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FEB - 6 1989

Calgon Vestal Laboratories
Division of Calgon Corporation
5035 Manchester Avenue
St. Louis, MO 63110

Attention: E. Nouss

Gentlemen:

Subject: Coverage 256
EPA Registration No. 1043-82

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. Refer to the enclosed Efficacy Evaluation and Technical Efficacy Review - II, and revise your labeling in accordance with the labeling comments outlined there.
 - b. Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.
 - c. Delete the statement "Only For Sale To, Use and Storage by Service Personnel."
 - d. The signal word "DANGER" must be placed directly below the child hazard warning statement (center panel only).

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CONCURRENCES

SYMBOL								
SURNAM								
DATE								

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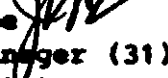
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2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,


John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosures

EPA - Approved for
HIV (AIDS) Virus*

COVER

GERM
E.P.A.

Germicide • Fungicide • Virus

Active Ingredients:

Octyl decyl dimethyl ammonium

Dioctyl dimethyl ammonium chloride

Didecyl dimethyl ammonium chloride

Alkyl (50% C₁₂, 40% C₁₀, 10% C₈)

Inert Ingredients:

One-Step Germicidal Disinfectant

Institut

Only for Sale To, Use

DANGER: KEEP OUT OF REACH OF CHILDREN

STATEMENT

In case of eye contact, flush with water.
For skin contact, flush with water.

Contents: One

Precautionary Statements

Hazard to Humans and Domestic Animals:

Concentrate corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. May be fatal if absorbed through the skin.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. For skin contact, flush thoroughly with water. Remove and wash contaminated clothing before reuse. If swallowed, drink large quantity of milk, egg white, gelatin solution, or water, avoid alcohol. Do not induce vomiting. Call physician immediately. **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DIRECTIONS FOR USE

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

Cleaning and disinfecting washable, hard, non-porous surfaces: Add one-half ounce (15cc) to each measured gallon of water used. Always add Coverage 256 to premeasured water. Gently mix for a uniform solution. Apply solution with a cloth, sponge, mop, or brush using normal cleaning methods. 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 a fresh solution. Coverage 256 is a complete product. Do not add other chemicals. Use only as directed. If frozen, thaw and remix before use.

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: This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, in a land fill approved for pesticides.

Container Disposal: Triple rinse and deposit in a waste container for incineration or burial in a land fill approved for pesticide containers.

General: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning.

BEST AVAILABLE COPY

Classified by Calgon Vestal, Inc. as "E" in the "Confidentiality" when used on floors, walls, woodwork, bathroom fixtures, equipment, and furniture. Coverage 256 may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo, or other combination type floors.

such as floors, walls, woodwork, bathroom fixtures, equipment, and furniture. Coverage 256 may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo, or other combination type floors.

Coverage 256 is intended for use only in institutions such as hospitals, nursing homes, industrial plants, schools, medical and dental offices, and veterinary clinics where disinfection, cleaning and deodorization are needed.

Germicidal: Passes A O A C Germicidal Use-Dilution Method (S aureus, S choleraesuis, Ps aeruginosa) when diluted with 400 ppm hard water to make a 1:256 (1/2 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20 C.

Broad Spectrum Data: In addition, the following organisms pass the A O A C use-dilution test in 400 ppm A O A C, hard water at a dilution of 1:256 in the presence of 5% organic soil (serum)

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|---|--|
| <i>Acinetobacter calcoaceticus</i> , ATCC 19606 | <i>Salmonella typhimurium</i> , ATCC 14028 |
| <i>Candida albicans</i> , Clinical Isolate | <i>Serratia marcescens</i> , ATCC 8198 |
| <i>Candida parapsilosis</i> , Clinical Isolate | <i>Shigella flexneri</i> , ATCC 10422 |
| <i>Citrobacter freundii</i> , ATCC 8090 | <i>Shigella sonnei</i> , ATCC 25931 |
| <i>Enterobacter aerogenes</i> , ATCC 13048 | <i>Staphylococcus aureus</i> , ATCC 11423 |
| <i>Enterobacter cloacae</i> , ATCC 25355 | <i>Staphylococcus aureus</i> (MRSA)
Multiply (Methicillin) Resistant - Clinical Isolate |
| <i>Escherichia coli</i> , ATCC 25922 | <i>Staphylococcus epidermidis</i> , ATCC 12228 |
| <i>Klebsiella pneumoniae</i> , ATCC 49583 | <i>Streptococcus faecalis</i> , ATCC 11454 |
| <i>Proteus vulgaris</i> , ATCC 13315 | <i>Streptococcus pyogenes</i> , ATCC 19615 |
| <i>Pseudomonas aeruginosa</i> , ATCC 27853 | |

Fungicidal: Passes A O A C Fungicidal Test (T mentagrophytes) when diluted with 400 ppm hard water to make a 1:256 (1/2 ounce per 1 gallon) solution, in the presence of 5% added organic soil (serum), 10 minutes at 20 C.

Virucidal: Passes Virucidal Qualification Test (Influenza A, (Japan); Herpes simplex Types 1 and 2; Vaccinia) when diluted with 400 ppm hard water to make a 1:256 (1/2 ounce per 1 gallon) solution in the presence of organic soil (serum), 10 minutes at 20 C on hard nonporous inanimate environmental surfaces.

When tested by an EPA-approved Dilution Method, the HIV (AIDS) virus with added 5% organic soil (serum), was completely inactivated by a 1:256 (1/2 ounce per 1 gallon) solution in 400 ppm AOAC hard water in 30 seconds at 20 C.

Odor Control: Eliminates most odors by killing odor-causing bacteria and simultaneously chemically neutralizing their odors, cleans unpleasant-smelling soils and leaves a pleasant lingering fragrance.



Calgon Vestal Laboratories
Division of Calgon Corporation
Subsidiary of Merck & Co., Inc.
St. Louis, MO 63133

EPA Est. No. 1043 MO 1 b360 ub

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

[Redacted]

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

1043-82