

## 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 0.3 mg boron/m<sup>3</sup> for boron. This MRL is based on a NOAEL of 0.8 mg boron/m<sup>3</sup> for significantly increased nasal secretions in volunteers (Cain et al. 2004) and an uncertainty factor of 3 (10<sup>0.5</sup> for human variability in the pharmacodynamic response to boron).

ATSDR has derived an acute-duration oral MRL of 0.2 mg boron/kg/day for boron. This MRL is based on a NOAEL of 22 mg boron/kg/day associated with a LOAEL of 44 mg boron/kg/day for increased incidence of external, visceral, and cardiovascular malformations and reduced body weight in the fetuses of rabbits administered boric acid via gavage on gestation days 6–19 (Price et al. 1996b) and an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for human variability).

ATSDR has derived an intermediate-duration oral MRL of 0.2 mg boron/kg/day for boron. This MRL is based on a BMDL<sub>05</sub> of 10.3 mg boron/kg/day estimated from fetal body weight data from two studies in which pregnant rats were exposed to boron in the diet on gestation days 0–20 (Heindel et al. 1992; Price et al. 1996a) and chemical-specific uncertainty factor of 66 (3.3 for toxicokinetic extrapolation from animals to humans, 3.16 for toxicodynamic extrapolation from animals to humans, 2.0 for variability in human toxicokinetics, and 3.16 for variability in human toxicodynamics).

EPA has established an oral reference dose (RfD) of 0.2 mg/kg/day based on decreased fetal weight in a developmental study in Sprague-Dawley rats orally exposed to boric acid from gestation days 0 to 20 (IRIS 2007). EPA has not established an inhalation reference concentration (RfC) for boron and compounds.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), boron oxide, boric acid, borax, and sodium tetraborate are exempt from tolerances for pesticide chemicals in food (EPA 2007b); they are also listed as inert ingredients of unknown toxicity (List 3) in EPA's Categorized List of Inert Pesticide Ingredients (EPA 2004).

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

## 8. REGULATIONS, ADVISORIES, AND GUIDELINES

**Table 8-1. Regulations, Advisories and Guidelines Applicable to Boron and Boron Compounds**

Agency	Description	Information	Reference		
<u>INTERNATIONAL</u>					
Guidelines:					
IARC	Carcinogenicity classification	No data	IARC 2006		
WHO	Air quality guidelines	No data	WHO 2000		
	Drinking water quality guidelines (boron)	0.5 mg/L <sup>a</sup>	WHO 2004		
<u>NATIONAL</u>					
Regulations and Guidelines:					
a. Air					
ACGIH	TLV (8-hour TWA)		ACGIH 2006		
	Borate compounds, inorganic (borax, boric acid, and sodium tetraborate)	2 mg/m <sup>3</sup>			
	Boron oxide	10 mg/m <sup>3</sup>			
	TLV (ceiling)				
	Boron tribromide	10 mg/m <sup>3</sup>			
	Boron trifluoride	3 mg/m <sup>3</sup>			
	STEL (15-minute TWA)				
	Borate compounds, inorganic (borax, boric acid, and sodium tetraborate)	6 mg/m <sup>3</sup>			
	AIHA	Boron trifluoride			AIHA 1999
		ERPG-1 <sup>b</sup>		2 mg/m <sup>3</sup>	
ERPG-2 <sup>b</sup>		30 mg/m <sup>3</sup>			
ERPG-3 <sup>b</sup>		100 mg/m <sup>3</sup>			
EPA	AEGL-1 <sup>c</sup> (boron trifluoride)		EPA 2007a		
	10 minutes	2.5 mg/m <sup>3</sup>			
	30 minutes	2.5 mg/m <sup>3</sup>			
	60 minutes	2.5 mg/m <sup>3</sup>			
	4 hours	2.5 mg/m <sup>3</sup>			
	8 hours	2.5 mg/m <sup>3</sup>			
	AEGL-2 <sup>c</sup> (boron trifluoride)				
	10 minutes	47 mg/m <sup>3</sup>			
	30 minutes	47 mg/m <sup>3</sup>			
	60 minutes	37 mg/m <sup>3</sup>			
	4 hours	24 mg/m <sup>3</sup>			
	8 hours	12 mg/m <sup>3</sup>			
	AEGL-3 <sup>c</sup> (boron trifluoride)				
	10 minutes	140 mg/m <sup>3</sup>			
30 minutes	140 mg/m <sup>3</sup>				

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Agency	Description	Information	Reference
	60 minutes	110 mg/m <sup>3</sup>	
	4 hours	72 mg/m <sup>3</sup>	
	8 hours	36 mg/m <sup>3</sup>	
<b>NATIONAL (cont.)</b>			
EPA	Regulated toxic substances and threshold quantities for accidental release prevention pursuant to Section 112(r) of the Clean Air Act		EPA 2008a 40 CFR 68.130
	Boron trichloride	5,000 pounds	
	Boron trifluoride	5,000 pounds	
NIOSH	REL		NIOSH 2005
	Borax (10-hour TWA)	5 mg/m <sup>3</sup>	
	Boron oxide (10-hour TWA)	10 mg/m <sup>3</sup>	
	Boron tribromide (ceiling)	10 mg/m <sup>3</sup>	
	Boron trifluoride (ceiling)	3 mg/m <sup>3</sup>	
	Sodium tetraborate (10-hour TWA)	1 mg/m <sup>3</sup>	
	IDLH (30-minute exposure)		
	Borax	No data	
	Boron oxide	2,000 mg/m <sup>3</sup>	
	Boron tribromide	No data	
	Boron trifluoride	70 mg/m <sup>3</sup>	
	Sodium tetraborate	No data	
OSHA	PEL for general industry		OSHA 2006c 29 CFR 1910.1000
	Boron oxide, total dust (8-hour TWA)	15 mg/m <sup>3</sup>	
	Boron trifluoride (ceiling)	3 mg/m <sup>3</sup>	
	PEL for shipyard industry		OSHA 2006a 29 CFR 1915.1000
	Boron oxide, total dust (8-hour TWA)	15 mg/m <sup>3</sup>	
	Boron tribromide (8-hour TWA)	10 mg/m <sup>3</sup>	
	Boron trifluoride (ceiling)	3 mg/m <sup>3</sup>	
	PEL for construction industry		OSHA 2006b 29 CFR 1926.55, Appendix A
	Boron oxide, total dust (8-hour TWA)	15 mg/m <sup>3</sup>	
	Boron tribromide (8-hour TWA)	10 mg/m <sup>3</sup>	
	Boron trifluoride (ceiling)	3 mg/m <sup>3</sup>	
	Threshold quantity of highly hazardous chemicals, toxics, and reactives		OSHA 2006d 29 CFR 1910.119
	Boron trichloride	2,500 pounds	
	Boron trifluoride	250 pounds	
<b>b. Water</b>			
EPA	Drinking water contaminant candidate list		EPA 1998 63 FR 10274
	Boron	Yes	

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Agency	Description	Information	Reference
<b>NATIONAL (cont.)</b>			
EPA	Drinking water standards and health advisories for boron		EPA 2006
	1-day health advisory for a 10-kg child	4 mg/L	
	10-day health advisory for a 10-kg child	0.9 mg/L	
	DWEL	7 mg/L	
	Lifetime	1 mg/L	
	10 <sup>-4</sup> Cancer risk	No data	
	National primary drinking water standards	No data	EPA 2003
c. Food			
EPA	Inert pesticide ingredients in pesticide products		EPA 2004
	Borax, boric oxide, boric acid, and sodium tetraborate	List 3 <sup>d</sup>	
	Tolerances and exemptions from tolerances for pesticide chemicals in food		EPA 2007c 40 CFR 180.101
	Borax, boron oxide, boric acid, and sodium tetraborate	Yes	
FDA	EAFUS		FDA 2007
	Borax, boric acid, and sodium tetraborate	Yes <sup>e</sup>	
	Indirect food additives: adhesives and components of coatings		FDA 2006 21 CFR 175.105
	Borax and boric acid	Yes	
d. Other			
ACGIH	Carcinogenicity classification		ACGIH 2006
	Borate compounds, inorganic (borax, boric acid, and sodium tetraborate)	A4 <sup>f</sup>	
EPA	Carcinogenicity classification (boron and boron compounds)	No data <sup>g</sup>	IRIS 2007
	RfC (boron and boron compounds)	Not recommended	
	RfD (boron and boron compounds)	0.2 mg/kg/day	
	Superfund, emergency planning, and community right-to-know; effective date of toxic chemical release reporting		EPA 2007b 40 CFR 372.65
	Boron tribromide, boron trichloride, and boron trifluoride	01/01/95	
	Extremely hazardous substances and their threshold planning quantities		EPA 2008b 40 CFR 355, Appendix A
	Boron trichloride	500 pounds	
	Boron trifluoride	500 pounds	

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Agency	Description	Information	Reference
<b>NATIONAL</b> ( <i>cont.</i> )			
NTP	Carcinogenicity classification	No data	NTP 2005

<sup>a</sup>Provisional guideline value because calculated guideline value is below the level that can be achieved through practical treatment methods, source protection, etc.

<sup>b</sup>ERPG-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 1999).

<sup>c</sup>AEGL-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; 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 2007c).

<sup>d</sup>List 3: inerts of unknown toxicity

<sup>e</sup>The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

<sup>f</sup>A4: not classifiable as a human carcinogen

<sup>g</sup>Data are inadequate for an assessment of human carcinogenic potential.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = Acute Exposure Guideline Levels; AIHA = American Industrial Hygiene Association; CFR = Code of Federal Regulations; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; 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; 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; WHO = World Health Organization