

PM-31

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AUG 25 1995

Brulin & Company, Inc.
2920 Dr. Andrew J. Brown Avenue
P.O. Box 270
Indianapolis, IN 42606

Attention: Berma Zootman
Compliance/Regulatory Affairs Manager

Subject: Broadspec 256
EPA Registration No. 106-79
MOU Compliance Amendment dated October 18, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended will be acceptable provided that you make the labeling change listed below before you release the product for shipping bearing the amended label.

1. Revise the microorganism Trichophyton interdigitale to read Trichophyton mentagrophytes everywhere it appears on the label.

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

BROADSPEC 256

GERMICIDAL DETERGENT

STAPHYLOCIDAL PSEUDOMONACIDAL
VIRUCIDAL* FUNGICIDAL MILDEWCIDAL

ACTIVE INGREDIENTS:

Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	5.36%
Octyl decyl dimethyl ammonium chloride	4.02%
Didecyl dimethyl ammonium chloride	2.71%
Dioctyl dimethyl ammonium chloride	2.01%
INERT INGREDIENTS:	<u>85.90%</u>
TOTAL	100.00%

DILUTION: 1 TO 256 . . . ONE-HALF OUNCE PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER

See Side Panel for Statement of Practical Treatment and Additional Precautionary Statements

EPA Reg. No. 106-79

EPA Est. No. 106-IN-1

NET CONTENTS 1 U.S. GALLON

Manufactured and Sold By:
BRULIN & COMPANY, INC.
HOME OFFICE/PLANT: P.O. Box 270 Indianapolis, IN 46206-0270
1-800-776-7149

INDIANAPOLIS IN TAMPA FL RICHMOND CA

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 25 1995

79-C-REV

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

106-79

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BROADSPEC 256 is a "one-step" concentrated multi purpose germicidal detergent effective in hard waters up to 400 ppm hard water (calculated as CaCO₃) in the presence of 5% organic serum. The activity of **BROADSPEC 256** has been evaluated by the current AOAC use dilution test and found to be effective against the following pathogenic organisms:

Pseudomonas aeruginosa
Staphylococcus aureus
phage type 80
Salmonella typhi
Staphylococcus aureus
phage type 42B/52/81
Salmonella choleraesuis
Streptococcus pyogenes
Enterobacter cloacae
Klebsiella pneumoniae
Proteus mirabilis
Shigella flexneri

Brevibacterium ammoniagenes
Staphylococcus aureus (MRSA)
Multiply (Methicillin)
Resistant Clinical Isolate
* HIV-1 (AIDS Virus)
* Adenovirus Type 2
* Herpes Simplex Type 1
* Influenza Type A/Mich.
* Vaccinia
* Adenovirus Type 4
* Herpes Simplex Type 2
* Rubella

* Avian Infectious Bronchitis
* Avian Influenza A/Mich
* Canine Parvovirus
* Bovine Parvovirus
* Infectious Bovine Rhinotracheitis
* Canine Distemper
* Feline Leukemia
* Feline Picornavirus
Streptococcus faecalis
Staphylococcus aureus
Shigella dysenteria

Staphylococcus aureus
phage type 81
Staphylococcus epidermidis
Enterobacter aerogenes
Escherichia coli
Serratia marcescens
Proteus vulgaris
Shigella sonnei
Salmonella schottmuelteri
Trichophyton interdigitale
Candida albicans
Aspergillus niger
Poliovirus Type 1

***Kills HIV-1 on PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/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 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)(associated with AIDS).

STATEMENT OF PRACTICAL TREATMENT

In case of skin contact, wash thoroughly with soap and water. **In case of eye contact**, immediately flush eyes with water for 15 minutes and get prompt medical attention. **If swallowed**, drink promptly a large quantity of egg whites, or gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

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

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

DANGER. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Avoid contamination of food, water or feed.

Wear 106 79

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

USE: Floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, exterior bowl surfaces, empty basins, non-critical medical devices, hair/nail care instruments, showers, and lavatory fixtures. For institutional and commercial use only such as hospitals and nursing homes, schools and colleges, medical and dental offices, barber/beauty shops, and veterinary clinics.

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that 1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or 2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enters normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

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CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES:

Add one-half ounce of **BROADSPEC 256** to each gallon of water used. Always add **BROADSPEC 256** to premeasured water. Gently mix for a uniform solution. Apply solution by normal methods with brush, coarse spray devices, sponge, cloth, mop, or immersion. Thoroughly wet all surfaces to be cleaned. Treated surfaces should remain wet for 10 minutes. Remove gross soil mechanically before cleaning begins. Discard solution when it becomes dirty and replace with fresh solution. Rinsing is not necessary unless floors are to be waxed. **BROADSPEC 256** is a complete product. Do not add other chemicals. Use only as directed.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 SURFACES/OBJECTS SOILED 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 **BROADSPEC 256**. This pre-cleaning may be accomplished with any cleaning solution including **BROADSPEC 256**.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

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

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate 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 Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL - PLASTIC CONTAINER: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed, by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL: Consult federal, state or local disposal authorities for approved alternate procedures.

4 October 1994

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