Community Water Fluoridation

Water Fluoridation Additives

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

Sources of Fluoride Additives

Most fluoride additives used in the United States are produced from phosphorite rock. 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-$CaSO4$) slurry. The phosphoric and fluoride gases that are released in the process are then separated. The fluoride gas is captured and used to create fluorosilicic acid.

According to the American Water Works Association Standards Committee on Fluorides, the sources of fluoride products used for water fluoridation in the United States are as follows:

- Approximately 90% are produced during the process of extracting phosphate from phosphoric ore.
- Approximately 5% come from the production of hydrogen fluoride or sodium fluoride.
- Approximately 5% come from the purification of high-quality quartz.

Since the early 1950s, FSA has been the main additive used for water fluoridation in the United States. The favorable cost and high purity of FSA make it a popular additive. Sodium fluorosilicate and sodium fluoride come from processing FSA, or from processing hydrogen fluoride. 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 completely neutralize the fluorosilicate, the result is sodium fluoride. About 90% of the sodium fluoride used in the United States comes from FSA.

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 harmful health effects from contaminated water, the EPA sets a Maximum Contaminant Level (MCL) concentration allowed for various organisms or substances.

Although the EPA does not specifically regulate levels of “direct additives,” which are additives added to water in the course of treatment, it does specify that the addition of chemicals as part of the treatment process should not be more than 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 for food additives, which includes bottled water, and EPA has regulatory oversight of 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 (now NSF International) 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 in operation.

EPA Regulatory Criteria for Fluoride Additives

All additives used by 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 AWWA and NSF International. Both of these organizations are nonprofit, nongovernmental organizations.

Fluoridated community water systems adjust fluoride to approximately 0.7 milligrams per Liter (mg/L). Because in some rare locations fluoride is naturally present in water at much higher levels, the EPA established a Maximum Contaminant Level (MCL) 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 known 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 light passing through the water.

Studies have shown that silicofluorides achieve virtually complete dissolution and ionic disassociation at the concentrations used when 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 they have the same results for ionic disassociation.

AWWA Standards

The AWWA sets the minimum requirements for the design, installation, performance, and manufacturing of fluoride products used for adjusting water content. The AWWA standards for fluoride additives are ANSI/AWWA B701 (sodium fluoride), ANSI/AWWA B702 (sodium fluorosilicate), and ANSI/AWWA B703 (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.

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. It includes a detailed audit of the production of the additive products, validation testing of quality, and auditing of all locations for logistic handling. There are also specific criteria for imported products from other countries, and in conjunction with NSF/ANSI Standard 223, there is conformity in quality controls regardless of where certification occurs or which entity performs the certification.

Forty-seven states have laws or regulations requiring product compliance with Standard 60. NSF/ANSI standards 60 and 61 (a related standard that applies to products that come in contact with water) 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. More information on Standard 60 is posted on NSF's website .

Independent organizations, including NSF International and Underwriters Laboratories, verify that fluoride additives meet 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 met the stated goals of preventing problems with trace contaminants in U.S. water treatment additives. More information is available in the following article: Brown, Cornwell, MacPhee. Trace contaminants in water treatment chemicals . (Journal of the American Water Works Association 2004;96:12:111–125.)

Measured Levels of Impurities

Fluoride additives are analyzed for potential impurities including arsenic, lead, and radionuclides. Verification of compliance with NSF/ANSI Standard 60 must also be certified. NSF hosts a detailed fact sheet on the documented quality of fluoride additives, including impurities [PDF–142KB]). The fact sheet is based on separate product samples analyzed from 2000 to 2017.

The majority of fluoridation products certified by NSF do not contain detectable concentrations of lead, radionuclides or other heavy metals when dosed into water.

Trace amounts of arsenic are the most common contaminants found in fluoride products. The EPA allowable amount for arsenic in drinking water is 10 parts per billion. Additionally, NSF/ANSI 60 sets a single product allowable concentration of 1 part per billion. NSF quality testing found arsenic was periodically detected in about half of all samples. However, the mean arsenic concentration is 1/50th of the U.S. EPA MCL and none of the samples exceeded 1/10th the U.S. EPA MCL. Other impurities in the NSF International-certified fluoride product testing were found to be even lower than the arsenic levels, with only 1%–6% of fluoride products containing detectable levels that are all less than 5% of the U.S. EPA MCL.

FDA Regulatory Criteria for Fluoride

The U.S. Food and Drug Administration (FDA) does not regulate additives used for community drinking water (i.e., tap water), because its regulatory reach concerns the safety and efficacy of food, drugs, or cosmetic-related products. However, 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 require labeling identifying the additive used. Bottlers typically use NSF/ANSI Standard 60-certified fluoride product.

In 2006, FDA announced that bottled water with fluoride levels greater than 0.6 and up to 1.0 mg/L could be labeled with the following statement: "Drinking fluoridated water may reduce the risk of tooth decay." CDC's fact sheet, Bottled Water and Fluoride, provides additional information on FDA requirements

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

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 exceed the amount of impurities allowed by AWWA and NSF/ANSI in drinking water.

The U.S. Pharmacopeia-National Formulary (USP-NF) publishes 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. The USP does not include acceptance criteria for fluorosilicic acid or sodium fluorosilicate. As a result, the manufacturer is responsible for quality assurance and reporting. The USP does not provide specific protection levels for individual contaminants, but establishes a relative maximum exposure level for a group of related contaminants. Some potential impurities have no restrictions by the USP, including arsenic, some heavy metals regulated by the U.S. EPA, and radionuclides. 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 an NSF/ANSI Standard 60-certified product.

In addition, 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 exposure to fluoride dust by water plant operators than the more powder-like USP-grade sodium fluoride.

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 in fluoride drinking water additives and that no intermediates or other products were observed at pH levels as low as 3.5. In addition, the metabolism of fluoride does not differ depending on the chemical compound used or whether the fluoride is present naturally or added to the water supply.

- 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.
- 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.

Additional Resources

American Water Works Association for Fluoride Additives Standards B701–99, B702–99 and B703–00, and Manual of Practice No. 4, Water Fluoridation Principles and Practices, 2004.

Community Water Fluoridation: Questions and Answers

Temporary Shortages of Fluoridation Additives: FAQs

NSF International International , 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.

Page last reviewed: November 18, 2020