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8/2/2000

DATA EVALUATION REPORT

ZIRAM

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (81-4)

Prepared for

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

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Task Order No. 97-22F

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

ZIRAM Primary Eye Irritation Study (OPP 81-4; OPPTS 870.2400)

EPA Reviewer: Virginia A. Dobozy,V.M.D, M.P.H.,_____Date _____
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Reregistration Branch 1 (7509C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS 870.2400 [§81-4]

DP BARCODE: D235025
P.C. CODE: 034805

SUBMISSION CODE: S521512
TOX. CHEM. NO.: 931

TEST MATERIAL (PURITY): Ziram 76% WG (77.2%)

SYNONYMS: Zinc dimethyldithiocarbamate

CITATION: Liggett, M. (1990) Eye irritation to rabbits with Ziram 76% WG. Huntingdon Research Centre Ltd., P.O. Box 2, Huntingdon, Cambridgeshire, PE18 6ES, England. HRC Study Report No. 9069D/UCB 329/SE, March 15, 1990. MRID 41454401. Unpublished.

SPONSOR: UCB Chemicals Corporation, 5505 Robin Hood Road, Norfolk, VA 23513

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 41454401) ~60 mg (equivalent to 0.1 mL) of Ziram 76% WG (77.2%, Batch no. P891006) was instilled into the lower everted lid of one young adult female New Zealand White rabbit. The contralateral eye served as an untreated control. The eyes were examined for ocular irritation 1 and 24 hours after instillation. Irritation was scored according to the Draize method.

The test material induced severe corneal opacity, iridial inflammation, and severe erythma and edema within 24 hours of treatment. Necrosis of the nictitating membrane was also present. The study was terminated after 24 hours for humane reasons. **In this study, Ziram 76% WG was a severe eye irritant. Ziram 76% WG is in TOXICITY CATEGORY I for primary eye irritation.**

This study is classified as acceptable (guideline) and does satisfy the guideline requirement for a primary eye irritation study (81-4) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Ziram 76% WG

   Description: small beige granules
   Lot/Batch #: P891006
   Purity: 77.2% a.i.
   CAS #: 137-30-4

2. Vehicle and/or positive control

   None

3. Test animals

   Species: rabbit
   Strain: New Zealand White
   Age and weight at dosing: ~11 weeks, 2635 g
   Source: Froxfield Farms (U.K.) Ltd., Petersfield, Hampshire, England
   Acclimation period: not given (acclimated to the laboratory environment)
   Diet: SDS Standard Rabbit Diet, *ad libitum*
   Water: tap water, *ad libitum*
   Housing: individually in metal cage with a perforated floor
   Environmental conditions:
   Temperature: ~19°C
   Humidity: 30-70%
   Air changes: 19/hour
   Photoperiod: 12 hour light/dark

B. STUDY DESIGN and METHODS

1. In life dates

   Start: November 6, 1989; end: November 7, 1989

2. Animal assignment and treatment

   The granular test material (~60 mg equivalent to 0.1 mL) was instilled into the lower everted lid of one female rabbit and the eye lids held together for approximately one second. The contralateral eye served as an untreated control. The eyes were examined for ocular irritation 1 and 24 hours after instillation with aid of a handheld flashlight. Irritation was scored according to the Draize method. Due to the severity of the response only one animal was used for the study and the study was terminated after 24 hours.

II. RESULTS AND DISCUSSION

A. The ocular irritation scores following instillation of ~60 mg (equivalent to 0.1 mL) test material into one eye of a female rabbit are shown in Table 1.

TABLE 1. Ocular irritation scores for Ziram 76% WG

Ocular structure		Time after dosing (Hour)	
		1	24
Cornea		0	2
Iris		0	1
Conjunctivae	Redness	2	2[a]
	Chemosis	2	3

Data from page 11, MRID 41454401.

[a] Necrosis of nictitating membrane

The rabbit developed opacity covering the entire corneal surface and iridial inflammation within 24 hours of treatment. The rabbit developed severe erythema (diffuse crisom-red conjunctivae) and severe edema (considerable conjunctival swelling with the eyelids about half-closed and a copious discharge) within 24 hours of treatment. Necrosis of the nictitating membrane was also present.

The test material was corrosive and is placed TOXICITY CATEGORY I for primary eye irritation.

B. DEFICIENCIES

Only one animal was used for the study and the study was terminated after 24 hours. Based on the result of the study, this is acceptable due to the severity of the response.

SignOff Date:	8/2/00
DP Barcode:	D172447
HED DOC Number:	014277
Toxicology Branch:	RAB2