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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Zinc Omadine: Review of an Acute Dermal Toxicity Study in Rabbits.

EPA ID# 088002-001258
Case No. 815252

DP Barcode D172949
Chem. ID No. 088002

FROM: John E. Whalan, D.A.B.T., Toxicologist
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John E. Whalan
6-8-93

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
KLB
6/21/93

Olin Corporation submitted an Acute Dermal Toxicity Study in Rabbits dosed with zinc omadine powder E85656 TER (95% a.i.). This study is Acceptable, and satisfies data requirement 81-2 for an Acute Dermal Toxicity study. The Toxicity Category is III. The limit test dose of 2000 mg/kg resulted in only 1 death.



Reviewed by: John E. Whalan *JW 6-8-93*
Section I, Tox. Branch I (H7509C)
Secondary reviewer: Roger L. Gardner *Roger Gardner 6-16-93*
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GUIDELINE: 81-2

DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity Study in Rabbits

MRID NO: 421467-01

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 B

SUBMITTED BY: Olin Corporation

TESTING FACILITY: MB Research Laboratories, Inc.

TITLE OF REPORT: Acute Dermal Toxicity in Rabbits/LD₅₀ in Rabbits.

AUTHOR(S): Daniel R. Cerven

REPORT ISSUED: November 25, 1991

CONCLUSIONS: Five male and 5 female New Zealand White rabbits were dermally treated with an aqueous paste of zinc omadine powder E85656 TER (95% a.i.) at a limit test dose of 2000 mg/kg. One male died on day 2 without agonal signs. Clinical signs, found only in 2 females, included reduced hind limb mobility, diarrhea, reduced feces, and weight loss. Very slight erythema was found on day one in 3 of 5 males, and in 1 of 5 females. One male had very slight edema on day one. Gross lesions included yellow-stained nose and mouth, congested lungs, pale intestines, and a yellow-stained dosing site in the male which died, and brown-stained anogenital area in the female with diarrhea.

STUDY CLASSIFICATION: This study is **Acceptable**, and satisfies data requirement 81-2 for an Acute Dermal Toxicity study. It places zinc omadine powder E85656 TER (95% a.i.) into **Toxicity Category III**. Neither the test article purity (supplied by registrant) nor the dermal scoring reference were reported. This study received Quality Assurance review.

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PROTOCOL: Five male and 5 female New Zealand White rabbits (σ 2.1-2.8 kg; ϕ 2.2-2.6 kg) were prepared by having the dorsal trunk clipped 24-hours prior to dosing. An aqueous paste of the test article was applied to the dosing site of each rabbit at a limit test dose level of 2000 mg/kg. The dosing site was covered with a gauze patch, and held in place with non-irritating tape. The torso was then wrapped with plastic which was secured with non-irritating tape. After 24 hours, the dressings were removed and the doses washed off with distilled water. Food and water were available *ad libitum*.

The dosing sites were scored for dermal irritation according to the method of Draize immediately after dose removal, and on days 7 and 14. The rabbits were observed for clinical signs 1, 2, and 4 hours after dosing, and once daily during the 14-day recovery period. Body weights were recorded pretest, weekly, and at death or termination. All rabbits were necropsied and abnormal tissues were preserved.

RESULTS: One male rabbit died on day 2 without any agonal signs. The study report suggested that this animal may have orally ingested the test article during preening. The other males appeared normal throughout the study. One female had reduced hind limb mobility on days 3-5, while another had reduced hind limb mobility on day 3, diarrhea on days 8-11 and 14, reduced feces on days 12-14, and a 17% decrease in body weight between days 7 and 14. Another female lost 9% of its body weight between days 0 and 7, but had no signs of anorexia or diarrhea.

Very slight erythema was found in 3 of 5 males and in 1 of 5 females on day one. Only 1 male had very slight edema on day one. The male which died had gross findings of yellow-stained nose and mouth, congested lungs, pale intestines, and a yellow-stained dosing site. The anogenital area of the female with diarrhea was stained brown.