

## 8. REGULATIONS AND ADVISORIES

Because of methoxychlor's potential to cause adverse health effects in exposed people, a number of regulations and guidelines have been established by international, federal, and state agencies. The international, national, and state regulations and guidelines regarding methoxychlor in air, water, and other media are summarized in Table 8-1.

In addition to these values, ATSDR and EPA have established additional guidelines to protect people from the adverse health effects from ingesting methoxychlor. ATSDR has withdrawn the previous MRL of 0.02 mg/kg/day for acute-duration exposure derived in the 1994 profile (see Appendix A for further discussion). An intermediate-duration oral MRL of 0.005 mg/kg/day was derived based on the LOAEL of 5 mg/kg/day for accelerated onset of puberty (i.e., precocious vaginal opening) in immature female rats exposed to methoxychlor *in utero*, during lactation, and after weaning (Chapin et al. 1997). This MRL supercedes the previous MRL of 0.02 mg/kg/day for intermediate-duration exposure derived in the 1994 profile. A chronic-duration oral MRL was not derived. A reference dose (RfD) of 0.005 mg/kg/day was derived (in 1991) by EPA based on the NOEL for maternal toxicity in rabbits dosed during gestational days 7-19 (IRIS 2001; Kincaid Enterprises 1986).

IARC (2001) has classified methoxychlor as a Group 3 carcinogen (not classifiable as to its carcinogenicity to humans) and NCI (1978) concluded that there was insufficient evidence to classify methoxychlor as a carcinogen. Similarly, EPA has classified methoxychlor as a Group D carcinogen, not classifiable as to human carcinogenicity (IRIS 2002).

On January 14, 2000, EPA issued a suspension order to Kincaid Enterprises, Inc. to prevent further manufacture and sale of their methoxychlor products. The order affects the technical product and three products manufactured by Kincaid, but does not directly affect other companies that manufacture methoxychlor products. The order was issued because the registrant failed to submit overdue (per an agreement signed in September of 1998) environmental fate studies. At the time of the writing of this profile, EPA is in the process of issuing a notice of intent to suspend to all companies that use methoxychlor in their products (EPA 2002) ([http://www.epa.gov/oppfead1/cb/csb\\_page/updates/methox.htm](http://www.epa.gov/oppfead1/cb/csb_page/updates/methox.htm)).

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor**

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 3 <sup>a</sup>	IARC 2001
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air:			
ACGIH	TLV (8-hour TWA)	10 mg/m <sup>3</sup>	ACGIH 2001
EPA	RAC	50 µg/m <sup>3</sup>	EPA 2001p 40CFR266, Appendix IV
NIOSH	REL	Potential occupational carcinogen	NIOSH 2001
	IDLH	5,000 mg/m <sup>3</sup>	
OSHA	PEL (8-hour TWA)—total dust	15 mg/m <sup>3</sup>	OSHA 2001b 29CFR1910.1000
	PEL (8-hour TWA) for construction workers—total dust	15 mg/m <sup>3</sup>	OSHA 2001c 29CFR1926.55
	PEL (8-hour TWA) for shipyard workers—total dust	15 mg/m <sup>3</sup>	OSHA 2001a 29CFR1915.1000
USC	Listed as hazardous air pollutant		USC 2001 42 USC 7412
b. Water			
EPA	Designated as hazardous substance in accordance with Section 311(b)(2)(A) of the Clean Water Act		EPA 2001s 40CFR116.4
	Drinking water standard	0.04 ppm	EPA 2001c 40CFR141.32 (e)(43)
	Groundwater monitoring Suggested method	PQL	EPA 2001d 40CFR264, Appendix IX
	8080	2 µg/L	
	8270	10 µg/L	

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor (continued)**

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	Health advisories		EPA 2000
	10-kg child		
	1-day	0.05 mg/L	
	10-day	0.05 mg/L	
	DWEL <sup>b</sup>	0.2 mg/L	
	Lifetime	0.04 mg/L	
	Interim primary drinking water standard for owners and operators of hazardous waste TSD facilities—maximum level	0.1 mg/L	EPA 2001g 40CFR265, Appendix III
	Land disposal restrictions; universal treatment standards		EPA 2001h 40CFR268.48
	Wastewater concentration	0.25 mg/L <sup>2</sup>	
	Non-wastewater concentration	0.18 mg/kg <sup>2</sup>	
	Maximum concentration of constituents for groundwater protection	0.1 mg/L	EPA 2001i 40CFR264.94
	MCL—apply to community water systems and non-transient, non-community water systems	0.04 mg/L	EPA 2001j 40CFR141.61(c)
	MCL—promulgated under the Safe Drinking Water Act	0.1 mg/L	EPA 2001k 40CFR 257, Appendix I
	MCLG	0.04 mg/L	EPA 2001m 40CFR141.50(b)
National recommended water quality criteria		EPA 1999j	
Freshwater	0.03 µg/L		
Saltwater	0.03 µg/L		
Human health for consumption of water and organism	100 µg/L		
Radiation protection—maximum concentration for groundwater protection	0.1 mg/L	EPA 2001o 40CFR192, Table 1 to Subpart A	
Reportable quantity of hazardous substance designated pursuant to Section 311 of the Clean Water Act	1 pound	EPA 2001b 40CFR117.3	

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor (continued)**

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
c. Food			
EPA	Tolerances for residues	100 ppm	EPA 2001n 40CFR180.120
	Alfalfa, clover, cowpeas, grass for forage, peanut forage, and soybean forage		
	Apples, apricots, asparagus, beans, beets, blackberries, blueberries, boysenberries, broccoli, brussel sprouts, cabbage, carrots, cauliflower, cherries, collards, corn, cranberries, cucumbers, currants, dewberries, eggplants, gooseberries, grapes, kale, kohlrabi, lettuce, loganberries, melons, mushrooms, nectarines, peaches, peanuts, pears, peas, peppers, pineapples, plums, pumpkins, quinces, radishes, raspberries, rutabagas, spinach, squash, strawberries, summer squash, tomatoes, turnips, youngberries	14 ppm	
	Sweet potatoes and yams from preharvest and postharvest application	7 ppm	
	Fat of meat from cattle, goats, hogs, horses, or sheep	3 ppm	
	Barley, corn, oats, rice, rye, sorghum grain, and wheat from storage-bin treatment	2 ppm	
	Milk fat reflecting negligible residues in milk	1.25 ppm	
Potatoes and horseradish	1 ppm		
FDA	Beverages—bottled water concentration	0.04 mg/L	FDA 2001 21CFR165.110
USDA	Federal seed act regulations—not harmful when present at a rate less than the number of ppm indicated	2 ppm	USDA 2001 7CFR201.31a

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor (continued)**

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
d. Other			
ACGIH	Carcinogenicity classification	A4 <sup>c</sup>	ACGIH 2001
EPA	Carcinogenicity classification RfD RfC	Group D <sup>d</sup> 5x10 <sup>-3</sup> mg/kg/day Not verifiable	IRIS 2001
	Health based limits for exclusion of waste-derived residues—concentration limits for residues	1x10 <sup>-1</sup> mg/kg	EPA 2001e 40CFR266, Appendix VII
	Identification and listing of hazardous waste—hazardous waste number	U247	EPA 2001f 40CFR261.33(e)
	Maximum concentration of contaminants for toxicity characteristic—regulatory level	10 mg/L	EPA 2001j 40CFR261.24
	Organic pesticide active ingredient—pesticide code	34001	EPA 1999i 40CFR455, Subpart E
	Pesticide class	Chlorinated organic pesticide	EPA 2001q 40CFR180.3(e)(4)
	Reportable quantity of hazardous substance designated pursuant to Section 311(b)(4) of the Clean Water Act and Section 112 of the Clean Air Act	1 pound	EPA 2001a 40CFR302.4
	Toxic chemical release reporting; community right-to-know—effective date for reporting	01/01/87	EPA 2001r 40CFR372.65
<u>STATE</u> Regulations and Guidelines:			
a. Air			
Arkansas	RAC	50 µg/m <sup>3</sup>	BNA 2001
Idaho	AAC EL OEL	0.5 mg/m <sup>3</sup> 0.667 pounds/hour 10 mg/m <sup>3</sup>	ID Dept. of Health and Welfare 1999
Montana	Occupational air contaminant—TLV	15 mg/m <sup>3</sup>	BNA 2001

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor (continued)**

Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
New Hampshire	Regulated toxic air pollutant—OEL	10 mg/m <sup>3</sup>	BNA 2001
New York	Dangerous air contaminant—TLV	15 mg/m <sup>3</sup>	BNA 2001
South Carolina	RAC	50 µg/m <sup>3</sup>	BNA 2001
	Toxic air emissions Category	3 <sup>e</sup>	BNA 2001
	Maximum allowable category concentration	50 µg/m <sup>3</sup>	
Tennessee	RAC	50 µg/m <sup>3</sup>	BNA 2001
Texas	Occupational health—TLV	15 mg/m <sup>3</sup>	BNA 2001
Vermont	Hazardous air contaminant		BNA 2001
Washington	Acceptable source impact level, 24-hour average	33 µg/m <sup>3</sup>	WA Dept. of Ecology 1998
	Threshold for hazardous air pollutants—threshold level	0.5 tons/year	BNA 2001
Wyoming	RAC	50 µg/m <sup>3</sup>	BNA 2001
b. Water			
Alaska	MCL	0.04 mg/L	AK Dept. of Environ. Conserv. 1999
Arizona	Drinking water standard and guideline	340 ug/L	FSTRAC 1999
California	MCL	0.04 mg/L	CA Dept. of Health Services 2000
Colorado	Groundwater organic chemical standard	40 µg/L	CO Dept. of Public Health and Environ. 1999
Georgia	Groundwater criteria concentration	0.04 mg/L	BNA 2001
Hawaii	MCL applying to community and non-community, non-transient water systems	0.04 mg/L	HI Dept. of Health 1999a

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor (continued)**

Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
Hawaii	Toxic pollutant standard		HI Dept. of Health 1999b
	Freshwater		
	Acute	No standard	
	Chronic	0.03 µg/L	
	Saltwater		
	Acute	No standard	
Chronic	0.03 µg/L		
	Fish Consumption	No standard	
Illinois	Water supply standard	0.1 mg/L	IL Environ. Protection Agency 1999
Kansas	Water quality standard		KS Dept. of Health and Environ. 2001
	Aquatic life		
	Acute	Not available	
	Chronic	0.3 µg/L	
	Public health		
	Food procurement	Not available	
	Domestic water supply	40 µg/L	
Maine	Drinking water standard and guideline	100 µg/L	FSTRAC 1999
Missouri	Water quality standards		BNA 2001
	Aquatic life	003 µg/L	
	Drinking water supply	40 µg/L	
	Groundwater	40 µg/L	
New Jersey	Groundwater quality criteria	40 µg/L	NJ Dept. of Environ. Protection 1993
South Dakota	MCL	0.04 mg/L	SD Dept. of Environ. & Natural Resources 1998
Vermont	Groundwater quality standards		BNA 2001
	Enforcement standard	40 µg/L	
	Preventive action limit	4 µg/L	
Wisconsin	Groundwater quality standards		BNA 2001
	Enforcement standard	40 µg/L	
	Preventive action limit	4 µg/L	
c. Food	No data		

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**Table 8-1. Regulations and Guidelines Applicable to Methoxychlor (continued)**

Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
d. Other			
Arizona	Soil remediation level		BNA 2001
	Residential	330 mg/kg	
	Non-residential	3,400 mg/kg	
California	Characteristics of toxicity		BNA 2001
	Regulatory level	10 mg/L	
	STLC	10 mg/L	
	TTLC	100 wet weight mg/kg	

<sup>a</sup>Group 3: unclassifiable as to its carcinogenicity to humans

<sup>b</sup>DWEL: A lifetime exposure concentration protective of adverse, non-cancer health effects, that assumes all of the exposure to a contaminant is from drinking water.

<sup>c</sup>A4: not classifiable as a human carcinogen

<sup>d</sup>Group D: not classifiable as to human carcinogenicity

<sup>e</sup>Category 3: High toxicity—those pollutants that may cause chronic effects that result in death or permanent injury after very short exposure to small quantities.

AAC = acceptable ambient concentration; ACGIH = American Conference of Governmental Industrial Hygienists; BNA = Bureau of National Affairs; CFR = Code of Federal Regulations; DWEL = drinking water equivalent level; EL = emissions screening level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FSTRAC = Federal-State Toxicology and Regulatory Alliance Committee; 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; OEL = occupational exposure level; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation limit; RAC = reference air concentration; ppm = parts per million; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STLC = soluble threshold limit concentration; TLV = threshold limit value; TSD = treatment, storage, and disposal; TTLC = total threshold limit concentration; TWA = time-weighted average; USC = United States Code; USDA = U.S. Department of Agriculture