

920-85

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 07-29-85 OUT 09-19-85

Reviewed By Dennis G. Guse Date 09-19-85
EPA Reg. No. or File Symbol 777-51
EPA Petition or EUP No. None
Date Division Received 06-12-85
Type Product General Disinfectant (Household)
Data Accession No(s). 258827
Product Manager 31 (Lee)
Product Name Lysol Brand Basin/Tub/Tile Pump Spray Cleaner

Company Name Lehn & Fink Products Group, Division of Sterling Drug
Submission Purpose Amendment general revision of label, expanded
claims, formula change, additional brand names
Type Formulation Ready-to-use liquid pump spray

Active Ingredient(s):	Z
Alkyl (67% C12, 25% C14, 7% C16, 1% C8, C10, C18) dimethyl benzyl ammonium chlorides	0.08
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chlorides	0.02

200.0 Introduction

200.1 Uses

The product is registered as a pump spray cleaner-disinfectant for general (home) use on bathroom basin, tub, tile, and other household surfaces (last accepted label dated 01-17-77).

The current submission is an amendment for general upgrading of the label, expanded efficacy claims, minor formula change, and some additional brand names, and includes efficacy data to support the currently proposed label and formulation.

201.0 Data Summary

201.1 Brief Description of Tests

- a. Bactericidal and fungicidal reports by Karen O'Donnell and H. L. Melzer, Lehn & Fink Products Group, Sterling Drug, Inc., Montvale, NJ 07645, dated 02-22-85 (Accession No. 258827).
- b. Virucidal reports by Karen Funk, Lehn & Fink Products Group, Sterling Drug, Inc., Montvale, NJ 07645, dated 02-13-85 (Accession No. 258827).

201.2 Test Summaries

a. Bactericidal and Fungicidal Reports

1. Method: AOAC Use-Dilution Method.
2. Modifications: 1 ml blood serum was added to 19 ml inoculum and dried on carriers for 30 minutes at 37C and 20% RH to represent 5% (v/v) organic soil.
3. Samples: Lysol Brand Disinfectant Bathroom Cleaner For Basin, Tub & Tile, Formula V-0641-9, Sample No. 1 (made 11-15-84; tested 11-29-84), No. 2 (made 12-06-84; tested 12-13-84), and No. 3 (made 12-06-84; tested 02-07-84 - 60 day shelf life).
4. Dilution: Undiluted.
5. Exposure: 10 minutes at 20C.
6. Test Organisms: Staphylococcus aureus (phenol resistance 1:60), Salmonella choleraesuis (phenol resistance 1:90), Pseudomonas aeruginosa (phenol resistance 1:80), Streptococcus faecalis ATCC 828 (phenol resistance 1:60), and Trichophyton mentagrophytes ATCC 9533 (phenol resistance 1:65).
7. Subculture Medium/Neutralizer: - Letheen broth (S. aureus, S. choleraesuis, P. aeruginosa), trypticase soy broth with letheen (S. faecalis), and Sabouraud dextrose broth with letheen (T. mentagrophytes). No stasis was observed in primary subculture medium after inoculation and reincubation with less than 10 microorganisms /ml of each test culture.

8. Incubation: 48 hours at 37C (S. aureus, S. choleraesuis, P. aeruginosa, and S. faecalis), and 7 days at 30C (T. mentagrophytes).

9. Results:

Test Organism	Viability Test	CFU/Cylinder		Test Batch	Positive/Total Carriers
		Wet	Dry		
<u>S. aureus</u>	1	5.0x10 ⁷	6.3x10 ⁶	1	0/60
" "	2	5.6x10 ⁷	6.0x10 ⁶	2	0/60
" "	-	-	-	3	0/60
<u>S. choleraesuis</u>	1	1.5x10 ⁸	1.2x10 ⁶	1	0/60
" "	2	2.3x10 ⁸	2.0x10 ⁶	2	0/60
" "	-	-	-	3	0/60
<u>P. aeruginosa</u>	1	1.0x10 ⁸	1.7x10 ⁶	1	0/60
" "	2	1.0x10 ⁸	2.0x10 ⁶	2	0/60
" "	-	-	-	3	0/60
<u>S. faecalis</u>	1	1.5x10 ⁹	4.3x10 ⁷	1	0/10
" "	2	1.3x10 ⁹	6.4x10 ⁷	2	0/10
<u>T. mentagrophytes</u>	1	1.4x10 ⁴	4.0x10 ⁴	1	0/10
" "	-	-	-	2	0/10

10. Conclusions: Satisfactory performance vs. all test organisms undiluted in the presence of 5% blood serum at a contact time of 10 minutes.

Tests submitted for Aspergillus niger by the AOAC Use-Dilution Method and Hard Surface Mildew Fungistatic Test are not summarized here since claims against this organism are not considered to be related to human health, i.e., as a mildewcide and mildewstat.

b. Virucidal Reports

- Method: 0.2/0.5 ml of virus pool is spread over the surface of a 100-mm glass Petri dish and allowed to dry for 30/20 minutes at 35C. After drying, 1.8/4.5 ml of undiluted disinfectant is added to the Petri dish and allowed to remain for 10 minutes. Then 10-fold serial dilutions of the sample is made in MEM/PBS + 5% calf serum. 0.2 ml of each dilution is then inoculated into each of 4 cell cultures/chick embryos and incubated at 35C for 7/2 days at 35C. The presence of virus is determined by CPE/hemagglutination. Virus controls consisted of dried virus overlayed with diluent instead of disinfectant. Toxicity controls consisted of the addition of diluent to the undiluted disinfectant without virus.
- Modifications: 5% inactivated Bobby calf serum was added to virus inoculum as organic soil.

3. Samples: Lysol Brand Disinfectant Bathroom Cleaner For Basin, Tub & Tile, Formula V-0641-9, Sample No. 1 (made 01-04-85; tested 01-14/16-85) and Sample No. 2 (made 01-07-85; tested 01-14/16-85).
4. Dilution: Undiluted.
5. Exposure: 10 minutes at room temperature.
6. Test Viruses: Herpes simplex virus Type 1 (Vero cells in MEM + 2% fetal calf serum), Herpes simplex Type 2 ATCC VR-734 (Vero cells in MEM + 2 % fetal calf serum), and Influenza virus Type A2 Japan 305/57 ATCC VR-100 (10-day-old fertilized chick embryos).
7. Subculture Medium/Neutralizer: MEM/PBS + 5% calf serum.
8. Incubation: 7 days at 35C in 5% CO₂ (Herpes) and 42 hours at 35C in humid atmosphere (Influenza).
9. Results:

Test Virus	Test Batch	ID-50 or LD-50 (-Log 10)			
		Virus Control	Virus-Germicide	Toxicity	Reduction
Herpes simplex Type 1	1	7.5	2.5*	2.5*	5.0
" " " "	2	7.5	2.5*	2.5*	5.0
Herpes simplex Type 2	1	7.5	2.5*	2.5*	5.0
" " " "	2	7.5	2.5*	2.5*	5.0
Influenza Type A2	1	8.2	0.5*	0.5*	7.7
" " " "	2	8.2	0.5*	0.5*	7.7

*Toxicity of germicide

10. Conclusions: Satisfactory performance vs. all test viruses undiluted in the presence of 5% blood serum at a contact time of 10 minutes.

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Date Division Received 06-12-85
Data Accession No(s). 258827
Product Manager No. 31 (Lee)
Product Name Lysol Brand Basin/Tub/Tile Pump Spray Cleaner
Company Name Lehn & Fink Products Group, Division of Sterling Drug

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data are acceptable to support effectiveness of the product, as currently formulated and tested, as a "one-step" cleaner-disinfectant for hospital or general use against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa on moderately soiled (5% blood serum), hard, non-porous surfaces when the surfaces are thoroughly wet by the undiluted solution for a contact time of 10 minutes.

The submitted data are also acceptable to support effectiveness of the product as a disinfectant against Streptococcus faecalis, fungicide (pathogenic fungi) against Trichophyton mentagrophytes (athlete's foot fungi), and virucide against Influenza Type A2/Japan and Herpes simplex Types 1 and 2 under the same conditions as indicated above.

202.1 Efficacy Not Related to Human Health

The submitted data against Aspergillus niger to support efficacy as a mildewcide and mildewstat is not considered to be directly related to human health. Therefore, under the efficacy data waiver, such data are not required to be submitted or reviewed.

203.0 Labeling

On the back panel, the claim "Lysol . . . cleans and disinfects any hard non-porous surface including . . ." must be revised to eliminate "any", which is too inclusive and could be construed to include dinnerware, cookware, glassware, and other food-contact items which are not intended or provided for in the labeling.

There is no objection to the proposed additional brand names "Lysol Brand (Direct/Excel/Eclipse/Triumph/Spectra/The Works) Multi-Purpose Cleaner Disinfectant".