Reviewed by Srinivas Gowda Date 06/08/94

EPA Reg. No. or File Symbol 44486-15 (106-79)

EPA Petition or EUP No. None

Date Division Received 05-02-93

Type Product Hospital Disinfectant

MRID No (s) None

Product Manager PM 31 (Lee)

Product Name Broadspec 256 Germicidal Detergent

Company Name Brulin and Company, Inc.

Submission Purpose Review of AOAC Tuberculocidal Test data from EMSL [EMSL Sample Nos. 92-0877 (Lot No. UD120) and 92-0878 (Lot No. UD122)]

Type Formulation Liquid concentrate to be used diluted

Active Ingredient (s):

n-Alkyl (C14, 50%; C12, 40%; C16, 10%)
  dimethyl benzyl ammonium chloride ....................... 5.36

Octyl decyl dimethyl ammonium chloride ................... 4.02

Didecyl demethyl ammonium chloride ..................... 2.71

Diocetyl dimethyl ammonium chloride .................... 2.01
200.0  **Introduction**

200.1  **Uses:**

Refer to the last accepted label dated Nov. 6, 1990.

200.2  **Background Information:**

The submission received 05-02-94, is for review of EMSL's AOAC Tuberculocidal Test data developed under the (post-registration testing) contract at a 1:256 dilution in the presence of 200 ppm CaCO₃ hard water for a contact time of 10 minutes at 20°C.

201.0  **Data Summary**

201.2  **Brief Description of Test:**

AOAC Use-Dilution Test results by Terry C. Covert, Microbiologist, Bacteriology Branch, Environmental Monitoring systems Laboratory, Cincinnati, Ohio 45268, dated April 26, 1994.

201.3  **Test Summaries**

**AOAC Tuberculocidal Test**


**Modifications:** 1:256 dilution was made in 200 ppm CaCO₃ hard water.

5% fetal bovine serum was incorporated into the culture suspensions.

**Samples:**

<table>
<thead>
<tr>
<th>EMSL Sample Number</th>
<th>Date Diluted</th>
<th>Date Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>92-0877 (Lot UD120)</td>
<td>11-05-93</td>
<td>11-05-93</td>
</tr>
<tr>
<td>92-0878 (Lot UD122)</td>
<td>11-05-93</td>
<td>11-05-93</td>
</tr>
</tbody>
</table>

**Dilution:** 1:256 in 200 ppm CaCO₃ hard water

**Exposure:** 10 minutes at 20°C.
Subculture Medium/Neutralizer:

Modified Proskauer-Beck Medium
Middlebrook 7H9 Broth
Kirchner's Medium
TB Broth
Lethene Neutralizer Blanks

Incubation of subcultures: 90 days at 37°C.

Test Organisms

Mycobacterium bovis (BCG) Organon Teknika

Carriers Tested: Porcelain penicylinders.

Test Results:

<table>
<thead>
<tr>
<th>EMSL Sample No.</th>
<th>Dilution Tested</th>
<th>Water Hardness</th>
<th>No. Positives/Total Carriers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MPBM</td>
<td>M7H9B</td>
<td>KB</td>
</tr>
<tr>
<td>92-0877</td>
<td>1:256</td>
<td>200</td>
<td>10/10</td>
</tr>
<tr>
<td>92-0878</td>
<td>1:256</td>
<td>200</td>
<td>9/10</td>
</tr>
<tr>
<td>Phenol</td>
<td>(1+50)</td>
<td>(1+75)</td>
<td>0/10</td>
</tr>
</tbody>
</table>

Conclusions:

The submitted data on EMSL Sample Nos. 92-0877 (Lot No. UD120) and 92-0878 (Lot No. UD122) by the AOAC Tuberculocidal Test Method demonstrate ineffectiveness of the product as a tuberculocide against Mycobacterium bovis (BCG) when tested at a 1:256 dilution in the presence of 200 ppm CaCO₃ hard water for a contact time of 10 minutes at 20°C.
EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 44486-15
EPA Petition or EUP No. None
Date Division Received 05-02-93
Type Product Hospital Disinfectant
MRID No (s) None
Product Manager PM 31 (Lee)
Product Name Broadspec 256 Germicidal Detergent
Company Name Brulin and Company, Inc.
Recommendations

Efficacy Not Supported By The Data:

AOAC Tuberculocidal Test

The submitted data on EMSL Sample Nos. 92-0877 (Lot No. UD120) and 92-0878 (Lot No. UD122) by the AOAC Tuberculocidal Test Method demonstrate ineffectiveness of the product as a tuberculocide against Mycobacterium bovis (BCG) when tested at a 1:256 dilution in the presence of 200 ppm CaCO₃ hard water for a contact time of 10 minutes at 20°C.