UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: January 18, 1980 1/24/80 Caswell No. 892B

SUBJECT: (1) Durability of Dow Corning 5700 Antimicrobial Agent on Fabrics When Exposed to Simulated Human Sweat.
(2) Mutagenicity Data Review

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Registrant: Dow Corning Corp
EPA No. 34292-1

Active Ingredient: 3-(trimethoxysilyl)-propyldimethyloctadecyl ammonimum chloride

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

Conclusions: The following question have been raised from the review of these studies and are contingent to the registration of the use of this product on textiles.

1. What is the significance of those values reported for the concentrations of active ingredient in the extract for cotton fiber at a pH4 (table II of this report)?

2. Is the nature of the active ingredient in this extract such that it is likely to be aborbed dermally?

3. Refer to addendum I and II of this report for those questions raised on the mutagenicity studies reviewed by Irving Mauer.

Procedure

To determine the amount Dow Corning 5700 antimicorobial agent that might be removed from treated natural, synthetic and blended fabrics in contact with simulated human sweat, 6"x6" swatchs of the respective fabrics were subjected to the following treatment.

Fabric	Wt. Dry gram	Conc. Of 5700 %	Duration of Exposure	Wet Wt gram
Synthetic-100% polyester	3.6-4	1.42	20 min	9.7-10.8
Blend 50/50 poly ester	3.8-4	0.74	15 sec.	8.2-8.7
cotton 100% cotton	3.2-3.4	0.74	15 sec.	6.8-7.3

Following the treatment with the test material the swatches were wash with tap water for one munute, air dried for 30 min, then in tap water for three minutes and then air dried for 30 minutes. A sample of each fabric was ironed and subjected to temporatures in the range of 120-140°F.

The exaggerated test to determine the effect of sweat on fabrics treated with this antimicrobial agent involved using a 60:1 weight ratio of simulated human *sweat to treated fabric with a contact time of 24 hours at 37°c. The pH of sweat was adjusted to both pH4 and to pH7. The treatment concentrations and contact time were more than double recommended values. An additional study was submitted to supplement the present study. This involved the treatment of a nylon-reinforced non-woven fabric with Dow Corning 5700 and subjecting the sample to simulated human sweat at pH6. Analysis of the liquids were carried out using a classical spectrophotometric analytical technique that was modified to obtain a 50 parts per billion limit of detection.

Results

All test samples showed no detectable levels of active ingredient above 50 ppb, except for the cotton samples subjected to sweat adjusted to pH4. At pH4 the amount of active ingredient found in the extract was 235, 250 and 240 ppb for each of the respective cotton samples tested. A question was raised on the nature and particle size of the active ingredient found in the extract, prompted a phone call January 10, 1980, from Dr. Spencer of the Toxicology Branch to Mr. Abbott of Dow Corning concerning the values reported for the cotton treated samples at a pH4. All samples of the extract were filtered and represent a particle size of one micron or less.

* Biological Handbook
Blood and Other Body Fluids
Dorothy Dittmer
Federation of American Socities for Experimental Biology 1961

Addendum I

Dow Corning 5700 ("Quat")

II. Transformation Assay in Presence of MA

cover (1) Material tested in cover memo as "T1482", but attached p.1,3 study is T1483. Is this same? Is TX1671 ~~is~~ the same as TX1559 (used in Ames testing)?

p.4 (2) Why dilute in DMSO if material comes in methanol? Protection from light? (use of brown vials?)

(3) Concentration of the active ingredient?

p.5 (4) Why acetone mentioned as solvent vehicle?

p.7 (5) What are concentrations above and below LD_{50} (LD_{95}/LD_{50})?

p.7 (6) Explanation of the foci (types) to be ascertained, and why only Type III considered transformants? What criteria used for each type, and for transformation?

p.8 FF (7) The expression of doses (in terms of "delivered dose") should be explained, as well as how "LD_{50}" can be calculated as a % (Table I). (One can't really talk about a "dose-response" with the terms given here.)

p.6, (8) In order to ascertain optimal activating abilities of other species or tissues for test material, why wasn't mouse (eg. BALB) liver preparations used (or other species)?

Table I (9) How (and why) was relative survival "estimated"? Weren't 250 cells initially seeded (as given in Appendix A)?

(10) Why were cells fixed at 4 days for cytotoxicity test, when protocol (Appendix A) indicates 7-10 days?

Table III (11) How are CAR's (number of cells at risk) determined?

(12) How is TF calculated? What do figures ($<0.19 \times 10^{-4}$) mean when the number of Type III foci equals 0?

p.12 (13) That the "concentrations of the test compound were consistent on a volumetric basis in terms of a delivered dose" would be more firmly supported by weight data on precipitates.

Addendum II

Dow Corning 5700 ("Quat")

I. Ames Test

p.2 (1) What is TX 1559? Is this same as test material A of cover abstract sheet?

p.4,B (2) In overlay plate test, is photo reactivity also a problem? Report does not state plates were incubated in a darkened incubator.

Table II (3) The range of dosages used (as reported in Table II) are not 2 to 3 log difference (as indicated at bottom of p.5, normal protocol). Also, was highest dose (500ug) at the limit of solubility of preparation?

p.6, B (4) Since the material is an anti microbial, results of a test in bacteria are moot. Nonetheless, some pattern of survival should have been included.

Table II (5) Are the tests materials, TX-1559 A through D the same as those of abstract cover sheet?

(6) Since 10 replicate counts were made for each count listed in Table II, some measure of variation should accompany each average in the table.

(7) Any conclusions should be based on consistent results of at least two independent tests. Was this done here?

(8) Since toxicity may delay appearance of revertents (and this material in an anti-microbial), were any plates incubated for 72 hours?

(9) Was a background lawn of non-revertents observed at any dosage level? This would give assurance test was run at non-bactericidal concentrations.

(10) Were preliminary tests run to ascertain toxicity, and survival curves?

Table II (11) It is noted that the counts for solvent controls and positive controls are identical for all 4 tests of test materials, A thru D. It is not stated in protocol whether the same controls were used for all tests (?)

(12) Was the (induced) S-9 tested for optimal activity? (E.g., mutagencity of dimethylbenzanthracene).