

## 8. REGULATIONS AND ADVISORIES

Table 8-1 summarizes international, national, and state regulations and guidelines on human exposure to PBBs.

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.

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.

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**Table 8-1. Regulations and Guidelines Applicable to PBBs<sup>a</sup>**

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification		IARC 1987
	Decabromobiphenyl	Group 2B <sup>b</sup>	
	Hexabromobiphenyl	Group 2B <sup>b</sup>	
	Octabromobiphenyl	Group 2B <sup>b</sup>	
<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			
	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	Chemical substances subject to proposed or final TSCA rules or orders	Regulated under <u>TSCA section(s)</u>	EPA 1998
	Decabromobiphenyl	5(a)(2)	
	Hexabromo-1,1'-biphenyl	5(a)(2)	
	Octabromobiphenyl	5(a)(2)	
	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)
	Polybrominated biphenyls	01/01/87	

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	TSCA; significant new uses subject to reporting of polybrominated biphenyl Decabromodiphenyl Hexabromo-1,1'-biphenyl Octabromobiphenyl	The significant new use is any use	EPA 2002n 40CFR721.1790
NTP	Carcinogenicity classification Decabromobiphenyl Octabromobiphenyl Polybrominated biphenyl	Reasonably anticipated to be human carcinogens	NTP 2002

<sup>a</sup>Polybrominated biphenyls category includes: decabromobiphenyl (CAS# 13654-09-6); hexabromobiphenyl (CAS# 59080-40-9); hexabromo-1,1'-biphenyl (CAS# 36355-01-8); ; octabromobiphenyl (CAS# 27858-07-7); octabromobiphenyl (CAS# 61288-13-9) (CAS# 32534-81-9); polybrominated biphenyl (CAS# 59536-65-1); and polybrominated biphenyl mixture (CAS# 67774-32-7).

<sup>b</sup>Group 2B: possibly carcinogenic to humans.

ACGIH = American Conference of Governmental Industrial Hygienists; CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; 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; REL = recommended exposure limit; TLV = threshold limit value; TSCA = Toxic Substances Control Act; TWA = time-weighted average