UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: April 26, 1978

002488

SUBJECT: Q9-5700 Antimicrobial Agent - Caswell No. 892B
Registration No. 34292-1

FROM: Carlos A. Rodriguez CAR 4.26.78
Toxicology Branch/RD

TO: Joseph Tavano
Product Manager #31

Registrant: Dow Corning Corporation
South Saginaw Road
Midland, MI 48640

Recommendation:

The mutagenic study and teratogenic study are both IBT studies. These studies must be validated by the Registrant before a decision by the Toxicology Branch can be made of accepting them.

Formulation:

Active Ingredient:

3(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride ----- 42%

Inert Ingredients:

Methanol ---------- 50%

[redacted]

Not in RPAR list of chemicals

Manufacturing process information not included.

Uses: For Industrial Use Only, as a final bacteriostatic, fungistatic, algistatic preservative finish for textiles in the presence of moisture.

Toxicology: 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.

Male albino rats were treated orally with the test compound for 5 consecutive days at dose levels of either 100 or 1,000 mg/kg of TX-1347. Control animals were treated in a similar manner with 10 mg/kg of corn oil. All animals were weighed daily to assure accurate dosage on a mg/kg of body weight basis. Observations were made daily to detect any deaths or untoward behavioral reactions. The test animals were injected with a histidine dependent strain of S. typhimurium (strain G-46) culture into the last dose. (continued on next page)

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Positive control rats received an intramuscular injection of 100 mg of DMN (dimethylnitrosamine) simultaneously with the bacterial injection. After 3-hour exposure, the bacteria were recovered and the number of bacteria no longer dependent on an external source of histidine was determine. The number of revertants (mutants) obtained from rats treated with TX-1347 revealed no difference from the number of revertants (mutants) in the control animals. Strain sensitivity was exhibited by the positive control animals with a 7 to 8 fold increase in mutation rates over the spontanous rate for the concurrent control.

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.

Teratology Study: 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.

Protocol: 19 pregnant rats were fed on days 1-15 of gestation, 0, 100, 300, and 1,000 mg/kg/day of TX-1348. Control animals were treated with corn oil. The pups were dilivered on the 20th day of gestation by Cesarian section. 2/3 of the fetuses obtained were subjected to skeletal exmination. Internal development was evaluated using the free-hand razor blade section of Wilson in the rest of fetuses.

Results: Maternal nody weights and body weight gains of dams exposed to TX-1348 were similar to controls. Dams exposed to the material TX-1348 displayed no untoward behvaioral reactions. Results of the sacrificed on gestation by day 20 revealed no reproductive effects. Body weights of fetuses given TX-1348 were essentially same as control fetuses. No external abnormalities were revealed among fetuses receiving the test material. The skeletal findings were similar between test and control group.

Evaluation: TX-1348 was found to be non-teratogenic in this test system.

Typists:TH

RD inital G.E.Whitmore 4/26/78

R for GEW 5/8/78

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