Caswellfile



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

004392

MEMORANDUM

T0:

Mr. William Miller, PM 16

Registration Division (TS-767)

FROM:

Byron T. Backus

Toxicologist

Toxicology Branch

THROUGH: Clint Skinner, Ph.D. Chit Skinner 4-8-8)

Head, Section III

Theodore Farber, Ph.D. Chief, Toxicology Branch

Hazard Evaluation Division (TS-769)

Caswell Number: 358

Registrant: American Cyanamid

Action Requested:

The Registration Division has asked for a review of a dermal sensitization study conducted on technical dimethoate.

Recommendations:

The study has been classified as Core Minimum Data, and is acceptable. The test material, under the conditions of this study, gave no evidence of being a dermal sensitizer.

Comment:

No rationale is given as to why the technical dimethoate was "moistened" with paraffin oil rather than water or saline solution, particularly as the positive control was applied in ethanol-water (during the initial 3-week period) and in acetone (for challenge). However, as the dimethoate was applied as a paste, and as there was no indication of any dermal sensitization reaction, the study is acceptable.

Compound:

Dimethoate

Study type:

Dermal sensitization - guinea pig

Citation:

Madison, W. A., Glaza, S. M. <u>Dermal Sensitization Study with Technical Dimethoate CL 12,880 in Guinea Pigs. Study no. 6123-126; HLA No. 40501647.</u> Study conducted at Hazleton Laboratories America, Inc. 3301 Kinsman Blvd., P.O. Box 7545, Madison WI. Study dated 09-13-84. Received at EPA 10-03-84; and in Acc. 254924.

Reviewed by:

Byron T. Backus Toxicologist Toxicology Branch

Byron T Back - 8/85

Approved by:

Clint Skinner, Ph.D. Section Head Review Section III Toxicology Branch

Core Classification:

Minimum

Conclusion:

1. Under the conditions of this study, the test material was not a dermal sensitizer.

Materials:

Young adult male albino guinea pigs of the Hartley strain (from Hazleton, Dutchland Inc.), 428-569 g.

Test material: Technical Dimethoate CL 12,880; lot no. 611A, 97.3% active.

Procedure:

There were 3 groups (each consisting of 10 animals) in the main study. Animals in one group received one 6-hr occluded exposure/week for 3 weeks (the sensitizing period) to 0.2 g amounts of the test material "moistened" with paraffin oil to form a paste. Guinea pigs in the positive control group received one 6-hr occluded exposure/week for 3 weeks to 0.4 mls of 0.3% w/v 2,4-dinitrochlorobenzene in 80% aqueous ethanol. The same application

site was used for each exposure during this period, except for the third week when the positive controls received the DNCB at a different site because of irritation where it had been previously applied. The animals in the third (naive) group were not treated with anything during this 3-week period. Two weeks after the third "sensitizing" exposure, a challenge dose of 0.2 g of dimethoate moistened with paraffin oil was applied to the animals previously exposed to this material and those not previously exposed to anything. Guinea pigs which had been previously exposed to the DNCB were challenged with a 0.1% w/v solution of DNCB in acetone. All challenges were made at previously unexposed dermal sites.

The application sites were read and scored (Draize) at 24 and 48 hours following each exposure (sensitizing and challenge).

Results:

There were no dermal reactions (all scores zero) at any time to any application (either "sensitizing," "challenge" or that which was made to the naive animals) of dimethoate moistened with paraffin. All guinea pigs in the positive control group reacted to the DNCB, with particularly strong reactions (including subcutaneous hemorrhage) following the second "sensitizing" application. All positive control animals had a reaction to the DNCB solution at challenge.

Discussion:

No rationale is given as to why the dimethoate was mixed with paraffin oil rather than water or saline solution. However, as no indication of any dermal sensitization reaction was observed, the study can be classified as core minimum data.