UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

007152

APR 28 1989

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Primary Dermal Irritation Study with Triox

Caswell No. 96 — HED TOX Project No. 9-1225
Record No. 242934 — MRID No.410072-01

FROM: Sidney Stolzenberg, Ph.D. S J Stolzenberg 4/26/89
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THRU: Michael Ioannou, Ph.D. M.J. Ioannou 4-26-89
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and

Marcia van Gemert, Ph.D. M van Gemert 4/27/89
Acting Branch Chief, TOX Branch II (HFAS)
Health Effects Division (H7509C)

Applicant: Ortho
Chevron Chemical Co.
Richmond, CA 94804-0010

ACTION REQUESTED:

Review acute dermal irritation study with Triox. This study was previously submitted but not reviewed because of a technical deficiency related to compliance.

1

CONCLUSION (Summary)

Based on the submitted data of an acute dermal irritation study with rabbits, Triox may be considered as moderately irritating to the skin and classified as follows:

	Intact Skin	Abraded Skin
P.I.S. at 1 hour:	3.2	3.1
P.I.S. at 72 hours:	3.7	3.6

TOX Category: III

Core Classification: ~~Supplementary~~ Invalid

We are presently uncertain of the composition of the test substance used in the present study. This study may be upgraded to Minimum when this is made clear to us.

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Reviewed by: Sidney Stolzenberg, Ph.D. 4/26/89
Section I, TOX Branch II, HFAS/HED (H7509C)
Secondary Reviewer: Michael Ioannou, Ph.D. 4-26-89
Section I, TOX Branch II, HFAS/HED (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation

Caswell No. 96

GUIDELINE: 81-5

HED Project No. 9-1225

TEST MATERIAL: Triox

MRID No. 410072-01

SYNONYMS: Prometon, CC-15015

Iden. No. 239-2381

STUDY NUMBER(S): CEHC 2563

SPONSOR: Ortho
Chevron Chemical Co.
Richmond, CA 94806-0010

TESTING FACILITY: Chevron Environmental Health Center
Richmond, CA 94804

TITLE OF REPORT: The Four-Hour Skin Irritation Potential of CC-15015 (SX-1716).

AUTHOR(S): N.S. Hirose, B.S.

REPORT ISSUED: 9/19/86

CONCLUSIONS AND RECOMMENDATIONS

P.I.S., based on a sum of the erythema and edema in the data shown in table I submitted with this report, was found to be as follows:

	Intact Skin	Abraded Skin
P.I.S. at 1 hour:	3.2	3.1
P.I.S. at 72 hours:	3.7	3.6

TOX Category: III

The substance should be considered moderately irritating to the skin.

Core Classification: Supplementary

The classification of this study may be upgraded to Minimum when the composition of the test substance is specified.

3

A. MATERIAL

1. Test substance: CC-15015, coded SX-1716; a [illegible] liquid, supplied by Ortho Consumer Products Division i[illegible] CA. From the page in the submitted report which in[illegible] results of an analysis for Pramitol in the test substa[illegible] not possible for us to determine what was the composit[illegible] test substance. This page is shown in the appendix.

2. Test animals: Rabbit, New Zealand White, female supplied by R and R Rabbitry, Stanwood, WA. Age of animals was 24-26 weeks, weight was not specified.

3. Statistics: Not performed.

4. Compliance:

- A signed statement of compliance with FIFRA GLP is included.
- A signed statement of Quality Assurance is included.
- A signed statement of confidentiality is included.

B. STUDY DESIGN:

Six rabbits were shaved and a day later, 0.5 ml of test substance, undiluted, was applied to 2 abraded and 2 intact sites on the back of each test animal. Each area of application measured 1 square inch. After 4 hours of contact with the test substance, the gauze, tape and plastic wrapping which held the compound in place on the skin were removed, the compound exposed skin was then washed, and graded for erythema and edema according to the Draize Scoring system. Time periods of scoring after removal of the patch were 1, 24, 48, 72 hours, 7 and 14 days. The skin application sites were then prepared for histopathology and examined microscopically.

C. RESULTS:

Mean skin irritation scores for erythema and edema at the abraded and intact sites for all time periods were shown in Table 1 of the submitted report and appears in the Appendix of this DER. Every animal without exception showed grades 1-4 for erythema and grades 1 or 2 for edema during the first 3 days. P.I.S. scores that were calculated (sum of erythema and edema combined at 1 and 72 hours) are shown in the Conclusion-Recommendation section of this DER.

4

[illegible] -1716)

Time After Treatment	Irritation	Mean Score (Range)(a) Intact	Abraded
1 Hour	Erythema	2.3 (2-3)	2.2 (2-3)
	Edema	0.9 (0-2)	0.9 (0-1)
24 Hours	Erythema	2.8 (2-4)	2.7 (2-3)
	Edema	1.2 (0-2)	1.3 (1-2)
48 Hours	Erythema	3.0 (2-4)	3.0 (2-4)
	Edema	1.1 (0-2)	1.0 (0-2)
72 Hours	Erythema	2.7 (2-3)	2.5 (2-3)
	Edema	1.0 (0-2)	1.1 (0-2)
7 Days	Erythema	1.3 (0-2)	1.4 (0-2)
	Edema	0.0 (-)	0.0 (-)
14 Days	Erythema	1.2 (0-2)	1.2 (0-2)
	Edema	0.0 (-)	0.0 (-)

Primary Irritation Score[b]: 3.6

(a) Mean of six animals.
(b) Sum of the combined individual scores for erythema and edema at each site at 1, 24, and 72 hours divided by 72 observations.

RIN-0334-94 PROMETON REVIEWS (080804)

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