

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 7, 1998

MEMORANDUM:

Subject: Acute Toxicity Review for
EPA Reg. No.: 70871-R 70871-E
DP Barcode: D246360 D246364
Case No: 061691 061695

To: Velma Noble, PM31 / Tracy Lantz
Regulatory Management Branch
Antimicrobials Division (7510W)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

Through: Karen Hicks, Acting Team Leader *Karen P. Hicks*
Toxicology and Chemistry Team
Efficacy and Science Support Branch
Antimicrobials Division (7510W) 8/26/98

Applicant: Bioshield Technologies, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	5
<u>Other Ingredient(s):</u>	<u>95</u>
Total:	100%

BACKGROUND: Bioshield Technologies has submitted a primary eye irritation study to support "Bioshield AM 500" and "Bioshield AM 500 I." The study was conducted by Stillmeadow, Inc. The MRID number is 445535-01.

RECOMMENDATIONS: ESSB findings are:

The primary eye irritation study is acceptable to support both registration numbers 70871-R and 70871-E.

The acute toxicity profile for reg. nos. 70871-E and 70871-R are currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	III ¹	acceptable
acute inhalation toxicity	2	
primary eye irritation	II ¹	acceptable
primary skin irritation	III ¹	acceptable
dermal sensitization	2	

Notes:

1. The results of the studies other than the primary eye irritation study were derived from a previous AD/RSSB review.
2. ESSB was unable to find any reviews of acute inhalation toxicity or dermal sensitization studies submitted for these products. - See Wallace Powell's review of 9/2/97

LABELING:

No precautionary labeling can be recommended until the fulfillment of the requirement for the acute inhalation toxicity and dermal sensitization studies.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31
MRID No.: 445535-01

Reviewer: Ian Blackwell
Study Completion Date: 4/28/98
Report No.: 4263-98

Testing Laboratory: Stillmeadow, Inc.
Author(s): Janice O. Kuhn, PhD

Quality Assurance (40 CFR §160.12): Included

Test Material: AM500; "yellow gel"

Dosage: 0.1 mL

Species: New Zealand White albino rabbits

Sex: 3 males + 3 females

Weight: males = 2.475-2.900; females = 2.775-3.000

Age: young adult

Source: Ray Nichols Rabbitry

Summary:

1. **Toxicity Category:** II
2. **Classification:** acceptable

Procedure (Deviations From §81-4): none

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	10	21
Corneal Opacity	2/6	1/6	1/6	1/6	1/6	0/6	0/6	---
Iritis	2/6	0/6	0/6	0/6	0/6	0/6	0/6	—
Conjunctivae								
Redness	6/6	6/6	5/6	3/6	3/6	1/6	0/6	—
Chemosis	0/6	3/6	2/6	2/6	2/6	0/6	0/6	—
Discharge	6/6	2/6	2/6	2/6	2/6	0/6	0/6	---

Stippling was observed in 4/6 animals at one hour.

Iritial constriction was observed in 2/6 animals through day 4.

Ocular blanching was observed in 2/6 animals through day 4 and 1/6 through day 7.

--- = no observations at this point