

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES



JUN 5 2009

Ms. Mary Pisculli Reckitt Benckiser Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054-0225

Subject:

Tergiquat Germicidal Cleaner EPA Registration No.: 675-36 Amendment Date: March 5, 2009 EPA Receipt Date: March 9, 2009

Dear Ms. Pisculli,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions listed below.

Proposed Amendment

- Add label claims, ATCC Numbers, Terminal Sterilant Statement
- · Updated directions and microorganisms' nomenclature
- Update Container Disposal Statements for PR Notice 2007-4

Conditions

Revise the label as follows:

- 1) Revise the 7th claim on page 2 by deleting the term, powerful, because it implies heightened efficacy.
- 2) Revise the 10th claim on page 2 deleting the term, "suggested," to bring the phrase in compliance with PR Notice 2000-5, Mandatory Labeling.
- 3) Revise the 2nd statement of the 15th claim on page 2 by deleting the term, recommended to bring the statement in compliance with PR Notice 2000-5, Mandatory Labeling.
- 4) Revise the "Personal Protection" statement under the HIV directions on page 3 by deleting the term, or, and state "and." The items listed under personal protection are not optional when cleaning blood and body fluids.

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5) Revise the 7th statement under the "Precautionary Statements" on page 4 to read "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

6) The container rule no longer separates "Storage and Disposal" by container size; it is distinguished by use pattern such as residential, industrial, institutional, or commercial. Delete the container disposal statements for containers 1 gallon or less for institutional use sites.

Add an "Environmental Hazards" section to page 4 with the statement, "This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp."

General Comments

A stamped copy of the accepted 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 concerning this letter, please contact Jacqueline Campbell at (703) 308-6415 and Velma Noble (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Quella Copeland

Enclosure: Stamped Label

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<< Front Panel >>

ACTIVE INGREDIENTS:

0.7% 97.0% OTHER INGREDIENTS: TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER: See back (side) panel for additional precautionary statements and first aid.

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

<< Front or Back Panel >>

EPA Reg. No.: 675-36

EPA Est. No .:

09019-OH-001 09019-OH-002

See bottom or side (for LoVDate code)

<< Back Panel >>

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

@ RBI (year)

(or) Visit us at www.reckittprofessional.com

Made in U.S.A.

Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)

Contains no phosphates
This (bottle) (container) is made of x% post-consumer recycled plastic.

<< Back Panel - Optional text >>

Company Logo (Reckitt Benckiser Professional)

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

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<< Front or Back Panel - Marketing / Product Performance 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 powerful detergent agents.

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

- · Chrome / Stainless Steel Fixtures
- Display Cases
- · Non-medical Chrome / Stainless Steel

· Counters

- Floors / Walls
- Tables

Equipment

- · Medical Lamps / Stands / Trays
- Waste Cans

(Great) 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 Office Buildings
- Restrooms
 School (College)

- Dental Offices
 Doctor's Office
- Hotels / MotelsKennel
- Physician's Office
- Veterinary Office

- ✓ Suggested areas of application for (this product):

 Use on hard, non-porous environmental surfaces (in Institutions and Industrial Facilities).
- Cleans, disinfects, sanitizes and counteracts odors.

 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 cerefully 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) fulfilis 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) is recommended for use under 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 <u>Virus Type 1</u>, Influenza A₂ <u>Virus</u>, 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 <u>enterica</u>, 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.

<<-Terminal Sterilant Statement - unqualified metal surfaces >>

This product is not to be used as a terminal sterllant / 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.

IOTE: 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.

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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 Solled 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,

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:

Pre-clean heavily soiled hard, non-porous surfaces according to Cleaning directions,
 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:

Pre-clean heavily soiled hard, non-porous surfaces according to Cleaning directions,
 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.

Remove all animals and feeds from premises, animal transporation vehicles, crates, etc.

Remove all litter, droppings and manure from walls, floors and surfaces of facilities occupied of traversed by animals.

Thoroughly clean all surfaces with soap or detergent and rinse with water.

Saturate surfaces with a use solution of 2 oz. per gallon of water [1:64] for a period of 10 minutes.

- 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.
- Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been 6, absorbed, dried or set.
- 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 <u>HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [</u>HIV-1 <u>AIDS VIRUS</u>] 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 solled with blood / body fluids, use disposable latex gloves, gowns, masks or 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. 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.
lf 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
Add skyllight a	CONTACT NUMBER
	Questions? Comments or In case of an emergency call toll free 1-800-677-9218. 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.

STORAGE: Store in areas inaccessible to small children. Keep securely closed.

DISPOSAL: Non-refillable container. Do not reuse or refill this container. Discard in trash or offer for recycle, if available,

<< Professional containers greater than 1 gallon and less than 5 gallon >>

STORAGE AND DISPOSAL

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

STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed.

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: Non-refillable container. Do not reuse or refill this container. Offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local

authorities, by burning. If burned, stay out of smoke.

Bacteria:

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ATCC # VR-538

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

Disinfection - Hard non-porous surfaces

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

Herpes Simplex Virus Type 1 Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]

Influenza Az Virus

Vaccinia

Fungi:

Trichophylon mentagrophyles