

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 4, 2016

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

Subject: PRIA Label Amendment – Addition of organisms, updating label language

Product Name: Tergiquat Germicidal Cleaner

EPA Registration Number: 675-36 Application Date: November 10, 2015

Decision Number: 511231

Dear Ms. DeCarlo:

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

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with FIFRA section 6. If you have any questions, please contact Emilia Oiguenblik by phone at 703 347 0199, or via email at Oiguenblik.emilia@epa.gov or Eric Miederhoff by phone at 703 347 8028, or via email at Miederhoff.eric@epa.gov

Sincerely,

Eric Miederhoff
Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped label, Efficacy review

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<< FRONT PANEL >>

ACTIVE INGREDIENTS:

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 >>

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EPA Est. No. 09019-OH-001 777-MO-001 777-PA-001

09019-OH-002 312-WI-1

(See bottom or side) (for Lot / Date code)

<< BACK PANEL >>

Questions? (()) (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

Reckitt
Benckiser
HEALTH-HYGIENE-HOME

NSF certification symbol:

NSF.

<< 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.

ACCEPTED

04/04/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

675-36

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<< 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.

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:

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

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

- Cafeteria
- Health Care Facility
- Kitchen
- Restaurants

- Day Care Centers
- Hospitals
- Nursing Homes
- Restrooms

- Dental Offices
- Hotels / Motels
- Office Buildings
- School (College)

- Doctor's Office
- Kennel
- Physician's Office
- Veterinary Office

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.

(This product is) (GERMICIDAL**) (BACTERICIDAL*) (STAPHYLOCIDAL*) (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*

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, Staphylococcus aureus 80/81 [Penicillin Resistant], Streptococcus pyogenes, Streptococcus salivarius and Trichophyton mentagrophytes.

<< Terminal Sterilant Statement - qualified metal surfaces >>

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

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^{*} On hard, non-porous environmental surfaces

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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.

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
	Comments or In case of an emergency call toll free (1-800-677-9218) (1-800-560-6619). Container or label with you when calling a Poison Control Center or doctor or going for treatment.
	NOTE TO PHYSICIAN
Measu	Probable mucosal damage may contraindicate the use of gastric lavage. res 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 Designation – used on product labels						
Single asterisk (*)	Bacteria * / Fungi	Used for identifying disinfection against specific bacteria or fungi				
Dagger (†)	Viruses †	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				

Tergiquat Germicidal Cleaner Amendment: 11-09-2015v3

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