

8. REGULATIONS AND ADVISORIES

No international regulations pertaining to fluorides were found. The national and state regulations and guidelines regarding fluorides, hydrogen fluoride, and fluorine in air, water, and other media are summarized in Table 8-1.

A chronic-duration oral MRL of 0.05 mg fluoride/kg/day has been derived for fluoride. This MRL is based on a NOAEL of 0.15 mg fluoride/kg/day and a LOAEL of 0.25 mg fluoride/kg/day for skeletal effects (increased fracture rate) (Li et al. 2001). The MRL was derived by dividing the NOAEL by an uncertainty factor of 3 to account for human variability.

An acute-duration inhalation MRL of 0.02 ppm fluoride has been derived for hydrogen fluoride. This MRL is based on a minimal LOAEL of 0.5 ppm for upper respiratory tract inflammation in humans exposed to hydrogen fluoride for 1 hour (Lund et al. 1997, 1999). The MRL was derived by dividing the unadjusted LOAEL by an uncertainty factor of 30 (3 for a use of a minimal LOAEL and 10 to account for human variability).

An acute-duration inhalation MRL of 0.01 ppm has been derived for fluorine. This MRL is based on a NOAEL of 10 ppm for respiratory irritation in humans exposed to fluorine for 15 minutes (Keplinger and Suissa 1968). The MRL was derived by dividing the 24-hour adjusted NOAEL of 0.1 ppm by an uncertainty factor of 10 to account for human variability.

EPA (IRIS 2003) derived an oral reference dose (RfD) of 0.06 mg/kg/day for fluorine (soluble fluoride). The RfD was based on a NOAEL of 0.06 mg/kg/day and a LOAEL of 0.12 mg/kg/day for the cosmetic effect of dental fluorosis in children (Hodge 1950). The NOAEL was divided by an uncertainty factor of 1 to derive the RfD.

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Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification Fluoride and sodium fluoride	Group 3 ^a	IARC 1987
WHO	Drinking water guideline Fluoride	1.5 mg/L	WHO 2001
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV-TWA Fluoride Fluorine STEL (ceiling) Fluorine Hydrogen fluoride	2.5 mg/m ³ 1.0 ppm 2.0 ppm 3.0 ppm	ACGIH 2000
EPA	Accidental release prevention Threshold quantity Fluorine Hydrogen fluoride Accidental release prevention Toxic end point Fluorine Hydrogen fluoride	1,000 pounds 1,000 pounds 0.0039 mg/L 0.0160 mg/L	EPA 2001b 40CFR68.130 Table 1 EPA 2001a 40CFR68 Appendix A
OSHA	PEL (8-hour TWA) General industry Fluoride Fluorine Hydrogen fluoride PEL (8-hour TWA) Construction industry Fluoride Fluorine Hydrogen fluoride PEL (8-hour TWA) Shipyards Fluoride Fluorine Hydrogen fluoride Highly hazardous chemicals Threshold quantity Fluorine Highly hazardous chemicals Threshold quantity Hydrogen fluoride	2.5 mg/m ³ 0.2 mg/m ³ 2.0 mg/m ³ 2.5 mg/m ³ 0.2 mg/m ³ 2.0 mg/m ³ 2.5 mg/m ³ 0.2 mg/m ³ 2.0 mg/m ³ 1,000 pounds 1,000 pounds	OSHA 2001c 29CFR1910.1000 Table Z-1 OSHA 2001f 29CFR1926.55 Appendix A OSHA 2001a 29CFR1915.1000 Table Z OSHA 2001d 29CFR1910.119 Appendix A OSHA 2001e 29CFR1926.64 Appendix A

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Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
OSHA	Brazing and gas welding fluxes shall have a cautionary wording to indicate that they contain fluorine compounds		OSHA 2001b 29CFR1910.252(c)(1)
NIOSH	REL (TWA)		NIOSH 2001a
	Fluorine	0.2 mg/m ³	NIOSH 2001b
	Hydrogen fluoride	2.5 mg/m ³	NIOSH 2001c
	Sodium fluoride	2.5 mg/m ³	
NIOSH	IDLH		NIOSH 2001a
	Fluorine	25 ppm	NIOSH 2001b
	Hydrogen fluoride	30 ppm	NIOSH 2001c
NIOSH	Sodium fluoride	250 ppm	
USC	HAP		USC 2001 42USC7412
b. Water			
EPA	BPT effluent limitation—fluoride		EPA 2001c
	Maximum for 1 day	6.1 kg/kkg	40CFR415.82
	Average of daily values for 30 consecutive days	2.9 kg/kkg	
	Effluent limitation—fluoride		EPA 2001e
	Maximum for 1 day	75 mg/L	40CFR422.42
	Average of daily values for 30 consecutive days	25 mg/L	
	Groundwater protection standards at inactive uranium processing sites—listed constituents include fluorine and hydrogen fluoride		EPA 2001f 40CFR192 Appendix I
	MCLG—fluoride	4.0 mg/L	EPA 2001j 40CFR141.51(b)
	MCL—fluoride	4.0 mg/L	EPA 2001k 40CFR141.62(b)
	Secondary MCL—fluoride	2.0 mg/L	EPA 2001l 40CFR143.3
EPA	Water pollution—hazardous substance designation	Hydrogen fluoride Sodium fluoride	EPA 2001r 40CFR116.4
c. Food			
EPA	Pesticides—fluorine compounds; residue tolerances		EPA 2001n 40CFR180.145
	Apricots, beets, blackberries, blueberries, boysenberries, broccoli, brussels sprouts, cabbage, cauliflower, citrus fruits, collards, cranberries	7 ppm	

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Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine

Agency	Description	Information	Reference														
NATIONAL (cont.)																	
EPA	Pesticides—fluorine compounds; residue tolerances Cucumbers, dewberries, eggplant, grapes, kale, kohlrabi, lettuce, loganberries, melons, nectarines, peaches, peppers, plums, pumpkins, radish, raspberries, rutabaga, squash, strawberries, tomatoes, turnip, youngberries	7 ppm	EPA 2001n 40CFR180.145														
		Potatoes		2 ppm													
		Potatoes, processing waste		22 ppm													
		Kiwifruit		15 ppm													
FDA	Adhesive component, indirect food additive—for use only as bonding agent for aluminum foil, stabilizer, or preservative Hydrogen fluoride Sodium fluoride	Total fluoride from all sources not to exceed 1% by weight of the finished adhesive	FDA 2000e 21CFR175.105(c)(5)														
		Bottled water—no fluoride added		<table border="0"> <tr> <td><u>Temperature^b</u></td> <td><u>mg/L</u></td> </tr> <tr> <td>53.7–below</td> <td>2.4</td> </tr> <tr> <td>53.8–58.3</td> <td>2.2</td> </tr> <tr> <td>58.4–63.8</td> <td>2.0</td> </tr> <tr> <td>63.9–70.6</td> <td>1.8</td> </tr> <tr> <td>70.7–79.2</td> <td>1.6</td> </tr> <tr> <td>79.3–90.5</td> <td>1.4</td> </tr> </table>	<u>Temperature^b</u>	<u>mg/L</u>	53.7–below	2.4	53.8–58.3	2.2	58.4–63.8	2.0	63.9–70.6	1.8	70.7–79.2	1.6	79.3–90.5
	<u>Temperature^b</u>	<u>mg/L</u>															
	53.7–below	2.4															
	53.8–58.3	2.2															
	58.4–63.8	2.0															
	63.9–70.6	1.8															
	70.7–79.2	1.6															
	79.3–90.5	1.4															
	Bottled water—fluoride added	<table border="0"> <tr> <td><u>Temperature^b</u></td> <td><u>mg/L</u></td> </tr> <tr> <td>53.7–below</td> <td>1.7</td> </tr> <tr> <td>53.8–58.3</td> <td>1.5</td> </tr> <tr> <td>58.4–63.8</td> <td>1.3</td> </tr> <tr> <td>63.9–70.6</td> <td>1.2</td> </tr> <tr> <td>70.7–79.2</td> <td>1.0</td> </tr> <tr> <td>79.3–90.5</td> <td>0.8</td> </tr> </table>	<u>Temperature^b</u>	<u>mg/L</u>	53.7–below	1.7	53.8–58.3	1.5	58.4–63.8	1.3	63.9–70.6	1.2	70.7–79.2	1.0	79.3–90.5	0.8	
	<u>Temperature^b</u>	<u>mg/L</u>															
	53.7–below	1.7															
	53.8–58.3	1.5															
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63.9–70.6	1.2																
70.7–79.2	1.0																
79.3–90.5	0.8																
Over-the-counter drug products Labeling—fluoride, fluorine, and sodium fluoride		FDA 2000b 21CFR355.50															
		FDA 2000c 21CFR355.60															
Over-the-counter drug products Testing—fluoride		FDA 2000d 21CFR355.70															
Over-the-counter drug products Active ingredient—fluorine, hydrogen fluoride, and sodium fluoride		FDA 2000a 21CFR355.10															
		FDA 2000f 21CFR310.545(a)(2)															

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Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
FDA	Surface component, food contact—sodium fluoride for use as preservative only		FDA 2000h 21CFR177.2800 (d)(5)
d. Other			
ACGIH	Carcinogenicity classification Fluoride BEI Fluorides in urine Prior to shift End of shift	A4 ^c 3 mg/g creatinine 10 mg/g creatinine	ACGIH 2000
CPSC	Requirements for child-resistant packaging for household products containing elemental fluoride	More than 50 mg and more than 0.5%	CPSC 2001 16CFR1700
DOT	Hazardous materials Reportable quantity Fluorine Hydrogen fluoride Sodium fluoride	 10 pounds 100 pounds 1,000 pounds	DOT 2001 40CFR172.101 Appendix A
EPA	RfD—fluorine Toxic chemical release reporting; Community Right-to-Know—effective date Fluorine Hydrogen fluoride Contaminated soil—fluoride Hazardous waste—health based limits for exclusion of waste-derived-residue Fluorine residue concentration limit Hazardous waste—identification and listing Fluorine Hydrogen fluoride Pesticides—residue tolerances Sodium fluoride Superfund—reportable quantity Fluorine Hydrogen fluoride Sodium fluoride	 01/01/95 01/01/87 Concentrations greater than 10 times UTS 4.0 mg/kg P056 U134 Not more than 25% of pesticide formulation 1 pound 5,000 pounds 5,000 pounds	IRIS 2003 EPA 2001q 40CFR372.65 EPA 2001d 40CFR268.49(f) EPA 2001g 40CFR266 Appendix VII EPA 2001h 40CFR261.33(e) EPA 2001i 40CFR261.33(f) EPA 2001m 40CFR180.1001(d) EPA 2001o 40CFR302.4 Appendix A

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Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine

Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
EPA	Superfund—extremely hazardous		EPA 2001p 40CFR355 Appendix A
	Reportable quantity		
	Fluorine	10 pounds	
	Hydrogen fluoride	100 pounds	
	Threshold planning quantity		
	Fluorine	500 pounds	
	Hydrogen fluoride	100 pounds	
<u>STATE</u>			
a. Air			
Connecticut	HAP—fluoride, fluorine, and hydrogen fluoride		BNA 2001
Hawaii	Air contaminant—hydrogen fluoride		BNA 2001
Idaho	Toxic air pollutants		BNA 2001
	Fluoride		
	OEL	2.5 mg/m ³	
	EL	0.167 pounds/hour	
	AAC	0.125 mg/m ³	
	Fluorine		
	OEL	2.0 mg/m ³	
Michigan	PEL (TWA)		BNA 2001
	Fluoride	2.5 mg/m ³	
	Fluorine	0.2 mg/m ³	
Montana	Hydrogen fluoride	3.0 ppm	BNA 2001
	Air contaminant (TWA)		
	Fluoride	2.5 mg/m ³	
New Mexico	Fluorine	0.2 mg/m ³	BNA 2001
	Hydrogen fluoride	2.0 mg/m ³	
	Toxic air pollutant		
New York	Fluorides		BNA 2001
	OEL	2.5 mg/m ³	
	Emissions	0.167 pounds/hour	
	Fluorine		
	OEL	2.0 mg/m ³	
New York	Emissions	0.133 pounds/hour	BNA 2001
	Air contaminant (TLV)		
	Fluoride	2.5 mg/m ³	
	Fluorine	0.2 mg/m ³	
	Hydrogen fluoride	2.0 mg/m ³	

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Agency	Description	Information	Reference		
<i>STATE (cont.)</i>					
Washington	Toxic air pollutant—ASIL	Fluoride	8.3 $\mu\text{g}/\text{m}^3$	BNA 2001	
		Fluorine	5.3 $\mu\text{g}/\text{m}^3$		
		Hydrogen fluoride	8.7 $\mu\text{g}/\text{m}^3$		
	PEL	Fluoride	2.5 mg/m^3	BNA 2001	
		Fluorine	0.2 mg/m^3		
		Hydrogen fluoride (STEL)	3.0 ppm		
Wisconsin	Emission rate (pounds/hour)	<25 feet	>25 feet	BNA 2001	
		Fluoride	0.2088		0.8640
		Fluorine	0.1656		0.6720
		Hydrogen fluoride	0.1272		0.4800
b. Water					
Alaska	MCL—fluoride	4.0 mg/L	BNA 2001		
	Secondary MCL—fluoride	2.0 mg/L			
Arizona	Drinking water guideline—fluoride	4.0 mg/L	HSDB 2003		
	Reporting limit—fluoride	2.0 mg/L	BNA 2001		
California	Drinking water standards—fluoride	2.0 mg/L	HSDB 2003		
Connecticut	MCL—fluoride	4.0 mg/L	BNA 2001		
Delaware	Drinking water standards—fluoride	1.8 mg/L	HSDB 2003		
Georgia	MCL—fluoride	4.0 mg/L	BNA 2001		
Hawaii	Drinking water standards—fluoride	1.4–2.4 mg/L	HSDB 2003		
Idaho	Groundwater quality standards—fluoride	4.0 mg/L	BNA 2001		
Kansas	Agriculture—fluoride		BNA 2001		
	Livestock	2.0 mg/L			
	Irrigation	1.0 mg/L			
	Public health food—fluoride				
Maine	Domestic water supply	2.0 mg/L	HSDB 2003		
	Drinking water guideline—fluoride	2.4 mg/L			
	Maximum exposure guideline	2.4 mg/L			
Mississippi	Action level	1.2 mg/L	BNA 2001		
	Groundwater standards—fluoride	4.0 ppm	BNA 2001		
Nebraska	MCL—fluoride	4.0 mg/L	BNA 2001		

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Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
New Jersey	Groundwater quality criteria— fluoride	2.0 mg/L	BNA 2001
	PQL—fluoride	0.5 mg/L	
New York	Groundwater effluent limitations— fluoride	3.0 mg/L	BNA 2001
	MCL—fluoride	2.2 mg/L	BNA 2001
North Carolina	Drinking water standards— fluoride	4.0 mg/L	HSDB 2003
North Dakota	MCL—fluoride	4.0 mg/L	BNA 2001
Oklahoma	MCL—fluoride	4.0 mg/L	BNA 2001
Pennsylvania	Drinking water standards— fluoride	2.0 mg/L	HSDB 2003
Rhode Island	MCLG—fluoride	4.0 ppm	BNA 2001
	MCL—fluoride	4.0 ppm	
South Dakota	Groundwater quality standards— fluoride	2.4 mg/L	BNA 2001
Tennessee	MCL—fluoride	4.0 ppm	BNA 2001
Texas	MCL—fluoride	4.0 mg/L	BNA 2001
Utah	Groundwater standards	4.0 mg/L	BNA 2001
	MCL—fluoride	4.0 mg/L	BNA 2001
Vermont	Groundwater quality standards— fluoride		BNA 2001
	Enforcement standard	4.0 mg/L	
	Preventive action level	2.0 mg/L	
	MCL—fluoride	4.0 mg/L	BNA 2001
Washington	MCL—fluoride	4.0 mg/L	BNA 2001
West Virginia	Groundwater standards	Not to exceed 4.0 mg/L	BNA 2001
Wisconsin	MCLG—fluoride	4.0 mg/L	BNA 2001
	MCL—fluoride	4.0 mg/L	
	Groundwater standards—fluoride		BNA 2001
	Enforcement standard	4.0 mg/L	
	Preventive action limit	0.8 mg/L	
c. Food		No data	
d. Other			
Connecticut	Use of pesticides; control of registrations and uses—sodium fluoride	For use as a wood preservative	BNA 2001

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Agency	Description	Information	Reference
<i>STATE (cont.)</i>			
Minnesota	Hazardous substance—fluoride (as F, as dust), fluorides (inorganic), fluorine, and hydrogen fluoride		BNA 2001
New Jersey	Hazardous substance—fluorine and hydrogen fluoride		BNA 2001

^aGroup 3: not classifiable as to its carcinogenicity to humans

^bTemperature: annual average of maximum daily air temperatures (EF)

^cA4: not classifiable as a human carcinogen

AAC = acceptable ambient concentrations; ACGIH = American Conference of Governmental Industrial Hygienists; ASIL = acceptable source impact levels; BEI = biological exposure indices; BNA = Bureau of National Affairs; BPT = best practicable control technology; CFR = Code of Federal Regulations; CPSC = Consumer Product Safety Commission; DOT = Department of Transportation; EL = emissions levels; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; 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; 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 limit; PQL = practical quantitation level; REL = recommended exposure limit; RfD = reference dose; STEL = short term exposure limit; TLV = threshold limit values; TWA = time-weighted average; USC = United States Code; UTS = universal treatment standards; WHO = World Health Organization

