CASWELL FILE

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

JUN 2 2 1993

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Zinc Omadine:** Review of a Primary Dermal Irritation Study in Rabbits.

EPA ID# 088002-001258
Case No. 815252

DP Barcode D172957
Chem. ID No. 088002

FROM: John E. Whalan, D.A.B.T., Toxicologist
Section 1, Toxicology Branch I
Health Effects Division (H7509C)

John E Whalan 6-10-93

TO: Bruce Sidwell (PM Team # 53)
Special Review and Reregistration Division (H7508W)

THRU: Roger L. Gardner, Section Head
Section 1, Toxicology Branch I
Health Effects Division (H7509C)

Roger Gardner 6-16-93 KB 6/21/93

Olin Corporation submitted a Primary Dermal Irritation Study in Rabbits dosed with zinc omadine powder E85656 TER (95 a.i.). This study is Acceptable, and satisfies data requirement 81-5 for a Primary Dermal Irritation Study. The Toxicity Category is IV.

Reviewed by: John E. Whalan *JW 6-10-93* **GUIDELINE:** 81-5
Section I, Tox. Branch I (H7509C)
Secondary reviewer: Roger L. Gardner *Roger Gardner 6-16-93*
Section I, Tox. Branch I (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation Study in Rabbits

MRID NO: 421467-04

CHEM. ID NO.: 088002

TEST MATERIAL: Zinc Omadine Powder E85656 TER (95% a.i.; off-white powder)

SYNONYMS: Zinc, 2-pyridinethiol-1-oxide

STUDY NUMBER(S): MB 91-707 C

SUBMITTED BY: Olin Corporation

TESTING FACILITY: MB Research Laboratories, Inc.

TITLE OF REPORT: Primary Dermal Irritation in Albino Rabbits

AUTHOR(S): Daniel R. Cerven

REPORT ISSUED: November 25, 1991

CONCLUSIONS: Zinc omadine powder E85656 TER induced very slight erythema and slight edema which reversed after 48 hours. Only half the treated rabbits were affected, and there were no other clinical signs.

STUDY CLASSIFICATION: This study is **Acceptable**, and satisfies data requirement 81-5 for a Primary Dermal Irritation study. It places zinc omadine powder E85656 TER (95% a.i.) into **Toxicity Category IV**. The test article purity, which was not reported, was provided by the registrant. This study received Quality Assurance review.

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PROTOCOL: Six male New Zealand White rabbits (2.4-2.8 kg) were individually housed in suspended cages. Bedding was changed twice weekly. Food and water were available *ad libitum*. The day before dosing, the dorsal trunk skin was clipped free of hair to provide 10 cm^2 dosing sites.

Each rabbit was dosed with 0.5 g of the test article that had been moistened with distilled water to make a paste. The trunk was wrapped with a semi-occlusive dressing secured with a non-irritating tape. After 4 hours, the dressings were removed, and the dosing sites were gently washed with distilled water.

Following removal of the dressing, the dosing sites were evaluated for trauma at intervals of 30 and 60 minutes, and 24, 48, and 72 hours. Erythema and edema were scored according to the method of Draize. Dermal ulceration and necrosis and general clinical observations were also recorded at each observation interval.

RESULTS: Very slight erythema was observed in 3 of 6 rabbits between 30 and 60 minutes after dose removal. Two of these had slight (well-defined) edema at this time which reversed to very slight at 24 hours. There was no evidence of irritation at 48 hours. There were no clinical signs in any rabbits.