

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 20, 2018

Elaine Richardson Regulatory Affairs Manager Brulin & Co., Inc. P.O. Box 270 Indianapolis, IN 46206

Subject: Notification per PRN 98-10 – Change Primary Brand Name

Product Name: Unicide RTU

EPA Registration Number: 106-81 Application Date: December 6, 2018

Decision Number: 547164

Dear Ms. Richardson:

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.

The primary brand name "Unicide RTU" has been added to the product record. The previous primary brand name "Maxima RTU" will be added as an alternate brand name.

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

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Sincerely,

for

Eric Miederhoff, Product Manager 31 Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

UNICIDE RTU

GERMICIDAL DETERGENT or GERMICIDAL CLEANER or GERMICIDAL DISINFECTANT or DISINFECTANT DETERGENT or DISINFECTANT CLEANER

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL* FUNGICIDAL MILDEWCIDAL

NOTIFICATION

106-81

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:

12/20/2018

ACTIVE INGREDIENTS:

Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride	0.0375%
Octyl decyl dimethyl ammonium chloride .	0.0281%
Didecyl dimethyl ammonium chloride	0.0189%
Dioctyl dimethyl ammonium chloride	0.0141%
OTHER INGREDIENTS:	<u>99.9014</u> %
TOTAL	100.0000%

KEEP OUT OF REACH OF CHILDREN CAUTION

See Side Panel for First Aid and Additional **Precautionary Statements**

EPA Reg. No. 106-81

EPA Est. No. 106-IN-1

NET CONTENTS 1 U.S. QUART

Manufactured and Sold By:

BRULIN & COMPANY, INC.

HOME OFFICE/PLANT: P. O. Box 270 • Indianapolis, IN 46206-0270 1-800-776-7149

UNICIDE RTU is a "one-step" multi-purpose germicidal detergent effective in hard waters up to 400 ppm hard water (calculated as CaCO₃) in the presence of 5% organic serum. The activity of UNICIDE RTU has been evaluated by the AOAC use dilution test (14th Edition, 1984) and found to be effective against the following pathogenic organisms:

Pseudomonas aeruginosa Staphylococcus aureus phage type 80 Salmonella typhi Staphylococcus aureus phage type 42B/52/81 Salmonella enterica Streptococcus pyogenes Enterobacter cloacae Klebsiella pneumoniae Proteus mirabilis Shigella flexneri * HCV (Hepatitis C Virus)

Brevibacterium ammoniagenes Staphylococcus aureus (MRSA) Multiply (Methicillin) Resistant Clinical Isolate

* HIV-1 (AIDS Virus)

* Adenovirus Type 2

* Herpes Simplex Type 1

* Influenza Type A/Mich.

* Vaccinia

* Adenovirus Type 4

* Herpes Simplex Type 2

* Rubella Virus, Vaccine Strain

* HBV (Hepatitis B Virus)

* Avian Infectious Bronchitis

* Avian Influenza A/Mich.

* Infectious Bovine Rhinotracheitis

* Canine Distemper

* Feline Leukemia

* Feline Picornavirus

Enterococcus faecalis -Vancomycin Resistant Streptococcus faecalis

Staphylococcus aureus Shigella dysenteria

Acinetobacter baumannii

Staphylococcus aureus

phage type 81

Staphylococcus epidermidis

Enterobacter aerogenes Escherichia coli

Serratia marcescens Proteus vulgaris

Shigella sonnei Salmonella schottmuelleri Trichophyton mentagrophytes

Candida albicans Aspergillus niger

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if swallowed or absorbed by the skin. Avoid contact with eye, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

Have product container with you when calling a poison control center or doctor or going for treatment.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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 the eye. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS (for containers > 5 gallon)

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

USE: For institutional and commercial use only such as hospitals and nursing homes, schools and colleges, medical and dental offices, barber/beauty shops, and veterinary clinics. Use to clean and disinfect non-medical (i.e., industrial and fire-fighting) respirators in industrial, commercial and institutional premises.

CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES:

This product is for use on floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, bowl surfaces, empty basins, noncritical medical devices, hair/nail care instruments, showers, and lavatory fixtures, tanning beds and other hard, nonporous surfaces. Remove gross filth or heavy soil prior to application of product. Apply UNICIDE RTU with a brush, coarse spray device, sponge, cloth or mop. Thoroughly wet all hard, nonporous surfaces to allow surfaces to remain wet for 10 minutes. Remove excess solution or allow to air dry. Rinsing is not necessary unless floors are to be waxed. UNICIDE RTU is a complete product. Do not add other chemicals. Use only as directed.

VETERINARY CLINICS:

For cleaning and disinfecting the following hard, non-porous surfaces: utensils, instruments, cages, kennels, stables, and catteries. Not to be applied to equipment used for animal food or water. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all liter, droppings, and manure from floors, walls, and surfaces of facilities occupied or transversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with UNICIDE RTU for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters, or ropes as well as

shovels, scrapers, and forks used to remove litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

* Kills HBV, HCV and HIV-1 on PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings 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 Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV, HCV AND HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of UNICIDE RTU. This pre-cleaning may be accomplished with any cleaning solution including UNICIDE RTU.

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.

CONTACT TIME: Leave surfaces wet for 4 minutes for HIV-1 and 10 minutes for HBV and HCV, respectively. For the other viruses, bacteria, and fungi on this label, use a 10 minute contact time.

TOILET BOWL/URINAL DISINFECTANT/CLEANER APPLICATION

Remove gross filth or heavy soil prior to application of product.

Empty toilet bowl or urinal and apply solution to exposed surfaces including under the rim with a cloth, mop, sponge or coarse spray. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

CLEANING AND DISINFECTING HARD NON-POROUS SURFACES ON PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORS):

Preclean equipment if heavily soiled to ensure proper surface contact. Apply UNICIDE RTU to hard, non-porous surfaces of the respirator with brush, coarse spray device, sponge, cloth, or immersion. Thoroughly wet all surfaces to be disinfected. Treated surfaces must remain wet for 10 minutes. Remove excess solution from equipment prior to storage. Comply with all OSHA regulations for cleaning respiratory protection (29 CFR§1910.134).

MOLD AND MILDEW CONTROL DIRECTIONS:

To control the growth of mold and mildew and their odors on hard, nonporous surfaces, apply use-solution to thoroughly wet treated surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappears.

FUNGICIDAL DIRECTIONS:

UNICIDE RTU is an effective fungicide against Trichophyton Mentagrophytes (the Athletes Foot Fungus) when used on surfaces in areas such as shower and bath areas (follow disinfection directions).

BARBER/BEAUTY SHOPS:

Use UNICIDE RTU to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before reuse. Prepare a fresh solution daily or more often if the solution becomes visibly cloudy, dirty, or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

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) contacts 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.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in areas inaccessible to small children. Keep container closed when not in use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.