

675-36

01/18/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 18 2012

Mary C. Pisculli
Regulatory & Registration Compliance Specialist
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Subject: Tergiquat Germicidal Cleaner
EPA Registration Number 675-36
Application Dated October 21, 2011
EPA Received Date October 24, 2011

Dear Ms. Pisculli:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment:

- Label amendments
Per Agency letter dated 6/05/10

General Comments:

- 1. Delete "(website)" from the statement, "For ingredient (and other) information, (www.rbnainfo.com)." Since websites are an extension of labeling, you must list specific website addresses.
2. Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 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. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through

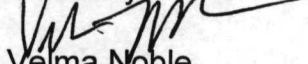
Table with 3 rows: SYMBOL, SURNAME, DATE and 8 columns.

the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped label

<< FRONT PANEL >>

ACTIVE INGREDIENTS:

Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) 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 8791-MO-1
09019-OH-002 312-WI-1

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

<< BACK PANEL >>

Questions? () (Comments?) (Call:) 1-800-677-9218


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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 18 2012

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 675-36

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.

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

(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)
Ideal for Food Service & Processing Areas

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

Kills Salmonella enterica and E. coli

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

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

- Cafeteria
- Day Care Centers
- Dental Offices
- Doctor's Office
- Health Care Facility
- Hospitals
- Hotels / Motels
- Kennel
- Kitchen
- Nursing Homes
- Office Buildings
- Physician's Office
- Restaurants
- Restrooms
- School (College)
- 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) fulfills the criteria of Appendix F of the Grade 'A' pasteurized Milk Ordinance 1965 Recommendations of the U.S. Public Health Service in waters up to 700 ppm of hardness calculated as CaCO₃, when tested at 1:128 dilution by the AOAC Germicidal and Detergent Sanitizers Official Method. (This product) can be used under the U.S.D.A. Inspection and Grading Program and in plants operating under the U.S. Department of Commerce Fishery Inspection Program as a sanitizer for all surfaces always requiring a rinse.

(This product) is 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*

* On hard, non-porous environmental surfaces

Passes AOAC Use-Dilution Test at 1:64 [2 oz. per gallon] against: 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, Staphylococcus 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.

<< 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.

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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 device. 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 heavily soiled hard, non-porous surfaces according to Cleaning directions.
2. Dilute 1 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 heavily soiled 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 10 minutes.

To Control Mold & Mildew (on hard, non-porous environmental surfaces): Clean first, then apply a 1:64 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.

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 or traversed by animals.
3. Thoroughly clean all surfaces with soap or detergent and rinse with water.
4. Saturate surfaces with a use solution of 2 oz. per gallon of water [1:64] 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.

Health Care Facilities: Use a 1:64 solution of (this product) for floors, walls, furniture, bed frames and all hard, non-porous surfaces. (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.

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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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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. 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 or offer for recycling, if available.

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

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

Disinfection - Hard non-porous surfaces

Bacteria:	Corynebacterium diphtheria	ATCC # 11913
	Enterobacter aerogenes	ATCC # 13048
	Enterococcus (Streptococcus) faecalis	ATCC # 828
	Escherichia coli	ATCC # 11229
	Klebsiella pneumoniae	ATCC # 9997
	Niesseria elongata	ATCC # 25259
	Proteus vulgaris	ATCC # 9920
	Pseudomonas aeruginosa	ATCC # 15422
	Salmonella enterica	ATCC # 10708
	Salmonella paratyphi	ATCC # 9281
	Salmonella schottmuelleri	ATCC # 10719
	Serratia marcescens	ATCC # 8195
	Shigella dysenteria	ATCC # 11835
	Staphylococcus aureus	ATCC # 6538
	Staphylococcus aureus 80/81 [Penicillin Resistant]	
	Streptococcus pyogenes	ATCC # 12384
	Streptococcus salivarius	ATCC # 9222

Viruses:	Adenovirus Type 5	
	Cytomegalovirus	ATCC # VR-538
	Herpes Simplex Virus Type 1	
	Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]	
	Influenza A ₂ Virus	
	Vaccinia	

Fungi:	Trichophyton mentagrophytes
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