

8. REGULATIONS, ADVISORIES, AND GUIDELINES

MRLs are substance specific estimates that are intended to serve as screening levels. They 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 1 ppm for 1-bromopropane based on a $BMCL_{1SD}$ of 97.4 ppm for reduced forelimb strength in male rats exposed for 14 days (Honma et al. 2003). The $BMCL_{1SD}$ was duration adjusted (8/24 hours) to a $BMCL_{(HEC)}$ of 32.3 ppm and an uncertainty factor of 30 was used (3 for dosimetric adjustment and 10 for human variability).

ATSDR has derived an intermediate-duration inhalation MRL of 0.1 ppm for 1-bromopropane based on a NOAEL of 10 ppm for increased spontaneous locomotor activity in rats (Honma et al. 2003). The NOAEL was duration adjusted (8/24 hours) to a $NOAEL_{(HEC)}$ of 3.33 ppm and an uncertainty factor of 30 was used (3 for extrapolation from animals to humans with dosimetric adjustment and 10 for human variability).

ATSDR has derived a chronic-duration inhalation MRL of 0.02 ppm for 1-bromopropane based on a minimal LOAEL of 1.28 ppm for a mild neurological impairment (decreased vibration sense as measured by increased vibration sense threshold) in female 1-bromopropane production workers (Li et al. 2010). The LOAEL was adjusted for continuous exposure (5/7 days x 12/24 hours) to a LOAEL of 0.46 ppm and an uncertainty factor of 30 was used (3 for use of a minimal LOAEL and 10 for human variability).

ATSDR has derived an acute oral MRL of 0.2 mg/kg/day for 1-bromopropane based on a $BMDL_{1SD}$ of 19.75 mg 1-bromopropane/kg/day for impaired learning and memory in rats exposed via gavage for 12 days (Zhong et al. 2013). An uncertainty factor of 100 was used (10 for extrapolation from animals to humans and 10 for human variability).

IARC and the EPA have not evaluated the carcinogenicity of 1-bromopropane (IARC 2014; IRIS 2014). However, ACGIH has assigned 1-bromopropane a classification of “A3 – *Confirmed animal carcinogen with unknown relevance to humans*” (ACGIH 2014, 2016) and the Department of Health and Human Services has classified 1-bromopropane as “*reasonably anticipated to be a human carcinogen*” (NTP 2016).

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OSHA has not set permissible exposure limits (PELs) to protect workers against adverse health effects resulting from exposure to 1-bromopropane (OSHA 2013a, 2013b). ACGIH has recommended a TLV-TWA of 0.1 ppm 1-bromopropane for workers (ACGIH 2014, 2016). No guidelines for worker exposure limits have been recommended by NIOSH (2014). The EPA has not derived RfDs or RfCs for 1-bromopropane.

The World Health Organization (WHO) has not established any air quality guidelines for 1-bromopropane (WHO 2010). 1-Bromopropane is not designated as a hazardous air pollutant, and no acute exposure guidelines (AEGs) have been derived (EPA 2013a, 2014a). The Department of Energy (DOE) has established values for responding to potential releases of airborne 1-bromopropane for use in community emergency planning. The values established by the DOE (2012) are the Protective Active Criteria (PAC-1, -2, and -3). The PAC-1, -2, and -3 values are 18, 18, and 700 ppm, respectively, represent increasing severity of effects (mild, irreversible, and life threatening, respectively) for a 1-hour exposure (DOE 2012). The American Industrial Hygiene Association (AIHA) has not established Emergency Response Planning Guidelines (ERPGs-1, -2, -3) for 1-bromopropane (AIHA 2014).

WHO has not established any drinking water guidelines for 1-bromopropane (WHO 2011) and the EPA has not set drinking water standards for 1-bromopropane (EPA 2009a, 2009b, 2012, 2013c, 2013d, 2014c). The FDA has not set allowable levels for 1-bromopropane in bottled water (FDA 2013).

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

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

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	No data	IARC 2014
WHO	Air quality guidelines	No data	WHO 2010
	Drinking water quality guidelines	No data	WHO 2011
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV-TWA	0.1 ppm	ACGIH 2014, 2016
AIHA	ERPGs	No data	AIHA 2014
DOE	PACs		DOE 2012
	PAC-1	18 ppm	
	PAC-2	18 ppm	
	PAC-3	700 ppm	
EPA	AEGLs	No data	EPA 2013a
	Regulated toxic and flammable substances under Section 112(r) of the Clean Air Act	No data	EPA 2013b 40 CFR 68.130
	Hazardous Air Pollutants	No data	EPA 2014a
	NAAQS	No data	EPA 2014b
	Protection of stratospheric ozone – listing of substitutes for ozone-depleting substances		
	In solvent cleaning	Acceptable (final rule)	EPA 2007a 72 FR 30142
	In adhesives and aerosols	Unacceptable (proposed rule)	EPA 2007b 72 FR 30168
In coatings	Acceptable subject to use conditions (proposed rule)		
NIOSH	REL	No data	NIOSH 2014
	IDLH	No data	
OSHA	PEL (8-hour TWA) for general industry	No data	OSHA 2013a 29 CFR 1910.1000, Table Z-1
	Highly hazardous chemicals	No data	OSHA 2013b 29 CFR 1910.119, Appendix A

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Agency	Description	Information	Reference
NATIONAL (cont.)			
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act	No data	EPA 2013c 40 CFR 116.4
	Drinking water contaminant candidate list	No data	EPA 2009a 74 FR 51850
	Drinking water standards and health advisories	No data	EPA 2012a
	National primary drinking water standards	No data	EPA 2009b
	National recommended water quality criteria	No data	EPA 2014c
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	No data	EPA 2013d 40 CFR 117.3
c. Food			
FDA	Allowable levels for contaminants in bottled water	No data	FDA 2013 21 CFR 165.110
	EAFUS ^a	No data	FDA 2014
d. Other			
ACGIH	Carcinogenicity classification	A3 ^b	ACGIH 2014, 2016
EPA	Carcinogenicity classification	No data	IRIS 2014
	RfC	No data	
	RfD	No data	
	Chemical substances subject to proposed or final TSCA rules or orders	No data	EPA 1998a
	TSCA Work Plan Chemical Risk Assessment	No data	EPA 2016
	Chemicals subject to EPCRA and Section 112(r) of the Clean Air Act	No data	EPA 2006
	Identification and listing of hazardous waste	No data	EPA 2013e 40 CFR 261, Appendix VIII
	Master Testing List	No data	EPA 2014d
	RCRA waste minimization PBT priority chemical list	No data	EPA 1998b 63 FR 60332
	Standards for owners and operators of hazardous waste TSD facilities; groundwater monitoring list	No data	EPA 2013f 40 CFR 264, Appendix IX
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance and reportable quantity	No data	EPA 2013g 40 CFR 302.4

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Agency	Description	Information	Reference
NATIONAL (cont.)			
	Effective date of toxic chemical release reporting	July 1, 2017	EPA 2013h 40 CFR 372.65; EPA 2015
	Extremely hazardous substances and its threshold planning quantity	No data	EPA 2013i 40 CFR 355, Appendix A
DHHS	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen	NTP 2016

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

^bA3: Confirmed animal carcinogen with unknown relevance to humans.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AEL = acceptable exposure limit; AIHA = American Industrial Hygiene Association; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; DHHS = Department of Health and Human Services; DOE = Department of Energy; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; EPCRA = Emergency Planning and Community Right-To-Know Act; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; FR = Federal Register; GRAS = generally recognized as safe; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; NAAQS = National Ambient Air Quality Standards; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = protective action criteria; PBT = persistent, bioaccumulative, and toxic; PEL = permissible exposure limit; RCRA = Resource Conservation and Recovery Act; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit values; TSCA = Toxic Substances Control Act; TSD = treatment, storage, and disposal; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization