

4/14/92

DOC 930010

FINAL

DATA EVALUATION REPORT

TREO SPF 15 Lotion

Study Type: Acute Dermal Toxicity in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
Environmental Protection Agency
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DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-2 and 152-11: Acute dermal toxicity in rabbits

EPA IDENTIFICATION NUMBERS

Tox. Chem. Number: 21901
MRID Number: 421513-05

TEST MATERIAL: TREO SPF 15 Lotion

SYNONYMS: Oil of Citronella

SPONSOR: Primavera Products, Inc., 950 Third Avenue, New York, NY

STUDY NUMBER: 063011

TESTING FACILITY: United States Testing Company, Inc., Biological Services Division, 1415 Park Avenue, Hoboken, NJ

TITLE OF REPORT: Acute Dermal Toxicity Test

AUTHOR: Charles Tong

STUDY COMPLETED: November 19, 1991

CONCLUSIONS: The acute dermal LD₅₀ for TREO SPF 15 lotion was greater than 2 g/kg in male and female rabbits.

CORE CLASSIFICATION: Core Supplementary, using Guideline requirements 81-2 and 152-11. This study can be upgraded pending submission of the purity and stability data on the test material.

TOXICITY CATEGORY: III-Caution

A. MATERIALS

1. Test Material

Test material: TREO SPF 15 lotion
Purity: Not determined
Physical description: Off-white lotion
Lot number: Not reported
Storage conditions: Not reported
Stability: Not determined

2. Controls

Animals: None needed
Test substance: None needed

3. Test Animals

Species: Rabbit
Strain: New Zealand albino
Source: Ace Animals, Boyertown, PA
Sex: Male and female
Numbers: Five males and five females
Housing: Individual
Acclimation: Seven days
Age: Not reported
Weight (day 0): 2.6-3.0 kg (males), 2.5-3.0 kg (females)
Feeding: Feed (commercial pelleted rabbit food) and water provided ad libitum.
Selection: By weight

4. Exposure

Route of administration: Dermal
Dose level: 2 g/kg (limit dose)

B. TEST PERFORMANCE

Fur was removed from the backs and flanks of the test animals using electric clippers. Care was taken to avoid abrading the skin. The study author did not indicate the number of hours prior to exposure the fur was removed. Twenty percent of the body surface area was cleared for application of the test substance. A single dose of 2 g/kg of TREO SPF 15 lotion was administered topically, as a neat solution, to the prepared skin sites. The test substance was held in contact with the skin for 24 hours with a single layer of gauze dressing. The trunks of the animals were occluded with plastic film and secured with elastic wrapping to prevent leakage and ingestion. After the 24-hour exposure, the residual test substance was removed with water and isopropyl alcohol.

Clinical observations were performed immediately after administration of the test substance and daily for 14 days. Individual body weights were recorded on days 0, 7, and 14. Necropsies were performed on all animals.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

No deaths occurred. All animals appeared normal throughout the 14-day observation period. One male and one female exhibited slight weight loss

by day 7; however, both animals gained weight by day 14. One female exhibited overall weight loss throughout the study. No abnormal necropsy observations were noted. Based on these results, the acute dermal LD₅₀ for TREO SPF 15 lotion in male and female rabbits was greater than 2 g/kg.

D. QUALITY ASSURANCE MEASURE

A signed Quality Assurance Statement was presented, but not dated. A Good Laboratory Practice compliance statement was included.

E. REVIEWERS' COMMENTS

The acute dermal LD₅₀ for TREO SPF 15 lotion in male and female rabbits was greater than 2 g/kg, the limit dose for an acute dermal study. Based on these results, the Toxicity Category for TREO SPF 15 lotion is III-Caution.

This study was classified as Core Supplementary, according to Guideline Series 81-2 and 152-11, because purity and stability data were not determined. Other possible ingredients in the lotion were not specified. The age of the rabbits was not reported. This study can be upgraded pending submission of the above-referenced information/data.

The reviewers note that the Quality Assurance Statement was signed, but not dated.