US EPA ARCHIVE DOCUMENT

8-16-89

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

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

Srinivas Gowda 8/24/89

Reviewed By Srinivas Gowda Date 08/16/89

EPA Reg. No. or File Symbol 777-32

EPA Petition or EUP No. None

Date Division Received 01-30-89

Type Product(s): General Disinfectant Spray

MRID No(s) 409810-01

Product Mgr. No. 31 (Lee)

Product Name(s) Lysol® Brand Foaming Disinfectant Basin Tub & Tile Cleaner (Aerosol)

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 pressurized aerosol spray

Active Ingredient (s): %

Alkyl (67% C_{12}, 25% C_{14}, 7% C_{16}, 1% C_{18}, $-C_{10}$, $-C_{18}$) dimethyl benzyl ammonium chlorides.....0.08

Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chlorides.....0.02

200.00 Introduction

200.1 Use (s)

Refer to the most recently accepted labeling dated 04-28-87 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 A_2 (Japan), and Herpes Simplex Type 2 in the presence of moderate amount of organic soil (5% blood serum) when used as directed on the label as a disinfectant for a contact time of 10 minutes at room temperature (no-reuse).

201.0 Data Summary

201.1 Brief Description of Test (MRID 409810-01)

"Virucidal Efficacy of Lysol Basin, Tub, and Tile Cleaner" Project No. 6470 by Bonnie J. Bowdon, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, Alabama, 35255, dated 07-12-88.

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 ($HTLV\text{-}III_{RF}$).

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 cm^2 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: Dried virus films were sprayed with disinfectant until wet allowed to remain in contact for a total exposure period of 10 minutes at approximately 23°C. After exposure, the volume of fluid in the dish was adjusted to 2.0 ml with PBS, the bottom of the dish was scraped with a rubber policeman, and an aliquot of virus-disinfectant mixture was immediately added to a Sephadex column for separation of virus from disinfectant by gel filtration (10 minutes exposure in plate + 3 minutes centrifugation in Sepahdex gel filter).

e. Test Samples: Lysol Basin, Tub and Tile Cleaner

Batch Nos. IL18063 and B8054N

Manufacturing Dates: Not listed.

Date Sample Received: 05-12-88.

Test Dates: 05-23-88 to 03-31-88.

f. Use-Dilution: None.

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

i. Results:

	Disinfectant Exposure				ID-50/LD-50 (-Log 10	
Test Sample	Temperature	Time	Organic Soil	Hard Water	IL18063	B8054N
Virus Control	NA	NA	10% Serum	NA	7.00	7.00
Virus + Non-Virucidal Disinfectant	20-25°C	13 Minutes	"	"	6.0	6.0
Virus + Disinfectant	20-25°C	13 Minute	"	None	2.5	2.5
Toxicity Control	NA	NA	NA	"	2.5	2.5
Log Reduction	20-25°C	13 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 as an undiluted pressurized spray for a contact time of 13 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 777-32

Date Division Received 01-30-89

MRID No.(s). 409810-01

Product Manager No. PM-31 (Lee)

Product Name(s) Lysol® Brand Foaming Disinfectant Basin Tub & Tile Cleaner (Aerosol)

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) when used undiluted (pressurized spray) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (10% blood serum) for a contact time of 13 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. Include 13 minute contact time for disinfection against HIV-1 (AIDS virus).

c. 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.

d. Also, refer to the attached Federal Register Notice for clarification of HIV (AIDS virus) labeling policy for antimicrobial pesticide products.

e. Change "Herpes Simplex type 1" to read "Herpes Simplex Type 2".

f. Include major areas in which the product is recommended for use (e.g. homes, schools).