

PM-14

Reg # 3282-81

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February 1, 1996

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5-497519

Reckitt & Colman Inc.
225 Summit Ave.
Montvale, NJ 07645-1575

Attention: Ms. Ruth Trager

Subject: d-Con Ready Mixed Generation II
EPA Registration No. 3282-81
Your amended application of November 8, 1995

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following changes and submit one (1) copy to us before your ship product:

- A. In your precautionary statements, we have required, in the past, the following text:

CAUTION

May be harmful or fatal if swallowed.

However, the second precautionary statement would appear to be inconsistent with the Regulations [40 CFR 156.10(h)] for the following reasons:

1. A product supported by an acute oral toxicity study in Category III requires the signal word, "CAUTION" and the precautionary statement: "May be **harmful** if swallowed."
2. A product supported by an acute oral toxicity study in Category II requires the signal word, "WARNING" and the precautionary statement: "May be **fatal** if swallowed."

According to our files, the acute oral toxicity study supporting this 0.005% Brodifacoum product is in Toxicity Category III. Therefore, in order to make the labeling for this product consistent with the regulations, you should modify the above precautionary statements as follows:

CAUTION

May be **harmful** if swallowed.

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B. Modify the proposed revised labeling that you submitted for this product on November 11, 1995, as indicated below.

1. On the labels for the 12-oz and 3-lb outer containers, organize the heading and subheadings in the "DIRECTIONS FOR USE" in the manner indicated below (and in PR Notice 94-7) and modify this entire section to read as shown below. Note that some of the text in the "USE RESTRICTIONS", "SELECTION OF TREATMENT AREAS", and "APPLICATION DIRECTIONS" sections must be changed.

"DIRECTIONS FOR USE"

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

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooved livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

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USE RESTRICTIONS: This product may be used to control house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II also may be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or signs of rodents have been seen. Remove as much alternative food as possible. Use tamper-resistant bait stations wherever necessary (see "IMPORTANT").

APPLICATION DIRECTIONS:

[The paragraph immediately below applies to the 12-oz box but not to the 3-lb box.]

The amount of bait contained in the trays in this box is unlikely to be sufficient to kill more than 3 to 12 rats. More than one box may be needed to control larger infestations.

To Control Norway and Roof Rats: Place 1-4 bait trays per placement. Space placements at intervals of 15-30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for at least 10 days.

To Control House Mice: Open tray and apply 1/4-1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals in infested areas. Larger placements (up to 2 ounces) may be needed at points of extremely high mouse activity. Maintain a supply of fresh bait for at least 15 days.

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For Rats and Mice: Check bait locations every 2 days for signs of feeding. Replenish bait if more than 1/2 of the original amount has been removed by rodents. Replace contaminated or spoiled bait immediately if rodent activity still is evident. If trays are not fed from for 5 consecutive days, relocate them to other places where rodent activity exists and where placements consistent with the requirements of this label can be made. Collect and dispose of all dead animals and leftover bait properly.

To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed."

Preserve this format and content when labels are printed. Do not include any graphics with these directions.

2. On the front panels of the outer box labels, replace

CAN KILL IN ONE FEEDING

Rats and mice will die within 4 or 5 days

with

Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins.

Make this same substitution on the left side panel of the 12-oz box label and from wherever else it might appear on the labels for all outer packaging used for this product.

3. Delete from the front panels of the outer box labels the claim "flavor attractive to mice and rats". From the data that have been submitted to us and linked to this product (MRID Nos. 413082-01 and 415247-01), it does not appear that this bait is very attractive to CD Strain Norway rats, at least. Data submitted subsequently (MRID No. 416037-01) suggested better

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acceptance by Wistar strain rats, but we were unable at the time that the submission was reviewed to establish a link between the bait used and the 3282-81 product. Consequently, we have not accepted that study for 3282-81, and the rat claims for this product technically are not supported (see our letter of October 30, 1990). Until this matter is resolved, claims to the effect that the 3282-81 product is especially attractive to target rodents are not acceptable.

- 4. Delete from the back panel of the 12-oz box label (and from wherever it might appear on the 3-lb box) the sentence

d-CON Pellets Generation II can kill in one feeding when used as directed.

- 5. As written, the claim, on the box labels, which reads

"SOLVING AMERICA'S RODENT PROBLEMS FOR OVER 40 YEARS"

is false and misleading. This product has not been registered for 40 years. What seems to be true is that d-CON baits have been used to control commensal rodents for more than 40 years. Therefore, an acceptable claim would be

"d-CON BAIT: KILLING RATS AND MICE IN AMERICA FOR MORE THAN 40 YEARS".

- 6. Either delete the single-feeding claim from the front panel of the label for individual bait trays or modify the claim to read

"Rats and mice may consume a lethal dose in one feeding with first dead rodents appearing 4 or 5 days after feeding begins."

As these trays are not to be sold individually, we question the need for this claim on the label for the bait trays.

- 7. On the back panel of the label for the bait tray, replace

See outer box for complete Directions for Use.

with the text shown at the beginning of the next page.

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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. Read the entire label on the outer package before using this product. It is illegal to sell these bait trays individually.

Note that bait trays sold individually would be misbranded because they would lack complete "DIRECTIONS FOR USE" and "STORAGE AND DISPOSAL" text. As the 3-oz contents are below the minimum requirement for a single placement of "loose" anticoagulant bait used to control commensal rats, an individually-sold container of that amount could not bear claims for controlling Norway rats or roof rats.

When setting up labels for printing, make sure that logos and other not-required items do not obscure or detract from required label statements.

- C. In accordance with PR Notice 93-8, change the last sentence in your "Environmental Hazards" section from "Keep out of any body of water." to "Do not apply directly to water."
- D. Revise your "STORAGE AND DISPOSAL" statement as follows:

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Securely wrap container and any unused bait in newspaper and discard in trash.

If these 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.

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

Sincerely yours,



Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

Enclosures: 1. Stamped Label
2. A-79 Enclosure

Peacock WP#8:A:Brodifac\3282-81:305-5407,-6600:2/1/96

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d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
FRONT LABEL

(GOOD HOUSEKEEPING SEAL)

d-CON®
READY MIXED GENERATION II

ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 11 1981

KILLS MICE AND RATS

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
Registration No. 3282-81

flavor attractive to mice and rats

CAN KILL IN ONE FEEDING
Mice and rats will die within 4 or 5 days

Keep out of reach of children.

CAUTION: May be harmful or fatal if swallowed.

Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....	0.005%
INERT INGREDIENTS.....	99.995%
	TOTAL 100.000%

4 READY-TO-USE BAITs FILLED TRAYS
NET CONTENTS 4/3.0 OZ. (85g) NET WT. 12 OZ. (340g)

16 READY-TO-USE BAITs FILLED TRAYS
NET WT. 3 LBS.

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d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
BACK LABEL

d-CON® READY MIXED GENERATION II

KILLS MICE AND RATS

d-CON Ready Mixed Generation II can kill in one feeding when used as directed. Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

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

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of House Mice, Norway Rats, and Roof Rats in and around homes, industrial, commercial, agricultural and public buildings. d-CON Ready Mixed Generation II may also be used in and around transport vehicles (ships, trains, aircraft) and related port or terminal buildings. Do not use in sewers. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Place trays in or near points where you have seen mice or rat signs such as droppings, runways, burrows, or gnawing marks. Once areas requiring baiting have been identified, proceed as follows:

d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
BACK LABEL CONTINUED

APPLICATION DIRECTIONS:

1. Place one ready-to-use bait tray in each potential feeding location. Place trays in dark, out-of-the-way locations, where rodents are likely to find them.
For House Mice: Use only one tray per location.
For Norway and Roof Rats: Start with one tray per location. Add trays, up to a maximum of four per location, if you determine that there is high rat activity at the location.
2. For best results, leave trays undisturbed for at least two days after placement. However, if contents have been scattered or mostly consumed sooner, replace trays. Clean up spilled bait. Check bait every two days, replacing trays as needed or until signs of rodent activity cease. Trays not fed from for five consecutive days may be relocated as needed. When there are no longer any signs of rodent activity, dispose of trays properly.

For complete control, continue baiting for at least 15 days. If you are in an area where there is a danger of reinfestation from adjoining property, permanent bait stations should be maintained. Stations should be checked periodically.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait **IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE.** For 24 hour emergency assistance, call your local Poison Control Center. **IF BAIT IS EATEN BY ANIMALS OR PETS:** Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K₁ are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K₁ is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Vitamin K₁ is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K₁ should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

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d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
12 OZ. AND 3 LB. OUTER BOX
BACK LABEL CONTINUED

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

STORAGE AND DISPOSAL:

Store in original container in areas inaccessible to small children and pets. Bait that cannot be used according to label instructions must be disposed of according to applicable federal, state or local procedures.

MADE IN THE USA

SOLVING AMERICA'S RODENT PROBLEMS FOR OVER 40 YEARS

SATISFACTION GUARANTEED OR YOUR MONEY BACK

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assumes the risk of any such use.

SELLER DISCLAIMS ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

Distributed by: Household Products Division
Reckitt & Colman Inc. Montvale, NJ 07645

EPA Reg. No. 3282-81
EPA Est. No. 3282-OH-1; 475-MS-1; 2393-WI-1

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d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
3 OZ. BAIT TRAY
FRONT PANEL

d-CON®
READY MIXED GENERATION II

KILLS MICE AND RATS

READY-TO-USE BAIT TRAY

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

CAN KILL IN ONE FEEDING

Mice and rats will die within 4 or 5 days

Keep out of reach of children.

CAUTION: May be harmful or fatal if swallowed.
Read additional precautionary statements on back panel.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....	0.005%
INERT INGREDIENTS.....	99.995%
	TOTAL 100.000%

NET WT. 3 OZ. BAIT TRAY (85g)

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d-CON® READY MIXED GENERATION II
EPA REG. NO. 3282-81
3 OZ. BAIT TRAY
BACK PANEL

Kills Warfarin-Resistant House Mice and Warfarin-Resistant Norway Rats.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Place bait in areas not accessible to children, pets, domestic animals or wildlife or in tamper-resistant bait boxes.

KEEP OUT OF REACH OF CHILDREN.

CAUTION: May be harmful or fatal if swallowed. Keep away from humans, domestic animals, and pets. Wash hands after handling bait **IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE.** For 24 hour emergency assistance, call your local Poison Control Center. **IF BAIT IS EATEN BY ANIMALS OR PETS:** Call your local veterinarian.

NOTE TO PHYSICIAN AND VETERINARIAN: This product may reduce the clotting ability of the blood and cause hemorrhaging. The anticoagulant action of this product may produce prolonged prothrombin times for 20 to 30 days after exposure. If poisoning occurs, intramuscular and oral administration of Vitamin K₁ are indicated, as in poisoning from overdose of dicumarol (bishydroxy coumarin). **FOR HUMAN CASES:** Vitamin K₁ is antidotal at doses of 10 to 20 mg (not mg/kg). Repeated treatments may need to be given for up to 30 days (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary. **FOR ANIMAL CASES:** Vitamin K₁ is antidotal at 5 mg/kg intramuscularly. Oral Vitamin K₁ should be given for up to 30 days at 5 mg/kg (based on monitoring of prothrombin times). In severe cases blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

ACTIVE INGREDIENT: Brodifacoum 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one.....	0.005%
INERT INGREDIENTS	<u>99.995%</u>

See outer box for complete Directions For Use.

Household Products Division
Reckitt & Colman Inc. Montvale, NJ 07645

EPA Reg. No. 3282-81
EPA Est. No. 3282-OH-1; 475-MS-1; 2392-WI-1