

Brulin & Company
P.O. Box 270
Indianapolis, IN 46206-0270

MAY 25 2000

Subject: Broadspec 256
EPA Registration No. 106-79
Amendment Dated December 1, 1999

Attn: Berma L. Johnson
Compliance/Regulatory Affairs Manager

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. The subject product "Broadspec 256" (EPA Reg. No. 106-79) is a registered product seeking an amendment to their label for use to clean and disinfectant non-medical respirators in industrial, commercial and institutional premises. Broadspec 256 is registered as 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 proposed label changes are acceptable. Submit one(1) copy of the final printed label before this product is released for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL	7510W						
SURNAME	Z. Jones						
DATE	5-23-2000						

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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.
* Infectious Bovine Rhinotracheitis
* Canine Distemper
* Feline Leukemia
* Feline Picornavirus
Streptococcus faecalis
Staphylococcus aureus
Shigella dysenteriae
Staphylococcus aureus phage type 81

Staphylococcus epidermidis
Enterobacter aerogenes
Escherichia coli
Serratia marcescens
Proteus vulgaris
Shigella sonnei
Salmonella schottmuelleri
Trichophyton mentagrophytes
Candida albicans
Aspergillus niger
Poliiovirus 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 general anesthesia.

ACCEPTED
with COMMENTS
in EPA Letter dated:
MAY 25 2000

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 106-79

ENVIRONMENTAL HAZARDS (Note: For five gallon or larger containers only)

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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, lavatory fixtures, tanning beds and other hard, nonporous surfaces. 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. Use to clean and disinfect non-medical (i.e., industrial and fire-fighting) respirators in industrial, commercial and institutional premises.

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

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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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

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.

CLEANING AND DISINFECTING HARD NON-POROUS SURFACES ON PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORS):

Preclean equipment if heavily soiled to ensure proper surface contact. 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 to hard, non-porous surfaces of the respirator with brush, coarse spray device, sponge, cloth, or immersion. Thoroughly wet all surfaces to be disinfected. Treated surfaces should remain wet for 10 minutes. Remove excess solution from equipment prior to storage. Comply with all OSHA regulations for cleaning respiratory protection (29 CFR§1910.134)

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.

ACCEPTED
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at the time the pesticide,
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