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Bruce E. Mann

File Symbol 777-32

EUP No. None

Date Division Received

Type Product General Disinfectant Spray

Data Accession No(s). Previously submitted under 242617

Product Manager PM-31 (Lee)

Product Name Lysol Brand Disinfectant Basin/Tub/Tile Cleaner (Aerosol)

Company Name Lehn & Fink Products

Submission Purpose An amendment

Type Formulation Pressurized aerosol spray

Active Ingredient(s):	%
Alkyl (67% C12; 25% C14; 7% C16; 1% C8- C10 -C18) dimethyl benzyl ammonium chlorides	0.06
Alkyl (50% C14; 40% C12; 10% C16) dimethyl benzyl ammonium chloride	0.80

200.0 Introduction

200.1 Use(s)

Refer to the last accepted label dated 11-23-76, and the current proposed label dated 04-15-86.

200.2 Factors Affecting Review

Applicant's with products proposed for amendment for registration which duplicate a formulation which is already registered may rely upon basic data or confirmatory data for the registered product to support their applications. In this case, the chemical composition, the label claims and recommendations for use must be identical in substance to those accepted for the registered product. However, the previously submitted efficacy data in the presence of an organic load must be evaluated in the light of current scientific criteria in support of the proposed "one-step" label claims and recommendations.
Since the proposed amendment consists of upgrading and the addition of a virucidal claim, upgrading efficacy claims, directions for use, basic efficacy data to support the amend - dment, and since some of the basic data have been reviewed for an identical product(#675-33), a review will not be made of previously efficacy reviews; a review of current data in support of the subject product will be provided.

200.3 Background Information
Refer to the previous comments of the last review dated 10-30-86 and the last accepted label for claims and use pattern.
The current submission is a rereview of previously submitted and a review of recently submitted efficacy data which were generated in the presence of organic soil to support efficacy against Ps. aeruginosa, S. aureus and S. choleraesuis as a "One-Step Disinfectant Cleaner". Also, the reports include fungicidal and virucidal data tested in organic soil. All data reports submitted for a rereview and for a first review in support of this amendment are summarized below.

201.0 Data summary

201.1 Previously submitted under Accession # 240659, # 240649, #240660,#240647,#004433,#009052, #240717, #240716, and #240646.
Refer to 201.1 and 201.2 of the previous review for a brief description of tests and for test summaries for the above.

201.2 Currently Submitted Data(Old data were previously submitted under #248617.)
The microbiology data were performed by Lehn & Fink Product Division, 225 Summit Avenue, Montivale, NJ 07645. Reports by Karen O'Donnell, dated 10-22-81. Also, the funngicidal data were performed by Karen O'Donnel, dated 10-22-81. Reports for fungistatic activity also were included.
Virucidal data performed by Herbert Prince of Gilbraltar Laboratories under report #16816 and #15075, dated 01-29-82, 12-10-82

201.2 A. Brief Description of Tests

Lysol Basin Tub and Tile Formula V-2881-4 Germicidal Activity in the presence of Organic Soil by Karen O'Donnel.

AOAC Germicidal Spray Test Method, 13 th, ed. 1980 (Required Test Bacteria) against Ps. aeruginosa, S. aureus, and S. choleraesuis.

The reports submitted for V-2881-4 are summarized below.

a. Method: AOAC Germicidal Spray Products Method.

b. Modifications: 5% blood serum added to the bacterial suspension.

c. Samples: Lysol Basin Tub/Tile/Formula V-288-4(Aerosol) EPA Reg No 777-32, Sample #1 05-13-81, Tested 05-21-81; Sample #2 06-09-81, Tested 06-10-81, and Sample #3 07-08-81, Tested 09-18-81(60 day).

d. Dilution: Undiluted spray.

e. Exposure Time: 10 minutes at room temperature.

f. Test Organisms:
Salmonella choleraesuis(Phen. Res. 1:90)
Staphylococcus aureus(Phen. Res. 1:65)
Pseudomonas aeruginosa(Phen. Res. 1:85)

The control survival/slide for the number of surviving organisms on the untreated control slide in the presence of 5% blood serum before and after drying were performed on each indicated organism.

g. Subculture Medium/Neutralizer: Letheen broth; checked for absence of stasis after ioculation and re-incubation of negative tubes with 10 microorganisms/ml of each test culture

h. Incubation: 48 hours at 37^{0}C.

i. Results:

Test Organism	Test Sample	Positives/Total Tested
S. cholereasuis	Sample 1	0/60
" "	Sample 2	0/60
" "	Sample 3(60 day)	0/60
S. aureus	Sample 1	0/60
" "	Sample 2	0/60
" "	Sample 3(60 day)	0/60
Ps aeruginosa	Sample 1	0/60
" "	Sample 2	0/60
" "	Sample 3(60 day)	0/60

h. Conclusions: Satisfactory performance for the product under the test conditions against Ps. aeruginosa, S. aureus and S. choleraesuis in 5% organic soil with the undiluted spray product.

B. Brief Description of Tests

Lysol Basin Tub & Tile -Formula V-2881-4 Fungicidal Activity in the presence of Organic Soil.

AOAC Germicidal Spray Test Method, 13th, ed., 1980. (Trichophyton mentagrophytes)

The reports submitted for V-2881 are summarized below.

a. Method: AOAC Germicidal Spray Product Method.
b. Modifications: 5% blood serum added to the spore suspension.
c. Samples:
   Sample #2 V-2881
   Sample #3 V-2881(60 day).
d. Dilution: Undiluted spray.
e. Exposure Time: 10 minutes.
f. Test Organism:
   Trichophyton mentagrophytes(Phen Res: 1:60).
g. Subculture Medium/Neutralizer: Not listed.
h. Control survival studies were not submitted and no data were povided to document the absence of static effect of the active ingredient.
i. Results

Test Organism	Test Sample	No Pos/No. of Slides Tested
T. mentagrophytes	Sample #2	0/10
" "	Sample #3(60 day)	0/10
Control slides		2 +/ 2 Tested.

j. Conclusions: Satisfactory performance against T. mentagrophytes under the test conditions as a pressurized spray, however, data must be provided for survival and for the presence or absence of statsis as described in item 7 of DIS/TSS-2 enclosure.

C. Brief Description of Tests

Hard surface Mildew Fungistatic Test Method. Federal Register, EPA Guidelines Registering Pesticides, June 25, 1975, vol. 123, p 265851. Fungistatic Activity in the presence of organic soil.

The submitted fungistatic data tested against sample #2 and sample #3(60 day) appear to be adequate under the test conditions. Conclusions: Satisfactory performance as a fungistat under in the presence of organic soil against Aspergillus niger

D. Brief description of Tests

AOAC Germicidal Spray Test Method(EPA Virucidal Method).
Federal Register 10, #123, 06-25-75
Tested against H. simplex 2 and Influenza A2/Japan

A. The reports submitted for Foam Cleaner V-2881, Samples 1 & 2 - Virucidal Activity-EPA Test Method.

Virus: Influenza/A2 305/57 Asian
Sample:Foam Cleaner V-2881-4, Sample #1
Dlution: Full strength (Undiluted pressurized spray).

Results: The submitted virucidal attached reports developed by the modified-EPA Germicidal Spray Method against influenza A2/Japan appear to be adequate and are acceptable.

Virus Inactivation(Virus control-virus germicide=Log. Reduction in Titer).

Average $TCID_{50}$(neg. log 10)

Virus	Sample	Control	Germicide	Toxicity	Inactivation*
Influenza A2	Sample 1	ID_{50} 6.5	< 1	<1	5.5
"	Sample 2	ID_{50} 6.5	< 1	<1	5.5

*Change in log. reduction.

Conclusions: Satisfactory performance as a virucide against influenza A2/Japan under the test conditions as a spray.

B. The reports submitted for Foam Cleaner Disinfectant Cleaner Aerosol V-2881-4, Batch A & B Virucidal EPA Assay Method.

Virus: Herpe simplex Type 2/(CL-5)
Sample: Disinfect/Cleaner Aerosol V-2881-4, Batch A & B.
Dilution: Full strength(undiluted spray)

Results: The submitted virucidal attached reports developed by the modified-EPA Germicidal Spray Method against Herpes simplex Type 2 appear to be adequate and are acceptable.

Virus Inactivation(Virus control-virus germicide=Log. Reduction in Titer).

Average $TCID_{50}$(neg. log 10)

Virus	Sample	Control	Germicide	Toxicity	Inactivation*
H. simplex 2	V-2881-4 (Batch A)	6.5	<2.5	<2.5	4.00
H. simplex 2	V-2881-4 (Batch B)	6.5	<2.5	<2.5	4.00

*Change in log. reduction.

Conclusions: Satisfactory perfomance as a virucide against H. simplex 2 in in the presence of 5% organic soil as a pressurized spray.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 777-32

Date Division Received

Date Accession No(s). Previously submitted under 248617

Product Manager No. PM-31 (Lee)

Product Name Lysol Brand Disinfectant Basin/Tub/Tile Cleaner (Aerosol)

Company Name Lehn & Fink Products

202.0 Recommendations

202.1 Claims Related to Human Health

202.1.1 Efficacy Supported by the Data

A. The submitted data developed by the AOAC Germicidal Spray Test Method support the efficacy of this product and are acceptable as a pressurized spray for this product as a hospital/general disinfectant against Salmonella choleraesuis, Staphylococcus aureus and Pseudomonas aeruginosa in the presence of 5% blood serum when used as a undiluted (aerosol) pressurized product to thoroughly wet hard, non-porous, inanimate surfaces by the spray and allowed to remain wet for at least 10 minutes..

B. The submitted virucidal data support effectiveness of the subject product as a virucide against Herpes simplex Type 2 and influenza A2/Japan 305/57(Asian) for hospital and/or general use areas on hard, non-porous, inanimate surfaces with a moderate soil load(5% serum) when thoroughly wetted by the spray and allowed to remain wet for 10 minutes as a undiluted pressurized spray product.

C. The submitted data support the product effectiveness as a fungicide(Pathogenic) against Trichophyton mentagrophytes for the appropriate use areas in the presence of 5% soil when thoroughly wetted by the spray and allowed to remain wet for at least 10 minutes.

D. The data also support the product as a hard surface mildew fungistat against Aspergillus niger in the presence of 5% organic soil.

203.0 Label

The applicant proposed label of 04-15-86 must be revised to reflect the following instructions.

A. The label must be provided with the major areas of use as described in item 1 of DIS/TSS-15 enclosure.

B. The label comments made in the previous review of 10-30-86 concerning graphic illustration of toilet bowls must be provided for by the applicant.

C. All wordings implicating the products usage as a disinfectant less than 10 minutes must be deleted.