

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<sub>14</sub>, 50%; C<sub>12</sub>, 40%; C<sub>16</sub>, 10%)  
dimethyl benzyl ammonium chloride.....5.36  
Octyl decyl dimethyl ammonium chloride.....4.02  
Didecyl demethyl ammonium chloride.....2.71  
Dioctyl 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 CaCO<sub>3</sub> 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 CaCO<sub>3</sub> 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 CaCO<sub>3</sub>hard 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 CaCO<sub>3</sub> hard water for a contact time of 10 minutes at 20°C.

BroadSpec 250 is a "one-step" concentrated multi-purpose germicidal detergent effective in hard waters up to 400 ppm hard water (calculated as  $\text{CaCO}_3$ ) in the presence of 5% organic serum. The activity of BroadSpec 250 has been evaluated by the current A.O.A.C. use dilution test and found to be effective against the following pathogenic organisms:

*Mycobacterium tuberculosis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
     phage type 80  
*Salmonella* (part)  
*Staphylococcus aureus*  
     phage type 478/82/81  
*Stenotrophomonas maltophilia*  
*Streptococcus pyogenes*  
*Enterobacter cloacae*  
*Klebsiella pneumoniae*  
*Proteus mirabilis*

- *Streptococcus pneumoniae*
- *Streptococcus aureus*
- *Multidrug-resistant*
- *Resistant Clinical Isolates*
- *MRSA (Methicillin-resistant)*
- *Acinetobacter Type 3*
- *Enterobacter Type 4*
- *Enterobacter Type 5*
- *Enterobacter Type 6*
- *Enterobacter Type 7*
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[illegible]

phage type 31  
*Staphylococcus epidermidis*  
*Enterobacter aerogenes*  
*Escherichia coli*  
*Serratia marcescens*  
*Proteus vulgaris*  
*Streptococcus*  
*Gaermonia* (coliform)  
*Techniphan* (aerobic)  
*Candida albicans*  
*Aspergillus niger*

[illegible]

**PELEHENTI**

DAL PSEUDOMONAS DAL  
NIGRODAL.

E.298 .....  
405 .....  
E.71 .....  
F.01 .....  
G.00 .....  
G.00 .....

**KEEP OUT OF REACH** of children. Apply solution to the clean surface to be cleaned for 5 minutes. Remove dirt and residue with damp product. Do not

\*KIDNEY, HEART, AND PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD OR BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects are likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (asealed with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES  
CONTACTED WITH BLOOD/BODY FLUIDS:**

**PERSONAL PROTECTION:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Biorespec 2S-B. This pre-cleaning may be accomplished with any cleaning solution includ-

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of by prospect 28a.

CONTACT TIME: Leave surfaces wet for 4 minutes. This contact time will not control other common types of bacteria and viruses.

Not Contents

RECEIVED  
JAN 11 1960  
U.S. DEPT. OF AGRICULTURE  
WASHINGTON, D.C. 20250  
OFFICE OF THE SECRETARY  
Agriculture  
1000  
66-15

**PROHIBITIONS:** Do not use empty containers of PESTICIDE DISPOSAL or make a makeshift or flammable or volatile. Do not use your State Pesticide Regulation Office for a COMPLAINT DISPOSAL, or purchase and use it burned, away out of the burner, away out of the burner, away out of the burner.

106-79  
EPA Reg No.  
4  
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Notes:

- 1. *Staphylococcus aureus* phage type 81
- 2. *Staphylococcus epidermidis*
- 3. *Enterobacter aerogenes*
- 4. *Escherichia coli*
- 5. *Stenotrophomonas maltophilia*
- 6. *Proteus vulgaris*
- 7. *Shigella sonnei*
- 8. *Salmonella enteritidis*
- 9. *Brucella abortus*
- 10. *Candida albicans*
- 11. *Aspergillus niger*

**TYPE 1:**  
is PREVIOUSLY SOILED WITH  
is an expected likelihood of soil-  
surface/object likely to be soiled  
of human immunodeficiency virus

**GARIST HAV-1 OF SURFACES:**  
1) handling items soiled with blood  
learned from surfaces and objects  
with any cleaning solution. Insti-  
d be autoclaved and disposed of  
control other common types of

**BROADSPEC™ 256**  
**GERMICIDAL DETERGENT**

TUBERCULOCOCAL, STYPHYLOCOCAL, PSEUDOMONACOCAL  
VIRUCIDAL - TUBACIDAL

**ACTIVE INGREDIENTS**

diethyl benzyl ammonium chloride	6,500
Diethyl benzyl ammonium chloride	4,025
Diethyl dimethyl ammonium chloride	2,715
Diethyl dimethyl ammonium chloride	2,01
METHANOL	85,80

...ONE HALF OUNCE PER GALLON  
DILUTION: 1 to 250...

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

also from Paul M. Addison, Laboratory Supervisor  
EPA Reg. No. 4446-18 EPA Lab. No. 4446-18-1

ACCEPTED  
with COMMENTS  
J. EPA Field Office  
Not Comments

NOV 6 1980

44486-15

✓ **CHRYSLER LABORATORIES, INC.**  
FEDERAL BUREAU OF INVESTIGATION  
219 MILLER ST., 10th Fl.  
NEW YORK 17, N.Y.

# DRUGS FOR USE

**USE:** Floors, walls, mirrors, glass, metal surfaces, nonporous solid surfaces, linoleum, enamel, painted surfaces, decorative toppings, painted surfaces, exterior door surfaces, ceilings, instruments, showers, and linens. **CAUTION:** For institutional use only, such as hospitals and nursing homes, schools and colleges, medical and dental offices, and veterinary clinics.

**CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES:** Add one-half ounce of 2-Ble solution to each gallon of water used. Scrub and Broad-Spec 2-Ble is premeasured water. Dilute only for 1. Use solution. Apply solution by normal methods, with brush, mechanical spray device, sponge, cloth or mop. The surface to be cleaned, then remove excess solution with wiping out applicator. Insured surfaces should remain ten minutes. Remove gross film mechanically by sweeping before cleaning begins. Diluted solution then 1. Use daily and replace with fresh solution. Rinsing is not necessary unless floors are to be waxed. Broad-Spec 2-Ble is a stable product. Do not add other chemicals. Use Only as directed.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
**DANGER**

## Precautionary Statements

**KEEP OUT OF REACH OF CHILDREN. Caution:** Causes eye and skin irritation. Do not get in eyes, on skin or on clothes. Wear goggles or face shield and rubber gloves when handling. Remove and wash contaminated clothing before re-use. Harmful if swallowed. Avoid contamination of food, water or feed.

**Call a physician immediately.**

NOTE TO PHYSICIAN: Probable maximum damage may contraindicate the use of gastric lavage.

## FINANCIAL AND BIOLOGICAL

PROHIBITED: DO NOT CONSUME water, food or feed by storage or disposal. Open dumping is prohibited. Do not use empty container.

or the waste is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Response Institute at the nearest Regional Office for guidance.

**CONTAINER DISPOSAL — PLASTIC CONTAINER:** Triple size (or equivalent) than other for recycling or second use.

Q. What is the purpose of the proposed alternative procedure?

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EPA-709 N.  
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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 CaCO<sub>3</sub> hard water for a contact time of 10 minutes at 20°C.