UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 6-13-2003

106-81



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

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUN 1 3 2003

Berma L. Johnson Compliance/Regulatory Affairs Manager Brulin & Company 2920 Dr. Andrew J. Brown Indianapolis, IN 46205

Maxima RTU Subject: EPA Registration No. 106-81 Amendment dated: March 11, 2003 EPA Received date: March 19, 2003

Dear: Ms. Berma L. Johnson:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with the following conditions .

# **Proposed Amendment**

- Addition of Mildewcidal
- Addition of barber/beauty shops-hair/nail care instruments, tanning beds Addition of non-medical respirators (Personal Protective Equipment)

# Conditions

e following statements are required:

- To control the growth of mold and mildew and their odors on hard, nonporous surfaces, apply usesolution to thoroughly wet treated surfaces completely. Let air dry. Repeat application weekly or 1. when growth or odor reappears
- Maxima RTU is an effective fungicide against Trichophyton Mentagropytes ( the Athletes Foot Fungicidal Directions 2. Fungus) when used on surfaces in areas such as shower and bath areas (Follow disinfection directions)

CONCURRENCES									
YMBOL	7510(c)		•						
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<b>кте</b> )	6/11/03								
PA Form 1320-1A (1/90)			Printed on Recycled	Paner	OFFICIAL FILE COOL				

Page Two

# **General Comments**

If the conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6 (e). Your release for shipment of this product constitutes acceptance of the conditions. A stamped label is enclosed for your records. Please submit three copies (3) of your final printed label before distributing or selling the product bearing the revised labeling. If you have any questions concerning this letter, please contact me at (703) 308-6233.

Sincerely,

Velma Nóble Product Manager (31) Regulatory Management Branch1 Antimicrobial Divisions (7510c)

# MAXIMA RTU GERMICIDAL DETERGENT

#### STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL\* FUNGICIDAL MILDEWCIDAL

# ACTIVE INGREDIENTS:

Alkyl (C14, 50%; C12, 40%; C16, 10%)	
dimethyl benzyl ammonium chloride	0.0328%
Octyl decyl dimethyl ammonium chloride	0.0246%
Didecyl dimethyl ammonium chloride	0.0166%
Dioctyl dimethyl ammonium chloride	0.0123%
INERT INGREDIENTS:	99.9137%
TOTAL	

ACCEPTED ' with COMMENTS in EPA Letter Dated:

# KEEP OUT OF REACH OF CHILDREN CAUTION

JUN 1 3 2003

See Side Panel for First Aid and Additional ame Precautionary Statements regi

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amonded, for the pesticide, registered under EPA Reg. No. 106-81

EPA Reg. No. 106-81

EPA Est. No. 106-IN-1

NET CONTENTS 1 U.S. QUART

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 RTU 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 RTU 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 fiexneri

81-B March 2003 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 Picomavirus

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 Shigela sonnei Salmonella schottmuellen Trichophyton mentagrophytes Candida albi.ar.s Aspergillus niger

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## PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION.** Causes moderate eye irritation. Harmful if swallowed or absorbed by the skin. Avoid contact with eye, skin, or clothing. Wash thoroughly with soap and water after handling.

#### **FIRST AID**

Have product container 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 the eye. Call a poison control center or doctor for treatment advice.

If on skin: 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.

#### ENVIRONMENTAL HAZARDS (for containers $\geq$ 5 gallon)

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, noncritical medical devices, hair/nail care instruments, showers, and 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.

#### CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES:

Remove gross filth or heavy soil prior to application of product. Apply Maxima RTU with a brush, coarse spray device, sponge, cloth or mop. Thoroughly wet all hard, non-porous surfaces to allow surfaces to remain wet for 10 minutes. Remove excess solution or allow to air dry. Rinsing is not necessary unless floors are to be waxed. MAXIMA RTU is a complete product. Do not add other chemicals. Use only as directed.

#### **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 Maxima RTU for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters, or ropes as well as shovels, scrapers, and forks used to remove litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

\* 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 Vrus (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:

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 RTU. This pre-cleaning may be accomplished with any cleaning solution including MAXIMA RTU.

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. For the other viruses, bacteria, and fungi on this label, use a 10 minute contact time.

#### TOILET BOWL/URINAL DISINFECTANT/CLEANER APPLICATION

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

Empty toilet bowl or urinal and apply 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.

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

Preclean equipment if heavily soiled to ensure proper surface contact. Apply MAXIMA RTU to hard, nonporous 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).

#### BARBER/BEAUTY SHOPS:

Use MAXIMA RTU to disinfect hard, nonporous instruments and tools. Completely immerse combs. bruches, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily solled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and by before reuse. Prepare a fresh solution daily or more often if the solution becomes visibly cloudy, dirty, or solled.

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

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.

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small 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:** - (Larger than 1 gallon) - 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.

- (1 gallon and smaller) - Do not reuse empty container. Wrap container and

put in trash.