

8. REGULATIONS AND ADVISORIES

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

ATSDR has adopted the EPA's chronic RfD of 0.0007 mg/kg/day recommended by the NAS (2005) for the chronic oral MRL for perchlorate. NAS based the RfD derivation on a NOEL of 0.007 mg/kg/day corresponding to a nonstatistical significant change in thyroidal uptake of radioactive iodine in volunteers exposed to potassium perchlorate in water for 14 days (Greer et al. 2002). As indicated by the NAS (2005), iodide uptake inhibition is a key biochemical event that precedes all potential thyroid-mediated effects of perchlorate exposure. Using a nonadverse effect that is upstream of adverse effects is a conservative approach to perchlorate hazard assessment. An uncertainty factor of 10 was applied to the NOEL for the protection of sensitive subpopulations.

EPA (IRIS 2007) has developed a chronic RfD of 0.0007 mg/kg/day for perchlorate based on the NAS (2005) recommendation to use a NOEL of 0.007 mg/kg/day for changes in thyroid hormone and TSH in serum, and thyroidal uptake of radioactive iodine in volunteers exposed to potassium perchlorate in water for 14 days (Greer et al. 2002) as the basis for an RfD. An uncertainty factor of 10 was applied to the NOEL for the protection of sensitive subpopulations. This RfD leads to a drinking water equivalent level (DWEL) of 24.5 ppb (EPA 2006c). EPA calculates the DWEL using the RfD, multiplied by an adult body weight of 70 kg, and divided by a tap water consumption value of 2 L/day. EPA's Office of Solid Waste and Emergency Response has provided guidance for perchlorate that indicates that the RfD and its corresponding DWEL of 24.5 ppb are respectively the recommended "to be considered" (TBC) value and the preliminary remediation goal (PRG) for cleanup under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (EPA 2006c).

The federal government has set standards and guidelines to protect people from the possible harmful health effects of perchlorate. Specifically, EPA would consider discarded perchlorate to be a solid waste and depending on the fact-specific circumstances, EPA believes that discarded perchlorate could be a hazardous waste under the Solid Waste Disposal Act (EPA 2006b). That is, because perchlorates are oxidizing chemicals, waste discarded chemical formulations of perchlorate and its salts are likely to be classified as D001 RCRA hazardous waste under 40 CFR 261.23, which regulates wastes that meet the reactivity characteristic. Such a determination is generally based on the nature of the waste at the point of generation; however, characteristic hazardous waste, such as D001, ceases to be hazardous waste once it

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no longer exhibits the hazardous waste characteristics. In addition, CERCLA 101(14) defines “hazardous substances.” According to that section, “the term hazardous substance means. . . . any hazardous waste having the characteristics identified under or listed pursuant to Section 3001 of the Solid Waste Disposal Act” Therefore, depending on the fact-specific circumstances, discarded perchlorate could be classified as a D001 hazardous waste and therefore, under certain circumstances, EPA would consider perchlorate a CERCLA hazardous substance.

DOT has designated perchlorate as a hazardous material and limits the quantity that is transported aboard aircraft and vessels. DOT also provides identification and protective guidance for an emergency response to a transportation incident involving a hazardous material. FDA has restricted potassium perchlorate from coming in contact with food containers.

DOD must comply with any EPA cleanup standards and processes under all applicable environmental laws and regulations, including the CERCLA, RCRA, the CWA, and the SDWA. DOD policy requires for the testing of perchlorate when it is reasonably expected that a release has occurred. Specifically, DOD policy states that in the absence of federal or state standards, if perchlorate levels exceed 24 ppb in water, a site-specific risk assessment must be conducted. When an assessment indicates that the perchlorate contamination could result in adverse health effects, the site must be prioritized for risk management (DOD 2006b). DOD will also comply with applicable state or federal promulgated standards, whichever is more stringent. Additionally, DOD established the Emerging Contaminants Directorate in 2006 to help the department proactively approach emerging contaminants to enable a fully informed, risk-based investment decision process that protects human health and DOD operational capabilities (DOD 2008); perchlorate is one of seven contaminants on DOD’s action list.

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Table 8-1. Regulations and Guidelines Applicable to Perchlorates

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	No data	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 (8-hour TWA)	No data	ACGIH 2004
DOT	Hazardous Materials Table	Yes	DOT 2007 49CFR172.101
	Ammonium perchlorate, magnesium perchlorate, potassium perchlorate, and sodium perchlorate		
NIOSH	REL (10-hour TWA)	No data	NIOSH 2005
OSHA	Threshold quantity for highly hazardous chemicals for general industry		OSHA 2005d 29CFR1910.119, Appendix A
	Ammonium perchlorate	7,500 pounds	
	Threshold quantity for highly hazardous chemicals for construction industry		OSHA 2005c 29CFR1926.64, Appendix A
	Ammonium perchlorate	500 pounds	
b. Water			
EPA	National primary drinking water regulations; monitoring requirements for unregulated contaminants		EPA 2005a 40CFR141.40 (a)(3)
	Perchlorate		
	EPA analytical method	314.0	
	Minimum reporting level	4.0 µg/L ^a	
	Sampling location	EPDTS ^b	
	Period during which monitoring be completed	2001–2003	
	Office of Solid Waste and Emergency Response		
	Perchlorate Preliminary Remediation Goal (PRG)	24.5 µg/L	EPA 2006c
DOD	Policy on DOD Required Actions Related to Perchlorate	24 µg/L	DOD 2006b

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
c. Food			
FDA	Substances for use as basic component of single and repeated use food contact surfaces; closures with sealing gaskets for food containers		FDA 2005 21CFR177.1210 (b)(5)
	Potassium perchlorate	Not to exceed 1%	
d. Other			
ACGIH	Carcinogenicity classification	No data	ACGIH 2004
EPA	Carcinogenicity classification	Not likely to be carcinogenic	IRIS 2007
	RfC ^c	Has not been derived ^d	
	RfD ^c	7x10 ⁻⁴ mg/kg/day	
	Standards for owners and operators of hazardous waste TSD facilities; potentially incompatible waste; the mixing of Group 6-A (perchlorate) with Group 6-B may have the potential consequence as noted	Generation of toxic hydrogen cyanide or hydrogen sulfide gas	EPA 2005b 40CFR264, Appendix V
NTP	Carcinogenicity classification	No data	NTP 2004
<u>STATE</u>			
California	Presumed hazardous wastes	Yes	CalEPA 2007 22 CCR Chapter 11, Appendix X
	Ammonium perchlorate, magnesium perchlorate, potassium perchlorate, and sodium perchlorate		
	Public health goal for perchlorate in drinking water	6 ppb	CalEPA 2004
Massachusetts	Maximum contaminant level for perchlorate	2 ppb	MassDEP 2006b
	Right-to-Know list	Yes	MassDPH 2006 105 CMR 670, Appendix A
	Ammonium perchlorate, magnesium perchlorate, potassium perchlorate, and sodium perchlorate		

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Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
New Jersey	List of hazardous substances Ammonium perchlorate, lithium perchlorate, potassium perchlorate, and sodium perchlorate	Yes	NJDEP 2007 NJAC 7:13, Appendix A
	Workplace hazardous substance list and special health hazard substance list Ammonium perchlorate, magnesium perchlorate, potassium perchlorate, and sodium perchlorate	Yes	NJDHSS 2006 NJAC 8:59, Subchapter 9
Pennsylvania	Hazardous substance list Ammonium perchlorate, magnesium perchlorate, potassium perchlorate, and sodium perchlorate	Yes	PADLI 2007 Title 34, Chapter 323, Appendix A
Rhode Island	Hazardous substance list Ammonium perchlorate, magnesium perchlorate, potassium perchlorate, and sodium perchlorate	Yes	RIDLT 2007

^aMinimum reporting level was established at a concentration, which is at least 1/4th the lowest known adverse health concentration, at which acceptable precision and accuracy has been demonstrated in spiked matrix samples.

^bEntry Points to the Distribution System (EPTDS), after treatment, representing each non-emergency water source in use over the 12-month period of monitoring; this only includes entry points for sources in operation during the months in which sampling is to occur. Sampling must occur at the EPTDS, unless the State has specified other sampling points that are used for compliance monitoring under 40 CFR 141.24(f)(1), (2), and (3). See 40 CFR 141.40(a)(5)(ii)(C) for a complete explanation of requirements, including the use of source (raw) water sampling points.

^cIRIS record for perchlorate and perchlorate salts include ammonium perchlorate, lithium perchlorate, potassium perchlorate, and sodium perchlorate.

^dAn inhalation RfC has not been derived because the available inhalation data are insufficient to characterize dose-response relationships or portal-of-entry modulation of internal dose.

ACGIH = American Conference of Governmental Industrial Hygienists; CFR = Code of Federal Regulations; CCR = California Code of Regulations; CMR = Code of Massachusetts Regulations; DOT = Department of Transportation; EPA = Environmental Protection Agency; EPTDS = Entry Points to the Distribution System; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; NIOSH = National Institute for Occupational Safety and Health; NJAC = New Jersey Administrative Code; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit values; TSD = treatment, storage, and disposal; TWA = time-weighted average; WHO = World Health Organization