

8/8/90

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION  
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 06-14-90 OUT 07-31-90

Reviewed By Emily H. Mitchell <sup>284</sup> <sub>8/8/90</sub> Date 07-30-90

EPA Reg. No. or File Symbol 1130-6

EPA Petition or EUP No. None

Date Division Received 07-18-90

Type Product(s) Hospital Towelette

Data Accession No.(s) 415267-01 & 02

Product Mgr. No. PM 31 (Lee)

Product Name(s) BURNISHINE® GERMICIDAL CLOTH

Company Name(s) BURNISHINE Products

Submission Purpose Amendment to Add Virucidal & Fungicidal Claims

Chemical & Formulation Saturated Towelette

Active Ingredient(s): 8

n-Alkyl (C <sub>12</sub> 68%, 32% C <sub>14</sub> )	
dimethyl ethylbenzyl ammonium chloride . . . . .	0.14%
n-Alkyl (C <sub>12</sub> 60%, C <sub>16</sub> 30%, C <sub>12</sub> 5%, C <sub>18</sub> 5%)	
dimethyl benzyl ammonium chloride . . . . .	0.14%

200.0 Introduction

200.1 Uses:

Refer to last accepted label on 05-24-89.

200.2 Background Information:

The submission received 06-14-90, is a resubmission with amendments to the label. Efficacy data and new labels provided.

201.0 Data Summary (MRID Nos. 415267-01 & 02)

201.1 Brief Description of Tests:

a. Reports of Fungicidal Tests by:

Kyle H. Sabinovic, Ph.D.  
Shaldra Biotest, Inc.  
P.O. Box 2610-W  
Bethesda, MD 20817

b. Reports of Virucidal Tests by:

Philip R. Roane, Ph.D.  
Integrity Bioservices Inc.  
12280 Wilkins Ave.  
Rockville, MD 20852

a. Fungicidal Tests

1. Method: A.O.A.C. Fungicidal Slide Test,  
15th Edition, 1990, Volume I, Chapter 6.

2. Modifications: 5% horse blood serum

3. Samples:

<u>Sample</u>	<u>Date Started</u>	<u>Completed Test</u>
9H66884	02/15/90	02/25/90
9J72264	02/15/90	02/25/90

4. Dilution: N/A

5. Exposure: 5 minutes

6. Subculture Medium/Neutralizer: Lethen Broth

7. Incubation of Subcultures: 10 days at 25-30°C

8. Test Organism:

<u>Test Organism</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Trichophyton mentagrophytes</u>	9553	1:60
<u>Candida albicans</u>	10231	1:60

9. Test Results:

<u>Sample</u>	<u>No. of Carriers Exposed</u>	<u>No. of Carriers showing Growth</u>	<u>Organism</u>
9H66884	10	0/10	T. <u>mentagrophytes</u>
9J72264	10	0/10	T. <u>mentagrophytes</u>
9H66884	10	0/10	C. <u>albicans</u>
9J72264	10	0/10	C. <u>albicans</u>

10. Conclusions: Results show satisfactory performance of the product against Trichophyton mentagrophytes & Candida albicans for a contact time of 5 minutes.

b. The submitted for Aspergillus niger are not summarized in this report since claims against this organism are not considered to be related to human health.

c. Virucidal Tests

1. Method: EPA Test Method (DIS/TSS-7)
2. Modifications: 5% blood serum
3. Samples:

<u>Sample Number</u>	<u>Test Date</u>
H10A=110187	06-17-88
H10B=110187	06-17-88

4. Dilution: N/A
5. Exposure: 3 minutes at 20°C
6. Recovery Medium/Neutralizer/Diluent:  
Lethen Broth

7. Incubation: 37°C for 7 days
8. Test Virus Host System: MRC-5
9. Drying Time and Temperature: 2 hours at 20°C
10. Assay System for Virus Recovery:  
Cytopathic Effect
11. Method For Estimating 50 per cent end point:  
Reed Muench Method
12. Test Virus:  
Rhinovirus (ATCC VR 286)
13. Test Results:

ID-50 (-log 10)

<u>Test Virus</u>	<u>Sample No.</u>	<u>Virus Control</u>	<u>Virus Disin.</u>	<u>Toxicity Control</u>	<u>Virus Inactivation</u>
Rhinovirus	H10A=110187	6.50	2.50	2.50	4.00
	H10B=110187	6.50	2.50	2.50	4.00

14. Conclusions: Results show satisfactory performance of the product against the tested virus Rhinovirus, for a contact time of 3 minutes.