Efficacy Evaluation and Technical Management Section

Efficacy Review I

Antimicrobial Program Branch

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

Reviewed By Srinivas Gowda  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): 8

Alkyl (50% C14, 40% C12, 10% C16)
dimethyl benzyl ammonium chlorides .............................. 2.7
EPA Form 8570-17 (Rev. 11-88)

Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Green - Return with completed review

### Data Review Record

**Product Name:** Lysol Brand Disinfectant Odorizng

**Chemical Name:**

<table>
<thead>
<tr>
<th>Identifying Number</th>
<th>Record Number</th>
<th>Code</th>
<th>MRID/Accession Number</th>
<th>Study Guideline or Narrative</th>
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<tbody>
<tr>
<td>777-94</td>
<td>300</td>
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**Reference No.:**

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<tr>
<th>Date Rec'd (EPA)</th>
<th>Prod/Review Mgr/DCI</th>
<th>PM Team No.</th>
<th>Date to HED/EFED/RD/BEAD</th>
<th>Proj Return Date</th>
<th>Date Returned to RD/SPRD</th>
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<tr>
<td>1-30-89</td>
<td>Lee</td>
<td>3</td>
<td>7/8/89</td>
<td>8/6/89</td>
<td>7/24/89</td>
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**Instructions:**

Please review efficacy data against AIDS.

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**Check Applicable Box:**

- [ ] Adverse 6(a)(2) Data (405)
- [ ] Generic Data (Peregrination)(660)
- [ ] Special Review Data (870)
- [ ] Product Specific Data (Peregrination)(655)

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

- [ ] Yes (Please identify the study(ies))

**Type of Review:***

<table>
<thead>
<tr>
<th>HED</th>
<th>EFED</th>
<th>SRRD</th>
<th>RD</th>
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<tbody>
<tr>
<td>Science Analysis &amp; Coordination</td>
<td>Ecological Effects</td>
<td>Peregistration</td>
<td>Insecticide-Rodenticide</td>
</tr>
<tr>
<td>Toxicology/HFA</td>
<td>Environmental Fate &amp; Groundwater</td>
<td>Generic Chemical Support</td>
<td>Fungicide-Herbicide</td>
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<tr>
<td>Toxicology/IR</td>
<td></td>
<td></td>
<td>Antimicrobial</td>
</tr>
<tr>
<td>Dietary Exposure</td>
<td></td>
<td></td>
<td>(eff)</td>
</tr>
<tr>
<td>Nondietary Exposure</td>
<td></td>
<td></td>
<td>Product Chemistry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Precautionary Labeling</td>
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<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Biological Analysis</td>
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</table>

**Reviews Also Sent to:**

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<tr>
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<th>PC</th>
<th>PL</th>
<th>TOX/RFA</th>
<th>TOX/IR</th>
<th>DEB</th>
<th>EA</th>
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<th>AC</th>
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<td>EEB</td>
<td>EFGWB</td>
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</tbody>
</table>

**Data Review Criteria:**

- A. Policy Note No. 31
  - 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
- B. Section 18
  - 1 = data in support of section 3 in lieu of section 18
- C. Inert Ingredients
  - 1 = data in support of continued use of List 1 inert

**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. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, Alabama, 35255, dated 06-16-88.

201.2 Test Summary:


b. Test Virus: Human immunodeficiency virus Type 1 (HTLV-III/LAV).

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:

<table>
<thead>
<tr>
<th>Test Sample</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Organic Soil</th>
<th>Hard Water</th>
<th>ID-50/LD-50 (-Log 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virus Control</td>
<td>NA</td>
<td>NA</td>
<td>10% Serum</td>
<td>NA</td>
<td>7.00</td>
</tr>
<tr>
<td>Virus + Non-Virucidal Disinfectant</td>
<td>20-25°C</td>
<td>10 Minutes</td>
<td>&quot;</td>
<td>&quot;</td>
<td>6.0</td>
</tr>
<tr>
<td>Virus + Disinfectant</td>
<td>20-25°C</td>
<td>10 Minutes</td>
<td>&quot;</td>
<td>None</td>
<td>2.5</td>
</tr>
<tr>
<td>Toxicity Control</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>&quot;</td>
<td>2.5</td>
</tr>
<tr>
<td>Log Reduction</td>
<td>20-25°C</td>
<td>10 Minute</td>
<td>10% Serum</td>
<td>&quot;</td>
<td>3.5</td>
</tr>
</tbody>
</table>

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).
FRESH SCENT

Lysol deodorizing cleaner
CUTS GREASE

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.

727-44

Lysol deodorizing cleaner

cuts grease, disinfects, deodorizes

Kills dangerous STAPH and STREP CERMS, INFLUENZA VIRUS A and
HOUSEHOLD GERMS on environmental surfaces in homes and com-
mercial areas. Prevents MOLD and MILDEW and the odors they cause.

For general cleaning, disinfecting, and
deoarizing

Floors, Woodwork, Garbage Cans, Cabinets,
Floors: No Wax Floors, Stairs, Stairwells, Storage &
Kitchen, Bathrooms, Porch, Decks, Patios,
all hard, nonporous surfaces

General Dilution: 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 gallon of warm water (1 gal.) thoroughly
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.

MD-BT towels: use as directed, then rinse.

For Disinfecting Tub & Bowl: Use 1/4 oz. (3 tbsp) full strength in bowl.

To prevent Mold & Mildew: Repeat application when necessary.

This product contains no phosphates or phosphate.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

WARNING: Avoid contact with eyes. Causes eye irritation. May be
harmful if swallowed. Avoid contact with 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 plenty of large
quantity of water and call physician.

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

Lysol Brand Disinfectant Deo-
larizing Cleaner is renewable
when used as directed for
disinfection, but is not compa-
ition from other Lysol Brand
Products.

EPA-Est. No. MD-2 ML-2 MD-2 ML-2
LITH AND FIVE PREP.

ITEM 4062
25/4
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.