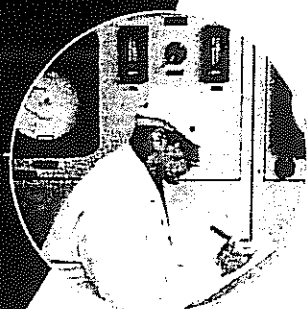




*NSF International Standard /
American National Standard*

NSF/ANSI 60 - 2009

**Drinking Water Treatment Chemicals -
Health Effects**



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Chair, Joint Committee on Drinking Water Treatment Chemicals
c/o NSF International
789 North Dixboro Road, P.O. Box 130140
Ann Arbor, Michigan 48113-0140 USA
Phone: (734) 769-8010 Telex: 753215 NSF INTL
FAX: (734) 769-0109
E-mail: info@nsf.org
Web: <http://www.nsf.org>

NSF/ANSI 60 – 2009

NSF International Standard/
American National Standard
for Drinking Water Additives —

**Drinking water treatment chemicals —
Health effects**

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NSF/ANSI Standard
for Drinking Water Additives —

Drinking water treatment chemicals —
Health effects

1 Purpose, scope, and normative references

1.1 Purpose

This Standard establishes minimum health effects requirements for the chemicals, the chemical contaminants, and the impurities that are directly added to drinking water from drinking water treatment chemicals. This Standard does not establish performance or taste and odor requirements for drinking water treatment chemicals.

1.2 Scope

This Standard contains health effects requirements for drinking water treatment chemicals that are directly added to water and are intended to be present in the finished water. This Standard also contains health effects requirements for other chemical products that are directly added to water but are not intended to be present in the finished water. Chemicals covered by this Standard include, but are not limited to, coagulation and flocculation chemicals, softening, precipitation, sequestering, pH adjustment, and corrosion/scale control chemicals, disinfection and oxidation chemicals, miscellaneous treatment chemicals, and miscellaneous water supply chemicals.

Contaminants produced as by-products through reaction of the treatment chemical with a constituent of the treated water are not covered by this Standard.

1.3 Normative references

The following documents contain requirements, which by reference in this text, constitute requirements of this Standard.

APHA, *Standard Methods for the Examination of Water and Wastewater*, twentieth edition³

ASTM E29-02, *Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications*⁴

ASTM E506-98, *Standard Test Method for Mercury in Liquid Chlorine*⁴

ASTM G22-76 (1996), *Standard Practice for Determining Resistance of Plastics to Bacteria*⁴

CGA, G-6.2-1994, *Commodity Specification for Carbon Dioxide*⁵

³ American Public Health Association, 800 I Street NW, Washington, DC 20001 www.apha.org

⁴ ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2859 www.astm.org

⁵ Compressed Gas Association, 1725 Jefferson Davis Highway, Suite 1004, Arlington, VA 22202-4102 www.cganet.com

Foreword²

In response to a competitive request for proposals from the U.S. Environmental Protection Agency (USEPA), a Consortium led by NSF International (NSF) agreed to develop voluntary third-party consensus standards and a certification program for all direct and indirect drinking water additives. Other members of the Consortium include the Water Research Foundation (formerly the American Water Works Association Research Foundation), the Association of State Drinking Water Administrators, the Conference of State Health and Environmental Managers, and the American Water Works Association. (COSHEM has since become inactive as an organization.) Each organization was represented on a steering committee with oversight responsibility for the administration of the cooperative agreement. The Steering Committee provided guidance on overall administration and management, and the member organizations will remain active after the expiration of the cooperative agreement.

The standards were developed using a voluntary consensus process. All parties at interest were represented, including regulatory agencies, industry, and water suppliers; consultants; and other users of products covered by the standards.

Two standards for additives products have been adopted. NSF/ANSI 61: *Drinking water system components - Health effects* currently covers indirect additives. NSF/ANSI 60, and subsequent product certification against it, will replace the USEPA Additives Advisory Program for drinking water treatment chemicals. For more information with regard to USEPA's actions, refer to the July 7, 1988 Federal Register (53FR25586).

NSF/ANSI 60 has been developed to establish minimum requirements for the control of potential adverse human health effects from products added to water for its treatment. It does not attempt to include product performance requirements, which are currently addressed in standards established by such organizations as the American Water Works Association, the American Society for Testing and Materials, and the American National Standards Institute. Because this Standard complements the standards of these organizations, it is recommended that products also meet the appropriate requirements specified in the standards of such organizations.

The Standard and the accompanying text are intended for voluntary use by certifying organizations, utilities, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products.

This version of NSF/ANSI 60 – 2009 includes the following revisions:

- Issue 42 Prep K weights which modified the minimum recorded weight in the method for Preparation K (B.3.12) to provide practical limitations for weights recorded during the estimation of chemical tested on a dry weight basis

Please note that the footnote in Table D1 that states that the Single Product Acceptable Concentration (SPAC) for bromate will be lowered to 0.003 mg/L is still under evaluation by the NSF Joint Committee on Drinking Water Treatment Chemicals. At this time, it has not been demonstrated that the drinking water industry demand for hypochlorite chemicals cannot be adequately met at the lower SPAC. The next revision of this standard will be made up to date with the decision of the Joint Committee.

This Standard was developed by the NSF Joint Committee on Drinking Treatment Chemicals using the consensus process described by the American National Standards Institute.

² The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

Consortium Organizations

NSF International

Popularly referred to as NSF, NSF International is a non-commercial agency. It is incorporated under the laws of Michigan as a not-for-profit organization devoted to research, education, and service. It seeks to solve problems involving man and his environment. It wishes to promote health and enrich the quality of life through conserving and improving that environment. Its fundamental principle of operation is to serve as a neutral medium in which business and industry, official regulatory agencies, and the public come together to deal with problems involving products, equipment, procedures, and services related to health and the environment. It is conceived and administered as a public service organization.

NSF is perhaps best known for its role in developing Standards and Criteria for equipment, products, and services that bear upon health. NSF was the lead organization in the Consortium responsible for developing this Standard. NSF conducts research; tests and evaluates equipment, products, and services for compliance with standards and criteria; and grants and controls the use of NSF registered Marks.

NSF offers product certification (Listing Services) for all products covered by its Standards. Each program has established policies governing the associated product evaluation, Listing Services, follow-up and enforcement activities. The NSF Listing Mark is widely recognized as a sign that the product or service to which it relates complies with the applicable NSF Standard(s).

Water Research Foundation

The mission of the Water Research Foundation (WRF) is to sponsor practical, applied research in behalf of the drinking water industry of North America. The scope of the research program embraces all aspects of water supply operation, from development and maintenance of water resources to treatment technologies and water quality issues, from storage and distribution system operations to health effects studies and utility planning and management activities. WRF serves as the centralized industry institution for planning, managing, and funding cooperative research and development in drinking water, including the subsequent transfer of technology and results for practical application by the water utility community.

WRF's purpose in this cooperative program is to provide a communication link with the water utilities throughout North America and serve as the focal point for identification of research needs of the water supply industry with respect to the additives program.

The Association of State Drinking Water Administrators

The Association of State Drinking Water Administrators (ASDWA) is a non-profit organization whose eligible membership is comprised of drinking water program administrators in each of the 50 states and seven U.S. territories. Through the organization, representatives speak with a collective voice to Congressional committees, the United States Environmental Protection Agency, professional and trade associations, water utilities, and the general public on issues related to state drinking water programs. With its mission of protecting the public health through assurance of high quality drinking water, and promoting responsible, reasonable, and feasible drinking water programs at the state and federal levels, the Association is a valued contributor to the consortium and to the program. It provides the link between the additives program and the state drinking water programs.

Annex A (normative)

Toxicology review and evaluation procedures

A.1 General requirements

This annex defines the toxicological review and evaluation procedures for the evaluation of substances imparted to drinking water through contact with drinking water system components. It is intended to establish the human health risk, if any, of the substances imparted to drinking water under the anticipated use conditions of the product. Annex D (normative) of this Standard contains evaluation criteria that have been determined according to the requirements of this annex.

The following general procedure shall be used to evaluate drinking water substances under this Standard:

a) A determination shall be made as to whether a published (publicly available in printed or electronic format) and peer reviewed quantitative risk assessment for the substance is available.

b) When a quantitative risk assessment is available, the reviewer shall determine whether the assessment is currently used in the promulgation of a drinking water regulation or published health advisory for the substance (see the requirements of annex A, section A.3).

– If the assessment is used in the promulgation of a drinking water regulation, the Single Product Allowable Concentration (SPAC) shall be derived from the regulatory value(s); or

– If the 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 drinking water substance.

NOTE – When reviewing an assessment used in the promulgation of a drinking water regulation, it is recommended that the regulatory authority be contacted to verify the currency of the assessment under consideration.

c) If a published and peer reviewed quantitative risk assessment is not currently available for the substance, the Total Allowable Concentration (TAC) and SPAC shall be derived after review of the available toxicology data for the substance (see annex A, section A.4).

– When the data requirements for qualitative risk assessment are satisfied (see annex A, section A.4.2 and table A1), a qualitative risk assessment shall be performed according to annex A, section A.7; or

– When the data requirements for quantitative risk assessment are satisfied (see annex A, section A.4.3 and table A2), a quantitative risk assessment shall be performed according to annex A, section A.7.

Annex A, figure A1 provides an overview of the toxicity data review requirements of this annex.

A.2 Definitions

A.2.1 benchmark dose: The lower 95% confidence limit on the dose that would be expected to produce a specified response in X% of a test population. This dose may be expressed as BMD_x (adapted from Barnes et al., 1995).

- completeness and currency of the data review of each assessment;
- technical competence of the organization(s) which sponsored the assessment; and
- species and route(s) of exposure for which the assessment was performed.

When multiple published risk assessments are reviewed and are determined to be of equivalent quality, the following hierarchy shall be used to select the appropriate assessment, based on sponsoring organization:

- USEPA;
- Health Canada;
- international bodies such as the World Health Organization (WHO) or the International Programme on Chemical Safety (IPCS);
- European bodies such as the Drinking Water Inspectorate (DWI) and KIWA; and
- entities such as other federal or state regulatory agencies, private corporations, industry associations, or individuals.

A.4 Data requirements for new or updated risk assessments

A.4.1 General requirements

For each substance requiring a new or updated risk assessment, toxicity data to be considered shall include, but not be limited to, assays of genetic toxicity, acute toxicity (1 to 14 d exposure), short-term toxicity (14 to 28 d exposure), subchronic toxicity (90 d exposure), reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, chronic toxicity (including carcinogenicity), and human data (clinical, epidemiological, or occupational) when available. To more fully understand the toxic potential of the substance, supplemental studies shall be reviewed, including, but not limited to, mode or mechanism of action, pharmacokinetics, pharmacodynamics, sensitization, endocrine disruption, and other endpoints, as well as studies using routes of exposure other than ingestion. Structure activity relationships, physical and chemical properties, and any other chemical specific information relevant to the risk assessment shall also be reviewed.

Toxicity testing shall be performed in accordance with the most recent adopted toxicity testing protocols such as those described by the Organization For Economic Cooperation and Development (OECD), U.S. Environmental Protection Agency, and U.S. Food and Drug Administration (FDA). All studies shall be reviewed for compliance with Good Laboratory Practice (21 CFR, Pt 58/40 CFR, Pt 792).

NOTE – Review of the study according to the approach suggested in Klimisch, et al., 1997 may also be used to determine the quality of reported data.

A weight-of-evidence approach shall be employed in evaluating the results of the available toxicity data. This approach shall include considering the likelihood of hazard to human health and the conditions under which such hazard may be expressed. A characterization of the expression of such effects shall also be included, as well as the consideration of the substance's apparent mode of action. The quality and quantity of toxicity data available for the substance shall determine whether the evaluation is performed using a qualitative risk assessment approach (see annex A, section A.4.2) or a quantitative risk assessment approach (see annex A, section A.4.3).

A.4.2 Data requirements for qualitative risk assessment

Toxicity testing requirements for the qualitative risk assessment procedure are defined in annex A, table A1. A minimum data set consisting of a gene mutation assay and a chromosomal aberration assay shall be required for the performance of a qualitative risk assessment. Modifications in the specified toxicity testing requirements (inclusions or exclusions) shall be permitted when well supported by peer reviewed scientific judgment and rationale.

NOTE – Modifications may include, but are not limited to, the following types of considerations: alternate assays of genetic toxicity, and supplemental toxicity studies other than those specified.

Required studies and available supplemental studies shall be reviewed in order to perform a qualitative risk estimation in accordance with annex A, section A.7.2.

A.4.3 Data requirements for quantitative risk assessment

Toxicity testing requirements for the quantitative risk assessment procedure are defined in annex A, table A2. A minimum data set consisting of a gene mutation assay, a chromosomal aberration assay, and a subchronic toxicity study shall be required for the performance of a quantitative risk assessment. The required studies and preferred criteria are defined in annex A, table A2. Modifications to the minimum data set shall be permitted when well-supported by peer reviewed scientific judgment and rationale.

NOTE – Modifications may include, but are not limited, to acceptance of studies using alternate routes of exposure, alternate assays of genetic toxicity, and supplemental toxicity studies other than those specified.

Required studies, additional studies, and available supplemental studies shall be reviewed in order to perform a quantitative risk estimation in accordance with annex A, section A.7.3.

Additional studies for the evaluation of reproductive and developmental toxicity (as specified in annex A, table A2) shall be required to be reviewed when:

- results of the required minimum data set studies and any supplemental studies indicate toxicity to the reproductive or endocrine tissues of one or both sexes of experimental animals; or
- the compound under evaluation is closely related to a known reproductive or developmental toxicant.

A.5 Data requirements for evaluating short-term exposures

Extractants from products used in contact with drinking water may be elevated initially, but rapidly decline with continued product contact with water. Examples include, but are not limited to, solvent-containing coatings and solvent cements. Short-term exposure paradigms, appropriate for potentially high initial substance concentrations, shall be used to evaluate potential acute risk to human health of short-term exposures. The short-term exposure period shall be defined as the first 14 d of in-service life of the product.

Sound scientific judgment shall be used to determine whether calculation of a Short-term Exposure Level (STEL) is appropriate for a given contaminant. The NOAEL or LOAEL for the critical short-term hazard of the substance shall be identified. The following types of studies shall be considered for identification of short-term hazard:

- short-term (less than 90 d duration) toxicity study in rodents or other appropriate species with a minimum 14-d post-treatment observation period, clinical observations, hematology and clinical chemistry, and gross pathology (preferably an oral study in rodents);

- reproduction or developmental assays (for substances having these endpoints as the critical effects); or
- subchronic 90-d study in rodents or other species (preferably an oral study in rats).

The critical study shall be used to calculate a Short-term Exposure Level (STEL) in accordance with annex A, section A.8.

Selection of uncertainty factors for calculation of a STEL shall consider the quality and completeness of the database for assessing potential short-term effects. Selection of uncertainty factors shall also consider data that quantify interspecies and intraspecies variations. Other parameters that shall be considered in the determination of a STEL include identification of any sensitive subpopulations, the potential for adverse taste and odor, and solubility limitations at the calculated STEL. The STEL shall be calculated using assumptions to protect for a child's exposure to the contaminant in the absence of data that demonstrate adults are more sensitive than children. In the absence of appropriate data to calculate a STEL, see annex A, section A.7.1.2.


A.6 Risk estimation for published assessments

Calculation of the SPAC is intended to account for the potential contribution of a single substance by multiple products or materials in the drinking water treatment and distribution system. In any given drinking water treatment and distribution system, a variety of products and materials may be added to or contact the treated water prior to ingestion. The SPAC calculation is intended to ensure that the total contribution of a single substance from all potential sources in the drinking water treatment and distribution system does not exceed its acceptable concentration.

A.6.1 SPAC calculation for regulated substances

To calculate the SPAC, an estimate of the number of potential sources of the substance from all products in the drinking water treatment and distribution system shall be determined. The SPAC shall be calculated as follows:


$$\text{SPAC (mg/L)} = \frac{\text{promulgated regulatory value (mg/L)}}{\text{estimated number of drinking water sources}}$$

In the absence of specific data regarding the number of potential sources of the substance in the drinking water treatment and distribution system, the SPAC shall be calculated as 10% of the promulgated regulatory value. 

A.6.2 SPAC calculation for other published risk assessments

Review of the risk assessment shall include evaluation of the risk estimation, if one is provided. If the existing risk estimation has been performed in a manner consistent with the procedures in annex A, section A.7.3 for non-carcinogenic or carcinogenic endpoints, the SPAC shall be calculated as follows:

$$\text{SPAC (mg/L)} = \frac{\text{existing risk estimation (mg/L)}}{\text{estimated number of drinking water sources}}$$

In the absence of specific data regarding the number of potential sources of the substance in the drinking water treatment and distribution system, the SPAC shall be calculated as 10% of the existing risk estimation. 

If the existing risk estimation is not consistent with annex A, section A.7.3, or a risk estimation is not provided, a TAC and SPAC shall be calculated for the substance according to the procedures in annex A, section A.7.3.

A.7 Risk estimation using new and updated risk assessments

The method of risk estimation used for new and updated risk assessments shall be determined by the quantity and quality of toxicity data identified for the contaminant of concern (see annex A, section A.4). When available toxicity data are insufficient to perform the qualitative or quantitative risk assessments, or when toxicity data are available, but the normalized contaminant concentration does not exceed the applicable threshold of evaluation value, a threshold of evaluation shall be determined for the substance according to annex A, section A.7.1 if applicable. For all other data sets, the risk estimation shall be performed according to annex A, sections A.7.2 or A.7.3.

A.7.1 Threshold of evaluation

The following thresholds of evaluation shall be considered when available toxicity data do not meet the minimum requirements to perform a risk estimation using either the qualitative or quantitative approaches. Application of the threshold of evaluation shall also be considered for the evaluation of normalized contaminant concentrations which do not have existing risk assessments, and which do not exceed the defined threshold of evaluation concentrations. In this case, a qualitative review of the available data shall be performed to determine whether adverse health effects can result at the threshold of evaluation exposure concentrations defined in annex A, section A.7.1.1.

A.7.1.1 Threshold of evaluation for chronic exposure

Performance of a risk assessment shall not be required for an individual substance having a normalized concentration less than or equal to the following threshold of evaluation values:

- static normalization conditions:

toxicity testing shall not be required for an individual substance having a normalized concentration less than or equal to the threshold of evaluation value of 3 µg/L.

- flowing normalization conditions:

toxicity testing shall not be required for an individual substance having a normalized concentration less than or equal to the threshold of evaluation value of 0.3 µg/L.

These threshold of evaluation values shall not apply to any substance for which available toxicity data and sound scientific judgment such as structure activity relationships indicate that an adverse health effect results at these exposure concentrations.

A.7.1.2 Threshold of evaluation for short-term exposure

If an appropriate short-term toxic effect is not identified by the available data, the initial (D 1) laboratory concentration shall not exceed 10 µg/L. This threshold of evaluation value shall not apply to any chemical for which available toxicity data and sound scientific judgment, such as structure activity relationships, indicate that an adverse health effect can result at the 10 µg/L concentration upon short-term exposure to the chemical.

A.7.2 TAC determination for qualitative risk assessment

TACs for qualitative risk assessments shall be determined as indicated in annex A, table A3.