

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: April 13, 1978

SUBJECT: Validation of IBT Studies (IBT No. F1905, IBT No. 601-04030, IBT No. 663-06493, IBT No. 8533-10127, IBT NO. 8531-08440, IBT No. 8533-10126, Caswell#829B)

FROM: William Dykstra, Ph.D
Toxicology Branch

WJD 4/13/78

TO: Joseph Tavano
Product Manager #31

Registrant: Dow Corning Corp.

EPA Registration No. 34292-1

Recommendations:

1. The Auditor of the IBT Studies, Dr. Norman G. White found no discrepancies between protocols, raw data and final report in any of the IBT Studies. Each study is certified by Dow Corning Corp.

Review

Name of Auditor: Norman G. White, Ph.D., CSP (Curriculum Vitae included)

TOX Studies Validated done by IBT

1. Human Repeated Insult Patch Test with TX-793, Sept. 26, 1972, IBT No. F1905.
2. 28-Day Subacute Dermal Toxicity Study with Treated Fabrics in Albino Rabbits, Dec. 31, 1973, IBT No. 601-04030.
3. Acute Vapor Inhalation Toxicity Study with Dow Corning Q9-5700 in Albino Rats. Feb. 14, 1975; IBT No. 663-06493
4. Host-Mediated Assay for Detection of Mutations Induced by TX-1347 in Albino Rats. Feb. 21, 1977; IBT No. 8533-10127
5. Three-week Vaginal Irritation Study with Treated Panty Hose Fabric (Cotton and Nylon) in Beagle Dogs; June 16, 1976; IBT No. 8531-08440
6. Teratogenic Study with TX-1348 in Albino Rats; May 6, 1977; IBT No. 8533-10126

Dr. Norman G. White has audited all of the above identified IBT studies submitted in support of EPA Reg.#34292-1. He respectively submitted (signature) that in every study:

- (a) The protocol follows standard practice procedures for the study and there is no evidence to indicate that they were not completed as originally designed.

- (b) There were no discrepancies between the original raw data available and the final report as submitted.
- (c) All subjects and animals are accounted for in the test results and the results, as stated, are supported by the data.
- (d) It is his opinion that the above identified IBT studies are in order.

Each audit is certified by March 20, 1978 by W.J. Hargreaves - Executive Vice President.

For GEW 4/18/78

Typists: TH