

3377-59

08/11/2000

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Albemarle Corporation  
451 Florida Street  
Baton Rouge, LA 70801

AUG 11 2000

Subject: ACLD-64  
EPA Registration No. 3377-59  
Amendment Date: 4/11 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. 451201-01, is acceptable and satisfies product chemistry guideline 830.6317.

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

**Efficacy**

Since ACLD-64 is a use dilution of ACLD-256 (EPA Reg. No. 3377-57), efficacy data submitted on ACLD-256 will also support this product as well as ACLD -128 (EPA Reg. No. 3377-58).

The efficacy data in MRID Nos. 450385-02 and 450385-03 support this product's effectiveness as a fungicide and mildewcide against *Trichophyton mentagrophytes* (ATCC 3522) and *Aspergillus niger* (ATCC 6275), respectively, when used as directed in 5% organic soil load

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in 400 ppm hard water for ten minutes. The study supports the increased contact time from 5 minutes to 10 minutes.

The efficacy studies to support the claims of antibiotic resistant in MRID Nos. 450985-04 thru 450925-10 are unacceptable because the studies are incomplete. Organisms to be labeled as "antibiotic resistant" must be identified by a specific organism number and origin (American Type Culture, CDC, clinical isolate), and scientific data must be submitted to verify the resistance results. When you submit the data, include the following:

- a. Results of the testing including the values of all antibiotics tested
- b. The scientific method used to obtain the results (Kirby-Bauer agar disk diffusion, automated MIC procedures, or agar gradient diffusion). If automated procedures are used, the manufacture of such automation must be specified.
- c. Quality control procedures used to verify results.
- d. A clear link of the identity of the organisms used in the efficacy testing to those for which valid antibiotic susceptibility testing was performed.

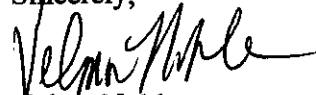
#### Label Recommendations

1. On page 2, delete all the antibiotic resistance organisms from the label. You may state that these organisms are clinical isolates.
2. On page 3, the Veterinary Practice/Animal Life Science Laboratories directions will need to be revised to reflect the following:

After the last statement in this 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.*"

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-64

One Step Germicidal Cleaner and Deodorant

Staphylocidal/Pseudomonacidal/Salmonellacidal/Fungicidal/Virucidal

**ACTIVE INGREDIENTS:**

Didecyl dimethyl ammonium chloride .....	2.8775%
N-Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%) dimethyl benzyl ammonium chloride .....	2.3625%
OTHER INGREDIENTS:.....	94.7600%

KEEP OUT OF THE REACH OF CHILDREN

## DANGER

See additional precautionary statements on back panel

EPA Registration No. 3377-59

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

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

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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-64** saves time, labor, and cost. It is specially formulated to be non-dulling to floor finishes and requires no rinsing. **ACLD-64** 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-64** is a broad-spectrum germicidal cleaner and deodorant that is effective at 1:64 (2 ounces 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, \*Strain 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### CLEANING/DEODORIZING

Apply use solution (1:64 dilution) to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, or sprayer. Allow surfaces to air dry.

**MILDEWCIDAL:** At a 1:64 dilution in 400 ppm hard water (calculated as CaCO<sub>3</sub>) and 5% organic blood serum, ACLD-64 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 1:64 (2 ounces 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 2 ounces 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 2 ounces of ACLD-64 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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**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 2 ounces 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 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.

ACCEPTED  
With Comments

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