2-1-90

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 11-02-89 OUT 01-29-90

Reviewed By Emily H. Mitchell WEC 2/1/90 Date 01-29-90

EPA Reg. No. or File Symbol 777-TL

EPA Petition or EUP No. None

Date Division Received 01-24-90

Type Product(s) Pine Cleaner

Data Accession No.(s) 413009-06-08 & 413009-10-13

Product Mgr. No. PM 32 (Kempter)

Product Name(s) BARRAGE™ Pine Cleaner

Company Name(s) Lehn & Fink Products-Division of Sterling Drug, Inc.

Submission Purpose New Submission with efficacy data and proposed label.

Chemical & Formulation Liquid Concentrate to be used diluted

Active Ingredient(s):	%
Pine Oil	9.00%
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.80%
Octyl decyl dimethyl ammonium chloride	0.25%
Dioctyl dimethyl ammonium chloride	0.125%
Didecyl dimethyl ammonium chloride	0.125%

200.0 Introduction

200.1 Uses:

For disinfecting, general cleaning and deodorizing hard non-porous surfaces and for laundry use. Kills household germs, athlete's foot fungus, dangerous Staphylococcus aureus, Streptococcus faecalis, Pseudomonas aeruginosa, and prevents mold and mildew. Also kills Influenza A_2 (Japan) and Herpes Simplex, Type 1 and 2 on hard non-porous surfaces.

200.2 Background Information:

The submission received 11-02-89, is a new submission with efficacy data and proposed label.

201.0 Data Summary (MRID Nos. 413009-06-08 & 413009-10-13)

201.1 Brief Description of Tests:

a. Reports of Bactericidal and Fungicidal by:
Joseph Rubino, Janice Bauer, & Ernest Sachs,
Lehn & Fink Products Group, Microbiology Laboratory
225 Summit Ave, Montvale, N.J. 07645

b. Reports of Virucidal Tests by Timothy Cusack,
Lehn & Fink Products Group, Microbioloty Laboratory
225 Summit Ave, Montvale, N.J. 07645

c. Reports of Laundry Sanitizer Test by Diane Albano,
Lehn & Fink Products Group, Microbiology Laboratory
225 Summit Ave, Montvale, N.J. 07645

201.2 Test Summaries:

a. Bactericidal Tests

1. Method: A.O.A.C. Use Dilution Test 14th Edition, 1984.

2. Modifications: 5% blood serum

3. Samples:

Test Bacteria	Lot Number	Date Tested
P. aeruginosa	579/1	1/7 & 1/13/88
	579/2	1/7 & 1/13/88
	579/3	1/13/88

Test Bacteria	Lot Number	Date Tested
S. aureus	579/1	1/7 & 1/13/88
	579/2	1/7 & 1/13/88
	579/3	1/13/88
S. choleraesuis	579/1	1/7 & 1/13/88
	579/2	1/7 & 1/13/88
	579/3	1/13/88
S. faecalis	579/2	2/24/88
	579/3	2/24/88

4. Dilution: 1:64

5. Exposure: 10 minutes

6. Subculture Medium/Neutralizer: Letheen Broth

7. Incubation of Subcultures: 48 hours at 37°C

8. Test Bacteria:

Test Bacteria	Phenol Resistance
Pseudomonas aeruginosa	1:85
Staphylococcus aureus	1:80
Salmonella choleraesuis	1:85
Streptococcus faecalis	1:60

9. Test Results:

Test Bacteria	Lot No.	No. Carriers Tested	No. of Carriers Demonstrating Growth
Pseudomonas aeruginosa	579/1	60	1/60
	579/2	60	1/60
	579/3	60	1/60
Staphylococcus aureus	579/1	60	0/60
	579/2	60	0/60
	579/3	60	1/60
Salmonella choleraesuis	579/1	60	0/60
	579/2	60	0/60
	579/3	60	1/60
Streptococcus faecalis	579/2	10	0/10
	579/3	10	0/10

10. Survival of Control Carriers:

Test Organism with 5% Blood Serum	Number of Survivors After Drying
Salmonella choleraesuis	2.24×10^5 2.41×10^5
Staphylococcus aureus	3.2×10^6 3.4×10^6
Pseudomonas aeruginosa	9.4×10^6 1.7×10^7
Streptococcus faecalis	4.36×10^7 6.44×10^7

11. Conclusions: Results show satisfactory performance of the product against all tested bacteria for a contact time of 10 minutes.

b. Fungicidal Tests

1. Method: Official Methods of Analysis of the A.O.A.C., 14th Edition, 1984.

2. Modifications: 5% blood serum

3. Samples:

Test Organism	Batch No.	Date Made	Date Tested
T. mentagrophytes	750/1	11-24-87	04-06-88
	750/2	12-08-87	04-06-88

4. Dilution: 1:64

5. Exposure: Not Listed

6. Subculture Medium/Neutralizer: Sabouraud Dextrose Broth

7. Incubation of Subcultures: Not Listed

8. Test Organism:

Test Organism	ATCC No.	Phenol Resistance
Trichophyton mentagrophytes	9533	1:90

9. Test Results:

Test Organism	Batch No.	No. Carriers Tested	No. of Carriers Demonstrating Growth
T. mentagrophytes	750/1	10	0/10
	750/2	10	0/10

10. Survival of Control Carriers:

Test Organsim with 5% Blood Serum	No. of Survivors After Drying
T. mentagrophytes	1.8×10^4
	2.0×10^4

11. Conclusions: Results show satisfactory performance of the product against all test fungi when used at 1:64 dilution. However, the exposure time and incubation time and temperature must be submitted.

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

d. Virucidal Tests

1. Method: EPA Test Method (DIS/TSS-7)

2. Modifications: 5% fetal calf serum
400 ppm hard water

3. Samples:

Sample Number

Herpes Simplex, Type 1 (A-11-25-87)
(B-11-30-87)

Herpes Simplex, Type 1 (A-11-25-87)
(B-11-30-87)

Influenza A2 (Japan 305/57) (A-11-25-87)
(B-11-30-87)

4. Dilution: 1:64

5. Exposure: 10 minutes

6. Recovery Medium/Neutralizer/Diluent:
Herpes Simplex, Type 1 & 2-MEM
Influenza A2-PBS

7. Incubation: 1 hour at room temperature

8. Test Virus Host System:
Herpes Simplex, Type 1 & 2-Vero Cells
Influenza A2-11 day Embryonated Chicken Eggs

9. Assay System for Virus Recovery:
Herpes Simplex, Type 1 & 2-Cytopathic Effect
Influenza A2- Cytopathic Effect

10. Method For Estimating 50 per cent end point:
Reed Muench Method

11. Test Virus:
Herpes Simplex, Type 1 (Sterling Winthrop Research Institute D-16)
Herpes Simplex, Type 2 (ATCC VR-734 Strain G)
Influenza A2, Japan 305/57 (ATCC JR-100)

12. Test Results:

		ID-50 (-log 10)			
Test Virus	Sample No.	Virus Control	Virus Disin.	Toxicity Control	Virus Inactivation
Herpes Simplex Type 1	A-11-25-87	5.67	2.5	2.5	3.17
	B-11-30-87	5.67	2.5	2.5	3.17
Herpes Simplex Type 2	A-11-25-87	5.5	2.5	2.5	3.0
	B-11-30-87	5.5	2.5	2.5	3.0
Influenza A2	A-11-25-87	5.5	1.0	1.0	4.5
	B-11-30-87	5.5	1.0	1.0	4.5

13. Conclusions: Results show satisfactory performance of the product against the tested viruses at a dilution of 1:64 for a contact time of 10 minutes.

e. Bactericidal Tests (Laundry Sanitizer Test)

1. Method: Proposed Test Method for Antimicrobial Laundry Additives, Petrocci & Clarke, Journal of The A.O.A.C. Vol. 52, No. 4, 1969.

2. Modifications: 5% blood serum

3. Samples:

Sample Number	Date Made
TZ-1771-4	11-24-87
TZ-1771-4	12-08-87
TZ-1771-4	02-22-88

4. Dilution: 1:64

5. Exposure: Not Listed

6. Subculture Medium/Neutralizer: Not Listed

7. Number of Swatches Per Jar: Not Listed

8. Incubation of Subcultures: Not Listed

9. Test Bacteria:

Test Bacteria	ATCC No.
Staphyloccus aureus	Not Listed
Klebsiella pneumoniae	Not Listed

10. Test Results: Refer to attached Tables.

11. Conclusions: Results show satisfactory performance of the product as a laundry sanitizer against Staphyloccus aureus and Klebsiella pneumoniae (>99.9 % reduction) at a dilution of 1:64. However, verification is needed for the number of fabric swatches per sample. Exposure times, subculture medium, and incubation temperaure must be submitted.

Page_____ is not included in this copy.

Pages 9 through 9 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

__✓__ Information about a pending registration action.

__✓__ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 777-TL

Date Division Received 01-24-90

Data Accession No.(s) 413009-06-08 & 413009-10-13

Product Manager No. PM 32 (Kempter)

Product Name BARRAGE™ Pine Cleaner

Company Name Lehn & Fink Products-Division of Sterling Drug, Inc.

10

202.0 Recommendations

202.1 Efficacy Supported by the Data:

a. The submitted efficacy data appear adequate to support effectiveness of the product as a bactericide against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Streptococcus faecalis when used at a 1:64 dilution for a contact time of 10 minutes.

b. The submitted efficacy data appear adequate to support effectiveness of the product as a fungicide against Trichophyton mentagrophytes. However, the exposure time and incubation time and temperature must be submitted. Refer to 202.3 below.

c. The submitted efficacy data appear adequate to support effectiveness of the product as a virucide against Influenza A2 (Japan), Herpes Simplex, Types 1 and 2 when used at a 1:64 dilution for a contact time of 10 minutes.

d. The submitted efficacy data appear adequate to support effectiveness of the product as a laundry sanitizer against Staphylococcus aureus and Klebsiella pneumoniae. However, verification is needed for the number of fabric swatches per sample. Exposure time, subculture medium, and incubation temperaure must be submitted. Refer to 202.3 below.

202.2 Claims Not Related to Human Health:

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

202.3 Additional Data Required to Support Efficacy:

a. The exposure time and incubation time and temperature for the fungicidal data must be submitted.

b. For laundry sanitizing data verification is needed for the number a fabric swatches per sample. Exposure time, subculture medium, and incubation temperature must be submitted.

203.0 Labeling

a. Toilet bowl cleaning must have separate directions for use that specify removal or expulsion of residual bowl water prior to application of the product. The label directions must specify adding product directly to the bowl water, swab the bowl completely using a scrub brush or mop, making sure to get under the rim and let stand 10 minutes, then flush.

b. Move "Kills household germs in toilet and diaper pails" to appear under section for general cleaning/ deodorizing uses.

c. Change "MOLD AND MILDEW PREVENTION" to read "TO CONTROL MOLD AND MILDEW"

12