Published January 17, 2019

Fact Sheet on Bromochlorodimethylhydantoin (BCDMH) Products

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 Standard 60

NSF/ANSI Standard 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 ten 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 completing the product evaluation 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 were 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 NSF Product Certification…

FIFRA

BCDMH is regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), in addition to being within the scope of NSF/ANSI Standard 60. The requirements of FIFRA and NSF/ANSI Standard 60 as they apply to BCDMH are discussed on the next page. For General Information on FIFRA…

Bromochlorodimethylhydantoin (BCDMH)

BCDMH Properties and Water Applications

Bromochlorodimethylhydantoin or BCDMH possesses antimicrobial properties and is used in many applications, including the treatment of recreational and drinking water. BCDMH is added to water to disinfect water or control microbial growth on the surfaces of water distribution system components. In ground water wells, BCDMH is an effective control for slime-forming iron-bacteria, thereby improved aesthetic qualities of the water.

BCDMH is typically a mixture of two related chemicals:

- 1-Bromo-3-chloro-5,5-dimethylhydantoin (CAS# 16079-88-2)
- 3-Bromo-1-chloro-5,5-dimethylhydantoin (CAS# 126-06-7)

Both chemicals release their chlorine and bromine components in water to create hypochlorous and hypobromous acid, which are the active antimicrobial agents. The dimethylhydantoin component serves as the delivery mechanism for the chloride and bromide ions and itself does not have antimicrobial properties. This also serves to make the parent chemical very shelf stable, which is a desirable property for chemicals applied at remote water wells using automated dosing equipment.

BCDMH and FIFRA

Disinfectants such as BCDMH require EPA registration under FIFRA when used, sold, or distributed within the United States. FIFRA registration is not a requirement of NSF/ANSI Standard 60, because NSF/ANSI Standard 60 is a human health effects standard and BCDMH can be used, sold, and distributed in other countries. Thus, FIFRA registration is not a precondition to applying for, obtaining, or maintaining NSF certification.

Moreover, it is the responsibility of the chemical manufacturer or distributor to follow all applicable laws and regulations, including obtaining FIFRA registration for the U.S. market; and the responsibility of the municipal water utility to follow all applicable federal and state requirements for drinking water treatment and quality.

BCDMH Drinking Water Criteria

Neither the EPA nor Health Canada has established drinking water guidelines or regulatory limits for the halohydantoin class of chemicals, including 1-bromo-3-chloro-5,5-dimethylhydantoin or 3-bromo-1-chloro-5,5-dimethylhydantoin. Consequently, according to NSF/ANSI Standard 60, Annex A, it must be determined if a published, peer-reviewed risk assessment exists for the chemical of interest that is of suitable quality to use for the derivation of drinking water criteria.

In 2009, NSF toxicologists identified a 2007 risk assessment conducted by the U.S. EPA on the halohydantoins entitled *U.S. EPA Reregistration Eligibility Decision for Halohydantoins (EPA-379-R-07-001)*. The U.S. EPA identified 5,5-dimethylhydantoin (DMH) as the appropriate surrogate for assessing the toxicity of the halohydantoin class of chemicals. From the toxicology data available for DMH, the

U.S. EPA identified chronic dietary reference doses (RfDs[a]) of 3 mg/kg-day (all populations) and 1 mg/kg-day (females 13-50 years of age). The 1 mg/kg-day dietary RfD was based on a No Observable Adverse Effect Level (NOAEL) of 100 mg/kg-day from a developmental study in rabbits which reported an adverse effect (skeletal variations) at dose of 500 mg/kg-day.

As prescribed in Annex A of NSF/ANSI Standard 60: Drinking Water Treatment Chemicals – Health Effects, NSF adopted the U.S. EPA oral RfD of 1 mg/kg-day for DMH and adjusted the oral RfD based on the molar ratio of DMH and BCDMH to arrive at a maximum concentration for drinking water applications (SPAC[b]) of 9 mg/L. NSF presented the proposed drinking water criteria for halohydantoins for external peer review by the NSF Health Advisory Board (HAB[c]) in the spring of 2010 and the NSF HAB approved the drinking water criteria at that time[d]. NSF has not evaluated the toxicology dataset for the halohydantoins since 2010. Consequently, any studies completed since 2010 are not included in the NSF document and the methodologies used to derive the drinking water criteria in the NSF document do not necessarily represent current-state risk assessment best practices. However, based on a preliminary review, NSF toxicologists have concluded that the maximum allowable concentration of BCDMH in drinking water of 9 mg/L continues to be valid.

BCDMH Potential Contaminants

NSF/ANSI Standard 60 establishes a minimum test battery for all BCDMH products and includes metals of toxicological concern, oxyhalides, and volatile organic compounds (VOCs). Metals analysis includes arsenic, barium, beryllium, cadmium, chromium, copper, mercury, lead, antimony, selenium, and thallium. Oxyhalide analysis includes bromate, chlorate, and perchlorate. VOC analysis targets over sixty volatile organic compounds and includes both regulated and non-regulated compounds. All detected compounds shall not exceed the health effects criteria (SPAC) listed in NSF/ANSI Standard 60.

Additional questions regarding Certification of BCDMH products can be directed to NSF International at info@nsf.org.

[a] Reference dose (RfD) is an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

[b] Single Product Allowable Concentration (SPAC) is the maximum concentration of a chemical that a single product can contribute.

[c] The NSF HAB is an external panel of toxicology experts with members from academia, industry and regulatory agencies (include U.S. EPA and Health Canada)

[d] Prior to the 2010 derivation, NSF had established in 1996 a Maximum Allowable Level (MAL) for BCDMH of 3 mg/L. The assessment relied on the toxicology data of 5,5-dimethylhydantoin (DMH) as a surrogate for BCDMH based on dissociation of chlorine and bromine which form hypochlorous and hypobromous acid in water. NSF considered all relevant published and unpublished toxicology data available at that time in the assessment, identified a No Observable Adverse Effect Level (NOAEL) of 100 mg/kg-day from a developmental toxicity study in rabbits, and derived an MAL of 1.66 mg/L for DMH. The molar ratio of DMH and BCDMH was used to adjust the MAL for DMH to arrive at an MAL of 3 mg/L for BCDMH.

More Information on NSF/ANSI Standard 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 Standard 60 (Annex A) that a determination must 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 the 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 shall 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 Standard 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 ten percent of the regulatory level to ensure that the consumer is adequately protected from adverse health effects if 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 the Standard 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 the NSF Standards department provides the support and structure for the development and publication of product standards, it is the 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 U.S. EPA, as well as other regulatory, water utility and product manufacturer representatives. Every NSF Standard is reviewed by another NSF Committee, the 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 their 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 the 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, the 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 Standard 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 must meet Standard 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 Standard 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.

More Information on FIFRA

Disinfectants, algaecides, bactericides, and molluscicides for water treatment when used, sold or distributed in the United States are regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This registration is managed by the US Environmental Protection Agency (EPA) and the primary objective of FIFRA is to ensure that, when applied as instructed, pesticide products will demonstrate effective biocidal properties and also will not cause unreasonable risk to human health or the environment. The EPA defines a pesticide as any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest or is a plant regulator, defoliant, desiccant, or nitrogen stabilizer. Pesticide products, such as disinfectants, sold within the U.S. fall under the scope of FIFRA and require registration by the pesticide product manufacturer or distributor. Registration requires the chemical manufacturer to submit to the EPA Office of Pesticides all requested applications and use instructions for the pesticide product, as well as the chemical formula and safety data.

Chemical manufacturers and distributors are responsible for compliance with all country laws and regulations, including FIFRA in the U.S. NSF/ANSI Standard 60 does not include requirements for pesticide registration under FIFRA as a precondition to applying for and obtaining NSF certification because this standard is accepted in multiple countries, most notably Canada and Israel. Moreover, it is the responsibility of the manufacturer to submit and obtain FIFRA registration for all pesticide related applications; and the responsibility of the municipal utility to follow all applicable federal and state requirements for drinking water quality, including FIFRA requirements in the US.

More information about the basics of FIFRA can be found at the EPA website.

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

FIFRA – Federal Insecticide, Fungicide and Rodenticide Act

MUL – maximum use level

NSF – NSF International (formerly the National Sanitation Foundation)

SPAC – single product allowable concentration