MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

September 6, 2000

TO: File for N,N'-ethylene Bis-octadecanamide (CAS No. 110-30-5)

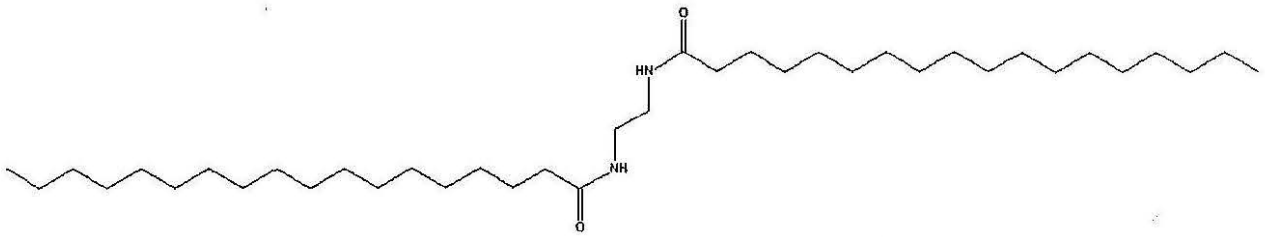
FROM: Michael Depa, Toxics Unit, Air Quality Division

SUBJECT: Screening Level Determination

The initial threshold screening level (ITSL) for N,N'-ethylene bis-octadecanamide is 0.1 µg/m³ (annual averaging time).

The following references or databases were searched to identify data to determine the screening level: Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS), the Registry of Toxic Effects of Chemical Substances (RTECS), the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV), National Institute of Occupational Safety and Health (NIOSH) Pocket Guide to Hazardous Chemicals, Environmental Protection Bureau Library, International Agency for Research on Cancer (IARC) Monographs, Chemical Abstract Service (CAS) Online (1967- June 2000), National Library of Medicine (NLM), Health Effects Assessment Summary Tables (HEAST), and National Toxicology Program (NTP) Status Report. The EPA has not established a reference concentration (RfC) or reference dose (RfD) for N,N'-ethylene bis-octadecanamide. There are no occupational exposure limits for N,N'-ethylene bis-octadecanamide. The molecular weight is 593 g, and the molecular formula is C38H76N2O2. The Molecular structure is pictured in Figure 1. The melting point is 140-144°C. Water solubility is <4.9 mg/L. N,N'-ethylene bis-octadecanamide is expected to be a waxy solid at standard temperature and pressure.

Figure 1. Molecular Structure of N,N'-Ethylene Bis-Octadecanamide



Animal Studies

There was one toxicity study available. Groups of male CD rats were exposed to 0 or 112 mg/m³ N,N'-ethylene bis-octadecanamide for 6 hours (Warheit et al., 1990). The number of animals per dose group was not reported. The authors reported that the mass mean aerodynamic diameter (MMAD) for N,N'-ethylene bis-octadecanamide was 5.2 µm, with 72% of particles less than 10 µm. The surviving animals were evaluated at 0, 24, 48, and 172 hours and at 1 month postexposure. Fluid and cells from sham and exposed animals were recovered by bronchoalveolar lavage (BAL) and measure for cellular and biochemical parameters at 0, 24, 48 172 hrs, and 1 month postexposure. Pulmonary macrophages (PM) were cultured and

studied for in vitro and *in vivo* phagocytosis, as well as surface morphology. The lungs of additional animals exposed to N,N'-ethylene bis-octadecanamide were fixed for assessment by histopathology, and transmission electron microscopy. The authors stated that there was a mild inflammatory response at 24 hrs. postexposure, but cell differentials were not significantly different from controls at 48 hrs. after exposure. BAL levels of lactate dehydrogenase, alkaline phosphatase and protein were slightly different from controls only at 8 days postexposure, and had returned to control values by 1 month or recovery. N,N'-ethylene bis-octadecanamide exposure had no adverse effects on either morphology or the phagocytic capacity of PM recovered from exposed animals. Histopathologic analysis of lung tissue from N,N'-ethylene bis-octadecanamide exposed rats revealed normal lung architecture.

Screening Level Development

The study by Warheit et al. (1990) was identified as the only toxicity study available. Many deficiencies were recognized in this study (see Table 1).

Table 1. Warheit et al. (1990) Study Deficiencies

Data Not Reported
number of animals per dose group
body weight
mortality
clinical observations
clinical chemistry
organ weight (including lung weight)
water consumption
food consumption

This study was determined to be inadequate for the derivation of a screening level because of the poor toxicity reporting and study design. Although it was not reported, it is possible that there were no deaths during exposure or during the observation period lasting up to 1 month. As a worst case scenario, the exposure concentration could be considered a lethal concentration 50% (LC50). A surrogate screening level was developed according to Rule 232(1)(h).

Surrogate Screening Level = LD50/(500 x 40 x 100) x 1/(0.167) x W_a/I_a

Surrogate Screening Level = (2850 mg/kg)/(2000000) x 1/(0.167) x (0.225 kg)/(0.0.235 m^3)

Surrogate Screening Level = 0.00816 mg/m^3

Surrogate Screening Level = 8 $\mu g/m^3$ (annual averaging time)

Since there was no adequate toxicological data with which to derive a screening level, Rule 232(1)i was used to establish the screening level of 0.1 $\mu g/m^3$ with an annual averaging time.

References

EPA. 1988. Recommendations for and documentation of biological values for use in risk assessment. National Technical Information Service PB 88-179874.

Warheit DB, Carakostas MC, Hartsky MA. 1990. Assessments of lung toxicity to Acrawax®C following acute inhalation exposure. Drug and Chemical Toxicology. Volume 13(1), pages 1-8.

MD:LH