10-19-88

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 08/17/88 OUT 10/12/88

Srinivas Gowda 10/19/88

Reviewed By Srinivas Gowda Date 10-12-88

EPA Reg. No. or File Symbol 5813-EU

EPA Petition or EUP NO. None

Date Division Received 08-16-88

Type Product Hospital/General Disinfectant

MRID Number 406149-05

Product Manager 32 (Kempter)

Product Name Tilex

Company Name The Chlorax Company

Submission Purpose Resubmission with requested efficacy data

Type Formulation Non-pressurized spray (undiluted) and liquid concentrate diluted for use

Active Ingredient(s): %

Sodium hypochlorite.....2.0

200.0 Introduction

200.1 Uses

Proposed labels are attached.

200.2 Background Information

Refer to the previous review for this product by EETM, APB, RD, dated 12-04-85. The current submission consists of additional efficacy data, in response to the difficiencies cited in the previous review.

201.0 Data Summary

201.2 Brief Description of Test

Bactericidal, Fungicidal, and Mildewstat Test Reports by Barbara Colina, Linda Hargis and Gayle Mulberry, Hill Top Research, Inc., Miamiville, Ohio 45147, dated 03-29-88 (MRID No. 406149-05).

201.3 Test Summaries

a. Bactericidal Test

1. Method: Modified A.O.A.C. Use-dilution Method

2. Modifications: 5% Horse Serum (soil load) was incorporated in the inoculum.

3. Samples:

Batch No.	Mfg. Dates	Test Dates
M-1367, 2004.31.5	Not listed	06-03 to 06-05-83
M-1367, 2004.41-1	"	"
*M-1407, 8/23/83	08-23-86	08-30 to 09-01-83

*60 days old.

4. Dilution: 1:17

5. Exposure: 5 minutes at 20°C

6. Subculture Medium/ Neutralizer:

Fluid Thioglycollate Medium USP XX

7. Incubation of Subcultures: 48 hours at 37°C

8.

Test Bacteria	ATCC No.	Phenol Res
Staphylococcus aureus	6538	1:60

9. Survival of Inoculum on Control Carriers After Drying:

Test Organism	Count per carrier
S. aureus	2.8×10^6 to 4.1×10^6

10. Test Results

Test Organism	Batch No.	# Carriers Tested	# Positives/ Total Carriers	
			Primary	Secondary
S. aureus	M-1367, 2004.31-5	60	0/60	1/60
	M-1367, 2004.41-1	60	1/60	0/60
	M-1407, 8/23/83	60	1/60	1/60

11. Conclusions: Satisfactory performance vs test bacteria at a 1:17 dilution, in the presence of 5% blood serum at a contact time of 5 minutes.

RIN 3724-95

EFFICACY REVIEW FOR EPA REG. NO. 5813-24

Page____ is not included in this copy.

Pages 4 through 6 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

✓ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-II

Antimicrobial Program Branch

EPA Petition or File Symbol	5813-EU
Date Division Received	08-16-88
MRID Number	406149-05
Product Manager	32 (Kempter)
Product Name	Tilex
Company Name	The Chlorax Company

202.0 Recommendations

202.1 Efficacy Supported By The Data

a. The submitted data developed by the AOAC Germicidal Spray products Test support efficacy of the subject product as a one-step disinfectant-cleaner in both medical and non-medical use areas when applied undiluted in a non-pressurized spraying device to thoroughly wet hard, non-porous surfaces having a moderate organic soil load for a 1-minute contact time.

These data also support efficacy claims against the following infectious microorganisms when the product is used as indicated above:

Salmonella choleraesuis
Staphylococcus aureus
Pseudomonas aeruginosa
Streptococcus pyogenes
Trichophyton metagrophytes

b. The submitted data developed by the AOAC Use Dilution Test support efficacy of the subject product as a one-step general disinfectant-cleaner (against Gram-positive and Gram-negative bacteria) in non-medical use areas when applied at a 1:17 dilution to thoroughly wet, hard, non-porous surface having a moderate organic soil load for a 5-minute contact time.

202.2 Non-Health-Related Uses

Efficacy claims to control mildew are considered to have aesthetic significance not directly related to human health do not require supporting efficacy data as explained in the DIS/TSS-16 enclosure.

203.0 Labelling

To provide adequate label directions to disinfect hard, non-porous surfaces, the following revisions are required:

a. Removal of gross filth and heavy soil deposits prior to application of the product for disinfecting.

b. Identification of the hard, non-porous surfaces recommended for disinfection.

c. Application of the undiluted product by spraying or with a sponge until the surfaces are thoroughly wet.

d. Identification of the recommended use areas (e.g. homes, schools, motels).

e. Additional data demonstrating product efficacy at a 1:17 dilution in the presence of 5% blood serum in 5 minutes against Pseudomonas aeruginosa would be required if usage of this product is recommended in hospital and other medical use areas.