



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Berma Johnson  
Brulin Corporation  
2920 Dr. Andrew J. Brown Avenue  
Indianapolis, IN 46205-4066

FEB - 8 2002

Subject: Maxima 128  
EPA Registration No. 106-73  
  
Maxima 256  
EPA Registration No. 106-72  
  
Broadspec 256  
EPA Registration No. 106-79

Dear Ms. Johnson,

This letter is to acknowledge an error in the Agency letters dated January 31, 2002 for the products, Maxima 128, Maxima 256, and Broadspec 256. The use solution for veterinary clinics was incorrect; the correct use solution is 0.5 oz per gallon of water for Maxima 256 and Broadspec 256, and 1 oz per gallon of water for Maxima 128.

Enclosed are revised letters with the appropriate use dilution. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

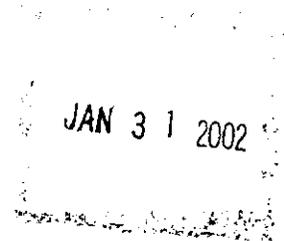
A handwritten signature in black ink that reads "Velma Noble".

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Berma Johnson  
Brulin & Comapny, Inc.  
2920 Dr. Andrew J. Brown Avenue  
Indianapolis, IN 46205



Subject: Broadspec 256  
EPA Registration No. 106-79  
Amendment Dated: August 1, 2001  
EPA Receipt Date: August 6, 2001

Dear Ms. Johnson:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- Addition of an organism, Hepatitis B Virus

**Conditions**

Revise the label as follows:

1. Specific directions must be cited on the label for the disinfection of hair/nail implements in barber/beauty shops. The following language is suggested:

**Barber/Beauty Shops:** 0.5 oz of product per gallon of water to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before reuse. Prepare a fresh solution daily or more often if the solution becomes visible cloudy, dirty, or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

2. Also, Specific directions for veterinary clinics must be added to the label. The following language is suggested:

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Veterinary Clinics: For cleaning and disinfecting the following hard, non-porous surfaces: equipment not to be used for animal food or water, utensils, instruments, cages, kennels, stables, and catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all liter, droppings, and manure from floors, walls, and surfaces of facilities occupied or transversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with a use solution of 0.5 oz of product per gallon of water for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

- 3. Under the "Storage and Disposal" instructions, delete the phrases, "Open dumping is prohibited" and "Do not reuse empty container," which appear above the pesticide storage statements.

**Acceptable Data**

Virucidal Efficacy utilizing Duck HBV	Submitted study, MRID 454738-01	Acceptable
Virucidal Efficacy Duck HBV Confirmatory Assay	Submitted study, MRID 454738-02	Acceptable

**General Comments**

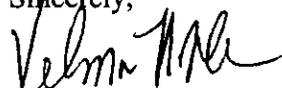
A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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# BROADSPEC 256

## GERMICIDAL DETERGENT

STAPHYLOCIDAL PSEUDOMONACIDAL  
VIRUCIDAL\* FUNGICIDAL MILDEWCIDAL

### ACTIVE INGREDIENTS:

Alkyl (C14, 50%; C12, 40%; C16, 10%)	
dimethyl benzyl ammonium chloride .....	5.63%
Octyl decyl dimethyl ammonium chloride .....	4.22%
Didecyl dimethyl ammonium chloride .....	2.85%
Dioctyl dimethyl ammonium chloride .....	2.11%
<b>INERT INGREDIENTS:</b> .....	<b>85.19%</b>
<b>TOTAL</b> .....	<b>100.00%</b>

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 5 U.S. GALLONS

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

79-N  
26 July 2001

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
JAN 31 2002

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

**BROADSPEC 256** is a "one-step" concentrated multi-purpose germicidal detergent effective in hard waters up to 400 ppm hard water (calculated as CaCO<sub>3</sub>) 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  
\* HBV (Hepatitis B Virus)  
\* HIV-1 (AIDS Virus)  
\* Adenovirus Type 2  
\* Herpes Simplex Type 1  
\* Influenza Type A/Mich.  
\* Vaccinia  
\* Adenovirus Type 4  
\* Herpes Simplex Type 2  
\* Rubella Virus, Vaccine Strain

\* Avian Infectious Bronchitis  
\* Avian Influenza A/Mich.  
\* 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 schottmuelleri*  
*Trichophyton mentagrophytes*  
*Candida albicans*  
*Aspergillus niger*  
*Poliovirus Type 1*  
*Enterococcus faecalis* -  
Vancomycin Resistant

**FIRST AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. **IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

*Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.*

**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:** 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 for use on floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, bowl surfaces, empty basins, non-critical medical devices, hair/nail care instruments, showers, lavatory fixtures, tanning beds and other hard, nonporous surfaces. 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 DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

ACCEPTED  
SUBSIDIARY INSTRUCTIONS  
in EPA Letter Dated:  
JAN 31 2002

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

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 0.5 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.

**\*Kills HBV and 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 Hepatitis B Virus (HBV) and human immunodeficiency virus Type 1 (HIV-1)(associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV AND HIV-1 SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

Use 0.75 ounce of **BROADSPEC 256** to each gallon of water for HBV efficacy.

**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 and 10 minutes for HIV-1 and HBV, respectively. The 4 minute 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)

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

JAN 31 2002

**TOILET BOWL/URINAL DISINFECTANT/CLEANER APPLICATION**

*Remove gross filth or heavy soil prior to application of product.*

*1. Add 0.5 oz. to the bowl (1.0 gal.) and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.*

*2. Empty toilet bowl or urinal and apply a 0.5 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or mechanical spray. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.*

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

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Keep container closed when not in use. 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:** 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 31 2002

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Fungicide, and Rodenticide Act as  
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