



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

MAY 18 1992

MEMORANDUM

SUBJECT: SACB Review of a Mutagenicity Study Submitted to Support the Registration of the End-Use Product Treo™ 3-Way Protecting Lotion (HED Project No. 2-1070; I.D. No. 065233-R; Caswell No. 618; Shaughnessy No. 021901; Barcode D173189; MRID No. 421513-10)

TO: Richard Mountfort (PM-10)
Registration Division (H7505C)

FROM: J. Thomas McClintock, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

JTMC
5/15/92

THROUGH: Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
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Reto Engler

ACTION REQUESTED: In response to a request by the Registration Division for an expedited review, SACB has performed a secondary review of a mutagenicity study submitted by Primavera Laboratories, Inc. to support the registration of Treo™ 3-Way Protecting Lotion (end-use product; EP), an insect repellent that uses low concentrations of plant derivatives to deter ticks and biting flies. SACB has provided a summary of the results below. All other toxicity studies using the EP as the test material were previously reviewed by SACB (see 15 May 1992 memorandum from J. T. McClintock to R. Mountfort).

CONCLUSION: 152B-17. Mutagenicity Assay. Due to the unacceptable high spontaneous reversion rates and the marked reduction in the sensitivity to direct-acting mutagens observed in strains TA98 and TA100, no conclusions could be reached from this assay conducted with Treo SPF 15 lotion.

CLASSIFICATION: Unacceptable. This study should be repeated using established procedures and the technical grade material as the test substance. The purity and stability of the test material should also be included in the repeat study.

