

7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding formaldehyde in air, water, and other media are summarized in Table 7-1.

ATSDR has derived an acute inhalation MRL of 0.04 ppm on the basis of clinical symptoms (increased itching, sneezing, mucosal congestion, transient burning sensation of the eyes and of the nasal passages) and nasal alterations (elevated eosinophil counts and a transient increase in albumin content of nasal lavage fluid) in humans (Pazdrak et al. 1993). This MRL is based on a minimal LOAEL of 0.4 ppm and an uncertainty factor of nine (three for use of a minimal LOAEL and three for human variability).

An intermediate-duration inhalation MRL of 0.03 ppm was derived based on a NOAEL of 0.98 ppm and a LOAEL of 2.95 ppm (22 hours/day, 5 days/week for 26 weeks) for clinical signs of nasopharyngeal irritation (hoarseness and nasal congestion and discharge) and lesions in the nasal epithelium (squamous metaplasia and hyperplasia) observed in monkeys (Rusch et al 1983). An uncertainty factor of 30 (3 for extrapolation from animals to humans and 10 for human variability) was used to derive the MRL.

A chronic inhalation MRL of 0.008 ppm was derived based on a minimal LOAEL of 0.24 ppm for histological evidence of mild damage to the nasal epithelial tissue (squamous metaplasia, loss of ciliated cells, goblet cell hyperplasia, and mild dysplasia in biopsied tissue) in formaldehyde exposed chemical workers (Holmstrom et al. 1989c). To derive the MRL, the minimal LOAEL was divided by an uncertainty factor of 30 (3 for the use of a minimal LOAEL and 10 for human variability).

An intermediate oral MRL of 0.3 mg/kg/day was based on a NOAEL and LOAEL of 25 and 125 mg/kg/day for gastrointestinal tract effects in rats exposed for 4 weeks to formaldehyde in drinking water (Til et al. 1988b). An uncertainty factor of 100 (10 for extrapolation from animals to humans and 10 for human variability) was applied to the NOAEL to derive the MRL.

ATSDR derived a chronic oral MRL of 0.2 mg/kg/day based on a NOAEL and LOAEL of 15 and 82 mg/kg/day for gastrointestinal tract effect in rats exposed for up to 2 years to formaldehyde in drinking water (Til et al. 1989). An uncertainty factor of 100 (10 for extrapolation from animals to humans and 10 for human variability) was applied to the NOAEL to derive the MRL.

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde

Agency	Description	Information	References	
<u>INTERNATIONAL</u>				
Guidelines:				
IARC	Carcinogenic classification	Group 2A ^a	IARC 1995	
WHO	Drinking-water guideline values for health-related organics	None	WHO 1984	
<u>NATIONAL</u>				
Regulations:				
a. Air:				
OSHA	Permissible Exposure Limit (PEL) 8-hr. Time weighted average (TWA) 15-min. Short-term exposure limit (STEL)	0.75 ppm	29 CFR 1910.1048 OSHA 1992	
		2 ppm		
EPA-OAR	Standards of Performance for New Stationary Sources	Hazardous Air Pollutants	Yes	Clean Air Act Amendment Title III, Section 112 (b) U.S. Congress 1990
		Equipment Leaks of VOCs in the Synthetic Organic Chemicals Manufacturing Industry (SOCMI)	Yes	40 CFR 60.489 EPA 1983a
		VOC Emissions from SOCMI Air oxidation unit processes-chemicals affected	Yes	40 CFR 60.617 EPA 1990a
		VOC Emissions from SOCMI Distillation operation-chemical affected	Yes	40 CFR 60.667 EPA 1990b
		VOC Emissions from SOCMI Reactor processes-chemicals affected	Yes	40 CFR 60.707 EPA 1993a
		National Emission Standards for Organic Hazardous Air Pollution from the Synthetic Organic Chemical Manufacturing Industry-Delegation of Authority	Yes	40 CFR 63.106 EPA 1994a
		Chemical Accident Prevention Provisions-Regulated Toxic Substances and Threshold Quantities for Accidental Release Prevention-Formaldehyde Solution	15,000 pounds	40 CFR 68.130 EPA 1994b

Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
EPA-OAR	Regulation of Fuels and Fuel Additives-Reformulated Gasoline-Simple Emission Model	Yes	40 CFR 80.42 EPA 1994c
	Complex emissions models; baseline exhaust emission	Phase I Summer Winter <u>(mg/mile)</u> 4.85 7.27	40 CFR 80.45 EPA 1994d
		Phase II Summer Winter <u>(mg/mile)</u> 9.38 15.84	
	Vehicle test procedures	Yes	40 CFR 80.51 EPA 1994e
	Measurement methods for formaldehyde and acetaldehyde	Yes	40 CFR 80.56 EPA 1994f
	Conventional gasoline baseline emissions determinations	Yes	40 CFR 80.90 EPA 1994g
	Control of Air Pollution from New and In-use Motor Vehicles and New and In-use Motor Vehicle Engines-Certification and Test Procedures	Yes	40 CFR 86 EPA 1977a
	NESHAP for Source Category; Pulp and Paper Production (proposed rule)	Yes	58 FR 66078 EPA 1993b
	List of Regulated Substances and Thresholds for Accidental Release Prevention (proposed rule)	500 pounds (threshold)	58 FR 5102 EPA 1993c
	Control of Air Pollution from New and In-use Motor Vehicles and engines; Technical Amendments to the Test Procedures for Methanol-fueled Motor Vehicles and Motor Vehicle Engines and Petroleum-fueled Motor Vehicles (proposed rule)	Yes	58 FR 11816 EPA 1993d
HAP: Proposed Regulations Governing Constructed, Reconstructed or Modified Major Sources (proposed rule)	Yes	59 FR 15504 EPA 1994h	
b. Water			
EPA-OW	Designation of Hazardous Substances-List of Hazardous Substances, Table 116.4	Yes	40 CFR 116.4 EPA 1978

NATIONAL (cont.)

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
	Determination of Reportable Quantities for Hazardous Substances- RQ Pursuant to Section 311 CWA, Table 117.3	100 pounds	40 CFR 117.3 EPA 1985b
	EPA Permit Programs: NPDES-Toxic Pollutants and Hazardous Substances Required to be Identified by Existing Dischargers if Expected to be Present, Table V	Yes	40 CFR 122, App. D EPA 1983b
	Criteria and Standards for the NPDES-Instructions for Form 2C, Application for Permit to Discharge Wastewater	Yes	40 CFR 125 EPA 1984
	Organic Chemicals, Plastics, and Synthetic Fibers		
	Commodity organic chemicals (applicability)	Yes	40 CFR 414.60 EPA 1987a
c. Food:			
FDA	Indirect Food Additives: Adhesives and Components of Coatings	Yes	21CFR 175.105 FDA 1977a
	Indirect Food Additives: Paper and Paperboard		
	Components of paper and paperboard in contact with aqueous and fatty foods	Yes	21 CFR 176.170 FDA 1977 b
	Components of paper and paperboard in contact with dry food	Yes	21 CFR 176.180 FDA 1977c
d. Other:			
EPA-OERR	List of Hazardous Substances and Reportable Quantities	1000 pounds (453.6 kg) (statutory)	40 CFR 302.4 EPA 1985a
		100 pounds (45.4 kg) (final RQ)	
EPA-OSW	Identification and Listing of Hazardous Waste		
	Definition of a Hazardous Waste	Yes	40 CFR 261.3 EPA 1992a
	Discarded commercial chemical products, off-specification, container residues, and spills	Yes	40 CFR 261.33 EPA 1980

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
	Basis for listing hazardous wastes-constituent for listing (K010)	Yes	40 CFR 261, App. VII EPA 1981
	Basis for listing - hazardous constituent (U122)	Yes	40 CFR 261, App. VIII EPA 1988b
	Standards for Management of Specific Hazardous Wastes Facilities		
	Regulation of residues	Yes	40 CFR 266.112 EPA 1985c
	Methods Manual for Compliance with BIF Regulations (Method 0011A, Analysis of Aldehydes and Ketones by High Performance Liquid Chromatography)	Yes	40 CFR 266, App. IX EPA 1991b
	Land Disposal Prohibition and Establishment of Treatment Standards-Waste to be evaluated by 8/8/88	Yes	40 CFR 268.10 EPA 1986a
	Treatment Standards-Applicability	Yes	40 CFR 268.4 EPA 1987b
	Emergency Planning and Notification-Extremely Hazardous Substances and Their Threshold Planning Quantities	100 pounds (RQ) 500 pounds (threshold)	40 CFR 355, App. A EPA 1987c
	Toxic Chemical Release Reporting: Community Right-to-Know--Specific Chemical Listing-Chemicals and Chemical Categories	Yes	40 CFR 372.65 EPA 1988c
	Hazardous Waste Management System; Carbamate Production Identification and Listing of Hazardous Waste and CERCLA Hazardous Substance Designation and Reportable Quantities (notice of proposed rulemaking-K157 waste)	1 pound (statutory RQ)	59 FR 9808 EPA 1994i
	Land Disposal Restrictions for Newly Identified and Listed Hazardous Wastes and Hazardous Soil	Yes	62 FR 7502 EPA 1997

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
	Treatment standards, U122 waste	<u>Wastewater</u> WETXO or CHOXD; CARBN; or INCIN <u>Nonwastewater</u> CMBST	
Guidelines:			
a. Air:			
ACGIH	Ceiling Limit for Occupation Exposure (TLV-STEL)	0.3 ppm (0.37 mg/m ³)	ACGIH 1998
NIOSH	Recommended Exposure Limit for Occupation Exposure (8-hr TWA)	0.016 ppm	NIOSH 1992
	Recommended Exposure Limit for Occupation Exposure (15-min Ceiling)	0.1 ppm	
	Immediately Dangerous to Life and Health	20 ppm	
b. Water:			
EPA	1-d Health Advisory (child)-draft	10 mg/L	EPA 1995; IRIS 1999
	10-d Health Advisory (child)-draft	5 mg/L	
	Lifetime Health Advisory (adult)-draft	1 mg/L	
	Longer-term Health Advisory-draft	5 mg/L (child) 20 mg/L (adult)	
d. Other:			
ACGIH	Group (Cancer Ranking)	A2 ^b	ACGIH 1998
EPA	Cancer Classification	B1 ^c	IRIS 1999
	RfD	0.2 mg/kg/day	
NIOSH	Cancer Classification	Ca ^d	NIOSH 1992, 1994c
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:			
	Average Acceptable Ambient Air Concentrations		EPA 1992c
AZ	1 hour	2x10 ¹ µg/m ³	
	24 hours	1.2x10 ¹ µg/m ³	

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
<u>STATE</u> (cont.)			
	Annual	$8 \times 10^{-2} \mu\text{g}/\text{m}^3$	
CT	8 hours	$1.2 \times 10^1 \mu\text{g}/\text{m}^3$	
FL-FtLdle	8 hours	$1.5 \times 10^{-2} \mu\text{g}/\text{m}^3$	
FL-Pinella	8 hours	$4.5 \mu\text{g}/\text{m}^3$	
	24 hours	$1.8 \mu\text{g}/\text{m}^3$	
	Annual	$7.7 \times 10^{-2} \mu\text{g}/\text{m}^3$	
IN	8 hours	$6 \mu\text{g}/\text{m}^3$	
	Annual	$7.7 \times 10^{-2} \mu\text{g}/\text{m}^3$	
IN-Innap	8 hours	$1.8 \times 10^1 \mu\text{g}/\text{m}^3$	
KS	Annual	$7.69 \times 10^{-2} \mu\text{g}/\text{m}^3$	
KS-KC	Annual	$7.69 \times 10^{-2} \mu\text{g}/\text{m}^3$	
LA	Annual	$7.69 \mu\text{g}/\text{m}^3$	
MA	24 hours	$3.3 \times 10^{-1} \mu\text{g}/\text{m}^3$	
	Annual	$8 \times 10^{-2} \mu\text{g}/\text{m}^3$	
ME	15 minutes	$6.7 \times 10^1 \mu\text{g}/\text{m}^3$	
	1 year	$4 \times 10^{-2} \mu\text{g}/\text{m}^3$	
MI	Annual	$8 \times 10^{-2} \mu\text{g}/\text{m}^3$	
NC	15 minutes	$1.5 \times 10^{-1} \mu\text{g}/\text{m}^3$	
NC-Forco	15 minutes	$1.5 \times 10^1 \mu\text{g}/\text{m}^3$	
ND	NA	BACT	
NV	8 hours	$7.1 \times 10^{-2} \mu\text{g}/\text{m}^3$	
NY	1 year	$5 \times 10 \mu\text{g}/\text{m}^3$	
OK	24 hours	$1.2 \times 10^1 \mu\text{g}/\text{m}^3$	
PA-Phil	1 year	$7.2 \mu\text{g}/\text{m}^3$	
	Annual	4.82 ppb	
SC	24 hours	$7.5 \mu\text{g}/\text{m}^3$	
SD	8 hours	$1.2 \times 10^1 \mu\text{g}/\text{m}^3$	
TX	30 minutes	$1.5 \times 10^1 \mu\text{g}/\text{m}^3$	
	Annual	$1.5 \mu\text{g}/\text{m}^3$	
VA	24 hours	$1.2 \times 10^1 \mu\text{g}/\text{m}^3$	
VT	Annual	$8 \times 10^{-2} \mu\text{g}/\text{m}^3$	
WA-Olympia		$5 \times 10^{-2} \text{ppm}$	
<u>STATE</u> (cont.)			

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Table 7-1. Regulations and Guidelines Applicable to Formaldehyde (continued)

Agency	Description	Information	References
WA-SWEST	Annual	$7.7 \times 10^{-2} \mu\text{g}/\text{m}^3$	
b. Water			
	Water Quality Criteria: Human Health		
CA	Drinking water (guideline)	30 $\mu\text{g}/\text{L}$	FSTRAC 1995
MD	Drinking water (guideline)	10 $\mu\text{g}/\text{L}$	
ME	Drinking water (guideline)	30 $\mu\text{g}/\text{L}$	
NJ	Drinking water (guideline)	100 $\mu\text{g}/\text{L}$	

^a 2A = probable human carcinogen ^c B1 = probable human carcinogen

^b A2 = suspected human carcinogen ^d Ca = potential occupational carcinogen

BACT = Best Available Control Technology; BIF = Boilers and Industrial Furnaces; CARBN = Carbon adsorption; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CHOXD = Chemical or electrolytic oxidation; CMBST = Combustion; CWA = Clean Water Act; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FSTRAC = Federal State Toxicology and Regulatory Alliance committee; FSUBS = Fuel Substitution; HAP = Hazardous Air Pollutants; IARC = International Agency for Research on Cancer; INCIN = Incineration; MCLG = Maximum Contaminant Level Goal; NA = not applicable; NAS = National Academy of Sciences; NESHAP = National Emission Standards for Hazardous Air Pollutants; NIOSH = National Institute of Occupational Safety and Health; NPDES = National Pollution Discharge Elimination System; OAR - Office of Air and Radiation; ODW = Office of Drinking Water; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Wastes; OTS = Office of Toxic Substances; PEL = Permissible Exposure Limit; RCRA = Resource Conservation and Recovery Act; RfD = Reference Dose; RQ = Reportable Quantities; SOCMI = Synthetic Organic Chemicals Manufacturing Industry; STEL = Short-term exposure Limit; TLV = Threshold Limit Value; TWA = Time-weighted Average; VOC = Volatile Organic Compound; WHO = World Health Organization; WETOX = Wet Air Oxidation

No acute-duration oral MRL value was derived for formaldehyde. A more detailed discussion of MRLs for formaldehyde is presented in Section 2.5 and in Appendix A of this profile.

The EPA oral reference dose (RfD) for formaldehyde is 0.2 mg/kg/day for causing gastrointestinal damage. No reference concentration (RfC) was reported for the compound (IRIS 1999).

The National Toxicology Program (1998) noted that formaldehyde is reasonably anticipated to be a human carcinogen. The International Agency for Research on Cancer (IARC) has classified formaldehyde as 2A, probably carcinogenic to humans, based on limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animals (IARC 1995). The EPA has classified formaldehyde as a B1 compound, probable human carcinogen based on limited evidence in humans and sufficient evidence in animals (EPA 1991a; IRIS 1999).

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Formaldehyde is on the list of chemicals subject to the requirements of "The Emergency Planning and Community Right-to-Know act of 1986" (EPCRA) (EPA 1988a). Section 313 of Title III of EPCRA, requires owners and operators of certain facilities that manufacture, import, process, or otherwise use the chemicals on this list to report annually their release of those chemicals to any environmental media (U.S. Congress 1986).

OSHA requires employers of workers who are occupationally exposed to formaldehyde to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PELs). The employer must use controls and practices, if feasible, to reduce exposure to or below an 8-hour time-weighted average (TWA) of 0.75 ppm. The 15-minute, short-term exposure limit (STEL) for formaldehyde is 2 ppm (OSHA 1992).

The EPA regulates formaldehyde under the Clean Air Act (CAA) and has designated formaldehyde as a hazardous air pollutant (HAP). The major source category for which formaldehyde emissions are controlled is the synthetic organic chemicals manufacturing industry (SOCMI)—equipment leaks, air oxidation unit processes, and distillation operations (EPA 1983a, 1990a, 1990b).

Formaldehyde is regulated by the Clean Water Effluent Guidelines as stated in Title 40, Section 414, of the Code of Federal Regulations (EPA 1987a). The point source category for which specific Regulatory Limitations are listed is the waste water discharge from the manufacture of formaldehyde as a commodity organic chemical (EPA 1987a). The Resource Conservation and Recovery Act (RCRA) identifies formaldehyde as a toxic waste if it is discarded as a commercial product, manufacturing intermediate, or off-specification commercial chemical product. Formaldehyde is assigned the hazardous waste number, U122 (EPA 1980).

Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), owners of vessels or facilities are required to immediately report release of formaldehyde equal to or greater than the reportable quantity of 100 pounds (45.4 kg) (EPA 1985a). When formaldehyde is used as a post-harvest fungicide for various raw agricultural commodities that are used only as animal feed (e.g., barley, corn, rye grass soybean hay, and oats), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) exempts formaldehyde from the tolerance requirement for residues in or on the commodity (EPA 1975).

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The Food and Drug Administration (FDA) identifies formaldehyde as an indirect food additive for use only as a component of adhesives (FDA 1977a). When used in accordance with specified conditions, the food additive formaldehyde may be safely used in the manufacture of animal feeds (FDA 1976).