

675-36

2-10-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 10 2003

Mr. Bob MacDonald
Agent for Reckitt Benckiser, Inc.
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Tergiquat
EPA Registration No. 675-36
Amendment Date: November 11, 2002
EPA Receipt Date: November 15, 2002

Dear Mr. MacDonald,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Update Label and CSF

Conditions

1. Page 1: Revise the phrase, "environmental surfaces," to read "*hard, nonporous* environmental surfaces."
2. Page 2: At the bottom of the page, delete "Salmonella" and replace it with *S. choleraesuis*. When listing organisms that are killed by this product, you must always use the organism's complete scientific name, genus and species, which may be followed up by the shortened/abbreviated name in parenthesis; for example, *Salmonella choleraesuis* (Salmonella). You may also abbreviate an organisms name by using the first initial of the genus and listing the species' complete name which is demonstrated above.
3. Page 2: Since this product is fungicidal, the organism *Trichophyton mentagrophytes*, must be listed on the label.
4. Page 4: The "Cleaning/Sanitizing" directions must be revised to state :
 - a. Preclean hard, nonporous surfaces. Use 1 oz. per gallon of water. Apply sanitizer use solution with a cloth, sponge, or sprayer, thoroughly wetting surfaces. Treated surfaces must remain wet for 1 minute. Wipe dry with a sponge, mop, or cloth or allow to air dry.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

b. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge, or cloth. Avoid breathing spray mist.

c. Prepare a fresh solution daily or more often if solution become visibly diluted, soiled, or cloudy.

5. Page 4: The "Cleaning/Disinfecting" directions must be revised to state:

a. Preclean hard, nonporous surfaces. Use 2 oz. per gallon of water. Apply disinfecting solution with a cloth, sponge, or sprayer, thoroughly wetting surfaces. Treated surfaces must remain wet for 10 minutes. Wipe dry with a sponge, mop, or cloth or allow to air dry.

b. Food contact surfaces must be rinsed with potable water prior to reuse. Do not use on glasses, dishes, or utensils.

c. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge, or cloth. Avoid breathing spray mist.

d. Prepare a fresh solution daily or more often if solution become visibly diluted, soiled, or cloudy.

6. Page 4: The "Directions for Use" must be revised by adding the following text, "*When used on surfaces such as locker rooms, restroom, and exercise facilities, this product is an effective fungicide against Trichophyton mentagrophytes (Agent causes Athlete's Foot Fungus) when used as a disinfectant.*"

7. Page 4: The following language must be added to the label in regard to the surfaces in the food service/dietary areas, dairies, food processing plants, supermarkets, and fast food operations:

Before used 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.

8. Page 4: Since this product is used in hospitals and nursing homes in critical care areas, the following MOU language from PR Notice 94-4 must be added to the label:

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 semicritical medical devices prior to sterilization or high level disinfection.

- 9. Page 4: Under Veterinary Practice/Animal Care/Animal Laboratory, add the statement, *“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.”* The statement should appear after the contact time sentence.
- 10. Page 5: Bold the capitalized headings that are associated with the HIV directions.
- 11. Page 5: Based on products that are substantially similar to this product, revise the “Precautionary Statements” to reflect the following language:

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.

General Comments

The Confidential Statement of Formula dated November 11, 2002 is acceptable. It is in compliance with PR Notice 91-2 and in agreement with the label.

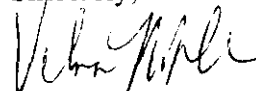
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

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TERGIQUAT

Germicidal Cleaner

[CLEANS] [DISINFECTS] [SANITIZES] [COUNTERACTS ODORS]

[For use by Professional Maintenance Personnel Only in [Food Service Areas,] [Food Processing Plants,] [Dairies,] [Schools,] [Hospitals] [and] [Nursing Homes] [and on Environmental Surfaces in [Institutional] [and] [Industrial] Facilities].]

[One Product Cleans & Disinfects]
[Concentrated Cleaning Power]
[Ideal For [Food Service] [&] [Processing Areas]]

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:	<u>97.0%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN
DANGER

See Back (Side) Panel for Additional Precautionary Statements

Net Contents: [One Gallon (128 fl. oz.) 3.79 Liters] { for one gallon size }
[Five Gallons (640 fl. oz.) 18.93 Liters] { for five gallon size }
[55 Gallons (7,040 fl. oz) 208.20 Liters] { for 55 gallon size }

ACCEPTED
with COMMENTS
in EPA Letter Dated:
FEB 10 2003

Under the Federal Insecticide,
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amended, for the pesticide,
registered under EPA Reg. No. **675-36**

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{This list of organisms is for informational purposes. The organisms may or may not be listed on the final printed label and if listed may use a different format.}

[On hard non porous inanimate environmental surfaces, this product kills the following bacteria, and viruses:]

BACTERIA:

- Staphylococcus aureus
- Staphylococcus aureus (Penicillin Resistant)
- Pseudomonas aeruginosa
- Escherichia coli
- Salmonella choleraesuis
- Salmonella paratyphi
- Salmonella schottmuelleri
- Shigella dysenteria
- Enterobacter aerogenes
- Proteus vulgaris
- Klebsiella pneumoniae
- Niesseria elongata
- Serratia marcescens
- Streptococcus (Enterococcus) faecalis
- Steptococcus pyogenes
- Streptococcus salivararius
- Corynebacterium diphtheria

VIRUSES:

- HIV-1 (AIDS Virus)
- Cytomegalovirus
- Herpes Simplex Type 1
- Vaccinia
- Influenza A₂ (England)
- Adenovirus Type 5

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{Labels with multiple uses must include the appropriate headings directly preceding the respective use directions. These headings are optional for labels with only one use pattern. }

[TERGIQUAT Germicidal Cleaner] [This product] is a synergistic combination of modern quaternary ammonium compounds and powerful detergent agents.

[TERGIQUAT Germicidal Cleaner] [This product] is:

- STAPHLOCIDAL*
- PSEUDOMONACIDAL*
- VIRUCIDAL* (against Lipophilic viruses including Herpes Simplex, Influenza A₂, Vaccinia)
- FUNGICIDAL* (against pathogenic fungi)
- CONTROLS THE GROWTH OF MOLD AND MILDEW*

* On hard, nonporous, environmental surfaces.

PASSES AOAC USE-DILUTION TEST AT 1:64 (2oz. per gallon) against:

- | | |
|---|---------------------------------------|
| Salmonella choleraesuis ATCC 10708 | Neisseria elongata ATCC 25259 |
| Salmonella paratyphi ATCC 9281 | Serratia marcescens ATCC 8195 |
| Salmonella schottmuelleri ATCC 10719 | Staphylococcus aureus ATCC 6538 |
| Shigella dysenteria ATCC 11835 | Staphylococcus aureus 80/81 |
| Enterobacter aerogenes ATCC 13048 | (Penicillin Resistant) |
| Escherichia coli (AMC 198) ATCC 11229 | Enterococcus faecalis ATCC 828 |
| Proteus vulgaris ATCC 9920 | Streptococcus pyogenes ATCC 12384 |
| Klebsiella pneumoniae ATCC 9997 | Streptococcus salivarius ATCC 9222 |
| Cytomegalovirus ATCC VR-538 | Corynebacterium diphtheria ATCC 11913 |
| Human Immunodeficiency Virus Type 1 (HIV-1) | Pseudomonas aeruginosa ATCC 15422 |

[TERGIQUAT Germicidal Cleaner] [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.

[TERGIQUAT Germicidal Cleaner] [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.

[GREAT] FOR USE [as a DISINFECTANT and /or SANITIZER][ON HARD NON-POROUS SURFACES][LOCATED] IN:

- | | | | |
|---------------|--------------------|-----------------|------------------|
| Hospitals | Day Care Centers | Hotels/Motels | Office Buildings |
| Nursing Homes | Physicians Offices | Restaurants | Bowling Alleys |
| Clinics | Health Clubs | Schools | Dental Offices |
| Ambulances | Veterinary | [Institutional] | |

[Kills Salmonella and E. coli]

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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.

FOR LIGHT DUTY CLEANING AND SANITIZING:

1. Use 1 ounce [1:128] of [TERGIQUAT Germicidal Cleaner] [this product] per gallon of water. [Provides 225ppm quaternary active ingredients]
2. Apply solution to surfaces with [cloth,] [mop] [or spray equipment]. [[TERGIQUAT Germicidal Cleaner] [this product] may be used in all types of pressure spraying equipment.]
3. All treated food contact surfaces must be rinsed with potable water prior to reuse. Follow local health regulations.

FOR HEAVY DUTY CLEANING AND DISINFECTING:

Use 2 ounces [1:64] of [TERGIQUAT Germicidal Cleaner] [this product] [per] [in a] gallon of water [provides 450 ppm quaternary active ingredients]. Apply as per Steps 2 and 3 above under Light Duty Cleaning and Sanitizing.

MOLD AND MILDEW:

For controlling mold and mildew on hard, nonporous environmental surfaces, clean first, then apply a 1:64 [TERGIQUAT Germicidal Cleaner] [this product] solution with [mop,] [cloth] [or sprayer] in an amount to moisten surfaces thoroughly. Do not rinse. Repeat application as necessary to maintain control.

SUGGESTED AREAS OF APPLICATION FOR [TERGIQUAT GERMICIDAL CLEANER] [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.

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Health Care Facilities: Use a 1:64 solution of [TERGIQUAT Germicidal Cleaner] [this product] for floors, walls, furniture, bed frames and all hard non-porous surfaces. Suitable for critical area disinfection such as O.R. and isolation areas. Suitable for use on conductive floors.

Veterinary: Use a 1:64 solution of [TERGIQUAT Germicidal Cleaner] [this product] for operating tables, equipment, floors, walls, kennels, cages, runs.

{The following language is for products with veterinary offices listed on the label:}

For Use in Veterinary Clinics, Animal Care, and Animal Laboratories: For cleaning and disinfecting the following hard, nonporous surfaces: feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 2 ounces per gallon of water

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(1:64) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, dried, or set. Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse with potable water before reuse.

KILLS HIV 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 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood/body fluids, use disposable latex gloves, gowns, masks, or eye protection. **CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces/objects before application of [TERGIQUAT Germicidal Cleaner] [This product]. **CONTACT TIME:** Allow surface to remain wet for 10 minutes. **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.

Precautionary Statements

Hazards to humans and domestic animals.

DANGER: Corrosive. Causes irreversible eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, clothing and gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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: Remove 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: 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.

CONTACT NUMBER

Questions? Comments or In case of an emergency call toll free (1-800-228-4722). 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.

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STORAGE/DISPOSAL {For sizes 1 gallon or less.}

Store in areas inaccessible to small children. Rinse empty container thoroughly and discard.

STORAGE AND DISPOSAL {For sizes over 1 gallon.}

Do not contaminate water, food, or feed by storage or 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

Triple rinse (or equivalent). Then 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.

ENVIRONMENTAL HAZARDS {For sizes 5 gallons or more}

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.

Questions? Comments? Call 1-800-228-4722.

Monday – [thru] Friday, 8:45 a.m. – [to] 4:30 p.m. [Eastern time].

[Visit us at www.reckittprofessional.com]

[Reckitt-Benckiser Inc. Professional (company logo)]

Reckitt Benckiser, Inc.
1655 Valley Road
Wayne, NJ 07474-0977

EPA Reg. No. 675-36

EPA Est. No. {Insert establishment number here}

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