CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding 2-butanone 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 2-butanone.

Agency	Description	Information	Reference
	Air		
EPA	RfC	5 mg/m ³ (1.7 ppm)	IRIS 2003
WHO	Air quality guidelines	Not listed	<u>WHO 2010</u>
	Water & Fo	ood	
EPA	Drinking water standards and health advisorie	<u>EPA 2018a</u>	
	1-Day health advisory (10-kg child)	75 mg/L	
	10-Day health advisory (10-kg child)	7.5 mg/L	
	DWEL	20 mg/L	
	Lifetime health advisory	4 mg/L	
	10 ⁻⁴ Cancer risk	No data	
	National primary drinking water regulations	Not listed	<u>EPA 2009</u>
	RfD	0.6 mg/kg/day	IRIS 2003
WHO	Drinking water quality guidelines	Not listed	<u>WHO 2017</u>
FDA	Substances Added to Food ^a	Approved under food additive and GRAS regulations	<u>FDA 2020</u>
	Cancer		
HHS	Carcinogenicity classification	No data	<u>NTP 2016</u>
EPA	Carcinogenicity classification	Data are inadequate for an assessment of human carcinogenic potential	<u>IRIS 2003</u>
IARC	Carcinogenicity classification	No data	IARC 2020
	Occupatio	nal	
OSHA	PEL (8-hour TWA) for general industry, shipyards, and construction	200 ppm	OSHA <u>2019a,</u> <u>2019b, 2019c</u>
NIOSH	REL (up to 10-hour TWA)	200 ppm	NIOSH 2019
	STEL (15-minute TWA)	300 ppm	
	IDLH	3,000 ppm	NIOSH 1994

Table 7-1. Regulations and Guidelines Applicable to 2-Butanone

Agency	Description	Information	Reference
	Emergency	v Criteria	
EPA	AEGLs-air		EPA 2018b
	AEGL 1 ^b		
	10-minute, 30-minute, 60-minute, 4-hour, and 8-hour	200 ppm	
	AEGL 2 ^b		
	10-minute	4,900 ppm ^c	
	30-minute	3,400 ppm ^c	
	60-minute	2,700 ppm ^c	
	4-hour	1,700 ppm	
	8-hour	1,700 ppm	
	AEGL 3 ^b		
	10-minute	10,000 ppm ^d	
	30-minute	10,000 ppm ^d	
	60-minute	4,000 ppm ^c	
	4-hour	2,500 ppm ^c	
	8-hour	2,500 ppm ^c	
DOE	PACs-air		DOE 2018
	PAC-1 ^e	200 ppm	
	PAC-2 ^e	2,700 ppm	
	PAC-3 ^e	4,000 ppm	

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^aThe 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 in food, delisted color additives, and some substances "no longer FEMA GRAS".

^bDefinitions of AEGL terminology are available from U.S. Environmental Protection Agency (EPA 2018c). ^cConcentration is ≥10% of the Lower Explosive Limit (LEL) of 18,000 ppm for methyl ethyl ketone. Safety considerations against the hazard of explosion must be taken into account.

^dConcentration is ≥50% of the LEL of 18,000 ppm for methyl ethyl ketone. Extreme safety considerations against the hazard of explosion must be taken into account.

^cDefinitions of PAC terminology are available from U.S. Department of Energy (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; 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; JECFA = Joint FAO/WHO Expert Committee on Food Additives; 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; STEL = short-term exposure limit; TWA = timeweighted average; WHO = World Health Organization