4-26-84

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-15-84 OUT 04-16-84

Dennis G. Guse 4/26/84

Reviewed By Dennis G. Guse Date 04-16-84

EPA Reg. No. or File Symbol 51267-R

EPA Petition or EUP No. None

Date Division Received 01-24-84

Type Product Hospital disinfectant & food contact surface sanitizer

Data Accession No(s). 252651

Product Manager 31 (Lee)

Product Name Bio-Clean

Company Name Bioserv, Inc.

Submission Purpose Application for new product with efficacy data and label

Type Formulation Liquid concentrate

Active Ingredient(s):	%
Esters of tri-n-butyl tin oxide	0.1
n-Alkyl (60% C14,30% C16,5% C12,5% C18) dimethyl benzyl ammonium chlorides	0.5
n-Alkyl (68% C12,32% C14) dimethyl ethylbenzyl ammonium chlorides	0.5
[redacted]	

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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200.0 Introduction

200.1 Uses

The proposed label bears recommendations for use of the product as a one-step cleaner-disinfectant, fungicide (pathogenic fungi), and virucide (Influenza A2, Herpes simplex, and related viruses) on floors, walls, sink tops, garbage pails, telephones, rest rooms, bed pans, and operating rooms in hospitals, nursing homes, and institutions at a use dilution of 2 oz/gal and an unspecified contact time, In addition, the product is recommended as a sanitizer for previously cleaned food equipment and food contact items at a use dilution providing 200 ppm of active quaternaries and an unspecified contact time without a final potable water rinse.

201.0 Data Summary

201.1 Brief Description of Tests

a. "(HC-D) Hospital Cleaning & Disinfecting Product, 'The Organo-Tin Regimen Product': Recent Evaluation of Antimicrobial Activity." Report by V. R. Saurino, Director, and D. L. Hetrick, MicroVac, Inc., Clinical and Research Laboratory, Boca Raton, Florida 33432, dated 01-29-80 (Accession No. 252651).

b. "The Influence of an Organotin Regimen on the Microbial Environment of a General Hospital." Report by V. R. Saurino and B. C. Saurino, Bioserv, Inc., Boca Raton, Florida 33432, undated (Accession No. 252651).

201.2 Test Summaries

a. In-Vitro Bactericidal Tests

1. Method: Singh Time Exposure Technique (Singh, B., Cutler, J. C., and Utidjian, H. M. D. 1972. Brit. J. Vener. Dis. 48, 57-58), which is a modification of the phenol coefficient procedure. A copy of the method was not submitted.

2. Sample(s): The samples were identified only as "(HC-D) Hospital Cleaning & Disinfecting Product".

3. Dilution(s): 1:256 to 1:49,152.

4. Exposure: 5, 10 and 15 minutes at an unspecified temperature.

5. Inoculum: 24-hour brain heart infusion broth cultures of the test organisms were used for transfer into the product dilution tubes.

6. Test Organisms: See attached tables. The phenol resistance of the test organisms was not provided.

7. Subculture Medium/Neutralizer: Brain heart infusion agar.

8. Incubation of Subcultures: 24 hours at 37C.

9. Test Results: See attached tables.

10. Conclusions: The results demonstrate intrinsic value of the product as an antimicrobial agent and show presumptive evidence of effectiveness as a broad spectrum disinfectant. However, the methodology employed and results obtained do not fulfill any requirements to support label claims for the product as a disinfectant against microorganisms related to human health.

b. In-Use Hospital Study

1. Method: Periodic monitoring was conducted in a 75-bed hospital over a period of a year utilizing Rodac plate and cotton swab sampling of surfaces on walls, floors, tables, and linens, and settling plate sampling of the air. The purpose was to compare the levels of bacteria recovered during periods when routine housekeeping cleaning and disinfecting procedures were conducted with an unidentified chlorophenolic product ("phenolic regimen") and when conducted with an unspecified organotin product ("organotin regimen").

2. Results: The actual results obtained in the study are too extensive to be summarized here. However, although a statistical analysis was not provided, the results strongly indicate that the mean bacterial counts were lower under the "organotin regimen" when compared to those under the "phenolic regimen". The lower counts obtained under the "organotin regimen" appeared to correlate with lower percentages of hospital-acquired infections, based on data provided by the hospital's infection committee.

3. Conclusions: In the absence of statistical validation of the data and details of the products and procedures employed in the disinfecting "regimens", the results appear to provide only presumptive evidence that the organotin product was more effective in reducing bacteriological contamination and the rate of hospital-acquired infections than the chlorophenolic product. The methodology employed and the results obtained do not fulfill any requirements to support label claims for the product as a disinfectant against microorganisms related to human health.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 51267-R

Date Division Received 01-24-84

Data Accession No(s). 252651

Product Manager No. 31 (Lee)

Product Name Bio-Clean

Company Name Bioserv, Inc.

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203.0 Labeling

The label review cannot be completed until the above requirements have been met. However, the following comments are provided for your information:

a. The use directions for disinfection must be revised as follows:

   1. Use the product name instead of "(Name)", i.e., "For best results, use Bio-Clean . . ."

   2. Provide instruction for thorough wetting of surfaces and the contact time necessary for disinfection, i.e., " . . . and other hard surfaces so as to thoroughly wet surfaces for a contact time of 10 minutes."

   3. Indicate whether the use solution is to be rinsed from the surface after the specified contact time or allowed to air dry.

   4. Provide instruction that a fresh solution should be prepared for each use.

   5. Specify removal of gross filth or heavy soil prior to disinfection, i.e., "For heavy soil or organic matter, a pre-cleaning step is required."

   6. Refer to the attached DIS/TSS-15 enclosure for guidance.

b. The use directions for sanitization of food contact surfaces, if retained, must be expanded to include all applicable items as indicated on the attached DIS/TSS-17 enclosure.

c. The virucidal claims must specifically identify the viruses tested, and " . . . and related viruses" must be deleted.

d. On the right panel, change "cross-infection" to read "cross-contamination"; change "For use on floors . . ." to read "For use on hard, non-porous surfaces such as floors, walls, sink tops, garbage pails, telephones, bed pans, and in operating rooms and rest rooms."

e. The [redacted] in this product should be considered as an inert ingredient. DJS 4/26/

INERT INGREDIENT INFORMATION IS NOT INCLUDED

202.0 Recommendations

202.1 Efficacy Supported by the Data

None.

The submitted data do not meet the requirements to support the efficacy claims on the proposed label.

202.2 Additional Data Required to Support Efficacy

a. To support efficacy of the product as a "one-step" cleaner-disinfectant for hospital use, fungicide against pathogenic fungi, and virucide, in the presence of moderate amounts of organic soil, data must be developed and submitted as indicated in the attached enclosures DIS/TSS-1, item (c), DIS/TSS-6, item (A), and DIS/TSS-7 (with each specific virus claimed). The required tests must be modified to include 5% blood serum as organic soil load as indicated in the attached DIS/TSS-2 enclosure, item 4, and microorganism survival after drying on control carriers as indicated in the DIS/TSS-2 enclosure, item 6. If the organic soil (5% blood serum) modification is not utilized in the required tests, the directions for use must specify pre-cleaning of surfaces prior to application of the product as a disinfectant. Refer to the attached DIS/TSS-3 enclosure for guidance in reporting of data.

b. To support efficacy of the product as a sanitizing rinse for previously cleaned food contact surfaces, data must be developed and submitted as indicated in the attached DIS/TSS-4 enclosure, item (2).

However, the formulation of the proposed product has not been cleared for use as a sanitizing solution on food contact surfaces under the Federal Food, Drug and Cosmetic Act. In addition, we have no information that this formulation has been previously registered for this pattern of use, therefore, the option of recommending a potable water rinse after treatment does not apply. The remaining options are to delete the recommendation for use of the product on food contact surfaces from the label, or submit a petition to the Food and Drug Administration for a food additive regulation for your formulation under 21 CFR 178.1010. For further information in this regard, you may wish to contact:

Chief, Petitions Control Branch
Division of Food and Color Additives
Food and Drug Administration
Dept. of Health and Human Services
200 C Street, SW
Washington, D.C. 20204

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