# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Brulin & Company, Inc. 2920 Dr. Andrew J. Brown Ave. Indianapolis, IN 46205

OCT 1 8 1999

Subject: Maxima 128

EPA Registration No. 106-72 Amendment Dated July 19, 1999

Attn: B

Berma Zootman Johnson

Compliance/Regulatory Aff. Mgr.

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. The revised corrected Confidential Statement of Formula (CSF) dated August 10, 1999 complies with 40 CFR Part 158.175, it agrees with the updated label ingredient statement and is acceptable. All ingredients in the CSF are cleared by the Agency for use in this product and the certified limits for all ingredients in this CSF comply with 40 CFR 158.175 and are acceptable.

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 (7510W)

CONCURRENCES			
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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	

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

ACCEPTED with COMMENTS in EPA Letter Dated:

# KEEP OUT OF REACH OF CHILDREN DANGER

OCT 18 1999

Under the Federal Insecticide. Pengicide, and Rodenticide Act as amended, for the pesticide,

See Side Panel for Statement of Practical Treatment and Additional gistered under EPA Reg. No. 106-704 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 \* Infectious Bovine Rhinotracheitis \* Canine Distemper \* Feline Leukemia \* Feline Picomavirus Streptococcus faecalis Staphylococcus aureus Shigella dysenteria

\* Avian Influenza A/Mich.

\* Canine Parvovirus

\* Bovine Parvovirus

\* Avian Infectious Bronchitis Staphylococcus aureus phage type 81 Staphylococcus epidermidis Enterobacter aerogenes Escherichia coll Serratia marcescens Proteus vulgaris Shigella sonnei Salmonella schottmuelleri ' Trichophyton mentagrophytes Candida albicans Aspergillus niger

\* 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 solling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be solled 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.

#### **PRECAUTIONARY STATEMENTS**

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

#### **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 en an activity of the local sewage treatment plant authority. Water Board or Regional Office of the EPA. in EPA Letter Dated:

OCT 18 1999

Under the Federal Insecticide, DIRECTIONS FOR USE Fangicide, and Rodenticide Act as amended, for the pesticide,

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

USE: Floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, exterior bowl surfaces, empty basins, noncritical medical devices, showers, and lavatory fixtures. For institutional use only such as hospitals and nursing homes, schools and colleges, medical and dental offices, and veterinary clinics.

## 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.

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

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

STORAGE: Store in original container. Keep away from children. Keep container closed when not in use.

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 with COMMENTS in EPA Letter Dated:

OCT 18 1999

Under the Federal Insecticide,
Pangicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 106-12

19 July 1999