CASWELL FILE
272E 7-11-89

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

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JUL 11 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Cyproconazole Technical: Second Primary Eye Irritation Study

TO: Lewis/Grable PM 21
Registration Division (H7505C)

FROM: K. Clark Swentzel
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EPA ID No.: 55947-RGG
Project No.: 9-1183
Caswell No.: 272E
Registrant: Sandoz Corp.

Requested Action

Review subject study

Background

A primary eye irritation study with Cyproconazole was previously submitted to the Agency. Since a positive reaction was observed in 2/6 rabbits, TB concluded that the data generated in that study were equivocal and that the study should be repeated in 6 different rabbits (EPA memorandum, Swentzel, HED, to Rossi, RD, January 17, 1989). The registrant responded by submitting the present study, which had been previously performed in 3 rabbits according to OECD guidelines.

Conclusion

The data in the second primary eye irritation study showed that the administration of Cyproconazole technical did not induce ocular irritation.

Tox. category: IV

Core-classification: minimum

Reviewed by: K. Clark Swentzel
Section 2 , Tox. Branch (H7509C)
Secondary reviewer: Marcia van Gemert, Ph.D.
Section 2 , Tox. Branch (H7509C) Marcia Gemert 7/7/89

DATA EVALUATION REPORT

STUDY TYPE: Primary Eye Irritation TOX. CHEM. NO.: 272E

MRID NO.: 410427-01

TEST MATERIAL: alpha-(4-chlorophenyl)-alpha-(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol

SYNONYMS: Cyproconazole; SAN 619F

STUDY NUMBER(S): 6332/85

SPONSOR: Sandoz Corp.

TESTING FACILITY: Sandoz Ltd.

TITLE OF REPORT: SAN 619F: Primary Eye Irritation Test in Rabbits

AUTHOR(S): F. Hamburger

REPORT ISSUED: March 30, 1985

CONCLUSIONS: The test material did not induce primary eye irritation; Tox. Category = IV

Classification: core-minimum

Quality Assurance statement: signed and dated

Test material

Cyproconazole technical, batch no. 8405, purity - 94.4%, described as beige white powder

Test animals

New Zealand white rabbits, 3 males, 2.5 ± 0.5 kg, 14 weeks of age, acclimation period - 5 days, supplier - KFM (CH - 4414 Fullinsdorf, Switzerland)

Food and water

Kliba no. 23-341-1, Klingentalmuhle AG. Basle and water (source not given) provided ad libitum

Environmental parameters

Room temperature - 21 ± 2°C, relative humidity - 30-70%, 15 air changes/hr, 12 hr light cycle

Procedures

Treatment and grading

The animals were examined before exposure in order to exclude rabbits with pre-existing corneal injury or eye irritation from the study. Three male rabbits were exposed to Cyproconazole technical following the Draize Method under OECD protocol guidelines. A 100 mg was placed into the conjunctival sac of the right eye; the eyelids were then held together for 1 second and released. The left eye served as a control.

The eyes were examined at 0.5, 24, 48, 72 and 96 hours post treatment; the test protocol indicated that the post treatment observation period would be extended (up to 21 days) if necessary. The eyes were examined with a slit lamp to detect possible changes in the cornea, conjunctiva or iris; changes were scored according to the grades on appended page 1.

Systemic toxicity

Individual body weights were determined on days 1 and 4 post treatment.

Results

Based on the scores shown on appended page 2 and summarized on appended page 3, the administration of Cyproconazole technical did not induce ocular irritation in this study.

All rabbits gained weight during the noted interval, however, there was no basis for comparison since no untreated animals were included in the study.

Conclusion

The test material did not induce primary eye irritation; Tox. Category = IV

Core classification: minimum

CYPROCONAZOLE Tox review 607325

Page_____ is not included in this copy.

Pages 4 through 6 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

X A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Tox Chem No. 272E File Last Updated _____ Current Date 7/5/89

Study/Lab/Study #/Date	Material	EPA MRID/Acc. No.	Results: LD_{50}, LC_{50}, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
Primary eye irritation/ Sandoz/6332-85/ March 30, 1985	Cyproconazole technical 94.4%	410427-01	Ocular administration of 100mg to each of 3 rabbits according to OECD test protocol guidelines. Response to TB evaluation of a previous primary eye irritation study which had equivocal data; a repeated study was requested. Primary eye irritation was not induced by the test material.	IV	minimum