MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

January 26, 2016

TO: N-Nitrosodiethanolamine File (CAS #1116-54-7)

FROM: Mike Depa, Toxics Unit, Air Quality Division

SUBJECT: Screening Level Derivation

The Initial Risk Screening Level (IRSL) and Secondary Risk Screening Level (SRSL) for N-nitrosodiethanolamine are calculated below. These screening levels were based on U.S. Environmental Protection Agency (EPA, 2000) Integrated Risk Information System (IRIS) Oral Slope Factor (OSF) of 2.8 per mg/kg/day for N-nitrosodiethanolamine. See the attached memo for more information regarding the basis of the OSF.

Pursuant to Rule 232(3)(f)(ii), the Inhalation Unit Risk was derived from the OSF as follows:

Inhalation Unit Risk = Oral Slope Factor x $20m^3/70kg$
Inhalation Unit Risk = $2.8\ (mg/kg/day)^{-1}$ x $20m^3/70kg$ x $mg/1000\mu g$
Inhalation Unit Risk = $8x10^{-4}\ (\mu g/m^3)^{-1}$

Pursuant to Rule 231(1) the IRSL and SRSL are calculated as follows:

IRSL = 1E-6/Inhalation Unit Risk
IRSL = $1E\text{-}6/8x10^{-4}\ (\mu g/m^3)^{-1}$
IRSL = $0.0012\ \mu g/m^3$

SRSL = 1E-5/Inhalation Unit Risk
IRSL = $1E\text{-}5/8x10^{-4}\ (\mu g/m^3)^{-1}$
IRSL = $0.012\ \mu g/m^3$

Pursuant to Rule 231(4) the averaging time is annual.

Reference

EPA. 2000. Integrated Risk Information System entry for N-nitrosodiethanoiamine. http://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0252_summary.pdf accessed January 26, 2016

attachment

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

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INTEROFFICE COMMUNICATION

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February 8, 2001

TO: N-nitrosodiethanolamine file (CAS #1116-54-7)

FROM: Gary Butterfield, Toxics Unit, Air Quality Division

SUBJECT: Screening Level for N- nitrosodiethanolamine

N-nitrosodiethanolamine is a yellow colored, viscous oil that cannot be volatilized with steam heating. Another instance demonstrating the poor volatility of this oily material, under conditions of vacuum distillation, i.e., at an atmospheric pressure of 1.5 mmHg, the boiling point is 114 degrees Celsius.

This material is a common contaminant of many mixtures that have di- or tri-ethanolamine and sodium nitrites. These are components of metal cutting fluids. One author reports that newly- made cutting oil does not have any N-nitrosodiethanolamine present. However, after storage for several months, N-nitrosodiethanolamine is found to be present at several parts per million. Besides metal cutting fluids, N-nitrosodiethanolamine has been detected in cosmetics, and other commonly available products. However, due to the low volatility, air exposure to this chemical is expected only under severely restricted circumstances. Generally, exposure to this chemical happens under oral and dermal exposure conditions.

The following references or databases were searched to identify data to determine the screening level: U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS), National Institute for Occupational Safety and Health (NIOSH) Registry for Toxic Effects of Chemical Substances (RTECS), American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), Michigan Department of Environmental Quality (DEQ) library, International Agency for Research on Cancer (IARC) Monographs, Chemical Abstract Service (CAS) Online (1967- Aug. 2000), National Library of Medicine (NLM) - Toxline, and National Toxicology Program (NTP) Status Report.

An August 16, 2000 CAS and NLM on-line literature search was conducted. The majority of data that was located from the searches was available in 1993 when EPA determined an oral slope factor for N-nitrosodiethanolamine. The EPA classifies this material as a class B2 carcinogen, see the IRIS write-up for additional details. In the key study reported by Lijinsky and Kovatch (1985), N-nitrosodiethanolamine was

administered to rats in drinking water for 100 weeks. The rats in this study developed increased incidences of hepatocellular carcinomas, cholangiocellular carcinomas and adenomas, and neoplastic nodules. Other chronic duration drinking water studies also found increased incidences of tumors from exposure to N-nitrosodiethanolamine.

The EPA has an oral slope factor in IRIS for this chemical. The oral slope factor can be converted to an inhalation slope factor in order to derive an IRSL and SRSL. There is no data to indicate that there is a significant difference in the toxicity depending on route of exposure. Additionally, pharmacokinetic and metabolism data are inadequate to determine equivalent exposure levels for inhalation exposure based on oral data. Therefore, the default conversion specified in R231(3)(f) is utilized to determine the inhalation slope factor.

The EPA IRIS oral slope factor is 2.8 $(mg/kg)^{-1}$. This oral slope factor converts to an inhalation slope factor of $8x10^{-4}$ $(\mu g/m^3)^{-1}$. Using this slope factor, it is possible to calculate inhalation screening levels that result in an IRSL of 0.0012 µg/ m^3, and a SRSL of 0.012 µg/m^3, both with annual averaging.

References:

EPA. 2000. Integrated Risk Information System entry for N-nitrosodiethanoiamine. http://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0252_summary.pdf

Lijinsky, W. and R.M. Kovatch. 1985. Induction of liver tumors in rats by nitrosodiethanolamine at low doses. Carcinogenesis. 6(12): 1679-1681.