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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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MEMORANDUM

SUBJECT: Zinc Omadine; Review of a Primary Eye Irritation Study in Rabbits Submitted as Sec. 6 (a)(2) Data.

EPA ID# 1258-841
Case No. 037356

Project No. 2-1169
Tox. Chem. No. 923

FROM: John E. Whalan, D.A.B.T., Toxicologist
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TO: John Lee (PM Team # 31)
Registration Division (H7505C)

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

Roger L. Gardner
2/18/92 *K/B*
2/18/92

Olin Corporation submitted a Primary Eye Irritation Study of Zinc Omadine in Rabbits in accordance with FIFRA Section 6(a)(2). This study is Acceptable, and satisfies data requirement 81-4 for a Primary Eye Irritation study; The Toxicity Category is I.

Ocular exposure to zinc omadine powder caused severe, irreversible irritation (i.e. corrosion) which persisted for 21 days. After 30 seconds of exposure, washing was of little benefit. Rabbits with unwashed eyes were sacrificed on day 7 for humane reasons.

Zinc omadine technical has been classified as Toxicity Category I due to severe eye trauma seen in several old studies. Although this new study satisfies a data gap discovered during FIFRA 88 screening, it does not qualify as Sec. 6 (a)(2) data because it does not offer any new information.

Reviewed by: John E. Whalan JW 2-18-92
Section I, Tox. Branch I (IRS) (H7509C)
Secondary reviewer: Roger L. Gardner *Roger Gardner*
Section I, Tox. Branch I (IRS) (H7509C) 2/18/92

GUIDELINE: 81-4

DATA EVALUATION REPORT

STUDY TYPE: Primary Eye Irritation Study in Rabbits

MRID NO: 421546-01

TOX. CHEM. NO.: 923

TEST MATERIAL: Zinc Omadine Powder E85656 TER (48% a.i.; off-white powder)

SYNONYMS: Zinc, 2-pyridinethiol-1-oxide

STUDY NUMBER(S): MB 91-707 D R/A

SUBMITTED BY: Olin Corporation

TESTING FACILITY: MB Research Laboratories, Inc.

TITLE OF REPORT: Primary Eye Irritation/Corrosion in Rabbits

AUTHOR(S): Daniel R. Cerven

REPORT ISSUED: January 2, 1991

CONCLUSIONS: Ocular exposure to zinc omadine powder caused severe, irreversible irritation (i.e. corrosion) which persisted for 21 days. Washing of the eye after 30 seconds of exposure was of little benefit. Rabbits with unwashed eyes were sacrificed on day 7 for humane reasons.

STUDY CLASSIFICATION: This study is Acceptable, and satisfies data requirement 81-4 for a Primary Eye Irritation study. It places zinc omadine technical into Toxicity Category I due to eye corrosion. This study received Quality Assurance review.

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PROTOCOL: One male and 8 female New Zealand rabbits (2.3-2.7 kg) were individually housed with food and water available *ad libitum*. Each rabbit was dosed with 0.1 ml equivalent of zinc omadine powder in the conjunctival sac of one eye. The eyelids were held closed for one second. The opposite eye served as a control. The treated eyes of 6 rabbits were unwashed. The treated eyes of the remaining 3 rabbits were washed for two minutes with lukewarm water 30 seconds after instillation.

The rabbit's eyes were evaluated for irritation 1 hour after dosing, and on days 1, 2, 3, and 7 in the unwashed eyes; and on days 1, 2, 3, 7, 14, and 21 in the washed eyes. Eye irritation was graded according to the method of Draize (1944). Sodium fluorescein was used on day 1 to assess corneal trauma.

RESULTS: The rabbits with unwashed eyes were sacrificed after 7 days for humane reasons because their eye trauma was judged to be irreversible. It was impossible to fully assess these 6 animals because of severe chemosis and discharge at 1 hour and on days 3 and 7. Throughout the study, the conjunctivae were a diffuse beefy red with pale areas, chemosis was severe with lids nearly closed, and discharge was moderate with some whitish exudate. Corneal opacity ranged from opalescent to opaque with greater than 75% corneal area involvement. Iridic reaction to light was sluggish on days 0-2, and there was no reaction to light on days 3-7. Thus, zinc omadine in the unwashed eyes of rabbits caused severe corrosion.

Eye irritation in the washed eyes was slightly less severe. Although no eye lesions were found in 1 of the 3 rabbits on days 14 and 21, the other two rabbits had little sign of reversibility by day 21. The conjunctivae slowly decreased from diffuse beefy red with pale areas, to crimson red with pale areas. Chemosis ranged from lids half closed to lids nearly closed. Discharge was moderate with some whitish exudate. None of the three had corneal involvement at 1 hour, but thereafter corneal opacity ranged from opalescent to opacity with pannus with 25-50% corneal area involvement. Iridic reaction to light was sluggish. Thus, 30 seconds of exposure to zinc omadine powder in the washed eyes of rabbits caused severe corrosion similar to that seen in unwashed eyes.