

## CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding chloroform 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 chloroform.

**Table 7-1. Regulations and Guidelines Applicable to Chloroform**

Agency	Description	Information	Reference
<b>Air</b>			
EPA	RfC	Not evaluated	<a href="#">IRIS 2001</a>
WHO	Air quality guidelines	Not listed	<a href="#">WHO 2010</a>
<b>Water &amp; Food</b>			
EPA	Drinking water standards and health advisories		<a href="#">EPA 2018b</a>
	1-Day health advisory (10-kg child)	4 mg/L	
	10-Day health advisory (10-kg child)	4 mg/L	
	DWEL	0.35 mg/L	
	Lifetime health advisory	0.07 mg/L	
	National primary drinking water regulations		<a href="#">EPA 2023e</a>
	Total trihalomethanes—MCL	0.080 mg/L	
	Chloroform—MCLG	0.07 mg/L	
	RfD	0.01 mg/kg/day <sup>a</sup>	<a href="#">IRIS 2001</a>
WHO	Drinking water quality guidelines		<a href="#">WHO 2022</a>
	Guideline value	0.3 mg/L	
	TDI	15 µg/kg body weight	
FDA	Substances added to food <sup>b</sup>	Approved for some indirect additives uses	<a href="#">FDA 2024a</a>
	Allowable level in bottled water		<a href="#">FDA 2023</a>
	Total trihalomethanes	0.080 mg/L	

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Agency	Description	Information	Reference
<b>Cancer</b>			
HHS	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen	<a href="#">NTP 2021</a>
EPA	Carcinogenicity classification IUR	Likely to be carcinogenic to humans <sup>c,d</sup> 2.3x10 <sup>-5</sup> per µg/m <sup>3</sup> e	<a href="#">IRIS 2001</a>
IARC	Carcinogenicity classification	Group 2B <sup>f</sup>	<a href="#">IARC 1999</a>
<b>Occupational</b>			
OSHA	PEL (ceiling limit <sup>g</sup> ) for general industry and construction	50 ppm (240 mg/m <sup>3</sup> )	OSHA <a href="#">2022a</a> , <a href="#">2022c</a>
	PEL (8-hour TWA) for shipyards	50 ppm (240 mg/m <sup>3</sup> )	<a href="#">OSHA 2022b</a>
NIOSH	STEL (60-minute) IDLH	2 ppm (9.78 mg/m <sup>3</sup> ) <sup>h</sup> 500 ppm <sup>h</sup>	<a href="#">NIOSH 2019</a>
<b>Emergency Criteria</b>			
EPA	AEGLs-air		<a href="#">EPA 2018c</a>
	AEGL 1 <sup>i</sup>	Not recommended	
	AEGL 2 <sup>i</sup>		
	10-minute	120 ppm	
	30-minute	80 ppm	
	60-minute	64 ppm	
	4-hour	40 ppm	
	8-hour	29 ppm	
	AEGL 3 <sup>i</sup>		
	10-minute	4,000 ppm	
	30-minute	4,000 ppm	
	60-minute	3,200 ppm	
	4-hour	2,000 ppm	
	8-hour	1,600 ppm	

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Agency	Description	Information	Reference
DOE	PACs-air		<a href="#">DOE 2018a</a>
	PAC-1 <sup>j</sup>	2 ppm	
	PAC-2 <sup>j</sup>	64 ppm	
	PAC-3 <sup>j</sup>	3,200 ppm	

<sup>a</sup>RfD for noncancer effect also considered to be protective against cancer risk (IRIS 2001).

<sup>b</sup>The Substances Added to Food inventory replaces EAFUS and contains the following types of ingredients: food and color additives listed in FDA regulations, flavoring substances evaluated by FEMA or JECFA, GRAS substances listed in FDA regulations, substances approved for specific uses in food prior to September 6, 1958, substances that are listed in FDA regulations as prohibited from use in food, delisted color additives, and some substances "no longer FEMA GRAS."

<sup>c</sup>Under the EPA's 1986 guidelines for carcinogen risk assessment (EPA 1986), Group B2 contains agents classified as probable human carcinogens.

<sup>d</sup>Using draft revised guidelines for carcinogen risk assessment (EPA 1996), which were finalized later (EPA 2005), chloroform was classified as: (1) likely to be carcinogenic to humans by all routes of exposure under high-exposure conditions that lead to cytotoxicity and regenerative hyperplasia in susceptible tissues, and (2) not likely to be carcinogenic to humans by any route of exposure under exposure conditions that do not cause cytotoxicity and cell regeneration.

<sup>e</sup>EPA reported that this IUR was developed in 1987 and does not incorporate newer data or the updated EPA cancer assessment guidelines. Per EPA, the methodology used to derive the IUR has two shortcomings: (1) it utilized a route-to-route extrapolation approach that did not employ a PBPK model, and (2) it incorporated a linear extrapolation approach for dose-response that implicitly assumes a risk of cancer at all nonzero exposures to chloroform (i.e., no threshold). EPA's mode-of-action analysis added in 2001, however, concluded that for cancer, chloroform exhibits a "threshold" by all routes of exposure. Thus, a chloroform dose exists that does not elicit cytotoxicity and presents no cancer risk. Therefore, the assumption underlying EPA's IUR dose-response approach (linear extrapolation with no threshold) is inconsistent with EPA's subsequent mode-of-action analysis.

<sup>f</sup>Group 2B: possibly carcinogenic to humans.

<sup>g</sup>Value not to be exceeded at any time.

<sup>h</sup>NIOSH considers the compound to be a potential occupational carcinogen.

<sup>i</sup>Definitions of AEGL terminology are available from EPA (2018d).

<sup>j</sup>Definitions of PAC terminology are available from DOE (2018b).

AEGL = acute exposure guideline levels; DOE = Department of Energy; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; FAO = Food and Agriculture Organization; FDA = Food and Drug Administration; FEMA = Flavor and Extract Manufacturers Association of the United States; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; IUR = inhalation unit risk; JECFA = Joint FAO/WHO Expert Committee on Food Additives; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = protective action criteria; PBPK = physiologically based pharmacokinetic; PEL = permissible exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TDI = tolerable daily intake; TWA = time-weighted average; WHO = World Health Organization