

10492-4

3-29-2004

1/5

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 29 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: Isotex 70 Disinfecting Towelettes  
EPA Registration Number 10492-4  
Your Notification Date March 3<sup>rd</sup>, 2004  
EPA Received Date March 3<sup>rd</sup>, 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								
SURNAME								
DATE								



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) 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. <b>Expedited Review.</b> 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.)

Deletion of food-contact use text; replacement with non-food contact text

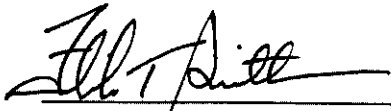
### Section - III

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"/> 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	
<b>Certification</b> 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 3/3/04			

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

4/5

# 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:**

5/5

**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 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**

**PERSONAL PROTECTION:** When using this disinfecting towelette, wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling HIV-1 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).

**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	
<b>If in eyes:</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
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