

10492-4

08-08-2007

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

080807

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

Subject: Isotex 70 Disinfecting Towelettes
EPA Registration Number 10492-4
Your Notification Dated July 25th, 2007
EPA Received Date July 25th, 2007

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to change the product name, is acceptable.

Old Product Name: Isotex 70 Disinfecting Towelettes

New Product Name: Discide Ultra Disinfecting Towelettes

The notification has been made part of the file.

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

Sincerely,

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

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

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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) Isotext 70 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 checked="" type="checkbox"/> Other - Explain below.

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

Notification to change the primary brand name to **DisCide Ultra Disinfecting Towelettes**; this name is currently an approved alternate brand name.

Section - III


1. Material This Product Will Be Packaged In:			
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	2. Type of Container <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"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	

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

<p align="center">Certification</p> <p>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.</p>		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 7/25/07	

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.



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

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

SciReg, Inc.
Science and Regulatory Consultants

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July 25, 2007

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

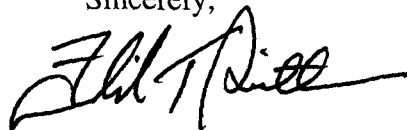
Re: Isotex 70 Disinfecting Towelettes (Reg. No. 10492-4)
- Notification to change the primary brand name

Dear Mr. Swindell:

On behalf of Palmero Health Care (PHC), enclosed please find an application, signed PR Notice 98-10 notification statement, and one revised label.

Should you have any questions, please call.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

DisCide ULTRA Disinfecting Towelettes

[A One-Step*] Disinfectant – [Cleaner – Decontaminant]

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Kills All Listed Pathogens In One Minute

Bactericidal ♦ Tuberculocidal ♦ Virucidal** ♦ Fungicidal*** ♦ Herpeccidal

DisCide ULTRA Disinfecting Towelettes are herbal scented, 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.

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

DisCide ULTRA Disinfecting Towelettes are effective against the following pathogens on hard non-porous, contact surfaces when used as directed:

- Hepatitis B Virus** (HBV) (1 min.)^a
- Hepatitis C Virus** (HCV) (1 min.)^a
- Human Coronavirus** (1 min.)^a
- HIV-1** (AIDS virus) (1 min.)^a
- Adenovirus type 2** (1 min.)^a
- Herpes Simplex Virus type 2** (genital herpes virus) (1 min.)^{a, b}
- Vancomycin Resistant Enterococcus faecalis (VRE) (1 min.)^a
- Methicillin Resistant Staphylococcus aureus (MRSA) (1 min.)^a
- Staphylococcus aureus (Staph) (1 min.)^{a, b}
- Pseudomonas aeruginosa (1 min.)^{a, b}
- Salmonella choleraesuis (1 min.)^{a, b}
- Escherichia coli (E. coli) (1 min.)^{a, b}
- Mycobacterium bovis (Tuberculosis bacteria) (1 min. at 20° C)^a
- Trichophyton mentagrophytes (Athlete's Foot fungus) (1 min.)^{a, b}

[^b Consumer-related claim; footnote will not be included on final printed label.]

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

*A precleaning step is required for HIV-1, HBV, and HCV.

***A precleaning step is required.

[^a Healthcare-related claim; footnote will not be included on final printed label.]

EPA Reg. No. 10492-4
EPA Est. No. 56952-WI-001

DisCide ULTRA Disinfecting Towelettes
meet 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.

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[Entire paragraph must be used for healthcare-related claims]

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.

[dispenser] **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: Thoroughly wet the surface with a DisCide ULTRA Disinfecting Towelette and allow to remain wet for 1 minute. **[The following statement will be included when making claims against Trichophyton mentagrophytes.]**When used as a fungicidal disinfectant, preclean the surfaces to be disinfected. A DisCide ULTRA Disinfecting Towelette can be used for this purpose. Then, thoroughly wet the surface with a DisCide ULTRA Disinfecting Towelette and allow to remain wet for 1 minute.

[Healthcare] For Disinfection 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.

[Consumer] For Disinfection 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, and other related hard, non-food-contact surfaces.

[Consumer] For Disinfection of: inanimate, hard, non-porous surfaces such as shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, door knobs and handles, 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, plexi-glass or leather. **DO NOT USE AS A BABY WIPE.** Discard towelette after use.

[If directions for HIV, HBV or HCV are included, the following two paragraphs must be used.]

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 to 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.

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: [dispenser] Do not reuse towelette or empty container. Wrap towelette container and discard in trash. [foil packages] Do not reuse towelette or empty packet. Dispose of used towelette and packet in trash.

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.

PALMERO HEALTH CARE, 120 GOODWIN PLACE, STRATFORD, CT 06615

www.palmerohealth.com