

Mary C. Pisculli
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054

JUN 15 2010

SUBJECT: Roccal II 10%
EPA Registration Number: 675-30
Application Date: March 17, 2010
Receipt Date: March 18, 2010

Dear Ms. Pisculli:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

Proposed Amendment

- Revise Storage and Disposal
- Update Organism Nomenclature
- Update Label language

Conditions

1. Revise the footnote on each page to indicate that "To use the *unqualified* term "germ" the product must be efficacious *against all 3* of the major classes of organisms." as per the CSPA Germs letter of 1/5/05 (attached.)

2. Revise the Barber and Beauty Shop Disinfection directions on page 4 as follows: "...Completely immerse *hard non-porous* combs, brushes..."

3. Revise the Eating Establishment Sanitizer and Food Preparation Surfaces directions on page 4 to be in agreement with DIS/TSS-17 by including the following: "3. Rinse with clean, hot potable water." and "Clean with detergent and rinse *with potable water.*" respectively.

CONCURRENCES								
SYMBOL	7510P							
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DATE	6/12/10							

4. Revise the Food Processing Plants equipment directions on page 4 to be in agreement with DIS/TSS-17 by including the following: "Clean first, *rinse with potable water* then sanitize..."

5. Revise the Public or Commercial Swimming Pool Maintenance directions on page 5 to include mandatory language as per PR Notice 2000-5 as follows: "...algicide additions *must* be made since a heavy..." and "...the appropriate amount of this product *is* added by pouring..."

6. Revise the Storage and Disposal statement to include the following language: "Triple rinse as follows: *Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip.* Fill the container 1/4 full with water and recap...and dispose of rinsate *as pesticide waste.* Repeat two more times. *Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.*"

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 Tracy Lantz at (703) 308-6415.

Sincerely,



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

7510P:T.Lantz:6/12/2010:675-30 acc amend

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ROCCAL® II 10%
(SANITIZING AGENT / GERMICIDE-ALGICIDE)
(DEODORIZER)

(1 oz. per gallon use dilution [800 ppm] is germicidal against Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli and Salmonella enterica.)

- (Bactericidal)
- (Virucidal†)
- (Kills mildew)
- (Prevents musty odors on hard surfaces)
- (Controls the growth of algae in public or commercial swimming pools)
- (For use in Food Service and Processing Areas)
- (Formulated for 3rd Sink and Clean-In-Place Applications)
- (Makes up to 512 gallons)
- (Concentrated)
- (Contains no phosphorous compounds)

(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 500 ppm of hardness calculated as CaCO₃ when tested by the AOAC Germicidal and Detergent Sanitizers – Official Method.)

ACTIVE INGREDIENT:

Alkyl (C₁₄, 50%, C₁₂, 40%, C₁₆ 10%) dimethyl benzyl ammonium chloride 10.00%

OTHER INGREDIENTS: 90.00%

TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER: See First Aid Statement and additional Precautions on back panel.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 15 2010

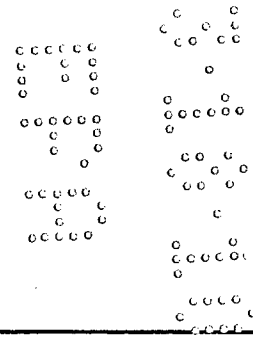
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

675-30

EPA Reg. No.: 675-30
EPA Est. No.: 8791-MO-1
09019-OH-001
09019-OH-002

Questions? Comments? Call: 1-800-677-9218
For ingredient and other information, www.rbnainfo.com

Made in U.S.A. © RBI (year)
Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)
Contains no phosphates
This (bottle) (container) is made of x% post-consumer recycled plastic.
Company Logo (Reckitt Benckiser) (rb)



NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, (optional text), [required qualifier].
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The product label must identify the specific bacteria, virus, fungus & mold.

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(On hard, non-porous inanimate environmental surfaces, this product kills the following bacteria, fungi and viruses:)

BACTERIA:

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Escherichia coli
- Salmonella enterica

FUNGI:

- Aspergillus niger

VIRUSES:

- HIV-1 (AIDS Virus)
- Herpes Simplex Virus Type 2
- Vaccinia Virus
- Influenza A₂ Virus [England]
- Adenovirus Type 5

FOOD CONTACT SANITIZER ORGANISMS:

- Staphylococcus aureus
- Escherichia coli

GENERAL AREAS OF USE (as a) (on hard, non-porous surfaces) (located in):

DISINFECTANT:

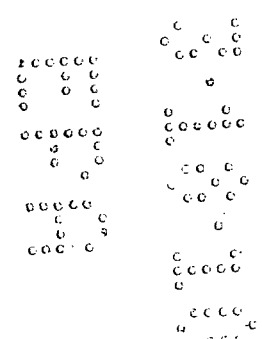
- (Hospitals), (Day Care Centers), (Hotels/Motels), (Office Buildings), (Nursing Homes), (Physicians Offices), (Restaurants), (Food & Drink Preparation and Service), (Federally Inspected Meat & Poultry Plants), (Clinics), (Health Clubs), (Schools), (Dental Offices), (Ambulances), (Institutional), (Restrooms), (Showers), (Barber & Beauty Shops) (Veterinary Hospitals).

SANITIZER:

- (Restaurants), (Food & Drink Preparation and Service), (Federally Inspected Meat & Poultry Plants), (Food Processing Equipment & Storage Areas), (Beverage Processing Equipment & Storage Areas)

ALGAECIDE:

- (Public or Commercial) (Swimming Pools), (Industrial Water Reservoirs [non-potable])



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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. Do not mix with soap or detergents. Read directions on container label before use.

GENERAL DISINFECTION:

To disinfect (floors, walls, furniture, bathtubs, shower stalls and toilet seats): Sponge or mop with 800 ppm solution (of this product) [1 oz. per gallon of water]. Let stand for 10 minutes. Rinse all surfaces that come into contact with food such as counters, appliances and tables with potable water before reuse. Prepare a fresh bucket of solution every time you clean or more often as needed.

DEODORIZATION AND DISINFECTION:

Flood-rinse, sponge or spray a solution of 1 oz. (of this product) per gallon of water on floors, walls and other hard, non-porous surfaces; making sure solution gets into cracks, crevices and corners where food spillage or other sources of malodors can occur. Let stand for 10 minutes.

For heavily soiled areas such as garbage cans, clean first; then use 1 oz. (of this product) per gallon of water. Let stand for 10 minutes.

TO PREVENT MOLD AND (&) MILDEW:

Clean hard, non-porous surfaces. Apply use solution, 1 oz. per gallon of water by spray, cloth, sponge or mop. Let stand 10 minutes then wipe or allow to air dry. Repeat application after 7 days or when new growth appears.

KILLS HIV-1 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 and eye protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (this product). Wet thoroughly by mop, sponge or spray with a solution of 1 oz. (of this product) per gallon of water.

CONTACT TIME: Allow surface / object to remain wet for 10 minutes.

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

VETERINARY HOSPITAL DISINFECTION:

For cleaning and disinfecting hard, non-porous surfaces including feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed 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 1 oz. per gallon of water 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.

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BARBER AND (&) BEAUTY SHOP DISINFECTION:

Pre-clean instruments and tools prior to disinfection. Prepare a 1600 ppm use solution by mixing 2 oz. per gallon of water [1 tablespoon to each quart of water]. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments for 10 minutes. Rinse thoroughly and dry before reuse. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, then dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to instruments.

EATING ESTABLISHMENT SANITIZER:

(including food service in hospitals and in nursing homes) (dishes, glasses and utensils)

1. Scrape and pre-rinse utensils before washing.
2. Wash with an appropriate detergent and hot water.
3. Rinse with clean, hot water.
4. Sanitize by immersing in a 200 ppm [1/4 oz. per gallon of water] solution for 2 minutes or for the contact time specified by the governing sanitary code.
5. Allow surfaces to air dry on clean drain board or rack. No rinsing required.

FOOD PREPARATION SURFACES:

Clean with detergent and rinse.

To sanitize: Sponge or mop with a solution of 1/4 oz. (of this product) per gallon of water [200 ppm]. Allow surface to remain wet for 2 minutes or for the contact time specified by the governing sanitary code. Allow surfaces to air dry. No rinsing required.

FOOD PROCESSING PLANTS, BAKERIES, CANNERIES, BEVERAGE PLANTS SANITIZER:

(This product) can be used in Federally inspected meat and poultry plants on all hard, non-porous surfaces in inedible product processing areas, non-processing areas and/or exterior areas, as a floor and wall cleaner and as a sanitizing agent for use in all departments for all surfaces not always requiring a rinse.

For use on:

Floors and Walls: To sanitize – flood-mop a solution of 1/2 oz. (of this product) per gallon of water [400 ppm] on cleaned surfaces. Allow surface to remain wet for 2 minutes or for the contact time specified by the governing sanitary code.

Equipment: Clean first then sanitize by wiping with a solution of 1/4 oz. (of this product) per gallon of water. Allow surface to remain wet for 2 minutes or for the contact time specified by the governing sanitary code. Allow surfaces to air dry. No rinsing required.

MILK PROCESSING PLANT SANITIZER:

First clean equipment and utensils thoroughly with cleansing agent, then sanitize by immersing in a solution of 200 ppm (of this product) [1/4 oz. per gallon of water] for 2 minutes or for the contact time specified by the governing sanitary code. Allow surfaces to air dry. No rinsing required.

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INDUSTRIAL NON-POTABLE WATER SUPPLY ALGAECIDE:

To control algae in industrial non-potable water supplies for industrial service and comfort cooling purposes.

INITIAL APPLICATION: When the system is noticeably fouled, apply 1 gallon (of this product) to each 50,000 gallons of water in the system. Repeat until control is achieved.

MAINTENANCE: When microbial control is evident, add 1 quart (of this product) to each 50,000 gallons of water in the system every 5 to 7 days, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

NOTE: Make-up water from evaporation does not require additional treatment (of this product). Make-up water due to leaks or use or discharges must be treated by the addition of (this product) at the rate of 3 oz. for each 1,000 gallons of water added.

PUBLIC OR COMMERCIAL SWIMMING POOL ALGAECIDE:

Ensure all pool equipment is working properly. Backwash the filter system following manufacturer's directions. Adjust pH to between 7.2 to 7.6. Maintain residual in accordance with label directions found on your sanitizer of choice. When using other products as outlined in directions for this product, always follow directions on those products.

DOSAGES FOR POOLS WHICH ARE FREE OF ALGAE OR CONTAIN ALGAE GROWTH:

INITIAL APPLICATION: For algae control of a clean pool, use 1 gallon of (this product) to each 50,000 gallons of pool water [2 ppm]. Pour directly into pool. More rapid distribution will be achieved by pouring a portion of the specified amount into several areas of the pool until all of the required quantity has been added. Recirculation accomplished by running the filter will assure rapid dispersion of product.

MAINTENANCE: Pour directly into pool at a rate of 1 quart of (this product) to each 50,000 gallons of water [0.5 ppm] every 5 to 7 days depending on weather and use factors. During sunny and humid periods, more frequent additions may be required. After each rain of consequence, add 1 quart of (this product) per 50,000 gallons of water. Even when the pool may not be in use for periods of time, algicide additions should be made since a heavy accumulation of algae growth is difficult to remove. The appropriate amount of this product should be added by pouring a portion of the specified amount into several areas of the pool until the required quantity has been added. Recirculation accomplished by running the filter will assure rapid dispersion of product.

RE-ENTRY INTERVAL: Swimmers are allowed to re-enter the pool 15 minutes after application of this product.

Ensure that water quality conditions are maintained for the successful use of this product.		
Swimming Pool Capacity Gallon of Water	Initial Treatment	Maintenance Dose
5,000	12.8 oz.	3.2 oz.
10,000	25.6 oz.	6.4 oz.
20,000	51.2 oz.	12.8 oz.
25,000	64 oz (2 quarts)	16 oz.
30,000	76.8 oz.	19.2 oz.
40,000	102.4 oz.	25.6 oz.
50,000	128 oz. (1 gallon)	32 oz (1 quart)

This product is effective in controlling the growth of the following types of algae:
Chlorella pyrenoidosa and Phormidium inundatum.

How to measure the gallon capacity of your pool:

Measure Length (L), Width (W) and average Depth (D) in feet.

For square or rectangular pools: $L \times W \times D \times 7.5 = \text{gallons}$

For circular or elliptical pools: $L \times W \times D \times 5.9 = \text{gallons}$

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PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes on skin or on clothing. Wear protective eyewear [safety glasses / face shield], protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Avoid contamination of food. Avoid breathing spray mist.

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">• <u>Take off</u> 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 <u>the</u> 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.	

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. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Agitate vigorously and dispose of rinsate. Repeat two more times. (Wrap container and) discard in trash or offer for recycling, if available.

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