6/6/88

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-07-88 Out 05-25-88

Srinivas Gowda 6.6.88

Reviewed By Srinivas Gowda Date 05-25-88

EPA Reg. No. or File Symbol 1130-6

EPA Petition or EUP NO. None

Date Division Received 10-20-87

Type Product Hospital Towelette (Saturated Towelette)

Data Accession No. 403839-01, 403839-02, & 406352-01

Product Manager 31 (Lee)

Product Name BURNISHINE® GERMICIDAL CLOTH

Company Name Burnishine Products

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

The submission received 10-20-87, is an application to add virucidal, tuberculocidal, "one-step" cleaner-sanitizer (non-food contact surfaces), and 5 minutes disinfecting claims to the label. Efficacy data and 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).

201.2 Test Summaries

a. Bactericidal Tests

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. However, testing was conducted on only one of the two samples required to support the efficacy. Also, the time/temperature employed for drying the microorganisms on the carrier was not specified.

b. Virucidal Tests:

1. Method: Modified A.O.A.C. Use-Dilution Method

2. Modifications: 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:

Batch No.	Mfg.Dates	Test Dates
06237	04-13-87	Not Listed
06257	"	"

4. Dilution: Undiluted

5. Exposure: 2 minutes at 20°C

6. Recovery Medium/Neutralizer/Diluent: Not listed

7. Incubation Time and Temperature:

Herpes Simplex Type II Not Listed

Influenza A_2/Honk kong "

8. Test Virus Host System:

Herpes Simplex Type II Not Listed

Influenza A_2/Honk kong "

9. Assay System for Virus Recovery:

Herpes Simplex Type II > + 2 Cytopathic Effect

Influenza A_2/Honk kong "

10. Drying Time and Temperature: Not Listed

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

12. Test Viruses

Herpes Simplex Type 2

Influenza A_2/Honk kong

13. Test Results

Test Virus	Batch No.	ID-50 or LD-50 (-log 10) Virus Control	Virus + Disinf.	Toxicity Control	Virus Inacti.
Herpes Simplex Type II	06237	6.5	2.5	2.5	4.0
	06257	6.5	2.5	2.5	4.0
Influenza A_2/ Honk kong	06237	6.5	2.5	2.5	4.0
	06257	6.5	2.5	2.5	4.0

14. Conclusions: The submitted data/test reports are incomplete and cannot be evaluated because the following procedural informations were not provided:

Volume of virus suspension inoculated and surface area of the petridish.

Time, temperature, and exposure conditions employed in the drying procedure.

Method (s) used in propagating the virus stock and composition of the virus inoculum.

Time and temperature employed during incubation of subcultures.

Data showing quantitative survival of the viruses on hard, surface carriers before and and after drying under specified conditions.

Specific descriptions of the method employed for quantitative assay of the infective virus (ID-50), including host cell system used, and the details of the assay procedure.

The manufacturing dates (s), and test date(s) for the product samples.

Technique employed to "resuspend" the virus film after the disinfectant treatment.

Maintainance media/Diluent/Recovery media/Neutralizer employed.

The test results indicating "Percent Inactivation >99.9" requires further explanation. It is not clear whether the results mean that virus was detected or was not detected.

Virus control titres (TCID-50: 10E6.5/ml), toxicity control titres (10E2.5/ml), and virus inactivation (10E4.0/ml) are same for all test viruses. Provide explanation.

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In the test report it is not clear if the data were developed by Modified A.O.A.C. Germicidal Spray Products Test or Use-Dilution Test, modified for testing the towelette. Please clarify.

c. 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. However, complete procedural information were not provided for towelette testing.

d. 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:

	# 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. However, complete procedural information were not provided for towelette testing.

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e. 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	Phenol Resistance
Mycobacterium bovis ATCC 19015	Not reported

9. Type of Carriers: Glass Slides

10. Survival of inoculum on control carriers: Not listed.

11. Test Results:

	# Positives/Total Carriers		
Batch No.	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

10. Conclusions: The submitted data demonstrate a satisfactory tuberculocidal performance at a contact time of 10 minutes at 20°C. However, complete procedural information were not provided for towelette testing. Also, control carrier counts and phenol resistance of the test organism were not reported.

f. 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

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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. Also, complete procedural information were not provided for towelette testing. Data were not also developed against S. aureus.