MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

July 2, 2001

TO: File for N-Propylethanolamine (CAS No. 16369-21-4)

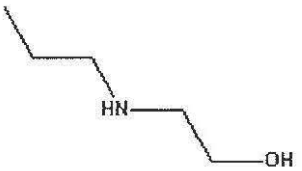
FROM: Michael Depa, Toxics Unit, Air Quality Division

SUBJECT: Development of the Screening Level

The initial threshold screening level (ITSL) for n-propylethanolamine is 28 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- May 2001), 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-propylethanolamine. The ACGIH and NIOSH have not established Occupational Exposure Limits (OELs). The molecular weight is 103.16 g, and the molecular formula is $C_5H_{13}NO$. The molecular structure is pictured in Figure 1.

Figure 1. Molecular Structure of N-Propylethanolamine



Toxicity Study

In a developmental study, groups of 5 female CD rats were dose by gavage with 0, 10, 30, 100, to 250 mg/kg/day from gestation day 0 through 11 (Elf Atochem, 1997). On gestation day 12, all females were euthanized. All females survived to the scheduled necropsy. No treatment-related clinical findings were observed at any dose level. Slight mean body weight losses and reductions in food consumption were noted during gestation days 3-7 and 7-9 in the 250 mg/kg/day group. Mean body weights in the 250 mg/kg/day group were reduce during gestation days 7-12. Mean body weights, body weight gains, and food consumption in the 10, 30, and 100 mg/kg/day groups were unaffected by n-propylethanolamine administration. No treatment-related internal findings were noted during the macroscopic examination. No treatment-related microscopic findings were observed in the liver and kidneys from the 250 mg/kg/day group. No effects on liver and kidney weights were observed in any of the treated groups. In the 250 mg/kg/day group, increased pre- and post-implantation losses, and reduced mean numbers of

corpora lutea, implantation sites, and viable embryos were noted when compared to the control group values. Intrauterine parameters in the 10, 30, and 100 mg/kg/day groups were unaffected by treatment with n-propylethanolamine. The authors concluded that maternal toxicity was expressed at a dose level of 250 mg/kg/day by slight mean body weight losses and reductions in food consumption during gestation days 3-7 and 7-9. No maternal toxicity was observed at dose levels of 10, 30 and 100 mg/kg/day. Toxicity to the pre- and post-implantational stages of the embryo was apparent at a dose level of 250 mg/kg/day by increased pre- and post-implantation losses and decreased numbers of corpora lutea, implantation sites, and viable embryos. Based on the results of this study the no observed effect level (NOEL) was 100 mg/kg/day for maternal toxicity and embryonic development.

Derivation of Screening Level

The ITSL was based on the toxicity study summarized above (Elf Atochem, 1997). The critical effect was observed at 250 mg/kg which included decreased maternal body weight. Reproductive effects at 250 mg/kg included pre- and post-implantation losses and decrease numbers of corpora lutea, and implantation sites. Developmental effects at 250 mg/kg included decreased number of viable embryos. Based on this information, n-propylethanolamine is considered a developmental effector.

The ITSL was calculated pursuant to Rule 232(1)(e) as follows:

$ITSL = NOAEL/(35 \times 100) \times W_a/I_a$

Where W_a and I_a are the weight and inhalation rate of the animal, respectively. The average weight of the female CD rat was obtained by taking the midpoint of the range of body weights from the study and determined to be 0.255 kg. The inhalation rate was determined to be 0.26 m^3 according to EPA (1988).

$ITSL = (100\ mg/kg)/3500 \times (0.255\ kg)/(0.26\ m^3)$

$ITSL = 0.028\ mg/m^3$

$ITSL = 28\ \mu g/m^3$ (annual averaging time)

The ITSL for n-propylethanolamine was established at 28 $\mu g/m^3$ (annual averaging time)

References

EPA. (1988) Recommendations for and documentation of biological values for use in risk assessment. PB 88-179874.

Elf Atochem. 1997. Support: Final report, study to evaluate early embryonic development in rats following maternal exposure to n-propylaminoethanol by oral gavage, with cover letter dated 12/12/1997. Obtained as microfiche from EPA, Office Technical Services

MD:DB
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