Efficacy Evaluation and Technical Management Section

Efficacy Review-I

Antimicrobial Program Branch

IN 07-06-88  OUT 10/31/88

Reviewed By Srinivas Gowda  Date 10/31/88

EPA Reg. No. or File Symbol  777-66

EPA Petition or EUP No.  None

Date Division Received  07-05-88

Type Product(s): General Disinfectant (Household)  

MRID No(s)  406636-01

Product Mgr. No.  31 (Lee)

Product Name(s)  Lysol Brand Disinfectant Direct Multi-Purpose*Cleaner

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

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

Chemical & Formulation  Ready-to-use liquid

Active Ingredient(s):

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
200.00 Introduction

200.1 Use (s)

Refer to the most recently accepted labeling dated 02-14-86. Also, proposed labels are attached.

200.2 Current Submission

The current submission is a proposed amendment to add virucidal claims 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/Japan in the presence of moderate amount of organic soil (5% blood serum) when used undiluted for a contact time of 10 minutes at room temperature (no-reuse).

201.0 Data Summary

201.1 Brief Description of Test (MRID 406636-01).

"Virucidal Efficacy of Direct Multipurpose Cleaner" Project No. 6470 by George C. Lavelle, Southern Research Institute, 2000 Ninth Avenue South, P.O. Box 55305, Birmingham, Alabama, 35255, dated 04-21-88.

201.2 Test Summary:


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: Direct Multipurpose Cleaner
   EPA Reg. No. 777-66
   Lot No. B7092D
   Lot No. B7196D
   Date Sample Received: 11-24-87
   Test Dates: 03-14-88 to 04-13-88.

f. Dilution: None (undiluted)

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 in RPMI-1640 containing 10% fetal bovine serum.

i. Results:

<table>
<thead>
<tr>
<th>Test Sample</th>
<th>Temperature</th>
<th>Time</th>
<th>Organic Soil</th>
<th>Hard Water</th>
<th>ID-50/LD-50 (−Log 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B7092D</td>
</tr>
<tr>
<td>Virus Control</td>
<td>NA</td>
<td>NA</td>
<td>10% Serum</td>
<td>NA</td>
<td>7.67</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>6.50</td>
</tr>
<tr>
<td>Virus + Disinfectant</td>
<td>20-25°C</td>
<td>10 Minutes</td>
<td>&quot;</td>
<td>None</td>
<td>3.50</td>
</tr>
<tr>
<td>Toxicity Control</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>3.50</td>
</tr>
<tr>
<td>Log Reduction</td>
<td>20-25°C</td>
<td>10 Minutes</td>
<td>10% Serum</td>
<td>&quot;</td>
<td>3.00</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 undiluted for a contact time of 10 minutes at room temperature (20-25°C).
EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW-II
Antimicrobial Program Branch

EPA Reg. No. or File Symbol  777-66
Date Division Received      07-05-88
MRID No.(s).                  406636-01
Product Manager No.        PM-31 (Lee)
Product Name  Lysol Brand Disinfectant Direct Multi-Purpose Cleaner
Company Name  Lehn & Fink Products, Division of 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) when used as an undiluted solution on hard, non-porous surfaces in the presence of a moderate amount of organic soil (10% blood serum) for a contact time of 10 minutes at room temperature (20-25°C).

203.0 **Labeling:**

Label reference to "HIV-1 (Causative Agent of AIDS)" must be revised to read "HIV-1 (AIDS virus)". 