

7. REGULATIONS AND ADVISORIES

Because of its potential to cause adverse health effects in exposed people, various international, national, and state agencies regulate HCCPD as a toxic or hazardous substance and have established standards, guidelines, and advisories for its manufacture, use, and disposal. Some of the major regulations regarding HCCPD in air, water, and other media are summarized in Table 7- 1.

An inhalation MRL of 0.01 ppm for intermediate-duration exposure was calculated based on a LOAEL of 0.2 ppm from a 14-week study by Rand et al. (1982b) that examined structural changes in the Clara cells of the lung epithelium in rats exposed to HCCPD. The critical effect was the appearance of electron-lucent granules in the Clara cells of the exposed animals.

A chronic-duration inhalation MRL of 0.2 ppb was calculated from a LOAEL of 0.01 ppm for the formation of yellowish-brown pigmentation of the nasal/tracheal and/or bronchial epithelium of male and female rats in the study by NTP (1994).

The EPA has calculated a chronic oral Reference Dose (RfD) of 0.007 mg/kg/day for HCCPD. Hyperplasia and focal inflammation of the forestomach were the critical effects (IRIS 1997). The EPA has not determined a reference concentration (RfC) for chronic inhalation exposures using HCCPD (IRIS 1997)

ATSDR has calculated an oral MRL for intermediate-duration exposures of 0.1 mg/kg/day using the same study and end point used in the derivation of the EPA RfD (Abdo et al. 1984).

The EPA has determined that HCCPD is not classifiable as to its human carcinogenicity because there is inadequate supporting data from human studies and no data from animal studies. Therefore, HCCPD has been assigned to cancer group D (IRIS 1997). The American Conference of Governmental Industrial Hygienists (ACGIH) also finds HCCPD to be “not classifiable as a human carcinogen.” ACGIH has assigned HCCPD to the cancer category A4, which indicates that there is cause for concern about its carcinogenicity but a conclusive assessment cannot be made from the available data (ACGIH 1998). The National Toxicology Program (NTP) of the U.S. Department of Health and Human Services and the

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International Agency for Research on Cancer (IARC) have not evaluated HCCPD for human carcinogenicity.

To protect workers against the adverse health effects that could result from exposure to chemicals, the Occupational Safety and Health Administration (OSHA) has promulgated permissible exposure limits (PELs) for more than 400 hazardous or toxic substances commonly found in the workplace (OSHA 1989). An employer must ensure that an employee's exposure to an OSHA-regulated substance in any 8-hour work shift of a 40-hour week does not exceed an 8-hour time-weighted average (TWA) determined for the substance (OSHA 1974). On January 18, 1989, OSHA promulgated a final rule that provided more protective PELs for approximately 376 toxic substances (OSHA 1989). Of the 428 substances considered in the rule, 164 substances, including HCCPD, had not been previously regulated by OSHA (OSHA 1989). The primary basis for setting a new limit for HCCPD was to avoid sensory irritations (e.g., eye irritation and intolerable odor) that had been associated with exposures to the substance (OSHA 1989). OSHA established an 8-hour TWA limit of 0.01 ppm for HCCPD. The new PEL was 10 times lower than the level associated with systemic damage and pulmonary irritation in animal exposure studies (OSHA 1989). Although OSHA set the new PEL so that employee risks of intense eye and pulmonary irritation and multiple organ damage would be reduced, all limits set in the 1989 promulgation were revoked in July 1992 by the 11th Circuit Court of Appeals (OSHA 1993). On March 23, 1993, OSHA resumed enforcing the air contaminant exposure limits that were in effect prior to the issuance of the new limits in 1989 (i.e., OSHA 1974 PELs). The Agency later published in the June 30, 1993, *Federal Register* a final rule announcing the revocation of the 1989 exposure limits (OSHA 1993). Because OSHA had not established a PEL for HCCPD prior to the 1989 promulgation, there is no current PEL for HCCPD. However, the National Institute for Occupational Safety and Health (NIOSH) and approximately 25 states have adopted the 0.01 ppm (0.1 mg/m³) exposure limit for HCCPD set by OSHA in 1989 (NIOSH 1992, 1997; OSHA 1993). ACGIH also adopted the 0.01 ppm (0.1 mg/m³) exposure limit for HCCPD (ACGIH 1998).

HCCPD has been designated as a hazardous substance pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 (EPA 1995a) and as an extremely hazardous substance under Section 313 of Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 (EPA 1996f). The statutory sources for designating HCCPD as a CERCLA hazardous waste are sections 311(b)(4) and 307(a) of the Clean Water Act (CWA) and section 3001 of the Resource Conservation and Recovery Act (RCRA) (EPA 1995a). The owners and operators of facilities that have HCCPD on their sites are required to immediately report releases of HCCPD to any environmental media,

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if the amount released exceeds the established “reportable quantity” of 10 pounds (4.54 kg) (EPA 1995a). Title III of SARA is also known as the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986. As a chemical subject to the emergency planning and release reporting requirements of EPCRA, owners and operators of certain facilities that have HCCPD on their sites in amounts exceeding the “threshold planning quantity” of 100 pounds must develop a program that addresses implementing emergency response plans and notifying the public of accidental releases (EPA 1996c, 1996f).

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Table 7-1. Regulations and Guidelines Applicable to HCCPD

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
WHO	Drinking Water Guideline Values	None	WHO 1996
IARC	Cancer Classification	None	IARC 1987
<u>NATIONAL</u>			
a. Air:			
OSHA	PEL -TWA	None	29 CFR 1910.1000 OSHA 1974
	Newly promulgated PEL; later vacated	0.01 ppm	54 FR 2464 OSHA 1989 58 FR 35338 OSHA 1993
U.S. Congress	National Emission Standards for Hazardous Air Pollutants (NESHAPs)	Yes	Clean Air Act Amendments, Title III U.S. Congress 1990
b. Water:			
EPA OW	Maximum Contaminant Level (MCL)	0.05 mg/L	40 CFR 141 EPA 1995e
	EPA Administered Permit Program National pollutant discharge elimination system (NPDES)	Yes	40 CFR 122 EPA 1995d
	Designation of Hazardous Substances List of hazardous substance	Yes	40 CFR 116 EPA 1989e
	Determination of Reportable Quantities for Hazardous Waste	10 pounds (4.54 kg)	40 CFR 117.3 EPA 1995b
c. Other:			
EPA OERR	Designation, Reportable Quantities, and Notification	10 pounds	40 CFR 302.4 EPA 1995a
	Emergency Planning and Notification Extremely hazardous substances and their threshold	10 pounds	40 CFR 355 EPA 1996f
EPA OSW	Identification and Listing of Hazardous Waste Hazardous waste constituents	Yes	40 CFR 261 EPA 1997a
	Land Disposal Restrictions (LDRs) Prohibitions on storage and surface disposed wastes regulated in the LDRs	Yes	40 CFR 268.32 and Appendix VII EPA 1996b
	Universal treatment standards	<u>Wastewater</u> 0.057 mg/L <u>Nonwastewater</u> 2.4 mg/L	40 CFR 268.48 EPA 1997b

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Table 7-1. Regulations and Guidelines Applicable to HCCPD (continued)

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
	Standards for the Management of Hazardous Waste and Specific Types of Hazardous Waste Facilities Health-based [concentration] limits for exclusion of waste-derived residues	0.2 mg/kg	40 CFR 266 EPA 1993
EPA OTS	Toxic Chemical Release Reporting: Community Right-to-Know	Yes	40 CFR 372.65 EPA 1997
	Health and Safety Data Reporting Rule	Yes	40 CFR 716.120 EPA 1996c
Guidelines:			
a. Air:			
ACGIH	Threshold Limit Value/Time-weighted average	0.01 ppm (0.1 mg/m ³)	ACGIH 1998
NIOSH	Recommended Exposure Limit/Time-weighted average	0.01 ppm (0.1 mg/m ³)	NIOSH 1997
b. Water:			
EPA OW	Maximum Contaminant Level Goals (MCLGs)	0.05 mg/L	40 CFR 141 EPA 1995e
	Effluent Guidelines and Standards	Yes	40 CFR 401a EPA 1981
c. Other			
EPA	RfD (oral)	7x10 ⁻³ mg/kg/day	IRIS 1997
	Carcinogenic Classification	Group D ^a	IRIS 1997
ACGIH	Carcinogenic Classification	Group A4 ^b	ACGIH 1998
<u>STATE</u>			
Regulations and Guidelines			
a. Air: Acceptable ambient air concentrations NATICH 1992			
AZ	1-hour	2.5 µg/m ³	
	24-hour	0.79 µg/m ³	
CT	8-hour	2 µg/m ³	
FL (Fort Lauderdale)	8-hour	0.001 mg/m ³	
FL (Pinella.)	8-hour	1 µg/m ³	
	24-hour	0.24 µg/m ³	
	Annual	5.0 µg/m ³	
FL (Tampa)	8-hour	0.001 mg/m ³	
IN	8-hour	0.5 µg/m ³	

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Table 7-1. Regulations and Guidelines Applicable to HCCPD (continued)

Agency	Description	Information	Reference
<u>STATE</u> (cont.)			
IN (Indianapolis)	8-hour	0.5 µg/m ³	
MA	24-hour	0.006 µg/m ³	
	Annual	0.01 µg/m ³	
NC	1-hour	0.01 mg/m ³	
	24-hour	0.0006 mg/m ³	
NC (Forsyth County)	1-hour	0.01 mg/m ³	
	24-hour	0.0006 mg/m ³	
ND	8-hour	0.0011 mg/m ³	
NV	8-hour	0.002 mg/m ³	
NY	Annual	0.33 µg/m ³	
OK	24-hour	1 µg/m ³	
SC	24-hour	0.5 µg/m ³	
TX	30-minute	1.1 µg/m ³	
	Annual	0.11 µg/m ³	
VA	24-hour	1.8 µg/m ³	
WA-SWEST	24-hour	0.3 µg/m ³	
b. Water	Drinking Water Guidelines and Standards		
ME	Guideline	50 µg/L	FSTRAC 1995

^a Group D not classifiable as to its human carcinogenicity.

^b Group A4 substances exhibit cause for concern as to their human carcinogenicity, however, a conclusive assessment cannot be made from existing data.

ACGIH = American Conference of Governmental Industrial Hygienists; CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; FR = Federal Register; FSTRAC = Federal-State Toxicology and Risk Analysis Committee; MCL = Maximum Contaminant Level; NATICH = National Air Toxics Information Clearinghouse; NIOSH = National Institute for Occupational Safety and Health; NPDES = National Pollutant Discharge Elimination System; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Wastes; OTS = Office of Toxic Substances; OW = Office of Water; PEL = Permissible Exposure Limit; REL = Recommended Exposure Limit; RfD = Reference Dose