



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 29, 2017

Fred Smith
Sr. Regulatory Specialist
Palmero Health Care
120 Goodwin Place
Stratford, CT 06615

Subject: Notification per PRN 98-10 – To additional marketing administrative language and add logo
Product Name: DisCide Ultra Disinfecting Spray
EPA Registration Number: 10492-5
Application Date: November 4, 2016
Decision Number: 523571

Dear Mr. Smith:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Zebora Johnson at (703) 308-7080 or via email at johnson.zebora@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Zeno Bain".

Zeno Bain,
Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

NOTIFICATION

10492-5

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/29/2017

DisCide ULTRA Disinfecting Spray

A One-Step Disinfectant - Cleaner - Decontaminant

Kills All Listed Pathogens In One Minute

Bactericidal ♦ Tuberculocidal ♦ Virucidal*

DisCide ULTRA Disinfecting Spray is 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 Spray** eliminates odors and is effective against the following pathogens on hard non-porous, contact surfaces when used as directed at the contact times listed below:

➤ Tuberculosis bacteria (Mycobacterium bovis)	(1 min. at 20°C)	➤ Klebsiella pneumoniae	(1 min.)
➤ Staphylococcus aureus (Staph)	(1 min.)	➤ MRSA (Methicillin Resistant Staphylococcus aureus)	(1 min.)
➤ Pseudomonas aeruginosa	(1 min.)	➤ VRE (Vancomycin Resistant Enterococcus faecium)	(1 min.)
➤ Salmonella enterica	(1 min.)	➤ HBV* (Hepatitis B Virus)	(1 min.)
➤ Escherichia coli (E. coli)	(1 min.)	➤ HCV* (Hepatitis C Virus)	(1 min.)
➤ Avian Influenza A Virus* (H3N2)	(30 sec.)	➤ RSV* (Respiratory Syncytial Virus)	(1 min.)
➤ Influenza A Virus* (Hong Kong)	(30 sec.)	➤ HIV-1* (AIDS virus)	(1 min.)
➤ Herpes Simplex Virus type 2* (genital herpes virus)	(1 min.)	➤ Human Coronavirus*	(30 sec.)
➤ Candida albicans	(1 min.)	➤ Adenovirus type 2*	(1 min.)
➤ Proteus mirabilis	(1 min.)	➤ Pandemic 2009 H1N1 influenza A Virus* (formerly called swine flu)	(30 sec.)
➤ Carbapenem-resistant E. coli:	(1 min.)	➤ Vaccinia virus*	(1 min.)
➤ Campylobacter jejuni	(1 min.)		
➤ Burkholderia cepacia	(1 min.)		
➤ Escherichia coli O157:H7	(1 min.)		
➤ MDR Acinetobacter baumannii	(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%**

KEEP OUT OF REACH
OF CHILDREN

WARNING

See back panel for additional
precautionary statements

EPA Reg. No. 10492-5
EPA Est. No.

DisCide ULTRA Disinfecting Spray meets the disinfection requirements of OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030).

NET CONTENTS:

Rev. 3/8/17

Deleted: alis)

Deleted: 11/4/16

Deleted: 6

(BACK PANEL)

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.

TO CLEAN, DECONTAMINATE, AND DISINFECT: Remove gross dirt and soil. Thoroughly wet the surface by spraying DisCide ULTRA Disinfecting Spray at a distance of 6-8 inches. 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 Spray 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.

*Virucidal Activity:

DisCide Ultra Disinfecting Spray is effective against the following viruses in 30 seconds or one minute when used according to label directions on hard, non-porous environmental surfaces: Avian Influenza A virus (H3N2), Influenza A virus (Hong Kong), Pandemic 2009 H1N1 influenza A virus (formerly called swine flu), RSV, HBV, HCV, Human coronavirus, HIV-1, Adenovirus type 2, Vaccinia virus, 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. DisCide ULTRA Disinfecting Spray can be used for this purpose.

CONTACT TIME: Thoroughly wet surface with DisCide ULTRA Disinfecting Spray. 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.

Rev. 3/8/17

Deleted: 11/4/16

Deleted: 6

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: Do not reuse empty container. Discard 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
The Healthcare Company With a Heart
120 GOODWIN PLACE, STRATFORD, CT 06615
www.palmerohealth.com

[Advertising]

You may also want to get these accessories for DisCide ULTRA gallon bottle:

Hold-It™ Gallon Bottle Holder

Make any gallon bottle easy to handle and store with our white metal holder. Mount as needed for easy access to bottle. Mounting hardware included.

Size: 5.5" x 4.5" x 4.5"

Order No. 3518

Topcat™ Dynamic 1-Touch™ Gallon Sprayer and Holster

Can cover larger areas with one-handed ease. The holster attaches to the neck of your one-gallon bottle, instantly turning it into the perfect power tool for any job. The no-drip nozzle adjusts from spray to stream and anything in between.

4 AA batteries included.

Order No. 4230

DisCide Ultra is also available in:

60 count, 10.5" x 10" Towelettes:

Order No. 10DIS

160 count, 6" x 6.75" Towelettes:

Order No. 60DIS

Quart bottle with sprayer:

Order No. 3565Q

4 oz. bottle with pump sprayer:

Order No. 3564

To order these or any other Palmero Health Care Products, call 1-800-344-6424 or visit www.palmerohealth.com.

Rev. [3/8/17](#)

Deleted: 11/4/16

Deleted: 6

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) (ATCC VR-2072)
- Influenza A Virus (Hong Kong) (ATCC VR-544)
- Respiratory Syncytial Virus (ATCC VR-26)
- Vaccinia Virus (ATCC VR-119)
- Vancomycin Resistant Enterococcus faecium (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)
- Carbapenem-resistant *E. coli*. (Clinical Isolate; BSLI #082710EcCP1)
- Campylobacter jejuni (ATCC 29428)
- Burkholderia cepacia (ATCC 25416)
- Escherichia coli O157:H7 (ATCC 35150)
- Multi-drug Resistant Acinetobacter baumannii (ATCC 19606)
- Klebsiella pneumoniae (ATCC 4352)

Deleted: alis

Deleted: 11/4/16

Deleted: 6

Rev. 3/8/17