

8. REGULATIONS AND ADVISORIES

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

ATSDR derived an acute-duration oral MRL of 0.0006 mg/kg/day for heptachlor. This MRL was based on a LOAEL of 1.8 mg/kg/day for impaired reproductive performance in female rats mated with unexposed males (Amita Rani and Krishnakumari 1995), an uncertainty factor of 1,000 (10 for use of a LOAEL, 10 for extrapolation from animals to humans, and 10 for human variability), and a modifying factor of 3 for the use of a serious end point.

ATSDR derived an intermediate-duration oral MRL of 0.0001 mg/kg/day for heptachlor. This MRL was based on a minimal LOAEL of 0.03 mg/kg/day for developmental immunological and neurological effects in rats (Moser et al. 2001; Smialowicz et al. 2001) and an uncertainty factor of 300 (3 for use of a minimal LOAEL, 10 for extrapolation from animals to humans, and 10 for human variability).

EPA (IRIS 2005) has derived an oral reference dose (RfD) for heptachlor of 5×10^{-4} mg/kg/day based on NOAEL of 0.15 mg/kg/day and LOAEL of 0.25 mg/kg/day for increased liver weight in rats exposed to heptachlor for 2 years and an uncertainty factor of 300 (10 for extrapolation from animals to humans, 10 for human variability, and 3 to account for limitations in the database particularly the lack of a chronic study in a second species).

EPA (IRIS 2005) also derived an RfD of 1.3×10^{-5} mg/kg/day for heptachlor epoxide. This RfD is based on a LOAEL of 0.0125 mg/kg/day for increased relative liver weight identified in a dog study submitted to EPA by Dow Chemical Company and an uncertainty factor of 1,000 to account for inter and intraspecies extrapolation and because a NOAEL was not attained. The studies which serve as the basis of the RfDs for heptachlor and heptachlor epoxide were not discussed in the toxicological profile because they were submitted to EPA under FIFRA and are not publicly available.

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Table 8-1. Regulations and Guidelines Applicable to Heptachlor and Heptachlor Epoxide

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification Heptachlor	Group 2B ^a	IARC 2004
WHO	Air quality guidelines	No data	WHO 2000
	Drinking water quality guidelines	Guideline values have not been established ^b	WHO 2004
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV-TWA Heptachlor ^c Heptachlor epoxide ^c	0.05 mg/m ³ 0.05 mg/m ³	ACGIH 2004
EPA	Hazardous air pollutant Heptachlor	Yes	EPA 2004b 42 USC 7412
NIOSH	REL (10-hour TWA) Heptachlor ^{d,e} IDLH Heptachlor	0.5 mg/m ³ 35 mg/m ³	NIOSH 2005
OSHA	PEL (8-hour TWA) for general industry Heptachlor ^f PEL (8-hour TWA) for construction industry Heptachlor ^f PEL (8-hour TWA) for shipyard industry Heptachlor ^f	0.5 mg/m ³ 0.5 mg/m ³ 0.5 mg/m ³	OSHA 2005c 29 CFR 1910.1000 OSHA 2005b 29 CFR 1926.55 OSHA 2005a 29 CFR 1915.1000
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311 of the Clean Water Act Heptachlor Drinking-water health advisories Heptachlor 1-day health advisory for a 10-kg child ^g 10-day health advisory for a 10-kg child ^h DWEL ⁱ 10 ⁻⁴ Cancer risk ⁱ	Yes 0.01 mg/L 0.01 mg/L 0.02 mg/L 0.0008 mg/L	EPA 2005a 40 CFR 116.4 EPA 2004a

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Agency	Description	Information	Reference
NATIONAL (cont.)			
EPA	Drinking-water health advisories		EPA 2004a
	Heptachlor epoxide		
	1-day health advisory for a 10-kg child ^g	0.01 mg/L	
	10-day health advisory for a 10-kg child ^h	No data	
	DWEL ⁱ	0.0004 mg/L	
	10 ⁻⁴ Cancer risk ^j	0.0004 mg/L	
	National primary drinking water regulations ^k		EPA 2002a
	Heptachlor		
	MCL	0.0004 mg/L	
	MCLG	Zero	
	Heptachlor epoxide		
	MCL	0.0002 mg/L	
	MCLG	Zero	
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act		EPA 2005b 40 CFR 117.3
	Heptachlor	1 pound	
	Water quality criteria for human health consumption of:		EPA 2002b
	Heptachlor ^l		
	Water + organism	7.9x10 ⁻⁵	
	Organism only	7.9x10 ⁻⁵	
	Heptachlor epoxide ^l		
	Water + organism	3.9x10 ⁻⁵	
	Organism only	3.9x10 ⁻⁵	
c. Food			
FDA	Action level		FDA 2000
	Heptachlor		
	Artichokes; asparagus; Brassica (cole) leafy vegetables; bulb vegetables; cereal grains; citrus fruits; eggs; figs; fruiting vegetables; leafy vegetables; legume vegetables; peanuts; pome fruits; root and tuber vegetables; salsify tops; small fruits and berries; stone fruits; and sugarcane	0.01 ppm	
	Cottonseed, cucurbit vegetables, pineapple, and rabbit (fat basis)	0.02 ppm	
	Fish (edible portion)	0.3 ppm	
	Milk (fat basis)	0.1 ppm	

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<u>NATIONAL</u> (cont.)			
FDA	Bottled water		FDA 2004
	Heptachlor	0.0004 mg/L	21 CFR 165.110
	Heptachlor epoxide	0.0002 mg/L	
d. Other			
ACGIH	Carcinogenicity classification		ACGIH 2004
	Heptachlor	A3 ^m	
	Heptachlor epoxide	A3 ^m	
EPA	Carcinogenicity classification		IRIS 2005
	Heptachlor	B2 ⁿ	
	Heptachlor epoxide	B2 ⁿ	
	RfC		
	Heptachlor	Not available at this time	
	Heptachlor epoxide	Not available at this time	
	RfD		
	Heptachlor	5.0x10 ⁻⁴ mg/kg/day	
	Heptachlor epoxide	1.3x10 ⁻⁵ mg/kg/day	
	Inhalation unit risk		
	Heptachlor	1.3x10 ⁻³ per ug/m ³	
	Heptachlor epoxide	2.6x10 ⁻³ per ug/m ³	
	Oral slope factor		
	Heptachlor	4.5 per mg/kg-day	
	Heptachlor epoxide	9.1 per mg/kg-day	
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance		EPA 2005c
	Heptachlor ^o		40 CFR 302.4
	Reportable quantity	1 pound	
	RCRA waste number	P059	
	Heptachlor epoxide ^p		
	Reportable quantity	1 pound	
	RCRA waste number	No data	
	Effective date of toxic chemical release reporting		EPA 2005e
	Heptachlor	01/01/87	40 CFR 372.65

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
	Threshold amounts for manufacturing (including importing), processing, and otherwise using such toxic chemicals		EPA 2005d 40 CFR 372.28
	Heptachlor	10 pounds	
NTP	Carcinogenicity classification	No data	NTP 2005

^aGroup 2B: possibly carcinogenic to humans

^bGuideline values have not been established: heptachlor and heptachlor epoxide occurs in drinking water at concentrations well below those at which heptachlor epoxide toxic effects may occur.

^cSkin 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.

^dPotential occupational carcinogen

^eSkin designation: indicates the potential for dermal absorption; skin exposure should be prevented as necessary through the use of good work practices and gloves, coveralls, goggles, and other appropriate equipment.

^fSkin designation

^g1-Day health advisory: the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for up to 1 day of exposure. The 1-day health advisory is normally designed to protect a 10-kg child consuming 1 liter of water per day.

^h10-Day health advisory: the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for up to 10 days of exposure. The 10-day health advisory is also normally designed to protect a 10-kg child consuming 1 liter of water per day.

ⁱDWEL: a lifetime exposure concentration protective of adverse, noncancer health effects that assumes all of the exposure to a contaminant is from drinking water.

^j10⁻⁴ Cancer risk: the concentration of a chemical in drinking water corresponding to an excess estimated lifetime cancer risk of 1 in 10,000.

^kPotential health effects from ingestion of water include liver damage and increased risk of cancer. The contaminant in drinking water is the residue of a banned termiticide (heptachlor) and the breakdown of heptachlor from epoxide heptachlor.

^lThis criterion is based on carcinogenicity of 10⁻⁶ risk.

^mA3: not classifiable as a human carcinogen

ⁿB2: probable human carcinogen

^oHeptachlor: designated CERCLA hazardous substance pursuant to Section 311(b)(2) and 307(a) of the Clean Water Act, Section 112 of the Clean Air Act, and Section 3001 of RCRA.

^pHeptachlor epoxide: designated CERCLA hazardous substance pursuant to Section 307(a) of the Clean Water Act.

ACGIH = American Conference of Governmental Industrial Hygienists; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; DWEL = drinking-water equivalent level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; RCRA = Resource Conservation and Recovery Act; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit values; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization