

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 128

EPA Registration Number: 106-72 Application Date: December 6, 2018

Decision Number: 547166

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 128" has been added to the product record. The previous primary brand name "Maxima 128" 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 128

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

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL* FUNGICIDAL MILDEWCIDAL

ACTIVE INGREDIENTS:

Alkyl (C₁₄, 50%; C₁₂, 40%; C₁₆, 10%) dimethyl benzyl ammonium chloride 3.200% Octyl decyl dimethyl ammonium chloride 2.400% Didecyl dimethyl ammonium chloride...... 1.617% Dioctyl dimethyl ammonium chloride...... 1.200% OTHER INGREDIENTS: 91.583%

DILUTION: 1 TO 128 . . . ONE OUNCE PER GALLON

NOTIFICATION

106-72

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

KEEP OUT OF REACH OF CHILDREN **DANGER**

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

EPA Reg. No. 106-72

EPA Est. No. 106-IN-1

NET CONTENTS 5 U.S. GALLONS

Manufactured and Sold By:

BRULIN & COMPANY, INC.

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

UNICIDE 128 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 128 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 Staphylococcus epidermidis Salmonella typhi Shigella flexneri Shigella dysenteria Salmonella enterica

Streptococcus pyogenes Enterobacter cloacae Klebsiella pneumoniae Proteus mirabilis

Brevibacterium ammoniagenes Staphylococcus aureus (MRSA)

* HBV (Hepatitis B Virus)

* HCV (Hepatitis C Virus) * HIV-1 (AIDS Virus)

* Adenovirus Type 2

* Herpes Simplex Type 1 * Influenza Type A/Mich.

* Vaccinia

* Adenovirus Type 4

* Herpes Simplex Type 2

* Avian Infectious Bronchitis * Avian Influenza A/Michigan/

* Rubella Virus, Vaccine Strain

* Infectious Bovine

Rhinotracheitis * Canine Distemper * Feline Leukemia * Feline Picornavirus

2/79-H1N9

Enterococcus faecalis -Vancomycin Resistant Aspergillus niger Candida albicans Streptococcus faecalis Enterobacter aerogenes

Escherichia coli Serratia marcescens Proteus vulgaris Shigella sonnei

Salmonella schottmuelleri Trichophyton mentagrophytes Acinetobacter baumannii

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.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **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. **IF ON SKIN OR CLOTHING:** 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 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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS (5 gallon or larger)

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. Add one ounce of UNICIDE 128 to each gallon of water used. Always add UNICIDE 128 to premeasured water. Gently mix for a uniform solution. Apply solution by normal methods with brush, coarse spray devices, sponge, cloth or mop. Remove gross filth before cleaning and disinfecting begins. Thoroughly wet all surfaces, then remove excess solution with a wrung out applicator. Treated surfaces must remain wet for 10 minutes. Fresh solution is prepared daily or more often if the solution becomes diluted or soiled. Rinsing is not necessary unless floors are to be waxed. UNICIDE 128 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 a use solution of 1.0 oz. of UNICIDE 128 per gallon of water for a period of 10 minutes. 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:

Use 1.50 ounce of UNICIDE 128 to each gallon of water for HBV efficacy.

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 128. This pre-cleaning may be accomplished with any cleaning solution including UNICIDE 128.

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. The 4 minute contact time will not control other common types of viruses and bacteria.

(Note to reviewer: The following directions are for one-time use portion control packets)

(For 1.5 ounce packet)

Mix each packet with 1 gallon of water. Refer to carton label for full instructions.

(For 6 ounce packet)

Mix each packet with 4 gallons of water. Refer to carton label for full instructions.

(For 7.5 ounce packet)

Mix each packet with 5 gallons of water. Refer to carton label for full instructions.

TOILET BOWL/URINAL DISINFECTANT/CLEANER APPLICATION

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

From Concentrate. Add 0.75 oz. to the bowl. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From Use Solution. Empty toilet bowl or urinal and apply a 1 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or mechanical 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. Add one ounce of **UNICIDE 128** to each gallon of water used. Always add **UNICIDE 128** to premeasured water. Gently mix for a uniform solution. Apply solution 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).

BARBER/BEAUTY SHOPS:

Use 1 oz. per gallon of water 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.

LAUNDRY ADDITIVE TO SANITIZE AGAINST BACTERIA IN COMMERCIAL - INDUSTRIAL - FACILITIES

UNICIDE 128 sanitizes laundry such as bedspreads, sheets, pillowcases, diapers, towels, and other wet linens by reducing the growth of bacteria. Add 16 ounces of UNICIDE 128 per 100 pounds of dry laundry to the final rinse cycle. At this level UNICIDE 128 is an effective sanitizer in hard water up to 200 ppm.

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. Do not reuse empty container.

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.

Optional marketing statement: "One (1) gallon (quart) of concentrate makes 128 gallons (quarts) of disinfectant."