

## 7. REGULATIONS AND ADVISORIES

The national and state regulations and guidelines pertaining to 3,3'-dichlorobenzidine in air, water, and other media are summarized in Table 7- 1.

There is no oral reference dose (RfD) for 3,3'-dichlorobenzidine. The health effects data for 3,3'-dichlorobenzidine were reviewed by the EPA RfD/RfC Work Group and determined to be inadequate for derivation of an inhalation RfC (IRIS 1998).

The EPA has determined that 3,3'-dichlorobenzidine is a probable human carcinogen, B2 classification (IRIS 1998). The International Agency for Research on Cancer (IARC) has classified 3,3'-dichlorobenzidine as a Group 2B carcinogen-possibly carcinogenic to humans (IARC 1987). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies 3,3'-dichlorobenzidine as A3, which indicates that the chemical is carcinogenic in experimental animals when administered at a relatively high dose (ACGIH 1997). The National Toxicology Program (NTP) of the U.S. Department of Health and Human Services has determined that 3,3'-dichlorobenzidine and its salt may reasonably be expected to be cancer-causing agents (NTP 1998).

3,3'-Dichlorobenzidine is on the list of chemicals subject to the requirements of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (EPA 1988a). 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).

3,3'-Dichlorobenzidine is one of a number of carcinogenic compounds regulated by OSHA. To control exposures to 3,3'-dichlorobenzidine in workplace air and to protect the health of workers, OSHA's regulatory standards provide strict guidelines for manufacturing, processing, repackaging, handling, using, and storing the compound (OSHA 1996). These standards also include the requirements for personal protective equipment, training, labeling, posting, and engineering controls. In addition to engineering controls such as continuous local exhaust ventilation and workplace practices such as full body protective clothing, the employer must maintain medical surveillance records (OSHA 1996). OSHA requires that initial medical screening and regular medical examinations be made available to any employee who is

## 7. REGULATIONS AND ADVISORIES

exposed to 3,3'-dichlorobenzidine at potentially hazardous levels. The employer must also provide a training program that informs its employees of the carcinogenic hazards of 3,3'-dichlorobenzidine, the nature of the operation involving the chemical that could result in exposure, decontamination procedures, and specific emergency procedures to be used if exposure does occur (OSHA 1996). OSHA also regulates 3,3'-dichlorobenzidine under the Hazard Communication Standard (HCS) and as a chemical hazard in laboratories (NTP 1998). The HCS has established uniform requirements to make sure that the hazards of all chemicals imported into, produced, or used in workplaces are evaluated and that information on the hazards they pose is transmitted to affected employers and exposed employees (OSHA 1998).

EPA regulates 3,3'-dichlorobenzidine under the Clean Air Act (CAA) and has designated 3,3'-dichlorobenzidine as a hazardous air pollutant (HAP) (EPA 1994; U.S. Congress 1990). The major source category for which the national emissions standards for new stationary sources are applicable to 3,3'-dichlorobenzidine emissions is the synthetic organic chemicals manufacturing industry (SOCMI)-equipment leaks (EPA 1994).

3,3'-Dichlorobenzidine is regulated by the Clean Water Effluent Guidelines in Subchapter N of Title 40 of the *Code of Federal Regulations*. Electroplating is the point source category for which 3,3'-dichlorobenzidine is controlled as a total toxic organic (EPA 1981). The point source categories for which 3,3'-dichlorobenzidine has a specific regulatory limitation are steam electric power generation (EPA 1982) and metal finishing (EPA 1983a). The EPA has proposed a reportable quantity of 10 pounds for 3,3'-dichlorobenzidine for its water quality criteria for the protection of human health (IRIS 1998).

The Resource Conservation and Recovery Act (RCRA) identifies 3,3'-dichlorobenzidine as the hazardous constituent in various hazardous wastes. It is the regulated constituent in hazardous wastes assigned the waste code U073 (EPA 1988b).

Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), owners of vessels or facilities are required to immediately report releases of 3,3'-dichlorobenzidine equal to or greater than the reportable quantity of 1 pound (0.454 kg) (EPA 1985). It is subject to the requirements under the Superfund Amendments and Reauthorization Act (SARA) of 1986 (IRIS 1998).

## 7. REGULATIONS AND ADVISORIES

Although the Food and Drug Administration (FDA) classifies 3,3'-dichlorobenzidine as a carcinogen, the agency has not enacted regulatory guidelines (NTP 1998) or issued advisories specifically targeting 3,3'-dichlorobenzidine as being a danger in the food supply.

EPA has selected 3,3'-dichlorobenzidine and its mixtures for priority consideration for testing under the Toxic Substances Control Act (TSCA) (IRIS 1998).

## 7. REGULATIONS AND ADVISORIES

**Table 7-1. Regulations and Guidelines Applicable to 3,3-Dichlorobenzidine**

Agency	Description	Information	References
<b>INTERNATIONAL</b>			
Guidelines: IARC	Carcinogenic classification	Group 2B <sup>a</sup>	IARC 1987
WHO	Drinking-water guideline values for health-related organics	None	WHO 1984
<b>NATIONAL</b>			
Regulations:			
a. Air:			
OSHA	Toxic and Hazardous Substances-Carcinogens (4-nitrobiphenyl, etc.)	Yes	29 CFR 1910.1003 OSHA 1996
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 F: National Emission Standards for Organic Hazardous Air Pollution from the Synthetic Organic Chemical Manufacturing Industry (SOCMI)	Yes	40 CFR 63.106 EPA 1994b
b. Water			
EPA OW	EPA Administered Permit Programs: The NPDES- Organic toxic pollutants in each of four fractions in analysis by GC/MS	Yes	40 CFR 122, App. D EPA 1983b
	Methods for organic chemical analysis of municipal and industrial wastewater (Methods 605, 625, and 1625)	Yes	40 CFR 136, App. A EPA 1984b
	Designated as a toxic pollutant under Section 307 (a)(1) of the Federal Water Pollution Control Act	Yes	40 CFR 401.15 EPA 1979b
	General pretreatment regulations for existing and new sources of pollution-		
	List of toxic pollutants	Yes	40 CFR 403, App. B EPA 1986c
	Electroplating Point Source Category- General definition	Yes	40 CFR 413.02 EPA 1981a
	Steam Electric Power Generating Point Source Category Pretreatment standards for new sources (PSNS) Maximum for any time	0 mg/L	40 CFR 423.17 EPA 1982c
	List of 126 priority pollutants	Yes	40 CFR 423, App. A EPA 1982d

## 7. REGULATIONS AND ADVISORIES

**Table 7-1. Regulations and Guidelines Applicable to 3,3-Dichlorobenzidine (continued)**

Agency	Description	Information	References
<u>NATIONAL (cont.)</u>			
	Metal Finishing Point Source Category Metal finishing subcategory- Definition of total toxic organics (TTO)	>0.01 mg/L	40 CFR 433.11 EPA 1983a
c. Other: DOT	Hazardous Substances Other Than Radionuclides: RQ	1 pound (0.454 kg)	49 CFR 172.101, App. A DOT 1990
EPA-OERR	List of Hazardous Substances and Reportable Quantities	1 pound (0.454 kg) (CERCLA statutory)	40 CFR 302.4 EPA 1985
		1 pound (0.454 Kg) (final RQ)	
	Toxic Chemical Release Reporting: Community Right-to-know Specific toxic Chemical Listings	Yes	40 CFR 372.65 EPA 1988a
EPA-OSW	Criteria for Municipal Solid Waste Landfills		
	List of hazardous inorganic and organic constituents	Yes	40 CFR 258, App. II EPA 1991a
	Identification and Listing of Hazardous Wastes Subpart D: Lists of Hazardous Wastes Discarded commercial products, off-specification species, container residues, and spill residues (U073)	Yes	40 CFR 261.33 EPA 1980a
	Hazardous Constituents	U073	40 CFR 261, App. VIII EPA 1988b
	Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities		
	Ground-water monitoring list	Yes	40 CFR 264, App. IX EPA 1987a
	Land Disposal Restrictions- Subpart B: Schedule for land disposal prohibition and establishment of treatment standards	Yes	40 CFR 268.11 EPA 1986b

## 7. REGULATIONS AND ADVISORIES

**Table 7-1. Regulations and Guidelines Applicable to 3,3-Dichlorobenzidine (continued)**

Agency	Description	Information	References
<u>NATIONAL (cont.)</u>			
	Subpart C: Prohibitions on land disposal	Yes	40 CFR 268.35 EPA 1990b
	Subpart D: Treatment Standards Treatment standards for hazardous waste and Universal treatment standards--Technical amendment of final rule (40 CFR 268.40--waste code U073)	WETOX or CHOXD; CARBN or INCIN	62 FR 7502 EPA 1997
	List of halogenated organic compounds regulated under 268.32	Yes	40 CFR 268, App. III EPA 1987b
	Organometallic lab packs	Yes	40 CFR 268, App. IV EPA 1991b
Guidelines:			
a. Air: NIOSH	Recommended Exposure Limit for Occupation Exposure	Use 29 CFR 1910.1007	NIOSH 1997
b. Water EPA OW	Ambient Water Quality Criteria for Human Health water and fish fish only	0.01 µg/L 0.02 µg/L	IRIS 1998
c. Other: ACGIH	Cancer classification	A3 <sup>b</sup>	ACGIH 1997
EPA OWRS	Cancer classification	B2 <sup>c</sup>	IRIS 1998
	Drinking Water Concentrations at Specified Risk Levels E-4 (1 in 10,000) E-5 (1 in 100,000) E-6 (1 in 1,000,000)	8.0 µg/L 0.8 µg/L 0.08 µg/L	
NTP	Cancer classification	Reasonably anticipated to be a human carcinogen	NTP 1998
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:	Average Acceptable Ambient Air Concentrations		
MI	Annual	2.00x10 <sup>-3</sup> µg/m <sup>3</sup>	NATICH 1992
ND	Not specified	0.0 BACT	
NY	1 Year	1.00 µg/m <sup>3</sup>	
OK	Not specified	0.0	

## 7. REGULATIONS AND ADVISORIES

**Table 7-1. Regulations and Guidelines Applicable to 3,3-Dichlorobenzidine (continued)**

Agency	Description	Information	References
<u>STATE (cont.)</u>			
PA-Philadelphia	Not specified	0.0	
RI	Annual	$2.0 \times 10^{-3} \mu\text{g}/\text{m}^3$	
SC	24 hours	$1.50 \times 10^{-1} \mu\text{g}/\text{m}^3$	
VA	24 hours	$0.0 \mu\text{g}/\text{m}^3$	
b. Water	Water Quality Criteria: Human Health		
AZ	Drinking water (guideline)	0.020 $\mu\text{g}/\text{L}$	FSTRAC 1990
FL	Domestic/drinking	20 $\mu\text{g}/\text{L}$	Sittig 1994
KS	Drinking water (guideline)	0.21 $\mu\text{g}/\text{L}$	FSTRAC 1990
MA	Domestic/drinking	80 $\mu\text{g}/\text{L}$	Sittig 1994
MI	Domestic/drinking	0.077 $\mu\text{g}/\text{L}$	
MN	Drinking water (guideline)	0.21 $\mu\text{g}/\text{L}$	FSTRAC 1990
NH	Drinking water (guideline)	0.02 $\mu\text{g}/\text{L}$	
NJ	Domestic/drinking	60 $\mu\text{g}/\text{L}$	Sittig 1994
OR	Domestic/drinking	0.2 $\mu\text{g}/\text{L}$	

<sup>a</sup> Group 2B defines the agent as possibly carcinogenic to humans. The category is generally used for agents for which there is limited evidence in humans in the absence of sufficient evidence in experimental animals.

<sup>b</sup> Cancer classification A3 indicates that the agent is carcinogenic in experimental animals at a relatively high dose.

<sup>c</sup> Group B defines the substance as a probable human carcinogen where there is limited evidence in epidemiologic studies (Group B1) and/or sufficient evidence from animal studies.

ACGIH = American Conference of Governmental Industrial Hygienists; BACT = Best Available Control Technology; CARBN = carbon adsorption; CHOXD = chemical or electrolytic oxidation; DOT = Department of Transportation; EPA = Environmental Protection Agency; FSTRAC = Federal State Toxicology and Regulatory Alliance committee; GC/MS = Gas Chromatography/Mass Spectroscopy; IARC = International Agency for Research on Cancer; INCIN = incineration; NATICH = Nation Air Toxics Information Clearinghouse; NIOSH = National Institute of Occupational Safety and Health; NPDES = National Pollution Discharge Elimination System; NTP = National Toxicology Program; OAR = Office of Air and Radiation; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Wastes; PSNS = Performance Standards for New Sources; RQ = Reportable Quantities; SOCMI = Synthetic Organic Chemicals Manufacturing Industry; TTO = Total Toxic Organics; WETOX = wet air oxidation; WHO = World Health Organization

