

## 8. REGULATIONS AND ADVISORIES

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

ATSDR has derived an acute-duration inhalation MRL of 0.07 ppm for chlorine based on a NOAEL of 0.5 ppm for sensory irritation and pulmonary effects in volunteers exposed for up to 8 hours/day (Anglen 1981; D'Alessandro et al. 1996; Rotman et al. 1983; Schins et al. 2000; Shusterman et al. 1998, 2003b). The NOAEL was duration-adjusted for continuous exposure. An uncertainty factor of 3 was used to account for sensitive populations.

ATSDR has derived an intermediate-duration inhalation MRL of 0.002 ppm for chlorine based on a LOAEL of 0.5 ppm for tracheal lesions in rats exposed 6 hours/day, 5 days/week for 62 days (Kutzman 1983). An uncertainty factor of 90 was used (3 for extrapolation from animals to humans with dosimetric adjustment, 3 for use of a minimal LOAEL, and 10 for human variability).

ATSDR has derived a chronic-duration inhalation MRL of 0.00005 ppm for chlorine based on an increased incidence of nasal lesions in monkeys exposed to chlorine 6 hours/day, 5 days/week for 1 year (Klonne et al. 1987). The MRL was derived using benchmark modeling of incidence data for nasal lesions in monkeys. The predicted exposure concentration associated with a 10% extra risk ( $BMC_{10}$ ) for nasal lesions in monkeys was 0.04 ppm; the lower 95% confidence limit on this concentration ( $BMCL_{10}$ ) was 0.02 ppm. An uncertainty factor of 30 was used (3 for extrapolation from animals to humans with dosimetric adjustment and 10 for human variability).

Oral MRLs were not derived for aqueous chlorine for the following reasons. MRLs are derived when reliable and sufficient data exist to identify a target organ(s) of effect or the most sensitive health effect(s) for a specific duration within a given route of exposure. Scientifically, as part of having sufficient and reliable data, it is important to be able to see the full, or at least a significant range, of the dose-response curve. In the case of the oral database for aqueous chlorine, no reliable LOAEL could be identified at levels of aqueous chlorine that could reasonably be encountered in the environment. It is a matter of policy of ATSDR not to derive free-standing MRLs.

EPA (IRIS 2007) has established an oral reference dose (RfD) for chlorine of 0.1 mg/kg/day based on a NOAEL of 14.4 mg/kg/day for systemic effects in Fischer-344/N rats exposed to chlorine in the drinking

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water for 2 years (NTP 1992). The uncertainty factor used in this assessment was 100 (10 for interspecies extrapolation and 10 for the protection of sensitive human subpopulations).

EPA has not derived an inhalation reference concentration (RfC) for chlorine gas.

The International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), and EPA has not classified chlorine, sodium hypochlorite, or hypochlorous acid for human carcinogenicity (IARC 2006; IRIS 2007; NTP 2005). The American Conference of Governmental Industrial Hygienists (ACGIH) has classified chlorine as an A4 carcinogen (not classifiable as a human carcinogen) (ACGIH 2006).

OSHA has required employers of workers who are occupationally exposed to chlorine to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PELs) (OSHA 2006c). The employer must use engineering and work practice controls to reduce exposures to not exceed 1 ppm for chlorine at any time (ceiling) (OSHA 2006c).

EPA has designated chlorine as a hazardous air pollutant (HAP) under the Clean Air Act (CAA) (EPA 2007b). Chlorine and sodium hypochlorite are 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 10 and 1 pounds, respectively (EPA 2007e). Chlorine is also considered to be an extremely hazardous substance (EPA 2007f). The RQ represents the amount of a designated hazardous substance which, when released to the environment, must be reported to the appropriate authority.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), chlorine gas is exempt from the requirement of a tolerance for pesticide chemicals in food when used as pre- or postharvest in solution on all raw agricultural commodities (EPA 2007h) and sodium hypochlorite is exempt from the requirement of a tolerance for residues in food (EPA 2007k).

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**Table 8-1. Regulations and Guidelines Applicable to Chlorine and Chlorine Compounds**

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	No data	IARC 2006
WHO	Air quality guidelines	No data	WHO 2000
	Drinking water quality guidelines Chlorine	5 mg/L <sup>a</sup>	WHO 2004
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA) (chlorine)	0.5 ppm	ACGIH 2006
	STEL (15-minute TWA) (chlorine)	1 ppm	
AIHA	ERPG-1 <sup>b</sup> (chlorine)	1 ppm	AIHA 2004
	ERPG-2 <sup>b</sup> (chlorine)	3 ppm	
	ERPG-3 <sup>b</sup> (chlorine)	20 ppm	
	Odor threshold (chlorine)	0.08 ppm	
EPA	AEGL-1 <sup>c</sup> (chlorine)		EPA 2007a
	10 minutes	0.5 ppm	
	30 minutes	0.5 ppm	
	60 minutes	0.5 ppm	
	4 hours	0.5 ppm	
	8 hours	0.5 ppm	
	AEGL-2 <sup>c</sup> (chlorine)		
	10 minutes	2.8 ppm	
	30 minutes	2.8 ppm	
	60 minutes	2.0 ppm	
	4 hours	1.0 ppm	
	8 hours	0.71 ppm	
	AEGL-3 <sup>c</sup> (chlorine)		
	10 minutes	50 ppm	
	30 minutes	28 ppm	
	60 minutes	20 ppm	
	4 hours	10 ppm	
	8 hours	7.1 ppm	
		Hazardous air pollutant (chlorine)	
	Regulated toxic substance and the threshold quantity for accidental release prevention (chlorine)	2,500 pounds <sup>d</sup>	EPA 2007d 40 CFR 68.130
NIOSH	REL (ceiling) (chlorine)	0.5 ppm	NIOSH 2005
	IDLH (chlorine)	10 ppm	

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<b>NATIONAL (cont.)</b>			
OSHA	PEL (ceiling) for general industry (chlorine)	1 ppm	OSHA 2006c 29 CFR 1910.1000
	PEL (ceiling) for shipyard industry (chlorine)	1 ppm	OSHA 2006a 29 CFR 1915.1000
	PEL (ceiling) for construction industry (chlorine)	1 ppm	OSHA 2006b 29 CFR 1926.55, Appendix A
	Toxic and reactive highly hazardous chemical which presents a potential for a catastrophic event at or above the threshold quantity (chlorine)	1,500 pounds	OSHA 2006d 29 CFR 1910.119
<b>b. Water</b>			
EPA	Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act (chlorine)	Yes	EPA 2007i 40 CFR 116.4
	Drinking water standards and health advisories (chlorine)		EPA 2006
	1-day health advisory for a 10-kg child	3 mg/L	
	10-day health advisory for a 10-kg child	3 mg/L	
	DWEL	5 mg/L	
	Lifetime	4 mg/L	
	10 <sup>-4</sup> Cancer risk	No data	
	National primary drinking water regulations (chlorine [as Cl <sub>2</sub> ]) <sup>e</sup>		EPA 2003
	MRDL	4.0 mg/L	
	Public health goal (MRDLG)	4.0 mg/L	
Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	Chlorine	10 pounds	EPA 2007j 40 CFR 117.3
	Sodium hypochlorite	100 pounds	
<b>c. Food</b>			
EPA	Chlorine is exempt from the requirement of a tolerance for pesticide chemicals in food when used as preharvest or postharvest in solution on all raw agricultural commodities	Yes	EPA 2007h 40 CFR 180.1095
	Sodium hypochlorite is exempt from the requirement of a tolerance for residues in food	Yes	EPA 2007k 40 CFR 180.1235

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FDA	EAFUS (ingredient added directly to food that FDA has either approved as a food additive or listed or affirmed as GRAS) (chlorine and sodium hypochlorite)	Yes	FDA 2007a
	Food additives permitted for direct addition to food for human consumption (sodium hypochlorite)	Yes	FDA 2007b 21 CFR 172
	Indirect food additives: adhesives and components of coatings (sodium hypochlorite)	Yes	FDA 2006 21 CFR 175
d. Other			
ACGIH	Carcinogenicity classification (chlorine)	A4 <sup>f</sup>	ACGIH 2006
EPA	Carcinogenicity classification (chlorine)	No data	IRIS 2007
	RfD (chlorine)	0.1 mg/kg/day	
	RfC (chlorine)	No data	
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance (chlorine and sodium hypochlorite)	Yes <sup>g</sup>	EPA 2007e 40 CFR 302.4
	Reportable quantity		
	Chlorine	10 pounds	
	Sodium hypochlorite	1 pound	
	Extremely hazardous substance and the threshold planning quantity (chlorine)	100 pounds	EPA 2007f 40 CFR 355, Appendix A
	Effective date of toxic chemical release reporting (chlorine)	01/01/87	EPA 2007g 40 CFR 372.65
EPA	TSCA Master Testing List		EPA 2007c
	Chlorine	Yes <sup>h</sup>	
	Sodium hypochlorite	Yes <sup>i</sup>	

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Agency	Description	Information	Reference
NTP	Carcinogenicity classification	No data	NTP 2005

<sup>a</sup>For effective disinfection, there should be a residual concentration of free chlorine of  $\geq 0.5$  mg/litre after at least 30 minute contact time at pH <8.0 (WHO 2004).

<sup>b</sup>ERPG-1 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing other than mild, transient adverse health effects or without perceiving a clearly defined objectionable odor; ERPG-2 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms that could impair an individual's ability to take protective action; and ERPG-3 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects (AIHA 2004).

<sup>c</sup>AEGL-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, however, the effects are not disabling and are transient and reversible upon cessation of exposure; 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; and 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 (EPA 2007a).

<sup>d</sup>Regulated toxic and flammable substance under Section 112 of the Clean Air Act

<sup>e</sup>Potential health effects from exposure above the MCL include anemia and nervous system effects in infants and young children; the common source of the contaminant in drinking water is the use of chlorine as a water additive used to control microbes (EPA 2003).

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

<sup>g</sup>Designated CERCLA hazardous substance pursuant to Section 112 of the Clean Air Act.

<sup>h</sup>The Office of Air and Radiation recommended chlorine for acute toxicity testing for health effects. Chlorine is a hazardous air pollutant and was added to the Master Testing List in 1995. EPA is initiating development of a testing action via TSCA Section 4 FRM, a TSCA Section 4 ECA, or a VTA (EPA 2007c).

<sup>i</sup>The Organization for Economic Cooperation and Development recommended sodium hypochlorite for a "base set" of screening level test data (SIDS), which include health effects and environmental effects and fate. Sodium hypochlorite was added to the Master Testing List in 1995 and EPA is initiating development of a testing action via CTPU-VTA (EPA 2007c).

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; CTPU = Chemical Testing Program Underway; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; ECA = Enforceable Consent Agreement; EPA = Environmental Protection Agency; ERPG = Emergency Response Planning Guidelines; FDA = Food and Drug Administration; FRM = Final Rule-Making; 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; MRDL = Maximum Residual Disinfectant Level; MRDLG = Maximum Residual Disinfectant Level Goal; NIOSH = National Institute for Occupational Safety and Health; 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; SIDS = Screening Information Data Set; STEL = short-term exposure limit; TLV = threshold limit values; TSCA = Toxic Substances Control Act; TWA = time-weighted average; USC = United States Code; VTA = Voluntary Testing Agreement; WHO = World Health Organization