



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 04 2005

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Fred Smith
Regulatory Agent for,
c/o Palmero Health Care
120 Goodwin Place
Stratford, CT 06497

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

Subject: Isotex 70 Disinfecting Towelettes
EPA Registration Number 10492-4
Your Amendment Dated May 19th, 2005
EPA Received Date May 20th, 2005

The amendment referred to above, submitted in connection with registration under section 3 (c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add disinfectant claims to the product labeling, is acceptable.

The efficacy data (MRID No. 465672-01), support the use of the product, Isotex 70 Disinfecting Towelette, as a One-Step disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute at 20.0 degrees Celsius.

The submitted efficacy data support the use of the product, Discide Ultra Disinfecting Spray, as a One-Step disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute at 20.0 degrees Celsius.

<i>Pseudomonas aeruginosa</i>	MRID No. 465534-01
<i>Salmonella choleraesuis</i>	MRID No. 465534-01
<i>Staphylococcus aureus</i>	MRID No. 465534-01
<i>Escherichia coli</i>	MRID No. 465534-02
<i>Enterococcus faecium</i> (VRE)	MRID No. 465534-03
<i>Staphylococcus aureus</i> (MRSA)	MRID No. 465534-04

The efficacy data (MRID No. 465534-01) support the use of the product, Discide Ultra disinfecting Spray, as a One-Step disinfectant with fungicidal activity against soil load for a contact time of 1 minute at 20.0 degrees Celsius.

The submitted efficacy data support the use of the product, Discide Ultra Disinfecting Spray, as a One-Step disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute at 20 degrees Celsius.

Human Hepatitis C virus MRID Nos. 465534-06 and 465534-07
Human Coronavirus MRID No. 465534-08

Please note: Acceptance of this data to support a label claim for Human coronavirus (or canine coronavirus) does not support a label claim for this product as an effective disinfectant against the causative agent for Severe Acute Respiratory Syndrome (SARS).

The proposed label claims that the product, Isotex 70 Disinfecting Towelettes, is a One-Step disinfectant with tuberculocidal activity against Mycobacterium bovis BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute at 20.0 degrees Celsius, are supported by the submitted data.

The proposed label claims that the product, Isotex 70 Disinfecting Towelettes, is a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute at 20.0 degrees Celsius, are supported by the submitted data: Hepatitis B virus (HBV), Hepatitis C Virus (HCV), Human Coronavirus, HIV-1 (AIDS virus), Adenovirus type 2, and Herpes Simplex Virus type 2 (genital herpes virus).

The proposed label claims that the product, Isotex 70 Disinfecting Towelettes, is a One-Step disinfectant with fungicidal activity against Trichophyton mentagrophytes on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute at 20 degrees Celsius, are not supported by the submitted data. It will be acceptable provided that you, revise your product labeling by creating a separate section for the Trichophyton mentagrophytes use directions. Also, ensure that a precleaning step is included.

Delete the current Trichophyton verbage from the disinfection section.

On page 2 of the proposed label, delete leather from the list of non-porous surfaces.

A stamped label is enclosed for your records.

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)

Isotex 70 Disinfecting Towelettes

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

Kills All Listed Pathogens In One Minute

Bactericidal ♦ Tuberculocidal ♦ Virucidal ♦ Fungicidal*** ♦ Herpeicidal**

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:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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10492-4 10492-4

***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 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 rooms, 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 SURFACES SOILED WITH BLOOD/BODY FLUIDS: **PRECAUTIONS:** Avoid contact with 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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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No.

104924

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

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