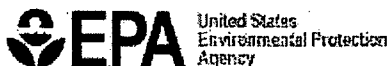


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, D.C. 20460

FEB 11 2009



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 September 29, 2008

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

1. The submitted efficacy Data (MRID #475543-01 through 475543-05) support the use of the liquid, non-towelette product, DisCide ULTRA Disinfecting Spray, as a disinfectant against the following microorganisms on hard, non-porous surfaces at room temperature in the presence of a 5% organic soil load for a contact time of 1 minute:

Candida albicans	1 minute	MRID #475543-01
Avian Influenza A (H3N2) virus	30 seconds	MRID #475543-02
Influenza A virus	30 seconds	MRID #475543-03
Human Coronavirus	30 seconds	MRID #475543-03
Proteus mirabilis	1 minute	MRID #475543-05

RECOMMENDATIONS

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

Candida albicans
Proteus mirabilis

Data provided by the applicant support these claims. Acceptable results against *S. aureus* (ATCC 6538) (MRID 440006-07), *S. enterica* (ATCC 10708) (MRID 440006-07), *P. aeruginosa* (ATCC 15442) (MRID 440006-07), *Mycobacterium bovis* (BCG) (MRID 465672-01) and *T. mentagrophytes* (ATCC 9533) (MRID 440006-08), allow for bridging of *Candida albicans* and *Proteus mirabilis* to the proposed label.

2. The proposed label claims that the product, DisCide ULTRA Disinfecting Towelettes, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 30 seconds:

Avian Influenza A (H3N2) virus
Influenza A virus
Human Coronavirus

Data provided by the applicant support these claims.

Please note that the submitted data provided for the liquid product is permitted to be used to support the towelette product for the same organisms/contact time. This has previously been permitted since the registration of this product. However, for future submissions you will need to provide certain efficacy data on the towelette product before we will accept any further efficacy modifications to the towelette product label. Also please note that for reregistration you will need to provide the following studies to support a towelette product based on testing using a towelette product. We will not continue to bridge all data from the liquid product (10492-5)

- 1) Full set of hospital/broad spectrum bacterial data using a towelette and using the towelette protocol (3 batches, 1 batch aged 60 days or longer).
- 2) A test using the most resistant non-enveloped virus for which there is a label claim in order to bridge other virus claims
- 3) If there is a TB claim then the TB claim must be submitted by testing the towelette.
- 4) If there is a pathogenic fungi claim, then data must be submitted by testing using the towelette.

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.

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.

If 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

Kills All Listed Pathogens In One Minute

*Virucidal ♦ Tuberculocidal ♦ Bactericidal ♦ Herpeccidal ♦ Fungicidal

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 and other related hard, non-food-contact surfaces such as shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, and door knobs and handles.

DisCide ULTRA Disinfecting Towelettes eliminate odors and are effective against the following pathogens on hard non-porous, contact surfaces when used as directed:

- | | |
|---|--|
| ➤ Tuberculosis bacteria (1 min. at 20°C)
(Mycobacterium bovis) | ➤ MRSA (1 min.)
(Methicillin Resistant Staphylococcus aureus) |
| ➤ Staphylococcus aureus (Staph) (1 min.) | ➤ VRE (1 min.)
(Vancomycin Resistant Enterococcus faecalis) |
| ➤ Pseudomonas aeruginosa (1 min.) | ➤ HBV* (1 min.)
(Hepatitis B Virus) |
| ➤ Salmonella enterica (1 min.) | ➤ HCV* (1 min.)
(Hepatitis C Virus) |
| ➤ Escherichia coli (E. coli) (1 min.) | ➤ RSV* (1 min.)
(Respiratory Syncytial Virus) |
| ➤ Avian Influenza A Virus* (30 sec.)
(H3N2 strain) | ➤ HIV-1* (AIDS virus) (1 min.) |
| ➤ Influenza A Virus* (30 sec.)
(Hong Kong strain) | ➤ Human Coronavirus* (30 sec.) |
| ➤ Herpes Simplex Virus type 2* (1 min.)
(genital herpes virus) | ➤ Adenovirus type 2* (1 min.) |
| ➤ Candida albicans (1 min.) | |
| ➤ Proteus mirabilis (1 min.) | |

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%**

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with COMMENTS
EPA Letter Dated:

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10492-4

KEEP OUT OF REACH
OF CHILDREN

WARNING

See back panel for additional precautionary statements

EPA Reg. No. 10492-4
EPA Est. No.

DisCide ULTRA 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 CLEAN, DECONTAMINATE, AND DISINFECT: Remove gross dirt and soil. Thoroughly wet the surface with a DisCide ULTRA Disinfecting Towelette and allow to remain wet for the required contact time.

Healthcare For Disinfection and Deodorization 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. DisCide ULTRA Disinfecting Towelettes may be used to preclean or decontaminate medical instruments prior to sterilization or high-level disinfection.

Consumer For Disinfection and Deodorization 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, shopping carts, child-restraint seats, exercise and weight-lifting equipment, office equipment, computer screens and key pads, telephones, cell phones, 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 or plexi-glass. **DO NOT USE AS A BABY WIPE.** Discard towelette after use.

***Virucidal Activity:**

DisCide Ultra Disinfecting Towelettes are effective against the following viruses in 30 seconds or one minute when used according to label directions on hard, non-porous environmental surfaces: MRSA, VRE, Avian Influenza A (H3N2 strain), Influenza A (Hong Kong strain), RSV, HBV, HCV, Human coronavirus, HIV-1, Adenovirus type 2, and Herpes Simplex virus type 2.

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 surfaces to remain wet for 1 minute, then 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.

with COMMENTS
EPA Label Label

FEB 11 2009

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

10492-4

6/7

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 DisCide XRA Hand Sanitizing Wipes, 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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Optional Text

- Hepatitis B Virus (as duck HBV)
- Hepatitis C Virus (ATCC VR-1422)
- Human Coronavirus (ATCC VR-740)
- HIV-1 (AIDS virus)
- Adenovirus type 2 (ATCC VR-864)
- Herpes Simplex Virus type 2 (ATCC VR-734)
- Avian Influenza A Virus H3N2 strain (ATCC VR-2072)
- Influenza A Virus Hong Kong strain (ATCC VR-544)
- Respiratory Syncytial Virus (ATCC VR-26)
- Vancomycin Resistant Enterococcus faecalis (ATCC 51559)
- Methicillin Resistant Staphylococcus aureus (ATCC 33592)
- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (ATCC 10708)
- Escherichia coli (ATCC 11229)
- Mycobacterium bovis (ATCC 27289)
- Candida albicans (ATCC 10231)
- Proteus mirabilis (ATCC 9240)

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