

8. REGULATIONS AND ADVISORIES

A chronic-duration oral MRL of 0.002 mg beryllium/kg/day was derived for beryllium. This MRL is based on a benchmark dose (defined as the 95% lower confidence limit of the dose corresponding to a 10% increase in the incidence of small intestine lesions compared to controls) of 0.56 mg beryllium/kg/day. The benchmark dose was divided by an uncertainty factor of 100 (10 for extrapolation from animals to humans and 10 for intrahuman variability) and a modifying factor of 3 (to account for the lack of a study that supports the gastrointestinal effects found in the Morgareidge et al. [1976] dog study and the uncertainty as to whether the benchmark dose level is the NOAEL).

A chronic oral reference dose (RfD) of 0.002 mg beryllium/kg/day has been derived and verified by EPA for beryllium (IRIS 2002). The RfD is based on a benchmark dose of 0.46 mg beryllium/kg/day for small intestine lesions in dogs exposed to beryllium sulfate in the diet for 33–172 weeks (Morgareidge et al. 1976). This benchmark concentration was divided by an uncertainty factor of 300 to account for extrapolation from animals to humans (10), human variability (10), and database gaps (3), particularly adequate reproductive and developmental toxicity studies and studies examining immunological end points. The chronic-duration oral MRL and the RfD were both derived using a benchmark analysis and the same incidence data set. The difference in the benchmark doses is due to the differences in the mathematical model fit to the incidence data (ATSDR used a probit model with a chi-square goodness-of-fit statistic p-value of 0.9999 and EPA used a weibull model with a chi-square goodness of fit statistic p-value of 0.96) and the higher number of significant figures that EPA used to express beryllium doses.

A chronic inhalation reference concentration (RfC) of 0.02 $\mu\text{g}/\text{m}^3$ has been derived for beryllium (IRIS 2000). The RfC is based on two human studies finding chronic beryllium disease in workers at a facility manufacturing beryllia ceramics (Kreiss et al. 1996) and in residents living near a beryllium manufacturing facility (Eisenbud et al. 1949). The Kreiss et al. (1996) study identified a LOAEL of 0.55 $\mu\text{g}/\text{m}^3$ for beryllium sensitization and subclinical chronic beryllium disease, and the Eisenbud et al. (1949) study identified a NOAEL of 0.01–0.1 $\mu\text{g}/\text{m}^3$ for chronic beryllium disease. The LOAEL identified in the Kreiss et al. (1996) study was used for the operational derivation of the RfC. This LOAEL was divided by an uncertainty of 10 to account for less-than-chronic exposure duration (1), use of a LOAEL (3), human variability (1), and database limitations (3), particularly the poor quality of exposure monitoring in the co-principal studies and other epidemiology studies.

8. REGULATIONS AND ADVISORIES

NTP (1999, 2002) lists beryllium and certain beryllium compounds (beryllium-aluminum alloy, beryllium chloride, beryllium fluoride, beryllium hydroxide, beryllium oxide, beryllium phosphate, beryllium sulfate, beryllium zinc silicate, and beryl ore) as substances reasonably anticipated to be carcinogens.

IARC (2001) has classified beryllium and beryllium compounds in Group 1, carcinogenic to humans, and EPA classifies inhaled beryllium in Group B1, a probable human carcinogen (IRIS 2002).

The international, national, and state regulations and guidelines regarding beryllium in air, water, and other media are summarized in Table 8-1.

8. REGULATIONS AND ADVISORIES

Table 8-1. Regulations and Guidelines Applicable to Beryllium

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification—beryllium and beryllium compounds	Group 1 ^a	IARC 2001
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	Beryllium and compounds (as Be) TLV (8-hour TWA) STEL (15-minute TWA)	0.002 mg/m ³ 0.01 mg/m ³	ACGIH 2001
DOD	Requires notification to the EPA when conducting operations, construction, or modification of a source of hazardous air pollutants—beryllium		DOD 2001 32CFR650.132
EPA	National emission standards for hazardous air pollutants—beryllium emissions to the atmosphere from rocket-motor test sites	Shall not exceed 75 µg minutes/m ³ of air within the limits of 10–60 minutes, accumulated during any 2 consecutive weeks, in any area in which an effect adverse to public health could occur	EPA 2001i 40CFR61.42
	National emission standards for hazardous air pollutants—if combustion products from the firing of beryllium propellant are collected in a closed tank	Emissions from such tank shall not exceed 2 g/hour and a maximum of 10 g/day	EPA 2001i 40CFR61.42
	National emission standards for hazardous air pollutants Beryllium emissions to the atmosphere from stationary sources	Shall not exceed 10 grams over a 24-hour period	EPA 2001i 40CFR61.32
	Request approval from the Administrator to meet an ambient concentration limit on beryllium in the vicinity of the stationary source	0.01 µg/m ³ , averaged over a 30-day period	

8. REGULATIONS AND ADVISORIES

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

Agency	Description	Information	Reference
NATIONAL (cont.)			
NIOSH	Beryllium and beryllium compounds (as Be)		NIOSH 2001
	REL (10-hour TWA) ^b IDLH	5x10 ⁻⁴ mg/m ³ 4 mg/m ³	
OSHA	PEL (8-hour TWA)—beryllium and beryllium compounds (as Be)	2 µg/m ³	OSHA 2001a 29CFR1910.1000 Table Z-1
	Acceptable ceiling concentration—beryllium and beryllium compounds	5 µg/m ³	OSHA 2001a 29CFR1910.1000 Table Z-2
	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift for a maximum duration of 30 minutes—beryllium and beryllium compounds	25 µg/m ³	OSHA 2001a 29CFR1910.1000 Table Z-2
	PEL (8-hour TWA) for construction workers—beryllium and beryllium compounds (as Be)	2 µg/m ³	OSHA 2001c 29CFR1926.55
	PEL (8-hour TWA) for shipyard workers—beryllium and beryllium compounds (as Be)	2 µg/m ³	OSHA 2001b 29CFR1915.1000
	Welding or cutting indoors, outdoors, or in confined spaces involving beryllium-containing base or filler metals shall be done using local exhaust ventilation and airline respirators		OSHA 2001d 29CFR1910.252 (c)(8)
USC	Listed as a hazardous air pollutant—beryllium compounds		USC 2001 42 USC 7412
b. Water			
EPA	Groundwater monitoring—beryllium (total)		EPA 2001b 40CFR264, Appendix IX
	Suggested methods	<u>PQL</u>	
	6010	3 µg/L	
	7090	50 µg/L	
	7091	2 µg/L	

8. REGULATIONS AND ADVISORIES

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

Agency	Description	Information	Reference
NATIONAL (cont.)			
EPA	Land disposal restrictions; universal treatment standards for beryllium		EPA 2001e 40CFR268.48
	Wastewater standard	0.82 mg/L ²	
	Non-wastewater standard	1.22 mg/L TCLP	
	MCLG—beryllium	0.004 mg/L	EPA 2001g 40CFR141.51(b)
	MCL—beryllium	0.004 mg/L	EPA 2001f 40CFR141.62(b)
	National recommended water quality criteria for human health for consumption of beryllium	EPA has not calculated human health criteria for this contaminant	EPA 1999a
	Water and organism		
	Organism only		
	Health Advisories for beryllium		EPA 2000a
	10-kg child		
	1-day	30 mg/L	
	10-day	30 mg/L	
	DWEL ^c	0.07 mg/L	
c. Food			
FDA	Bottled water allowable limit—beryllium	0.004 mg/L	FDA 2001 21CFR165.110
d. Other			
ACGIH	Carcinogenicity classification—beryllium and compounds	A1 ^d	ACGIH 2001
DOE	Chronic beryllium disease prevention program		DOE 2001 10CFR850
EPA	Beryllium and compounds		IRIS 2001
	Carcinogenicity classification	B1 ^e	
	RfC	2×10^{-2} µg/m ³	
	RfD	2×10^{-3} mg/kg/day	
	Health based limits for exclusion of waste-derived residue—beryllium		EPA 2001c 40CFR266, Appendix VII
	TCLP extract concentration limits	7×10^{-3} mg/L	

8. REGULATIONS AND ADVISORIES

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

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	Identification and listing of beryllium powder as a hazardous waste—hazardous waste number	P015	EPA 2001d 40CFR261.33(e)
	Reportable quantity regarded as a CERCLA hazardous substance under Section 307(a) of the Clean Water Act		EPA 2001a 40CFR302.4
	Beryllium and compounds	1 pound	
	Beryllium chloride, beryllium fluoride, and beryllium nitrate	5,000 pounds	
	Standards for management of hazardous waste		EPA 2001j 40CFR266, Appendix V
	Unit risk Risk specific doses	2.4x10 ⁻³ µg/m ³ 4.2x10 ⁻³ µg/m ³	
	Toxic chemical release reporting; community right-to-know, effective date for reporting—beryllium	01/01/87	EPA 2001k 40CFR372.65
	Toxic pollutant designated pursuant to Section 307(a)(1) of the Clean Water Act—beryllium and compounds		EPA 2001l 40CFR401.15
NTP	Carcinogenicity classification-beryllium and compounds	Known human carcinogens	NTP 1999, 2002
<u>STATE</u> Regulations and Guidelines:			
a. Air			
North Carolina	Toxic air pollutant—beryllium Chronic toxicant (24 hours)	4.1x10 ⁻⁶ mg/m ³	BNA 2001
Vermont	Hazardous ambient air standard ^f —beryllium, total	1.3x10 ⁻³ µg/m ³	VT Agency of Natural Resources 1998
Washington	Acceptable source impact levels (at 10 ⁻⁶ risk), annual average—beryllium and compounds	4.2x10 ⁻⁴ µg/m ³	WA Dept. of Ecology 1998
Wisconsin	Hazardous air contaminants without acceptable ambient concentrations requiring application of best available control technology—beryllium and beryllium compounds (as Be)	25 pounds/year ²	WI Dept. of Natural Resources 1997

8. REGULATIONS AND ADVISORIES

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

Agency	Description	Information	Reference
<u>STATE (cont.)</u>			
b. Water			
Alaska	Primary MCL—beryllium	0.004 mg/L	AK Dept. of Environ. Conservation 1999
Arizona	Aquifer water quality standard—beryllium	0.004 mg/L	BNA 2001
	Drinking water guideline—beryllium	0.007 µg/L	HSDB 2001
California	Primary MCL—beryllium	0.004 mg/L	CA Dept. of Health Services 2000
Hawaii	MCL—beryllium	0.004 mg/L	HI Dept. of Health 1999a
	Toxic pollutant standards—beryllium		HI Dept. of Health 1999b
	Freshwater		
	Acute	43 mg/L	
	Chronic	No standard	
	Saltwater		
Acute	No standard		
Chronic	No standard		
Fish Consumption	0.038 mg/L		
Kansas	Water quality standards—beryllium, total		KS Dept. of Health and Environ. 1999
	Aquatic life	130 mg/L	
	Acute	5.3 mg/L	
	Chronic		
	Public health	0.13 mg/L	
Food procurement	4.0 mg/L		
Domestic water supply			
Kentucky	Domestic water supply use—beryllium concentration	0.04 µg/L	BNA 2001
Minnesota	Drinking water guideline—beryllium	0.08 µg/L	HSDB 2001
New Jersey	Groundwater standards—beryllium		NJ Dept. of Environ. Protection 1993
	Groundwater quality criteria PQL	0.008 µg/L 20 µg/L	

8. REGULATIONS AND ADVISORIES

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

Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
Rhode Island	Beryllium Groundwater quality standard Preventive action limit	0.004 mg/L 0.002 mg/L	BNA 2001
South Dakota	MCL for community and non-transient non-community water systems—beryllium	0.004 mg/L	SD Dept. of Environ. & Natural Resources 1998
Vermont	Groundwater quality standard—beryllium Enforcement standard Preventive action level	4.0 µg/L 1.0 µg/L	BNA 2001
c. Food	No data		
d. Other			
Connecticut	Direct exposure criteria for soil—beryllium Residential criteria Industrial/commercial criteria	2 mg/kg 2 mg/kg	BNA 2001
Massachusetts	Human health-based toxicity values—beryllium Chronic oral RfD Oral cancer slope factor	2.0x10 ⁻³ mg/kg/day 4.3 (mg/kg/day) ⁻¹	BNA 2001
Minnesota	Health risk limits Slope factor Health risk limit	4.3 (mg/kg/day) ⁻¹ 0.08 µg/L	BNA 2001

^aGroup 1: carcinogenic to humans

^bPotential occupational carcinogen

^cDWEL: A lifetime exposure concentration protective of adverse, non-cancer health effects that assumes all of the exposure to a contaminant is from a drinking water source.

^dA1: confirmed human carcinogen. The agent is carcinogenic to humans based on the weight of evidence from epidemiologic studies.

^eB1: probable human carcinogen

^fIndicates value derived using an inhalation cancer potency factor

ACGIH = American Conference of Governmental Industrial Hygienists; BNA = Bureau of National Affairs; CERCLA = Comprehensive Environmental Response Compensation and Liability Act; CFR = Code of Federal Regulations; DOD = Department of Defense; DOE = Department of Energy; DWEL = drinking water equivalent level; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure level; PQL = practical quantitation limits; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TCLP = toxicity characteristic leaching procedure; TLV = threshold limit value; TWA = time-weighted average; USC = United States Code