

4/14/92 DOC 930014
FINAL

DATA EVALUATION REPORT

TREO SPF 15 Lotion

Study Type: Guinea Pig Skin Sensitization Test
(The Guinea Pig Maximization Test)

Prepared for:

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Office of Pesticide Programs
Environmental Protection Agency
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DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-6 and 152-15: Guinea pig skin sensitization test (Maximization Test)

EPA IDENTIFICATION NUMBERS

Tox. Chem. Number: 21901
MRID Number: 421513-09

TEST MATERIAL: TREO SPF 15 lotion

SYNONYMS: Oil of Citronella

SPONSOR: Primavera Laboratories, 950 Third Avenue, 20th Floor, New York, NY

STUDY NUMBER: 063629-1

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

TITLE OF REPORT: Guinea Pig Skin Sensitization per Kligman on TREO SPF 15 Lotion

AUTHOR: Charles C. Tong

STUDY COMPLETED: November 19, 1991

CONCLUSIONS: TREO SPF 15 lotion was not considered to be a skin sensitizing agent in guinea pigs when tested according to the Maximization Test.

CORE CLASSIFICATION: Core Supplementary. This study was classified as Core Supplementary, according to Guideline series 81-6 and 152-15, because naive and challenge controls were not run concurrently and purity and stability data were not reported.

TOXICITY CATEGORY: Not applicable

A. MATERIALS

1. Test Material

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

2. Test Animals

Species: Guinea pigs
Strain: Hartley albino
Sex: Male and female
Source: Ace Animals, Boyertown, PA
Receipt date: 05/21/91
Numbers: 10
Housing: 5-6/cage
Age: Young adult
Weight (initial): 283-337 g
Feeding: Feed (guinea pig ration) and water provided ad libitum.
Acclimation: Seven days
Selection: By health and weight

3. Test Material

(a) Primary irritation screen

- Route of administration: Topical application
- Solution used: 10%, 25%, 50%, and 100% concentration of the test sample

(b) Induction phase (day 0)

- Route of administration: Intradermal injection (0.1 mL)
- Solution used: Freund's adjuvant (100%), a 50/50 dilution of test material and Freund's adjuvant (v/v), and undiluted test material

(c) Induction phase (day 7)

- Route of administration: Topical application
- Solution used: Undiluted test material on skin pre-irritated with sodium lauryl sulfate (SLS) for 24 hours

(d) Challenge phase

- Route of administration: Topical application
- Solution used: Undiluted test material

B. TEST PERFORMANCE

TREO SPF 15 lotion was evaluated for dermal sensitization potential using a methodology by B. Magnusson and A.M. Kligman¹.

Primary irritation screen

The study author reported that the primary skin irritation test showed that the sample was not irritating at 100% concentration. Therefore, the test sample was administered neat in the induction and challenge phases.

Induction--intradermal injection (day 0)

On day 0, the shoulder region (area of skin site was not specified) of each guinea pig was shaved and received duplicate intradermal injections of: (1) 0.1 mL Freund's adjuvant alone; (2) 0.1 mL test material (100%); and (3) 0.1 mL test material and Freund's adjuvant (50/50 dilution).

Induction--topical application (day 7)

The same skin site which was previously injected was treated by topical patch administration. The test material was applied under an occlusive patch for 48 hours to skin that had been pre-irritated with a dilution of SLS for 24 hours. The body of the guinea pig was then wrapped with an elastoplast bandage.

Challenge test--topical application

On day 14, the test material was topically applied to a previously unused flank or belly of the guinea pig. It was administered under an occlusive patch. The skin site was not irritated intentionally by SLS treatment. After 24 hours of contact, the skin was evaluated for erythema and edema at 1, 24, and 48 hours.

Body weights

Individual body weights were recorded on days 0, 7, and 17.

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

Induction

The study author reported that during the induction phase, all test animals were normal.

Challenge

All animals were normal (0% sensitization rate) at 1, 24, and 48 hours postchallenge.

Body Weights

All animals gained weight throughout the study.

¹Magnusson B. and Kligman AM. "The Identification of Contact Allergens by Animal Assay, The Guinea Pig Maximization Test". Journal of Investigative Dermatology, Vol. 52, No. 3.

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

This study was classified as Core Supplementary. Although the reviewers agree with the study author's conclusion that TREO SPF 15 lotion was not considered to be a skin sensitizing agent, naive and challenge controls should have been run concurrently to reaffirm the reliability of the test system. The reviewers also note that purity and stability were not reported and the Quality Assurance Statement was signed, but not dated.