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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC - 4 1997

MEMORANDUM

SUBJECT: 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride: review of a data waiver request

EPA Identification Numbers:

P.C. Code: 107401
DP Barcode: D239858
Submissions: S531642
MRID: N/A

TO: Velma Noble / Julie Fairfax
PM Team # 31
Regulatory Management Branch I
Antimicrobials Division (7510W)

FROM: Timothy F. McMahon, Ph.D. 11/24/97
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THRU: Winston Dang, Ph.D.
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and

Norm Cook 12/04/97
Chief, RASSB
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Registrant: BioShield Technologies, Inc.

Action Requested: Review of available acute toxicity data for 3-(trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride in support of data waiver requests for BST Mold and Mildew Remover and All Purpose Cleaner 25.

Background Product ingredient source information not included.

The registrant (BioShield Technologies, Inc.) has submitted a request for waiver of conduct of acute toxicity studies for the formulation BST Mold and Mildew Remover, containing the active ingredient 3-(trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride at a concentration of 0.25%. [redacted] The registrant has cited the data on Dow Corning 5772 in support of this waiver request.

The following Toxicology data is available in support of this active ingredient. It is noted that the acute toxicity tests were performed on a 50% formulation.

3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride (non-food)

Study Type	MRID No.	Required	Satisfied
Acute Oral	40385201	Y	Y (Cat. IV)
Acute Dermal	40385201	Y	Y (Cat. III)
Acute Inhalation	41157803	Y	N (Cat. II)
Primary Eye Irr.	40385201	Y	Y (Cat. I)
Primary Dermal Irr.	40385201	Y	Y (Cat. III)
Dermal Sensitization		Y	N

Reccomendations:

The Risk Assessment and Science Support Branch (RASSB), Antimicrobials Division (AD), has examined the request from the registrant for waiver of acute toxicity testing of BST Mold and Mildew Remover based on data available for the same active ingredient at a higher concentration.

RASSB concludes that:

1) Of the studies cited by the registrant, several appear to have not been reviewed by the Agency. Specifically, MRID No's 42456511, 43219901, 42456513, and 42197401. If the registrant has knowledge that these studies were reviewed, these data should be provided to the Antimicrobials Division.

2) The registrant has employed the signal word "Caution" on the proposed label for BST Mold and Mildew Remover, but there are no product specific data to suport this claim. It is understood that the product represents a significant dilution of the active ingredient, but for many quaternary amonium compounds, Category I labeling statements have been applied even at low concentrations. The registrant should accept Category I labeling for the product or generate product specific acute toxicity data for primary eye irritation and primary dermal irritation, as these were the studies upon which the Category I labeling statements would be based.

3) It is noted that for a non-food use of this active ingredient, the following data gaps appear to exist and **are required**, based on a review of the available data for 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride: an acceptable dermal sensitization test; an acceptable subchronic toxicity test; an acceptable developmental toxicity test; acceptable mutagenicity tests (the only acceptable mutagenicity test on file os listed as MRID # 41296803, mouse micronucleus assay). If the registrant has information to support data requirements in these areas, these data should be submitted to Antimicrobials Division. The registrant should also be aware of the proposed Subpart W, Part 158, Antimicrobial Data Requirements, in which immunotoxicity testing and neurotoxicity testing requirements exist for non-food uses of antimicrobial pesticides.