

8. REGULATIONS AND ADVISORIES

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

ATSDR has derived an intermediate-duration oral minimal risk level (MRL) of 1 mg Al/kg/day for aluminum. This MRL is based on a NOAEL of 26 mg Al/kg/day and a LOAEL of 130 mg Al/kg/day for neurodevelopmental effects in the offspring of mice exposed to aluminum lactate in the diet on gestation day 1 through lactation day 21 followed by pup exposure until postnatal day 35 (Golub and Germann 2001). The MRL was derived by dividing the NOAEL by an uncertainty factor of 100 (10 for animal to human extrapolation and 10 for human variability) and a modifying factor of 0.3 to account for the higher bioavailability of the aluminum lactate used in the principal study, as compared to the bioavailability of aluminum in the human diet and drinking water.

ATSDR has derived a chronic-duration oral MRL of 1 mg Al/kg/day for aluminum. This MRL is based on a LOAEL of 100 mg Al/kg/day for neurological effects in mice exposed to aluminum lactate in the diet during gestation, lactation, and postnatally until 2 years of age (Golub et al. 2000). The MRL was derived by dividing the LOAEL by an uncertainty factor of 300 (3 for the use of a minimal LOAEL, 10 for animal to human extrapolation, and 10 for human variability) and a modifying factor of 0.3 to account for the higher bioavailability of the aluminum lactate used in the principal study, as compared to the bioavailability of aluminum in the human diet and drinking water.

EPA has not derived a reference dose (RfD) or reference concentration (RfC) for aluminum, but has derived an RfD for aluminum phosphide of 4×10^{-4} mg/kg/day based on a NOAEL of 0.51 mg/kg of food or 0.025 mg/kg/day (phosphine) converted to 0.043 mg/kg/day of aluminum phosphide for body weight and clinical parameters observed in a rats during a chronic oral study (IRIS 2006).

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

Agency	Description	Information	Reference		
<u>INTERNATIONAL</u>					
Guidelines:					
IARC	Carcinogenicity classification for aluminum production	Group 1 ^a	IARC 1987		
WHO	Air quality guidelines	No data	WHO 2000		
	Drinking water quality guidelines for aluminum ^b	≤0.1 mg/L in large water treatment facilities ≤0.2 mg/L in small water treatment facilities	WHO 2004		
<u>NATIONAL</u>					
Regulations and Guidelines:					
a. Air					
ACGIH	TLV (8-hour TWA) for aluminum and compounds (as Al)		ACGIH 2005		
	Metal dust	10 mg/m ³			
	Pyro powders	5 mg/m ³			
	Soluble salts	2 mg/m ³			
	Alkyls (NOS)	2 mg/m ³			
	TLV (8-hour TWA) for aluminum oxide ^c	10 mg/m ³			
	EPA	AEGL-1 for aluminum phosphide ^d		Not recommended due to insufficient data	EPA 2006a
		AEGL-2 for aluminum phosphide ^d			
		10 minutes		4.0 ppm	
		30 minutes		4.0 ppm	
60 minutes		2.0 ppm			
4 hours		0.50 ppm			
8 hours		0.25 ppm			
AEGL-3 for aluminum phosphide ^d					
10 minutes		7.2 ppm			
30 minutes		7.2 ppm			
60 minutes		3.6 ppm			
4 hours		0.90 ppm			
8 hours		0.45 ppm			
	Hazardous air pollutant	No data	EPA 2006c 42 USC 7412		

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Agency	Description	Information	Reference
NATIONAL (cont.)			
NIOSH	REL (10-hour TWA) Aluminum	10 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)	NIOSH 2005
	Aluminum oxide	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)	
OSHA	PEL (8-hour TWA) for general industry for aluminum metal (as Al) and aluminum oxide	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)	OSHA 2005b 29 CFR 1910.1000
	PEL (8-hour TWA) for shipyard industry for aluminum metal (as Al) and aluminum oxide	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)	OSHA 2005a 29 CFR 1915.1000
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act for aluminum sulfate	Yes	EPA 2006b 40 CFR 116.4
	Drinking water standards and health advisories	No data	EPA 2004
	National primary drinking water standards	No data	EPA 2003
	National secondary drinking water standards for aluminum	0.05–0.2 mg/L	EPA 2006f 40 CFR 143.3
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act for aluminum sulfate	5,000 pounds	EPA 2006h 40 CFR 117.3
	Water quality criteria for human health for aluminum		EPA 2006e
	Freshwater CMC Freshwater CCC	750 µg/L 87 µg/L	
c. Food			
FDA	Bottled drinking water for aluminum	0.2 mg/L	FDA 2005 21 CFR 165.110
d. Other			
ACGIH	Carcinogenicity classification for aluminum oxide	A4 ^e	ACGIH 2005
EPA	Carcinogenicity classification for aluminum phosphide	No data	IRIS 2006
	RfC for aluminum phosphide	No data	
	RfD for aluminum phosphide	4x10 ⁻⁴ mg/kg/day	

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	Identification and listing of hazardous substances; hazardous waste number for aluminum phosphide	P006	EPA 2006d 40 CFR 261, Appendix VIII
	Pesticide classified as restricted use for aluminum phosphide	Yes ^f	EPA 2006g 40 CFR 152.175
	Pesticide exemptions from the requirement of a tolerance		EPA 2006i 40 CFR 180.910
	Aluminum hydroxide (for use as a diluent and carrier)	Yes ^g	
	Aluminum oxide (for use as a diluent)	Yes ^g	
	Aluminum sulfate (for use as a safener adjuvant)	Yes ^g	EPA 2006m 40 CFR 180.920
	Superfund, emergency planning, and community right-to-know		EPA 2006i 40 CFR 302.4
	Designated CERCLA hazardous substance	Yes	
	Reportable quantity		
	Aluminum phosphide	100 pounds	
	Aluminum sulfate	5,000 pounds	
	Effective date of toxic chemical release reporting		EPA 2006k 40 CFR 372.65
	Aluminum (fume or dust)	01/01/87	
	Aluminum oxide (fibrous forms)	01/01/87	
	Aluminum phosphide	01/01/95	
	Extremely hazardous substances and their threshold planning quantities for aluminum phosphide	500 pounds	EPA 2006j 40 CFR 355, Appendix A

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Agency	Description	Information	Reference
NATIONAL (<i>cont.</i>)			
NTP	Carcinogenicity classification	No data	NTP 2005

^aGroup 1: carcinogenic to humans

^bReason for not establishing a guideline value: owing to limitations in the animal data as a model for humans and the uncertainty surrounding the human data, a health-based guideline value cannot be derived; however, practicable levels based on optimization of the coagulation process in drinking-water plants using aluminium-based coagulants are derived: ≤ 0.1 mg/L in large water treatment facilities, and ≤ 0.2 mg/L in small facilities.

^cTWA: the value is for particulate matter containing no asbestos and $<1\%$ crystalline silica.

^dAEGL-1 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. AEGL-2 is the airborne concentration 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. AEGL-3 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

^eA4: not classifiable as a human carcinogen.

^fPesticide classified as restricted use: limited to use by or under the direct supervision of a certified applicator for agricultural crop uses. Criteria influencing restriction includes inhalation hazard to humans.

^gPesticide exemptions from the requirement of a tolerance: residues of the following materials are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = Acute Exposure Guideline Level; Al = aluminum; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CCC = Criterion Continuous Concentration; CMC = Criteria Maximum Concentration; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; NIOSH = National Institute for Occupational Safety and Health; NOS = not otherwise specified; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; 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