

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 24 1997

Brulin and Company, Inc.
P.O. Box 270
Indianapolis, IN 46206-0270

Attn: Berma L. Zootman, Manager
Compliance/Regulatory Affairs

Subject: Maxima 256
EPA Registration No. 106-73
Amendment Dated January 20, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your product labels to the nominal concentration, is acceptable.

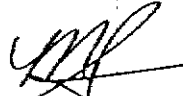
The provided five batch analysis with MRID No. 442043-01, agree with the revised labels and the nominal concentration, and is acceptable.

However, you must submit a revised Confidential Statement of Formula which would comply with PR Notice 91-2 (the nominal concentration) and the revised labels.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely yours,



Marshall Swindell
Acting Product Manager (31)
Regulatory Management Branch 1
Antimicrobial Division (7504C)

Enclosure

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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MAXIMA 256 GERMICIDAL DETERGENT

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL* FUNGICIDAL

ACTIVE INGREDIENTS:

- Alkyl (C₁₂, 50%; C₁₄, 40%; C₁₆, 10%)
- dimethyl benzyl ammonium chloride 5.60%
- Octyl decyl dimethyl ammonium chloride 4.20%
- Didecyl dimethyl ammonium chloride 3.26%
- Diocetyl dimethyl ammonium chloride 1.68%

INERT INGREDIENTS: 85.26%
TOTAL 100.00%

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

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See Side Panel for Statement of Practical Treatment and Additional
Precautionary Statements

EPA Reg. No. 106-73

EPA Est. No. 106-IN-1

NET CONTENTS 1 U.S. GALLON

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 24 1997

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

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
 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

* Avian Infectious Bronchitis
 * Avian Influenza A/Mich.
 * Canine Parvovirus
 * Bovine Parvovirus
 * Infectious Bovine
 Rhinotracheitis
 * Canine Distemper
 * Feline Leukemia
 * Feline Picornavirus
 * 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

* Kills 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 human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

STATEMENT OF PRACTICAL TREATMENT

In case of skin contact, wash thoroughly with soap and water. In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. If swallowed, drink promptly a large quantity of egg whites, or gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

with COMMENTS
in EPA Letter Dated

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

MAR 24 1997

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Under the Federal Insecticide, Fungicide, and Rodenticide Act registered under EPA Reg. No.

106-73

DANGER. KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Avoid contamination of food, water or feed.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

USE: Floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, exterior bowl surfaces, empty basins, noncritical medical devices, showers, and lavatory fixtures. For institutional use only such as hospitals and nursing homes, schools and colleges, medical and dental offices, and veterinary clinics.

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. Thoroughly wet all surfaces to be cleaned, then remove excess solution with a wrung out applicator. Treated surfaces should remain wet for 10 minutes. Remove gross filth mechanically by sweeping before cleaning begins. 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.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST 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 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. This contact time will not control other common types of viruses and bacteria.

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.

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STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. 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 - PLASTIC CONTAINER: 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.

GENERAL: Consult federal, state or local disposal authorities for approved alternate procedures.

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