Programme, International Programme on Chemical Safety. 1991. Health and Safety Guide No. 57. <http://www.inchem.org/documents/hsg/hsg/hsg057.htm>.
- ⁸ Recent work by Lu *et al.*, 2010; Swenberg *et al.*, 2010; and Moeller *et al.*, 2011 demonstrate that inhaled formaldehyde does not enter the blood, bone marrow or travel to internal tissues beyond the nose.
- ⁹ Hauptman, M. *et al.*, 2003. Mortality from lymphohematopoietic malignancies among workers in formaldehyde industries. *JNCI*. 95:1615-1623. This study was updated in Freeman LEB, *et al.*, 2009. Mortality from

lymphohematopoietic malignancies among workers in formaldehyde industries: the National Cancer Institute cohort. *Journal of the National Cancer Institute*. 101:751-761.

10 Marsh and Youk reanalyzed the Hauptmann 2003 data and found that there were no significant differences in the death rate for the exposed workers and the general non-exposed population. See WHO. 2010. at pg. 130 and March GM, Youk AO. 2004. Reevaluation of mortality risks from leukemia in the formaldehyde cohort study of the National Cancer Institute. *Regulatory Toxicology & Pharmacology*. 40:113-124. Importantly, the WHO reports that average exposures below 0.63 mg/m³ (510 ppb) are protective against lymphohematopoietic malignancies in general. WHO. 2010. at pg. 131.

11 Studies using controlled exposures in chambers found subjects with asthma did not experience an asthma attack when intentionally exposed to formaldehyde. WHO concluded that a relationship between formaldehyde and measurable lung effects has not been found in controlled human exposure studies and epidemiological studies below 1 mg/m³ (80 ppb). WHO. 2010. at pg. 120.

12 1 mg/m³ is one milligram per cubic meter. In this document, these scientific units (mg/m³) have been converted to parts per billion (ppb) for the ease of the reader. One part per billion is 1,000 parts per million. The standard calculation for this conversion is ppb = ppm (1,000) = (x mg/m³)(24.45) / 30.03 the molecular wt of formaldehyde. CDC offers a web-based conversion program at: <http://www.cdc.gov/niosh/docs/2004-101/calc.htm>.

13 WHO, p. 120

14 Importantly, WHO concluded that “there is no evidence indicating an increased sensitivity to sensory irritation to formaldehyde among people often regarded as susceptible (asthmatics, children, and older people).” WHO. 2010. at pg. 139

15 EPA. 2010. Draft Toxicological Review of Formaldehyde – Inhalation Assessment. at pgs. 2-8; and Salthammer, *et al.*, 2010. Formaldehyde in the indoor environment. *Chemical Reviews*. 110:2536-2572. EPA reports that Salthammer concludes that “the average exposure of the population to formaldehyde is 20 to 40 µg/m³ under normal living conditions.” 20 µg/m³ converts to 16 ppb and 40 µg/m³ converts to 32 ppb. See endnote 12 for conversion calculation.

16 WHO, p. 129 WHO specifically reported that “...for the purposes of indoor air guideline setting, that no excess nasopharyngeal cancer was reported at a mean formaldehyde exposure level at or below 1.25 mg/m³ and with peak exposures below 5 mg/m³.” 1.25 mg/m³ is 1,020 ppb; see footnote 12 for conversion equation.

17 Marsh GM. *et al.* 2007. Work in the metal industry and nasopharyngeal cancer mortality among formaldehyde-exposed workers. *Regulatory Toxicology & Pharmacology*. 48:308-319. and WHO. 2010. at pg. 129.

18 Marsh GM. *et al.* 2007; and WHO. 2010. at pg. 129.

19 WHO p. 108 and p. 122-3

20 Exhaled carbon dioxide is in concentrations between 0.56 ppb (0.001 mg/m³) to 5.5 ppb (0.01 mg/m³) with an average exhaled carbon dioxide of 2.78 ppb (0.005 mg/m³).

21 One parts per billion is 0.001 mg/m³ (ppm)

22 The metabolic capabilities in the nose and upper respiratory tract prevent any inhaled formaldehyde from entering the blood because it is changed into methanediol and is present at constant levels in the blood as methanediol and therefore bathes every organ.

23 WHO p. 111

24 Kimbell JE. *et al.*, 2001. Dosimetry modeling of inhaled formaldehyde: binning nasal flux predictions for quantitative risk assessment. *Toxicological Sciences*, 64:111-121. as reported in WHO, 2010, WHO Guidelines for Indoor Air Quality: Selected Pollutants. at pg. 108.

25 WHO p. 122, see ref 155

26 Recent work by Lu *et al.*, 2010; Swenberg *et al.*, 2010; and Moeller *et al.*, 2011 demonstrates that inhaled formaldehyde does not trigger the necessary adducts in the blood or bone marrow, which is an essential element for leukemia causation.

27 WHO, p.141