CHAPTER 7. REGULATIONS AND GUIDELINES

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

Agency	Description	Information	Reference
rigeney	Air	momaton	
EPA	RfC	No data	IRIS 2003
WHO	Air quality quidelines	No data	WHO 2010
	Water & F	Food	
EPA	Drinking water standards and health advisories		EPA 2012
	1-Day health advisory for a 10-kg child	15 mg/L	_
	10-Day health advisory for a 10-kg child	15 mg/L	_
	DWEL	7 mg/L	_
	Lifetime health advisory	0.1 mg/L	_
	10 ⁻⁴ Cancer risk	4 mg/L	_
	National primary drinking water regulations	No data	<u>EPA 2009</u>
	RfD	2x10 ⁻¹ mg/kg/day	IRIS 2003
WHO	Drinking water quality guidelines	No data	<u>WHO 2017</u>
FDA	EAFUS	Yes ^{a,b}	FDA 2013
	Cance	r	
HHS	Carcinogenicity classification	No data	<u>NTP 2016</u>
EPA	Carcinogenicity classification	Group C ^d	IRIS 2003
	Oral slope factor	9.5x10⁻⁴ per (mg/kg)/day	
IARC	Carcinogenicity classification	No data	IARC 2017
	Occupati	onal	
OSHA	PEL (8-hour TWA) for general industry, construction, and shipyards	25 ppm ^e ; 140 mg/m ^{3f}	OSHA <u>2016a, 2016b,</u> <u>2017</u>
NIOSH	REL (up to 10-hour TWA)	4 ppm (23 mg/m ³)	NIOSH 2016
	IDLH	200 ppm	_

Table 7-1. Regulations and Guidelines Applicable to Isophorone

Agency	Description	Information	Reference
		Emergency Criteria	
EPA	AEGLs-air	No data	EPA 2016
DOE	PACs-air		DOE 2016a
	PAC-1 ^g	12 ppm	
	PAC-2 ^g	33 ppm	
	PAC-3 ⁹	200 ppm	

Table 7-1. Regulations and Guidelines Applicable to Isophorone

^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.

^bStatus: fully up-to-date toxicology information has been sought.

^cA3: confirmed animal carcinogen with unknown relevance to humans.

^dC: possible human carcinogen.

^eParts of vapor or gas per million parts of contaminated air by volume at 25°C and 760 torr.

^fApproximate milligrams of substance per cubic meter of air.

⁹Definitions of PAC terminology are available from U.S. Department of Energy (DOE 2016a).

AEGL = acute exposure guideline levels; DOE = Department of Energy; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; 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; 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; TWA = time-weighted average; WHO = World Health Organization