

10492-4

03-07-2008

1/5



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SciReg, Inc.
Agent for Palmero Health Care (PHC)
12733 Director's Loop
Woodbridge, VA 22192

MAR 7 2008

Attention: Fred Smith
Regulatory Manager

Subject: Discide Ultra Disinfecting Towelettes
EPA Reg. No. 10492-4
Amendment Application Date: January 22, 2008

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. The Agency has no objection to the request for revising your product label to add pre-cleaning instructions (based off EPA approval letter submitted to your company on December 19, 2007). A stamped label is enclosed for your records.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

M. Swindell
cf. for Marshall Swindell

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

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 are effective against the following pathogens on hard non-porous, contact surfaces when used as directed:

- | | | | |
|--|------------------|--|----------|
| ➤ Tuberculosis bacteria
(Mycobacterium bovis) | (1 min. at 20°C) | ➤ MRSA
(Methicillin Resistant
Staphylococcus aureus) | (1 min.) |
| ➤ Staphylococcus aureus (Staph) | (1 min.) | ➤ VRE
(Vancomycin Resistant
Enterococcus faecalis) | (1 min.) |
| ➤ Pseudomonas aeruginosa | (1 min.) | ➤ HBV*
(Hepatitis B Virus) | (1 min.) |
| ➤ Salmonella enterica | (1 min.) | ➤ HCV*
(Hepatitis C Virus) | (1 min.) |
| ➤ Escherichia coli (E. coli) | (1 min.) | ➤ RSV*
(Respiratory Syncytial Virus) | (1 min.) |
| ➤ Avian Influenza A Virus*
(H3N2 strain) | (1 min.) | ➤ HIV-1* (AIDS virus) | (1 min.) |
| ➤ Influenza A Virus*
(Hong Kong strain) | (1 min.) | ➤ Human Coronavirus* | (1 min.) |
| ➤ Herpes Simplex Virus type 2*
(genital herpes virus) | (1 min.) | ➤ Adenovirus type 2* | (1 min.) |
| ➤ Trichophyton mentagrophytes
(Athlete's Foot fungus) | (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% 36.51%

OTHER INGREDIENTS 100.00%

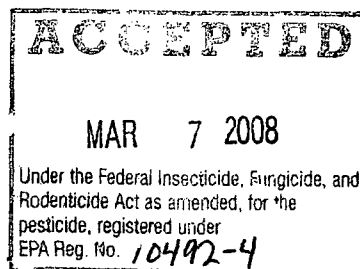
TOTAL INGREDIENTS 100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for additional precautionary statements

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



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 1 minute. 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, 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 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.

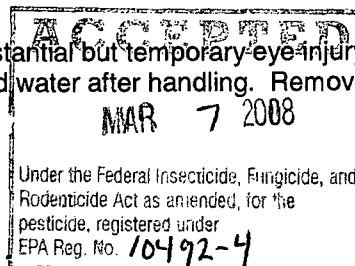
CLEANING PROCEDURE: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. A DisCide ULTRA Disinfecting Towelette can be used for this purpose.

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.

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.

4/5

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

ACCEPTED
MAR 7 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 10462-4

5/15

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)
- Trichophyton mentagrophytes (ATCC 9533)

