Water Fluoridation Additives

On this page:

Types of Fluoride Additives

Community water systems in the United States use one of three additives for water fluoridation. Decisions on which additive to use are based on cost of product, product-handling requirements, space availability, and equipment.

The three additives are:

- Fluorosilicic acid: a water-based solution used by most water fluoridation programs in the United States. Fluorosilicic acid is also referred to as hydrofluorosilicate, FSA, or HFS.
- Sodium fluorosilicate: a dry additive, dissolved into a solution before being added to water.
- Sodium fluoride: a dry additive, typically used in small water systems, dissolved into a solution before being added to water.

Back to top (#content)

Sources of Fluoride Additives

Most fluoride additives used in the United States are produced from phosphorite rock. Phosphorite is used primarily in the manufacture of phosphate fertilizer. Phosphorite contains calcium phosphate mixed with limestone (calcium carbonates) minerals and apatite—a mineral with high phosphate and fluoride content. It is refluxed (heated) with sulfuric acid to produce a phosphoric acid-gypsum (calcium sulfate-$CaSO_4$) slurry.

The heating process releases hydrogen fluoride (HF) and silicon tetrafluoride (SiF_4) gases which are captured by vacuum evaporators. These gases are then condensed to a water-based solution of 23% FSA with the remainder as water.

Approximately 95% of FSA used for water fluoridation comes from this process. The remaining 5% of FSA is generated during the manufacture of hydrogen fluoride or from the use of hydrogen fluoride in the manufacturing of solar panels and electronics.

Since the early 1950s, FSA has been the chief additive used for water fluoridation in the United States. The favorable cost and high purity of FSA make it a popular source. Sodium fluorosilicate and sodium fluoride are dry additives that come largely from FSA.

FSA can be partially neutralized by either table salt (sodium chloride) or caustic soda to get sodium fluorosilicate. If enough caustic soda is added to neutralize the fluorosilicate completely, it results in sodium fluoride. Sodium fluoride is also produced by mixing caustic soda with hydrogen fluoride, although approximately 90% of the sodium fluoride used in the United States comes from FSA.

Back to top (#content)

Regulatory Scope on Additives

The U.S. Environmental Protection Agency (EPA) has authority over safe community drinking water, as specified in the Safe Drinking Water Act. On the basis of the scientific study of potential adverse health effects from contaminated water, the EPA sets a Maximum Contaminant Level (MCL) concentration allowed for various organisms or substances.

Although EPA does not specifically regulate levels of “direct additives,” which are chemicals added to water in the course of treatment, it does specify that the addition of chemicals as part of treatment should not exceed the MCL concentration for regulated substances. This MCL limit includes the levels naturally occurring in the source water, plus the contribution from direct additives. In 1979, EPA executed a Memorandum of Understanding with the U.S. Food and Drug Administration (FDA) to establish and clarify areas of authority in controlling additives in drinking water. FDA has regulatory oversight on food additives, which includes bottled water, and EPA has regulatory oversight on direct additives in public drinking water supplies.

Because of the decision to transfer the additives program to the private sector, EPA declared a moratorium in 1980 on issuing new advisory opinions on additives. EPA awarded a cooperative agreement to a group of nonprofit, nongovernmental organizations led by the National Sanitation Foundation (NSF) in 1985 to develop a new additives program. Three years later, EPA announced that the new National Sanitation Foundation/American National Standards Institute (NSF/ANSI) Standard 60 was functioning.

A good reference for drinking water treatment quality-assurance practices of governmental authorities in various countries is the **Overview of National and International Guidelines and Recommendations on the Assessment and Approval of Chemicals Used in the Treatment of Drinking Water**

(http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/watergde.pdf) * (PDF–476K). It also gives context to the United States AWWA and NSF/ANSI standards and practices.

Back to top (#content)

EPA Regulatory Criteria for Fluoride Additives

All additives used at water treatment plants, including fluoride additives, must meet strict quality standards that assure the public's safety. These additives are subject to a stringent system of standards, testing, and certificates by the American Water Works Association (AWWA) and the National Sanitation Foundation/American National Standards Institute (NSF/ANSI). Both of these entities are nonprofit, nongovernmental organizations.

Optimally fluoridated community water systems add fluoride to a level between 0.7 – 1.2mg/L. Fluoride is sometimes naturally present in water at much higher levels, so the EPA established a Maximum Contaminant Level for fluoride of 4.0 mg/L (parts per million).

The EPA has not established an MCL for silicates, the second most prevalent substance in FSA, because there are no recognized health concerns. NSF/ANSI Standard 60, however, has a Maximum Allowable Level of 16 mg/L for sodium silicates as corrosion control agents. This is mainly to control turbidity—a measure of water clarity or how much the material suspended in water decreases the passage of light through the water.

Studies have shown that silicofluorides achieve virtually complete dissolution and ionic disassociation at the concentrations they are added to the drinking water. The equilibrium reached at the pH, temperature, and fluoride concentration used in water fluoridation account for this. One study reported that no intermediates or other products were observed at pH levels as low as 3.5. (Finney WF, Wilson E, Callender A, Morris MD, Beck LW. Reexamination of hexafluorosilicate hydrolysis by fluoride NMR and pH measurement. *Environ Sci Technol* 2006;40:8:2572).

The studies that examined potential health effects from sodium fluoride additives in drinking water should also apply to FSA because of the same disassociation results.

Back to top (#content)

AWWA Standards

The AWWA sets the minimum requirements for a product's design, installation, performance, and manufacturing. The AWWA standards for fluoride additives are ANSI/AWWA B701-06 (sodium fluoride), ANSI/AWWA B702-07 (sodium fluorosilicate) and ANSI/AWWA B703-08 (FSA). AWWA's standards are prepared by its Fluoride Standards Committee, with oversight by the Standards Council, concurrence by the AWWA Board of Directors, and concurrence by ANSI. AWWA standards are reviewed and updated at least every 5 years. AWWA standards stipulate product quality testing requirements and verification.

Back to top (#content)

NSF/ANSI Standards for Drinking Water Additives

The NSF/ANSI standard 60 limits a chemical or product's contribution of contaminants to drinking water applications. Standard 60 provides for product purity and safety assurance that aim to prevent adding harmful levels of contaminants from chemicals and water treatment additives.

Forty-six states have laws or regulations requiring product compliance with Standard 60. NSF/ANSI standards 60 and 61 were developed by a consortium of associations, including NSF, AWWA, ANSI, the Association of State Drinking Water Administrators, and the Conference of State Health and Environmental Managers. Standards 60 and 61 are accepted by the EPA as the requirements for controlling potential harmful effects from products added to water for its treatment. These standards replaced the former EPA Additives Advisory Program.

Independent verification organizations, including NSF International and Underwriters Laboratories, verify that fluoride additives comply with the NSF/ANSI standards. These organizations test fluoride additives for regulated metal compounds and other substances that have an EPA MCL. For a fluoride additive product to meet certification standards, regulated metal compounds added by the water treatment process must have a concentration less than 10% of the MCL.

A comprehensive assessment of the ANSI/NSF Standard 60 for more than 50 additives was published in 2004. This peer-reviewed assessment concluded that the process successfully achieved the stated goals of preventing problems with trace contaminants in U.S. water treatment additives. More information is available from Brown, Cornwell, MacPhee. Trace contaminants in water treatment chemicals. *Journal American Water Works Association* 2004;96:12:111–125.

Back to top (#content)

Measured Levels of Impurities

Fluoride additives are analyzed for impurities that have been identified as having the potential to occur. Those impurities include arsenic, lead, and radionuclides. Verification on compliance with NSF/ANS standard 60 must also be certified. NSF presents **a detailed fact sheet on the documented quality of fluoride additives** (http://www.nsf.org/business/water_distribution/pdf/NSF_Fact_Sheet.pdf) * (PDF–74KB) The fact sheet is based on separate product samples analyzed from 2000 to 2006.

Consumers sometimes raise concerns about arsenic in drinking water and the fact that fluoride additives may contain some arsenic. The EPA allowable criterion for arsenic consumption in drinking water is 10 parts per billion. NSF quality testing has found that most fluoride additive samples do not have detectable levels of arsenic. For those samples that do test positive, the arsenic level that an average consumer would experience over an entire year of drinking water at a maximum dosage of 1.2 mg/L fluoride would only be about1.2% of the EPA allowable amount.

Other impurities in the NSF International-certified fluoride product testing were found to be even lower than the arsenic levels, with only 1%–3% of fluoride products containing detectable levels of metals. The average exposure to a typical consumer would be less than 0.1% of the EPA allowable levels.

Back to top (#content)

FDA Regulatory Criteria for Fluoride

The U.S. Food and Drug Administration (FDA) does not regulate additives to community drinking water, because its regulatory reach concerns the safety and efficacy of food, drugs, or cosmetic-related products. Because the FDA has authority over bottled water as a consumer beverage (Federal Register, Volume 44, No. 141, July 20, 1979), they do regulate the intentional addition of fluoride to bottled water and requires labeling identifying the additive used. Bottlers typically use NSF/ANSI Standard 60-certified fluoride

product.

In 2006, the FDA announced that bottled water with greater than 0.6 and up to 1.0 mg/L could be labeled with the statement "Drinking fluoridated water may reduce the risk of tooth decay." **Questions About Bottled Water and Fluoride** (../bottled_water.htm) provides additional information on FDA requirements. Fluoride in bottled water that is marketed as a consumer beverage is also included.

The FDA also regulates fluoride in over-the-counter drug products, such as toothpaste and mouthwash, and in prescription items, such as fluoride supplements and professional-strength gels and foams. The FDA does not have criteria on allowable impurities in sodium fluoride or fluorosilicates products.

Back to top (#content)

United States Pharmacopeia (USP) Grade Fluoride Products

Some have suggested that pharmaceutical grade fluoride additives should be used for water fluoridation. Pharmaceutical grading standards used in formulating prescription drugs are not appropriate for water fluoridation additives. If applied, those standards could actually increase the amount of impurities as allowed by AWWA and NSF/ANSI in drinking water.

The U.S. Pharmacopeia-National Formulary (USP-NF) presents monographs on tests and acceptance criteria for substances and ingredients by manufacturers for pharmaceuticals. The USP 29 NF–24 monograph on sodium fluoride provides no independent monitoring or quality assurance testing. That leaves the manufacturer with the responsibility of quality assurance and reporting. Some potential impurities have no restrictions by the USP including arsenic, some heavy metals regulated by the U.S. EPA, and radionuclides.

The USP does not provide specific protection levels for individual contaminants, but tries to establish a relative maximum exposure level of a group of related contaminants. The USP does not include acceptance criteria for fluorosilicic acid or sodium fluorosilicate.

Given the volumes of chemicals used in water fluoridation, a pharmaceutical grade of sodium fluoride for fluoridation could potentially contain much higher levels of arsenic, radionuclides, and regulated heavy metals than a NSF/ANSI Standard 60-certified product.

AWWA-grade sodium fluoride is preferred over USP-grade sodium fluoride for use in water treatment facilities because the granular AWWA product is less likely to result in dusting exposure of water plant operators than the more powder-like USP-grade sodium fluoride.

Back to top (#content)

Fluoride Additives Are Not Different From Natural Fluoride

Some consumers have questioned whether fluoride from natural groundwater sources, such as calcium fluoride, is better than fluorides added "artificially," such as FSA or sodium fluoride. Two recent scientific studies listed below demonstrate that the same fluoride ion is present in naturally occurring fluoride or fluoride drinking water additives and that no intermediates or other products were observed at pH levels as low as 3.5. In addition, fluoride metabolism is not affected differently by the chemical compounds nor are they affected by whether the fluoride is present naturally or artificially.

- The ionic speciation study conducted in 2006 mentioned previously (Finney WF, Wilson E, Callender

A, Morris MD, Beck LW. Re-examination of hexafluorosilicate hydrolysis by fluoride NMR and pH measurement. *Environ Sci Technol* 2006;40:8:2572)

- The pharmacokinetics of ingested fluoride was studied by a 2008 study (G.M. Whitford, F.C. Sampaio, C.S. Pinto, A.G. Maria, V.E.S. Cardoso, M.A.R. Buzalaf, Pharmacokinetics of ingested fluoride: Lack of effect of chemical compound, Archives of Oral Biology, 53 (2008) 1037–1041).

Back to top (#content)

Additional Resources

- **Community Water Fluoridation: Questions and Answers** (../cwf_qa.htm)
- **Temporary Shortages of Fluoridation Additives: FAQs** (shortages_faq.htm)
- **American Water Works Association** (http://www.awwa.org/) ,* for Fluoride Additives Standards B701–99, B702–99 and B703–00, and Manual of Practice No. 4, Water Fluoridation Principles and Practices, 2004.
- **NSF International International** (http://www.nsf.org/) ,* for Drinking Water Treatment Chemicals Standards NSF/ANSI 60–2002 and NSF/ANSI 61–2002.
- Brown, Cornwell, MacPhee. Trace contaminants in water treatment chemicals: sources and fate. *J Am Water Works Assoc* 2004 Dec:111.

One or more documents on this Web page is available in Portable Document Format (PDF). You will need **Acrobat Reader** (http://www.cdc.gov/nccdphp/shared/pdfinfo.htm) to view and print these documents.

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