

8. REGULATIONS, ADVISORIES, AND GUIDELINES

MRLs are substance specific estimates, which are intended to serve as screening levels, are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites.

ATSDR has derived an acute-duration inhalation MRL of 0.1 ppm, based on a LOAEL of 40 ppm for reduced male fetal weight from exposed pregnant mice. The LOAEL of 40 ppm was adjusted for intermittent exposure (6 hours/day) resulting in a duration-adjusted LOAEL of 10 ppm. A LOAEL_{HEC} (human equivalent concentration) of 10 ppm was derived (see Appendix A), which was divided by an uncertainty factor of 90 (3 for use of a minimally adverse effect, 3 for extrapolation from animals to humans, and 10 for human variability)

EPA (IRIS 2009) has established an inhalation reference concentration (RfC) for 1,3-butadiene of 0.9 ppb based on a BMCL₁₀ of 0.88 ppm for ovarian atrophy in female B6C3F1 mice exposed to 1,3-butadiene by inhalation for 6 hours/day, 5 days/week for up to 103 weeks.

EPA has not established an oral reference dose (RfD) for 1,3-butadiene (IRIS 2009).

OSHA has required employers of workers who are occupationally exposed to 1,3-butadiene to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PELs) (OSHA 2009b). The employer must use engineering and work practice controls to reduce exposures to not exceed 1 ppm for 1,3-butadiene at any time (OSHA 2009b).

EPA has designated 1,3-butadiene as a hazardous air pollutant (HAP) under the Clean Air Act (CAA) (EPA 2009b). 1,3-Butadiene is on the list of chemicals appearing in "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986" and has been assigned a reportable quantity (RQ) limit of 100 pounds (EPA 2009d). The RQ represents the amount of a designated hazardous substance which, when released to the environment, must be reported to the appropriate authority.

The international and national regulations, advisories, and guidelines regarding 1,3-butadiene in air, water, and other media are summarized in Table 8-1.

8. REGULATIONS AND ADVISORIES

Table 8-1. Regulations, Advisories, and Guidelines Applicable to 1,3-Butadiene

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 1 ^a	IARC 2009
WHO	Air quality guidelines	No guideline value is recommended at this time	WHO 2000
	Drinking water quality guidelines	No	WHO 2006
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	2 ppm	ACGIH 2008
AIHA	ERPG-1 ^b	10 ppm	AIHA 2008
	ERPG-2 ^b	200 ppm	
	ERPG-3 ^b	5,000 ppm	
EPA	RfC	0.9 ppb	IRIS 2009
	Inhalation unit risk	3×10^{-5} per $\mu\text{g}/\text{m}^3$	
EPA	AEGL-1 ^c		EPA 2009a
	10 minutes	670 ppm	
	30 minutes	670 ppm	
	60 minutes	670 ppm	
	4 hours	670 ppm	
	8 hours	670 ppm	
	AEGL-2 ^c		
	10 minutes	6,700 ppm	
	30 minutes	6,700 ppm	
	60 minutes	5,300 ppm	
	4 hours	3,400 ppm	
	8 hours	2,700 ppm	
	AEGL-3 ^c		
	10 minutes	27,000 ppm	
	30 minutes	27,000 ppm	
	60 minutes	22,000 ppm	
	4 hours	14,000 ppm	
	8 hours	6,800 ppm	
	Level of distinct odor awareness	3.7 ppm	
	Hazardous air pollutant	Yes	EPA 2009b 42 USC 7412

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
	Regulated flammable substances and threshold quantities for accidental release prevention ^d	10,000 pounds	EPA 2009c 40 CFR 68.130
NIOSH	REL (10-hour TWA)	Potential occupational carcinogens	NIOSH 2005
	IDLH (10% LEL)	2,000 ppm	
	Target organs	Eyes, respiratory system, central nervous system, and reproductive system	
OSHA	PEL (8-hour TWA) for general industry	1 ppm	OSHA 2009b
	STEL (15-minutes)	5 ppm	29 CFR 1910.1051
b. Water			
EPA	Drinking water standards and health advisories	No	EPA 2006a
	National primary drinking water standards	No	EPA 2003b
	National recommended water quality criteria	No	EPA 2006b
c. Food			
FDA	EAFUS ^e	No	FDA 2008
d. Other			
ACGIH	Carcinogenicity classification	A2 ^f	ACGIH 2008

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Agency	Description	Information	Reference
EPA	Carcinogenicity classification	Carcinogenic to humans	IRIS 2009
	RfD	No data	
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance	Yes ^g	EPA 2009d 40 CFR 302.4
	Reportable quantity	100 pounds	
EPA	Effective date of toxic chemical release reporting	01/01/1987	EPA 2009e 40 CFR 372.65
NTP	Carcinogenicity classification	Known to be a human carcinogen	NTP 2005

^aGroup 1: carcinogenic to humans

^bERPG-1 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing other than mild, transient health effects; ERPG-2 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing irreversible or other serious adverse effects; and ERPG-3 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without life-threatening health effects (AIHA 2008).

^cAEGL-1 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects, however, the effects are not disabling and are transient and reversible upon cessation of exposure; AEGL-2 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape; and AEGL-3 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death (EPA 2009a).

^dBasis for listing: flammable gas

^eThe EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

^fA2: suspected human carcinogen

^gDesignated CERCLA hazardous substance pursuant to Section 112 of the Clean Air Act

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; GRAS = Generally Recognized As Safe; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; LEL = lower explosive limit; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TLV = threshold limit values; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization