

10492-4

04-16-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 16 2004

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

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

Subject: Isotex 70 Disinfecting Towelettes
EPA Registration Number 10492-4
Your Notification Dated March 18th, 2004
EPA Received Date March 18th, 2004

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add the term "HBV" or "Hepatitis B virus" within the "Directions for Use" section for HIV, is acceptable.

Your Notification has been made part of the permanent records for this file.

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							
SURNAME							
DATE							

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SciReg, Inc.
Science and Regulatory Consultants

March 18, 2004

Mr. Marshall Swindell
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

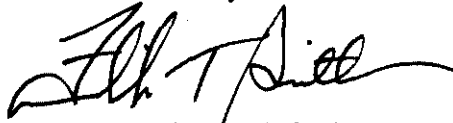
Re: Isotex 70 Disinfecting Towelettes (Reg. No. 10492-4)
- Notification Consistent with PR Notice 98-10
- Addition of "HBV" to Directions For Use

Dear Mr. Swindell:

Enclosed please find a revised draft label that includes "HBV" within the Directions For Use. Per comments from California's Department of Pesticide Regulation, the words, "HBV" or "Hepatitis B Virus" must be included within the same directions for HIV. Note that EPA has already accepted the claims against HBV; only the above-identified words are being added on the rear panel where HIV language currently exists. One copy of the label is highlighted to show these additions.

Should you have any questions, please call.

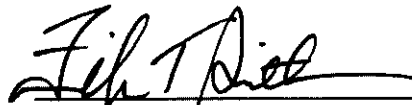
Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

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.

A handwritten signature in black ink, appearing to read "F. T. Smith", written over a horizontal line.

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

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

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ 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) Isotex 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 type="checkbox"/> Other - Explain below.

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

In accordance with PR Notice 98-10 and as requested by California's Department of Pesticide Regulation, the subject label is being modified so that the Directions For Use on HBV mirror those for HIV.

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) _____
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
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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.

2. Signature 	3. Title Agent (SciReg, Inc.)	6. Date Application Received (Stamped)
4. Typed Name Frederick T. Smith	5. Date 3/18/04	

Isotex 70 Disinfecting Towelettes

Kills A Wide Range of Pathogens In One Minute*

Bactericidal ♦ Tuberculocidal ♦ Virucidal ♦ Fungicidal ♦ Herpeccidal**

Isotex 70 Disinfecting Towelettes are herbal scented, non-woven disposable towelettes impregnated with a 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.

Isotex 70 Disinfecting Towelettes are 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) (1 min.)
- * Adenovirus type 2** (1 min.)
- * Herpes Simplex Virus type 2** (genital herpes virus) (1 min.)
- * Vancomycin Resistant Enterococcus faecalis (VRE) (1 min.)
- * Methicillin Resistant Staphylococcus aureus (MRSA) (1 min.)
- * Staphylococcus aureus (Staph) (1 min.)
- * Pseudomonas aeruginosa (1 min.)
- * Salmonella choleraesuis (1 min.)
- * Escherichia coli (E. coli) (1 min.)
- * Trichophyton mentagrophytes (Athlete's Foot fungus) (1 min.)
- * Mycobacterium bovis (Tuberculosis bacteria) (5-minute 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 36.51%

TOTAL INGREDIENTS 100.00%

WARNING

**KEEP OUT OF REACH
OF CHILDREN**

See back panel for additional
precautionary statements

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

Isotex 70 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.

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 DISINFECT: Completely preclean surfaces to be disinfected. An Isotex 70 Disinfecting Towelette can be used for this purpose. Then, thoroughly wet the surface with another towelette and 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. **DO NOT USE AS A BABY WIPE.** Discard towelette after use.

is HIV-1 and HBV 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) and Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) and HBV FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

PERSONAL PROTECTION: When using this disinfecting towelette, wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling HIV-1 and HBV 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. An Isotex 70 Disinfecting Towelette can be used for this purpose.

CONTACT TIME: Thoroughly wet surface with a new Isotex 70 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) and HBV.

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

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