

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date RD Received: 6 December 93 Review Start Date: 23 Dec 93Date EPA Received: 7 October 93Project Return Date: 5 May 94 Review Completion Date: 3 Jan 94Reviewed by: Michele E. Wingfield Date: 3 Jan 94EPA Reg. No. or File Symbol: 777-IGEPA Petition or EUP No.: NoneProduct Type: Hospital DisinfectantMRID No(s): 429599-07 thru 429599-12Product Manager & Team No.: Ruth Douglas-32Product Name: Lysol Brand Disinfectant Bleach PlusCompany Name: L and F ProductsSubmission Purpose: Me-Too with additional usesProduct Formulation: Liquid to be diluted for use.**ACTIVE INGREDIENT(S)**

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 35225. Dated June 8, 1993

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

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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.