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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 6 1999

MEMORANDUM

SUBJECT: Human Exposure Considerations:
Human Exposure Assessment for **BIOSHIELD AM 500**
Microbiostatic Agent Containing the Active Ingredient
3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride.

TO: Dennis Edwards, Chief
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Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Doreen Aviado, Biologist *Doreen Aviado 12/2/99*
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Registrant: BioShield Technologies, Inc.

DP Barcode: D256889 (S563593)

**Pesticide
Chemical No.:** 107401

**A.I. Chemical
Name:** 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride

EPA Reg. No.: 70871-1

SUMMARY:

The Antimicrobials Division (AD), Regulatory Management Branch I, received a label amendment to expand the currently registered BIOSHIELD AM 500 use patterns specified on the master labeling to 1) allow for direct product application by "homeowners" in addition to the already registered "commercial/industrial" end user applications; and 2) allow for additional specified household substrates, finished articles, and consumer goods to be listed as use sites.

The registrant submitted an amended "BIOSHIELD AM 500" master label inclusive of all the intended use patterns, and draft alternate labeling for selective products intended to be marketed as "BIOSHIELD For Carpet & Upholstery" and "BIOSHIELD Mold, Mildew, Odor Protector And Inhibitor".

The Risk Assessment and Science Support Branch (RASSB) was asked to evaluate the potential for human exposure associated with the "residential" use patterns and expanded use sites proposed under this label amendment. At this time, the scope of this evaluation was limited to conducting a non-dietary exposure assessment for commercial and homeowner applications in residential settings. AD/RASSB did not conduct a formal risk assessment since it was determined that risk concerns are not anticipated for the active ingredient in the formulated BIOSHIELD AM 500 product, and therefore toxicological endpoints were not selected. As per the toxicology review conducted by Timothy McMahon for this submission:¹

"The available Toxicology data for 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride showed a lack of toxicological effects at dose levels up to and including a limit dose (i.e. 1000 mg/kg/day). The Agency recognizes as a matter of policy that chemicals which do not show any significant effects when tested to a limit dose do not require endpoint selection and risk assessment, based upon the existence of effects only at very high and unrealistic exposures. Therefore, for the proposed uses of 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride, RASSB at this time has no risk concerns for this chemical."

Therefore, AD/RASSB provides in this review only an overview of the exposure potential associated with the BIOSHIELD AM 500 product based on the information provided in the submission (specifically the revised labeling information on use directions, use rates, application methods/equipment, and protective clothing). The exposure assessment concluded that the potential for adverse handler exposures associated with the revised product use patterns are minimal.

BACKGROUND:

BIOSHIELD AM 500 Microbiostatic Agent is a silicone quaternary ammonium salt containing 5.0% 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride as the active ingredient.

BIOSHIELD AM 500 was first registered on October 13, 1998 for industrial and commercial uses on a variety of substrates to inhibit the growth of bacteria, fungi (including mold and mildew), and algae. The product is

¹ Refer to separate toxicology review memorandum by Timothy McMahon for this submission under D260609.

supplied as a liquid concentrate in 2, 4, 8, 16, 20, 22, or 36 fluid ounce containers and 1, 5, 55, 150, or 300 gallon containers and can be diluted with either water or solvents to make labeling-specified use solutions for spray/dipping/soaking and related applications.

The active ingredient, 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride, is currently registered for indirect food-contact, and non-food uses. At time of initial product registration AD/RASSB did not conduct a human exposure assessment or human health risk assessment for the dietary/non-dietary use patterns associated with this chemical.

The BIOSHIELD AM 500 product has been classified under Toxicity Category II due to the substantial, but temporary eye irritation potential for the active ingredient as observed in the primary eye irritation study in the rabbit conducted in support of registration.² The product labeling reflects the "WARNING" signal word and precautionary statements for Toxicity Category II. Results from other product toxicity studies for acute dermal toxicity and primary skin irritation indicated Toxicity Category III. An acute inhalation toxicity study was not submitted at time of registration, but the toxicity has been inferred as Toxicity Category III. Toxicology data on file with the Agency for the technical source product in a 50% formulation of 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride also shows low acute toxicity observed for single exposures by the oral and inhalation routes as Toxicity Category IV, and for the dermal route as Toxicity Category III.³

HUMAN EXPOSURE CONSIDERATIONS:

Product Use Profile:

The "revised" master product labeling proposed for BIOSHIELD AM 500 Microbiostatic Agent indicates use on a variety of porous and hard surface organic and inorganic substrates found in commercial/industrial and residential settings. The proposed labeling expands the use sites for treatment of consumer goods and articles such as "sleeping bags, clothing apparel, carpeting, sails, toilets, sheets, tents, shoes, upholstery, vinyl, and fiberglass" in homes. Also, directions for use are now specified for homeowners in addition to commercial applicators.

The labeling includes the following precautionary statements, specified personal protective equipment (PPE), and use directions to minimize handler dermal/eye exposures, and bystander contact:

"Warning. Causes substantial but temporary eye injury. Harmful if absorbed through skin or inhaled. Do not get in eyes or on skin. Avoid contact with skin and avoid breathing vapor. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse."

² Refer to Ian Blackwell's August 31, 1998 Acute Toxicity Review Memorandum for BIOSHIELD AM 500 (D246360).

³ Refer to separate toxicology review memorandum by Timothy McMahon for this submission under D260609.

The following summarizes the specified use application rates and potential handler exposures:

BIOSHIELD AM 500 Product Use Profile

Types of Applications:	Labeling Specified PPE Worn for Dermal/Eye Protection:	Product Use Dilutions/Active Ingredient Concentrations	Application Method/Equipment	Frequency of Applications
Commercial/Industrial Applications (Non-Residential Sites)	Goggles/ FaceShield and Gloves	<u>2.5 to 25% BIOSHIELD Treatment Solution:</u> (containing up to 12,500 ppm of the a.i.) 0.2 to 2 oz AM 500 to 8 oz water or solvent -or- 3.2 to 32 oz AM 500 to 1 gal water or solvent	<u>Brush, Dipping, Padding, Soaking, Spraying, Fogging or Foam Finishing Techniques</u> to give a final treatment of 0.1 to 1.0% by weight active ingredient.	<ul style="list-style-type: none"> Retreat clothes/fabrics after 4 washings; Treat non-porous substrates weekly; Retreat upholstery and carpet substrates every 3 months or after every cleaning, whichever is sooner.
Commercial/Industrial Applications (Residential Sites)	Goggles/ FaceShield and Gloves	<u>5% BIOSHIELD Treatment Solution :</u> (containing 2,500 ppm of the a.i.) 6 oz. AM 500 to 1 gal water (treats 200 sq ft per diluted gal of water)	<u>Spraying</u> using Pump Sprayer, Carpet/Upholstery Steamers, Rotary Jet Extraction Cleaners; <u>Dipping/Soaking</u> for 3 minutes, remove item and dry.	<ul style="list-style-type: none"> Retreat when odor, mold/mildew/bacteria stains return.
Homeowner Applications	Goggles/ FaceShield and Gloves	<u>5 to 6.25% BIOSHIELD Treatment Solution:</u> (containing up to 3,100 ppm of the a.i.) 6 to 8 oz. AM 500 to 1 gal water (treats 200 sq ft per diluted gal of water)	<u>Spraying</u> using Pump Sprayer; <u>Dipping/Soaking</u> for 3 minutes, remove item and dry.	

Handler Exposure Potential:

Based on the product use profile occupational handlers are potentially exposed to a maximum of 12,500 ppm of the active ingredient (a.i.) during commercial/industrial applications, and typically 2,500 ppm of the a.i. for residential applications. Residential handlers are potentially exposed to a maximum of 3,100 ppm in homeowner applications. With the labeling requirement that PPE be worn during handling, the estimated dermal exposure potential is further reduced. Also, requiring that children and pets be removed from treatment areas will protect against potential bystander exposures.

Considering that the acute toxicology profile established for both the BIOSHIELD AM 500 end use product concentrate (5% a.i. as 50,000 ppm) and the active ingredient technical source product (50% a.i. as 500,000 ppm) identified no significant acute toxicity hazards associated with the oral, dermal, and inhalation routes, the Agency is confident that the intended product use patterns pose no adverse exposure potential for handlers.

Human Exposure Data Requirements:

Human exposure data are required under FIFRA (40CFR 158, Subdivisions K, and U) when based on the antimicrobial pesticide's toxicity, certain toxicological criteria trigger the need for such data, (e.g., the Acute Toxicity Studies indicate Category I or II Toxicity) and the human activities associated with the use patterns can lead to potential adverse exposures to handlers and bystanders. Based on this exposure assessment and the previously cited toxicology reviews for BIOSHIELD AM 500 and 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride, neither the toxicity nor the exposure criteria have been met to trigger the need for human exposure data requirements. AD/RASSB reserves the right to request such data in the future if warranted.

CONCLUSIONS:

AD/RASSB concludes from this assessment that no risk concerns have been identified for the active ingredient, 3-(Trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride, and that the potential for adverse handler exposures associated with the amended BIOSHIELD AM 500 Microbiostatic Agent product use patterns are minimal.

cc: Doreen Aviado/RASSB/AD (7510C)
Chemical File
Circulation