

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.

An MRL of 0.05 mg/kg/day has been derived for acute-duration oral exposure (≤ 14 days) to toxaphene. The MRL is based on a NOAEL of 5 mg/kg/day and a serious LOAEL of 10 mg/kg/day for neurological effects (convulsions, salivation, and vomiting) in male and female beagle dogs (Chu et al. 1986). The NOAEL of 5 mg/kg/day was divided by an uncertainty factor of 100 (10 for extrapolation from animals to humans and 10 for human variability).

An MRL of 0.002 mg/kg/day has been derived for intermediate-duration oral exposure (15–364 days) to toxaphene based on decreased anti-SRBC (IgM) titers as an indicator of depressed humoral immunity in monkeys. Benchmark dose (BMD) modeling was conducted using mean anti-SRBC (IgM) titre data collected from female cynomolgus monkeys that received toxaphene from the diet for 44 weeks prior to primary immunization with SRBC (Tryphonas et al. 2001). The resulting $BMDL_{1SD}$ of 0.22 mg/kg/day was divided by an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for sensitive individuals).

EPA (IRIS 2010) has not established an oral reference dose (RfD) or inhalation reference concentration (RfC) for toxaphene.

The International Agency for Research on Cancer (IARC) has classified toxaphene as a Group 2B carcinogen (possibly carcinogenic to humans) (IARC 2009). The National Toxicology Program (NTP) has determined that toxaphene is reasonably anticipated to be a human carcinogen (NTP 2005), and EPA has classified toxaphene as a B2 carcinogen (probable human carcinogen) (IRIS 2010). The American Conference of Governmental Industrial Hygienists (ACGIH) has classified toxaphene as an A3 carcinogen (confirmed animal carcinogen with unknown relevance to humans) (ACGIH 2009).

OSHA has required employers of workers who are occupationally exposed to toxaphene to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PELs) (OSHA 2009). The employer must use engineering and work practice controls to reduce toxaphene exposures to or below 0.5 mg/m^3 at any time (ceiling) (OSHA 2009).

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EPA has designated toxaphene as a hazardous air pollutant (HAP) under the Clean Air Act (CAA) (EPA 2006b). Toxaphene is on the list of chemicals appearing in "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986" and has been assigned a reportable quantity (RQ) limit of 1 pound (EPA 2009e). The RQ represents the amount of a designated hazardous substance which, when released to the environment, must be reported to the appropriate authority.

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

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Table 8-1. Regulations and Guidelines Applicable to Toxaphene

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 2B ^a	IARC 2009
WHO	Air quality guidelines	No	WHO 2000
	Drinking water quality guidelines	No ^b	WHO 2006
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	0.5 mg/m ^{3c}	ACGIH 2009
	STEL (15-minute TWA)	1 mg/m ^{3c}	
	TLV-basis (critical effect)	Central nervous system convulsions; liver damage	
AIHA	ERPG values	No	AIHA 2010
DOE	TEELs		DOE 2010
	TEEL-0 ^d	0.5 mg/m ³	
	PAC-1 ^e	1 mg/m ³	
	PAC-2 ^f	20 mg/m ³	
EPA	PAC-3 ^g	200 mg/m ³	EPA 2010b EPA 2006b 42 USC 7412 EPA 2009h 40 CFR 68.130
	AEGL values	No	
	Hazardous air pollutant	Yes	
	Regulated toxic substances and threshold quantities for accidental release prevention	No	
	Second AEGL Chemical Priority List	Yes ^h	
NIOSH	REL (10-hour TWA)	No ⁱ	NIOSH 2005
	IDLH	200 mg/m ³	
	Potential Occupational Carcinogen	Yes	
	Target organs	Central nervous system, skin	
OSHA	Category of Pesticide	Group I ^j	NIOSH 1992 OSHA 2009 29 CFR 1910.1000, Table Z-1
	PEL (8-hour TWA) for general industry	0.5 mg/m ³ⁱ	
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act	Yes	EPA 2009b 40 CFR 116.4

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Agency	Description	Information	Reference
NATIONAL (cont.)			
EPA	Drinking water standards and health advisories		EPA 2009c
	1-Day health advisory for a 10-kg child	0.004 mg/L	
	10-Day health advisory for a 10-kg child	0.004 mg/L	
	DWEL	0.01 mg/L	
	Lifetime	No	
	10 ⁻⁴ Cancer risk	0.003 mg/L	
	Drinking water contaminants list	Yes	EPA 2010c
	National primary drinking water regulations		EPA 2009d
	MCL	0.003 mg/L	
	Potential health effects from exposure above the MCL	Kidney, liver, or thyroid problems; increased risk of cancer	
	Common sources of toxaphene in drinking water	Runoff/leaching from insecticide used on cotton and cattle	
	Public health goal	Zero	
	National recommended water quality criteria	Yes	EPA 2006a
	Freshwater		
	CMC (acute)	0.73 µg/L	
	CCC (chronic)	0.0002 µg/L ^k	
	Saltwater		
	CMC (acute)	0.21 µg/L	
	CCC (chronic)	0.0002 µg/L ^k	
	Human health for the consumption of:		
	Water + organism	0.00028 µg/L ^{l,m}	
	Organism only	0.00028 µg/L ^{l,m}	
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	1 pound	EPA 2009i 40 CFR 117.3
	Groundwater Monitoring List	Yes	EPA 2009a 40 CFR 264, Appendix IX
c. Food			
FDA	Bottled drinking water	0.003 mg/L	FDA 2010a 21 CFR 165.110

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Agency	Description	Information	Reference
NATIONAL (cont.)			
FDA	EAFUS ⁿ	No	FDA 2010b
d. Other			
ACGIH	Carcinogenicity classification	A3 ^o	ACGIH 2009
	Biological exposure indices (end of shift at end of workweek)	No	
EPA	Carcinogenicity classification	B2 ^p	IRIS 2010
	Oral slope factor	1.1 (mg/kg-day) ⁻¹	
	Drinking water unit risk	3.2x10 ⁻⁵ (µg/L) ⁻¹	
	Inhalation unit risk	3.2x10 ⁻⁴ (µg/m ³) ⁻¹	
	RfC	No	
	RfD	No	
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance	Yes ^q	EPA 2009a 40 CFR 302.4
	Reportable quantity	1 pound	
	Effective date of toxic chemical release reporting	01/01/1987	EPA 2009g 40 CFR 372.65
	Extremely hazardous substances and its threshold planning quantity	No	EPA 2009f 40 CFR 355, Appendix A
	Toxic pollutants designated pursuant to Section 307(a)(1) of the Clean Water Act	Yes	EPA 2009j 40 CFR 401.15
NTP	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen ^r	NTP 2005

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Agency	Description	Information	Reference
	^a Group 2B: possibly carcinogenic to humans.		
	^b Chemical is excluded from guideline value derivation because of determination that toxaphene is unlikely to occur in drinking water.		
	^c Skin notation: refers to the potential significant contribution to the overall exposure by the cutaneous route, including mucous membranes and the eyes, and by contact with vapors, liquids, and solids.		
	^d TEEL-0 is the threshold concentration below which most people will experience no adverse health effects.		
	^e PAC-1 is the airborne concentration (expressed as or mg/m ³) of a substance above which it is predicted that the general population, including susceptible individuals, could experience discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure.		
	^f PAC-2 is the airborne concentration (expressed as mg/m ³) 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.		
	^g PAC-3 is the airborne concentration (expressed as mg/m ³) of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.		
	^h Camphchlor is included on the list of 371 priority chemicals that are acutely toxic and represent the selection of chemicals for AEGL development by the NAC/AEGL committee during the next several years.		
	ⁱ Skin designation: indicates the potential for dermal absorption.		
	^j Group I pesticides pose a significant risk of adverse acute health effects at low concentrations, or carcinogenic, teratogenic, neurotoxic, or reproductive effects.		
	^k This criterion is based on a 304(a) aquatic life criterion issued in 1980 or 1986, and was issued in toxaphene (EPA 440/5-86-006). This CCC is currently based on the FRV procedure. Since the publication of the Great Lakes Aquatic Life Criteria Guidelines in 1995 (60 FR 15393-15399, March 23, 1995), the Agency no longer uses the Final Residue Value procedure for deriving CCCs for new or revised 304(a) aquatic life criteria. Therefore, the Agency anticipates that future revisions of this CCC will not be based on the FRV procedure (EPA 2006b).		
	^l This criterion has been revised to reflect The EPA's q1* or RfD, as contained in IRIS as of May 17, 2002. The fish tissue bioconcentration factor from the 1980 Ambient Water Quality Criteria document was retained in each case (EPA 2006b).		
	^m This criterion is based on carcinogenicity of 10 ⁻⁶ risk.		
	ⁿ 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.		
	^o A3: confirmed animal carcinogen with unknown relevance to humans.		
	^p B2: probable human carcinogen; based on increased incidence of hepatocellular tumors in mice and thyroid tumors in rats and supported by mutagenicity in Salmonella.		
	^q Designated CERCLA hazardous substance pursuant to Section 311(b)(2) of the Clean Water Act, section 307(a) of the Clean Water Act, Section 112 of the Clean Air Act, and Section 3001 of RCRA.		
	^r Based on sufficient evidence of carcinogenicity in experimental animals.		

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CCC = criterion continuous concentration; CMC = criterion maximum concentration; DOE = U.S. Department of Energy; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = U.S. Environmental Protection Agency; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; FRV = final residue value; GRAS = generally recognized as safe; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MTL = Master Testing List; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = protective action criteria; PEL = permissible exposure limit; RCRA = Resource Conservation and Recovery Act; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TEEL = temporary emergency exposure limit; TLV = threshold limit values; TSCA = Toxic Substances Control Act; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization