10-20-87

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 08-04-87 OUT 10-13-87

Reviewed By Emily H. Mitchell WEC 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:

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

4. Dilution: 1:128

5. Exposure: 10 minutes at 20°C

6. Subculture Medium/Neutralizer: Letheen Broth

7. Incubation of Subcultures: 48 hours at 36°C

8. Test Bacteria:

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

9. Survival of Inoculum on Control Carriers:

Test Organism	Density of Survivors Before Drying	Density of Survivors After Drying
S. aureus	1.2×10^6/cylinder	1.0×10^6/cylinder
S. choleraesuis	1.1×10^6/cylinder	1.0×10^6/cylinder
P. aeruginosa	1.1×10^6/cylinder	1.0×10^6/cyclinder

10. Test Results:

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

Lot No.	Preparation Dates	Tests Dates
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: Letheen Broth with 0.07% lecithin and 0.5% polysorabe 80 (Tween 80)

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

8. Test Organisms:

Test Fungi	ATCC No.	Phenol Res.
Trichophyton mentagrophytes	9533	1:60

9. Test Results:

Test Fungi	Lot No.	Primary Subculture Exposure Time (mins)			Secondary Subculture Exposure Time (mins)		
		5	10	15	5	10	15
T. mentagrophytes	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:

Batch No.	Preparation Dates	Test Dates
I	12-31-84	Not Listed
II	12-31-84	Not Listed

4. Dilution: Undiluted

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:

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

9. Test Results:

	Number of Positive Carriers			
Batch No.	Middlebrook 7H9 Difco 8	Kirchner	Proskauer-Beck (Modified)	Total
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 orginal laboratory.

d. Virucidal Tests

1. Method: A.O.A.C. Use Dilution Method/DIS/TSS 7

2. Modification: 5% sterile horse serum

3. Samples:

Batch No.	Date Started	Date Complete
870304	03-30-87	04-03-87

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% CO_2 atmosphere up to 5 days and Herpes Simplex Type 2 - 37°C in a humidified, 5% CO_2 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)

12. Test Results:

Herpes Simplex Type 2

Disinfectant (ppm)	Control $TCID_{50}$	$TCLD_{50}$	Test $TCID_{50}$	Reduction log_{10}
200	$10^{6.5}$	$10^{2.5}$	-	$10^{4.5}$
100	$10^{6.5}$	$10^{1.5}$	$10^{2.66}$	$10^{3.84}$
50	$10^{6.5}$	-	$10^{3.5}$	$10^{3.0}$
25	$10^{6.5}$	-	$10^{5.5}$	$10^{1.5}$

Influenza A2/Hong Kong

Disinfectant (ppm)	Control $TCID_{50}$	$TCLD_{50}$	Test $TCID_{50}$	Reduction log_{10}
200	$10^{6.0}$	$10^{2.5}$	-	$10^{3.5}$
100	$10^{6.0}$	$10^{1.5}$	$10^{2.5}$	$10^{3.5}$
50	$10^{6.0}$	-	$10^{3.5}$	$10^{2.5}$
25	$10^{6.0}$	-	$10^{4.5}$	$10^{1.5}$

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.