DATA EVALUATION REPORT

Disodium Octoborate Tetrahydrate

Study Type: Primary Eye Irritation in Rabbits

Prepared for:

Registration Division
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U.S. Environmental Protection Agency
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Clement Number: 269-32
Project Officer: Caroline Gordon

Approved by:

EPA Reviewer: Signature: _____
Date: _____

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-4: Primary eye irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 425210-03

PC Number:

TEST MATERIAL: Disodium Octoborate Tetrahydrate

SYNONYM(S): 20 MULE TEAM® TIM-BOR®

SPONSOR: U.S. Borax Research Corporation; Anaheim, CA

STUDY NUMBER: 89-3708-21

TESTING FACILITY: HillTop Biolabs Inc; Miamiville, OH

TITLE OF REPORT: Eye Irritation Study without Rinsing in Rabbits

AUTHOR(S): R.L. Doyle

STUDY COMPLETED: May 5, 1989

CONCLUSIONS: The instillation of the test material in rabbit eyes did not produce corneal opacity. However, iritis was noted in 5/6 eyes 1 hour after treatment. Conjunctival irritation was observed in all eyes 1 hour after treatment and in 2/6 eyes 24 hours after treatment.

CORE CLASSIFICATION: ~~Core-supplementary~~ Unacceptable. This study does not satisfy the Guideline requirements (81-4) for a primary eye irritation study. ~~It is unclear whether or not eyes were rinsed in this study.~~ CIS

TOXICITY CATEGORY:

A. MATERIALS

Test Compound

Test material: Disodium Octoborate Tetrahydrate
Identification number: Lot No. 9B13622
Active ingredient: Disodium Octoborate
Formulation:
Purity:
Physical description: Fine white powder
Storage condition: Room temperature
Stability: Not reported

Dose level: 0.053 g

3. Test Animals

Species: Rabbit
Strain: New Zealand White
Source: Clerco Research Farm
Number of animals: 6
Sex: 3 Male, 3 Female
Age: Young adult
Mean body weight: Not reported
Environmental conditions: Not reported

B. TEST PERFORMANCE

1. Eye Examination: Eyes were examined 24 hours prior to testing by Fluorescein staining.

2. Test Material Application: The test material was applied at a dose of 0.053 g to the eye (lower lid) of each of the rabbits. Eyelids were gently held together for one second. The opposite eye was left untreated and served as the control. The treated eyes were washed following the 24 hour exposure interval.

3. Observation Period: All eyes were examined for irritation at 1, 24, 48, and 72 hours following application.

4. Scoring System: Eyes were scored for ocular lesions according to the method of Draize.

C. REPORTED RESULTS: A summary of ocular effects is presented below:

Summary of Incidence of Positive[a] Ocular Effects

	Observation Intervals								
	Hour				Day				
	1	24	48	72	4	7	10	14	21
Cornea									
Opacity	0/6	0/6	0/6	0/6	/	/	--	--	--
Iris									
Iritis	5/6	1/6	1/6	0/6	/	/	--	--	--
Conjunctivae									
Redness	6/6	2/6	1/6	0/6	/	/	--	--	--
Chemosis	5/6	0/6	0/6	0/6	/	/	--	--	--

[a]The following grades for each tissue are considered positive:

Opacity (Density) - Grades 1, 2, 3, and 4
Iris - Grades 1 and 2
Conjunctivae (Redness) - Grades 2 and 3
(Chemosis) - grades 2, 3, and 4

Iritis (grade 1) was observed in all rabbits at the 1 hour interval. Iritis persisted in one rabbit till 48 hours. No corneal opacity was seen. Conjunctivae (grades 2 and 3) were seen in all rabbits 1 hour after exposure. Conjunctivae (grade 2) was observed in 2/6 rabbits at the 24 hour interval. No positive ocular scores were noted beyond the 24 hour period.

Based on these findings, the test material is best classified as toxicity category III, irritation clearing in 7 days or less.

D. REVIEWERS' COMMENTS: It is unclear whether or not eyes were rinsed in this study. Although the title and summary/conclusions of the study report indicate that eyes were not rinsed, the methods section of the report states that eyes were rinsed 24 hours after exposure. In addition, a previous study (MRID# 425210-01; February 1989) in rabbits evaluated the eye irritation potential of the test material following rinsing after 24 hours. Therefore, this study is considered Core Supplementary, and may be upgraded if the Sponsor can clarify the issue as to whether or not eyes were rinsed in the present study.

E. QUALITY ASSURANCE MEASURES: The test was performed under GLPs (A quality assurance statement was signed and dated 6/22/89).