

3377-68

12/06/2000

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg Number:

Date of Issuance:

3377-68

DEC - 6 2000

Term of Issuance:

Conditional

Name of Pesticide Product:

HD-128

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Albemarle Corporation
451 Florida Street
Baton Rouge, LA 70801

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 3377-68".
 - b. Add the company name and address to the label because it is a required feature of the pesticide product. It may be placed any where on the label, but is typically located on the front panel of the pesticide label (40 CFR 156.10 (c)).
 - c. Since this product is classified in toxicity category I for primary skin irritation and III for acute dermal toxicity, you need to include the phrase, "protective clothing" to the statement, "Wear goggles/face shield and rubber gloves when handling.
 - d. Under Veterinary Practice/Animal Laboratories directions, add the following statement as the last sentence in this section, "After disinfecting the feeding and watering equipment, rinse with potable water."

Signature of Approving Official:

Velma Noble
Velma Noble

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

Date

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3. Submit two (2) copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

A stamped label is enclosed for your records. 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)

Enclosures: Acute Toxicity Data Evaluation
Efficacy Data Evaluation

HD-128

Heavy Duty, One-Step Disinfectant, Germicidal Cleaner and Deodorant

Staphylocidal/Pseudomonacidal/Salmonellacidal/Fungicidal/Virucidal

ACTIVE INGREDIENTS:

| | |
|--|---------|
| Didecyl dimethyl ammonium chloride | 5.630% |
| N-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride..... | 4.608% |
| OTHER INGREDIENTS:..... | 89.762% |

KEEP OUT OF THE REACH OF CHILDREN

DANGER

See additional precautionary statements on back panel

EPA Registration No. 3377-

EPA Est. _____

Net Contents: _____

ACCEPTED
with COMMENTS
in EPA Letter Dated

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 3377-68

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

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. May be fatal if inhaled. Do not breathe spray mist. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Harmful if swallowed or absorbed through skin. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove clothing and wash before reuse.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

- HD-128 is a broad-spectrum germicidal cleaner and deodorant that is effective at 1:128 (1 ounce per gallon) dilution in the presence of 400 ppm hard water (calculated as CaCO₃) plus 5% organic blood serum.
- HD-128 contains no phosphorous or nonyl phenol ethoxylate detergents.
- HD-128 saves time, labor, and cost. It is specially formulated to be non-dulling to floor finishes and requires no rinsing.
- HD-128 is recommended for use on non-food contact surfaces in hospitals, nursing homes, schools and colleges, veterinary clinics, animal life science laboratories, and hotels.
- HD-128 is effective against the following organisms:

Bactericidal in 10 minutes against: *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Salmonella choleraesuis* ATCC 10708 and *Listeria monocytogenes* ATCC 15315.

Bactericidal in 5 minutes against: *Enterobacter aerogenes* ATCC 13048, and *Shigella dysenteriae* ATCC 13313, *Enterococcus faecium* ATCC 19434, *Escherichia coli* ATCC 11223, *Salmonella typhi* ATCC 6539, *Shigella flexneri* ATCC 29508, *Streptococcus pyogenes* ATCC 19615, *Shigella sonnei* ATCC 11060, *Staphylococcus epidermidis* ATCC 12228, *Yersinia*

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enterocolitica ATCC 23715, Vancomycin Resistant *Enterococcus faecium* (VRE), *Escherichia coli* 0157:H7 ATCC 35150, *Salmonella choleraesuis* (ssp pullorum) ATCC 9120, *Salmonella choleraesuis* (ssp enteritidis) ATCC 13076, *Klebsiella pneumoniae* ATCC 4352, Antibiotic Resistant *Staphylococcus epidermidis*, Antibiotic Resistant *Escherichia coli*, Antibiotic Resistant *Enterococcus faecium*, Methicillin Resistant *Staphylococcus aureus* (MRSA) ATCC 33591, Penicillin Resistant *Streptococcus pneumoniae* ATCC 35088

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

*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; Bovine Viral Diarrhea Virus ATCC VR-543, Strain NADL.

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

Mildewcidal in 10 minutes against: *Aspergillus niger* ATCC 6275.

Fungicidal in 10 minutes against: *Trichophyton mentagrophytes* ATCC 9533, blood serum and 300 ppm hard water.

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 (1:128 dilution) to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, or sprayer. Allow surfaces to air dry.

MILDEWCIDAL: At a 1:128 dilution in 400 ppm hard water (calculated as CaCO₃) and 5% organic blood serum, HD-128 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 mentagrophytes*, the fungus causing athlete's foot, on environmental surfaces such as shower room floors, locker room benches, and bath mats at 1:128 (1 ounce per gallon) in 300 ppm hard water (calculated as CaCO₃) and 5% blood serum 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 1 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

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soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 ounce of HD-128 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.

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 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 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.

STORAGE

Store in areas inaccessible to children.

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: (1 gallon or less) Do not reuse empty container. Wrap container and put in trash. (5 gallon - 55 gallon plastic) Triple rinse or equivalent. 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. (totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact appropriate vendor for tote pickup.

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