## **CHAPTER 7. REGULATIONS AND GUIDELINES**

Pertinent international and national regulations, advisories, and guidelines regarding N-nitrosodi-npropylamine 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. No MRLs were derived for N-nitrosodi-n-propylamine; see Appendix A for detailed information.

Agency	Description	Information	Reference		
Air					
EPA	RfC	No data	IRIS 2002		
WHO	Air quality guidelines	No data	<u>WHO 2010</u>		
Water & Food					
EPA	Drinking water standards and health advisories	No data	<u>EPA 2012</u>		
	National primary drinking water regulations	No data	<u>EPA 2009</u>		
	RfD	No data	IRIS 2002		
WHO	Drinking water quality guidelines	No data	<u>WHO 2017</u>		
FDA	EAFUS	No data <sup>a</sup>	FDA 2013		
Cancer					
ACGIH	Carcinogenicity classification	No data	ACGIH 2016		
HHS	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen <sup>b</sup>	<u>NTP 2016</u>		
EPA	Carcinogenicity classification	B2 <sup>c,d</sup>	IRIS 2002		
	Oral slope factor	7.0E+0 (mg/kg/day) <sup>-1</sup>	-		
IARC	Carcinogenicity classification	Group 2B <sup>e</sup>	IARC 1987		
Occupational					
ACGIH	TLV	No data	ACGIH 2016		
OSHA	PEL (8-hour TWA) for general industry, shipyards, and construction	No data	<u>OSHA 2016a, 2016b, 2016c</u>		
NIOSH	REL (up to 10-hour TWA)	No data	NIOSH 2016		

## Table 7-1. Regulations and Guidelines Applicable to n-Nitrosodi-n-Propylamine

Agency	Description	Information	Reference		
Emergency Criteria					
EPA	AEGLs-air	No data	EPA 2016		
AIHA	ERPGs	No data	<u>AIHA 2015</u>		
DOE	PACs-air		DOE 2016a		
	PAC-1 <sup>f</sup>	5.6 mg/m <sup>3</sup>			
	PAC-2 <sup>f</sup>	62 mg/m <sup>3</sup>			
	PAC-3 <sup>f</sup>	95 mg/m³			

## Table 7-1. Regulations and Guidelines Applicable to n-Nitrosodi-n-Propylamine

<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.

<sup>b</sup>Based on sufficient evidence of carcinogenicity in experimental animals.

°Group B2: probable human carcinogen.

<sup>d</sup>Based on increased tumor incidence at multiple sites in two rodent species and in monkeys administered the compound by various routes.

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

<sup>f</sup>Definitions 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; 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; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; 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; TWA = time-weighted average; WHO = World Health Organization