

106-81

03/19/2004

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR 19 2004

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

Subject: MAXIMA RTU
EPA Reg. No. 106-81
Application Dated: Feb 06, 2004
Receipt Date: Feb 18, 2004

Dear Berma L. Johnson

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9. is acceptable.

Proposed Notification

- Addition of alternative statements - "Germicidal Cleaner", "Germicidal Disinfectant", "Disinfectant Detergent", "Disinfectant Cleaner",

Comments

Based on a review of the material submitted, the following comments apply:
This application for notification to add alternative statements as listed above is acceptable. A copy has been placed in our records for future reference.

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

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510c)0

CONCURRENCES

SI	7510c						
SURNAME	ACENSKAS						
DATE	3-16-04						

The Brulin Corporation

Creating a Safer Environment

EPA Registration Number 106-81

Maxima RTU

Notification dated 6 February 2004

Notification of additional use statements – "Germicidal Cleaner", "Germicidal Disinfectant", "Disinfectant Detergent", "Disinfectant Cleaner".

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Berna L. Johnson
Compliance/Regulatory Affairs Manager





Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

<p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number _____
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Application for Pesticide - Section I

1. Company/Product Number 106-81	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) MAXIMA RTU	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Brulin & Company, Inc. 2920 Dr. Andrew J. Brown Ave. Indianapolis, IN 46205 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Current use statement is "Germicidal Detergent". Addition of alternative statements - "Germicidal Cleaner", "Germicidal Disinfectant", "Disinfectant Detergent", "Disinfectant Cleaner".
 Additions are identified in red on attached labels. No other changes have been made.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 qt, 0.5, 1, 2.5, 55 gal	5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other screenprinted, "sleeves" <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Berma L. Johnson	Title Compliance/Regulatory Affairs Manager	Telephone No. (Include Area Code) 317 923-3211, extension 3291

Certification		6. Date Application Received (Stamp)
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title Compliance/Regulatory Affairs Manager	
4. Typed Name Berma L. Johnson	5. Date 6 February 2004	

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 ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 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:	<u>99.9137%</u>
TOTAL	100.0000%

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 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

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 Picornavirus
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
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 \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 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 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 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 pre-clean 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.

