

JUN 18 2003

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

Subject: Roccal II 10%
EPA Registration No. 675-30
Amendment Date: March 24, 2003
EPA Receipt Date: March 25, 2003

Dear Mr. MacDonald,

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

- Response to Agency letter dated February 5, 2003

Comments

Revise the label as follows:

1. On page 3, delete all the sanitizing claims. This product does not have data to support a 30 second sanitizing contact time. Actually, it only supports a food contact sanitizer claim with a "2 minute contact time." Agency regulations require that food contact sanitizing directions must carry one minute contact time at the very least.
2. On page 6, add the statement, "allow surfaces to air dry. No rinsing required." to all the food contact sanitizing directions.
3. Page 6: Revise the "Food Processing Plants, Bakeries, Canneries, Beverage Plants Sanitizer" claim by deleting the term "disinfectant" and replace it w/ "sanitizing."

General Comments

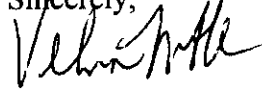
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

2/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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)

CONCURRENCES

SYMBOL								

3/11

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 choleraesuis.]

[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] {for the one gallon size}

[Makes up to 2,560 Gallons] {for the five gallon size}

[Makes up to 28,160 Gallons] {for the 55 gallon size}

[Concentrated]

[Contains no phosphorous compounds]

[ROCCAL® II 10% 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.]

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUN 18 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 675-30

Active Ingredients:

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: [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}

Note: Bracketed[]information is optional text. Text separated by a comma(,)denotes-and/or-options.
{Bracketed Text}is for administrative purposes only and will not appear on the printed label.

{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, fungi and viruses:]

BACTERIA:

Staphylococcus aureus
Pseudomonas aeruginosa
Escherichia coli
Salmonella choleraesuis

FUNGI:

Aspergillus niger

VIRUSES:

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

FOOD CONTACT SANITIZER ORGANISMS:

Staphylococcus aureus
Escherichia coli

{Alternate Language for Sanitization Claims}

[Kills [Eliminates] 99.9% of Bacteria** in seconds.]
[Eliminates [Kills] 99.9% of Bacteria** in 30 seconds.]
[Kills [Eliminates] Bacteria**]
[Kills [Eliminates] 99.9% of Bacteria** on hard, non-porous surfaces in seconds.]
[Eliminates [Kills] 99.9% of Bacteria** on hard nonporous surfaces in 30 seconds.]
[Kills [Eliminates] Bacteria** on hard, non-porous surfaces [in seconds].]

[Fast Acting Sanitizer]

[**Kills [Eliminates] 99.9% Staphylococcus aureus [Staphylococcus], Escherichia coli [E. coli] on hard, non-porous surfaces in 30 seconds.]

{part or all of the above listing of organism(s) must be on label when bacteria** sanitizer claims are made.} {a symbol other than ** may be used}

6/11

{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.}

GENERAL AREAS OF USE

[Great] [For use] [as a DISINFECTANT [on hard nonporous surfaces] [located] [in:] [Hospitals,] [Day Care Centers,] [Hotels/Motels,] [Office Buildings,] [Nursing Homes,] [Physicians Offices,] [Restaurants,] [Food] [and] [Drink] [Preparation] [and] [Service,] [Federally Inspected Meat and Poultry Plants,] [Clinics,] [Health Clubs,] [Schools,] [Dental Offices,] [Ambulances,] [Institutional] [Restrooms] [and] [Showers,] [Barber] [and] [Beauty Shops,] [Veterinary Hospitals]] [as a SANITIZER [on hard nonporous surfaces] [located] [in:] [Restaurants,] [Food] [and] [Drink] [Preparation] [and] [Service,] [Federally Inspected Meat and Poultry Plants,] [Food Processing Equipment] [and] [Storage Areas,] [Beverage Processing Equipment] [and] [Storage Areas]] [as an ALGAECIDE [in:] [Public] [or] [Commercial] [Swimming Pools] [and] [Industrial Water Reservoirs (non-potable)]]].

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL DISINFECTION

To disinfect [Floors,] [Walls,] [Furniture,] [Bathtubs,] [Shower Stalls,] [Toilet Seats] [and] [other] hard non-porous surfaces. Sponge or mop with 800 ppm ROCCAL® II 10% (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. per gallon ROCCAL® II 10% 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] [and] [refuse] cans, clean first, then use 1 oz. ROCCAL® II 10% per gallon of water. Let stand for 10 minutes.

BARBER AND BEAUTY SHOP DISINFECTION

Preclean 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] [and] [tools] 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, noncontaminated receptacle. Prolonged soaking may cause damage to instruments.

7/11

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, cranes, 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.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS:** on hard nonporous surfaces: on precleaned 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 and objects before application of ROCCAL® II 10%. Wet thoroughly by mop, sponge or spray with a solution of 1 oz. ROCCAL® II 10% per gallon of water **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 local regulations for infectious waste disposal.

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].

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) ROCCAL® II 10% solution for 2 minutes or for the contact time specified by the governing sanitary code.
5. **AIR DRY** on clean drainboard or rack.

Food Preparation Surfaces: Clean with detergent and rinse. To sanitize, [sponge] [or] [mop] with a solution of 1/4 oz. ROCCAL® II 10% 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.

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

ROCCAL® II 10% is recommended for use in Federally inspected meat and poultry plants on all hard nonporous surfaces in inedible product processing areas, non-processing areas and/or exterior areas, as a floor and wall cleaner and as a disinfectant agent for use in all departments for all surfaces not always requiring a rinse.

Recommended for use on:

Floors and Walls: To sanitize – flood-mop a solution of 1/2 oz. per gallon (400 ppm) ROCCAL® II 10% ppm 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. per gallon ROCCAL® II 10%. Allow surface to remain wet for 2 minutes or for the contact time specified by the governing sanitary code.

MILK PROCESSING PLANT SANITIZER

First clean equipment and utensils thoroughly with cleansing agent, then sanitize by immersing in a solution of 200 ppm ROCCAL® II 10% (1/4 oz. per gallon) for 2 minutes or for the contact time specified by the governing sanitary code.

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

9/11

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 – 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 one gallon of ROCCAL® II 10% 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 one quart of ROCCAL® II 10% to each 50,000 gallons of water (0.5ppm) 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 one quart of ROCCAL® II 10% 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.

Reentry 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	2 quarts (64 oz.)	16 oz.
30,000	76.8 oz.	19.2 oz.
40,000	102.4 oz.	25.6 oz.
50,000	1 gallon (128 oz.)	1 quart (32 oz.)

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: $L \times W \times D \times 7.5 =$ gallons. For Circular or Elliptical Pools: $L \times W \times D \times 5.9 =$ gallons.

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

10/11

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 ROCCAL® II 10% to each 50,000 gallons of water in the system. Repeat until control is achieved.

MAINTENANCE: When microbial control is evident, add 1 quart ROCCAL® II 10% 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 ROCCAL® II 10% treatment. Make-up water due to leaks or use or discharges must be treated by the addition of ROCCAL® II 10% at the rate of 3 oz. for each 1000 gallons added.

Precautionary Statements

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 or faceshield), 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: 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.

11/11

STORAGE/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

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. 675-30

EPA Est. No. {Insert establishment number here}