

7. REGULATIONS AND ADVISORIES

Because of its potential to cause adverse health effects in exposed people, numerous regulations and advisories have been established for hydrazines by various international, national and state agencies. Major regulations and advisories pertaining to hydrazine, 1,1-dimethylhydrazine, and 1,2-dimethylhydrazine are summarized in Tables 7-1, 7-2, and 7-3, respectively.

ATSDR has derived an intermediate-duration inhalation MRL of 4×10^{-3} ppm for hydrazine, as described in Appendix A. The MRL is based on a LOAEL of 0.2 ppm for fatty liver changes in female mice (Haun and Kinkead 1973). The LOAEL was adjusted for intermittent exposure (6 hours/day, 5 days/week), converted to a Human Equivalent Concentration (HEC), and divided by an uncertainty factor of 300 (10 for use of a LOAEL, 3 for extrapolation from animals to humans, and 10 for human variability).

ATSDR has derived an intermediate-duration inhalation MRL of 2×10^{-4} ppm for 1,1-dimethylhydrazine, as described in Appendix A. The MRL is based on a LOAEL of 0.05 ppm for hepatic effects (hyaline degeneration of the gall bladder in female mice) (Haun et al. 1984). The LOAEL was adjusted for intermittent exposure (6 hours/day, 5 days/week), converted to an HEC, and divided by an uncertainty factor of 300 (10 for use of a LOAEL, 3 for extrapolation from animals to humans, and 10 for human variability).

ATSDR has derived an intermediate-duration oral MRL of 8×10^{-4} mg/kg/day for 1,2-dimethylhydrazine, as described in Appendix A. The MRL is based on a LOAEL of 0.75 mg/kg/day for mild hepatitis in male mice (Visek et al. 1991). The LOAEL was divided by an uncertainty factor of 1,000 (10 for use of a LOAEL, 10 for extrapolation from animals to humans, and 10 for human variability).

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TABLE 7-1. Regulations and Guidelines Applicable to Hydrazine

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
IARC	Carcinogenic classification	Group 2B ^a	IARC 1994
<u>NATIONAL</u>			
Regulations:			
a. Air:			
EPA OAQPS	Hazardous Air Pollutant	Yes	Public Law 101-549 Section 112
	High-risk Pollutant (proposed) List of Regulated Substances and Threshold for Accidental Release Prevention - Proposed	Yes 5,000 pounds	EPA 1991c EPA 1993
OSHA	PEL TWA	0.1 ppm (0.1 mg/m ³), skin ^b	NIOSH 1994
b. Food:			
FDA	Boiler water additive-limits for steam that will contact food	0	21 CFR 173.310
c. Other:			
EPA OERR	Reportable quantity	1 pound	EPA 1989 (40 CFR 302.4)
	Extremely Hazardous Substance TPQ	1,000 pounds	EPA 1987 (40 CFR 355)
EPA OSW	Hazardous Waste Constituent (Appendix VIII)	Yes	EPA 1980 (40 CFR 261)
	Land Disposal Restrictions	Yes	EPA 1990b, 1991a (40 CFR 268)
	Burning of Hazardous Waste in Boilers and Industrial Furnaces- Residue Concentration Limit	1x10 ⁻⁴ mg/kg	EPA 1991b
EPA OTS	Toxic Chemical Release Reporting Rule	Yes	EPA 1988b (40 CFR 372)
	Priority Testing List (Section 4E)	Yes	EPA 1991d
Guidelines:			
a. Air:			
ACGIH	TLV TWA	Suspected human carcinogen, 0.1 ppm (0.13 mg/m ³), skin	ACGIH 1994a
	Proposed TLV TWA	Animal carcinogen, 0.01 ppm (0.013 mg/m ³), skin	

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TABLE 7-1. Regulations and Guidelines Applicable to Hydrazine (*continued*)

Agency	Description	Information	References
NIOSH	REL Ceiling (120 minutes)	Potential occupational carcinogen 0.03 ppm (0.04 mg/m ³)	NIOSH 1994
b. Other:			
EPA	Carcinogenic Classification	Group B2 ^c	IRIS 1995
	Cancer slope factor (q ₁ [*])		
	q ₁ [*] (oral)	3.0 (mg/kg-day) ⁻¹	
	q ₁ [*] (inhalation)	1.7x10 ¹ (mg/kg-day) ⁻¹	
DHHS	Carcinogenic Classification	May reasonably be anticipated to be a carcinogen	NTP 1994
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:	Acceptable ambient air concentrations		NATICH 1995
Connecticut		1.0 µg/m ³ (8 hour)	
Florida		1.0 x 10 ⁻³ mg/m ³ (8 hour)	
		3.1 x 10 ⁻² µg/m ³ (24 hour)	
		1.3 x 10 ⁻¹ µg/m ³ (8 hour)	
		3.4 x 10 ⁻⁴ µg/m ³ (1 year)	
Kansas		2.0 x 10 ⁻⁴ µg/m ³ (1 year)	
Louisiana		2.0 x 10 ⁻² µg/m ³ (1 year)	
Maine		2.0 x 10 ⁻⁴ µg/m ³ (1 year)	
Massachusetts		7.0 x 10 ⁻³ µg/m ³ (24 hour)	
		2.0 x 10 ⁻³ µg/m ³ (annual)	
Michigan		2.0 x 10 ⁻⁴ µg/m ³ (1 year)	
Nevada		2.0 x 10 ⁻³ mg/m ³ (8 hour)	
New York		3.3 x 10 ⁻¹ µg/m ³ (1 year)	
North Carolina		6.0 x 10 ⁻⁴ mg/m ³ (24 hour)	
North Dakota		0 (best available control technology)	
Oklahoma		3.93 x 10 ⁻¹ µg/m ³ (24 hour)	
Pennsylvania		2.4 x 10 ⁻¹ µg/m ³ (1 year)	
		2.4 x 10 ⁻¹ ppb (1 year)	
Rhode Island		3.0 x 10 ⁻⁴ µg/m ³ (annual)	
South Carolina		5.0 x 10 ⁻¹ µg/m ³ (24 hour)	

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TABLE 7-1. Regulations and Guidelines Applicable to Hydrazine (continued)

Agency	Description	Information	References
Texas		1.3 x 10 ⁻¹ µg/m ³ (30 minute)	
		1.3 x 10 ⁻² µg/m ³ (annual)	
Virginia		1.3 µg/m ³ (24 hour)	

^a Group 2B: Possible human carcinogen

^b Due to a Federal court decision, not enforceable as of March 22, 1993 (Hanson 1993).

^c Group B2: Probable human carcinogen

ACGIH = American Conference of Governmental Industrial Hygienists; DHHS = Department of Health and Human Services; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OAQPS = Office of Air Quality Planning and Standards; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Waste; OTS = Office of Toxic Substances; PEL = Permissible Exposure Limit; REL = Recommended Exposure Limit; TLV = Threshold Limit Value; TPQ = Threshold Planning Quantity; TWA = Time-Weighted Average

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TABLE 7-2. Regulations and Guidelines Applicable to 1,1-Dimethylhydrazine

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
IARC	Carcinogenic classification	Group 2B ^a	IARC 1994
<u>NATIONAL</u>			
Regulations:			
a. Air:			
EPA OAQPS	Hazardous Air Pollutant List of Regulated Substances and Threshold for Accidental Release Prevention - Proposed	Yes 5,000 pounds	Public Law 101-549 EPA 1993
	NESHAP for Source Categories: Organic HAPs from Synthetic Organic Chemical Manufacturing Industry - Proposed	Yes	EPA 1992a
OSHA	Skin PEL TWA	.5 ppm (1 mg/m ³)	NIOSH 1994
b. Other:			
EPA OERR	Reportable quantity	10 pounds	EPA 1989 (40 CFR 302.4)
	Extremely Hazardous Substance TPQ	1,000 pounds	EPA 1987 (40 CFR 355)
EPA OSW	Hazardous Waste Constituent (Appendix VIII)	Yes	EPA 1980 (40 CFR 261)
	Land Disposal Restrictions	Yes	EPA 1990b EPA 1991a EPA 1992b (40 CFR 268)
EPA OTS	Toxic Chemical Release Reporting Rule	Yes	EPA 1988b (40 CFR 372)
	Priority Testing List (Section 4E)	Yes	EPA 1991d
Guidelines:			
a. Air:			
ACGIH	TLV TWA	Suspected human carcinogen, 0.5 ppm (1.2 mg/m ³), skin	ACGIH 1994a
	Proposed TLV TWA	Animal carcinogen, 0.01 ppm (0.25 mg/m ³) skin	

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TABLE 7-2. Regulations and Guidelines Applicable to 1,1-Dimethylhydrazine (*continued*)

Agency	Description	Information	References
NIOSH	REL Ceiling (120 minutes)	Potential occupational carcinogen 0.06 ppm (0.15 mg/m ³)	NIOSH 1994
b. Other: EPA	Carcinogenic Classification Cancer slope factor (q ₁ *) q ₁ * (oral) q ₁ * (inhalation)	Group B2 ^c 2.6 (mg/kg-day) ⁻¹ 3.5 (mg/kg-day) ⁻¹	HEAST 1992
DHHS	Carcinogenic Classification	May reasonably be anticipated to be a carcinogen	NTP 1994
STATE			
Regulations and Guidelines:			
a. Air:	Acceptable ambient air concentrations		NATICH 1995
Connecticut		11 µg/m ³ (8 hour)	
Florida		1.0 x 10 ⁻² mg/m ³ (8 hour) 6.0 x 10 ⁻² µg/m ³ (24 hour) 2.5 x 10 ⁻¹ µg/m ³ (8 hour)	
Nevada		2.4 x 10 ⁻² mg/m ³ (8 hour)	
New York		3.3 µg/m ³ (1 year)	
North Dakota		0 (best available control technology)	
Oklahoma		1.5 µg/m ³ (24 hour)	
Pennsylvania		2.4 µg/m ³ (1 year) 1.2 ppb (1 year)	
South Carolina		5.0 µg/m ³ (24 hour)	
Texas		2.5 x 10 ⁻¹ µg/m ³ (30 minute) 2.5 x 10 ⁻² µg/m ³ (annual)	
Virginia		12 µg/m ³ (24 hour)	
Washington		3.3 µg/m ³ (24 hour)	

^a Group 2B: Possible human carcinogen

^b Due to a Federal court decision, not enforceable as of March 22, 1993 (Hanson 1993).

^c Group B2: Probable human carcinogen

ACGIH = American Conference of Governmental Industrial Hygienists; EPA = Environmental Protection Agency; DHHS = Department of Health and Human Services; HAP = Hazardous Air Pollutants; IARC = International Agency for Research on Cancer; NESHAP = National Emission Standards for Hazardous Air Pollutants; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OAQPS = Office of Air Quality Planning and Standards; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Waste; OTS = Office of Toxic Substances; PEL = Permissible Exposure Limit; REL = Recommended Exposure Limit; TLV = Threshold Limit Value; TPQ = Threshold Planning Quantity; TWA = Time-Weighted Average.

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TABLE 7-3. Regulations and Guidelines Applicable to 1,2-Dimethylhydrazine

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
IARC	Carcinogenic classification	Group 2B ^a	IARC 1994
<u>NATIONAL</u>			
Regulations:			
a. Other:			
EPA OERR	Reportable quantity	1 pound	EPA 1989 (40 CFR 302.4)
EPA OSW	Hazardous Waste Constituent (Appendix VIII)	Yes	EPA 1980 (40 CFR 261)
	Land Disposal Restrictions	Yes	EPA 1990b EPA 1991a (40 CFR 268)
EPA OTS	Toxic Chemical Release Reporting Rule - Proposed	Yes	EPA 1992d (40 CFR 372)
Guidelines:			
a. Other:			
EPA	Carcinogenic Classification	Group B2 ^b	HEAST 1992
	Cancer slope factor (q ₁ *)		
	q ₁ * (oral)	3.7 x 10 ¹ (mg/kg-day) ⁻¹	
	q ₁ * (inhalation)	3.7 x 10 ¹ (mg/kg-day) ⁻¹	
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:	Acceptable ambient air concentrations		NATICH 1991
South Carolina		5.0 µg/m ³ (24 hour)	

^a Group 2B: Possible human carcinogen

^b Group B2: Probable human carcinogen

EPA = Environmental Protection Agency; IARC = International Agency for Research on Cancer; OERR = Office of Emergency and Remedial Response; OSW = Office of Solid Waste; OTS = Office of Toxic Substances

