

11-4-88

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 07-06-88

OUT 10/31/88

Reviewed By Srinivas Gowda <sup>WEC</sup> <sub>11/4/88</sub> 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):

8

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 A<sub>2</sub>/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: -

- 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<sub>RF</sub>).
- 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 cm<sup>2</sup> 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:

<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>B7092D</u>	<u>B7196D</u>
Virus Control	NA	NA	10% Serum	NA	7.67	7.67
Virus + Non-Virucidal Disinfectant	20-25°C	10 Minutes	"	"	6.50	6.50
Virus + Disinfectant	20-25°C	10 Minutes	"	None	3.50	3.50
Toxicity Control	NA	NA	NA	"	3.50	3.50
Log Reduction	20-25°C	10 Minutes	10% Serum	"	3.00	3.00

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).

7-5-88

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)".