

US EPA ARCHIVE DOCUMENT

DATA EVALUATION REPORT

Disodium Octaborate Tetrahydrate

Study Type: Primary Eye Irritation in Rabbits

Prepared for:

Registration Division
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Work Assignment Number: 269
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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

EPA Registration No.: 1624-39

Tox Chem. No.:

MRID No.: 425210-01

PC Number:

TEST MATERIAL: Disodium Octoborate Tetrahydrate

SYNONYM(S): 20 MULE TEAM® TIM-BOR®

SPONSOR: U.S. Borax Research Corp., Anaheim, CA

STUDY NUMBER: 88-3442-21(C)

TESTING FACILITY: HillTop Biolabs, Inc., Miamiville, OH

TITLE OF REPORT: Primary Eye Irritation of Disodium Octoborate Tetrahydrate

AUTHOR(S): R.L. Doyle

STUDY COMPLETED: February 21, 1989

CONCLUSIONS: The instillation of the test material in rabbit eyes did not produce corneal opacity. However, iritis and conjunctival irritation were noted in unflushed eyes 1 hour after treatment. Iritis persisted in 2 rabbits at the 24-hour interval. No positive ocular effects were seen following 24-hour postexposure

CORE CLASSIFICATION: ~~Core-Minimum~~ ^{Unacceptable} This study ^{does not} satisfies the Guideline requirements (81-4) for a primary eye irritation study. However, it is recommended that future submissions report environmental conditions. CEG

TOXICITY CATEGORY: III

A. MATERIALS

Test Compound

Test material: Disodium Octoborate Tetrahydrate
Identification number: Lot No. 8G1D
Active ingredient: Disodium Octoborate
Formulation:
Purity: Not reported
Physical description: White powder
Storage condition: Room temperature
Stability: Not reported

Dose level: 0.049 g

3. Test Animals

Species: Rabbits
Strain: New Zealand white
Source: Unspecified approved U.S.D.A. Supplier
Number of animals: 6
Sex: 3 Males and 3 Females
Age: Young adult
Mean body weight: Not reported
Environmental conditions: Temperature: Not reported
Humidity: Not reported
No. air changes per hour: Not reported
Photoperiod: 12 hour light/dark cycle

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 0.049 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 eyes were rinsed after 24 hours and fluorescein staining was utilized for scoring.
3. Observation Period: All eyes were examined for irritation at 1, 24, 48 and 72 hours and 4, 7 and 10 days 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	0/6	0/6	0/6	--	--	
Iris										
Iritis	6/6	2/6	0/6	0/6	0/6	0/6	0/6	--	--	
Conjunctivae										
Redness	2/6	0/6	0/6	0/6	0/6	0/6	0/6	--	--	
Chemosis	6/6	0/6	0/6	0/6	0/6	0/6	0/6	--	--	

^aThe 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) and conjunctive (grade 2) were seen in all rabbits at the 1 hour interval. A blistered appearance to the conjunctiva was also noted in 5/6 animals. Iritis (grade 1) persisted in 2/6 rabbits at the 24 hour interval, but cleared by 48 hours postexposure. No positive ocular scores were seen following the 24 hour interval; only grade 1 conjunctivae was noted in all rabbits following 24 hours postexposure. The grade 1 conjunctivae persisted in 1 rabbit until day 10. These findings show that the test material produced iritis and conjunctival irritation when applied with rinsing (24 hours after application) to the eyes of 6 rabbits.

- D. REVIEWERS' COMMENTS: The reviewers do not agree with the study author's classification of the test material in category II. The study author based their classification on the observation that grade 1 conjunctivae (a nonpositive ocular response) persisted in 1 rabbit till day 10. The reviewers assess that the most appropriate category for the test material (following rinsing after 24 hours) is III (irritation clearing in 7 days or less). Also, it is recommended that future submissions report environmental conditions.
- E. QUALITY ASSURANCE MEASURES: The test was performed under GLPs (A quality assurance statement was signed and dated 3/2/89).

Tox Chem. No.File Last Updated
3/24/93Current Date

Study/Species/Lab/Study# Date	Material	MRID No.	Results	Tox. Cat.	Core Grade
81-4/Rabbit/New Zealand White/ Hill Top Biolabs/89-3708-21 5/5/89	Sodium Octoborate Tetrahydrate	425210-03	Iritis and conjunct- ival irritation		Supple- mentary <i>Unacceptable</i>
81-4/Rabbit/New Zealand White/ Hill Top Biolabs/89-3708-21 5/5/89	Sodium Octoborate Tetrahydrate	425210-01	Iritis and conjunct- ival irritation	III	Minimum <i>Unacceptable</i>
81-5/Rabbit/New Zealand White/ Hill Top Biolabs/88-3442-21 42521-02	Sodium Octoborate Tetrahydrate	42521-02	Slight irritation	IV	Minimum <i>Supplementary</i>