



*NSF International Standard /
American National Standard*

NSF/ANSI 60 - 2013

Drinking Water Treatment Chemicals - Health Effects



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NSF International Standard/
American National Standard
for Drinking Water Additives —
**Drinking water treatment chemicals —
Health effects**

Standard Developer

NSF International

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Designated an ANSI Standard

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American National Standards Institute

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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 – 2013 includes the following revisions:

- Issue 53: This issue specifies requirements regarding the use of non-potable water in the production of drinking water treatment chemicals under the general requirements of section 3.
- Issue 58: Rounding procedures have been clarified under section 1.5 and Annex A.
- Issue 59: The normative reference for *Standard Methods for the Examination of Water and Wastewater* was updated to the most recent edition and language was added under section 1.3 to address undated normative references.

This Standard was developed by the NSF Joint Committee on Drinking Water Additives – 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.

Suggestions for improvement of this Standard are welcome. This Standard is maintained on a Continuous Maintenance schedule and can be opened for comment at any time. Comments should be sent to Chair, Joint Committee on Drinking Water Additives – Treatment Chemicals at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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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.

The Conference of State Health and Environmental Managers

The Conference of State Health and Environmental Managers (COSHEM), known formerly as the Conference of State Sanitary Engineers (CSSE), is currently inactive as an organization. It brought to the consortium expertise and involvement of state health and environmental program managers. The Conference was the focal point for health concerns of all state environmental programs, including drinking water, wastewater, air, solid and hazardous wastes, radiological, occupational, health, and food. A standing committee on water supply focused on drinking water issues and kept the membership informed. The Conference played an important role early in the program through two-way communication with state health and environmental program decision makers.

American Water Works Association

The purpose for which the American Water Works Association (AWWA) is formed is to promote public health, safety, and welfare through the improvement of the quality and quantity of water delivered to the public and the development and furtherance of understanding of the problems relating thereto by:

- advancing the knowledge of the design, construction, operation, water treatment and management of water utilities, and developing standards for procedures, equipment, and materials used by public water supply systems;
- advancing the knowledge of problems involved in the development of resources, production, and distribution of safe and adequate water supplies;
- educating the public on the problems of water supply and promoting a spirit of cooperation between consumers and suppliers in solving these problems; and
- conducting research to determine the causes of problems of providing a safe and adequate water supply and proposing solutions thereto in an effort to improve the quality and quantity of the water supply provided to the public.

AWWA brings to the Consortium its established position as the largest public drinking water association in North America, with a broad range of membership, including utilities, consultants, manufacturers/ distributors/ agents, contractors, and other organizations with a direct interest in drinking water.

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.

Acknowledging the fact that indigenous microorganisms may be present in drinking water, products resulting in the intentional introduction of microorganisms for the treatment of drinking water are excluded from the scope of the Standard.

1.3 Normative references

The following documents contain requirements, which by reference in this text, constitute requirements of this Standard. At the time this Standard was balloted, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the recent editions of the documents indicated below. The most recent published edition of the document shall be used for undated references.

21 CFR 587, *Good Laboratory Practice for Non-Clinical Laboratory Studies*³

40 CFR Part 160, *Good Laboratory Practice Standards*⁴

40 CFR Part 798, *Health Effects Testing Guidelines*⁴

³ US Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 <www.fda.gov>.

⁴ Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 <www.gpo.gov>.

APHA, AWWA, WEF, *Standard Methods for the Examination of Water and Wastewater*, twenty-second edition^{5, 6, 7}

ASTM E29-02. *Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications*⁸

ASTM G22-76 (1996). *Standard Practice for Determining Resistance of Plastics to Bacteria*⁶

CGA, G-6.2-1994. *Commodity Specification for Carbon Dioxide*⁹

OECD, *Guidelines for the Testing of Chemicals*, May 1996¹⁰

USEPA-600/4-79-020. *Methods for the Chemical Analysis of Water and Wastes*, March 1983¹¹

USEPA-600/4-80-032. *Prescribed Procedures for Measurement of Radioactivity in Drinking Water*⁹

USFDA, *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives in Food*⁹

1.4 Alternate chemicals

Chemicals or mixtures of chemicals used for the various purposes discussed in this Standard, but not specifically referenced, shall be acceptable provided they meet the requirements of this Standard.

1.5 Significant figures and rounding

When determining conformance with the specifications in this standard, the Absolute Method in ASTM E29 *Standard Practice for Using Significant Digits in Test Data to Determine Conformance With Specifications* shall be used. When rounding data, the Rounding Procedure in section 6.4 of ASTM E29 shall be used.

2 Definitions

2.1 analytical summary: A list of the analytical procedures, both chemical and microbiological, which are selected to determine whether a product is compliant to the requirements of the Standard.

2.2 at-the-tap: Referring to the point of delivery of potable water.

2.3 blend: A treatment product composed of two or more individual chemicals that do not react with one another.

2.4 blender: A manufacturer who produces a physical mixture of two or more ingredients. The mixture may be further diluted with potable water.

⁵ American Public Health Association, 800 I Street NW, Washington, DC 20001 <www.apha.org>.

⁶ American Water Works Association, 6666 W. Quincy Ave., Denver, CO 80235 <www.awwa.org>

⁷ Water Environment Federation, 601 Wythe Street, Alexandria, VA <www.wef.org>

⁸ ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2859 <www.astm.org>.

⁹ Compressed Gas Association, 1725 Jefferson Davis Highway, Suite 1004, Arlington, VA 22202-4102 <www.cganet.com>.

¹⁰ Organization for Economic Cooperation and Development, 2 Rue Andre-Pascal, 75775 Paris Cedex 16, France <www.oecd.org>.

¹¹ US Environmental Protection Agency, Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268 <www.epa.gov>.

NOTE – The definition of blender pertains to physical mixtures of ingredients, and not to chemical products that are produced by a chemical reaction in blended processes.

2.5 bulk transfer facilities: A facility/location where a source product is transferred from one bulk vessel to another, with or without intermediate product storage.

2.6 by-product: A contaminant produced secondarily to the production of a principal compound.

2.7 certified product: A single product or trade designation that appears in the public listings of a Standard 60 certification agency.

2.8 chemical stock: a store or supply accumulated or available for product manufacture.

2.9 contaminant: Any physical, chemical, biological, or radiological substance or matter in water.

NOTE – Consistent with the definition in the federal Safe Drinking Water Act, a contaminant can have either a beneficial or detrimental effect on the potability of water.

2.10 diluter: A manufacturer that produces a product composed of a single source product, diluted with water to a specific concentration.

2.11 direct additive: A drinking water treatment chemical and any of its contaminants added directly to water during the production of drinking water.

2.12 drinking water: Water intended for human consumption.

2.13 evaluation dose: The concentration of a direct additive used to evaluate the impurities imparted to drinking water.

2.14 facility: a building, special room, etc. that facilitates or makes possible some activity.

2.15 good manufacturing practice: The practice of maximizing the purity of the product by maintaining and practicing appropriate quality control and quality assurance procedures.

2.16 indirect additive: A contaminant that is extracted into drinking water through contact with surfaces of materials or products used for drinking water treatment, storage, transmission, or distribution.

2.17 manufacturer: The original chemical manufacturer, in which some process is used to produce a drinking water treatment chemical.

2.18 maximum contaminant level (MCL): The maximum concentration of a contaminant permitted in a public drinking water supply as defined by the federal Safe Drinking Water Act.

NOTE – If the manufacturer requests review relevant to alternate regulatory requirements, the certifying agency can consider alternative regulatory levels, e.g. Canadian Maximum Acceptable Concentrations (MACs).

2.19 maximum use level: The maximum concentration of a direct additive that has been found to be acceptable under this Standard. This refers to the total quantity used in the process train, regardless of the number of application points.

2.20 normalization: The process of adjusting laboratory results to account for differences between laboratory and at-the-tap exposures.

2.21 normalized concentration: A value for a contaminant concentration from a laboratory evaluation that has been adjusted to reflect the contaminant concentration at-the-tap.

2.22 product family: A group of products, under the same chemical category, under which a Standard 60 certification agency has bracketed a single designated test product (one of the products in the group) for testing purposes.

2.23 repackager: A company, other than the original product manufacturer or the same production facility, that opens the packaging of a product, places it into another container, seals, and labels the product.

2.24 relabeller: A company that places a new product label on a source product without opening the original packaging.

2.25 single product allowable concentration (SPAC): The maximum concentration of a contaminant in drinking water that a single product is allowed to contribute under Annex A of this Standard.

2.26 source product: The original product that is repackaged, relabeled, or diluted by a chemical distributor to produce a new finished product.

2.27 storage: space or a place for storing.

2.28 total allowable concentration (TAC): The maximum concentration of a non-regulated contaminant permitted in a public drinking water supply as defined by Annex A of this Standard.

2.29 typical use level: An application level that has been used historically in water treatment. The typical use level is not the maximum use level for the product except where specifically stated.

2.30 unannounced facility inspection: An audit of a chemical supplier's facility, without prior notice, that includes compliance checks to the NSF/ANSI 60 standard and product certification agency's program policies. Note: A delay of 1-2 hr between arrival time of the inspector and before the onset of the inspection due to security, safety and personnel availability issues is acceptable.

3 General requirements

3.1 General

Direct additives shall be evaluated and tested in accordance with Annexes A and B. The SPAC of a contaminant shall be calculated as outlined in Annex A. Under the provisions of this Standard, a product shall not contribute any contaminant to drinking water in excess of the contaminant's SPAC.

Direct additives under this Standard shall be:

- the treatment or water supply product itself;
- the product-specific contaminants listed in each of the product sections of this Standard; and
- other constituents as identified in the formulation review.

Figure 3.1 provides an overview of the evaluation process.

3.2 Formulation submission and review

3.2.1 The manufacturer shall submit, at a minimum, the following information for each product:

- a proposed maximum use level for the product, which is consistent with the requirements of Annex A;

- complete formulation information, which includes the following:
 - the composition of the formulation (in percent or parts by weight for each chemical in the formulation);
 - the reaction mixture used to manufacture the chemical, if applicable;
 - chemical abstract number (CAS number), chemical name, and supplier for each chemical present in the formulation;
 - a list of known or suspected impurities within the treatment chemical formulation and the maximum percent or parts by weight of each impurity; and
 - the source and type of water used in the manufacture of the treatment chemical as well as any available documentation regarding quality monitoring of such water source, if applicable;
- a description or classification of the process in which the treatment chemical is manufactured, handled, and packaged;
- selected spectra (e.g. UV/visible, infrared) shall be required for some additive products or their principle constituents; and
- when required by Annex A a list of published and unpublished toxicological studies relevant to the treatment chemical and the chemicals and impurities present in the treatment chemical.

3.2.2 The formulation information provided by the manufacturer shall be reviewed, and this review shall determine any formulation-dependent contaminants to be evaluated in addition to the product-specific analytes identified in each product section (see 4 through 8).

3.2.3 If the finished product contains water, the formulation information provided by the manufacturer shall be reviewed to determine if the water source used in the manufacturing of the finished product requires testing.

Water sources that require testing include, but are not limited to, the following: non-treated surface water; non-treated ground water; non-treated rain water; and water collected from other non-treated sources. Testing of water sources shall include the following analyses; metals, VOCs, base/neutral/acid scan, radionuclides, herbicides/pesticides, and dioxin/furan scan.

Water sources that do not require testing include the following: treated or non-treated water sources that comply with state or national drinking water standards, deionized water, distilled water, demineralized water, water treated on-site to drinking water quality with the exception of disinfection, drinking water treated with a reverse osmosis system, ground water treated on-site to drinking water quality or a higher purity grade and recirculated water or condensate water originating from water sources that do not require testing.

NOTE 1 - Testing related to water sources may be performed on the finished product or on a separate water sample; however, any test conducted on the finished product itself, as part of such product's certification testing battery, may be omitted from testing performed on a separate water sample.

NOTE 2 – Metals analysis shall include antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, and thallium.

3.3 Sampling, preparation, and analysis of samples

Sample collection, preparation, and analysis shall be done in accordance with methods outlined in Annex B.

3.4 Contaminant concentrations

3.4.1 Individual treatment chemicals

Contaminant concentrations for individual treatment chemicals shall be no greater than the limits established in accordance with Annex A.

3.4.2 Blends of treatment chemicals

For products which are blended entirely of treatment chemicals which have met the requirements of this Standard as individual treatment chemicals, contaminant concentrations from the individual treatment chemicals shall be no greater than the limits established in accordance with Annex A.

For products which are blended using one or more treatment chemical(s) which have not met the requirements of this Standard, contaminant concentrations of the blended product shall be no greater than the limits established in accordance with Annex A.

Evaluation of products that are blends shall also consider whether contaminant concentrations from the individual chemicals are changed by the use of the chemicals in combination.

3.5 Product labeling

The product container or documentation shipped with the product, such as a product technical data sheet, or MSDS shall be clearly identified with the manufacturer's name and address, product identification, net weight, lot number, maximum use level and certification markings of applicable certification organizations. When applicable, the manufacturer shall specify any special precautions for handling, storage and use.

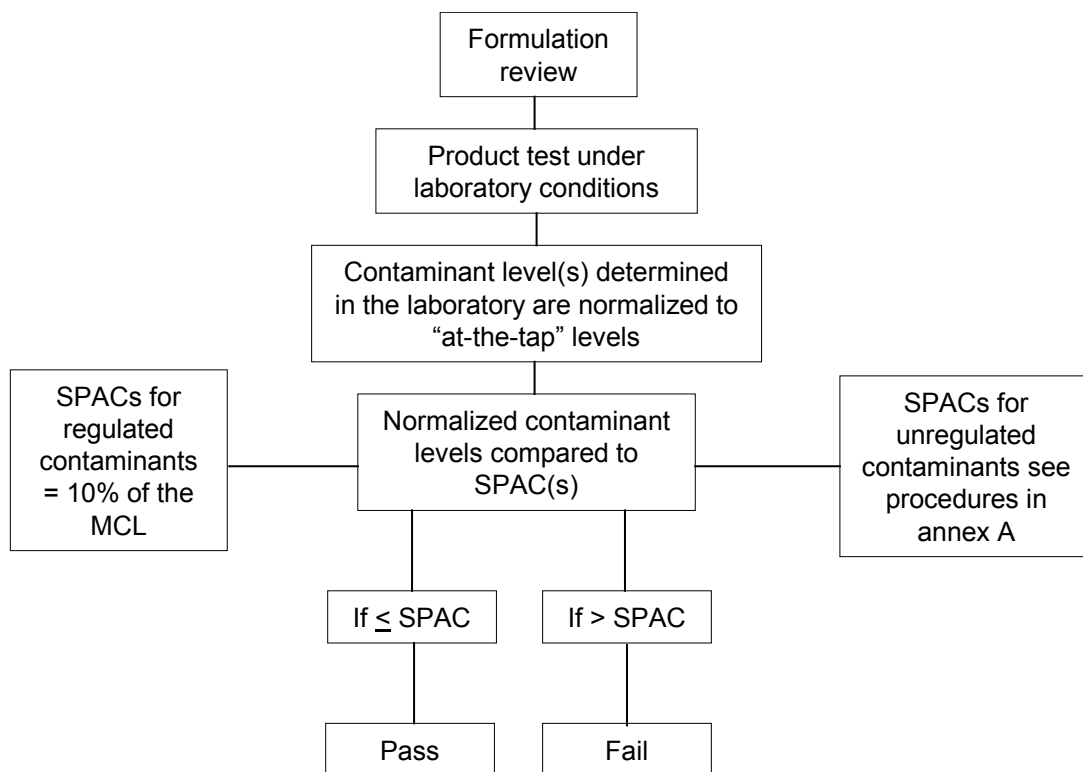


Figure 3.1 – Product evaluation overview

3.6 Formulation control

The manufacturer shall have practices in place to ensure that the product is manufactured according to the approved formulation, and to ensure that no changes in manufacturing processes, product composition, or raw materials can occur without prior authorization by the certification body. The practices shall ensure that no contamination is introduced by product packaging, transfer and storage equipment, or dilution water. Containers shall either be dedicated to one category of chemical, or written records of cleaning (e.g. wash tickets) must be available for review. Documentation of these practices shall be available for review.

3.7 Product traceability

The manufacturer shall establish and maintain practices that ensure all products and product blends are uniquely labeled according to the requirements of 3.5. These practices shall provide for traceability from raw materials to finished products.

3.8 Conformity assessment requirements

This section applies to certification organizations only. All products certified under this standard shall conform to the following requirements.

3.8.1 Product testing

Except as noted, a product shall be sampled and tested at least once per calendar year for the chemistry-specific analytes (Tables 4.1, 5.1, 6.1 & 7.1) and other parameters identified in the product analytical summary from the formulation review. The product with the highest concentration may be tested as the representative of a series of analogous lower concentration products. For a diluted, blended, or repackaged certified product a minimum of one product per facility shall be tested annually. Products that are unavailable for testing by the certification agency for more than 3 years from the last test date cannot be considered compliant with this standard.

3.8.2 Facility inspections

Except as noted, facilities producing certified products shall receive an unannounced inspection at least once per calendar year. The inspection frequency may be increased in cases of non-compliance. Such inspections shall include (but not be limited to):

- visual inspection of production;
- sample collection pursuant to 3.6.1;
- formulation validation;
- analytical procedures and methods review;
- records review related to formulation control; and
- records review of chemical stock control.

Announced inspections can be authorized in lieu of unannounced inspections for the initial inspection, security concerns, intermittently staffed facilities, and during accreditation reviews.

3.9 Product security

Products to be sold for drinking water treatment applications shall be protected to maintain the quality required by this standard. Appropriate, effective measures shall be made to control access to products at all points of manufacturing, blending, diluting, packaging, repackaging, storage, shipping and handling and to provide the manufacturer and the purchasing user of product with the ability to detect tampering (see Annex H).

3.9.1 Definition of tamper-evident packaging

Packaging having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

3.9.2 Security requirements for packaged products

Packaged product shall be stored, shipped, and delivered in tamper-evident packaging as defined in Section 3.9.1. Properly constructed, labeled, and sealed multi-wall containers such as bags and fiber drums constitute two forms of acceptable tamper-evident packaging.

3.9.2.1 Bags and super sacks

Packages for product shipped without reusable openings shall be constructed and properly sealed to make opening or substitution obvious to the purchaser. The packages shall display the company's name, and employ seals that are destroyed upon opening, or that make resealing unlikely (e.g. serialized tags), or other equivalent tamper-evident measures so that once opened, the tamper-evident feature of the seal the packaging cannot be restored nor readily duplicated.

3.9.2.2 Drums and small containers

Drums and small containers used for product shall be constructed and properly sealed to make opening or substitution obvious to the purchaser. Openings in the containers shall be sealed with tamper-evident seals and the packages shall display the company's name. Packages shall employ seals that are destroyed upon opening, or that make resealing unlikely (e.g. ultrasonic seals), or other equivalent tamper-evident measures so that once opened, the tamper-evident feature of the seal cannot be restored nor readily duplicated.

3.9.3 Security requirements for bulk shipments

Bulk quantities of product shall be secured during storage and distribution by employing one or more of the following security measures. These requirements are applicable to a single load delivered to one or multiple locations. This requirement applies to all tank truck chemical deliveries, and to railcar chemical deliveries that are direct to drinking water utilities or to other end users involved in the addition of the delivered chemical to drinking water.

3.9.3.1 Tamper-evident seals

Bulk shipping containers shall have tamper protection provided at all openings capable of loading or unloading chemicals. Vents shall have tamper protection provided unless they are protected by construction that makes them incapable of receiving chemicals. Bulk shipping containers may be sealed with a uniquely numbered, non-reusable, tamper-evident seal on each opening in the shipping container. If tamper-evident seals are used, the seals shall remain in place until removed at the point of delivery. Seal numbers shall be recorded and disclosed on shipping documents provided to the purchaser at the time of delivery and kept available for review by the certification body.

3.9.3.2 Chain of custody

A continuous chain of custody may be used to document secure distribution of product. Maintaining a continuous chain of custody requires that the product is under the control of responsible individuals, that direct access to the product is restricted to those individuals, and that the shipping container is sealed or locked at all times during shipping. If chain of custody is used, a copy of a completed, signed chain of custody form showing continuous and secure custody between the certification holder and purchaser shall be provided to the purchaser at the time of delivery and kept available for review by the certification body.

3.9.3.3 Alternative method

An alternative method or methods agreed upon by the certification holder and the purchaser may be used for bulk shipments if the alternative method provides protection against tampering that is equivalent to this Standard. If alternative methods are used, the agreement with the purchaser and description of the alternative methods shall be in written form and kept available for review by the certification body.

3.9.4 Tamper-evident integrity

The tamper-evident features employed on all final product packaging, seals, and bulk shipping containers shall be designed to remain intact when handled in a reasonable manner during manufacture, storage, shipment and delivery to the purchaser.

4 Coagulation and flocculation chemicals

4.1 Coverage

This section covers products used as coagulants, flocculants, and filtration aids in treating drinking water. Products include individual treatment chemicals, blends of treatment chemicals, and dilutions of these products. Uses include removal of suspended solids, color, dissolved components, and sludge dewatering (where recycle flows exist).

4.2 Definitions

4.2.1 bentonite: An adsorptive and colloidal native hydrated aluminum silicate clay consisting principally of montmorillonite.

4.2.2 clay: Soil consisting of inorganic materials, which are primarily minerals, the grains of which have diameters less than 0.002 mm.

4.2.3 coagulant: A direct additive used in water treatment to induce coagulation.

4.2.4 coagulation: The destabilization of colloidal and dispersed particles, inducing growth to larger particle sizes.

4.2.5 copolymer: A polymer consisting of two or more monomers as repeating units.

4.2.6 DADMAC: Diallyldimethylammonium chloride monomer.

4.2.7 EPI/DMA: Epichlorohydrin/dimethylamine copolymer.

4.2.8 filtration aid: A direct additive used in water treatment to enhance the filterability of water.

4.2.9 flocculant: A direct additive used in water treatment to induce flocculation.

4.2.10 flocculation: The agglomeration of coagulated and finely divided suspended matter into aggregates or complexes.

4.2.11 hectorite: A swelling and gelling clay of the montmorillonite group.

4.2.12 metal salt coagulant: An inorganic salt used in water treatment for coagulation, usually contains a multivalent cation of iron or aluminum.

4.2.13 monomer: Basic reactive unit(s) from which higher molecular weight molecules (polymers) are formed.

4.2.14 polyacrylamide: A class of polymers produced from acrylamide monomer. These polymers can be anionic, cationic, or non-ionic in charge.

4.2.15 polyDADMAC: A polymer produced from DADMAC monomer.

4.2.16 polyelectrolyte: A polymer with multiple charged functional groups.

4.2.17 polymer: A high molecular weight molecule made from lower molecular weight basic reactive units (monomers).

4.2.18 sludge conditioner: A chemical added to sludge to improve its dewatering ability.

4.2.19 suspended solids: Solid organic or inorganic particles physically held in suspension by agitation or flow.

4.3 General requirements

4.3.1 General information about the products covered in this section is summarized in Table 4.1.

4.3.2 Metal salt coagulants

Metal salt coagulant products shall not be evaluated for residual levels of the parent metal (e.g., aluminum or iron) after flocculation of the product.

4.4 Sample requirements

Samples of product obtained for testing and evaluation shall have been manufactured from a formulation identical to that of the commercially available product.

4.5 Sample preparation

4.5.1 Analytical summary

An analytical summary shall be prepared for each product. The analytical summary shall consist of the minimum test batteries of chemistry-specific analytes identified in Table 4.1 and any formulation-dependent analytes identified during the formulation review (see 3.2)

4.5.2 Selection of preparation method

4.5.2.1 Individual treatment chemicals

The test sample shall be prepared for analysis per the appropriate preparation method indicated in Table 4.1, if applicable.

4.5.2.2 Blends of treatment chemicals

Preparation method(s) for blends of treatment chemicals (e.g., a blend of a metal salt coagulant and a polymer) shall be selected according to the individual treatment chemicals in the blended product.

NOTE – For example, a blend of a metal salt coagulant and a polymer is prepped using method K (see Annex B, section B.3.12) for analysis of the metal salt contaminants, and the product is not prepped for analysis of the polymer contaminants. Separate aliquots of the sample are used for analysis of each component of the blend.

4.6 Analysis

Following preparation (see 4.5.2), the sample shall be analyzed for the contaminants identified on the analytical summary per the methods outlined in Annex B, section B.4.

4.7 Normalization

4.7.1 Nonpolymer chemicals

The concentration of contaminants detected in the analysis solution shall be adjusted to reflect the contaminant concentration in the finished drinking water according to the following equation:

$$\frac{\text{mg contaminant}}{\text{L analysis solution}} \times \frac{\text{L analysis solution}}{\text{mg product}} \times \frac{\text{mg product}}{\text{L drinking water}} = \frac{\text{mg contaminant}}{\text{L drinking water}}$$

[analysis solution] [lab prep solution] [maximum use level] [at-the-tap exposure]

4.7.2 Polymer chemicals

The concentration of contaminants detected in the analysis solution shall be adjusted to reflect the contaminant concentration in the finished drinking water according to the following equation:

$$\frac{\mu\text{g contaminant}}{\text{g product}} \times \frac{1 \text{ g}}{1000 \text{ mg}} \times \frac{\text{mg product}}{\text{L drinking water}} = \frac{\mu\text{g contaminant}}{\text{L drinking water}}$$

[analysis solution] [maximum use level] [at-the-tap exposure]

4.8 Evaluation of contaminant concentrations

4.8.1 General

The normalized concentration of each contaminant shall be no greater than the SPAC determined in accordance with the requirements of Annex A.

4.8.2 Blends

The maximum use level of each treatment chemical in a blended product shall not exceed its maximum use level when evaluated as an individual treatment chemical.

The following table is a generic listing of the types of products covered in this section. This table is not intended to be a complete list of all products used for coagulation and flocculation applications. Inclusion of a product does not indicate either a use endorsement of the product or an automatic acceptance under the provisions of this Standard. Annex F, Table F1, includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

Table 4.1 – Coagulation and flocculation products – product identification and evaluation

Chemical type (Description)	Synonyms	Formula (CAS number)	Approximate molecular weight	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
acrylamide/acrylic acid copolymer ³ (polyelectrolytes)	—	(31212-13-2)	4 - 30 million	—	1.0 ⁴	acrylamide, acrylic acid, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile
activated silica (coagulant)	silicic acid	SiO ₂ · nH ₂ O (1343-98-2)	78 @ n = 1	method A, Annex B, section B.3.2	5.0	metals ⁵ , radionuclides, base/neutral scan ⁶
aluminum chloride (metal salt coagulant)	aluminum trichloride	AlCl ₃ (41630-01-7) (7446-70-0)	133.34	method K, Annex B, section B.3.12	70.0/26.8 ⁷	metals ⁵ , base/neutral scan ⁶
aluminum chlorohydrate (metal salt coagulant)	aluminum chloride hydroxide, basic aluminum hydroxide, alum	Al ₂ Cl(OH) ₅ (12042-91-0)	variable	method K, Annex B, section B.3.12	—	metals ⁵ , base/neutral scan ⁶
aluminum sulfate (metal salt coagulant)	aluminum alum, cake alum, aluminum trisulfate	Al ₂ (SO ₄) ₃ · nH ₂ O (10043-01-3)	594.4 (n =14)	method K, Annex B, section B.3.12	156/26.8 ⁷	metals ⁵ , base/neutral scan ⁶
anionic polyacrylamide (dry) ³ (polyelectrolytes)	—	(31212-13-2)	4 - 30 million	—	1.0 ⁴	acrylamide, acrylic acid, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile
anionic polyacrylamide (emulsion) ³ (polyelectrolytes)	—	(31212-13-2)	4 - 30 million	—	4.0 ⁴	acrylamide, acrylic acid, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile

Table 4.1 – Coagulation and flocculation products – product identification and evaluation

Chemical type (Description)	Synonyms	Formula (CAS number)	Approximate molecular weight	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
bentonite/montmorillonite (clays)	wilkinite, montmorillonite, volclay	RO.33(Al, Mg)_2 $\text{Si}_4\text{O}_{10}(\text{OH})_2 \cdot n\text{H}_2\text{O}$ (R = Na, K, Mg or Ca) (1302-78-9)	Unknown	method F, Annex B, section B.3.7	200	metals ⁵ , radionuclides, base/neutral/acid scan
cationic polyacrylamide (dry) ³ (polyelectrolytes)	acrylamide/acryl- oxy-ethyltrimethyl ammonium chloride (dry)	(9003-05-8)	4 - 20 million	—	1.0 ⁴	acrylamide, cationic monomer, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile
cationic polyacrylamide (emulsified) ³ (polyelectrolytes)	acrylamide/acryl- oxy-ethyltrimethyl ammonium chloride (emulsified)	(9003-05-8)	4 - 20 million	—	4.0 ⁴	acrylamide, cationic monomer, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile
ferric chloride (metal salt coagulant)	iron (III) chloride, iron trichloride	$\text{FeCl}_3 \cdot n\text{H}_2\text{O}$ (7705-08-0)	162.22 (n = 0) 270.30 (n = 6)	method K, Annex B, section B.3.12	60.0/20.7 ⁸ 100.0/20.7 ⁸	metals ⁵ , VOCs, base/neutral/acid scan ⁶
ferric sulfate (metal salt coagulant)	ferric persulfate ferric tersulfate iron (III) sulfate	$\text{Fe}_2(\text{SO}_4)_3 \cdot n\text{H}_2\text{O}$ (10028-22-5)	399.88 (n = 0)	method K, Annex B, section B.3.12	100.0/28 ⁸	metals ⁵ , base/neutral/acid scan ⁶
ferrous chloride (metal salt coagulant)	iron (II) chloride, iron dichloride	FeCl_2 (7758-94-3)	126.75	method K, Annex B, section B.3.12	—	metals ⁵ , VOCs, base/neutral/acid scan ⁶
ferrous sulfate (metal salt coagulant)	iron (II) sulfate	$\text{FeSO}_4 \cdot n\text{H}_2\text{O}$ (7720-78-7)	151.91 (n = 0) 278.0 (n = 7)	method K, Annex B, section B.3.12	43.7/16.1 ⁸ 80.0/16.1 ⁸	metals ⁵ , base/neutral/acid scan ⁶
hectorite (clay)	—	—	—	method F, Annex B, section B.3.7	200	metals ⁵ , radionuclides, base/neutral scan
hydrolyzed polyacrylamide (polyelectrolytes)	HPAM	ammonium salt (26100-47-0) sodium salt (25085-02-3)	4 - 30 million	—	1.0 ⁴	acrylamide, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile

Table 4.1 – Coagulation and flocculation products – product identification and evaluation

Chemical type (Description)	Synonyms	Formula (CAS number)	Approximate molecular weight	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
non-ionic polyacrylamide (dry) ³ (polyelectrolytes)	PAM, PAMD	(9003-05-8)	4 - 20 Million	—	1.0 ⁴	acrylamide, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile
non-ionic polyacrylamide (emulsion) ³ (polyelectrolytes)	PAM, PAMD	(9003-05-8)	4 - 20 Million	—	4.0 ⁴	acrylamide, acrylonitrile, 3-hydroxypropane nitrile, isobutane nitrile
poly (diallyldimethyl- ammonium chloride) (polyelectrolytes)	polyDADMAC	(26062-79-3)	10 Thousand - 3 Million	—	25.0 ⁹	DADMAC monomer, dimethylamine
polyaluminum chloride (metal salt coagulant)	polybasic aluminum chloride, aluminum chlorhydroxide	$Al_2(OH)_xCl_{3-x} \cdot nH_2O$ (1327-41-9) (12042-91-0)	248.2 (n = 0) variable	method K, Annex B, section B.3.12	—/26.8 ⁷	metals ⁵ , base/neutral scan ⁶
polyaluminum chlorosulfate (metal salt coagulant)	PACS	—	variable	method K, Annex B, section B.3.12	—/26.8 ⁷	metals ⁵ , base/neutral scan ⁶
polyaluminum silicate sulfate (metal salt coagulant)	PASS, aluminum hydroxide sulfate	(53810-32-5)	variable	method K, Annex B, section B.3.12	—/26.8 ⁷	metals ⁵ , base/neutral scan ⁶
poly (epichlorohydrin/ dimethylamine) (polyamines) (polyelectrolytes)	EPI/DMA, polyamine	(25988-97-0) or (42751-79-1)	30 thousand - 3 million	—	20.0 ¹⁰	epichlorohydrin, 1,3-Dichloro-2-propanol, 1,2-dichloro-3-propanol, glycidol, dimethylamine, ethylenediamine (if used as a branching agent)
polyethyleneamines (polyelectrolytes)	—	(26913-06-4)	25 thousand - 1 million	—	10.0 ¹¹	ethylene dichloride, ethylene diamine, epichlorohydrin, glycidol, 1,3-dichloro-2-propanol, 1,2-dichloro-3-propanol
resin amines (polyelectrolytes)	melamine/formal- dehyde polymer	(9003-08-1)	10 thousand minimum	—	10.0 ¹¹	melamine, formaldehyde

Table 4.1 – Coagulation and flocculation products – product identification and evaluation

Chemical type (Description)	Synonyms	Formula (CAS number)	Approximate molecular weight	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
sodium aluminate (metal salt coagulant)	aluminum sodium oxide	Na ₂ Al ₂ O ₄ (1302-42-7)	163.94	method K, Annex B, section B.3.12	43/26.8 ⁷	metals ⁵ , base/neutral scan ⁶
sodium silicate ¹² (coagulant)	water glass	Na ₂ O(SiO ₂) _n typically n = 3 (1344-09-8)	122 @ n = 1	method A, Annex B, section B.3.2	7.8	metals ⁵
starch, anionic (coagulant)	starch, base- hydrolyzed	(68412-33-9)	—	—	10	metals ⁵

¹ The typical use level is an application level which has been used historically in water treatment. The typical use level is not the maximum use level for the product unless specifically stated.

² Analysis for all chemistry-specific analytes in these minimum test batteries shall be performed each time the product is evaluated. Analysis shall also include formulation-dependent analytes as identified during formulation review. Testing for specific repackagings, blends, or dilutions of previously certified products may be waived.

³ If nitrogen-containing initiators are used in these chemical types, evaluation shall include analysis for the initiator and any initiator by-products.

⁴ The typical use level for this product is based on an acrylamide polymer application of 1 mg/L and an acrylamide monomer level of 0.05% in the polymer, or equivalent (40 CFR 141.111) for a carryover of not more than 0.5 ppb of acrylamide monomer into the finished water.

⁵ Metals = antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, thallium

⁶ A GC/MS analysis shall also be performed on this chemical type when recycled materials are used in the manufacturing process.

⁷ The first value is the typical use level as indicated by the chemical formula. The second value is the typical use level as aluminum oxide for the aluminum salts (aluminum chloride, aluminum sulfate, polyaluminum chloride, and sodium aluminate).

⁸ The first value is the typical use level as indicated by the chemical formula. The second value is the typical use level as Fe for the iron salts (ferric chloride, ferric sulfate, ferrous chloride, and ferrous sulfate).

⁹ The typical use level for this product is based on a polyDADMAC polymer application of 25 mg/L and a carryover of not more than 50 ppb of DADMAC into the finished water.

¹⁰ The typical use level for this product is based on a EPI/DMA polymer application of 20 mg/L and a epichlorohydrin monomer level of 0.01% in the polymer, or equivalent (40 CFR 141.111) for a carryover of not more than 2 ppb of epichlorohydrin monomer into the finished water.

¹¹ The typical use level of this product is expressed as mg/L of active polymer in the product as sold.

¹² Sodium silicate may be used in conjunction with an acid-forming substance to produce activated silica. The net concentrations of sodium silicate and acid-forming substance are not to exceed the maximum use levels for these chemicals individually.

5 Chemicals for corrosion and scale control, softening, precipitation, sequestering, and pH adjustment

5.1 Coverage

This section covers chemicals and chemical blends used in drinking water treatment for softening, precipitation, and pH adjustment, and to control corrosion, scale, and metallic color problems.

5.2 Definitions

5.2.1 blended phosphate: A product containing at least two active and distinct phosphate species, one of which is a polymeric phosphate, each at 5% or greater of the total dry weight. A blended phosphate can contain other intentional ingredients (acids, bases, silicates, etc.) up to 5% individually, and up to 10% of the total dry weight of the product.

5.2.2 corrosion and scale control chemicals: Chemicals that either alter the treated water chemistry or interact with the surface of metallic materials in the water distribution system to inhibit corrosion or to prevent the formation of scale deposits.

5.2.3 dry weight: The weight of all ingredients except water and waters-of-hydration.

5.2.4 pH adjustment chemical: A chemical that either increases or decreases the pH of the treated water.

5.2.5 precipitation chemical: A chemical that causes a component of a solution to form an insoluble matter.

5.2.6 sequestering chemical: Any compound that in aqueous solution binds with a metal or metallic ion to form a water soluble complex or chelate.

5.2.7 softening chemical: A chemical that either decreases or masks the presence of the dissolved concentration of calcium ion, magnesium ion, or both, in the treated water.

5.2.8 zinc orthophosphate: A product manufactured from orthophosphate and zinc salts. The proportion (ratio) of zinc to phosphate is variable.

5.3 General requirements

General information and evaluation requirements for the products covered in this section are summarized in Table 5.1.

5.4 Sample requirements

Samples of product obtained for evaluation shall have been manufactured from a formulation identical to that of the commercially available product.

5.5 Sample preparation

5.5.1 Analytical summary

An analytical summary shall be prepared for each product. The analytical summary shall consist of the minimum test batteries of chemistry-specific analytes identified in Table 5.1 and any formulation-dependent analytes identified during the formulation review (see 3.2).

5.5.2 Selection of preparation method

5.5.2.1 Sample preparation for individual treatment chemicals

The test sample shall be prepared for analysis per the appropriate method indicated in Table 5.1, if applicable.

5.5.2.2 Sample preparation for blends of treatment chemicals

Preparation method(s) for blends of treatment chemicals (e.g., a blend of different phosphate species) shall be selected according to the individual treatment chemicals in the blended product.

NOTE – For example, a blend of phosphoric acid and another phosphate species is prepped using Annex B, method D for analysis of the phosphoric acid contaminants, and Annex B, method B for analysis of the phosphate species contaminants. Separate aliquots of the sample are used for analysis of each component of the blend.

5.6 Analysis

Following preparation (see 5.5.2), the sample solution shall be analyzed for the contaminants identified on the analytical summary per the methods referenced in Annex B, section B.4.

5.7 Normalization

The concentration of contaminants detected in the analysis solution shall be adjusted to reflect the contaminant concentration in the finished drinking water according to the following equation:

$$\frac{\text{mg contaminant}}{\text{L solution}} \times \frac{\text{L analysis solution}}{\text{g product}} \times \frac{1 \text{ g}}{1000 \text{ mg}} \times \frac{\text{mg product}}{\text{L drinking water}} \times \frac{1000 \text{ } \mu\text{g}}{1 \text{ mg}} = \frac{\text{ } \mu\text{g contaminant}}{\text{L drinking water}}$$

[analysis solution] [lab prep solution] [maximum use level] [at-the-tap exposure]

5.8 Evaluation of contaminant concentrations

5.8.1 General

The normalized concentration of each contaminant shall be no greater than its SPAC determined in accordance with the requirements of Annex A.

5.8.2 Blends

The maximum use level of each treatment chemical in a blended product shall not exceed its maximum use level when evaluated as an individual treatment chemical.

The following table is a generic listing of the types of products covered in this section of the standard. This table is not intended to be a complete list of all products used for corrosion and scale control, softening, precipitation, sequestering, and pH adjustment. Inclusion of a product does not indicate either a use endorsement of the product or an automatic acceptance under the provisions of this Standard. Annex F, Table F1 includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

Table 5.1 – Chemicals for corrosion and scale control, softening, sequestering, precipitation, and pH adjustment – product identification and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level ¹ (mg/L)	Minimum Test Batteries of Chemistry-specific analyses ²
calcium carbonate ³ (pH adjustment)	limestone	CaCO ₃ (471-34-1)	100.9	method C, Annex B, section B.3.4	650	metals ⁴ , radionuclides, base/neutral/acid scan ⁹
calcium hydroxide (pH adjustment)	slaked or hydrated lime	Ca(OH) ₂ (1305-62-0)	74.10	method C, Annex B, section B.3.4	650	metals ⁴ , radionuclides ¹⁰ , fluoride ¹⁰
calcium oxide (pH adjustment)	lime, quicklime	CaO (1305-78-8)	56.0	method C, Annex B, section B.3.4	500	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
carbon dioxide (pH adjustment)	—	CO ₂ (124-38-9)	44	method E, Annex B, section B.3.6	200	VOCs
dipotassium orthophosphate (corrosion control)	potassium phosphate, dibasic	K ₂ HPO ₄ (7758-11-4)	174.2	method B, Annex B, section B.3.3	18.4 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
disodium orthophosphate (corrosion control)	sodium phosphate, dibasic	Na ₂ HPO ₄ (7758-79-4)	142.0	method B, Annex B, section B.3.3	14.9 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
ethylenediamine tetraacetic acid (sequestering)	EDTA	C ₁₀ H ₁₆ N ₂ O ₈ (60-00-4)	292.3	method A, Annex B, section B.3.2	1.0	metals ⁴
hydrochloric acid ⁶ (pH adjustment)	muriatic acid	HCl (7647-01-0)	36.5	method D, Annex B, section B.3.5	40	metals ⁴ , VOCs
magnesium carbonate hydroxide (pH adjustment)	magnesium carbonate pentahydrate	(MgCO ₃) ₄ · Mg(OH) ₂ · 5H ₂ O (39409-82-0)	232.57	method C, Annex B, section B.3.4	115	metals ⁴

Table 5.1 – Chemicals for corrosion and scale control, softening, sequestering, precipitation, and pH adjustment – product identification and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level ¹ (mg/L)	Minimum Test Batteries of Chemistry-specific analyses ²
magnesium hydroxide (pH adjustment)	magnesium hydrate, magnesite	Mg(OH) ₂ (1309-42-8)	58.3	method C, Annex B, section B.3.4	150	metals ⁴
magnesium oxide (pH adjustment)	magnesium monoxide, maglite	MgO (1309-48-4)	40.32	method C, Annex B, section B.3.4	100	metals ⁴
monopotassium orthophosphate (corrosion control)	potassium phosphate, monobasic	KH ₂ PO ₄ (7778-77-0)	136.1	method B, Annex B, section B.3.3	14.3 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
monosodium orthophosphate (corrosion control)	sodium phosphate, monobasic	NaH ₂ PO ₄ (7558-80-7)	120.0	method B, Annex B, section B.3.3	12.6 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
phosphoric acid (corrosion control)	orthophosphoric acid	H ₃ PO ₄ (7664-38-2)	97.9	method D, Annex B, section B.3.5	13.8 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
polyphosphoric acid (corrosion control)	—	(8017-16-1)	variable	method D, Annex B, section B.3.5	9.0 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
potassium hydroxide (pH adjustment)	caustic potash	KOH (1310-58-3)	56.10	method B, Annex B, section B.3.3	100	metals ⁴
potassium tetrametaphosphate (corrosion control)	KTMP	(KPO ₃) ₄	472.3	—	—	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
potassium tripolyphosphate (corrosion control)	KTPP	K ₅ P ₃ O ₁₀ (13845-36-8)	448.4	method A, Annex B, section B.3.2	15.7 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
sodium acid pyrophosphate ⁶ (corrosion control)	SAPP	Na ₂ H ₂ P ₂ O ₇ (7758-16-9)	222.0	method A, Annex B, section B.3.2	11.7 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
sodium bicarbonate (pH adjustment)	baking soda	NaHCO ₃ (144-55-8)	84.0	method B, Annex B, section B.3.3	100	metals ⁴

Table 5.1 – Chemicals for corrosion and scale control, softening, sequestering, precipitation, and pH adjustment – product identification and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level ¹ (mg/L)	Minimum Test Batteries of Chemistry-specific analyses ²
sodium bisulfate (pH adjustment)	sodium pyrosulfate, sodium hydrogen sulfate	NaHSO ₄ (7681-38-1)	120.1	method B, Annex B, section B.3.3	2.4	metals ⁴
sodium calcium magnesium polyphosphate, glassy (corrosion control)	—	(MPO ₃) _n · M ₂ O M=Na, .5 Ca, .5 Mg; n=5 (65997-17-3)	variable	method A, Annex B, section B.3.2	15.0 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
sodium carbonate (pH adjustment)	soda ash	Na ₂ CO ₃ (497-19-8)	105.0	method B, Annex B, section B.3.3	100	metals ⁴
sodium hydroxide (pH adjustment)	caustic soda	NaOH (1310-72-2)	40.1	method B, Annex B, section B.3.3	100	metals ⁴
sodium polyphosphate, glassy ⁶ (corrosion control)	SHMP, sodium hexametaphos- phate	(NaPO ₃) _n · Na ₂ O typically n=14 (68915-31-1)	variable	method A, Annex B, section B.3.2	10.7-11.9 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
sodium sesquicarbonate (pH adjustment)	carbonic acid, sodium salt	Na ₂ CO ₃ · NaHCO ₃ · 2H ₂ O (533-96-0)	226.0	method B, Annex B, section B.3.3	100	metals ⁴
sodium silicate (corrosion inhibitor)	activated silica	Na ₂ O(SiO ₂) _n typically n=3 (1344-09-8)	242 @ n=1	method A, Annex B, section B.3.2	16.0	metals ⁴
sodium trimetaphosphate (corrosion control)	metaphosphoric acid, trisodium salt	Na ₃ P ₃ O ₉ (7785-84-4)	306	method A, Annex B, section B.3.2	10.7 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
sodium tripolyphosphate (corrosion control)	STPP, pentasodium tripolyphosphate	Na ₅ P ₃ O ₁₀ (7758-29-4)	368	method A, Annex B, section B.3.2	12.9 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹

Table 5.1 – Chemicals for corrosion and scale control, softening, sequestering, precipitation, and pH adjustment – product identification and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level ¹ (mg/L)	Minimum Test Batteries of Chemistry-specific analyses ²
sodium zinc polyphosphate, glassy (corrosion control)	—	$(MPO_3)_n \cdot M_2O$ M = Na and/or 2n at 1 : 0.5	variable	method A, Annex B, section B.3.2	12.3-13.6 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
sulfuric acid ⁶ (pH adjustment)	oil of vitriol	H ₂ SO ₄ (7664-93-9)	98.0	method D, Annex B, section B.3.5	50	metals ⁴ , VOCs
tetrapotassium pyrophosphate ⁷ (corrosion control, sequestering)	TKPP diphosphoric acid tetrapotassium salt	K ₄ P ₂ O ₇ (7320-34-5)	330.34	method A, Annex B, section B.3.2	17.4 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
tetrasodium ethylenediaminetetra- acetic acid (sequestering)	EDTA, sodium salt	Na ₄ C ₁₀ H ₁₂ N ₂ O ₈	360.2	method A, Annex B, section B.3.2	1.0	metals ⁴
tetrasodium pyrophosphate (corrosion control, sequestering)	TSPP, sodium pyrophosphate, sodium diphosphate	Na ₄ P ₂ O ₇ (7722-88-5)	266	method A, Annex B, section B.3.2	14.05 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
tripotassium orthophosphate (corrosion control)	potassium phosphate, tribasic	K ₃ PO ₄ (7778-53-2)	212.27	method A, Annex B, section B.3.2	22.4 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
trisodium orthophosphate (corrosion control)	sodium phosphate, tribasic	Na ₃ PO ₄ (7601-54-9)	163.94	method A, Annex B, section B.3.2	17.3 ⁵	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
zinc chloride (corrosion control)	zinc dichloride, zinc chloride fume	ZnCl ₂ (7646-85-7)	135.4	method B, Annex B, section B.3.3	4.0 ⁷	metals ⁴
zinc orthophosphate (corrosion control)	—	Zn ₃ (PO ₄) ₂ (7779-90-1)	386.04	method A, Annex B, section B.3.2	4.0 ⁷	metals ⁴ , radionuclides ¹¹ , fluoride ¹¹
zinc sulfate (corrosion control)	zinc vitriol, sulfuric acid, zinc salt	ZnSO ₄ · H ₂ O (7733-02-0)	179.6	method B, Annex B, section B.3.3	5.0 ⁷	metals ⁴

Table 5.1 – Chemicals for corrosion and scale control, softening, sequestering, precipitation, and pH adjustment – product identification and evaluation

¹ The typical use level is an application level that has been used historically in water treatment. The typical use level is not the maximum use level for the product, except where specifically stated.

² Analysis for all chemistry-specific analytes in these minimum test batteries shall be performed each time the product is evaluated. Analysis shall also include formulation-dependent analytes as identified during formulation review. Testing for specific repackages, blends, or dilutions of previously certified products may be waived.

³ This product differs from other products covered in this section because it dissolves slowly over time. Calcium carbonate is exposed using the following ratio: 156g product/250 mL deionized water, in accordance with Annex B, section 3.4 (method C).

⁴ Metals = antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, thallium.

⁵ Equivalent to 10 mg PO₄/L, on a dry basis. This typical use level is based on potential ecological effects of phosphates at levels exceeding 10 mg PO₄/L.

⁶ The potential impurities for these products may vary considerably depending on source.

⁷ Calculated from the USEPA RfD for zinc, this use level is based on 2mg/L as zinc.

⁸ Calcium Oxide products may be bracketed by the testing of Calcium Hydroxide products, produced at the same location and from the same source of calcium oxide.

⁹ BNA scan not run if no waste fuels used in the manufacturing process.

¹⁰ Radionuclides and Fluoride not run when CaO is sampled from the same location.

¹¹ Radionuclides and Fluoride not run if product is a blend or repackage of certified materials.

– concluded –

6 Disinfection and oxidation chemicals

6.1 Coverage

This section covers products used in drinking water disinfection and oxidation processes. It is not intended to include ambient air.

6.2 Definitions

6.2.1 disinfection: The process of destruction, inactivation, or rendering harmless of certain microorganisms, usually vegetative forms of pathogenic bacteria, viruses and protozoa.

6.2.2 low-bromate hypochlorite: A hypochlorite product contributing a bromate residual in the finished drinking water of less than or equal to 0.003 mg/L at its maximum use level. The maximum use level for a low-bromate hypochlorite will be based on 10 mg Cl_2 /L and may not be adjusted to meet the low-bromate SPAC of 0.003 mg/L.

6.2.3 oxidation: The process through which a substance combines with oxygen. The conversion of organic or inorganic materials by loss of electrons.

6.3 General requirements

6.3.1 General information about the products covered in this section is summarized in Table 6.1.

6.3.2 Hypochlorite treatment chemicals

Bromate is a known contaminant of the hypochlorite chemical production process. Based on the limited number of sources of bromate in drinking water (ozonation is another known source), the SPAC for bromate has been determined to be 0.005 mg/L, 50% of the US EPA MCL of 0.01 mg/L. All hypochlorite treatment chemicals shall meet the bromate SPAC of 0.005 mg/L.

NOTE – Revisions to bromate requirements of this section have been made and are located in Annex G of this Standard. Please refer to that annex for additional details. The revisions contained in Annex G are informational at this time and are scheduled to be incorporated into this section January 1, 2013.

6.3.2.1 General

Bromate is a known impurity of the hypochlorite chemical production process. Because of the potential cancer risk associated with human exposure to bromate, it is recommended that production or introduction of bromate into drinking water be limited. The two major sources of bromate in drinking water are ozonation of water containing bromide and use of hypochlorite treatment chemicals containing bromate (sodium and calcium hypochlorites). All hypochlorite treatment chemicals shall meet the bromate Single Product Acceptable Concentration (SPAC) of 0.005 mg/L.

Hypochlorite treatment chemicals that meet the requirements of this Standard, but that do not meet the definition of a low-bromate hypochlorite (see 6.2.2) shall include the following statement in manufacturer's product literature that references this Standard:

The maximum use level for hypochlorite products is based on 10 mg Cl_2 /L. However, in certain circumstances a hypochlorite product may only meet the bromate SPAC of 5 ug/L if the maximum use level is lowered to a concentration of less than 10 mg Cl_2 /L. In these instances, the following statement shall be included on the product packaging and/or bill of lading:

"This product has been restricted to a maximum use level (MUL) that is less than 10 mg Cl_2 /L, the typical use level for hypochlorite products under NSF/ANSI Standard 60."

Although the maximum use level may be less than 10 mg Cl₂/L, it shall not be less than 2 mg Cl₂/L.

6.3.2.2 Low-bromate hypochlorite treatment chemicals

All low-bromate hypochlorite treatment chemicals shall not exceed 30% of the bromate MCL, or 0.003 mg/L. The manufacturer's use instructions that reference this Standard for hypochlorite products evaluated as low-bromate shall include the following statement:

"Based on testing to the requirements of NSF/ANSI 60, use of this product at a dose of [maximum use level] or less is expected to contribute a bromate residual of 0.003 mg/L or less to the finished drinking water."

NOTE – This statement is intended to provide guidance to water utilities using ozonation who wish to minimize additional bromate residuals in the treated drinking water.

6.3.3 Perchlorate in hypochlorite samples

6.3.3.1 Manufacturer's Use Instructions

Because aged solutions of hypochlorite may contain elevated levels of chlorate and perchlorate, Certification Listings and the manufacturer's use instructions, or documentation supplied with the product, shall reference the recommended handling and storage practices contained in AWWA B300 – Hypochlorites.

6.3.3.2 Production Dates and Repackaging Dates

The manufacturing date, and if applicable the repackaging date, for the product shall be included on the documentation supplied with any shipment.

6.4 Sample requirements

Samples of product obtained for evaluation shall have been manufactured from a formulation identical to that of the commercially available product.

6.4.1 Hypochlorite for oxyhalide analysis

As samples of liquid hypochlorite decompose overtime, producing additional chlorate and perchlorate, those collected for oxyhalide analysis shall be quenched upon collection if the analysis is not to be performed immediately. Details on the quenching agent used and the date and time of addition shall be recorded with the sample.

A suitable quenching agent shall be used that will not interfere with the analytical method. Quenching agents that may be used include, but are not limited to, those in Table 6.1.

Table 6.1 – Quenching Agent Guide

Quenching Agent ¹	Guidance on Rate of Use ²
malonic acid	0.75:1 mol ratio, or approximately 11 g malonic acid for every 10 g free available chlorine expected
hydrogen peroxide	1.1:1 mol ratio, or approximately 5.3 g hydrogen peroxide (i.e., 18 g of a 30% hydrogen peroxide solution) for every 10 g free available chlorine expected

¹ Each quenching chemical bears potential hazards and appropriate safety precautions need to be followed when used.

² Source: *Hypochlorite – An Assessment of Factors That Influence the Formation of Perchlorate and Other Contaminants*, AWWA-WRF, 2009.

6.5 Sample preparation

6.5.1 Analytical summary

An analytical summary shall be prepared for each product. The analytical summary shall consist of the minimum test batteries of chemistry specific analytes identified in Table 6.1 and any formulation-dependent analytes identified during the formulation review (see 3.2).

6.5.2 Selection of preparation method

The test sample shall be prepared for analysis per the appropriate preparation method indicated in Table 6.2.

6.6 Analysis

Following preparation (see 6.5.2), the sample solution shall be analyzed for the contaminants identified on the analytical summary per the methods referenced in Annex B, section B.4.

6.7 Normalization

The concentration of contaminants detected in the analysis solution shall be adjusted to reflect the contaminant concentration in the finished drinking water according to the following equation:

$$\frac{\text{mg contaminant}}{\text{L solution}} \times \frac{\text{L analysis solution}}{\text{g product}} \times \frac{1 \text{ g}}{1000 \text{ mg}} \times \frac{\text{mg product}}{\text{L drinking water}} \times \frac{1000 \mu\text{g}}{1 \text{ mg}} = \frac{\mu\text{g contaminant}}{\text{L drinking water}}$$

[analysis solution] [lab prep solution] [maximum use level] [at-the-tap exposure]

6.8 Evaluation of contaminant concentrations

The normalized concentration of each contaminant shall be no greater than the SPAC determined in accordance with the requirements of Annex A.

The following table is a generic listing of the types of products covered in this section of the standard. This table is not intended to be a complete list of all products used for disinfection and oxidation applications. Inclusion of a product does not indicate either a use endorsement of the product or an automatic acceptance under the provisions of this Standard. Annex F includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

Table 6.2 – Disinfection and oxidation products – product identification, and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry- specific analyses ²
ammonia, anhydrous ⁹ (disinfection & oxidation)	ammonia gas	NH ₃ (7664-41-7)	17.0	method E, Annex B, section B.3.6	5	metals ³ , VOCs
ammonium hydroxide (disinfection & oxidation)	liquid ammonia	NH ₄ OH (1336-21-6)	35.0	method B, Annex B, section B.3.3	10	metals ³
ammonium sulfate (disinfection & oxidation)	dry ammonia	(NH ₄) ₂ SO ₄ (7783-20-2)	132.0	method A, Annex B, section B.3.2	25	metals ³
calcium hypochlorite ⁴ (disinfection & oxidation)	—	Ca(OCl) ₂ (7778-54-3)	143.1	Method A; Annex B, B.3.2	10 ⁵	metals ³ , VOCs, bromate, chlorate, perchlorate
Chlorine ¹⁰ (disinfection & oxidation)	chlorine gas	Cl ₂ (7782-50-5)	71.0	method E, Annex B, section B.3.6	10 ⁶	VOCs
hydrogen peroxide (disinfection & oxidation)	—	H ₂ O ₂ (7722-84-1)	34.0	method A, Annex B, section B.3.2	23 ⁷	metals ³ , VOCs
iodine ⁸ (disinfection & oxidation)	—	I ₂ (7553-56-2)	254.0	method A, Annex B, section B.3.2	1	metals ³
potassium permanganate (oxidation)	permanganate	KMnO ₄ (7722-64-7)	158.0	method B, Annex B, section B.3.3	15	metals ³
sodium chlorate (disinfection & oxidation)	—	NaClO ₃ (7775-09-9)	106.5	method A, Annex B, section B.3.2	8	metals ³ , VOCs, perchlorate
sodium chlorite (disinfection & oxidation)	—	NaClO ₂ (7758-19-2)	90.5	method A, Annex B, section B.3.2	7	metals ³ , VOCs
sodium hypochlorite ^{4, 11} (disinfection & oxidation)	liquid bleach	NaOCl (7681-52-9)	74.5	method B, Annex B, section B.3.3	10 ⁵	metals ³ , VOCs, bromate, chlorate, perchlorate

Table 6.2 – Disinfection and oxidation products – product identification, and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry- specific analyses ²
¹ The typical use level is an application level that has been used historically in water treatment. The typical use level is not the maximum use level for the product, except where specifically stated. ² Analysis for all chemistry-specific analytes in these minimum test batteries shall be performed each time the product is evaluated. Analysis shall also include formulation-dependent analytes as identified during formulation review. Testing for specific repackages, blends, or dilutions of previously certified products may be waived. ³ Metals = antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, and thallium. ⁴ Hypochlorite products shall include the appropriate statement in product literature, per the requirements of 6.3.2, and 6.3.3. ⁵ Equivalent to 10 mg Cl ₂ /L, on a dry basis. The residual level of chlorine in the treated water is to be compliant with the applicable state or federal requirement. ⁶ Equivalent to 10 mg Cl ₂ /L, on a dry basis. Use levels up to 30 mg Cl ₂ /L may be acceptable for short-term applications such as shock chlorination and disinfection of new installations. The residual level of chlorine in the treated water is to be compliant with the applicable state or federal requirement. ⁷ The 23 mg/L value in the Typical Use Level column represents the maximum use level based on a 35% hydrogen peroxide solution and a hydrogen peroxide SPAC of 8 mg/L. The maximum use level for other concentrations of hydrogen peroxide can be derived in the same manner. ⁸ Iodine disinfection is acceptable for short-term or emergency use, but it is not recommended for long-term or routine community water supply application. ⁹ Testing on anhydrous ammonia products may be bracketed based on the testing of ammonium hydroxide (aqua ammonia), if the aqua ammonia solution is prepared with the same respective anhydrous ammonia product. ¹⁰ Chlorine products may be bracketed based on testing of sodium hypochlorite bleach, prepared from the same chlorine source, or annual analysis may alternate between the chlorine and sodium hypochlorite product. ¹¹ When all certified ingredients are used, testing for this chemical may be alternated every other year.						

– concluded –

7 Miscellaneous treatment applications

7.1 Coverage

This section covers those chemicals, chemical compounds, blends, and mixtures intended for use in a variety of drinking water applications. These uses include fluoridation, defluoridation, algae control, dechlorination, antioxidants, dyes, and tracers. These products are generally applied directly to the water supply. Residuals of chemicals used for fluoridation, algae control, dyes, and tracers are likely to persist in the finished drinking water. Chemicals used for dechlorination, defluoridation, and an antioxidant are intended to be consumed by reaction, and residuals of these products are not likely to be found in the finished drinking water.

7.2 Definitions

7.2.1 algicide: A product added to the water in order to control or eliminate the growth of algae.

7.2.2 antioxidant: A product added to the water to retard or prevent the oxidation of other constituents in the water.

7.2.3 dechlorination: The process of removing or reducing the amount of chlorine in the drinking water.

7.2.4 defluoridation: The process of removing or reducing the amount of fluoride in the drinking water.

7.2.5 dyes/tracers: Products that are visually or analytically detectable, and are added to the water for the purpose of modeling water flow or for the detection of leaks and cross-connections, etc.

7.2.6 fluoridation: The process of adding fluoride to drinking water at a beneficial concentration as a means of reducing the incidence of dental caries in the population consuming the water.

7.3 General requirements

7.3.1 General information about the products covered in this section is summarized in Table 7.1.

7.3.2 Special labeling requirements

A product, which qualifies under this section for a specific and limited use, shall be clearly labeled to reflect this specific use and limitation.

7.4 Sample requirements

Samples of product obtained for evaluation shall have been manufactured from a formulation identical to that of the commercially available product.

7.5 Sample preparation

7.5.1 Analytical summary

An analytical summary shall be prepared for each product. The analytical summary shall consist of the minimum test battery of chemistry specific analytes identified in Table 7.1 and any formulation-dependent analytes identified during the formulation review (see 3.2).

7.5.2 Selection of preparation method

The test sample shall be prepared for analysis per the appropriate preparation method indicated in Table 7.1.

7.6 Analysis

Following preparation (see 7.5.2), the sample solution shall be analyzed for the contaminants identified on the analytical summary per the methods referenced in Annex B, section B.4.

7.7 Normalization

The concentration of contaminants detected in the analysis solution shall be adjusted to reflect the contaminant concentration of the finished drinking water according to the following equation:

$$\frac{\text{mg contaminant}}{\text{L solution}} \times \frac{\text{L analysis solution}}{\text{g product}} \times \frac{1 \text{ g}}{1000 \text{ mg}} \times \frac{\text{mg product}}{\text{L drinking water}} \times \frac{1000 \text{ } \mu\text{g}}{1 \text{ mg}} = \frac{\text{ } \mu\text{g contaminant}}{\text{L drinking water}}$$

[analysis solution] [lab prep solution] [maximum use level] [at-the-tap exposure]

7.8 Evaluation of contaminant concentrations

The normalized concentration of each contaminant shall be no greater than the SPAC determined in accordance with the requirements of Annex A.

7.9 Sodium chloride evaluated for use in electrolytic sodium hypochlorite generators

In addition to meeting the requirements of sections 7.1 to 7.8, sodium chlorides evaluated for use in electrolytic sodium hypochlorite generators shall meet the requirements of this section.

7.9.1 Bromide concentration

The manufacturer shall submit a specification declaring the maximum bromide concentration for the product. Verification that the bromide concentration is less than or equal to the manufacturer's specification shall be performed on product in accordance with the analytical requirements of B.4.2.2.1.

The bromide specification shall not exceed 54 mg/kg in NaCl for electrolytic sodium hypochlorite generators at a 10 mg Cl₂/L chlorine maximum feed concentration. A higher concentration of bromide is permitted in NaCl used in generators delivering lower maximum feed concentrations of chlorine so that the total concentration of bromate does not exceed 0.003 mg/L. Although a maximum feed concentration may be less than 10 mg Cl₂/L, it shall not be less than 2 mg Cl₂/L.

Sodium chlorides evaluated as "low-bromide" salts shall not have a bromide specification in excess of 54 mg/kg.

Note: The 54 mg/kg limit is based on a use assumption that 0.003 mg/L bromate will be produced from 3.5 lbs of NaCl containing 54 mg/kg bromide with 15 gallons of water to produce via electrolysis 1 pound of free available chlorine (FAC) equivalent disinfectant and dosed to effect a 10 mg/L FAC in the finished drinking water.

7.9.2 Denotion of bromide content specification

In all instances where compliance with this standard is indicated for a product use in electrolytic sodium hypochlorite generators (e.g. product packaging, product literature, certification listings), an indication of the maximum bromide concentration specification and associated maximum feed concentration of chlorine attested by this standard shall also be indicated.

The following table is a generic listing of the types of products covered in this section of the standard. This table is not intended to be a complete list of all products used for miscellaneous treatment applications. Inclusion of a product does not indicate either a use endorsement of the product or an automatic acceptance under the provisions of this Standard. Annex F, Table F1, includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

Table 7.1 – Miscellaneous treatment application products – product identification, and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
ammonium hexafluorosilicate (fluoridation)	ammonium silico- fluoride, ammonium fluosilicate	(NH ₄) ₂ SiF ₆ (16919-19-0)	178.14	method B, Annex B, section B.3.3	1.2 ³	metals ⁴ radionuclides
calcium fluoride (fluoridation)	fluorspar, fluorite	CaF ₂ (7789-75-5)	78.08	method B, Annex B, section B.3.3	1.2 ³	metals ⁴ radionuclides
copper ethanolamine complexes (algicide)	—	Cu(NH ₂ C ₂ H ₄ OH) ₄ ⁺⁺	variable	method A, Annex B, section B.3.2	1.0 ⁵	metals ⁴ formulation dependent organics
copper sulfate (algicide)	cupric sulfate	CuSO ₄ (7758-98-7)	159.61	method A, Annex B, section B.3.2	1.0 ⁵	metals ⁴
copper triethanolamine complexes (algicide)	—	Cu(N(C ₂ H ₄ OH) ₃) ⁺⁺	variable	method A, Annex B, section B.3.2	1.0 ⁵	metals ⁴ formulation dependent organics
ferrous chloride (chlorite reduction)	iron (II) chloride, iron dichloride	FeCl ₂ (7758-94-3)	126.75	method K, Annex B, section B.3.12	—	metals ⁴ , VOCs
fluosilicic acid (fluoridation)	hydrofluosilicic acid	H ₂ SiF ₆ (16961-83-4)	144.11	method B, Annex B, section B.3.3	1.2 ³	metals ⁴ , radionuclides
magnesium silicofluoride (fluoridation)	magnesium hexafluorosilicate	MgSiF ₆ (16949-65-8)	166.40	method B, Annex B, section B.3.3	1.2 ³	metals ⁴
potassium chloride (softening)	potassium salt	KCl (7447-40-7)	74.55	method A, annex B, section B.3.2	1,000 ⁸	metals ⁴ , radionuclides,
potassium fluoride (fluoridation)	—	KF (7789-23-3)	58.10	method B, Annex B, section B.3.3	1.2 ³	metals ⁴

Table 7.1 – Miscellaneous treatment application products – product identification, and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
sodium bisulfite (dechlorinator & antioxidant)	sodium acid sulfite	NaHSO ₃ (7631-90-5)	104.07	method A, Annex B, section B.3.2	18 ⁶	metals ⁴
sodium chloride (softening or electrolytic chlorination)	sodium salt	NaCl (7647-14-5)	58.44	method A, annex B, section B.3.2	800 ⁸	metals ⁴ , radionuclides, bromide ⁹
sodium fluoride (fluoridation)	florocid	NaF (7681-49-4)	42.0	method B, Annex B, section B.3.3	1.2 ³	metals ⁴ , radionuclides
sodium metabisulfite (dechlorinator & antioxidant)	sodium pyrosulfite	Na ₂ S ₂ O ₅ (7681-57-4)	190.13	method A, Annex B, section B.3.2	15	metals ⁴
sodium silicofluoride (fluoridation)	sodium fluosilicate	Na ₂ SiF ₆ (16893-85-9)	132.0	method B, Annex B, section B.3.3	1.2 ³	metals ⁴
sodium sulfite (dechlorinator & antioxidant)	—	Na ₂ SO ₃ (7757-83-7)	126.06	method A, Annex B, section B.3.2	22 ⁶	metals ⁴
sulfur dioxide (dechlorinator & antioxidant)	sulfurous oxide	SO ₂ (7446-09-5)	64.07	method F, Annex B, section B.3.7	10	metals ⁴
tricalcium phosphate (defluoridation)	hydroxyapatite	Ca ₅ (PO ₄) ₃ OH (12167-4-7)	502	method B, Annex B, section B.3.3	120 ⁷	metals ⁴ , radionuclides, fluoride

Table 7.1 – Miscellaneous treatment application products – product identification, and evaluation

Chemical type (primary use)	Synonyms	Formula (CAS number)	Molecular weight (g)	Preparation method	Typical use level (mg/L) ¹	Minimum Test Batteries of Chemistry-specific analyses ²
¹ The typical use level is an application level that has been used historically in water treatment. The typical use level is not the maximum use level for the product, except where specifically stated. ² Analysis for all chemistry-specific analytes in these minimum test batteries shall be performed each time the product is evaluated. Analysis shall also include formulation-dependent analytes as identified during formulation review. Testing for specific repackages, blends, or dilutions of previously certified products may be waived. ³ Based on mg Fluoride Ion per L water. Total concentration of fluoride ion in finished water may include fluoride which occurs naturally in the source water. ⁴ Metals = antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, and thallium. ⁵ Based on mg Copper per L water. ⁶ Based on chlorine level of 12 mg/L prior to treatment. ⁷ Based on fluoride level of 15 mg/L prior to treatment. ⁸ Based on treating up to 40 grains of hardness. ⁹ Bromide analysis required for NaCl for use in electrolytic chlorination only.						

– concluded –

8 Miscellaneous water supply products

8.1 Coverage

This section covers products used in a variety of drinking water supply applications. These products are not routinely used to produce a treatment effect in the water they may contact. The products can be fed continuously, applied intermittently, or flushed from the water supply system prior to its return to use. These products include, but are not limited to, antifoamers, separation process scale inhibitors and cleaners, water well drilling aids, water well rehabilitation aids, well pump lubricating oils, backfill materials for cathodic protection or electrical installations, and distribution system cleaning aids.

8.2 Definitions

8.2.1 backfill materials for cathodic protection or electrical installations: Conductive materials that surround cathodic protection electrodes or electrical grounding electrodes in order to enhance their electrical contact to earth.

8.2.2 bore hole sealants: Products used in sealing and grouting wells used as drinking water sources.

8.2.3 distribution system rehabilitation aids: Products used in the rehabilitation and cleaning of the distribution system used to convey potable water.

8.2.4 regenerants: Products used to restore ion exchange resins and water softeners to a state suitable for further service.

8.2.5 separation process cleaners: Products used in reverse osmosis and distillation units to remove built-up scale.

8.2.6 separation process scale inhibitors: A sequestering agent specifically used to prevent the build-up of scale during a separation process such as reverse osmosis or evaporative desalinization. This use of the scale inhibitor is designed to have low carryover into the finished water.

8.2.7 well drilling aids: Products used in drilling and development of wells used as drinking water sources.

8.2.8 well rehabilitation aids: Products used in the rehabilitation and the cleaning of wells used as drinking water sources.

8.3 General requirements

General information about the products covered in this section is summarized in Table 8.1.

8.3.1 Support of microbiological growth

8.3.1.1 Well application products

All products used in well applications shall not support microbiological growth when evaluated in accordance with Annex C. Well cleaning aids used in conjunction with sodium hypochlorite, calcium hypochlorite or chlorine, as well as all well pump lubricating oils, are excluded from this requirement.

8.3.1.2 Other miscellaneous water supply products

The following product types shall be exempt from the microbiological growth support requirement:

- products that have antimicrobial activity; or
- products that are inorganic in composition.

8.3.2 Published instructions

For products designed to be flushed out prior to using the system for drinking water, the manufacturer's product data sheet shall contain instructions for proper flushing and draining before placing a system back into service. A product that qualifies under this section for a specific and limited use shall be clearly identified in the manufacturer's product data sheet. Polyacrylamide-containing well-drilling additives shall be identified in the manufacturer's product data sheet to indicate that these products are not acceptable for use in constructing wells in highly porous formations such as cavernous limestone.

Instructions and certification listings for well pump lubricating oils shall indicate that the products have not been evaluated for the potential to support microbial growth.

8.4 Sample requirements

When required for evaluation, a sample of the product equivalent to that used in field applications shall be obtained.

8.5 Sample preparation

8.5.1 Analytical summary

An analytical summary shall be prepared for each product to be tested. The analytical summary shall consist of the product-specific analytes identified in Table 8.1 and any formulation-dependent analytes identified during the formulation review (see 3.2).

8.5.2 Selection of preparation method

When applicable, the test sample shall be prepared for analysis per the appropriate preparation method indicated in Table 8.1. For sealants/grouts that can be exposed as a solid mass, the manufacturer shall provide instructions for sample preparation.

8.6 Analysis

Following preparation (see 8.5.2), the sample solution shall be analyzed for the contaminants identified on the analytical summary per the methods referenced in Annex B, section B.4.

8.7 Normalization of contaminant concentrations

8.7.1 General

The concentration of the product's active ingredient(s) and any contaminants detected in the analysis solution shall be adjusted to reflect the concentration in the finished drinking water when the product is used in accordance with the manufacturer's use instructions. When appropriate, the applicant shall provide data, which define the decay curve for removal of the product from the water supply system when the manufacturer's recommended flushing procedures are utilized.

The following equation shall be used to calculate contaminant concentrations for products other than those specified in 8.7.2, 8.7.3, 8.7.4, and 8.7.5:

where:

$$\text{laboratory contaminant concentration} \times \frac{\text{analysis solution (L)}}{\text{product (g)}} \times \frac{1 \text{ g}}{1000 \text{ mg}} \times \text{product dosage (mg/L)} = \text{normalized contaminant concentration}$$

8.7.2 Well-drilling additives

8.7.2.1 Turbid well-drilling additives

Ingredient and contaminant concentrations for turbid well-drilling additives shall be multiplied by the dilution factor required to reduce the analysis solution to a turbidity of 1 NTU.

8.7.2.2 Nonturbid well-drilling additives

Residual levels of ingredients or contaminants present in non-turbid well-drilling additives shall be calculated on the basis of the following assumptions:

- the aquifer contains 3.1×10^6 L (815,500 U.S. gal) of water, based on a 0.5 acre aquifer of 6.1 m depth (20 ft) and 25% porosity;
- the amount of well-drilling fluid used is 3780 L (1,000 U.S. gal), to which the drilling fluid additive has been added at the manufacturer's maximum recommended level;
- the bore hole is 61 m (200 ft) in total depth, the screen is 6.1 m (20 ft) in length, and the bore hole is 25.4 cm (10 in) in diameter; and
- the amount of well drilling fluid removed from the well during construction is equal to the combined volumes of the casing, the screen, and the bore hole annulus around the casing and the screen, plus an additional amount removed through well disinfection and development (90% removed).

NOTE – Example calculation of a residual level is provided in Table 8.2.

8.7.3 Well-drilling foamers

8.7.3.1 Assumptions

Residual levels of ingredients or contaminants from well-drilling foamers shall be calculated based on the following assumptions:

- the aquifer contains 3.1×10^6 L (815,500 U.S. gal) of water, based on a 0.5 acre aquifer of 6.1 m (20 ft) depth and 25% porosity;
- the bore hole is 61 m (200 ft) in total depth and 25.4 cm (10 in) in diameter;
- after the bore hole has been blown free of foam, a foam layer of 6.40 mm (0.25 in) remains on the bore hole wall;
- all foamer ingredients and contaminants in the foam layer enter the aquifer; and
- the foamer addition rate percentage is calculated as the manufacturer's maximum recommended use rate of the foamer per unit volume of water (e.g., 0.946 L [0.25 gal] foamer per 158.987 L [42 gal] water equals 0.6%).

NOTE – The volume of the foam layer on the bore hole wall is determined by subtracting the volume of a cylinder with a diameter equal to the inside diameter of the foam layer (2787 L [736 gal]) from the volume of a cylinder with a diameter equal to the bore hole diameter (3088 L [816 gal]). For the well specified, the foam layer volume is 301 L (66 gal).

8.7.3.2 Foam factor

The following test shall be used to determine the foam factor for the well-drilling foamer:

- a) Prepare 100 mL of foamer solution at the manufacturer's recommended foamer usage rate using tap water;
- b) Carefully decant the foamer solution in a graduated Waring¹² blender jar or equivalent. Cover and blend at high speed for 60 seconds;
- c) Turn blender off and immediately measure and record the foam volume in mL; and
- d) Calculate the foam factor by dividing the foam volume by 100 mL.

8.7.3.3 Normalization equation

The following equation shall be used to calculate the normalized ingredient and contaminant exposure(s) from well-drilling foamers:

$$\frac{\text{laboratory concentration of ingredient or contaminant}}{\text{foam factor}} \times \frac{\text{foam volume (301 L)}}{\text{foam factor}} \times \frac{\% \text{ foamer addition rate}}{3.1 \times 10^6 \text{ L}} = \text{normalized concentration}$$

8.7.4 Bore hole sealants

8.7.4.1 Assumptions

Residual levels of ingredients and contaminants from bore hole sealants shall be based on the following assumptions:

- the aquifer contains 3.1×10^6 L (815,500 U.S. gal) of water, based on a 0.5 acre aquifer of 6.1 m (20 ft) depth and 25% porosity;
- the bore hole is 61 m (200 ft) in total depth, the screen is 6.1 m (20 ft) in length, and the bore hole diameter is 25.4 cm (10 in);
- a 10.2 cm (4 in) diameter casing is used;
- the surface area of the sealant/grout exposed to the aquifer is 11 m^2 (118 ft^2), based on 25% of the sealant/grout column being in direct contact with water from the aquifer; and
- the volume of sealant/grout exposed to the aquifer is 583 L (154 U.S. gal), based on 25% of the sealant/grout column being in direct contact with water from the aquifer.

NOTE – The surface area and volume exposure assumptions are based on a worst-case that 25% of the sealant/grout column is in direct contact with the aquifer. The surface area of 11 m^2 (118 ft^2) is 25% of the surface area of a cylinder 25.4 cm (10 in) in diameter and 54.9 m (180 ft) in length. The volume of 583 L (154 U.S. gal) is 25% of the volume of the annular space formed by a bore hole 25.4 cm (10 in) in diameter and 54.9 m (180 ft) in length that contains a well casing of 10.2 cm (4 in) diameter.

8.7.4.2 Normalization options for sealants/grouts

The following options shall be selected based on the sample preparation and exposure method used.

¹² Waring Products, Division of Conair Corporation, 1 Crystal Drive, McConnellsburg, PA 17233 <www.waringproducts.com>.

8.7.4.2.1 For sealants or grouts, which have been exposed as a solid mass, the following equation shall be used to calculate the normalized ingredient and contaminant concentrations:

$$\text{laboratory concentration of ingredient or contaminant} \times \frac{SA_F}{SA_L} \times \frac{V_L}{3.1 \times 10^6 \text{ L}} = \text{normalized concentration of ingredient or contaminant}$$

where:

SA_F = surface area of sealant/grout exposed in the field (assumed to be 11 m² [118 ft²]);

SA_L = surface area of sealant/grout exposed in the laboratory; and

V_L = volume of extraction water used in the laboratory.

8.7.4.2.2 Ingredient and contaminant concentrations for solid swelling well sealants which have been prepared using method G (see Annex B, section B.3.8) shall be multiplied by the dilution factor required to reduce the analysis solution to a turbidity of 1 NTU.

8.7.4.2.3 For sealants/grouts that cannot be exposed in the laboratory as a solid mass, or for ingredients or contaminants for which an adequately sensitive analytical method is not available, the following alternate calculation procedure shall be used:

a) Calculate the mass (in mg) of the ingredient or contaminant in 583 L (154 U.S. gallons) of sealant/grout based on the manufacturer's preparation instructions; and

b) Divide this mass by the aquifer volume (3.1×10^6 L) to calculate the normalized exposure to the ingredient or contaminant.

8.7.5 Separation process chemicals

8.7.5.1 Reverse osmosis chemicals

For chemicals of greater than 500 molecular weight, normalized concentrations of ingredients and contaminants shall be calculated based on a carryover of 0.5 weight percent of the concentration in the feedwater when the product is dosed at the manufacturer's recommended use level.

$$\text{feedwater concentration of the active ingredient or contaminant} \times 0.5\% = \text{normalized concentration of the active ingredient or contaminant}$$

For chemicals of less than 500 molecular weight, the manufacturer shall provide data to justify the use of the 0.5 weight percent feedwater concentration normalization factor or to establish an alternate normalization factor. In the absence of data to justify otherwise, a 100% carryover shall be assumed for ingredients and contaminants of less than 500 molecular weight.

8.7.5.2 Other membrane separation process chemicals

For other chemicals used in other membrane separation processes (e.g., microfiltration, nanofiltration, ultrafiltration, and electrodialysis/electrodialysis reversal), the manufacturer shall provide data regarding the anticipated carryover of product ingredients and contaminants. These data shall be specific for use of the chemical in the separation process(es) for which evaluation has been requested. These data shall be used to calculate an appropriate carryover factor to estimate the normalized concentration(s) of the product ingredients and contaminants. In the absence of data to justify otherwise, a 100% carryover shall be assumed for ingredients and contaminants from these membrane separation process chemicals.

8.7.5.3 Evaporation process chemicals

Normalized concentrations of non-volatile, high boiling point ingredients and contaminants shall be calculated based on a carryover of 0.1 weight percent of the concentration in the feedwater when the product is dosed at the manufacturer's recommended use level.

$$\text{feedwater concentration of the active ingredient or contaminant} \times 0.1\% = \text{normalized concentration of the active ingredient or contaminant}$$

In the absence of data to justify otherwise, a 100% carryover shall be assumed for ingredients and contaminants which are volatile or which have boiling points close to that of water.

8.7.6 Backfill materials for cathodic protection or electrical installations

The following equation shall be used to calculate the normalized contaminant exposure(s) from backfill materials for cathodic protection or electrical installations:

$$\text{laboratory concentration of ingredient or contaminant} \times \frac{M_F}{M_L} \times \frac{V_L}{V_F} = \text{normalized concentration of ingredient or contaminant}$$

where:

M_F = mass (g) of the backfill material required for an installation of the maximum recommended diameter and for an aquifer of 6.1 m (20 ft) depth

M_L = mass (g) of the backfill material exposed during the laboratory test

V_L = volume of water used for laboratory exposure

V_F = volume of water in the aquifer assumed to be in contact with contaminants from the backfill material 1.1×10^6 L (293,760 gal)

NOTE – The assumed volume of water is based on a 0.5 acre aquifer of 25% porosity and 6.1 m (20 ft) depth. The well and the backfill installation are located a minimum of 30.5 m (100 ft) apart within the defined aquifer. The extractants from the backfill material are assumed to be within the volume of water defined by a circle of 30.5 m (100 ft) diameter of the same depth and porosity as the aquifer.

8.8 Evaluation of contaminant concentrations

The normalized concentration of each ingredient or contaminant shall be no greater than the Single Product Allowable Concentration (SPAC) determined in accordance with the requirements of Annex A. For residential well application products, calculation of the SPAC for a specific contaminant under 8 shall consider such factors as the more limited number of materials in contact with the drinking water distribution system in a well installation, and the limited one-time use of many well application products (e.g., products used to drill and develop the well).

The following table is a generic listing of some of the types of products covered in this section of the standard. The chemicals described in this table can be fed continuously, applied intermittently, or flushed from the water supply system prior to its return to use. Products incorporated in this table include regenerants and well-drilling aids. This table is not intended to be a complete list of all products used for miscellaneous water supply applications. Inclusion of a product does not indicate either a use endorsement of the product or an automatic acceptance under the provisions of this Standard. Annex F, Table F1 includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

**Table 8.1 – Miscellaneous water supply products –
Product identification and evaluation (limited contact)**

Product	Product - specific analyses	Preparation method
antifoamers	formulation dependent	method I, Annex B, section B.3.10
distribution system rehabilitation materials	formulation dependent	
backfill materials for cathodic protection or electrical installations	formulation dependent	method G, Annex B, section B.3.8
scale inhibitors	formulation dependent	method H, Annex B, section B.3.9
well development/rehabilitation materials		
Acids	formulation dependent	method D, Annex B, section B.3.5
bases (caustics)	formulation dependent	method B, Annex B, section B.3.3
disinfectants	formulation dependent	see 6
flocculants	formulation dependent	see 4
frac sand	formulation dependent	method G, Annex B, section B.3.8
scale removers	formulation dependent	method H, Annex B, section B.3.9
drilling additives		
bentonite-based drilling additives	regulated metals, radionuclides, pesticides/herbicides, and other formulation dependent impurities	method F, Annex B, section B.3.7
biocides	formulation dependent	
clay thinners	formulation dependent	
defoamers	formulation dependent	
filtration control	formulation dependent	
foamers	formulation dependent	method I; Annex B, section B.3.10
loss circulation materials	formulation dependent	
lubricants (e.g., grease)	formulation dependent	
Oxygen scavengers	formulation dependent	
polymer-based drilling additives	formulation dependent	method J, Annex B, section B.3.11
regenerants	formulation dependent	
viscosifiers	formulation dependent	
weighting agents	formulation dependent	
well pump lubricating oils	formulation dependent	method I, Annex B, section B.3.10
bore hole sealants		
bentonite-based grouts	regulated metals, radionuclides, herbicides/pesticides, and other formulation dependent impurities	method F, Annex B, section B.3.7 or per manufacturer's instructions
cements	regulated metals, radionuclides, and other formulation dependent impurities	per manufacturer's instructions

Table 8.2 – Example calculation of a residual contaminant level from a well drilling additive

residual contaminant	monomer from an organic polymer (0.05% monomer in polymer)
assumed well casing diameter	4 in
weight of monomer in 14.2 L (3.75 gal) of polymer – manufacturer's recommended use level	$14.2 \text{ L of polymer} \times 0.0005 = 7.1 \times 10^{-3} \text{ L of monomer} = 7.1 \text{ mL of monomer}$ $7.1 \text{ mL of monomer} = 8.0 \text{ g monomer (density of monomer is 1.122 g/mL)}$
percent removal of the drilling fluid	90%
weight of monomer remaining in aquifer after installation	$8.0 \text{ g} \times 10\% = 0.8 \text{ g monomer remaining in the aquifer (90\% removed during construction)}$
concentration of monomer remaining in aquifer	$\frac{0.8 \text{ g monomer}}{3.1 \times 10^6 \text{ L water}} = \frac{0.25 \text{ } \mu\text{g monomer}}{\text{L water}}$ <p>0.25 ppb is concentration of monomer remaining in the aquifer</p>

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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).

NOTE – For the purposes of this Standard, the benchmark dose shall be calculated at the 10% response level.

A.2.2 continuous data: A measurement of effect that is expressed on a continuous scale, e.g., body weight or serum enzyme levels (USEPA, 1995).

A.2.3 critical effect: The first adverse effect, or its known precursor, that occurs as the dose rate increases (USEPA, 1994).

A.2.4 ED₁₀: Effective dose 10; a dose estimated to cause a 10% response in a test population (USEPA, 1996a).

A.2.5 genetic toxicity: Direct interaction with DNA that has the potential to cause heritable changes to the cell.

A.2.6 health hazards (types of) (USEPA, 1994 and 1999)

A.2.6.1 acute toxicity: Effects that occur immediately or develop rapidly after a single administration of a substance. Acute toxicity may also be referred to as immediate toxicity.

A.2.6.2 allergic reaction: Adverse reaction to a chemical resulting from previous sensitization to that chemical or to a structurally similar one.

A.2.6.3 chronic effect: An effect that occurs as a result of repeated or long-term (chronic) exposures.

A.2.6.4 chronic exposure: Multiple exposures occurring over an extended period of time or a significant fraction of the animal's or the individual's lifetime.

A.2.6.5 chronic toxicity: The capability of a substance to cause adverse human health effects as a result of chronic exposure.

A.2.6.6 irreversible toxicity: Toxic effects to a tissue that cannot be repaired.

A.2.6.7 local toxicity: Effects that occur at the site of first contact between the biological system and the toxicant.

A.2.6.8 reversible toxicity: Toxic effects which can be repaired, usually by a specific tissue's ability to regenerate or mend itself after chemical exposure.

A.2.6.9 systemic toxicity: Effects that are elicited after absorption and distribution of a toxicant from its entry point to its target tissue.

A.2.7 LED₁₀: Lowest effective dose 10; the lower 95% confidence limit on a dose estimated to cause a 10% response in a test population (USEPA, 1996a).

A.2.8 lowest observed adverse effect level (LOAEL): The lowest exposure concentration at which statistically or biologically significant increases in frequency or severity of effects are observed between the exposed population and its appropriate control group (USEPA, 1994).

A.2.9 margin of exposure (MOE): The LED₁₀ or other point of departure, such as a NOAEL, divided by the environmental dose of interest (USEPA, 1996a).

A.2.10 model: A mathematical function with parameters that can be adjusted so that the function closely describes a set of empirical data. A mathematical or mechanistic model is usually based on biological or physical mechanisms, and has model parameters that have real world interpretation. Statistical or empirical models are curve-fitted to data where the math function used is selected for its numerical

properties and accuracy. Extrapolation from mechanistic models (e.g., pharmacokinetic equations) usually carries higher confidence than extrapolation using empirical models (e.g., logit) (USEPA, 1994).

A.2.11 no observed adverse effect level (NOAEL): An exposure concentration at which no statistically or biologically significant increases in the frequency or severity of adverse effects are observed between an exposed population and its appropriate control. Some physiological effects may be produced at this concentration, but they are not considered as toxicologically significant or adverse, or as precursors to adverse effects (USEPA, 1994).

A.2.12 nonregulated substance: A substance for which a statutory concentration limit does not exist.

A.2.13 peer review: A documented critical review of a scientific or technical work product conducted by qualified individuals or organizations who are independent of those who performed the work, but who are collectively equivalent or superior in technical expertise to those who performed the work. It includes an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the work product and the documentation that supports the conclusions reached in the report. Peer review is intended to ensure that the work product is technically adequate, competently performed, properly documented, and satisfies established requirements (USEPA, 1998).

A.2.14 point of departure: A data point or an estimated point that can be considered to be in the range of observation. The standard point of departure is the LED₁₀, which is the lower 95% confidence limit on a dose associated with 10% extra risk (adapted from Barnes et al., 1995).

A.2.15 qualitative risk assessment: An estimation of the risk associated with the exposure to a substance using a non-quantitative methodology.

A.2.16 quantal data: A dichotomous measure of effect; each animal is scored “normal” or “affected” and the measure of effect is the proportion of scored animals that are affected (USEPA, 1995).

A.2.17 quantitative risk assessment: An estimation of the risk associated with the exposure to a substance using a methodology that employs evaluation of dose response relationships.

A.2.18 range of extrapolation: Doses that are outside of the range of empirical observation in animal studies, human studies, or both (adapted from Barnes et al., 1995).

A.2.19 range of observation: Doses that are within the range of empirical observation in animal studies, human studies, or both (adapted from Barnes et al., 1995).

A.2.20 reference dose (RfD): An estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (USEPA, 1994).

A.2.21 regulated substance: A substance for which a quantitative human health risk assessment has been performed and utilized in promulgation of a statutory concentration limit for drinking water.

A.2.22 toxicodynamics: Variations in the inherent sensitivity of a species or individual to chemical-induced toxicity, resulting from differences in host factors that influence the toxic response of a target organ to a specified dose (TERA, 1996).

A.2.23 toxicokinetics: Variations in absorption, distribution, metabolism, and excretion of a compound that account for differences in the amount of parent compound or active metabolite(s) available to a target organ (TERA, 1996).

A.2.24 treatment technique: A technology or one or more procedures used to control the concentration of a substance in a drinking water supply when it is neither technically nor economically feasible to ascertain the concentration of the substance (U.S. Safe Drinking Water Act, 1996).

A.2.25 weight-of-evidence: The extent to which the available biomedical data support the hypothesis that a substance causes cancer or other toxic effects in humans (adapted from USEPA, 1994).

A.3 Data requirements for published risk assessments

A.3.1 General requirements

Evaluation of all published risk assessments shall include review of the written risk assessment document and a determination of whether additional toxicity data exist that were not considered in the assessment. If additional toxicity data are identified that were not considered in the risk assessment, the risk assessment shall be updated in accordance with Annex A, section A.4.

The following shall be documented when utilizing an existing risk assessment:

- the source of the risk assessment;
- identification and discussion of any data not addressed by the assessment; and
- comparison and contrast of the existing risk assessment to the requirements of Annex A, section A.4 with respect to selection of uncertainty factors or other assumptions.

A.3.2 Substances regulated by USEPA or Health Canada

If a substance is regulated under the USEPA's National Primary Drinking Water Regulations and USEPA has finalized a Maximum Contaminant Level (MCL) or other means of regulation such as a treatment technique (see Annex A, section A.2.18), no additional collection of toxicological data shall be required prior to performance of the risk estimation (see Annex A, section A.6.1). Where Health Canada has finalized a Maximum Allowable Concentration (MAC), no additional toxicological evaluation shall be required prior to performance of the risk estimation (see Annex A, section A.6.1). Annex D contains a list of regulatory values (MCL or MAC) and their corresponding SPACs. This list includes consensus evaluation criteria for those substances that are regulated by both countries.

A.3.3 Substances regulated by other agencies

If a substance is regulated by agencies including the U.S. Food and Drug Administration (Code of Federal Regulations, Title 21 Food and Drug Regulations), or state, national, or international regulatory bodies other than those specified in Annex A, section A.3.2, the relevance of the regulation to drinking water shall be evaluated. This evaluation shall include a review of the quantitative risk assessment that supports the regulation, and a determination of whether additional toxicity data exist that have not been considered in the current assessment. No additional collection of toxicological data shall be required when the regulation provides sufficient information for performance of the risk estimation (see Annex A, section A.6.1). If additional toxicity data are identified which were not considered in the current risk assessment, a revised risk assessment incorporating those data shall be performed as indicated in Annex A, sections A.4 and A.7.

A.3.4 Evaluation of multiple published risk assessments

When multiple published assessments are available for a specific substance, the available assessments shall be reviewed and a rationale shall be provided for the selection of the assessment considered to be the most appropriate for the evaluation of human exposure through drinking water. Factors used to determine the appropriate assessment shall include, but not be limited, to the following:

- 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 a 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:

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

If available the unrounded estimated risk estimation that the promulgated regulatory value is based on shall be used in the calculation of the SPAC. 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. The calculated SPAC shall be rounded to one significant figure, unless it is based on a regulatory value with more than one significant figure. In that case the SPAC shall be rounded to the same number of significant figures as the 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:

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

The unrounded value of the estimated risk estimation shall be used in the calculation of the SPAC. 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. The calculated SPAC shall be rounded to one significant figure.

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.

A.7.3 TAC calculation for quantitative risk assessment

The procedure used to calculate the TAC for a new risk assessment (including qualitative assessments that are updated upon generation of new data) shall be determined by the toxicologic endpoint identified as the critical effect (see Annex A, section A.2.3). For a substance having a non-carcinogenic endpoint, a TAC shall be calculated according to Annex A, section A.7.3.1. For a substance having carcinogenic potential, a TAC shall be calculated according to Annex A, section A.7.3.2.

The minimum data set for the quantitative risk assessment (as defined in Annex A, section A.4.3 and Table A2) shall first be evaluated for genotoxic potential according to the requirements of Annex A, Table A3. Based on the review of genotoxic potential, the need for supplemental studies or chronic toxicity and carcinogenesis data shall be determined.

A.7.3.1 Assessment of non-carcinogenic endpoints

For non-carcinogenic endpoints, the TAC shall be calculated using either the NOAEL/LOAEL procedure outlined in Annex A, section, A.7.3.1.1, or the benchmark dose (BMD) procedure outlined in Annex A, section A.7.3.1.2, as appropriate. The rationale for the selection of the procedure shall be provided in the assessment.

NOTE – Selection of the appropriate TAC calculation procedure will depend on the characteristics of the data set identified for the substance. Simple data sets consisting of a small number of studies may be best evaluated using the procedure in Annex A, section A.7.3.1.1. Complex data sets consisting of several studies, or which involve reproduction or developmental endpoints may be best evaluated using the benchmark dose procedure in Annex A, section A.7.3.1.2. The appropriateness of the fit of the data to the BMD shall also be considered.

A.7.3.1.1 NOAEL or LOAEL approach

The substance data set shall be reviewed in its entirety, and the highest NOAEL for the most appropriate test species, relevant route of exposure, study duration, mechanism, tissue response, and toxicological endpoint shall be identified. If a NOAEL cannot be clearly defined from the data, the lowest LOAEL for the most appropriate test species, relevant route of exposure, and toxicological endpoint shall be utilized.

The general procedure for calculating the TAC using this approach is as follows:

a) determine the critical study and effect from which the NOAEL or LOAEL will be identified according to the following hierarchy (USEPA, 1993 and Dourson et al., 1994):

- adequate studies in humans;
- adequate studies in animal models most biologically relevant to humans (e.g., primates), or that demonstrate similar pharmacokinetics to humans;
- adequate studies in the most sensitive animal species (the species showing an adverse effect at the lowest administered dose using an appropriate vehicle, an adequate study duration, and a relevant route of exposure); and
- effects that are biologically relevant to humans.

b) calculate the reference dose (RfD) according to the following equation (based on USEPA, 1993):

$$\text{RfD (mg/kg/d)} = \frac{\text{NOAEL or LOAEL (mg/kg/d)}}{\text{UF}} \times \frac{\text{number of d dosed per week}}{7 \text{ d}}$$

NOTE – When other than daily dosing was used in the critical study, the RfD calculation shall be adjusted to reflect a daily dosing schedule.

c) calculate the TAC based on the RfD with adjustment for significant contribution(s) of the substance from sources other than drinking water according to the following equation:

$$\text{TAC (mg/L)} = \frac{[\text{RfD (mg/kg/d)} \times \text{BW (kg)}] - [\text{total contribution of other sources (mg/d)}]}{\text{DWI (L/d)}}$$

The calculated TAC shall be rounded to one significant figure.

where:

NOAEL = Highest NOAEL for the critical effect in the most appropriate species identified after review of data set; if a NOAEL is not defined, the LOAEL shall be used with a corresponding adjustment in the uncertainty factor (see Annex A, Table A4).

BW = Assumed body weight of individual to be protected in kg (generally 10 kg [22 lbs] for a child, and 70 kg [154 lbs] for an adult).

UF = Uncertainty factor (total) based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see Annex A, Table A4). These are often referred to as safety factors.

DWI = Drinking Water Intake is the assumed average daily drinking water consumption per d (generally 1 L [0.26 gal] for a child and 2 L [0.53 gal] for an adult).

NOTE 1 – In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% shall be applied (USEPA, 1991).

NOTE 2 – If calculation of the non-drinking water contribution of a substance exceeds the value of the (RfD x BW), verify that all potential exposures to the substance in the critical study have been accounted, e.g., is the substance present as a contaminant in the feed as well as dosed into the drinking water, etc.

A.7.3.1.2 Benchmark dose approach

The benchmark dose level (BMDL) for the substance shall be calculated by modeling the substance's dose response curve for the critical effect in the region of observed responses. The benchmark response (BMR) concentration shall be determined by whether the critical response is a continuous endpoint measurement or a quantal endpoint measurement. The BMR shall be calculated at the 10% response level.

The general procedure for calculating the TAC using the BMDL is as follows:

a) calculate the reference dose (RfD) according to the following equation:

$$\text{RfD (mg/kg/d)} = \frac{\text{BMDL (mg/kg/d)}}{\text{UF}} \times \frac{\text{number of d dosed per week}}{7 \text{ d}}$$

NOTE – When other than daily dosing was used in the critical study, the RfD calculation shall be adjusted to reflect a daily dosing schedule.

b) calculate the TAC based on the RfD with adjustment for significant contribution(s) of the substance from sources other than water according to the following equation:

$$\text{TAC (mg/L)} = \frac{[\text{RfD (mg/kg/d)} \times \text{BW (kg)}] - [\text{total contribution of other sources (mg/d)}]}{\text{DWI (L/d)}}$$

The calculated TAC shall be rounded to one significant figure.

where:

BMDL = The lower confidence limit on the dose that produces a specified magnitude of change (10%) in a specified adverse response (BMD₁₀).

BW = Assumed body weight of individual to be protected in kg (generally 10 kg [22 lbs] for a child, and 70 kg [154 lbs] for an adult).

UF = Uncertainty factor (total) based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see Annex A, Table A4). These are often referred to as safety factors.

DWI = Drinking Water Intake is the assumed average daily drinking water consumption per day (generally 1 L [0.26 gal] for a child and 2 L [0.53 gal] for an adult).

NOTE 1 – In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% shall be applied (USEPA, 1991).

NOTE 2 – If calculation of the non-drinking water contribution of a substance exceeds the value of the (RfD x BW), verify that all potential exposures to the substance in the critical study have been accounted, e.g., is the substance present as a contaminant in the feed as well as dosed into the drinking water, etc.

A.7.3.1.3 Selection of uncertainty factors (UF)

Uncertainty factors used for the risk estimation shall include consideration of the areas of uncertainty listed in Annex A, Table A4. A default value of 10 shall be used for individual areas of uncertainty when adequate data are not available to support a data-derived uncertainty factor. Selection of the values of each uncertainty factor shall consider the following criteria (adapted from Dourson et al., 1996).¹³

A.7.3.1.3.1 Human variability

Selection of the human variability factor shall be based on the availability of data that identify sensitive subpopulations of humans. If sufficient data are available to quantitate the toxicokinetic and toxicodynamic variability of humans (see Annex A, sections A.2.22 and A.2.23), factor values of 3, 1, or a value determined from the data shall be considered. In the absence of these data, the default value of 10 shall be used.

A.7.3.1.3.2 Interspecies variability

Selection of the interspecies variability factor shall be based on the availability of data that allow for a quantitative extrapolation of animal dose to the equivalent human dose for effects of similar magnitude or

¹³ The Food Quality Protection Act (FQPA) of 1996 reemphasized the review and evaluation of toxicity data for the protection of children's health. U.S. EPA has been very responsive to this initiative and published a draft document outlining the use of an uncertainty factor for children's protection and other database deficiencies (USEPA, 1999). Currently this factor is applied to pesticide evaluations only. In addition, publications by Renwick (1993) and the International Programme for Chemical Safety (IPCS) (1994) suggest the use of specific data in lieu of default values for uncertainty factors. This suggestion has been actively discussed at subsequent IPCS meetings and several individual chemical examples have been published (IPCS, 1999). The use of data-derived uncertainty factors, or judgment, as replacements to default values of 10-fold for each area of uncertainty is encouraged by several federal and international agencies and organizations (Meek, 1994; Dourson, 1994).

for a NOAEL. This includes scientifically documented differences or similarities in physiology, metabolism and toxic response(s) between experimental animals and humans. If sufficient data are available to quantitate the toxicokinetic and toxicodynamic variabilities between experimental animals and humans (see Annex A, sections A.2.22 and A.2.23), factor values of 3, 1, or a value determined from the data shall be considered. In the absence of these data, the default value of 10 shall be used.

A.7.3.1.3.3 Subchronic to chronic extrapolation

Selection of the factor for subchronic to chronic extrapolation shall be based on the availability of data that allow for quantitative extrapolation of the critical effect after subchronic exposure to that after chronic exposure. Selection shall also consider whether NOAELs differ quantitatively when different critical effects are observed after subchronic and chronic exposure to the compound. When the critical effect is identified from a study of chronic exposure, the factor value shall be 1. When sufficient data are available to quantitate the difference in the critical effect after subchronic and chronic exposure, or when the principal studies do not suggest that duration of exposure is a determinant of the critical effects, a factor value of 3 or a value determined from the data shall be considered. In the absence of these data, the default value of 10 shall be used.

A.7.3.1.3.4 Database sufficiency

Selection of the factor for database sufficiency shall be based on the ability of the existing data to support a scientific judgment of the likely critical effect of exposure to the compound. When data exist from a minimum of five core studies (two chronic bioassays in different species, one two-generation reproductive study, and two developmental toxicity studies in different species), a factor value of 1 shall be considered. When several, but not all, of the core studies are available, a factor value of 3 shall be considered. When several of the core studies are unavailable, the default value of 10 shall be used.

A.7.3.1.3.5 LOAEL to NOAEL extrapolation

Selection of the factor for LOAEL to NOAEL extrapolation shall be based on the ability of the existing data to allow the use of a LOAEL rather than a NOAEL for non-cancer risk estimation. If a well-defined NOAEL is identified, the factor value shall be 1. When the identified LOAEL is for a minimally adverse or reversible toxic effect, a factor value of 3 shall be considered. When the identified LOAEL is for a severe or irreversible toxic effect, a factor value of 10 shall be used.

A.7.3.2 Assessment of carcinogenic endpoints

Risk assessment for carcinogenic endpoints shall be performed using the linear approach, the non-linear approach, or both, consistent with the proposed USEPA Cancer Risk Assessment Guidelines (USEPA, 1996a). For substances that have been identified as known or likely human carcinogens (as defined by these Guidelines), a dose response assessment shall be performed. This dose response assessment shall include analysis of dose both in the range of observation (animal and human studies) and in the range of extrapolation to lower doses.

A.7.3.2.1 Analysis in the range of observation

Curve-fitting models shall be selected based on the characteristics of the response data in the observed range. The model shall be selected, to the extent possible, based on the biological mode of action of the substance taken together in a weight of evidence evaluation of the available toxicological and biological data. The selected model shall be used to determine the LED₁₀, which will either be the point of departure (see Annex A, section A.2.14) for linear low dose extrapolation or the basis of the margin of exposure (MOE) analysis (see Annex A, section A.2.9) for a non-linear assessment.

NOTE – See Annex A, figure A2 for a graphical representation of this analysis.

The following types of models shall be considered, as appropriate to the mode of action of the substance under evaluation, the availability of adequate data, and the current state of risk assessment approaches:

- statistical or distribution models:
 - log-probit;
 - logit; or
 - Weibull.
- mechanistic models:
 - one-hit;
 - multihit;
 - multistage; or
 - cell kinetic multistage.
- model enhancement and dose scaling:
 - time to tumor response;
 - physiologically based toxicokinetic models;
 - biologically based dose-response models; or
 - surface area conversion.

If none of the available models provide a reasonable fit to the dataset, the following shall be considered to see if lack of fit can be resolved (USEPA, 1995):

- interference at higher dose concentrations from competing mechanisms of toxicity that are a progressive form of the response of interest;
- saturation of metabolic or delivery systems for the ultimate toxicant at higher dose concentrations; and
- interference at higher dose concentrations due to toxic effects unrelated to the response of interest.

NOTE – When adjusting for these possibilities does not provide a reasonable fit, one suggested approach is to delete the high dose data and refit the models based on the lower dose concentrations since these doses are the most informative of the exposure concentrations anticipated to be encountered by humans.

A.7.3.2.2 Analysis in the range of extrapolation

The choice of procedure for low dose extrapolation shall be based on the biological mode of action of the substance. Depending upon the quantity and quality of the data, and upon the conclusion of the weight of evidence evaluation, the following procedures shall be used: linear, non-linear, or linear and non-linear.

A.7.3.2.2.1 Linear analysis

The linear default assumption shall be used when the toxicological data support a mode of action due to DNA reactivity or another mode of action which is anticipated to be linear in nature. It shall also be used when no data are available to justify an alternate approach. For linear extrapolation, a straight line is constructed from the point of departure on the dose response curve to the zero dose/zero response point.

A.7.3.2.2.2 Non-linear analysis

The non-linear default assumption shall be used when the toxicological data are sufficient to support the assumption of a non-linear mechanism of action, and no evidence for linearity is available. A margin of exposure (MOE) analysis shall be used for non-linear assessment. The margin of exposure shall be calculated by dividing the point of departure by the human exposure concentration of interest.

A.7.3.2.2.3 Linear and non-linear analysis

Linear and non-linear assessments shall be provided when the weight of evidence or the mode of action analysis indicates differing modes of action for different target tissues, or to evaluate the implications of complex dose response relationships. Where the results of linear and non-linear evaluations differ, the range of estimates shall be discussed, along with a justification for the estimate used in evaluation of the substance.

A.7.3.3 Determination of the TAC for carcinogenic endpoints

The selected model shall be used to determine the dose equivalent to the LED₁₀. For linear analyses, the TAC shall be determined by linear extrapolation of the LED₁₀ to the origin of the dose response curve for the selected level of risk. For non-linear analyses, the TAC shall be equal to the human exposure concentration of interest that represents the selected MOE (LED₁₀/exposure of interest). For both types of analyses, the level of risk or margin of exposure shall be selected in accordance with the USEPA Cancer Risk Assessment Guidelines (USEPA, 1996a).

A.7.4 SPAC calculation for new or updated risk assessments

Calculation of the SPAC is intended to account for 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.7.4.1 SPAC determination for qualitative risk assessment

The SPAC for qualitative risk assessments shall be equal to the value of the TAC.

A.7.4.2 SPAC determination for quantitative risk assessment

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:

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

The unrounded value of the TAC shall be used in the calculation of the SPAC. 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 TAC. The calculated SPAC shall be rounded to one significant figure.

A.8 Risk estimation for short-term exposure (STEL calculation)

The STEL shall be calculated using the following equation:

$$\text{STEL (mg/L)} = \frac{\text{NOAEL or LOAEL (mg/kg/d)}}{\text{UF}} \times \frac{\text{BW (kg)}}{\text{DWI (L/d)}} = \frac{\text{number of d dosed per week}}{7 \text{ d}}$$

NOTE – When other than daily dosing was used in the critical study, the STEL calculation shall be adjusted to reflect the dosing schedule.

The calculated STEL shall be rounded to one significant figure.

where:

NOAEL = Highest NOAEL for the critical effect in a study of less than or equal to 90 d duration (see Annex A, section A.5); if a NOAEL is not defined, the LOAEL shall be used with a corresponding adjustment to the uncertainty factor (see Annex A, Table A4).

BW = Assumed body weight of the individual to be protected (in kg), generally 10 kg [22 lbs] for a child and 70 kg [154 lbs] for an adult. The default body weight shall reflect that of a child, in the absence of data which demonstrate that adults are more sensitive than children.

UF = Uncertainty factor based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see Annex A, Table A4); also referred to as safety factors.

DWI = Drinking Water Intake is the assumed average daily drinking water consumption in L/d, generally 1 L [0.26 gal] for a child and 2 L [0.53 gal] for an adult. The default water consumption shall reflect that of a child, in the absence of data that demonstrate that adults are more sensitive than children.

A.9 Development of chemical class-based evaluation criteria

A.9.1 Identification of the need for chemical class-based evaluation criteria

Annex A provides a threshold of evaluation to be utilized when the required toxicity data to perform qualitative or quantitative risk assessment (see Annex A, section A.4) are unavailable, or when the required data are available, but the normalized contaminant concentrations do not exceed the threshold of evaluation concentrations (see Annex A, section A.7.1). However, normalized contaminant concentrations for chemicals that do not meet minimum data requirements may exceed the threshold of evaluation concentrations. In this case it may be possible to determine chemical class-based evaluation criteria for the substance on the basis of the known toxicities of other chemicals of similar structure and functionality. Those criteria can then be used as surrogates to the TAC and SPAC established on the basis of chemical-specific information.

Class-based evaluation criteria shall not be used for any substance for which adequate data exist to perform a chemical-specific risk assessment.

A.9.2 Procedure for defining class-based evaluation criteria

A.9.2.1 Establishment of the chemical class

The chemical class for which the class-based evaluation criteria are to be established shall consist of a clearly defined and closely related group of substances, and shall be defined according to chemical structure (e.g., aliphatic, aromatic, etc.), primary chemical functional group(s) (e.g., alcohol, aldehyde, ketone, etc.), and molecular weight or weight range.

A.9.2.2 Review of chemical class toxicity information

Once the chemical class has been defined according to Annex A, section A.9.2.1, information on chemicals of known toxicity, which are included in the defined chemical class shall be reviewed. An appropriate number of chemicals of known toxicity shall be reviewed to establish class-based evaluation criteria. Sources of data for chemicals of known toxicity shall include, but not be limited to, the following:

- USEPA regulatory values and other risk assessments, including Maximum Contaminant Levels (MCL), Health Advisories, and Integrated Risk Information System (IRIS) entries;
- Health Canada risk assessments;
- risk assessments previously performed to the requirements of NSF/ANSI 61, Annex A;
- state or provincial drinking water standards and guidelines; and
- World Health Organization (WHO) or other international drinking water standards and guidelines.

An MCL and SPAC (regulated contaminants) or a TAC and SPAC (nonregulated contaminants) shall be identified for each chemical of known toxicity that is being used to determine the class-based evaluation criteria. Carcinogenic potential shall be evaluated using a quantitative structure-activity relationship program (e.g., Oncologic®¹⁴ or equivalent) to verify the carcinogenic potential of the chemical of unknown toxicity is no greater than that of the chemicals being used to define the class-based evaluation criteria.

A.9.2.3 Determination of the class-based evaluation criteria

After review of the available toxicity information specified in Annex A, section A.9.2.2, the class-based evaluation criteria shall not exceed the lowest MCL or TAC and SPAC identified for the chemicals of known toxicity in the defined chemical class. These evaluation criteria shall be used as surrogates for the TAC and SPAC for each chemical of unknown toxicity that meets the specifications of the defined chemical class (see Annex A, section A.9.2.1), until such time as sufficient toxicity data are available to determine chemical-specific evaluation criteria.

The class-based evaluation criteria shall not be applied to any substance for which available data and sound scientific judgment, such as structure-activity relationship considerations, indicate that adverse health effects may result at the established class-based evaluation criteria concentrations. If, after a chemical class is defined and its evaluation criteria established, a substance of greater toxicological significance is identified within the class, the class-based evaluation criteria shall be reevaluated and revised to the acceptable concentrations of the new substance.

NOTE – It is recommended that documentation supporting class-based evaluation criteria be subject to the external peer review requirements of Annex A, section A.10.15.

A.10 Key elements of a risk assessment for drinking water additive chemicals

This section establishes the minimum criteria for the documentation of the data review performed on each drinking water additive chemical that requires a new or updated assessment. The assessment shall include, but not be limited to, evaluation of the elements detailed in this section.

A.10.1 Abstract

A summary shall be provided of the following:

- overview of the key toxicology studies;

¹⁴ LogiChem, Inc., PO Box 357, Boyertown, PA 19512 <www.logichem.com>.

- rationale for the selection of the critical effect and the corresponding NOAEL or other endpoint for calculation;
- major assumptions used in the assessment and areas of uncertainty; and
- presentation of the RfD, TAC, SPAC and STEL values.

A.10.2 Physical and chemical properties

The assessment shall define the following parameters for the substance, as applicable:

- chemical formula, structure, CAS number, and molecular weight;
- physical state and appearance;
- melting point or boiling point;
- vapor pressure;
- solubility in water;
- density;
- organoleptic properties (taste and odor thresholds);
- dissociation constant (pKa); and
- partition coefficients (octanol/water, air/water).

A.10.3 Production and use

The assessment shall review the method(s) of production of the substance, whether it is a synthetic or a naturally occurring substance, and the principal uses of the chemical. This includes any use as a water treatment chemical or a food additive (direct or indirect) and its presence in such products as medicines, personal care products or cosmetics.

A.10.4 Analytical methods

For each identified analytical method for the substance, the following shall be summarized:

- analytical matrix;
- sample preparation, if applicable;
- method of analysis;
- type of detector or the wavelength for spectroscopic methods; and
- detection limit.

A.10.5 Sources of human and environmental exposure

The assessment shall describe the substance's natural occurrence, if any, and its presence in food or other media. Human exposure from drinking water, food, and air shall be described, including occupational exposures. The major source(s) and route(s) of human exposure shall be identified.

A.10.6 Comparative kinetics and metabolism

All references describing the absorption, distribution, metabolism, and excretion of the substance shall be reviewed. Both human data (when available) and animal data shall be included.

A.10.7 Effects on humans

A summary of each relevant reference documenting human exposure to the substance that is used in the hazard assessment shall be provided. These exposures can include both case reports of incidental human exposure to the substance, and epidemiological studies, which explore the association between human exposure and specific toxic endpoints. Primary literature references shall be reviewed whenever possible.

Supporting data or other studies not utilized in the hazard assessment can be summarized in tabular form.

A.10.8 Effects on laboratory animals and *in vitro* test systems

A summary of each key study of the substance in experimental animals or *in vitro* test systems that is used in the hazard assessment shall be provided. The references used shall meet established toxicity study guidelines, as defined in Annex A, section A.4.1, or any deficiencies shall be clearly identified. Studies shall include, but are not limited to the following: single exposure, short-term exposure (repeated dose study of < 28 d), long-term and chronic exposure (repeated dose study of ≥ 28 d), genotoxicity, reproduction and developmental toxicity, immunotoxicity, and neurotoxicity. Primary literature references shall be reviewed whenever possible.

Supporting data or other studies not utilized in the hazard assessment can be summarized in tabular form.

A.10.9 Effects evaluation

The effects evaluation is intended to provide an overall summary of the data reviewed for the substance and describe its mode/mechanism of action, if possible. This evaluation also serves to define the level of hazard represented by exposure to the substance at relevant human concentrations. This evaluation shall contain three major elements: hazard identification (assessment), dose-response assessment, and exposure characterization.

A.10.9.1 Hazard identification

The hazard identification (assessment) shall identify and discuss the following issues:

- the key data that define the basis of the concern to human health;
- the characterization of the substance as carcinogenic or non-carcinogenic, the basis for this characterization, and the critical effect(s);
- the extent to which this characterization is a function of study design (e.g., adequate number of doses used, effects noted only at highest dose, study performed at the maximum tolerated dose);
- the conclusions of the key study(ies) and whether they are supported or conflicted by other data;
- the significant data gaps for the substance and any relevant non-positive data;
- the available human data (case reports or epidemiological studies), and how they support or do not support the conclusions from the key study(ies);
- the mechanism by which the substance produces the adverse effect(s) noted in the key study, and whether this mechanism is relevant to humans; and
- the summary of the hazard assessment including confidence in the conclusions, alternate conclusions which may also be supported by the data, significant data gaps, and the major assumptions used in the assessment.

A.10.9.2 Dose-response assessment

The dose-response assessment shall identify and discuss the following issues:

- the data used to define the dose-response curve, and in which species the data were generated;
- if animal data were used, whether the most sensitive species was evaluated;
- if human data were used, whether positive and negative data were reported;
- whether the critical data were from the same route of exposure as the expected human exposure (drinking water), and if not, discuss whether pharmacokinetic data are available to extrapolate between routes of exposure;
- for non-carcinogens, the methodology employed to calculate the RfD and the selection of the uncertainty factors which were used;
- for carcinogens, the dose-response model selected to calculate the LED₁₀ and the rationale supporting its selection; and
- document the RfD calculation (see Annex A, section A.7.3).

A.10.9.3 Exposure characterization

The exposure characterization shall identify and discuss the following issues:

- the most significant source(s) of environmental exposure to the substance, and the relative source contribution of each;
- the population(s) most at risk of exposure, and identify highly exposed or sensitive subpopulations; and
- any issues related to cumulative or multiple exposures to the substance.

A.10.10 Risk characterization

A.10.10.1 TAC derivation

The TAC derivation shall contain an explanation of all factors contributing to the TAC calculation, including adjustment for sources of the substance other than water. The TAC calculation shall be based on the oral RfD calculated during the dose response assessment in Annex A, section A.10.9.2. The TAC calculation shall include adjustment for significant contributions of the substance from sources other than water, e.g., food and air. In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% shall be applied.

A.10.10.2 STEL derivation

When a short-term exposure level is calculated for a substance, the calculation shall be based on the NOAEL or LOAEL of the selected study (as defined in Annex A, section A.5) with adjustment for body weight and daily water consumption of the protected individual, including any sensitive subpopulations. The default body weight and water consumption shall reflect that of a child, in the absence of data which demonstrate that adults are more sensitive to the substance than children. A rationale for the selection of uncertainty factors used in the calculation shall also be provided.

A.10.11 Risk management (SPAC derivation)

The TAC calculation shall form the basis of the SPAC calculation. The SPAC is equal to the TAC for qualitative risk assessments. For quantitative risk assessments, the SPAC shall be calculated as a percentage of the TAC value, based on the estimated total number of sources of the substance in the drinking water treatment and distribution system. In the absence of these data, the SPAC shall be calculated as 10% of the TAC value (default multiple source factor of 10 to account for other sources of the substance in drinking water).

A.10.12 Risk comparisons and conclusions

A review of other evaluations of the substance performed by other organizations (international, national, state or provincial agencies, or other entities) shall be provided. Consistencies and differences between evaluations shall be noted. Any uncertainties in these evaluations shall be discussed. A summary of the overall risk of the substance shall be made, including a discussion about compounds of comparable risk (e.g., similar structure, chemical class) when possible.

A.10.13 References

An alphabetized list of all reviewed citations (both cited and not cited in the assessment) shall be provided in an established format such as that described in *The Chicago Manual of Style*.

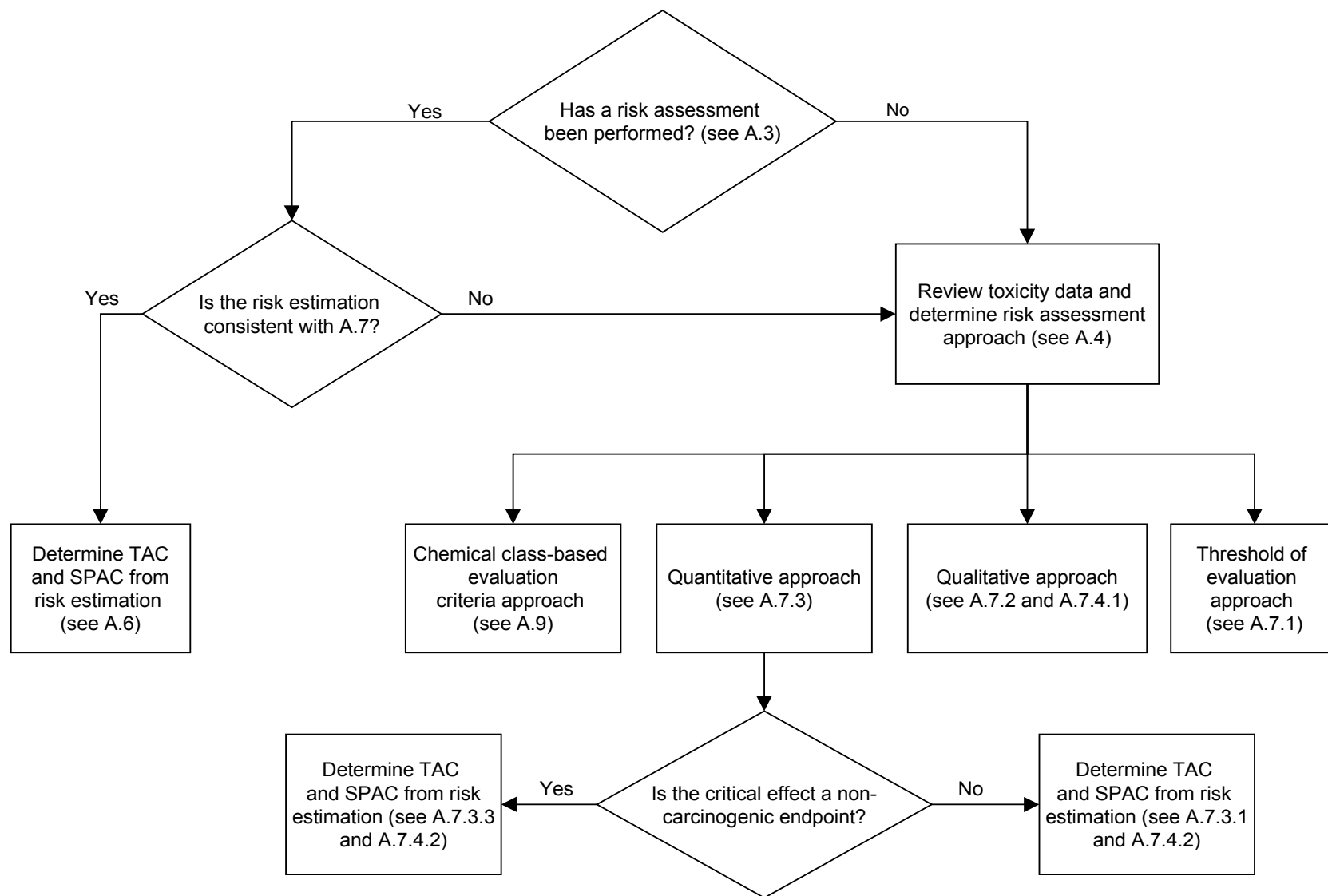
A.10.14 Appendices

Supporting documents, complex calculations, data summary tables, unique definitions, and other pertinent information shall be included in appendices to the document.

A.10.15 Peer review

Risk assessments performed to the requirements of this annex shall undergo external peer review (USEPA, 1998) by an independent group of individuals representing toxicological expertise in the regulatory, academic, and industrial sectors, with the exception of the following:

- substances evaluated using the threshold of evaluation (see A.7.1);
- substances evaluated to a TAC of 10 µg/L using the qualitative approach and concluded to be nongenotoxic (see Annex A, sections A.4.2 and A.7.2); and
- nonregulatory criteria that have already undergone peer review, such as USEPA IRIS assessments.

**Figure A1 - Annex A toxicity data review process**

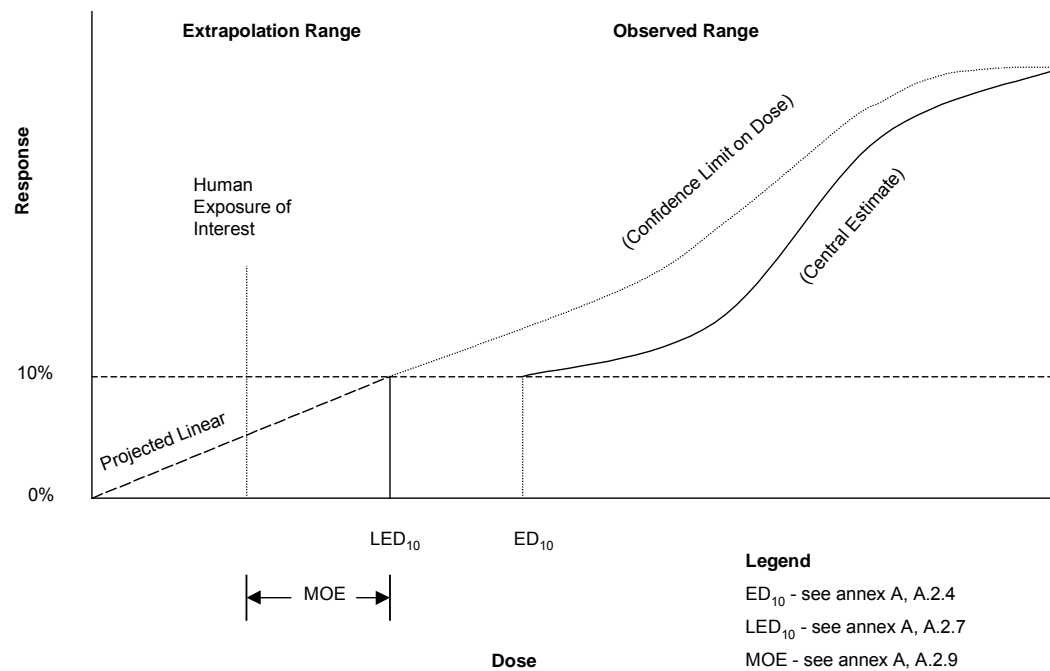


Figure A2 – Graphical presentation of data and extrapolations (USEPA, 1996a)

Table A1 – Qualitative risk assessment data requirements

Study type	Preferred criteria
Required studies	
gene mutation assay ¹	bacterial reverse mutation assay performed with and without exogenous metabolic activation using <i>Salmonella typhimurium</i> (preferred strains are TA97, TA98, TA100, TA102, TA1535, and TA1537) or <i>Escherichia coli</i> (preferred strains are WP2 <i>uvrA</i> or WP2 <i>uvrA</i> [pKM101])
chromosomal aberration assay ¹ (<i>in vitro</i> preferred)	metaphase analysis in mammalian cells and without exogenous metabolic activation
<i>in vivo</i>	metaphase analysis or micronucleus assay in mammalian species
Supplemental studies	
supplemental genotoxicity studies	mouse lymphoma assay, SCE ² , UDS ³ , HGPRT ⁴ , DNA binding (post labeling assay)
bioaccumulation potential	octanol/water partition coefficient
pharmacokinetics	absorption, distribution, metabolism, and excretion data in humans, other mammalian species, or both
structural/functional assessment	structure/activity relationship analysis
acute or short-term toxicity ⁵	1 to 14 d study or 14 to 28 d study using oral exposure route
cell proliferation/cell cycle assays	proliferating cell nuclear antigen (PCNA)
sensitization	guinea pig intradermal injection
<i>in vivo</i> gene mutation assay	transgenic gene mutation assays
endocrine disruption assays	receptor binding/transcriptional activation assays, frog metamorphosis assay, steroidogenesis assay
human data	epidemiological, occupational, or clinical studies
¹ The gene mutation assay and the chromosomal aberration assay (<i>in vitro</i> or <i>in vivo</i>) shall constitute the minimum data set required to perform a qualitative risk assessment. When one or both <i>in vitro</i> genotoxicity studies are positive, the <i>in vivo</i> assay shall be required to be reviewed. ² Sister chromatid exchange assay; SCEs are not considered to be mutagenic effects because the exchange is assumed to be reciprocal with no gain, loss, or change of genetic material. However, they do indicate that the test material has interacted with the DNA in a way that may lead to chromosome damage. In <i>in vitro</i> studies, SCEs do not provide adequate evidence of mutagenicity, but do identify the need for definitive chromosomal aberration studies. When evidence of <i>in vitro</i> clastogenicity exists, the induction of SCEs is often used as evidence of likely <i>in vivo</i> clastogenic activity because the <i>in vitro</i> aberration data demonstrate the clastogenic activity of the compound and the <i>in vivo</i> SCE data demonstrate that the compound interacted with the DNA in the target tissue. ³ Unscheduled DNA synthesis assay. ⁴ Hypoxanthine guanine phosphoribosyl transferase assay. ⁵ Minimum reported parameters shall include clinical observations, hematology and clinical chemistry, and gross pathology.	

Table A2 – Quantitative risk assessment data requirements

Study type	Preferred criteria
Required studies	
gene mutation assay ¹	bacterial reverse mutation assay performed with and without exogenous metabolic activation using <i>Salmonella typhimurium</i> (preferred strains are TA97, TA98, TA100, TA102, TA1535, and TA1537) or <i>Escherichia coli</i> (preferred strains are WP2 <i>uvrA</i> or WP2 <i>uvrA</i> (pKM101))
chromosomal aberration assay ¹ (<i>in vitro</i> preferred)	metaphase analysis in mammalian cells and without exogenous metabolic activation
<i>in vivo</i>	metaphase analysis or micronucleus assay in mammalian species
subchronic toxicity ¹	90-d assay in rodent species by oral route of exposure
Additional studies (required as indicated)	
reproduction assay ²	two-generation reproductive assay in a rodent species
developmental assay ²	teratology study (two species, one rodent and one non-rodent, are preferred)
chronic study ³	two-year bioassay in rodent species by oral route of exposure
Supplemental studies	
supplemental genotoxicity studies	mouse lymphoma, SCE ⁴ , UDS ⁵ , HGPRT ⁶ , DNA binding (post labeling assay)
bioaccumulation potential	octanol/water partition coefficient
pharmacokinetics	absorption, distribution, metabolism, and excretion data in humans, other mammalian species, or both
structural/functional assessment	structure/activity relationship analysis
acute or short-term toxicity ⁷	1 to 14 d or 14 to 28 d study using oral exposure
cell proliferation/cell cycle assays	proliferating cell nuclear antigen (PCNA)
sensitization	guinea pig intradermal injection
<i>in vivo</i> gene mutation assay	transgenic gene mutation assays
endocrine disruption assays	receptor binding/transcriptional activation assays, frog metamorphosis assay, steroidogenesis assay
human data	epidemiological, occupational, or clinical studies

Table A2 – Quantitative risk assessment data requirements

Study type	Preferred criteria
¹ The gene mutation assay, the chromosomal aberration assay (<i>in vitro</i> or <i>in vivo</i>), and the subchronic toxicity study shall constitute the minimum data set required to perform a quantitative risk assessment. When one or both <i>in vitro</i> genotoxicity studies are positive, the <i>in vivo</i> assay shall be required to be reviewed.	
² It is recommended that results of a screening assay, such as OECD No. 422, <i>Combined repeated dose toxicity study with reproduction/developmental toxicity screening test</i> , or data from other repeated dose assays which include histopathological examination of the reproductive tissues of each sex be reviewed prior to a determination that these assays are required for evaluation.	
³ A chronic study with evaluation of carcinogenic endpoints is required when review of the minimum data set concludes that the substance is likely to be a human health hazard at exposures of 10 µg/L or less.	
⁴ Sister chromatid exchange assay; SCEs are not considered to be mutagenic effects because the exchange is assumed to be reciprocal with no gain, loss, or change of genetic material. However, they do indicate that the test material has interacted with the DNA in a way that may lead to chromosome damage. In <i>in vitro</i> studies, SCEs do not provide adequate evidence of mutagenicity, but do identify the need for definitive chromosomal aberration studies. When evidence of <i>in vitro</i> clastogenicity exists, the induction of SCEs is often used as evidence of likely <i>in vivo</i> clastogenic activity because the <i>in vitro</i> aberration data demonstrate the clastogenic activity of the compound and the <i>in vivo</i> SCE data demonstrate that the compound interacted with the DNA in the target tissue.	
⁵ Unscheduled DNA synthesis assay.	
⁶ Hypoxanthine guanine phosphoribosyl transferase assay.	
⁷ Minimum reported parameters include clinical observations, hematology and clinical chemistry, and gross pathology.	

– concluded –

Table A3 – TACs for qualitative risk assessment

Conclusion of data review	TAC
The weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the substance is not a hazard at exposures of 10 µg/L or less.	10 µg/L
The weight of evidence review of the required genotoxicity studies, a repeated dose study of less than 90 dduration ¹ , and all other relevant data concludes that the substance is not a human health hazard at exposures of 50 µg/L or less.	≤ 50 µg/L
The weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the data are insufficient to determine the potential human health hazard of the substance at exposures of 10 µg/L or less.	supplemental studies or chronic toxicity and carcinogenesis bioassay required for review
The weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the substance is likely to be a human health hazard at exposures of 10 µg/L or less.	chronic toxicity and carcinogenesis bioassay required for review
¹ Required study parameters include organ and body weights, clinical chemistry and hematology, gross pathology, and histopathology.	

Table A4 – Uncertainty factors

Areas of uncertainty	Factor
Intraspecies extrapolation (species variation): This factor accounts for variations in chemical sensitivity among individuals in a species including toxicokinetic and toxicodynamic parameters.	1, 3, or 10
Interspecies extrapolation (animal to human): This factor accounts for variations in chemical sensitivity between experimental animals and humans including toxicokinetic and toxicodynamic parameters.	1, 3, or 10
Less than lifetime duration of exposure: This factor is intended to extrapolate experimental results from subchronic to chronic exposure.	1, 3, or 10
Use of LOAEL rather than NOAEL ¹ : This factor addresses the uncertainty in developing a reference dose from a LOAEL rather than a NOAEL.	1, 3, or 10
Lack of database completeness: This factor accounts for the absence of data for specific toxic endpoints.	1, 3, or 10
¹ This adjustment is not required for BMD calculations. NOTE – When uncertainties exist in four areas, a 3000-fold composite uncertainty factor is appropriate. When uncertainties exist in five areas, a 10,000-fold composite uncertainty factor is appropriate. This consolidation of individual factors recognizes that each individual factor is conservative, and multiplication of four or five uncertainty factors is likely to result in an overly conservative RfD. Datasets that would result in a composite uncertainty factor of greater than 10,000-fold are considered too weak for quantitative risk assessment (see A.4.2 for qualitative risk assessment requirements) (Dourson, 1994).	

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Annex B

(normative)

Sampling, preparation, and analysis of samples

B.1 General

Samples of products to be analyzed for impurities shall be prepared and analyzed as detailed in this section:

- coagulation and flocculation chemicals (also see 4, Table 4.1);
- corrosion and scale control, softening, precipitation, sequestering, and pH adjustment chemicals (also see 5, Table 5.1);
- disinfection and oxidation chemicals (also see 6, Table 6.1);
- miscellaneous treatment applications (also see 7, Table 7.1); and
- miscellaneous water supply products (also see 8, Table 8.1).

The analysis methods listed for a product are based on detecting impurities that may be present when established methods of production are used and the materials are derived from known sources. If the products are produced using alternate methods or originate from alternate sources, the analytical procedures may require modification. Alternate analytical procedures shall be described in detail, by the manufacturer, with appropriate literature references.

B.2 Sampling

A representative sample of the product/material shall be obtained in accordance with requirements outlined below at a point prior to shipment. No sample shall be taken from a broken or leaky container.

B.2.1 Liquid samples

B.2.1.1 Sampling from bulk

A specified quantity of sample shall be obtained from a bulk storage tank, or bulk shipping vessel, through normal connections. Where available on site, sampling from bulk shipping vessels is preferred, as it is representative of the final container of product being shipped to the customer. For hypochlorite, samples shall be taken from the oldest production lot that is on-site at the time.

B.2.1.2 Sampling from packages

Sufficient sample shall be collected from packaged inventory to fulfill the sample quantity requirements specified in the relevant subsection of B.3. For hypochlorite, samples shall be taken from the oldest production lot that is on-site at the time.

B.2.1.3 Sampling from production

Sufficient sample shall be collected from production to fulfill the requirements of the quantity needed for the product sample according to the relevant subsection of B.3.

B.2.1.4 Sampling from retains

Up to ten samples shall be collected, covering the length of the specified retain period or six months, whichever is greater, but not to exceed 12 months in the age of material sampled. A portion shall be collected from each retain, and the samples shall be mixed thoroughly to form a composite.

B.2.1.5 Sample for analysis

The sample obtained according to Annex B, sections B.2.1.1, B.2.1.2, B.2.1.3, or B.2.1.4, shall be mixed thoroughly. This sample shall be poured into two approximately 250 mL, airtight, moisture-proof glass containers and sealed. If a glass container is not appropriate, the manufacturer shall recommend a type of sample container. Each sample container shall be clearly labeled with the product name, manufacturer's name, sampling date, production location, and lot number, and shall be signed by the person responsible for sampling.

One sample shall be used for analysis as described in Annex B, sections B.3 and B.4. The remaining sample shall be retained for reevaluation purposes (if necessary) for at least one year or until results are received by the certification agency.

B.2.2 Solid samples

B.2.2.1 Sampling from bulk

B.2.2.1 Sampling from bulk

Specified amount of sample shall be obtained from storage tank or bulk shipping vessel through normal connections. Where available on site, sampling from bulk shipping vessels is preferred, as it is representative of the final container of product being shipped to the customer.

B.2.2.2 Sampling from packages

Sufficient sample shall be collected from packaged inventory to fulfill the sample quantity requirements specified in the relevant subsection of B.3.

B.2.2.3 Sampling from production

Sufficient sample shall be collected from production to fulfill the sample quantity requirements specified in the relevant subsection of B.3.

B.2.2.4 Sampling from retains

Up to ten samples shall be collected, covering the length of the specified retain period or six months, whichever is greater, but not to exceed twelve months in the age of material sampled. A portion shall be collected from each retain, and the samples shall be mixed thoroughly to form a composite.

B.2.2.5 Sample for analysis

The sample obtained per Annex B, section B.2.2.1, B.2.2.2, B.2.2.3, or B.2.2.4, shall be mixed thoroughly. This sample shall be poured into two approximately 200 g, airtight, moisture-proof glass containers and sealed. If a glass container is not appropriate, the manufacturer shall recommend a type of sample container. Each sample container shall be clearly labeled with the product name, manufacturer's name, sampling date, production location, and lot number, and shall be signed by the person responsible for sampling.

B.2.3 Gas samples

A representative sample shall be obtained using an appropriate gas-sampling cylinder. The sample shall be acquired in accordance with the manufacturer's specifications and precautions.

B.2.4 Blends and mixtures

Samples collected for analysis shall be verified as being identical to the product initially submitted.

B.3 Preparation of samples

The methods included in this section have been written for trained chemical laboratory personnel. Appropriate quality assurance procedures and safety precautions shall be followed.

B.3.1 General

Acid-washed glassware and equipment, organic-free deionized water for dilutions, trace metals grade acids, and reagent blanks shall be used in all preparation methods referenced in this section.

B.3.1.1 Reagent blank

A reagent blank shall be prepared using the same reagents and in the same manner as a product sample, but no product sample shall be added.

B.3.1.2 Reagent water

All test samples shall be prepared using a reagent water produced through one or more of the following treatment processes: distillation, reverse osmosis, ion exchange, or other equivalent treatment processes. The reagent water shall have the following general water characteristics:

- electrical resistivity, minimum 18 MΩ-cm at 25 °C (77 °F); and
- total organic carbon (TOC) maximum 100 µg/L.

For each specific analyte of interest, the reagent water shall not contain the target analyte at a concentration greater than one-half the designated analytical report limit of that analyte.

B.3.2 Method A

This method shall be used for ammonium sulfate, calcium hypochlorite, copper ethanolamine, copper sulfate, copper triethanolamine, ethylenediaminetetraacetic acid, iodine, potassium tripolyphosphate, sodium acid pyrophosphate, sodium bisulfite, sodium calcium magnesium polyphosphate, sodium chlorate, sodium chlorite, sodium metabisulfite, sodium polyphosphate, sodium silicate, sodium sulfite, sodium trimetaphosphate, sodium tripolyphosphate, sodium zinc polyphosphate, sodium zinc potassium polyphosphate, tetrapotassium pyrophosphate, tetrasodium ethylenediaminetetraacetic acid, tetrasodium pyrophosphate, tripotassium orthophosphate, trisodium orthophosphate, and zinc orthophosphate.

NOTE – For bromate, chlorate and perchlorate analysis of calcium hypochlorite, no preparation of the quenched sample is required. Bromate analysis can be performed on the sample as received.

The following procedure shall be followed for sample preparation to this method:

- a) Dilute the sample to a strength equivalent to 10 times the maximum use dose of the chemical using organic-free deionized water.^{15, 16}

¹⁵ All sample weights are on a dry product mass basis.

Formula:

$$\begin{array}{ccccccc} \text{mg/L} & \times & 10 & \times & \text{required volume of} & = & \text{mg} \\ & & & & \text{sample solution (L)} & & \\ \text{(maximum use} & & \text{(multiple factor)} & & & & \text{(amount sample} \\ \text{dose)} & & & & & & \text{to be weighed)} \end{array}$$

- b) Preserve the sample according to the requirements of Table B1.¹⁷

B.3.3 Method B

This method shall be used for ammonium hexafluorosilicate, ammonium hydroxide, blended phosphates, calcium fluoride, dipotassium orthophosphate, disodium orthophosphate, fluosilicic acid, magnesium silicofluoride, monopotassium orthophosphate, monosodium orthophosphate, potassium fluoride, potassium hydroxide, potassium permanganate, sodium bicarbonate, sodium bisulfate, sodium carbonate, sodium fluoride, sodium hydroxide, sodium hypochlorite, sodium sesquicarbonate, sodium silicofluoride, tricalcium phosphate, zinc chloride, and zinc sulfate.

NOTE – For bromate, chlorate and perchlorate analysis of sodium hypochlorite, no preparation of the quenched sample is required. Bromate, chlorate and perchlorate analysis can be performed on the sample as received.

The following procedure shall be followed for sample preparation to this method:

- a) Dilute the sample to a strength equivalent to 10 times the maximum use dose of the chemical using organic-free deionized water.^{14, 15, 18}

Formula:

$$\begin{array}{ccccccc} \text{mg/L} & \times & 10 & \times & \text{required volume of} & = & \text{mg} \\ & & & & \text{sample solution (L)} & & \\ \text{(maximum} & & \text{(multiple factor)} & & & & \text{(amount sample to be} \\ \text{use dose)} & & & & & & \text{weighed)} \end{array}$$

- b) Acidify with concentrated hydrochloric acid (HCl) to pH < 2.¹⁶
- c) Quantitatively transfer to a volumetric flask of a size corresponding with the required volume of sample solution determined above and dilute to volume with organic-free deionized water.
- d) Preserve the sample according to the requirements of Annex B, Table B1.

¹⁶ Use polyethylene or PTFE beakers for fluoride chemicals.

¹⁷ If the sample does not dissolve completely into solution, heat gently until all sample is in solution. (Do not boil.)

¹⁸ Tricalcium phosphate and other compounds will not dissolve until the addition of hydrochloric acid.

B.3.4 Method C

This method shall be used for calcium carbonate, calcium hydroxide, calcium oxide, magnesium carbonate hydroxide, and magnesium oxide.

The following procedure shall be followed for sample preparation to this method:

- a) Sample pulverization shall be performed as follows:
 - 1) Crush approximately 125 g of sample to pass a No. 100 U.S. Standard Sieve, using a nonmetallic crusher such as an acid-washed glass mortar and pestle.
 - 2) Mix thoroughly and store in an airtight, moisture-proof container.
- b) Pipette 20 mL of organic-free deionized water into 500 mL beaker.
- c) Place the beaker on 60 °C (140 °F) hot plate and add stir bar.
- d) Slowly add 10 times the maximum use dose of the test sample.

Formula:

$$\begin{array}{ccccccc} \text{mg/L} & \times & 10 & \times & \text{required volume of} & = & \text{mg} \\ & & & & \text{sample solution (L)} & & \\ \text{(maximum use} & & \text{(multiple} & & & & \text{(amount sample to} \\ \text{dose)} & & \text{factor)} & & & & \text{be weighed)} \end{array}$$

- e) Mix thoroughly to include all of pulverized sample, making a paste. If the sample spatters, remove from hot plate.
- f) When paste has a smooth, homogeneous consistency, remove from hot plate.
- g) While stirring, slowly add 325 mL of 82 °C (180 °F) organic-free deionized water.
- h) Cool to room temperature.
- i) Filter through GF/C filter under vacuum into 500 mL beaker.
- j) Add 10 mL of 1 M sodium carbonate solution and stir for 5 minutes. Quantitatively transfer this solution into a second filter apparatus and filter again through a GF/C filter.
- k) Using a 3 mL plastic, disposable, pipette, adjust the pH with 1:4 nitric acid (HNO₃) until it remains between 1.8 and 2.0 for 5 min.
- l) Quantitatively transfer to 1000 mL (1 L) volumetric flask and dilute to volume with dilute nitric acid (1:20, HNO₃:water) solution.

B.3.5 Method D

This method shall be used for hydrochloric acid, phosphoric acid, polyphosphoric acid, and sulfuric acid.

The following procedure shall be followed for sample preparation to this method:

- a) Into a 500 mL volumetric flask, add approximately 250 mL of organic-free water.
- b) Slowly, and with agitation, add 5 mL of sample (for liquids) or 5 g of sample (for solids).

- c) Dilute to volume with organic-free deionized water.
- d) Preserve the sample according to the requirements of Annex B, Table B1.

B.3.6 Method E

This method shall be used for ammonia, carbon dioxide, chlorine, oxygen, and sulfur dioxide.

The following procedure shall be followed for sample preparation to this method:

- a) Calculate the amount of sample needed to prepare a dissolved gas sample that has a concentration equivalent to 10 times the maximum use level, or the maximum amount which can be dissolved in water, whichever is smaller.

Formula:

$$\begin{array}{ccccccc} \text{mg/L} & \times & 10 & \times & \text{required volume of} & = & \text{mg} \\ \text{(maximum use} & & \text{(multiple factor)} & & \text{sample solution (L)} & & \text{(amount sample to be} \\ \text{dose)} & & & & & & \text{weighed)} \end{array}$$

- b) Fill a 1000 mL (1 L) gas sampling flask with approximately 1000 mL (1 L) of 4 °C (39 °F) organic-free water.
- c) Weigh the flask, air stone cap assembly, and contents to the nearest 0.01 g. Record weight and tare. If preparing oxygen gas, record the weight of the gas cylinder and contents instead of the flask assembly.
- d) Bubble the product through the air stone cap assembly until the desired weight is obtained. (Caution: perform procedure in a well-ventilated hood.) For oxygen, bubble the gas through the air stone cap assembly for 10 min.
- e) Record the final weight of the flask, assembly and contents to the nearest 0.01g; the increase in weight is equal to the product weight. For oxygen, weigh the final weight of the cylinder; the decrease in weight is equal to the oxygen product weight.
- f) Preserve and store sample in accordance with the analysis test method requirements.¹⁹

B.3.7 Method F

This method is applicable to well-drilling muds and solid swelling well sealants.

- Moisten 25 g of sample using 100 mL reagent water in an appropriately sized beaker.
- Cover with a watch glass and allow to stand 24 h.
- After 24 h, make a solution of 1 g moistened sample per 1 L reagent water.
- Place on a stirring plate until sample is fully dispersed.
- Collect a sample for turbidity analysis prior to addition of Superfloc.²⁰

¹⁹ The method detailed is applicable to analysis of water samples. In some cases, the gas can be analyzed directly as follows:

- chlorine for carbon tetrachloride ASTM E806
- carbon dioxide CGA G-6.2-1985

- f) Add 1.5 mL of 1% SuperFloc® for each liter of sample solution prepared.
- g) Remove from stirring plate and let stand for a minimum of 1 h.
- h) Filter sample under vacuum.
- i) Preserve the filtrate according to the requirements of Annex B, Table B1.

B.3.8 Method G

This method is applicable to the following products: frac sands and backfill materials for cathodic protection or electrical installations.

B.3.8.1 Conditioning

The analysis sample obtained shall be initially prepared according to the manufacturer's written specifications. The product sample shall be allowed to air dry prior to exposure, if needed.

B.3.8.2 Preparation

Samples shall be prepared according to the following procedure:

- a) Following conditioning as described in Annex B, section B.3.8.1, combine the manufacturer's recommended amount or 1250 ± 50 g of sample with 2 L reagent water in a 4 L Erlenmeyer flask.
- b) Seal with PTFE film and agitate for 1 min.
- c) Expose sample for 24 h.
- d) Decant, discard, and replace extractant water.
- e) Expose extractant water 24 h.
- f) Immediately filter and collect analysis samples.
- g) Preserve according to the requirements of Annex B, Table B1.

B.3.9 Method H

This method shall be used for reverse osmosis and distillation process chemicals.

Dry products shall be prepared according to the manufacturer's instructions. No preparation shall be required for liquid products, which shall be analyzed as received.

B.3.10 Method I

This method shall be used for well-drilling foams.

Chemical analyses for contaminants shall be conducted on the liquid product, as received.

²⁰ Cytec Industries, Inc., 5 Garret Mountain Plaza, West Paterson, NJ 07424 <www.cytec.com>.

B.3.11 Method J

This method shall be used for polymers used as well-drilling aids and in reverse osmosis or distillation processes.

Polymers shall be analyzed according to the methods described in Annex B, sections B.4.3.1 through B.4.3.3, as applicable.

B.3.12 Method K

This method shall be used for metal salt coagulants such as alum, ferric chloride, ferrous chloride, ferric sulfate, ferrous sulfate, and polyaluminum chloride.

B.3.12.1 Preparation

For the preparation of coagulant solutions, the amount of product on a dry weight basis shall be determined. To calculate the weight of the material (dry basis) in a coagulant solution, the following procedure shall be followed.

- a) Weigh a clean, dry 100 mL volumetric flask to the nearest 0.01g (Wt A).
- b) Pipette a known volume (20-50 mL) of well-mixed coagulant solution into the flask. (Take care not to touch the ground glass.)
- c) Weigh the flask and contents to the nearest 0.01g (Wt C).
- d) Dilute the solution to volume with DI water. (Take care not to wet the ground glass.) Do not mix.
- e) Weigh the flask and contents to the nearest 0.01g (Wt D).
- f) After weighing, mix the contents thoroughly and transfer into a 125 mL bottle.
- g) Thoroughly rinse the flask with DI water, allow the neck of the flask to dry, then fill the flask to volume with DI water. (Take care not to wet the ground glass.)
- h) Weigh the flask and water to the nearest 0.01g (Wt B).
- i) The weight of the material (dry basis) shall be calculated as follows:
 - $\text{Wt B} - \text{Wt A} = \text{weight of water} = W;$
 - $\text{Wt C} - \text{Wt A} = \text{weight of sample solution} = X;$
 - $\text{Wt D} - \text{Wt C} = \text{weight of water added} = Y;$
 - $\text{Wt D} - \text{Wt B} = \text{weight of material (dry basis) in sample solution} = M;$
 - $W - Y = \text{weight of water equivalent to sample solution} = Z ;$
 - $X/Z = \text{SPG of sample solution; and}$
 - $X - Z = \text{weight of material (dry basis) in sample solution} = M.$

NOTE – If the material is alum, to account for waters of hydration:

- $M = \text{Wt of } \text{Al}_2(\text{SO}_4)_3; \text{ and}$
- $M \times 1.7372 = \text{Wt of } (\text{Al}_2(\text{SO}_4)_3 \cdot 14 \text{ H}_2\text{O}).$

For other metal salt coagulants with waters of hydration, similar calculations shall be made.

If the test material is provided as a dry product:

- a) Weigh 10 times the maximum use dose of the chemical in an acid-washed 1 L volumetric flask.
- b) Dilute to volume with deionized distilled water, or follow manufacturer's instructions for dissolving the material and then dilute to volume.

NOTE – Contaminants of interest can be determined on the base (unflocked) material. If the level of contaminants in the base material meets the requirements of this Standard (i.e., \leq SPAC), then no analyses need be performed for the flocked material. If the SPAC is exceeded, then the flocked supernatant may be analyzed and the contaminant levels compared to the appropriate SPACs.

B.3.12.2 Analysis of chemical before flocking

For analysis of the base material, the base material shall be prepared as described below.

- a) Pipette an aliquot of the solution into a 250 mL griffin beaker and add DI water to 100 mL.
- b) Carefully add 2 mL of 30% H_2O_2 and 1 mL of concentrated nitric acid to the solution in the beaker.
- c) Heat for 1 h at 95 °C (203 °F), or until the volume is slightly less than 50 mL.
- d) Cool to ambient temperature and quantitatively transfer the solution into a 100 mL volumetric flask. Dilute the volume with DI water and mix thoroughly.

B.3.12.3 Analysis of solution after flocking

For analysis of the flocked material, the following preparation steps shall be followed.

- a) The volume of solution to give the equivalent of 10 times the evaluation dose shall be calculated by the following equation:

$$\left[\frac{\text{mg}}{\text{L}} \times 10 \times 1 \text{ L} \right] \div \left[\text{gm} \div 100 \text{ mL} \times \frac{1000 \text{ mg}}{\text{gm}} \right] = \text{mL}$$

(evaluation dose) (multiple factor) (dry wt. sample in solution)

- b) Pipette the calculated aliquot into a 1 L volumetric flask and dilute to volume with DI water.
- c) Transfer a 100 mL aliquot into a 200 mL beaker.
- d) Add 0.1 M NaOH with constant stirring until the desired pH is reached and the pH holds for 1 min.
- e) Allow the mixture to stand undisturbed for at least 1 h.

- f) Filter through GF/C (or equivalent) filter with the aid of vacuum.
- g) Preserve the sample according to the requirements of Annex B, Table B1.

B.3.13 Method Z

This method shall be used for tracer dyes.

- a) Preheat a sufficient volume of organic-free deionized water to 82 °C (180 °F).
- b) Use a graduated cylinder to measure 950 mL of the hot water and transfer into a beaker with a stir bar.
- c) Weigh a quantity of the tracer dye equivalent to 10 times the maximum use dose when diluted to 1 L. Transfer dye to the beaker of hot water with stirring.
- d) Cool to room temperature.
- e) Transfer solution to a 1 L (0.26 gal) volumetric flask and dilute to volume with room temperature organic-free deionized water.

B.4 Analysis methods

B.4.1 General

This section is divided into three parts: inorganics (metals and others), organics, and radionuclides.

B.4.2 Inorganics

B.4.2.1 Metals

Analyses for metals shall be performed in accordance with currently accepted USEPA methods (see 40 CFR Part 141), except as otherwise provided for herein. When no USEPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition).

If neither of these references includes the required method, a method from another recognized source shall be allowed, and the method cited and validated. If no recognized method is available, a method shall be developed, provided the method is fully documented and validated, including all appropriate quality assurance procedures. The method used to determine the contaminant level shall have an analytical concentration range, such that the report limit is no greater than 50% of the lowest contaminant concentration being sought. Quality control standards shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times the target limit.

B.4.2.2 Nonmetallic inorganics

Analyses for inorganics (other than metals) shall be performed in accordance with currently accepted USEPA methods (see 40 CFR Part 141), except as otherwise provided for herein. When no USEPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition).

If neither of these references includes the required method, a method from another recognized source shall be allowed, and the method cited and validated. If no recognized method is available, a method shall be developed, provided the method is fully documented and validated, including all appropriate quality assurance procedures. The method used to determine the contaminant level shall have an analytical concentration range, such that the report limit is no greater than 50% of the lowest contaminant

concentration being sought. Quality control standards shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times the target limit.

B.4.2.2.1 Oxyhalides in hypochlorite

The analysis of bromate, chlorate and perchlorate shall be performed in accordance with B.4.2.2. Selection of the method shall take into consideration the type of quenching agent used in order to minimize interference.

Spiked samples shall be processed with each analytical batch or every 10 samples, whichever is the greater number. A spiked sample shall be prepared for each hypochlorite type. The percent recovery of spiked samples shall be within 80%-120%. Matrix spikes shall be performed in duplicate. The matrix spike, matrix spike duplicate shall have a calculated Relative Percent Difference of $\leq 20\%$.

If the analytical methodology performed employs an Internal Standard or Surrogate, the % recovery criteria for either quality control compound shall be within 70%-130%, or if outside that range, a sample spike performed and demonstrated a percent recovery of 80%-120% obtained. For analytical methodologies not employing an Internal Standard or Surrogate, spiked samples shall be processed with each analytical batch or every 5 samples, whichever is the greater number.

Blank samples shall be prepared using the same reagents and quantities used in the sample preparation, placed in vessels of the same type, and processed with the samples.

B.4.2.2.2 Bromide in sodium chloride

The analysis of bromide in sodium chloride shall be performed in accordance with B.4.2.2.

Spiked samples shall be processed with each analytical batch or every 10 samples, whichever is the greater number. A spiked sample shall be prepared for each batch. The percent recovery of spiked samples shall be within 80%-120%. Matrix spikes shall be performed in duplicate. The matrix spike, matrix spike duplicate shall have a calculated Relative Percent Difference of $< 20\%$.

If the analytical methodology performed employs an Internal Standard or Surrogate, the % recovery criteria for either quality control compound shall be within 70%-130%, or if outside that range, a sample spike performed and demonstrated a percent recovery of 80%-120% obtained. Blank (Control) samples shall be prepared using the same reagents and quantities used in the sample preparation, placed in vessels of the same type, and processed with the samples.

B.4.3 Organics

Analyses for organics shall be performed in accordance with currently accepted USEPA methods (see 40 CFR Part 141), except as otherwise provided for herein. When no USEPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition).

If neither of these references includes the required method, a method from another recognized source shall be allowed, and the method cited and validated. If no recognized method is available, a method shall be developed, provided the method is fully documented and validated, including all appropriate quality assurance procedures. The method used to determine the contaminant level shall have an analytical concentration range, such that the report limit is no greater than 50% of the lowest contaminant concentration being sought. Quality control standards shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times the target limit.

B.4.3.1 Epichlorohydrin-dimethylamine copolymer (EPI-DMA)**B.4.3.1.1 General**

Sample analysis shall be by gas chromatography with flame ionization detection (FID). An internal standard comprised of 100 µg/mL 1,3-dichloroacetone in 1:1 methylene chloride/isopropanol shall be used. Alternate methods shall be allowed to be used but shall be validated.

B.4.3.1.2 Apparatus

The following apparatus shall be used in this analysis:

- gas chromatograph, equipped with a split/splitless capillary injection port and a flame ionization detector;
- capillary column: 30 m x 0.53 mm DB-Wax, 1.0 µ film thickness;
- analytical balance, 0.1 mg accuracy;
- syringe, GC - 10 µL;
- Pasteur pipettes;
- 40 mL glass vials with polytetrafluoroethylene (PTFE) faced septa;
- 2 mL GC glass vials with PTFE-faced septa;
- 10 mL volumetric flasks;
- 0.45 µm syringe filters; and
- 10 mL disposable syringe.

B.4.3.1.3 Reagents

The following reagents shall be used in this analysis:

- epichlorohydrin, 99+% (EPI);
- 1,3-dichloro-2-propanol, 98% (DCIP);
- 1,2-dichloro-3-propanol;
- glycidol;
- 1,3-dichloroacetone (internal standard);
- 2-propanol (IPA); and
- methylene chloride.

B.4.3.1.4 Procedure**B.4.3.1.4.1 Preparation of solutions**

The following standards and solutions shall be prepared.

- a) Prepare a stock solution of each compound of interest by weighing approximately 0.1 g of the neat material into a 10 mL volumetric flask, and dilute to volume with methylene chloride.
- b) Prepare an internal standard stock solution by weighing 0.1 g 1,3-dichloroacetone into a 10 mL volumetric flask, and dilute to volume with methylene chloride.

- c) Prepare a dilution standard at 1000 µg/mL by adding the appropriate volumes of each stock standard to a 10 mL volumetric flask containing methylene chloride/isopropanol (1:1). Add an appropriate volume of the internal standard stock solution to give a 1,3-dichloroacetone concentration of 100 µg/mL and dilute to mark.
- d) Prepare an extracting solution by weighing 0.0500 g of 1,3-dichloroacetone into a 500 mL volumetric flask and add 250 mL methylene chloride to dissolve. Dilute to mark with isopropanol. The resulting solution shall be used to prepare calibration standards and as the extracting solution for the polymer products.
- e) Prepare five calibration standards at concentrations of 5.0, 10, 25, 50, and 200 µg/mL by serial dilution of the 1000 µg/mL dilution standard using the extracting solution.

B.4.3.1.4.2 Extraction of samples

Polymer samples shall be extracted as follows.

- a) Add 5.0 mL of extracting solution to 10.0 g of polymer in a 40 mL glass vial.
- b) Mix the solution on a wrist action shaker for 1 h.
- c) Allow the two layers to separate.
- d) Use a Pasteur pipette to transfer approximately 2 mL of extract to a syringe fitted with a filter.
- e) Filter the extract prior to injection onto the instrument (extract should be free of any polymer droplets).

NOTE – Analyze the extract within 8 h of extraction since aged extracts are unstable and will not produce accurate results.

B.4.3.1.4.3 Instrument conditions

The polymer extract shall be analyzed under the following conditions:

- oven temperature - multiple ramp:
 - a) 40 to 125 °C (104 to 257 °F) at 20 °C (36 °F)/min; initial hold – 5.0 min; final hold - 2.5 min;
 - b) 125 to 150 °C (257 to 302 °F) at 20 °C (36 °F)/min; final hold – 2.0 min; and
 - c) 150 to 175 °C (302 to 347 °F) at 20 °C (36 °F)/min; final hold – 10.0 min.
- injector temperature: 235 °C (455 °F);
- detector temperature: 300 °C (572 °F);
- injection volume: 3.0 µL;
- column head pressure: 5 psi; and
- injection port - splitless mode, purge valve on at 0.5 min.

B.4.3.1.5 Calculations

A linear regression of the five calibration standards shall be used to calculate the concentration of each analyte in the sample extract (in µg/mL). The following equation shall be used to calculate the concentration of the analyte in the polymer sample:

$$\text{curve concentration (}\mu\text{g/mL)} \times \frac{5.0 \text{ mL}}{10 \text{ g polymer sample}} = \frac{\mu\text{g analyte}}{\text{g polymer sample}}$$

B.4.3.2 Acrylamide monomer in polyacrylamide

Acrylamide monomer shall be determined using the method described in "Determination of acrylamide monomer in polyacrylamide and in environmental samples by high performance liquid chromatography," *Analytical Chemistry* 50: 1959 (1978). Alternate methods shall be allowed to be used but shall be validated.

B.4.3.3 Dimethyldiallylammonium chloride monomer in polyDADMAC**B.4.3.3.1 General**

Sample analysis shall be by high performance liquid chromatography (HPLC) with ultraviolet (UV) detection. Alternate methods shall be allowed to be used but shall be validated.

B.4.3.3.2 Apparatus

The following apparatus shall be used in this analysis:

- high performance liquid chromatograph equipped with UV detector;
- column: 250 x 4.6 mm Alltima C18, 5µ (Alltech catalog #88054 or equivalent);
- analytical balance, 0.1 mg accuracy;
- syringe, HPLC - 20 µL;
- 10 mL volumetric flasks; and
- 0.45 µm syringe filters.

B.4.3.3.3 Reagents

The following reagents shall be used in this analysis:

- 1-octane sulfonic acid, Na salt;
- tetramethylammonium hydroxide;
- o-phosphoric acid;
- n-butanol;
- acetonitrile; and
- diallyldimethylammonium chloride monomer (mDADMAC).

B.4.3.3.4 Procedure**B.4.3.3.4.1 Preparation of mobile phase**

A mobile phase solution shall be prepared by adding the following to 900 mL of HPLC grade water:

- 1.08 g of 1-octane sulfonic acid, Na salt;
- 5.0 mL of 1.0 M tetramethylammonium hydroxide;
- 100 mL acetonitrile; and
- 25 mL of n-butanol.

The pH of the solution shall be adjusted to 3.0 by adding o-phosphoric acid.

B.4.3.3.4.2 Analysis solution

An analysis solution shall be prepared as follows:

- a) Dissolve a 2.0 g aliquot of the polyDADMAC sample in 10 mL of deionized water.
- b) Filter approximately 2 mL of this solution through a 0.45 µm syringe filter.
- c) Dilute 1.0 mL of the filtrate to 10 mL with mobile phase solution.

B.4.3.3.4.3 Calibration standards

Four calibration standards shall be prepared at concentrations of 20, 50, 200, and 500 µg/mL by serial dilution of the m-DADMAC stock standard using the mobile phase solution.

B.4.3.3.4.4 Instrument conditions

The analysis solution containing the polymer sample shall be analyzed under the following conditions:

- column temperature: ambient;
- column flow: 2.0 mL/min;
- injection volume: 20 µL;
- detector: UV at 200 nm; and
- retention time of mDADMAC = 6.5 min.

B.4.3.3.5 Calculations

A linear regression of the four calibration standards shall be used to calculate the concentration of each analyte in the sample extract (in µg/mL). The following equation shall be used to calculate the concentration of the analyte in the polymer sample:

$$\text{curve concentration } (\mu\text{g/mL}) \times \frac{10.0 \text{ mL}}{2 \text{ g polymer sample}} \times 10 = \frac{\mu\text{g analyte}}{\text{g polymer sample}}$$

B.4.3.4. Dimethylamine in polyDADMAC and Epichlorohydrin/dimethylamine polymers

B.4.3.4.1 General

This procedure shall be used for the analysis of Dimethylamine in polyDADMAC and Epichlorohydrin/dimethylamine polymers. Alternate methods shall be allowed to be used but shall be validated.

B.4.3.4.2. Apparatus

The following apparatus shall be used in this analysis:

- gas chromatograph with electron capture detector and autosampler;
- 100% dimethyl siloxane .32mm x 30M, 1.0µ film capillary column;
- hot plate;
- disposable pipets;
- syringes –various sizes;
- 40 ml VOA vials; and
- appropriately sized volumetric flasks

B.4.3.4.3 Reagents

The following reagents shall be used in this analysis:

- toluene;
- dimethylamine(40% wt);
- hexachlorobenzene(100 ug/ml);
- 2,4-dinitrofluorobenzene;
- sodium hydroxide;
- sodium tetraborate; and
- 1,4-dioxane.

B.4.3.4.4 Analytical procedure**B.4.3.4.4.1 Preparation of reagent solutions**

- a) Prepare a 2.0N solution of NaOH by adding 8 g of NaOH into 100ml of deionized water.
- b) Prepare a 2.5% sodium tetraborate solution by adding 2.5g of sodium tetraborate into 100ml of deionized water.
- c) Prepare 2,4-dinitrofluorobenzene derivatizing solution by adding .625 g of 2,4-dinitrofluorobenzene into 25ml of 1,4-dioxane.
- d) Prepare a stock standard solution at 1000 ug/ml by weighing out approximately 25 mg of dimethylamine (40% w/w) into 10ml of deionized water.
- e) Prepare a dilution standard at 100 ug/ml by adding 1 ml of stock standard solution to 10 ml of deionized water.
- f) Prepare four calibration standards at concentrations of 10, 50, 200, 500 ug/L by serial dilution of the 100 ug/ml dilution standard into deionized water.

B.4.3.4.4.2 Preparation of calibration standards and samples

- a) Add 10 ml of each calibration standard to a 40 ml VOA vial
- b) For each sample add 0.5g of sample to 100 ml of deionized water. Cap and shake for 30 min. Add 1ml of sample and 9ml of deionized water to a 40 ml VOA vial.
- c) For each QC, MS (Matrix Spike) and MSD (Matrix Spike Duplicate), add 0.5 g of sample to 100ml of deionized water. Spike at 50 mg/Kg or level equivalent to that found in sample. Cap and shake for 30 min. Add 1ml of each QC sample and 9ml of deionized water to a 40 ml VOA vial.

B.4.3.4.4.3 Derivatization and extraction of standards and sample the vials

- a) To each standard and sample add 5.0 ml of 2.5% sodium tetraborate and 1.0 ml of the 2,4-dinitrofluorobenzene solution.
- b) Cap the vials and place them in a 60° C water bath for 20 min.
- c) Remove the vials and add 2.0 ml of 2.0 N sodium hydroxide.
- d) Return the vials to the water bath for 30 min.
- e) Place the vials in an ice bath until they reach room temperature.

- f) To each vial add 5.0 ml of toluene.
- g) Cap the vials and shake for 2 min.
- h) Allow the samples to set for approximately 5 min.
- i) Transfer 1.0 ml of toluene layer into 1.8ml autosampler vial.
- j) Add 10 uL of hexachlorobenzene into each vial and cap the vial.

B.4.3.4.4 Run conditions

- a) Set up the GC with the GC column.
- b) Set the GC with the following temperature program:

initial temperature	150° C
final temperature	220° C
rate	4° C/min
initial time	1 min
final time	10 min
injector temperature	235° C
detector temperature	300° C
signal range	1

B.4.3.4.5 Calculations

A linear regression of the four standards is to be used to calculate the concentration in each sample extract. The following equation shall be used to calculate the concentration of dimethylamine in the polymer sample:

$$\frac{\text{curve concentration } (\mu\text{g/L}) \times (1\text{L}/1000\text{ ml}) \times 100\text{ ml} \times 10}{0.5\text{ g polymer sample}} = \frac{\mu\text{g dimethylamine}}{\text{g polymer sample}}$$

B.4.4 Radionuclides

Analyses for radionuclides shall be performed in accordance with *Prescribed Procedures for Measurement of Radioactivity in Drinking Water*, EPA-600/4-80-032, except as otherwise provided for herein. When no USEPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition).

If neither of these references includes the required method, a method from another recognized source shall be allowed, and the method cited and validated. If no recognized method is available, a method shall be developed, provided the method is fully documented, including all appropriate quality assurance procedures. The method used to determine the contaminant level shall have an analytical concentration range, such that the report limit is no greater than 50% of the lowest contaminant concentration being sought. Quality control standards shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times the target limit.

B.5 Estimated contaminant exposure concentration

To estimate the exposure concentration of a contaminant in the finished drinking water, the following calculations shall be used. These calculations adjust the contaminant concentrations measured in the laboratory preparation solution to the evaluation or maximum dose. The resulting value is compared to the SPAC, as determined in Annex A.

$$\frac{\text{mg contaminant}}{\text{L solution}} \times \frac{\text{L analysis solution}}{\text{g product}} \times \frac{\text{g}}{1000 \text{ mg}} \times \frac{\text{mg product}}{\text{L drinking water}} \times \frac{1000 \text{ } \mu\text{g}}{1 \text{ mg}} = \frac{\text{ } \mu\text{g contaminant}}{\text{L drinking water}}$$

(analysis concentration) (lab prep solution) (evaluation dose) $\mu\text{g/L} = \text{ppb}$

Table B1 – Preservation of prepared sample solutions

Contaminant	Preservative	Container	Storage
herbicides/ pesticides	none	amber glass with PTFE cap	4 °C (39 °F)
Metals	1.25 mL HNO ₃ per 125 mL of sample	HDPE plastic	room temperature
organics	none	amber glass with PTFE cap	4 °C (39 °F)
radionuclides	10 mL HNO ₃ per 1L of sample	HDPE plastic	room temperature
VOCs	4 drops 50% HCl per 160 mL of sample	glass vial with PTFE cap	4 °C (39 °F)

Annex C (normative)

Evaluation of microbiological growth potential

C.1 Background

This annex contains the protocol for determining a product's potential to support microbiological growth. The protocol presented in this section is a modification of American Society for Testing and Materials (ASTM) Standard G22-76, *Standard Practice for Determining Resistance of Plastics to Bacteria*. The protocol involves exposing a product to nutrient salts agar (lacking a carbon source for microbial growth support) inoculated with a standard suspension of *Pseudomonas aeruginosa*. Following one week of incubation, bacterial growth is visually assessed. This test is a qualitative assessment of microbiological growth support propensity.

C.2 Products covered

This method is applicable to all products used in well applications which are required to be evaluated for the potential to support microbial growth per Section 8.3.1 such as well-drilling aids, muds, and grouts. Products shall be prepared according to manufacturer's instruction.

C.3 Inoculum

C.3.1 Test organism

P. aeruginosa, American Type Culture Collection (ATCC) #13388,²¹ maintained on nutrient agar slants, shall be used as the test organism. The inoculum shall be prepared from not fewer than 2 successive transfers in nutrient broth. Following passage of the bacterial suspension, the broth culture shall be centrifuged, decanted, and resuspended in sterile saline (0.8% NaCl) solution. The bacterial cell concentration shall be determined. The viability of the culture shall be determined prior to initiation of the test.

C.3.2 Agar seeding

The following procedure shall be used to seed the agar:

- a) Melt sufficient sterile nutrient salts agar and cool to approximately 45 °C (113 °F).
- b) Pipette into the melted and cooled agar a sufficient volume of bacterial cell suspension to yield an approximate concentration of 50,000 viable cells/mL agar.
- c) Pour sufficient seeded agar into suitable sterile dishes to provide an agar layer 0.5 in (13 mm) thick. Allow the agar to harden.
- d) Using a sterile standard gel cutter, cut and remove a plug of agar, approximately 1.2 in (30 mm) in diameter, leaving a well in the center of the agar plate.

²¹ American Type Culture Collection, P.O. Box 1549, Manassas, VA 20108 <www.atcc.org>.

C.3.3 Uninoculated controls

Uninoculated control specimens shall be prepared as described in Annex C, section C.3.2 using uninoculated nutrient salts agar.

C.4 Product exposure

The product exposure shall be performed using the following procedure:

- a) Fill the central well in the agar with the product, prepared according to manufacturer's instructions. Care shall be taken to assure contact of the product with the agar on all sides of the well; and
- b) Cover and incubate the culture dishes at 35 to 37 °C (95 to 99 °F) and not less than 85% relative humidity for a minimum of 7 d. Covered dishes containing nutrient salts agar shall be considered to have the desired humidity.

NOTE – Covers on large dishes may be sealed with masking tape.

C.5 Evaluation

Samples shall be considered to support microbiological growth if, following the 7-d incubation period, a zone of microbial growth surrounding the central well in the agar can be visually determined. Samples determined to support microbial growth shall undergo the confirmatory testing protocol in C.6.

NOTE – Well products are required to be evaluated against Annex C of Standard 60 for a qualitative assessment of their propensity to support microbial growth. The current method in Annex C may give false positive results due to interactions or interferences between certain product formulation constituents and the test medium, which may result in changes to the agar that can be interpreted to represent microbial growth. Therefore, the test method in C.6 is required for validating positive results.

C.6 Confirmatory microbial growth testing protocol

C.6.1 Equipment autoclave

- incubator, 36 ± 1°C
- centrifuge
- water bath, 45 ± 1°C
- pH meter
- analytical balance
- Quebec colony counter
- rotary shaker

C.6.2 Supplies

- Culture - *P. aeruginosa*, ATCC #13388,²⁰ obtain from ATCC, rehydrate with nutrient broth and maintain on nutrient agar slants;
- Glassware, 1 and 10 mL disposable pipettes; 20 x 150 mm culture tubes;
- 500 mL screw-cap flask;
- Racks, any convenient style to hold 20 x 150 mm tubes;

- 500 mL sterile Erlenmeyer flasks;
- 250 mL sterile Erlenmeyer flasks;
- Petri dishes, 100 x 15 mm standard petri dishes;
- Sterile centrifuge tubes;
- Metal caps, size 20 for culture tubes;
- Culture media;
- Nutrient agar/broth. Rehydrate per manufacturer's recommendation. Dispense 10 mL portions into test tubes. Autoclave for 15 min at 121°C and slant agar tubes with a slope approximately 6.3 cm long;
- Nutrient-salts media (for Experimental group and Negative Control group). Prepare this medium by dissolving in 1 L of water the designated amounts of the following reagents: (a commercially available substitute may be chosen), autoclave for 20 min at 121°C;

potassium dihydrogen orthophosphate (KH_2PO_4)	0.7 g
potassium monohydrogen orthophosphate (K_2HPO_4)	0.7 g
magnesium sulfate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$)	0.7 g
ammonium nitrate (NH_4NO_3)	1.0 g
sodium chloride (NaCl)	0.005 g
ferrous sulfate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$)	0.002 g
zinc sulfate ($\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$)	0.002 g
manganese sulfate ($\text{MnSO}_4 \cdot \text{H}_2\text{O}$)	0.001 g
distilled water	1000 mL

- Nutrient-salts media (for Positive Control group). Prepare this medium by dissolving in 1 L of water the designated amounts of the following reagents: (a commercially available substitute may be chosen), autoclave for 20 min at 121°C;

potassium dihydrogen orthophosphate (KH_2PO_4)	0.7 g
potassium monohydrogen orthophosphate (K_2HPO_4)	0.7 g
magnesium sulfate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$)	0.7 g
ammonium nitrate (NH_4NO_3)	1.0 g
sodium chloride (NaCl)	0.005 g
ferrous sulfate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$)	0.002 g
zinc sulfate ($\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$)	0.002 g
manganese sulfate ($\text{MnSO}_4 \cdot \text{H}_2\text{O}$)	0.001 g
Glucose	5.0 g
distilled water	1000 mL

- Standard Plate Count Agar. Rehydrate per manufacturer's recommendation. Autoclave for 15 min at 121 °C;

- Pseudomonas Isolation Agar (PIA): Rehydrate per manufacturer's recommendation. Autoclave for 15 min at 121 °C;
- Phosphate Buffer Dilution Water (PBDW); and
- Saline solution, 0.8% NaCl.

C.6.3 Analytical Procedure

C.6.3.1 Preparation of test inoculum

- a) Inoculate a tube of nutrient broth from stock culture and incubate at $35^{\circ} \pm 1^{\circ}\text{C}$ for 24 ± 2 h.
- b) Before testing make at least two successive daily transfers in nutrient broth.
- c) Following passage of the bacterial suspension, centrifuge the broth culture decant and resuspend the bacteria in sterile saline (0.8% NaCl) solution. Repeat the centrifugation and washing steps for a total of three events.
- d) Determine the bacterial cell concentration using viable staining and epifluorescence microscopy. The density may also be evaluated using pour plating with Standard Plate Count Agar.

C.6.3.2 Preparation of flasks for growth evaluation

C.6.3.2.1 Experimental group – Client's product amended to minimal growth medium

- a) Cool the Experimental/Negative Control Nutrient Salts Media A to $45^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- b) Aseptically transfer 300 mL of the Experimental/Negative Control Nutrient Salts Media into three sterile 500 mL Erlenmeyer flasks, so that a total of 900 mL of media will be utilized. Label flasks appropriately.
- c) Pipette into cooled media a volume of bacterial cell suspension sufficient to yield a concentration of about 5.0×10^4 viable cells/mL of media.
- d) Aseptically transfer 3 g or 3 mL (1%) of the client's product to each of the flasks after they have been prepared in accordance with manufacturer's instructions in C.2.
- e) Place flasks on rotary shaker set at 150 rpm.
- f) Incubate at $35^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 7 d while shaking.

C.6.3.2.2 Negative control group

- a) Aseptically transfer 300 mL of each Experimental/Negative Control Nutrient Salts Media into three separate sterile 500 mL Erlenmeyer flask. Label flasks appropriately.
- b) Pipette into cooled media a volume of bacterial cell suspension sufficient to yield a concentration of about 5.0×10^4 viable cells/mL of media.
- c) Place flasks on rotary shaker set at 150 rpm. Incubate at $35 \pm 1^{\circ}\text{C}$ for 7 d while shaking.

C.6.3.2.3 Positive Control group

- a) Aseptically transfer 300 mL of the Positive Control Nutrient Salts Media into 3 separate sterile 500 mL Erlenmeyer flask. Label flasks appropriately.
- b) Pipette into cooled media a volume of bacterial cell suspension sufficient to yield a concentration of about 5.0×10^4 viable cells/mL of media.
- c) Place flasks on rotary shaker set at 150 rpm. Incubate at $35 \pm 1^\circ\text{C}$ for 7 d while shaking.

C.6.4 Evaluation

C.6.4.1 Bacterial growth analysis will be performed using the pour plate methodology (Standard Methods for the Examination of Water and Wastewater, 20th Edition) with PIA serving as the growth medium.

C.6.4.2 Day 0, 1, 3, 5, 7

- Remove 1 mL from each of the experimental and control flasks. This 1 mL aliquot will be used for initial density determination.
- Perform serial dilutions in PBDW from 10^0 through 10^{-6} .
- Pour plate the dilutions in duplicate in molten PIA ($45 \pm 1^\circ\text{C}$) and incubate the plates for 24 h at $35 \pm 1^\circ\text{C}$.
- Enumerate total number of colonies for each media type.
- *P. aeruginosa* should exhibit a blue green coloration.

C.6.5 Acceptance criteria

C.6.5.1 The geometric mean of the daily individual samples will be calculated for the experimental group, the negative control group and the positive control group.

C.6.5.2 The geometric means will be converted to \log_{10} .

C.6.5.3 For each sampling day, the experimental group's \log_{10} value will be compared to the negative control group's \log_{10} value. The data obtained from each sampling day will be evaluated via a Two-tailed Student's T-Test. A 95% CI will be implemented. The statistical analyses will be run to detect any significant differences between the product group and negative control group

C.6.5.4 If the statistical analysis reveals a p value of < 0.05 , the product shall be considered as a FAIL.

C.6.5.5 To be considered a PASS, the difference between the product and negative control shall not be significant according to the Student's T-Test ($p \geq 0.05$).

C.6.5.6 The positive control group shall also display a p value of < 0.05 when compared to the negative control group for this testing to be considered valid.

C.6.5.7 Media sterility control**C.6.5.7.1 Negative controls**

For each medium, an uninoculated plate shall be incubated concurrently with each day's processed samples.

C.6.5.7.2 Positive controls

For each medium, check analytical procedures by inoculating with known positive control cultures. Use *P. aeruginosa* ATCC# 13388.²⁰ The plates shall be incubated concurrently with each day's processed samples.

NOT FOR
DISTRIBUTION
OR SALE

Annex D

(normative)

Normative drinking water criteria

D.1 General

The drinking water criteria in this annex shall be used as normative evaluation criteria for the determination of product compliance with the health effects requirements of this Standard. The values in these tables include the consensus USEPA and Health Canada drinking water criteria for contaminants evaluated by these two agencies. They also include criteria for non-regulated contaminants that have been developed according to the toxicity data requirements of Annex A, and that have been externally peer reviewed. Non-regulatory USEPA guidance values that have been reviewed and found to satisfy Annex A toxicity data requirements are also included, as well as chemicals that have been evaluated using the threshold of evaluation approach.

The drinking water criteria in this annex have not been evaluated for taste and odor considerations at the concentration limits indicated.

The substances listed in Tables D1, D2, D3, and D4 are not intended to encompass all of the potential analytes of interest that need to be considered when evaluating products to the requirements of this Standard. The user is cautioned that each product may have formulation dependent analytes of interest for which acceptable concentration limits have not been determined. In these cases, the user is required to develop acceptable concentration limits based on the requirements of Annex A of NSF/ANSI 60 in order to determine full compliance with the Standard.

These tables are specific to NSF/ANSI 60. While the tables may be used for evaluation of impurities in drinking water system components, the substances listed in these tables may not have been evaluated for use as indirect drinking water additives under NSF/ANSI 61. Use as indirect drinking water additives may require the consideration of different exposure parameters than those used for NSF/ANSI 60 evaluation.

D.2 USEPA and Health Canada drinking water criteria

Table D1 contains drinking water criteria for contaminants regulated by the USEPA and established by Health Canada. Values for each contaminant have been agreed upon by representatives of both agencies for the purpose of evaluating products against the health effects requirements of NSF/ANSI 60. For each substance, the values in the table represent a consensus decision regarding the selection of the most appropriate assessment upon which to base NSF/ANSI 60 evaluation.

At the time of publication, the indicated values were valid. These values are subject to change, however, and the user is encouraged to contact USEPA or Health Canada for the most current values. Some of these values have been developed using a linear multistage model to predict theoretical excess carcinogenic risk at low exposure concentrations. Where the database is sufficient and the compound mode of action can be determined, the USEPA is replacing the default linear multistage model with either a biologically based cell kinetic multistage model or a margin of exposure analysis. Cancer potency (q1*) values developed using the linear multistage model may be reevaluated in the future.

D.3 NSF International peer-reviewed drinking water criteria

Table D2 contains drinking water criteria for unregulated substances for which NSF International has determined Total Allowable Concentrations (TAC) and Single Product Allowable Concentrations (SPAC) in accordance with Annex A of this Standard. These criteria have been externally peer reviewed.

At the time of publication, the indicated values were valid. These values are subject to change, however, and the user is encouraged to contact NSF International for the most current values.

D.4 Drinking water criteria based on USEPA guidance concentrations

Table D3 contains drinking water criteria for unregulated contaminants for which the acceptable drinking water concentrations are based on USEPA guidance values, including those in the USEPA Health Advisory and Integrated Risk Information System (IRIS) databases. A relative source contribution factor has been applied to calculation of the drinking water criteria when a relative source contribution factor was not applied as part of the USEPA risk assessment. In the absence of sufficient information to determine a data-derived relative source contribution factor, a default 20% drinking water contribution is assumed.

At the time of publication, the indicated values were valid. These values are subject to change, however, and the user is encouraged to contact USEPA for the most current values. Some of these values have been developed using a linear multistage model to predict risk at low exposure concentrations and may be reevaluated in the future.

D.5 Threshold of evaluation (TOE) chemical list

Table D4 contains the list of chemicals that have been evaluated under the threshold of evaluation, due to the lack of the minimum data to determine chemical specific concentrations in accordance with the requirements of Annex A (see Annex A, section A.7.1). Qualification to the threshold of evaluation category includes a comprehensive literature search for the particular substance and consideration of structure-activity relationships.

**Table D1 – U.S. Environmental Protection Agency and Health Canada
NSF/ANSI 60 drinking water criteria**

Contaminant (reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
acrylamide (as a monomer in drinking water treatment polymers) (40 CFR §141.111, §141.110)	TT ² (0.05% dosed at 1 ppm, or equivalent)	TT ² (0.05% dosed at 1 ppm, or equivalent)
alachlor (40 CFR §141.60, §141.61)	0.002	0.0002
aldicarb aldicarb sulphone aldicarb sulfoxide (40 CFR §141.60, §141.61)	0.007	0.0007
aldrin / dieldrin issue date: 10/94	0.0007	0.00007
atrazine issue date: 04/93	0.003	0.0003
atrazine and metabolites issue date: 04/93	0.005	0.0005
azinphos-methyl issue date: 02/86	0.02	0.002
bendiocarb issue date: 02/86	0.04	0.004
benzene (40 CFR §141.60, §141.61)	0.005	0.0005
benzo(a)pyrene (PAH) (40 CFR §141.60, §141.61)	0.0002	0.00002
bromodichloromethane – see trihalomethanes (total)	N/A	N/A
bromoform – see trihalomethanes (total)	N/A	N/A
bromoxynil issue date: 03/87	0.005	0.0005
carbaryl issue date: 02/86	0.09	0.009
carbofuran (40 CFR §141.60, §141.61)	0.04	0.004
carbon tetrachloride (40 CFR §141.60, §141.61)	0.005	0.0005
chlordane (40 CFR §141.60, §141.61)	0.002	0.0002
chlorodibromomethane see trihalomethanes (total)	N/A	N/A
chloroform see trihalomethanes (total)	N/A	N/A
chlorpyrifos issue date: 02/86	0.09	0.009
cyanazine issue date: 02/86	0.01	0.001

**Table D1 – U.S. Environmental Protection Agency and Health Canada
NSF/ANSI 60 drinking water criteria**

Contaminant (reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
cyanobacterial toxin (microcystin-LR) issue date: 04/02	0.0015	0.00015
2,4-D (40 CFR §141.60, §141.61)	0.07	0.007
dalapon (40 CFR §141.60, §141.61)	0.2	0.02
diazinon issue date: 02/86	0.02	0.002
dibromo-3-chloropropane (1,2-) (40 CFR §141.60, §141.61)	0.0002	0.00002
dicamba issue date: 03/87	0.12	0.012
dichlorobenzene o- (40 CFR §141.60, §141.61)	0.6	0.06
dichlorobenzene m- (see o-dichlorobenzene)	0.6	0.06
dichlorobenzene p- (40 CFR §141.60, §141.61)	0.075	0.0075
dichloroethane (1,2-) (40 CFR §141.60, §141.61)	0.005	0.0005
dichloroethylene (1,1-) (40 CFR §141.60, §141.61)	0.007	0.0007
dichloroethylene (cis-1,2-) (40 CFR §141.60, §141.61)	0.07	0.007
dichloroethylene (trans-1,2) (40 CFR §141.60, §141.61)	0.1	0.01
dichloromethane (40 CFR §141.60, §141.61)	0.005	0.0005
dichloropropane (1,2-) (40 CFR §141.60, §141.61)	0.005	0.0005
diclofop-methyl issue date: 03/87	0.009	0.0009
di(2-ethylhexyl)adipate (40 CFR §141.60, §141.61)	0.4	0.04
di(2-ethylhexyl)phthalate (PAE) (40 CFR §141.60, §141.61)	0.006	0.0006
dimethoate issue date: 02/86	0.020	0.002
dinoseb (40 CFR §141.60, §141.61)	0.007	0.0007
diquat (40 CFR §141.60, §141.61)	0.02	0.002
diuron issue date: 03/87	0.15	0.015

**Table D1 – U.S. Environmental Protection Agency and Health Canada
NSF/ANSI 60 drinking water criteria**

Contaminant (reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
endothall (40 CFR §141.60, §141.61)	0.1	0.01
endrin (40 CFR §141.60, §141.61)	0.002	0.0002
epichlorohydrin (as a monomer in drinking water treatment polymers) (40 CFR §141.111, §141.110)	TT ² (0.01% dosed at 20 ppm, or equivalent)	TT ² (0.01% dosed at 20 ppm, or equivalent)
ethylbenzene (40 CFR §141.60, §141.61)	0.7	0.07
ethylene dibromide (EDB) (40 CFR §141.60, §141.61)	0.00005	0.000005
glyphosate (40 CFR §141.60, §141.61)	0.7	0.07
heptachlor (40 CFR §141.60, §141.61)	0.0004	0.00004
heptachlor epoxide (40 CFR §141.60, §141.61)	0.0002	0.00002
hexachlorobenzene (40 CFR §141.60, §141.61)	0.001	0.0001
hexachlorocyclopentadiene (40 CFR §141.60, §141.61)	0.05	0.005
lindane (40 CFR §141.60, §141.61)	0.0002	0.00002
malathion issue date: 02/86	0.19	0.019
methoxychlor (40 CFR §141.60, §141.61)	0.04	0.004
metolachlor issue date: 02/86	0.05	0.005
metribuzin issue date: 02/86	0.08	0.008
monochlorobenzene (40 CFR §141.60, §141.61)	0.1	0.01
nitrilotriacetic acid issue date: 01/90	0.4	0.04
oxamyl (Vydate) (40 CFR §141.60, §141.61)	0.2	0.02
paraquat (as dichloride) issue date: 02/86	0.01	0.001
parathion issue date: 02/86	0.05	0.005
pentachlorophenol (40 CFR §141.60, §141.61)	0.001	0.0001
phorate issue date: 02/86	0.002	0.0002

**Table D1 – U.S. Environmental Protection Agency and Health Canada
NSF/ANSI 60 drinking water criteria**

Contaminant (reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
picloram issue date: 06/88	0.19	0.019
polychlorinated biphenyls (PCB) (40 CFR §141.60, §141.61)	0.0005	0.00005
simazine (40 CFR §141.60, §141.61)	0.004	0.0004
styrene (40 CFR §141.60, §141.61)	0.1	0.01
2,3,7,8-TCDD (dioxin) (40 CFR §141.60, §141.61)	3E-08	3E-09
terbufos issue date: 01/87	0.001	0.0001
tetrachloroethylene (40 CFR §141.60, §141.61)	0.005	0.0005
2,3,4,6-tetrachlorophenol issue date: 02/87	0.1	0.01
toluene (40 CFR §141.60, §141.61)	1	0.1
toxaphene (40 CFR §141.60, §141.61)	0.003	0.0003
2,4,5-TP (40 CFR §141.60, §141.61)	0.05	0.005
trichlorobenzene (1,2,4-) (40 CFR §141.60, §141.61)	0.07	0.007
trichloroethane (1,1,1-) (40 CFR §141.60, §141.61)	0.2	0.02
trichloroethane (1,1,2-) (40 CFR §141.60, §141.61)	0.005	0.0005
trichloroethylene (40 CFR §141.60, §141.61)	0.005	0.0005
2,4,6-trichlorophenol issue date: 02/87	0.005	0.0005
trifluralin issue date: 02/89	0.045	0.0045
trihalomethanes (total)	0.08	0.008
bromodichloromethane	—	—
bromoform	—	—
chlorodibromomethane	—	—
chloroform	—	—
(40 CFR §141.64)		
vinyl chloride (40 CFR §141.60, §141.61)	0.002	0.0002
xlenes (total) (40 CFR §141.60, §141.61)	10	1

**Table D1 – U.S. Environmental Protection Agency and Health Canada
NSF/ANSI 60 drinking water criteria**

Contaminant (reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Regulated metals		
antimony (40 CFR §141.60, §141.62)	0.006	0.0006
arsenic (40 CFR §141.60, §141.62)	0.010	0.001
barium (40 CFR §141.60, §141.62)	2	0.2
beryllium (40 CFR §141.60, §141.62)	0.004	0.0004
boron Health Canada issue date: 09/1990	5	0.5
cadmium (40 CFR §141.60, §141.62)	0.005	0.0005
chromium (total) (40 CFR §141.60, §141.62)	0.1	0.01
copper (40 CFR §141.80; 65 FR 1950)	TT ² (action level 1.3 mg/L)	0.13
lead (at tap) (40 CFR §141.80; 65 FR 1950)	TT ² (action level 0.015 mg/L)	0.0015
mercury (inorganic) (40 CFR §141.60, §141.62)	0.002	0.0002
selenium (40 CFR §141.60, §141.62)	0.05	0.005
thallium (40 CFR §141.60, §141.62)	0.002	0.0002
Other inorganics		
asbestos (40 CFR §141.60, §141.62)	7 ³ MFL	0.7 MFL
bromate (40 CFR §141.64)	0.01	0.005 ⁴
chloramines (total as Cl ₂) (40 CFR §141.65)	4 ⁵	0.4
chlorate	1	0.2
chlorine (free as Cl ₂) (40 CFR §141.65)	4 ⁵	0.4
chlorine dioxide (as ClO ₂) (40 CFR §141.65)	0.8 ⁵	0.08
chlorite (40 CFR §141.64)	1	0.1
cyanide (as free cyanide) (40 CFR §141.60, §141.62)	0.2	0.02
fluoride (40 CFR §141.60, §141.62)	1.2 ⁶	1.2 as a direct additive ⁶ 0.12 as a contaminant
haloacetic acids (total) (40 CFR §141.64)	0.06	0.006
nitrate (as N) (40 CFR §141.60, §141.62)	10	1

**Table D1 – U.S. Environmental Protection Agency and Health Canada
NSF/ANSI 60 drinking water criteria**

Contaminant (reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Other inorganics		
nitrite (as N) (40 CFR §141.60, §141.62)	1	0.1
nitrate + nitrite (both as N) (40 CFR §141.60, §141.62)	10	1
Radionuclides		
beta particle and photon activity (40 CFR §141.16)	4 mrem/y	0.4 mrem/y
gross alpha particle activity (40 CFR §141.15)	15 pCi/L	1.5 pCi/L
combined radium 226 and 228 (40 CFR §141.15)	5 pCi/L	0.5 pCi/L
uranium Health Canada issue date: 10/1999	0.02 mg/L 13 pCi/L	0.002 mg/L 1.3 pCi/L
<p>¹ The references for criteria based on U. S. primary drinking water regulations are from the U. S. Code of Federal Regulations, Title 40 (Protection of Environment), revised as of July 1, 2011. This document is available on-line at <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>. Issue dates are given for criteria based on Health Canada guidelines. Additional information on the guidelines for these chemicals is available at <http://hc-sc.gc.ca/ewh-semt/pubs/water-eau/index-eng.php#tech_doc></p> <p>² TT - Treatment technique.</p> <p>³ MFL = Million fibers per liter, with fiber length > 10 microns.</p> <p>⁴ Revisions to bromate requirements of this section have been made and are located in Annex G of this Standard. Please refer to that annex for additional details. The revisions contained in Annex G are informational at this time and are scheduled to be incorporated into this section January 1, 2013.</p> <p>⁵ Value represents the maximum residual disinfectant level (MRDL).</p> <p>⁶ "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States," August 17, 2001 / Morbidity & Mortality Weekly Report 50 (RR14); 1-42.</p>		

– concluded –

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Inorganics				
aluminum	7429-90-5	9	2	NSF action level ¹ External peer review date: 05/10/2011
bromine bromide	7726-95-6 24959-67-9	10 (total ²)	1 (total ²)	NSF action level ¹ External peer review date: 09/21/2011
iodine	7553-56-2	0.3	0.1	NSF action level ¹ External peer review date: 04/25/2002
lanthanum carbonate	587-26-8	4	0.4	NSF action level ¹ External peer review date: 10/29/2009
thiocyanate potassium salt sodium salt ammonium salt	333-20-0 540-72-7 1762-95-4	0.2 (total as SCN ²)	0.02 (total as SCN ²)	NSF action level ¹ External peer review date: 09/03/2003
titanium and titanium dioxide	7440-32-6 13463-67-7	90 (total as Ti ²)	9 (total as Ti ²)	NSF action level ¹ External peer review date: 09/04/2003
tungsten	7440-33-7	0.01	0.01	NSF action level ¹ External peer review date: 04/06/2005
Organics				
acetophenone	98-86-2	0.2	0.02	NSF action level ¹ External peer review date: 09/03/2003
adipic acid	124-04-9	30	3	NSF action level ¹ External peer review date: 04/06/2005
benzaldehyde	100-52-7	40	4	NSF action level ¹ External peer review date: 09/20/2011
benzophenone	119-61-9	0.3	0.03	NSF action level ¹ External peer review date: 09/21/2011
benzyl alcohol	100-51-6	3	0.3	NSF action level ¹ External peer review date: 04/26/2002
bisphenol A diglycidyl ether	1675-54-3	1 (total)	0.1 (total)	NSF action level ¹ External peer review date: 10/03/2002
bisphenol A diglycideryl ether	5581-32-8			
1-bromo-3-chloro-5,5-dimethylhydantoin	16079-88-2	50	9	NSF action level ¹ External peer review date: 05/05/2010

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
t-butanol	75-65-0	9	0.9	NSF action level ¹ External peer review date: 10/03/2002
di-t-butyl peroxide	110-05-4	0.01	0.01	NSF action level ¹ External peer review date: 10/03/2002
n-butyl acetate	123-86-4	1	0.1	NSF action level ¹ External peer review date: 04/25/2002
t-butyl acetate	540-88-5	0.6	0.06	NSF action level ¹ External peer review date: 04/17/2007
p-tert-butylphenol	98-54-4	0.5	0.05	NSF action level ¹ External peer review date: 10/05/2010
γ-butyrolactone	96-48-0	4	0.4	NSF action level ¹ External peer review date: 10/04/2002
2-chloro-1,4-benzenediamine	615-66-7	0.3	0.03	NSF action level ¹ External peer review date: 04/20/2004
4-chloro-1,2-benzenediamine	95-83-0	0.2	0.02	NSF action level ¹ External peer review date: 04/20/2004
4-chloro-1,3-benzenediamine	5131-60-2	0.3	0.03	NSF action level ¹ External peer review date: 04/06/2005
4-chlorobenzo-trifluoride	98-56-6	0.3	0.03	NSF action level ¹ External peer review date: 04/07/2006
p-chloro-m-cresol	59-50-7	0.7	0.07	NSF action level ¹ External peer review date: 04/25/2002
1,2-cyclohexane dicarboxylic acid, di-isononyl ester (DINCH)	474919-59-0 (US) 166412-78-8 (outside US)	5	0.5	NSF action level ¹ External peer review date: 10/15/2008
cyclohexanone	108-94-1	30	3	NSF action level ¹ External peer review date: 04/26/2002
diacetone alcohol	123-42-2	3	0.3	NSF action level ¹ External peer review date: 05/10/2011
1,3-dibromo-5,5-dimethylhydantoin	77-48-5	60	10	NSF action level ¹ External peer review date: 05/05/2010

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
2,2-dibromo-3-nitrilopropionamide	10222-01-2	0.4	0.09	NSF action level ¹ External peer review date: 04/20/2004
2,6-dichloro-1,4-benzenediamine	609-20-1	0.02	0.002	NSF action level ¹ External peer review date: 04/22/2009
2,4-dichlorobenzoic acid	50-84-0	0.1	0.01	NSF action level ¹ External peer review date: 04/21/2004
1,3-dichloro-5,5-dimethylhydantoin	118-52-5	40	7	NSF action level ¹ External peer review date: 05/05/2010
diethanolamine	111-42-2	0.1	0.01	NSF action level ¹ External peer review date: 04/17/2007
diethylene glycol mono-n-butyl ether	112-34-5	0.6	0.06	NSF action level ¹ External peer review date: 10/05/2010
diethylenetriamine	111-40-0	0.3	0.03	NSF action level ¹ External peer review date: 09/20/2011
diethyl 2-ethoxysuccinate	17596-10-0	2	0.2	NSF action level ¹ External peer review date: 10/29/2009
di(2-ethylhexyl) terephthalate	6422-86-2	1	0.1	NSF action level ¹ External peer review date: 04/17/2008
diethyltoluene-diamine, mixed isomers	68479-98-1 75389-89-8	0.0006 (total ²)	0.00006 (total ²)	NSF action level ¹ External peer review date: 10/06/2010
dimethyl glutarate	1119-40-0	0.01	0.01	NSF action level ¹ External peer review date: 04/22/2009
dimethyl succinate	106-65-0	0.01	0.01	NSF action level ¹ External peer review date: 04/22/2009
dimethyl terephthalate	120-61-6	3	0.3	NSF action level ¹ External peer review date: 04/23/2009
di(2-propylheptyl) phthalate	53306-54-0	0.4	0.04	NSF action level ¹ External peer review date: 10/10/2006
dodecanedioic acid	693-23-2	30	30	NSF action level ¹ External peer review date: 10/07/2005
1,2-epoxybutane	106-88-7	0.06	0.006	NSF action level ¹ External peer review date: 04/22/2009

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
ethanolamine	141-43-5	0.6	0.06	NSF action level ¹ External peer review date: 04/17/2007
ethylenediamine	107-15-3	10	2	NSF action level ¹ External peer review date: 04/06/2005
ethyl t-butyl ether	637-92-3	20	2	NSF action level ¹ External peer review date: 10/06/2010
2-ethylhexanoic acid	149-57-5	0.7	0.07	NSF action level ¹ External peer review date: 04/06/2005
2-ethylhexanol	104-76-7	0.8	0.08	NSF action level ¹ External peer review date: 04/17/2008
fatty acids, C12-21 and C18-unsaturated, 2,2,6,6-tetramethyl-4-piperidiny esters	167078-06-0	0.05	0.05	NSF action level ¹ External peer review date: 05/06/2010
furfural	98-01-1	0.2	0.02	NSF action level ¹ External peer review date: 09/03/2003
hexamethylene-diamine	124-09-4	10	1	NSF action level ¹ External peer review date: 04/06/2006
1(3H)-isobenzofuranone	87-41-2	0.01	0.01	NSF action level ¹ External peer review date: 04/06/2006
laurolactam	947-04-6	0.4	0.04	NSF action level ¹ External peer review date: 10/15/2008
melamine	108-78-1	3.0	0.3	NSF action level ¹ External peer review date: 04/14/1999
methanol	67-56-1	20	2	NSF action level ¹ External peer review date: 04/06/2006
4-methoxy-benzaldehyde	123-11-5	6	0.6	NSF action level ¹ External peer review date: 09/20/2011
3-methyl-2-buten-1-ol	556-82-1	0.5	0.05	NSF action level ¹ External peer review date: 05/10/2011
2-methyl-3-buten-2-ol	115-18-4	0.05	0.05	NSF action level ¹ External peer review date: 05/10/2011
3-methyl-3-buten-1-ol	763-32-6	(total ²)	(total ²)	NSF action level ¹ External peer review date: 05/10/2011

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
methyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	6386-38-5	0.02 (total ²)	0.002 (total ²)	NSF action level ¹ External peer review date: 04/20/04
3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionic acid	20170-32-5			
4,4'-methylene dianiline	101-77-9	0.0008	0.00008	NSF action level ¹ External peer review date: 04/22/2009
4,4'-methylenebis(2,6-diisopropylaniline)	19900-69-7	0.05	0.05	NSF action level ¹ External peer review date: 10/29/2009
methyl isoamyl ketone (MIAK)	110-12-3	0.06	0.006	NSF action level ¹ External peer review date: 04/25/2002
methyl isobutyl ketone (MIBK)	108-10-1	7	0.7	NSF action level ¹ External peer review date: 10/06/2005
mineral oils				NSF action level ¹ External peer review date: 04/24/2004
high viscosity, ≥ 11 centistokes		700	70	
medium and low viscosity Class I, 8.5-11 centistokes	8012-95-1 (USP)	700	70	
medium and low viscosity Class II, 7.0-8.5 centistokes	8042-47-5 (white)	40	4	
medium and low viscosity Class III, 3.0-7.0 centistokes		1	0.1	
N-butylbenzene-sulfonamide	3622-84-2	0.01	0.01	NSF action level ¹ External peer review date: 09/20/2011
N,N-dimethylacetamide	127-19-5	2	0.2	NSF action level ¹ External peer review date: 10/05/2010

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
oligomeric cyclic ethers CBEL (total OCE 3-6) OCE-3: 1,6,11-trioxacyclo-pentadecane OCE-4: 1,6,11,16-tetraoxacyclo-pentadecane OCE-5: 1,6,11,16,21-pentaoxacyclo-pentadecane OCE-6: 1,6,11,16,21,26-hexaoxacyclo-pentadecane	295-63-6 17043-02-6 56890-57-4 64001-05-4	3 (total ²)	0.4 (total ²)	NSF action level ¹ External peer review date: 10/04/2002
phenyl glycidyl ether	122-60-1	0.006	0.0006	NSF action level ¹ External peer review date: 10/03/2002
poly(dimethyl diallyl ammonium chloride) (polyDADMAC)	26062-79-3	5	2	NSF action level ¹ External peer review date: 10/06/2010
di-propylene glycol n-butyl ether	29911-28-2	2	0.2	NSF action level ¹ External peer review date: 10/03/2002
propylene glycol n-butyl ether	5131-66-8	2	0.2	NSF action level ¹ External peer review date: 10/03/2002
terephthalic acid	100-21-0	3	0.3	NSF action level ¹ External peer review date: 10/16/2008
2,2,6,6-tetramethyl-4-piperidinol 2,2,6,6-tetramethyl-4-piperidinone	2403-88-5 826-36-8	0.05 (total ²)	0.05 (total ²)	NSF action level ¹ External peer review date: 05/10/2011
tetramethyl-succinonitrile	3333-52-6	0.01	0.01	NSF action level ¹ External peer review date: 05/06/2010
tetramethylthiourea	2782-91-4	0.01	0.01	NSF action level ¹ External peer review date: 09/20/2011
o-toluidine	95-53-4	0.03	0.003	NSF action level ¹ External peer review date: 05/05/2010

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
triallylisocyanurate	1025-15-6	0.04	0.04	NSF action level ¹ External peer review date: 05/06/2010
2,4,4'-trichloro-2'-hydroxydiphenyl ether	3380-34-5	0.5	0.05	NSF action level ¹ External peer review date: 10/19/2000
triethanolamine	102-71-6	3	0.3	NSF action level ¹ External peer review date: 10/10/2006
triethyl citrate	77-93-0	4	0.4	NSF action level ¹ External peer review date: 11/05/2004
triethyl phosphate tripropyl phosphate tributyl phosphate	78-40-0 513-08-6 126-73-8	0.2 (total ²)	0.02 (total ²)	NSF action level ¹ External peer review date: 10/10/2006
2,2,4-trimethyl-1,3-pentanediol diisobutyrate	6846-50-0	0.4 (total ²)	0.04 (total ²)	NSF action level ¹ External peer review date: 05/10/2011
2,2,4-trimethyl-1,3-pentanediol monoisobutyrate	25265-77-4 and 18491-15-1			
2,2,4-trimethyl-1,3-pentanediol	144-19-4			
propanoic acid, 2-methyl-, 3-hydroxy-2,2,4-trimethylpentyl ester	77-68-9			
propanoic acid, 2-methyl-, 2,2-dimethyl-1-(2-hydroxy-1-methylethyl)propyl ester	74367-33-2			
propanoic acid, 2-methyl-, 3-hydroxy-2,4,4-trimethylpentyl ester	74367-34-3			
1,3,5-trioxane	110-88-3	0.7	0.07	NSF action level ¹ External peer review date: 04/20/04

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation
Organics				
tris-(2-butoxyethyl) phosphate	78-51-3	0.4	0.04	NSF action level ¹ External peer review date: 05/10/2011
¹ NSF action levels have been derived according to the requirements of NSF/ANSI 60 – Annex A.				
² The total concentration of the specified CAS #s in each grouping shall not exceed the TAC or SPAC.				

– concluded –

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Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Inorganics				
chromium III	16065-83-1	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 04/28/1998
chromium VI	18540-29-9	0.02	0.002	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 04/28/1998
manganese	7439-96-5	0.3	0.03	Derived from the oral RfD on the USEPA IRIS database, with a 3x modifying factor because of the large contribution from food sources and a default 20% relative source contribution for drinking water. Verification date: 05/12/1995
molybdenum	7439-98-7	0.04	0.004	USEPA Draft Health Advisory issue date: 1993
perchlorate ⁴	014797-73-0	0.015 (total ⁵)	0.005 (total ⁵)	USEPA Interim Health Advisory Issue Date: 2008
sodium perchlorate	7601-89-0	0.006 (total ⁵)	0.002 (total ⁵)	California MCL
potassium perchlorate	7778-74-7			
lithium perchlorate	7791-03-9			
ammonium perchlorate	7790-98-9	0.002 (total ⁵)	0.0007 (total ⁵)	Massachusetts MCL
silver	7440-22-4	0.1	0.01	USEPA Lifetime Drinking Water Health Advisory Issue date: 1992
strontium	7440-24-6	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/23/1992

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
acetone	67-64-1	6	0.6	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 05/29/03
acrolein	107-02-8	0.004	0.0004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 05/16/2003
acrylic acid	79-10-7	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 02/17/1994
acrylonitrile	107-13-1	0.0006	0.00006	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 02/11/1987
benzyl chloride	100-44-7	0.002	0.0002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 03/01/1989
bromochloromethane	74-97-5	0.09	0.009	USEPA Lifetime Drinking Water Health Advisory issue date: 1989
bromomethane	74-83-9	0.01	0.001	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/26/1988

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
butylbenzyl phthalate	85-68-7	1	0.1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/15/1989
n-butanol	71-36-3	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/14/1986
carbon disulfide	75-15-0	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 08/05/1985
chloral hydrate	302-17-0	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 11/16/1999
2-chlorotoluene	95-49-8	0.1	0.01	Based on the oral RfD and lifetime drinking water health advisory in the USEPA 2011 Edition of the Drinking Water Standards and Health Advisories
4-chlorotoluene	106-43-4	0.1	0.01	Based on the oral RfD and lifetime drinking water health advisory in the USEPA 2011 Edition of the Drinking Water Standards and Health Advisories
1,4-dibromobenzene	106-37-6	0.07	0.007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 05/15/1986
1,2-dibromoethane	106-93-4	0.0002	0.00002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Agency Completion Date: 07/26/2004

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
dichloroacetic acid	79-43-6	0.007	0.0007	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ upper bound risk levels. Agency Consensus Date: 08/20/2003
di-n-butyl phthalate	84-74-2	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 01/22/1986
1,3-dichloropropene mixed isomers cis- trans-	542-75-6 10061-01-5 10061-02-6	0.004 (total ⁵)	0.0004 (total ⁵)	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Agency Consensus Date: 04/20/2000
diethyl phthalate	84-66-2	0.6	0.6	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 07/16/1987
2,4-dimethylphenol	105-67-9	0.1	0.01	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/21/1990
2,6-dimethylphenol	576-26-1	0.004	0.0004	Derived from the oral RfD on the USEPA IRIS database with an default 20% relative source contribution for drinking water. verification date: 01/22/1986
3,4-dimethylphenol	95-65-8	0.007	0.0007	Derived from the oral RfD on the USEPA IRIS database with an default 20% relative source contribution for drinking water. verification date: 01/22/1986
diphenylamine	122-39-4	0.2	0.02	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 07/22/1986

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
1,4-dithiane	505-29-3	0.07	0.007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/24/1992
1,4-dioxane	123-91-1	0.03	0.003	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels Verification date: 02/03/88
ethylene glycol	107-21-1	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 03/19/1987
ethylene glycol monobutyl ether	111-76-2	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 11/16/1999
formaldehyde	50-00-0	1	0.1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 06/20/1990
1,2,3,4,6,7,8-hepta-chlorodibenzo-p-dioxin	35822-46-9	0.000003	0.0000003	Toxic Equivalency Factor: 0.01
1,2,3,4,6,7,8-hepta-chlorodibenzofuran	67562-39-4	0.000003	0.0000003	Toxic Equivalency Factor: 0.01
1,2,3,4,7,8,9-hepta-chlorodibenzofuran	55673-89-7	0.000003	0.0000003	Toxic Equivalency Factor: 0.01
hexabromobenzene	87-82-1	0.01	0.001	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 11/06/1985
1,2,3,4,7,8-hexachloro-dibenzo-p-dioxin	39227-28-6	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,7,8,9-hexachloro-dibenzo-p-dioxin	19408-74-3	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,6,7,8-hexachloro-dibenzo-p-dioxin	57653-85-7	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,4,7,8-hexachloro-dibenzofuran	70648-26-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
1,2,3,7,8,9-hexachloro-dibenzofuran	72918-21-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,6,7,8-hexachloro-dibenzofuran	57117-44-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
2,3,4,6,7,8-hexachloro-dibenzofuran	60851-34-5	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
isopropylbenzene (cumene)	98-82-8	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 06/06/1997
maleic anhydride	108-31-6	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 03/24/1988
methyl ethyl ketone (MEK)	78-93-3	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 09/10/2003
methyl mercury	22967-92-6	0.0007	0.00007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/19/2001
methyl methacrylate	80-62-6	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 11/25/1997
2-methyl naphthalene	91-57-6	0.03	0.003	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 12/11/2003

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
naphthalene	91-20-3	0.1	0.01	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 07/01/1998
nitroguanidine	556-88-7	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/17/1989
N-nitroso-di-n-butylamine	924-16-3	0.00006	0.000006	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/29/86
N-nitroso-N-methylethylamine	10595-95-6	0.00002	0.000002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/11/87
N-nitroso-di-N-propylamine	621-64-7	0.00005	0.000005	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/11/87
N-nitrosodiethanolamine	1116-54-7	0.0001	0.00001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 01/28/87
N-nitrosodiethylamine	55-18-5	0.000002	0.0000002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/29/86
N-Nitrosodimethylamine	62-75-9	0.000007	0.0000007	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 10/29/86
N-nitrosodiphenylamine	86-30-6	0.07	0.007	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/11/87
N-nitrosopyrrolidine	930-55-2	0.0002	0.00002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/14/86
1,2,3,4,6,7,8,9-octa-chlorodibenzo-p-dioxin	3268-87-9	0.0003	0.00003	Toxic Equivalency Factor: 0.0001
1,2,3,4,6,7,8,9-octachlorodibenzofuran	39001-02-0	0.0003	0.00003	Toxic Equivalency Factor: 0.0001
1,2,3,7,8-penta-chlorodibenzo-p-dioxin	40321-76-4	0.00000003	0.000000003	Toxic Equivalency Factor: 1
1,2,3,7,8-penta-chlorodibenzofuran	57117-41-6	0.00000006	0.000000006	Toxic Equivalency Factor: 0.05
2,3,4,7,8- penta-chlorodibenzofuran	57117-31-4	0.00000006	0.000000006	Toxic Equivalency Factor: 0.5

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
pentachloronitrobenzene	82-68-8	0.02	0.002	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 04/15/1987
phenol	108-95-2	2	0.2	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 08/28/2002
m-phenylenediamine	108-45-2	0.04	0.004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/26/1986
phthalic anhydride	85-44-9	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/24/1988
propylene oxide	75-56-9	0.001	0.0001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 04/05/1990
pyridine	110-86-1	0.007	0.0007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 08/13/1987
quinoline	91-22-5	0.0001	0.00001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Agency Consensus Date: 09/21/2001
sodium diethyldithiocarbamate	148-18-5	0.2	0.02	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 10/09/1985
2,3,7,8-tetra-chlorodibenzo-p-dioxin	1746-01-6	0.00000003	0.000000003	Toxic Equivalency Factor: 1
2,3,7,8-tetrachlorodibenzofuran	51207-31-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
1,1,1,2-tetrachloroethane	630-20-6	0.01	0.001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 05/04/1988
1,1,2,2-tetrachloroethane	79-34-5	0.002	0.0002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 06/26/1986
1,2,4-tribromobenzene	615-54-3	0.04	0.004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/15/1986
tributyltin oxide	56-35-9	0.002	0.0002	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus date: 07/02/1997
trichlorofluoromethane	75-69-4	2	0.2	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/31/1985
1,2,3-trichloropropane	96-18-4	0.04	0.004	USEPA Lifetime Drinking Water Health Advisory issue date: 1989
1,3,5-trinitrobenzene	99-35-4	0.2	0.02	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 08/27/1997

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
<p>¹ Criteria are derived from the oral RfD on the USEPA IRIS database as follows:</p> <p>Oral RfD (mg /kg-d) x (70 kg /2 L/d) x relative source contribution factor = TAC (mg/L)</p> <p>where:</p> <p>70 kg = assumed adult body weight</p> <p>2 L/d = assumed adult water consumption</p> <p>relative source contribution factor = percentage of daily exposure to the substance represented by drinking water (default value is 20%)</p> <p>Other criteria have been used directly, unless otherwise noted.</p> <p>² The IRIS verification date represents the date the oral RfD or the cancer risk assessment was peer reviewed by the USEPA. Refer to the online IRIS database for the complete update and revision history of the IRIS files: <www.epa.gov/IRIS>.</p> <p>³ Toxic Equivalency Factors (TEFs) have been established as a means to compare the potency of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) to individual congeners of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs). The USEPA uses an approach to dioxin risk assessment methodology in which levels of dioxins and furans are analytically determined, the concentration of each congener is multiplied by its respective TEF value, and all the products are totaled to a single 2,3,7,8-TCDD equivalent.</p> <p>Van den Berg et al. 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and Wildlife. Environmental Health Perspectives 106(12):775:792.</p> <p>U.S. Environmental Protection Agency. 2000. Chapter 9: Toxic Equivalency Factors (TEFs) for Dioxin and Related Compounds. From Exposure and Human Health Risk Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds. NCEA-I-0386. September 2000. SAB Review Draft. <www.epa.gov/ncea/pdfs/dioxin/part2/fm-chap9.pdf></p> <p>⁴ Compliance to Single Product Allowable Concentrations based on US State or other regulatory levels may be demonstrated by establishing the SPAC as 1/3 of the regulatory level.</p> <p>⁵ The total concentration of the specified CAS #s in each grouping shall not exceed the TAC or SPAC.</p>				

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Inorganics	
cerium	007440-45-1
gallium	007440-55-3
hafnium	007440-58-6
palladium	007440-05-3
rhenium	007440-15-5
ruthenium	007440-18-8
tantalum	007440-25-7
yttrium	007440-65-5
Organics	
acenaphthylene	000208-96-8
acetamide, 2,2-dibromo	000598-70-9
acetic acid, 2-cyano-	000372-09-8
acetic acid, propyl ester	000109-60-4
acetone, acetyl	000123-54-6
acetophenone, 2,2-dimethoxy-2-phenyl-	024650-42-8
acetophenone, p-isopropyl-	000645-13-6
acetophenone, 2'-methyl-	000577-16-2
acetophenone, 4-methyl	000122-00-9
acetophenone, alpha-hydroxy-	000582-24-1
acetophenone, 3'-methyl-	000585-74-0
acetophenone, 4'-isopropenyl	005359-04-6
acetophenone, 4'-hydroxy-	000099-93-4
aconitic acid, tributyl ester	007568-58-3
acridine	000260-94-6
acrylic acid, 2-cyano-, ethyl ester	007085-85-0
adipic acid, monomethyl ester	000627-91-8
alcohols, C12-C15, ethoxylated propoxylated	068551-13-3
alkenes, C6-10, hydroformylation products, high boiling	068526-82-9
allyl ether	000557-40-4
allyl phenol ether	001746-13-0
aminopiperidine, 4, 2,2,6,6-tetramethyl-	036768-62-4
aminoundecanoic acid, 12-	000693-57-2
ammonium chloride, octadecyldimethyl{3-(trimethoxysilyl)propyl}	027668-52-6
amphetamine	000300-62-9
aniline, 2,6-diethyl-	000579-66-8
aniline, N-ethyl-	000103-69-5
aniline, 2-ethyl-	000578-54-1
aniline, 3-ethyl-	000587-02-0
aniline, 2-ethyl-6-methyl-	024549-06-2
aniline, 4-ethyl-	000589-16-2
aniline, 2-propyl-	001821-39-2
aniline, 4-n-propyl-	002696-84-6
aniline, 4-nitro-	000100-01-6
benzaldehyde azine	000588-68-1
benzaldehyde, 3,5-di-tert-butyl-4-hydroxy-	001620-98-0
benzaldehyde, 4-hydroxy-3-methoxy (Vanillin)	000121-33-5
benzaldehyde, 3,5-dimethoxy-4-hydroxy-	000134-96-3
benzaldehyde, 2,6-dimethyl-	001123-56-4
benzaldehyde, 3,5-dimethyl-	005799-95-3

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
benzaldehyde, 2-hydroxy-	000090-02-8
benzaldehyde, 2-hydroxy-4-methoxy	000673-22-3
benzaldehyde, hydroxymethoxy-	106799-60-4
benzaldehyde, 2-methyl-	000529-20-4
benzaldehyde, 3-methyl-	000620-23-5
benzaldehyde, 4-methyl-	000104-87-0
benzaldehyde, 2-, 3-, 4-methyl- mixed isomers	001334-78-7
benzaldehyde, tert-butylmethyl-	066949-23-3
benzaldehyde, 2,4,5-trimethyl-	005779-72-6
benzaldehyde, 2,4,6-trimethyl-	000487-68-3
benzanilide	000093-98-1
benzene, 1-butylheptyl-	004537-15-9
benzene, 1-butylnonyl-	004534-50-3
benzene, 1-butyloctyl-	002719-63-3
benzene, 1-chloro-2-(trifluoromethyl)-	000088-16-4
benzene, 1-chloro-3-(trifluoromethyl)-	000098-15-7
benzene, cyclopropyl-	000873-49-4
benzene, 1,2,3-trichloro-	000087-61-6
benzene, (1,1-dimethylethoxy)-	006669-13-2
benzene, 1,1'-[(1-propenylthio)methylene]bis-, (Z)-	056195-66-5
benzene, 1-ethenyl-2-methyl-	000611-15-4
benzene, 1-ethenyl-3-methyl-	000100-80-1
benzene, 1-ethenyl-4-methyl-	000622-97-9
benzene, 2-ethoxyethenyl-	017655-74-2
benzene, 1-ethyldecyl-	002400-00-2
benzene, 1-ethylnonyl-	004536-87-2
benzene, 1-ethylundecyl-	004534-52-5
benzene, 1-hexylheptyl-	002400-01-3
benzene, (2-methoxy-1-methylethyl)-	065738-46-7
benzene, 1-methyldecyl-	004536-88-3
benzene, 1-methyldodecyl-	004534-53-6
benzene, 1-methylundecyl-	002719-61-1
benzene, divinyl-	001321-74-0
benzene, (1-methoxy-1-methylethyl)-	000935-67-1
benzene, 1,1-oxybis-	000101-84-8
benzene, 1,3-dimethyl-5-isopropyl-	004706-90-5
benzene, 4,6-diisopropyl-1,3-dimethyl-	005186-68-5
benzene, 1-pentylheptyl-	002719-62-2
benzene, 1-propenyl-	000637-50-3
benzene, 2-propenyl-	000300-57-2
benzene, 1-propyldecyl-	004534-51-4
benzene, 1-propylnonyl-	002719-64-4
benzene, 1-propyloctyl-	004536-86-1
benzene, trans-1-propenyl-	000873-66-5
benzeneacetaldehyde	000122-78-1
benzeneacetic acid, alpha-oxo-, methyl ester	015206-55-0
benzeneamine, 4-(1-methylethyl)-N-phenyl-	005650-10-2
benzenediamine, ar,ar-diethyl-ar-methyl	068479-98-1
benzenediamine, 5-chloro-1,3-	033786-89-9

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
benzenedicarboxylic acid, 1,2-, bis(2-propylpentyl) ester	070910-37-1
benzenedimethanol, a,a,a',a'-tetramethyl-1,4-	002948-46-1
benzenedimethanol, a,a,a',a'-tetramethyl-1,3-	001999-85-5
benzenemethanamine, 1,3-	001477-55-0
benzenemethanamine, N-(phenylmethylene)-	000780-25-6
benzenemethanol, alpha-methyl-, -(R)-	001517-69-7
benzenemethanol, alpha-methyl-, -(S)-	001445-91-6
benzenemethanol, 4-(1-methylethyl)-	000536-60-7
benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-	020170-32-5
benzenesulfonamide, 4-methyl-	000070-55-3
benzenesulfonyl isocyanate, 4-methyl	004083-64-1
benzenetricarboxylic acid, 1,2,4-	000528-44-9
benzimidazolone, 3-methyl-2-	001849-01-0
benzimidazolone, 4-methyl-	019190-68-2
benzisothiazolin-3-one	002634-33-5
benzofuran, methyl-	025586-38-3
benzoic acid, 2-cyano-	003839-22-3
benzoic acid, 2,5-dichloro-	000050-79-3
benzoic acid, 3,4-dichloro-	000051-44-5
benzoic acid, mixed isomers (2,4- or 2,5-dichloro-)	035915-19-6
benzoic acid, diester with diethylene glycol	000120-55-8
benzoic acid, m-methyl-	000099-04-7
benzoic acid, o-methyl-	000118-90-1
benzoic acid, p-methyl-	000099-94-5
benzoic acid, 4-tert-butyl-	000098-73-7
benzonitrile	000100-47-0
benzoquinone, 2,6-dimethyl-1,4-	000517-61-7
benzoquinone, 2,6-di-t-butyl-	000719-22-2
benzoquinone, 2,5-di-tert-pentyl-p-	004584-63-8
benzothiazole, 2-(cyclohexylamino)-	028291-75-0
benzothiazole, ethylamino-	028291-69-2
benzothiazole, 2-(methylmercapto)-	000615-22-5
benzothiazole, 2-methyl-	000120-75-2
benzothiazole, 2-methoxy-	063321-86-8
benzothiazole, 2-(morpholiniothio)-	000102-77-2
benzothiazole-2-thione, N-methyl-	002254-94-6
benzotriazole	000095-14-7
benzotriazole, 2-(2-hydroxy-5-methyl-phenyl)-	002440-22-4
benzothiazolinone, 2-	000934-34-9
benzotropolidene, 3,4-	000264-09-5
benzoxazole, N-methyl-2-	019776-98-8
benzyl ethyl ether	000539-30-0
benzyl alcohol, 4-ethoxy	006214-44-4
benzyl alcohol, alpha, alpha, 4-trimethyl-	001197-01-9
benzyl alcohol, a,a-dimethyl-p-isopropyl-	003445-42-9
benzylamine	000100-46-9
benzylamine, N,N-dimethyl-	000103-83-3
benzylidiphenylphosphine oxide	002959-74-2
benzyltriphenylphosphonium	015853-35-7

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
benzyltriphenylphosphonium, salt with 4,4'-(2,2,2-trifluoro-1-(trifluoromethyl) ethylidene)bis(phenol) (1:1)	075768-65-9
binaphthyl sulfone	032390-26-4
bisphenol A bis(polypropylene glycol) ether	037353-75-6
bisphenol F, 2,4-	002467-03-0
bisphenol F diglycidyl ether	002095-03-6
borneol	000507-70-0
bromobenzene	000108-86-1
bromophenol	032762-51-9
bromophenol, 2-	000095-56-7
bromophenol, 3-	000591-20-8
bromophenol, 4-	000106-41-2
1-butanamine,N,N-dibutyl-	000102-82-9
butanedioic acid	000110-15-6
butanediol diglycidyl ether, 1,4-	002425-79-8
butanediol dimethacrylate, 1,4-	002082-81-7
butane, 2-ethoxy-2-methyl-	000919-94-8
butanenitrile	000109-74-0
butanetricarboxylic acid, 2-phosphono-, 1,2,4-	037971-36-1
butanoic acid	000107-96-2
butanoic acid, 3,3-dimethyl-	001070-83-3
butanone, 4-(4-hydroxyphenyl)-2-	005471-51-2
butanone, 1-phenyl-2-	001007-32-5
buten-1-ol, 2-methyl-2-	004675-87-0
butenal, methyl-	001115-11-3
butene, 2,3-dichloro-2-methyl-	000507-45-9
butenoic acid, trans-2-	000107-93-7
butenoic acid, 2-	003724-65-0
butenoic acid, 3-	000625-38-7
butyl isocyanate, n-	000111-36-4
butylamine, N-butyldiene	004853-56-9
caprolactone	000502-44-3
carbodiimide, di-t-butyl-	000691-24-7
carbonic acid, diisopropyl ester	006482-34-4
castor oil, hydrogenated, ethoxylated	061788-85-0
chloroethane, 1-butoxy-2-	010503-96-5
chloriodomethane	000593-71-5
cinnamate, 2-ethylhexyl-4-methoxy-	005466-77-3
cresol, alpha-ethoxy-p-	057726-26-8
cresol, 2-tert-butyl-m-	013037-79-1
cyanamide, diethyl-	000617-83-4
cyanostyrene, α	000495-10-3
cyanovaleic acid, 4-	unknown
cyclododecane	000294-62-2
cyclohexadecane	000295-65-8
cyclohexadiene-1-one, 2,6-(1,1-dimethylethyl)-4-methylene-2,5-	002607-52-5
cyclohexadiene-1-one, 2,6-di-tert-butyl-4-hydroxy-4-methyl-2,5-	010396-80-2
cyclohexanamine, 4,4'-methylene-bis-	001761-71-3
cyclohexanamine, N-methyl-	000100-60-7

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
cyclohexanamine, N-cyclohexyl-	000101-83-7
cyclohexanamine, N,N-dimethyl-	000098-94-2
cyclohexenecarbonitrile	027456-25-3
cyclohexanedimethanamine, 1,3-	002579-20-6
cyclohexane, cis-1-methyl-4-isopropyl-	006069-98-3
cyclohexane, 1-isopropyl-4-methyl-	000099-82-1
cyclohexanemethanol, trans-alpha,alpha,4-trimethyl-	005114-00-1
cyclohexane, methyl-	000108-87-2
cyclohexanol	000108-93-0
cyclohexanol, 3-methyl-	000591-23-1
cyclohexanol, trimethyl-	001321-60-4
cyclohexanol, 4-tert-butyl-	000098-52-2
cyclohexanone, 2-hydroxy	000533-60-8
cyclohexanone, 2-(1-hydroxycyclohexyl)-	028746-99-8
cyclohexen-1-one, 3-methyl-2-	001193-18-6
cyclohexene, 4-cyano also (1-cyano-3-cyclohexene)	000100-45-8
cyclohexyl isocyanate	003173-53-3
cyclohexylurea, dimethyl-	031468-12-9
cyclooctadiene, dichloro-	029480-42-0
cyclopentane, trimethyl	030498-64-7
cyclopentylidenecyclopentan-2-one	000825-25-2
cyclopentanol, 2-methyl-	024070-77-7
cyclopentanone	000120-92-3
cyclopentylcyclopentanone, 2-	004884-24-6
decadien-1-al, trans,trans-2,4-	025152-84-5
decadienal, 2,4-	002363-88-4
decamethylcyclopentasiloxane	000541-02-6
decanamide, N,N-dimethyl-	014433-76-2
decane, 1,10-diamino	000646-25-3
decanedioic acid, bis(2,2,6,6-tetramethyl-4-piperidinyl)-	052829-07-9
decanedioic acid, dimethyl ester	000106-79-6
decane, 1-methyl-3,5,7-triaza-1-azoniatricyclo(3.3.1.1(3,7))	076902-90-4
decanoic acid, methyl ester	000110-42-9
decylamine, n-	002016-57-1
dehydroabietic acid	001740-19-8
dehydroacetic acid	000520-45-6
di-o-tolylguanidine, 1,3-	000097-39-2
diazacyclotetradecane-2,9-dione, 1,8-	056403-09-9
dibenzylamine	000103-49-1
dibenzyl ether	000103-50-4
dibutyl cyanamide, N,N-	002050-54-6
1,3-dicyclohexylurea	002387-23-7
diethylene glycol monomethacrylate homopolymer	027598-43-2
diethyleneglycol monophenyl ether	000104-68-7
diethylurea, 1,3-	000623-76-7
diglycol chlorohydrin	000628-89-7
dihydro-5-pentyl-2(3H)-furanone	000104-61-0
dihydrobenzofuran, 2,3-	000496-16-2
dihydrofuran, 4-methyl-2,3-	034314-83-5

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
dihydromethoxymethyl oxopyridinecarbonitrile	000524-40-3
dihydromethyl benzimidazolone	005400-75-9
diiodomethane	000075-11-6
dimethyl ditallow ammonium chloride	068783-78-8
dimethyl thioacetamide	000631-67-4
dimethyl-3,3'-thiobispropionate	004131-74-2
dimethyl-p-benzoquinone, 2,5-	000137-18-8
dimethylaminopyridine	001122-58-3
dimethylbenzaldehyde, 2,4-	015764-16-6
dimethylbenzaldehyde, 2,5	005779-94-2
dimethylbenzaldehyde, 3,4-	005973-71-7
dimethylcyanamide	001467-79-4
dimethyldiphenyl sulphone	005097-12-1
dimethyldithiocarbamate, methyl	003735-92-0
dimethyldodecanamide, N,N-	003007-53-2
dimethylhexane-2,5-diol, 2,5-	000110-03-2
dioctyldiphenylamine	026603-23-6
dioxacyclododecane-7,12-dione, 1,6-	000777-95-7
dioxadithionane, 1,3,6,7-	005980-67-6
dioxane, 4-phenyl-1,3-	000772-00-9
dioxathiocane, 1,3,6-	002094-92-0
dioxolane-1,3, 4-ethyl	029921-38-8
diphenylamine, 4-hydroxy-	000122-37-2
diphenyl sulfide	000139-66-2
diphenylamine, 4-(diisopropylamino)	064092-29-1
diphenylethanedione, 1,2-	000134-81-6
dipropylamine, 3,3'-diamino-	000056-18-8
dipropylene glycol dibenzoate	027138-31-4
disulfide, dimethyl	000624-92-0
dithiolane-2-thione, 1,3-	000822-38-8
docosane	000629-97-0
docosenamide (erucamide)	000112-84-5
dodecamethylcyclohexasiloxane	000540-97-6
dodecanamide	001120-16-7
dodecanamine, 1-	000124-22-1
dodecylamine, N,N-dimethyl-	000112-18-5
dodecyl glycidyl ether	002461-18-9
ethane, 1,2-diphenoxy-	000104-66-5
ethan-1-one, 1-(methylphenyl)-	026444-19-9
ethane, 1-(3-hydroxyphenyl)-2-phenyl-	033675-75-1
ethanediamide, N-(2-ethoxyphenyl)-N'-(2-ethylphenyl)-	023949-66-8
ethanol, 2-[2-[2-[2[(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethoxy]-	049796-75-0
ethanol, 2-[2-[2-[(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethoxy]-	058705-51-4
ethanol, 2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]-	002315-61-9
ethanol, 2-(4-methoxyphenoxy) -	005394-57-0
ethanone, 1-(4-hydroxy-3-methoxyphenyl)-	000498-02-2
ethanone, 1-(4-(1-hydroxy-1-methylethyl)phenyl)-	054549-72-3
ethanone, 1-[3-(methoxymethyl)phenyl]-	112766-37-7
ethanone, 1-[4-(methoxymethyl)phenyl]-	022072-50-0

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
ethyl hydroxyphthalide	000485-26-7
ethylbenzene acetate	000101-97-3
ethylcyclopentanone	004971-18-0
ethylene glycol dimethacrylate	000097-90-5
ethylene glycol monoethyl ether acetate	000111-15-9
ethylhexyl acetate, 2-	000103-09-3
ethylhex-2-en-1-al, 2-	000645-62-5
fenchyl alcohol	001632-73-1
ethyl-4-ethoxybenzoate	023676-09-7
fenchyl alcohol, alpha-	000512-13-0
fenchyl alcohol, alpha-	014575-74-7
fluorenone	000486-25-9
formamide, N,N-diethyl-	000617-84-5
formamide, N-methyl-N-phenyl-	000093-61-8
formamide, N-cyclohexyl-	000766-93-8
formamide, N-(1,1-dimethylethyl)-	002425-74-3
formamide, N,N-dimethylthio-	000758-16-7
formamide, N,N-di-n-butyl-	000761-65-9
formamidine, N,N-dimethyl-N'-cyclohexyl-	003459-75-4
formylcyclopentene, 1-	006140-65-4
fumaric acid, diethyl ester	000623-91-6
furan, 2-pentyl-	003777-69-3
furan, tetrahydro-2,2,5,5-tetramethyl-	015045-43-9
fumaric acid, bis(2-ethylhexyl) ester	000141-02-6
furfural, 5-methyl	000620-02-0
furylmethylketone, 5-methyl-2-	001193-79-9
geraniol	000106-24-1
glutaraldehyde	000111-30-8
glycidyl ether, 2-methylphenyl-	002210-79-9
guanidine, 1,2,3-triphenyl-	000101-01-9
heneicosane	000629-94-7
heptacosane	000593-49-7
heptadecanoic acid, 16-methyl-, methyl ester	005129-61-3
heptanol, 2-propyl-1-	010042-59-8
heptyl aldehyde, n-	000111-71-7
hexacosane	000630-01-3
hexadecanamide	000629-54-9
hexanoic acid, 2-ethyl-, methyl ester	000816-19-3
hexanoic acid, methyl ester	000106-70-7
hex-1-ene, 2-ethyl-	001632-16-2
hex-2-en-1-ol, cis-	000928-94-9
hex-2-en-1-ol, trans-	000928-95-0
hex-5-en-1-ol	000821-41-0
hexadecanamide	000629-54-9
hexadecanamide, N,N-dimethyl-	003886-91-7
hexadecene-1	000629-73-2
hexafluoropropene	000116-15-4
hexamethylene oxide	000592-90-5
hexamethylene dibenzamide	005326-21-6

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
hexamethyleneimine, 1-ethyl-	006763-91-3
hexamethylene oxide	000592-90-5
hexanal, 2-ethyl-	000123-05-7
hexanal	000066-25-1
hexanamine, 2-	005329-79-3
hexane, 2,5-dimethyl-	000592-13-2
hexane-2,5-dione	000110-13-4
hexaoxacyclotriacontane, 1,6,11,16,21,26-	064001-05-4
hexen-2-one, 3-, 3,4-dimethyl-	020685-46-5
hexen-2-one, 4-, 3,4-dimethyl-	053252-21-4
hexen-2-one, 3-methyl-4-	072189-24-3
hexen-2-one, 5-methyl-3-	005166-53-0
hexen-2-one, 5-methyl-5-	003240-09-3
hexyne-2,5-diol, 2,5-dimethyl-3-	000142-30-3
hydrocinnamic acid	006386-38-5
hydroxydiphenylamine, 3-	000101-18-8
hydroxypropyl methacrylate, 2-	000923-26-2
icosane	000112-95-8
imidazole, methylphenyl-	000670-91-7
indan-1-ol	006351-10-6
indan-1-one	000083-33-0
indene, 1H-, 2,3-dihydro-1-methyl-	000767-58-8
indene, 1H-, 2,3-dihydro-4-methyl-	000824-22-6
indene, 1H-, 2,3-dihydro-5-methyl-	000874-35-1
indene, 2,3-dihydro- also (2,3-dihydro-1H-)	000496-11-7
indene	000095-13-6
isoalkanes, C9-C12	090622-57-4
isobutylene	000115-11-7
isobutyramide	000563-83-7
isobutyric acid	000079-31-2
isobutyronitrile	000078-82-0
isocrotonic acid	000503-64-0
isoindole, 2H-, 4,7-dione	056460-94-7
isophorone diamine	002855-13-2
isovanillin	000621-59-0
maleic anhydride, 2,3-dimethyl-	000766-39-2
menthane, 1,2:8,9-diepoxy-	000096-08-2
mephenesin	000059-47-2
methacrylate, lauryl-	000142-90-5
methacrylic acid, 2-hydroxyethyl ester	000868-77-9
methacrylic acid, 3-(trimethylsilyl)propyl ester	002530-85-0
methane, chlorodifluoro-	000075-45-6
methane, di-t-butoxy	002568-93-6
methane, di-t-butyl-	001070-87-7
methoxybenzene	000100-66-3
methyl anthranilate	000134-20-3
methyl-1 bicyclo[4.2.0]octa-1,3,5-triene, 3-	022250-74-4
methylcarbamate, methyl N-butyl-N-	054644-60-9
methylcoumarin, 7-diethylamino-4-	000091-44-1

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
methyl (Z)-octadec-11-enoate	001937-63-9
methyl palmitate	000112-39-0
methyl laurate	000111-82-0
methyl salicylate	000119-36-8
methyl stearate	000112-68-1
methyl-4-isopropyl cyclohexane, trans-1-	001678-82-6
methyldiethyl carbamate	004652-44-2
methylene bis(4-methyl-6-tertbutyl-phenol), 2,2'	000119-47-1
2,2'-methylenediphenol	002467-02-9
4,4'-methylenediphenol	000620-92-8
methylenephenethyl alcohol, beta-	006006-81-1
methylindene	029036-25-7
methyl nadic anhydride	025134-21-8
methylpiperidine, 1-	000626-67-5
methylthioacetone	035120-10-6
morpholine, methyl-	000109-02-4
morpholine, 4-dodecyl-	001541-81-7
morpholinecarbaldehyde, 4-	004394-85-8
morpholinecarboxamide, N-cyclohexyl-4-	003417-54-7
morpholinepropanenitrile, 4-	004542-47-6
N-butyl formamide	000871-71-6
N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate	000078-44-4
naphthylenamine, N-phenyl-2-	000135-88-6
naphthalene, dimethyl-	028804-88-8
naphthalene, 1,2-dimethyl-	000573-98-8
naphthalene, 1,3-dimethyl-	000575-41-7
naphthalene, 1,4-dimethyl-	000571-58-4
naphthalene, 1,5-dimethyl-	000571-61-9
naphthalene, 1,7-dimethyl-	000575-37-1
naphthalene, 1,8-dimethyl-	000569-41-5
naphthalene, 2,3-dimethyl-	000581-40-8
naphthalene, 2,6-dimethyl-	000581-42-0
naphthalene, 2,7-dimethyl-	000582-16-1
naphthalene, 1-ethyl-	001127-76-0
naphthalene, 2-ethyl-	000939-27-5
naphthalene, ethyl	027138-19-8
nonacosane	000630-03-5
nonanal	000124-19-6
nonanal, 2-oxo-	002363-87-3
nonanoic acid, 9-oxo-	002553-17-5
nonanoic acid, n-	000112-05-0
norbornene, 5-ethylidene-2-	016219-75-3
octacosane	000630-02-4
octadecadienoic acid, (Z,Z)-9,12-, butyl ester	002634-45-9
octadecane, n-	000593-45-3
octadecenoic acid, 6(Z), methyl ester	002777-58-4
octadecenoic acid, 6-, methyl ester	052355-31-4
octadecenoic acid, 7-, methyl ester	057396-98-2
octadecenoic acid, 8-, methyl ester	002345-29-1

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
octadecenoic acid, 9(E)-, methyl ester	001937-62-8
octadecenoic acid, 9(Z)-, methyl ester	000112-62-9
octadecenoic acid, 9-, methyl ester	002462-84-2
octadecenoic acid, 10-, methyl ester	013481-95-3
octadecanamide	000124-26-5
octadecenamide	000301-02-0
octadecene, 1-	000112-88-9
octadien-1-ol, 3,7-dimethyl-2,6-	000624-15-7
octadien-2-ol, 2,6-dimethyl-5,7-	005986-38-9
octadien-3-ol, 2,6-dimethyl-1,7-	022460-59-9
octadien-3-ol, 3,7-dimethyl-1,6-	000078-70-6
octadien-3-ol, 3,7-dimethyl-4,6-	018479-54-4
octanal	000124-13-0
octanoate, methyl-	000111-11-5
octaphenyl pentaethylene glycol ether, tert-	038621-31-7
oct-2-enoic acid	001470-50-4
octen-3-ol, 1-	003391-86-4
octylphenoxy pentaethoxyethanol, tert-	037809-81-7
oleate, n-butyl-	000142-77-8
oxabicyclo (4.1.0) heptane-3-carboxylic acid, 7-	002386-87-0
oxamide, di-tert-butyl-	037486-48-9
oxaspirodecadienedione, di-(t-butyl)	082304-66-3
oxirane, [(dodecyloxy)methyl]-	002461-18-9
oxononan-1-al, 4-	074327-29-0
oxybis(propanenitrile)	001656-48-0
palmitate, isopropyl-	000142-91-6
palmitic acid, n-butyl ester	000111-06-8
pentacosane	000629-99-2
pentane, 1-amino	000110-58-7
pentanediol, 2,2,4-trimethyl-1,3-	000144-19-4
pentanedione, 1-phenyl-1,4-	000583-05-1
pentanenitrile	000110-59-8
pentaoxacyclopentacosane, 1,6,11,16,21-	056890-57-4
pentaohexadecanol	023778-52-1
pentenal, trans-2-	001576-87-0
penten-2-ol, 3-	001569-50-2
penten-2-one, 3,4-dimethyl-3-	000684-94-6
perfluorooctanoic acid	000335-67-1
peroxide, tert-butyl-	000110-05-4
phenanthrene	000085-01-8
phenetidine, o-	000094-70-2
phenol, 4-ethoxy-	000622-62-8
phenol, o-(1-phenylethyl)-	004237-44-9
phenol, (phenylethyl)-	051937-33-8
phenol, o-(alpha, alpha-dimethylbenzyl)-	018168-40-6
phenol, p-(alpha, alpha-dimethylbenzyl)-	000599-64-4
phenol, p-phenylethyl-	006335-83-7
phenol, 4-(2-propenyl)-	000501-92-8
phenol, 3,5-dibenzyl-2,4,6-trimethyl-	unknown

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
phenol, 2,6-di-t-butyl-4-methoxy-	000489-01-0
phenol, 2,2'-methylenebis (6-tert-butyl)-4-ethyl-	000088-24-4
phenol, 2,4,6-tris(dimethylaminomethyl)-	000090-72-2
phenol, 4-(1-phenylethyl)-	001988-89-2
phenol, 2-allyl-	001745-81-9
phenothiazine	000092-84-2
phenoxypropanol, 1- (or 2-)	041593-38-8
phenyl isothiocyanate	000103-72-0
phenyl-1-buten-4-ol, 4-	000936-58-3
phenylbutane, 2-	000135-98-8
phenylene) bis-ethanone, 1,1'-(1,4-	001009-61-6
phenylene) bis-ethanone, 1,1'-(1,3-	006781-42-6
phenylenediamine, N,N-bis(1,3-dimethylbutyl)-N'-phenyl-p-	019929-72-7
2,2'-p-phenylenedioxydiethanol	000104-38-1
phenylethanol, 2-	000060-12-8
(phenylimino) cyclohexadiene	002406-04-4
phenylindan, 1,1,3-trimethyl-3-	003910-35-8
phorone	000504-20-1
phosphate, diphenyl-2-ethylhexyl-	001241-94-7
phosphinic acid, P-phenyl-, Na salt	004297-95-4
phosphonic acid, (nitrilotris(methylene))tri-, pentasodium	002235-43-0
pinanol	000473-54-1
pinanol (or cis-2-pinanol)	004948-28-1
pinanol, trans-2-	004948-29-2
pinocampeol (also pinocamphone)	000547-60-4
piperazine, 1-(2-aminoethyl)-	000140-31-8
piperidine, 1-formyl	002591-86-8
piperidine, 2-propyl-	000458-88-8
piperidene, 2,2,6,6-tetramethyl-	000768-66-1
piperidinol, 1,2,2,6,6-pentamethyl-4-	002403-89-6
piperidone, 2-	000675-20-7
poly(oxy-1,2-ethanediyl), a-isotridecyl-w-hydroxy-, phosphate	073038-25-2
propanal, 2,2-dimethyl-3-hydroxy-	000597-31-9
propanal, 3-phenyl	000104-53-0
propanaminium chloride, N,N,N-trimethyl-3-((1-oxo-2-propenyl)amino)-1-	045021-77-0
propane, 1,1-dimethoxy-2-methyl	041632-89-7
propanediol, 2-ethyl-2-butyl-1,3-	000115-84-4
propanenitrile, 3-(diethylamino)-	005351-04-2
propanenitrile, 3,3'-oxybis-	001656-48-0
propanenitrile, 3,3'-thiobis-	000111-97-7
propanoic acid, 2-methyl-, 1-(1,1-dimethylethyl)-2-methyl-1,3-propanediyl ester	074381-40-1
propanoic acid, 3-ethoxy-, ethyl ester	000763-69-9
propanoic acid, ethyl ester	000105-37-3
propanoic acid, 2,2-dimethyl-	000075-98-9
propanol, 1-amino-2 -	000078-96-6
propanol, 1-[4-(1,1-dimethylethyl)phenoxy]-2-	002416-30-0
propanol, 1-phenoxy 2-	000770-35-4
propanol, phenyl	000093-54-9

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
propanol, phenyl-1-	001335-12-2
propanol, 1-propoxy-2-	001569-01-3
propanone, 1-phenyl-1-	000093-55-0
propanone, 1-, 2-hydroxy-2-methyl-1-phenyl-	007473-98-5
propenamide, 3-(2-methylphenyl)-2-	146669-23-0
propenoic acid, 2-methyl-, 1-methyl-1,3-propanediyl ester, 2-	001189-08-8
propenoic acid, 2-methyl-2-, polymer with octadecyl-2-methyl-2-propenoate	027401-06-5
propenone, (dihydroxy methoxyphenyl) phenyl-	018956-15-5
pyrazine, 2-methyl-	000109-08-0
pyrene	000129-00-0
pyridine, 2-ethyl-	000100-71-0
pyridine, 2-methyl-	000109-06-8
pyridine, 3-methyl-	000108-99-6
pyridine, 4-methyl-	000108-89-4
pyridine, 2,3-dimethyl-	000583-61-9
pyridine, 2,4-dimethyl-	000108-47-4
pyridine, 2,5-dimethyl-	000589-93-5
pyridine, 2,6-dimethyl-	000108-48-5
pyridine, 3,4-dimethyl-	000583-58-4
pyridine, 3,5-dimethyl-	000591-22-0
pyridine, trimethyl-	029611-84-5
pyridine, 2,4,6-trimethyl-	000108-75-8
pyridine, 1,2,3,4-tetrahydro-1,2,2,6-tetramethyl-	063867-76-5
pyridine, 1,2,3,6-tetrahydro-1,2,3,4-tetramethyl-	090949-18-1
pyridine, 1,2,3,6-tetrahydro-1,2,4,5-tetramethyl-	090949-19-2
pyridine, 1,2,3,6-tetrahydro-1,2,4,6-tetramethyl-, cis-	023513-16-8
pyridine, 1,2,3,6-tetrahydro-1,3,3,6-tetramethyl-	122913-54-6
pyridine, 1,2,3,6-tetrahydro-1,4,5,6-tetramethyl-	090949-20-5
pyridine, 1,2,3,6-tetrahydro-2,2,2,6-tetramethyl-	001124-69-2
pyridine, 1,2,5,6-tetrahydro-2,2,5,5-tetramethyl-	155904-89-5
pyridine, 2,3,4,5-tetrahydro-2,2,4,6-tetramethyl-	200561-41-7
pyridine, 2,3,5-trimethyl-	000695-98-7
pyridine, 2,3,6-trimethyl-	001462-84-6
pyrrolidine	000123-75-1
pyrrolidinone, 1-decyl-2-	055257-88-0
pyrrolidinone, 1-dodecyl-2-	002687-96-9
pyrrolo(1,2-a)pyrazine-1,4-dione, hexahydro-3-(2-methylpropyl)-	005654-86-4
quaternary ammonium, ditallow dimethyl chloride	061789-80-8
quinoline, 3,4-dihydro-2,4,4-trimethyl-	063177-93-5
sodium p-sulfophenyl methallyl ether	001208-67-9
soya alkylamines, ethoxylated	061791-24-0
squalene	000111-02-4
squalene	007683-64-9
stearic acid, butyl ester	000123-95-5
styrene, alpha-methyl-	000098-83-9
styrene, methyl- (mixed isomers)	025013-15-4
succinic acid, diethyl ester	000123-25-1
sulfonylbis(4-methyl)-benzene, 1,'	000599-66-6
terephthalic acid, monomethyl ester	001679-64-7

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
terpineol, alpha-	000098-55-5
tert-butylamine	000075-64-9
tetracosane	000646-31-1
tetradecamethylcyclotrisiloxane	000107-50-6
tetradecanamide	000638-58-4
tetradecanamine, 1-	002016-42-4
tetradecane	001120-36-1
tetraethyleneglycol di-(2-ethylhexoate)	018268-70-7
tetraethyleneglycol dimethacrylate	000109-17-1
tetrahydrofuran, diphenyl-	050637-09-7
tetrahydrofurfuryl alcohol	000097-99-4
tetrahydropyridine, 2,3,4,5-	000505-18-0
tetramethyl urea	000632-22-4
tetramethyldec-5-yne-4,7-diol, 2,4,7,9-	000126-86-3
tetramethyldecynediol	001333-17-1
2,6,10,14-tetramethylhexadecane	000638-36-8
tetramethylpyrazine, 2,3,5,6-	001124-11-4
tetraoxacycloicosane, 1,6,11,16-	017043-02-6
tetrathiacyclooctadecane, 1,3,10,12-tetraoxa-6,7,15,16-	099634-55-6
4,4'-thiobis-(6-t-butyl-o-cresol)	000096-66-2
1,4-thoxane	015980-15-1
toluene, 2,6-diamino-	000823-40-5
toluenesulfonamide, N-ethyl-4-	000080-39-7
toluenesulfonic acid, p-, butyl ester	000778-28-9
toluidine, N,N-diethyl-p-	000613-48-9
triallyl cyanurate	000101-37-1
tributylphosphine oxide	000814-29-9
trichloroaniline, 2,4,5-	000636-30-6
trichloroaniline, 2,3,4-	000634-67-3
trichlorotrifluoroethane	026523-64-8
tricosane, also (n-tricosane)	000638-67-5
tridecane, 6-phenyl-	004534-49-0
triethylamine	000121-44-8
triethyleneglycol dimethacrylate	000109-16-0
triethylsilanol	000597-52-4
trimethylcyclohexanone	050874-76-5
trimethylolpropane trimethacrylate	003290-92-4
trioxane, 1,3,5-trimethyl-	000123-63-7
trioxepane, 1,3,5-	005981-06-6
triphenylphosphate	000115-86-6
triphenylphosphine oxide	000791-28-6
triphenylphosphine sulfide	003878-45-3
tropic acid	000552-63-6
undecanoic acid	000112-37-8
urea, N,N-bis-(1,1-dimethylethyl)-	005336-24-3
urea, 1,3-diphenyl-	000102-07-8
urea, 1,1,3,3-tetrabutyl-	004559-86-8
urea, N,N',N'-trimethyl-	000623-14-4
valeronitrile, 2,4-dimethyl-	034372-09-3

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
vinylidene fluoride	000075-38-7
xyleneol, 4-tert-butyl-2,6-	000879-97-0
xyleneol, 6-tert-butyl-3,4-	001445-23-4
xyleneol, 6-tert-butyl-1,4-	001879-09-0
¹ For the chemicals listed in this table, the evaluation criteria are 0.003 mg/L under static conditions, and 0.0003 mg/L under flowing conditions.	

– concluded –

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Annex E²²

Informational drinking water criteria

E.1 General

The drinking water criteria in this annex have not undergone external peer review.

The drinking water criteria in this annex are intended to be used as guidance in the determination of evaluation criteria for those compounds that do not have normative evaluation criteria established. Some of these values, as noted in the tables, are currently under external peer review for inclusion as normative criteria. The values in these tables include criteria that have been developed according to the requirements of Annex A, but have not been externally peer reviewed. The tables also include non-regulatory USEPA values that have been reviewed but failed to satisfy Annex A toxicity data requirements. Compounds that have been detected only at concentrations below the threshold of evaluation (see Annex A, section A.7.1) to which the threshold of evaluation protocol has been applied are also listed here.

The drinking water criteria in this annex have not been evaluated for taste and odor considerations at the concentration limits indicated.

In the event that one of the chemicals listed in this annex is detected at concentrations exceeding the guidance evaluation criteria values, a complete toxicity data review should be conducted. The review should be performed according to Annex A requirements prior to using the informational evaluation criteria values to determine product compliance to this Standard.

The substances listed in Annex E, Tables E1 and E2 are not intended to encompass all of the potential analytes of interest that need to be considered when evaluating products. The user is cautioned that each product may have formulation dependent analytes of interest for which concentration limits have not been determined. In these cases, the user is required to develop acceptable concentration limits based on the requirements of Annex A of NSF/ANSI 60 in order to determine full compliance with the Standard.

These tables are specific to NSF/ANSI 60. While the tables may be used for evaluation of impurities in drinking water system components, the substances listed in these tables may have not been evaluated for use as indirect additive drinking water treatment chemicals under NSF/ANSI 61 *Drinking water system components – Health effects*.¹ Use as indirect additive drinking water additives may require the consideration of different exposure parameters than those used for NSF/ANSI 60 evaluation.

E.2 NSF International drinking water criteria (not externally peer reviewed)

Annex E, Table E1 contains drinking water criteria for unregulated contaminants that have been identified as extractants from products covered by this Standard. For criteria set by NSF International, the TAC and SPAC criteria have been determined in accordance with Annex A of NSF/ANSI 60 - 2000. External peer review is in progress on these evaluation criteria, as noted in the table. As external peer review is completed, those criteria will be submitted for inclusion as normative evaluation criteria in this Standard.

In the absence of sufficient information to determine a data-derived relative source contribution factor, a default 20% drinking water contribution is assumed.

²² The information contained in this annex 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 annex 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.

Some of the SPAC values do not represent 10% of the corresponding TAC values; either a data deficiency precluded setting of the TAC at a higher value, or a data-derived multiple source factor other than the 10% default value was applied.

E.3 Informational threshold of evaluation chemicals

Annex E, Table E2 contains chemicals that have been evaluated using the threshold of evaluation (see Annex A, section A.7.1), but that may have sufficient toxicity data available that would enable chemical specific risk assessments to be performed if needed. To date, these chemicals have not been detected at concentrations exceeding the threshold of evaluation criteria. In the event that these chemicals are detected at concentrations exceeding the threshold of evaluation criteria, a toxicity data review should be conducted according to Annex A prior to using the threshold of evaluation to determine product compliance to this Standard.

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Table E1 – NSF International drinking water criteria (not externally peer reviewed)

Substance	CAS #	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ¹
Inorganics			
aluminum	7429-90-5	2	NSF action levels ³ Issue date: 07/90
bismuth	7440-69-9	0.01 (non-section 9) ² 0.05 (section 9) ²	NSF action levels ³
lithium	7439-93-2	0.3	NSF action levels ³
nickel	7440-02-0	0.02	NSF action levels ³
vanadium	7440-62-2	0.003	NSF action levels ³
Organics			
acetaldehyde	75-07-0	0.01	NSF action levels ³
2,2'-azobisisobutyronitrile	78-67-1	0.01	NSF action levels ³ Issue date: 07/01/96
butylacrylamine, tert-	107-58-4	0.01	NSF action levels ³
butyl acrylate	141-32-2	0.01	NSF action levels ³
chloroethane	75-00-3	0.004	NSF action levels ³ issue date: 01/10/92
chloromethane	74-87-3	0.003	Based on the USEPA Lifetime Health Advisory. issue date: 1989
dibutylamine	111-92-2	0.01	NSF action levels ³
dichloropropanol includes: 2,3-dichloro-1-propanol 1,3-dichloro-2-propanol	26545-73-3 616-23-9 96-23-1	0.009 (total)	NSF action levels ³
diethanolamine	111-42-4	0.01	NSF action levels ³
diethylene triamine	111-40-0	0.01	NSF action levels ³
diisononyl phthalate	28553-12-0	0.05	NSF action levels ³
dimethylamine	124-40-3	0.120	NSF action levels ³ issue date: 11/06/98 (in external peer review)
ethanolamine	141-43-5	0.01	NSF action levels ³
ethyl acrylate	140-88-5	0.001	NSF action levels ³
ethylenediamine	107-15-3	0.2	NSF action levels ³
1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	2809-21-4	0.02	NSF action levels ³ issue date: 07/08/99 (in external peer review)
3-hydroxypropane nitrile	109-78-4	0.01	NSF action levels ³ Issue date: 09/03/97
maleic acid	110-16-7	0.05	NSF action levels ³
methacrylic acid	79-41-4	0.02	NSF action levels ³
nonyl phenol	25154-52-3	0.002	NSF action levels ³ issue date: 06/10/99

Table E1 – NSF International drinking water criteria (not externally peer reviewed)

Substance	CAS #	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ¹
Organics			
polyoxyethylene dodecyl phenol	9014-92-0	0.01	NSF action levels ³ issue date: 12/28/96
polyoxyethylene (6) dodecyl phenol		0.05	
polyoxyethylene (9) dodecyl phenol		0.05	
polyoxyethylene (40) dodecyl phenol		0.05	
polyoxyethylene (6) lauryl ether	9002-92-0	0.05	NSF action levels ³ issue date: 12/28/96
polyoxyethylene nonylphenol	9016-45-9	0.05 (total)	NSF action levels ³ issue date: 12/28/96
polyoxyethylene (4, 9, 15, 30, or 40) nonyl phenol		0.01 (total)	
polyoxyethylene (6 or 20) nonyl phenol			
polyoxyethylene octylphenol			
polyoxyethylene (9) octyl phenol	9002-93-1	0.05 (total)	NSF action levels ³ issue date: 12/28/96
polyoxyethylene (40) octyl phenol			
polyoxyethylene sorbitan monoalkylanoate	9005-65-6	1 (total)	NSF action levels ³ Alkyl group is a fatty acid. issue date: 01/97
polyoxyethylene sorbitan monooleate	9005-64-5		
polyoxyethylene sorbitan monolaurate	9005-66-7		
polyoxyethylene sorbitan monopalmitate	9005-67-8		
polyoxyethylene sorbitan monostearate			
polyoxyethylene sorbitan tristearate	9005-71-4	0.05	NSF action levels ³ issue date: 12/96
sodium dodecyl sulfate	151-21-3	0.01	NSF action levels ³
sodium xylenesulfonate	1300-72-7	0.05	NSF action levels ³ issue date: 04/96
sorbitan monoalkylanoate	1338-43-8 1338-40-5 1338-41-6	0.05 (total)	NSF action levels ³ alkyl group is a fatty acid. issue date: 12/96
sorbitan monooleate			
sorbitan			
monopalmitate			
sorbitan monostearate			
terephthalic acid	100-21-0	0.01	NSF action levels ³
n-triacontane	638-68-6	0.07	NSF action levels ³ Issue date: 06/10/99
triethanolamine	102-71-6	0.05	NSF action levels ³
trimethylamine	75-50-3	0.001	NSF action levels ³

Table E1 – NSF International drinking water criteria (not externally peer reviewed)

Substance	CAS #	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ¹
Organics			
trimethylbenzene, 1,2,4-	95-63-6	0.05	NSF action levels ³ Issue date: 06/10/99
vinyl acetate	108-05-4	0.002	NSF action levels ³
white mineral oil	8042-47-5	0.01 (10-26 CTS) 0.05 (68-100 CTS)	NSF action levels ³ SPAC is a function of viscosity. issue date: 04/02/96
¹ Criteria are derived from the oral RfD on the USEPA IRIS database as follows: Oral RfD (mg /kg-d) x (70 kg /2 L/d) x relative source contribution factor = TAC (mg/L) where: 70 kg = assumed adult body weight; 2 L/d = assumed adult water consumption; and relative source contribution factor = percentage of daily exposure to the substance represented by drinking water (default value is 20%) ² For NSF/ANSI 61, section 9 products, a 100% multiple source factor was applied during the SPAC calculation, since no other sources of bismuth were expected within the one liter draw specified for section 9. For non-section 9 products, a 20% multiple source factor was applied. ³ NSF action levels have been derived according to the requirements of ANSI/NSF 60 - 2000, Annex A. External peer review is in progress on some of these substances, as noted.			

– concluded –

Table E2 – Threshold of evaluation chemicals having datasets from which specific TAC/SPAC values, or CBEL values, could be set using Annex A¹

Substance	CAS#
Inorganics	
cobalt	007440-48-4
titanium	007440-32-6
Organics	
acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	000137-58-6
benzalazine	064896-26-0
benzamide	000055-21-0
benzophenone	000119-61-9
benzoguanamine	000091-76-9
benzotriazole, 1,2,3-	000095-14-7
benzyl acetate	000140-11-4
benzyl alcohol, 3,5-di-tert-butyl-4-hydroxy-	000088-26-6
cyanoguanidine	000461-58-5
cyclohexene	000110-83-8
dichlorodifluoromethane	000075-71-8
diethylaminoethanol	000100-37-8
dimethylacetamide, n,n-	000127-19-5
dimethyl adipate	000627-93-0
dimethylaminopropanenitrile	001738-25-6
dimethylformamide, n,n-	000068-12-2
dimethyl phthalate	000131-11-3
diphenyl guanidine, 1,3- (or n,n-)	000102-06-7
diphenyl-p-phenylenediamine, n,n'-	000074-31-7
ethanol, 2-diethylamino-	000100-37-8
ethanol, 2-(dimethylamino)-	000108-01-0
ethanol, 2-phenoxy-	000122-99-6
ethanol, 1-phenyl-	000098-85-1
fluoranthene	000206-44-0
fluorescein	002321-07-5
fluorescein, dipotassium salt	006417-85-2
furanmethanol, 2-	000098-00-0
heptanoic acid, n-	000111-14-8
hexamethylenetetramine	000100-97-0
hexanoic acid, n-	000142-62-1
isobutyl isobutyrate	000097-85-8
(isopropylamino)diphenylamine, 4-	000101-72-4
Isopropyltoluene	000099-87-6
methyl acrylate	000096-33-3
methyldiethanolamine, n-	000105-59-9
methylene diphenyl diisocyanate	000101-68-8
methylene bis(n-iso-butylbenzenamine)	088990-59-4
phenylene diamine, n-(1,3-dimethylbutyl)-n'-phenyl-p-	000793-24-8
phenylenediamine, n-phenyl-p-	000101-54-2
phthalic acid, o-	000088-99-3
piperidine	000110-89-4

Table E2 – Threshold of evaluation chemicals having datasets from which specific TAC/SPAC values, or CBEL values, could be set using Annex A¹

Substance	CAS#
Organics	
sebacate, bis(2-ethylhexyl)-	000122-62-3
silane, gamma-aminopropyl triethoxy-	000919-30-2
tacrine	000321-64-2
tetramethylene sulfone	000126-33-0
tetramethyl piperidinone	000826-36-8
thiabendazole	000148-79-8
triallyl isocyanurate	001025-15-6
triethylene diamine	000280-57-9
tris(2-ethylhexyl) phosphate	000078-42-2
vanillin, o-	000148-53-8

¹ For the chemicals in this table, the evaluation criteria are 0.003 mg/L under static conditions and 0.0003 mg/L under flowing conditions. The chemicals that appear in this table have been detected only at concentrations not exceeding these threshold of evaluation concentrations as established in this standard (see Annex A, A.7.1), and have not been evaluated for specific TAC and SPAC values. If any of these chemicals are detected at concentrations exceeding the threshold of evaluation, toxicity data shall be reviewed to determine whether specific TAC and SPAC values can be established, prior to using threshold of evaluation to determine compliance with the Standard.

– conclude –

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Annex F²³

Chemical product index

Table F1 – Chemical product index

Chemical name/synonym	Section reference	Table reference	Name used in standard
acrylamide/acrylic acid copolymer	4	4.1	same
activated silica	5	5.1	see sodium silicate
alum	4	4.1	see aluminum sulfate
aluminum alum	4	4.1	see aluminum sulfate
aluminum chloride	4	4.1	same
aluminum chloride hydroxide	4	4.1	see polyaluminum chloride
aluminum chloride hydroxide sulfate	4	4.1	see polyaluminum chloride
aluminum sodium oxide	4	4.1	see sodium aluminate
aluminum sulfate	4	4.1	same
aluminum trichloride	4	4.1	see aluminum chloride
aluminum trisulfate	4	4.1	see aluminum sulfate
ammonia, anhydrous	6	6.2	same
ammonia gas	6	6.2	see ammonia, anhydrous
ammonium hexafluorosilicate	7	7.1	same
ammonium hydroxide	6	6.2	same
ammonium sulfate	6	6.2	same
ammonium silicofluoride	7	7.1	see ammonium hexafluorosilicate
ammonium fluosilicate	7	7.1	see ammonium hexafluorosilicate
antifoamers	8	8.1	same
baking soda	5	5.1	see sodium bicarbonate
bentonite	4	4.1	same
biocides	8	8.1	same
cake alum	4	4.1	see aluminum sulfate
calcium carbonate	5	5.1	same
calcium fluoride	7	7.1	same
calcium hydroxide	5	5.1	same
calcium hypochlorite	6	6.2	same
calcium oxide	5	5.1	same
carbon dioxide	5	5.1	same
cationic polyacrylamide	4	4.1	same
caustic potash	5	5.1	see potassium hydroxide
caustic soda	5	5.1	see sodium hydroxide
cements	8	8.2	same
china clay	4	4.1	see kaolinite
chlorine	6	6.2	same
chlorine gas	6	6.2	see chlorine
clay thinners	8	8.1	same
copper ethanolamine complexes	7	7.1	same
copper sulfate	7	7.1	same

²³ The information contained in this annex 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 annex 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.

Table F1 – Chemical product index

Chemical name/synonym	Section reference	Table reference	Name used in standard
copper triethanolamine complexes	7	7.1	same
cupric sulfate	7	7.1	see copper sulfate
DADMAC	4	4.1	see diallyldimethylammonium chloride acrylamide copolymer
defoamers	8	8.1	same
descalers/scale inhibitors	8	8.1	same
development/rehabilitation materials	8	8.1	same
DKP	5	5.1	see dipotassium orthophosphate
DMDAAC	4	4.1	see diallyldimethylammonium chloride acrylamide copolymer
diallyldimethylammonium chloride acrylamide copolymer	4	4.1	same
DSP	5	5.1	see disodium orthophosphate
diphosphoric acid, tetrapotassium salt	5	5.1	see tetrapotassium pyrophosphate
dipotassium hydrogen phosphate	5	5.1	see dipotassium orthophosphate
dipotassium monophosphate	5	5.1	see dipotassium orthophosphate
dipotassium orthophosphate	5	5.1	same
dipotassium phosphate	5	5.1	see dipotassium orthophosphate
disodium diphosphate	5	5.1	see sodium acid pyrophosphate
disodium hydrogen phosphate	5	5.1	see disodium orthophosphate
disodium monophosphate	5	5.1	see disodium orthophosphate
disodium orthophosphate	5	5.1	same
disodium phosphate	5	5.1	see disodium orthophosphate
drilling fluids	8	8.1	same
dry ammonia	6	6.2	see ammonium sulfate
EPI./DMA	4	4.1	see polyamines
EDTA	5	5.1	see ethylenediaminetetraacetic acid
EDTA, sodium salt	5	5.1	see tetrasodium ethylenediaminetetraacetic acid
ethylenediaminetetraacetic acid	5	5.1	same
ferric chloride	4	4.1	same
ferric persulfate	4	4.1	see ferric sulfate
ferric sulfate	4	4.1	same
ferric tersulfate	4	4.1	see ferric sulfate
ferrous sulfate	4	4.1	same
filtration control	8	8.1	same
florocid	7	7.1	see sodium fluoride
fluorite	7	7.1	see calcium fluoride
fluosilicic acid	7	7.1	same
fluorspar	7	7.1	see calcium fluoride
foamers	8	8.1	same
frac sands	8	8.1	same
glassy sodium phosphate	5	5.1	see sodium polyphosphates, glassy
graham's salt	5	5.1	see sodium polyphosphates, glassy
gravel	8	8.1	same
grouts	8	8.1	same
HPAM	4	4.1	see hydrolyzed polyacrylamide

Table F1 – Chemical product index

Chemical name/synonym	Section reference	Table reference	Name used in standard
hydrated lime	5	5.1	see calcium hydroxide
hydrochloric acid	5	5.1	same
hydrofluosilicic acid	7	7.1	see fluosilicic acid
hydrolyzed polyacrylamide	4	4.1	same
hydroxyapatite	7	7.1	see tricalcium phosphate
iodine	6	6.2	same
iron (II) sulfate	4	4.1	see ferrous sulfate
iron (III) chloride	4	4.1	see ferric chloride
iron (III) sulfate	4	4.1	see ferric sulfate
iron trichloride	4	4.1	see ferric chloride
KTPP	5	5.1	see potassium tripolyphosphate
kaolinite	4	4.1	same
lime	5	5.1	see calcium oxide
limestone	5	5.1	see calcium carbonate
liquid bleach	6	6.2	see sodium hypochlorite
liquid ammonia	6	5.1	see ammonium hydroxide
loss circulation materials	8	8.1	same
lubricants	8	8.1	same
MKP	5	5.1	see monopotassium orthophosphate
MSP	5	5.1	see monosodium orthophosphate
magnesia	5	5.1	see magnesium oxide
magnesium carbonate hydroxide	5	5.1	same
magnesium oxide	5	5.1	same
magnesium silicofluoride	7	7.1	same
magnesium hexafluorosilicate	7	7.1	see magnesium silicofluoride
monophosphoric acid	5	5.1	see phosphoric acid
monopotassium dihydrogen phosphate	5	5.1	see monopotassium orthophosphate
monopotassium orthophosphate	5	5.1	same
monopotassium phosphate	5	5.1	see monopotassium orthophosphate
monopotassium monophosphate	5	5.1	see monopotassium orthophosphate
monosodium dihydrogen phosphate	5	5.1	see monopotassium orthophosphate
monosodium orthophosphate	5	5.1	same
monosodium phosphate	5	5.1	see monosodium orthophosphate
monosodium monophosphate	5	5.1	see monosodium orthophosphate
montmorillonite	4	4.1	see bentonite
muriatic acid	5	5.1	see hydrochloric acid
oil of vitriol	5	5.1	see sulfuric acid
orthophosphoric acid	5	5.1	see phosphoric acid
oxygen scavengers	8	8.1	same
PAM	4	4.1	see polyacrylamide
PAMD	4	4.1	see polyacrylamide
PPA	5	5.1	see polyphosphoric acid

Table F1 – Chemical product index

Chemical name/synonym	Section reference	Table reference	Name used in standard
pentapotassium triphosphosphate	5	5.1	see potassium triphosphosphate
pentasodium triphosphosphate	5	5.1	see sodium triphosphosphate
permanganate	6	6.2	see potassium permanganate
phosphoric acid	5	5.1	same
polyDADMAC	4	4.1	see poly(diallyldimethylammonium chloride)
polyDMAAC	4	4.1	see poly(diallyldimethylammonium chloride)
polyacrylamide	4	4.1	same
polyaluminum chloride	4	4.1	same
polyamines	4	4.1	same
polybasic aluminum chloride	4	4.1	see polyaluminum chloride
poly(diallyldimethylammonium chloride)	4	4.1	same
polyethyleneamines	4	4.1	same
polyphosphoric acid	5	5.1	same
porcelain clay	4	4.1	see kaolinite
potassium fluoride	7	7.1	same
potassium hydroxide	5	5.1	same
potassium permanganate	6	6.2	same
potassium phosphate, dibasic	5	5.1	see dipotassium orthophosphate
potassium phosphate, monobasic	5	5.1	see monopotassium orthophosphate
potassium phosphate, tribasic	5	5.1	see tripotassium orthophosphate
potassium pyrophosphate	5	5.1	see terapotassium pyrophosphate
potassium triphosphate	5	5.1	see potassium triphosphosphate
potassium triphosphosphate	5	5.1	see potassium triphosphosphate
quicklime	5	5.1	see calcium oxide
regenerants	8	8.1	same
resin amines	4	4.1	same
SAPP	5	5.1	see sodium acid pyrophosphate
SHMP	5	5.1	see sodium polyphosphates, glassy
STP	5	5.1	see sodium triphosphosphate
STPP	5	5.1	see sodium triphosphosphate
slaked lime	5	5.1	see sodium hydroxide
soda ash	5	5.1	see sodium carbonate
sodium acid pyrophosphate	5	5.1	same
sodium aluminate	4	4.1	same
sodium acid sulfite	7	7.1	see sodium bisulfate
sodium bicarbonate	5	5.1	same
sodium bisulfate	5	5.1	same
sodium bisulfite	7	7.1	same
sodium calcium magnesium polyphosphate, glassy	5	5.1	same
sodium carbonate	5	5.1	same
sodium chlorate	6	6.2	same
sodium chlorite	6	6.2	same
sodium dihydrogen pyrophosphate	5	5.1	see sodium acid pyrophosphate

Table F1 – Chemical product index

Chemical name/synonym	Section reference	Table reference	Name used in standard
sodium fluoride	7	7.1	same
sodium fluosilicate	7	7.1	see sodium silicofluoride
sodium hexametaphosphate	5	5.1	see sodium polyphosphates, glassy
sodium hydrogen sulfate	5	5.1	see sodium bisulfate
sodium hydroxide	5	5.1	same
sodium hypochlorite	6	6.2	same
sodium metabisulfite	7	7.1	same
sodium phosphate, monobasic	5	5.1	see monosodium orthophosphate
sodium phosphate, dibasic	5	5.1	see disodium orthophosphate
sodium phosphate, tribasic	5	5.1	see trisodium orthophosphate
sodium polyphosphates, glassy	5	5.1	same
sodium pyrophosphate	5	5.1	see tetrasodium pyrophosphate
sodium pyrosulfate	5	5.1	see sodium bisulfate
sodium pyrosulfite	7	7.1	see sodium metabisulfite
sodium sesquicarbonate	5	5.1	same
sodium silicate	5	5.1	same
sodium silicofluoride	7	7.1	same
sodium sulfite	7	7.1	same
sodium tetrapolyphosphate	5	5.1	see sodium polyphosphates, glassy
sodium trimetaphosphate	5	5.1	same
sodium triphosphate	5	5.1	see sodium tripolyphosphate
sodium tripolyphosphate	5	5.1	same
sodium zinc potassium polyphosphate, glassy	5	5.1	same
sodium zinc phosphate, glassy	5	5.1	same
starch, anionic	4	4.1	same
starch, base hydrolyzed	4	4.1	see starch, anionic
sulfur dioxide	7	7.1	same
sulfuric acid	5	5.1	same
sulfurous oxide	7	7.1	see sulfur dioxide
superphosphoric acid	5	5.1	see polyphosphoric acid
TKP	5	5.1	see tripotassium orthophosphate
TKPP	5	5.1	see tetrapotassium pyrophosphate
TSPP	5	5.1	see tetrasodium pyrophosphate
TSP	5	5.1	see trisodium orthophosphate
tetrapotassium diphosphate	5	5.1	see tetrapotassium pyrophosphate
tetrapotassium pyrophosphate	5	5.1	same
tetrasodium diphosphate	5	5.1	see tetrasodium pyrophosphate
tetrasodium ethylenediaminetetra-acetic acid	5	5.1	same
tetrasodium pyrophosphate	5	5.1	same
tricalcium phosphate	7	7.1	same
tripotassium monophosphate	5	5.1	see tripotassium orthophosphate
tripotassium orthophosphate	5	5.1	same
tripotassium phosphate	5	5.1	see tripotassium orthophosphate
trisodium monophosphate	5	5.1	see trisodium orthophosphate
trisodium orthophosphate	5	5.1	same

Table F1 – Chemical product index

Chemical name/synonym	Section reference	Table reference	Name used in standard
trisodium phosphate	5	5.1	see trisodium orthophosphate
viscosifiers	8	8.1	same
weighting agents	8	8.1	same
well grouting/sealing materials	8	8.1	same
wilkinite	4	4.1	see bentonite
zinc chloride	5	5.1	same
zinc orthophosphate	5	5.1	same
zinc sulfate	5	5.1	same

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Annex G²⁴ (informative)

Revisions to the evaluation of bromate

G.1 Background

Bromate is a known impurity of the hypochlorite chemical production process. Because of the potential cancer risk associated with human exposure to bromate, its introduction into drinking water has been regulated by the USEPA and Health Canada. The two major sources of bromate in drinking water are ozonation of water containing bromide and use of hypochlorite treatment chemicals containing bromate (sodium and calcium hypochlorites).

Bromate was first noted as a contaminant in hypochlorite to the Drinking Water Additives Joint Committee in 2000. At that time, the Chlorine Institute and the Chlorine Chemistry Council (now the Chlorine Chemistry Division of ACC), on behalf of hypochlorite manufacturers, presented the current capability of the industry to produce low-bromate hypochlorite products and reported that adding bromate as a required analysis against the Single Product Allowable Concentration (SPAC) of 0.001 mg/L in effect at the time would result in significantly fewer certified hypochlorite products.

The SPAC of 0.001 mg/L in effect at the time was based on the US EPA MCL of 0.010 mg/L bromate divided by the default source contribution factor in the standard of 10. Using the data-driven source contribution approach enabled in Annex A and accounting for up to three sources of bromate in drinking water (ozonated water containing bromide, bromate containing hypochlorites, and a 3rd unspecified source) the SPAC calculates to 0.003 mg/L. The SPAC was ultimately accepted at 0.005 mg/L in 2002 based on the two known sources, but as an interim measure only.

G.2 Reduction in the Single Product Acceptable Concentration

To reduce the burden of bromate in drinking water, a reduction in the level of bromate in hypochlorite drinking water chemicals is required. Beginning January 1, 2013, the Single Product Allowable Concentration for bromate will be lowered to 0.003 mg/L.

G.3 Additional information on bromate

Bromate is a disinfection by-product that may be formed when water containing bromide is disinfected with ozone. A second source of bromate in drinking water results from the use of sodium and/or calcium hypochlorite products. Bromide originates in the raw material, known as brine, used to manufacture these product types. Brine solution is fed into an electrolytic cell that cleaves the sodium (or calcium) ion and chloride ion. With the addition of water, sodium (or calcium) hydroxide and chlorine are formed. These two chemicals are then brought together to form either sodium or calcium hypochlorite.

There are three different electrolytic cell types that may be used: mercury, membrane and diaphragm. Studies have shown that if a mercury or membrane electrolytic cell is used, 80% of the bromide originating from the brine will end up in the chlorine while the remaining 20% ends up in the sodium or calcium hydroxide. When a diaphragm cell is used, 40% of the bromide ends up in the chlorine and 60%

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in the sodium or calcium hydroxide. When the chlorine and sodium (or calcium) hydroxide are combined to produce the hypochlorite product the bromide ion is converted to bromate.

Bromate has been classified as a B2, probable human carcinogen (sufficient data in animals; no data in humans). Studies of carcinogenicity in rats reported tumors at multiple sites, including the kidney, the thyroid, and the peritoneum. The exact mechanism by which bromate causes tumors is not known, however it is assumed that the mode of action that produced the tumors in rats is relevant to humans.

EPA has classified bromate as a carcinogen that interacts with DNA and established a MCLG of 0. The MCL value of 10 ug/L was developed based on available analytical detection methods which were reliable only to a practical quantification limit (PQL) of 0.010 mg/L (EPA, 1994). Analytical methods are now available that can reliably measure bromate concentrations as low as 1 ug/L (EPA, 2003).

The current MCL of 10 ug/L is equivalent to a lifetime cancer risk of 2×10^{-4} , a value that is greater than the EPA's acceptable range of 10^{-4} to 10^{-6} . This higher risk factor was deemed acceptable based on additional considerations such as the potential risk associated with a decrease in current levels of microbial protection and risks from increases in levels of disinfection by-products from other disinfectants. Health Canada has also set their Maximum Acceptable Contaminant (MAC) level at 10 ug/L and determined the lifetime cancer risk to be 2.19×10^{-4} . The MAC was designated as an interim value because the lifetime cancer risk associated with ingesting drinking water containing 10 ug/L bromate is greater than the range that is considered to be essentially negligible (HC, 1998).

When setting the MCL, the main focus of bromate contamination was ozonation systems. EPA's Technical Working Group estimated that hypochlorite solutions contributed an average of 1 ug/L bromate whereas ozone systems contributed less than 10 ug/L bromate but approximately 20% contributed greater than 5 ug/L bromate. Based on this data, non-ozone systems are not required to monitor for bromate.

G.4 References

Health Canada (1998) Guidelines for Canadian Drinking Water Quality: Guideline Technical Document — Bromate. Water, Air and Climate Change Bureau, Healthy Environments and Consumer Safety Branch, Health Canada, Ottawa, Ontario. <http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/doc_sup-appui/bromate/index_e.html>.

U.S. EPA. 2003d. National primary drinking water regulations: Stage 2 disinfectants and disinfection byproducts rule; National primary and secondary drinking water regulations: *Federal Register*. August 18, 2003 68 (159): 49547-49596. Proposed rule.

U.S. EPA. 1994a. National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Proposed Rule. *Fed. Reg.*, 59:145:38668. (July 29, 1994).

Annex H²⁵
(informative)**Examples of Tamper Evidence**

While there is a clear need to protect all materials used in the treatment of potable water from tampering, there is also a clear understanding that tamper evidence (T/E) does not equal tamper proof. It is also understood that while a determined effort will find ways to subvert any tamper management protocol, it is the intent of this rule to make it much more difficult to do so. With that in mind the following visual examples of typical temper evident measures are offered as a guide to future compliance with the rule. The general guide is that, if it takes less than a few minutes with simple hand tools to access the contents of a vessel, it then needs to be protected with appropriate T/E measure. Similarly if access is not-logical, non-obvious or only indirect then normally T/E measure would not be appropriate for that area. On vessels with domes it is appropriate that the dome be protected with T/E measures. On vessels with dispersed fittings then the above should be the guide.

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Loading ports



Figure 1 - Common load point protected; torqued bolts are not.



Figure 2 - Common load point protected; torqued bolts are not.

Typical off-loading ports

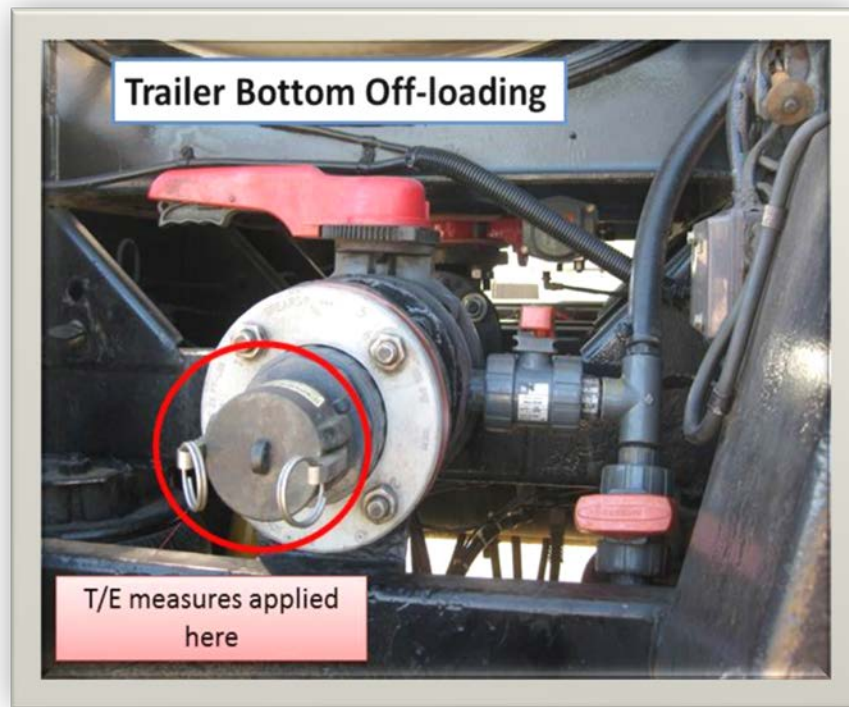


Figure 3- Common off-load point protected; torqued bolts and misc. air fittings are not.



Figure 4- Common off-load point protected; torqued bolts and misc. air fittings are not.

Areas of a truck trailer not normally requiring tamper evident measures



Figure 5 - Air fittings and offloading hoses not protected



Figure 6- Miscellaneous in-line plumbing not protected

Areas of a truck trailer not normally requiring tamper evident measures (cont.)



Figure 7- Miscellaneous in-line plumbing not protected



Figure 8- Miscellaneous in-line plumbing not protected

Areas of a truck trailer not normally requiring tamper evident measures (cont.)



Figure 9- Miscellaneous in-line plumbing not protected



Figure 10 - Torqued bolts not protected

Areas of a truck trailer not normally requiring tamper evident measures (cont.)



Figure 11- Off-loading hose not protected

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Standards²⁶

The following standards established and adopted by NSF as minimum voluntary consensus standards are used internationally:

- 2 Food equipment
- 3 Commercial warewashing equipment
- 4 Commercial cooking, rethermalization, and powered hot food holding and transport equipment
- 5 Water heaters, hot water supply boilers, and heat recovery equipment
- 6 Dispensing freezers
- 7 Commercial refrigerators and freezers
- 8 Commercial powered food preparation equipment
- 12 Automatic ice making equipment
- 13 Refuse processors and processing systems
- 14 Plastics piping system components and related materials
- 18 Manual food and beverage dispensing equipment
- 20 Commercial bulk milk dispensing equipment
- 21 Thermoplastic refuse containers
- 24 Plumbing system components for recreational vehicles
- 25 Vending machines for food and beverages
- 29 Detergent and chemical feeders for commercial spray-type dishwashing machines
- 35 High pressure decorative laminates (HPDL) for surfacing food service equipment
- 36 Dinnerware
- 37 Air curtains for entranceways in food and food service establishments
- 40 Residential wastewater treatment systems
- 41 Non-liquid saturated treatment systems
- 42 Drinking water treatment units – Aesthetic effects
- 44 Residential cation exchange water softeners
- 46 Evaluation of components and devices used in wastewater treatment systems
- 49 Biosafety cabinetry: Design, construction, performance, and field certification
- 50 Equipment for swimming pools, spas, hot tubs, and other recreational water facilities
- 51 Food equipment materials
- 52 Supplemental flooring
- 53 Drinking water treatment units – Health effects
- 55 Ultraviolet microbiological water treatment systems
- 58 Reverse osmosis drinking water treatment systems
- 59 Mobile food carts
- 60 Drinking water treatment chemicals – Health effects
- 61 Drinking water system components – Health effects
- 62 Drinking water distillation systems
- 140 Sustainable carpet assessment
- 169 Special purpose food equipment and devices
- 170 Glossary of food equipment terminology
- 173 Dietary supplements
- 177 Shower filtration systems – Aesthetic effects
- 184 Residential dishwashers
- 222 Ozone generators
- 245 Wastewater treatment systems - nitrogen reduction
- 305 Personal care products containing organic ingredients
- 321 Goldenseal root (*Hydrastis canadensis*)
- 330 Glossary of drinking water treatment unit terminology
- 332 Sustainability assessment for resilient floor coverings
- 336 Sustainability assessment for commercial furnishings fabric
- 342 Sustainability assessment for wallcovering products
- 350 Onsite residential and commercial water reuse treatment systems
- 350-1 Onsite residential and commercial graywater treatment systems for subsurface discharge
- 359 Valves for crosslinked polyethylene (PEX) water distribution tubing systems
- 360 Wastewater treatment systems – Field performance verification
- 372 Drinking water treatment system components – Lead content
- 14159-1 Hygiene requirements for the design of meat and poultry processing equipment
- 14159-2 Hygiene requirements for the design of hand held tools used in meat and poultry processing equipment
- 14159-3 Hygiene requirements for the design of mechanical belt conveyors used in meat and poultry processing equipment

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***THE HOPE OF MANKIND rests in the
ability of man to define and seek out
the environment which will permit him
to live with fellow creatures of the
earth, in health, in peace, and in
mutual respect.***

January 24, 2014