



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

August 31, 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)

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: This is an addendum to an 8/7/98 ESSB review of file symbols 70871-R and 70871-E. In that review the acute toxicity profile for these two products was:

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

Since that review, ESSB has been presented with additional reviews and registrant letters that were not in the previous submission.

RECOMMENDATIONS:

As a result of the additional information the acute toxicity profile for 70871-R and -E is:

acute oral toxicity	IV	acceptable
acute dermal toxicity	III	acceptable
acute inhalation toxicity	III	cited <sup>1</sup> (see 1 below)
primary eye irritation	II	acceptable
primary skin irritation	III	acceptable
dermal sensitization		unknown <sup>2</sup> (see 2 below)

1. This information is **inferred** from the product label of [REDACTED] which is the source of the active ingredient used in file symbols 70871-R and -E. [REDACTED]
2. A 5/14/97 letter requests a waiver of the six acute toxicity studies. This reviewer assumes that this is because [REDACTED] is labeled as being a corrosive product. Typically, if a product is dermally corrosive, the dermal sensitization study is waived because the user is to avoid all dermal contact with this product. (Dermal contact is avoid because the product has the potential to burn or severely irritate the skin.) However, the same registrant letter lists a dermal sensitization study and MRID number. The study listed was conducted on another product with the same active ingredient but a very different overall composition. Unless it is positive for dermal sensitization, that study (MRID number 421974-01) will not be sufficient to support this product.

It is noted, however, that while [REDACTED] is listed as being corrosive, file symbols 70871-R and -E are not. Thus, file symbols 70871-R and -E do not have the scientific support for a waiver for a dermal sensitization study. ESSB recommends that a dermal sensitization study be conducted to support file symbols 70871-R and -E.

Product ingredient source information not included.

LABELING:

Date: 08/31/98

LABEL REVIEW SYSTEM

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ID #: 070871-00002 BIOSHIELD AM 500 I

SIGNAL WORD: WARNING

PRECAUTIONARY STATEMENTS:

Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear goggles or face shield. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention. For Category III, add "if symptoms persist."

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

Probable mucosal damage may contraindicate the use of gastric lavage.