



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

EPA Reg.
Number:

10492-5

Date of Issuance:

MAR 31 1998

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Discide Ultra
Disinfecting Spray

Name and Address of Registrant (include ZIP Code):

Palmero Health Care
120 Goodwin Place
Stratford, CT 06497

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 Registration No. "10492-5".

Marshall Swindell, *Martha J. Seng / for*
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Date:

MAR 31 1998

b. Delete the term "Human" from the phrase "Kills a Wide Range of Human Pathogens in One Minute". The term denotes application to the living body. Since the intent of use for this product is limited to inanimate environment, this word must be replaced by an appropriate descriptive term for the effects claimed in the inanimate applications recommended.

c. On the front panel, revise the statement "Isotex 70 Disinfecting Towelettes are effective against the following human pathogens when used as directed" to read "Isotex 70 disinfecting towelettes are effective against the following pathogens on hard non-porous surfaces when used as directed".

d. On the back panel, include the following HIV-1 statement above the "Special Instructions" for the HIV-1 claim.

"Kills HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

e. On the back panel, under the "TO DISINFECT" heading, revise the last sentence to read "When used as a tuberculocidal disinfectant, allow the surface to remain wet for 5 minutes at 20°C".

f. On the back panel, include a "Storage and Disposal heading.

g. The term "virucidal" and the two viruses on the front panel must be keyed with an double "Asterisk" or some other symbol to denote the specific viruses that have been tested.

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

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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 the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at 703-305-6217.

Sincerely,

Martha J. Swindell / for

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Enclosure

DisCide Ultra Disinfecting Spray

495

Kills A Wide Range of Human Pathogens In One Minute***Bactericidal ♦ Tuberculocidal ♦ Virucidal ♦ Fungicidal ♦ Herpeccidal**

DisCide Ultra Disinfecting Spray is an herbal scented, dual chain quaternary ammonium/high level alcohol solution.

Use In Health Care & Alternate Care Settings such as hospitals, intensive care units, emergency medical settings, central supply, laboratories, clinics, nursing homes and dental suites.

DisCide Ultra Disinfecting Spray is effective against the following human pathogens when used as directed (see back panel):

- ♦ HIV-1 (AIDS virus)
- ♦ Methicillin Resistant *Staphylococcus aureus* (MRSA)
- ♦ Vancomycin Resistant *Enterococcus faecalis* (VRE)
- ♦ *Staphylococcus aureus* (Staph)
- ♦ *Pseudomonas aeruginosa*
- ♦ *Salmonella choleraesuis*
- ♦ *Escherichia coli* (E. coli)
- ♦ Adenovirus type 2
- ♦ Herpes Simplex Virus type 2 (genital herpes virus)
- ♦ *Mycobacterium bovis* (Tuberculosis bacteria) (5-minute contact time required)*
- ♦ *Trichophyton mentagrophytes* (Athlete's Foot fungus)

ACTIVE INGREDIENTS

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride 0.12%

n-alkyl (60% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride 0.12%

Isopropyl alcohol 63.25%

INERT INGREDIENTS 36.51%

TOTAL INGREDIENTS 100.00%

Inert Ingredients do not include toilettes

WARNING

**KEEP OUT OF REACH
OF CHILDREN**

See back panel for additional
precautionary statements

EPA Reg. No. 10492-
EPA Est. No. 8325-PA-001

DisCide Ultra Disinfecting Spray meets the disinfection requirements of
OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030).

NET CONTENTS:

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 31 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
10492-5

(BACK PANEL)

595

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

TO DISINFECT: Completely pre-clean surfaces to be disinfected. DisCide Ultra Disinfecting Spray can be used for this purpose. Then, hold the DisCide bottle approximately 12 inches from the surface and thoroughly wet. Allow to remain wet for 1 minute. When used as a tuberculocidal disinfectant, allow the surface to remain wet for 5 minutes.

For Disinfection of: inanimate, pre-cleaned, hard, non-porous surfaces such as chairs, counter tops, drawer pulls, carts, baskets, tables, cabinets, telephones and other related hard surfaces in hospitals, operating rooms, intensive care and emergency units, dental or veterinary offices, surgery, recovery, anesthesia, X-Ray, Cat. Lab, orthopedics, newborn nursery, respiratory therapy, radiology, central supply, emergency medical vehicles, police and fire vehicles, correctional facilities, schools and school medical facilities, school buses, day care and non-food contact surfaces. Use on stainless steel, glass, formica and other similar surfaces. Use care when using on varnished surfaces, plexi-glass or leather.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

PERSONAL PROTECTION: Wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling HIV-1 infected blood or body fluids.

CLEANING PROCEDURE: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. DisCide Ultra Disinfecting Spray can be used for this purpose.

CONTACT TIME: Thoroughly wet surface with DisCide Ultra Disinfecting Spray. Allow to air dry. The efficacy of a 1 minute contact time has been shown to be adequate against HIV-1 (AIDS virus).

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

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals: WARNING. Avoid contact with eyes. In case of eye contact, flush with plenty of water for at least 15 minutes. If irritation persists, call a physician.

Physical or chemical hazards: Flammable. Keep away from heat or open flame.

DISPOSAL: Do not reuse empty container. Discard in trash.

For product emergency, contact Chem-Tel Inc. at 1-800-255-3924, 24 hours.

For technical information on this and other fine PHC spray disinfectants, antimicrobial hand asepsis products and other infection control products, call 1-800-344-6424 or fax 203-377-8988.

PALMERO HEALTH CARE, 120 GOODWIN PLACE, STRATFORD, CT 06497

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