106-81

2/15/2008

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 1 5 2008

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

Subject:

Maxima RTU

EPA Registration 106-81

Amendment Dated: Feb 04, 2008 EPA Received Date: Feb 05, 2008

Dear Berma L. Johnson

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

Proposed Amendment

Revised Label Response to letter dated Nov 29, 2007

General Comments

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

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703)308-6233.

Sincerely

CONCURRENCES

Veima Noble

Product Manager (3.1)

Regulatory Management Branch 1

Antimicrobial Division (75.10c)

EPA Form 1320-1A (1/90)

Printed on Recycled Parer

OFFICIAL FILE COPY

MAXIMA RTU

GERMICIDAL DETERGENT or GERMICIDAL CLEANER or GERMICIDAL DISINFECTANT OF DISINFECTANT CLEANER

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL* FUNGICIDAL MILDEWCIDAL

ACTIVE INGREDIENTS:

Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride	0.0375%
Octyl decyl dimethyl ammonium chloride	0.0281%
Didecyl dimethyl ammonium chloride	0.0189%
Dioctyl dimethyl ammonium chloride	0.0141%
OTHER INGREDIENTS:	
TOTAL	100.0000%

ACCEPTED

FFR 15 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. / 66—81

KEEP OUT OF REACH OF CHILDREN CAUTION

See Side Panel for First Aid and Additional Precautionary Statements

EPA Reg. No. 106-81

EPA Est. No. 106-IN-1

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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 CaCO₃) 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 flexneri

* HCV (Hepatitis C Virus)

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

in 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

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 ≥ 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, nonperous 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:

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. 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: utensils, instruments, cages, kennels, stables, and catteries. Not to be applied to equipment used for animal food or water. 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, HCV 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), Hepatitis C Virus (HCV), and human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV, HCV 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 for HIV-1 and 10 minutes for HBV and HCV, 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 coarse spray. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

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

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

MOLD AND MILDEW CONTROL DIRECTIONS:

To control the growth of mold and mildew and their odors on hard, nonporous surfaces, apply use-solution to thoroughly wet treated surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappears.

FUNGICIDAL DIRECTIONS:

Maxima RTU is an effective fungicide against Trichophyton Mentagrophytes (the Athletes Foot Fungus) when used on surfaces in areas such as shower and bath areas (follow disinfection directions).

BARBER/BEAUTY SHOPS:

trash.

Use MAXIMA RTU 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 visibly 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 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