

US EPA ARCHIVE DOCUMENT

70871-5



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

November 29, 1999

MEMORANDUM

Subject: Efficacy Label Review for BST Protectant 75, EPA Reg. No. 70871-L.
DP Barcode: D254818

To: Velma Noble, PM 31/ Tracy Lantz
Regulatory Management Branch I
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Applicant: Bioshield Technologies, Inc.
Norcross, GA, USA

Formulation From Label:

BST Protectant 75:

<u>Active Ingredient(s)</u>	<u>% by wt</u>
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	0.75
<u>Inert Ingredient(s)</u>	<u>99.25</u>
Total	100.00

BioShield AM 500 I

<u>Active Ingredient(s)</u>	<u>% by wt</u>
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	5.0
<u>Inert Ingredient(s)</u>	<u>95.0</u>
Total	100.00

BACKGROUND:

Product manager has requested review of the label for BST Protectant 75. This new product is a dilution of BioShield AM 500 I. These products are intended for the treatment of articles wherein the intention is to provide a durable bacteriostatic and fungistatic coating. The purpose of this coating is to protect the treated article. Claims are not allowed for any public health effect. Consequently, no efficacy data is provided with this application for Agency review.

RECOMMENDATIONS: PSB findings are:

General comments:

The BST Protectant 75 product label that has been submitted appears to use a master label approach in which extensive listings of claims and "approved uses" are presented for approval. Apparently items from these lists as well as possibly different directions will be used in the creation of "final" product labels. If it is the intention of the applicant to provide identically formulated products to both manufacturers and to end use consumers with different label claims, use sites, and instructions then they should provide separate labels for each product and obtain a separate registrations for each product. Submission of master labels for approval is in general an unsatisfactory approach to label construction. This approach makes it difficult or impossible for the Agency to accurately determine of the acceptability of the final labels it never sees prior to their being placed on products distributed for sale.

Based on the label it appears the product is intended for use by both commercial and residential consumers. Product sizes up to 300 gallons are listed on the label. The label provides inadequate support for both purposes. The applicant should make two separate labels for this product and establish a distinction between the formulator/manufacturer users and residential consumers based on the anticipated difference between the product sizes that will be sold to the different consumer groups. Comments below will provide guidance for improving the label for both commercial and residential consumer use.

The length of the BST Protectant 75 product label along with the additional use of collateral labeling results in considerable redundancy. While there is nothing intrinsically objectionable about label redundancy, the applicant is instructed to provide greater consistency between corresponding label sections, such as the "Direction for Use" section. If the applicant believes additional and more detailed information regarding a product needs to be provided through the use of a "technical" bulletin that is entirely permissible, however every

effort should be made to keep the primary product labeling as comprehensive and useful as possible.

BST Protectant 75 label specific comments:

- #1 On page one of the label is a list of claims of product performance in a section immediately after the heading MICROBIOSTATIC AGENT & PROTECTANT. The claims on lines 3,4,6,7,18,20 and 22 which assert "long lasting" action are indefinite in nature and open to confusing interpretation and speculation. Please provide additional guidance as part of this type of claim which helps consumers determine how frequently re-treatment with the product is needed to maintain performance. For example, specify how many washings before it is appropriate to retreat an item of clothing to maintain the bacteriostatic, fungistatic, mildewstatic activities or in the case of objects located outside and exposed to weathering suggest how much time between treatments.
- #2 In the same section, the claim on line 9 suggests activity beyond that of a protectant. Please specify that the activity on the surface only provides protection for the treated item.
- #3 Same section, the claim on line 10 is scientifically inaccurate and an exaggeration of the performance of the product. This statement must be eliminated. While silanes coat and bind quite well they are not permanent, they wear off and the longevity of these coatings is directly dependent upon the severity and frequency of the wear they are subjected to during use or washing. Furthermore if this were a true statement then there would be no need for routine application as stated in the Direction for Use (Option 2).
- #4 Same section, line 12 is a public health related claim that is based on speculation and is without scientific evidence to support it. Furthermore the product is being registered as a coating treatment, not a cleaning agent. This claim must be eliminated.
- #5 Same section, the claims in lines 15, 17 and 21 overstate the activity of the product. The product is a bacteriostatic agent, it does not eliminate, it only controls. Please delete or correct these statements accordingly.
- #6 Same section, the claim in line 16 includes the term "germs." By definition this term is understood to mean, "a microbe or microorganism, usually a pathogenic one." The use of the word germ(s) infers a public health claim. Please delete this term or the entire claim.
- #7 On page one the STATEMENT OF PRACTICAL TREATMENT is incorrect and provides the opposite instructions regarding treatment if the product is swallowed from those provided on the BioShield AM 500 I label. Please provide the same statement for the BST Protectant 75 label as that appearing on the BioShield AM 500 I label.
- #8 On page two the first statement after the heading APPROVED USES is incorrect. Building treatment and building uses are not approved for this product. These uses should be deleted and the sentence terminated with the statement "...drapery treatment."

#9 On page two, the second statement after the heading APPROVED USES is indefinite. The statement long lasting must be qualified by additional information as described previously.

#10 On the second page of the label, the self-sanitizing claim against *Trichophyton mentagrophytes* is a public health claim. This claim must be removed or the data supporting this claim must be submitted to the Agency for review and acceptance.

#11 On page three of the label Recreation Vehicles is listed as a substrate. Please specify what parts of the vehicle. Also listed on both pages three and four are walls (indoor/outdoor) are listed for treatment. The treatment and/or washing of buildings is not approved. Consequently the treatment of walls should be eliminated otherwise this might suggest building treatment.

#12 On page three of the BST Protectant 75 label and on page ten of the BST Protectant 75 collateral label, the claim is made that the product has a "minimum shelf life of 12 months." On page four of the BioShield AM 500 I label and on page four of the BioShield AM 500 I collateral label the claim is made that the product has a "minimum shelf life of 12 months." The use of the term "minimum" suggest an indefinite period beyond 12 months. If the applicant wishes to make claims for a period of time beyond 12 months, they must provide the storage stability data to substantiate such a claim. The phrase, "has a minimum shelf life of 12 months" should be replaced with "shelf life of up to 12 months." *This correction should be made both to the already approved label for BioShield AM 500 I and for the proposed label for BST Protectant 75.*

#13 On page three of the label the statement for Container Disposal is incomplete. Please provide the same statement as that which is used on the label for the BioShield AM 500 I product.

#14 In the ENVIRONMENTAL HAZARDS section on page four of the label please provide the same ENVIRONMENTAL HAZARDS dialogue as that appearing on the label for the BioShield AM 500 I product. The reason for this, it is especially important that the information regarding the de-activation of the product be included in this section of the label.

#15 On page four of the label the fact that the product may be diluted 1:4 or used full strength makes no difference in the directions. The Option 2 directions include the suggestion that the diluted product be routinely applied. If the intention is to have two different labels for this product, then provide two distinct and separate labels for review. Otherwise Options 1 and 2 must be combined into a single set of "Directions for Use" and an explanation included which indicates a more durable coating can be obtained from use of undiluted product and that more frequent re-treatment is needed when using the diluted product.

#16 On page one of the collateral labeling in the statement for Primary Uses the phrase "...and building cleaning and treatment..." must be deleted. This product is not approved for this use.

#17 Also on page one of the collateral labeling in the statement for Primary Uses and on page two in the DESCRIPTION section the phrase "long lasting" must be qualified as

previously described in item # t.

#18 On pages three and four of the collateral labeling are uses listed for walls and recreation vehicles. Please see item #10 above, this is the same problem.

#19 On page four of the collateral label please correct the Directions for Use sections as previously stated in item #14 above.

#20 In the ENVIRONMENTAL HAZARDS section on page five of the collateral label please provide the same ENVIRONMENTAL HAZARDS dialogue as that appearing on page four of the collateral label for the BioShield AM 500 I product. The reason for this is it is especially important that the information regarding the de-activation of the product be included in this section of the label.

#21 On page five of the collateral label the statement for Container Disposal is incomplete. Please provide the same statement as that which is used on page five of the label for the BioShield AM 500 I product.

END