

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 intermediate-duration inhalation MRL of 0.006 mg/m³ for lower-brominated PBDEs based on a NOAEL for changes in thyroid hormones in rats (Great Lakes Chemical Corporation 2000).

ATSDR has derived an acute-duration oral MRL of 0.00006 mg/kg/day for lower-brominated PBDEs based on a LOAEL for endocrine effects in rat dams and reproductive and neurobehavioral effects in F1 offspring from a series of reports (Kuriyama et al. 2005, 2007; Talsness et al. 2005). ATSDR has derived an intermediate-duration oral MRL of 0.000003 mg/kg/day for lower-brominated PBDEs based on a minimal LOAEL for decreased testosterone in male rats (Zhang et al. 2013b).

ATSDR has derived an acute-duration oral MRL of 0.01 mg/kg/day for decaBDE based on a NOAEL for neurobehavioral effects in mice (Johansson et al. 2008). ATSDR has derived an intermediate-duration oral MRL of 0.0002 mg/kg/day for decaBDE based on a minimal LOAEL for increased serum glucose in rats (Zhang et al. 2013a).

IARC has classified PBDE as a Group 3 carcinogen (*not classifiable as to its carcinogenicity to humans*) based on inadequate evidence of carcinogenicity in humans and inadequate or limited evidence in experimental animals (IARC 2014). The EPA assigns the cancer category Group D (*not classifiable as to human carcinogenicity*) to mono-, di-, tri-, tetra-, penta-, hexa-, octa-, and nonaBDEs (IRIS 2003a, 2003b, 2003c, 2003d, 2003e, 2004, 2005, 2006) and reports “*inadequate information*” to classify the specific congeners 2,2',4,4'-tetraBDE, 2,2',4,4',5-pentaBDE, and 2,2',4,4',5,5'-hexaBDE (IRIS 2008b, 2008c, 2008d). However, EPA assigns a classification of “*suggestive evidence of carcinogenic potential*” for decaBDE (IRIS 2008a). The Department of Health and Human Services has not classified PBDEs as carcinogens (NTP 2011). ACGIH has no data regarding cancer classifications for PBDEs (ACGIH 2014).

The EPA's reference doses (RfDs) for penta-, octa-, and decaBDEs are 2x10⁻³, 3x10⁻³, and 7x10⁻³ mg/kg/day, respectively (IRIS 2003c, 2004, 2008a). For the specific congeners 2,2',4,4'-tetraBDE, 2,2',4,4',5-pentaBDE, and 2,2',4,4',5,5'-hexaBDE, the RfDs are 1x10⁻⁴, 1x10⁻⁴, and

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2×10^{-4} mg/kg/day, respectively (IRIS 2008b, 2008c, 2008d). No reference concentrations (RfCs) were derived for PBDEs.

OSHA has not set PELs to protect workers against adverse health effects resulting from exposure to PBDEs (OSHA 2013a, 2013b). No guidelines for worker exposure limits have been recommended by ACGIH (2014) or NIOSH (2014).

WHO has not established any air quality guidelines for PBDEs (WHO 2010). PBDEs are not designated as hazardous air pollutants, 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 monoBDE for use in community emergency planning. The values established by the DOE (2012) are the Protective Action Criteria (PAC-1, -2, and -3). The PAC-1, -2, and -3 values are 0.29, 3.2, and 19 mg/m³, respectively, and 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 no Emergency Response Planning Guidelines (ERPGs-1, -2, -3) for PBDEs (AIHA 2014).

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

Under the Toxic Substances Control Act (TSCA), mono-, penta-, octa-, and decaBDEs are on the list of chemicals that manufacturers and importers must report for each plant site at which they manufactured or imported PBDEs during the reporting period specified (EPA 1998a). MonoBDE (represented by CAS Registry Number 101-55-3) has been designated as a hazardous substance pursuant to CERCLA of 1980 (EPA 2013g). The owner and operator of any facility that produces, uses, or stores a CERCLA hazardous substance is required to immediately report releases to any environmental media, if the amount released is equal to or exceeds the specified "reportable quantity" assigned to the substance. The reportable quantity for monoBDE is 100 pounds (45 kg) (EPA 2013g). However, PBDEs are no longer manufactured or imported in the United States as of January 2014 (EPA 2013j).

The Emergency Planning and Community Right-to-Know Act (EPCRA) has identified decaBDE as a toxic chemical and monoBDE as hazardous waste, and the Master Testing list includes penta-, octa-, and decaBDEs (EPA 2006, 2013e, 2014d). MonoBDE is on the Resource Conservation and Recovery Act

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(RCRA) waste minimization persistent, bioaccumulative, and toxic (PBT) priority chemical list and the groundwater monitoring list (EPA 1998b, 2013f).

The international and national regulations, advisories, and guidelines regarding PBDEs 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 PBDEs

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification DecaBDE	Group 3 ^a	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	No data	ACGIH 2014
AIHA	ERPGs	No data	AIHA 2014
DOE	PACs		DOE 2012
	MonoBDE		
	PAC-1	0.29 mg/m ³	
	PAC-2	3.2 mg/m ³	
EPA	PAC-3	19 mg/m ³	
	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
NIOSH	NAAQS	No data	EPA 2014b
	REL	No data	NIOSH 2014
OSHA	IDLH	No data	
	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
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 2012
	National primary drinking water regulations	No data	EPA 2009b

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Agency	Description	Information	Reference
NATIONAL (cont.)			
	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 ^b	No data	FDA 2014
d. Other			
ACGIH	Carcinogenicity classification	No data	ACGIH 2014
EPA	Carcinogenicity classification		
	MonoBDE	Group D ^c	IRIS 2006
	DiBDEs	Group D ^c	IRIS 2005
	TriBDEs	Group D ^c	IRIS 2003e
	TetraBDEs	Group D ^c	IRIS 2003d
	PentaBDEs	Group D ^c	IRIS 2004
	HexaBDEs	Group D ^c	IRIS 2003a
	OctaBDEs	Group D ^c	IRIS 2003c
	NonaBDEs	Group D ^c	IRIS 2003b
	DecaBDE	Suggestive evidence of carcinogenic potential	IRIS 2008a
	2,2',4,4'-tetraBDE	Inadequate information	IRIS 2008b
	2,2',4,4',5-pentaBDE	Inadequate information	IRIS 2008c
	2,2',4,4',5,5'-hexaBDE	Inadequate information	IRIS 2008d
	RfC	No data	
	RfD		
	PentaBDEs	2x10 ⁻³ mg/kg/day	IRIS 2004
	OctaBDEs	3x10 ⁻³ mg/kg/day	IRIS 2003a
	DecaBDE	7x10 ⁻³ mg/kg/day	IRIS 2008a
	2,2',4,4'-tetraBDE	1x10 ⁻⁴ mg/kg/day	IRIS 2008b
	2,2',4,4',5-pentaBDE	1x10 ⁻⁴ mg/kg/day	IRIS 2008c
	2,2',4,4',5,5'-hexaBDE	2x10 ⁻⁴ mg/kg/day	IRIS 2008d
	Chemical substances subject to proposed or final TSCA rules or orders		EPA 1998a
	MonoBDE	TSCA Section 5(a)(2)	
	PentaBDEs	TSCA Section 4	
	OctaBDEs	TSCA Section 4	
	DecaBDE	TSCA Section 4	
	EPCRA Section 313 Toxic Chemicals		EPA 2006
	DecaBDE	Yes	

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NATIONAL (cont.)			
	Identification and listing of hazardous waste		EPA 2013e
	MonoBDE	Yes	40 CFR 261, Appendix VIII
	Master Testing List		EPA 2014d
	PentaBDEs	Yes	
	OctaBDEs	Yes	
	DecaBDE	Yes	
	RCRA waste minimization PBT priority chemical list		EPA 1998b
	MonoBDE	Yes	63 FR 60332
	Standards for owners and operators of hazardous waste TSD facilities; groundwater monitoring list		EPA 2013f
	MonoBDE	Yes	40 CFR 264, Appendix IX
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance and reportable quantity		EPA 2013g
	MonoBDE		40 CFR 302.4
	Statutory code	2,4	
	Final RQ pounds	100	
	Effective date of toxic chemical release reporting		EPA 2013h
	DecaBDE	1/1/87	40 CFR 372.65
	Extremely hazardous substances and its threshold planning quantity	No data	EPA 2013i
			40 CFR 355, Appendix A
DHHS	Carcinogenicity classification	No data	NTP 2011

^aGroup 3: Not classifiable as to its carcinogenicity to humans

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

^cGroup D: Not classifiable as to human carcinogenicity

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; BDE = brominated diphenyl ether; 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; PBDE = polybrominated diphenyl ether; 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; RQ = reportable quantity; TLV = threshold limit values; TSCA = Toxic Substances Control Act; TSD = treatment, storage, and disposal; TWA = time-weighted average; WHO = World Health Organization