

10-20-87

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 08-04-87

OUT 10-13-87

Reviewed By Emily H. Mitchell ^{WEL 10-20-87} Date 10-13-87

EPA Reg. No. or File Symbol 51267-R

EPA Petition or EUP No. None

Date Division Received 08-07-87

Type Product(s) Hospital/ General Disinfectant

Data Accession No.(s) 402773-01, 402773-02 & 402773-03,

Product Mgr. No. PM 31 (Lee)

Product Name(s) BIO-CLEAN Cleaner/Disinfectant Deodorizer

Company Name(s) Bioserv, Inc.

Submission Purpose Resubmission with efficacy data and proposed
label submitted.

Chemical & Formulation Liquid

Active Ingredient(s):

	%
n-alkyl (C ₁₄ -60%, C ₁₆ -30%, C ₁₂ -5%, C ₁₈ -5%)	
dimethyl benzyl ammonium chloride	5.0%
n-alkyl (C ₁₂ -68% C ₁₄ -32%)	
dimethyl ethylbenzyl ammonium chloride	5.0%
Bis (tributylin) oxide	1.0%

201.3 Test Summaries:

a. Bactericidal Tests

1. Method: A.O.A.C. Use Dilution Method 13th Edition, 1980.
2. Modifications: 5% Fetal Bovine Serum was added to the inoculum as organic soil.
3. Samples:

<u>Lot No.</u>	<u>Preparation Dates</u>	<u>Test Dates</u>
120484	12-04-84	Not Listed
120784	12-07-84	
081484	08-14-84	

4. Dilution: 1:128
5. Exposure: 10 minutes at 20°C
6. Subculture Medium/Neutralizer: Lethen Broth
7. Incubation of Subcultures: 48 hours at 36°C
8. Test Bacteria:

<u>Test Bacteria</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Staphylococcus aureus</u>	6538	1:60
<u>Salmonella choleraesuis</u>	10708	1:90
<u>Pseudomonas aeruginosa</u>	15442	1:80

9. Survival of Inoculum on Control Carriers:

<u>Test Organism</u>	<u>Density of Survivors Before Drying</u>	<u>Density of Survivors After Drying</u>
S. aureus	1.2 x 10 ⁶ /cylinder	1.0 x 10 ⁶ /cylinder
S. choleraesuis	1.1 x 10 ⁶ /cylinder	1.0 x 10 ⁶ /cylinder
P. aeruginosa	1.1 x 10 ⁶ /cylinder	1.0 x 10 ⁶ /cylinder

10. Test Results:

<u>Test Organisms</u>	<u>ATCC No.</u>	<u>No. Carriers Tested</u>	<u>No. Positives/Total Carriers</u>	
			<u>Primary</u>	<u>Secondary</u>
<u>S. aureus</u>	6538	60	0/60	0/60
		60	0/60	0/60
		60	0/60	0/60
<u>S. choleraesuis</u>	10708	60	0/60	0/60
		60	0/60	0/60
		60	0/60	0/60
<u>P. aeruginosa</u>	15442	60	0/60	0/60
		60	0/60	0/60
		60	0/60	0/60

11. Conclusion: Results show satisfactory performance of the product against all test bacteria at a 1:128 dilution with 5% fetal bovine serum at a contact time of 10 minutes.

b. 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	
01285 (75-2)	01-10-85	
100784 (75-1-A)	10-07-84	

4. Dilution: Undiluted
5. Exposure Time: 5, 10, & 15 minutes at 20°C.
6. Subculture Medium/Neutralizer: Lethen Broth with 0.07% lecithin and 0.5% polysorbate 80 (Tween 80)

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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>
T. <u>mentagrophytes</u>	01385	-	-	-	-	-	-
	00185	-	-	-	-	-	-
	01285	-	-	-	-	-	-
	100784	-	-	-	-	-	-

10. Survival of Inoculum on Control Carriers
Before and After Drying: Not Listed

11. Conclusions: Results show satisfactory performance of product against Trichophyton mentagrophytes undiluted with 5% blood serum at a contact time of 10 minutes. However, the amount of inoculum should be provided.

c. Tuberculocidal Test:

1. Method: A.O.A.C. Confirmative In Vitro Test

2. Modifications: 5% blood serum load

3. Samples:

<u>Batch No.</u>	<u>Preparation Dates</u>	<u>Test Dates</u>
I	12-31-84	Not Listed
II	12-31-84	Not Listed

4. Dilution: Undiluted

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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>Batch 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) undiluted with 5% blood serum at a contact time of 10 minutes. However, validation data must be developed by testing one additional sample by a laboratory, other than the one who developed the original data using the same test conditions as the original laboratory.

d. Virucidal Tests

1. Method: A.O.A.C. Use Dilution Method/DIS/TSS 7
2. Modification: 5% sterile horse serum
3. Samples:

<u>Batch No.</u>	<u>Date Started</u>	<u>Date Complete</u>
870304	03-30-87	04-03-87

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4. Dilution: Undiluted
5. Exposure: 10 minutes at room temperature
6. Recovery Medium/Neutralizer/Diluent:
Influenza A2/Hong Kong 18/86 - Cell Cultures grown in Eagles MEM containing 10% fetal calf serum and Virus Cultures were maintained in serum-free media which was replaced every 2 days.
Herpes Simplex Type 2 - Cell Cultures grown in Eagles MEM containing 4% fetal calf serum and Virus Cultures were maintained in serum-free Vero cell media.
7. Incubation: Influenza A2/Hong Kong - 37°C in humidified, 5% CO₂ atmosphere up to 5 days and Herpes Simplex Type 2 - 37°C in a humidified, 5% CO₂ atmosphere until approximately 90% of the monolayer showed cytopathic effect (CPE).
8. Test Virus Host System:
Herpes Simplex Type 2 - Vero Cells
Influenza Type A2/Hong Kong - Rhesus Monkey Kidney Cells
9. Drying Time and Temperature: Allowed to air dry inside of a biohazard hood.
10. Assay System for Virus Recovery:
Herpes Simplex Type 2 - Vero Cells - Cytopathic

Influenza A2/Hong Kong - Fresh guinea pig erythrocytes - Hemadsorption
11. Method of Estimating 50 per cent end point: Reed Muench Method (per method)

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12. Test Results:

Herpes Simplex Type 2

Disinfectant (ppm)	Control TCID ₅₀	TCLD ₅₀	Test TCID ₅₀	Reduction log ₁₀
200	106.5	102.5	-	104.5
100	106.5	101.5	102.66	103.84
50	106.5	-	103.5	103.0
25	106.5	-	105.5	101.5

Influenza A2/Hong Kong

Disinfectant (ppm)	Control TCID ₅₀	TCLD ₅₀	Test TCID ₅₀	Reduction log ₁₀
200	106.0	102.5	-	103.5
100	106.0	101.5	102.5	103.5
50	106.0	-	103.5	102.5
25	106.0	-	104.5	101.5

13. Conclusions: This product showed satisfactory performance against all test viruses when used at a 200 ppm concentration of active ingredients for a contact time of 10 minutes.