7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines pertaining to n-hexane in air, water, and other media are summarized in Table 7-1.

A chronic-duration inhalation MRL of 0.6 ppm has been derived by ATSDR, based on a LOAEL of 58 ppm for reduced motor nerve conduction velocity in occupationally exposed workers (Sanagi et al. 1980).

The Environmental Protection Agency (EPA) inhalation reference concentration (RfC) for *n*-hexane is 0.2 mg/m^3 (0.06 ppm by volume). No reference dose (RfD) has been derived for this compound (IRIS 1998).

The EPA has determined that *n*-hexane is not classifiable as to its human carcinogenicity (Group D) (EPA 1996f). The International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) have not classified *n*-hexane for carcinogenicity (IARC 1987). Although the American Conference of Governmental Industrial Hygienists (ACGIH) has not classified *n*-hexane for carcinogenicity, it has assigned a biological exposure index (BEI) of 5 mg/g creatinine for the neurotoxic metabolite of *n*-hexane, 2,5-hexanedione in urine (ACGIH 1996). The BEI is a reference value intended as a guideline for the evaluation of potential health hazards in the workplace (ACGIH 1996).

OSHA requires employers of workers who are occupationally exposed to *n*-hexane to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PELs). The employer must use controls and practices, if feasible, to reduce exposure to or below an 8-hour time-weighted average (TWA) of 500 ppm (1,800 mg/m^3) (OSHA 1974). The PEL for *n*-hexane was to have been lowered to 50 ppm in 1989; however, a U.S. Court of Appeals decision overturned a number of PELs promulgated in 1989, including that for *n*-hexane. The PEL in force prior to this decision (500 ppm) is currently in effect.

According to the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986, 42 U.S.C. Section 11023, industries are required to submit chemical release and off-site transfer information to the EPA. Section 313 of Title III of EPCRA requires owners and operators of certain facilities that manufacture, import, process, or otherwise use the chemicals on this list to report annually their release of

those chemicals to any environmental media (U.S. Congress 1986). The Toxics Release Inventory (TRI) contains this information. This database will be updated yearly and provides a list of industrial production facilities and emissions. On January 22, 1994, the EPA proposed that *n*-hexane be added to the list of chemicals subject to the requirements of EPCRA (EPA 1994a). The proposed rule was adopted on November 22, 1994 (EPA 1994e). *n*-Hexane was added to the TRI process, with data available for an inventory baseline of 1996 (TRI96 1998).

The EPA regulates *n*-hexane under the Clean Air Act (CAA) and has designated *n*-hexane as a hazardous air pollutant (HAP) (U.S. Congress 1990; EPA 1994b, 1994c). *n*-Hexane is included on the list of organic HAPS from the synthetic organic chemicals manufacturing industry (SOCMI) (EPA 1994b). The major SOCMI source categories for which EPA has established national emission standards are process vents, storage vessels, transfer operations, wastewaters (EPA 1994d), polymers and resins (EPA 1996a), petroleum refineries (EPA 1995a), offsite waste and recovery operations (EPA 1996b), and wood-furniture manufacturing operations (EPA 1995b). The SOCMI new stationary sources for which EPA has promulgated performance standards for *n*-hexane are distillation operations (EPA 1990) and reactor processes (EPA 1993b). In September 1996, the EPA promulgated national emission standards for hazardous air pollutants (NESHAP) from existing and new plant sites that emit organic HAPS during the manufacture of one or more elastomers (EPA 1996f). *n*-Hexane and several other HAPS (e.g., styrene, acrylonitrile, toluene, and 1,3-butadiene) identified as being emitted by these Group I polymer and resins sources can cause reversible and irreversible toxic effects following exposure. Emissions data evaluated in conjunction with the development of the elastomer standards showed that implementing the NESHAP could potentially reduce emissions of these HAPS (EPA 1996f). The EPA estimates that implementing the final rule would reduce organic HAP emissions from existing affected sources by more than 6,300 megagrams (6.3×10^6 kg) per year (Mg/yr). Since the majority of organic HAPS to be regulated by the standard are volatile organic compounds (VOCs), implementing the standard would also reduce VOC emissions (EPA 1996f).

n-Hexane is regulated by the Clean Water Effluent Guidelines in Subchapter N of Title 40 of the Code of Federal Regulations. The source category for which the discharge of *n*-hexane in process wastewaters is applicable is the organic chemicals, plastics, and synthetic fibers manufacturing industry (EPA 1987b). This industry includes manufacturers of cyclic crudes and intermediates, dyes, organic pigments, and certain industrial organic chemicals (EPA 1987b). On May 1, 1995, the EPA published a proposed rule to establish a pretreatment standards of 796 μL (1-day maximum) and a new sources performance

standards of 573 μg/L (1-day maximum) for the fermentation, extraction, chemical synthesis, and mixing compounding and formulating subcategories under the pharmaceutical manufacturing point source category (EPA 1995c). The proposed rule continues to be reviewed.

On March 1, 1994, the EPA proposed to regulate *n*-hexane under the Resource Conservation and Recovery Act (RCRA) by including *n*-hexane as part of the basis for listing K1.56 waste (i.e., organic waste from the production of carbamates and carbamoyl oximes) in 40 CFR 261, Appendix VII (EPA 1994f). The proposed rule would also add *n*-hexane to the list of hazardous constituents given in 40 CFR 261, Appendix VIII (EPA 1994f). Although the proposed rule was adopted on February 9, 1995, the EPA did not add *n*-hexane and several other chemicals to appendices VII or VIII (EPA 1995g). In addition to these chemicals no longer being significant to the carbamate industry, the results of the Agency's multi-pathway risk analysis showed that they did not present significant environmental or health-based risks (EPA 1995g).

Table 7-1. Regulations and Guidelines Applicable to *n*-Hexane

Agency	Description	Information	References
INTERNATIONAL			
Guidelines:			
WHO	Drinking-water guideline values for health-related organics	None	WHO 1984
NATIONAL			
Regulations: a. Air:			
OSHA[a]	Air contaminants Permissible exposure limit (PEL): 8-hour time-weighted average (TWA)	500 ppm (1,800 mg/m^3)	29 CFR 1910.1000 OSHA 1974
EPA OAR	Hazardous Air Pollutants	Yes	Clean Air Act Amendment Title III, Section 112 (b) U.S. Congress 1990
	Standards of Performance for New Stationary Sources-		
	Subpart NNN: standards of performance for voc emissions from synthetic organic manufacturing industry (socmi) distillation operations--chemicals affected	Yes	40 CFR 60.667 EPA 1990
	Subpart RRR: standards of performance for voc emissions from synthetic organic manufacturing industry (socmi) reactor process--chemicals affected	Yes	40 CFR 60.707 EPA 1993b
	National emission standards for hazardous air pollutants for source categories		
	Subpart F: national emission standards for organic hazardous air pollution from the socmi	Yes	40 CFR 63.100 EPA 1994b
	SOCMI chemicals	Yes	40 CFR 63.106 EPA 1994c
	Subpart G: national emission standards for organic hazardous air pollutants from the socmi for process vents, storage vessels, transfer operations, and wastewater	Yes	40 CFR 63, Appendix, Tables 8, 9 and 34 EPA 1994d
	Subpart U: national emission standards for HAP emissions: group I polymers and resins	Yes	40 CFR 63.506 EPA 1996a
	Subpart CC: national emission standards for HAPs from petroleum refineries	Yes	40 CFR 63., Appendix Tables 1, 5, and 7 EPA 1995a
	Subpart DD: national emission standards for HAPs from off-site waste and recovery operations	Yes	40 CFR 63.698 EPA 1996b

Table 7-1. Regulations and Guidelines Applicable to *n*-Hexane (continued)

Agency	Description	Information	References
NATIONAL (cont.)			
	Subpart JJ: national emission standards for HAPs from wood furniture manufacturing operations-applicability	Yes	40 CFR 63.800 EPA 1995b
b. Water			
EPA OW	Organic Chemicals, Plastics, and Synthetic Fibers		
	Applicability; description of the bulk organic chemicals subcategory	Yes	40 CFR 414.70 EPA 1987b
	Effluent Guidelines and Standards: Pretreatment Standards and New Source Performance Standards: pharmaceutical manufacturing category (proposed rule)	1-day maximum / Monthly Average (μg/L)	60 FR 21592 EPA 1995c
	Fermentation subcategory		
	PSES: in-plant monitoring	796 / 268	
	PSNS: in-plant monitoring	573 / 212	
	Extraction subcategory		
	PSES: in-plant monitoring	796 / 268	
	PSNS: in-plant monitoring	573 / 212	
	Chemical synthesis subcategory		
	PSES: in-plant monitoring	796 / 268	
	PSNS: in-plant monitoring	573 / 212	
	Mixing Compounding and Formulating Subcategory		
	PSES: in-plant monitoring	796 / 268	
	PSNS: in-plant monitoring	573 / 212	
c. Other:			
DOT	Hazardous Materials Table	UN 1208	49 CFR 172.101 DOT 1990
EPA-OERR	List of Hazardous Substances and Reportable Quantities	1 pound (0.454 Kg) (CERCLA statutory) 5000 pounds (2270 Kg) (final RQ)	40 CFR 302.4 EPA 1993a
	Toxic Chemical Release Reporting: Community Right-to-know		
	Addition of certain chemicals; toxic chemical releases reporting; community right-to-know (proposed rule: 40 CFR 372)	Yes	59 FR 1788 EPA 1994a
	Addition of certain chemicals; toxic chemical releases reporting; community right-to-know (final rule: 40 CFR 372)	Yes	59 FR 61432 EPA 1994e

Table 7-1. Regulations and Guidelines Applicable to *n*-Hexane (continued)

Agency	Description	Information	References
NATIONAL (cont.)			
EPA-OSW			
	Identification and Listing of Hazardous Wastes		
	Hazardous waste management system: carbamate production identification and listing of hazardous waste; and CERCLA hazardous substance designation and reportable quantities (proposed rule--40 CFR 261, Appendix VIII)	Proposed to include hexane as a hazardous constituent in K156 waste	59 FR 9808 EPA 1994f
	Hazardous waste management system: carbamate production identification and listing of hazardous waste; and CERCLA hazardous substance designation and reportable quantities (final rule)	Hexane removed from final list of chemicals to be added to Appendix VIII basis for listing for K156 waste	60 FR 7824 EPA 1995e
Guidelines:			
a: Air:			
ACGIH	Permissible Exposure Limit (PEL)-Time-weighted Average (TWA) Hexane	 50 ppm (176 mg/m^3)	ACGIH 1996
	Other isomers:	500 ppm (1760 mg/m^3)	
	Short-term exposure limit (STEL) Ceiling Other isomers	 100 ppm (3500 mg/m^3)	
NIOSH	Recommended Exposure Limit (REL) for Occupational Exposure Hexane *TWA*	 *50 ppm* (180 mg/m^3)	NIOSH 1992
	Other isomers TWA	100 ppm (350 mg/m^3)	
	ceiling	510 ppm (1800 mg/m^3)	
b. Water:			
EPA ODW	1-day Health Advisory (child)-draft	10 mg/L	EPA 1996f
	10-day Health Advisory (Child)	4 mg/L	
	Lifetime Health Advisory (Adult)	0.75 mg/L	
	Long-term Health Advisory--up to approximately 7 years (10% of an Individual's Lifetime) of exposure	4 mg/L (child) 10 mg/L (adult)	

Table 7-1. Regulations and Guidelines Applicable to *n*-Hexane (continued)

Agency	Description	Information	References
NATIONAL (cont.)			
d. Other:			
ACGIH	Biological Exposure Indices (BEI)	5 mg 2,5-hexanedione/ g creatinine	ACGIH 1996
EPA	Cancer Classification	D[b]	EPA 1996f
	Reference Concentration (RfC)	0.2 mg/m^3 (0.06 ppm)	IRIS 1998
STATE			
Regulations and Guidelines:			
a. Air:	Average Acceptable Ambient Air Concentrations (n-Hexane)		NATICH 1992
AZ	1 hour	5.30x10^3 µg/m^3 (1.5 ppm)	
	24 hours	1.40x10^3 µg/m^3 (0.397 ppm)	
CT	8 hours	3.60x10^3 µg/m^3 (1.0 ppm)	
FL-Pinella	8 hours	1.8x10^3 µg/m^3 (0.511 ppm)	
	24 hours	4.23x10^2 µg/m^3 (0.120 ppm)	
LA	8 hours	4.19x10^{+3} µg/m3 (1.2 ppm)	
NC	24 hours	1.10 mg/m^3 (0.312 ppm)	NATICH 1992
	15 minutes	3.6x10^2 mg/m^3 (102.1 ppm)	
NC-Forsyth County	24 hours	1.0 mg/m^3 (0.284 ppm)	
ND	8 hour	1.76 mg/m^3 (0.499 ppm)	
NV	8 hours	4.29 mg/m^3 (1.2 ppm)	
OK	24 hours	1.76x10^4 µg/m^3 (5.0 ppm)	
TX	30 minutes	1.76x10^3 µg/m^3 (0.499 ppm)	
	Annual	1.76x10^2 µg/m^3 (0.050 ppm)	
VA	24 hours	2.90x10^4 µg/m^3 (8.2 ppm)	
	24 hours	4.29x10^3 µg/m^3 (1.2 ppm)	

Table 7-1. Regulations and Guidelines Applicable to *n*-Hexane (continued)

Agency	Description	Information	References
STATE (cont.)			
WA-SWEST	24 hours	$5.99x10^2$ µg/m^3 (0.170 ppm)	
	Average Acceptable Ambient Air Concentrations (Other Isomers)		NATICH 1992
FL-Pinella	8 hours	$3.60x10^4$ µg/m^3 (10.2 ppm)	
	24 hours	$8.64x10^3$ µg/m^3 (2.5 ppm)	
NC-Forsyth County	15 minutes	3.60 mg/m^3 (1.0 ppm)	
ND	8 hours	$1.76x10^1$ mg/m^3 (5.0 ppm)	
	1 hour	$3.5x10^1$ mg/m^3 (9.9 ppm)	
WA-SWEST	24 hours	$5.99x10^3$ µg/m^3 (1.7 ppm)	
b. Water			
	Water Quality Criteria: Human Health		
AZ	Drinking water (guideline)	$4.0x10^3$ µg/L	FSTRAC 1995
ME	Drinking water (guideline)	$4.0x10^3$ µg/L	
MI	Drinking water (guideline)	$2.9x10^3$ µg/L	Sittig 1994
MN	Drinking water (guideline)	$4.0x10^3$ µg/L	FSTRAC 1995
NC	Drinking water (guideline)	$14.3x10^3$ µg/L	
NJ	Drinking water (standard)	33 µg/L	
RI	Drinking water (guideline)	$4.0x10^3$ µg/L	FSTRAC 1990
VT	Drinking water (standard)	$4.0x10^3$ µg/L	

[a] The PEL for *n*-hexane was to have been lowered to 50 ppm in 1989. However, a U.S. Court of Appeals rescinded the 1989 PELs promulgated by OSHA. Only PELs in place prior to the 1989 rule are currently allowed (58 FR 35338, June 30, 1993).

[b] Cancer classification D indicates that the agent has not been classified for carcinogenicity. There is inadequate or no human and animal evidence of carcinogenicity.

ACGIH = American Conference of Governmental Industrial Hygienists; BEI = Biological Exposure Indices; CFR = Code of Federal Regulations; CWA = Clean Water Act; DOT = Department of transportation; EPA = Environmental Protection Agency; FSTRAC = Federal State Toxicology and Regulatory Alliance Committee; HAP = Hazardous Air Pollutants; IARC = International Agency for Research on Cancer; INCIN = Incineration; NATICH = National Air Toxics Information Clearinghouse; NIOSH = National Institute of Occupational Safety and Health; OAR - Office of Air and Radiation; ODW = Office of Drinking Water; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Wastes; OW = Office of Water; PEL = Permissible Exposure Limit; PSES = Pretreatment Standards for Existing Sources; PSNS = Pretreatment Standards for New Sources; RQ = Reportable Quantities; SOCMI = Synthetic Organic Chemicals Manufacturing Industry; STEL = Short-term Exposure Limit; TWA = Time-weighted Average; VOC = Volatile Organic Compound; WHO = World Health Organization