

106-73

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 256
EPA Registration No. 106-73
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. Jark						
DATE	2/3/2010						

- 2.) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows: "...Do not get in eyes, on skin, or on clothing... Wash thoroughly with soap and water after handling *and before eating, drinking, chewing gum, using tobacco or using the toilet...*"
- 3.) Revise the directions for Cleaning and Disinfecting Washable Hard Non-Porous Surfaces to be in agreement with PR Notice 2000-5 and to provide additional clarification by stating: "...Remove gross *filth before cleaning and disinfecting* begins. Thoroughly wet all surfaces, *then remove excess solution...* Treated surfaces *must* remain wet for 10 minutes. Fresh solution *is* prepared daily..."
- 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."

Data Matrix

The Agency has corrected the typographical error on your data matrix. On page one, the study in support of Physical/Chemical Characteristics, Color, Physical State, Odor, Density, pH, Flammability, Storage Stability, Viscosity, and Corrosion is MRID #42260801. Make the same corrections to the matrix in your files.

Efficacy Data

The following data may be used to support this product. The review of this data is attached.

Data Requirement	Means of Support	Status
AOAC Use Dilution <i>Acinetobacter baumannii</i>	Submitted study, MRID 478354-01	Acceptable, 1:256, 5% soil, contact time of 10 minutes

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.

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, DER D369315
7510P:T.Lantz:2/2/2010:106-73 relying on new data

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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%
- Diocetyl dimethyl ammonium chloride..... 2.40%
- OTHER INGREDIENTS: 83.17%
- TOTAL 100.00%

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

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

FEB 9 2010

KEEP OUT OF REACH OF CHILDREN
DANGER

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

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 | Brevibacterium ammoniagenes | * Avian Infectious Bronchitis | Aspergillus niger |
| Staphylococcus aureus | Staphylococcus aureus (MRSA) | * Avian Influenza A/Michigan/
2/79-H1N9 | Candida albicans |
| Staphylococcus epidermidis | * HBV (Hepatitis B Virus) | * Rubella Virus, Vaccine Strain | Streptococcus faecalis |
| Salmonella typhi | * HCV (Hepatitis C Virus) | * Infectious Bovine
Rhinotracheitis | Enterobacter aerogenes |
| Shigella flexneri | * HIV-1 (AIDS Virus) | * Canine Distemper | Escherichia coli |
| Shigella dysenteria | * Adenovirus Type 2 | * Feline Leukemia | Serratia marcescens |
| Salmonella choleraesuis | * Herpes Simplex Type 1 | * Feline Picornavirus | Proteus vulgaris |
| Streptococcus pyogenes | * Influenza Type A/Mich. | * Enterococcus faecalis -
Vancomycin Resistant | Shigella sonnei |
| Enterobacter cloacae | * Vaccinia | | Salmonella schottmuelleri |
| Klebsiella pneumoniae | * Adenovirus Type 4 | | Trichophyton mentagrophytes |
| Proteus mirabilis | * Herpes Simplex Type 2 | | 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.

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. 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, lavatory fixtures, tanning beds and other hard, nonporous 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: 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 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, 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:

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 for HIV-1 and 10 minutes for HBV and HCV, 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.

From Concentrate. Add 0.5 oz. to the bowl. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From Use Solution. 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):

Preclean 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 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.

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. 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.~~

~~(Containers 1 gallon or less)~~

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

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