

8. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding di-*n*-butyl phthalate in air, water, and other media are summarized in Table 8-1.

An MRL of 0.5 mg/kg/day has been derived for acute-duration oral exposure to di-*n*-butyl phthalate based on a NOAEL of 50 mg/kg/day for developmental effects in the offspring of rats orally exposed by gavage to di-*n*-butyl phthalate on gestational days 12–21 (Mylchreest et al. 2000).

A chronic MRL for DNB was not derived. There were no adequate chronic-duration oral studies identified for humans or animals. EPA verified an RfD of 0.1 mg/kg/day based on a study by Smith (1953)(IRIS 1999). In this study, 10 rats were fed diets containing 0.01-1.25 % dibutyl phthalate. Half of the high dose group died within the first week of exposure. ATSDR did not have confidence in this study to derive an MRL due to the lack of detail and apparent conflict in the reported results. EPA also had low confidence in the study; the RfD received a low rating.

The health effects data for di-*n*-butyl phthalate were evaluated by EPA and determined to be inadequate for derivation of an inhalation RfC; the RfC is considered not verifiable (IRIS 1999).

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Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenic classification	No data	
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV-TWA	5 mg/m ³	ACGIH 2000
EPA	RAC	100 µg/m ³	EPA 2001p 40CFR266 Appendix IV
NIOSH	REL (TWA) IDLH	5 mg/m ³ 4,000 mg/m ³	NIOSH 2001
OSHA	PEL (8-hour TWA) General industry	5 mg/m ³	OSHA 2001c 29CFR1910.1000 Table Z-1
	PEL (8-hour TWA) Construction industry	5 mg/m ³	OSHA 2001b 29CFR1926.55 Appendix A
	PEL (8-hour TWA) Shipyard industry	5 mg/m ³	OSHA 2001a 29CFR1915.1000
USC	HAP		USC 2001 42USC7412
b. Water			
DOT	Marine pollutant		DOT 2001b 49CFR172.101 Appendix B
EPA	Effluent guidelines—aluminum forming point source category TTO	>0.01 mg/L	EPA 2001h 40CFR467.02
	Effluent guidelines—coil coating point source category TTO	>0.01 mg/L	EPA 2001g 40CFR465.02
	Effluent guidelines—metal finishing point source category TTO	>0.01 mg/L	EPA 2001q 40CFR433.11

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
(continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
EPA	Effluent guidelines; steam electric power generating point source category—priority pollutants		EPA 2001o 40CFR423 Appendix A
	Human health consumption Water and organism Organism only	2.7 mg/L 12 mg/L	EPA 1999c
	NPDES—permit application testing requirements	Organic toxic pollutants in each of four fractions in analysis by GC/MS volatiles	EPA 2001l 40CFR122 Appendix D Table II
	NPDES—permit testing requirements for publicly owned treatment works		EPA 2001m 40CFR122 Appendix J Table 2
	Process waste water discharges resulting from the manufacture of bulk organic chemicals		EPA 2001a 40CFR414.70
	Standards for owners/operators of hazardous waste TSD facilities— groundwater monitoring (PQL)	5 µg/L	EPA 2001i 40CFR264 Appendix IX
	Toxic pollutant effluent limitations and standards for direct discharge point sources that use end-of-pipe biological treatments—effluent limitations Maximum for any 1-day Maximum for any monthly average	57 µg/L 27 µg/L	EPA 2001u 40CFR414.91(b)
	Toxic pollutant effluent limitations and standards for direct discharge point sources that do not use end-of-pipe biological treatments—effluent limitations Maximum for any 1-day Maximum for any monthly average	43 µg/L 20 µg/L	EPA 2001v 40CFR414.101(b)

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
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Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
EPA	Toxic pollutant standards for indirect discharge point sources—effluent limitations		EPA 2001w 40CFR414.111(b)
	Maximum for any 1-day Maximum for any monthly average	43 µg/L 20 µg/L	
	Water quality standards—toxics criteria for those states not complying with Clean Water Act Section 303(c)(2)(B)	No data	EPA 2001t 40CFR131.36
c. Food			
FDA	Indirect food additive—adhesives and components of coating		FDA 2000a 21CFR175.105
	Indirect food additive—adhesives and components of coatings; catalysts and cross-linking agents for epoxy resins	For use only in coatings for containers having a capacity of 1,000 gallons or more when intended for repeated use in contact with alcoholic beverages containing up to 8% of alcohol by volume	FDA 2000f 21CFR175.300(b)
	Indirect food additive—limitations on cellophane for food packaging	Alone or in combination with other phthalates—total phthalates do not exceed 5%	FDA 2000b 21 CFR 177.1200
	Indirect food additive—paper and paperboard components		FDA 2000d 21CFR176.170
	Indirect food additive—paper and paperboard components	Adjuvant substances permitted to be used in the preparation of slimicides	FDA 2000g 21CFR176.300(d)

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
(continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
FDA	Indirect food additive—polyester resins, cross-linked; solvents for inhibitors, accelerators, and catalysts	Quantity used does not exceed that reasonably required to accomplish intended physical or technical effect	FDA 2000e 21CFR177.2420(b)
	Indirect food additives—rubber articles intended for repeated use	Total not to exceed 30% by weight of rubber product	FDA 2000c 21CFR177.2600
d. Other			
ACGIH	BEI Carcinogenic classification	No data	ACGIH 2000
CPSC	Consumer product limits	No data	
DOT	Reportable quantity	10 pounds	DOT 2001a 49CFR172.101 Appendix A Table 1
EPA	Carcinogenic classification	Group D ^a	IRIS 2001
	RfD	0.1 mg/kg/day	
	Designated hazardous substance		EPA 2001c 40CFR116.4
	Health and environmental protection standards for uranium and thorium mill tailings—listed constituent		EPA 2001k 40CFR192 Appendix I
	Identification and listing of hazardous waste	U069	EPA 2001f 40CFR261.33
	Land disposal restrictions—universal treatment standards		EPA 2001x 40CFR268.48(a)
	Wastewater standard	0.057 mg/L ²	
	Nonwastewater standard	28 mg/kg ³	
	Municipal solid waste landfills—hazardous inorganic and organic constituents		EPA 2001j 40CFR258 Appendix II
	Suggested method	8060 8270	
	PQL	5 µg/L 10 µg/L	

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
(continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
EPA	Pollutants eligible for a removal credit	If requirements for total hydrocarbons are met when sewage sludge is fired in a sewage sludge incinerator	EPA 2001n 40CFR403 Appendix G
	Reportable quantity	100 pounds	EPA 2001d 40CFR302.4
	Toxic chemical release reporting; Community Right-to-Know—effective date	01/01/87	EPA 2001b 40CFR372.65
	TSCA—health and safety data reporting; studies not subject to the reporting requirements		EPA 2001r 40CFR716.120(c)
	TSCA—testing consent order for environmental effects	01/09/89	EPA 2001s 40CFR799.5000
<u>STATE</u>			
Regulations and Guidelines:			
a. Air			
Arkansas	RAC	100 µg/m ³	BNA 2001
California	RAC	100 µg/m ³	BNA 2001
Delaware	RAC	100 µg/m ³	BNA 2001
Idaho	Toxic air pollutants		BNA 2001
	OEL	5.0 mg/m ³	
	EL	0.333 pounds/hour	
	AAC	0.25 mg/m ³	
Illinois	RAC	100 µg/m ³	BNA 2001
Kansas	Ambient air quality standards	10 tons/year	CDC 1999
Kentucky	RAC	100 µg/m ³	BNA 2001
Minnesota	HAP threshold	10 tons/year	BNA 2001
New Hampshire	Regulated toxic air pollutant		BNA 2001
	OEL	5 mg/m ³	
Rhode Island	HAP		BNA 2001
<u>STATE</u> (cont.)			

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
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Agency	Description	Information	References
South Carolina	RAC	100 µg/m ³	BNA 2001
	Toxic air emissions—maximum allowable concentration	25 µg/m ³	BNA 2001
Tennessee	RAC	100 µg/m ³	BNA 2001
Vermont	Hazardous ambient air standard Averaging time Action level (8-hours)	500 µg/m ³ 8 hours 21 pounds	BNA 2001
Wisconsin	<25 ft \$25 ft <75 ft \$75 ft	0.269 pounds/hour 1.04 pounds/hour 8.11 pounds/hour	Wisconsin DNR 2001
	Ambient air concentrations	120 µg/m ³	
Wyoming	RAC	100 µg/m ³	BNA 2001
b. Water			
Alaska	Groundwater clean-up level	3.65 mg/L	BNA 2001
Arkansas	Groundwater monitoring (PQL)	5 µg/L	BNA 2001
Delaware	Freshwater		BNA 2001
	Fish ingestion only	13 mg/L	
	Fish and water ingestion	2.8 mg/L	
	Marine/Estuarine		
	Fish and shellfish ingestion	2.1 mg/L	
Florida	Drinking water guideline	0.7 mg/L	HSDB 2001
Georgia	Instream concentration	12.1 mg/L	BNA 2001
Illinois	Groundwater monitoring (PQL)	5 µg/L	BNA 2001
Kentucky	Hazardous constituents for groundwater monitoring (PQL)	5 µg/L	BNA 2001
	Maximum allowable instream concentration	2.7 mg/L	
Louisiana	Groundwater monitoring (PQL)	5 µg/L	BNA 2001
Maine	Drinking water guideline	0.22 mg/L	HSDB 2001
Massachusetts	Groundwater monitoring (PQL)	5 µg/L	BNA 2001
Michigan	Groundwater quality treatment technology standard	35 µg/L	BNA 2001
Minnesota	Drinking water guideline	0.7 mg/L	HSDB 2001

STATE (cont.)

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
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Agency	Description	Information	References
Nebraska	Aquatic life criteria		BNA 2001
	Acute	No data	
	Chronic	12 mg/L	
New Hampshire	Drinking water guideline	0.8 mg/L	HSDB 2001
	Water quality criteria		BNA 2001
	Water and fish ingestion	2.7 mg/L	
	Fish consumption only	12 mg/L	
	Ambient groundwater quality standard	34 mg/L	BNA 2001
New Jersey	Groundwater quality criteria	900 µg/L	BNA 2001
	PQL	20 µg/L	
New Mexico	Groundwater parameter (PQL)	0.01 mg/L	BNA 2001
New York	Groundwater monitoring (PQL)	5 µg/L	BNA 2001
Oklahoma	Hazardous constituent (PQL)	5 µg/L	BNA 2001
South Carolina	Water quality criteria		BNA 2001
	Organism consumption	12 mg/L	
	Groundwater monitoring (PQL)	5 µg/L	
Vermont	Consumption of water and organism	2.7 mg/L	BNA 2001
	Consumption of organism only	12 mg/L	
Virginia	Hazardous constituent (PQL)	5 µg/L	BNA 2001
	Public water supply	2.7 mg/L	BNA 2001
	All other surface waters	12 mg/L	
Wisconsin	Drinking water guideline	0.1 mg/L	HSDB 2001
	Groundwater standard		BNA 2001
	Enforcement standard	100 mg/L	
	Preventive action limit	20 mg/L	
c. Food		No data	
d. Other			
Alabama	RfD	0.1 mg/kg/day	BNA 2001
Delaware	Direct exposure criteria for soil		BNA 2001
	Residential	1,000 ppm	
	Industrial/commercial	2,500 ppm	
Massachusetts	RfD	0.1 mg/kg/day	BNA 2001
<u>STATE (cont.)</u>			
Minnesota	RfD	0.1 mg/kg/day	BNA 2001
	Health risk limit	700 µg/L	

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**Table 8-1. Regulations and Guidelines Applicable to Di-*n*-butyl Phthalate
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Agency	Description	Information	References
Missouri	Hazardous constituents		BNA 2001
New York	Reportable quantity		BNA 2001
	Air	10 pounds	
	Land/water	1 pound	

^aGroup D: inadequate or no human and animal evidence of carcinogenicity

AAC = acceptable ambient concentrations; ACGIH = American Conference of Governmental Industrial Hygienists; BEI = biological exposure index; BNA = Bureau of National Affairs; CDC = Center for Disease Control; CFR = Code of Federal Regulations; CPSC = Consumer Product Safety Commission; DNR = Department of Natural Resources; DOT = Department of Transportation; EL = emissions level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; GC/MS = gas chromatography/mass spectroscopy; HAP = hazardous air pollutant; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life and health; IRIS = Integrated Risk Information System; NIOSH = National Institute of Occupational Safety and Health; NPDES = National Pollutant Discharge Elimination System; OEL = occupational exposure level; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation limit; RAC = reference air concentration; REL = recommended exposure limit; RfD = oral reference dose; TLV = threshold limit value; TSCA = Toxic Substances Control Act; TSD = treatment, storage, and disposal; TTO = total toxic organics; TWA = time-weighted average; USC = United States Code