

10492-5

12/15/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 15 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Fred T. Smith
Senior Regulatory Manager for,
Palmero Health Care
120 Goodwin Place
Stratford, CT 06615

Mail to: Sci Reg., Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: DisCide Ultra Disinfecting Spray
EPA Registration Number 10492-5
Your Amendment Dated August 7th, 2003
EPA Received Date August 7th, 2003


The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, in response to our letter dated June 5th, 2003, concerning the addition of the Hepatitis B Virus claim to the product labeling, is acceptable.

The receipt of this data completes the information needed to support the label claim of the effectiveness of DisCide Ultra Disinfecting Spray against Hepatitis B Virus on hard non-porous surfaces when exposed for a period of one minute.

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

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703) 308-6237.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

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DisCide Ultra Disinfecting Spray

Kills A Wide Range of Pathogens In One Minute*

Bactericidal ♦ Tuberculocidal ♦ Virucidal ♦ Fungicidal ♦ Herpeccidal**

DisCide Ultra Disinfecting Spray is 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 pathogens on hard non-porous, contact surfaces when used as directed:

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

ACTIVE INGREDIENTS	
n-alkyl (80% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	0.12%
n-alkyl (88% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride	0.12%
Isopropyl alcohol	63.25%
OTHER INGREDIENTS	36.51%
TOTAL INGREDIENTS	100.00%

WARNING
KEEP OUT OF REACH
OF CHILDREN
 See back panel for additional precautionary statements

EPA Reg. No. 10492-5
EPA Est. No. 8155-OH-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:
DEC 15 2003

Rev. 8/6/2003

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

10492-5

DIRECTIONS FOR USE:

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

General Precautions and Restrictions

This product is not to be used as a 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) contact 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.

TO DISINFECT: Completely preclean 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 visibly wet for 5 full minutes at 20° C.

For Disinfection of: inanimate, precleaned, 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 food-contact surfaces. Use on stainless steel, glass, formica and other similar surfaces. Use care when using on varnished surfaces, plexi-glass or leather. Note: Use on food-contact surfaces is required to be followed by a potable water rinse.

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).

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.** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Physical or Chemical Hazards: Flammable. Keep away from heat or open flame.

FIRST AID

If in eyes:	<ul style="list-style-type: none"> • 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.
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HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chem•Tel Inc. at 1-800-255-3924.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 15 2003

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store away from heat.

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 10492-9

For technical information on DisCide Ultra Spray, Towelettes, Aerosols, and DisAseptic Antibacterial Hand Asepsis Towelettes, call 1-800-344-6424 or fax 203-377-8988.