

8. REGULATIONS, ADVISORIES, AND GUIDELINES

MRLs are substance-specific estimates that are intended to serve as screening levels. They are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites.

ATSDR has derived a chronic-duration inhalation MRL of 0.006 ppm based on color vision impairment in humans chronically exposed to tetrachloroethylene in the workplace at a LOAEL of 7.3 ppm (Cavalleri et al. 1994). The LOAEL was converted to an equivalent continuous exposure concentration of 1.7 ppm ($7.3 \text{ ppm} \times 8/24 \text{ hours} \times 5/7 \text{ days}$) and adjusted using an uncertainty factor of 100 (10 for human variability and 10 for use of a LOAEL) and a modifying factor of 3 for database deficiencies (for inadequate information on potential low-dose immune system effects). The chronic-duration inhalation MRL was adopted as the acute- and intermediate-duration inhalation MRLs. A chronic-duration oral MRL of 0.008 mg/kg/day was derived based on route-to-route extrapolation from the chronic-duration inhalation MRL. The chronic-duration oral MRL was adopted as the acute- and intermediate-duration oral MRLs.

IARC has classified tetrachloroethylene as a Group 2A carcinogen (*probably carcinogenic to humans*) (IARC 2014). The World Health Organization (WHO) has established an air quality guideline value of 0.25 mg/m³ for tetrachloroethylene as an annual average (WHO 2010) and a drinking water quality guideline value of 0.04 mg/L for tetrachloroethylene (WHO 2011).

OSHA established a permissible exposure limit (PEL) of 100 ppm for tetrachloroethylene (OSHA 2013b). OSHA has required employers of workers who are occupationally exposed to tetrachloroethylene to institute engineering controls and work practices to reduce and maintain employee exposure at or below the PEL. NIOSH has classified tetrachloroethylene as a *potential occupational carcinogen* (NIOSH 2013) and established an immediately dangerous to life or health (IDLH) value of 150 ppm. The American Conference of Governmental Industrial Hygienists (ACGIH) has recommended a threshold limit value (TLV) of 25 ppm for an 8-hour workday and a short-term exposure level (STEL) of 100 ppm (ACGIH 2012).

The American Industrial Hygiene Association (AIHA) and the Department of Energy (DOE) have established values for airborne tetrachloroethylene when responding to potential releases for use in community emergency planning (AIHA 2011; DOE 2012). These values represent increasing severity of

8. REGULATIONS, ADVISORIES, AND GUIDELINES

effects (mild, irreversible, and life threatening) for a 1-hour exposure. Tetrachloroethylene is also designated as a HAP (EPA 2013b).

EPA has classified tetrachloroethylene as *likely to be carcinogenic in humans by all routes of exposure* (EPA 2012a). NTP has classified tetrachloroethylene as *reasonably anticipated to be a human carcinogen* (NTP 2016) and ACGIH (2012) has classified tetrachloroethylene as an A3 carcinogen (*confirmed animal carcinogen with unknown relevance to humans*).

EPA (IRIS 2012) has derived an oral reference dose for tetrachloroethylene of 0.006 mg/kg/day based on route-to-route extrapolation from the inhalation reference concentration. The EPA (IRIS 2012) inhalation reference concentration of 0.04 mg/m³ (0.006 ppm) for tetrachloroethylene was derived based on the midpoint between two LOAELs: 15 mg/m³ (2 ppm) and 56 mg/m³ (8 ppm) for two controlled human inhalation exposure studies in which neurotoxicity was observed (Cavalleri et al. 1994; Echeverria et al. 1994); an uncertainty factor of 1,000 was applied in the derivation.

EPA has designated tetrachloroethylene as a HAP under the Clean Air Act (CAA) (EPA 2013b). Tetrachloroethylene is 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 100 pounds (EPA 2012f). 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 Toxic Substances Control Act (TSCA), tetrachloroethylene is on the list of chemicals that manufacturers and importers must report for each plant site at which they manufactured or imported tetrachloroethylene during the reporting period specified (EPA 2012j).

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

8. REGULATIONS, ADVISORIES, AND GUIDELINES

Table 8-1. Regulations, Advisories, and Guidelines Applicable to Tetrachloroethylene

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	2A ^a	IARC 2014
WHO	Air quality guidelines (annual average)	0.25 mg/m ³	WHO 2010
	Drinking water quality guidelines	0.04 mg/L	WHO 2011
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	25 ppm	ACGIH 2012
	STEL	100 ppm	
AIHA	ERPG-1 ^{b,c}	100 ppm	AIHA 2011
	ERPG-2	200 ppm	
	ERPG-3	1,000 ppm	
DOE	PAC-1 ^d	35 ppm	DOE 2012
	PAC-2	230 ppm	
	PAC-3	1,200 ppm	
EPA	AEGL-1 ^e		EPA 2013a
	10-minutes	35 ppm	
	30-minutes	35 ppm	
	60-minutes	35 ppm	
	4-hours	35 ppm	
	8-hours	35 ppm	
	AEGL-2		
	10-minutes	230 ppm	
	30-minutes	230 ppm	
	60-minutes	230 ppm	
	4-hours	120 ppm	
	8-hours	81 ppm	
	AEGL-3		
	10-minutes	1,600 ppm	
	30-minutes	1,600 ppm	
60-minutes	1,200 ppm		
4-hours	580 ppm		
8-hours	410 ppm		

8. REGULATIONS, ADVISORIES, AND GUIDELINES

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	Hazardous air pollutant	Yes	EPA 2013b 42 USC 7412
NIOSH	NAAQS	No data	EPA 2013c
	REL (10-hour TWA)	Potential occupational carcinogen	NIOSH 2013
OSHA	IDLH	150 ppm	
	PEL (8-hour TWA) for general industry	100 ppm	OSHA 2013b
	Acceptable ceiling concentration	200 ppm	29 CFR 1910.1000, Table Z-2
	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift	300 ppm for 5 minutes in any 3 hours	
	Highly hazardous chemicals	No data	OSHA 2013a 29 CFR 1910.119, Appendix A
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act	No data	EPA 2012b 40 CFR 116.4
	Drinking water contaminant candidate list	No data	EPA 2009a 74 FR 51850
	Drinking water standards and health advisories		EPA 2012c
	One-day (mg/L) in a 10-kg child	2 mg/L	
	Ten-day (mg/L) in a 10-kg child	2 mg/L	
	DWEL	0.5 mg/L	
	Life-time	0.01 mg/L	
	National primary drinking water standards		EPA 2009b
	MCL ^f	0.005 mg/L	
	Public health goal	Zero	
	National recommended water quality criteria: human health for the consumption of (at 10 ⁻⁴ risk)		EPA 2009c
	Water + organism	0.69 µg/L	
	Organism only	3.3 µg/L	
Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	No data	EPA 2012e 40 CFR 117.3	
c. Food			
FDA	EAFUS ^g	No	FDA 2013

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
d. Other			
ACGIH	Carcinogenicity classification	A3 ^h	ACGIH 2012
EPA	Carcinogenicity classification	Likely to be carcinogenic in humans by all routes of exposure	IRIS 2012
	RfC	0.04 mg/m ³	
	RfD	0.006 mg/kg/day	
	Oral slope factor	2.1x10 ⁻³ per mg/kg/day	
	Inhalation unit risk	1.8x10 ⁻³ per ppm	
	Identification and listing of hazardous waste	U210	EPA 2012d 40 CFR 261, Appendix VIII
	Inert pesticide ingredients in pesticide products approved for nonfood use only	No data	EPA 2013d
	Master Testing List	Yes ⁱ	EPA 2013e
	RCRA waste minimization PBT priority chemical list	No data	EPA 1998 63 FR 60332
	Standards for owners and operators of hazardous waste TSD facilities; groundwater monitoring list	Yes	EPA 2012f 40 CFR 264, Appendix IX
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance and reportable quantity pursuant to Section 307(a) of the Clean Water Act, Section 112 of the Clean Air Act, and Section 3001 of RCRA	100 pounds	EPA 2012g 40 CFR 302.4
	Effective date of toxic chemical release reporting	01/01/1987	EPA 2012h 40 CFR 372.65
	Extremely hazardous substances and its threshold planning quantity	No data	EPA 2012i 40 CFR 355, Appendix A
	TSCA chemical lists and reporting periods	No data	EPA 2012j 40 CFR 712.30
	TSCA health and safety data reporting		EPA 2012k
	Effective date	06/01/1987	40 CFR 716.120
	Reporting date	06/01/1997	

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Table 8-1. Regulations, Advisories, and Guidelines Applicable to Tetrachloroethylene

Agency	Description	Information	Reference
NATIONAL (<i>cont.</i>)			
NTP	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen	NTP 2016

^aGroup 2A: probably carcinogenic to humans.

^bERPG-1: maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor; ERPG-2: maximum airborne concentration below which it is believed that 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; ERPG-3: is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects (AIHA 2011).

^cOdor should be detectable near ERPG-1.

^dPAC-1: mild, transient health effects; PAC-2: irreversible or other serious health effects that could impair the ability to take protective action; PAC-3: life-threatening health effects (DOE 2012).

^eAEGL-1: 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, these effects are not disabling and are transient and reversible upon cessation of exposure; AEGL-2: 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: the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death (EPA 2013a).

^fPotential health effects from long-term exposure above the MCL could cause liver problems and increased risk of cancer; common sources of contaminant in drinking water include discharges from factories and dry cleaners (EPA 2009b).

^gThe EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

^hA3: confirmed animal carcinogen with unknown relevance to humans.

ⁱTesting action development underway for acute development and immunological health effects.

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; DOE = Department of Energy; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; FR = Federal Register; 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; NAAQS = National Ambient Air Quality Standards; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = protective action criteria; PBT = persistent, bioaccumulative, and toxic; 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 level; TLV = threshold limit values; TSCA = Toxic Substances Control Act; TSD = treatment, storage, and disposal; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization