MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

August 27, 2001

TO:

File for Cyclopolydimethylsiloxane (CASRN 69430-24-6)

FROM:

Mary Lee Hultin, Toxics Unit, Air Quality Division

SUBJECT:

Initial Threshold Screening Level

The initial threshold screening level (ITSL) for cyclopolydimethylsiloxane (CASRN 69430-24-6) 30 µg/m³ based on an annual averaging time.

The following references or databases were searched to identify data to determine the ITSL: IRIS, RTECS, CESARS, EPB-CCD, MDEQ library, CAS-online, NLM-online, NIOSH Pocket Guide, and ACGIH Guide.

A 28-day subchronic oral toxicity study of Dow Corning® X2-7551, a clear, colorless viscous liquid containing 95% CASRN 69430-24-6, was conducted on Sprague-Dawley rats (10/sex/group; Hoffman and Zimmer, 1989). The animals received 100, 500, or 1000 mg/kg BW/day via gavage. Water was the control. The animals were necropsied at the end of 28 days. The only effect seen was a slight but statistically significant decrease in albumin and globulin for both sexes in the high-dose group terminated at 28 days. The adversity of this finding is questionable because gross and histological effects were not seen in the gastrointestinal tract, the liver, or the kidneys nor in the immune system. Therefore, the NOAEL will be considered as 500 mg/kg/d since the protein changes could not be dismissed as merely due to biological variation. An additional group of 5 rats/sex was dosed at the highest level for 28 days, followed by a 14-day observation period prior to necropsy. No effects were seen in the recovery group.

Results from acute toxicity studies on dimethyl hydrolyzate, a compound containing 58% CASRN 69430-24-6, indicated that the rat LD₅₀ was >15.4 g/day and the rat LC₅₀ was >8750 mg/m³ (Dow Corning Corporation, 1974).

The Hoffman and Zimmer (1989) study with a NOAEL of 500 mg/kg/day was used to derive the ITSL.

ITSL = NOAEL/(35 x 100) x (BW_{model})/(Inh. Rate_{model}) x b/a NOAEL = 500 mg/kg/day

BW Sprague-Dawley rat = 0.267 (male) or 0.204 (female) kg

Inh. Rate Sprague-Dawley rat = 0.899 (male) or 0.972 (female) m³/kg/day

a = absorption efficiency by inhalation route of exposure (assumed = 1 for lack of data)

b = absorption efficiency by oral route of exposure (assumed = 1 for lack of data)

ITSL = 0.04243 (male rat data) or 0.02998 (female rat data) mg/m³

Lower value chosen as it is more protective

ITSL = $0.02998 \text{ mg/m}^3 \times 1000 \mu\text{g/m}^3 = 29.98 \mu\text{g/m}^3 = 30 \mu\text{g/m}^3$

The ITSL for cyclopolydimethylsiloxane (CASRN 69430-24-6) = $30 \mu g/m^3$ based an annual averaging time.

Reference:

Dow Chemical Corporation. 1974. "Acute Toxicologic Properties of Dow Corning Dimethylhydrolyzate According to the Consumer Products Safety Commission in Compliance with the FHSA." EPA Doc. #86940001524, OTS0590158.

Hoffman, R. D., and M. A. Zimmer. 1989. "A 28-Day Subchronic Oral Toxicity Study of Dow Corning X2-7551 in Rats." EPA Doc. #86940001393, OTS0590097.

MLH:CB:DB

cc: Cathy Simon, AQD Sheila Blais, AQD Chris Bush, AQD