MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

NOVEMBER 14, 1994

TO: File for Dodecamethylcyclohexasiloxane (CAS# 540-97-6)

FROM: Michael Depa, Toxics Unit

SUBJECT: Screening Level Determination

The initial threshold screening level (ITSL) for dodecamethylcyclohexasiloxane is 400 μ g/m³ based on an annual averaging time.

Since there was no toxicity information for dodecamethylcyclohexasiloxane the screening level was set at the default value of 0.04 μ g/m³ (annual) on May 5, 1994. However, new toxicity information has become available which could be used to set an ITSL.

The following references or databases were searched to identify data to determine the ITSL: IRIS, RTECS, ACGIH Threshold Limit Values, NIOSH Pocket Guide to Hazardous Chemicals, Environmental Protection Bureau Library, Health Effects Assessment Summary Tables, and NTP Status Report, and IARC Monographs. Review of these sources found that EPA has not established an RfC or RfD for dodecamethylcyclohexasiloxane. Occupational exposure limits were not available. A 28 day gavage study performed by Dow Corning Corporation was made available by Gordon Philbrook of Wacker Silicones Corporation and is described below.

Groups of 6 male and 6 female Charles River CD (Sprague-Dawley) rats approximately eight weeks of age were given dodecamethylcyclohexasiloxane doses of 0 or 1,500 mg/kg/day for 5 days/week for 28 days (Dow Corning, 1990). There was no changes in body weight gain, food consumption, and relative or absolute organ weight. No gross pathological changes were observed in any of the organs or tissues. A NOAEL

of 1,500 mg/kg/day was identified from this study. This NOAEL was used to determine the ITSL as follows:

ITSL = $\frac{\text{NOAEL (mg/kg)}}{\text{UF}_1 \times \text{UF}_2 \times \text{UF}_3} \times \frac{W_a}{I_a}$ ITSL = $\frac{1,500 \text{ mg/kg}}{10 \times 10 \times 35} \times \frac{0.309 \text{ kg}}{0.305 \text{ m}^3}$

 $ITSL = 0.4 mg / m^3$

 $ITSL = 400 \ \mu g / m^3$

Where:

 W_a is the average weight of the male (372.6 g) and female (244.6 g) rats I_a is the default inhalation rate of the rat (EPA, 1988),

 UF_1 is an uncertainty factor of 10 to account for differences between humans and experimental species,

 UF_2 is an uncertainty factor of 10 to account for sensitive individuals within the human population, and

 UF_3 is an uncertainty factor of 35 to account for experimental conditions that are less than subchronic (90 days) but more than acute¹.

The ITSL for dodecamethylcyclohexasiloxane is 400 μ g/m³ based on an annual averaging time.

REFERENCES:

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

Dow Corning. 1990. A 28-day subchronic oral gavage feasibility study of various low molecular weight silicone oligomers in rats. 1990-I0000-35105. February 12, 1990.

¹ This uncertainty factor also accounts for the small dose groups (n = 6) and the small number of dose levels.