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Fact Sheet on Fluoridation Products and Fluoride

Background

NSF International (www.nsf.org) is an independent, global not-for-profit organization that facilitates standards development, and tests and certifies products for the food, water, health sciences and consumer goods industries to minimize adverse health effects and protect the environment. Founded in 1944, NSF is committed to protecting human health and safety worldwide. NSF International is a Pan American Health Organization/World Health Organization (WHO) Collaborating Center on Food Safety, Water Quality and Indoor Environment.

NSF/ANSI 60

NSF/ANSI 60: *Drinking Water Treatment Chemicals - Health Effects* 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 to allow for a comprehensive evaluation of the products and their ingredients. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level (MUL), so that trace levels of contaminants can be detected. A further evaluation of test results is required to determine if the concentrations of any detected contaminants have the potential to cause adverse human health effects. When health effects criteria have not been established for a given product or contaminant, the standard requires that health effects criteria be derived according to the requirements of Annex A prior to approval under this standard. For More Information on NSF/ANSI 60…

Product Certification

NSF's testing and certification program for drinking water treatment products was developed in the late 1980s to ensure that individual U.S. states and waterworks facilities have a mechanism to determine which products are most suitable for use. The NSF certification program requires annual, unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged and transported with appropriate safe guards in place to protect against potential contamination. NSF also requires annual testing and evaluation of each NSF certified product to confirm contaminants do not exceed drinking water health effects criteria. For More Information on Product Certification…

Fluoride

Fluoride Properties and Water Applications

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of greatly reducing the incidence of tooth decay and therefore improving the health of the community. For more information please visit the U.S. Centers for Disease Control and Prevention: www.cdc.gov/fluoridation/.

NSF certifies three products in the fluoridation category:

1. Fluorosilicic acid (aka fluosilicic acid or hydrofluosilicic acid)
2. Sodium fluorosilicate (aka sodium silicofluoride)
3. Sodium fluoride

All three products readily dissociate in water to release fluoride and related ions. In the case of the fluorosilicates, they fully dissociate to fluoride and silicate ions in association with either hydrogen or sodium ions[1]. In the case of sodium fluoride, it fully dissociates to form fluoride and sodium ions.

Treatment products that are used for fluoridation are specifically addressed in Section 7 of NSF/ANSI 60. The standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by an evaluation of potential health effects resulting from exposure to the products or associated contaminants. The following text explains 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 Drinking Water Criteria

NSF/ANSI 60 requires, when available, that the U.S. or Canadian regulatory values be used to determine the acceptable level for a chemical of interest. The EPA MCL for fluoride ion in water is 4 mg/L and the Health Canada MAC for fluoride is 1.5 mg/L to protect against skeletal fluorosis. However, in 2003, representatives from the EPA and Health Canada reviewed the evaluation criteria in NSF/ANSI 60 and recommended that the TAC and SPAC for fluoride ion in drinking water contributed by fluoridation products be lowered to 1.2 mg/L to match the upper bound of the U.S. Public Health Service/Centers for Disease Control recommended fluoride concentration range to prevent dental fluorosis (an aesthetic effect). The Drinking Water Additives Joint Committee for NSF/ANSI 60 supported this recommendation and set the acceptance criteria for fluoride ion equivalent to the maximum recommended fluoride ion dose. For treatment chemicals other than fluoridation products, the allowable fluoride contribution is 0.12 mg/L, or a tenth the TAC.

In 2015, the U.S. Department of Health and Human Services recommended that the optimal range of water fluoridation of 0.7 to 1.2 ppm (mg/L) be updated to an optimal concentration of 0.7 ppm (mg/L) due to observations of increasing amounts of fluoride in food that is processed with fluoridated drinking water. Some U.S. states have elected to adopt this optimal concentration for fluoridation of community water supplies. Testing these chemicals at the higher use level of 1.2 ppm (as is currently done) provides a more conservative screening for contaminants in or associated with use of these products.

More recently, the U.S. Centers for Disease Control and Prevention (CDC) has proposed that the recommended operational range for community water supplies be narrowed to 0.6 mg/L to 1.0 mg/L fluoride ion[2]. The CDC advised that this change is to reflect demonstrated ability of water utilities to maintain control of fluoride concentration around the 0.7 mg/L optimum concentration. The Drinking

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[1] 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)

[2] Centers for Disease Control and Prevention. *Proposed Guidance Regarding Operational Control Range Around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride*. Federal Register Vol. 83, No. 135.

Water Additives Joint Committee for NSF/ANSI 60 is reviewing whether it should lower the fluoride ion typical use level from 1.2 mg/L to 1.0 mg/L. If this request is approved by the Drinking Water Additives Joint Committee, it will be incorporated into NSF/ANSI 60 in 2019.

Silicate Drinking Water Criteria

Fluorosilicates do not require a toxicological assessment specifically for the fluorosilicate ion, because measurable levels of this ion do not exist in potable water at the fluoride concentrations and pH levels typical of public drinking water.[3] There is currently no U.S. EPA-derived MCL or Health Canada MAC for silicate in drinking water. The current sodium silicate typical use level (TUL) of 16 mg/L is listed in Table 5.1 of NSF/ANSI 60, which was based on the value for sodium silicate published in the Water Chemicals Codex.[4] A fluorosilicate product, applied at its maximum use level (noted below), results in silicate drinking water levels that are substantially below the 16 mg/L TUL. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride currently permitted by NSF/ANSI 60 (1.2 mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the TUL allowed by NSF/ANSI 60 for silicate.

Fluoridation Product Use Levels

Allowable use levels for fluoridation chemicals are limited by the NSF/ANSI 60 limits for fluoride ion. Per the previous section, the silicate contribution is not a limiting factor. The allowable maximum use levels (MUL) for NSF/ANSI 60 certified fluoridation products in 2018 are:

1. Fluorosilicic acid: 6 mg/L
2. Sodium fluorosilicate: 2 mg/L
3. Sodium fluoride: 2.3 mg/L

Potential Contaminants in Fluoridation Chemicals

The product review conducted by NSF for a water treatment 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 chemicals attributable to the products present in the finished drinking water. The identified chemicals of interest are subsequently evaluated during testing of 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. The manufacturing process is documented by an NSF auditor at the initial audit of the manufacturing site and during each subsequent annual unannounced audit of the facility. The manufacturing process, ingredients and potential contaminants are reviewed annually, and the product is tested for any potential contaminants of interest. A minimum test battery for all fluoridation products includes heavy metals of toxicological concern and radionuclides because they may be contained in phosphate ore.

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,

[3] 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)

[4] National Academy of Sciences, Water Chemicals Codex, 1982

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 shown in the official NSF listing for the product (available at www.nsf.org).

NSF has compiled data on the levels of contaminants found in or through use of all fluoridation products that have applied for, or have been approved for, certification by NSF under NSF/ANSI 60. The results in Tables 1, 2, and 3 include those from the initial and annual monitoring tests for fluoridation products that NSF certified to NSF/ANSI 60 from 2012 to 2017 (Table 1), 2007 to 2011 (Table 2) and 2000 to 2006 (Table 3). This summary includes 245 separate samples analyzed during the time period of 2000 to 2006, 216 samples in the period of 2007 to 2011, and 328 samples in the period of 2012 to 2017. The concentrations reported represent contaminant levels expected when the products are dosed into water at the manufacturer's maximum use level (MUL). For the time periods summarized below, the typical product certification and evaluation were based on a fluoride ion dose of 1.2 mg/L. Lower product use levels 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).

The data reported in Tables 1, 2, and 3 demonstrate that very low concentrations of contaminants are associated with fluoridation chemicals. In fact, NSF was only able to detect the reported trace amounts by dosing the chemicals into reagent water at 10 times the manufacturer's maximum use level (as required by NSF/ANSI 60) and then mathematically adjusting the laboratory results to expected field dose. If the products had been dosed into water at the manufacturer's maximum use level, only one copper contaminant concentration would have been above the analytical method detection limits. This is demonstrated by comparing the results in columns 3 and 4 with the detection limits in column 5. The low concentrations of contaminants documented for this most current time period are explained, at least in part, by the ongoing effectiveness of NSF/ANSI 60 and the NSF certification program for drinking water treatment additives. The levels in Table 1 are comparable to those documented earlier for the 2000-2011 time period, which is further attested to by a 2004 article in the Journal of the American Water Works Association entitled, "Trace Contaminants in Water Treatment Chemicals."[3]

Summary

All the fluoridation products tested by NSF, when evaluated at their maximum use level in water, meet the health effects requirements of NSF/ANSI 60. Arsenic was periodically detected in 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. The majority of fluoridation products certified by NSF do not contain detectable concentrations of lead, radionuclides or other heavy metals when dosed into water at their maximum use level. In summary, fluoridation products certified by NSF do not contribute a significant contaminant burden to drinking water.

Table 1. Fluoridation product chemical contaminant analysis from 2012-2017 (328 samples)

	Percentage of Samples With Detectable Levels	Mean[1] Contaminant Concentration in All Samples (ppb)	Maximum Contaminant Concentration in Detectable Samples (ppb)	Analytical Method Detection Levels (ppb)	NSF/ANSI 60 Single Product Allowable Concentration (ppb)	U.S. EPA Maximum Contaminant or Action Level (ppb)
Antimony	<1%	0.022	0.07	0.5	0.6	6
Arsenic	52%	0.16	0.9	1	1	10
Barium	<1%	0.045	0.5	1	200	2000
Beryllium	0%	ND	ND	0.5	0.4	4
Cadmium	0%	ND	ND	0.2	0.5	5
Chromium	<1%	0.044	0.2	1	10	100
Copper	6%	0.061	2.8	1	130	1300
Lead	5%	0.037	0.3	0.5	1.5[3]	15
Mercury	<1%	0.0088	0.02	0.2	0.2	2
Radionuclides – alpha	<1%	0.12 pCi/L	0.5 pCi/L	3 pCi	1.5 pCi/L	15 pCi/L
Radionuclides – beta	<1%	0.16 pCi/L[2]	0.6 pCi/L[2]	4 pCi	0.4 mrem/yr[2]	4 mrem/yr[2]
Selenium	1%	0.096	1.1	2	5	50
Thallium	<1%	0.0088	0.02	0.2	0.2	2

[1]Mean values were calculated by setting the non-detectable (ND) values to half of the method detection level.

[2]The corrected gross beta detection in radioactivity (pCi) per volume of water (L) is compared against the U.S. EPA limit of 4 mrems/yr for beta particle emitters in drinking water. A mrem is a dose equivalent unit from ionizing radiation to an organ, organ system or the total body. The conversion factor from pCi/L to mrem is based on the strength of the beta radiation from a particular beta emitting isotope. The beta detections above were determined to be less than the 0.4mrem/yr limit of NSF/ANSI 60.

[3]The NSF/ANSI 60 single product allowable concentration (SPAC) for lead was lowered from 1.5 µg/L to 0.5 µg/L in the published 2017 edition of NSF/ANSI 60. However, this standard edition was published at the end of 2017 and all the lead results summarized in Table 1 were compared against the 1.5 µg/L SPAC.

Table 2. Fluoridation product chemical contaminant analysis from 2007-2011 (216 samples)

	Percentage of Samples With Detectable Levels	Mean[1] Contaminant Concentration in All Samples (ppb)	Maximum Contaminant Concentration in Detectable Samples (ppb)	Analytical Method Detection Levels (ppb)	NSF/ANSI 60 Single Product Allowable Concentration (ppb)	U.S. EPA Maximum Contaminant or Action Level (ppb)
Antimony	0%	ND	ND	0.5	0.6	6
Arsenic	50%	0.15	0.6	1	1	10
Barium	2%	0.042	0.6	1	200	2000
Beryllium	0%	ND	ND	0.5	0.4	4
Cadmium	0%	ND	ND	0.2	0.5	5
Chromium	<1%	0.039	0.3	1	10	100
Copper	<1%	0.039	0.091	1	130	1300
Lead	<1%	0.037	0.088	1	1.5	15
Mercury	0%	ND	0.04	0.2	0.2	2
Radionuclides – alpha	<1%	0.18 pCi/L	0.3 pCi/L	3 pCi/L	1.5 pCi/L	15 pCi/L
Radionuclides – beta	<1%	0.19 pCi/L[2]	0.5 pCi/L[2]	4 pCi/L	0.4 mrem/yr[2]	4 mrem/yr[2]
Selenium	0%	ND	ND	2	5	50
Thallium	<1%	0.0079	0.01	0.2	0.2	2

[1]Mean values were calculated by setting the non-detectable (ND) values to half of the method detection level.

[2]The corrected gross beta detection in radioactivity (pCi) per volume of water (L) is compared against the U.S. EPA limit of 4 mrems/yr for beta particle emitters in drinking water. A mrem is a dose equivalent unit from ionizing radiation to an organ, organ system, or the total body. The conversion factor from pCi/L to mrem is based on the strength of the beta radiation from a particular beta emitting isotope. The beta detections above were determined to be less than the 0.4mrem/yr limit of NSF/ANSI 60.

Table 3. Fluoridation product chemical contaminant analysis from 2000-2006 (245 samples)

	Percentage of Samples With Detectable Levels	Mean[1] Contaminant Concentration in All Samples (ppb)	Maximum Contaminant Concentration in Detectable Samples (ppb)	Analytical Method Detection Levels (ppb)	NSF/ANSI 60 Single Product Allowable Concentration (ppb)	U.S. EPA Maximum Contaminant or Action Level (ppb)
Antimony	0%	ND	ND	0.5	0.6	6
Arsenic	43%	0.12	0.6	1	1	10
Barium	<1%	0.001	0.3	1	200	2000
Beryllium	0%	ND	ND	0.5	0.4	4
Cadmium	1%	0.001	0.12	0.2	0.5	5
Chromium	<1%	0.001	0.2	1	10	100
Copper	3%	0.02	2.6	1	130	1300
Lead	2%	0.005	0.6	1	1.5	15
Mercury	<1%	0.0002	0.04	0.2	0.2	2
Radionuclides – alpha	0%	ND	ND	3 pCi/L	1.5 pCi/L	15 pCi/L
Radionuclides – beta	0%	ND	ND	4 pCi/L[2]	0.4mrem/yr[2]	4 mrem/yr[2]
Selenium	<1%	0.016	3.2	2	5	50
Thallium	<1%	0.0003	0.06	0.2	0.2	2

[1]Mean values were calculated by setting the non-detectable (ND) values to half of the method detection level.

[2]The corrected gross beta detection in radioactivity (pCi) per volume of water (L) is compared against the U.S. EPA limit of 4 mrems/yr for beta particle emitters in drinking water. A mrem is a dose equivalent unit from ionizing radiation to an organ, organ system, or the total body. The conversion factor from pCi/L to mrem is based on the strength of the beta radiation from a particular beta emitting isotope.

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

American Dental Association (ADA)

https://www.ada.org/en/public-programs/action-for-dental-health/prevention-and-education

U.S. Centers for Disease Control and Prevention (CDC)

http://www.cdc.gov/fluoridation

More Information on NSF/ANSI 60

The standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by an evaluation of potential health effects resulting from exposure to the products and/or associated contaminants during the anticipated use(s) of the product. It is a requirement of NSF/ANSI 60 (Annex A) that a determination be made as to whether a published and peer-reviewed quantitative risk assessment for the substance is available. If the substance is regulated by the U.S. EPA or Health Canada, these regulatory limits are to be used to derive the drinking water criteria for the regulated chemical of interest. If the identified published assessment is not the basis of a drinking water regulation, the assessment and its corresponding reference dose must be reviewed for its appropriateness in evaluating the human health risk of the substance. If a published assessment is not identified or an identified assessment is deemed unacceptable, it is required that a comprehensive risk assessment be conducted from which drinking water criteria are derived. The non-regulatory drinking water criteria derived from a risk assessment are known as total allowable concentrations (TAC), as stipulated in Annex A.

Single Product Allowable Concentrations (SPAC)

Guidance for derivation of drinking water criteria known as single product allowable concentrations (SPAC) is provided in Annex A of NSF/ANSI 60. The SPAC is defined as the maximum concentration of a contaminant in drinking water that a single product can contribute. For contaminants regulated by the U.S. EPA or Health Canada, the SPAC is set to a default level that is not to exceed 10 percent of the regulatory level to address the possibility that multiple sources of the contaminant exist in the water supply. For contaminants that are not regulated, the SPAC is derived from the total allowable concentration (TAC), which is defined as the maximum concentration of a non-regulated contaminant permitted in public drinking water supply. The default SPAC in these instances is one-tenth of the TAC to account for the possibility that more than one product in the water and/or its distribution system could contribute the contaminant of interest to drinking water. Whether the chemical of interest is regulated or not, a lower or higher number of sources of the chemical in the drinking water supply can be specified if chemical-specific data are available to warrant deviating from the default.

How the Standard Was Developed

Development of NSF/ANSI 60 was initiated in 1985 at the request of U.S. EPA as part of a larger EPA/FDA MOU under the Safe Drinking Water Act, to establish modern testing, evaluation and acceptance criteria for product added directly to water during its treatment, storage and distribution. The NSF International-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), completed development in 1988.

Who Maintains the Standard

NSF/ANSI 60 is one of nearly 90 consensus-based standards to which NSF has contributed significantly. While NSF's Standards department provides the support and structure for the development and publication of product standards, it is the Joint Committee on Drinking Water Additives which continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups including the U.S. EPA as well as other regulatory, water utility and product manufacturer representatives. Every NSF standard is reviewed by NSF's Council of Public Health Consultants (CPHC) whose role is to determine that the health-effects standards developed with support from NSF continue to aid in the protection of public health. The American National Standards Institute (ANSI) has an oversight role in the standards process to ensure that the documents are developed and maintained according to their guidelines; ANSI makes all proposed revisions to ANSI standards available for public comment on its website at www.ansi.org

More Information on Product Certification

Product Review and Testing

The product review conducted by NSF for a water treatment 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 chemicals attributable to the products present in the finished drinking water. The identified chemicals of interest are subsequently evaluated during testing of the product. The manufacturing process is documented by an NSF auditor at an initial audit of the manufacturing site and during each annual unannounced inspection of the facility. The manufacturing process, ingredients, potential contaminants and label information are reviewed annually, and the product is tested for any potential contaminants of interest at NSF laboratories.

NSF's Mark and Public Product Listings

All NSF certified products bear the NSF mark, maximum use level, lot number or date code, and production location on the product packaging or documentation shipped with the product.
NSF maintains listings of certified products at www.nsf.org/certified-products-systems. These listings are updated daily and list the products at their allowable maximum use levels.

History of the Product Certification Program

The NSF testing and certification program for drinking water treatment products was developed in the 1980s at the request of the U.S. EPA to provide an updated, science-based process to evaluate the use of drinking water treatment chemicals in public water supplies, based on NSF/ANSI 60. This certification program was intended by U.S. EPA to eventually replace the EPA's Advisory Program to States, which it did in 1990. The states quickly adopted EPA's recommendations to rely on certified products to help ensure that individual U.S. states and waterworks facilities have a mechanism to identify and select treatment chemicals for use in public water supplies.

Who Uses the Standard

According to the latest Association of State Drinking Water Administrators (ASDWA) Survey on State Adoption of NSF/ANSI Standards 60 and 61, 49 U.S. states require that chemicals used in treating potable water meet NSF/ANSI 60 requirements. In Canada, nine provinces/territories require drinking water treatment chemicals to comply with the requirements of NSF/ANSI 60. Certification to NSF/ANSI 60 is also recognized in several other countries, including Brazil, Israel, UAE, Saudi Arabia, Singapore and South Africa. Manufacturers can choose to apply to NSF International or another ANSI-accredited certifying body for certification to the standard. If you have questions on your state's requirements, or how the NSF/ANSI 60 certified products are authorized in your state, contact your state's Drinking Water Administrator or download a state survey summary at
http://www.nsf.org/newsroom_pdf/water_asdwa_survey.pdf.

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

CDC – Centers for Disease Control and Prevention

COSHEM – Conference of State Health and Environmental Managers

EPA – U.S. Environmental Protection Agency

MAC – maximum allowable level

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

TAC – total allowable concentration