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 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)  
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:**

<table>
<thead>
<tr>
<th>Batch</th>
<th>Test Dates</th>
<th>Date Prepared</th>
</tr>
</thead>
<tbody>
<tr>
<td>092288*</td>
<td>7-20-89</td>
<td>9-22-88</td>
</tr>
<tr>
<td>120188</td>
<td>8-03-89</td>
<td>12-01-88</td>
</tr>
<tr>
<td>022289</td>
<td>8-04-89</td>
<td>2-22-89</td>
</tr>
</tbody>
</table>

*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: Letheen broth

8. Incubation: 48 hours at 37°C.

9. Results:

<table>
<thead>
<tr>
<th>Batch</th>
<th># Positive/Total Carriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>092288</td>
<td>0/60</td>
</tr>
<tr>
<td>120188</td>
<td>0/60</td>
</tr>
<tr>
<td>022289</td>
<td>0/60</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Batch</th>
<th>Test Date</th>
<th>Date Prepared</th>
</tr>
</thead>
<tbody>
<tr>
<td>120188</td>
<td>2-23-89</td>
<td>1-17-89</td>
</tr>
<tr>
<td>120188</td>
<td>3-02-89</td>
<td>1-17-89</td>
</tr>
</tbody>
</table>

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

6. Exposure: 10 minutes at 20°C.

7. Subculture: Letheen broth

8. Incubation: 48 hours at 37°C.

9. Results:

<table>
<thead>
<tr>
<th>Batch</th>
<th># Positive/Total Carriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>120188</td>
<td>0/10</td>
</tr>
<tr>
<td>120188</td>
<td>0/50</td>
</tr>
</tbody>
</table>
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".