

106-72

1-31-2002

Page 186



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 cursive script that reads "Velma Noble".

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

276

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

FEB - 8 2002

Subject: Maxima 128  
EPA Registration No. 106-72  
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 for veterinary clinics must be added to the label. The following language is suggested:

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 1 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.

2. 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.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**General Comments**

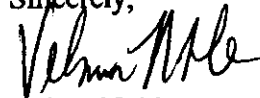
A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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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# MAXIMA 128 GERMICIDAL DETERGENT

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL\* FUNGICIDAL

**ACTIVE INGREDIENTS:**

Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%)	
dimethyl benzyl ammonium chloride .....	2.80%
Octyl decyl dimethyl ammonium chloride.....	2.10%
Didecyl dimethyl ammonium chloride .....	1.42%
Diocetyl dimethyl ammonium chloride .....	1.05%
<b>INERT INGREDIENTS:</b> .....	<b>92.63%</b>
<b>TOTAL</b> .....	<b>100.00%</b>

DILUTION: 1 TO 128 ... ONE 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. 106-72

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

MAXIMA 128 is a "one-step" 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 MAXIMA 128 has been evaluated by the AOAC use dilution test (14th Edition, 1984) 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 Virus, Vaccine Strain  
\* HBV (Hepatitis B Virus)

\* Avian Infectious Bronchitis  
\* Avian Influenza A/Mich.  
\* Infectious Bovine  
Rhinotracheitis  
\* Canine Distemper  
\* Feline Leukemia  
\* Feline Picornavirus  
*Enterococcus faecalis* -  
Vancomycin Resistant  
*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*

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
JAN 31 2002

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

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 use only such as hospitals and nursing homes, schools and colleges, medical and dental offices, and veterinary clinics. This product is for use on floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, bowl surfaces, empty basins, noncritical medical devices, showers, and lavatory fixtures.

CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES:

Add one ounce of MAXIMA 128 to each gallon of water used. Always add MAXIMA 128 to premeasured water. Gently mix for a uniform solution. Apply solution by normal methods with brush, coarse spray devices, sponge, cloth or mop. Thoroughly wet all surfaces to be cleaned, then remove excess solution with a wringer or squeegee. Treated surfaces should remain wet for 10 minutes. Remove gross filth mechanically by sweeping or scrubbing. Fresh solution should be prepared daily or more often if the solution becomes diluted. EPA Letter Dated 10/24/99 is not necessary unless floors are to be waxed. MAXIMA 128 is a complete product. Do not add other chemicals. Use only as directed.

JAN 31 2002  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 106-72

\* 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 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

Use 1.50 ounce of MAXIMA 128 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 MAXIMA 128. This pre-cleaning may be accomplished with any cleaning solution including MAXIMA 128.

**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.

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

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

1. Add 0.75 oz. to the bowl (0.75 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 1 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.

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 enter 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.

**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.

31 July 2001

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
JAN 31 2002