February 15, 2013

NSF Fact Sheet on Fluoridation Products

Introduction

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, 47 U.S. 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 greatly reducing the incidence of tooth decay and therefore 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

All three product types dissociate in water to form sodium, fluoride, and in the case of the first two, silicate ions.

NSF/ANSI Standard 60

NSF International is a not-for-profit standards development and conformity assessment organization. Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an 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). This group developed NSF/ANSI Standard 60, at the request of the US Environmental Protection Agency (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 including the US EPA, as well as other regulatory, water utility and product manufacturer representatives.

While NSF provides the support and structure for the development and publication of product standards that are focused on public health safety, it is the Joint Committees and the regulatory, product user and product manufacturer members that discuss and decide on the content and structure of the Standards. Every NSF Standard, including NSF 60 is reviewed by another NSF Committee, the Council of Public Health Consultants whose role is to determine that the NSF Standards continue to protect 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 their website at www.ansi.org

NSF/ANSI 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 to allow for a toxicological evaluation. The standard requires testing of the treatment chemical products, typically by dosing these in water at ten times the maximum use level, so that trace levels of contaminants can be detected. A further toxicological evaluation of test results is required to determine if the concentrations of any detected contaminants have the potential to cause adverse human health effects. The standard sets criteria for the derivation of single product allowable concentrations (SPAC) of chemicals of interest. For contaminants regulated by the U.S. EPA, the SPAC is set to a default level that is not to exceed ten percent of the regulatory level in order to ensure that the consumer is adequately protected in the event that multiple sources of the contaminant exist in the water supply. A lower or higher number of sources can be specified if data are available to warrant deviating from the default. It is required by Standard 60 that a comprehensive risk assessment be conducted if the US EPA has not established a Maximum Contaminant Level (MCL) for a chemical. Under these circumstances, the evaluation procedures contained in Annex A of NSF 60 are followed to derive the SPAC.

NSF Certification

The testing and certification program for drinking water treatment products was developed by NSF so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were most suitable 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 appropriate safe guards in place to protect against potential contamination. NSF also requires annual testing and evaluation of each NSF Certified product to confirm the absence of contaminants at concentrations of concern. NSF Certified products include 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.

Treatment products that are used for fluoridation are specifically addressed in Section 7 of NSF/ANSI Standard 60. 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

As noted above, NSF/ANSI Standard 60 requires, when available, that the US EPA MCL be used to determine the acceptable level for a chemical of interest. The EPA MCL for fluoride ion in water is 4 mg/L. The data-derived 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 the SPAC for fluoride ion, the allowable maximum use levels (MUL) for NSF 60 Certified fluoridation products are:

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

The US Department of Health and Human Services recently made the recommendation that the current optimal range of water fluoridation of 0.7 to 1.2 ppm (mg/L) be updated to an optimal dose of 0.7 ppm (mg/L) due to observations of increasing amounts of fluoride in food that is processed with fluoridated drinking water. Although this recommendation is still under review, some US states have elected to adopt this new optimal dose for fluoridation of community water supplies. At some point in the future, NSF/ANSI 60 may be revised to reflect this lower maximum use level. However, 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.

Silicate

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.[1] There is currently no US EPA-derived MCL for silicate in drinking water. NSF established a SPAC for silicate at 16 mg/L based on the typical use level of sodium silicate in Table 5.1 of NSF/ANSI 60, which was based on the value from the Water Chemicals Codex.[2] 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 currently permitted

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

by the Standard (1.2mg/L) would only contribute 0.8 mg/L of silicate – or five percent of the SPAC allowed by NSF 60.

Potential Contaminants

The NSF toxicology review 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 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, and the product is tested for any potential contaminants of interest. A minimum test battery for all fluoridation products includes 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, 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 listed by, NSF under Standard 60. The results in Tables 1 and 2 include those from the initial and annual monitoring tests for fluoridation products that NSF Certified to NSF/ANSI 60 between 2007 to 2011 (Table 1) and between 2000 to 2006 (Table 2), respectively. This summary includes 245 separate samples analyzed during the time period of 2000 to 2006, and 216 samples in the period 2007 to 2011. The concentrations reported represent contaminant levels expected when the products are dosed into water at the manufacturer's maximum use level (MUL). 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 and 2 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 water at ten times the manufacturers maximum use level (as required by the Standard). If the products had been dosed into water at the manufacturer's maximum use level, all contaminant levels would have been below 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 is explained, at least in part, to the on-going effectiveness of NSF/ANSI Standard 60 and the NSF certification program for drinking water treatment additives. The levels are comparable to those documented earlier for the 2000-2006 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

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

Table 1 Results 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 Standard 60 Single Product Allowable Concentration	USEPA Maximum Contaminant or Action Level
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 pCi/L	<1%	0.18	0.3 pCi/L	3 pCi	1.5 pCi/L	15 pCi/L
Radionuclides – beta mrem/yr	<1%	0.19 pCi/L[2]	0.5 pCi/L[2]	4 pCi	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 ½ of the method detection level.

[2]The corrected gross beta detection in radioactivity (pCi) per volume of water (L) is compared against the US 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 60.

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[3] Brown, R., et al., "Trace Contaminants in Water Treatment Chemicals: Sources and Fate." Journal of the American Water Works Association 2004: 96:12:111.

Table 2 Results 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 Standard 60 Single Product Allowable Concentration	US EPA Maximum Contaminant or Action Level
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 pCi/L	0%	ND	ND	3 pCi	1.5 pCi/L	15 pCi/L
Radionuclides – beta mrem/yr	0%	ND	ND	4 pCi[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 ½ of the method detection level.

[2]The corrected gross beta detection in radioactivity (pCi) per volume of water (L) is compared against the US 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 web sites:

American Dental Association (ADA)
http://www.ada.org/sections/newsAndEvents/pdfs/fluoridation_facts.pdf

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

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