UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

June 4, 2001

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No. 70871-R[redacted]LAM 3651 P
DP Barcode 273615
Case No. 0070871

From: Nancy Whyte, Microbiologist
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Applicant: Bioshield Technologies Inc.
4405 International Blvd., Suite B109
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Formulation Label:

Active Ingredient(s)	% by wt.
3-(trimethyloxysilyl) propyldimethyloctadecyl ammonium chloride	36.60%
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}, 10% C_{18}) dimethyl benzyl ammonium chloride	6.40%
Octyl decyl benzyl ammonium chloride	4.80%
Dioctyl dimethyl ammonium chloride	1.92%
Didecyl dimethyl ammonium chloride	2.88%
Inert Ingredients	48.40%
Total	100.00%

I. Background:

This is a new product registration for a product used as a disinfectant for homes and commercial institutions such as schools, daycare centers, churches, and correctional facilities on a wide variety of non-food contact environmental surfaces. It may be applied as a liquid or sprayed using a pump spray. The efficacy data to support label claims were submitted in two study documents (MRID Nos. 453476-01 and -02). The product is available in a wide variety of sizes ranging from 2 oz-36 oz. and 1, 5, and 55 gallons

II. Use Directions:

For disinfection, the product is diluted by adding 0.5 ounces to 1 gallon water, and stirring before adding to pump sprayer. The surface to be treated in to be completely covered with the product and allowed to stand for 10 minutes before wiping dry. The label also lists sanitizing directions, but this product has not satisfied testing for sanitization and no claims can be made.

III. Agency Standards for Proposed Change:

The Agency standards for a disinfectant liquid are found in DIS-TSS-1 and DIS-TSS-2 which specify the use of the Association of Official Analytical Chemists (AOAC) Use-Dilution Method for efficacy testing. The product must be tested against *Salmonella choleraesuis* ATCC 10708 and *Staphylococcus aureus* ATCC 6538. For hospital or medical environment use, the product must be tested against *Pseudomonas aeruginosa 15442*. All organisms must be killed on 59 of 60 carriers by at least 3 samples of the product, one of which must be at least 60 days old. For sanitizing food contact surfaces, the standard is found in DIS-TSS-4 using the AOAC Germicidal and Detergent Sanitizers Method. One sample of a product from each of three batches, one which must be at least 60 days old, must be tested against *Escherichia coli ATCC 11229* and the *Stapylococcus* organism. The number of organism must be reduced by 99.999%. To be effective in the presence of organic soil, the procedure must be modified to simulate to include a representative soil such as 5% blood serum by adding it to the test culture preparations prior to the drying of the carriers.

IV. Summary of Submitted Study:

The efficacy testing studies to support label claims for effectiveness of this product were conducted by ViroMed Biosafety Laboratories, Inc. in St. Paul, MN Quality Assurance and Good Laboratory Practices Statements were included in the report. Studies conducted to support the disinfectant label claims were initiated in April 1999 and completed in July 1999. The AOAC Use-Dilution Method was employed in the testing. An organic soil load of 5% fetal bovine serum was used, and the dilutions were made in AOAC 400 ppm hard water. The product was diluted.1:355 as requested by the registrant. Lot # B029961A-2 of the sample, (preparation date not provided) was used in the first study set up April 23, 1999 to test the effectiveness of the product against *Salmonella choleraesuis ATCC 19708, Staphylococcus aureus* ATCC 6538, and *Pseudomonas aeruginosa* ATCC 15442. Stainless steel penicylinders were used as carriers. and 60 carriers were inoculated for each organism tested against the three samples (540 total). The cylinders were exposed to the product samples for 10 minutes. Results using Lot #B029916A-2 demonstrated effectiveness of the product against *Salmonella choleraesuis, Staphylococcus aureus,* and *Pseudomonas aeruginosa* when diluted 1:355 and

exposed for 10 minutes in the presence of organic soli.

In the second test set up April 26 and May 3, using Lot #B029916B-2 under the same conditions demonstrated effectiveness against *Salmonella* and *Stapylococcus.*. Testing against *Pseudomonas* conducted on the same day using the same lot number of product showed growth in 16 carriers out of 60. Following this test the registrant requested an amendment to the testing procedure to include an additional dilution of 1:256 for testing *Pseudomonas* following the failure of the product to demonstrate effectiveness of the product at the dilution used initially (1:335) for this organism. This test, set up June 4, 1999 also failed to demonstrate effectiveness of the product, showing growth in 2 carriers out of 60 when tested against *Pseudomonas aeruginosa* for an exposure time of 10 minutes in presence of an organic soil load. Repeat testing of the same organism under the same conditions, set up June 23, 1999 demonstrated effectiveness of the product when only one carrier showed growth.

Lot #B0299216-C-2 was tested against all organisms on April 26, 1999 using the same conditions as for the other product samples. There was no growth in any carriers for *Salmonella*, 1 carrier out of 60 showed growth of *Staphylococcus*, and *Pseudomonas* showed growth in 2 carriers out of 60. Repeat testing of the product on May 3 showed no growth of *Staphylococcus aureus* in any carriers when exposed to the product for 10 minutes in the presence of organic soil. The second testing of the product, diluted 1:256, against *Pseudomonas aeruginosa* showed growth on only 1 carrier out of 60, demonstrating effectiveness of the product under the same conditions. Neutralization controls and carrier quantization results confirmed valid testing procedures.

The efficacy studies done to support label claims for use of the product as a sanitizing rinse on precleaned nonporous food contact surfaces were conducted in May and June 1999 using Lot #B029916A-2 and Lot #B029916B-2 against *Escherichia coli* ATCC 11229 and *Staphylococcus aureus* ATCC 6538. No dates of preparation for the product samples were given. The product samples were prepared by diluting the product to a concentration of 1:640 in 500 ppm AOAC Hard Synthetic Water. A 5% organic soil load was simulated using fetal bovine serum. The organisms were exposed to the product for periods of 30 seconds and 60 seconds. Pre- and post-treated aliquots prepared in agar and incubated for 48 +/- 4 hours at 35-37°C confirmed the reduction in numbers of organisms to the Agency standard mandated by requirements.

V. Labeling:

1. The registrant is making no label claims for effectiveness against *Pseudomonas aeruginosa.*

2. This product contains over 6% methanol and is quite toxic for normal household use.

3. The component which is present at a concentration of 31.5%, 3-(trimethyoxysilyl) propyldimethyloctadecyl ammonium chloride has not been cleared for food contact use.

4. Efficacy testing of organisms (*Klebsiella pneumoniae* or *Enterobacter aerogenes)* to support sanitization claims for non-food contact surfaces was not conducted.

5. Efficacy testing to support disinfection claims against *Escherichia coli* was not conducted. The label claim for this organism must be removed.

VI. Comments and Recommendations:

1. Label claims for sanitization of food-contact surfaces must be removed from the label because one of the active ingredients has not been cleared for food-contact use.

2. Label claims for sanitization of non-food contact use must be removed because efficacy testing has not been conducted to support label claims for effectiveness of the product for these uses.

PM Please Note:

Please check with RASSB concerning the safety of this product for household use.