

10492-5

12/16/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Palmero Health Care
120 Goodwin Place
Stratford, CT 06615

DEC 16 2009

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

Attention: Frederick T. Smith

Subject: DisCide Ultra Disinfecting Spray
EPA Registration No. 10492-5
Notification Dated December 1, 2009

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- To Add H1N1 Claims

General Comment

Based on a review of the submitted material, the following comments apply:

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

Please note that the Storage and Disposal section must comply with the "Container Rule" per PR Notice 2007-4.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 10492-5	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DisCide Ultra Disinfecting Spray	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Palmero Health Care 120 Goodwin Place Stratford, CT 06615 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of addition of Pandemic 2009 H1N1 claim consistent with PR Notice 98-10.

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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. Per Container	If "Yes" Package wgt	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph	<input type="checkbox"/> Other _____		
		<input type="checkbox"/> Paper glued			
		<input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Frederick T. Smith	Title Agent (SciReg, Inc.)	Telephone No. (Include Area Code) 703/494-6500
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 12/1/09	

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SciReg, Inc.
Science and Regulatory Consultants

December 1, 2009

Mr. Marshall Swindell
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

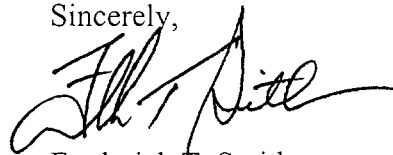
Re: DisCide Ultra Disinfecting Spray (Reg. No. 10492-5)

Dear Mr. Swindell:

On behalf of Palmero Health Care (PHC), enclosed please find a notification consistent with PR Notice 98-10 to add a claim against Pandemic 2009 H1N1 Influenza A virus. As required, a completed application and two copies of the label, one of which is marked to show the change, are provided.

Should you have any questions, please let me know. Thanks very much.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

DisCide ULTRA Disinfecting Spray

A One-Step Disinfectant – Cleaner – Decontaminant

Kills All Listed Pathogens In One Minute

*Virucidal ♦ Tuberculocidal ♦ Bactericidal ♦ Herpeccidal ♦ Fungicidal

DisCide ULTRA Disinfecting Spray is a dual chain quaternary ammonium/high level alcohol solution.

Healthcare 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 where control of the cross-contamination hazards between treated surfaces is required.

Consumer Use on hard, non-food-contact surfaces in kitchens, food service areas and bathrooms and other related hard, non-food-contact surfaces such as shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, and door knobs and handles.

DisCide ULTRA Disinfecting Spray eliminates odors and is effective against the following pathogens on hard non-porous, contact surfaces when used as directed:

- | | |
|--|---|
| ➤ Tuberculosis bacteria (Mycobacterium bovis) (1 min. at 20°C) | ➤ MRSA (Methicillin Resistant Staphylococcus aureus) (1 min.) |
| ➤ Staphylococcus aureus (Staph) (1 min.) | ➤ VRE (Vancomycin Resistant Enterococcus faecalis) (1 min.) |
| ➤ Pseudomonas aeruginosa (1 min.) | ➤ HBV* (Hepatitis B Virus) (1 min.) |
| ➤ Salmonella enterica (1 min.) | ➤ HCV* (Hepatitis C Virus) (1 min.) |
| ➤ Escherichia coli (E. coli) (1 min.) | ➤ RSV* (Respiratory Syncytial Virus) (1 min.) |
| ➤ Avian Influenza A Virus* (H3N2 strain) (30 sec.) | ➤ HIV-1* (AIDS virus) (1 min.) |
| ➤ Influenza A Virus* (Hong Kong strain) (30 sec.) | ➤ Human Coronavirus* (30 sec.) |
| ➤ Herpes Simplex Virus type 2* (genital herpes virus) (1 min.) | ➤ Adenovirus type 2* (1 min.) |
| ➤ Candida albicans (1 min.) | ➤ Pandemic 2009 H1N1 influenza A Virus* (formerly called swine flu) (30 sec.) |
| ➤ Proteus mirabilis (1 min.) | |

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 36.51%

TOTAL INGREDIENTS 100.00%

KEEP OUT OF REACH OF CHILDREN

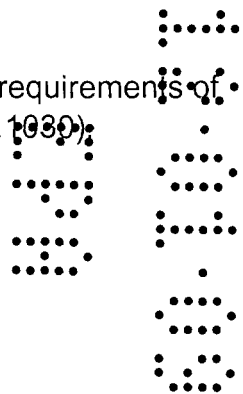
WARNING

See back panel for additional precautionary statements

EPA Reg. No. 10492-5
EPA Est. No.

DisCide ULTRA Disinfecting Spray meets the disinfection requirements of 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.

TO CLEAN, DECONTAMINATE, AND DISINFECT: Remove gross dirt and soil. Thoroughly wet the surface with DisCide ULTRA Disinfecting Spray and allow to remain wet for the required contact time.

Healthcare For Disinfection and Deodorization of: inanimate, hard, non-porous surfaces such as chairs, stools, counter tops, drawer pulls, door knobs and handles, carts, baskets, tables, cabinets, lighting fixtures, bassinets, bed rails, incubators, physical therapy equipment, shower stalls, toilet exteriors and toilet seats, telephones and other related hard surfaces in hospitals, operating and surgical rooms, intensive and critical care units, emergency units, dental and veterinary offices, surgery, recovery, anesthesia, X-Ray, Cat. Lab, blood collection and donation centers, isolation units, orthopedics, newborn nursery, respiratory therapy, radiology, pediatrics, physical therapy, rehabilitation, ophthalmology, optometry, hospices, central supply, emergency medical vehicles, police and fire vehicles, correctional facilities, funeral homes, morgues, spas, health clubs, salons, schools and school medical facilities, school buses, day care and non-food-contact surfaces. DisCide ULTRA Disinfecting Spray may be used to preclean or decontaminate medical instruments prior to sterilization or high-level disinfection.

Consumer For Disinfection and Deodorization of: inanimate, hard, non-porous kitchen/food service and bathroom surfaces such as counter tops, drawer pulls, carts, baskets, tables, cabinets, door knobs and handles, appliance exteriors, shower stalls, toilet exteriors and toilet seats, bathroom and lighting fixtures, sinks, flooring, walls, vanities, diaper pails, trash cans, telephones, shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, and other related hard, non-food-contact surfaces.

Use on stainless steel, glass, formica and other similar surfaces. Use care when using on varnished surfaces or plexi-glass.

*Virucidal Activity:

DisCide Ultra Disinfecting Spray is effective against the following viruses in 30 seconds or one minute when used according to label directions on hard, non-porous environmental surfaces: MRSA, VRE, Avian Influenza A (H3N2 strain), Influenza A (Hong Kong strain), Pandemic 2009 H1N1 influenza A virus (formerly called swine flu), RSV, HBV, HCV, Human coronavirus, HIV-1, Adenovirus type 2, and Herpes Simplex virus type 2.

Kills HIV-1, HBV, and HCV 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), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS), HBV, and HCV 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, HBV, and HCV 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.

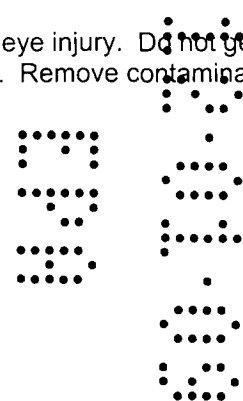
CONTACT TIME: Thoroughly wet surface with DisCide ULTRA Disinfecting Spray. Allow surfaces to remain wet for 1 minute, then air dry. The efficacy of a 1 minute contact time has been shown to be adequate against HIV-1 (AIDS virus), HBV, and HCV.

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.



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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.

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.

STORAGE AND DISPOSAL

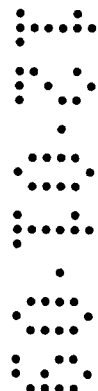
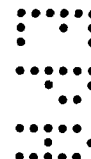
Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store away from heat.

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

For technical information on DisCide ULTRA Spray, Towelettes, Aerosols, and DisCide XRA Hand Sanitizing Wipes,
call 1-800-344-6424 or fax 203-377-8988.

PALMERO HEALTH CARE, 120 GOODWIN PLACE, STRATFORD, CT 06615
www.palmerohealth.com



Optional Text

- Hepatitis B Virus (as duck HBV)
- Hepatitis C Virus (ATCC VR-1422)
- Human Coronavirus (ATCC VR-740)
- HIV-1 (AIDS virus)
- Adenovirus type 2 (ATCC VR-864)
- Herpes Simplex Virus type 2 (ATCC VR-734)
- Avian Influenza A Virus H3N2 strain (ATCC VR-2072)
- Influenza A Virus Hong Kong strain (ATCC VR-544)
- Respiratory Syncytial Virus (ATCC VR-26)
- Vancomycin Resistant Enterococcus faecalis (ATCC 51559)
- Methicillin Resistant Staphylococcus aureus (ATCC 33592)
- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (ATCC 10708)
- Escherichia coli (ATCC 11229)
- Mycobacterium bovis (ATCC 27289)
- Candida albicans (ATCC 10231)
- Proteus mirabilis (ATCC 9240)

