

US EPA ARCHIVE DOCUMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
ANTIMICROBIAL PROGRAM BRANCH
EFFICACY REVIEW - FORM 1

Date RD Received: 6 December 93 Review Start Date: 23 Dec 93

Date EPA Received: 7 October 93

Project Return Date: 5 May 94 Review Completion Date: 3 Jan 94

Reviewed by: *Michele E. Wingfield* Date: *3 Jan 94*

EPA Reg. No. or File Symbol: *777-IG*

EPA Petition or EUP No.: None

Product Type: Hospital Disinfectant

MRID No(s): 429599-07 thru 429599-12

Product Manager & Team No.: Ruth Douglas-32

Product Name: Lysol Brand Disinfectant Bleach Plus

Company Name: L and F Products

Submission Purpose: Me-Too with additional uses

Product Formulation: Liquid to be diluted for use.

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
Sodium Hypochlorite	2.0

200.0 INTRODUCTION

200.1 USE(S):

The proposed product, Lysol Brand Disinfectant Bleach Plus EPA Reg# 777-IG, is a "one-step" hospital disinfectant cleaner. Refer to the attached labeling for specific uses.

200.2 BACKGROUND INFORMATION

The submission is a Me-Too application with additional uses. Efficacy data in support of label claims is included.

201.0 DATA SUMMARY

201.1 BRIEF DESCRIPTION OF TESTS

MRID# 429599-07 AND 429599-08
AOAC Use-Dilution Test, AOAC Index, 15th Ed., 1990.
Performed at L & F Products Microbiology Laboratory, 1
Philips Parkway, Montvale, NJ 07645. Submitted by Bruce
Paoletta and Joseph Rubino, dated September 8, 1993.

MRID# 429599-09
AOAC Fungicidal Activity of Disinfectants, AOAC Index,
15th Ed., 1990. Submitted by Bruce Paoletta and Joseph
Rubino, L & F Products Microbiology Laboratory, dated
September 8, 1993.

MRID# 429599-10 and 429599-11
Virucidal Efficacy of Disinfectants
Submitted by Timothy M. Cusack, L&F Products Virology
Laboratory, dated June 11, 1993.

MRID# 429599-12
Virucidal Efficacy of Disinfectants
Submitted by Bonnie J. Bowden, Southern Research
Institute, 2000 Ninth Avenue South, Birmingham, Alabama
352255. Dated June 8, 1993

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration No.: 777-IG

Date EPA Received: 7 October 93

Date RD Received: 6 December 93

Project Return Date: 5 May 94

Review Start Date: 23 December 93

Review Completion Date: 3 January 94

MRID No(s): 429599-07 thru 429599-12

Product Manager & Team No.: Ruth Douglas-32

Product Name: Lysol Brand Disinfectant Bleach Plus

Company Name: L & F Products

202.0 **RECOMMENDATIONS**

202.1 **EFFICACY SUPPORTED BY THE DATA**

a. The submitted data supports the effectiveness of the product as a hospital and/or general use disinfectant against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Streptococcus faecalis, when used at a dilution of 1:50, in the presence of organic soil (5% horse serum), on hard, non-porous, inanimate surfaces for a contact time of 5 minutes at 20±1°C.

b. The submitted data also supports the effectiveness of the product as a fungicide (pathogenic fungi) against Trichophyton mentagrophytes for the appropriate use areas under the above stated conditions.

c. The submitted data also supports the effectiveness of the product as a virucide against Herpes Simplex Type 1, Herpes Simplex Type 2, and the Human Immunodeficiency Virus Type 1 (HIV-1/AIDS Virus), when used at a dilution of 1:50, in the presence of organic soil, on pre-cleaned, hard, non-porous, inanimate surfaces for a contact time of 5 minutes at ambient temperature (≈26-28°C).

However, additional data/information is needed to complete the review. Refer to 202.3

202.2 **EFFICACY NOT SUPPORTED BY THE DATA**

No efficacy data was submitted to support the claim for Respiratory Syncytial Virus.

202.2 **CLAIMS NOT RELATED TO HUMAN HEALTH**

a. The submitted data against Aspergillus niger to support efficacy as a fungistat is not directly related to human health. Therefore, under the efficacy data waiver, such data are not required to be submitted or reviewed.

202.3 **ADDITIONAL DATA/INFORMATION REQUIRED TO SUPPORT EFFICACY**

1. Conclusion on page 7 of MRID# 429599-10 states a 10 minute contact time for the assay. Verify contact time of 5 minutes.

203.0

LABELING

FRONT LABEL

- a. Change "All Purpose Cleaner with Bleach...." to "Multipurpose Cleaner with Bleach...."
- b. Change "Meets AOAC efficacy standard...." to read "Meets AOAC Use-Dilution Test efficacy standards....".

BACK LABEL

- a. Under "DIRECTIONS FOR USE" change "Spray on surface and let stand 5 minutes." to read "Spray on surface until thoroughly wet and let stand 5 minutes."
- b. Under "DIRECTIONS FOR USE" revise statement "Kills staph...HIV/AIDS (Human Immunodeficiency Virus)." to read "Kills staph...HIV/AIDS (Human Immunodeficiency Virus), on pre-cleaned, hard, non-porous, inanimate surfaces."
- c. Delete virucidal claim against Respiratory Syncytial Virus, or submit data to support the claim.
- d. List the major area(s) in which the product is recommended for use and the type of surfaces, objects, or items intended for treatment. Refer to items 1 and 2 of the DIS/TSS-15 enclosure.