

8. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding vinyl chloride in air, water, and other media are summarized in Table 8-1.

ATSDR has derived three MRL values for vinyl chloride. An acute-duration inhalation MRL of 0.5 ppm was derived for vinyl chloride based on a NOAEL for developmental effects for mice (John et al. 1977, 1981). An intermediate-duration inhalation MRL of 0.03 ppm was derived for vinyl chloride based on a LOAEL of 10 ppm for increased incidences of hepatic centrilobular hypertrophy in rats (Thornton et al. 2002). A chronic-duration oral MRL of 0.003 mg/kg/day was derived for vinyl chloride based on a human equivalent NOAEL of 0.09 mg/kg/day for liver cell polymorphism in rats (Til et al. 1983, 1991).

EPA (IRIS 2004) has derived an RfD of 0.003 mg/kg/day for vinyl chloride, based on a NOAEL for liver cell polymorphism in rats administered vinyl chloride in the diet for a lifetime (Til et al. 1983, 1991).

EPA (IRIS 2004) has derived an RfC of 0.1 mg/m³ (0.04 ppm) for vinyl chloride, based on route-to-route extrapolation (using PBPK modeling) from a NOAEL for liver cell polymorphism in rats administered vinyl chloride in the diet for a lifetime (Til et al. 1983, 1991).

The FDA is responsible for regulating vinyl chloride as an indirect food additive. With regard to components of coatings, paper, and paperboard, the FDA states that when vinyl chloride is copolymerized with certain other substances, it is a safe food-contact surface. The amount of vinyl chloride content permitted varies depending on the nature of the polymer and its use (FDA 1994).

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Table 8-1. Regulations and Guidelines Applicable to Vinyl Chloride

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 1 ^a	IARC 1987
WHO	Drinking water guideline	0.3 µg/L ^b	WHO 2000
	Air quality guideline (10 ⁻⁶ cancer risk)	1 µg/m ³	WHO 2000
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	1 ppm	ACGIH 2003
EPA	Hazardous air pollutant		EPA 2004k 42USC7412
	Regulated toxic substances pursuant to Section 112(r) of the Clean Air Act and threshold quantities for accidental release prevention	10,000 pounds ^c	EPA 2004a 40CFR68.130
NIOSH	REL (10-hour TWA)	Potential occupational carcinogen	NIOSH 2004
	IDLH	No data	
OSHA	PEL for general industry		OSHA 2004a 29CFR1910.1017
	8-hour TWA	1 ppm	
	15-minute TWA	5 ppm	
	PEL for construction industry		OSHA 2004c 29CFR1926.1117
	8-hour TWA	1 ppm	
	15-minute TWA	5 ppm	
	PEL for shipyard industry		OSHA 2004b 29CFR1915.1017
	8-hour TWA	1 ppm	
	15-minute TWA	5 ppm	
b. Water			
	Drinking water standards	0.002 mg/L	EPA 2004j 40CFR141.32
	Drinking water standards and health advisories		EPA 2004c
	1-Day HA for a 10-kg child	3.0 mg/L	
	10-Day HA for a 10-kg child	3.0 mg/L	
	DWEL	0.1 mg/L	
	10 ⁻⁴ Cancer risk	0.002 mg/L	
	MCL	0.002 mg/L	EPA 2004i 40CFR141.61
	MCLG	Zero	EPA 2004g 40CFR141.50
c. Food			
FDA	Bottled water	0.002 mg/L	FDA 2003a 21CFR165.110

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Agency	Description	Information	Reference
NATIONAL (cont.)			
FDA	Drug products withdrawn or removed from the market for reasons of safety or effectiveness	All aerosol drug products containing vinyl chloride	FDA 2003c 21CFR216.24
	Indirect food additive for use only as a component of adhesives		FDA 2003b 21CFR175.105
d. Other			
ACGIH	Carcinogenicity classification	A1 ^d	ACGIH 2003
EPA	Carcinogenicity classification	Group A ^{e,f}	IRIS 2005
	Oral slope factor		
	Continuous lifetime exposure during adulthood	7.2×10^{-1} (mg/kg/day) ⁻¹	
	Continuous lifetime exposure from birth	1.4 (mg/kg/day) ⁻¹	
	Drinking water unit risk		
	Continuous lifetime exposure during adulthood	2.1×10^{-5} (µg/L) ⁻¹	
	Continuous lifetime exposure from birth	4.2×10^{-5} (µg/L) ⁻¹	
	Inhalation unit risk		
	Continuous lifetime exposure during adulthood	4.4×10^{-6} (mg/m ³) ⁻¹	
	Continuous lifetime exposure from birth	8.8×10^{-6} (mg/m ³) ⁻¹	
	Hazardous waste identification	U043	EPA 2004d 40CFR261, Appendix VIII
	RfC	1×10^{-1} mg/m ³	
	RfD	3×10^{-3} mg/kg/day	
	Superfund; community right-to-know; toxic chemical release reporting; effective date	01/01/1987	EPA 2004m 40CFR372.65
	Superfund; designated as a hazardous substance pursuant to Section 307(a) of the Clean Water Act, Section 112 of the Clean Air Act, and Section 3001 of RCRA		EPA 2004b 40CFR302.4
	Reportable quantity	1 pound	
	Unlisted hazardous waste; characteristic of toxicity; RCRA waste number	D043	
NTP	Carcinogenicity classification	Known to be a human carcinogen	NTP 2005
STATE			
a. Air			
California	Ambient air quality standard (24-hour averaging time) ⁹	0.01 ppm	CalEPA 2005

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Agency	Description	Information	Reference
<u>STATE</u> (cont.)			
b. Water			
California	Public health goal	0.05 µg/L	CalEPA 2000
	Drinking water guidelines and standards		HSDB 2005
Arizona		0.015 µg/L	
California		0.5 µg/L	
Connecticut		2.0 µg/L	
Florida		1.0 µg/L	
Maine		0.2 µg/L	
Minnesota		0.2 µg/L	
New Jersey		2.0 µg/L	
Wisconsin		0.2 µg/L	
c. Food			
	No data		
d. Other			
	No data		

^aGroup 1: Carcinogenic to humans.

^bFor substances that are considered to be carcinogenic, the guideline value is the concentration in drinking water associated with an upper-bound excess lifetime cancer risk of 10^{-5} (one additional cancer per 100,000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). Concentrations associated with upper-bound estimated excess lifetime cancer risks of 10^{-4} and 10^{-6} can be calculated by multiplying and dividing, respectively, the guideline value by 10.

^cVinyl chloride: Mandated for listing by Congress and it is a flammable gas.

^dGroup A1: Confirmed human carcinogen.

^eGroup A: Human carcinogen; according to EPA Risk Assessment Guidelines (EPA 1986).

^fVinyl chloride *is a known human carcinogen by the inhalation route of exposure*, based on human epidemiological data, and by analogy *the oral route* because of positive animal bioassay data as well as pharmacokinetic data allowing dose extrapolation across routes. Vinyl chloride *is also considered highly likely to be carcinogenic by the dermal route* because it is well absorbed and acts systemically (EPA 1996).

^gThe Air Resources Board has identified vinyl chloride as 'toxic air contaminants' with no threshold level of exposure for adverse health effects determined. These actions allow for the implementation of control measures at levels below the ambient concentrations specified for these pollutants.

ACGIH = American Conference of Governmental Industrial Hygienists; CFR = Code of Federal Regulations; DWEL = drinking water equivalent level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HA = Health Advisory; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; RCRA = Resource Conservation and Recovery Act; RfC = reference concentration; RfD = reference dose; STEL = short-term exposure limit; TLV = threshold limit values; TWA = time-weighted average; USC = United States Codes; WHO = World Health Organization