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Current Regulatory Limit: n-Nitrosodimethylamine (NDMA)

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n-NITROSODIMETHYLAMINE (NDMA)	CASRN: 62759	Update: 1/2004
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Current Massachusetts Regulatory Limit: ORSGL = 0.00001 mg/L.

Federal Regulatory Limit: The U.S. EPA has not published an MCL for n-Nitrosodimethylamine (NDMA).

Basis for Criteria: The ORSGL is based on the analytical practical quantitation (PQL) for this chemical in water. This PQL has been identified by the state of Ca as the concentration of NDMA that most analytical laboratories are capable of detecting in drinking water.

Critical Effects: NDMA has been found to be carcinogenic in all experimental animals tested. NDMA produces liver tumors after oral administration in rats and tumors in liver and kidney after inhalation exposures in rats and mice. It is a transplacental carcinogen when administered via various routes to pregnant mice, rats and hamsters. It is also mutagenic and is structurally related to known carcinogens. Since this chemical has consistently been found to be a potent carcinogen, and it is expected that this endpoint is the most sensitive effect, the focus of animal studies has been on carcinogenicity. As a result, other non-cancer endpoints have not been well studied. Available data are considered inadequate as a basis for their characterization (WHO, 2002). Non-cancer effects observed in these studies include liver toxicity, kidney internal bleeding and death especially associated with acute exposures to high doses also associated with longer-term exposure to low doses (WHO, 2002; ATSDR, 1999).

Cancer Assessment: B2 (by the old U.S. EPA carcinogen classification system). U.S. EPA's Proposed Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1999) classification would correspond to the descriptor "likely to be carcinogenic to humans".

Class: Organic

Analytical Information:

PQL: 0.00001 mg/L



SDMS DocID

485600

Analytical Methods:

Gas chromatographic/mass spectrometric methods offer the most sensitive and measurement systems for analysis of NDMA in the low ng/L range. High-resolution electron impact mass spectrometry, and low-resolution chemical ionization (using ammonia, methanol, etc.) or other mass spectrometric techniques with equivalent sensitivity are acceptable (CDHS, 2003).

PQLs and analytical methods may have been updated since this guidance value revised. Updated analytical methods for drinking water and their associated PQL found at <http://www.epa.gov/safewater/methods/methods.html>.

Other Regulatory Data:

Any Health Advisories, Reference Doses (RfDs), cancer assessments or Cancer Factors (CPFs) referenced in this document pertain to the derivation of the current guidance value. Updated information may be obtained from the following source:

Health Advisories - The U.S. EPA provides guidance for shorter-term exposures to chemicals based on their non-cancer effects. Current health advisories may be more current than those used to derive MCLs and may be found at <http://www.epa.gov/safewater/methods/methods.html>.

RfDs, cancer assessments and CPFs - For specific information pertaining to deriving drinking water criteria, consult the Federal Register notice that announces the availability of the most current guidance for that chemical. In addition, information on other RfDs and CPFs as well as cancer assessments for specific chemicals may be found in the U.S. EPA Integrated Risk Information System (IRIS) at <http://www.epa.gov/iris>. Please note that the information in IRIS may differ from that used in the derivation process as published in the Federal Register notice.

References:

ATSDR (Agency for Toxic Substances and Disease Registry). December 1989. Toxicological Profile for N-Nitrosodimethylamine. U.S. Public Health Service (in collaboration with U.S. Environmental Protection Agency).

CDHS (California Department of Health Services). May 16, 2003 (Last Update). Laboratory Analyses. General Considerations, Acceptable Analytical Approaches: Laboratories Capable of Low-Level analyses for NDMA. Available on the Internet at <http://www.dhs.ca.gov/ps/ddwem/chemicals/NDMA/NDMAlabs.htm>.

U.S. EPA (U.S. Environmental Protection Agency). July 1999. Guidelines for Carcinogen Risk Assessment. Review Draft. NCEA-F-0644. Risk Assessment Forum.

WHO (World Health Organization). 2002. Concise International Chemical Assessment Series Document 38: N-Nitrosodimethylamine. (first draft: R.G. Liteplo and M.E. Meek, University of Toronto, Canada, Ottawa, Canada and W. Windle, Environment Canada, Ottawa, Canada). Published under the joint sponsorship of the United Nations Environment Programme, International Labour Organization, and the World Health Organization, and produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals. Geneva.





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