

8. REGULATIONS AND ADVISORIES

ATSDR has derived acute- and intermediate-duration oral MRLs for copper. These MRLs are intended to protect against the health effects associated with exposure to copper-contaminated drinking water; it assumes that the affected population will have a normal intake of copper from the diet. The acute-duration oral MRL is 0.01 mg copper/kg/day. It is based on the occurrence of gastrointestinal disturbances in women ingesting 0.0731 mg Cu/kg/day in drinking water for 2 weeks; no adverse effects were observed at a drinking water dose of 0.0272 mg Cu/kg/day (Pizarro et al. 1999). To calculate an MRL, the NOAEL of 0.0272 mg Cu/kg/day was divided by an uncertainty factor of 3 to account for human variability.

An intermediate-duration oral MRL of 0.01 mg copper/kg/day was derived for copper. This MRL is based on the occurrence of gastrointestinal disturbances in men and women ingesting 0.091 mg Cu/kg/day in drinking water for 2 months; no adverse effects were observed at a drinking water dose of 0.042 mg Cu/kg/day (Araya et al. 2003b). To calculate an MRL, the NOAEL of 0.042 mg Cu/kg/day was divided by an uncertainty factor of 3 to account for human variability.

International, national, and state regulations and guidelines regarding human exposure to copper are summarized in Table 8-1.

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Table 8-1. Regulations and Guidelines Applicable to Copper

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification Copper 8-hydroxyquinoline	Group 3 ^a	IARC 2002
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA) Fume (Cu) Dusts and mists (as Cu)	0.2 mg/m ³ 1.0 mg/m ³	ACGIH 2001
EPA	Serious health effects form ambient air exposure (Cu)		EPA 2002b 40CFR1910.1000
NIOSH	REL (10-hour TWA) Fume (as Cu) Dusts and mists (as Cu)	0.1 mg/m ³ 1.0 mg/m ³	NIOSH 2002
OSHA	IDLH Fume, dusts, and mists (as Cu) PEL (8-hour TWA) for general industry Fume (as Cu) Dusts and mists (as Cu) PEL (8-hour TWA) for construction industry Fume (as Cu) Dusts and mists (as Cu) PEL (8-hour TWA) for shipyard industry Fume (as Cu) Dusts and mists (as Cu)	100 mg/m ³ 0.1 mg/m ³ 1.0 mg/m ³ 0.1 mg/m ³ 1.0 mg/m ³ 0.1 mg/m ³ 1.0 mg/m ³ 0.1 mg/m ³ 1.0 mg/m ³	OSHA 2002c 29CFR1910.1000 OSHA 2002b 29CFR1926.55 OSHA 2002a 29CFR1915.1000
b. Water			
DOT	Marine pollutant (Cu metal powder and cupric sulfate)		DOT 2002 49 CFR172.101, Appendix B
EPA	Drinking water standard Action level (Cu) MCLG (Cu) Groundwater monitoring (Cu) Suggested method 6010 7210	1.3 mg/L 1.3 mg/L <u>PQL</u> 60 µg/L 200 µg/L	EPA 2002c EPA 2002d 40CFR141.51(b) EPA 2002g 40CFR264, Appendix IX

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	Hazardous substance in accordance with Section 311(b)(2)(A) of the Clean Water Act (cupric sulfate and cupric sulfate ammoniated)		EPA 2002j 40CFR116.4
	Reportable quantity of hazardous substance designated pursuant to Section 311 of the Clean Water Act		EPA 2002k 40CFR117.3
	Cupric sulfate	10 pounds	
	Cupric sulfate, ammoniated	100 pounds	
	Secondary MCL for public water systems (Cu)	1.0 mg/L	EPA 2002e 40CFR143.3
	Toxic pollutant designated pursuant to Section 307(a)(1) of the Federal Water Pollution Control Act and is subject to effluent limitations (Cu and compounds)		EPA 2002a 40CFR401.15
	Water quality criteria (Cu)		EPA 1999
	Fresh water		
	CMC	13.0 µg/L	
	CCC	9.0 µg/L	
	Salt water		
	CMC	4.8 µg/L	
	CCC	3.1 µg/L	
Human health for consumption of water and organism	1,300 µg/L		
Organoleptic effect criteria	1,000 µg/L		
c. Food and Drugs			
EPA	Exemption from requirement of a tolerance in meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use as an algacide, herbicide, and fungicide when used in accordance with good agricultural practices (Cu)		EPA 2002f 40CFR180.1021
FDA	Bottled water; allowable level (Cu)	1.0 mg/L	FDA 2001a 21CFR165.110
	Clinical chemistry test system; copper test system measures copper levels in plasma, serum, and urine	Exempt from premarket notification procedures in Subpart E of Part 807	FDA 2001b 21CFR862.1190
	Color additives exempt from certification—copper powder for use in externally applied drugs	Cu not less than 95%	FDA 2001e 21CFR73.1647

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
FDA	Color additives exempt from certification—copper powder for use in cosmetics		FDA 2001f 21CFR73.2647
	Direct food substance affirmed as generally recognized as safe when used as a nutrient supplement or as a processing aid (cupric sulfate)		FDA 2001c 21CFR184.1261
	Drug products containing certain active ingredients offered over-the-counter; inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses (Cu)	Weight control drug product	FDA 2001g 21CFR310.545(a)(20)
	Trace minerals added to animal feeds as nutritional dietary supplements are generally recognized as safe when added at levels consistent with good feeding practices (Cu compounds)		FDA 2001i 21CFR582.80
IOM	Recommended dietary allowance (RDA) Tolerable upper intake level	0.9 mg/day 10 mg/day	IOM 2001
d. Other			
EPA	Carcinogenicity classification (Cu)	Group D ^b	IRIS 2004
	RfC	No data	
	RfD	No data	
	Reportable quantity designated as a CERCLA hazardous substance under Section 307(a) of the Clean Water Act (Cu)	5,000 pounds	EPA 2002h 40CFR302.4
	Reportable quantity designated as a CERCLA hazardous substance under Section 311(b) (4) of the Clean Water Act (cupric sulfate)	10 pounds	EPA 2002h 40CFR302.4
	Toxic chemical release reporting; community right-to-know; effective date of reporting (Cu)	01/01/87	EPA 2002i 40CFR372.65(a)
<u>STATE</u>			
Regulations and Guidelines			
a. Air			
Illinois	Toxic air contaminant (Cu)		BNA 2001
Louisiana	Toxic air pollutant ^c		BNA 2001
	Minimum emission rate (Cu and compounds)	25 pounds/year	

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Agency	Description	Information	Reference
<u>STATE (cont.)</u>			
New Mexico	Toxic air pollutant		BNA 2001
	Fume (Cu)		
	OEL	0.2 mg/m ³	
	Emissions	0.0133 pounds/ hour	
	Dusts and mists (as Cu)		
	OEL	1.0 mg/m ³	
Vermont	Cu compounds		BNA 2001
	Hazardous ambient air standard	100 µg/m ³	
	Averaging time	8 hours	
	Action level	4 pounds/hour	
b. Water			
Arizona	Drinking water guideline (Cu)	1,300 µg/L	HSDB 2004
North Carolina	Groundwater quality standard (Cu)	1.0 mg/L	BNA 2001
c. Food			
No data			
d. Other			
Arizona	Soil remediation levels (Cu and compounds)		BNA 2001
	Residential	2,800 mg/kg	
	Non-residential	63,000 mg/kg	
Florida	Toxic substance in the workplace (Cu fume, dust, and mist)		BNA 2001

^aGroup 3: unclassifiable as to carcinogenicity to humans

^bGroup D: not classifiable as to human carcinogenicity

^cClass II: suspected human carcinogen and known or suspected human reproductive toxin

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; CCC = criterion continuous concentration; CMC = criteria maximum concentration; Cu = copper; DOT = Department of Transportation; 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 and health; IOM = Institute of Occupational Medicine; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; OEL = occupational exposure limit; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limits; PQL = practical quantitation limits; RDA = recommended dietary allowance; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit value; TWA = time-weighted average