MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

August 15, 2001

TO: File for Dimethyl Siloxanes and Silicones, Reaction Products with Silica (CASRN 67762-90-7)

FROM: Mary Lee Hultin, Toxics Unit, Air Quality Division

SUBJECT: Initial Threshold Screening Level

The initial threshold screening level (ITSL) for dimethyl siloxanes and silicones, reaction products with silica (CASRN 67762-90-7) remains at 0.1 $\mu g/m^3$ based on an annual averaging time.

The following references or databases were searched to identify data to determine the ITSL: the file for the compound, IRIS, HEAST, RTECS, EPB-CCD, MDEQ library, NTP Management Status Report, IARC, CAS-online, NLM-online, NIOSH Pocket Guide, ACGIH Guide, Handbook of Environmental Data on Organic Chemicals, Patty's Industrial Hygiene & Toxicology, Merck Index, and Condensed Chemical Dictionary.

The best available data were from studies on CAB-O-SIL® TS-720, identified in the reports as CAB-O-SIL N70-TS (Hoechst Celanese Corporation, 1983). CAB-O-SIL® TS-720 treated fumed silica is a high-purity silica which has been treated with a dimethyl silicone fluid. The treatment replaces many of the surface hydroxyl groups on the fumed silica with a polydimethylsiloxane polymer. This treatment makes the silica extremely hydrophobic. The compound is used in coatings, epoxy resins, greases, powders, and silicone rubber formulations (Cabot Corporation, 2001). According to the Material Safety Data Sheet on CAB-O-SIL® TS-720, the compound is comprised 100% of CASRN 67762-90-7 (Cabot Corporation, 2000).

A 28-day dust inhalation toxicity study of CAB-O-SIL N70-TS was conducted on CD rats (10/sex/group; Hoechst Celanese Corporation, 1983). The initial target concentration was 0.06 mg/L air, but was reduced to 0.03 mg/L air after 9 male rats died shortly after exposure on the first day. The animals were exposed 6 hours/day, 5 days/week for 4 weeks. The mean particle size in the dust chamber ranged from a high of 0.3668 µm during the first week to a low of 0.2255 µm during the second week of exposure. Groups were necropsied at 1, 2, and 4 weeks into the exposure period. A fourth group was allowed to recover, with half of the animals being necropsied at 6 weeks after and the other half at 12 weeks after the completion of the exposure period. The majority of exposed rats exhibited a crusty muzzle and nose and irregular breathing during exposure, with some showing signs of salivation. Exposed rats initially lost body weight (statistically non-significant), and then gains paralleled controls. Hematological results at the 2- and 4-week necropsies showed a significant increase in relative number of neutrophils and decrease in relative number of lymphocytes. The recovery groups were essentially normal in hematological parameters. Serum chemistry results for those aniimals sacrificed at the 4-week necropsy showed a 20% increase in serum glutamic oxaloacetic transaminase. Gross pathology revealed lung discoloration of varying degrees in all exposed rats, with some clearing in the recovery groups. Lung weights of exposed animals of both sexes were statistically greater than controls. Histologically, the animals that died the first day of exposure had acute pulmonary hemorrhages accompanied by bronchiolar plugs with emphysema. Those animals sacrificed after the second week of exposure showed lungs with chronic-active interstitial/

alveolar inflammation, multifocal in distribution, often surrounding areas of emphysema. Those sacrificed at the end of the fourth week of exposure had mild to very severe pulmonary chronic interstitial/alveolar consolidative lesions, usuallly diffuse in distribution. The recovery groups showed some scarring and healing from these conditions. While it was determined that the lung was the target organ in this study, the question remained whether some lesions may have been due to the initial gravimetric concentration of 0.06 mg/L CAB-O-SIL® N70-TS.

There was an acute dust inhalation toxicity study reported for "Cab-O-Sil dust" (Cabot Corporation, 1982), however the specific tradename was not indicated and there are several CAB-O-SIL® formulations, making it unclear as to whether CASRN 67762-90-7 may have been studied.

The acute oral toxicity of CAB-O-SIL® N70-TS was assessed in Sprague-Dawley rats (5/sex; Cabot Corporation, 1981). A 10% weight/volume suspension was prepared with corn oil as the vehicle. Because the dose of 5 g/kg BW was too large for 1 administration, it was administered in 4 portions about 2.5 hrs apart. The mean administered dose was 1148 ± 11 mg for males and 988 ± 25 mg for females. There were no deaths during the 14-day observation period. All animals had poor coat quality the first 3 days following dosing. All animals experienced loose stools within the first 24 hrs following dosing. Some animals initially experienced crusty muzzles. There were no clinical signs of toxicosis, and necropsy revealed no pathological changes.

The ITSL could have been derived from the 28-day study (Hoechst Celanese Corporation, 1983) had multiple doses been tested or had one dose been given consistently throughout. The high mortality associated with that original level also diminished the quality of the data. Therefore, it was determined that the studies on CAB-O-SIL® N70-TS could not be used to determine the ITSL, and the ITSL remains at trace.

The ITSL for dimethyl siloxanes and silicones, reaction products with silica, is 0.1 µg/m^3 based on annual averaging.

References:

Cabot Corporation. 1981. "Eight Toxicity Studies with Cab-O-Sil N-70-TS. (410-0691: Acute oral toxicity study in rats of Cab-O-Sil N-70-TS at a dose level of 5 grams per kilogram of body weight.)" EPA Doc. #86-930000478, OTS0537804.

Cabot Corporation. 1982. "Eight Toxicity Studies with Cab-O-Sil N-70-TS. (410-0826: One hour acute dust inhalation toxicity study in rats of Cab-O-Sil N70TS.)" EPA Doc. #86-930000478, OTS0537804.

Cabot Corporation. 2000. Material Safety Data Sheet for CAB-O-SIL® TS-720, Treated Fumed Silica.

Cabot Corporation. 2001. Product information sheet for CAB-O-SIL® TS-720, Treated Fumed Silica.

Hoechst Celanese Corporation. 1983. "Twenty-eight-Day Dust Inhalation Toxicity Study of Cab-O-Sil N70-TS in Albino Rats." EPA Doc. # 88-930000052, OTS0538314.

MLH:CB:DB
cc: Cathy Simon, AQD
Sheila Blais, AQD