

8. REGULATIONS AND ADVISORIES

International, national, and state regulations and advisories regarding benzidine in air, water, and other media are summarized in Table 8-1. These values have been established because of benzidine's potential to cause adverse health effects in exposed people.

The EPA (IRIS 2001) has calculated a chronic oral Reference Dose (RfD) for benzidine of 3×10^{-3} mg/kg/day based on a LOAEL of 2.7 mg/kg/day for brain cell vacuolization and liver cell alterations observed in female mice exposed for their lifetimes to 20 ppm benzidine dihydrochloride in the drinking water (Littlefield et al. 1983). A NOAEL was not established. The LOAEL of 2.7 mg/kg/day benzidine was divided by uncertainty factors of 10 for extrapolation from animals to humans, 10 for human variability in sensitivity, and 10 for the uncertainty in estimating a NOAEL from a LOAEL. The EPA (IRIS 2001) has derived an inhalation cancer slope factor of 2.3×10^2 (mg/kg/day)⁻¹ based on the incidence of bladder cancer in workers exposed to benzidine as reported by Zavon et al. (1973). An oral slope factor of 2.3×10^2 (mg/kg/day)⁻¹ was also estimated from the inhalation exposure data (IRIS 2001).

Benzidine is on the list of chemicals appearing in "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.

OSHA standards strictly regulate the use of a solid or liquid mixture containing less than 0.1 percent by weight or volume of benzidine (29CFR 1910.1003). No permissible exposure limit (PEL) is established.

Under the Resource Conservation and Recovery Act (RCRA), benzidine is listed as a hazardous waste when it is a discarded commercial product, off-specification species, container residue, or spill residue thereof (EPA 1980b).

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Table 8-1. Regulations and Guidelines Applicable to Benzidine

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 1 ^a	IARC 2001
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	Carcinogenicity classification ^b	A1 ^c	ACGIH 2000
EPA	National emission standards for HAP's for source categories—demonstration of early reduction of high-risk pollutants		EPA 2001e 40CFR63.74
NIOSH	REL not established	potential carcinogen	NIOSH 1999
OSHA	PEL not established	carcinogen	OSHA 2001 29CFR1910.1003
USC	HAP		USC 2001 42USC7412
b. Water			
EPA	Electroplating point source category	>1x10 ⁻² mg/L	EPA 2000a 40CFR413.02(i)
	Metal finishing point source category	>1x10 ⁻² mg/L	EPA 2000b 40CFR433.11(e)
	Toxic pollutant effluent standards		EPA 2000c 40CFR129.104
	Ambient water criterion	0.1 µg/L	
	Benzidine manufacturer calculated over 1-month monthly average daily loading sample representing any work day	10 µg/L 0.130 kg/kkg 50 µg/L	
	Benzidine based-dye applicators calculated over 1-month sample representing any work day	10 µg/L 25 µg/L	

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Table 8-1. Regulations and Guidelines Applicable to Benzidine (continued)

Agency	Description	Information	References
<u>NATIONAL (cont.)</u>			
EPA	Toxic pollutant effluent standards—regulated toxic pollutant		EPA 2001h 40CFR129.4
	Water quality criteria for human health for consumption of:		EPA 1999a
	Water and organism	1.2x10 ⁻⁴ µg/L ^d	
	Organism only	5.4x10 ⁻⁴ µg/L ^d	
c. Food			
FDA	Limit in color additives for foods FD&C Yellow No. 5	# 1ppb	FDA 2000a 21CFR74.705
	Limit in color additives for foods FD&C Yellow No. 6	# 1ppb	FDA 2000b 21CFR74.706
d. Other			
DOT	Reportable quantity	1 pound	DOT 2001 49CFR172.101 Appendix A
EPA	Carcinogenicity classification	Group A ^e	EPA 2001a
	Cancer slope factor (inhalation and oral)	2.3x10 ² (mg/kg/day) ⁻¹	
	Carcinogenic inhalation unit risk	6.7x10 ⁻² (µg/m ³) ⁻¹	IRIS 2001
	Carcinogenic drinking water unit risk	6.7x10 ⁻³ (µg/L) ⁻¹	
	CERCLA—toxic pollutant	Subject to section 307(a) of CERCLA	EPA 2000d 40CFR401.15
	Community Right-to-Know; toxic chemical release reporting—effective date	01/01/87	EPA 1999c 40CFR372.65
	Health and environmental protection standards at uranium and thorium tail millings—listed constituent		EPA 2001b 40CFR192 Appendix I
	Health based limits for exclusion of waste-derived residues—concentration limit for residue	1x10 ⁻⁶ mg/kg	EPA 2001c 40CFR266 Appendix VII

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Table 8-1. Regulations and Guidelines Applicable to Benzidine (continued)

Agency	Description	Information	References
<u>NATIONAL (cont.)</u>			
EPA	Identification and listing of hazardous waste—discarded commercial chemical containers, off-specification species, container residues, and spill residues	U021	EPA 2000e 40CFR261.33
	Identification and listing of hazardous waste—comparable/Syngas fuel exclusion		EPA 2001d 40CFR261.38
	Minimum required detection limit	2,400 mg/kg	
	Reportable quantity	1 pound	EPA 1999b 40CFR302.4
	RfD	3×10^{-3} mg/kg/day	IRIS 2001
	Risk specific doses		EPA 2001f 40CFR266
	Unit risk	6.7×10^{-2} µg/L	Appendix V
	RsD	1.5×10^{-4} µg/L	
	Steam electric power generating point source category—priority pollutants		EPA 2001g 40CFR423 Appendix A
	TSCA—health and safety data reporting		EPA 2001i 40CFR716.120
	Effective date	06/01/87	
	Sunset date	06/01/87	
	TSCA—significant new uses of chemical substances		EPA 2001j 40CFR721.1660
	TSD facilities—compounds with a Henry's law constant	less than 0.1 Y/K	EPA 2001k 40CFR265 Appendix VI
<u>STATE</u>			
Regulations and Guidelines:			
a. Air			
Georgia	Instream concentration	5.35×10^{-4} µg/L	GDNR 2000
Kansas	Ambient air quality standard	3×10^{-4} tons/year	CDC 1999
b. Water			
Arizona	Drinking water guideline	1×10^{-4} µg/L	HSDB 2001

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Table 8-1. Regulations and Guidelines Applicable to Benzidine (continued)

Agency	Description	Information	References
<u>STATE (cont.)</u>			
Florida	Drinking water guideline	250 µg/L	HSDB 2001
New Hampshire	Drinking water guideline	2x10 ⁻⁴ µg/L	HSDB 2001
c. Food		No data	
d. Other		No data	

^aGroup A1: sufficient evidence for carcinogenicity in animals and humans

^bSkin notation: danger of cutaneous absorption

^cGroup A: human carcinogen

^dThis criterion is based on carcinogenicity of 10⁻⁶ risk. Alternate risk levels may be obtained by moving the decimal point (e.g., for a risk level of 10⁻⁵, move the decimal point in the recommended criterion one place to the right).

^eGroup A: human carcinogen

ACGIH = American Conference of governmental Industrial Hygienists; CDC = Center for Disease Control; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; DOT = Department of Transportation; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; GDNR = Georgia Department of Natural Resources; HAP = hazardous air pollutant; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; REL = recommended exposure limit; RfD = oral reference dose; RsD = risk specific dose; TSCA = Toxic Substances Control Act; TSD = transport, storage, and disposal; USC = United States Code