

106-72

12/20/2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Brulin & Co., Inc.  
2920 Dr. Andrew J. Brown  
Indianapolis, IN 46206

DEC 20 2000

Subject: Maxima 128  
EPA Registration No. 106-72  
Amendment Dated October 24, 2000

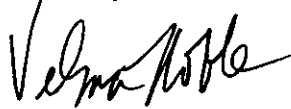
Attn: Berma L. Johnson  
Compliance/Regulatory Affairs Manager

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable for the deletion of the two (2) organisms (Canine Parvovirus And Bovine Parvovirus) from the label, and for the addition of the organism (Enterococcus Faecalis Vancomycin Resistant) to the label.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product is released for shipment.

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 (7510C)

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Z. Jones						
DATE	12-20-00						

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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%  
 Dioctyl dimethyl ammonium chloride..... 1.05%

INERT INGREDIENTS: ..... 92.63%  
 TOTAL..... 100.00%

DILUTION: 1 TO 128 . . . ONE OUNCE PER GALLON

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 20 2000  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 106-72

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

\* 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 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* , , , , ,

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Harmful if swallowed.

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.

ACCEPTED with COMMENTS in EPA Letter Dated:

DEC 20 2000

DIRECTIONS FOR USE

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

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, exterior 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 wrung out applicator. Treated surfaces should remain wet for 10 minutes. Remove gross filth mechanically by sweeping before cleaning begins. Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled. Rinsing is not necessary unless floors are to be waxed. MAXIMA 128 is a complete product. Do not add other chemicals. Use only as directed.

\* 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).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF 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 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. This contact time will not control other common types of viruses and bacteria.*

*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.*

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in EPA Letter Dated:  
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20 October 2000