

NOV 23 1994

The Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

Attn: Stephen F. Sutherland, D.V.M.

Subject: Roccal-D
EPA Registration No. 1023-66
Amendment Dated September 30, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the deletion of animal pathogens from the label, is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. Revised the statement "For use in veterinary hospitals and premises ..." to read "For use in veterinary hospitals and non-medical premises ...".
 - b. Change the heading "First Aid" to read "Statement of Practical Treatment".
 - c. On the front panel, include the heading "Precautionary Statements".
 - d. On the front panel, under "Note to Physician", delete the last sentence beginning with "Measures against....."
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

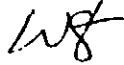
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A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

(3 7 5)

ROCCAL-D

DIRECTIONS FOR USE

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

FOR DISINFECTION OF ALL HARD INANIMATE SURFACES including floors, walls, examination tables, operating tables, diagnostic and therapeutic equipment and devices, furniture, cages, and carts.

Clean all surfaces with a suitable detergent and rinse thoroughly with water. Apply ROCCAL-D dilution by mop, sponge or spray to thoroughly wet the surfaces for at least 10 minutes before allowing the surfaces to air dry.

For use in veterinary hospitals and premises, and where effectiveness against *Pseudomonas aeruginosa* and *Salmonella typhimurium* is required, apply ROCCAL-D at 1:200 dilution.

For use as a general disinfectant in areas such as kennels, runs, vehicles, animal bathing areas, laboratory animal facilities, and nonfood areas in barns, apply ROCCAL-D at 1:400 dilution.

FOR DISINFECTION OF EATING AND DRINKING UTENSILS for animals not intended as food sources for human consumption. Scrape and prewash with warm water, soak in ROCCAL-D 1:400 dilution for at least 10 minutes and rinse with potable water. Prepare fresh solution daily or sooner if it becomes soiled or diluted.

For use by professional and paraprofessional personnel in veterinary hospitals and other animal facilities.

PREPARATION OF USE DILUTIONS

DILUTION 1:400 Add 10 mL (2 teaspoons) of ROCCAL-D to 1 gallon of water.

DILUTION 1:200 Add 20 mL (4 teaspoons) of ROCCAL-D to 1 gallon of water.

Do not mix ROCCAL-D with soap or anionic detergents.

EPA Reg. No. 1023-66

EPA Est. No. 13891-IN-2

814 834 005

Manufactured for
The Upjohn Company
Kalamazoo, MI 49001, USA

NDC 0009-3561-03

ROCCAL-D

VIRUCIDE† • DISINFECTANT

Active Ingredients

Alkyl dimethyl benzyl ammonium chlorides (67% C₁₂)

Inert Ingredients

Total Ingredients

Dilute with water

STORAGE &

STORAGE: Store in original container in areas inaccessible to animals. Keep securely closed. Do not contaminate food or feed.

DISPOSAL: Do not reuse empty container. Rinse thoroughly. †Virucidal for Canine Distemper virus, Canine Herpes virus on hard inanimate surfaces.

DANGER: Keep out of reach of children

Corrosive to tissues. Causes eye damage and skin irritation. Wear goggles or face shield and rubber gloves when using. Avoid contamination of food.

FIRST AID: In case of contact, immediately flush eye with water. For eyes, call a physician. Remove and wash contaminated clothing. If swallowed, drink promptly a large quantity of milk, or drink large quantities of water. Avoid alcohol. Call a physician.

NOTE TO PHYSICIAN: Probable mucosal damage and respiratory depression, and

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NDC 0009-3561-03

ROCCAL-D

VIRUCIDE† • DISINFECTANT • DETERGENT • DEODORANT

Active Ingredients

Alkyl [†] dimethyl benzyl ammonium chlorides *(67% C ₁₂ , 25% C ₁₄ , 7% C ₁₆ , 1% C ₈ , C ₁₀ , and C ₁₈)	20.00%
Inert Ingredients	80.00%
Total Ingredients	100.00%

Dilute with water as directed

STORAGE AND DISPOSAL

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

Keep securely closed. Do not contaminate food or feed.

DISPOSAL: Do not reuse empty container. Rinse thoroughly with water and detergent. Discard in trash.

†Virucidal for *Canine Distemper virus*, *Canine Herpes virus*, and *Pseudorabies virus* at dilutions recommended for hard inanimate surfaces.

DANGER: Keep out of reach of children.

Corrosive to tissues. Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing.

Wear goggles or face shield and rubber gloves when handling the concentrate. Harmful or fatal if swallowed. Avoid contamination of food.

FIRST AID: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.

For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or, if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

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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DIS
Bactericidal by AOA
 • *Pseudomonas aerugi.*
 • *Staphylococcus aurei.*
 • *Salmonella choleraes*

†Virucidal for:
 • *Canine Distemper viri*
 • *Canine Herpes virus*
 • *Pseudorabies virus*
 at dilutions recommen

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ROCCAL-D

VIRUCIDE†

DISINFECTANT • DETERGENT • DEODORANT

Bactericidal by AOAC Use-Dilution Test for:

- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Salmonella choleraesuis*
- *Salmonella typhimurium*
- *Corynebacterium diphtheriae*

†Virucidal for:

- *Canine Distemper virus*
- *Canine Herpes virus*
- *Pseudorabies virus*

at dilutions recommended for hard inanimate surfaces.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 23 1994

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

1023-66

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