

10492-4

6/15/2010

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

JUN 15 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Palmero Health Care
120 Goodwin Place
Stratford, CT 06615

Attention: Frederick T. Smith
Senior Regulatory Specialist

Subject: Discide Ultra Disinfecting Towelettes
EPA Reg. No. 10492-4
Notification Letter Dated May 27, 2010
Application Dated May 27, 2010

This will acknowledge receipt of your notification for the aforementioned product label, submitted under the provisions of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3© (9). Based on a review of the submitted material, the following apply:

- To update the Container Disposal text.
- To add the company logo for the subject product.

The Notification is in compliance with PR Notices 98-10 and 2007-4 and is acceptable. This information has been made a part of your file.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

A handwritten signature in black ink that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
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 10492-4 | 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 Towelettes | 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 type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Notification of minor label changes per PR Notice 98-10 and revisions per PR Notice 2007-4.
 This notification is consistent with the provisions of PR Notice 98-10, PR Notice 2007-4, and EPA regulations at 40 CFR 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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, PR Notice 2007-4, and 40 CFR 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of

Section - III

| | | | | | |
|---|--|---|---|---|-------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="checkbox"/> Metal <input checked="" 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 1 lb. 5 oz. and 1 lb. 7 oz. | | 5. Location of Label Directions <input checked="" 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 checked="" 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. | | | Date Application Received (Stamped) |
| 2. Signature | 3. Title Agent (SciReg, Inc.) | | |
| 4. Typed Name Frederick T. Smith | 5. Date 5/29/10 | | |

DisCide[®] ULTRA

DISINFECTING TOWELETTES

A One-Step Disinfectant - Cleaner - Decontaminant

Kills All Listed Pathogens IN ONE MINUTE

◆ Bactericidal ◆ Tuberculocidal ◆ Virucidal ◆ Fungicidal ◆ Herpeccidal

DisCide ULTRA Disinfecting Towelettes are non-woven disposable towelettes impregnated with 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 keypads, telephones, cell phones, and door knobs and handles. DisCide ULTRA Disinfecting Towelettes eliminate odors and are effective against the following pathogens on hard non-porous, contact surfaces when used as directed:

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

DisCide ULTRA Disinfecting Towelettes meet the disinfection requirements of OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030):



NET CONTENTS: 1 lb 5 oz
60 TOWELETTES (10.5 X 10 IN.)

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. 10492-4 • EPA Est. No. 56952-WI-001

Reorder: 10DIS

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DIRECTIONS FOR USE

81062-381E

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 START FEED: Remove large cover from container and discard seal. From center of towelette roll, pull up a towelette corner, twist into a point and thread through hole in container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically, ready for next use. When not in use, keep small center cap closed to prevent moisture loss.

TO CLEAN, DECONTAMINATE, AND DISINFECT: Remove gross dirt and soil. Thoroughly wet the surface with a DisCide ULTRA Disinfecting Towelette 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 Towelettes 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. **DO NOT USE AS A BABY WIPE.** Discard towelette after use.

*Virucidal Activity:

DisCide Ultra Disinfecting Towelettes are 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. A DisCide ULTRA Disinfecting Towelette can be used for this purpose.

CONTACT TIME: Thoroughly wet surface with a DisCide ULTRA Disinfecting Towelette. 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store away from heat.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Dispose of used towelette in trash.

FIRST AID

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|-------------|--|
| 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.

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

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