

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 3 1996

Convatec  
Division of E.R. Squibb & Sons Inc.  
5011 Manchester Avenue  
St. Louis, MO 63110-2096

Attention: Mike Ebers  
Niki Uebinger  
Regulatory Specialists

Subject: COVERAGE 256  
EPA Registration No. 1043-82  
Your Amendment Dated October 12, 1995  
EPA Received Date October 17, 1995

The amendment referred to above, submitted in response to the Agency letter of December 19, 1994, and in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to remove all references to healthcare use, and delete efficacy claims against Pseudomonas aeruginosa (ATCC 9027) and HIV-1, has been reviewed by the Agency and found to be acceptable, provided you make the following labeling changes before you release the product for shipment bearing the amended labeling.

1. Per the Agency letter of December 19, 1994, please remove all references to Pseudomonas aeruginosa (ATCC 9027). Remove Ps. aeruginosa from the sentence "Passes A.O.A.C. Germicidal Use-Dilution Method (S. aureus, S. choleraesuis, Ps. aeruginosa) when diluted with 400 ppm..." and delete it from the list of organisms under the heading "Broad Spectrum Data:".

2. Under "PRECAUTIONARY STATEMENTS" change "Hazard to Humans and Domestic Animals:" to read "Hazards to Humans and Domestic Animals: DANGER".

3. Before the "DIRECTIONS FOR USE" section, insert the PR Notice 95-1 effluent discharge statement:

"ENVIRONMENTAL HAZARDS: 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."

CONCURRENCES

|         |          |  |  |  |  |  |  |
|---------|----------|--|--|--|--|--|--|
| SYMBOL  | 75052    |  |  |  |  |  |  |
| SURNAME | D. Arado |  |  |  |  |  |  |
| DATE    | 10/2/96  |  |  |  |  |  |  |

4. Revise the "Pesticide Disposal:" statement on the one (1) gallon product container labeling to read:

"Do not reuse empty container. Wrap container in several layers of newspaper and put in trash."

For the five (5) and fifty-five (55) gallon product container labeling, use the following pesticide disposal statements or refer to PR Notices 83-3 and 84-1 for additional guidance:

"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."

A stamped copy of the COVERAGE 256 product labeling is enclosed for your records. Submit one (1) copy of the final printed labeling before you release the product for shipment.

If you have any questions concerning this letter, please contact Doreen Aviado of my staff at (703) 305-6554.

Sincerely,



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

Enclosure

394

### PRECAUTIONARY STATEMENTS

#### Hazard to Humans and Domestic Animals:

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.

**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 (one half 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 (one half 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-poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Use a 1:256 dilution (one half ounce per gallon of water). Do not use in milking stalls, parlors or houses. 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 with soap or detergent and rinse with water. 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 water-proof 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.

#### 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:** 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.

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

# COVERAGE<sup>®</sup> 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 <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride..... | 6.14%         |
| <b>Inert Ingredients:</b> .....   | <b>84.66%</b> |

One-Step Germicidal Detergent and Deodorizer for 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)



CALGON VESTAL LABORATORIES, INC.  
St. Louis, Missouri 63110

0022

Classified by Underwriters Laboratories Inc. as to Electrical Conductivity when used on conductive floors and spontaneous heating. Coverage 256 for use with Listed Electrical Concentrates. Electrical Concentrates should be used with caution.

484

# 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%  |
| Diocetyl dimethyl ammonium chloride.....  | 2.30%  |
| Didecyl dimethyl ammonium chloride.....   | 2.30%  |
| Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>10</sub> ) dimethyl benzyl ammonium chloride..... | 6.14%  |
| Inert Ingredients:.....   | 84.66% |

One-Step Germicidal Detergent and Deodorizer for 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)



CALGON VESTAL LABORATORIES, INC.  
St. Louis, Missouri 63110

Classified by Underwriters Laboratories Inc. as to Electrical Conductivity when used on conductive floors and spontaneous heating. Coverage 256 for use with Listed Electrically Conductive Flooring of the vinyl type. 9-42P.

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, glazed 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 veterinary clinics, animal husbandry, poultry and feed processing facilities, animal research facilities, food processing, preparation and service 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 (one half ounce per 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):

|   |  |  |  |  |
|---|--|--|--|--|
| <i>Acinetobacter calcoaceticus</i> , ATCC 19606 | <i>Citrobacter freundii</i> , ATCC 8090    | <i>Mycoplasma gallisepticum</i> , ATCC 19610 | <i>Salmonella typhimurium</i> , ATCC 14028 | <i>Staphylococcus aureus</i> (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate |
| <i>Bordetella avium</i> , ATCC 35086            | <i>Enterobacter aerogenes</i> , ATCC 13048 | <i>Pasteurella multocida</i> , ATCC 29777    | <i>Serratia marcescens</i> , ATCC 8100     | <i>Staphylococcus epidermidis</i> , ATCC 12228   |
| <i>Bordetella bronchiseptica</i> , ATCC 10580   | <i>Enterobacter cloacae</i> , ATCC 23355   | <i>Proteus vulgaris</i> , ATCC 13315         | <i>Shigella flexneri</i> , ATCC 12022      | <i>Streptococcus faecalis</i> , ATCC 19433   |
| <i>Campylobacter jejuni</i> , ATCC 29428        | <i>Escherichia coli</i> , ATCC 25922       | <i>Pseudomonas aeruginosa</i> , ATCC 9027    | <i>Shigella sonnei</i> , ATCC 25931        | <i>Streptococcus pyogenes</i> , ATCC 19615   |
| <i>Candida albicans</i> , Clinical Isolate      | <i>Klebsiella pneumoniae</i> , ATCC 13883  | <i>Pseudomonas cepacia</i> , 25609           | <i>Staphylococcus aureus</i> , ATCC 25923  |  |
| <i>Candida parapsilosis</i> , Clinical Isolate  | <i>Listeria monocytogenes</i> , ATCC 19111 | <i>Salmonella enteritidis</i> , ATCC 13076   |  |  |

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

Fungistat: Passes A.O.A.C. Fungicidal Test (*Aspergillus niger*, ATCC 6275) when diluted with 400 ppm A.O.A.C. 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°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:

|                                    |  |   |                                |
|------------------------------------|--|---|--------------------------------|
| Avian infectious bronchitis        | <i>Chlamydia psittaci</i> (Feline Pneumonitis) | Infectious laryngotracheitis, ATCC VR-783 | Newcastle Disease, ATCC VR-109 |
| Avian infectious laryngotracheitis | Feline rhinotracheitis, ATCC VR-636            | Influenza A, (Japan-305)                  | Porcine pseudorabies           |
| Canine distemper, ATCC-128         | Herpes simplex Types 1 and 2                   | Marek's Disease, ATCC VR-2002             | Vaccinia virus                 |
| Canine parainfluenza, ATCC VR-399  | Infectious bronchitis, ATCC VR-22              | Mouse hepatitis, ATCC VR-764              |                                |

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 (2 ounces per gallon) in 400 ppm hard water in 5% organic soil (serum) in 10 minutes at 20-25°C on hard non-porous environmental surfaces.

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.

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ACCEPTED  
with COMMENTS  
in EPA Letter Dated

OCT 3 1996

EPA Est. No. 1043-MO-1

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

6360-06F(995)

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