

106-81

02-09-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 9 2010

Ms. Berma Johnson  
Compliance/Regulatory Affairs Manager  
Brulin & Co., Inc.  
P.O. Box 270  
Indianapolis, IN 46206

Subject: Maxima RTU  
EPA Registration No. 106-81  
Amendment Date: August 14, 2009  
EPA Receipt Date: August 19, 2009

Dear Ms. Johnson,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the conditions below.

**Proposed Amendment**

- Addition of microorganisms

**Conditions**

Revise the label as follows:

- 1.) Revise the organism list on page one by correcting "*Salmonella choleraesuis*" to read "*Salmonella enterica*."

CONCURRENCES							
SYMBOL	7510P						
SURNAME	J. Lentz						
DATE	2/4/2010						

- 2.) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows: "...Wash thoroughly with soap and water after handling *and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.*"
- 3.) As per PR Notice 2001-1, reorder the First Aid statement to list the most toxic through least toxic route of exposure as follows: "If On Skin," "If In Eyes," followed by "If Swallowed."
- 4.) Revise the directions for Cleaning and Disinfecting Hard Non-Porous Surfaces on Personal Protective Equipment to be in agreement with PR Notice 2000-5 as follows: "...Treated surfaces *must* remain wet for 10 minutes..."
- 5.) Revise your label at this time to be in compliance with PR Notice 2007-4. The following statement has been approved as alternate language for products used against public health pests in all sized container when used in commercial, industrial and institutional settings. Delete the current Container Disposal language and revise to read exactly as follows:

"Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations."

**General Comments**

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label 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.

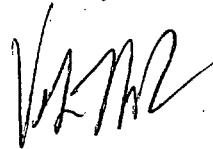
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If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label  
7510P:T.Lantz:2/2/2010:106-81 relying on new data

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# MAXIMA RTU

**GERMICIDAL DETERGENT or GERMICIDAL CLEANER or GERMICIDAL DISINFECTANT or DISINFECTANT DETERGENT or DISINFECTANT CLEANER**

**STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL\* FUNGICIDAL MILDEWCIDAL**

**ACTIVE INGREDIENTS:**

- Alkyl (C<sub>14</sub>, 50%; C<sub>12</sub>, 40%; C<sub>16</sub>, 10%)
- dimethyl benzyl ammonium chloride.....0.0375%
- Octyl decyl dimethyl ammonium chloride .....0.0281%
- Didecyl dimethyl ammonium chloride .....0.0189%
- Diocetyl dimethyl ammonium chloride .....0.0141%

OTHER INGREDIENTS: ..... 99.9014%  
 TOTAL..... 100.0000%

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 9 2010

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

**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

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    | Brevibacterium ammoniagenes     | * Avian Infectious Bronchitis | Staphylococcus aureus       |
| Staphylococcus aureus     | Staphylococcus aureus (MRSA)    | * Avian Influenza A/Mich.     | phage type 81               |
| phage type 80             | Multiply (Methicillin)          | * Infectious Bovine           | Staphylococcus epidermidis  |
| Salmonella typhi          | Resistant Clinical Isolate      | Rhinotracheitis               | Enterobacter aerogenes      |
| Staphylococcus aureus     | * HIV-1 (AIDS Virus)            | * Canine Distemper            | Escherichia coli            |
| phage type 42B/52/81      | * Adenovirus Type 2             | * Feline Leukemia             | Serratia marcescens         |
| Salmonella choleraesuis   | * Herpes Simplex Type 1         | * Feline Picomavirus          | Proteus vulgaris            |
| Streptococcus pyogenes    | * Influenza Type A/Mich.        | Enterococcus faecalis -       | Shigella sonnei             |
| Enterobacter cloacae      | * Vaccinia                      | Vancomycin Resistant          | Salmonella schottmuelleri   |
| Klebsiella pneumoniae     | * Adenovirus Type 4             | Streptococcus faecalis        | Trichophyton mentagrophytes |
| Proteus mirabilis         | * Herpes Simplex Type 2         | Staphylococcus aureus         | Candida albicans            |
| Shigella flexneri         | * Rubella Virus, Vaccine Strain | Shigella dysenteria           | Aspergillus niger           |
| * HCV (Hepatitis C Virus) | * HBV (Hepatitis B Virus)       | Acinetobacter baumannii       |                             |

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

## 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. 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 litter, 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:**

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 receptacle. 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.