8. REGULATIONS AND ADVISORIES

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

ATSDR derived an intermediate-duration oral MRL for inorganic tin of 0.3 mg Sn/kg/day (as stannous chloride) based on a NOAEL of 32 mg/kg/day for hematological effects in rats in a 90-day feeding study (De Groot et al. 1973). An uncertainty factor of 100 was applied to the NOAEL (10 for animal to human extrapolation and 10 for human variability).

ATSDR derived an intermediate-duration oral MRL of 0.005 mg/kg/day for dibutyltin chloride based on a LOAEL of 5 mg/kg/day for immunological effects in rats in a 4–6-week feeding study (Seinen et al. 1977b). An uncertainty factor of 1,000 was applied to the LOAEL (10 for animal to human extrapolation, 10 for the use of a LOAEL, and 10 for human variability).

ATSDR derived an intermediate-duration oral MRL of 0.0003 mg/kg/day for tributyltin oxide based on a NOAEL of 0.025 mg/kg/day for immunological effects in rats in a 4.5–6-month dietary study in rats (Vos et al. 1990). An uncertainty factor of 100 was applied to the NOAEL (10 for animal to human extrapolation and 10 for human variability).

ATSDR derived a chronic-duration oral MRL of 0.0003 mg/kg/day for tributyltin oxide based on a NOAEL of 0.025 mg/kg/day for immunological effects in rats in an 18-month dietary study in rats (Vos et al. 1990). An uncertainty factor of 100 was applied to the NOAEL (10 for animal to human extrapolation and 10 for human variability).

EPA (IRIS 2005) derived an oral reference dose (RfD) of 0.0003 mg/kg/day for tributyltin oxide using a benchmark dose analysis of immunological effects in rats in an 18-month dietary study (Vos et al. 1990). A 10% relative change was chosen as the benchmark response (BMR).

EPA (IRIS 2005) has assigned tributyltin oxide to group D weight-of-evidence classification: not classifiable as to human carcinogenicity, or to a group for which there is “inadequate information to assess carcinogenic potential,” according to updated guidelines (EPA 2003g).

Table 8-1. Regulations and Guidelines Applicable to Tin and Tin Compounds

Agency	Description	Information	Reference
INTERNATIONAL			
Guidelines:			
IARC	Carcinogenicity classification	No data	
WHO	Drinking water guideline Tin and inorganic tin compounds	No numerical value based on low toxicity	WHO 1993
NATIONAL			
Regulations and Guidelines:			
a. Air:			
ACGIH	TLV (8-hour TWA) Tin (as Sn) Metal Oxide and inorganic compounds, except tin hydride Organic compounds[a] STEL	 2.0 mg/m^3 2.0 mg/m^3 0.1 mg/m^3 0.2 mg/m^3	ACGIH 2003
NIOSH	REL (10-hour TWA) Tin (as Sn) Inorganic compounds, except tin oxides IDLH Organic compounds, except cyhexatin[b] IDLH Stannous oxide	 2.0 mg/m^3 100 mg/m^3 0.1 mg/m^3 25 mg/m^3 2.0 mg/m^3	NIOSH 2003a, 2003b
OSHA	PEL (8-hour TWA) for general industry Tin (as Sn) Inorganic compounds, except oxides Organic compounds	 2.0 mg/m^3 0.1 mg/m^3	OSHA 2003a 29 CFR 1910.1000, Table Z-1
	PEL (8-hour TWA) for construction industry Tin (as Sn) Inorganic compounds, except oxides Organic compounds	 2.0 mg/m^3 0.1 mg/m^3	OSHA 2003c 29 CFR 1926.55, Appendix A
OSHA	PEL (8-hour TWA) for shipyard industry Tin (as Sn) Inorganic compounds, except oxides Organic compounds Tin oxide (as Sn) Total dust Respirable fraction	 2.0 mg/m^3 0.1 mg/m^3 15 mg/m^3 5.0 mg/m^3	OSHA 2003b 29 CFR 1915.1000

Table 8-1. Regulations and Guidelines Applicable to Tin and Tin Compounds

Agency	Description	Information		Reference
NATIONAL *(cont.)*				
USNRC	Occupational values			USNRC 2003
	Oral ingestion for Class D[c]	ALI (µCi)		10 CFR 20,
	^{110}Tin	4.0×10^{3}		Appendix B
	^{111}Tin	7.0×10^{4}		
	^{113}Tin (LLI wall)[d]	2.0×10^{3}		
	^{113}Tin	2.0×10^{3}		
	^{117m}Tin (LLI wall)[d]	2.0×10^{3}		
	^{117m}Tin	2.0×10^{3}		
	^{119m}Tin (LLI wall)[d]	3.0×10^{3}		
	^{119m}Tin	4.0×10^{3}		
	^{121}Tin (LLI wall)[d]	6.0×10^{3}		
	^{121}Tin	6.0×10^{3}		
	^{121m}Tin (LLI wall)[d]	3.0×10^{3}		
	^{121m}Tin	4.0×10^{3}		
	^{123}Tin (LLI wall)[d]	5.0×10^{2}		
	^{123}Tin	6.0×10^{2}		
	^{123m}Tin	5.0×10^{4}		
	^{125}Tin (LLI wall)[d]	4.0×10^{2}		
	^{125}Tin	5.0×10^{2}		
	^{126}Tin	3.0×10^{2}		
	^{127}Tin	7.0×10^{3}		
	^{128}Tin	9.0×10^{3}		
	Occupational values			USNRC 2003
	Inhalation[e] for Class D[c]	ALI (µCi)	DAC (µCi/mL)	10 CFR 20,
	^{110}Tin	1.0×10^{4}	5.0×10^{-6}	Appendix B
	^{111}Tin	2.0×10^{5}	9.0×10^{-5}	
	^{113}Tin	1.0×10^{3}	5.0×10^{-7}	
	^{117m}Tin (bone and surf)[d]	1.0×10^{3}	No data	
	^{117m}Tin	2.0×10^{3}	5.0×10^{-7}	
	^{119m}Tin	2.0×10^{3}	1.0×10^{-6}	
	^{121}Tin	2.0×10^{4}	6.0×10^{-6}	
	^{121m}Tin	9.0×10^{2}	4.0×10^{-7}	
	^{123}Tin	6.0×10^{2}	3.0×10^{-7}	
	^{123m}Tin	1.0×10^{5}	5.0×10^{-5}	
	^{125}Tin	9.0×10^{2}	4.0×10^{-7}	
	^{126}Tin	6.0×10^{1}	2.0×10^{-8}	
	^{127}Tin	2.0×10^{4}	8.0×10^{-6}	
	^{128}Tin	3.0×10^{4}	1.0×10^{-5}	

Table 8-1. Regulations and Guidelines Applicable to Tin and Tin Compounds

Agency	Description	Information		Reference
NATIONAL *(cont.)*				
USNRC	Occupational values			USNRC 2003
	Inhalation[e] for Class W[f]	ALI (µCi)	DAC (µCi/mL)	10 CFR 20,
	^{110}Tin	1.0×10^{4}	5.0×10^{-6}	Appendix B
	^{111}Tin	3.0×10^{5}	1.0×10^{-4}	
	^{113}Tin	5.0×10^{2}	2.0×10^{-7}	
	^{117m}Tin	1.0×10^{3}	6.0×10^{-7}	
	^{119m}Tin	1.0×10^{3}	4.0×10^{-7}	
	^{121}Tin	1.0×10^{4}	5.0×10^{-6}	
	^{121m}Tin	5.0×10^{2}	2.0×10^{-7}	
	^{123}Tin	2.0×10^{2}	7.0×10^{-8}	
	^{123m}Tin	1.0×10^{5}	6.0×10^{-5}	
	^{125}Tin	4.0×10^{2}	1.0×10^{-7}	
	^{126}Tin	7.0×10^{1}	3.0×10^{-8}	
	^{127}Tin	2.0×10^{4}	8.0×10^{-6}	
	^{128}Tin	4.0×10^{4}	1.0×10^{-5}	
b. Water				
EPA	Drinking water standards	No data		
c. Food				
FDA	Direct food substances affirmed as GRAS in accordance with good manufacturing practices; stannous chloride (anhydrous and dehydrated)	Not to exceed 0.0015% calculated as tin for all food categories		FDA 2003a 21 CFR 184.1845
	Food additives permitted for direct addition to food for human consumption; stannous chloride (food additive) may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material	Not to exceed 20 pmm calculated as tin		FDA 2003b 21 CFR 172.180
	Indirect food additives; adhesives; bis(tributyltin)oxide	For use as a preservative only		FDA 2003d 21 CFR 175.105(c)(5)
	Indirect food additives; polymers; polyurethane resins	Dibutyltin chloride		FDA 2003e 21 CFR 177.1680(b)
	Indirect food additives; resinous and polymeric coatings	Stannous chloride		FDA 2003c 21 CFR 175.300
	Indirect food additives; rubber articles intended for repeated use; stannous chloride	Activators (total not to exceed 5% by weight of rubber product)		FDA 2003f 21 CFR 177.2600(c)(4)
	Substances GRAS in accordance with good manufacturing or feeding practices; stannous chloride	Not to exceed 0.0015% calculated as tin		FDA 2003g 21 CFR 582.3845
d. Other				
ACGIH	Carcinogenicity classification	A4[g]		ACGIH 2003
EPA	Carcinogenicity classification			IRIS 2005
	Bis(tributyltin oxide)	D[h]		

Table 8-1. Regulations and Guidelines Applicable to Tin and Tin Compounds

Agency	Description	Information		Reference
NATIONAL *(cont.)*				
EPA	RfD			IRIS 2005
	Bis(tributyltin oxide)	$3x10^{-4}$ mg/kg/day		
	RfC			IRIS 2005
	Bis(tributyltin oxide)	No data		
	Community right-to-know; release reporting; effective date of reporting			EPA 2003f 40 CFR 372.65
	Bis(tributyltin)oxide	01/01/95		
	Triphenyltin chloride	01/01/95		
	Emergency release notification	Tin		EPA 2003c 40 CFR 355.40
	Extremely hazardous			EPA 2003d 40 CFR 355, Appendix A
	Trimethyltin chloride			
	Reportable quantity	500 pounds		
	Threshold planning quantity	500/10,000 pounds		
	Triphenyltin chloride			
	Reportable quantity	500 pounds		
	Threshold planning quantity	500/10,000 pounds		
	Municipal solid waste landfills; hazardous constituent; tin (total)	Method 6010	PQL 40 µg/L	EPA 2003a 40 CFR 258, Appendix II
	Notification requirements of releases	Tin		EPA 2003b 40 CFR 302.6
	Standards for owners and operators of hazardous waste TSD facilities; groundwater monitoring; tin (total)	Method 7870	PQL $8x10^{3}$ µg/L	EPA 2003e 40 CFR 264, Appendix IX
USNRC	Effluent concentrations for Class D[c]	Air (µCi/mL)	Water (µCi/mL)	USNRC 2003 10 CFR 20, Appendix B
	^{110}Tin	$2.0x10^{-8}$	$5.0x10^{-5}$	
	^{111}Tin	$3.0x10^{-7}$	$1.0x10^{-3}$	
	^{113}Tin (LLI wall)[d]	$2.0x10^{-9}$	No data	
	^{113}Tin	No data	$3.0x10^{-5}$	
	^{117m}Tin	$3.0x10^{-9}$	$3.0x10^{-5}$	
	^{119m}Tin (LLI wall)[d]	$3.0x10^{-9}$	No data	
	^{19m}Tin	No data	$6.0x10^{-5}$	
	^{121}Tin (LLI wall)[d]	$2.0x10^{-8}$	No data	
	^{121}Tin	No data	$8.0x10^{-5}$	
	^{121m}Tin (LLI wall)[d]	$1.0x10^{-9}$	No data	
	^{121m}Tin	No data	$5.0x10^{-5}$	
	^{123}Tin (LLI wall)[d]	$9.0x10^{-10}$	No data	
	^{123}Tin	No data	$9.0x10^{-6}$	
	^{123m}Tin	$2.0x10^{-7}$	$7.0x10^{-4}$	
	^{125}Tin (LLI wall)[d]	$1.0x10^{-9}$	No data	
	^{125}Tin	No data	$6.0x10^{-6}$	
	^{126}Tin	$8.0x10^{-11}$	$4.0x10^{-6}$	
	^{127}Tin	$3.0x10^{-8}$	$9.0x10^{-5}$	
	^{128}Tin	$4.0x10^{-8}$	$1.0x10^{-4}$	

Table 8-1. Regulations and Guidelines Applicable to Tin and Tin Compounds

Agency	Description	Information	Reference
NATIONAL *(cont.)*			
USNRC	Effluent concentrations for		USNRC 2003
	Class W[f]	Air (µCi/mL)	10 CFR 20,
	^{110}Tin	2.0×10^{-8}	Appendix B
	^{111}Tin	4.0×10^{-7}	
	^{113}Tin	8.0×10^{-10}	
	^{117m}Tin	2.0×10^{-9}	
	^{119m}Tin	1.0×10^{-9}	
	^{121}Tin	2.0×10^{-8}	
	^{121m}Tin	8.0×10^{-10}	
	^{123}Tin	2.0×10^{-10}	
	^{123m}Tin	2.0×10^{-7}	
	^{125}Tin	5.0×10^{-10}	
	^{126}Tin	9.0×10^{-11}	
	^{127}Tin	3.0×10^{-8}	
	^{128}Tin	5.0×10^{-8}	
	Release to sewers for Class D[c;]		USNRC 2003
	monthly average concentration		10 CFR 20,
	^{110}Tin	5.0×10^{-4} µCi/mL	Appendix B
	^{111}Tin	1.0×10^{-2} µCi/mL	
	^{113}Tin	3.0×10^{-4} µCi/mL	
	^{117m}Tin	3.0×10^{-4} µCi/mL	
	^{119m}Tin	6.0×10^{-4} µCi/mL	
	^{121}Tin	8.0×10^{-4} µCi/mL	
	^{121m}Tin	5.0×10^{-4} µCi/mL	
	^{123}Tin	9.0×10^{-5} µCi/mL	
	^{123m}Tin	7.0×10^{-3} µCi/mL	
	^{125}Tin	6.0×10^{-5} µCi/mL	
	^{126}Tin	4.0×10^{-5} µCi/mL	
	^{127}Tin	9.0×10^{-4} µCi/mL	
	^{128}Tin	1.0×10^{-3} µCi/mL	
STATE			
a. Air	No data		
b. Water			
Florida	Drinking water guideline		HSDB 2003
	Tin	4.2 mg/L	
Minnesota	Drinking water guideline		HSDB 2003
	Tin	4.0 mg/L	

Table 8-1. Regulations and Guidelines Applicable to Tin and Tin Compounds

Agency	Description	Information	Reference
STATE *(cont.)*			
c. Food	No data		
d. Other	No data		

[a]Skin notation: refers to the potential significant contribution to the overall exposure by the cutaneous route, including mucous membranes and the eyes, either by contact with vapors or, of probable greater significance, by direct skin contact with the substance.
[b]Skin designation
[c]Class D: refers to the retention (clearance half-times of <10 days) for all compounds except those given for W.
[d]When an ALI is defined by the stochastic dose limit, this value alone, is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. (Abbreviated organ or tissue designations are used: LLI wall = lower large intestine wall; St. wall = stomach wall; Blad wall = bladder wall; and Bone surf = bone surface.)
[e]The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 µm and for class D and W of radioactive material, which refers to their retention (clearance half-times of <10 days and 10–100 days, respectively) in the pulmonary region of the lung.
[f]Class W: refers to the retention (clearance half-times of 10–100 days) for sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate.
[g]A4: not classifiable as a human carcinogen
[h]D: not classifiable as to human carcinogenicity

ACGIH = American Conference of Governmental Industrial Hygienists; ALI = annual limits on intakes; CFR = Code of Federal Regulations; DAC = derived air concentration; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; GRAS = generally recognized as safe; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; LLI = lower large intestine; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure level; TLV = threshold limit values; TSD = treatment, storage, and disposal; TWA = time-weighted average; USNRC = Nuclear Regulatory Commission; WHO = World Health Organization