

9.2-88

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I
Disinfectants Branch

IN 06-13-88 OUT 08-26-88

DBB 9/2/88

Reviewed By *Emily H. Mitchell* Date 08-26-88
 EPA Reg. No. or File Symbol 51267-R
 EPA Petition or EUP No. None
 Date Division Received 06-13-88
 Type Product(s) Hospital/ General Disinfectant
 Data Accession No.(s) 406492-01 & 406492-02
 Product Mgr. No. PM 31 (Lee)
 Product Name(s) BIO-CLEAN
 Company Name(s) Bioserve, Inc.
 Submission Purpose Resubmission with efficacy data and proposed label submitted.
 Chemical & Formulation Liquid to be diluted

Active Ingredient(s):	%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	5.0%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	5.0%
Bis (tributyltin) oxide	1.0%

200.0 Introduction

200.1 Uses:

A cleaner, disinfectant, and deodorizer designed for use in hospitals, nursing homes, hotels, motels, animals housing of various types, and institutions where housekeeping will be prime importance in controlling the hazard of cross contamination of environmental surfaces.

200.2 Background Information:

The submission received 06-13-88, is a resubmission with efficacy data and proposed product label.

201.0 Data Summary (Accession Nos. 406492-01 & 406492-02)

201.2 Brief Description of Tests:

- a. Reports of Fungicidal Tests by Terry Vigneault, Northview Laboratories, Inc., 1880 Holste Road, Northbrook, IL 60062. A.O.A.C. 13th Edition, 1980. The fungi tested was Trichophyton mentagrophytes (dated 04-18-88).
- b. Reports of Tuberculocidal Tests by Janet J. Keller, Nelson Laboratories, Inc., 4535 South 2300 East, Salt Lake City, UT 84117. The test organism was Mycobacterium bovis (dated 04-20-87).
- c. Reports of Tuberculocidal Tests by Terry Vigneault, Northview Laboratories, Inc., 1880 Holste Road, Northbrook, IL 60062. A.O.A.C. 13th Edition, 1980. The test organism was Mycobacterium bovis (dated 04-18-88).

201.3 Test Summaries:

a. Fungicidal Tests

1. Method: A.O.A.C. Fungicidal Test, 13th Edition, 1980.
2. Modifications: 5% fetal bovine serum was incorporated into the fungal suspension.

3. Samples:

<u>Lot No.</u>	<u>Preparation Dates</u>	<u>Tests Dates</u>
01385 (75-1A)	01-10-85	Not Listed
00185 (75-2A)	01-10-85	

4. Dilution: 1:128

5. Exposure Time: 5, 10, & 15 minutes at 20°C.

6. Subculture Medium/Neutralizer: Lethen Broth with 0.07% lecithin and 0.5% polysorabe 80 (Tween 80)

7. Incubation of Subculture: 25°C for 10 days

8. Test Organisms:

<u>Test Fungi</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Trichophyton mentagrophytes</u>	9533	1:60

9. Test Results:

<u>Test Fungi</u>	<u>Lot No.</u>	<u>Primary Subculture</u>			<u>Secondary Subculture</u>		
		<u>Exposure Time (mins)</u>			<u>Exposure Time (mins)</u>		
		<u>5</u>	<u>10</u>	<u>15</u>	<u>5</u>	<u>10</u>	<u>15</u>
<u>T. mentagrophytes</u>	01385	-	-	-	-	-	-
	00185	-	-	-	-	-	-

10. Conclusions: Results show satisfactory performance of product against Trichophyton mentagrophytes at a 1:128 dilution with 5% blood serum at a contact time of 10 minutes.

b. Tuberculocidal Test:

1. Method: A.O.A.C. Confirmative In Vitro Test
2. Modifications: 5% blood serum load
3. Samples:

<u>Sample No.</u>	<u>Preparation Dates</u>	<u>Test Dates</u>
I-120484	12-04-85	Not Listed
II-081484	08-14-84	Not Listed

4. Dilution: 1:128
5. Exposure Time: 10 minutes at 20°C
6. Subculture Medium/Neutralizer:
Subcultures were made in Middlebrook 7H9 (Difco 8)
Kirchner Broth
Proskauer Beck (Modified)
7. Incubation of Subcultures: 36°C at 90 days
8. Test Organism:

<u>Test Organism</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Mycobacterium bovis</u> (BCG)	Not Listed	1:50(no growth) 1:75(growth)

9. Test Results:

<u>Sample No.</u>	<u>Number of Positive Carriers</u>			<u>Total</u>
	<u>Middlebrook 7H9 Difco 8</u>	<u>Kirchner</u>	<u>Proskauer-Beck (Modified)</u>	
I	0/10	0/10	0/10	0/10
II	0/10	0/10	0/10	0/10

10. Conclusions: Results show satisfactory performance of product against Mycobacterium bovis (BCG) at a 1:128 with 5% blood serum at a contact time of 10 minutes.

4

c. Tuberculocidal Test:

1. Method: A.O.A.C. Confirmative In Vitro Test
2. Modifications: None
3. Samples:

<u>Sample No.</u>	<u>Preparation Dates</u>	<u>Test Dates</u>
870304-B	08-21-87	11-21-87

4. Dilution: 1:128
5. Exposure Time: 10 minutes at 20°C
6. Subculture Medium/Neutralizer:
Subcultures were made in Middlebrook 7H9 (Difco 8) TB Broth Proskauer Beck (Modified)
7. Incubation of Subcultures: 37°C ± 2°C for 90 days.
8. Test Organism:

<u>Test Organism</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Mycobacterium bovis</u> (BCG)	Not Listed	Not Listed

9. Test Results:

<u>Sample No.</u>	<u>Number of Positive Carriers</u>			<u>Total</u>
	<u>Middlebrook 7H9 Difco 8</u>	<u>TB Broth</u>	<u>Proskauer-Beck (Modified)</u>	
870304-B	0/10	0/10	0/10	0/10

10. Conclusions: Results show satisfactory performance of product against Mycobacterium bovis (BCG) at a 1:128 with a contact time of 10 minutes. However, 5% blood serum was not added to the suspension.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II
Disinfectants Branch

EPA Reg. No. or File Symbol 51267-R
Date Division Received 06-13-88
Data Accession No.(s) 406492-01 & 406492-02
Product Manager No. PM 31 (Lee)
Product Name BIO-CLEAN
Company Name Bioserv, Inc.

6 ~~1~~ 1

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted fungicidal data are acceptable to support effectiveness of the product as a fungicide against Trichophyton mentagrophytes (pathogenic fungi) when used at a 1:128 dilution in the presence of 5% blood serum at a contact time of 10 minutes at 20°C.
- b. The submitted tuberculocidal data are acceptable to support effectiveness of the product as a tuberculocide against Mycobacterium bovis (BCG) when used at a 1:128 dilution in the presence of 5% blood serum at a contact time of 10 minutes. However, acceptance is pending upon the submission of additional data as indicated in 202.2 below.

202.2 Additional Data/Information Required to Support Efficacy:

- a. To support the tuberculocidal claim, validation data submitted by the additional laboratory should be developed using the same test procedure and the same test conditions as the original laboratory. For additional testing requirements refer to the attached Tuberculocidal Data-Call-In Notice dated 06-13-86. The original data was developed with 5% blood serum therefore the additional laboratory should use the same procedure.

203.0 Labeling

- a. In lieu of additional data requirement, delete tuberculocidal claims.
- b. Change "Herpes simplex type 2" to "Herpes Simplex Type 2".
- c. Change "... contact time of approximately 10 minutes" to read "... contact time of at least 10 minutes at a temperature of 20°C or higher" (Both the contact time and temperature conditions necessary for tuberculocidal effectiveness must be stated on the label.). *DE/ 9/2/88*