10492-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 2 9 2004

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Frederick T. Smith Agent for SciReg, Inc. Palmero Health Care 120 Goodwin Place Stratford, CT 06615

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

Subject: DisCide Ultra Disinfecting Spray EPA Registration Number 10492-5 Your Notification Date March 3rd, 2004 EPA Received Date March 3rd, 2004

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Rodenticide, and Fungicide Act(FIFRA), as amended, to replace "food contact" text" language with "non-food contact" text, is acceptable.

Your notification has been made part of the permanent record.

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)

CONCURRENCES							
SYMBOL							
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DATE							 ***************

OFFICIAL FILE COPY

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EPA Form 8750-1 (Rev. 3-94) Previous editions are obsolete

EPA Reg. No. 10492-5 March 3, 2004

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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Frederick *I*. Smith Senior Regulatory Specialist SciReg, Inc.*

*SciReg, Inc. is the authorized agent for Palmero Health Care

DisCide ULTRA Disinfecting Spray

Kills A Wide Range of Pathogens In One Minute*

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 (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride	0.12%
n-alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride	0.12%
Isopropyl alcohol	63.25%
OTHER INGREDIENTS	<u>36.51%</u>
TOTAL INGREDIENTS 1	00.00%

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 or OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030).

NET CONTENTS:

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.

<u>TO DISINFECT</u>: 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 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.

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

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

<u>CLEANING PROCEDURE:</u> 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.

<u>CONTACT TIME:</u> 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.

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

	FIRST AID					
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. 					
1	HOT LINE NUMBER					
Have the pro	oduct container or label with you when calling a poison control center or c					
also contact	Chem•Tel Inc. at 1-800-255-3924.	د د ز ذ م م				
Do not contar	ND DISPOSAL minate water, food, or feed by storage and disposal.					
	<u>STORAGE:</u> Store away from heat. <u>DISPOSAL</u> : Do not reuse empty container. Discard in trash.	ECLEGA 9,53 6 6 9,53 6 7 9 9				
	information on DisCide ULTRA Spray, Towelettes, Aerosols, and DisAse all 1-800-344-6424 or fax 203-377-8988.	ptic Antibacterial Hand Asepsis				
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