

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 29, 2016

Jennifer De Carlo Regulatory Operations Lead for, Reckitt Benckiser LLC. D/B/A Reckitt Benckiser Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054-0225

Subject: Notification per PRN 98-10 – To delete a microorganism from the product label Product Name: Tergiquat Germicidal Cleaner EPA Registration Number: 675-36 Application Date: September 22, 2016 Decision Number: 521796

Dear Ms. De Carlo:

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.

Page 2 of 2 EPA Reg. No. 675-36 Decision No. 521796

If you have any questions, you may contact Karen M. Leavy at (703)-308-6237 or or via email at Leavy.Karen@epa.gov.

Sincerely,

Kauen M. Leary for,

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

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NOTIFICATION

675-36

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:

09/29/2016

<< FRONT PANEL >>

ACTIVE INGREDIENTS:	
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	2.3%
Didecyl dimethyl ammonium chloride.	0.7%
OTHER INGREDIENTS:	97.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER: See back (side) panel for additional precautionary statements and first aid.

NET CONTENTS: 128 FL. OZ. (1 GAL.) 3.79 L

<< FRONT / BACK PANEL >>

EPA Reg. No.	675-36		
EPA Est. No.	09019-OH-001	777-MO-001	777-PA-001
	09019-OH-002	312-WI-1	
(See bottom or s	side) (for Lot / Date	code)	

<< BACK PANEL >>

Questions? (C) (Comments?) (Call:) (1-800-677-9218) (1-800-560-6619) For ingredient and other information, (www.rbnainfo.com) (website) Distributed by: Reckitt Benckiser, Parsippany, NJ 07054(-xxxx) Made in U.S.A. © {year} RB Contains no phosphates This (bottle) (container) is made of 25% post-consumer recycled plastic.

Company graphic logo



NSF certification symbol:



<< BACK PANEL – Optional text >>

Recycle Symbol (This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination (This product) meets AOAC Germicidal efficacy standards for hospital disinfectants NSF certification symbol

NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, (optional text), [required qualifier]. The term *"this product"* used throughout this document may be replaced with the marketed product brand name. To use the term "germ**" the product must be efficacious against 2 of the 3 major classes of organisms. The product label must identify the specific bacteria, virus, fungus & mold. The term (x) is a placeholder that represents a number between 1 and 99.

<< FRONT / BACK PANEL – CLAIMS – use as bullet point or in paragraph format >>

For Commercial Use

(Cleans) (Disinfects) (Sanitizes) (Counteracts Odors) (Concentrated cleaning power) (One product cleans & disinfects) For use by Professional Maintenance Personnel only.

Page No.:

For use in (Food Service Areas) (Food Processing Plants) (Dairies) (Schools) (Hospitals) (Nursing Homes) Suitable for Food Service & Processing Areas

For use on hard, non-porous environmental surfaces in (Institutional) (and) (Industrial) facilities.

Kills Salmonella enterica and E. coli

Kills: {insert organisms from list on pages 5 and 6}

(This product) is a synergistic combination of modern quaternary ammonium compounds and detergent agents.

(This product) disinfects hard, non-porous (environmental) surfaces such as:

Hospitals

- Chrome / Stainless Steel **Display Cases** Non-medical Chrome / Stainless • Fixtures Steel Counters Floors / Walls Tables
- Medical Lamps / Stands / Equipment Waste Cans Trays

(Suitable) for use as a (disinfectant) (and) (sanitizer) on hard, non-porous surfaces located in:

Health Care Facility

- Cafeteria
- Day Care Centers
- Dental Offices
 - Hotels / Motels Doctor's Office
 - Kennel

Cleans, disinfects, sanitizes and counteracts odors.

Use on hard, non-porous environmental surfaces (in Institutions and Industrial Facilities). Areas of application for (this product):

- Food Service and Dietary Areas equipment, counters, floors, waste cans •
- Dairies equipment, floors, walls
- Food Processing Plant equipment, floors, walls •
- Supermarkets equipment, display cases, floors, walls, waste cans
- Fast Food Operations equipment, counters, waste cans, floors, walls
- Schools washrooms, locker rooms, classrooms, equipment, walls floors

Before use in food service / dietary areas, dairies, food processing plants, supermarkets and fast food operations,

all food products and packaging materials must be removed from the room or carefully protected.

When used on surfaces in locker rooms, restrooms and exercise facilities, this product is an effective fungicide against Trichophyton mentagrophytes (Athlete's Food Fungus) when used as a disinfectant.

Kitchen

Nursing Homes

Office Buildings

Physician's Office

(GERMICIDAL**) (BACTERICIDAL*) (STAPHYLOCIDAL*) (This product is) (PSEUDOMONACIDAL*) (FUNGICIDAL*) (- against pathogenic fungi)

(VIRUCIDAL†) (- against Lipophilic viruses: Herpes Simplex Virus Type 1, Influenza A₂ Virus, Vaccinia) Controls the growth of mold and mildew*

* On hard, non-porous environmental surfaces

Passes AOAC Use-Dilution Test at 1:16 [8 oz. per gallon] against: Aspergillus niger, Corynebacterium diphtheria, Cytomegalovirus, Enterobacter aerogenes, Enterococcus faecalis, Escherichia coli, Human Immunodeficiency Virus Type 1, Klebsiella pneumoniae, Neisseria elongata, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella enterica, Salmonella paratyphi, Salmonella schottmuelleri, Serratia marcescens, Shigella dysenteria, Staphyloccus aureus, Staphylocccus aureus 80/81 [Penicillin Resistant], Streptococcus pyogenes, Streptococcus salivarius and Trichophyton mentagrophytes.

<< Terminal Sterilant Statement – gualified metal surfaces >>

This product is not for use on critical & semi-critical medical devices or medical equipment surfaces.

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- - Restaurants
 - Restrooms
 - School (College) •
 - Veterinary Office

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<< Terminal Sterilant Statement - unqualified metal surfaces >>

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 pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To Clean Heavily Soiled Surfaces:

- 1. Dilute 2 oz. of (this product) per gallon of water.
- 2. Apply solution with a cloth, sponge or sprayer; thoroughly wetting the surface.
- 3. For sprayer applications, use a coarse spray devise. Spray 6-8 inches from surface. Rub with a brush, sponge or cloth. Avoid breathing spray mist.
- 4. Wipe dry with a clean sponge, mop or cloth or allow to air dry.
- 5. Food contact surfaces must be rinsed with clean (potable) water prior to reuse. Do not use on glasses, dishes or utensils.
- 6. Prepare a fresh solution daily or more often if solution becomes visibly dirty, soiled or cloudy.

To Sanitize:

- 1. Pre-clean hard, non-porous surfaces according to Cleaning directions.
- 2. Dilute 2 oz. of (this product) per gallon of water.
- 3. Apply to surface until thoroughly wet and allow to remain wet for 60 seconds (1 minute).

To Disinfect:

- 1. Pre-clean hard, non-porous surfaces according to Cleaning directions.
- 2. Dilute 8 oz. of (this product) per gallon of water.
- 3. Apply to surface until thoroughly wet and allow to remain wet for 10 minutes.

To Control Mold & Mildew (on hard, non-porous environmental surfaces): Clean first, then apply a 1:16 solution of (this product) with a mop, cloth or sprayer in an amount to moisten surfaces thoroughly. Do not rinse. Repeat application as necessary to maintain control.

	(Insert Brand Name)	
Dilution Ratio	Quantity Needed Product	Quantity Needed Water
1:64	2 oz.	128 oz.
1:16	8 oz.	128 oz.
1		

To (sanitize)(and)(disinfect): (see use directions)(use as directed).

For Use in Veterinary Clinics, Animal Care and Animal Laboratories:

For cleaning and disinfecting the following hard, non-porous surfaces: operating tables, equipment, floors, walls, kennels, cages, runs, feeding and watering equipment, utensils, instruments, stables, catteries, etc.

- 1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
- 2. Remove all litter, droppings and manure from walls, floors and surfaces of facilities occupied of traversed by animals.
- 3. Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 4. Saturate surfaces with a use solution of 8 oz. per gallon of water [1:16] for a period of 10 minutes.
- 5. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.
- 6. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, dried or set.
- 7. Thoroughly scrub all treated feeding and watering appliances with soap or detergent and rinse with clean (potable) water before reuse.

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Health Care Facilities: Pre-clean hard, non-porous surfaces according to Cleaning directions. Use a 1:16 solution of (this product) for floors, walls, furniture, bed frames and all hard, non-porous surfaces. Apply to surface until thoroughly wet and allow to remain wet for 10 minutes. (This product) is suitable for disinfecting critical care areas such as O.R. and isolation rooms. This product is also, suitable for use on conductive floors.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] 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 / body fluids; and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of HIV-1 [associated with AIDS].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 [AIDS Virus] ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood / body fluids, use disposable latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURES: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of (this product).

CONTACT TIME: Allow surfaces / objects to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood / body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.

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

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. 			
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 the Poison Control Center or doctor. Do not give anything by mouth to an unconscious person 				
	CONTACT NUMBER			
Questions? Comments or In case of an emergency call toll free (1-800-677-9218) (1-800-560-6619). Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.				
NOTE TO PHYSICIAN				
Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.				

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in original container in areas inaccessible to children. Keep securely closed. **PESTICIDE DISPOSAL:** Pesticide wastes may be 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 the label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse (or equivalent). Follow pesticide disposal instructions for rinsate. Then discard in trash

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or offer for recycling, if available.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp.

<< This page is for information purposes only. >>

<< 1-min Sanitization (hard non-porous	ATCC No	<< 10-min Disinfection (hard non-	
surfaces) - Bacteria >>		porous surfaces) - Viruses >>	
Enterobacter aerogenes	(13048)	Adenovirus Type 5	
Staphylococcus aureus	(6538)	Cytomegalovirus	(VR-538)
		Herpes Simplex Virus Type 1	
<< 10-min Disinfection (hard non-porous		Human Immunodeficiency Virus Type 1	
surfaces) - Bacteria >>		[HIV-1 AIDS Virus]	
		2009-H1N1 Influenza A Virus (Novel H1N1)	
Acinetobacter baumannii	(19606)	Influenza A ₂ Virus	
Corynebacterium diphtheria	(11913)	Respiratory Syncytial Virus (RSV)	
Enterobacter aerogenes	(13048)	Vaccinia	
Enterococcus (Streptococcus) faecalis	(828)		
Escherichia coli	(11229)	<< Hard Surface Mildew Fungistat >>	
Escherichia coli O157:H7	(43888)	Aspergillus niger	(6275)
Klebsiella pneumonia	(9997)		
Methicillin Resistant Staphylococcus aureus	(33592)	<< 10-min Disinfection (hard non-	
(MRSA)		porous surfaces) - Fungi >>	
Niesseria elongata	(25259)	Trichophyton mentagrophytes	(9533)
Proteus vulgaris	(9920)		
Pseudomonas aeruginosa	(15422)		
Salmonella enterica	(10708)		
Salmonella paratyphi	(9281)		
Salmonella schottmueller	(10719)		
Serratia marcescens	(8195)		
Shigella dysenteria	(11835)		
Staphylococcus aureus	(6538)		
Staphylococcus aureus 80/81 [Penicillin			
Resistant]			
Streptococcus pyogenes	(12384)		
Streptococcus salivarius	(9222)		
Vancomycin Resistant Enterococcus faecalis (VRE)	(51575)		

	Symbol Desi	gnation – used	l on product la	<u>abels</u>
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Single asterisk(*) Dagger(†)	Bacteria * / Fungi Viruses †	Used for identifying disinfection against specific bacteria or fungi Used for identifying disinfection against specific viruses
Double asterisk (**)	Germs **	Used for identifying disinfection against specific bacteria & viruses / fungi
Triple asterisk (***)	Sanitizes ***	Used for identifying sanitization against bacteria
Double dagger (++)	Allergens ++	Used for identifying the removal of specific non-living allergens

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