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10/18/88

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 09-23-88 Out 10-12-88

Reviewed By Srinivas Gowda Srinivas Gowda 10/18/88 Date 10-12-88

EPA Reg. No. or File Symbol 1130-6

EPA Petition or EUP NO. None

Date Division Received 07-21-88

Type Product Hospital Towelette (Saturated Towelette)

MRID Nos. 403839-01, 403839-02, 406352-01 & 407493-01 to 407493-04

Product Manager 31 (Lee)

Product Name BURNISHINE® GERMICIDAL CLOTH

Company Name Burnishine Products

Submission Purpose Resubmission: Amendment to add virucidal, tuberculocidal,"one-step" sanitizer (NFCS), and bactericidal (5 min. contact time) claims with efficacy data and revised proposed labeling.

Type Formulation Single-use disposable towelette saturated with ready-to-use liquid in unit packets.

Active Ingredient(s):	%
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides	0.14
n-Alkyl (60% C_{12}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides	0.14
Isopropyl alcohol	8.00

200.0 Introduction

200.1 Use(s)

Single-use disposable saturated towelette for use as a "one-step" disinfectant-cleaner, in hospitals on hard, non-porous surfaces such as tables, carts, baskets, counters, cabinets, and telephones in the presence of moderate amounts organic soil (5% blood serum) at the level of 2800 ppm quaternary. Also, a "one-step" cleaner-sanitizer for non-food-contact surfaces and "one-step" disinfectant cleaner for food contact surfaces with potable water rinse.

200.2 Background Information

Refer to the previous review for this product by EE&TMS, APB, RD, dated 05-25-88. The current submission consists of additional efficacy data, in response to the difficiencies cited in the previous review. Revised labels were provided.

201.0 Data Summary

201.1 Brief Description of Test

Bactericidal test reports by Terry Vigneault, Northview Laboratories, Inc., 1880 Holste Road, Northbrook, Illinois 60060, dated 03-31-87 (MRID No. 403839-01).

Tuberculocidal and sanitizer (NFCS) test reports by Kyle H. Sibinovic, Shaldra Biotest Inc., P.O. Box 34317 - W. Bethesda, MD 20817, dated 10-10-87 (MRID No. 403839-02).

Virucidal test reports by Philip R. Roane, Integrity Bioservices Inc., 12280 Wilkins Avenue, Rockville, MD 20852, dated 09-28-87 (MRID No. 403839-02). ✗

Confirmatory Tuberculocidal Test reports by Richard Gammon, Presque Isle Cultures, P.O. Box 8191 - Presque Isle, PA. 16505, dated 05-10-88 (MRID No. 406352-01).

Bactericidal and sanitizer (NFCS) Test reports by Kyle H. Sibinovic, Shaldra Biotest Inc., P.O. Box 34317 - W. Bethesda, MD 20817, dated 07-12-88 (MRID No. 407493-01).

Confirmatory Tuberculocidal Test reports by Richard Gammon, Presque Isle Cultures, P.O. Box 8191 - Presque Isle, PA. 16505, dated 05-10-88 (MRID No. 407493-02).

Virucidal test reports by Philip R. Roane, Integrity Bioservices Inc., 12280 Wilkins Avenue, Rockville, MD 20852, dated 09-28-87 & 02-20-88 (MRID No. 407493-03 & 407493-04). Corrected. ✗

201.2 Test Summaries

a. Bactericidal Tests (MRID No. 403839-01)

1. Method: Modified A.O.A.C. Germicidal Spray Products Test Method, modified for testing the towelette.

2. Modifications: 5% blood serum was added to inoculum preparation. The inoculated glass slide (1 towelette per slide) was wiped 10 times with the towelette under a laminar flow hood using sterile surgical gloves. After wiping enough liquid was expressed from the towelette to completely cover the slide. The towelette and the slide were held in individual closed petri dishes to minimize evaporation for a contact time of 5 minutes and subcultured separately in letheen broth for 2 days at 35°C.

3. Samples: "QP" Quick Pick-Up Germicidal Cloths

Batch No.	Mfg. Dates	Test Dates
"QP"	Not listed	Not listed

4. Dilution: Undiluted

5. Exposure: 5 minutes
Exposure Temperature: Not Listed

6. Subculture Medium/ Neutralizer: Letheen Broth

7. Incubation: 2 days at 35°C

8.

Test Bacteria	ATCC No.	Phenol Res.
Staphylococcus aureus	6538	1:65
Pseudomonas aeruginosa	15442	1:85
Salmonella choleraesuis	10708	1:95

9. Survival of Inoculum on Control Carriers:

Test Organisms	Organisms/Cylinder
S. aureus	1.1×10^6
P. aeruginosa	1.0×10^6
S. choleraesuis	1.0×10^6

10. Test Results:

Organism	Batch No.	Type Carrier	# Carriers Tested	# Positives/Total Carriers Tested	
				Primary	Secondary
S. aureus	"QP"	Slide	60	0/60	0/60
		Towelette	60	0/60	0/60
S. choleraesuis	"	Slide	60	0/60	0/60
		Towelette	60	0/60	0/60
P. aeruginosa	"	Slide	60	0/60	0/60
		Towelette	60	0/60	0/60

11. Conclusions: Satisfactory performance vs. test organisms.

b. Bactericidal Tests (MRID No. 407493-01)

1. Method:Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection, Efficacy Data Requirements, US EPA and A.O.A.C. Germicidal Spray Products Test.

2. Modifications: 5% horse serum as soil

3. Samples:

Batch No.	Mfg. Dates	Test Dates
06237	Not listed	07-30 to 08-02-87
06257	"	"

4. Dilution: Undiluted (Towelette)

5. Exposure: 5 minutes @ 20°C

6. Subculture Medium/ Neutralizer: Letheen Broth At the conclusion of incubation period, 10 tubes of the primary culture medium were inoculated with approximately 10 test organisms/ml and reincubated. No. of organisms inoculated by back count was 7/ml.

7. Incubation: 48 hours at 37°C

8.

Test Bacteria	ATCC No.	Phenol Res.
Staphylococcus aureus	6538	1:60
Pseudomonas aeruginosa	15442	1:80
Salmonella choleraesuis	10708	1:90
Klebsiella pneumoniae	4352	1:90

9. Survival of Inoculum on Control Carriers:

Test Organisms	Organisms/Cylinder
S. aureus	$1.3 - 1.7 \times 10^6$
P. aeruginosa	$1.2 - 1.4 \times 10^6$
S. choleraesuis	$1.3 - 1.7 \times 10^6$
K. pneumoniae	$1.1 - 1.3 \times 10^6$

10. Test Results:

Organism	Batch No.	Type Carrier	# Carriers Tested	# Positives/Total Carriers Tested
S. aureus	06237	Glass Slide	60	0/60
	06257	"	60	0/60
	06237	Towelette Residue	60	0/60
	06257	"	60	0/60
S. choleraesuis	06237	Glass Slide	60	0/60
	06257	"	60	0/60
	06237	Towelette Residue	60	0/60
	06257	"	60	0/60
P. aeruginosa	06237	Glass Slide	60	0/60
	06257	"	60	0/60
	06237	Towelette Residue	60	0/60
	06257	"	60	0/60
K. pneumoniae	06237	Glass Slide	60	0/60
	06257	"	60	0/60
	06237	Towelette Residue	60	0/60
	06257	"	60	0/60

11. Conclusions: Satisfactory performance vs. test organisms.

c. Virucidal Tests [MRID No.407493-03 (corrected) & -04]

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

2. Modifications: 10% Fetal Bovine Serum as organic soil.

Virus suspensioins containing 10% Fetal Bovine Serum was dried on replicate petri dishes. The disinfectant solution was dispensed in accordance with the directions for application such that 0.5 ml was delivered to the surface of each of the petri dishes. The viruses were each propagated on the appropriate tissue culture and were assayed either on the same line or on a second acceptable line.

3. Samples: Bernichine Germicidal Wipe

Batch No.	Mfg.Dates	Test Dates
1030-16-1	06-17-87	09-02 to 09-28-87
1130-16-1	"	"
NE4087A	04/87	12-15 to 12-22-87
NE4087B	04/87	"

4. Dilution: Undiluted

5. Exposure: Poliovirus 1 - 3 minutes at 20°C
Herpes Simplex II - 30 seconds at 20°C
Influenza A_2/HK - "

6. Recovery Medium: EMEM 90% & F.B.S. 10%
Neutralizer: 0.01% $NaHSO_3$
Neutralizer Time: 10 minutes at 20°C

7. Incubation Time and Temperature:

Herpes Simplex Type II	7 days @ 33°C
Influenza A_2/Honk kong	7 days @ 33°C
Poliovirus 1	7 days @ 37°C

8. Test Virus Host System:

Herpes Simplex Type II	Vero
Influenza A_2/Honk kong	MKRH
Poliovirus 1	BGM

9. Assay System for Virus Recovery:

   Herpes Simplex Type II > + 2 Cytopathic Effect

   Influenza A_2/Honk kong "

   Poliovirus 1 "

10. Drying Time and Temperature: 2 hours @ 20°C

11. Method for Estimating 50 Per Cent end-point: Reed-Muench Method.

12. Test Viruses

   Herpes Simplex Type 2 G-strain

   Influenza A_2/Honk kong

   Poliovirus 1 - Brunhilde-VR-ATCC-58

13. Test Results

		ID-50 or LD-50 (-log 10)			
Test Virus	Batch No.	Virus Control	Virus + Disinf.	Toxicity Control	Virus Inacti.
Herpes Simplex Type II	1030-16-1	6.5	2.5	2.5	4.0
	1130-16-1	6.5	2.5	2.5	4.0
Influenza A_2/ Honk kong	1030-16-1	6.5	2.5	2.5	4.0
	1130-16-1	6.5	2.5	2.5	4.0
Poliovirus 1	NE4087A	7.5	3.5	3.5	4.0
	NE4087B	7.5	3.5	3.5	4.0

14. Conclusions: Satisfactory performance vs test viruses.

d. Tuberculocidal Test

1. Method: Modified A.O.A.C. Germicidal Spray Products Test. 14th Edition, 1984.

2. Modifications: 5% horse serum as soil.

3. Samples: Burnishine Germicidal Wipes >60 days old.

Batch No.	Mfg. Dates	Test Dates
NE4087A	02-05-87	05-15-87
NE4087B	"	"
NE4087C	"	"

4. Dilution: None (Undiluted)

5. Exposure Time: 10 minutes at 20°C

6. Subculture Medium: Mod. Proskauer Beck Broth (MPB)
7H9 Broth (7H9BR)
TB Both (TBBR) or

Neutralizer: Letheen Broth with Tween 80.

7. Incubation of Subcultures: 90 days at 37°C.

8.

Test Organism	Phenol	Resistance
Mycobacterium bovis ATCC 1028	1:50	No Growth
	1:70	Growth

9. Type of Carriers: Porcelain penicylinders

10. Survival of inoculum on control carriers:

4.60×10^5 to 5.70×10^5

11. Test Results:

	# Positives/Total Carriers		
Batch No.	MPBBR	7H9BR	TBBR
NE4087A	0/10	0/10	0/10
NE4087B	0/10	0/10	0/10
NE4087C	0/10	0/10	0/10
Viability Check	5/5	5/5	5/5

10. Conclusions: The submitted data demonstrate a satisfactory tuberculocidal performance in the presence of 5% blood serum at a contact time of 10 minutes at 20°C.

e. Tuberculocidal Test

1. Method: Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection, Efficacy Data Requirements, US EPA and A.O.A.C. Germicidal Spray Products Test.

2. Modifications: 5% horse serum as soil.

3. Samples: Burnishine Germicidal Wipes >60 days old.

Batch No.	Mfg. Dates	Test Dates
06237	04-13-87	06-28-87
06257	"	"

4. Dilution: None (Undiluted)

5. Exposure Time: 10 minutes at 20°C

6. Subculture Medium: Mod. Proskauer Beck Broth (MPB)
7H9 Broth (7H9BR)
TB Both (TBBR) or

Neutralizer: Letheen Broth with Tween 80.

7. Incubation of Subcultures: 90 days at 37°C.

8.

Test Organism	Phenol Resistance	
Mycobacterium bovis ATCC 1028	1:50	No Growth
	1:70	Growth

9. Type of Carriers: Glass Slides plus towelettes residue

9. Survival of inoculum on control carriers:

4.40×10^5 to 5.35×10^5

9. Test Results:

Batch No.	Carrier	# Positives/Total Carriers MPBBR	7H9BR	TBBR
06237	Glass slides	0/10	0/10	0/10
	Towelette residue	0/10	0/10	0/10
06257	Glass slides	0/10	0/10	0/10
	Towelette residue	0/10	0/10	0/10

10. Conclusions: The submitted data demonstrate a satisfactory tuberculocidal performance in the presence of 5% blood serum at a contact time of 10 minutes at 20°C.

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f. Confirmatory Tuberculocidal Test (Validation data)

1. Method: A.O.A.C., 14th Edition, 1984. Chapter 4. Directions for pre-saturated or impregnated towelettes for hard surface disinfection. DIS/TSS-10A, 04-15-82.

2. Modifications: Not Listed

3. Samples:

Batch No.	Mfg. Dates	Test Dates
H10 Disinfectant lot 0288-3140 in wipes.	Not listed	2-1 to 5-1-88
H10 Disinfectant lot 0888-3140 in wipes.	"	"

4. Dilution: None (Undiluted)

5. Exposure Time: 10 minutes at 20°C

6. Subculture Medium: Mod. Proskauer Beck Broth (MPB)
Kirchners medium (KM)
TB Both (TB)

7. Incubation of Subcultures: 90 days at 37°C.

8. Test Organism: Mycobacterium bovis ATCC 19015

9. Phenol Resistance:

Time	Survival Counts	$\log_{10}$
0 min	1.09×10^6	6.03
5 "	3.2×10^5	5.5
10 "	1.69×10^5	5.23
15 "	1.59×10^5	5.20
20 "	1.48×10^5	5.17

Culture tested against 0.8% phenol test solution showed no less than 0.5 $\log_{10}$ and no more than 1.0 $\log_{10}$ kill in 20 min at 25°C.

10. Type of Carriers: Glass Slides

11. Survival of inoculum on control carriers:

1.5×10^5 to 1.1×10^6

12. Test Results:

Batch No.	# Positives/Total Carriers MPB	KM	TB
0288-3140	0/10	0/10	0/10
0888-3140	0/10	0/10	0/10
Viability Check	3/3	3/3	3/3

13. Conclusions: The submitted data demonstrate a satisfactory tuberculocidal performance at a contact time of 10 minutes at 20°C.

10

g. Sanitizer Test For Inanimate, Non-Food Contact Surfaces:

1. Method: Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection, Efficacy Data Requirements, US EPA and A.O.A.C. Germicidal Spray Products Test.

2. Modifications: 5% horse serum as soil.

3. Test Samples: Burnishine Germicidal Wipes >60 days old.

Samples	Mfg. Dates	Test Dates
06237	04-13-87	08-15-87
06257	"	"

4. Dilutions: None (Undiluted).

5. Exposure: 5 minutes at 20°C.

6. Subculture Medium/Neutralizer:Letheen Broth with Tween 80

7. Plate Count Medium: Nutrient Agar

8. Incubation: 48 hours at 37°C

9. Test Bacteria:

		Phenol Res.
Klebsiella pneumoniae	ATCC No. 4352	<1:90

10. Test Surface: Glass slide plus towelette residue

11. Survival of inoculum on control carriers:

1.1×10^6 to 1.45×10^6

12. Test Results:

Batch No.	Type Carrier	# Carriers Tested	# Positive/Total Carriers Tested
06237	Glass slide	20	0/20
	Towelette residue	20	0/20
06257	Glass slide	20	0/20
	Towelette residue	20	0/20
Viability Check	Glass slide	5	5/5

13. Conclusions: Satisfactory performance vs. test organism. However, test report did not specify any procedure used to insure neutralization of the germicide in subcultures was achieved. Data were not also developed against S. aureus. No additional data are required to be submitted.

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