

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

ANTIMICROBIAL PROGRAM BRANCH

Date RD Received 07-12-90 Review Start Date 08-13-90

Project Return Date 08-23-90 Review Completion Date 08-13-90

Reviewed by Arnold E. Layne *Arnold E. Layne* ^{WEG} _{8/11/90} Date 08-13-90

EPA Reg. No. or File Symbol 9367-UL

EPA Petition or EUP No. NONE

Date EPA Received 05-22-90

Type Product(s) LIMITED DISINFECTANT

MRID No(s) 415446-02

Product Mgr. No. 31 (LEE)

Product Name MINT-O

Company Name(s) Theochem Laboratories, Inc.

Submission Purpose New application.

Type Formulation Liquid to be used diluted.

Active Ingredient(s) 8

Alkyl (C145%, C1628%, C1214%) dimethyl
benzyl ammonium chlorides.....1.00

200.0 Introduction

200.1 Use(s):

The proposed product, Mint-O, is a disinfectant and deodorant for use in restrooms, locker rooms, kitchens, and waste receptacles.

200.2 Background Information

The submission received by RD on 7-12-90 is a new application with efficacy data and proposed product labeling.

201.0 Data Summary MRID #415446-02

Data report dated 10-3-89 was prepared by Paul H. Clarke of Stepan Company. Other data reports, dated 03-14-89, were prepared by Nina L. Crossley and Mark R. Entrup of Hilltop Biolabs, Inc.

201.1 Brief Description of Tests

- a. Disinfection: A.O.A.C. Use Dilution Test, 14th Ed., Chapter 4, 1984.
- b. Disinfection: A.O.A.C. Use Dilution Method, 14th Ed., Chapter 4, 1984.

201.2 Test Summaries

- a. Disinfection: MRID #415446-02

1. Method: AOAC Use Dilution Test

2. Modification: Inoculum contained 5% horse serum as the organic soil load. All dilutions were prepared in sterile deionized water.

3. Dilution: 6 ounces per gallon

4. Samples:

<u>Batch</u>	<u>Test Dates</u>	<u>Date Prepared</u>
092288*	7-20-89	9-22-88
120188	8-03-89	12-01-88
022289	8-04-89	2-22-89

*represents 60 day old sample

5. Test Organism:

Salmonella choleraesuis ATCC #10708 Phenol Res.: 1:90

6. Exposure: 10 minutes at 20°C.

7. Subculture: Lethen broth

8. Incubation: 48 hours at 37°C.

9. Results:

<u>Batch</u>	<u># Positive/Total Carriers</u>
092288	0/60
120188	0/60
022289	0/60

All control carrier survival studies were $\geq 1.2 \times 10^6$ org.

10. Conclusion: The results show adequate performance of the product against Salmonella choleraesuis.

b. Disinfection: MRID #415446-02

1. Method: AOAC Use Dilution Method

2. Modification: None

3. Dilution: 6 ounces/gallon (1:21.33 v/v)

4. Samples:

<u>Batch</u>	<u>Test Date</u>	<u>Date Prepared</u>
120188	2-23-89	1-17-89
120188	3-02-89	1-17-89

5. Test Bacteria: Salmonella choleraesuis
ATCC #10708 Phenol Res.: 1:90

6. Exposure: 10 minutes at 20°C.

7. Subculture: Lethen broth

8. Incubation: 48 hours at 37°C.

9. Results:

<u>Batch</u>	<u># Positive/Total Carriers</u>
120188	0/10
120188	0/50

10. Conclusion:

Results indicate adequate performance of the product against Salmonella choleraesuis.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW FORM - II

Antimicrobial Program Branch

EPA Reg. No. 9367-UL

Date EPA Received 05-22-90

Date RD Received 07-12-90

Project Return Date 08-23-90

Review Start Date 08-13-90

Review Completion Date 08-13-90

MRID No(s). 415446-02

Product Manager No. 31 (LEE)

Product Name(s) MINT-O

Company Name Theochem Laboratories, Inc.

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data (MRID #415446-02) supports the effectiveness of the product, diluted 6 ounces per gallon, as a limited disinfectant against Salmonella choleraesuis, when tested in the presence of 5% serum on hard, non-porous inanimate surfaces for a contact time of 10 minutes.

203.0 Labeling

1. Revise "This product is designed as a disinfectant deodorant..." to read "This product is designed as a limited disinfectant deodorant against gram negative bacteria..."
2. Revise "GENERAL DISINFECTANT" to read "LIMITED DISINFECTANT".