

D. Formaldehyde

CAS number: 50-00-0

1. Overview

Formaldehyde is used in a wide number of applications. It can be used as a solvent, a fixative, and to make binders or adhesives such as phenol, urea, or melamine resins. Examples of products made using formaldehyde are insulation, composite wood, paints, laboratory solutions, cosmetics, personal care products and preservatives (Agency for Toxic Substances and Disease Register [ATSDR], 1999; National Toxicology Program [NTP], 2010). The Environmental Protection Agency (EPA) Inventory Update Reporting (IUR) data show that for each of the five inventories since 1990, one billion pounds or more of formaldehyde was produced or imported into the U.S. (Environmental Protection Agency [EPA], 2010a). Living systems also produce formaldehyde in small amounts. It does not persist in the environment nor does it bioaccumulate.

Formaldehyde volatilizes easily and is pervasive in the air. Outdoor ambient air sample concentrations of formaldehyde have been reported at 0.2 ppb in rural areas and 10-20 ppb urban and industrial areas (ATSDR, 1999). Often, formaldehyde concentration is higher in indoor air, though the levels depend on the type of building materials used in the structure's construction and the type of materials inside the structure (e.g., furniture, paints). Levels up to 800 ppb have been reported in residences, but the overall median was 2.5 ppb (ATSDR, 1999).

Formaldehyde can cause respiratory and eye irritation, and may contribute to symptoms of asthma (EPA, 2010b; International Agency for Research on Cancer [IARC], 2006). EPA has created a draft document with candidate Reference Concentrations for formaldehyde in the range of 2.8 ppb to 11 ppb based on respiratory endpoints. Dermal contact with formaldehyde can be irritating to skin, with evidence that formaldehyde can cause skin sensitization (ATSDR, 1999; EPA, 2010b; IARC, 2006). Formaldehyde will also irritate the gastrointestinal tract when ingested (ATSDR, 1999).

Formaldehyde has been associated with nasal cancers in workers exposed to formaldehyde in occupational settings (ATSDR, 1999; EPA, 2010b; NTP, 2010). It has been named a Group 1 carcinogen by the International Agency for Research on Cancer (IARC), meaning that "there is sufficient evidence in humans for the carcinogenicity of formaldehyde" (IARC, 2006). The National Toxicology Program (NTP) classified formaldehyde as "reasonably anticipated to be a human carcinogen," though there is currently a proposal to reclassify formaldehyde as "known to be a human carcinogen" (NTP, 2010). The EPA Integrated Risk Information System (IRIS) currently lists formaldehyde as Class B1: probable human carcinogen, though the draft IRIS document states "Formaldehyde is Carcinogenic to Humans by the Inhalation Route of Exposure" (EPA, 2010b).



In summary, formaldehyde is pervasive, causes eye and respiratory effects, is carcinogenic and can be found at relatively high levels in indoor air concentrations (EPA, 2010b). As described below, recent federal legislation related to formaldehyde emissions from wood composites will help to reduce human exposure to formaldehyde in indoor environments. Consumer awareness also will be a factor that can help reduce risks to children from formaldehyde in certain consumer products.

2. Exposure and Environmental Disposition

(Note: The section includes examples of exposure and environmental information. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention (CDC)

Agency for Toxic Substances and Disease Registry (ATSDR)

The Toxicological Profile for formaldehyde notes that formaldehyde is produced naturally and through human activity. Examples of formaldehyde concentrations typically in indoor air (median 2.5 ppb) and outdoor air (1 ppb – 68 ppb) are provided. Indoor air is one of the primary routes of exposure to formaldehyde for the general public, though reduction in use of urea-formaldehyde insulation foam has reduced the amount of formaldehyde in residences. Manufactured wood products have been another source of formaldehyde in indoor air (ATSDR, 1999).

b. Environmental Protection Agency

(1) Inventory Update Report (IUR)

Data from the 2006 EPA IUR indicate that formaldehyde is used in the following product categories at the indicated rates:

Chemical	Maximum concentration in product category	Used in a product intended for children up to age 14
Adhesives and sealants	31-60%	NRO
Fabrics, textiles and apparel	31-60%	No
Glass and ceramic products	31-60%	No
Lawn and garden products (non-pesticide)	31-60%	No
Other	31-60%	No
Paper Products	1-30%	No
Rubber and Plastic Products	NRO	NRO
Transportation Products	31-60%	No
Wood and Furniture	31-60%	No
NRO = “not readily obtainable”		
(EPA, 2010a)		

None of the products listed indicate specific intent for children. However, children use or contact consumer products in these categories, such as Rubber and Plastic products and Wood and Furniture.

(2) EPA Toxic Release Inventory (TRI)

The EPA Toxic Release Inventory (TRI) data show that in 2009 there were about 14.6 million pounds of formaldehyde released in the United States (EPA, 2010d). In Minnesota in 2009, there were 47,692 pounds of formaldehyde released from 15 companies (EPA, 2010c). Most of these releases were point source air emissions (e.g., stack discharge). This is down from a peak of 758,994 pounds reported released in Minnesota from 18 companies in 1988. In the past ten years, the highest quantity of formaldehyde released was 353,553 pounds in 2003 from stack or point source air emissions or fugitive air emissions (EPA, 2010e).

c. National Institute of Health (NIH)

(1) Household Products database

As of November 2010, the Household Products Database lists 45 products that contain formaldehyde. Examples of product use categories are arts and crafts, home maintenance, personal care products, and pet care. Most of the products list formaldehyde at levels of 2.5% of the product composition or lower, though a fish pond treatment product is listed at 10% - 25% formaldehyde (National Library of Medicine [NLM], 2010). This list represents products for which material safety data sheets (MSDSs) are available. Products like furniture and cabinets do not appear to be included in this database.

(2) Hazardous Substances Data Bank (HSDB)

HSDB indicates formaldehyde is used in pesticides, disinfectants, resins, plastics, fertilizers, foam insulation, textile finish, preservatives, stabilizers, food additives, embalming fluids, brightening agent, chemical production, and for several other purposes (Hazardous Substance Data Bank [HSDB], 2010).

3. Toxicity

(Note: This section includes examples of toxicity information. This summary is not intended to be comprehensive.)

a. Environmental Protection Agency

Integrated Risk Information System (IRIS)

In June 2010, IRIS published draft candidate Reference Concentrations (RfC) and a carcinogenicity characterization for formaldehyde. The draft document containing this information is under review. Reference Dose (RfD) and carcinogenicity information were available in IRIS from prior work.

Oral Reference Dose:

2×10^{-1} mg/kg/day (reduced weight gain – histopathology)

Uncertainty Factor: 100 (EPA, 1990)

Cancer: B1 Probable human carcinogen (EPA, 1991)

Candidate Reference Concentrations (range: draft only)

2.8 – 11 ppb

Uncertainty Factor: to be determined (EPA, 2010b)

b. National Institutes of Health

National Toxicology Program (NTP)

The NTP listed formaldehyde as “reasonably anticipated to be a human carcinogen” in 1981 (NTP, 2005), and is currently evaluating a possible change in classification to “known to be a human carcinogen” (NTP, 2010). NTP has assembled a background document on formaldehyde as part of this process, available at http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/November/Formaldehyde_BD_Final.pdf. Formaldehyde is also noted as an eye, respiratory, and skin irritant, and a skin sensitizer.

c. World Health Organization

International Agency for Research on Cancer (IARC)

In 2006, IARC published “IARC Monographs of the Evaluation of Carcinogenic Risks to Humans. Formaldehyde, 2-Butoxyethanol, and 1-tert-Butoxypropan-2-ol” (IARC, 2006). This document contains an overview of the toxicity of formaldehyde, including carcinogenic effects, and classifies formaldehyde as a Group 1 carcinogen.

4. Statutory Requirements

The table and information summary below provide some of the current information about formaldehyde and indicates how it meets the criteria of Minn. Stat. 116.9401 – 116.9407.

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity		
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	<p>EPA IRIS: B1: Probable human carcinogen</p> <p>IARC: Group I: Sufficient evidence in humans for the carcinogenicity of formaldehyde.</p> <p>NTP: Reasonably anticipated to be a human carcinogen</p> <p><i>Note: There is a proposal for NTP to change its rating of formaldehyde to: “Known to be a human carcinogen.”</i></p> <p>Reproductive effects</p>	<p>EPA 1991</p> <p>IARC 2006</p> <p>NTP 2005 NTP 2010</p> <p>EPA 2010b</p>
Subd. (e)(3) disrupt the endocrine or hormone system		

Statute	Information	References
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Nervous system effects	ATSDR 1999 EPA 2010b
	Eye irritation	ATSDR 1999 EPA 2010b
	Respiratory effects	ATSDR 1999 EPA 2010b NTP 2010
	Skin irritation, skin sensitization	ATSDR 1999 NTP 2010
	Immune system effects	IARC 2006 EPA 2010b NTP 2010
Subd. (e)(5) be persistent, bioaccumulative, and toxic;		
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	1 billion pounds or more	EPA 2010b
Subd (2) Meets any of the following criteria:		
Subd. (a)(2)(i): the chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine, or other bodily tissues or fluids		
Subd. (a)(2)(ii): the chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment	Indoor air	ATSDR 1999 EPA 2010b HSDB 2010
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Found in ambient air	ATSDR 1999 EPA 2010b HSDB 2010

5. Current Regulations and Planned Actions

a. Federal

(1) Consumer Product Safety Commission (CPSC)

Because urea-formaldehyde insulation can off-gas formaldehyde in the first months after being installed, in 1982 the CPSC voted to ban this type of insulation in the U.S. The ban was repealed by the courts in 1983 (CPSC, 1997). The CPSC continues to provide information to consumers about safe levels of formaldehyde.

(2) Environmental Protection Agency

Pressed or composite woods can off-gas formaldehyde into the indoor environment. Manufacturers have reduced the amount of formaldehyde released from pressed wood products when compared to products from several decades ago.

The amount of formaldehyde released from many of these products should decline even further after the implementation of the Formaldehyde Standards for Composite Wood Products Act, which was signed into law in 2010 and will be implemented in stages during the next few years. Under the new regulation, both domestically manufactured and imported composite wood will need to comply with formaldehyde emissions standards. The emission limits vary based on the type of wood used in the product. The Act contains requirements similar to the State of California Air Resources Board standards. Because most U.S. manufacturers were already in compliance with the California requirements, many welcomed the new legislation as a way to equalize the requirements for domestic and imported composite wood products (Composite Panel Association, 2009).

This new law will require EPA to create rules under the Toxic Substances Control Act (TSCA) to test and certify standards in manufacturing facilities and products.

b. States

Examples of state-level regulations: Information for states was obtained from the Lowell Center for Sustainable Production's U.S. State Chemicals Policy database, available from <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>. (The information below is not intended to be comprehensive.)

Minnesota

Year: 1994

Health Risk Limit for Formaldehyde: 1000 µg/L (in groundwater) (MDH, 2010b)

Year: 2002

Acute Health Risk Value for Formaldehyde: 94 µg/m³ (in air) (MDH, 2010a)

Year: 2006

Chronic Risk Assessment Advice: 2 µg/m³ (in air) (MDH, 2006)

California

Year: 2007

Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products - 2007

This law establishes limits on the amount of formaldehyde that can be emitted from composite wood products.

California Inhalation Reference Exposure Level for formaldehyde: 2 ppb

Massachusetts

Year: 1960

A law requires urea-formaldehyde foamed in place insulation to be banned from commerce.

New Hampshire:

Year: 1965

A law bans urea-formaldehyde foam insulation and requires that particle board manufactured with urea-formaldehyde or homes manufactured with urea-formaldehyde not be sold without a cautionary warning.

Washington

Year: 2010

Under the Children's Safe Product Act, formaldehyde was named a Chemical of High Concern for Children. Washington plans to implement reporting requirements for manufacturers related to this designation (Washington, 2010).

6. Conclusion

Because formaldehyde causes respiratory effects, is a carcinogen, and there is potential that children will be exposed to it in the home, MDH is naming formaldehyde a Priority Chemical.

7. References

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