

PM 31 106-117

1043

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 8 1995

Brulin & Company, Inc.
2920 Dr. Andrew J. Brown Avenue
P.O. Box 270
Indianapolis, IN 42606

Attention: Berma Zootman
Compliance/Regulatory Affairs Manager

Subject: Pro Quat 256B
EPA Registration No. 106-77
MOU Compliance Amendment dated July 24, 1995

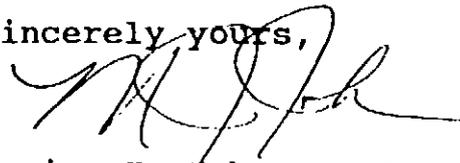
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, will be acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

1. Revise the microorganism Trichophyton interdigitale to read Trichophyton mentagrophytes everywhere it appears on the label.
2. Revise the statement "Discard solution when it becomes dirty and replace with fresh solution." to read "Prepare a fresh solution daily or more often if the solution becomes diluted or soiled."

A stamped copy of your labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

of 3

ProQuat 256^B GERMICIDAL DETERGENT

STAPHYLOCIDAL * PSEUDOMONACIDAL
VIRUCIDAL * FUNGICIDAL

ACTIVE INGREDIENTS:

Octyl Decyl Dimethyl Ammonium Chloride	6.0%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₀ , 10%) Dimethyl Benzyl Ammonium Chloride	4.0%
Dioctyl Dimethyl Ammonium Chloride	3.0%
Didecyl Dimethyl Ammonium Chloride	3.0%
INERT INGREDIENTS	84.0%
TOTAL	100.0%

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

KEEP OUT OF REACH OF CHILDREN DANGER

See Right Panel for Additional Precautionary Statements.

E.P.A. Reg. No. 106-77

E.P.A Est. No. 106-IN-1

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

ProQuat 256^B is a "one-step" concentrated 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 ProQuat 256^B has been evaluated by the current A.O.A.C. use-dilution test and found to be effective against the following pathogenic organisms:

- | | | |
|-------------------------|---------------------------------------|-------------------------------------|
| Pseudomonas aeruginosa | Brevibacterium ammoniagenes | Streptococcus faecalis |
| Staphylococcus aureus | * Adenovirus Type 2 | Staphylococcus aureus |
| phage type 80 | * Vaccinia | Shigella dysenteriae |
| Salmonella typhi | * Influenza A/Brazil | Staphylococcus aureus phage type 81 |
| Staphylococcus aureus | * Influenza A ₁ /Hong Kong | Staphylococcus epidermidis |
| phage type 42B/52/81 | * Herpes Simplex Type 1 | Enterobacter aerogenes |
| Streptococcus pyogenes | * HIV-1 (AIDS Virus) | Escherichia coli |
| Enterobacter cloacae | Trichophyton interdigitale | Serratia marcescens |
| Klebsiella pneumoniae | Candida albicans | Proteus vulgaris |
| Proteus mirabilis | Staphylococcus aureus (MRSA) | Shigella sonnei |
| Shigella flexneri | Multiply (Methicillin)- | Salmonella schottmuelleri |
| Salmonella choleraesuis | Resistant Clinical Isolate | |

* 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).

ACCEPTED
with COMMENTS
in EPA Letter Dated:

77-A **BEST COPY AVAILABLE**

AUG -- 8 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the pesticide registration and EPA Reg. No 106 77

3043

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 ProQuat 256[®]. This pre-cleaning may be accomplished with any cleaning solution including ProQuat 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 1 minute. This contact time will not control other types of viruses and bacteria.

DIRECTIONS FOR USE

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

USE: Floors, walls, 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.

DISINFECTING WASHABLE HARD NON-POROUS SURFACES: Add one-half ounce of ProQuat 256[®] to each gallon of water used. Always add ProQuat 256[®] to premeasured water. Gently mix for a uniform solution. Apply solution by normal methods with brush, 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 ten minutes. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution when it becomes dirty and replace with fresh solution. ProQuat 256[®] is a complete product. Do not add other chemicals. Use only as directed.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method in 400 ppm hard water, 1:256 (1/4 oz./gallon) in the presence of 5% organic serum, 10 minutes at 20°C.

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test when diluted with 400 ppm hard water, 1:256 (1/4 oz./gallon) in the presence of 5% organic serum, 10 minutes at 20°C.

VIRUCIDAL: Passes A.O.A.C. Virucidal Qualification Test when diluted with 400 ppm hard water, 1:256 (1/4 oz./gallon) in the presence of 5% organic serum, 10 minutes at 20°C.

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

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 rinseate 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 authorities for approved alternative procedures.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG - 8 1995

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the FIFRA Act of 1972,
this product is registered under
EPA Reg. No. 106-77

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.

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

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