

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 06 1993

Calgon Vestal Laboratories
Division of Calgon Corporation
P.O. Box 147
St. Louis, MO 63166

Attn: Michael Ebers

Subject: Coverage 256
EPA Registration No. 1043-82
Amendment dated October 26, 1992

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to include additional efficacy claims to the pesticide label, is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

- a. On the center panel, the "Virucide" claim must be keyed by a symbol to the paragraph listing the specific tested viruses.
- b. Change the word "porcelain" to read "glazed porcelain".
- c. Under the heading "Fungicide" delete "Aspergillus niger, ATCC 6275". You may wish to include "Aspergillus niger" under the heading "Fungistat".

2. Submit five (5) copies of 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.

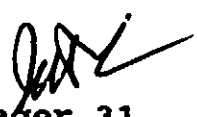
A stamped copy of the labeling is enclosed for your records.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely,

John H. Lee 
Product Manager 31
Antimicrobial Program Branch
Registration Division H7505C

Enclosure

CENTER PANEL

Calgon Vestal
COVERAGE® 256

GERMICIDAL DETERGENT

E.P.A. Reg. No. 1043-82

Germicide • Fungicide • Virucide • Detergent • Deodorizer • Concentrate

Active Ingredients

Octyl decyl dimethyl ammonium chloride	...	4.60%
Dioctyl dimethyl ammonium chloride	...	2.30%
Didecyl dimethyl ammonium chloride	...	2.30%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	...	6.14%
Inert Ingredients	...	84.66%

One-Step Germicidal Detergent and Deodorizer for Health Care and Food Processing Institutions, Industrial, Research, Veterinary and Agricultural Use.

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

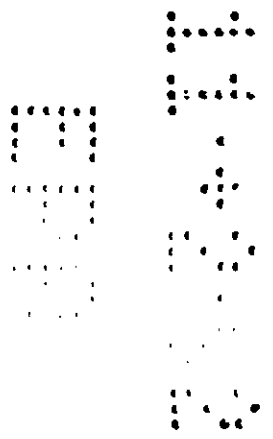
In case of eye contact, flush with water for 15 minutes. Get prompt medical attention. For skin contact, flush with water. See side panel for additional precautionary statements.

CONTENTS: One U.S. Gallon
(3.78 Liters)

ACCEPTED
with COMMENTS
in EPA Letter Batch

APR 06 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
and amended, for the pesticide
registered under EPA Reg. No.
1043-82



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 a large quantity of egg white, gelatin solution, or water. Avoid alcohol. Do not induce vomiting. Call a 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, brush or coarse spray 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.

CLEANING AND DISINFECTING Pharmaceutical and Manufacturing Facilities: Add one-half ounce (15 cc) to each measured gallon of water used. Always add this product to premeasured water. Gently mix for a uniform solution. Apply solution with a cloth, sponge, mop, brush or coarse spray 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. This is a complete product. Do not add other chemicals. Use only as directed.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY FACILITY CLEANING AND DISINFECTING: Remove or cover all food, feedstuffs, packaging materials and livestock. Remove all litter, manure and other debris from floors and walls; scrape if necessary. Empty all troughs, racks, feeders and waterers. Saturate all surfaces with a 1:256 solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen adhering soils. Allow to soak for 10 minutes, then pick up excess with a wrung-out applicator. Flush feeders and waterers with potable water after disinfecting. Drain all surfaces, ventilate buildings and allow to air-dry before use or rehousing animals.

CLEANING AND DISINFECTING FOOD PREPARATION AND PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen all soils. Allow to soak for 10 minutes. Thoroughly rinse all wetted and cleaned surfaces with potable water.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging (wet misting) as an adjunct either preceding or following regular cleaning and disinfecting procedures in research and manufacturing facilities, in poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Use a 1:256 dilution (1/2 ounce per gallon of water). Remove all animals and feed from areas to be fogged. Remove all litter and manure from surfaces or areas traversed by animals. Empty all trough, racks and other feeding and watering appliances. Thoroughly clean all surfaces. Fog the desired area at 32 to 64 ounces of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before reentering fogged area. Before fogging remove or cover any food or packaging material with waterproof coverings. Treated surfaces must be thoroughly scrubbed with Coverage 256 at a 1:256 dilution and rinsed with potable water before reuse. Do not rehouse livestock or employ equipment until treatment has dried.

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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of 1:256 use-solution (1/2 ounce per gallon). Prepare and apply solution as directed in paragraph above.

CONTACT TIME: While the HIV-1 virus is inactivated in 30 seconds, use a 10 minute contact time for disinfection of all organisms on this label.

INFECTIOUS MATERIALS DISPOSAL: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposals.

STORAGE AND DISPOSAL

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

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, or in a landfill approved for pesticides.

CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning. If frozen thaw and remix before use.



DIVISION OF CALGON CORPORATION
SUBSIDIARY OF MERCK & CO., INC.

ST. LOUIS, MO 63133

ACCEPTED
with COMMENTS
to EPA Letter Dated:

APR 06 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
and amended, for the pesticide
registered under EPA Reg. No.
1043-12

BEST AVAILABLE COPY

Coverage 256 is a research-developed, hard water effective, phosphate-free, concentrated, germicidal detergent system formulated to simultaneously clean, disinfect and deodorize in the presence of 5% organic soil (serum). It may be used for cleaning and disinfecting of washable hard non-porous surfaces 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 in institutions such as hospitals, nursing homes, industrial plants, schools, medical and dental offices pharmaceutical, cosmetic and food processing, preparation and service facilities, in animal husbandry, poultry and feed processing facilities, veterinary clinics, animal research facilities, and in other indoor areas where infectious contamination control is a necessity. **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.

It has also been shown in the A.O.A.C. Use-Dilution Test, when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 solution (1/2 ounce per 1 gallon of water) in the presence of 5% organic soil (serum), 10 minutes at 20°C to inactivate:

- Acinetobacter calcoaceticus, ATCC 19606
- Bordetella avium, ATCC 35086
- Bordetella bronchiseptica, ATCC 10580
- Campylobacter jejuni, ATCC 29428
- Candida albicans, Clinical Isolate
- Candida parapsilosis, Clinical Isolate
- Citrobacter freundii, ATCC 8090
- Enterobacter aerogenes, ATCC 13048
- Escherichia coli, ATCC 25922
- Klebsiella pneumoniae, ATCC 13883
- Listeria monocytogenes, ATCC 19111
- Mycoplasma gallisepticum, ATCC 19610
- Pasteurella multocida, ATCC 27853
- Proteus vulgaris, ATCC 13315

- Pseudomonas aeruginosa, ATCC 9027
- Pseudomonas cepacia, ATCC 25609
- Salmonella enteritidis, ATCC 13076
- Salmonella typhimurium, ATCC 14028
- Serratia marcescens, ATCC 8100
- Shigella flexneri, ATCC 12022
- Shigella sonnei, ATCC 25931
- Staphylococcus aureus, ATCC 25923
- Staphylococcus aureus, (MRSA, Multiple (Methicillin)-Resistant Clinical Isolate)
- Staphylococcus epidermidis, ATCC 12228
- Streptococcus faecalis, ATCC 19433
- Streptococcus pyogenes, ATCC 19615

ACCEPTED WITH COMMENTS to EPA Letter Brief

APR 06 1993

Under the Federal Insecticide, Fungicide, and Rodenticide Act amended, for the pesticide registered under EPA Reg. No. 1043-FA

Fungicide: Passes A.O.A.C. Fungicidal Test (*T. mentagrophytes* and *Aspergillus niger*, ATCC 6275) when diluted with 400 ppm A.O.A.C. 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.

***Virucide:** Coverage 256 is effective against the following viruses according to the EPA-approved virucidal assay method when diluted with 400 ppm hard water to make a 1:256 (1/2 ounce per gallon) solution, in the presence of 5% organic soil (serum) in 10 minutes at 20-25°C on hard non-porous environmental surfaces:

- Canine distemper, ATCC-128
- Canine parainfluenza, ATCC VR-399
- Chlamydia psittaci (Feline Pneumonitis)
- Feline rhinotracheitis, ATCC VR-636
- Herpes simplex Types 1 and 2
- Infectious bronchitis, ATCC VR-22

- Infectious laryngotracheitis, ATCC VR-783
- Influenza A₂ (Japan-305)
- Marek's Disease, ATCC VR-2002
- Mouse hepatitis, ATCC VR-764
- Newcastle Disease, ATCC VR-109
- Vaccinia virus

Effective against Canine parvovirus, ATCC VR-953, Feline calicivirus, ATCC VR-782, Infectious bursal disease (Lukert strain) according to the EPA-approved virucidal assay method when diluted 1:64 in 400 ppm hard water in 5% organic soil (serum) in 10 minutes at 20-25°C on hard non-porous environmental surfaces.

When tested by an EPA-approved Dilution Method the HIV-1 (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 A.O.A.C. hard water in 30 seconds at 20°C. Although efficacy at 30 seconds contact time has been shown to be adequate against HIV-1 this time would not be sufficient for other organisms. Use a 10 minute contact time for disinfection against all of the organisms claimed.

Odor Control: Eliminates most odors by killing odor-causing bacteria and simultaneously chemically neutralizing their odors. Cleans unpleasant smelling soils.

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