

CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding BCME in air, water, and other media are summarized in Table 7-1. This table is not an exhaustive list, and current regulations should be verified by the appropriate regulatory agency.

ATSDR develops MRLs, which are substance-specific guidelines intended to serve as screening levels by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. See Section 1.3 and Appendix A for detailed information on the MRLs for BCME.

Table 7-1. Regulations and Guidelines Applicable to Bis(Chloromethyl)Ether

Agency Description		Information	Reference
Air			
EPA	RfC	No data	IRIS 2002
WHO	Air quality guidelines	No data	WHO 2010
Water & Food			
EPA	Drinking water standards and health advisories	No data	EPA 2012
	National primary drinking water regulations	No data	EPA 2009
	RfD	No data	IRIS 2002
WHO	Drinking water quality guidelines	No data	WHO 2017
FDA	EAFUS	No data ^a	FDA 2013
Cancer			
ACGIH	Carcinogenicity classification	A1 ^{b,c}	ACGIH 2001, 2016
HHS	Carcinogenicity classification	Known to be a human carcinogen ^d	NTP 2016
EPA	Carcinogenicity classification	Group A ^{e,f}	IRIS 2002
IARC	Carcinogenicity classification	Group 1 ^{g,h}	IARC 2012 , 2017
Occupational			
ACGIH	TLV	0.001 ppm (0.0047 mg/m ³)	ACGIH 2001, 2016
OSHA	Requirements for areas containing a carcinogen	Does not pertain to solid or liquid mixtures containing <0.1% by weight or volume	OSHA 2016
NIOSH	REL	Potential occupational carcinogen	NIOSH 2016

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Agency Description		Information	Reference
Emergency Criteria			
EPA	AEGLs-air		EPA 2016
	AEGL 1	NR ⁱ	
	AEGL 2		
	10-minute	0.055 ppm	
	30-minute	0.055 ppm	
	60-minute	0.044 ppm	
	4-hour	0.028 ppm	
	8-hour	0.020 ppm	
	AEGL 3		
	10-minute	0.23 ppm	
	30-minute	0.23 ppm	
	60-minute	0.18 ppm	
	4-hour	0.11 ppm	
	8-hour	0.075 ppm	
DOE	PACs-air		DOE 2016a
	PAC-1 ^j	0.004 ppm	
	PAC-2 ^j	0.044 ppm	
	PAC-3 ^j	0.18 ppm	

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

^bA1: confirmed human carcinogen.

^cBased on pulmonary cancer and nasal tumors in experimental animal studies and among exposed workers.

^dBased on sufficient evidence of carcinogenicity from studies in humans.

^eGroup A: human carcinogen.

^fBased on statistically significant increases in lung tumors (oat cell carcinomas) observed in six studies of exposed workers and bioassay data from rats and mice.

^gGroup 1: carcinogenic to humans.

^hBased on sufficient evidence in humans for cancer of the lung and sufficient evidence of carcinogenicity in experimental animals.

ⁱNR = not recommended due to insufficient data.

^jDefinitions of PAC terminology are available from DOE (2016b).

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; DOE = Department of Energy; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = Protective Action Criteria; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit values; WHO = World Health Organization