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1/7

Jan. 5. 2007 1:51PM

BRULIN & CO INC

No. 7320 P. 2/13



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

JUN 3 0 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

Subject: Maxima 256
EPA Registration No. 106-73
Amendment Date: February 14, 2005
EPA Receipt Date: February 17, 2005

Dear Ms. Johnson,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Addition of Laundry Sanitization Claim

Conditions

Revise the label as follows:

1. Make the following changes to the following organism's nomenclature:
 - a. Delete the descriptors, "phage type 42B/52/81, 80 and 81," for *Staphylococcus aureus*.
 - b. Delete the phrase, "Multiply(Methicillin) Resistant Clinical Isolate" for *Staphylococcus aureus* (MRSA).
 - c. Avian Influenza A/Mich must be revised to read "Avian Influenza A/Michigan/2/79-H1N9".

Please Note: This virus is not synonymous with the strain of Avian Influenza virus ("Bird Flu") that is causing a concern as a worldwide public health threat.

2/17

- 2. Delete the term, "Institutional," from the Laundry Additive directions because data was not submitted to support this claim. Institutional implies that this product may be used to sanitize hospital, nursing homes, medical/dental facility linens which requires data demonstrating this product's effectiveness against *Pseudomonas aeruginosa*.
- 3. The "Toilet Bowl/Urinal Disinfectant/Cleaner Directions" must have the following subheadings to clarify the directions.
 - a. Delete 1. and state "From Concentrate." Also, delete the phrase, "(1.0 gal) and mix."
 - b. Delete 2. and state "From Use Solution."
- 4. The proposed label supports "Storage and Disposal instructions for containers greater than one gallon; however your product is in containers one gallon or less. Therefore, you must add the following "Storage and Disposal" Instructions:

(Containers 1 gallon or less)

Storage and Disposal: Store in original container in areas inaccessible to small children and persons unfamiliar with this product's use. Keep container close when not in use. Do not reuse empty container. Discard in trash.

Acceptable Data

Data Requirement	Means of Support	Status
Evaluation of Laundry Sanitizer against <i>K. pneumoniae</i>	Submitted study, MRID 464785-01	Acceptable, 1:192 in hard water
Evaluation of Laundry Sanitizer against <i>S. aureus</i>	Submitted study, MRID 464785-02	Acceptable, 1:192 in hard water

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies 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) when the Agency requires all registrants of similar products to submit such data.

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 or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

3/1

Sincerely,



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

Enclosure: Stamped Label
Efficacy Data Evaluation

4/7

MAXIMA 256

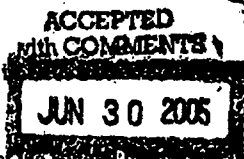
GERMICIDAL DETERGENT or GERMICIDAL CLEANER or GERMICIDAL DISINFECTANT or DISINFECTANT DETERGENT or DISINFECTANT CLEANER

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL* FUNGICIDAL MILDEWCIDAL

ACTIVE INGREDIENTS:

- Alkyl (C₁₄, 50%; C₁₂, 40%; C₁₆, 10%) dimethyl benzyl ammonium chloride..... 6.40%
- Octyl decyl dimethyl ammonium chloride 4.80%
- Didecyl dimethyl ammonium chloride 3.23%
- Dioctyl dimethyl ammonium chloride 2.40%

INERT INGREDIENTS: 83.17%
TOTAL..... 100.00%



Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 106-73

DILUTION: 1 TO 256 . . . ONE-HALF OUNCE PER GALLON

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See Side Panel for First Aid and Additional Precautionary Statements

EPA Reg. No. 106-73

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 256 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 256 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
- Salmonella typhi
- Staphylococcus aureus
- Salmonella choleraesuis
- Streptococcus pyogenes
- Enterobacter cloacae
- Klebsiella pneumoniae
- Proteus mirabilis
- Shigella flexneri

- Brevibacterium ammoniagenes
- Staphylococcus aureus (MRSA)
- 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
- Staphylococcus epidermidis
- Enterobacter aerogenes
- Escherichia coli
- Serratia marcescens
- Proteus vulgaris
- Shigella sonnei
- Salmonella schottmuelleri
- Trichophyton mentagrophytes
- Candida albicans
- Aspergillus niger

5/7

FIRST AID

Have the product container or label 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 eye. Call a poison control center or doctor for treatment advice. **IF ON SKIN OR CLOTHING:** 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.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS (5 gallon or larger)

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, 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:

Add one-half ounce of MAXIMA 256 to each gallon of water used. Always add MAXIMA 256 to premeasured water. Gently mix for a uniform solution. Apply solution by normal methods with brush, coarse spray devices, sponge, cloth or mop. Remove gross filth mechanically by sweeping before cleaning begins. Thoroughly wet all surfaces to be cleaned, then remove excess solution with a wrung out applicator. Treated surfaces should remain wet for 10 minutes. 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 256 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

6/7

detergent and rinse with potable water. Saturate surfaces with a use solution of 0.5 oz. of Maxima 256 per gallon of water for a period of 10 minutes. 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 Virus (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:

Use 0.75 ounce of MAXIMA 256 to each gallon of water for HBV efficacy.

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 256. This pre-cleaning may be accomplished with any cleaning solution including MAXIMA 256.

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. The 4 minute contact time will not control other common types of viruses and bacteria.

TOILET BOWL/URINAL DISINFECTANT/CLEANER APPLICATION:

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

1. Add 0.5 oz. to the bowl (1.0 gal.) and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.
2. Empty toilet bowl or urinal and apply a 0.5 oz./gal. use-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-POROUS SURFACES ON PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORS):

Pre-clean equipment if heavily soiled to ensure proper surface contact. Add one-half ounce of MAXIMA 256 to each gallon of water used. Always add MAXIMA 256 to premeasured water. Gently mix for a uniform solution. Apply solution 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).

BARBER/BEAUTY SHOPS:

Use 0.5 oz. per gallon of water 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

7/7

removed after 10 minutes, rinsed, dried, and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

LAUNDRY ADDITIVE TO SANITIZE AGAINST BACTERIA IN COMMERCIAL - INDUSTRIAL - FACILITIES

Maxima 256 sanitizes laundry such as bedspreads, sheets, pillowcases, diapers, towels, and other wet linens by reducing the growth of bacteria. Add 8 ounces of Maxima 256 per 100 pounds of dry laundry to the final rinse cycle. At this level Maxima 256 is an effective sanitizer in hard water up to 200 ppm.

X 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. Do not reuse empty container.

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: 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.

Optional marketing statement: "One (1) gallon (quart) of concentrate makes 256 gallons (quarts) of disinfectant."