



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 13, 2016

Patricia Biggio
Regulatory Specialist
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: PRIA Label Amendment – Adding New Organisms and Efficacy Claims
Product Name: DisCide Ultra Disinfecting Spray
EPA Registration Number: 10492-5
Application Date: May 23, 2016
Decision Number: 517667

Dear Ms. Biggio:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 10492-5
Decision No. 517667

with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

DisCide ULTRA Disinfecting Spray

A One-Step Disinfectant – Cleaner – Decontaminant

Kills All Listed Pathogens In One Minute

Bactericidal ♦ Tuberculocidal ♦ Virucidal*

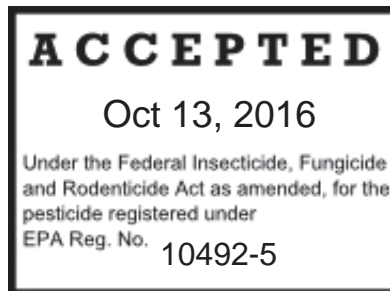
DisCide ULTRA Disinfecting Spray is a dual chain quaternary ammonium/high level alcohol solution.

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 faecalis)	(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 <i>E. coli</i> :	(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:

(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.

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, 120 GOODWIN PLACE, STRATFORD, CT 06615

www.palmerohealth.com

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 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)
- 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)