

US EPA ARCHIVE DOCUMENT

Formaldehyde

TEACH Chemical Summary



U.S. EPA, Toxicity and Exposure Assessment for Children's Health

This TEACH Chemical Summary is a compilation of information derived primarily from U.S. EPA and ATSDR resources, and the TEACH Database. The TEACH Database contains summaries of research studies pertaining to developmental exposure and/or health effects for each chemical or chemical group. TEACH does not perform any evaluation of the validity or quality of these research studies. Research studies that are specific for adults are not included in the TEACH Database, and typically are not described in the TEACH Chemical Summary.

I. INTRODUCTION

Formaldehyde is a colorless flammable gas with a pungent odor, and is highly reactive with many substances (1-3). Formalin is a solution of formaldehyde gas in water, and formalin is used as a disinfectant and as a preservative of biological samples (1-4). Formaldehyde is also used as a chemical intermediate in industry (1). Formaldehyde occurs in many biological systems as a metabolic by-product (1). Formaldehyde is also commonly found in household products, e.g., pressed wood products that contain urea-formaldehyde resins, carpeting, foam insulation (prior to 1982), cosmetics, nail hardeners, some finger paints, and some cleaning products (1-4). Formaldehyde is also a component of cigarette smoke (1-4). Formaldehyde has been found in industrial exhaust, and is used in some sterilizing and preserving solutions in medical and school settings (1-3).

Although there is some concern about childhood dermal exposure, the dominant pathway of childhood exposure to formaldehyde is from ambient and indoor air, particularly in homes with new cabinets made of pressed wood products or new carpeting (1). Concentrations of formaldehyde in ambient air may be of concern in several areas of the U.S. (5-10).

The primary targets affected by formaldehyde exposure are the lungs and mucous membranes (eyes, nose, and mouth) (1-3). Occupational studies have demonstrated that adult exposure to formaldehyde is associated with naso/pharyngeal cancers and possibly with leukemia (1, 3). Formaldehyde is classified as a probable human carcinogen by the U.S. EPA (11), and as carcinogenic to humans by the World Health Organization (3). In studies of children, exposure to formaldehyde was associated with irritation of the respiratory tract (12-17), skin (18-21), and eyes (22). Formaldehyde exposure of children has also been associated with formaldehyde-specific immunoglobulin (Ig)E antibody production (22, 23).

Supporting references and summaries are provided in the TEACH database at: <http://www.epa.gov/teach/>.

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II. EXPOSURE MEDIA AND POTENTIAL FOR CHILDREN'S EXPOSURE¹

Exposure Media	Relative Potential for Children's Exposure ^{2,3}	Basis ⁴
Ambient Air	Higher	Concentrations of formaldehyde in ambient air may be of concern in several areas in the U.S. (see Considerations for Decision Making). Background levels of formaldehyde exceeded the U.S. EPA Air Concentration at Specified Risk Level of 1 in one million in over 90% of census tracts analyzed from 1996 emissions data. Major sources of formaldehyde in ambient air include emissions from power plants, manufacturing facilities, and incinerators; and mobile sources such as cars, trucks, and construction equipment.
Indoor Air	Higher	Formaldehyde contamination of indoor air can result from off-gassing of certain building materials (e.g., some forms of particle board and other pressed wood products; new carpeting), and from mainstream and second-hand cigarette smoke. For those reasons, indoor levels of formaldehyde can be substantial, even in non-smoking homes. Formaldehyde is also used in medical settings, and in preservatives of biological samples often in school settings.
Diet	Lower	Formaldehyde has been found at low levels in some foods, but diet is not a major source of exposure.
Sediment	Lower	Formaldehyde is not generally found in sediment.
Soil	Lower	Formaldehyde is not generally found in soil.
Drinking Water	Lower	Formaldehyde is not generally found in drinking water.
Ground and Surface Water	Lower	Formaldehyde is not generally found in surface or groundwater.

¹ For more information about child-specific exposure factors, please refer to the "Child-Specific Exposure Factors Handbook" (<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55145>).

² The Relative Potential for Children's Exposure category reflects a judgment by the TEACH Workgroup, U.S. EPA, that incorporates potential exposure pathways, frequency of exposure, level of exposure, and current state of knowledge. Site-specific conditions may vary and influence the relative potential for exposure. For more information on how these determinations were made, go to http://www.epa.gov/teach/teachprotocols_chemsumm.html.

³ Childhood represents a lifestage rather than a subpopulation, the distinction being that a subpopulation refers to a portion of the population, whereas a lifestage is inclusive of the entire population.

⁴ Information described in this column was derived from several resources (e.g., 1-4) including studies listed in the TEACH Database (<http://www.epa.gov/teach>).

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III. TOXICITY SUMMARY^{5, 6}

Adult epidemiological studies have found formaldehyde to be significantly associated with cancer of the respiratory tract, including nasopharyngeal (nose/throat) cancer (1, 2). The World Health Organization (WHO) International Agency for Research on Cancer (IARC) reported “strong but not sufficient evidence for a causal association between leukemia and occupational exposure to formaldehyde” (2). Formaldehyde exposure has also been associated with inflammation and toxicity of the gastrointestinal tract in adults (1).

In children, inhalation exposure to formaldehyde were associated with irritation of the respiratory tract (12-17, 22), asthma (12, 13, 15), and irritation of eyes (22). Dermal exposure via patch tests have resulted in skin irritation (positive patch test result), possibly mediated by an allergic response (18-21). One study in rats reported that formaldehyde was found to be teratogenic for fetuses from inhalation-exposed, iron-deficient pregnant mothers (24).

Carcinogenicity Weight-of-Evidence Classification⁷: Formaldehyde is classified by the U.S. EPA as B1, a probable human carcinogen, based on site-specific neoplasms (tumors) of the respiratory tract in workers who were occupationally exposed to formaldehyde, and nasal squamous cell carcinomas in rats and mice (<http://www.epa.gov/iris/subst/0419.htm>, II.A.1) (11). The WHO IARC classified formaldehyde as carcinogenic to humans (Group 1) (<http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf>) (2).

⁵ Please refer to research article summaries listed in the TEACH Database for details about study design considerations (e.g., dose, sample size, exposure measurements).

⁶ This toxicity summary is likely to include information from workplace or other studies of mature (adult) humans or experimental animals if child-specific information is lacking for the chemical of interest. Summaries of articles focusing solely on adults are not listed in the TEACH Database because the TEACH Database contains summaries of articles pertaining to developing organisms.

⁷ For recent information pertaining to carcinogen risk assessment during development, consult “Guidelines for Carcinogen Risk Assessment and Supplemental Guidance on Risks from Early Life Exposure” at <http://www.epa.gov/cancerguidelines>.

IV. EXPOSURE AND TOXICITY STUDIES FROM THE TEACH DATABASE

This section provides a brief description of human and animal studies listed in the TEACH Database. These descriptions generally include the overall conclusion in each study without evaluation or assessment of scientific merit by TEACH. For more details about doses and exposure levels, query the TEACH Database. Any consideration of adverse events should include an understanding of the relative exposure on a body weight basis. In many cases, exposure levels in animal studies are greater than exposure levels normally encountered by humans.

A. HUMAN EXPOSURE AND EFFECTS

- ▶ Childhood exposure to formaldehyde in air may be common. Sampling of air in schools and homes showed measurable levels of formaldehyde (5, 8, 14, 15, 25-31). A survey of formaldehyde sampling in New York City showed levels in air inside homes of nonsmoking families exceeded levels in outdoor air (15). Daily formaldehyde intake for individuals in homes with people who smoke was estimated to be 30-67 μg , based on indoor air formaldehyde concentrations in those homes (30). A study of indoor, outdoor, and personal air samples (collected from individuals' breathing zone) in Mexico City indicated that 100% of samples were positive for formaldehyde; concentrations in indoor air and personal air samples were significantly higher than in outdoor air samples (31).
- ▶ Two studies showed an increased rate of miscarriage in women exposed to formaldehyde (32, 33), although in both studies the women may have been exposed to multiple chemicals. No increased rate of miscarriage was seen in two other occupational exposure studies of medical personnel (34, 35).
- ▶ Formaldehyde is an irritant which can elicit adverse respiratory responses in children and adults (12-17, 22). Additional health effects in children associated with formaldehyde exposure include irritation to eyes and skin (18-22). In elementary school environments, symptoms of mucous membrane irritation in adults who worked there were associated with elevated formaldehyde levels in indoor air (14, 29). One study of children in China found no significant association between formaldehyde air concentrations (up to 20 $\mu\text{g}/\text{m}^3$) and symptoms of respiratory irritation (36). Irritation of mucous membranes of the gums and mouth were reported following contact formaldehyde exposure at these sites (37). In the U.S., 6,358 cases of formalin exposure of children ages 13-19 years old, and 1,855 cases of children less than 13 years old, were reported to poison control centers in 1996-2001 (38).
- ▶ Immune system effects of formaldehyde exposure have been studied in children. Two children's studies have detected formaldehyde-specific IgE antibodies in their blood (22, 23). One study provided suggestive evidence that children may have an increased tendency to develop specific antibodies to formaldehyde after exposure to low levels of formaldehyde in indoor air (22). Another study found that atopic children (children with multiple allergies) may be more vulnerable to the irritant effects of formaldehyde exposure when compared to the general childhood population (13). There was no association between formaldehyde exposure and increased antibody production among children with asthma in one study (39). Furthermore, the presence of formaldehyde-specific IgE antibodies to formaldehyde was not associated with incidence of asthma in another study (23).

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- ▶ Some studies of formaldehyde exposure found no health effects in children. In one study, there was no difference in the incidence of respiratory irritation in children living close to a foundry that used formaldehyde, as compared to children living further away from the foundry (40). In another study, no significant differences in respiratory irritation were measured between children living in homes with urea/formaldehyde foam insulation, and children living in homes without such insulation (41).

B. EXPERIMENTAL ANIMAL EXPOSURE AND EFFECTS

- ▶ Adult male sperm quantity and quality was decreased following inhalation exposure of rats during adulthood; co-treatment with vitamin E offered some protective effects (42).
- ▶ The nutritional status of exposed pregnant rats may influence the effects of inhalation exposure to formaldehyde on fetal health. One study reported that inhalation exposure of pregnant iron-deficient rats to formaldehyde resulted in a greater incidence of malformations in fetuses, as compared to pregnant iron-sufficient control rats (24).
- ▶ There was no observed increase in resorption (death) of fetuses or fetal malformations following formaldehyde ingestion exposure in mice (43), inhalation exposure in rats (44), or dermal exposure in hamsters (45).
- ▶ One study reported changes in a region of the brain following neonatal inhalation exposure of rats to formaldehyde from birth for 30 days, and some of these changes were significant in adulthood, after formaldehyde exposure was stopped (46). This study reported significantly increased volume of the dentate gyrus region of the brain at 30 days of age, and significantly decreased numbers of granule cells in this region at 90 days of age (adulthood) (46).

V. CONSIDERATIONS FOR DECISION-MAKERS

This section contains information that may be useful to risk assessors, parents, caregivers, physicians, and other decision-makers who are interested in reducing the exposure and adverse health effects in children for this particular chemical. Information in this section focuses on ways to reduce exposure, assess possible exposure, and, for some chemicals, administer treatment.

- ▶ A detailed compilation of information pertaining to exposure and health effects of formaldehyde is available from the U.S. Centers for Disease Control Agency for Toxic Substances and Disease Registry in the Toxicological Profile for Formaldehyde (1). A Hazard Summary for Formaldehyde is also available from the U.S. EPA (4).
- ▶ The U.S. Consumer Product Safety Commission provides a summary of information on formaldehyde, and includes recommendations for avoiding and reducing exposure to formaldehyde in the home (47). Recommendations include purchasing wood products labeled to be in conformance with American National Standards Institute (ANSI) criteria for formaldehyde emissions (labeled as ANSI grades PBU, D2, or D3 on the wood panel itself), increasing ventilation in the home by opening doors and windows, and installing exhaust fans.

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- ▶ Information about indoor air quality, and recommendations for ways to reduce exposure to formaldehyde indoors are available from the U.S. EPA (48). Recommendations include 1) use "exterior-grade" pressed wood products (lower-emitting because they contain phenol resins, not urea resins); 2) use air conditioning and dehumidifiers to maintain moderate temperatures and reduce humidity levels; and 3) increase ventilation, particularly after bringing new sources of formaldehyde into the home.
- ▶ The U.S. EPA performed statewide estimates of formaldehyde-modeled ambient air concentrations for all 50 states (5-7, 9, 10). Using emissions data from 1990 (5), estimated concentrations of formaldehyde across the U.S. exceeded the U.S. EPA Air Concentration at Specified Risk Level of $1\text{E-}6$ ($0.08\ \mu\text{g}/\text{m}^3$; see Toxicity section) in over 90% of the census tracts analyzed. More recent information is available based on the 1999 national-scale assessment, reported on a regional basis (6, 9, 10). The U.S. EPA concluded from 1999 results that ambient air concentrations of formaldehyde in some regions may be of concern (i.e., more than 10,000 people living in census tracts where the typical exposure exceeded the reference concentration for formaldehyde) (9, 10). Using the current IRIS cancer potency estimate and the 1999 air toxics assessment, the U.S. EPA concluded that formaldehyde would be considered a national risk driver for cancer (upper bound lifetime cancer risk exceeding 10 in a million to more than 25 million people), as it was in the 1996 national-scale assessment (10).
- ▶ Formaldehyde is listed as number 247 out of 275 substances on the 2005 Priority List of Hazardous Substances for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 104 (i), as amended by the Superfund Amendments and Reauthorization Act (SARA). This is a prioritized list ranking chemicals in order of concern for those most commonly found at sites listed on the National Priorities list (NPL) (49).
- ▶ Consult the "Child-Specific Exposure Factors Handbook," EPA-600-P-00-002B, for factors to assess children's inhalation rates (50). An updated External Draft of the 2006 version of this handbook is available (51).

VI. TOXICITY REFERENCE VALUES

A. Oral/Ingestion

U.S. EPA Reference Dose (RfD) for Chronic Oral Exposure: $2\text{E-}1$ (or 0.2) mg/kg-day, based on reduced weight gain and histopathology of the gastrointestinal tract in adult rats (www.epa.gov/iris/subst/0419.htm, I.A.1) (11); last Workgroup Verification Date 6/20/90.

U.S. EPA Drinking Water Advisories (10 kg child): 1 day = 10 mg/L, 10 day = 5 mg/L (<http://www.epa.gov/waterscience/criteria/drinking/standards/dwstandards.pdf>) (52); last revised Winter, 2006.

U.S. ATSDR Minimal Risk Level (MRL) Oral: 0.3 mg/kg/day (intermediate oral), based on gastrointestinal effects; 0.2 mg/kg/day (chronic oral), based on gastrointestinal effects (<http://www.atsdr.cdc.gov/mrls/index.html>) (53); last revised 7/99.

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B. Inhalation

U.S. EPA Cancer Inhalation Exposure Air Unit Risk: 1.3E-5 (or 0.000013) per ($\mu\text{g}/\text{m}^3$), based on nasal squamous cell carcinomas in adult male rats, using extrapolation methods of linearized multistage procedure, extra risk (<http://www.epa.gov/iris/subst/0419.htm#quainhal>, II.C) (11); last Workgroup Verification Date 2/3/88.

U.S. EPA Air Concentrations at Specified Risk Levels: 1E-4 (or 1 in 10,000), 8E+0 (or 8.0) $\mu\text{g}/\text{m}^3$; 1E-5 (or 1 in 100,000), 8E-1 (or 0.8) $\mu\text{g}/\text{m}^3$; 1E-6 (or 1 in 1,000,000), 8E-2 (or 0.08) $\mu\text{g}/\text{m}^3$ (<http://www.epa.gov/iris/subst/0419.htm#quainhal>, II.C) (11); last Workgroup Verification Date 2/3/88.

U.S. ATSDR Minimal Risk Level (MRL) Inhalation: 0.04 ppm (acute inhalation), based on respiratory effects; 0.03 ppm (intermediate inhalation), based on respiratory effects; 0.008 ppm (chronic inhalation), based on respiratory effects (<http://www.atsdr.cdc.gov/mrls/index.html>) (53); last revised 7/99.

VII. U.S. FEDERAL REGULATORY INFORMATION

- ▶ Urea-formaldehyde foam was used as an insulating material until 1982, when it was banned by the U.S. Consumer Product Safety Commission. The ban was overturned in the courts, but the action greatly reduced the use of this foam in residential products (47).
- ▶ The U.S. EPA IRIS is currently reviewing toxicity values for formaldehyde, and review progress is published (54).
- ▶ The U.S. EPA Office of Pesticide Programs is currently preparing a Reregistration Eligibility Decision (RED) for formaldehyde; a RED is a complete review of the human health and environmental effects of pesticides first registered before November 1, 1984, to make decisions about future pesticide uses of formaldehyde (55).
- ▶ Formaldehyde is one of 188 hazardous air pollutants (HAPs) listed under section 112(b) of the 1990 Clean Air Act Amendments, and is regulated from more than 170 industrial source categories (56).
- ▶ The U.S. Food and Drug Administration (FDA) regulates formaldehyde as a food additive (used as a defoaming agent, and in the feed of animals used for food sources including some chicken and fish) (57).
- ▶ The U.S. EPA requires reporting of quantities of certain chemicals that exceed a defined reportable quantity, and that quantity varies for different chemicals. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 "Toxic Chemicals," quantities of formaldehyde greater than 25,000 pounds manufactured or processed, or greater than 10,000 pounds otherwise used, is required; under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), reporting releases of formaldehyde of any quantity exceeding 100 pounds is required (58).

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VIII. BACKGROUND ON CHEMICAL

A. CAS Number: 50-00-0

B. Physicochemical Properties: Formaldehyde is a colorless flammable gas, or gas dissolved in water (as formalin) with a pungent odor, and is highly reactive with many substances (1, 3). For more information, go to the National Library of Medicine ChemID Web site (<http://chem.sis.nlm.nih.gov/chemidplus>) and search for formaldehyde.

C. Production: Commercial formaldehyde is produced and sold as an aqueous solution containing 37 to 50 percent formaldehyde by weight. The annual production varied from 6.4 to 8.1 billion pounds per year between 1991-1995 in the U.S. (1). Formaldehyde occurs in industrial effluents (1, 59). The major sources of formaldehyde emissions into outdoor air are from power plants, manufacturing facilities, incinerators, and automobile exhaust. Cigarette smoke is another important source of formaldehyde. Formaldehyde may also be present in food, either naturally, as an additive, or as a result of contamination (1, 3, 57).

D. Uses: Formaldehyde is used predominantly as a chemical intermediate in industrial processes (1, 3). It also has minor uses in agriculture, concrete and plaster additives, cosmetics, disinfectants, fumigants, photography, and wood preservation. Formaldehyde is used in the manufacture of plastics, amino and phenolic resins used in construction materials, paper, carpets, textiles, paint, particle board, and plywood. Total TRI reported disposals and releases of formaldehyde in 2005 were over 22 million pounds; these releases are likely representative of only a portion of actual releases because only some facilities (i.e., landfills) are required to report to the U.S. EPA (59).

E. Environmental Fate: Formaldehyde in air is readily broken down by sunlight, with a half-life of approximately 30-50 minutes (3). Formaldehyde in liquid form (formalin) is stable over time (1, 3).

F. Synonyms and Trade Names: BFV, 1 FA, Fannoform, Floguard 1015, FM 282, Formalin, Formalin 40, Formalith, Formic aldehyde, Formol, Fyde, Hoch, Ivalon, Karsan, Lysoform, Methaldehyde, Methyl aldehyde, Methyl oxide, Methylene oxide, Morbicid, Oxomethane, Oxymethylene, Paraform, Superlysoform (for a more complete list, go to the National Library of Medicine ChemID Web site (<http://chem.sis.nlm.nih.gov/chemidplus>) and search for formaldehyde).

Additional information on formaldehyde is available in the TEACH Database for Formaldehyde, and at the following Web sites:

<http://www.epa.gov/iaq/formalde.html>

<http://www.surgeongeneral.gov/library/secondhandsmoke/>

www.atsdr.cdc.gov/toxprofiles/tp111.pdf

www.epa.gov/ttn/atw/nata/

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