

3377-66

11-8-2001

4/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Ann Oxford
Manager, Regulatory Affairs
Albemarle Corporation
451 Florida Street
Baton Rouge, LA 70801

NOV 09 2001

Subject: HD 64
EPA Registration No. 3377-66
Amendment Date: May 18, 2001
EPA Receipt Date: May 22, 2001

Dear Ms. Oxford,

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- Confidential Statements of Formulas for Alternate Formulation # 6-11
- Add additional organisms to label: Hepatitis B Virus, *Proteus vulgaris* (ATCC 13315), *Streptococcus pneumonia* (Penicillin Resistant) (ATCC 70671)
- Minor Label Changes

General Comments

Product Chemistry

The Confidential Statements of Formulas for Alternate Formulations # 6-11 dated May 18, 2001 are acceptable. They are in compliance with PR Notice 91-2 and in agreement with the label.

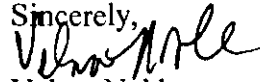
Efficacy

The efficacy studies submitted May 18, 2001 for 3377-67 are acceptable for this product in demonstrating effectiveness against Hepatitis B Virus, *Proteus vulgaris* (ATCC 13315), *Streptococcus pneumonia* (Penicillin Resistant) (ATCC 70671) at a use dilution of 2 oz/gallon of water.

		CONCURRENCES					
SYMBOL	7500						
SURNAME	M. Malone						
DATE	11/9/01						

A stamped label is enclosed for your records. Please submit one (1) copy of the final printed label to the Agency before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

3/6

HD-64

Heavy Duty, One-Step Disinfectant, Germicidal Cleaner and Deodorant
Staphylocidal/Pseudomonacidal/Salmonellacidal/Fungicidal/Virucidal

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride	2.815%
N-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride	2.304%
OTHER INGREDIENTS:	94.881%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

See additional precautionary statements on back panel



In case of an emergency endangering life or property involving this product, call collect (225) 344-7147.

EPA Registration No. 3377-66
EPA Est. No. 71728-IL-1, 10324-IL-1

Net Contents: _____

ACCEPTED
with COMMENTS
in EPA Letter Dated:
NOV 09 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for use as a disinfectant registered under EPA Reg. No. 3377-66

4/6

**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, rubber gloves and protective clothing 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-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 CaCO₃) plus 5% organic blood serum

- **HD-64** contains no phosphorous or nonyl phenol ethoxylate detergents.
- **HD-64** saves time, labor, and cost. It is specially formulated to be non-dulling to floor finishes and requires no rinsing.
- **HD-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.

- **HD-64** is effective against the following organisms:

Bactericidal in 10 minutes against: *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Salmonella choleraesuis* ATCC 10708, *Listeria monocytogenes* ATCC 15315 and *Proteus vulgaris* ATCC 13315.

Bactericidal in 5 minutes against: *Enterobacter aerogenes* ATCC 13048, *Shigella dysenteriae* ATCC 13313, *Enterococcus faecium* ATCC 19434, *Escherichia coli* ATCC 11229, *Salmonella typhi* ATCC 6539, *Shigella flexneri* ATCC 29508, *Streptococcus pyogenes* ATCC 19615, *Shigella sonnei* ATCC 11060, *Staphylococcus epidermidis* ATCC 12228, *Yersinia 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, Oxacillin Resistant *Streptococcus pneumoniae* ATCC 35088 and Penicillin Resistant *Streptococcus pneumoniae* ATCC 70061

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

***Virucidal in 5 minutes** against: Hepatitis B Virus (HBV), 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.

5/16

Fungicidal in 10 minutes against: *Trichophyton mentagrophytes* ATCC 9533, tested in 5% 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 pre-clean 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 CaCO₃) and 5% organic blood serum, HD-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 mentagrophytes*, 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) 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 2 ounces product per gallon of water. Remove gross filth and heavy soil deposits. Thoroughly wet surfaces by applying 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 should remain on the surface for 10 minutes or to air dry.

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 HD-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. After disinfecting the feeding and watering equipment, rinse with potable water.

***KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B 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) and/or HBV (Hepatitis B virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV 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. HBV is inactivated after a five minute 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.

6/6

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 sprayer. 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.

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.

[reusable container statement] Container can be reused once the container is empty. Empty container of concentrate into dilution dispenser {specific equipment can be named to replace "dilution dispenser".} Dispenser will automatically dilute a disinfectant solution. Remove concentrate label. Refill container with use dilution of concentrate from the dispenser. Replace cap with spray nozzle provided. Place correct use dilution label on the spray bottle.

(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.