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### 7. REGULATIONS AND ADVISORIES

Because of its potential to cause adverse health effects in exposed people, a number of regulations and guidelines have been established for manganese. These are summarized in Table 7-1.

An MRL of 0.00004 mg manganese/m³ (0.04 μg manganese/m³) in respirable dust has been derived for chronic inhalation exposure to manganese. The MRL is based on a surrogate NOAEL value of 0.074 mg manganese/m³ (74 μg manganese/m³) that was determined using benchmark dose analysis (BMD) of the raw data from the study by Roels et al. (1992) which reported neurological effects among battery factory workers exposed to manganese. A NOAEL of 0.071 mg manganese/m³ (71 μg manganese/m³) derived from BMD analysis of the individual exposure and response data in foundry workers from the study by Iregren (1990) is comparable. These two BMDL<sub>10</sub> NOAEL estimates are consistent with a NOAEL of 0.051 mg/m³, median respirable dust, for exposures in a metal producing plant reported by Gibbs et al. (1999). The sensitive endpoint used as the basis for this MRL, neurological effects among manganese exposed workers, was also reported in studies by Roels et al. (1987a), Mergler et al. (1994), and Lucchini et al. (1995, 1999).

Based on the BMDL $_{10}$  value of 0.074 mg manganese/m $^3$ , a chronic inhalation MRL of 0.00004 mg manganese/m $^3$  (0.04 µg manganese/m $^3$ ) was derived using (1) an uncertainty factor of 10 for human variability, (2) factors of 5/7 and 8/24 to account for intermittent exposure (5 days/week, 8 hours/day), (3) an uncertainty factor of 10 to account for limitations in the inhalation database, including the lack of data on developmental effects and data on the potential for reproductive effects in women, and the potential for differences in toxicity from different forms of manganese and, (4) a modifying factor of 5 for the potential for increased susceptibility in children based upon differences in the pharmacokinetic handling of manganese in the young.

The upper range of the estimated safe and adequate daily dietary intake of 5 mg/day (NRC 1989) has been adopted as a provisional guidance value (0.07 mg/kg/day) for oral exposure to manganese. This guidance is necessary because, although manganese is an essential nutrient, its prevalence at hazardous waste sites puts some individuals at risk for exposure to toxic levels.

The EPA has derived a chronic inhalation RfC of  $5\times10^{-5}$  mg/m<sup>3</sup> for respirable manganese (IRIS 1998). This value is based on the LOAEL of 0.15 mg/m<sup>3</sup> from a study of people exposed to manganese dioxide (Roels et al. 1992). The LOAEL was calculated by dividing the geometric mean concentration of the lifetime-

integrated respirable dust concentration by the average duration of employment in the facility. EPA calculated the RfC by adjusting for continuous exposure and dividing by an uncertainty factor of 1,000 (a factor of 10 for use of a LOAEL, a factor of 10 to protect sensitive individuals, and a factor or 10 for database limitations reflecting both the less-than-chronic periods of exposure and the lack of developmental data, as well as potential but unquantified differences in the toxicity of different forms of manganese). The estimated breathing rate in the exposed workers was assumed to be 10 m³/workday.

The EPA has derived a chronic oral RfD of 0.14 mg/kg/day for manganese (IRIS 1998). This value is equal to the average daily intake of manganese in the diet (10 mg/day) that is considered adequate and safe. The RfD was derived assuming an average body weight of 70 kg, and was based on a composite of data including chronic humans' NOAELs (WHO 1973), "safe and adequate levels" from the National Academy of Sciences (NRC 1989), and research by Schroeder et al. (1966). An uncertainty factor was not employed because (a) the information used to determine the RfD for manganese was taken from many large populations, (b) humans exert an efficient homeostatic control over manganese such that body burdens are kept constant with variations in diet, (c) there are no subpopulations that are believed to be more sensitive to manganese at this level, and (d) manganese is an essential element that is required for normal human growth and maintenance of health. However, the EPA has recommended that a "modifying factor of 3 be applied when assessing risk from manganese in drinking water or soil because the study by Kondakis et al. (1989) raises significant concerns about possible adverse neurological effects at doses not far from the range of essentiality.

Table 7-1. Regulations and Guidelines Applicable to Manganese

Agency	Description	Information	References
NTERNATIONAL			
wно	Guideline value in drinking water for aesthetic quality	0.1 mg/L	WHO 1984a
	Recommended exposure limit in workplace air - respirable manganese particles	0.3 mg/m <sup>3</sup>	WHO 1986
	Recommended air quality guideline for Europe (annual average)	0.15 µg/m³	WHO 1997
ATIONAL		·	
egulations: Air:			
a. Air: EPA OAQPS	Ban on use of methylcyclopentadienyl manganese tricarbonyl (MMT) as a fuel additive in unleaded gasoline	Yes	EPA 1978, 1979, 1981
	Ban on use of MMT as fuel additive in unleaded gasoline overturned	Yes	EPA 1995
OSHA	PEL TWA  Manganese fume, as manganese	5 mg/m³(C)°	OSHA 1998 (29 CFR
	Manganese cyclopentadienyl tricarbonyl, as manganese (skin) Manganese tetroxide	0.1 mg/m <sup>3</sup>	1910.1000) (Table Z-1)
	Manganese, elemental and inorganic compounds (proposed)	0.2 mg/m <sup>3</sup>	
	STEL Manganese fume	3 mg/m <sup>3</sup>	
	Ceiling Manganese compounds, as manganese	5 mg/m³	
Water: EPA OWRS	General permits under NPDES for total manganese	Yes	40 CFR 122.21, April 2, 1992, Appendix D, Table IV
Food: FDA	Concentration in bottled water	0.05 mg/L	FDA 1993 (21 CFR 103.35)
Other: EPA OERR	Reportable quantity  Manganese, tricarbonyl methyl- cyclopentadienyl	1 ib	EPA 1998a (40 CFR 302.4)
	Potassium permanganate	100 lbs	EPA 1998a (40 CFR 302.4)
	Reportable quantity  Manganese, tricarbonyl methyl- cyclopentadienyl	100 lbs	EPA 1998b (40 CFR 355)
	Extremely Hazardous Substance TPQ Manganese, tricarbonyl methyl- cyclopentadienyl	100 lbs	EPA 1998b (40 CFR 355)
EPA OSW	Monitor at hazardous waste facilities to establish groundwater quality	Yes	40 CFR 265.92 January 31, 1985

# Table 7-1. Regulations and Guidelines Applicable to Manganese (continued)

Agency	Description	Information	References
NATIONAL (cont.)			
EPA OTS	Toxic chemical release reporting manganese; manganese compounds	Yes	EPA 1998c (40 CFR 372.65)
DOJ DEA	Potassium permangate ranked as essential chemical in illegal drug production. Records of sales and uses required for amounts over 500 kg.	Yes	DOJ 1990
iuidelines:			
Air:			
ACGIH	TLV TWA  Manganese dust and compounds, as manganese	5 mg/m³	ACGIH 1998
	Manganese tetroxide, compound	1 mg/m³	
	and manganese fume, as manganese Manganese cyclopentadienyl	0.1 mg/m³	
	tricarbonyl, as manganese (skin) 2-Methylcyclopentadienyl manganese	0.2 mg/m³	
	tricarbonyl, as manganese	ow my m	
	STEL Manganese fume	3 mg/m³	
	Manganese tune	5 mg/m	
Water: EPA ODW	Secondary MCL for aesthetic quality	0.05 mg/L	40 CFR 143.3 January 30, 1991 (EPA 1998d)
Other:			
EPA	Carcinogenic Classification RfD (oral) RfC (inhalation)	Group D* 0.14 mg/kg/day <sup>f</sup> 5x10 <sup>-5</sup> mg/m <sup>3</sup>	IRIS 1998
ATE			
gulations and			
Guidelines: <sup>b</sup>			
Air:	Acceptable ambient air concentrations (unless otherwise	specified)	NATICH 1992 (unless otherwise specified)
Manganese Arizona		8.00 µg/m³ (24 hr)	
Connecticut		20 μg/m³ (8 hr)	
		100 μg/m <sup>3</sup> (30 min)	
Florida-Pinella		12.0 μg/m³ (24 hr)	
Louisiana Nevada		27.6 μg/m³ (8 hr) 1.19E-1 mg/m³ (8 hr)	
North Carolina		3.10E-2 mg/m <sup>3</sup> (24 hr)	
North Carolina-Forco		.031 mg/m <sup>3</sup> (24 hr)	
North Dakota		3.0E-2 mg/m³ (1 hr)	
Oklahoma	do not form Westerlands	100.0 μ/m³ (24 hr)	OR DEC 1000
Oregon Pennsylvania	de minimus Emission rates	0.8 tons/yr 2.4E-01 μg/m³ (annual)	OR DEQ 1999
Rhode Island		2.4 μg/m³ (1 hr)	
South Carolina	Maximum allowable concentration	25 μg/m³	SC DHEC 1999
		20 μg/m³ (8 hr)	
South Dakota		30.0 μ/m³ (annual) 119 μg/m³ (annual)	VT DEC 1999a
Texas			A I DEC IAAA
Texas Vermont		17.() up/m³ (24 hr)	
Texas	Manganese dust and compounds, threshold level	17.0 μg/m³ (24 hr) 0.5 tons/yr	WA DE 1999a
Texas Vermont Virginia	Manganese dust and compounds, threshold level		WA DE 1999a
Texas Vermont Virginia Washington		0.5 tons/yr	WA DE 1999a

Table 7-1. Regulations and Guidelines Applicable to Manganese (continued)

gency	Description	Information	References
Connecticut		2.0 µg/m³ (8 hr)	CT DEP 1999
		10 μg/m <sup>3</sup> (30 min)	CI DEL 1999
Florida-Pinella		.24 μg/m³ (24 hr)	
Nevada	Ban on MMT in unleaded gasoline	Yes	NV DCNR 1999a
Nevada		2.00 μg/m³ (8 hr)	mma 4000
New Hampshire	Ambient air limit	0.357 μg/m³ (24 hr)	NH DES 1999
North Carolina-Forco		.6 μg/m³ (24 hr)	
North Dakota		1.0 μg/m³ (8 hr)	
Texas		.1 μg/m³ (annual)	
Virginia		1.70 μg/m³ (24 hr)	7774 DE 1000-
Washington	Threshold level	0.1 tons/yr	WA DE 1999a
Washington-Southwest		.3 μg/m³ (24 hr)	
Manganese fume, as mar			
Connecticut	Hazardous limiting values for hazardous air pollutants	20 μg/m³ (8 hr)	CT DEP 1999
•••		100 μg/m³ (30 min)	TD DIRTH 1000.
Idaho		0.05 mg/m <sup>3</sup> (24 hr)	ID DHW 1999a
Manganese tetroxide			
Connecticut	Hazardous limiting values for hazardous air pollutants	20 μg/m³ (8 hr)	CT DEP 1999
		100 μg/m³ (30 min)	
Nevada		0.24 mg/m <sup>3</sup> (8 hr)	i
New Hampshire	Ambient air limit	1.006 µg/m³ (24 hr)	NH DES 1999
North Carolina		6.20 μg/m³ (24 hr)	
North Carolina-Forco	6.2 μg/m³ (24 hr)	10 13:01:	
North Dakota		10 μg/m³ (8 hr)	
Texas		1.0 μg/m³ (annual)	
Virginia	· ·	16 μg/m³ (24 hr)	
Potassium permanganate,			
New Hampshire	Ambient air limit	1,006 µg/m³ (24 hr)	NH DES 1999
Water:			
Drinking water	Drinking water quality standards		FSTRAC 1990 (unless
			otherwise specified)
Illinois		150 μg/L°	
Kansas		50 μg/L	
Nevada	Secondary standard	0.1 mg/L (100 μg/L)	NV DCNR 1996b
	(Standard above which must notify public)	0.05 mg/L (50 μg/L)	
New Hampshire	Secondary MCL	0.05 mg/L (50 μg/L)	NH DES 1999
New Mexico		200 μg/L	NMHED 1990
New York	MCL	300 μg/L	NY DEC 1999
	If both Mn and Fe present	[total] $\leq 0.5 \text{ mg/L} (500 \text{ µg/L})$	
Wisconsin	•	50 μg/L <b>*</b>	WDHSS 1990
Groundwater			
Idaho	Secondary standard	0.05 mg/L (50 μg/L)	ID DHW 1999b
New Hampshire	For potable drinking supply	50 μg/L	NH DES 1999
	Ground water quality criteria for potable drinking water supply	50 μg/L	NJ DEP 1999
New Jersey			
New Jersey Vermont	Enforcement standard		VT DEC 1999
New Jersey Vermont		840 µg/L 420 µg/L	

## Table 7-1. Regulations and Guidelines Applicable to Manganese (continued)

Agency	Description	Information	References
Water for irrigation Nevada		200 μg/L	NV DCNR 1999c

ACGIH = American Conference of Governmental Industrial Hygienists; DEA = Drug Enforcement Agency; DOJ = Department of Justice; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; MCL = Maximum Contaminant Level; NIOSH = National Institute for Occupational Safety and Health; NPDES = National Pollutant Discharge Elimination System; OAQPS = Office of Air Quality Planning and Standards; ODW = Office of Drinking Water; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Safety and Health Administration; OSW = Office of Solid Wastes; OTS = Office of Toxic Substances; OWRS = Office of Water Regulations and Standards; PEL = Permissible Exposure Limit; RfC = reference concentration; RfD = reference dose; STEL = Short Term Exposure Limit; TLV = Threshold Limit Value; TPQ = Threshold Planning Quantity; TWA = Time-Weighted Average; WHO = World Health Organization

<sup>\*</sup>Group D = not classifiable as to human carcinogenicity

All data on state regulations and guidelines from NATICH 1992 unless noted otherwise.

<sup>\*</sup>Only for communities serving less than or 1,000 persons or less than or 300 service connections

Groundwater standard

<sup>°</sup>C = ceiling limit

This reference dose is for the total oral intake of manganese. When assessing exposure to manganese from food, the modifying factor is 1; however, when assessing exposure to manganese from drinking water or soil, a modifying factor of 3 is recommended.