



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

NOV 10 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

THRU: Robert B. Jaeger, Section Head *RPJ 11/1/83*
Review Section #1
Toxicology Branch/HED (TS-769) *WJL 11/8/83*

SUBJECT: Need to replace IBT Studies. Reg. No. 34292-1
(Dow Corning 5700). CASWELL No. 892 B.

Comments:

Toxicology Branch has concluded that the additional IBT studies listed by Mr. Lee in the review request dated 10/21/83 and reproduced below are not required for registration of the DC 5700 product by EPA.

The fact that they were invalidated becomes a mute point if they are not needed or required for registration.

The leaching data provided by the registrant adequately demonstrates the lack of need to repeat these studies.

1. Human Repeated Insult Patch Test, Sept. 26, 1972, IBT No. F1905.
2. 28-Day Subacute Dermal Toxicity Study with Treated Fabrics in Albino Rabbits, Dec. 31, 1975, IBT. No. 601-064030.
3. Host-Mediated Assay for Detection of Mutations Induced by TX-1347 in Albino Rats, Feb. 21, 1977, IBT No. 8533-10127.

4. Three-week Vaginal Irritation Study with Treated Panty Hose Fabric (Cotton and Nylon) in Beagle Dogs, June 16, 1976, IBT No. 8531-08440.

5. Teratogenic Study with TX-1348 in Albino Rats, May 6, 1977, IBT No. 8533-10126.

Henry W. Spencer, Ph.D. *HWS*
Review Section #1 *11/7/83*
Toxicology Branch/HED (TS-769)

TS-769:SPENCER:s11:X73710:11/7/83

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Note to HED Reviewer

Subject: IBT Studies Submitted for Dow Corning 5700 Antimicrobial Agent
EPA Reg. No. 34292-1

Please note that certain data listed below do not appear to be pertinent to the product's use pattern. Also other data below are not required to be submitted by EPA regulations. The latter data apparently was submitted voluntarily by Dow Corning Corporation. Please determine which of the following studies are required to be repeated to support the safety of this product. The labeling for all use patterns are attached. If you require additional information contact Marshall Swindell (557-3675; CM-2, Room 254).

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