

8-16-89

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 07-08-89 OUT 08/16/89

Reviewed By Srinivas Gowda WEG/89
Date 08/16/89

EPA Reg. No. or File Symbol 777-44

EPA Petition or EUP No. None

Date Division Received 01-30-89

Type Product(s): General Disinfectant

MRID No(s) 409811-01

Product Mgr. No. 31 (Lee)

Product Name(s) Lysol® Brand Disinfectant Deodorizing Cleaner

Company Name (s) Lehn & Fink Products Group, Sterling Drug Inc.

Submission Purpose Amendment to add virucidal claim against HIV-1
(AIDS virus) with efficacy data and labeling

Chemical & Formulation Liquid to be used diluted

Active Ingredient (s):

Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆)
dimethyl benzyl ammonium chlorides.....2.7



United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain
National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

Lysol Brand Disinfectant Deodorizing Ch.

Chemical Name

2.

Identifying Number

777-44

3.

Record Number

4. Action

Code

300

5. MRID/

Accession Number

6.

Study Guideline or Narrative

7. Reference No.

8. Date Rec'd (EPA)

1-30-89

9. Prod/Review Mgr/DCI

Lee

10. PM/RM Team No.

31

11. Date to HED/
EFED/RD/BEAD

7/8/89

12. Proj Return Date

8-16-89

13. Date Returned
to RD/SRRD

7/24/89

Instructions

Please review efficacy data against
AIDS.

This Section Applies to Review of Studies Only

14. Check Applicable Box



Adverse 6(a)(2) Data (405)



Special Review Data (870)



Generic Data (Reregistration) (660)



Product Specific Data (Reregistration) (655)

15. No. of Individual Studies
Submitted

16. Have any of the above studies (in whole or in part) been previously submitted for review?



Yes (Please identify the study(ies))



No

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input checked="" type="checkbox"/> SAC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure	<input type="checkbox"/> DEB	
		Nondietary Exposure	<input type="checkbox"/> NDE	
EFED		Ecological Effects	<input type="checkbox"/> EEB	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD	X	Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial (eff)	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

☐ Confidential Statement of Formula
(EPA Form 8570-4) Attached (Trade Secrets)

☒ Label Attached

200.00 Introduction

200.1 Use (s)

Refer to the most recently accepted labeling dated 03-25-83 and proposed labeling dated 01-30-89.

200.2 Current Submission

The current submission is a proposed amendment to add a virucidal claim for the product as a disinfectant against HIV-1 (AIDS virus) with supporting efficacy data and revised labelings.

200.3 Previously Accepted Virucidal Claims: The last accepted label bears virucidal claims for the product against Influenza A₂ in the presence of moderate amount of organic soil (5% blood serum) when used at a 1:64 dilution for a contact time of 10 minutes at room temperature (no-reuse).

201.0 Data Summary

201.1 Brief Description of Test (MRID 409811-01)

"Virucidal Efficacy of Lysol Deodorizing Cleaner"
Project No. 6470 by Bonnie J. Bowdon, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, Alabama, 35255, dated 06-16-88.

201.2 Test Summary:

- a. Method: EPA Product Performance Guidelines and the specifics in the SRI HIV test protocol approved by EE & TMS (Efficacy), APB, RD, dated 05-23-88 (EPA letter dated 05-26-88 & 08-03-88).
- b. Test Virus: Human immunodeficiency virus Type 1 (HTLV-III_{RF}).
- c. Virus Inoculum & Drying Procedure: Two-tenths ml of virus pool in RPMI-1640, containing 10% heat-inactivated fetal bovine serum, was dried on the bottom of glass petri dishes (28 cm² area) at 23°C until visibly dry (approx. 45 minutes), then incubated at 35-37°C in a dry-air oven for an additional 30 minutes.
- d. Test Procedure: 2.0 ml of disinfectant was applied to dried virus film for 10 minutes at room temperature (23°C) (7 minutes exposure in plate + 3 minutes centrifugation in Sephadex gel filter).

e. Test Samples: Lysol Deodorizing Cleaner

Batch Nos. B7146N and B7168D

Manufacturing Dates: Not listed.

Date Sample Received: 11-24-87.

Test Dates: 05-09-88 to 06-17-88.

f. Use-Dilution: 1:64 in sterile deionized water.

g. Host Infection & Virus assay: Polybrene-treated MT2 T-cells were inoculated and incubated for 7 days at 37°C for virus infection. Primary virus infection was scored by lytic cytopathic effect (CPE). H-9 T-cells were also inoculated and monitored for virus infection by the antigen capture (ELISA) method for up to 28 days.

h. Neutralizer/Diluent: Sephadex gel filtration was employed for neutralization and filtrates were diluted ten-fold serially for assay of infectivity.

i. Results:

<u>Test Sample</u>	<u>Disinfectant Exposure</u>		<u>ID-50/LD-50 (-Log 10)</u>			
	<u>Temperature</u>	<u>Time</u>	<u>Organic Soil</u>	<u>Hard Water</u>	<u>B7146N</u>	<u>B7168D</u>
Virus Control	NA	NA	10% Serum	NA	7.00	7.00
Virus + Non-Virucidal Disinfectant	20-25°C	10 Minutes	"	"	6.0	6.0
Virus + Disinfectant	20-25°C	10 Minute	"	None	2.5	2.5
Toxicity Control	NA	NA	NA	"	2.5	2.5
Log Reduction	20-25°C	10 Minute	10% Serum	"	3.5	3.5

NA = Not Applicable

j. Conclusions: The data meet the requirements for demonstrating virucidal performance of the product against HIV-1 in the presence of moderate amount of organic soil (10% blood serum) when used at a 1:64 dilution for a contact time of 10 minutes at room temperature (20-25°C).

Cleanin
s Up To 4 Mc
All Tanks



FRESH SCENT!

Lysol

BRAND DISINFECTANT

DEODORIZING

DISINFECTANT

CUTS GREASE

ACTIVE INGREDIENTS

Allyl isothiocyanate, 40% (w/v)	2.70%
Dimethyl benzyl ammonium chloride (DDBAC)	0.34%
Tetrasodium (hydroxyethyl) ethylenediamine	0.12%
Tetrasodium	56.53%
INERT INGREDIENTS	130.07%
TOTAL	189.76%

WARNING: SEE BACK PANEL FOR DILUTION INSTRUCTIONS

40 FL. OZ. (1.073 FL. OZ.)

1.182 L. EPA Reg No. 777-44

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAR 25 1983

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

777-44

BEST DOCUMENT AVAILABLE

Lysol deodorizing
cleaner

BRAND DISINFECTANT

cuts grease, disinfects, deodorizes

Kills dangerous SAPHO and STREP GERMS, INFLUENZA VIRUS A₂ and HOUSEHOLD GERMS on environmental surfaces in homes and commercial areas. Prevents MOLD and MILDEW and the odors they cause.

For general cleaning, disinfecting, and deodorizing

Walls, Woodwork, Garbage Cans, Cabinets,
Floors and Wax Floors, Tile, Enamel, Storage &
Kitchen, Bathroom, Porcelain, Dinner Pails, Pet Areas,
all hard, nonporous surfaces

General Classification: It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DIRECTIONS: Use 1/2 cup in half a pint of warm water (1 gal.) Wipe for mop to wet surfaces thoroughly. Rinse food preparation areas with water. For sensitive skin, use rubber gloves.

Tough Cleaning: Use full strength on lipstick, tar, gum, oil, hard grease and scuff marks; then rinse.

For Vase Floors: Use as directed. Then rinse.

For Disinfecting Toilet Bowl: Use 1/2 oz. (3 fl. oz.) full strength in bowl. To Prevent Mold & Mildew: Repeat application when necessary.

This product contains no phosphorous or phosphates.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: IRRITANT: Avoid contact with eyes. Causes eye irritation. May be harmful if swallowed. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT: In case of accidental contact immediately flush eyes with large amount of water for at least 15 minutes and call physician. If accidentally swallowed, drink promptly a large quantity of water and call physician.

STORAGE/DISPOSAL: Do not reuse empty container. Wrap container and put in trash collection.

Lysol Brand Disinfectant Deodorizing Cleaner is germicidal when used as directed for disinfection, but differs in composition from other Lysol Brand Products.

EPA Est. 777-1147 (See Back Panel)

LEHN AND FINKE, PPH

LEHN & F
225 SUMM

ITEM

LDX
252



EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 777-44

Date Division Received 01-30-89

MRID No.(s). 409811-01

Product Manager No. PM-31 (Lee)

Product Name(s) Lysol® Brand Disinfectant Deodorizing Cleaner

Company Name (s) Lehn and Fink Products Group, Sterling Drug Inc.

202.0 Recommendations

202.1 Efficacy Supported By The Data

The submitted data meet the requirements to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (10% blood serum) when used at a 1:64 dilution for a contact time of 10 minutes at room temperature (20-25°C).

203.0 Labeling

- a. Label reference to "HIV-1 (causative agent of AIDS)" must be revised to read "HIV-1 (AIDS virus)".
- b. Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current Labeling Policy for HIV Efficacy Claims. Your labeling must be revised in accordance with requirements outlined in this policy notice.
- c. Also, refer to the attached Federal Register Notice for clarification of HIV (AIDS virus) labeling policy for antimicrobial pesticide products.
- d. The complete nomenclature of Influenza A₂ must be indicated on the label for this virus because there are several identified strains available for testing.
- e. Include major areas in which the product is recommended for use (e.g. homes, schools).
- f. Provide instructions for removal of gross filth or heavy soil. In addition, instructions must be provided for thorough cleaning of surfaces prior to application of the product, unless the product has been shown to be effective in the presence of moderate amounts of organic soil.
- g. Include a statement such as "Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled".
- h. The label directions for disinfection of toilet bowl surfaces must specify flushing and adding product directly to the bowl water and should indicate the thorough swabbing of all bowl surfaces with the use solution using a scrub brush or mop, making sure to get under the rim and let stand for at least 10 minutes, then flush.