UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

To Be Discarded

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: DOW CORNING® 5700: Review of data package.

413333

Tox.Chem No.: 892B
MRID No.: 413394-01, 02, 03
~~413551-01~~, 02
HED Project No.: 0-0562
DP Barcode: N/A
Submission No.: N/A
PC Code: 107401
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From: John C. Redden, Toxicologist
Section 3
Toxicology Branch 1
Health Effects Division (H7509C)

JCR Redden 7/29/93

To: James Wilson
Antimicrobial Branch
Registration Division (H7505C)

Thru: Karen L. Hamernik, Ph.D.
Acting, Section Head Section 3
Toxicology Branch 1
Health Effects Division (H7509C)

ACTION: Review the submitted studies.

CONCLUSIONS:

A study entitled "Range-Finding Developmental Toxicity Study in Rats" MRID No. 413394-01 was submitted with this package. This study had been previously submitted to the Agency as MRID No. 414380-02, and was reviewed In HED Document Nos. 8446 and 10138.

A 14 day range-finding dermal study (MRID No. 4133394-02) was conducted with Dow Corning® Hydrolysate (4 animals per group (2 per sex)) at doses of 0, 100, 500, and 1,000 mg/kg/day of the test material suspended in propylene glycol (vehicle). No overt signs of toxicity or mortality were seen in any of the groups, nor were significant differences in mean body weights or food consumption seen in treated and control animals. No treatment-related effects were noted at gross necropsy.

The doses used in this study were selected for use in the 90-day subchronic dermal toxicity study.

A 90-Day Subchronic Dermal Toxicity Study of Dow Corning® 5700 Hydrolysate In Rats (MRID No. 413394-03) was reviewed with this package. No treatment related deaths, overt signs of toxicity, or changes in behavior were noted in any of the groups. No statistically significant differences were noted in either mean body weight or food consumption data between the test and control groups. Clinical pathology and organ weight data did not indicate any treatment-related effects. No significant histopathologic changes of biological or toxicological significance were seen in tissues from terminal sacrifice rats. The NOEL is > 1000 mg/kg/day (limit dose). This study is Core graded **Minimum**, and satisfies the requirement for Guideline § 82-3 90-day subchronic dermal toxicity study.
A study entitled "Mutagenicity Test on DC 5700 Hydrolysate in the L5178Y TK +/- Mouse Lymphoma Forward Mutation Assay: Confirmation Study" (MRID No. 413533-01) was also submitted for review. Under the conditions of this test DC 5700 Hydrolysate was negative in a L5178Y TK +/- mouse lymphoma forward mutation assay. The Core Classification is **Acceptable** for Guideline § 84-2, Gene Mutations.

Additionally a study entitled "Supplemental Studies to the Mutagenicity Test on DC 5700 Hydrolysate in the L5178Y TK+/- Mouse Lymphoma Forward Mutation Assay" (MRID No. 413533-02) was submitted for review. The purpose of these supplemental studies was to investigate the anomalous results obtained in mouse lymphoma forward mutation assays performed with DC 5700 Hydrolysate. The anomalous results observed in the first trial was, "primarily the result of physiological effects of test material treatment combined with variations in the heat-inactivation process that resulted in a weakening of the selective pressure. This work confirmed the evaluation of DC 5700 Hydrolysate as negative in the L5178Y TK+/- mouse lymphoma forward mutation assay under the conditions of testing and that initial anomalous results were the results of an artifact of the of the assay system." This is not an accepted protocol, but does provide useful information.

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