

10492-4

12-19-2007

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

DEC 19 2007



United States
Environmental Protection
Agency

Office of Pesticide Programs

Palmero Health Care
120 Goodwin Place
Stratford, CT 06615

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

Attention: Frederick T. Smith

Subject: DisCide Ultra Disinfecting Towelettes
EPA Registration No. 10492-4
Letter Dated August 6, 2007

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments/conditions listed below:

CONCLUSIONS

3. The submitted efficacy Data support the use of the product, DisCide ULTRA Disinfecting Towelettes, as 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:

Avian Influenza A (H3N2) virus	MRID #472019-02
Influenza A virus	MRID #472019-01
Respiratory syncytial virus	MRID #472019-03

RECOMMENDATIONS

1. The proposed label claim that the product DisCide ULTRA Disinfecting Towelettes, is an effective "one-step" disinfectant against the above microorganisms on hard, non-porous surfaces for a contact time of 1 minute.

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Data provided by the applicant support these claims.

4. To satisfy DIS/TSS-15 labeling requirements, please insert the following step in the directions for use: "Remove gross dirt and soil." or alternatively "Pre-clean heavily soiled surfaces prior to treatment." As noted in DIS/TSS-12, the suggested 5% organic soil load is considered appropriate for simulating lightly or moderately soiled surface conditions. Testing in the presence of a 5% organic soil load does not demonstrate efficacy in the presence of heavily soiled surfaces. As a result, surfaces that are heavily soiled must be pre-cleaned.

3. The following changes are required on the proposed label:
 - On page 1 of the label, change "Respiratory Syncytial Virus" to read "Respiratory Syncytial Virus".

 - On page 1 of the label, change "Salmonella choleraesuis" has been changed to "Salmonella enterica".

 - ATCC numbers are required in one of the following locations:
 - o On the data matrix
 - o On the master label (as optional text) with the listing of the organisms claimed, or
 - o As the final page of the master label (as optional text).

 - On page 2 of the label, under the "Special instructions for Cleaning and Decontamination Against HIV-1..." section, change "Allow to air dry". to Read "Allow surfaces to remain wet for 1 minute, then air dry." It is Important that surfaces remain wet for the duration of the contact time.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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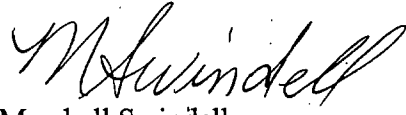
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Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions concerning this letter, please contact Martha L. Terry at (703) 308-6217.

Sincerely,



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

Enclosure

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*** ♦ Herpecidal

DisCide ULTRA Disinfecting Towelettes are 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, and 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}
- Avian Influenza A Virus** H3N2 strain (1 min.)^a
- Influenza A Virus** Hong Kong strain (1 min.)^{a, b}
- Respiratory Syncytial Virus** (RSV) (1 min.)^a
- 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}

*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.]

[^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%
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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

EPA Reg. No. 10492-4

EPA Est. No. 56952-WI-001

ACCEPTED
with COMMENTS

EPA Letter Dated:

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DisCide ULTRA Disinfecting Towelettes meet the disinfection requirements of:

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

NET CONTENTS:

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

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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 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.

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

DEC 19 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. Rev. 8/6/07

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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.

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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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