

**Question 2. Under General Requirements 3.2.1, formulation submission and review, ANSI/NSF 60 -1999, are manufacturers of hydrofluosilicic acid and silicofluorides required to “submit for each product, when available, a list of published and unpublished toxicological studies relevant to the treatment chemical and the chemicals and impurities present in the treatment chemical?”**

The standard requires that the manufacturer of a product submitted for certification provide toxicological information, if available. NSF requires that manufacturers seeking certification to the standard submit this information as part of their formulation or ingredient supplier submission.

**Has your document, General Requirements 3.2.1, Formulation submission and review, ANSI/NSF 60 - 1999, been peer reviewed for accuracy? If so, please provide the names, affiliations and contact information for the peer reviewers.**

The document (ANSI/NSF Standard 60) has been peer reviewed for accuracy. Joint Committee and CPHC members and contact information are contained in Attachments 3, 7, and 8.

**Please provide:**

**All lists complying with the above requirement submitted by manufacturers of hydrofluosilicic acid and silicofluorides.**

NSF has based its certification on the product use not exceeding the EPA’s MCL for fluoride. Separately, NSF has developed an MAL for silicates of 16 mg/L that supports the silicate portion of the products in question. In addition, potential contaminants are also limited by the standard. The supporting rationale for the silicate MAL is enclosed in Attachment 15.

**The complete record of all tests of each fluorine-bearing additive using ion chromatography, atomic absorption spectroscopy, and scintillation counting.**

NSF toxicology review and testing of fluorosilicate compounds looks for potential trace contaminants such as heavy metals and radionuclides. The formulation review step examines not only the product formulation, but also considers potential contaminants from the ingredients, processing aids, and any other factors impacting contaminants in the finished drinking water. Contaminants in the finished drinking water are not permitted to exceed one-tenth of the EPA’s regulated MCL (Maximum Contaminant Level) when the product is added to drinking water at its Maximum Use Level, unless it can be documented that a limited number of sources of the contaminant occur in drinking water.

NSF has reviewed its files and has compiled a summary of our findings (Table 1) in lieu of complete test reports. Individual test reports, as well as formulation information are protected by nondisclosure agreements with certification clients.

NSF searched its files to determine the level of contaminants found in these fluoridation products, when the product is dosed to water at the Maximum Use Level (MUL). The exact number of laboratory tests performed is not readily available



July 7, 2000

The Honorable Ken Calvert  
Chairman Subcommittee on Energy and the Environment  
Committee on Science  
U. S. House of Representatives  
Suite 2320, Rayburn House Office Building  
Washington, DC 20515-6301

Dear Mr. Chairman:

Thank you for your letter of May 8, 2000 to Dr. Joseph Cotruvo wherein you request information from NSF International (NSF) on fluoride containing compounds. We appreciate having received an extension in order to allow NSF staff sufficient time to provide a comprehensive response to your request.

This response is comprised of a general information section entitled *Background on NSF and the Drinking Water Additives Program* and a section that answers the 8 questions in your letter. I have attached additional documents that will also assist in answering your questions.

It is important to note that your questions relate to two separate issues, and departments, within NSF – standards and product certification. First, ANSI/NSF Standard 60 – the American National Standard developed by NSF and a consortium of major stakeholders consisting of the American Water Works Association (AWWA), the AWWA Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the now inactive Conference of State Health and Environmental Managers (COSHEM) was developed from 1985 to 1987. Second, NSF operates a separate product testing, certification and listing program based on the requirements of the standard.

The health based principles of Standard 60 were originally developed by the NSF Health Advisory Board (HAB) which is a panel of non-NSF health science experts. This group continues its role in an advisory and oversight function to NSF and its Toxicology staff to assure that ANSI/NSF Standards are consistent with current public health principles.

The standard and the certification program are recognized and utilized by AWWA and its member utilities, and adopted in most state regulations. More than 43 states have regulations in place requiring product compliance with ANSI/NSF Standard 60. (See Attachment 14). The program provides a product quality and safety assurance that aims to prevent addition of harmful levels of contaminants from treatment chemicals.

**A true and complete copy of all tests that identify the full composition of each fluorine-bearing additive, including all attendant organic substances, radionuclides and other chemicals.**

Compositional analyses are not required by the NSF standard. The verification of composition is performed during the annual unannounced plant inspection by NSF auditors who verify sources and ratios of labeled ingredients. Separately, there are industry standards from AWWA (American Water Works Association) (ANSI/AWWA B702-99 for Sodium Fluorosilicate and ANSI/AWWA B703a-97 for Fluosilicic Acid) that provide for compositional requirements.

**Copies of any and all tests or studies of each of the fluorine-bearing additives that consider or indicate degree of dissociation.**

The standard requires testing for contaminants that are likely to be present in the product. A study by N.T. Crosby, published in 1969 in the Journal of Applied Chemistry (Volume 19), establishes dissociation of fluorosilicates at 99% for 1ppm fluoride concentrations in drinking water.

**Copies of any and all studies that have been performed on laboratory animals using hydrofluosilicic acid or silicofluorides.**

NSF does not perform animal testing, although these may be required under Standard 60 if hazard/risk based action levels are exceeded. NSF toxicologists may review animal studies during the toxicology evaluation step of the product certification process.

**Copies of any risk assessment documents in NSF International files that pertain to fluorine-bearing pesticides, such as cryolite.**

Fluorine-containing pesticides such as cryolite are not required analyses under the standard, unless it is determined to be part of the formulation, or a potential contaminant. NSF would test for this or any other contaminants if indicated during the formulation review step.

**Question 3. Have any studies on hydrofluosilicic acid or silicofluorides been submitted to NSF under claimed Confidential Business Information protection?**

There have not been any studies on hydrofluosilicic acid or silicofluorides submitted to NSF under claimed Confidential Business Information protection.