

US EPA ARCHIVE DOCUMENT

6-8-94

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 05/16/94 OUT 06/08/94

Srinivas Gowda

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 (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 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

Method: AOAC Tuberculocidal Activity of Disinfectants, Confirmative In Vitro Test for Determining Tuberculocidal Activity, 15th Edition, 1990, Chapter 6.

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

5% fetal bovine serum was incorporated in to the culture suspensions.

Samples:

<u>EMSL Sample Number</u>	<u>Date Diluted</u>	<u>Date Tested</u>
92-0877 (Lot UD120)	11-05-93	11-05-93
92-0878 (Lot UD122)	11-05-93	11-05-93

Dilution: 1:256 in 200 ppm CaCO₃hard water

Exposure: 10 minutes at 20°C.

Subculture Medium/Neutralizer:

Modified Proskauer-Beck Medium

Middlebrook 7H9 Broth

Kirchners Medium

TB Broth

Lethen Neutralizer Blanks

Incubation of subcultures: 90 days at 37°C.

Test Organisms

ATCC No.

Mycobacterium bovis (BCG)

Organon Teknika

Carriers Tested: Porcelain penicylinders.

Test Results:

<u>EMSL Sample No.</u>	<u>Dilution Tested</u>	<u>Water Hardness</u>	<u>No. Positives/ Total Carriers</u>			
			<u>MPBM</u>	<u>M7H9B</u>	<u>KB</u>	<u>TBBB</u>
92-0877	1:256	200	10/10	0/10	9/10	NA
92-0878	1:256	200	9/10	0/10	5/10	NA
Phenol	(1+50)		0/10	0/10	0/10	0/10
	(1+75)		0/10	2/10	0/10	0/10

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.

202.0 Recommendations

202.1 **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.