US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: June 13, 1980

SUBJECT: Dow Corning 5700 Antimicrobial on Fabrics.

Caswell #892B

FROM: Henry Spencer
Toxicology Branch/HED (TS-769)

6/13/80

TO: John Lee, PM #31
Registration Division (TS-767)

Registrant: Dow Corning Corp.
EPA No. 34292-1

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Active Ingredient:

3-(trimethoxysilyl)-propylidimethyl-octadecyl ammonium chloride -42%

Inert Ingredient:

methanol 50%

[redacted]

Conclusions and Recommendations:

1. Toxicology Branch considers that the data submitted to date, support the registration of this material for only the following uses:

   100% polyesters
   50/50 polyester/cottons
   nylon-reinforced non-woven fabrics

   to be used exclusively in:

   a. carpets
   b. throw rugs
   c. mattress pads
   d. mattress ticking
   e. non-woven polyesters
   f. polyurethane foam where covered
   g. disposable polyurethane foam cushions for lapidus airfloats systems.
   h. athlelic and casual shoes.

2. The product label is to be labeled for Cat. I toxicity due to the corrosiveness to the eyes and skin. Handling requires goggles and protective gloves.

3. Additional data on dermal absorption of a C^{14} labeled test compound will be required before a hazard assessment of the compound will be made on the following uses:

   a. toweling
   b. mens underwear
   c. bed sheets
   d. outer wear apparel
   e. womens hosiery
   f. any fabric of 100% cotton which might be used next to the skin.

4. The data submitted on the durability of the D.C. 5700 material is sufficient to indicate that only extremely minute amounts of the material may be soluble in the 100% cotton fabric and then under a set of extreme conditions. In the cases cited in para. 1 above, the exposure will be reduced even further than might be anticipated from the sweat extraction study due to additional coverings in most cases.

5. The registrant had agreed that before the items in para. 2 above would be approved, additional studies to determine if the soluble moiety would cross the dermal barrier would be submitted.

6. Even though IBT data have been submitted prior to the final review, these data are not considered essential for para. 1 above.

Summary of TOX Data:

Host-Mediated Assay For Detection of Mutations Induced by TX-1347, Albino Rats, P.O. No. 3CR-1029-CCNB, February 21, 1977, IBT No. 8533-10127 Study, Submitted by Dow Corning Corp.

It is concluded that in this test system, TX-1347 does not produce a mutagenic response in S. Typhimurium (strain G46) following a host-mediated assay using albino rats.

Teratogenic Study with TX-1348, Albino Rats, P. O. No. 3CR-1029-CCBN, IBT No. 8533-10126, May 6, 1977, Submitted by Dow Corning Corporation. Considered to be negative at 1000 mg/kg/day (not validated).

Acute Rat Oral LD50 (50% formulation) - 12.27 gms/kg

Acute Rabbit Dermal LD50 (50% formulation) - > 7.95 gms/kg

Acute Rabbit Eye Irritation (50% formulation) - severe irritation and tissue destruction

Acute Rabbit Eye Irritation (50% formulation) -10% w/v produced cornel damage 2% w/v normal at 48 hours

Acute Rabbit Dermal Irritation (50% formulation*) - slight to moderate irritation

Subchronic Rabbit Dermal (50% formulation) - 10% w/v and 2% dilution produced from none to slight irritation

Human Repeated Patch Test (50% formulation) - very slight irritation noted in 2 of 50 subjects dosed once only-no sensitization noted.

28-Day Dermal Irritation in Rabbit with Treated Fabric (with 0.5% and 5% treated fabric) equal 1 X to 10 X, IBT #001004030, dated 12/31/73 (not validated) - no local or systemic effects were noted.