NATIONAL SANITATION FOUNDATION

STANDARD 60

FOR

DRINKING WATER TREATMENT CHEMICALS - HEALTH EFFECTS

As Prepared By
The NSF Joint Committee
on
Drinking Water Additives
and
Recommended for Adoption
by the NSF Council of Public Health Consultants

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by
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CONSORTIUM ORGANIZATIONS

National Sanitation Foundation

Popularly referred to as NSF, the National Sanitation Foundation is a noncommercial 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).

AWWA Research Foundation

The mission of the American Water Works Association Research Foundation (AWWARF) 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. AWWARF 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.

AWWARF'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 7 U.S. territories. Through the

PREFACE

In response to a competitive request for proposals from the U.S. Environmental Protection Agency (EPA), a Consortium led by the National Sanitation Foundation 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 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 Standard 61: Drinking Water System Components - Health Effects currently covers indirect additives. Standard 60, and subsequent product certification against it, will replace the EPA Additives Advisory Program for drinking water treatment chemicals. For more information with regard to EPA's actions, refer to the July 7, 1988 Federal Register (53FR25586).

Standard 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 (ASTM), and the American National Standards Institute (ANSI). 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.

Testing to determine the potential of a product to impart taste and/or odor to drinking water is not included in this Standard. However, conditions under which products may have a potential to impart taste and/or odor to drinking water are noted in the product sections of the Standard.

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.

DISCLAIMERS

The National Sanitation Foundation, in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this standard by anyone. NSF shall not incur any obligations or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this standard.

Participation in NSF's standards development activities by a representative of a regulatory agency (Federal, state, local) shall not be construed as the agency's endorsement of NSF or any of its standards.

This document has been reviewed by the Office of Drinking Water, U.S. Environmental Protection Agency, and approved for publication. Approval does not signify that the contents necessarily reflect the views and policies of EPA, nor does mention of trade names or commercial products constitute endorsement or recommendation for use.

Partial funding by EPA for the development and implementation of NSF Standard 60 (EPA Cooperative Agreement #CR-812144) and participation of EPA representatives in the standards development or implementation activities do not constitute EPA's endorsement of NSF, NSF's policies, or the Standard.

NSF standards provide basic criteria to promote and protect public health. Provisions for safety have not been included in this Standard because governmental agencies or other national standards-setting organizations provide safety requirements.

Unless otherwise referenced, the appendices are not considered an integral part of NSF standards. They are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

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[1]This Appendix is not part of the Standard.

TABLE 4
MISCELLANEOUS TREATMENT APPLICATION PRODUCTS
PRODUCT IDENTIFICATION
AND EVALUATION

This 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. Appendix G includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

CHEMICAL NAME [PRIMARY USE]	SYNONYMS	FORMULA [CAS NUMBER]	MOLECULAR WEIGHT(g)	DESCRIPTION [1]	EVALUATION DOSE (mg/L)	POTENTIAL IMPURITIES [2,3]
Ammonium Hexafluoro-silicate [Fluoridation]	Ammonium Silico-fluoride; Ammonium Fluosili-cate	$(NH_4)_2SiF_6$ [16919-19-0]	178.14	odorless, crystalline powder	1.2 [4]	Regulated Metals Radionucides
Calcium Fluoride [Fluoridation]	Fluorspar; Fluorite	CaF_2 [7789-75-5]	78.08	white powder or cubic crystals	1.2 [4]	Regulated Metals Radionuclides
Copper Ethanolamine complexes [Algicide]		$Cu(NH_2C_2H_4OH)_4^{++}$	variable	blue liquid	1.0 [5,6]	Regulated Metals Formulation Dependant Organics
Copper Sulfate [Algicide]	Cupric Sulfate	CuSO4 [7758-98-7]	159.61	blue crystals	1.0 [5,6]	Regulated Metals
Copper Triethanol-amine Complexes [Algicide]		$Cu[N(C_2H_4OH)_3]^{++}$	variable	blue liquid	1.0 [5,6]	Regulated Metals Formulation Dependant Organics
Fluosilicic Acid [Fluoridation]	Hydrofluosilicic Acid	H_2SiF_6 [16961-83-4]	88.0	white to straw yellow colored liquid, pun-gent odor	1.2 [4]	Regulated Metals
Magnesium Silicofluoride [Fluoridation]	Magnesium Hexafluoro-silicate	$MgSiF_6$ [16949-65-8]	166.40	white, odorless, efflorescent crystals	1.2 [4]	Regulated Metals

[1] General description of the commercially available product. NOTE: Caution should be exercised in handling these products. Refer to label or material safety data sheet for further information.

[2] Products with a direct mined source will be tested for radionuclides (gross alpha and gross beta).

[3] For the EPA MCL list, current with this printing of the standard, please refer to Appendix D.

[4] Based on mg Fluoride Ion per L water.

[5] Based on mg Copper per L water.

[6] It is a violation of Federal law to use any pesticide product in a manner inconsistent with the product's label

TABLE 4 (cont.)
MISCELLANEOUS TREATMENT APPLICATION PRODUCTS
PRODUCT IDENTIFICATION
AND EVALUATION

This 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. Appendix G includes a cross-reference index of the various chemicals (and the more common synonyms) contained in this table.

CHEMICAL NAME [PRIMARY USE]	SYNONYMS	FORMULA [CAS NUMBER]	MOLECULAR WEIGHT(g)	DESCRIPTION [1]	EVALUATION DOSE (mg/L)	POTENTIAL IMPURITIES [2, 3]
Potassium Fluoride [Fluoridation]		KF [7789-23-3]	58.10	white powder	1.2 [4]	Regulated Metals
Sodium Bisulfite [Dechlorinator & Antioxidant]	Sodium Acid Sulfite	$NaHSO_3$ [7631-90-5]	104.07	white crystalline powder	18 [5]	Regulated Metals
Sodium Fluoride [Fluoridation]	Florocid	NaF [7681-49-4]	42.0	white, yellow-white, or blue crystalline powder; hygroscopic	1.2 [4]	Regulated Metals
Sodium Metabisulfite [Dechlorinator & Antioxidant]	Sodium Pyrosulfite	$Na_2S_2O_5$ [7681-57-4]	190.13	white crystals or powder	15	Regulated Metals
Sodium Silicofluoride [Fluoridation]	Sodium Fluosilicate	Na_2SiF_6 [16893-85-9]	132.0	white or blue fine powder or crystals; hygroscopic	1.2 [4]	Regulated Metals
Sodium Sulfite [Dechlorinator & Antioxidant]		Na_2SO_3 [7757-83-7]	126.06	crystals or powder	22 [5]	Regulated Metals
Sulfur Dioxide [Dechlorinator & Antioxidant]	Sulfurous Oxide	SO_2 [7446-09-5]	64.07	colorless, nonflammable gas	10	Regulated Metals
Tricalcium Phosphate [Defluoridation]	Hydroxyapatite	$Ca_5(PO_4)_3OH$ [12167-4-7]	502	odorless, tasteless powder	120 [6]	Regulated Metals

[1] General description of the commercially available product. NOTE: Caution should be exercised in handling these products. Refer to label or material safety data sheet for further information.

[2] Products with a direct mined source will be tested for radionuclides (gross alpha and gross beta).

[3] For the EPA MCL list, current with this printing of the standard, please refer to Appendix D.

[4] Based on mg Fluoride Ion per L water.

[5] Based on chlorine level of 12 mg/L.

APPENDIX A

TOXICOLOGY REVIEW AND EVALUATION PROCEDURES

(This Appendix is part of the Standard)

1.0 General

2.0 Application and Evaluation Stage
- 2.0.1 Product Use
- 2.0.2 Formulation Information
- 2.0.3 Exposure Data
- 2.0.4 Regulatory, Codex, or Other Acceptances for Substances
- 2.0.5 Justification for Submitted Information
- 2.0.6 Selection of Substances for Testing
- 2.0.7 Toxicity Test Guidelines
  - A. Level I (< 10 ppb)
  - B. Level II (10-50 ppb)
  - C. Level III (50-1000 ppb)
  - D. Level IV (>1000 ppb)
- 2.0.8 Application Verification

3.0 Risk Estimation (Calculation of MAL)
- 3.0.1 Regulated Contaminants
- 3.0.2 Unregulated Contaminants

APPENDIX A
TOXICOLOGY REVIEW AND EVALUATION PROCEDURES

1.0 GENERAL: These product review and test guidelines are to assist in establishing the toxicity, if any, of the products under anticipated use conditions. Prior to initiating new toxicity testing, the applicant is strongly encouraged to discuss information requirements and test protocols with the certifying agency. If an EPA Maximum Contaminant Level (MCL) is available, no new toxicity testing and evaluation (Sections 2.0.6 and 2.0.7) may be necessary, but a risk estimate (Maximum Allowable Level or MAL) must be calculated per Appendix A, Section 3.0.

"shall" in the 2009 + 2013 versions

2.0 APPLICATION AND EVALUATION STAGE

2.0.1 PRODUCT USE: The applicant shall identify the function and physical properties of the product.

2.0.2 FORMULATION INFORMATION: The applicant shall submit formulation information for the product in the form prescribed by the certifying agency, including complete product formulation (constituents in parts-per-hundred) and method of manufacture. The following information shall be provided for each constituent, as applicable: Chemical Abstracts Registry Number, structural formula, molecular weight, and source. A list of known or suspected impurities/contaminants shall be provided and their concentrations in the product noted. Selected spectra (e.g., UV/visible, infrared) may also be required for some additive products or their principal constituent(s).

2.0.3 EXPOSURE DATA: Estimated exposure concentrations for substances being tested will be determined according to the protocols described in Appendix B.

2.0.4 REGULATORY, CODEX, OR OTHER ACCEPTANCES FOR SUBSTANCES: If the product contributes a substance to water which is listed in the U.S. Code of Federal Regulations (CFR), Title 21 (Food and Drug Regulations) or other applicable references, the references shall be provided. The certifying agency will evaluate the relevance of the reference to the intended drinking water use.

2.0.5 JUSTIFICATION FOR SUBMITTED INFORMATION: All health and safety information relevant to the evaluation of the product shall be provided to the certifying agency as noted in Section 2.0.7. The manufacturer shall describe how the submitted data satisfy the toxicity testing guidelines outlined in Section 2.0.7. To the extent the information and justification provided by the manufacturer satisfy the certification agency requirements, further toxicity testing according to the

guidelines presented in Sections 2.0.6 and 2.0.7 may not be required.

2.0.6 SELECTION OF SUBSTANCES FOR TESTING: Toxicity testing guidelines presented in Section 2.0.7 are designed to examine the health impact of contaminants contributed to drinking water. Substances for testing could include, but are not limited to, the product as formulated, product constituents, total extractants, and any other chemicals contributed to the water as a result of product use. Manufacturers shall provide a rationale to justify their selection of test substances.

2.0.7 TOXICITY TEST GUIDELINES: Minimum testing guidelines for an additive are based on the anticipated human exposure to the additive, calculated using estimates of the concentration(s) of the test substance at the tap (see Section 3.0 for regulated and unregulated contaminants and the calculations described in Appendix B, Section 11.0). Toxicity testing guidelines are described for each of the following four ranges of concentrations in tap water: Level I (<10 ppb), Level II (≥10 and <50 ppb), Level III (≥50 and <1000 ppb), Level IV (≥1000 ppb) in Figures A1, A2, A3, and A4 respectively. These guidelines are not intended to be a rigid set of requirements, and may be modified, based on best scientific judgment, to either exclude and/or include certain toxicity testing. Each testing level includes a Supplemental Studies category for additional studies, if indicated. Supplemental Studies could include metabolism, pharmacokinetics, immunotoxicity, neurotoxicity, and other endpoints as appropriate. In some instances a second test species may be required for a traditional toxicity test. Toxicity testing shall be done in accordance with the most current versions of toxicity testing protocols such as those described by the Organization For Economic Cooperation and Development (OECD, 1985), U.S. Environmental Protection Agency (EPA, 1982), and Food and Drug Administration (FDA, 1982). All studies initiated to comply with this standard shall be conducted in accordance with Good Laboratory Practice (21 CFR, Pt 58/40 CFR, Pt 792).

A. LEVEL I (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT CONCENTRATIONS <10 PPB)

Level I toxicity test guidelines include genetic toxicity testing and, if indicated, Supplemental Studies. Genetic toxicity testing includes one assay from each of the following categories of genotoxicity tests: gene mutation (preferably Ames Salmonella assay with and without activation), and chromosomal aberrations (preferably <u>in vivo</u>

APPENDIX A
TOXICOLOGY REVIEW AND EVALUATION PROCEDURES

1.0 GENERAL: These product review and test guidelines are to assist in establishing the toxicity, if any, of the products under anticipated use conditions. Prior to initiating new toxicity testing, the applicant is strongly encouraged to discuss information requirements and test protocols with the certifying agency. If an EPA Maximum Contaminant Level (MCL) is available, no new toxicity testing and evaluation (Sections 2.0.6 and 2.0.7) may be necessary, but a risk estimate (Maximum Allowable Level or MAL) must be calculated per Appendix A, Section 3.0.

2.0 APPLICATION AND EVALUATION STAGE

2.0.1 PRODUCT USE: The applicant shall identify the function and physical properties of the product.

2.0.2 FORMULATION INFORMATION: The applicant shall submit formulation information for the product in the form prescribed by the certifying agency, including complete product formulation (constituents in parts-per-hundred) and method of manufacture. The following information shall be provided for each constituent, as applicable: Chemical Abstracts Registry Number, structural formula, molecular weight, and source. A list of known or suspected impurities/contaminants shall be provided and their concentrations in the product noted. Selected spectra (e.g., UV/visible, infrared) may also be required for some additive products or their principal constituent(s).

2.0.3 EXPOSURE DATA: Estimated exposure concentrations for substances being tested will be determined according to the protocols described in Appendix B.

2.0.4 REGULATORY, CODEX, OR OTHER ACCEPTANCES FOR SUBSTANCES: If the product contributes a substance to water which is listed in the U.S. Code of Federal Regulations (CFR), Title 21 (Food and Drug Regulations) or other applicable references, the references shall be provided. The certifying agency will evaluate the relevance of the reference to the intended drinking water use.

2.0.5 JUSTIFICATION FOR SUBMITTED INFORMATION: All health and safety information relevant to the evaluation of the product shall be provided to the certifying agency as noted in Section 2.0.7. The manufacturer shall describe how the submitted data satisfy the toxicity testing guidelines outlined in Section 2.0.7. To the extent the information and justification provided by the manufacturer satisfy the certification agency requirements, further toxicity testing according to the

mammalian chromosome aberration or micronucleus test). Results from these two tests shall be used to determine the need for further testing. If there is no demonstrable genetic toxicity, no further genetic toxicity testing shall be required. If results are positive, a long-term cancer bioassay shall be required. If mutagenic activity is observed in one genetic toxicity test, additional genetic toxicity testing or Supplemental Studies may be recommended. Results from additional genetic toxicity testing or Supplemental Studies will be used to determine whether a long-term cancer bioassay (preferably oral route) will be required.

B. LEVEL II (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT CONCENTRATIONS BETWEEN ≥10 AND <50 PPB)

Level II toxicity test guidelines include the Level I genetic toxicity tests, a subchronic 90-day study (preferably oral route) in one species (preferably rat), and optional Supplemental Studies, if indicated. The results of genetic toxicity testing are evaluated as described above in Level I. Results from the subchronic testing and Supplemental Studies will be used to calculate a Maximum Allowable Level (MAL in mg/L) for the test substance based on the No-Observed-Adverse-Effect-Level (NOAEL) of the most appropriate species and toxic effect (see Appendix A, Section 3.0.2 and Table A5). If the estimated exposure concentration exceeds the MAL, then the manufacturer may reformulate to reduce exposure or a supplemental subchronic 90-day study may be conducted with additional dose levels to define the highest NOAEL. The MAL may then be recalculated based on the full complement of data. If the estimated exposure concentration (i.e., estimated concentration at the tap) still exceeds the MAL, then a chronic toxicity study (preferably in the rat and by the oral route) may be undertaken to define the highest NOAEL and to calculate an MAL. Concentrations of the compound in water will be allowed at or below the MAL. Genetic toxicity and one subchronic study will satisfy minimum testing requirements, provided exposure to the compound is less than or equal to the MAL. Should the anticipated exposure concentration exceed the chronic MAL, the manufacturer may adjust the product formulation

or dose to reduce potential exposure. Supplemental Studies may be useful to further define the relevance to humans of results observed in genetic toxicity, subchronic, or chronic studies.

C. LEVEL III (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT CONCENTRATIONS BETWEEN ≥50 AND <1000 PPB)

Level III toxicity test guidelines include all requirements of Level II, a teratology study in two species, and a reproductive toxicity study in one species (preferably rat). Teratology tests which provide data on toxic effects occurring in fetuses exposed during gestation are required in two species, unless supporting evidence is adequate to justify the use of one species only. Such evidence could include, but is not limited to, pharmacokinetics/metabolism data indicating the degree of similarity of absorption, distribution, metabolism, excretion (ADME) between laboratory species and humans, and existing data including teratology endpoints as a subset of a reproductive toxicity study. Supplemental Studies may be required.

Reproductive toxicity studies provide information on male and female reproductive function and prenatal and postnatal developmental effects in the offspring. The required two-generation reproductive toxicity study shall examine only first litters in each generation unless adverse or suspect reproductive or developmental affects are observed, in which case second litters may be required from at least one generation.

Results from the subchronic study, the reproductive toxicity and teratology studies, and Supplemental Studies will be used to calculate a MAL for the test substance based on the NOAEL of the most appropriate species and toxic effect (see Appendix A, Section 3.0.2 and Table A5). The need for further supplemental testing will be evaluated by comparing the estimated exposure concentration and the calculated MAL. If the estimated exposure concentration exceeds the MAL, additional studies may be undertaken to more precisely define the highest NOAEL for the pertinent endpoint(s). The MAL may then be recalculated from the full complement of data. Should the estimated exposure concentration exceed the MAL which was derived from one or more

subchronic studies, then data from a chronic study (preferably in the rat and via the oral route) shall be submitted. Exposure to the compound or product will be allowed at or below the MAL in water. Genetic toxicity, subchronic, and reproductive and teratology studies comprise the minimum testing requirements, provided exposure to the compound is less than or equal to the MAL. When chronic toxicity data are provided, a new MAL shall be calculated from these results and shall supersede any MAL derived from studies of shorter duration. Should that estimated exposure concentration continue to exceed the chronic MAL, the manufacturer may adjust product formulation or dose to reduce or eliminate the presence of the contaminant at the tap. Supplemental Studies may be useful to further define the relevance to humans of results observed in genetic toxicity, subchronic, reproductive, teratology, and chronic studies.

D. LEVEL IV (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT CONCENTRATIONS $\geq$1000 PPB)

Level IV toxicity testing guidelines include all requirements of Level III, as well as a chronic toxicity study (which may include a long-term cancer bioassay), and, if indicated, Supplemental Studies. (NOTE: Unlike Level I in which a long-term cancer bioassay is dependent on positive or equivocal results from the genetic toxicology studies, Level IV guidelines require a long-term feeding study for chronic toxicity, including cancer endpoints, with no consideration to the outcome of genetic toxicity tests.)

Results from the testing at this level shall be used to calculate a MAL for the test substance based on the NOAEL of the most appropriate species and toxic effect (see Section 3.2 and Table A5). Presence of the test substance in tap water shall be deemed acceptable at or below the MAL. If estimated exposure concentrations exceed the MAL, the manufacturer may adjust the product formulation or application rate to reduce or eliminate the presence of the contaminant at the tap. Supplemental Studies may be useful to further define results observed in testing at this level.

2.0.8 APPLICATION VERIFICATION: The applicant shall certify that, to the best of the applicant's knowledge, the information is accurate and complete.

3.0 RISK ESTIMATION: Calculation of the Maximum Allowable Level (MAL)

3.0.1 REGULATED CONTAMINANTS: If a substance is regulated by EPA's National Primary Drinking Water Regulations, the MAL for contribution by a single product shall not exceed ten (10) percent of the U.S. EPA final Maximum Contaminant Level (MCL) as cited in Appendix E. Exposure to the substance in water shall be deemed acceptable at or below the MAL. The estimated exposure concentrations for test substances shall be determined as described in Appendix B. Alternate estimates of levels of the substance contributed to the water shall be substantiated by the applicant. (NOTE: If the manufacturer requests review relevant to Canadian requirements, the certifying agency may consider alternative regulatory levels; e.g., Canadian Maximum Acceptable Concentrations [MACs] as cited in Appendix F.)

3.0.2 UNREGULATED CONTAMINANTS: The Maximum Drinking Water Level (MDWL) shall be calculated, as follows, depending on whether the substance is determined to be a noncarcinogen or carcinogen. For purposes of this standard, a substance is considered a carcinogen if it meets the USEPA criteria for classification as group A, B_1, or B_2, as defined in the current EPA guidelines (1982) for risk assessment. The Maximum Allowable Level (MAL) for a substance contributed by a single product and not regulated by EPA's National Primary Drinking Water Regulations shall not exceed ten (10) percent of the Maximum Drinking Water Level (MDWL). Occurrence of the substance in water shall be acceptable at or below the MAL. The estimated exposure concentrations for test substances shall be determined as described in Appendix B for each product category. Alternate estimates of concentrations of substances contributed to the water shall be substantiated by the applicant.

NONCARCINOGENS: For noncarcinogenic effects, the general formula for determining the Maximum Drinking Water Level (MDWL) is as follows:

$$\frac{\text{NOAEL}^1}{\text{UF(s)}} = \text{RfD}$$

then,

$$\frac{(\text{RfD})\ (\text{BW})}{\text{I}} = \text{MDWL}$$

[1]If no NOAEL is available the Lowest-Observed-Adverse-Effect-Level (LOAEL) may be used with a corresponding increase (1X to 10X) in the uncertainty factor.

Where:

NOAEL	=	Highest No-Observable-Adverse-Effect-Level for most appropriate species and toxic effect (mg/kg/day)
BW	=	Assumed body weight of individual to be protected (kg) (generally 10 kg for a child, 50 kg for evaluation of a reproductive toxicant, and 70 kg for an adult)
RfD	=	Reference dose based on highest NOAEL and indicating levels of exposure unlikely to cause injury (mg/kg/day). This is equivalent to the Acceptable Daily Intake (ADI) used by the World Health Organization (WHO).
UF	=	Uncertainty factors based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see Table A5). These are often referred to as safety factors.
I	=	Intake; Assumed average daily drinking water consumption (liters/day) (generally 1 liter for a child and 2 liters for an adult)
MDWL	=	Maximum Drinking Water Level (mg/L) (Based on lowest RfD)

CARCINOGENS: For chemical carcinogens, the following assumptions shall be applied to the estimation of risk in the absence of toxicologic, metabolic, pharmacokinetic, physiologic, or mechanistic data to the contrary:

A. Lifetime incidence in humans is taken to be the same as in animals receiving an equivalent dose rate.

B. The linearized multi-stage model is appropriate for low-dose extrapolation, and the upper 95% confidence limit on risk of the linear term is appropriate for expressing the upper-bound of potency.

C. Animal doses are converted to human-equivalent doses using a surface area correction.

D. Humans are taken to be as sensitive to the carcinogenic influence of the substance as the most sensitive animal species.

E. If the cancer study is terminated prematurely, lifetime incidence is calculated to increase by the third power of age.

F. Human data are preferable to animal data as a basis for estimating risk. For human data, the method of analysis is tailored to the completeness and quality of data available. A model that is linear at low dose is used for extrapolation. Negative (i.e., no association) epidemiologic human data can be used to suggest a theoretical upper-limit of risk.

G. The general formula for determining the MDWL is as follows:

$$\frac{(R)\ (BW)}{q1^*\ (I)} = MDWL$$

Where:

R	=	Acceptable risk level (i.e., 10^{-5})
BW	=	Assumed body weight of protected individual (kg) (usually 70 kg for an adult)
q1*	=	Slope factor for humans for the linearized multistage risk assessment model (mg/kg/day)
I	=	Intake; Assumed average daily drinking water consumption (liters/day) (generally 2 liters/day)
MDWL	=	Maximum Drinking Water Level (mg/L)

APPENDIX E
U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL PRIMARY DRINKING WATER STANDARDS (JULY 1987)[1]

Primary Contaminant	Regulated MCL (ppb or ug/L unless otherwise noted)
Inorganics	
Arsenic	50
Barium	1000
Cadmium	10
Chromium	50
Fluoride	4000
Lead	50
Mercury	2
Nitrate - N	10,000
Selenium	10
Silver	50
Organics	
Benzene	5
Carbon Tetrachloride	5
1,2 Dichloroethane	5
1,1 Dichloroethylene	7
p-Dichlorobenzene	75
Endrin	0.2
Lindane	4
Methoxychlor	100
Total Trihalomethanes	100
Toxaphene	5
Trichloroethylene	5
1,1,1 Trichloroethane	200
Vinyl Chloride	2
2,4,5-TP Silvex	10
2,4-D	100
Radionuclides	
Gross Alpha	<3 piC/L
Gross Beta	<5 piC/L
Radium - 226	5 piC/L[2]
Strontium - 90	8 piC/L[2]
Tritium	20000 piC/L[2]

[1]The reader is encouraged to consult the National Primary Drinking Water Regulations for the most recent MCLs.

[2]Only if gross alpha or gross beta results (as appropriate) are greater than the MCL specified, are the other primary radionuclides analyzed for.

CHEMICAL PRODUCT INDEX
(cont.)

CHEMICAL NAME/ SYNONYM	SECTION REFERENCE	TABLE REFERENCE	NAME USED IN STANDARD
Ferric Sulfate	Section 4	Table 1	same
Ferric Tersulfate	Section 4	Table 1	see Ferric Sulfate
Ferrous Sulfate	Section 4	Table 1	same
Filtration Control	Section 8	Table 5	same
Florocid	Section 7	Table 4	see Sodium Fluoride
Fluorite	Section 7	Table 4	see Calcium Fluoride
Fluosilicic Acid	Section 7	Table 4	same
Fluorspar	Section 7	Table 4	see Calcium Fluoride
Foamers	Section 8	Table 5	same
Frac Sands	Section 8	Table 5	same
Glassy Sodium Phosphate	Section 5	Table 2	see Sodium Polyphosphates, Glassy
Graham's Salt	Section 5	Table 2	see Sodium Polyphosphates, Glassy
Gravel	Section 8	Table 5	same
Grouts	Section 8	Table 5	same
HPAM	Section 4	Table 1	see Hydrolyzed Polyacrylamide
Hydrated Lime	Section 5	Table 2	see Calcium Hydroxide
Hydrochloric Acid	Section 5	Table 2	same
Hydrofluosilicic Acid	Section 7	Table 4	see Fluosilicic Acid
Hydrolyzed Polyacrylamide	Section 4	Table 1	same
Hydroxyapatite	Section 7	Table 4	see Tricalcium Phosphate
Iodine	Section 6	Table 3	same
Iron (II) Sulfate	Section 4	Table 1	Ferrous Sulfate