

3377-57

10-12-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Albermarle Corporation  
451 Florida Street  
Baton Rouge, LA 70801

OCT 12 2000

Subject: ACLD-256  
EPA Registration No. 3377-57  
Amendment Date: 4/12/00  
EPA Receive Date: 4/18/00

Attention: Ms. Ann Oxford

The amendment, referenced above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) to update the Confidential Statement of Formula (CSF) and add additional organisms to the label is acceptable provided you address the following comments before you release this product for shipment.

**Product Chemistry**

The Confidential Statements of Formulas for the basic and six (6) alternate formulations dated 3/31/00 are acceptable; they are in agreement with PR Notice 91-2 and the label. The request for broader certified limits for the dyes and fragrances are also acceptable.

The one year storage stability study, MRID No. 450986-01, is acceptable and satisfies product chemistry guideline 830.6317.

Please Note: All other CSFs on file are now obsolete.

**Efficacy**

The efficacy study, MRID No. 450385-02, demonstrated ACLD-128's effectiveness as a mildewcide against *Aspergillus niger* (ATCC 6275) when used as directed in 5% organic soil load in 400 ppm hard water for ten minutes.

The efficacy study, MRID No. 450385-03, showed this product's effectiveness against *Trichophyton mentagrophytes* (ATCC 3522) when used as directed in 5% organic soil load in 400 ppm hard water for ten minutes. The study ~~shows~~ <sup>shows</sup> the increased contact time from 5

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minutes to 10 minutes.

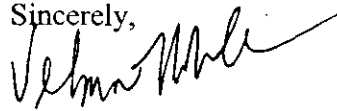
The efficacy studies, MRID Nos. 450985-04 thru 450925-10, demonstrate this product's effectiveness against the following antibiotic resistant organisms, *Staphylococcus epidermidis*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterococcus faecium* as well as penicillin resistant *Streptococcus pneumoniae*, Vancomycin resistant *Enterococcus faecium*, and methicillin resistant *Staphylococcus aureus* when used as directed in 5% organic soil load in 400 ppm hard water for 10 minutes.

**Label Recommendations**

1. After the last statement in the Veterinary Practice/Animal Life Science Laboratories section, you will need to state *"Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution should be made daily or visibly soiled."*
2. On April 11, 2000, The Agency published PR Notice 2000-3, First Aid Statements for Pesticide Product Labels. You will need to revise your "Statements of Practical Treatment" accordingly. It is the Agency's goal to have all the product labels revised by October 1, 2001.

A stamped copy of the label is enclosed for your records. You should submit one copy of the final printed label before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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# ACLD-256

One Step Germicidal Cleaner and Deodorant

Staphylocidal/Pseudomonacidal/Salmonellacidal/Fungicidal/\*Virucidal

**ACTIVE INGREDIENTS:**

Didecyl dimethyl ammonium chloride .....	11.51%
N-Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%) dimethyl benzyl ammonium chloride .....	9.45%
OTHER INGREDIENTS:.....	79.04%

**KEEP OUT OF THE REACH OF CHILDREN**

## DANGER

See additional precautionary statements on back panel

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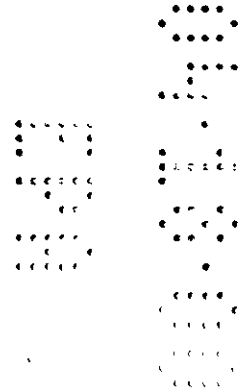
EPA Est. \_\_\_\_\_

Net Contents: \_\_\_\_\_

ACCEPTED  
with COMMENTS  
in EPA Letter dated

OCT 12 2000

Under the Toxic Substances Control Act, Fungicide, and Rodenticide Act, as amended, for the pesticide use specified, registered under EPA Registration No. 3377-57



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**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Corrosive. Causes irreversible eye damage and/or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get into eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Do not breathe spray vapor or spray mist. Wear a mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P or HE filter.

**FIRST AID**

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention.

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention

**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink large quantities of water. Avoid alcohol.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate gastric lavage.

This product contains no phosphorous or nonyl phenol ethoxylate detergents. ACLD-256 saves time, labor, and cost. It is specially formulated to be non-dulling to floor finishes and requires no rinsing. ACLD-256 is recommended for use on non-food contact surfaces in hospitals, nursing homes, schools and colleges, veterinary clinics, animal life science laboratories, and hotels. ACLD-256 is a broad-spectrum germicidal cleaner and deodorant that is effective at 1:256 (½ ounce per gallon) dilution in the presence of 400 ppm hard water (calculated as CaCO<sub>3</sub>) plus 5% organic blood serum against the following organisms:

Bactericidal in 10 minutes against: *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Salmonella choleraesuis* ATCC 10788, *Enterobacter aerogenes* ATCC 13048, and *Shigella dysenteriae* ATCC 9361.

Bactericidal in 5 minutes against: *Enterococcus faecium* ATCC 6569, *Escherichia coli* ATCC 8739, *Salmonella typhimurium* ATCC 14028, *Proteus mirabilis* GBL 34 Clinical Isolate, *Proteus vulgaris* ATCC 33240, *Salmonella typhi* ATCC 12022, *Serratia marscescens* ATCC GBL-NC 76 Industry Isolate, *Shigella flexneri* ATCC 19615, *Streptococcus pyogenes* ATCC 19615, *Shigella sonnei* ATCC 9290, *Staphylococcus epidermidis* ATCC 14990, *Yersinia enterocolitica* ATCC 23715, Vancomycin Resistant *Enterococcus faecium* (VRE), *Escherichia coli* 0157:H7 ATCC 35150, *Salmonella choleraesuis* (ssp pullorum) ATCC 19945, *Salmonella choleraesuis* (ssp enteritidis) ATCC 13076, *Listeria monocytogenes* ATCC 984, *Klebsiella pneumoniae* ATCC 13883, Antibiotic Resistant *Staphylococcus epidermidis*, Antibiotic Resistant *Escherichia coli*, Antibiotic Resistant *Enterococcus faecium*, Antibiotic Resistant *Klebsiella pneumoniae*, Methicillin Resistant *Staphylococcus aureus* (MRSA) ATCC 33591, Penicillin Resistant *Streptococcus pneumoniae* ATCC 35088

Fungicidal in 5 minutes against: *Candida albicans* ATCC 10231

Fungicidal in 10 minutes against: *Trichophyton mentagrophytes* ATCC 9533

\*Virucidal in 5 minutes against: \*Herpes simplex, Type 1 ATCC VR-733, Strain F(1), \*Herpes simplex Type 2 ATCC VR-734, Strain G, \*Influenza Virus Type A2 ATCC VR-544, Asian Influenza Virus Hong Kong, \*Pseudorabies Virus ATCC VR-135, Strain Aujeszky, \*Respiratory Syncytial Virus ATCC VR-26 Strain Long, \*Vaccinia Virus ATCC VR-119, Strain WR,

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Virucidal in 30 seconds against: \*Human Immunodeficiency Virus, Type 1, Strain HTLV-III, Vanderbilt U.

Mildewcidal in 10 minutes against: *Aspergillus niger*

**DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is not to be used as 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.

**CLEANING/DEODORIZING**

Apply use solution (1:256 dilution) to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, or sprayer. Allow surfaces to air dry.

**MILDEWCIDAL:** At a 1:256 dilution in 400 ppm hard water (calculated as CaCO<sub>3</sub>) and 5% organic blood serum, ACLD-256 will kill *Aspergillus niger* when applied to hard, nonporous surfaces. Follow disinfection instructions. Allow to dry on surface. Repeat when mildew growth returns.

**FUNGICIDAL:** Kills *Trichophyton metagrophytes*, the fungus causing athlete's foot, on environmental surfaces such as shower room floors, locker room benches, and bath mats at 1:256 (½ ounce per gallon) with a contact time of 10 minutes

**GENERAL DISINFECTION**

For use on the following hard, inanimate, nonporous surfaces: floors, walls, metal surfaces, glazed porcelain, and plastic surfaces. Can be used on the outside of appliances, microwaves, and refrigerators. Add ½ ounce product per gallon of water. Remove gross filth and heavy soil deposits then thoroughly wet surfaces for 10 minutes. Can be applied with a mop, sponge, cloth, as well as coarse spraying or soaking. For sprayer applications, use a coarse mist pump or trigger sprayer. Spray 6 - 8 inches from surface, rub with brush, sponge, or cloth. Do not breathe spray mist. NOTE: With spray applications, cover or remove all food products. Prepare a fresh solution daily or when solution becomes visibly dirty. Solution can remain on the surface to air dry unless used on a floor, which is to be waxed or polished.

**Veterinary Practice/Animal Life Science Laboratories Disinfection:** For cleaning and disinfecting hard non-porous surfaces including equipment, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of ½ ounce of ACLD-256 per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

**\*KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of HIV-1 (AIDS virus).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

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in EPA Letter Dated:

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**PERSONAL PROTECTION:** Disposable latex or vinyl gloves, gowns, face masks or eye coverings as appropriate, must be worn during all cleaning of blood/body fluids, and decontamination procedures.

**CLEANING PROCEDURE:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

**CONTACT TIME:** HIV-1 is inactivated after a thirty (30) second contact time. Use either a five (5) or ten (10) minute contact time for other organisms, as stated on the label.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood/body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

**NON-ACID TOILET BOWL DISINFECTANT DIRECTIONS:**

Remove gross filth prior to disinfection.

**FROM CONCENTRATE:** Add 1/2 ounce to the toilet bowl or urinal and mix. Brush thoroughly over exposed surfaces and under the rim with a cloth, mop, sponge, or spray. Allow to stand for ten (10) minutes then flush.

**FROM USE SOLUTION:** Empty toilet bowl or urinal and apply a 1/2 ounce per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge, or sprayer. Allow to stand for ten (10) minutes, then flush.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE**

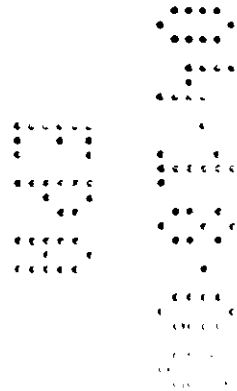
Store in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

**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 can not 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:** [5 gallon - 55 gallon plastic] 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.

[one gallon or less] Do not reuse empty container. Wrap container and put in trash.



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