US EPA ARCHIVE DOCUMENT

8-1-85

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 07-05-85 OUT 07-30-85

Reviewed By Dorothy M. Portner 8/1/85 Date 07-30-85

EPA Reg. No. 51267-R

EPA Petition or EUP No. None

Date Division Received 07-05-85

Type Product Hospital Disinfectant

Data Accession No(s). 258527

Product Manager PM-31 (Lee)

Product Name Bio-Clean

Company Name Bioserv, Inc.

Submission Purpose Resubmission with efficacy data and proposed label

Type Formulation Liquid concentrate to used diluted

Active Ingredient(s):	%
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides	0.5
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides	0.5
Bis (tributyltin) oxide	0.1

1

200.0 Introduction

200.1 Use

The previously proposed label is attached.

200.2 Background Information

The submission, received 7-05-85 in response to our letter of 4-30-84, included efficacy data and a proposed product label.

201.0 Data Summary (Accession No. 258527)

The submitted bactericidal, fungicidal, and tuberculocidal data were developed by Terry Vigneault of Northview Laboratories, Inc., Northbrook, IL. The submitted virucidal data were developed by David Pittman of Sekot Laboratories, N. Bay Village, FL.

201.1 Brief Description Of Test

A. Bactericidal Testing

Method: AOAC Use Dilution Test
Exposure Time: Not indicated
Organic Load: 5% Serum
Dilution: 1:128 (86 ppm active ingredients)
Subculture/Neutralization Medium: Not specified
Incubation Period: Not indicated

B. Fungicidal Testing

Method: AOAC Fungicidal Test
Organic Load: 5% Blood Serum
Dilution: Not indicated
Subculture/Neutralization Medium: Not specified
Incubation Period: Not indicated

C. Tuberculocidal Testing

Method: AOAC Tuberculocidal Activity Test
Organic Load: 5% Blood Serum
Dilution: Not indicated
Subculture/Neutralization Media: Not specified
Incubation Period: Not indicated

D. Virucidal Testing

The virucide assay methods employed for Influenza A virus and Herpes simplex, Type 2 virus are attached.

Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 51267-R

Data Division Received 07-05-85

Data Accession No(s). 258527

Product Manager No. PM 31 (Lee)

Product Name Bio-Clean

Company Name Bioserv, Inc

3

202.0 Recommendations

202.1 Efficacy Supported By Data

The submitted virucidal data support the product as a virucide against Influenza A_2 (Hong Kong) virus and Herpes simplex, Type 2 virus when product is applied on precleaned surfaces at a minimum 1:220 use dilution (1 oz. of product per 1 3/4 gallons of water providing an active ingredient concentration of 50 ppm) for a 10-minute contact time.

However, to support virucidal claim when the product is used according to label directions at a use dilution of 1 oz. per 1 gallon of water on hard, non-porous, surfaces having a moderate organic soil load for a 10-minute contact time, additional data would be required. For this retesting at the recommended use dilution for 10 minutes, 5% blood serum should be added to the a viral inoculum that is dried on the hard surface to provide an organic soil load as indicated in the DIS/TSS-2 enclosure. The virucidal activity of the product in the presence of an organic soil load can not be extrapolated from the data submitted.

202.2 Incomplete Data Reports

In order to validate the data, the information for the reporting of data indicated in the DIS/TSS-3 enclosure and a description of the specific procedural modifications employed in the testing (as indicated in the DIS/TSS-2 enclosure) are required. The additional information that must be provided to complete each submitted data report is indicated below:

1. The exposure time/temperature, the neutralization procedure, the subculture medium and the incubation period employed in developing the submitted bactericidal data by the AOAC Use Dilution Test.

2. The test dilution, the neutralization procedures, the subculture medium, and the incubation period employed in developing the submitted fungicidal data by the AOAC Fungicidal Test.

3. The test dilution, exposure time/temperature, the test results and phenol resistance with each of 3 subculture media, the neutralizer, and the incubation period employed in developing the submitted tuberculocidal data by the AOAC Tuberculocidal Activity Test.

202.3 Efficacy Not Supported By Data

Since no sanitizing data and adequate label directions for sanitization have been provided for this product, the sanitizer claim indicated on the proposed label is not acceptable.

4