TRICHLOROETHYLENE

#### 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.

The chronic-duration oral MRL of 0.0005 mg/kg/day was based on the results of three oral exposure studies reporting immunological, endocrine, and developmental effects in rats or mice (Johnson et al. 2003; Keil et al. 2009; Peden-Adams et al. 2006) and a PBPK model developed by EPA (2011e), which was used to calculate the idPOD human equivalency doses (HED<sub>99</sub>).

The ATSDR chronic-duration oral MRL of 0.0005 mg/kg/day was adopted as the ATSDR intermediateduration oral MRL for trichloroethylene.

The chronic-duration inhalation MRL of 0.0004 ppm was based on the results of two oral exposure studies that reported endocrine and developmental effects in rats and mice (Johnson et al. 2003; Keil et al. 2009) and a PBPK model developed by EPA, which was used to calculate the idPOD and route-to-route extrapolation to human equivalency concentrations (HEC<sub>99</sub>) for these studies.

The ATSDR chronic-duration inhalation MRL of 0.0004 ppm was adopted as the ATSDR intermediateduration inhalation MRL for trichloroethylene.

EPA has derived an oral reference dose (RfD) of  $5x10^{-4}$  mg/kg/day for chronic exposure to trichloroethylene based on drinking water studies in rats and mice (IRIS 2011).

EPA has derived a chronic inhalation reference concentration (RfC) of  $0.002 \text{ mg/m}^3$  (0.0004 ppm) for chronic exposure to trichloroethylene based on drinking water studies in rats and mice (IRIS 2011).

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

Agency		Description	Information	Reference
INTERNA	TIONAL			
Guidelines	:			
	IARC	Carcinogenicity classification	Group 1 <sup>a</sup>	IARC 2014
	WHO	Air quality guidelines <sup>b</sup>	2.3 µg/m³	WHO 2010
		Drinking water quality guidelines	0.02 mg/L <sup>c</sup>	WHO 2011
NATIONA	<u>L</u>			
Regulation				
Guidelines	:			
a. Air				
	ACGIH	TLV (8-hour TWA)	10 ppm	ACGIH 2012
		STEL	25 ppm	
	AIHA	ERPG-1 <sup>c,d</sup>	100 ppm	AIHA 2011
		ERPG-2°	500 ppm	
		ERPG-3°	5,000 ppm	
	DOE	PAC-1 <sup>e</sup>	130 ppm	DOE 2012
		PAC-2 <sup>e</sup>	450 ppm	
		PAC-3 <sup>e</sup>	3,800 ppm	
	EPA	AEGL-1 <sup>f</sup>		EPA 2013c
		10-minutes	260 ppm	
		30-minutes	180 ppm	
		60-minutes	130 ppm	
		4-hours	84 ppm	
		8-hours	77 ppm	
		AEGL-2 <sup>f</sup>		
		10-minutes	960 ppm	
		30-minutes	620 ppm	
		60-minutes	450 ppm	
		4-hours	270 ppm	
		8-hours	240 ppm	
		AEGL-3 <sup>f</sup>		
		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	EPA 2013d 42 USC 7412
		NAAQS	No data	EPA 2013g

	Description	Information	Reference
NIOSH		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
	Acceptable ceiling concentration	200 ppm	29 CFR 1910.1000,
	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift	300 ppm for 5 minutes in any 2 hours	Table Z-2
	Highly hazardous chemicals	No data	OSHA 2013a 29 CFR 1910.119, Appendix A
EPA			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 <sup>-4</sup>	0.3 mg/L	
	Public health goal	Zero	
	National primary drinking water standards		EPA 2009d
	MCL <sup>g</sup>	0.005 mg/L	
	Public health goal	Zero	
	National recommended water quality criteria: human health for the consumption of (at 10 <sup>-4</sup> 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
FDA	Allowable trichloroethylene level in bottled water	0.005 mg/L	FDA 2018 21 CFR 165.110
	OSHA	IDLH OSHA PEL (8-hour TWA) for general industry Acceptable ceiling concentration Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift Highly hazardous chemicals EPA Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act Drinking water contaminant candidate list Drinking water standards and health advisories DWEL Cancer risk at 10 <sup>-4</sup> Public health goal National primary drinking water standards MCL <sup>g</sup> Public health goal National recommended water quality criteria: human health for the consumption of (at 10 <sup>-4</sup> risk) Water + organism Organism only Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	IDLH25 ppm (10-hour TWA for all other exposures) 1,000 ppm (potential occupational carcinogen)OSHAPEL (8-hour TWA) for general industry Acceptable ceiling concentration acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift Highly hazardous chemicals100 ppmEPADesignated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water ActNo dataDrinking water contaminant candidate list Drinking water standards and health advisoriesNo dataDWEL0.2 mg/L Cancer risk at 10-40.3 mg/LPublic health goalZeroNational primary drinking water standardsZeroNational primary drinking water standards2.5 µg/LOrganism only30 µg/LReportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water ActNo dataFDAAllowable trichloroethylene level in0.005 mg/L

Agency		Description	Information	Reference
c. Food				
	FDA	EAFUS <sup>h</sup>	Yes	FDA 2013
d. Other				
	ACGIH	Carcinogenicity classification	A2 <sup>i</sup>	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 <sup>3</sup>	
		RfD	5x10⁻⁴ mg/kg/day	
		Oral slope factor	4.6x10 <sup>-2</sup> per mg/kg/day	
		Inhalation unit risk	4.1x10 <sup>-6</sup> per µg/m <sup>3</sup>	
		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 <sup>j</sup>	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

Agency		Description	Information	Reference
	NTP	Carcinogenicity classification	Known to be a human	NTP 2016
			carcinogen	

<sup>a</sup>Group 1: carcinogenic to humans.

<sup>b</sup>The concentration of airborne trichloroethylene associated with an excess lifetime cancer risk of 1 in 1,000,000. <sup>c</sup>Provisional guideline value due to uncertainties in the health database.

<sup>c</sup>ERPG-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 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).

<sup>d</sup>Odor should be detectable near ERPG-1.

<sup>e</sup>PAC-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).

<sup>f</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, 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 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).

<sup>9</sup>Potential 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).

<sup>h</sup>The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

<sup>i</sup>A2: suspected human carcinogen.

<sup>1</sup>Chemical testing program underway and voluntary testing agreement under SIDS for health and ecological effects and chemical fate.

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