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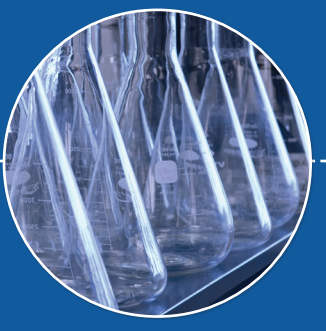
NSF/ANSI/CAN 600 - 2019

Health Effects Evaluation and Criteria for Chemicals in Drinking Water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for Drinking Water Additives –

Health Effects Evaluation and Criteria for Chemicals in Drinking Water

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Foreword[2]

The purpose of this Standard is to define the toxicological review and evaluation procedures for the evaluation of substances imparted to drinking water through contact with drinking water system components (and drinking water additives). 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. Table 4.1 contains evaluation criteria for the determination of product compliance to the health effects requirements of drinking water standards in which this Standard is cited, including NSF/ANSI/CAN 60 and NSF/ANSI/CAN 61. This information was previously published under NSF/ANSI 60, Annexes A and C, and NSF/ANSI 61, Annexes A and D. In 2018, NSF/ANSI/CAN 600 was developed to increase the accessibility of this information and create a single source for the multiple drinking water standards that reference these criteria.

This Standard was developed by the NSF Joint Committees on Drinking Water Additives using the consensus process described by the American National Standards Institute and the Standards Council of Canada's *Requirements and Guidance*. At the time of approval, the Joint Committees consisted of 10 public health / regulatory, 21 industry, 8 product certifier / testing lab, and 9 user representatives.

This Standard has been designated as a National Standard of Canada (NSC) in compliance with requirements and guidance set out by the Standards Council of Canada (SCC).

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 Committees on Drinking Water Additives at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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NSF/ANSI/CAN Standard
for Drinking Water Additives –

Health Effects Evaluation and Criteria for Chemicals in Drinking Water

1 General

1.1 Purpose

The following information defines the toxicological review and evaluation procedures for the evaluation of substances imparted to drinking water through contact with drinking water system components (and drinking water additives). 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. Table 4.1 of this Standard contains evaluation criteria that have been determined according to the requirements of this Standard.

2 Definitions

2.1 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 (US EPA, 2011a).

2.2 allergic reaction: Adverse reaction to a chemical resulting from previous sensitization to that chemical or to a structurally similar one (US EPA, 2011a).

2.3 analogue approach: The term analogue approach is used when read-across is employed between a few, very structurally similar substances for which it is not possible to establish a trend or a regular pattern. As a result of the structural similarity, a given (toxicological or other) property of one substance (the source) is used to predict the same property for another substance (the target), for which this property is not available. The outcome of a study conducted with the source substance is read-across for all investigated parameters to the target substance. A worst-case approach may also be used (ECHA, 2017). Examples have been published by the EC (2004, 2007).

2.4 benchmark dose (BMDL) (lower 95% confidence limit): 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 $BMDL_X$ (adapted from Barnes et al., 1995). The lowest, relevant BMDLx from a dataset can be considered a potential point-of-departure compared to available NOAEL and LOAEL values.

> NOTE — For the purposes of this Standard, the BMDL shall be calculated at the 10% response level for quantal data and one control standard deviation for continuous data, unless the data support a different response level and justification is provided. For example, a frank effect, such as neurotoxicity or a fetal effect, often warrant a lower benchmark response level, such as 5%.

2.5 chemical-specific adjustment factor (CSAF) approach: a method to incorporate quantitative, chemical-specific data on interspecies differences or human variability in either toxicokinetics or toxicodynamics (mode of action) into the risk assessment by modifying the relevant default UF (i.e., interspecies or intraspecies UF) (IPCS, 2005 and US EPA, 2014a).