Eloise W. Kailin, M.D. P.O. Box 2418 Sequim WA 98382

November 25, 2011

Secretary Kathleen G. Schelius U.S. HHS 200 Independence Ave. S.W. Washington D.C. 20201

Re: Classification of Products per 21 U.S.C. 360bbb-2

Dear Secretary Sebelius:

As you know, 21 U.S.C. 360bbb-2 allows a person to submit a request to the Secretary respecting the classification of a product and the component of the FDA that will regulate the product. I hereby request classification of fluoridation products as drugs and prescription drugs and I request that these products be regulated by CDER. According to NSF, International, fluoridation products that are tested and certified to NSF/ANSI Standard 60 are in three categories:

- 1. Fluorosilicie Acid (a.k.a. Fluosilicie Acid or Hydrofluosilicie Acid).
- 2. Sodium Fluorosilicate (a.k.a. Sodium Silicofluoride).
- 3. Sodium Fluoride

These fluoridation products are added to public water supplies for "preventing and reducing tooth decay." Appendix A hereto (from the NSF Fact Sheet on Fluoridation Chemicals). Because these substances are intended for use in the prevention of disease (dental caries, tooth decay) in man, they are anticaries drugs. (21 U.S.C. 321(g)(1)(B); See 21 CFR 355.3 ("Anticaries drug. A drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries)").) The FDA, through CDER, is responsible for ensuring that human drugs are safe and effective. (21 U.S.C. 393(b)(2)(B).) These fluoridation products do not meet OTC Conditions in 21 CFR Part 355 so they are not OTC drugs. Therefore they are federal prescription drugs. I attach an analysis detailing why these products are federal prescription drugs. (Appendix B hereto.) I also attach a listing of what I believe to be all manufacturers of fluoridation products used in the United States. (Appendix C hereto.) I request that these manufactures be sent a notice requiring them to register their fluoridation products pursuant to 21 CFR 207.25 or pursuant to other appropriate regulation.

Respectfully,

Elm Whalin B. D.

Eloise W. Kailin, M.D.

Appendix A to letter dated November 25, 2011 from Eloise W. Kailin, M.D. to Secretary Kathleen G. Sebelius



NSF Fact Sheet on Fluoridation Chemicals

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

- 1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
- 2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
- 3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

NSF Certification

NSF also developed a testing and certification program for these products, so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were appropriate for use. The certification program requires annual unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged, and transported with safe guards against potential contamination. NSF also requires annual testing and toxicological evaluation of each NSF Certified product. NSF Certified products have the NSF Mark, the maximum use level, lot number or date code and production location on the product packaging or documentation shipped with the product.

The use of this standard and the associated certification program have yielded benefits in ensuring that drinking water additives meet the health objectives that provide the basis for public health protection. NSF maintains listings of companies that manufacture and distribute treatment products at www.nsf.org. These listings are updated daily and list the products at their allowable maximum use levels. In recognition of the important safeguards that NSF Standard 60 provides to public drinking water supplies, 45 U.S. States and 10 Canadian Provinces and Territories require drinking water treatment chemicals to comply with the requirements of the standard.

Treatment products that are used for fluoridation are addressed in Section 7 of NSF/ANSI Standard 60. The products are allowed to be used up to concentrations that result in a maximum use level of 1.2 mg/L fluoride ion in water. The NSF standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by toxicological evaluation. The following text explains the rationale for the allowable levels established in the standard for 1) fluoride, 2) silicate, and 3) other potential contaminants that may be associated with fluoridation chemicals.

Fluoride

NSF/ANSI Standard 60 requires, when available, that the US EPA regulated maximum contaminant level (MCL) be used to determine the acceptable level for a contaminant. The EPA MCL for fluoride ion in water is 4 mg/L. The NSF Standard 60 single product allowable concentration (SPAC) for fluoride ion in drinking water from NSF Certified treatment products is 1.2 mg/L, or less than one-third of the EPA's MCL. Based on this the allowable maximum use level (MUL) for the NSF Certified fluoridation products are:

- 1. Fluorosilicie Acid: 6 mg/L.
- 2. Sodium Fluorosilicate: 2 mg/L.
- 3. Sodium Fluoride: 2.3 mg/L.

Silicate

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, NSF/ANSI Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a SPAC. NSF has established a SPAC for silicate at 16 mg/L. A fluorosilicate product, applied at its maximum use level, results in silicate drinking water levels that are substantially below the 16 mg/L SPAC established by NSF. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride allowed (1.2mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the SPAC allowed by NSF 60.

Potential Contaminants

The NSF toxicology review for a chemical product considers all chemical ingredients in the product as well as the manufacturing process, processing aids, and other factors that have an impact on the contaminants present in the finished drinking water. This formulation review identifies all the contaminants that need to be analyzed in testing the product. For example, fluosilicic acid is produced by adding sulfuric acid to phosphate ore. This is typically done during the production of phosphate additives for agricultural fertilizers. The manufacturing process is documented by an NSF inspector at an initial audit of the manufacturing site and during each annual unannounced inspection of the facility. The manufacturing process, ingredients, and potential contaminants are reviewed annually by NSF toxicologists, and the product is tested for any potential contaminants. A minimum test battery for all fluoridation products includes metals of toxicological concern and radionuclides.

Many drinking water treatment additives, including fluoridation products, are transported in bulk via tanker trucks to terminals where they are transferred to rail cars, shipped to distant locations or transferred into tanker trucks, and then delivered to the water treatment plants. These tanker trucks, transfer terminals and rail cars are potential sources of contamination. Therefore, NSF also inspects, samples, tests, and certifies products at rail transfer and storage depots. It is always important to verify that the location of the product distributor (the company that delivers the product to the water utility) matches that in the official NSF Listing for the product (available at www.nsf.org).

NSF has compiled data on the level of contaminants found in all fluoridation products that have applied for, or have been listed by, NSF. The statistical results in Table 1 (attached) include the test results for these products, as well as the annual monitoring tests from the period 2000 to 2006. This includes 245 separate samples analyzed during this time period. The concentrations reported represent contaminant levels that would be expected when the product is dosed into water at the Maximum Use Level (MUL). Lower product doses would produce proportionately lower contaminant concentrations (e.g. a 0.6 mg/L fluoride dose would produce one half the contaminant concentrations listed in Table 1.)

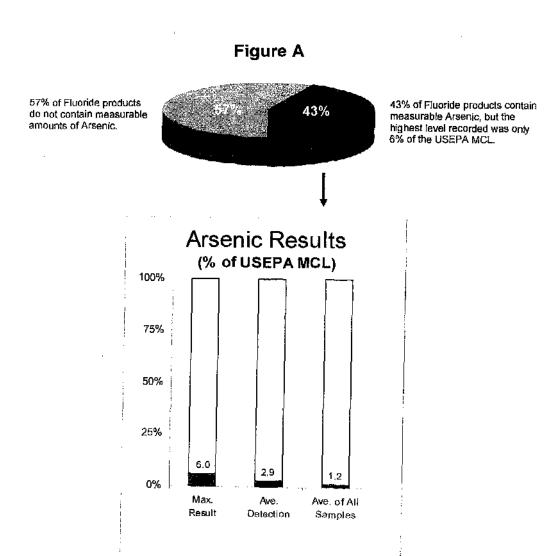
Table 1 documents that there is no contamination of drinking water from the fluoridation products NSF has tested and certified. NSF issued previous summaries of contaminant levels in fluoridation products for earlier reporting periods in 1999 and 2003. While some contaminant levels in those earlier periods were slightly higher than the current data for certain contaminants, there has not been a single fluoride product tested since the initiation of the program in 1988 with a contaminant concentration in excess of its corresponding SPAC. The documented reduction of impurities for this most current time period is due, at least in part, to the effectiveness of NSF/ANSI Standard 60 and the NSF certification program for drinking water treatment additives, and demonstrates the effectiveness of the program. The reduction in impurities is further attested to by an article in the Journal of the American Water Works Association entitled, "Trace Contaminants in Water Treatment Chemicals."

Arsenic

The results in Table 1 indicate that the most common contaminant detected in these products is arsenic, but it is detected in only 43% of the product samples. This means that levels of arsenic

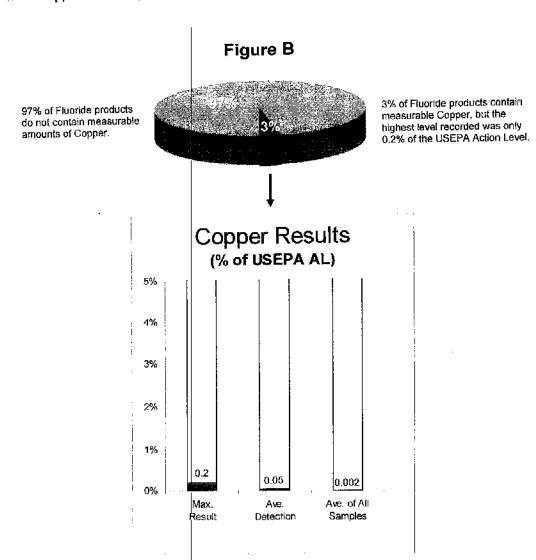
¹ Brown, R., et al., "Trace Contaminants in Water Treatment Chemicals: Sources and Fate." <u>Journal of the American Water Works Association</u> 2004: 96:12:111.

in 57% of the samples were non-detectable, even though products are tested at 10 times their maximum use level. All detections were at levels below the Single Product Allowable Concentration, if the product is added to drinking water at (or below) its maximum use level. The SPAC, as defined in NSF/ANSI Standard 60, is one tenth of the US EPA's MCL. The current MCL for arsenic is 10 ppb, the highest detection of arsenic from a fluoridation chemical was 0.6 ppb (shown on Table 1), and the average concentration was 0.12 ppb. Even the highest concentration of 0.6 ppb was only detected because the standard requires testing the chemical at 10 times its maximum use level to detect these trace levels of contaminants. Had the dose of fluoridation additives been tested in water at the maximum use level, instead of at 10 times their maximum use levels, the arsenic concentration measured would have been below the 1 ppb reporting limit for arsenic for 100 percent of the samples measured.



Copper

The second most common contaminant found, and on a much less frequent basis, is copper, and 97% of all samples tested had no detectable levels of copper. The average concentration of copper has been 0.02 ppb with 2.6 ppb being the highest concentration detected. This is well below the 130 ppb SPAC requirement of NSF 60.

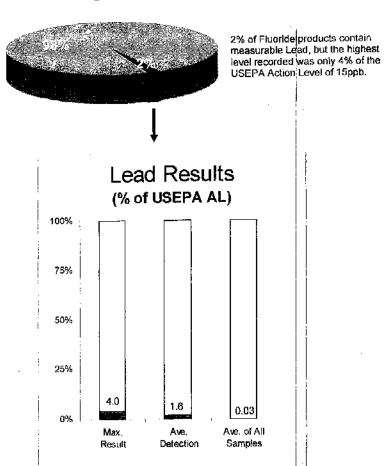


Lead

The third most common contaminant found is lead. It occurs on a much less frequent basis, and 98% of all samples tested had no detectable levels of lead. The average concentration of lead has been 0.005 ppb with 0.6 ppb being the highest concentration detected. This is well below the 1.5 ppb SPAC requirement of NSF 60.

Figure C

98% of Fluoride products do not contain measurable amounts of Lead.



Radionuclides

Fluoridation products are also tested for radionuclides. All samples tested have not had any detectable levels of alpha or beta radiation.

Summary

In summary, the majority of fluoridation products as a class, based on NSF test results, do not add measurable amounts of arsenic, lead, other heavy metals, or radionuclide contamination to drinking water.

Additional information on fluoridation of drinking water can be found on the following web sites:

American Water Works Association (AWWA) Fluoridation Chemical Standards http://www.awwa.org/Bookstore/producttopicsresults.cfm?MetaDataID=121&navItemNumber=5093

American Water Works Association (AWWA) position http://www.awwa.org/Advocacy/pressroom/fluoride.cfm

American Dental Association (ADA) http://www.ada.org/public/topics/fluoride/index.asp

U.S. Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/fluoridation

Table 1

	Percentage	Mean	Mean	Maximum	NSF/ANSI	US EPA
	of Samples	Contaminant.	Contaminant	Contaminant	Standard 60	Maximum
	with	Concentration	Concentration	Concentration	Single	Contaminant
	Detectable	in all samples	in detectable	in detectable	Product	or Action
	Levels	(ppb)	samples (ppb)	samples (ppb)	Allowable	Level
					Concentration	
Antimony	0%	ND	ND	ND	0.6	6
Arsenic	43%	0.12	0.29	0.6	1	10
Barium	<1%	100.0	0.3	0.3	200	2000
Beryllium	0%	ND	ND	ND	0.4	4
Cadmium	1%	0.001	0.08	0.12	0.5	5
Chromium	<1%	0.001	0.15	0.2	10	100
Copper	3%	0.02	0.68	2.6	130	1300
Lead	2%	0.005	0.24	0.6	1.5	15
Mercury	<1%	0.0002	0.04	0.04	0.2	2
Radionuclides - alpha pCi/L	0%	ND	ND	ND	1.5	15
Radionuclides	0%	ND	ND	ND	0.4	4
– heta mrem/yr			į			
Selenium	<1%	0.016	1.06			
			1.95	3.2	5	50
Thallium	<1%	0.0003	0.04	0.06	0.2	2

Abbreviations used in this Fact Sheet

ANSI - American National Standards Institute

AWWA - American Water Works Association

AWWARF - American Water Works Association Research Foundation

ASDWA - Association of State Drinking Water Administrators

COSHEM - Conference of State Health and Environmental Managers

EPA – U.S. Environmental Protection Agency

MCL - maximum contaminant level

mrem/yr - millirems per year - measurement of radiation exposure dose

MUL – Maximum use level

NSF - NSF International (formerly the National Sanitation Foundation)

ppb - parts per billion

PCi/L - pico curies per liter - concentration of radioactivity

SPAC - Single Product Allowable Concentration

Appendix B to letter dated November 25, 2011 from Eloise W. Kailin, M.D. to Secretary Kathleen G. Sebelius

FLUORIDATION PRODUCTS USED IN PUBLIC WATER SYSTEMS ARE DRUGS

1. Review of Federal drug laws and regulations

a. The 1906 and 1938 Acts

Drug regulation in the United States began with the Colonics and States adopting isolated laws as early as 1736. (Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 703-04 (D.C. Cir. 2007).) As early as 1848, the United States began limited drug regulation. (*Id.* at 704.) Congress adopted more comprehensive drug statutes in the Food and Drugs Act of 1906, which prohibited the manufacture of any drug that was "adulterated or misbranded." (*Id.* at 705.) This Act defined "drug" as:

all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals:

and defined "food" as including "articles used for food [and] drink." (Food and Drugs Act of 1906, 34 Stat. 768 (1906).)

Initially, this Act did not regulate false claims of the curative power of a drug but this was changed by Congress in 1912. (Samuels v. United States, 232 F. 536, 545 (8th Cir. 1916).) The 1906 Act, as amended, did not require government approval before a drug was introduced into the market. (United States v. Hiland, 909 F.2d 1114, 1125 (8th Cir. 1990).) This changed with the adoption by Congress of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of 1938 which required a FDA approved new drug application ("NDA") to demonstrate a drug was safe before entering the market. (Samuels at 545.) No new approvals were required for drugs marketed under the 1906 Act if their conditions of use remained unchanged. (Id.)

b. In 1952, after Congress defined prescription drugs, the FDA announced it would not enforce the FFDCA for fluoridated public water

The Durham-Humphrey Amendment of 1951 (65 Stat. 648) for the first time explicitly defined two classes of medications (prescription and over-the-counter ("OTC")). (Christopher v. SmithKline Beecham Corp., 635 F.3d 383, 385 (9th Cir. 2011).) In 1952, in response to this amendment, the FDΛ adopted a regulation stating:

- (a) The program for fluoridation of public water supplies recommended by the Federal Security Agency, through the Public Health Service, contemplates the controlled addition of fluorine at a level optimum for the prevention of dental caries.
- (b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. . . .
- (c) The Federal Security Agency will regard water supplies containing fluorine, within the limitations recommended by the Public Health Service, as not actionable under the Federal Food, Drug, and Cosmetic Act.

(Former 21 CFR 3.27 (1952); 17 FR 6732; *infra* at B 23.) This regulation was recodified to former 21 CFR 250.203 in 1975. (40 FR 13996; *infra* at B 24.) It was published, as amended, in 1995. (*Infra* at B 25-26.)

c. In 1996 the FDA reversed its position to not enforce the FFDCA regarding fluoridated water after the EPA/FDA MOU was terminated and after Congress adopted the DSHEA that defined minerals as drugs if used to prevent specific diseases

In 1996, the FDA determined that its 1952 regulation was obsolete or no longer necessary and the regulation was revoked. (61 FR 29476; *infra* at B 27.) The revocation of 21 CFR 250.203 occurred after the EPA announced the "Termination of the Federal Drinking Water Additive Program" effective April 7, 1990. (53 FR 25586-89; CP 142-45; *infra* at B 28-31.) The first and major Term of Agreement of a 1979 MOU between FDA and EPA was having EPA

develop and operate the federal regulatory drinking water additives program:

III. Terms of Agreement

A. EPA's responsibilities are as follows:

1. To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water)

(44 FR 42775-78; *infra* at B 33 and at B 38.) EPA's Federal Register announcement of termination of its regulatory Federal Drinking Water Additives Program was effective notice to FDA that it was terminating the 1979 MOU and it was no longer obligated by this MOU to establish and operate a federal regulatory program to control direct additives to drinking water. (44 FR 42776, *infra* at B 33 and B 39 ("This [MOU] shall continue in effect unless . . . terminated by either party upon thirty (30) days advance written notice to the other."))

The revocation of 21 CFR 250.203 also occurred after the adoption by Congress of the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417; "DSHEA"). This 1994 Act of Congress clarified Congressional intent that minerals including fluoride are drugs if the intended use is to prevent disease.

A dietary supplement is deemed to be "food," [21 U.S.C.] 321(ff), which is defined in part as "articles used for food or drink for man or other animals," *Id.* § 321(f)(1), except when it meets the definition of a "drug," which is defined in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

(Alliance for Natural Health U.S. v. Sebelius, 714 F.Supp.2d 48, 50 (D.D.C. 2010).) Under the DSHEA, dietary supplements include minerals. (21 U.S.C. 321(ff)(1)(B); *infra* at B 42.) In adopting the DSHEA, Congress clarified its intent that fluoride minerals when used to prevent

disease are drugs under federal law. (21 U.S.C. 321(ff)(postscript), *infra* at B 43.) The Commissioner of the FDA now concurs.¹ (*Infra* at B 44.)

d. The 1962 Amendments to the 1938 Act

The Congress amended the FFDCA in 1962 to change the standard for approval of a NDA or abbreviated NDA ("ANDA") from "safe" to "safe and effective" for the intended use.

(Samuels at 545.) For drugs with approved NDAs under the 1938 Act to retain these NDAs, they were required to demonstrate they were effective. (*Id.*; Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609, 612-15, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973).)

e. In 1972, the FDA established a new approval process for nonprescription drugs

In 1972, the FDA established a new approval process for non-prescription drugs. (21 CFR Part 330.) This process resulted in the establishment of over-the-counter ("OTC") monographs for various drug classifications including a monograph for anticaries drug products that do not require a prescription. (21 CFR Part 355.) The final rule for the anticaries drug monograph is in 60 FR 52473-510. Amendments to this final rule are in 60 FR 57927, 61 FR 52285-87, 64 FR 13296, and 68 FR 24879-80. This final rule, as amended, provides that all OTC anticaries drug products introduced to the market after April 7, 1997 must comply with general conditions in 21 CFR 330.1 and with anticaries monograph conditions in 21 CFR Part 355; otherwise a NDA or ANDA is required.

¹ Congress specifically asked FDA to address the relationship of "fluoride in drinking water and drug(s)." (Infra at B 44.) The FDA responded, in part, stating "the Environmental Protection Agency regulates fluoride in the water supply." (Id.) But EPA had terminated its water additive program more than ten years earlier. (Supra at B 2-3.) So FDA was referring to EPA regulating the Maximum Contaminant Level ("MCL") for fluoride that triggers clean-up under the SDWA and was not referring to fluoride additives or water with fluorides added.

On or after [April 7, 1997] no OTC drug product that is subject to the monograph and that contains a nonmonograph condition . . . may be initially introduced . . . into interstate commerce unless it is the subject of an approved application or abbreviated application.

(60 FR 52474; 61 FR 52285.) Also, it should be noted that FDΛ regulations provide that any anticaries drug that includes hydrogen fluoride requires an NDA. (21 CFR 310.545(a)(2) and (b).) Typical specification sheets for water treatment certified Fluorosilicic Λcid show a significant portion of the fluoride comes from hydrogen fluoride. (*Infra* at B 47.) Some of the fluoride in water treatment certified Sodium Fluoride also comes from hydrogen fluoride. (*Infra* at B 50.)

2. Water fluoridation products are drugs under federal statute

a. Water fluoridation products add fluoride minerals to public water supplies that are intended for use in the prevention of dental caries (tooth decay) which is a disease in man

Today, in almost every state, water fluoridation products are required to be certified to ANSI/NSF Standard 60. For example, in Washington State:

Any treatment chemicals, with the exception of commercially retailed hypochlorite compounds such as unscented Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60. The maximum application dosage recommendation for the product certified by the ANSI/NSF Standard 60 shall not be exceeded in practice.

WAC 246-290-220(3). NSF, the author of ANSI/NSF Standard 60, states in the NSF Fact Sheet on Fluoridation Chemicals:

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay

(Supra at Λ 1.) Earlier, this year IIIIS confirmed its belief that:

Community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay.

(76 FR 2386; *infra* at B 51.)

The FDA has concluded that the intended use of fluoride additives to prevent tooth decay is implied. The FDA finds that intended use "may be shown by the circumstances surrounding the distribution of the article." (21 CFR 801.4.) The FDA states:

in some instances, the mere presence of certain therapeutically active ingredients could make a product a drug even in the absence of drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g. fluoride in a dentifrice).

(59 FR 6088.) The intended use of fluoride in drinking water additives is also implied. The FDA's interpretation of "intent" is entitled to "considerable deference." (Young v. Community Nutrition Institute, 476 U.S. 974, 981, 106 S.Ct. 2360, 90 L.Ed.2d 959 (1986).) The Washington State Board of Health states,

The Board considers it self-evident that the purpose of water fluoridation is to help prevent tooth decay.

(*Infra* at B 52.)

The CDC states, "Tooth decay (dental caries) is an infectious, multifactorial disease."

(Infra at B 54.) The FDA defines "dental caries" as "A disease of calcified tissues of teeth characterized by demineralization of the inorganic portion and destruction of the organic matrix" and defines "anticaries drug" as "A drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries). (21 CFR 355.3(e) and (d).)

b. Minerals, that are intended for use in the prevention of disease, are federal drugs

Congress has adopted a specific statute that, under the intended use for water fluoridation products, designates these products as drugs.

The term "drug" means

- (Λ) articles recognized in the official United States Pharmacopocia . . .; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (Λ), (B), or (C)....

(21 U.S.C. 321(g)(1); *infra* at B 41; emphasis supplied.) The language quoted has not been amended since it was originally adopted in the 1938 Act. (52 Stat. 1041.)

c. The language in 21 U.S.C. 321(g)(1)(B) defining drugs must be interpreted "as broad as its literal language indicates"

As early as 1916, the federal Supreme Court concurred that products that were otherwise defined as "foods" would be "drugs" under the federal statute² when labeling for the substance includes statements of therapeutic (including preventative) effect. (Seven Cases v. United States, 239 U.S. 510, 513-14, 36 S.Ct. 190, 60 L.Ed. 411 (1916).)

After the 1938 Act was adopted, the federal Supreme Court again concurred that "food products" will be "drugs" based on "labeling." (Kordel v. United States, 335 U.S. 345, 346, 69 S.Ct. 106, 93 L.Ed. 52 (1948).) In 1969, the federal Supreme Court, in finding a product was a drug, explained,

² The relevant portion of the federal statute are quoted *supra* at B 1.

Congress intended to define "drug" [in 21 U.S.C. 321(g)(1)(B)] far more broadly than does the medical profession. . . . The word "drug" is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word.

(United States v. An Article of Drug... Bacto-Unidisk, 394 U.S. 784, 793, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969).) The Bacto-Unidisk Court continued:

Congress fully intended that the Act's coverage be as broad as its literal language indicates - and, equally clear, broader than any strict medical definition might otherwise allow. . . . the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.

(Id. at 798; emphasis supplied.) The Bacto-Unidisk Court finally directed,

we must take care not to narrow the coverage of a statute short of the point where Congress indicated it should extend.

(*Id.* at 801.)

In the construction of federal statutes, "the decisions of the Supreme Court of the United States are binding" upon all. (Beezer v. City of Scattle, 62 Wn.2d 569, 573, 383 P.2d 895 (1963).) Therefore, HHS and FDA and every court is required to construe the definition of drug as "articles intended for use in the . . . prevention of disease" as "broad as its literal language indicates." (Supra.)

d. Foods must be regulated as drugs if the "intended use" is to prevent disease

Interpretation of federal statutes by other federal courts are entitled to great weight.

(Bcczer at 573.) A long line of federal court cases has found that articles normally regulated as "foods" will be regulated as "drugs" if the intended use is to treat or prevent a disease:

The word "drug" is defined in 21 U.S.C. s 321(g)(1)(B) to include:

articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .

Thus, it is the intended use of an article which determines whether or not it is a "drug," and even the most commonly ingested foods and liquids are "drugs" within the meaning of the [FFDCA] if their intended use falls within the definition of s 321(g)(1)(B).

Gadler v. United States, 425 F.Supp. 244, 246-47 (D.Minn. 1977); see Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 336 (7th Cir. 1983); see also Bradley v. United States, 264 F.79 (5th Cir., 1920) where the court specifically found "mineral water" to be a "drug" when it is intended to treat disease.

In the determination of whether fluoridation products are drugs,

the only question under the FFDCA is whether the intended use of the product is to prevent disease, not whether the product actually prevents disease.

(<u>United States v. Bowen</u>, 172 F.3d 682, 686 (9th Cir. 1999).) Intent "may be derived or inferred from [any] relevant source." (<u>National Nutritional Foods Ass'n v. Mathews</u>, 557 F.2d 325, 334 (2nd Cir. 1977).) As discussed previously, the "intended use" of fluoridation products is to prevent dental caries (tooth decay) disease. (*Supra* at B 3-4.)

e. The DSHEA further clarifies the intent of Congress that fluorides, which are minerals, that are added to public drinking water to prevent the disease of dental caries, are a drug

Perhaps partly in response to the FDA's refusal to enforce the FFDCA for fluoridated water supplies (*supra* at B 2), Congress adopted the DSHEA in 1994, with explicit statutory language that made fluoride a drug when used with intent to prevent disease. Fluoride, being a

mineral, is a dietary supplement under DSHEA. (21 U.S.C. 321(ff)(1)(B); *infra* at B 42.)

Minerals are normally regulated as foods except when they are drugs. (21 U.S.C. 321(fl)(postscript) ("except for purposes of [21 U.S.C. 321(g)(1) defining drugs] a dietary supplement shall be deemed to be a food;") *infra* at B 43.)

f. Congress did not intend to exempt public water or water additives from the reach of federal drug laws

In 1974, Congress passed the Safe Drinking Water Act ("SDWA"). (88 Stat. 1661; codified at 42 U.S.C. 300f et seq.) The SDWA empowered the EPA to set standards for the control of contaminants in drinking water. (42 U.S.C. 300g-1(b); see In re Groundwater Cases, 154 Cal.App.4th 659, 677 (2007).) The SDWA authorizes EPA to adopt national primary drinking water regulations applicable to "public water systems." (42 U.S.C. 300f(1); see 42 U.S.C. 300f(4)(A).) Under the SDWA, national primary drinking water regulations identify contaminants that have adverse effects on human health and specify a maximum contaminant level ("MCL") for such contaminants. (42 U.S.C. 300f(1).) Pursuant to its authority under the SDWA, the EPA has since established MCLs for a wide variety of contaminants. (See 40 CFR Pt. 141 for substantive regulations, Pt. 142 for implementation regulations, and Pt. 143 for national secondary drinking water regulations that are not enforceable.) The fluoride MCL is 4.0 mg/l (four milligrams per liter equals four parts per million ("ppm")). (40 CFR 141.62(b)(1).)

But there is no SDWA statutory provision or implementing regulation that addresses or sets standards for fluoride water additives.³ (SDWA; 40 CFR Part 141 et seq.) Therefore, there

³ There is a SDWA statutory provision that directs the EPA to keep away from regulating drugs. (42 U.S.C. 300g-1(b)(11) ("No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water."))

is no possible statutory conflict where Congress intended the SDWA to interfere with the FFDCA or FDA authority to regulate drugs. If Congress wanted to exempt public drinking water from the definition of drugs in 21 U.S.C. 321(g)(1)(B) it certainly had the knowledge of how to do it (it had previously exempted "food" from subsection (1)(C)) and it certainly had the opportunity to do it in any one of the more than 20 significant amendments made to the FFDCA since 1980. (*Infra* at B 56-57.) The SDWA did not explicitly or implicitly repeal any drug provision of the FFDCA or any drug authority of the FDA.

g. The 1979 EPA/FDA MOU has been terminated but never did restrict FDA authority over drugs

i. <u>The 1979 MOU</u>

In 1979, EPA and FDA entered into an MOU where FDA agreed not to enforce its food authority over public drinking water in exchange for EPA creating a federal regulatory drinking water additives program. (*supra* at B 32-39.) In the FFDCA, Congress gave FDA authority to regulate foods to ensure they are "safe" (21 U.S.C. 393(b)(2)(A)) and drugs to ensure they are "safe and effective" (21 U.S.C. 393(b)(2)(B)). Normally for drinking water, only food regulations would be applicable and prior to 1979, the FDA generally regulated drinking water as a food. (*Infra* at B 32 and B 37.) But after passage of the SDWA, EPA and FDA were concerned that FDA's "food" authority and EPA's "public drinking water" authority might result in "duplicative and inconsistent regulations" so they entered an MOU. (*Infra* at B 32.) In the MOU, FDA agreed not to use its "food" authority to regulate public drinking water, based on a commitment that EPA would adopt regulations to control additives in public drinking water.

(*Infra* at B 32-33.)

There is no mention in the MOU that FDA would, or could, give up its "drug" authority over public drinking water and public drinking water additives. (Infra at B 32-39.) Congress required "drugs" to be "effective" (21 U.S.C. 393(b)(2)(B)) and Congress never gave EPA authority to regulate drug effectiveness. The MOU inartfully states:

[EPA and FDA] have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes.

(Infra at B 32.) Read in context with the other provisions of the MOU this can only possibly be true with respect to FDA's "food" authority and cannot be true with respect to FDA's "drug" authority. (Infra at B 32-34; See Board of Governors of the Federal Reserve System, 474 U.S. 361, 368, 106 S.Ct. 681, 88 L.Ed.2d 691 (1986) ("agency interpretation" cannot "alter the clearly expressed intent of Congress."))

In a subsequent section, the MOU states:

[EPA and FDA] agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over **drinking water as a "food"** under the [FFDCA].

(*Infra* at B 33; emphasis supplied.) Thus the MOU itself clarifies that the MOU only was intended to address FDA's regulations regarding "food." The MOU also inartfully states:

Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water.

(*Infra* at B 33.) In context of the whole agreement, EPA does not have exclusive jurisdiction when public drinking waters, and public drinking water additives, are "drugs" because Congress has given exclusive jurisdiction over drugs to the FDA. (21 U.S.C. 393(b)(2)(B); FDA v. Brown

& Williamson Tobacco Corp., 529 U.S. 120, 126, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000).)

Congress has clearly defined "drugs" in 21 U.S.C. 321(g)(1). Further EPA claims no authority that would give it jurisdiction over the determination of "effectiveness" of drugs. (*Infra* at B 32-35.)

ii. The 1979 MOU is terminated

In 1988, EPA published in the Federal Register a "Notice" that it was terminating EPA's commitment to FDA to create a federal regulatory drinking water additives program. (53 FR 25586-89; *infra* at B 28-31.) In this 1988 Notice, EPA admits that it "does not currently regulate the levels of additives in drinking water." (*Infra* at B 28.) EPA explained that the "SDWA does not require EPA to control the use of specific additives in drinking water." (*Infra* at B 28.) It states,

Resource constraints and the need to implement mandatory provisions of the SDWA precluded the Agency from implementing the comprehensive program originally envisioned . . .

(Infra at B 29.) The Notice describes how EPA was cooperating with a private third-party organization to have that organization take over the development and monitoring of standards for public drinking water additives and explained that it would be "up to the States and utilities to determine the suitability of any 'third-party' certification." (Infra at B 28-30.) Then it announced that effective April 7, 1990, it would withdraw all EPA and predecessor agency lists of acceptable water additive products and all EPA and predecessor agency advisory opinions on drinking water additives. (Infra at B 31.) EPA stated that "Discontinuance of the additives program at EPA does not relieve the Agency of its statutory responsibilities." (Infra at B 31.)

EPA's Federal Register published Notice that it was terminating its commitment to FDA to create a regulatory federal drinking water additives program was effective notice to FDA that EPA was exercising its option to terminate the MOU. (Supra at B 2-3.) Thus the 1979 MOU was terminated by 1990 and EPA removed the cloud over FDA's "food" jurisdiction regarding public fluoridated water. FDA never lost "drug" jurisdiction over fluoridated water, but its policy, that it would not enforce this jurisdiction, remained in effect from 1952 to 1996. (Supra at B 2-3.)

h. The intent of Congress clearly establishes that water fluoridation products are drugs under the FFDCA

In 1916, the federal Supreme Court concurred that Congress in adopting the 1906 Act directed that food be regulated as a drug when therapeutic (including preventative) effects are intended. (Supra at B 7.) In the 1938 Act, Congress significantly broadened, instead of limited, the definition of drugs. (Compare supra at B 1 and B 7.) In 1948, the federal Supreme Court again concurred "food products" will be "drugs" depending on "labeling." (Supra at B 7.)

In 1952, the FDA stated it would not enforce the FFDCA for fluoride added to public water supplies. (Supra at B 2.) In 1969, the federal Supreme Court ruled that the FFDCA definition of drugs is "as broad as its literal language indicates." (Supra at B 7-8.) In 1994, the Congress again specifically clarified that minerals will be drugs if they fall within the broad definition of drugs. (Supra at B 3-4 and 9-10.) In 1996, the FDA revoked its policy that it would not enforce the FFDCA for fluoride added to public water supplies. (Supra at B 2.)

Every department and agency and court is bound by the intent of Congress as explained by the federal Supreme Court. (Supra at B 8.) Therefore, the FDA should find that water

fluoridation products used in public water systems are drugs under federal law and regulation.

3. Water fluoridation products are federal prescription drugs

Under federal law, if water fluoridation products are federal drugs, they clearly are prescription drugs because of their toxicity and package quantity. For example, sodium fluoride used in water fluoridation typically comes in 50 pound or 25 kilogram bags. (*Infra* at B 50.) The 2009 Drug Topics Red Book show that bulk sodium fluoride in package sizes of 125 grams (about 1/4 pound) and larger is a prescription drug. (*Infra* at B 58 (see lower right corner of page).) The LD₅₀ (median lethal dose) for sodium fluoride based on goats and sheep is 100 mg/kg or 2.7 grams for a 60 pound kid. (*Infra* at B 59.) Bulk fluorosilicic acid comes in tanker truck deliveries. Water fluoridation products are not OTC drugs. (21 CFR Part 355.) Water fluoridation products do not have an approved new drug application or approved abbreviated new drug application. (*Infra* at B 60.) The FDA should conclude that water fluoridation products are federal prescription drugs.

4. FDA should request registration of all water fluoridation products as drugs pursuant to 21 CFR Part 207

It is requested that FDA request registration of all water fluoridation products as drugs pursuant to 21 CFR Part 207. To be used for water fluoridation, products must be certified to meet ANSI/NSF Standard 60. (Supra at B 5.) There are only three organizations that certify products to ANSI/NSF Standard 60 and their web addresses are www.nsf.org/, www.nsf.org/, and www.wqa.org/. Appendix C herein is intended to provide a complete list of water fluoridation products (checkmarked) certified to ANSI/NSF Standard 60 along with the company addresses (marked with vertical lines) and facility identifications (marked with *).

To facilitate determination of the legal drug status of these products, it is requested that FDA request for each fluoridation product an original certificate of analysis and copy of original product labeling (both on the package and from any other literature (electronic, print or otherwise) describing the product and describing the conditions of use that are recommended or suggested) when the product was first marketed along with the year first marketed. Further, it is requested that FDA request a copy of any modification in certificate of analysis or product labeling (again both on the package and from any other literature describing the product and describing the conditions of use that are recommended or suggested) along with the year of the modification.

Because certification to ANSI/NSF Standard 60 began around 1990, it is expected that product labeling was changed around that time to declare certification for all water fluoridation products that were marketed before that time. HHS has proposed a change in the recommended and suggested use of fluoridation products for all locations where the annual average of maximum daily air temperature is below 79.3 degrees. (76 FR 2383-88.) Fluoridation products have not been used following this new recommendation in such locations for a sufficient time to allow a consensus among experts that the products are safe and effective. Therefore approved new drug applications or approved abbreviated new drug applications should be required for all products intended to be marketed in these locations for use at the new dose level of 0.7 ppm fluoride.

Further, the FDA should not find the use of these fluoridation products to be demonstrated to be safe for three reasons. First, the FDA has already recommended that fluoride OTC products should not be swallowed except under professional supervision. (21 CFR Part

355.) The fluoridation products are intended to be swallowed. Warnings are required for OTC products to avoid swallowing by infants and even children under six. (21 CFR 355.50.) Bottled water regulations do not allow a health claim for added fluoride for products marketed to infants. (http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaim s/ucm073602.htm) Second, it has been reasonably established by scientific studies that fluoridated water increases the risk of hip fracture for people 65+ years old. Third, there is scientific consensus that fluoridated water causes dental fluorosis. HHS reported that 41% of people who were 12 to 15 years old in 1999 to 2004 had dental fluorosis with this dental fluorosis being moderate or severe for 3.6% of these people (one in twenty eight people). (76 FR 2385.) Even if water fluoridation is reduced to 0.7 ppm fluoride, these numbers are likely to increase because in 1992 when these people were 0 to 8 years old, only 56% of the people in the United States received fluoridated water. Today a much higher percentage of people get fluoridated water.

It has been repeatedly demonstrated in statistically significant primary studies that artificial water fluoridation is harmful because it increases risk of hip fracture in people 65+ years old. The relevant studies are identified in the York Review (M. McDonagh, P. Whiting, M. Bradley, et al., "A Systematic Review of Water Fluoridation," NHS Centre for Reviews and Dissemination, The University of York, Report 18 (2000) which is available at: http://www.vork.ac.uk/inst/crd/CRD_Reports/crdreport18.pdf).

The York Review is limited to review of human epidemiological studies of water fluoridation (around 1 ppm fluoride). (York Review at page 1 (which is page 16 of the download).) Over 3200 primary studies on water fluoridation from years 1939 to 2000 were

identified of which only eighteen investigated the association of hip fracture with water fluoridation. (*Id.* at page 10 and 48.) These eighteen studies provide a total of thirty analyses (men only, women only, or both in various age groups). (*Id.* at page 10 and 48.) A validity assessment was made for these studies to measure "The degree to which a result is likely to be 'true' and free from bias." (*Id.* at page 48 and 101.)

Of the said thirty analyses, eleven studied the effect of water fluoridation on hip fracture for people 65+ years old. (*Id.* at page 48.) Only four of these eleven studies produced statistically significant results according to the York Review. (*Id.*; see the definitions of "Relative Risk" and "Statistical significance" in the York Review at pages 99-100 (pages 114-15 in the download).) These four studies all find increased risk of hip fracture for people 65+ years old with water fluoridation. The York Review found no statistically significant studies published between years 1939 and 2000 that did not find increased risk of hip fracture for people 65+ years old with water fluoridation.

Explaining the above observations in more detail, I note that the York Review at page 48 presents the Relative Risk ("RR") and the 95% Confidence Interval ("95% CI") in Table 8.1. If a study has a RR of 1 inside the 95% CI, the study is not statistically significant to demonstrate more or less harm from water fluoridation. (York Review at 99-100.) In other words, a study with a RR of 1 inside the 95% CI should not be relied upon to demonstrate increased or decreased harm. A RR greater than 1 throughout the 95% CI is statistically significant proof that fluoridated water causes greater harm. *Id*.

Because all four of the statistically significant studies show increased risk of hip fracture for people 65+ years old, HHS and FDA should conclude that water fluoridation is not safe for

people 65+ years old.

For the record, the four relevant studies are identified in said Table 8.1 as Jacqmin-Gadda (1998), Danielson (1992), Jacobsen (women) (1992) and Jacobsen (men) (1992). The Jacqmin-Gadda (1998) study had the highest validity score and is therefore most "likely to be 'true' and free from bias" of the said four studies. Jacqmin-Gadda (1998) projects that it is most likely that there are two and one half times more such hip fractures with fluoridated water compared to without fluoridated water. (York Review at page 48 (page 63 of 125 in the download).) While the other three identified studies project lower rates of increase of such hip fractures, these other three studies have significantly lower "validity scores" reported in said Table 8.1.

It is reported "that approximately 50 percent of the fluoride ingested each day accumulates in bones." (P. Connett, J. Beck, and H.S. Micklem, The Case Against Fluoride - How Hazardous Waste Ended Up in Our Drinking Water and the Bad Science and Powerful Politics That Keep It There (White River Junction, VT: Chelsea Green Publishing Company, 2010) ("Connett (2010)") at page 172.) Fluoride "enters bone compartment easily, correlating with bone cell activity; . . . but then it leaves the bone compartment slowly . . . the whole body half life, once in the bone, is approximately 20 years . . ." (NRC, Fluoride in Drinking Water - A Scientific Review of EPA's Standards (Washington D.C.; The National Academies Press, 2006) at page 108.) Therefore knowing that people 65+ years old have an increased incidence of hip fracture caused by water fluoridation (as the statistically significant studies in the York Review repeatedly demonstrate) one would expect it likely that the longer people 65+ years old have drunk fluoridated water both before and after they are 65 years old, or the more fluoride they

have retained in their bones, the greater their increased risk of hip fracture would be. This might also be a factor that helps to explain the different magnitudes of increased risk projected by the said four studies.

The people with increased risk of hip fracture from excessive fluoride accumulation in their bones are exposed not only to this bio-accumulative element in their drinking water but to multiple other sources of fluoride as pointed out most recently (January, 2010) in a publication by EPA, "Relative Resource Analysis." The bones do not differentiate sources of fluoride, they just continue to store whatever comes along. Levels may reach 10,000 ppm and then skeletal fluorosis becomes a recognized diagnosis.

The outer sheath of bones is called the cortical bone. (Connett (2010) at page 17.) "The cortical bone is critical for protection against breakage when the bone is exposed to a heavy blow or torsional stress." (*Id.*) As reported in Connett (2010) at page 17 (citations omitted):

One of the earliest trials of fluoridation (Newburgh, New York, versus Kingston, New York, 1945-1955) found approximately twice as many cortical bone defects in the fluoridated city, Newburgh, compared with Kingston, the unfluoridated city. The fact that the defects occurred in the cortical part of the bone is significant for the potential for fractures.

Hip fracture for people 65+ years old is a significant health impact in the United States.

"About 300,000 Americans are hospitalized for a hip fracture every year." (Connett (2010) at page 173.) The Irish Forum (2002) (Forum on Fluoridation (Dublin, Ireland: Stationery Office, 2002) at 121 online at http://fluoridealert.org/re/fluoridation.forum.2002.pdf found that "Fracture of the hip is a major cause of morbidity and mortality [disease and death] in persons 65 years of age and older."

Aside from the fact that one in five patients die within 6 months of the fracture occurring, hip fractures lead to serious disability. Many basic functions such as dressing, climbing stairs, walking and transferring are markedly interfered with following a fracture. This can result in loss of both confidence and independence and an increased risk of development of medical complications.

(Irish Forum (2002) at 121.)

The York Review at page xiv (page 15 of 125 in the download) states in its Conclusions that it "presents a summary of the best available and most reliable evidence on the safety and efficacy of water fluoridation," but it also concludes "little high quality research has been undertaken." Besides finding the harm from dental fluorosis that is already recognized by HHS, these Conclusions in the York Review find "the research is of insufficient quality to allow confident statements about other potential harms." (York Review at page xiv.) In other words, the comprehensive York Review has found that the evidence available in year 2000 (after 55 years of water fluoridation) may not be used to make a confident statement that standard water fluoridation is safe from the other potential harms explored by the York Review.

The other potential harms explored by the York Review include other bone fractures, cancer, Down's syndrome, mortality, senile dementia, goitre, lowered IQ, hypersensitivity, and skeletal fluorosis. (York Review at 52, 54, 59-60.) The York Review concludes that no "confident statements" can be made regarding these "potential harms." (York Review at page xiv.) In its review of other bone fractures in Table 8.2 on page 49 of the York Review, only one study (Karagas (1996)) reports a statistically significant result and that result demonstrates increased risk of humerus fractures for men 65+ years old with fluoridated water.

Regarding cancer, an unrefuted published primary study, Bassin (2006) (Bassin E. B. et

al., "Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma (United States)," Cancer Causes and Control 17, no. 4 (May 2006) 421-28) reports that boys who drink fluoridated water when they are 6 to 8 years old will have a five- to sevenfold greater risk of contracting osteosarcoma (bone cancer) by the age of twenty. This is a deadly disease. This result was first suggested by Perry Cohn in 1992. (See Connett (2010) at pages 187-94.) The twofold increase in cortical bone defects in the fluoridated city in the Kingston-Newburgh study (supra at B 20.) was described in 1955 and again in 1977 as being "strikingly similar to that of osteogenic sarcoma [now called osteosarcoma]." (See Connett (2010) at page 181-94.)

In summary, FDA should determine that water fluoridation products are drugs and prescription drugs regulated by CDER. Given that approximately 75% of the people in the United States are being given this drug, and that the dose for the drug is now recommended by HHS to be reduced to 0.7 ppm, FDA should require approved new drug applications or approved abbreviated new drug applications for all water fluoridation products because of the change in dose. FDA should give notice that these products cannot continue to be sold without such approved new drug applications.

customs Form 4449 showing the name of the sirport, date and time of arrival, date and time of departure and purpose of the visit. The permit shall be surrendered to the collector of customs at the of final clearance for a foreign destimelon, who shall satisfy himself prior to the issuance of clearance that the air-craft received proper customs treatment

craft received proper customs treatment while in this country. The permit shall then it returned to the collector of customs a the port of issue.

(2) A copy of the permit shall be retained by the collector at the port where issued. If within 60 days after the issuence of such permit the said collector does not eccive a report of the outward clearance of the aircraft covered thereby, the matter shall be reported to the supervising customs agent for investigation.

gation.

(3) Civil aircraft registered in the United States arriving from a foreign country with passengers carried for hire or merchandise, after proper customs treatment of their cargo (passengers carried for him or merchandise), may be allowed to proceed upon their identity being established.

This order shall become effective on the date of its publication in the Federal REGISTER.

(R. S. 161, sec. 23, 2 Stat. 892, as amended. sec. 24, 43 Stat. 160, 2. S. 261, secs. 624. 644. 46 Stat. 759, 761, sec. 201, 387, 56 Stat. 683, 706, sec. 7, 44 Stat. 571, as amended; 5 U. S. C. 22, 8 U. S. C. 102, 232, 5 U. S. C. 66, 1624, 1644, 42 U. S. C. 202, 270, 49 U. S. C. 177)

Iseall D. I. Etrublinger,
Acting Commissioner of Customs.
Johl S. Graham,
Acting Secretary of the Treasury.
W. P. Dearing,
Acting Surgeon General,
U. S. Public Health Service.
John I. Thurston,
Acting Federal Security Administrator.
Philip B. Perlman,
Acting Attorney General.

JULY 17, 1952,

[F. R. Doc. 52-4054; File. July 22, 1952; 8:55 a. m.

[T. D. 63048]

PART 10-ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED FATE, ETC.

SUPPLIES FOR VESSELS

The Department of State has furnished the Treasury Department an upto-date list of countries which permit the withdrawal of supplies free of duty and tax by vessels of war of the United States while in ports of those countries. Therefore, § 10.59 (d), Custom: Regulations of 1943 (19 CFR 10.59 (U)), containing a list of counfries whose vessels of war shall be accorded the privilege of withdrawing supplies free of cistoms duties and internal-revenue tax while in ports of the United States, as provided for in section 309 (a), Tariff Act of 1930, as amended, is further amended to head as follows:

§ 10.59 Exemption from customs daties and internal revenue tax. •

(d) The privilege shall be accorded to vestels of war of the following countrie

Argent Austral Belgium Brazil. Canada. Chile. Colombia, Cuba. Denmark. The Dominican Re public. Ethiopia.

Finland.

Trance.

Heiti.

India.

Traland. Mexico. The Netherlands. New Zealand. Nicaragus. Norway. Panama. The Philippines. El Salvador. Spáin. Aweden. Thailand. urkev. pion of South Afortinay. Vene

(Sec. 5, 52 Stat. 1080; 19 V. S. 13091

[SEAL]

Great Britain.

PRANT DOW. Commissioner of C stoms.

Approved: July 16, 1952.

JOHN S. GRAHAM. Acting Secretary of the Treas

[F. R. Doc. 52-8025; Filed, July 22, 19] 8:48 a. m.)

TITLE 21—FOOD AND DRUGS

Chapter I-Food and Drug Administration, Federal Security Agency

PART 8-STATEMENTS OF GENERAL POLICY OR INTERPRETATION

FLUORIDATED WATER AND PROCESSED FOODS CONTAINING FLUORIDATED WATER

Pursuant to section 3 of the Administrative Procedure Act (50 Stat. 237, 238; 5 U.S. C. 1002), the following statement of policy is issued:

§ 3.27 Status of fluoridated water and foods prepared with fluoridated water under the Federal Food, Drug, and Cosmetic Act. (a) The program for fluoridation of public water supplies recommended by the Federal Security Agency, through the Public Health Service, contemplates the controlled addition of fluorine at a level optimum for the prevention of dental caries.

(b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. Nevertheless, a substantial number of inquiries have been received concerning the status of such water under the provisions of the act and the status, in interstate commerce, of commercially prepared foods in which fluoridated water has been used.

(c) The Federal Security Agency will regard water supplies containing fluorine, within the limitations recommended by the Public Health Service, as not actionable under the Federal Food, Drug. and Cosmetic Act. Similarly, commercially prepared foods within the jurisdiction of the act, in which a fluoridated water supply has been used in the processing operation, will not be regarded as actionable under the Federal law because of the fluorine content of the water so used, unless the process involves a significant concentration of fluorine from the water. In the latter instance the

facts with respect to the particular care will be controlling.

(Sec. 701, 52 Stat. 1055; 21 U. S. C. 371)

Dated: July 17, 1952.

JOHN L. THURSTON, [SEAL] Acting Administrator.

[F. R. Doc. 52-8041; Filed, July 22, 1962; 8:80 a. m.l

TITLE 26---INTERNAL REVENUE Chapter I-Bureau of Internat Revende, Department of the Treasury

opter C--Miscellaneous Exclus Taxas Subd 1T. D. 5920; Regs. 192]

Excise and Special Tax on PART 37 WAGERING

RECIST Y, RETURN AND PAYMENT OF TAX

Regulations 132 amended to require persons it ble for special (occupational)

persons I ble for special (occupational) wagering ax to file returns and pay tax hefore con mencing taxable activity and to file supplemental returns advising of all agents or employees engaged to receive wagers or with respect to all persons for whom wagers are received.

On June 3, 1952, notice of proposed rule making legarding amendment of \$22.50 of Regulations 132 was published in the Fromal Reguster (17 F. R. 4988). No objection to the rules proposed having been received, \$325.50 of Regulations 132 is amended to read as follows: follows:

follows:

§ 325.60 Register, return, and payment of tax. (a) No person shall engage in the business of a cepting wagers subject to the 10 percent excise tax imposed by section 32.5 of the Internal Revenue Code (see § 25.24) until he has filed a return on Form 11-C and paid the special tax imposed by section 3290. Ideewise, no person shall engage in receiving wagers for or on behalf of any person engaged in such business until he has filed a return on Form 11-C and paid the special tax imposed by section 3290 of the Internal Revenue Code. Filing of successive applications and payment of tax by such person are required on or hefore July 1 of each year thereafter during which taxable activity continues. The return, with remittance, shall be filed with the collector of internal revenue for the district in which is located the taxpayer's once or principal place of business. If such taxpayer resides in the United States, but has no office or principal place of business in the United States, but payer resides in the United States, but has no office or principal place of business in the United States, the return shall be filed with the collector of internal revenue for the district in which he resides. If the taxpayer has no office, residence, or principal place of husiness in the Indian. in the United States, the return shall be filed with the Collector of Internal Royenus, Baltimore, Maryland. The collec-tor, upon request, will furnish the taxpayer proper forms which shall be filled out and signed as indicated thousin, (b) Each return shall show the tax-

payer's full name. A person doing busi-ness under an alias, style, or trade name shall give his true name, followed by his allas, style, or trade name. In the case of a partnership, association, firm, Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMIN-ISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 9]

SUBCHAPTER C-DRUGS: GENERAL

Reorganization and Republication

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and af-fected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federai Regulations.

This is the ninth document in a series of recodification documents that will eventually include all regulations ad-ministered by the Food and Drug Ad-

ministration.

This recodification document represents a reorganization of material remaining in Subchapter C-Drugs that has general applicability, rather than strictly human or animal use. In addition certain related sections under Parts I and 3 have been redesignated as part of the ravised Subchapter C-Drugs:

The following table shows the relationship of the CFR section numbers under the former Subchapters A and C to their redesignation reflected in the new Parts

200 through 209:

Old	New	Old	New
Scation	Section	Section	Section
1.100	299.6	3,21	
1.101		3,22	
1.101a		3.27	
1.102		3.28	
1.108B		3.29	
1,102b		9.90	
1.102c	201.61	. 3'82	
1.102d		3.36	
1.103		3,37	
1.104		3.40	
	. 202.5 . 201.6	3.44	
1.108(b)		3.45	
	201.105	3.48	
	201.109	8.50	
	201.110	3,52	
	201115	3.63	
	201.118	3.66	
	201.117	3.61	
1.108(j)		3.62	
	201.120	3.63	
1.108(1)	201,122	3.64	
1.108(m)		3.67	201,305
1.100(n)		3.71	250,100
1.108(a)		3.74	
1.107	201,150	3.76	200,10
(a)801.1		3,77	
& (b)		3,81	
1.108(c)		3.84	
1.109		350	
1.110		3.91	
1.118		3.94	
3,3		3.95	250.110
3.4		3.501	
3.7		3.502	
3.8		3.503	
311		3.505	
3.12 =		3.500	
3,15		3.507	201,17
316	. 200100	3.508	201,18

Old	New	ola	New
Section	Section	Section	Section.
3.509		133.11	211.58
3.610	201.315	133,12	211.110
3.512	200.31	133.13	21.1.60
3.513		139.14	211.62
3.514		133,15	211.115
3,515	201.160	183.100	225.1
3,516	250,105	133.101	
3.518	201.161	133.102	225.30
132.1	207.3	193.103	
132.2	207.20	183.104	
132.3	207.21		225.102
182.4	207.22	`183.106	
132.5			225.80
132.6			226.58
132.7			228-110
132.8	_ 207.25		225.115
. 132,9	207.37	133.200	
132,10			225.20
132.11			228.30
132.31	_ 207.40		226.10
132.61			226.43
133.1	210.3		226.102
183,2	_ 211.1		226.40
138.3	_ 211.20		226.80
133.4			226.58
133.5			228.110 228.116
133.6 139.7			229,25
133.8	211.101	138.1	
133.9	211.10 211 K5	138 9	299,20
138.10	211 00		
VOD: YO			

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 200, 201, 202, 207, 210, 211, 225, 226, 229, 250, 290, and 299 of Subchapter C is set forth below.

Dated: March 21, 1975.

SAM D. PINE, Associate Commissioner for Compliance.

Therefore, 21 CFR is amended by relesignating portions of Parts 1 and 3 of Subchapter A and Parts 132, 133, and 138 of Subchapter C as Parts 200, 201, 202, 207, 210, 211, 225, 226, 229, 250, 290, and 299 of Subchapter C-Drugs: General, and republished to read as follows:

SUBCHAPTER C-DRUGS: GENERAL

Part

200-General

201-Labeling

202-Prescription Drug Advertising

207—Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

210—Current Good Manufacturing Practices in Manufacturing, Processing, Pack-ing, or Holding of Drugs: General

211-Outtent Good Manufacturing Practice for Finished Pharmaceuticals

225 Current Good Manufacturing Practice for Medicated Feeds

226—Current Good Manufacturing Practice for Medicated Premixes

Ourrent Good Manufacturing Practice for Certain Other Drug Products

250-Special Requirements for Specific Human Drugs

290-Controlled Drugs

299—Drugs; Official Names and Established Names

PART 200-GENERAL Subpart A.—General Provisions

Bec.	
200.6	Mailing of important information about drugs.
200.7	supplying pharmacists with indi- cations and desage information,
200.10	Contract facilities (including con- sulting laboratories) utilized as extraminal facilities by pharma- contical manufactures.
200,11	Use of octadecylamine in steam lines of drug establishments.
200.15	Definition of term "insulin."
200,18	Use of secondhand containers for the shipmont or storage of food and animal feed.
Subper	t B-Maguineturing Procedures Affecting

New Drug Status

200.30 Starilization of drugs by bradia-

200.31 Timed release desage forms.

-Requirements for Specific Classes of Drugs

200.50 Ophthalmic preparations and disponseza,

Subport D-Sultability of Specific Drug Components

200,100 Use of ox bile from condemned livers from slaughtered enimals in the manufacture of drugs.

200,101 Suprarenal glands from hog car-casses prior to final inspection.

AUTHORITY: Sec. 701, 52 Stat. 1056; 21 U.S.C. 371, unless otherwise noted.

Subpart A-General Provisions

§ 200.5 Mailing of important informa-tion about drugs.

Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail should be distinctive in appearance so that it will be promptly recognized and read. The Food and Drug Administration will make such mailings in accordance with the specifications set forth in this section. Manufacturers and distributors of drugs are asked to make such mailings as prescribed by this section and not to use the distinctive envelopes for ordinary

(a) Use first class mail and No. 10 white envelopes.

(b) The name and address of the agency or the drug manufacturer or distributor is to appear in the upper left corner of the envelops.

(c) The following statements are to appear in the far left third of the envelope front, in the type and size indicated, centered in a rectangular space approximately 3 inches wide and 2% inches high with an approximately %inch-wide border in the color indicated:

(1) When the information concerns a significant hazard to health, the statement:

IMPORTANT DRUG WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 38 point Gothic Bold type, "Drug" and "Warning" shall be in 38 point Gothic Condensed type, The rectangle's

Food and Drugs

21

PARTS 200 TO 299
Revised as of April 1, 1995

CONTAINING A CODIFICATION OF DOCUMENTS OF GENERAL APPLICABILITY AND FUTURE EFFECT

AS OF APRIL 1, 1995

With Ancillaries

Published by the Office of the Federal Register National Archives and Records Administration

as a Special Edition of the Federal Register ing of section 503(b) of the Federal Food, Drug, and Cosmetic Act unless it is lateled with the legend "Caution— Federal law prohibits dispensing without pre-cription."

- (e) Any drug for oral ingestion intended, appresented, or advertised for the prevention or treatment of pernicious anomia or which purports to contain any substance or mixture of substances isscribed in paragraph (d) of this section (other than diagnostic drugs containing radioactive cyanocobalanin) will be regarded as misbranded under sections 502(f)(2) and (i) of the act unless its labeling bears a statement to the effect that some patients afflicted with pernicious anemia may not respond to the orally ingested product and that there is no known way to predict which patients will respond or which patients may cease to respond to the drally ingested products. The labeling shall also bear a statement that policide examinations and laboratory stilles of pernicious anemia patients are essential and recommended.
- ommended.

 (f) Under section 40a of the Federal Food, Drug, and Cosmetic Act, intrinsic factor and intrinsic factor concentrate are regarded as good additives. No food additive regulation nor existing extension of the effective date of section 409 of the act authorizes these additives in foods, including foods for special dietary uses. Any food containing added intrinsic factor or intrinsic factor concentrate will be regarded as adulterated within the meaning of section 402(a)(2)(C) of the act.
- (g) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the act contrary to the provisions of this policy statement after the 180th day following publication of this statement in the FEDERAL REGISTER.

§ 250.203 Status of fluoridated water and foods prepared with fluoridated water.

(a) The program for fluoridation of public water supplies recommended by the Department of Health and Human Services, through the Public Health Service (Centers for Disease Control), contemplates the controlled addition

of fluorine at a level optimum for the prevention of dental carles.

(b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. Nevertheless, a substantial number of inquiries have been received concerning the status of such water under the provisions of the act and the status, in interstate commerce, of commercially prepared foods in which fluoridated water has been used.

(c) The Department of Health and Human Services will regard water supplies containing fluorine, within the limitations recommended by the Environmental Protection Agency, as not actionable under the Federal Food, Drug, and Cosmetic Act. Similarly. commercially prepared foods within the jurisdiction of the act, in which a fluoridated water supply has been used in the processing operation, will not be regarded as actionable under the Federal law because of the fluorine content of the water so used, unless the process involves a significant concentration of fluorine from the water. In the latter instance the facts with respect to the particular case will be controlling.

[40 FR 14033, Mar. 27, 1975, as amended at 48 FR 11428, Mar. 18, 1983]

Subpart D—Requirements for Drugs and Cosmetics

§ 250.260 Hexachlorophene, as a compotent of drug and cosmetic products.

(a) Antipacterial component. The use of hexachloraphene as an antibacterial component in drug and cosmetic products has expanded widely in recent years. It is used in such products be-cause of its bacteriostatic action against gram-positive organisms, especially against straigs of staphylococcus; however, hexactlorophene offers no protection against gram-negative infections. In addition the anti-bacterial activity depends largely on repeated use. A notice published in the PEDERAL REGISTER of April 4, 1972 (37 FR 6775), invited data of OTC antimicrobial ingredients, including hexachlorophene, for review by an Drug Advisory Review Panel to be convened under the procedures set forth the FEDERAL REGISTER of May 11, 1972



List of substances	Limitations
Monochlorobenzene Monochlorobenz- ene.	Not to exceed 500 parts per million as residual solvent in finished basic resin in para- graph (a)(1) of this section.
N-methyl-2- pyrrolidone.	Not to exceed 0.01 per- cent (100 parts per million) as residual solvent in finished basic resin in para- graph (a)(2) of this section.

Dated: May 17, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-14697 Filed 6-10-96; 8:45 am] BILLING CODE 4169-01-F

Food and Drug Administration

21 CFR Parts 200, 250, and 310 [Docket No. 95N-0310]

Revocation of Obsolete Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug
Administration (FDA) is revoking
certain regulations that are obsolete or
are no longer necessary to achieve
public health goals. These regulations
were among those identified for
revocation in a page-hy-page review
conducted in response to the
Administration's "Reinventing
Government" initiative, which seeks to
streamline government to ease the
burden on regulated industry and
consumers.

EFFECTIVE DATE: July 11, 1996.
FOR FURTHER INFORMATION CONTACT:
Christine F. Rogers, Center for Drug
Evaluation and Research (HFD-7), Food
and Drug Administration, 7500 Standish
Pl., Rockville, MD 20855, 301-5942041.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 13, 1995 (60 FR 53480), FDA published a proposed rule to revoke certain regulations. This was done in response to the President's order to all Federal agencies to conduct a page-by-page review of all their regulations and to

"eliminate or revise those that are outdated or otherwise in need of reform." The proposed rule contained a section-by-section analysis of all the regulations (21 CFR parts 100, 101, et al.) that FDA intended to revoke. This final rule pertains only to those regulations (21 CFR parts 200, 250, and 310) pertaining exclusively to the Center for Drug Evaluation and Research. No comments were received in response to the proposal to revoke these regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 98-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule, which is the revocation of certain regulations that are obsolete or are no longer necessary, is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order,

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule is the revocation of certain regulations that are obsolete or are no longer necessary, the agency is not aware of any adverse impact this final rule will have on any small entities, and the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 250

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 200, 250, and 310 are amended as follows:

PART 200---GENERAL

 The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

Sections 200.100 and 200.101 are removed and the heading for subpart D is reserved.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.104 [Removed]

4. Section 250,104 Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act is removed.

§ 250.203 [Removed]

5. Section 250.203 Status of fluoridated water and foods prepared with fluoridated water is removed.

PART 310—NEW DRUGS

The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 508, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360J, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

§310.101 [Removed]

7. Section 310.101 FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy is removed.

ENVIRONMENTAL PROTECTION AGENCY

[OW-FRL-3410-1]

Orinking Water Technical Assistance; Termination of the Federal Drinking Water Additives Program

AGENCY: Environmental Protection Agency (EPA). ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of Drinking Water (ODW), has operated an advisory program that gives technical assistance to concerned parties on the use of drinking water additives. On May 17, 1984, EPA proposed to terminate major elements of this Federal program and to assist in the establishment of a privatesector program which would offer assistance in evaluating drinking water additives. 49 FR 21004. EPA solicited proposals from qualified nongovernmental, nonprofit organizations for assistance under a cooperative agreement to establish a credible and efficient program in the private sector.

On September 17, 1985, EPA selected a consortium consisting of the National Sanitation Foundation (NSF), the American Water Works Association Research Foundation (AWWARF), the Conference of State Health and Environmental Managers (COSHEM), and the Association of State Drinking Water Administrators (ASDWA) to receive funds under a cooperative agreement to develop the private-sector program. EPA believes that the NSP-led program has proceeded satisfactorily. NSF Standard 60, covering many direct additives, was adopted on December 7, 1987; and NSF Standard 61, covering indirect additives, was adopted on June 3, 1988. Other stendards are forthcoming. The NSF-led program has begun offering testing, certification, and listing services, as described in 49 FR 21004, for certain classes of products covered by these standards. Accordingly, as the NSF-led program becomes operational, EPA will phase out its activities in this area, as described in this notice.

DATE: Any written comments on implementing this notice should be submitted to the address below by September 6, 1988.

ADDRESSES: Submit comments to: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW.. Washington, DC 20460. A copy of all comments will be available for review

during normal business hours at the U.S. **Environmental Protection Agency.** Criteria and Standards Division, Science and Technology Branch, Room 931ET, 401 M Street, SW., Washington, DC 20460. For further information on the NSF-led private-sector program, including standards development and testing, certification, and listing services, contact: Director, Drinking Water Additives Program, National Sanitation Foundation, P.O. Box 1488. Ann Arbor, MI 48106; or call (313) 789-8010. For information on alternative testing, certification, and listing programs, contact individual State regulatory authorities or the American Water Works Association, Technical and Professional Department, 6866 Onincy Avenue, Denver CO, 80235, or call (303) 794-7711. For information on the directory of products certified as meeting the criteria in a NSF standard. contact the American Water Works Association Research Foundation, 6666 Quincy Avenue, Denver CO, 80235, or call (303) 794-7711.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, or call (202) 362–2022.

L Introduction

The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f et seq.) provides for enhancement of the safety of public drinking water supplies through the establishment and enforcement of national drinking water regulations. The Environmental Protection Agency (EPA) has the primary responsibility for establishing the regulations, and the States have the primary responsibility for enforcing such regulations. The regulations control contaminants in drinking water which may have any adverse effect on public health. Section 1412, 42 U.S.C. 300g-1. The regulations include maximum contaminant levels (MCLs) or treatment techniques and monitoring requirements for these contaminants. Sections 1401 and 1412; 42 U.S.C. 300f and 300g-1. EPA also promulgates monitoring requirements for unregulated contaminants. Section 1445; 42 U.S.C. 300j-4. In addition, RPA has broad authorities to provide technical assistance and financial assistance (e.g., grants, cooperative agreements) to States and to conduct research. Sections 1442, 1443, 1444; 42 U.S.C. 300j-1, 300j-2, 300j-3.

The Agency has established MCLs for a number of harmful contaminants that occur naturally or pollute public drinking water supplies. In addition to such contaminants, there is a possibility that drinking water supplies may be contaminated by compounds "added" to drinking water, either directly or indirectly, in the course of treatment and transport of drinking water. Public water avatems use a broad range of chemical products to treat water supplies and to maintain storage and distribution systems. For instance, systems may directly add chemicals such as chlorine, alum, lime, and coagulant aids in the process of treating water to make it enitable for public consumption. These are known as "direct additives." In addition, as a necessary function of maintaining a public water system. storage and distribution systems (including pipes, tanks, and other equipment) may be fabricated from or painted, coated, or treated with products which may leach into or otherwise enter the water. These products are known as "indirect additives." Except to the extent that direct or indirect additives consist of ingredients or contain contaminants for which EPA has promulgated MCLs, EPA does not currently regulate the levels of additives in drinking water.

In 1979, EPA executed a Memorandum of Understanding (MOU) with the U.S. Food and Drug Administration (FDA) to establish and clarify areas of authorities with respect to control of additives in drinking water, 44 FR 42775, July 20, 1979. FDA is authorized to regulate "food additives" pursuant to the Federal Food, Drug, and Coametic Act (FFDCA). (21 U.S.C. 301 et seq.). Both agencies acknowledged in the MOU that "passage of the SDWA in 1974 repealed FDA's authority under the FFDCA over water used for drinking water purposes." The MOU stated that FDA would continue to have authority for taking regulatory action under the FFDCA to control additives in bottled drinking water and in water used in food and for food processing. The MOU went on to say that EPA had authority to control additives in public drinking water supplies.

While the SDWA does not require EPA to control the use of specific additives in drinking water, EPA has provided technical assistance to States and public water systems on the use of additives through the issuance of advisory opinions on the acceptability of many additive products. EPA has provided this technical assistance pursuant to its discretionary authority in section 1442(b)[1] to "collect and make available information pertaining to research, investigations and demonstrations with respect to

providing a dependable safe supply of drinking water together with appropriate recommendations in connection therewith." EPA has additional authorities under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 et seq.) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) that could be used to control additives in drinking water. TSCA authorizes EPA to regulate a new chemical substance before it is manufactured or any existing chemical substance before it is manufactured or processed for a use that EPA has determined to be a "significant new use." Although an additive product might come within the jurisdiction of TSCA, EPA has never invoked this authority. EPA has used its authority under FIFRA to control the use of pesticides, disinfectants, and certain other additives. For a more complete discussion of these authorities, see the MOU. 44 FR 42776.

In 1980, EPA declared a moratorium on the issuance of new advisory opinions on additives pending a review of past advisory opinions and the establishment of uniform test protocols and decision criteria. However, between 1980 and 1984, EPA continued to issue advisory opinions in cases where the new additive products were virtually identical to products previously reviewed. Resource constraints and the need to implement mandatory provisions of the SDWA precluded the Agency from implementing the comprehensive program originally envisioned for the issuance of additives advisory opinions. Thus, the Agency was not able to review the technical data supporting previous submissions (approximately 2,300 products from 525 manufacturers) nor was it able to develop test protocols or decision criteria for the consistent evaluation of new products. The result has been long delays in processing manufacturer petitions, inability to review and accept completely new products, and acceptance of products simply because they were virtually identical to older products. Hence, few products have been thoroughly evaluated for the safety of their formulations based on the latest scientific information.

Recognizing the need for continuing technical assistance in evaluating additive products and for providing advice to States and public water systems on the toxicological aspects of additive products, the Agency proposed to terminate its attempts to institute a formal advisory program, and to solicit proposals from nongovernmental, nonprofit organizations to establish such

a program in the private sector. The Agency believed that the proposal to assist in the establishment of a private-sector program was consistent with, and would best serve the goals of, the SDWA.

On May 17, 1984, EPA formally announced its intention to transfer the program to the private sector, which would function as to many other voluntary product-standard programs. 49 FR 21004. This was accomplished by requesting proposals from qualified organizations or consortia of organizations for the competitive award of a cooperative agreement designed to provide incentive for the establishment of a private-sector program. The 1984 notice stated that:

- EPA expected the activity to be selfsupporting.
- EPA would maintain an active interest in the development of the program, without assuming responsibility for or directing its approach.
- EPA would continue to establish regulations under the SDWA, FIFRA, and/or TSCA, as needed, for chemicals in treated, distributed drinking water that may originate as additives.
- Establishment of such a program would be consistent with the Administration's initiatives in the area of regulatory reform and offered an opportunity for an innovative alternative to regulation.

The May 1984 notice requested public comments on the proposal and solicited applications from qualified nongovernmental, nonprofit organizations for partial funding of the developmental phase of the program under a cooperative agreement. The response to the solicitation for comments indicated strong public support for the proposed approach. EPA received 108 public comments on the proposal. All but six supported this "third-party" approach. However, despite the Agency's open competition, EPA received only one application for financial assistance. The applicant was a consortium, led by the National Sanitation Foundation, which included the American Water Works Association Research Foundation, the Conference of State Health and Environmental Managers, and the Association of State Drinking Water Administrators. This single proposal met all of the basic criteria articulated in the May 1984 notice. Furthermore, EPA believed that the single applicant was very likely to succeed, because it represented an organization experienced in privatesector consensus standard-setting, State regulators, and water utilities.

EPA awarded the cooperative agreement to the NSF consortium on September 17, 1985, and committed funding of \$185,000 to NSF over a three-year period. The non-Federal (consortium and participating industry) contribution during the first three years of the program was projected to be approximately \$1.4 million.

The NSF program has the following major objectives:

- To develop systematic, consistent, and comprehensive voluntary consensus standards for public health safety evaluation of all products (previously EPA-accepted as well as new) intended for use in drinking water systems.
- To obtain broad-based participation in the standard-satting program from industry. States, and utilities.
- To provide for regular periodic review, update, and revision of the standards.
- To undertake needed research, testing, evaluation, and inspections and to provide the followup necessary to maintain the program.
- To establish a separate program for testing, evaluation, certification, and listing of additive products.
- To widely disseminate information about the program, and to make information about conforming products available to users.
- To maintain the confidentiality of all proprietary information.
- To fully establish the third-party program on a self-supporting basis.

NSF's established standard-setting process utilizes a tiered structure. Each standard is drafted by a task group and then presented to a Joint Committee, which includes 12 industry, 12 user, and 12 regulatory members. Following successful Joint Committee balloting, standards are reviewed by the Council of Public Health Consultants, which is a high level advisory group consisting of technical and policy experts from regulatory agencies and academia.

NSF has established task groups to develop standards for the product categories listed below. Each task group includes a member representing the regulatory agencies and a member representing the utilities. All manufacturers expressing interest in a particular product task group may participate as members of that group. Therefore, task group mambership is predominately manufacturers. In addition, a group of health effects consultants is addressing the toxicological and risk considerations for various product categories. NSF's role in the standard-setting process is administrative, that is, to bring together experts from government, industry,

utilities, users, and other relevant groups so that a standard which reflects a consensus of these interests can be developed. In addition, NSF staff provide technical leadership and laboratory support. Product categories and correspoding task groups are:

Protective Materials.

 Chemicals for Corrosion and Scale Control, Softening, Precipitation, Sequestering, and pH Adjustment.

Coagulation and Flocculation

Chemicals.

Miscellaneous Treatment

Chemicals.

Joining and Sealing materials.

Process Media.

- Pipes and Related Products.
- Disinfection and Oxidation Chamicals.

Mechanical Devices.

All of the task groups have made satisfactory progress during the term of the cooperative agreement. In addition, the health effects consultants have endorsed the bases of the standards. Standards have been drafted for all product categories, and final standards were published and implemented as follows:

Standard 60, December 1987

 Chemicals for Corrosion and Scale Control, Softening. Precipitation.
 Sequestering, and pH Adjustment.

 Disinfection and Oxidation Chemicals.

 Miscellaneous Treatment Chemicals (selected).

Standard 61. June 1988

· Process Media.

Development of the remaining standards is on schedule, and publication and implementation are expected on the following schedule:

Standards 60 and 61, expected October 1988

Protective Materials.

- Coagulation and Flocculation Chemicals.
- Miscellaneous Treatment Chemicals (additional).
 - Joining and Sealing Materials.
 - Pipes and Related Products.

Mechanical Devices.

EPA believes that the NSF program is successfully pursuing all of its objectives. Furthermore, the program is strongly supported by user and regulatory sectors. AWWARP, COSHEM, ASDWA, the Great Lakes Upper Mississippi River Board, the American Water Works Association (AWWA) (including the Utilities and Standards Councils and the Regulatory Agencies Division), and the Association of Metropolitan Water Agencies, among

others, have voiced strong support for the third-party program. The AWWA recently joined the NSF-led consortium and urged EPA to support national uniform accreditation of certifying entities for additives products. To date, more than 80 manufacturers are full participants in the standard-setting

program. The cooperative agreement between EPA and the consortium requires NSF to establish both a standard-setting program and a service for testing. certification, and listing. These are completely separate activities. EPA's intent is to support the development of a widely accepted uniform standard for each category of products while encouraging the development of competing sources for testing, certification, and listing. The cooperative agreement assures that at least one sound and reliable productevaluation service will be available to manufacturers, i.e., the consortium. However, the consortium's standards will allow for entities other than NSF to be evaluators of products.

EPA recognizes the authority and responsibility of the individual States to determine the acceptability of drinking water additives. Hence, it is up to the States and utilities to determine the suitability of any "third-party" certification. AWWARF will maintain a directory of products approved by all organizations claiming to conduct evaluations under Standards 60 and 61. However, AWWARF will not judge the competence or reliability of these organizations.

II. Announcement of Phase-Down of EPA's Additives Program

During the developmental phase of the NSF consortium's program, EPA has continued to review products and process requests for advisory opinions on a limited basis. The May 1984 notice stated that, "EPA does not intend to develop further interim administrative procedures, testing protocols or decision criteria for future evaluation of additive products. The use of existing informal criteria will continue until a third-party or alternative program is operational EPA may not be able to process all requests for opinions on additive products before the establishment of a cooperative agreement with a third party. The large volume of currently pending requests makes it unlikely that additional requests will be completely processed by that date." Likewise, EPA, In its acknowledgment letters to manufacturers requesting opinions on new products, explains that the Agency "* * * making a concerted effort to process petitions as quickly as possible.

However, EPA may not be able to process your request for an opinion on an additive product before the establishment of an alternative program as described in the Federal Register, Vol. 49, No. 97, 21003-8, May 17, 1984." Product reviews and issuance of advisory opinions have been limited to:

- Products composed entirely of other products which EPA had previously determined to be acceptable;
- Products composed entirely of ingredients which have been determined to be acceptable by EPA or the FDA, or other Federal agencies, for addition to potable water or equeous foods;
- Products composed entirely of ingredients listed in the "Water Chemicals Codex," National Academy of Sciences, November 1982, and in the "Water Chemicals Codex: Supplementary Recommendations for Direct Additives," National Academy of Sciences, 1984;
- Certain other products of particular interest to EPA or to other Federal agencies; and
- Products which, if effectively excluded from the marketplace by lack of approval, might jeopardize public health or safety.

Continued processing of petitions during the development of the privale-sector program minimized disruption of the marketplace from the viewpoint of manufacturers whose business depended in part on EPA acceptance of products, users who required water treatment products for the production of safe drinking water, and State officials who rely on the advice of EPA.

EPA believes that NSF is moving expeditiously and on schedule toward the full establishment of a third-party program covering products intended for use in drinking water systems. Priorities for standards development and implementation of a testing. certification, and listing program for various product categories have been based upon need, interest, complexity. and availability of information for developing standards. Direct drinking water additives were assigned high priority for the following reasons: (1) Use of direct additives is widespread in drinking water systems, so there are large population exposures to these chemicals; (2) as direct additives to drinking water, they present greater potential for water contamination than indirect mechanisms (e.g., migration from protective paints in pipes and storage tanks); and (3) the National Academy of Sciences' Water Chemicals Codex provided a good starting point for development of standards.

As originally planned, EPA is beginning to phase out the Agency's additives evaluation program. Thus, EPA will not accept new petitions or requests for advisory options after the date of this notice. While EPA will continue to process requests which are pending and those received on or before July 7, 1988, petition evaluations not completed by October 4, 1988, will be returned to the submitter. After that date, EPA will no longer evaluate additive products.

Petitions which are completely evaluated by October 5, 1988, will be added to the quarterly list of acceptable products published shortly after that date. That quarterly list will be the last such list issued by EPA. On April 7. 1990, EPA will withdraw its list of acceptable products, and the list and the advisories on these additives will expire. This means that: (1) The various lists published by EPA under the titles Report on Acceptable Drinking Water Additives, Report on Congulant Aids for Water Treatment, Report on Concrete Cootings/Admixture for Water Treatment, Report on Detergents, Sanitizers and Joint Lubricants for Water Treatment, Report on Evaporative Suppressants for Water Treatment, Report on Liners/Grouts/ Hoses and Tubings for Water Treatment, Report on Miscellaneous Chemicals for Water Treatment, Report on Protectivee Paints/Coatings for Water Treatment, and any and all other lists of drinking water products issued by EPA or its predecessor agencies regarding drinking water additives will be invalid after April 7, 1990; and (2) advisory opinions on drinking water additives issued by EPA and predecessor agencies will be invalid after that date.

EPA believes that, while in the past every effort has been made to provide the best possible evaluations, all products should be evaluated against carefully developed and considered nationally uniform standards. Many of the currently listed products were evaluated and accepted up to 20 years ago and have not been reevaluated since that time. Numerous products have been accepted because they were virtually identical to or were repackagings of older products. The result is that few products have been completely evaluated for the safety of their original or current formulations visa-vis the latest toxicological, chemical, and engineering information. A uniform evaluation of all products, old and new. will result in consistent quality of products, and will assure fair and equitable treatment to all manufacturers and distributors.

Henceforth, parties desiring to have existing or new products evaluated against the NSF standards should contact NSF or other organizations offering such evaluations. To contact NSF about the drinking water additives program write to: David Gregorka, National Sanitation Foundation, P.O. Box 1468, Ann Arbor, MI 48108, or call (313) 769-8010. Information on alternatives to NSF evaluation may be obtained by contacting State regulatory agencies or the AWWA, Technical and Professional Department, 6666 Quincy Avenue, Denver Co. 80235, or call (303) 794-7711, which is addressing certifier accreditation.

EPA believes that the 21 months between today and the expiration date of EPA's last list is sufficient time for manufacturers to submit their products to NSF or other certification entities for evaluation. The first NSF list will be published prior to April 7, 1990, thereby preventing any disruption in the marketplace. Furthermore, NSF had indicated that it will consider current EPA and other regulatory evaluations when evaluating products in order to ensure a smooth transition. States may choose to rely on the last EPA quarterly list of products until their individual

programs for accepting private-sector certification are fully implemented.

Parties desiring to market drinking water additive products are reminded that the individual States have the authority to regulate the sale and/or use of specific products as they see fit. Thus, reliance upon a particular standard or organization to certify that a product complies with a particular standard must be acceptable to the State in which the supplier wishes to do business.

Discontinuation of the additives program at EPA does not relieve the Agency of its statutory responsibilities. If contamination resulting from thirdparty sanctioned products occurs or seems likely, EPA will address that issue with appropriate drinking water regulations or other actions authorized under the SDWA: EPA is a permanent member of the NSF program Steering Committee, and senior EPA staff and management will continue to participate in this and other programs designed to assure that high-quality products are employed in the treatment of public drinking water. Also, the Agency will continue to sponsor research on contaminants introduced in public water supplies during water treatment, storage, and distribution.

III. Comments

Although this notice does not include a proposed or final regulation, EPA welcomes comments and suggestions that would assist the Agency in implementing the additives program phasedown. Please address all comments and suggestions to: Mr. Arthur H. Perler. Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20480.

Date: June 16, 1988.

William Whittington,

Acting Assistant Administrator for Water.

[FR Doc. 88–15232 Filed 7–8–88; 8:45 am]

BILLING CODE 2569-50-88

Federal facilities. Prior to making a tina recommendation to the Administrator U.S. EPA, the Regionel Administrator Region V, is providing opportunity fir public comment on the State of Wisconsin request. Any interested person may comment upon the State request by writing to the U.S. E.A. Region V Office, 230 South Dearborn Street, Chicago, Illinois 60604 Attention: Permit Branch, Such comments will be made available to the public for inspections received by Arguet 22, 1979, will be considered by U.S. EPA before taking final action on the Wisconsin request for authority to issue permits to Federal facilities.

The State's request, related documents, and ad comments received are on file and may be inspected and copied (@ 20 conts/page) at the U.S. EPA, Region V Office, in Chicago.

Copies of his notice are available upon request from the Enforcement Division of U.S. EPA. Region V. by contacting Denothy A. Price, Public Notice Glerk (312–353–2105), at the shove Address.

Delect July 13, 1979.
John McGuire,
Refional Administrator.
[5] Doc. 78-2227 Fied 2-16-72: 845 acc

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1275-4]

Orinking Water Technical Assistance; Implementation Plan for Control of Direct and Indirect Additives to Orinking Water and Memorandum of Understanding Bi: ween the Environmental Protection Agency and the Food and Drug Administration

AGENCY: Environmental Protection Agency and Food Drug Administration. ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The

agreement became effective on June 22.

ADDRESS: Submit comments to: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water, Environmental Protection Agency (WH-550), Washington, D.C. 20489.

FOR FURTHER INFORMATION CONTACT:
David W. Schnare, Ph.D., Office of
Drinking Water (WH-550),
Environmental Protection Agency,
Washington, D.C. 20430, (202) 755-5843;
or Gery Dykstra, Enforcement Policy
Staff (HFC-22), Food and Drug
Administration, 5600 Fishers Lane,
Rockville, MD 20857, (201) 443-2470.

SUPPLEMENTARY INFORMATION: In the spirit of interagency cooperation and to avoid the possibility of overlapping jurisdiction over additives and other substances in drinking water, FDA and EPA have entered into a memorandum of understanding to avoid duplicative and inconsistent regulation. In brief, the memorandum provides that EPA will have primary responsibility over direct and indirect additives and other substances in drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. FDA will have responsibility for water, and substances in water, used in food and for food processing and for hattled water under the Federal Food, Drug and Cosmetic Act.

Pursuant to the notice published in the Federal Register of October 3, 1974, [38 FR 35687] steting that future memorands of understanding, and agreements between FDA and others would be published in the Federal Register, the following memorandum of understanding is issued:

Mamorandum of Understanding Solween the Environmental Protection Agency and the Food and Drug Administration

I. Purpose

This Memorandum of Understanding satablishes an agreement between the Environmental Protection Agency (EPA) and the Pool and Drog Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

(1) That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

(2) That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

[3] That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives

has been the subject of Congressional as well as public concern;

(4) That the authority to control the use and application of direct and indirect additives to and substences in drinking water should be vested in a single regulatory agency to avoid duplicative and innonsistent regulation;

(5) That EPA has been mandated by Congress under the Sale Drinking Water Act (SDWA), as amended, to assure that the public is provided with sale drinking water.

(6) That EPA has been mandated by Congress under the Toxic Subatances Control Ant (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, inter also, testing and necessary restrictions of the use, manufacture, processing, distributor, and disposal of chemical substances and mixtures;

(7) That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FUFRA), as amended, lo assure, inter olin, that when used properly pesticides will perform their intended function without causing intended function without causing increasonable adverse effects on the environment; and.

(8) That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Ant (FFDCA), as amended, to protect the public from inter alia, the adulteration of food by food additives and poisoners and deleterious substances. It is the intent of the parties that;

[1] EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and

(2) FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background

(A) FDA Legal Authority. "Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA § 201(I)). Under Section 402. inter alia, a food may not contain any added poisonous or deleterious substance that may render it is wisus to health, or he prepared. packed or handled under unsanitary conditions. Tolerances may be set, under Section 403, limiting the quantity of any substance which is required for the production of food or cannot be aveided in fond. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or danying the use of a "load additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of otherwise affecting the characteristics of any food, if such aubstance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a lood under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes, Under the express provisions of Section 410

of the FFDCA, FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public dricking water system before the water enters a food processing establishment will be considered a food additive.

(B). EPA Legal Authority. The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the nafety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1413(c).

EPA's direct authority to control additives to drinking water sport from the existence of maximum anotaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA given EPA nuthority to regulate chemical substances, mixtures and under aome circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of Injury to health or the environment, or on algoriticant or ambalantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with premanufacturing notice. Under Section 6 the menufacture, processing, distribution, use, and disposel of a chemical substance of mixture determined to be harmful may be restricted or banned. Although Section 3(2)(8) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The PIPRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, inter alia. Is beling which specifies how, when, and where a pesticide may be legally used. In

addition. EPA has, under Section 408 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerances before using a pesticide in or around a deinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

(A) EPA's responsibilities are as follows:

{1) To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and PIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substances which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.

(2) To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water, the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 400 of the FFDCA.

(3) To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

(4) To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additions in drinking water in order to accumulate data concerning the health risks posed by the presence of those contaminants in drinking water.

(B) FDA's responsibilities are as follows: (1) To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing:

(2) To provide assistance to EPA to facilitate the transition of responsibilities, facilities

(a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

(b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

[c] To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement

This Mamorandum of Understanding shall continue in effect unless modified by, autual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Momorandom of Understanding will become effective on the date of the last signature.

Deted: June 13, 1979.

Douglas M. Costle.

Administrator, Environmental Protection
Agency.

Dated: June 22, 1979.

Donald Kennedy,

Administrator, Food and Drug

Administration.

Implementation Plan

BPA is concerned that direct and indirect additives may be adding barmful trace chemical contaminants into our Nation's drinking water during treatment, storage and distribution. Direct additives include such chemicals as chlorine, lime, alum, and coagulani, aides, which are added at the water treatment plant. Although these chemicals themselves may be harmless, they may contain small amounts of harmful chemicals if their quality is not controlled. Indirect additives include those contaminants which enter drinking water through leaching, from pipes, tanks and other equipment, and their associated paints and coatings, This notice is being published in the Federal Register to solicit public comment on EPA's implementation plan to assess and control direct and indirect additives in drinking water.

Legal Authorities

EPA and the Food and Drug Administration (FDA) signed a Memorandum of Understanding which recognizes that regulatory control over direct and Indirect additives in drinking water is placed in EPA. The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

In implementing its new responsibilities, EPA may utilize a veriety of statutory authorities, as appropriate. The authorities are identified in Appendix A.

Under the Safe Drinking Water Act. EPA has authority to set and enforce maximum contaminant levels and treatment techniques in drinking water for ubiquitous contaminants, to conduct research, to offer technical assistance to States and to protect against imminent

hazarda should such situations arise, Under the Toxic Substances Control Act, EPA has authority to review all new chemicals proposed for use related to drinking water, to mandate toxicological testing of existing and new chemicals where there is evidence that such materials may pose an unreasonable risk to bealth and the environment as well as authority to limit some or all uses of harmful chemicals. Posticide use is regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act. Thus, EPA believes it has adequate authority to deal with additives to drinking water where they may pose a problem.

Post Actions

For more than ten years, the Public Health Service and other organizations which have become part of EPA have provided advisory opinions on the toxicological safety of a variety of additives to drinking water. These historical informal opinions reflect a variety of information provided by mainfacturers and reflect changing toxicological concerns over the years. As such, they will require detailed review over the next few years.

General Approach

EPA intends to begin its responsibility over additives to drinking water with a series of analytical studies to determine the composition and significance of the health risks posed by contaminants related to direct and indirect additives to drinking water. A first step in this process will be monitoring studies of the contaminants actually getting into drinking water from generic categories of additives like bulk chemicals, paints and coatings, pipes and equipment.

In the initial six to twelve months, EPA will develop interim administrative procedures, testing protocols, and decision criteria for future toxicological advisories to the States. These will be distributed for public comment once they are developed. All existing opinions will remain in effect until a general review of past opinions can be undertaken using the new procedures. During this development phase, no new opinions will be rendered unless a proposed product can be shown to be virtually identical to a product for which an opinion has already been rendered, on the basis of chemical formulation and production process. New products or new uses of existing products which are proposed for use in drinking water will be subject to the pre-manufacture notice procedures of TSCA.

A more detailed outline of the steps to be taken by EPA follows.

 Problem Definition.—EPA will contract for in situ monitoring to determine use patterns and the contribution of trace contaminants to drinking water from;

a. bulk chemicals,

b. generic classes of paints and coatings.

c. pipes and equipment.

d. coagulant aida.

EPA has already contracted with the National Academy of Sciences to develop a CODEX system of quality control standards for chemicals (direct additives) used in the treatment of drinking water. This effort will take about three years to complete. When finished, the CODEX system, modeled on the existing FDA-inspired CODEX system for themicals used in processing food, will be largely self-enforcing.

For the indirect additives listed in items b and c above, considerable effort will be expended to identify the trace contaminants involved before the related health risks can be fully evaluated and appropriate recommendations for future use can be easessed.

2. Review of Post Advisories.—The same data base derived from in situ monitoring will serve as a basis for a structured reassessment of past toxicological advisories which will be conducted by generic classes of use e.g., paints, coagulant sides, etc. Past opinions will be reviewed to insure conformance with and satisfaction of new test protocols and decision criteria that will be developed.

3. Fature Toxicological Advisories.— Once initial procedures, test protocols and decision criteria are developed, EPA will resume offering toxicological opinions to the States.

General Policy

In assessing additives to drinking water, EPA will be guided by a policy of reducing public health risks to the degree it is feasible to do so. In such determinations, EPA will evaluate the risks and benefits associated with the materials of concern and their substitutes. Economic impacts of agency actions will also be analyzed.

Notwithstanding these procedures, EPA would use its authorities to protect against any direct or indirect additive to drinking water when data and information indicate that the use of any additive may pose an undue risk to public health.

Implementation

To fulfill this program, resources from the Office of Drinking Water, the Office of Research and Development, and the Office of Toxic Substances will be used. In addition, EPA looks forward to the cooperation of FDA and other Federal regulatory bodies. EPA intends to involve interested industry groups, independent testing groups, State regulatory bodies, interested members of the public, end industry standards groups, in a continued effort to ensure the safety of the Nation's drinking water.

Finally, EPA may recommend specialized legislative authority to regulate additives to drinking water should a situation arise for which legal authorities prove inadequate.

Lead responsibility for this new Federal initiative will be in EPA's Office of Drinking Water. Public comments on any or all aspects of the proposed program are requested, and should be directed to the address given in the opening escilons of this notice.

Dated: July 13, 1979. Thomas C. Jorling. Assistant Administrator for Water and Waste Management.

Appendix A

Sofe Drinking Water Act

Section 1412—establishment of national primary drinking water regulations applicable to public water systems to control contaminants in drinking water which may have any adverse effect on human health. This may include maximum contaminant levels, treatment techniques, monitoring requirements, and quality control and testing procedures.

Section 1431—use of emergency powers where a contaminant which is present in water, or is likely to enter a public water system, may present an imminent and substantial endengerment to the bealth of persons.

Section 1415—establishment of monitoring and reporting requirements applicable to public water systems.

Section 1450—authority to prescribe such regulations as see necessary or appropriate to carry out the Administrator's functions under the Act.

Toxic Substances Control Act

Section 4—lesting of chemical substances and mixtures.

Section 6—pre-manufacture notice required for new chemicals or significant new uses.

Section a—regulation of hazardous chemical substances and mixtures which pose on unreasonable risk of injury to health or the environment. Including restrictions on manufacture, processing, distribution, and use.

Section 7—imminent hazards authority including seizure and other relief through civil court action.

Section 6—reporting and retention of information as required by the Administrator, including health and safety studies and notice to the Administrator of substantial risks.

Section 10—research and development. Development of systems for storing, retrieving and disseminating data

Section 11—inspections and subpense and other enforcement and general administration provisions therein.

Federal Insecticide, Fungicide and Rodenticide Act

Section 3—registration of pesticides, including imposition of restrictions and labeling requirements.

Section 6—suspension and cancellation procedures.

FR Doc 70-27722 Filed 70-18-78 8-45 and publishing code 5566-01-8

BRILING CODE 4110-01-84

FEDERAL COMMUNICATIONS COMMISSION

[Report No. A-1s]

FM Broadcasting Applications Accepted for Filing and Notification of Cut-off Date; Erratum

Released: July 12, 1979.

The FM Application listed below was inadvertently included on the acceptance/cut-off notice, Report No. A-1, BC Mimeo No. 18676, pleased on June 25, 1979.

BPH-790nGRAE [New]: Creaton, Pennsylvania, Sherlock-Hart Broadcoating, Inc.

Req.: 94.3 MHz, Chemiel #232A ERP: 0.600 kW, HAAT: 900 feet

Accordingly, the pplication is removed from the acceptance/cutoff list and the August 8,4979, outoff date is deleted.

Federal Communications Commission.

William J. Triengeo.

Secretory

IFR Doc. 79-224227 ded 7-19-78: 845 am) ell.LING CODE (713-91-N

FEDERAL LABOR RELATIONS AUTHORITY

Official Time of Employees involved in Negotiating Collective Bargaining Agreements

AGENCY: Federal Labor Relations

ACTION: Notice Relating to Official Time.

SUMMARY: This notice principally relates to the interpretation of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214) on the questions of whether employees who are on official time under this section while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses, and whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargeining agreement. The notice further invites interested persons to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on such interpretation, and to submit written comments concerning these matters.

DATE: Written comments must be submitted by the close of besiness on August 24, 1979, to be considered.

ADDRESS: Send written comments to the Federal Labor Relations Authority, 1900 E Street, NW., Washington, D.C. 20424.

FOR FURTHER REFORMATION CONTACT: Hazold D. Kessler, Deputy Executive Director, 1800 E Street, NW., Washington, D.C. 20424, (202) 632–382

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority was established by Reorganization Plan No. 2 of 1978, effective January 1, 1978 (33 FR 38037). Since January 11, 1979, the Authority has conducted its organizations under the Federal Service Labor-Management Relations Stabile (92 Stat. 1191).

Upon receipt of requests and consideration thereof, the Authority has determined, in accordance with 5 CPR 2410.3(a) (1978) and sections 7105 and 7135(b) of the Status (92 Stat. 1198, 1215), that an interpretation is warranted concerning section 7131 of the Statute (92 Stat. 1214). Interested persons are invited to express their views in writing on this matter, as more fully explained in the Authority's notice set forth below:

To Heads of Agencies, Presidents of Labor Organizations and Other Interested Persons

The Authority has received a request from the American Federation of Covernment Employees (AFCE) for a statement of policy and guidance concerning whether employees

in the negotiation of a collective bargaining agreement are entitled payments from agencies for their and per diem expenses under the official time provisions of section 7131 Federal Service Labor-Manag ment Relations Statute (92 Stat. 1974). Additionally, the National Jederation of Federal Employees (NFFE) has requested a major policy statement as to the application of the optical time provisions of section 7.31[a] of the Statute (92 Stat. 1214) to all negotiations between an exclusive representative and an agency, regirdless of whether such negotiations pertain to the negotiation or reflegotiation of a basic collective bargening agreement. AFGE has raised a similar issue in its request.

The Authority hereby determines, in conformity with 5 CFR 2410.3(a) (1878) and section 7135(b) of the Statute (92 Stat. 1219), as well as section 7105 of the Statute (92 Stat. 1198), that an interpretation of the Statute is warranted on the following:

(if Whether employees who are on official time under section 7181 of the Slattite while representing an exclusive expresentative in the negotiation of a collective bergaining agreement are entitled to payments from agencies for their travel and per diem expenses.

(2) Whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement.

Before issuing an interpretation on the above, the Authority, pursuent to 5 CFR 2410.6 [1978] and section 7135[b] of the Statute [92 Stat. 1215], solicits your views in writing. You are further invited to address the impact, if any, of section 7135(a)[1] of the Statute [82 Stat. 1215] on the above matters and to submit your views as to whether oral argument should be granted. To receive consideration, such views must be submitted to the Authority by the close of business on August 24, 1979.

Issued, Washington D.C., July 13, 1979. Federal Labor Relations Authority. Ronald W. Haughton,

Chairman.

Hanry B. Frazier III,

Member.

[PR Dne: 79-23447 Filed 7-35-75; 8:45 and BILLING CODE 4025-01-8 FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA | FDA Centennial

MOU number: 225-79-2001

Memorandum of Understanding

Between
The Environmental Protection Agency

and

The Food and Drug Administration

i. Purpose;

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

- A. That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;
- B. That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;
- C. That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;
- D. That the authority to control the use and application of direct and indirect additives to end substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;
- E. That EPA has been mendated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;
- F. That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, inter alia, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;
- G. That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, <u>inter alia</u>, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,
- H. That FDA has been mandated by Congress under the Federal Food, Drug, and

Cosmetic Act (FFDCA), as amended, to protect the public from, <u>inter alia</u>, the adulteration of food by food additives and poisonous and deleterious substances.

It is the intent of the parties that:

A. EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

B. FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background:

A. FDA Legal Authority

"Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA Section 201(f)). Under Section 402, inter alia, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 406, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonable be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410 of the FFDCA, FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

B. EPA Legal Authority

The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the Act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 pemils EPA

to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with pre-manufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, inter alia labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

- A. EPA's responsibilities are as follows:
 - 1. To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substance which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.
 - To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.
 - 3. To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.
 - 4. Fo conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.
- B. FDA's responsibilities are as follows:
 - 1. To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.
 - To provide assistance to EPA to facilitate the transition of responsibilities, including:
 - To review existing FDA approvals in order to Identify their applicability to additives in drinking water.

- b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.
- c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement:

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Approved and Accepted for the Environmental Protection Agency

Signed by: Douglas P. Costle Administrator Environmental Protection Agency

Date: June 12, 1979

Approved and Accepted 'for the Food and Drug Administration

Signed by: Donald Kennedy Administrator Food and Drug Administration

Date: June 22, 1979

Domestic MOUs

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§ 321. Definitions; Generally.

Archive

United States Statutes

Title 21. Food and Drugs

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter II. DEFINITIONS

Current through P.L. 111-290

§ 321. Definitions; Generally

For the purposes of this chapter-

- (a) (1) The term "State", except as used in the last sentence of section **372 (a)** of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.
 - (2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.
- (b) The term "interstate commerce" means
 - (1) commerce between any State or Territory and any place outside thereof, and
 - (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.
- (c) The term "Department" means Department of Health and Human Services.
- (d) The term "Secretary" means the Secretary of Health and Human Services.
- (e) The term "person" includes individual, partnership, corporation, and association.
- (f) The term "food" means
 - (1) articles used for food or drink for man or other animals,
 - (2) chewing gum, and

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- (3) articles used for components of any such article.
- (g) (1) The term "drug" means
 - (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
 - (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
 - (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
 - (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343 (r)(1)(B) and 343 (r)
 (3) of this title or sections 343 (r)(1)(B) and 343 (r)(5)(D) of this title, is made in accordance with the requirements of section 343 (r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343 (r)
 (6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.
 - (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.
- (h) The term "device" (except when used in paragraph (n) of this section and in sections 331 (i), 343 (f), 352 (c), and 362 (c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-
 - recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
 - (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended

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- (dd) For purposes of sections **335a** and **335b** of this title, the term "drug product" means a drug subject to regulation under section **355**, **360b**, or **382** of this title or under section **262** of title 42.
- (ee) The term "Commissioner" means the Commissioner of Food and Drugs.
- (ff) The term "dietary supplement"-
 - (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
 - (2) means a product that-
 - (A) (i) is intended for ingestion in a form described in section 350 (c)(1)(B)(i) of this title; or
 - (ii) complies with section 350 (c)(1)(B)(ii) of this title;
 - (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
 - (C) is labeled as a dietary supplement; and
 - (3) does-
 - (A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342 (f) of

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this title; and

- not include
 - an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or
 - an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (q) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

- (gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.
- (hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.
 - (ii) The term "compounded positron emission tomography drug"-
 - (1) means a drug that
 - exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and
 - has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and
 - (2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator. accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

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Food and Drug Administration Rockville MD 20857

DEC 21 2000

The Honorable Ken Calvert
Chairman
Subcommittee on Energy and Environment
Committee on Science
House of Representatives
Washington, D.C. 20515-6301

Dear Mr. Chairman:

Thank you for the letter of May 8, 2000, to Dr. Jane E. Henney, Commissioner of Food and Drugs, regarding the use of fluoride in drinking water and drug products. We apologize for the delay in responding to you.

We have restated each of your questions, followed by our response.

1. If health claims are made for fluoride-containing products (e.g. that they reduce dental caries incidence or reduce pathology from esteoperosis), do such claims mandate that the fluoride-containing product be considered a drug, and thus subject the product to applicable regulatory controls?

Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal, is a drug that is subject to Food and Drug Administration (FDA) regulation. FDA published a final rule on October 6, 1995, for anticaries drug products for over-the-counter (OTC) human use (copy enclosed). This rule establishes the conditions under which OTC anticaries drug products are generally recognized as safe and effective and not misbranded. The rule has provisions for active ingredients, packaging conditions, labeling, and testing procedures that are required by manufacturers in order to market anticaries products. A new drug application (NDA) may be filed for a product containing fluoride that does not meet the provisions stated in the final rule. As you know, the Environmental Protection Agency regulates fluoride in the water supply.

2. Are there any New Drug Applications (NDA) on file, that have been approved, or that have been rejected, that involve a fluoride-containing product (including fluoride-containing vitamin products) intended for ingestion with the stated aim of reducing dental caries? If any such NDA's have been rejected, on what grounds were they rejected? If any such NDA have been approved, please provide the data on safety and efficacy that FDA found persuasive.

No NDAs have been approved or rejected for fluoride drugs meant for ingestion. Several NDAs have been approved for fluoride topical products such as dentifrices and gels. Fluoride products in the form of liquid and tablets meant for ingestion were in use prior to enactment of the Kefauver-Harris Amendments (Drug Amendments of 1962) to the Food, Drug, and Cosmetic Act in which efficacy became a requirement, in addition to safety, for drugs marketed in the United States (U.S.). Drugs in use prior to 1962 are being reviewed under a process known as the drug efficacy study implementation (DESI). The DESI review of fluoride-containing products has not been completed.

3. Does FDA consider dental fluorosis a sign of over exposure to fluoride?

Dental fluorosis is indicative of greater than optimal ingestion of fluoride. In 1988, the U.S. Surgeon General reported that dental fluorosis, while not a desirable condition, should be considered a cosmetic effect rather than an adverse health effect. Surgeon General M. Joycelyn Elders reaffirmed this position in 1994.

4. Does FDA have any action-level or other regulatory restriction or policy statement on fluoride exposure aimed at minimizing chronic toxicity in adults or children?

The monograph for OTC anticaries drug products sets acceptable concentrations for fluoride dentifrices, gels and rinses (all for topical use only). This monograph also describes the acceptable dosing regimens and labeling including warnings and directions for use. FDA's principal safety concern regarding fluoride in OTC drugs is the incidence of fluorosis in

Page 3 - The Honorable Ken Calvert

children. Children under two years of age do not have control of their swallowing reflex and do not have the skills to expectorate toothpaste properly. Young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride toothpaste. These concerns are addressed in the monograph by mandating maximum concentrations, labeling that specifies directions for use and age restrictions, and package size limits.

Thanks again for contacting us concerning this matter. If you have further questions, please let us know.

Simcerely

Melinda K. Plaisier Associate Commissioner for Legislation

Enclosure

"Final Rule/Federal Register - October 6, 1995 Over-the-Counter Anticaries Drug Products"

Web site administrator's note:

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Enter: On: 10/06/95

Enter: Search terms; anticaries

Fluorosilicae Acie

Fluorosilicic Acid, HFS, FSA)

Technical Data Sheet

CHEMICAL ANALYSIS	SPECIFICATION	TYPICAL ANALYSIS	
H ₂ SiF ₆ , %	23-25	23.5	
Heavy Metals (as Pb), %		< 0.02	
HF, %	1.0 max	0.5	
Color, APHA	100 max	< 20	_
P ₂ O ₅ , %		< 0.2	-

Product meets ANSI/AWWA Standard B703-06, and is certified by NSF International or Classified by UL to ANSI/NSF Standard 60. Maximum use level for potable water treatment is 6.0 mg/L.

PHYSICAL PROPERTIES

Physical Description	Aqueous solution, water white to straw-yellow, corrosive acid, irritating to skin and having pungent odor.
Molecular Weight	144.08
Specific Gravity 23% solution @ 75°F	1.212
Boiling Point of Aqueous 23% Solution	221°F (Decomposes)
Freezing Point of Aqueous 23% Solution	5°F (approx.)
Freezing Point of Aqueous 25% Solution	-4°F
pH of 1%, H ₂ SiF ₆	1.2

CONTAINERS

Tank truck, rubber or plastic-lined	40,000 lb (approx.)
Tank car, rubber or plastic-lined	196,000 lb net (approx.)

DOT AND FREIGHT DESCRIPTION

Hazardous Material Description	Fluorosilicic acid
Haz. Mat. Class, I.D.#, Packaging Group	8, UN 1778, PG II
Freight Classification	Hydrofluorosilicic Acid
Principal CAS Number	16961-83-4
RQ	None
Placard	Corrosive
Label	Corrosive







Fluorosilicic Acid (Hydrofluorosilicic Acid, HFS, FSA)

Technical Data Sheet

Use in public Water Treating Plants:

The reduction in dental caries by adjusting the fluoride content of public water supplies is a matter of common knowledge today, half a century following the first installation in Grand Rapids, Michigan, Approximately 170 million people in over three thousand communities are now drinking fluoride-treated water from water purification plants where fluoridation is currently practiced. Fluoridation is concerned with the controlled introduction to water of the fluoride ion. Other materials in the fluoride compound simultaneously introduced into the water with the fluoride ions are carriers which provide no benefits and are nontoxic. The addition of one part per million of fluoride requires that the product be soluble, of definite concentration and have high purity standards. In conformity with the American Water Works Association standard B703-94, the term fluorosilicic acid has replaced the more technical designation of hydrofluosilicic acid. After the original work with sodium fluoride proved the effectiveness of fluoride on tooth health and a broad fluoridation program was envisaged, new sources of fluoride and economics of their use were investigated. Fluorosilicic acid is a high purity source of fluoride. It is simpler to use than any other chemical approved for water fluoridation purposes, primarily because it is a liquid and can therefore be accurately measured and fed with a minimum of equipment. In contrast to powdered or granular chemicals, it presents no dust problems, no measuring problems and handling requires a minimum of labor. Today most of the large cities and many small ones are fluoridating with fluorositicic acid. It is readily available in tank cars or tank trucks and can also be supplied in 15-gallon carboys and 55-gallon drums. The addition of fluorosilicic acid to a water supply can be readily controlled to give a total fluoride (F) level of one part per million which has been established as effective for reducing tooth decay. It should be used in accordance with procedures approved by each state's department of health.

Acid Characteristics:

Fluorosilicic acid is a transparent, clear to straw-colored, corrosive liquid having the chemical formula of H_2SiF_6 . It is manufactured in modern rubber-lined equipment producing an acid of high commercial purity. Commercial water solutions of the acid are available, having concentration of between 23% and 25% H_2SiF_6 . Fluorosilicic acid is generally believed not to exist in the vapor phase, but only in solution. Upon vaporizing, it decomposes into hydrofluoric acid (HF) and silicon tetrafluoride. This equilibrium exists at the surface of strong solutions of fluorosilicic acid and if stored in glass containers, the small concentration of hydrofluoric acid may very slowly attack the glass above the solution level. For this reason, it is generally shipped in polyethylene containers rather than glass carboys. A 23% fluorosilicic acid-water solution weighs 10.1 pounds per gallon at 75°F, and has a fluoride (F) content of 18.20%.

Fig. 702 Fig. 4014

Fluorosilicic Acid (Hydrofluorosilicic Acid, HFS, FSA)

Technical Data Sheet

Installation:

In a typical large plant installation, rubber-lined vented storage tanks are usually mounted outside the building with the tanks ranging in size from 4,500 to 6,500 gallon capacities. These tanks, equipped with recording level gauges, feed the acid through plastic piping or tubing to the dosage unit. Feeding is regulated by controlled volume pumps. Metering is used for accurate flow records. Fluorosilicic acid may be handled in rubber-lined, saran or other available corrosive-resistant equipment as suggested below:

Pipes and lines - rubber, saran or polyethylene
Pumps - Lucite, saran or Hastellov

Valves - rubber-lined or polyethylene-lined

Tanks - rubber-lined, saran or polyethylene-lined

Acid should be pumped by positive diaphragm proportioning pumps.

Operation procedure:

The drum or drums of fluorosilicic acid should be mounted on a platform of sufficient size and capacity to permit weighing the amount used each day. Proportioning pumps deliver an accurate volume, but for small pumping rates, the dosage may be more satisfactorily regulated by periodic weighing of the drum. Whenever a drum of fluorosilicic acid is replaced on the scale, the time and weight should be recorded in the daily operating log. Whenever dosage is changed to a varying pumpage, the time and feeder setting should be recorded in the daily log.

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SHANGHAI MINTCHEM DEVELOPMENT CO., LTD

Specification Sheet

Sodium Fluoride

Physical Properties:

Formula	Na F	Molecular Weight	41.99	CAS NO	7681-49-4
U.N-NO	1690	Class	6.1	H.S-NO	2826110010

Character: White crystal or powder. Relative Density 2.558. It's odorless. Soluble in water and HE Insoluble in ethanol. Mellting point 993° C and boiling point 1695° C. Non flammable but toxic.

Chemical Parameters:

	ical parameters:	T				
NO.	Technological Specification	Granular S	Standard%	Powder :	Standard%	
1	NaF purity	98.59	98.5%min		98.5%min	
2	Sodium Carbonate	0.5%	0.5%max.		0.5%max.	
3	Na2SiF6	1.5%	max	1.5%max		
4	Silicon Dioxide	0.5%	max.	0.5%max.		
5	Sulphate	0.3%	0.3%max.		0.3%max.	
6	HF	0.1%max,		0.1%max,		
7	H2O(moisture)	0,5%max.		0.5%max.		
8	Heavy Metal(As Pb)	0.049	0.04%max.		%max.	
9	Available Fluoride	43.8%min.		43.8	%min.	
10	Water Insoluble matter	0.6%max.		0.6%	ómax.	
11		-20 mesh	98%min	+80 mesh	4 % max	
12	Particle Size	+100 mesh	50%min	+200 mesh	25 % max	
13		-325 mesh	*- <u> ,</u>			

APPLICATION: It is mainly used as fluxing agent, timber preservative and water treatment etc.

PACKAGE: Packing in plastic weaved bag 25kg each.

TRANSPORTATION: DG, Class 6.1, UN 1690

MANUFACTURER: SHANGHAI MINTCHEM DEVELOPMENT CO., LTD

上海办 Shanghai Office

上海市浦东新区牡丹路 89 弄 4 号 602 室 R602,4#,89Nong, Mudan Road Pudong Shanghai, China Tel: 0086 21 6845 1592 Fax: 0086 21 6845 0923 长沙办 Changsha Office

以沙市労动西路 108 号长沙市化工研究所 HX 綾 707 室 HX707,108# Laodong Road West Changsha, Hunan,China Tel: 0086 731 8552 9244/8552 9245/8552 9246 Fax: 0086 731 8551 8 167/8553 0 767

mid 1980's? (Evans R.W., Stamm JW., 1991). Across all age groups more than 90% of fluorosis cases were very mild or mild. (Evans R.W. Stamm JW., 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase. (Lo ECM et al, 1990). Although not fully generalizable to the current U.S context, these findings, along with those from the 1986–87 survey of U.S. schoolchildren, suggest that risk of fluorosis can be reduced and caries prevention maintained toward the lower end (i.e., 0.7 mg/L) of the 1962 USPHS recommendations for fluoride concentrations for community water systems.

Relationship of fluid intake and ambient temperature among children and adolescents in the United States:

The 1962 USPHS recommendations stated that community drinking water should contain 0.7-1.2 mg/L [ppm] fluoride, depending on the ambient air temperature of the area, These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950's. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more tap water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ *et al*, 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950's, and thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid.

Studies conducted since 2001 suggest that fluid intake in children does not increase with increases in ambient air temperature (Sohn W, et al. 2001; Beltrán-Aguilar ED, et al, 2010b). One study conducted among children using nationally representative data from 1988 to 1994 did not find an association between fluid intake and ambient air temperature (Sohn W, et al, 2001). A similar study using nationally representative data from 1999 to 2004 also found no association between fluid intake and ambient temperature among children or adolescents (Beltrán-Aguilar ED, et al. 2010b). These recent findings demonstrating a lack of an association between fluid intake among children and adolescents and ambient temperature support use of a single target concentration for community

water fluoridation in all temperature zones of the United States.

Conclusions

HHS recommends an optimal fluoride concentration of 0.7 mg/L for community water systems based on the following information:

· Community water fluoridation is the most cost-effective method of delivering fluoride for the prevention of tooth decay:

 In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence;

 Significant caries preventive benefits can be achieved and risk of fluorosis reduced at 0.7 mg/L, the lowest concentration in the range of the USPHS recommendation.

 Recent data do not show a convincing relationship between fluid intake and ambient air temperature. Thus, there is no need for different recommendations for water fluoride concentrations in different temperature zonas.

Surveillance Activities

CDC and the National Institute of Dental and Craniofacial Research (NIDCR), in coordination with other Federal agencies, will enhance surveillance of dental caries, dental fluorosis, and fluoride intake with a focus on younger populations at higher risk of fluorosis to obtain the best available and most current information to support effective efforts to improve oral health.

Process

The U.S. Department of Health and Human Services (HHS) convened a Federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence related to the 1962 USPHS Drinking Water Standards related to recommendations for fluoride concentrations in drinking water in the United States and to update these proposed recommendations. Panelists included representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the U.S. Environmenեվ Protection Agency, and the U.S. Department of Agriculture. The panelists evaluated existing recommendations for fluoride in drinking water, systematic reviews of the risks and benefits from fluoride in drinking water, the epidemiology of

dental caries and fluorosis in the U.S., and current data on fluid intake in children, aged 0 to 10 years, across temperature gradients in the U.S. Conclusions were reached and are summarized along with their rationale in this proposed guidance document, This guidence will be advisory, not regulatory, in nature. Guidance will be submitted to the Federal Register and will undergo public and stakeholder comment for 30 days, after which HHS will review comments and consider changes,

Dated: January 7, 2011.

Kathleen Schelius,

Secretary.

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 $^{^7\,\}mathrm{Fluorosis}$ prevalence ranged from 64% (SE = 4.1) to 47% [SE = 4.5] based on the upper right contral incisor only.



STATE OF WASHINGTON WASHINGTON STATE BOARD OF HEALTH

PO Box 47990 • Olympia, Washington 98504-7990

November 16, 2010

Mr. William Osmunson, DDS, MPH, President Washington Action for Safe Water 1418 -- 112th Ave NE, Suite 200 Bellevue, WA 98004

Dear Dr. Osmunson:

This letter provides formal notice that the Washington State Board of Health has denied your petition for rule making received on October 7, 2010 to add an intent statement in two places in WAC 246-290-460, regarding water fluoridation. The suggested statement was "with the intent to prevent dental caries." This was the fifth petition for rule making you submitted to the Board this year regarding this rule.

The Board's intent for setting an "optima?" fluoride concentration in WAC 246-290-460 is part of its requirement to "adopt rules for group A public water systems...to assure safe and reliable public drinking water and to protect the public health" under RCW 43.20.050(2)(a). The Board follows guidelines of the Centers for Disease Control and Prevention (CDC) regarding setting an appropriate level of fluoride in drinking water if the directors of a water system decide to fluoridate under the authority of RCW 57.08.012. The CDC promotes community water fluoridation as one of the ten great public health achievements of the twentieth century. It says fluoridation is the single most effective public health measure to prevent tooth decay. The Board supports this and other positions of the CDC. The Board considers it self evident that the purpose of water fluoridation is to help prevent tooth decay. The Board does not consider it efficient use of public resources to initiate and complete a rule making process to add to the rule the language requested by the petitioner.

The Board handled your request as a petition for rule making under RCW 34.05.330 and Board Policy 2005-001, Responding to Petitions for Rule Making. The statute requires the Board to respond within 60 days of receipt. RCW 34.05.330(3) allows a person to appeal a petition's denial to the Governor within 30 days. The Board's policy allows the Board Chair to respond to a petition for rule making without the petition being placed on a meeting agenda for full Board consideration. If you have questions about this decision, please contact Craig McLaughlin, Executive Director of the Board, at 360-236-4106 or crais mclaughlin@doh.wa.gov.

Sincerely,

KeithHigman

Chair

cc: Michelle Davis, Department of Health Gregg Grunenfelder, Department of Health State Board of Health Members





Recommendations and Reports

Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333



Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States

Summary

Widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries (i.e., tooth decay) in the United States and other economically developed countries. When used appropriately, fluoride is both safe and effective in preventing and controlling dental caries. All U.S. residents are likely exposed to some degree to fluoride, which is available from multiple sources. Both health-care professionals and the public have sought guidance on selecting the best way to provide and receive fluoride. During the late 1990s, CDC convened a work group to develop recommendations for using fluoride to prevent and control dental caries in the United States. This report includes these recommendations, as well as a) critical analysis of the scientific evidence regarding the efficacy and effectiveness of fluoride modalities in preventing and controlling dental caries, b) ordinal grading of the quality of the evidence, and c) assessment of the strength of each recommendation.

Because frequent exposure to small amounts of fluoride each day will best reduce the risk for dental caries in all age groups, the work group recommends that all persons drink water with an optimal fluoride concentration and brush their teeth twice daily with fluoride toothpasts. For persons at high risk for dental caries, additional fluoride measures might be needed. Measured use of fluoride modalities is particularly appropriate during the time of anterior tooth enamel development (i.e., age <6 years).

The recommendations in this report guide dental and other health-care providers, public health officials, policy makers, and the public in the use of fluoride to achieve maximum protection against dental caries while using resources efficiently and reducing the likelihood of enamel fluorosis. The recommendations address public health and professional practice, self-care, consumer product industries and health agencies, and further research. Adoption of these recommendations could further reduce dental caries in the United States and save public and private resources.

INTRODUCTION

Dental caries (i.e., tooth decay) is an infectious, multifactorial disease afflicting most persons in industrialized countries and some developing countries (1). Fluoride reduces the incidence of dental caries and slows or reverses the progression of existing lesions (i.e., prevents cavities). Although pit and fissure sealants, meticulous oral hygiene, and appropriate dietary practices contribute to caries prevention and control, the most effective and widely used approaches have included fluoride use. Today, all U.S. residents are exposed to fluoride to some degree, and widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries in the United States and other economically developed countries (1). Although this decline is a major public

Fluoridated Drinking Water and Processed Beverages and Food

Fluoridated drinking water contains a fluoride concentration effective for preventing dental caries; this concentration can occur naturally or be reached through water fluoridation, which is the controlled addition of fluoride to a public water supply. When fluoridated water is the main source of drinking water, a low concentration of fluoride is routinely introduced into the mouth. Some of this fluoride is taken up by dental plaque; some is transiently present in saliva, which serves as a reservoir for plaque fluoride; and some is loosely held on the enamel surfaces (76). Frequent consumption of fluoridated drinking water and beverages and food processed in fluoridated areas maintains the concentration of fluoride in the mouth.

Estimates of fluoride intake among U.S. and Canadian adults have ranged from ≤1.0 mg fluoride per day in nonfluoridated areas to 1–3 mg fluoride per day in fluoridated areas (77–80). The average daily dietary fluoride intake for both children and adults in fluoridated areas has remained relatively constant for several years (11). For children who live in optimally fluoridated areas, this average is approximately 0.05 mg/kg/day (range: 0.02–0.10); for children who live in nonfluoridated areas, the average is approximately half (11). In a survey of four U.S. cities with different fluoride concentrations in the drinking water (range: 0.37–1.04 ppm), children aged 2 years ingested 0.41–0.61 mg fluoride per day and infants aged 6 months ingested 0.21–0.54 mg fluoride per day (81,82).

In the United States, water and processed beverages (e.g., soft drinks and fruit juices) can provide approximately 75% of a person's fluoride intake (83). Many processed beverages are prepared in locations where the drinking water is fluoridated. Foods and ingredients used in food processing vary in their fluoride content (11). As consumption of processed beverages by children increases, fluoride intake in communities without fluoridated water will increase whenever the water source for the processed beverage is fluoridated (84). In fluoridated areas, dietary fluoride intake has been stable because processed beverages have been substituted for tap water and for beverages prepared in the home using tap water (11).

A study of lowa infants estimated that the mean fluoride intake from water during different periods during the first 9 months of life, either consumed directly or added to infant formula or juice, was 0.29–0.38 mg per day, although estimated intake for some infants was as high as 1.73 mg per day (85). As foods are added to an infant's diet, replacing some of the formula prepared with fluoridated water, the amount of fluoride the infant receives typically decreases (86). The lowa study also reported that infant formula and processed baby food contained variable amounts of fluoride. Since 1979, U.S. manufacturers of infant formula have voluntarily lowered the fluoride concentration of their products, both ready-to-feed and concentrates, to <0.3 ppm fluoride (87).

Drinking Water

Community Water. During the 1940s, researchers determined that 1 ppm fluoride was the optimal concentration in community drinking water for climates similar to the Chicago area (88,89). This concentration would substantially reduce the prevalence of dental caries, while allowing an acceptably low prevalence (i.e., 10%-12%) of very mild and mild enamel fluorosis and no moderate or severe enamel fluorosis. Water fluoridation for caries control began in 1945 and 1946, when the fluoride concentration was

(C.S. Department of Health & Human Services

U.S. Food

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finme > Regulatory Information > Legislation > Federal Food, Drug, and Cosmetic Act (FD&C Act)

Regulatory Information

Significant Amendments to the FD&C Act

Significant Amendments to the FD&C Act:

Since 1980, listed chronologically; date shown is when the Public Law was approved. "Summary" indicates link to a summary of the law; other links are to full text. Provisions of these Public Laws are incorporated into the FD&C Act.

- Infant Formula Act of 1980 (summary) 1
 Public Law (Pi.) 96-359 (Oct. 26, 1980)
- Orphan Drug Act² PL 97-414 (Jan. 4, 1983)
- Drug Price Competition and Patent Term Restoration Act of 1964 (summary).
 Pl. 98-417 (Sept. 24, 1984)
- Prescription Drug Marketing Act of 1987⁴
 Pt. 100-293 (Apr. 22, 1988)
- Generic Animal Drug and Patent Term Restoration Act of 1988 (summary) 5 PL 100-670 (Nov. 16, 1988)
- Nutrition Labeling and Education Act of 1990 (summary) ⁶
 PL 101-535 (Nov. 8, 1990)
- Safe Medical Devices Act of 1990 (summary) ⁷ PL 101-629 (Nov. 28, 1990)
- Medical Device Amendments of 1992 (summary) 8
 Pl. 102-300 (June 16, 1992)
- Prescription Drug Amendments of 1992; Prescription Drug User Fee Act of 1992 9 Pt 102-571 (Oct. 29, 1992)
- Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 10 PL 103-396 (Oct. 22, 1994)
- Dietary Supplement Health and Education Act of 1994¹¹ Pl. 103-417 (Oct. 25, 1994)
- FDA Export Reform and Enhancement Act of 1996 ¹²
 PL 104-134 (April 26, 1996)
- Food Quality Protection Act of 1996 ¹³
 PL 104-170 (Aug. 3, 1996)
- Animal Drug Availability Act of 1996 ¹⁴ PL 104-250 (Oct. 9, 1996)
- Food and Drug Administration Modernization Act (FDAMA) of 1997¹⁵ PL 105-115 (Nov. 21, 1997)
- Best Pharmaceuticals for Children Act 16
 PL 107-109 (Jan. 4, 2002)
- Medical Device User Fee and Modernization Act (MDUFMA) of 2002 ¹⁷ PL 107-250 (Oct. 26, 2002)
- Animal Drug User Fee Act of 2003 ¹⁸
 Pt 108-130 (Nov. 18, 2003)
- Pediatric Research Equity Act of 2003 19
 PL 108-155 (Dec. 3, 2003)
- Minor Use and Minor Species Animal Health Act of 2004 ²⁰ Pt 108-282 (Aug. 2, 2004)
- Dietary Supplement and Nonprescription Drug Consumer Protection Act ²¹ PL 109-462 (Dec. 22, 2006)
- Food and Drug Administration Amendments Act (FDAAA) of 2007 ²² PL 110-85 (Sept. 27, 2007)
- Family Smoking Prevention and Tobacco Control Act (Public Law 111-31) ²³ PL 111-31 (June 22, 2009)
- FDA Food Safety Modernization Act²⁴
 PL 111-353 (lan. 4, 2011)

Links on this page:

- 1. http://thomas.loc.gov/cgi-bin/bdquery/z7d096:HR06940:@@@E|TOM:/bss/d096query.html|#summary
- 2. /RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/OrphanDrugAct/default.nt m

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- 3. http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@@D&summ2=m&[TOM:/bss/d098query.html]
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- 5. /RegulatoryInformation/Legislation/FederalFoodOrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm147135.htm
- 6. http://thomas.loc.gov/cgi-bin/bdquery/z?d101:HR03562:@@@D&summ2=3&]TOM:/bss/d101query.html]
- 7. http://thomas.loc.gov/cgi-bin/bdquery/z?d101:HR03095:@@@D&summZ=1&|TOM:/bss/d101query.html|
- 8. http://thomas.loc.gov/cgi-bin/bdquery/z?d102;SN02783:@@@D&summ2=m&|TOM:/bss/d102query.html]
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- 14. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=104_cong_public_laws&docid=f:publ250.104
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- /RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/AnimalDrugUserFeeActof2 003/default.htm
- 19. http://frwebgate.access.gpo.gov/cgi-bln/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ155,108
- 20. /RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/MinorUseandMinorSpecies AnimalHealthActof2004/default.htm
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- 22. /RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministration/AmendmentsActof2007/default.htm
- 23. http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf

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UNITONE USA INC.

MATERIAL SAFETY DATA SHEET

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SODIUM FLLIGRIDE

PAGE: 007

VERSION: 007

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SPOSE OF CONTAINER AND UNUSED CONTENTS IN ACCORDANCE WITH FEDERAL, STATE esto LOCAL REGUIREMENTS.

14: TRANSPORT INFORMATION

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15. REQULATORY INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service



Food and Drug Administration Division of Freedom of Information 5600 Fishers Lane, HFI-35 Rockville, MD 20857

September 14, 2010

In Response Refer to File: 2010-6890

Eloise W. Kailin, MD P.O. Box 2418 Sequim, Washington 98382

Dear Requestor,

This is in response to your letter dated August 31, 2010, in which you requested any documents awarding FDA's permission to the City of Forks, Washington, zip code 98331-8618 or the City of Port Angeles, Washington 98362 to manufacture, dispense or distribute any legend or over the counter drug. You also requested any documents from either of these municipal entities requesting a new drug application (either NDA or ANDA) for a legend drug or over the counter drug.

A search of the records of the Center for Drug Evaluation and Research did not locate any permission from the FDA for City of Forks, Washington, zip code 98331-8618 or the City of Port Angeles Washington 98362 to manufacture, dispense of distribute any legend or over the counter drug.

A search of the records of the Center for Drug Evaluation and Research did not locate any approved new drug application of an approved abbreviated new drug application fluorosilicic acid or sodium fluoride.

The following charges may be included in a monthly invoice:

Reproduction \$ 0.00 Search \$11.50 Review \$00.00 Other \$0.00 TOTAL \$11.50 The above total may not reflect final charges for this request.

PLEASE DO NOT MAKE ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE

If there are any problems with this response, please notify us in writing of your specific problem(s) at the above address. Please reference the above file number.

This completes the response for the Center for Drug Evaluation and Research.

Roy Castle, MS, PD
Office of Regulatory Policy
Division of Information Disclosure Policy

Appendix C to letter dated November 25, 2011 from Eloise W. Kailin, M.D. to Secretary Kathleen G. Sebelius

This Appendix is intended to list all ANSI/NSF Standard 60 certified fluoridation products (checkmarked) along with company addresses (marked with vertical lines) and facility identifications (marked with *).



NSF Product and Service Listings

These NSF Official Listings are current as of **Wednesday**, **November 23**, **2011** at 12:15 a.m. Eastern Time. Please <u>contact NSF International</u> to confirm the status of any Listing, report errors, or make suggestions.

Alert: NSF is concerned about fraudulent downloading and manipulation of website text. Always confirm this information by clicking on the below link for the most accurate information: <a href="http://www.nsf.org/Certified/PwsChemicals/Listings.asp?ProductFunction=Fluoridation-Endowder-Listings.asp.

**The Conference of Conference On Conference O

NSF/ANSI STANDARD 60 Drinking Water Treatment Chemicals - Health Effects

ACCO Unlimited Corporation

5300 Northwest 55th Avenue Johnston, IA 50131 United States 800-548-2226 515-278-0487

Facility: Johnston, IA

Fluosilicic Acid

Trade Designation ACCO HFS-L

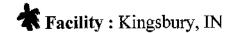
Product Function Fluoridation

Max Use 6mg/L

Alexander Chemical Corporation

1901 Butterfield Road Suite 120 Downers Grove, IL 60515 United States 800-445-9458 630-955-6050

C]



Hydrofluosilicic Acid

Trade Designation
Fluosilicic Acid - Water Treatment Grade
Hydrofluosilicic Acid - Water Treatment
Grade

Product Function
Fluoridation
Fluoridation

Max Use 6 mg/L 6 mg/L

American Development

Corporation

1456 State Camp Road P.O. Box 385 Vanceboro, NC 28586 United States 800-842-0764 252-244-0782 Visit this company's website



Facility: Vanceboro, NC

Fluosilicie Acid

Trade Designation
Fluosilicic Acid
HFS Acid
Hydroflusoilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 4mg/L 4mg/L 4mg/L

American Development

Corporation

821 William D. Jones Boulevard P.O. Box 620 Fayetteville, TN 37334 United States 888-542-8561 931-438-0653

Visit this company's website

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Facility: Fayetteville, TN

Fluosilicic Acid

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Trade Designation

Fluosilicic Acid

HFS Acid

Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L

BHS Marketing LLC

2320 West Indiana Avenue Salt Lake City, UT 84104 United States 801-973-8232



Facility: Southgate, CA

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Ilydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

* Facility: Stockton, CA

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Ilydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Facility: Distribution Center - Henderson, NV

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function Fluoridation Fluoridation Max Use 6mg/L 6mg/L

Facility: Distribution Center - Seattle, WA

Fluosilicie Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Brenntag Great Lakes LLC

4420 North Harley Davidson Avenue Wauwatosa, WI 53225 United States 262-252-3550 Visit this company's website



Facility: Ft. Wayne, IN

Fluorosilicie Acid

Trade Designation
Hydrofluorosilicic Acid 23%

Product Function
Fluoridation

Max Use 6mg/L

Brenntag Mid-South, Inc.

1405 Highway 136 West P.O. Box 20 Henderson, KY 42420-0020 United States 800-950-7267 270-827-3545 Visit this company's website



Facility: Orlando, FL

Fluosilicie Acid

Trade Designation
Hydrofluosilicic Acid[1]

Product Function Fluoridation

Max Use 6 mg/L

[1] Certification is based upon maximum product concentration of 25% fluosilicic ac

NOTE: All Listed products at this facility are NSF Certified, whether or not they b Mark.



K Facility: Indianapolis, IN

Hydrofluosilicic Acid

Trade Designation
Hydrofluosilicie Acid

Product Function Fluoridation

Max Use 6 mg/L

NOTE: All Listed products at this facility are NSF Certified, whether or not they b Mark.

🛊 Facility: Henderson, KY

Fluosilicic Acid

Trade Designation

Hydrofluosilicic Acid

Product Function
Fluoridation

Max Use 6 mg/L

NOTE: All Listed products at this facility are NSF Certified, whether or not they b Mark.

‡ Facility: St. Louis, MO

Fluosilicic Acid

Trade Designation	Product Function	Max Use
Fluorosilicic Acid Fluosilicic Acid	Fluoridation	6 mg/L
	Fluoridation	6 mg/L
	Fluoridation	6mg/L
Hexafluosilicic Acid	Fluoridation	6 mg/L
Hydrofluorosilicic Acid	Fluoridation	6mg/L
₩Hydrofluosilicic Acid	Fluoridation	6 mg/L

Brenntag Pacific, Inc.

10747 Patterson Place Santa Fe Springs, CA 90670 United States 323-562-9500

Facility: Richmond, CA

Hydrofluosilieic Acid

Trade Designation
Fluosilicie Acid
₩HFS Acid
■ Hydrofluosilicic Acid

Product Function	
Fluoridation	
Fluoridation	
Fluoridation	

Max Use 6mg/L 6mg/L 6mg/L

Facility: South Gate, CA

Hydrofluosilicic Acid

,	Trade Designation	Product Function	Max Use
We	Fluosilicie Acid	Fluoridation	6mg/L
	HFS Acid	Fluoridation	$6 \mathrm{mg/L}$
•	Hydrofluorosilicic Acid 23%-25%	Fluoridation	6mg/L
	Hydrofluosilicic Acid	Fluoridation	6mg/L

Brenntag Southwest

Route 2, Box 352-200 Nowata, OK 74048 United States 800-722-3145 918-273-2265



Hydrofluosilicic Acid
Trade Designation
Hydrofluosilicic Acid

Product Function Fluoridation

Max Use 6mg/L

Canada Colors and Chemicals Limited

6605 Hurontario Street Suite 400 Mississauga, ON L5T 0A3 Canada 905-454-6900

Facility: Elmira, Ontario, Canada

Hydrofluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid (PWTG)

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Carus Corporation

315 Fifth Street P.O. Box 599 Peru, IL 61354-0599

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United States 800-435-6856 815-223-1500

Facility: # 1 La Salle, IL

Hydrofluosilicie Acid

Trade Designation Flouride, 25% Hydrofluosilicic Acid, 25% Product Function Fluoridation Fluoridation

Max Use 6mg/L 6mg/L

[PO] The finished drinking water shall be monitored to ensure that levels of mangan do not exceed 0.05 mg/L.

Facility: #5 USA

Hydrofluosilicic Acid

Trade Designation ₩ Fluoride, 25%

Max Use Product Function Fluoridation 6mg/L Fluoridation 6mg/L Fluoridation 6mg/L

ClearTech Industries Inc.

2302 Hanselman Avenue Saskatoon, SK S7L 5Z3 Canada 306-664-2522

Facility: Calgary, Alberta, Canada

Hydrofluosilicie Acid

Trade Designation Hydrofluorosilicie Acid

Product Function Fluoridation

Max Use 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

Davis Supply, Inc. 2454 Palm Avenue

[7

Fort Myers, FL 33916 United States 800-749-5967 299-931-6700



Facility: Quincy, FL

Hydrofluosilicic Acid

Trade Designation
HydroFluosilicic Acid 23%

Product Function
Fluoridation

Max Use 6mg/L

DPC Enterprises

300 Jackson Hill Houston, TX 77007 United States 281-457-4888 Visit this company's website



Facility: Mobile, AL

Hydrofluosilicic Acid

Trade Designation

✓ Hydrofluosilicic Acid

Product Function Fluoridation

Max Use 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.



Facility: Festus, MO

Hydrofluosilicie Acid

Trade Designation
Hydrofluorosilicic Acid

Product Function
Fluoridation

Max Use 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

DPC Industries, Inc.

300 Jackson Hill P.O. Box 130410 Houston, TX 77219-0410

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United States 281-457-4888 Visit this company's website

Facility: Rosemount, MN

Hydrofluosilicic Acid

Trade Designation

Hydrofluosilicic Acid

Product Function
Fluoridation

Max Use 6 mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

* Facility: Omaha, NE

Hydrofluosilicie Acid

Trade Designation Hydrofluosilicic Acid Product Function
Fluoridation

Max Use 6 mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

🕏 Facility: Cleburne, TX

Hydrofluosilicic Acid

Trade Designation
Hydrofluosilicic Acid 24-30%

Product Function
Fluoridation

Max Use 6 mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

DPC Industries, Inc.

P.O. Box 24600 Houston, TX 77229-4600 United States 281-457-4835

Facility: #1 Houston, TX

Hydrofluosilicic Acid

Trade Designation

Product Function

Max Use

✓ Hydrofluorosilicic Acid

Fluoridation

6mg/L

DXI Industries, Inc.

300 Jackson Hill P.O. Box 130410 Houston, TX 77219-0410 United States 281-457-4888 Visit this company's website



Facility: Houston, TX

Hydrofluosilicic Acid

Trade Designation Hydrofluosilicic Acid Product Function Fluoridation

Max Use 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

DXI Industries, Inc.

P.O. Box 24600 Houston, TX 77229-4600 United States 281-457-4888



Facility: #1 USA

Hydrofluosilicic Acid

Trade Designation Hydrofluorosilicie Acid Product Function Fluoridation

Max Use 6mg/L

General Chemical, LLC

Water Treatment Chemicals 1421 Willis Avenue Syracuse, NY 13204 **United States** 315-478-2323 Visit this company's website

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Facility: Indianapolis, IN

Hydrofluosilicic Acid

Trade Designation
Hydrofluorosilicic Acid

Product Function Fluoridation

Max Use 6mg/L

NOTE: Only Listed products bearing the NSF Mark are Certified.

George S. Coyne Chemical Co.,

Inc.

3015 State Road Croydon, PA 19021 United States 800-523-1230 215-785-3000 Visit this company's website

🧸 Facility : Croydon, PA

Hydrofluosilicic Acid

Trade Designation

Hydrofluosilicic Acid 23%

Product Function
Fluoridation

Max Use 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whother or not they NSF Mark.

🔭 Facility: Fairless Hills, PA

Hydrofluosilicic Acid

Trade Designation
Hydrofluosilicic Acid 23%

Product Function Fluoridation

Max Use 6mg/L

Facility: Reading, PA

Hydrofluosilicie Acid

Trade Designation
Hydrofluosilicic Acid 23%

Product Function Fluoridation

Max Use 6mg/L

H. Krevit & Co., Inc.

73 Welton Street
New Haven, CT 06511
United States
800-922-6626
203-772-3350
Visit this company's website



Fluosilicie Acid

Trade Designation
HYDROFLUOSILICIC ACID 23-25%

Product Function Fluoridation

Max Use 6mg/L

NOTE: Only products bearing the NSF Mark are NSF Certified.

Harcros Chemicals Inc.

5200 Speaker Road P.O. Box 2930 Kansas City, KS 66110 United States 913-621-7844

Recility: Tampa, FL

Hydrofluosilicic Acid

Trade Designation	Product Function	Max Use
Trade Designation Fluorosilicic Acid	Fluoridation	6mg/L
Fluosilicie Acid	Fluoridation	6mg/L
V HFS	Fluoridation	6mg/L
Hydrofluorosilicic Acid	Fluoridation	6mg/L
HFS Hydrofluorosilicic Acid Hydrofluosilicic Acid	Fluoridation	6mg/L

Facility: Thomasville, NC

Hydrofluosilicic Acid

Trade Designation	Product Function	Max Use
✓Fluosilicic Acid 23%	Fluoridation	6 mg/L
✓ Hydrofluosilicic Acid 23%	Fluoridation	6 mg/L

Haviland Products Co.

421 Ann Street NW Grand Rapids, MI 49504 United States 800-456-1134 616-361-6691

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Facility: Grand Rapids, MI

Hydrofluosilicie Acid

Trade Designation
Hydrofluosilicic Acid

Product Function Fluoridation

Max Use 6 mg/L

Hawkins, Inc.

3100 East Hennepin Avenue Minneapolis, MN 55413 United States 612-331-6910

Facility: # 15 USA

Hydrofluosilicic Acid

Trade Designation
Hydrofluosilicic Acid

Product Function Fluoridation

Max Use 6mg/L

Hydrite Chemical Co.

300 N. Patrick Boulevard Brookfield, WI 53045 United States 262-792-8759

Facility: Milwaukee, WI

Hydrofluosilicie Acid

Trade Designation
Hydrofluosilicic Acid

Product Function
Fluoridation

Max Use 6 mg/L

Ideal Chemical and Supply

Company

4025 Air Park Street P.O. Box 18698 Memphis, TN 38181-0698 United States 901-363-7720



Facility: # 1 Memphis, TN

Fluosilicie Acid

_ Trade Designation	Product Function	Max Use
Fluosilicic Acid	Fluoridation	6mg/L
HFS	Fluoridation	6mg/L
✓ Hydrofluosilicic Acid	Fluoridation	6mg/L
Sodium HydroFluosilicic Acid 23	Fluoridation	$6 \mathrm{mg/L}$
Sodium HydroFluosilicic Acid 25	Fluoridation	6mg/L

J. R. Simplot Company

999 Main Street, Suite 1300 Boise, ID 83702 United States 208-336-2110 Visit this company's website

Facility: Rock Springs, WY

Fluosilicie Acid

Trade Designation	Product Function	Max Use
Fluorosilicic Acid	Fluoridation	6mg/L
Fluosilicic Acid	Fluoridation	6mg/L
✓ Hydrofluosilicic Acid	Fluoridation	6mg/L

Mark's Chemical, LLC

118 East North Avenue Monticello, WI 53570 United States 608-938-4633



🧸 Facility : Monticello, WI

Fluorosilicie Acid

Trade Designation Fluosilicic Acid Hydrofluosilicic Acid-23%

Product Function Fluoridation Fluoridation

Max Use 6mg/L 6mg/L

Martelle Water Treatment Inc.

2275 Royal Oaks Drive Janesville, WI 53548 United States 608-314-9371 Visit this company's website



Facility: Janesville, WI

Hydrofluosilicie Acid

Trade Designation Fluoride, 25% Hydrofluosilicic Acid, 25% Product Function Fluoridation Fluoridation

Max Use ·6mg/L 6mg/L

Monson Companies

154 Pioneer Drive Leominster, MA 01453 United States 888-295-8585 978**-**534-1425 Visit this company's website



Facility: South Portland, ME

Hydrofluosilicie Acid

Trade Designation Hydrofluosilicic Acid Solution, 23%

Product Function Fluoridation

Max Use 6mg/L

NAPCO Chemical Company,

Inc.

P.O. Box 1239 Spring, TX 77383-1239 United States 800-929-5976 281-651-6800



Facility: Spring, TX

Hydrofluosilicie Acid

Trade Designation
HFS 23%
Hydrofluorosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Onoda Chemical Industry Co.,

Ltd.

NIPPON BLDG. 6-2 Ohtemachi 2-Chome, Chiyoda-ku Tokyo 100-0004 Japan 81 3 6214 1023



Facility: Kitakyusyu City, Japan

Sodium Fluoride

Trade Designation
Sodium Fluoride

Product Function Fluoridation

Max Use 2.3 mg/L

PCS Sales (USA), Inc

1101 Skokic Boulevard, Suite 400 P.O. Box 3320 Northbrook, IL 60062 United States 847-849-4301



Facility: Aurora, NC

Fluosilicic Acid

Trade Designation
Fluosilicie Acid

Product Function
Fluoridation

Max Use 6mg/L

PENCCO, Inc.

P.O. Box 600 San Felipe, TX 77473 United States 800-864-1742 979-885-0005

Facility: Distribution Center - Richmond, CA

Hydrofluosilicic Acid

Trade Designation
Fluorosilicic Acid
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L

Facility: Distribution Center - South Gate, CA

Hydrofluosilicie Acid

Trade Designation
Fluorosilicie Acid
Fluosilicie Acid
Hydrofluosilicie Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L

Facility: Distribution Center - Willow Springs, IL

Hydrofluosilicie Acid

Trade Designation
Fluorosilicic Acid
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L

Facility: Distribution Center - Allston, MA

Hydrofluosilicie Acid

Trade Designation
Hydrofluosilicic Acid

Product Function
Fluoridation

Max Use 6mg/L

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Facility: Distribution Center - Elizabeth, NJ

Hydro	fluos	ilicic	Acid

Trade Designation
Hydrofluosilicic Acid

Product Function
Fluoridation

Max Use 6mg/L



Facility: Distribution Center - Painesville, OH

Hydrofluosilicic Acid

Trade Designation
Hydrofluosilicic Acid

Product Function Fluoridation

Max Use

6mg/L



Facility: Distribution Center - Spartanburg, SC

Hydrofluosilicie Acid

Trade Designation
Hydrofluosilicic Acid

Product Function Fluoridation

Max Use

6mg/L



Facility: Distribution Center - Sealy, TX

Hydrofluosilicie Acid

Trade Designation
Fluorosilicic Acid
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L



Facility: Distribution Center - Waxahachie, TX

Hydrofluosilicic Acid

Trade Designation
FLUOROSILICIC ACID
FLUOSILICIC ACID
HYDROFLUOROSILICIC ACID
HYDROFLUOSILICIC ACID

Product Function
Fluoridation
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L .6mg/L

6mg/L 6mg/L

PVS Nolwood Chemical

10900 Harper Avenue Detroit, MI 48213-3389 United States 800-284-9735 313-925-0300 Visit this company's website



Facility: Detroit, MI

Fluosilicic Acid

_ Trade Designation
Fluorosilicic Acid
Fluosilicic Acid
Hexafluosilicic Acid
Hydrofluosilicic Acid, 23%

Product Function
Fluoridation
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L 6mg/L

Reliable Industrial Supply Ltd.

50 Mumford Road Lively, ON P3Y 1L2 Canada 705-692-2959



Facility: Lively, Ontario, Canada

Hydrofluosilicic Acid

	Trade Designation
J	Fluorosilicie Acid
J	Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Rotem Amfert Negev Ltd.

Shazar Boulevard 3
P.O. Box 125
Beer Sheva 84101
Israel
972 8 6598871
Visit this company's website



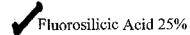
Facility: Araya, Israel

Fluosilicie Acid

Trade Designation

Product Function

Max Use



Fluoridation

6mg/L

SAL Chemical Company, Inc.

Half Moon Industrial Park 3036 Birch Drive Weirton, WV 26062 United States 800-879-1725 304-748-8200



Facility: #1 USA

Fluorosilicic Acid

Trade Designation
Fluorosilicic Acid
Hydrofluorosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Sierra Chemical Company

2302 Larkin Circle Sparks, NV 89431 United States 800-777-8965 775-358-0888



Facility: Stockton, CA

Fluorosilicic Acid

Trade Designation
Fluorosilicic Acid

✓ HFS Acid

✓ Hydrofluorosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

Solvay Fluor Mexico S.A. de

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Cd. Juarez, Chihuahua C.P. 32690 Mexico 52 16 33 0300

Facility: Chihuahua, Mexico

Fluosilicic Acid

Trade Designation
Fluosilicic Acid 23%-25%

Product Function
Fluoridation

Max Use 6 mg/L

NOTE: NSF has not conducted production control audits at this facility. Product Li based on type testing [ISO/IEC Guide 2: 1996 (E/F/R) 14.5].

Solvay Fluorides, LLC.

3333 Richmond Avenue Houston, TX 77098 United States 800-325-3332 713-525-6500

Facility: Distribution Center - Southgate, CA

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Facility: Distribution Center - Stockton, CA

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function Fluoridation Fluoridation Max Use 6mg/L 6mg/L

Facility: Alorton, IL

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Sodium Fluoride

Trade Designation
Sodium Fluoride

Product Function Fluoridation

Max Use 2.3 mg/L

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Facility: Distribution Center - East Chicago, IN

Fluosilicic Acid

Trade Designation
Fluosilicic Acid

Product Function
Fluoridation

Max Use 6mg/L

4

Facility: Distribution Center - Boston, MA

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function Fluoridation Fluoridation Max Use 6mg/L 6mg/L

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Facility: Distribution Center - Buffalo, NY

Fluosilicic Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

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Facility: Distribution Center - Philadelphia, PA

Fluosilicie Acid

Trade Designation
Fluosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

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Facility: Distribution Center - Beauharnois, Quebec, Canada

Fluosilicie Acid

Trade Designation

✓ Fluosilicic Acid

✓ Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

Solvay Fluorides, LLC.

3333 Richmond Avenue Houston, TX 77098 United States 800-325-3332 713-525-6500



Facility: #1 Japan

Sodium Fluoride

Trade Designation
Sodium Fluoride

Product Function Fluoridation

Max Use 2.3mg/L

Sowega Chlorinator Company,

Inc.

505 9th Avenue P.O. Box 3006 Albany, GA 31706 United States 800-230-1415 229-436-8512



Facility: Albany, GA

Hydrofluosilicic Acid

Trade Designation
Hydrofluorosilicic Acid

Product Function Fluoridation

Max Use 6mg/L

Sulco Chemicals Limited

60 First Street East Elmira, ON N3B 2Z5 Canada 519-669-1332



Facility: Elmira, Ontario, Canada

Hydrofluosilicic Acid Trade Designation

Product Function

Max Use

Fluosilicic Acid
Hydrofluosilicic Acid (PWTG)

Fluoridation Fluoridation

.6mg/L 6mg/L

Surry Chemicals, Inc.

241 Hickory Street P.O. Box 1447 Mount Airy, NC 27030 United States 800-800-2791 336-786-4607



Facility: Mount Airy, NC

Hydrofluosilicic Acid

Trade Designation
HFS 23%
HYDROFLUOSILISIC ACID 23%

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

The Mosaic Company

13830 Circa Crossing Drive Lithia, FL 33547 United States 813-671-6223 Visit this company's website

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Facility: Distribution Center - Birmingham, AL

Fluorosilicic Acid

Trade Designation
Fluosilicic Acid
HFS
Hydrofluorosilicic Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L 6mg/L

Facility: Riverview, FL

Fluosilicie Acid

Trade Designation
Fluorosilicic Acid
Fluosilicic Acid

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

	Hydrofluorosilicic Acid Hydrofluosilicic Acid	Fluoridation Fluoridation	6mg/L 6mg/L
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Facility: Distribution Center - East St. Louis, IL

Fluore	seilicic	Acid
TIMOLO	isilicic	ACIU

Trade Designation	Product Function	Max Use
Fluosilicic Acid	Fluoridation	6mg/L
HFS	Fluoridation	6mg/L
Hydrofluorosilicie Acid	Fluoridation	6mg/L
Hydrofluosilicie Acid	Fluoridation	6mg/L
	Fluosilicie Acid HFS Hydrofluorosilicie Acid	Fluosilicie Acid Fluoridation HFS Fluoridation Hydrofluorosilicie Acid Fluoridation

*Facility: Uncle Sam, LA

Fluosilicie Acid

_Trade Designation	Product Function	Max Use
Hydrofluosilicic Acid, Commercial Grade	Fluoridation	6 mg/L

Facility: Distribution Center - Baltimore, MD

Fluorosilicie Acid

Trade Designation	Product Function	Max Use
Fluosilicic Acid	Fluoridation	6mg/L
IIFS	Fluoridation	6mg/L
Hydrofluorosilicie Acid	Fluoridation	6mg/L
Hydrofluosilicic Acid	Fluoridation	6mg/L

Facility: Distribution Center - Allston, MA

Fluorosilicie Acid

▲ Trade Designation	Product Function	Max Use
Fluosilicie Acid	Fluoridation	6mg/L
♦ HFS	Fluoridation	6mg/L
	Fluoridation	.6mg/L
Hydrofluosilicic Acid	Fluoridation	6mg/L

Facility: Distribution Center - Elizabeth, NJ

Fluorosilicic Acid

Trade Designation Product Function Max Use

Facility: Distribution Center - Cincinnati, OH

İ	
Product Function	Max Use
Fluoridation	6mg/L
Fluoridation	6mg/L
Fluoridation	6mg/L
Fluoridation	6 mg/L
	Fluoridation Fluoridation Fluoridation

* Facility: Distribution Center - Cleveland, OH

Fluorosilicic Acid		
Trade Designation	Product Function	Max Use
Fluosilicic Acid	Fluoridation	6mg/L
√ HFS	Fluoridation	6mg/L
Hydrofluorosilicic Acid	Fluoridation	6mg/L
	Fluoridation	6mg/L

Facility: Distribution Center - Saginaw, TX

Fluorosilicie Acid	! :	
Trade Designation	Product Function	Max Use
✓ Fluosilicic Acid	Fluoridation	6mg/L
✓ HFS	Fluoridation	6mg/L
Hydrofluorosilicic Acid	Fluoridation	6mg/L
Hydrofluosilicic Acid	Fluoridation	6mg/L

Univar Canada Ltd.

9800 Van Horne Way Richmond, BC V6X 1W5 Canada

604-273-1441

Facility: Edmonton, Alberta, Canada

Hydrofluosilicic Acid

Trade Designation
Fluorosilicic Acid
Hydrofluosilicic Acid 25%

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

*

Facility: Valleyfield, Québec, Canada

Hydrofluosilicie Acid

Trade Designation

Hydrofluosilicic Acid 25%

Product Function
Fluoridation

Max Use 6mg/L

Univar USA Inc.

17425 Northeast Union Hill Road Redmond, WA 98052 United States 425-889-3400

Facility: Jacksonville, FL

Hydrofluosilicie Acid

Trade Designation
Fluorosilicic Acid
Fluosilicic Acid
HFS Acid
Hydroflousilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L 6mg/L

Facility: Norcross, GA

Hydrofluosilicie Acid

Trade Designation Hydrofluosilicic Product Function
Fluoridation

Max Use 6 mg/L

NOTE: Only products bearing the "NSF 60" designation are Certified by NSF Internati

Facility: St. Louis, MO

Hydrofluosilicic Acid

Trade Designation
Fluocilicic Acid
HFS
Hydrofluosilicic Acid

Product FunctionMax UseFluoridation6mg/LFluoridation6mg/LFluoridation6mg/L

NOTE: Only products bearing the "NSF 60" designation are Certified by NSF Internati

¥

Facility: Cincinnati, OH

Hydrofluosilicic Acid

Trade Designation

HFS Acid

Product Function Fluoridation

Max Use 5.9mg/L

NOTE: Only products bearing the "NSF 60" designation are Certified by NSF Internati

Facility: Bunola, PA

Fluosilicic Acid

Trade Designation
Hydrofluosilicic Acid

Product Function Fluoridation

Max Use 6mg/L

NOTE: Only products bearing the "NSF 60" designation are Certified by NSF Internati

Facility: Middletown, PA

Fluosilicie Acid

Trade Designation
Hydrofluosilicic Acid

Product Function
Fluoridation

Max Use 6mg/L

NOTE: Only products bearing the "NSF 60" designation are Certified by NSF Internati

Facility: Houston, TX

Hydrofluosilicic Acid

Trade Designation
Hydrofluosilic Acid

Product Function
Fluoridation

Max Use 6 mg/L

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NOTE: Only products bearing the "NSF 60" designation are Cortified by NSF Internati

Facility: Suffolk, VA

Hydrofluosilicic Acid

Trade Designation

Hydrofluosilicic Acid (23-25%)

Hydrofluosilicic Acid (37-42%)

Product Function
Fluoridation
Fluoridation

Max Use 6mg/L 3mg/L

NOTE: Only products bearing the "NSF 60" designation are Certified by NSF Internati

Univar USA Inc. (formerly Basic Chemical Solutions)

525 Seaport Boulevard Redwood City, CA 94063 United States 800-411-4BCS Visit this company's website

Facility: Distribution Center - Redwood City, CA

Hydrofluosilicic Acid

 Product Function
Fluoridation

Max Use 6mg/L

Facility: Distribution Center - Grantsville, UT

Hydrofluosilicic Acid

Trade Designation

Hydrofluosilicic Acid 23%

Product Function Fluoridation

Max Use 6mg/L

Vertex Chemical Corporation 11685 Manchester Road

11685 Manchester Road St. Louis, MO 63131 United States 314-471-0500

R Facility : Dupo, IL

Fluorosilicic Acid

Trade Designation
Fluosilicic Acid 23% - 25%
Hydrofluosilicic Acid
Hydrofluosilicic Acid 23%

Product Function

Fluoridation

Max Use

6mg/L

6mg/L

NOTE: All Listed products from this facility are NSF Certified, whether or not they NSF Mark.

Viking Chemical Co.

1827 18th Avenue P.O. Box 1595 Rockford, IL 61110 United States 815-397-0500

Facility: Rockford, IL

Fluosilieie Acid

Trade Designation
Fluosilicie Acid

Product Function Fluoridation

Max Use 6 mg/L

[1] Manganese sulfate is used in combination with potassium (or sodium) permanganat produce hydrous manganese oxides (HMOs) which are used to adsorb positively chaions, such as radium.

Water Guard, Inc.

1903 Herring Avenue P.O. Box 2226 Wilson, NC 27893 United States 252-237-5205

Facility: Wilson, NC

Fluosilicic Acid

Trade Designation
Fluorosilicic Acid
HFS Acid
Hydrofluosilicic Acid

Product Function
Fluoridation
Fluoridation
Fluoridation

Max Use 6mg/L 6mg/L 6mg/L

Webb Chemical Service Corporation

2708 Jarman Street
Muskegon Heights, MI 49444
United States
231-733-2181
Visit this company's website



Facility: Muskegon Heights, MI

Hydrofluosilicie Acid

_ Trade Designation	Product Function	Max Use
FSA	Fluoridation	6mg/L
Fluosilicic Acid	Fluoridation	6mg/L
Fluosilicic Acid, 23-40%	Fluoridation	6mg/L
♂ HFS	Fluoridation	6mg/L
→ Hydrofluosilicic Acid	Fluoridation	6mg/L

Number of matching Manufacturers is 53 Number of matching Products is 207 Processing time was 0 seconds

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Water Quality Association

11/23/2011



NSF/ANSI 60 International Standard for Drinking Water Additives

NSF/ANSI 60 Drinking Water Treatment Chemicals - Health Effects

This Standard establishes minimum health effects requirements for the chemicals, the chemical contaminants, and the impurities that are directly added to drinking water from drinking water treatment chemicals. This standard does not establish performance or taste and odor requirements for drinking water treatment chemicals.

Alpha Chemical Limited 40 Pettipas Drive Dartmouth, NS (Canada) B3B 1K2

Phone: (902) 481-2532

http://www.alphachemical.ns.ca

Facility: Dartmouth Nova Scotia

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Aluminum Sulfate 400 mg/L

Chemical: Polyaluminum Chloride

Polyaluminum Chloride 250 mg/L

Chemical: Sodium Hydroxide

Sodium Hydroxide, 50% 100 mg/L

Chemical: Sodium Hypochlorite

Alpha 12.5% 80 mg/L

Sodium Hypochlorite 12.5% 80 mg/L

Aqua-Chem, Inc. 104 Cunningham Road Bellevue, NE 68005

Phone: (402) 292-0242

Chemical: Sodium Hypochlorite

Trade Designation

Maximum Use (mg/L unless

otherwise indicated)

Aquachlor

105 mg/L

Brenntag Northeast, Inc.

81 West Huller Lane Reading, PA 19605 Phone: 610-926-4151

http://www.brenntagnortheast.com/en/

Chemical: Ferric Chloride

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Ferric Chloride 40% 250

Chemical: Hydrofluorosilicic Acid

Fluorosílicic Acd 23% 6

HF523 6

Hydrofluorosilicic Acid 6

Chemical: Hydrogen Peroxide

Hydrogen Peroxide 50% 2.1

Chemical: Phosphoric Acid

Phosphoric Acid 85% 12

Chemical: Sodium Hydroxide

Sodium Hydroxide 50% 200

Chemical: Sodium Hypochlorite

Sodium Hypochlorite 10% 50

Brenntag Southeast Inc.

2000 East Pettigrew Street

P.O. Box 1491

Durham, NC 27703

Phone: (919) 596-0681

http://www.brenntagsoutheast.com

Facility: Charlotte NC

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Aluminum Sulfate Liquid 26.8% 1 2 150 mg/L

Chemical: Ammonium Hydroxide

WQA Goldseal Certified Products	
Ammonium Hydroxide 15%	1 4 mg/L
Ammonium Hydroxide 19%	10 mg/L
Ammonium Hydroxide 26 deg. Baume	17 mg/L
Chemical: Ferric Chloride	
Liquid Ferric Chloride	250 mg/L
Chemical: Fluosillsic Acid	
Hydrofluosilicic Acid 23% ^{3 4}	6 mg/L
Chemical: Phosphoric Acid	
Phosphoric Acid 36-85% ⁵	13.8 mg/L
Chemical: Sodium Hydroxide	
Sodium Hydroxide 25%	400 mg/L
Sodium Hydroxide 50% ³	200 mg/L
Sodium Hydroxide Rayon 50% ³	200 mg/L
Chemical: Sodium Hypochlorite	
Sodium Hypochlorite Solution 15 ^{3 6}	84 mg/L

Carusol 20 7

176 mg/L

Facility: Durham NC

Chemical: Aluminum Sulfate

Chemical: Sodium Permanganate

Trade Designation	Maximum Use (mg/L unless otherwise indicated)
Aluminum Sulfate Liquid 26.8% 1 2	150 mg/L
Chemical: Ammonium Hydroxide	
Ammonium Hydroxide 15%	14 mg/L
Ammonium Hydroxide 19%	10 mg/L
Ammonium Hydroxíde 26 deg. Baume	17 mg/L
Chemical: Ferric Chloride	
Liquid Ferric Chloride	250 mg/L

6 mg/L

Hydrofluosilicic Acid 23% 3 4

Chemical: Fluosilisic Acid

Chemical: Sodium Hydroxide Sodium Hydroxide 25% 400 mg/L Sodium Hydroxide 50% 3 200 mg/L

Sodium Hydroxide Rayon 50% 3 200 mg/L Chemical: Sodium Hypochlorite

Sodium Hypochlorite Solution 15 ^{3 6} 84 mg/L

Chemical: Sodium Permanganate

Carusol 20 ⁷ 176 mg/L

Chemical: Sulfuric Acid

Sulfuric Acid 66 Be ⁵ 50 mg/L

Facility: Garden City GA

Chemical: Sodium Hydroxide

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Sodium Hydroxide 25% 400 mg/L

Sodium Hydroxide 50% ³ 200 mg/L

* Facility: Greensboro NC

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Aluminum Sulfate Liquid 26.8% 1 2 150 mg/L

Chemical: Ammonium Hydroxide

Ammonium Hydroxide 15% 14 mg/L

Ammonium Hydroxide 19% 10 mg/L

Ammonium Hydroxide 26 deg, 17 mg/L

Baume

Chemical: Blended Corrosion Inhibitor

AguaPure 3601 ⁵ 25 mg/L

AquaPure 3627 5 25 mg/L

AquaPure 3628 ⁵ 25 mg/L

AquaPure 3637 ⁵ 25 mg/L

AguaPure 3646 ⁵ 25 mg/L

AquaPure 3655 ⁵ 25 mg/L

AquaPure 3664 ⁵ 25 mg/L

AquaPure 3672 5 25 mg/L

AquaPure 3673 ⁵ 25 mg/L

AquaPure 3682 ⁵ 25 mg/L

AguaPure Ortho 36 ⁵ 13.8 mg/L

AquaPure SH-36 ⁵ 25 mg/L

AquaPure ZOP 437 5 28 mg/L

035

AquaPure ZOP 7878 ⁵	16 mg/ L
AquaPure ZOP 8080S ⁵	23 mg/L
AquaPure ZOP 824 ⁵	16 mg/L
AquaPure 3610 ⁵	25 mg/L
AquaPure 3691 ⁵	25 mg/L
AquaPure ZOP 1237 ⁵	15 mg/L
AquaPure ZOP 721 ⁵	25 mg/L
AquaPure ZOP 737 ⁵	25 mg/L
Brennfloc ZOP 437 ⁵	27 mg/L
Chamical: Farric Chlorida	

Chemical: Ferric Chloride

Liquid Ferric Chloride 250 mg/L

Chemical: Fluosilisic Acid

Mydrofluosilicic Acid 23% ^{3 4} 6 mg/L

Chemical: Sodium Carbonate

Soda Ash Dense 100 mg/L Soda Ash Light 100 mg/L

Chemical: Sodium Hydroxide

Sodium Hydroxide 25% 400 mg/L Sodium Hydroxide 50% 3 200 mg/L Sodium Hydroxide Rayon 50% 3 200 mg/L

Chemical: Sodium Hypochlorite

Sodium Hypochlorite Solution 15 3 6 84 mg/L

Chemical: Sodium Permanganate

Carusol 20⁷ 176 mg/L

Facility: Wilmington NC Chemical: Sodium Hydroxide

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Sodium Hydroxide 50% 3 200 mg/L

^{1:} The finished drinking water shall be monitored to ensure that levels of copper do not exceed 1.3 mg/L.

^{2:} Based on evaluation of health effects data, the level of aluminum in the finished drinking water shall not exceed 2 mg/L.

^{3:} The residual levels of chlorine (hypochlorite ion and hypochlorous acid), chlorine dioxide, chlorate lon, chloramine and disinfection by-products should be monitored in the finished drinking water to ensure compliance to all applicable regulations.

^{4:} The maximum use level corresponds to a fluoride ion concentration of 1.2 mg/L.

^{5:} For use with potable water only.

⁶ The Certification of this product has been restricted to a maximum use level that is less than the 10 ppm "typical use level" of chlorine specified for hypochlorite products under NSF/ANSI Standard 60, C36

^{7:} The finished drinking water should be monitored to ensure that levels of manganese do not exceed 0.05 mg/L.

Aquaculture 1

StormKlear LiquiFloc Classic

Strength 1

1.6 mg/L

Chemical: Sodium Alginate

SeaKlear PRS Stage 2 1

1.6 mg/L

Hawkins, Inc.

3100 East Hennepin Avenue Minneapolis, MN 55413 Phone: (612) 331-6910 http://www.Hawkinsinc.com

Chemical: Polyamines

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Aqua Hawk 4917A 200 mg/L

Facility: #1 St. Paul MN

Chemical: Hydrochloric Acid

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Hydrochloric Acid 40 mg/L

Hydrochloric Acid, 25% 56 mg/L Muriatic Acid, 25% 56 mg/L

Chemical: Sodium Hydroxide

Liquid Caustic Soda 100 mg/L

Facility: #2 St. Paul MN

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Alum 150 mg/L

Aluminum Sulfate 150 mg/L

Liquid Aluminum Sulfate 150 mg/L

Chemical: Blended Corrosion Inhibitor

 LPC-31
 36 mg/L

 LPC-4
 33 mg/L

 LPC-5
 27 mg/L

Chemical: Chlorine

Liquid Chlorine 30 mg/L

Liquid Chlorine 10 mg/L

^{1:} Use level should not exceed 1 ounce per 5,000 gallons.

Chemical: Ferric Chloride

Ferric Chloride Solution 250 mg/L

Chemical: Hydrofluorosilicic Acid

Hydrofluosilicic Acid 6 mg/L

Chemical: Miscellaneous Corrosion Chemicals

Aqua Hawk 307 7 mg/L⁻

Chemical: Polymer Blends

Agua Hawk 4007 158 mg/L

Chemical: Sodium Hydroxide

Caustic Soda 30% 166 mg/L Caustic Soda 50% 100 mg/L

Chemical: Sodium Hypochlorite

Azone 105 mg/L
Azone-15 84 mg/L
Sodium Hypochlorite (10%) 105 mg/L
Sodium Hypochlorite (12.5%) 84 mg/L

Chemical: Sulfuric Acid

Sulfuric Acid50 mg/LSulfuric Acid 40%50 mg/LSulfuric Acid 66°50 mg/LSulfuric Acid 93%50 mg/L

Chemical: Zinc Orthophosphate

LPC-9 15 mg/L

Facility: #3 USA

Chemical: Tripolyphosphate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Feed-Rite #5 12.9 mg/L

Facility: Billings MT

Chemical: Sodium Hypochlorite

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Azone-15 84 mg/L

#Facility: Black Hawk SD

Chemical: Hydrofluorosilicic Acid

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

✓ Hydrofluosilicic Acid 6 mg/L

Chemical: Sodium Hypochlorite

Azone-15 84 mg/L

Facility: Centralia IL

Chemical: Sodium Hypochlorite

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Azone-15 84 mg/L

Facility: Columbia MO

Chemical: Sodium Hypochlorite

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Azone-15 84 mg/L

Facility: Eldridge IA

Chemical: Sodium Hypochlorite

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Azone-15 84 mg/L Sodium Hypochlorite 10.0% ¹ 105 mg/L

Sodium Hypochlorite 12.5% ¹ 84 mg/L

Facility: Fargo ND

Chemical: Hydrofluorosilicic Acid

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Hydrofluosilicic Acid 6 mg/L

Chemical: Sodium Hypochlorite

Azone-15 84 mg/L

Sodium Hypochlorite (12.5%) 84 mg/L

Facility: Fond du Lac WI

Chemical: Hydrofluorosilicic Acid

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Hydrofluosilicic Acid 6 mg/L

Chemical: Sodium Hydroxide

Liquid Caustic Soda 100 mg/L

Chemical: Sodium Hypochlorite

Sodium Hypochlorite 10.0% ¹ 105 mg/L

Sodium Hypochlorite 12.5% ¹ 84 mg/L

Chemical: Sodium Silicate

Sodium Silicate 42 mg/L

🌺 Facility: Minneapolis MN

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Alum 150 mg/L

Aluminum Sulfate 150 mg/L

Liquid Aluminum Sulfate 150 mg/L

Chemical: Ammonium Hydroxide

Ammonium Hydroxide (19% 15 mg/L

Ammonia)

Ammonium Hydroxide (25% 11 mg/L

Ammonia)

Chemical: Ammonium Sulfate

Aqua Hawk 347 60 mg/L

Chemical: Anhydrous Ammonia

Anhydrous Ammonia 5 mg/L

Chemical: Aqua Ammonia

Aqua Ammonia 10 mg/L

Chemical: Blended Coagulation Chemicals

Aqua Hawk 4017 163 mg/L
Aqua Hawk 9957 1 mg/L
Aqua Hawk 127 415 mg/L
Aqua Hawk 447 150 mg/L

Aqua Hawk 457 150 mg/L

Chemical: Blended Corrosion Inhibitor

HWTG-Bleach and Alkali Conditioner 27 mg/L LPC-31 36 mg/L LPC-4 33 mg/L LPC-5 27 mg/L

LPC-6 36 mg/L

LPC-60 34 mg/L LPC-67 31.7 mg/L

LPC-AM 23 mg/L

Chemical: Dipotassium Orthophosphate

LPC-DP 30 mg/L

Chemical:	Ferric	Chioride
OII CIIII CAII		

Aqua Hawk 1000	250 mg/L
Aqua Hawk 1007	250 mg/L
Aqua Hawk 1047	250 mg/L
Ferric Chloride Solution	250 mg/L

Chemical: Hydrochloric Acid

Hydrochloric Acid	40 mg/L
Hydrochloric Acid, 25%	56 mg/L
Murlatic Acid, 25%	56 mg/L

Chemical: Hydrofluorosilicic Acid

₩ Hydrofluosilicic Acid 6 mg/L

Chemical: Miscellaneous Corrosion Chemicals

Aqua Hawk 307 7 mg/L

Chemical: Miscellaneous Treatment Chemicals

TonkaZorb 3 mg/L

Chemical: Phosphoric Acid

LPC-36 27 mg/L

Chemical: Polyacrylamide

Aqua Hawk 117 160 mg/L Aqua Hawk 9937 3.5 mg/L

Chemical: Polyaluminum Chloride

Aqua Hawk 607 ² 250 mg/L

Chemical: Polyamines

Aqua Hawk 6947 20 mg/L

Chemical: Polymer Blends

Aqua Hawk 107	80 mg/L
Aqua Hawk 2757	150 mg/L
Aqua Hawk 2787	125 mg/L
Aqua Hawk 2887	100 mg/L
Aqua Hawk 2987	40 mg/L
Aqua Hawk 4007	158 mg/L
Aqua Hawk 427	256 mg/L
Aqua Hawk D2707	286 mg/L

Chemical: Sodium Aluminate

Sodium Aluminate 38%	40 mg/L
Sodium Aluminate 45 %	40 mg/L

Chemical: Sodium Bisulfite

Sodium Bisulfite 38% 46 mg/L Sodium Bisulfite 40% 46 mg/L

Chemical: Sodium Hydroxide

Caustic Soda 30% 166 mg/L Liquid Caustic Soda 100 mg/L

Chemical: Sodium Hypochlorite

Azone 105 mg/L Azone-15 84 mg/L

Chemical: Sodium Permanganate

Sodium Permanganate 20% 176 mg/L

Chemical: Sodium Silicate

Sodium Silicate 42 mg/L SS #5 42 mg/L

Chemical: Sulfuric Acid

Sulfuric Acid 50 mg/L
Sulfuric Acid 40% 50 mg/L
Sulfuric Acid 66° 50 mg/L
Sulfuric Acid 93% 50 mg/L

Chemical: Zinc Orthophosphate

LPC-9 15 mg/L

Facility: Peotone IL

Chemical: Sodium Hypochlorite

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Azone-15 84 mg/L Sodium Hypochlorite 10.0% 1 105 mg/L Sodium Hypochlorite 12.5% 1 84 mg/L

Facility: Roca NE

Chemical: Sodium Hypochlorite

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Azone-15 84 mg/L

Facility: Sioux Falls SD

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Alum 150 mg/L

Aluminum Sulfate	150 mg/L
Aluminum Sulfate (AL)	150 mg/L
Liquid Aluminum Sulfate	150 mg/L
Chemical: Blended Corrosion Inhibitor	
LPC-31	36 mg/L
LPC-4	33 mg/L
LPC-5	27 mg/L
Chemical: Hydrofluorosilicic Acid	
Hydrofluosilicic Acid	6 mg/L
Chemical: Polymer Blends	
Aqua Hawk 2757	150 mg/L
Chemical: Sodium HydroxIde	
Liquid Caustic	100 mg/L
Sodium Hydroxide 30%	166 mg/L
Sodium Hydroxide 50%	100 mg/L
Chemical: Sodium Hypochlorite	
Azone-15	84 mg/L
Sodium Hypochlorite (12.5%)	84 mg/L
Facility: Slater IA	
Chemical: Hydrofluorosilicic Acid	
Trade Designation	Maximum Use (mg/L unless otherwise indicated)
Hydrofluosilicic Acid	6 mg/L
Chemical: Sodium Hydroxide	
Caustic Soda 30%	166 mg/L
Chemical: Sodium Hypochlorite	
Azone-15	84 mg/L
Facility: Superior WI	
Chemical: Hydrofluorosilicic Acid	
Trade Designation	Maximum Use (mg/L unless otherwise indicated)
Hydrofluosilicic Acid	6 mg/L
Chemicał: Sodium Hydroxide	
Caustic Soda 50%	100 mg /L
Chemical: Sodium Hypochlorite	
Azone-15	84 mg/L

C 43

Facility: Washburn ND

Chemical: Hydrofluorosilicic Acid

Trade Designation

Maximum Use (mg/L unless

otherwise indicated)

Hydrofluosilicic Acid

6 mg/L

Chemical: Sodium Hydroxide

Caustic Soda 50%

100 mg/L

Chemical: Sodium Hypochlorite

Azone-15

84 mg/L

Hygienic Solutions B.V. MGR.C Veermanlaan 58

1131 KY Volendam, THE NETHERLANDS

Phone: +31 299 323309 http://www.coolerclean.com

Chemical: Hydrogen Peroxide

Trade Designation

Maximum Use (mg/L unless

otherwise indicated)

CoolerClean Rinse

25 mg/l.

CoolerClean Spray

25 mg/L

Industrial Chemicals Inc 1125 Roberts Industrial Drive Birmingham, AL 35216 Phone: (205) 978-0450

http://www.industrialchem.com

Facility: Birmingham AL

Chemical: Aluminum Sulfate

Trade Designation

Maximum Use (mg/L unless

otherwise indicated)

Aluminum Sulfate Solution 1 2

150 mg/L

Chemical: Ferric Chloride

Ferric Chloride Tech 37-42%

250 mg/L

Chemical: Ferric Sulfate

Ferric Sulfate Solution 50%

600 mg/L

Chemical: Hydrofluorosilicic Acid

Hydrofluorosilicic Acid ³

6 mg/L

^{1:} The residual levels of chlorine (hypochlorite ion and hypochlorous acid), chlorine dioxide, chlorate ion, chloramine and disinfection by-products should be monitored in the finished drinking water to ensure compliance to all applicable regulations.

^{2:} Based on evaluation of health effects data, the level of aluminum in the finished drinking water shall not exceed 2 mg/L.

Chemical: Hydrogen Peroxide

Hydrogen Peroxide 35% Solution 4.5

Hydrogen Peroxide 50% ^{6 5}

Chemical: Phosphoric Acid

Phosphoric Acid 75% 12 mg/L

Phosphoric Acid 81-85% 12 mg/L

Chemical: Sodium Carbonate

Soda Ash Dense 100 mg/L

Chemical: Sodium Hydroxide

Sodium Hydroxide 25% Solution 100 mg/L

Sodium Hydroxide 50% 100 mg/L

Chemical: Sodium Hypochlorite

Sodium Hypochlorite 12.5% 84 mg/L

Chemical: Sulfuric Acid

Sulfuric Acid 93% 50.0 mg/L

Facility: Jonesboro GA

Chemical: Aluminum Sulfate

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

3 mg/L

3 mg/L

Aluminum Sulfate Solution 1 2 150 mg/L

Chemical: Ferric Chloride

Ferric Chloride Tech 37-42% 250 mg/L

Chemical: Ferric Sulfate

Ferric Sulfate Solution 50% 600 mg/L

Chemical: Hydrofluorosilicic Acid

Hydrofluorosilicic Acid ³ 6 mg/L

Chemical: Hydrogen Peroxide

Hydrogen Peroxide 35% Solution ^{4 5} 3 mg/L

Hydrogen Peroxide 50% ^{6 5} 3 mg/L

Chemical: Phosphoric Acid

Phosphoric Acid 75% 12 mg/L

Phosphoric Acid 81-85% 12 mg/L

Chemical: Sodium Carbonate

Soda Ash Dense 100 mg/L

Chemical: Sodium Hydroxide

Sodium Hydroxide 25% Solution 100 mg/L

Rowell Chemical Corporation/Milport Enterprises

15 Salt Creek Lane Suite 205

Hinsdale, IL 60521 Phone: (630) 920-8833

http://www.rowellchemical.com/

#

Facility: Milwaukee WI

Chemical: Ammonium Hydroxide

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Ammonia Solution 14 mg/L

Chemical: Chlorine

Chlorine ¹ 30 mg/L

Chemical: Fluorosilicic Acid

Fluorosilicic Acid 6.0 mg/L

Chemical: Sodium Hydroxide

Caustic Soda 50% 100 mg/L

Chemical: Sodium Hypochlorite

Sodium Hypochlorite ¹ 84 mg/L

Facility: Willow Springs IL

Chemical: Ammonium Hydroxide

Trade Designation Maximum Use (mg/L unless

otherwise indicated)

Ammonia Solution 14 mg/L

Chemical: Chlorine

Chlorine ¹ 30 mg/L

Chemical: Fluorosilicic Acid

Fluorosilicic Acid 6.0 mg/L

Chemical: Sodium Hydroxide

Caustic Soda 50% 100 mg/L

Chemical: Sodium Hypochlorite

Sodium Hypochlorite ¹ 84 mg/L

Southwestern Paint & Supply

3765 E. Avirton Hwy Tucson, AZ 85713

Phone: 520-747-1573

^{1:} The residual levels of chlorine (hypochlorite ion and hypochlorous acid), chlorine dioxide, chlorate ion, chloramine and disinfection by-products should be monitored in the finished drinking water to ensure compliance to all applicable regulations.

Peroxolyte All-Purpose

200 mg/L



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Wed, Nov 23, 2011

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International Headquarters & Laboratory
4151 Naperville Road
Lisle, IL 60532-3696
USA
630 505 0160, Fax 630 505 9637
Info@wga.org, www.wqa.org

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<u>ONLINE CERTIFICATIONS DIRECTORY</u>

FDPH.MH26173 **Drinking Water Treatment Chemicals**

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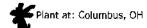
Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

BONDED CHEMICALS INC 2645 CHARTER ST COLUMBUS, OH 43228 USA

MH26173

ANSI/NSF STANDARD 60



Trade Dsg	Сатедогу	Max Use Level (mg/L)
Ferric Chloride Solution (37%)	Coagulation and Flocculation Products	400
Sodium Hydroxide Solution (50% Tech)	Corrosion and Scale Control, Softening, Sequestering, Precipitation and pH adjustment	200
Hypochiorite Solution 12-15%	Disinfection and Oxidation	80
Fluorosificic Acid	Miscellaneous Treatment Application Products	6.0

Last Updated on 2009-02-18

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FDPH.MH26042 **Drinking Water Treatment Chemicals**

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

BRENNTAG CANADA INC

43 JUTLAND RD TORONTO, ON M8Z 2G6 CANADA MH26042

ANSI/NSF STANDARD 60

Plant at: Calgary, Alberta. Canada

Trade Dsg	Category	Max Use Level (mg/L)
Phosphoric Acid 75%	Corrosion and Scale control	13.8

Plant at: Concord, ON

Trade Dsg	Category	Max Use Level (mg/L)
Ferric Sulfate		
Ferric Sulfate	Coagulation and Flocculation	600
30% Sodium Hydroxide	pH Adjustment	167
50% Sodium Hydroxide	pH Adjustment	100
Hydrofluosilicic Acid, 25%	Miscellaneous Treatment Application Products	. 6.0



Plant at: Cornwall, ON

Trade Dsg	Category	Max Use Level (mg/L)
Citric Acid	•	•
Watercare DP05	Disinfection and Oxidation	N/A
Ferric Sulfate		
Ferric Sulfate	Coagulation and Flocculation	600
Poly Aluminum Chloride	Coagulation and Flocculation	250
Aluminum Sulfate	Coagulation and Flocculation Products	150
Sodium Silicate	Coagulation and Flocculation Products	42
Phosphoric Acid 75%	Corrosion and Scale control	13.8
Phosphoric Acid 85%	Corrosion and Scale control	12
Citric Acid	Disinfection and Oxidation	N/A
30% Sodium Hydroxide	pH Adjustment	167
50% Sodium Hydroxide	pH Adjustment	100
Anhydrous Ammonia	Disinfection and Oxidation	5

Aqua Ammonía - 20.65 Degrees Baume	Disinfection and Oxidation	50
Aqua Ammonia - 26 Degrees Baume	Disinfection and Oxidation	35
Sodium Hypochlorite 12%	Disinfection and Oxidation	80
Sodium Hypochlorite 15%	Disinfection and Oxidation	66
Chlorine	Disinfection and Oxidation	30
Sodium Bisulfite 38%	Corrosion and Scale control	18
25% Sodium Hydroxide	pH Adjustment	200
Hydrofluosilicic Acid, 25%	Miscellaneous Treatment Application Products	6.0
Sulphur Dioxide	Miscellaneous Treatment Application Products	10

Plant at: Langly, BC

Trade Dsg	Category	Max Use Levei (mg/L)
Citric Acid		
Watercare DP05	Disinfection and Oxidation	N/A
Aluminum Sulfate	Coagulation and Flocculation Products	150
Phosphoric Acid 85%	Corrosion and Scale control	12
Citric Acid	Disinfection and Oxidation	N/A
30% Sodium Hydroxide	pH Adjustment	167
50% Sodium Hydroxide	pH Adjustment	100
Anhydrous Ammonia	Disinfection and Oxidation	5
Aqua Ammonia - 26 Degrees Baume	Disinfection and Oxidation	35
Sodium Hypochlorite 12%	Disinfection and Oxidation	80
Sodium Hypochlorite 15%	Disinfection and Oxidation	66
Chlorine	Disinfection and Oxidation	30
25% Sodium Hydroxide	pH Adjustment	200

Plant at: Leduc, AB

Trade Dsg	Category	Max Use Level (mg/L)
30% Sodium Hydroxide	pH Adjustment	167
50% Sodium Hydroxide	pl·l Adjustment	100
Sodium Bisulfite 38%	Corrosion and Scale control	18
25% Sodium Hydroxide	pH Adjustment	200

Plant al: Toronto, ON

Trade Dsg	Category	Max Use Level (mg/L)
Ferric Sulfate		<u> </u>
Ferric Sulfate	Coagulation and Flocculation	600
30% Sodlum Hydroxide	pH Adjustment	167
50% Sodium Hydroxide	pH Adjustment	100
25% Sodium Hydroxide	pH Adjustment	200



Trade Dsg	Category	Max Use Level (mg/L)
Sodium Carbonate		
Soda Ash	pH Adjustment	100
Hydrofluosilicic Acid, 25%	Miscellaneous Treatment Application Products	6.0

nt at: Winnipeg, MB

Trade Dsg	Category	Max Use Level (mg/L)
Citric Acid		
Watercare DP05	Disinfection and Oxidation	N/A
Polyaluminum Chloride		
Watercare A55010	Coagulation and Flocculation	293
Phosphoric Acid 75%	Corrosion and Scale control	13.8
Phosphoric Acid 85%	Corrosion and Scale control	12
Citric Acid	Disinfection and Oxidation	N/A
30% Sodium Hydroxide	pH Adjustment	167
50% Sodium Hydroxide	pH Adjustment	100
Sodium Hypochlorite 12%	Disinfection and Oxidation	80
Sodium Hypochlorite 15%	Disinfection and Oxidation	66
Chlorine	Disinfection and Oxidation	30
Sodium Metabisuiphite 38%	Disinfection and Oxidation	47
25% Sodium Hydroxide	pH Adjustment	200
Hydrofluosilicic Acid, 25%	Miscellaneous Treatment Application Products	6.0

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FDPH.MH46303 **Drinking Water Treatment Chemicals**

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

DUMONT CO INC 381 S CENTRAL AVE OVIEDO, FL 32765 USA MH46303

ANSI/NSF STANDARD 60



Plant at: Plant 1 USA

Trade Dsg	Category	Max Use Level (mg/L)
Ammonium Sulfate		
AS 1000	Disinfection and Oxidation	25
AS 4000	Disinfection and Oxidation	60
Blended Phosphates		
PT1025	Corrosion and Scale Control	37.0
PT1034	Corresion and Scale Control	28.0
PT1224	Corrosion and Scale Control	38.0
PT1233	Corrosion and Scale Control	29.0
PT1 524	Corrosion and Scale Control	38.0
PT1532	Corrosion and Scale Control	29.0
P12024	Corrosion and Scale Control	37.0
PT2032	Corrosion and Scale Control	28.0
PT2523	Corrosion and Scale Control	38.0
PT2536	Corrosion and Scale Control	32.0
PT3024	Corrosion and Scale Control	36.0
PT3030	Corresion and Scale Control	40.0
PT3032	Corrosion and Scale Control	27.0
PT3034	Corrosion and Scale Control	28.0
PT4030	Corrosion and Scale Control	48.0
PT4036	Corrosion and Scale Control	32.0
PT5024	Corrosion and Scale Control	32.0
PT5027	Corrosion and Scale Control	28.0
PT5032	Corrosion and Scale Control	25.0
PT5036	Corrosion and Scale Control	22.0
PT6030	Corrosion and Scale Control	52.7

PT6036	Corrosion and Scale Control	40.0
PT7035	Corrosion and Scale Control	23.0
PT7036	Corrosion and Scale Control	35.0
PT7528	Corrosion and Scale Control	47.0
PT7529	Corrosion and Scale Control	24.0
PT7541	Corrosion and Scale Control	18.0
PT8028	Corrosion and Scale Control	25.0
PT8031	Corrosion and Scale Control	56.3
PT8037	Corrosion and Scale Control	19.0
PT8529	Corrosion and Scale Control	23.0
PT8539	Corrosion and Scale Control	18.0
PT9030	Corrosion and Scale Control	22.0
PT9031	Corrosion and Scale Control	21.0
PT9040	Corrosion and Scale Control	17.0
PT 9 041	Corrosion and Scale Control	16.0
Ory OrthoPhosphates		
OT5757C	Corrosion and Scale Control	16.0
OT6565C	Corrosion and Scale Control	15.0
Dry Polyphosphate	•	
PT5757C	Corrosion and Scale Control	17.4
PT7 171 C	Corrosion and Scale Control	14.0
PT7777C	Corrosion and Scale Control	12.9
P18585C	Corrosion and Scale Control	12.0
PT8989C	Corrosion and Scale Control	10.7
Fluosiilcic Acid		
HFS 2300	Fluoridation	5.2
HF5 4000	Fluoridation	3
Miscellaneous Blended Pl	nosphates	
OT1414T	Corrosion and Scale Control	55.0
OT2525	Corrosion and Scale Control	20.0
ОТ2727Т	Corrosion and Scale Control	30
OT3535	Corrosion and Scale Control	20.0
ОТ3737	Corrosion and Scale Control	20.0
PT1717	Corrosion and Scale Control	65.6
PT2727	Corrosion and Scale Control	40.0
PT3029T	Corrosion and Scale Control	30
PT3434	Corrosion and Scale Control	32.4
PT3535	Corrosion and Scale Control	28.9
PT3737	Corrosion and Scale Control	25.4
PT5033	Corrosion and Scale Control	30.0
PT7030	Corrosion and Scale Control	30
PT7032		
	•	•



FDPH.MH18026 Drinking Water Treatment Chemicals

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

JCI JONES CHEMICALS INC SUITE 1100 1819 MAIN ST SARASOTA, FL 34236 USA MH18026

ANSI/NSF STANDARD 60

Plant at: Barberton, OH

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustmert	700
Sodium Hydroxide 25-15%	pH Adjustmert	200
Sodium Hydroxide 49-26%	pH Adjustmert	100
Sodium Hydroxide 50%	pH Adjustmert	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Píus	Disinfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sol (r) Bleach	Disinfection and Oxidation	190
Sunny Sol (r) Chlorine (A)	Disinfection and Oxidation	30

Plant at: Beech Grove, IN

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700
Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxide 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Pius	DisInfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sol (r) Bleach	Disinfection and Oxidation	190

Plant at: Caledonia, NY

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700

Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxide 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Plus	Disinfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sol (r) Bleach	Disinfection and Oxidation	190
Hydrofluorosilic Acid	Fluoridation	1.2
Sulfur Dioxide	Misceilaneous Treatment Application Products	10

Plant at: Charlotte, NC

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700
Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxide 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Plus	Disinfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sol (r) Bleach	Disinfection and Oxidation	190

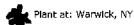
Plant at: Jasksonville, FL

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700
Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxlde 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Plus	Disinfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sol (r) Bleach	Disinfection and Oxidation	190

Plant at: Merrimack, NH

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700
Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxide 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Plus	Disinfection and Oxidation	100.

Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700
Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxide 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Plus	Disinfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sol (r) Bleach	Disinfection and Oxidation	190



Trade Dsg	Category	Max Use Level (mg/L)
Sodium Hydroxide 14-5%	pH Adjustment	700
Sodium Hydroxide 25-15%	pH Adjustment	200
Sodium Hydroxide 49-26%	pH Adjustment	100
Sodium Hydroxide 50%	pH Adjustment	100
Sunny Sol (r) 100	Disinfection and Oxidation	108
Sunny Sol (r) 100 Plus	Disinfection and Oxidation	100
Sunny Sol (r) 150	Disinfection and Oxidation	80
Sunny Sof (r) Bleach	Disinfection and Oxidation	190
Sodium Bisulfite 25%	Dechlorinator and Antioxidant	18
Sodium bisulfite 38-40%	Dechlorinator and Antioxidant	18
Hydrofluorosilic Acid	Fluoridation	1.2
Hydrofluorosilicic	Miscellaneous Treatment Application Products	-



(A) - The finished drinking water should be monitored to ensure complience with all applicable regulations

(r) - Registered Trademark

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<u>ONLINE CERTIFICATIONS DIRECTORY</u>

FDPH.MH17829 **Drinking Water Treatment Chemicals**

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

KC INDUSTRIES L.L.C. 2420 OLD HWY 60 PO BOX 646 MULBERRY, FL 33860 USA MH17829



Plant at: 001

ANSI/NSF STANDARD 60

Trade Dsg	Category	Max Use Level (mg/L)
Hydrofluosilie Acid*	Fluoridation	6.0
Sodium Silicofluoride*	Fluoridation	2.0



Plant at: Hunan, CHINA



Trade Dsg	Category	Max Use Level (mg/L)
Sodium fluoride (a)	Miscellaneous Treatment Application Products	2.3

(a) - This maximum use level corresponds to a maximum Fluoride concentration of $1.2\ mg/L$

* - The maximum use level is equivalent to a fluoride concentration of 1.2 mg/L

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FDPH.MH47618 Drinking Water Treatment Chemicals

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

KEY CHEMICAL INC 9503 DOVEWOOD PL WAXHAW, NC 28173 USA MH47618

ANSI/NSF STANDARD 60

Pla

Plant at: Bakersville, NC

Trade Osg	Category	Max Use Level (mg/L)
Hydroffuesilicic Acid 20-25% (Fluesificic Acid)	Fluoridation	6.0



Plant at: Spruce Pine, NC

Trade Dsg	Category	Max Use Level (mg/L)
Hydrofluosilicic Acid 20-25% (Fluosilicic Acid)	Fluoridation	6.0

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FDPH.MH45496 **Drinking Water Treatment Chemicals**

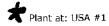
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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

LC BLENDING INC 3301 CARBIDE DR SULPHUR, LA 70665 USA MH45496

ANSI/NSF STANDARD 60



Trade Dsg	Category	Max Use Level (mg/L)		
Ammonium Hydroxide				
Ammonium Hydroxide - 29%	Disinfection and Oxidation	14		
Ammonium Sulfate				
40% Ammonium Sulfate Solution	Disinfection and Oxidation	62.5		
30% Ammonium Sulfate Solution	pH Adjustment	62.5		
Sodium Hydroxide				
AquaPro - C25	pH Adjustment	200		
AquaPro - C50	pH Adjustment	100		
LCB 2000	pH Adjustment	200		
LCB 4000	pH Adjustment	100		
Sodium Hypochlorite				
AquaPro - B10	Disinfection and Oxidation	100		
AquaPro - B12	Disinfection and Oxidation	80		
LCB 1017	Corrosion and scale control	20.0		
LCB 1020	Corrosion and scale control	20		
LCB 1111AM	Corrosion and scale control	91.5		
LCB 1117	Corrosion and scale control	18.2		
LCB 1120	Corrosion and scale control	19.4		
LCB 1136	Corrosion and scale control	35.0		
LCB 1141	Corrosion and scale control	18.0		
LCB 1155	Corrosion and scale control	18.2		
LCB 1200	Corrosion and scale control	15.0		
LCB 1213	Corrosion and scale control	16.7		
LCB 1224	Corrosion and scale control	32.0		
LCB 1230	Corrosion and scale control	52.7		

	Corrosion and scale control	18.0
ZO 265	Corrosion and scale control	15.0
ZP 184	Corrosion and scale control	35
ZP 184A	Corrosion and scale control	32.0
ZS-120	Corrosion and scale control	16
ZS-355D	Corrosion and scale control	5
Sulfuric Acid	pH Adjustment	50
LCB 2100	Disinfection and Oxidation	100
I.CB 2200	Disinfection and Oxidation	80
LCB 7878A	Corrosion and scale control	12.6
Aquapro SS100	Dechlorination/antioxidant	22
Aquapro SS330	DechlorInation/antioxidant	66
Aquapro CS-25	Miscellaneous Treatment Application Products	4
Hydrofluosilicic Acid 23%	Miscellaneous Treatment Application Products	3
Hydrofluosilicic Acid 40%	Miscellaneous Treatment Application Products	3

Trade Dsg	Category	Max Use Level (mg/L)
Dry Ammonium Sulfate	Disinfection and Oxidation	25

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FDPH.MH10116 **Drinking Water Treatment Chemicals**

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

MAIN POOL & CHEMICAL CO INC

MH10116

110 COMMERCE RD DUPONT, PA 18641 USA

ANSI/NSF STANDARD 60



Plant at: Avoca, PA

Trade Dsg	Category	Max Use Level (mg/L)
Aluminum Sulfate	Coagulation and Flocculation Products	156
Polyaluminum Chloride	Coagulation and Flocculation Products	250
45% Potassium Hydroxide	Corrosion and Scale Control, Softening, Sequestering, Precipitation and pH adjustment	100
Sodium Hydroxide (25%)	Corrosion and Scale Control, Softening, Sequestering, Precipitation and pH adjustment	200
Sodium Hydroxide (50%)	Corrosion and Scale Control, Softening, Sequestering, Precipitation and pH adjustment	100
Sodium Hypochlorite	Disinfection and Oxidation	80
Sodium Fluoride	Miscellaneous Treatment Application Products	2.3



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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

MOMENTIVE PERFORMANCE MATERIALS QUARTZ INC

4901 CAMPBELL RD WILLOUGHBY, OH 44094 USA MH17874

ANSI/NSF STANDARD 60

Plant at: Willoughby, OH

Trade Dsg	Category	Max Use Level (mg/L)
Hydrofluorosilicic Acid	Fluoridation	5.2

<u>Last Updated</u> on 2005-05-03

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

PRAYON S A RUE JOSEPH WAUTERS 144 4130 ENGIS, BELGIUM MH26736





Plant at: Prayon N.V.

Trade Dsg	Category	Max Use Level (mg/L)
Phosphoric Acid LS-75+ Liquid	Corrosion and Scale control	18.3
Phosphoric Acid LS-85+ Liquid	Corrosion and Scale control	13.8
Phosphoric Acid P5-75 Liquid	Corrosion and Scale control	13.8
Phosphoric Acid P5-85 Liquid	Corrosion and Scale control	13.8
Sodium Fluoride*	Fluoridation	2,6
Sodium Fluosificate*	Fluoridation	2.0



st - The maximum use level is equivalent to a fluoride concentration of 1.2 mg/L

<u>Last Updated</u> on 2010-01-07

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Drinking Water Treatment Chemicals

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PVS-NOLWOOD CHEMICALS INC 10900 HARPER AVE PO BOX 135900

DETROIT, MI 48213 USA

MH18629



Plant at: Distribution Center - Detroit, MI

ANSI/NSF STANDARD 60

_	Trade Dsg	Category	Max Use Level (mg/L)
√	Hdrofluorosilicic Acid (HFS)	Miscellaneous Treatment Application Products	6

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

SHANGHAI MINTCHEM DEVELOPMENT CO LTD

MH28896

ROOM 602 4 89 NONG MUDAN RD PUDONG ZONE 200000 SHANGHAI, CHINA

ANSI/NSF STANDARD 60



Plant at: Zhuzhou City, China

V	
✓	

Trade Dsg	Category	Max lise Level (mg/L)
Sodium Fluoride	Miscellaneous Treatment Application Products	2.6
Sodium Fluorosilicate	Miscellaneous Treatment Application Products	2.0

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

THATCHER CO 1905 FORTUNE RD PO BOX 27407 SALT LAKE CITY, UT 84127 USA MH17003

ANSI/NSF STANDARD 60

Plant at: Buckeye, AZ

Trade Dsg	Category	Max Use Level (mg/L)
T-Floc 1410	Coagulation and Flocculation	50
T-Floc 1417	Coagulation and Flocculation	100
T-Floc 1419	Coagulation and Flocculation	50
T-Floc 1420	Coagulation and Flocculation	25
Aluminum Sulfate	Flucculation	150
TI-2903	Corrosion and Scale Control	27.5
TI-2904	Corrosion and Scale Control	33
TI-2906	Corrosion and Scale Control	79
TI-2907	Corrosion and Scale Control	15.5
TI-2908	Corrosion and Scale Control	27.5
TI-3021	Corrosion and Scale Control	28
Citric Acid Solution (1)	Membrane Cleaner	N/A
Citric Acid Solution	pH Adjustment	250
Sodium Hydroxide 18%	pH Adjustment	278
Sodium Hydroxide 20%	pH Adjustment	250
Sodium Hydroxide 25%	pH Adjustment	200
Sodium Hydroxide 30%	pH Adjustment	167
Sodium Hydroxide 33%	pH Adjustment	152
Sodium Hydroxide 50%	pH Adjustment	100
Sulfuric Acid 20 - 39%	pH Adjustment	120
Sulfuric Acid 40 - 59%	pH Adjustment	84
Sulfuric Acid 60 - 79%	pH Adjustment	63
Sulfuric Acid 80 - 93%	pH Adjustment	50
Sulfuric Acid, 98%	pH Adjustment	50
Sodium Chlorite, 18.75%	Disinfection and Oxidation	37.3

Sodium Chlorite, 25%	Disinfection and Oxidation	28
Sodium Chlorite, 30%	Disinfection and Oxidation	23.3
Sadium Chlorite, 31%	Disinfection and Oxidation	22.6
Sodium Chlorite, 31.25%	Disinfection and Oxidation	22.4
Sodium Chlorite, 37%	Disinfection and Oxidation	18.9
Sodium Chlorite, 7.5%	Disinfection and Oxidation	93.3

Plant at: DeLand, Florida

Trade Dsg	Category	Max Use Level (mg/L)
TI-3031		
TI-3031	Corrosion and Scale Control	27.8
Compliance GT	Coagulation and Flocculation	43
Ferric Sulfate, 10 - 13% Iron	Coagulation and Flocculation	500
Sodium Aluminate	Coagulation and Flocculation	43
Aluminum Sulfate	Flocculation	150
Citric Acid Solution (1)	Membrane Cleaner	N/A
Citric Acid Solution	pH Adjustment	250
Ammonium Sulfate, 40%	DisInfection and Oxidation	62.5



Plant at: Henderson, NV

Trade Dsg	Category	Max Use Level (mg/L)
Aluminum Sulfate	Flocculation	150
Zinc Orthophosphate	Corrosion and Scale Control	20
Citric Acid Solution (1)	Membrane Cleaner	N/A
Citric Acid Solution	pH Adjustment	250
Sodium Hypochlorite	Disinfection and Oxidation	80
Hydrofluosilic Acid	Fluoridation	6.0



Plant at: Missoula, MT

Trade Dsg	Category	Max Use Level (mg/L)
Aluminum Sulfate	Flocculation	150
Π-3021	Corrosion and Scale Control	28



Plant at: Salt Lake City, UT

Category	Max Use Level (mg/L)
Coagulation and Flocculation	50
Coagulation and Flocculation	100
Coagulation and Flocculation	50
Coagulation and Flocculation	25
Coagulation and Flocculation	650
	Coagulation and Flocculation Coagulation and Flocculation Coagulation and Flocculation Coagulation and Flocculation

	Corrosion and Scale Control	16
TI-3021	Corrosion and Scale Control	28
Zinc Orthophosphate	Corrosion and Scale Control	20
Citric Acid Solution (1)	Membrane Cleaner	N/A
Citric Acid Solution	pH Adjustment	250
Soda ash	pH Adjustment	100
Sodium Hydroxide 18%	pH Adjustment	278
Sodium Hydroxide 20%	pH Adjustment	250
Sodium Hydroxide 25%	pH Adjustment	200
Sodium Hydroxide 30%	pH Adjustment	167
Sodium Hydroxide 33%	pH Adjustment	152
Sodium Hydroxide 50%	pH Adjustment	100
Anhydrous Ammonia	Disinfection and Oxidation	5
Aqua Ammonia 25%	Disinfection and Oxidation	40
Aqua Ammonia 28%	Disinfection and Oxidation	35
Chlorine	Disinfection and Oxidation	30
Sodium Hypochlorite	Disinfection and Oxidation	80
Sodium Bisulfite	Chlorine Removal, Misc.	18
Hydrofluosilic Acid	Fluoridation	6.0



Piant at: Williamson, NY

Trade Dsg	Category	Max Use Level (mg/l.)
Compliance GT	Coagulation and Flocculation	43
Sodium Aluminate	Coagulation and Flocculation	43
Aluminum Sulfate	Flocculation	150
Zinc Orthophosphate	Corrosion and Scale Control	16.5
Citric Acid Solution (1)	Membrane Cleaпer	N/A
Citric Acid Solution	pH Adjustment	250
Hydrofluosilic Acid	Fluoridation	6.0



(1) - These products are designed to be used off-line and flushed out prior to using the system for drinking water, following the manufacturer's use instructions. The pH or other water chemistry of the influent and effluent water should be monitored to ensure that all traces of the product have been removed before placing into service.

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<u>NLINE CERTIFICATIONS DIRECTORY</u>

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

UNIMIN CORP

CRYSTAL PLANT 136 CRYSTAL DR SPRUCE PINE, NC 28777 USA MH25246





Plant at: Bakersville, NC

Trade Dsg		Category	Max Vse Level (mg/L)	
Hydroflud	silicic Acid 20-25% (Fluosilicic Acid)		Fluoridation	6.0



lant at: Spruce Pine, NC

	Trade Dsg	Category_	Max Use Level (mg/L
V	Hydrofluosificic Acid 20-25% (Fluosificic Acid)	Fluoridation	6.0

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(mg/L)

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FDPH.MH17854 Drinking Water Treatment Chemicals

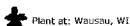
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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

WAUSAU CHEMICAL CORP 2001 N RIVER DR WAUSAU, WI 54403 USA

MH17854



ANSI/NSF STANDARD 60

Trade Dsg	Category	Max Use Level (mg/L)
Clar+Ion 700 Activator	Coagulation and Flocculation	10
23% Hydrofluosilicic Acid	Fluoridation	6.6
50% Liquid Caustic Soda	pH Adjustment	100
Hypo-Chior	DisInfection and Oxidation	80

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<u>ONLINE CERTIFICATIONS DIRECTORY</u>

FDPH.MH47183 **Drinking Water Treatment Chemicals**

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Drinking Water Treatment Chemicals

See General Information for Drinking Water Treatment Chemicals

ZHUZHOU MINGSHENG ZINC CHEMICAL CO LTD

TAOSHUI YOU COUNTRY ZHUZHOU, HUNAN 412303 CHINA MII47183



Plant at: Hunan, CHINA

Trade Dsg	Category

Trade Dsg	Category	Max Use Level (mg/L)
Sodium fluoride (a)	Miscellaneous Treatment Application Products	2.3

ANSI/NSF STANDARD 60

(a) - This maximum use level corresponds to a maximum Fluoride concentration of 1.2 mg/L

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