ISOPHORONE 84

## **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.

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

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	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 <sup>g</sup>	12 ppm			
	PAC-2 <sup>g</sup>	33 ppm			
	PAC-3 <sup>g</sup>	200 ppm			

<sup>&</sup>lt;sup>a</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.

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

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

cA3: confirmed animal carcinogen with unknown relevance to humans.

<sup>&</sup>lt;sup>d</sup>C: possible human carcinogen.

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

<sup>&</sup>lt;sup>f</sup>Approximate milligrams of substance per cubic meter of air.

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