

8. REGULATIONS AND ADVISORIES

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

ATSDR derived an acute-duration inhalation MRL of 0.003 ppm using a LOAEL of 0.3 ppm for nasal and throat irritation and decreased respiratory rate in volunteers exposed for 60 minutes (Weber-Tschopp et al. 1977). The LOAEL of 0.3 ppm was divided by an uncertainty factor of 100 (10 for using a LOAEL and 10 for human variability).

ATSDR derived an intermediate duration inhalation MRL of 0.00004 ppm using a LOAEL of 0.4 ppm for nasal epithelial metaplasia in rats in a 13-week study (Feron et al. 1978). The MRL was calculated by dividing the human equivalent LOAEL (0.012 ppm) by an uncertainty factor of 300 (10 for using a LOAEL, 3 for extrapolation from animals to humans using dosimetric adjustments, and 10 for human variability).

ATSDR derived an intermediate-duration oral MRL of 0.004 mg/kg/day based on a BMDL₁₀ of 0.36 mg/kg/day for forestomach squamous epithelial hyperplasia in mice in a 14-week gavage study (NTP 2006) and an uncertainty factor of 100 (10 for species extrapolation and 10 for human variability).

EPA (IRIS 2007) has derived an inhalation reference concentration (RfC) for acrolein of 2×10^{-5} mg/m³ based on a LOAEL of 0.9 mg/m³ (0.4 ppm) for nasal lesions in male and female rats exposed to acrolein 6 hours/day, 5 days/week for 13 weeks (Feron et al. 1978) and an uncertainty factor of 1,000 (3 for use of a minimal LOAEL, 3 for interspecies extrapolation using dosimetric adjustments, 10 for extrapolation from subchronic to chronic duration, and 10 to account for human variability and sensitive subpopulations).

EPA (IRIS 2007) has derived an oral reference dose (RfD) for acrolein of 5×10^{-4} mg/kg/day based on a NOAEL of 0.05 mg/kg/day for decreased survival in male and female rats treated by oral gavage for 2 years (Parent et al. 1992a) and an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for intraspecies variability).

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Table 8-1. Regulations and Guidelines Applicable to Acrolein

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 3 ^a	IARC 2004
WHO	Air quality guidelines	No data	WHO 2000
	Drinking water quality guidelines	No data	WHO 2004
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (ceiling limit) ^b	0.10 ppm	ACGIH 2004
NAS/NRC	AEGL-1 ^c		EPA 2005a
	10, 30, 60 minutes, 4 and 8 hours	0.03 ppm	
	AEGL-2 ^c		
	10 minutes	0.44 ppm	
	30 minutes	0.18 ppm	
	60 minutes, 4 and 8 hours	0.10 ppm	
	AEGL-3 ^c		
	10 minutes	6.2 ppm	
	30 minutes	2.5 ppm	
	60 minutes	1.4 ppm	
	4 hours	0.48 ppm	
	8 hours	0.27 ppm	
EPA	Hazardous air pollutant	Yes	EPA 2004b 42 USC 7412
	Regulated toxic substances and threshold quantities for accidental release prevention	5,000 pounds	EPA 2005d 40 CFR 68.130
	Toxic end points for accidental release prevention	1.1x10 ⁻³ mg/L	EPA 2005i 40 CFR 68, Appendix A
NIOSH	REL (10-hour TWA)	0.1 ppm	NIOSH 2005
	STEL	0.3 ppm	
	IDLH	2.0 ppm	
OSHA	PEL (8-hour TWA) for general industry	0.1 ppm	OSHA 2005a 29 CFR 1910.1000
	PEL (8-hour TWA) for construction industry	0.1 ppm	OSHA 2005b 29 CFR 1926.55
	PEL (8-hour TWA) for shipyard industry	0.1 ppm	OSHA 2005d 29 CFR 1910.1000
	Highly hazardous chemical and threshold quantity	150 pounds ^d	OSHA 2005c 29 CFR 1910.119
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311 of the Clean Water Act	Yes	EPA 2005b 40 CFR 116.4
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	1 pound	EPA 2005e 40 CFR 117.3
	Water quality criteria for human health consumption of:		EPA 2002
	Water + organism	190 µg/L	
	Organism only	290 µg/L	
c. Food			
		No data	

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Agency	Description	Information	Reference
NATIONAL (cont.)			
d. Other			
ACGIH	Carcinogenicity classification	A4 ^e	ACGIH 2004
EPA	Carcinogenicity classification	Cannot be determined ^f	IRIS 2005
	RfC	2x10 ⁻⁵ mg/m ³	
	RfD	5x10 ⁻⁴ mg/kg/day	
	Pesticide classified for restricted use	Yes ^g	EPA 2005c 40 CFR 152.175
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance ^h		EPA 2005f 40 CFR 302.4
	Reportable quantity	1 pound	
	RCRA waste number	P003	
	Effective date of toxic chemical release reporting	01/01/87	EPA 2005h 40 CFR 372.65
	Extremely hazardous substances		EPA 2005g
	Reportable quantity	1 pound	40 CFR 355,
	Threshold planning quantities	500 pounds	Appendix A
NTP	Carcinogenicity classification	No data	NTP 2005

^aGroup 3: not classifiable as to carcinogenicity to humans.

^bSkin 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.

^cAEGL-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.

^dHighly hazardous chemical: presents a potential for a catastrophic event at or above the threshold quantity.

^eA4: not classifiable as a human carcinogen.

^fPotential carcinogenicity cannot be determined because the existing "data are inadequate for an assessment of human carcinogenic potential for either the oral or inhalation route of exposure".

^gPesticide classified for restricted use because of the inhalation hazard to humans and the residue effects on avian species and aquatic organisms.

^hDesignated 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.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline level; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; NAS/NRC = National Academy of Sciences/National Research Council; 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; STEL = short-term exposure limit; TLV = threshold limit values; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization