

8. REGULATIONS, ADVISORIES, AND GUIDELINES

MRLs are substance specific estimates, which are intended to serve as screening levels, 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.

IARC has classified trichloroethylene as a Group 1 carcinogen (*carcinogenic to humans*) (IARC 2014). The World Health Organization (WHO) has established an air quality guideline value of 2.3 µg/m³ for trichloroethylene associated with an excess lifetime cancer risk of 1 in 1,000,000 (WHO 2010). WHO has not established a drinking water guideline for trichloroethylene (WHO 2011).

The Occupational Safety and Health Administration (OSHA) established a permissible exposure limit (PEL) of 100 ppm for trichloroethylene (OSHA 2013b). OSHA has required employers of workers who are occupationally exposed to trichloroethylene to institute engineering controls and work practices to reduce and maintain employee exposure at or below the PEL. NIOSH has classified trichloroethylene as a *potential occupational carcinogen* (NIOSH 2013) and established an immediately dangerous to life or health (IDLH) value of 1,000 ppm. The American Conference of Governmental Industrial Hygienists (ACGIH) has recommended a threshold limit value (TLV) of 10 ppm for an 8-hour workday and a short-term exposure level (STEL) of 25 ppm (ACGIH 2012).

The American Industrial Hygiene Association (AIHA) and the Department of Energy (DOE) have established values for airborne trichloroethylene when responding to potential releases for use in community emergency planning (AIHA 2011; DOE 2012). These values represent increasing severity of effects (mild, irreversible, and life threatening) for a 1-hour exposure.

EPA has classified trichloroethylene as “carcinogenic in humans” (IRIS 2011). Trichloroethylene is listed in the 13th Report on Carcinogens (RoC) as reasonably anticipated to be a human carcinogen (NTP 2014a). Since the report was released in October 2014, the National Toxicology Program (NTP) has completed its reevaluation of trichloroethylene for a possible change in its listing status in the RoC. The NTP recommends that trichloroethylene be listed in the 14th RoC as known to be a human carcinogen based on sufficient evidence from studies in humans (NTP 2014b). (See RoC Monograph on Trichloroethylene, available at <http://ntp.niehs.nih.gov/pubhealth/roc/candidates/tce.html>.) The next step is for the NTP to submit this listing recommendation for trichloroethylene to the Secretary of Health and

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Human Services to review and approve (<http://ntp.niehs.nih.gov/go/rocprocess>) for the 14th RoC.” ACGIH (2012) has classified trichloroethylene as an A2 carcinogen (*suspected human carcinogen*).

EPA has derived an oral reference dose (RfD) of 5×10^{-4} mg/kg/day for chronic exposure to trichloroethylene based on drinking water studies in rats and mice (IRIS 2011). ATSDR has adopted the RfD of 5×10^{-4} mg/kg/day as the chronic-duration oral MRL for trichloroethylene, as described in detail in Appendix A, and as the intermediate-duration oral MRL as well.

EPA has derived a chronic inhalation reference concentration (RfC) of 0.002 mg/m³ for chronic exposure to trichloroethylene based on drinking water studies in rats and mice (IRIS 2011). ATSDR has adopted the RfC of 0.002 mg/m³ as the chronic-duration inhalation MRL for trichloroethylene, as described in detail in Appendix A, and as the intermediate-duration inhalation MRL as well.

EPA has designated trichloroethylene as a HAP under the Clean Air Act (CAA) (EPA 2013d). Trichloroethylene 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 200 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.

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

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Table 8-1. Regulations and Guidelines Applicable to Trichloroethylene

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 1 ^a	IARC 2014
WHO	Air quality guidelines ^b	2.3 µg/m ³	WHO 2010
	Drinking water quality guidelines	No data	WHO 2011
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	10 ppm	ACGIH 2012
	STEL	25 ppm	
AIHA	ERPG-1 ^{c,d}	100 ppm	AIHA 2011
	ERPG-2 ^c	500 ppm	
	ERPG-3 ^c	5,000 ppm	
DOE	PAC-1 ^e	130 ppm	DOE 2012
	PAC-2 ^e	450 ppm	
	PAC-3 ^e	3,800 ppm	
EPA	AEGL-1 ^f		EPA 2013c
	10-minutes	260 ppm	
	30-minutes	180 ppm	
	60-minutes	130 ppm	
	4-hours	84 ppm	
	8-hours	77 ppm	
	AEGL-2 ^f		
	10-minutes	960 ppm	
	30-minutes	620 ppm	
	60-minutes	450 ppm	
	4-hours	270 ppm	
	8-hours	240 ppm	
	AEGL-3 ^f		
	10-minutes	6,100 ppm	
	30-minutes	6,100 ppm	
	60-minutes	3,800 ppm	
	4-hours	1,500 ppm	
	8-hours	970 ppm	
	Hazardous air pollutant	Yes	
NAAQS	No data	EPA 2013g	

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Agency	Description	Information	Reference
NATIONAL <i>(cont.)</i>			
NIOSH	REL (potential occupational carcinogen)	2 ppm (60-minute ceiling as anesthetic gas) 25 ppm (10-hour TWA for all other exposures)	NIOSH 2013
	IDLH	1,000 ppm (potential occupational carcinogen)	NIOSH 1994c
OSHA	PEL (8-hour TWA) for general industry	100 ppm	OSHA 2013b 29 CFR 1910.1000, Table Z-2
	Acceptable ceiling concentration	200 ppm	
	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift	300 ppm for 5 minutes in any 2 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	Yes	EPA 2012a 40 CFR 116.4
	Drinking water contaminant candidate list	No data	EPA 2009c 74 FR 51850
	Drinking water standards and health advisories		EPA 2012b
	DWEL	0.2 mg/L	
	Cancer risk at 10 ⁻⁴	0.3 mg/L	
	Public health goal	Zero	
	National primary drinking water standards		EPA 2009d
	MCL ^g	0.005 mg/L	
	Public health goal	Zero	
	National recommended water quality criteria: human health for the consumption of (at 10 ⁻⁴ risk)		EPA 2009e
	Water + organism	2.5 µg/L	
	Organism only	30 µg/L	
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	No data	EPA 2012d 40 CFR 117.3
c. Food			
FDA	EAFUS ^h	Yes	FDA 2013

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NATIONAL (<i>cont.</i>)			
d. Other			
ACGIH	Carcinogenicity classification	A2 ¹	ACGIH 2012
	BEI (end of shift end of workweek)		
	Trichloroethylene acid in urine	15 mg/L	
	Trichloroethylene in blood (without hydrolysis)	0.5 mg/L	
EPA	Carcinogenicity classification	Carcinogenic to humans	IRIS 2011
	RfC	0.002 mg/m ³	
	RfD	5x10 ⁻⁴ mg/kg/day	
	Oral slope factor	4.6x10 ⁻² per mg/kg/day	
	Inhalation unit risk	4.1x10 ⁻⁶ per µg/m ³	
	Identification and listing of hazardous waste	U228	EPA 2012c 40 CFR 261, Appendix VIII
	Inert pesticide ingredients in pesticide products approved for nonfood use only	No data	EPA 2013e
	Master Testing List	Yes ^j	EPA 2013f
	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 2012e 40 CFR 264, Appendix IX
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance and reportable quantity pursuant to Section 311(b)(2) of the Clean Water Act, Section 307(a) of the Clean Water Act, Section 112 of the Clean Air Act, and Section 3001 of RCRA	200 pounds	EPA 2012f 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 2012g 40 CFR 355, Appendix A
TSCA chemical lists and reporting periods	No data	EPA 2012i 40 CFR 712.30	
TSCA health and safety data reporting	No data	EPA 2012j 40 CFR 716.120	
NTP	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen ^k	NTP 2014a

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^aGroup 1: carcinogenic to humans.

^bThe concentrations of airborne trichloroethylene associated with an excess lifetime cancer risk of 1 in 1,000,000.

^cERPG-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).

^dOdor should be detectable near ERPG-1.

^ePAC-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).

^fAEGL-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, these 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; 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 adverse health effects or death (EPA 2013c).

^gPotential 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 metal degreasing sites and other factories (EPA 2009d).

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

ⁱA2: suspected human carcinogen.

^jChemical testing program underway and voluntary testing agreement under SIDS for health and ecological effects and chemical fate.

^kSince the 13th Report of Carcinogens (RoC) was released in October 2014, the National Toxicology Program (NTP) has completed its reevaluation of trichloroethylene for a possible change in its listing status in the RoC. The NTP recommends that trichloroethylene be listed in the 14th RoC as known to be a human carcinogen based on sufficient evidence from studies in humans. (See RoC Monograph on Trichloroethylene, available at <http://ntp.niehs.nih.gov/pubhealth/roc/candidates/tce.html>.) The next step is for the NTP to submit this listing recommendation for trichloroethylene to the Secretary of Health and Human Services to review and approve (<http://ntp.niehs.nih.gov/go/rocprocess>) for the 14th RoC.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; BEI = biological exposure indices; 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; SIDS = screening information data set; 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