

10. REGULATIONS AND ADVISORIES

Table 10-1 summarizes international, national, and state regulations and guidelines on human exposure to PBBs and PBDEs.

ATSDR has derived an MRL of 0.01 mg/kg/day for acute-duration oral exposure to PBBs. The MRL is based on a NOAEL for thyroid effects in rats (Allen-Rowland et al. 1981). Intermediate- and chronic-duration oral MRLs were not derived because serious developmental effects (fetal abortion and stillbirths) were observed in monkeys that had been exposed to PBBs for durations that spanned the intermediate and chronic categories at the lowest dose tested in the database. This dose, 0.012 mg/kg/day, caused increased menstrual cycle duration and implantation bleeding after 6–7 months of exposure and fetal deaths after 1 year of exposure in monkeys, with surviving infants having decreased birth weight and decreased postnatal weight gain and weight loss also occurring in maternal animals (Allen et al. 1978, 1979; Lambrecht et al. 1978). The reproductive effects are less serious, but concern for serious developmental toxicity following exposures of >1 year precludes deriving an MRL for intermediate-duration exposure. Derivation of an MRL for chronic oral exposure is precluded by the serious developmental effects that occurred following exposures exceeding 1 year in duration.

ATSDR has derived an MRL of 0.03 mg/kg/day for acute-duration oral exposure to lower brominated diphenyl ethers (BDEs). The acute oral MRL is based on a NOAEL of 1 mg/kg/day for reduced serum levels of thyroid T₄ hormone in fetal rats that were exposed to a commercial pentaBDE mixture on days 4–20 of gestation (Zhou et al. 2002). ATSDR also derived an MRL of 0.007 mg/kg/day for intermediate-duration oral exposure to lower brominated BDEs. The intermediate oral MRL is based on a minimal LOAEL of 2 mg/kg/day for liver effects in rats that were exposed to a commercial pentaBDE mixture for 90 days (WIL Research Laboratories 1984). A chronic-duration oral MRL was not derived for lower brominated BDEs due to insufficient data.

ATSDR has derived an MRL of 10 mg/kg/day for intermediate-duration oral exposure to decaBDE. This intermediate oral MRL is based on a NOAEL of 1000 mg/kg/day for developmental toxicity in rats exposed to decaBDE for 19 days during gestation (Hardy et al. 2002). No acute- or chronic-duration oral MRLs were derived for decaBDE due to insufficient data.

ATSDR has derived an MRL of 0.006 mg/m³ for intermediate-duration inhalation exposure to lower brominated BDEs. The intermediate inhalation MRL is based on a NOAEL of 1.1 mg/m³ for thyroid

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Table 10-1. Regulations and Guidelines Applicable to PBBs and PBDEs^a

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification		IARC 1987
	Decabromobiphenyl	Group 2B ^b	
	Decabromodiphenyl ether	Group 3 ^c	
	Hexabromobiphenyl	Group 2B ^b	
	Octabromobiphenyl	Group 2B ^b	
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	No data	
NIOSH	REL (10-hour TWA)	No data	
OSHA	PEL (8-hour TWA)	No data	
b. Water			
EPA	Standards for owners and operators of hazardous waste TSD facilities; groundwater monitoring for <i>p</i> -bromodiphenyl ether		EPA 2002e
	Suggested EPA method	8270	40CFR264,
	PQL	10 µg/L	Appendix IX
d. Food			
FDA	Indirect food additives; substances for use only as components of adhesives		FDA 2001 21CFR175.105 (c)(5)
	Hexabromo-1,1'-biphenyl		
e. Other			
EPA	Carcinogenicity classification		IRIS 2002
	Decabromodiphenyl ether	Group C ^d	
	Nonabromodiphenyl ether	Group D ^e	
	Octabromodiphenyl ether	Group D ^e	
	Hexabromodiphenyl ether	Group D ^e	
	Pentabromodiphenyl ether	Group D ^e	
	Tetrabromodiphenyl ether	Group D ^e	
	Tribromodiphenyl ether	Group D ^e	
	<i>p,p'</i> -Dibromodiphenyl ether	Group D ^e	
	<i>p</i> -Bromodiphenyl ether	Group D ^e	
EPA	Oral reference dose (RfD)		IRIS 2002
	Decabromodiphenyl ether	1x10 ⁻² mg/kg/day	

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Agency	Description	Information	Reference
	Octabromodiphenyl ether	3x10 ⁻³ mg/kg/day	
NATIONAL (cont.)			
EPA	Pentabromodiphenyl ether	2x10 ⁻³ mg/kg/day	
	Chemical substances subject to proposed or final TSCA rules or orders	Regulated under <u>TSCA section(s)</u>	EPA 1998
	Decabromobiphenyl	5(a)(2)	
	Decabromodiphenyl ether	4	
	Hexabromo-1,1'-biphenyl	5(a)(2)	
	Octabromobiphenyl	5(a)(2)	
	Octabromodiphenyl ether	4	
	<i>p</i> -Bromodiphenyl ether	5(a)(2)	
	Pentabromodiphenyl ether	4	
	EPCRA Section 313; toxic chemical		EPA 2001
	Decabromodiphenyl ether		
	Identification and listing of hazardous waste; commercial chemical products, manufacturing chemical intermediates, or off-specification commercial chemical products are identified as toxic wastes; EPA hazardous waste number		EPA 2002b 40CFR261.33(f)
	<i>p</i> -Bromodiphenyl ether	U030	
	Land disposal restrictions; universal treatment standards		EPA 2002c 40CFR268.48(a)
	<i>p</i> -Bromodiphenyl ether		
	Wastewater standard	0.055 mg/L	
	Nonwastewater standard	15 mg/kg	
	Municipal solid waste landfills; hazardous constituent	Suggested <u>methods</u>	<u>PQL</u> EPA 2002a 40CFR258, Appendix II
	<i>p</i> -Bromodiphenyl ether	8110	25 µg/L
		8270	10 µg/L
	Radiation protection; health and environmental protection standards for uranium and thorium mill tailings; listed constituent		EPA 2002d 40CFR192, Appendix I
	<i>p</i> -Bromodiphenyl ether		

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	CERCLA hazardous substance under Section 307(a) of the Clean Water Act and RCRA Section 3001; reportable quantity		EPA 2002f 40CFR302.4
	<i>p</i> -Bromodiphenyl ether	100 pounds	
	Chemicals subject to the Prior Informed Consent Procedure: International right-to-know		EPA 2002g
	Decabromobiphenyl		
	Hexabromobiphenyl		
	Octabromobiphenyl		
	Toxic chemical release reporting; community right-to-know; effective date for reporting		EPA 2002h 40CFR372.65(c)
	Decabromodiphenyl ether	01/01/87	
	Polybrominated biphenyls	01/01/87	
	TSCA; chemical information rules; manufacturers and importers must submit a Preliminary Assessment Information Manufacturers' Report for each site at which they manufacture or import each substance by the reporting date shown		EPA 2002i 40CFR712.30(d)
	Decabromodiphenyl ether	03/12/90	
	Octabromodiphenyl ether	03/12/90	
	Pentabromodiphenyl ether	03/12/90	
	TSCA; chemical substances required to be tested	Chemical substances known to be manufactured between 01/01/84 and date of promulgation	EPA 2002j 40CFR766.25 (a)(1)
	Decabromodiphenyl ether		
	Octabromodiphenyl ether		
	Pentabromodiphenyl ether		
TSCA; health and safety data reporting ^f	<u>Effective date</u>	<u>Sunset date</u>	EPA 2002l 40CFR716.120 (a)
Decabromodiphenyl ether	01/11/90	06/30/98	
Octabromodiphenyl ether	06/30/98	01/11/90	
Pentabromodiphenyl ether	01/11/90	06/30/98	

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	TSCA; reporting requirements including deadline for submitting the protocols		EPA 2002k 40CFR766.35
	Decabromodiphenyl ether	01/31/91	
	Octabromodiphenyl ether	01/31/91	
	Pentabromodiphenyl ether	02/06/95	
EPA	TSCA; significant new uses subject to reporting of <i>p</i> -bromodiphenyl ether	Significant new use includes manufacturing, importing, or processing of 10,000 pounds or more per year per facility for any use	EPA 2002m 40CFR721.3430
	TSCA; significant new uses subject to reporting of polybrominated biphenyl	The significant new use is any use	EPA 2002n 40CFR721.1790
	Decabromodiphenyl		
	Hexabromo-1,1'-biphenyl		
	Octabromobiphenyl		
	Voluntary children's chemical evaluation program		EPA 2002o
	Decabromodiphenyl ether		
	Octabromodiphenyl ether		
	Pentabromodiphenyl ether		
NTP	Carcinogenicity classification		NTP 2002
	Decabromobiphenyl	Reasonably anticipated to be human carcinogens	
	Octabromobiphenyl		
	Polybrominated biphenyl		
<u>STATE</u>			
Regulations and Guidelines:			
a. Air		No data	
b. Water			
Florida	Drinking water guideline <i>p</i> -Bromodiphenyl ether	10 µg/L	HSDB 2002
c. Food		No data	
d. Other			
Florida	Toxic substance Polybrominated biphenyl		BLR 2002

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Agency	Description	Information	Reference
<u>STATE</u> (cont.)			
Massachusetts	Hazardous substances requires the labeling of containers of toxic substances in the workplace		BLR 2002
	Decabromobiphenyl	Extraordinary hazardous ⁹	
	Decabromodiphenyl ether		
	Hexabromobiphenyl	Extraordinary hazardous ⁹	
	Hexabromo-1,1'-biphenyl	Extraordinary hazardous ⁹	
	Octabromodiphenyl	Extraordinary hazardous ⁹	
	<i>p</i> -Bromodiphenyl ether Polybrominated biphenyl		
Michigan	Critical materials register; requires all businesses discharging waste products into the water or any sewer system to report the annual amount		BLR 2002
Minnesota	<i>p</i> -Bromodiphenyl ether		
	Hazardous substance		BLR 2002
	Decabromodiphenyl ether Hexabromo-1,1'-biphenyl		
New Jersey	Hazardous substance; requires SIC employers to submit Community Right-to-Know survey listing environmental hazardous substances present at their facilities in quantities that exceed 500 pounds		BRL 2002
New York	Decabromodiphenyl ether		
	Hazardous substance		BLR 2002
	<i>p</i> -Bromodiphenyl ether		
	Reportable quantity (air) Reportable quantity (land)	100 pounds 100 pounds	

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Agency	Description	Information	Reference
STATE (cont.)			
Pennsylvania	Hazardous substance; requires employers to complete the Hazardous Substance Survey Form annually		BLR 2002
	Decabromodiphenyl ether	Environmental hazard	
	<i>p</i> -Bromodiphenyl ether	Environmental hazard	
	Polybrominated biphenyl	Special hazard	

^aPolybrominated biphenyls category includes: decabromobiphenyl (CAS# 13654-09-6); decabromodiphenyl ether (CAS# 1163-19-5); hexabromobiphenyl (CAS# 59080-40-9); hexabromo-1,1'-biphenyl (CAS# 36355-01-8); hexabromodiphenyl ether (CAS# 36483-60-0); nonabromodiphenyl ether (CAS# 63936-56-1); octabromobiphenyl (CAS# 27858-07-7); octabromobiphenyl (CAS# 61288-13-9); octabromodiphenyl ether (CAS# 32536-52-0); *p*-bromodiphenyl ether (CAS# 101-55-3); *p,p'*-dibromodiphenyl ether (CAS# 2050-47-7); pentabromodiphenyl ether (CAS# 32534-81-9); polybrominated biphenyl (CAS# 59536-65-1); polybrominated biphenyl mixture (CAS# 67774-32-7); tetrabromodiphenyl ether (CAS# 40088-47-9); and tribromodiphenyl ether (CAS# 49690-94-0).

^bGroup 2B: possibly carcinogenic to humans

^cGroup 3: not classifiable as to its carcinogenicity to humans

^dGroup C: possible human carcinogen

^eGroup D: not classifiable as to human carcinogenicity

^fHealth and safety data reporting: the listed chemical substances are subject to all provisions of 40CFR716. Manufacturers, importers, and processors of a listed substance are subject to the reporting requirements of Subpart A for that substance.

^gExtraordinary hazardous and designated carcinogen

ACGIH = American Conference of Governmental Industrial Hygienists; BRL = Business & Legal Reports, Inc.; CERCLA = Comprehensive Environmental Response Compensation and Liability Act; CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; EPCRA = Emergency Planning and Community Right-to-Know Act; FDA = Food and Drug Administration; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; 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; PQL = practical quantitation limits; RCRA = Resource Conservation Recovery Act; REL = recommended exposure limit; RfD = oral reference dose; SIC = Standard Industrial Classification; TLV = threshold limit value; TSCA = Toxic Substances Control Act; TSD = treatment, storage, and disposal; TWA = time-weighted average

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effects in rats that were exposed to a commercial octaBDE mixture for 13 weeks (Great Lakes Chemical Corporation 2001a, 2001b).

EPA derived reference doses (RfDs) for octaBDE and pentaBDE of 3×10^{-3} and 2×10^{-3} mg/kg/day, respectively (IRIS 2002). The current RfD for decaBDE is 1×10^{-2} mg/kg/day, but this is based on a study using a preparation that contained only 77% decaBDE; the RfD for decaBDE is currently under review by the IRIS program.

The National Academy of Sciences (NRC 2000) derived a RfD of 4 mg/kg/day for decabromodiphenyl oxide based on a NOAEL of 1,120 mg/kg/day for liver pathology in rats that were exposed for 103 weeks (NTP 1986).

IARC (1987) has classified decabromobiphenyl, hexabromobiphenyl, and octabromobiphenyl in Group 2B, possibly carcinogenic to humans. NTP (2002) has classified decabromobiphenyl, octabromobiphenyl, and polybrominated biphenyl as reasonably anticipated to be human carcinogens. EPA (IRIS 2002) has classified decabromodiphenyl ether in Group D, as a possible human carcinogen, and nonabromodiphenyl ether, octabromodiphenyl ether, hexabromodiphenyl ether, pentabromodiphenyl ether, tetrabromodiphenyl ether, tribromodiphenyl ether, *p,p'*-dibromodiphenyl ether, and *p*-bromodiphenyl ether in Group D, not classifiable as to human carcinogenicity.

The American Industrial Hygiene Association (AIHA) has established a Workplace Environmental Exposure Level (WEEL) of 5 mg/m³ for decaBPE (AIHA 1996).

Industry is required to report health and safety data for PBDEs, including decabromodiphenyl ether, octabromodiphenyl ether, and pentabromodiphenyl ether, under the Toxic Substances Control Act (TSCA) (EPA 2002).

The European Union has banned the sale of products containing more than 0.1% penta- and octaBDE effective August 15, 2004 (EU 2003b). In 2003, the state of California passed an identical ban, to go into effect January 1, 2008 (California Assembly 2003). A subsequent proposed bill would change the implementation date to June 1, 2006 (California Assembly 2004).