

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

10492-4

1/11/2006

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Science and Regulatory Consultant, Agent for
Palmero Health Care
c/o 12733 Director's Loop
Woodbridge, VA 22192

JAN 11 2006

Attention: Mr. Fred Smith

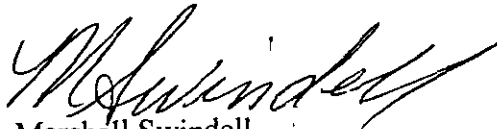
Subject: Aliphatic Alcohols Reregistration Eligibility Document
Isotex 70 Disinfecting Towelettes
EPA Registration No. 10492-4

This submission is in response to your eight month product reregistration for the Aliphatic Alcohols Reregistration Eligibility Decision (RED). According to our records, the science reviews have been completed. However, the Agency is unable to recommend this product for reregistration at this time. The product contains multiple active ingredients, one of which is not eligible for reregistration.

The labeling, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, The labeling approved October 4, 2005, comply with the Aliphatic Alcohols RED,

If you have any comments or questions concerning this letter, please contact me at (703) 308-6341 or Portia Jenkins at (703) 308-6230.

Sincerely,



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

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Isotex 70 Disinfecting Towelettes

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

284

Kills All Listed Pathogens In One Minute

Bactericidal ♦ Tuberculocidal ♦ Virucidal ♦ Fungicidal*** ♦ Herpecidal**

Isotex 70 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.

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.)^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

Isotex 70 Disinfecting Towelettes

meet the disinfection requirements of

OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030).

NET CONTENTS:

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

10492-4

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[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 an Isotex 70 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. An Isotex 70 Disinfecting Towelette can be used for this purpose. Then, thoroughly wet the surface with an Isotex 70 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 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.]

Use on 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. An Isotex 70 Disinfecting Towelette can be used for this purpose.

CONTACT TIME: Thoroughly wet surface with an 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), 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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with COMMENTS
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registered under EPA Reg. No.

10492-4

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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

www.palmerohealth.com

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