

## 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 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/m<sup>3</sup> (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 <sup>a</sup>	IARC 1987
WHO	Drinking water guideline (10 <sup>-6</sup> cancer risk)	0.5 µg/L	WHO 1996
	Air quality guideline (10 <sup>-6</sup> cancer risk)	1 µg/m <sup>3</sup>	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 and threshold quantities for accidental release prevention	10,000 pounds	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 shipyard industry		OSHA 2004b 29CFR1915.1017
	8-hour TWA	1 ppm	
	15-minute TWA	5 ppm	
OSHA	PEL for construction industry		OSHA 2004c 29CFR1926.1117
	8-hour TWA	1 ppm	
	15-minute TWA	5 ppm	
b. Water			
	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 <sup>-4</sup> Cancer risk	0.002 mg/L	
	Drinking water standards	0.002 mg/L	EPA 2004j 40CFR141.32
	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
<u>NATIONAL</u> (cont.)			
	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
FDA	Indirect food additive for use only as a component of adhesives		FDA 2003b 21CFR175.105
d. Other			
ACGIH	Carcinogenicity classification	A1 <sup>b</sup>	ACGIH 2003
EPA	Carcinogenicity classification	Group A <sup>cd</sup>	IRIS 2004
	Oral slope factor		
	Continuous lifetime exposure during adulthood	$7.2 \times 10^{-1}$ (mg/kg/day) <sup>-1</sup>	
	Continuous lifetime exposure from birth	$1.4$ (mg/kg/day) <sup>-1</sup>	
	Drinking water unit risk		
	Continuous lifetime exposure during adulthood	$2.1 \times 10^{-5}$ (µg/L) <sup>-1</sup>	
	Continuous lifetime exposure from birth	$4.2 \times 10^{-5}$ (µg/L) <sup>-1</sup>	
	Inhalation unit risk		
	Continuous lifetime exposure during adulthood	$4.4 \times 10^{-6}$ (mg/m <sup>3</sup> ) <sup>-1</sup>	
	Continuous lifetime exposure from birth	$8.8 \times 10^{-6}$ (mg/m <sup>3</sup> ) <sup>-1</sup>	
	RfC	$1 \times 10^{-1}$ mg/m <sup>3</sup>	
	RfD	$3 \times 10^{-3}$ mg/kg/day	
	Community right-to-know; release reporting; effective date	01/01/1987	EPA 2004m 40CFR372.65
	Hazardous waste identification	U043	EPA 2004d 40CFR261, Appendix VIII
	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; reportable quantity	1 pound	EPA 2004b 40CFR302.4
NTP	Carcinogenicity classification	Known to be a human carcinogen	NTP 2002
<u>STATE</u>			
a. Air			
California	Acute inhalation reference exposure level	$2 \times 10^5$ mg/m <sup>3</sup>	
b. Water			
Arizona	Drinking water guidelines and standards	0.015 µg/L	HSDB 2004

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Agency	Description	Information	Reference
<b>STATE (cont.)</b>			
California	MCL	0.5 µg/L	
	Public Health Goal	0.05 µg/L	
Connecticut		2.0 µg/L	
Florida		1.0 µg/L	
Maine		0.15 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		

<sup>a</sup>Group 1: Carcinogenic to humans.

<sup>b</sup>Group A1: Confirmed human carcinogen.

<sup>c</sup>Group A: Human carcinogen; according to EPA Risk Assessment Guidelines (EPA 1986).

<sup>d</sup>Vinyl chloride a known human carcinogen by the inhalation and oral route of exposure and is also considered highly likely to be carcinogenic by the dermal route of exposure (EPA 1996).

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