

7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding *N*-nitrosodiphenylamine in air, water, and other media are summarized in Table 7-1.

EPA has not derived an inhalation reference concentration or an oral reference dose for *N*-nitrosodiphenylamine (IRIS 1990). The quantitative estimate of carcinogenic risk from oral exposure is 4.9×10^{-3} mg/kg/day (IRIS 1990), based on transitional cell carcinomas of the bladder in rats exposed to *N*-nitrosodiphenylamine in the diet (NCI 1979). *N*-Nitrosodiphenylamine has a weight-of-evidence classification of B2, which indicates a probable human carcinogen (IRIS 1990).

N-Nitrosodiphenylamine is on the list of chemicals appearing in “Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986” (EPA 1987, 1988).

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TABLE 7-1. Regulations and Guidelines Applicable to *N*-Nitrosodiphenylamine

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
IARC	Carcinogenic classification	Group 3 ^a	IARC 1987
<u>NATIONAL</u>			
Regulations:			
a. Water:			
EPA OSW	Designated as a toxic pollutant under Section 307(a)(1) of the Clean Water Act; detected in treated effluents from a small number of discharge sources and uniquely related to those sources	Yes	EPA 1989b (40 CFR 401.15); EPA 1987d
	Hazard ranking	Low	EPA 1986b
	Groundwater monitoring requirement	Yes	EPA 1987b (40 CFR 264, Appendix IX); EPA 1987c
b. Other:			
EPA OERR	Reportable quantity	100 pounds	EPA 1985a (40 CFR 302); EPA 1985b
EPA OTS	Toxic chemical release reporting; Community Right-to-Know	Yes	EPA 1988 (40 CFR 372); EPA 1987e
Guidelines:			
a. Water:			
	Ambient water quality criteria for protection of human health ^b		
	Ingesting water and organisms:		EPA 1980b
	10 ⁻⁵	49,000 ng/L	
	10 ⁻⁶	4,900 ng/L	
	10 ⁻⁷	490 ng/L	
	Ingesting organisms only:		EPA 1980b
	10 ⁻⁵	161,000 ng/L	
	10 ⁻⁶	16,100 ng/L	
	10 ⁻⁷	1,610 ng/L	
	Drinking water concentrations:		IRIS 1990
	10 ⁻⁴	700 µg/L	
	10 ⁻⁵	70 µg/L	
	10 ⁻⁶	7 µg/L	
b. Other:			
EPA	Carcinogen classification	B2 ^c	IRIS 1990
	Unit risk (air)	No data	EPA 1990
	Unit risk (water)	1.4×10 ⁻⁷ (µg/L) ⁻¹	EPA 1990

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TABLE 7-1 (Continued)

Agency	Description	Information	References
STATE			
Regulations and Guidelines:			
a. Air:			
Maryland	Acceptable ambient air concentrations	0.00	NATICH 1991
Wisconsin	Hazardous air contaminants without acceptable ambient concentrations requiring application of best available control technology	250 pounds/year	CELDS 1990
b. Water:			
	Drinking water quality guidelines and standards		FSTRAC 1988
Kansas		71 µg/L	
Minnesota		71.1 µg/L	
California	Toxic materials limitations-- objectives for protection of human health (30-day average)	2.5 µg/L	CELDS 1990
Indiana	Water quality continuous criteria concentration for human health (4-day average): Outside mixing zone Point of water intake	161 mg/L 49 mg/L	CELDS 1990
Wisconsin	Human cancer criteria Public water supply: Warm water sport fish communities Cold water communities Great Lakes communities Non-water supply: Warm water sport fish communities Cold water communities Warm water forage and limited forage fish communities and limited aquatic life	45 µg/L 24 µg/L 24 µg/L 120 µg/L 36 µg/L 14,000 µg/L	DNR 1987
c. Other:			
Wisconsin	Designated as a toxic pollutant	Yes	CELDS 1990

^aGroup 3: not classifiable as to human carcinogenicity

^bBecause of its carcinogenic potential, the EPA-recommended concentration for N-nitrosodiphenylamine in ambient water is zero. However, because attainment of this level may not be possible, levels that correspond to upper-bound incremental lifetime cancer risks of 10^{-5} , 10^{-6} , and 10^{-7} are estimated.

^cGroup B2: possible human carcinogen

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

