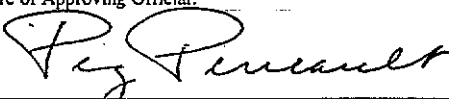
	U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) 401 "M" St., S.W. Washington, D.C. 20460	EPA Reg. Number: 12455-94	Date of Issuance: May 14, 1998
		Term of Issuance: Conditional	
		Name of Pesticide Product: FINAL® RODENTICIDE PLACE PAC	
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under FIFRA, as amended)			
Name and Address of Registrant (include ZIP Code): Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704 Attn: Christine E. Benter			
<p>S 531996 165/18 S 533726 166/18 S 536968 166/18 S 536969 166/13 S 536597 166/13</p>			
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.			
On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.			
Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.			
This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:			
I. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. Please note that the Reregistration Eligibility Decision (RED) for Brodifacoum will be issued shortly and you should receive a copy of the RED and the generic and product-specific Data Call-Ins (DCIs). Your technical product and all registered end-use products are subject to the requirements of the Brodifacoum RED and DCIs and you must submit acceptable responses within the timeframe(s) provided in the RED. If you do not receive copies of the RED and both DCIs, please contact Dennis Deziel (SRRD/Reregistration Branch I) at (703) 308-8173.			
continued on p.2			
Signature of Approving Official: 		Date: 5/14/98	

II. Comply with the conclusions and decisions of our review of all of your applications to date pertaining to EPA File Symbol 12455-OU. You have submitted the following applications pertaining to the registration of EPA File Symbol 12455-OU, Final ® Rodenticide Place Pac (50-g placepacks):

- A. Initial application for registration dated August 29, 1997, which included proposed labeling (first set of labels for this product), a Confidential Statement of Formula (CSF), and supporting administrative materials;
- B. Application for amended registration dated November 11, 1997, which included proposed revised labeling (second set of labels for this product) based on our comments dated October 16, 1997 regarding your proposed labeling for EPA Reg. No. 12455-91 (25-g placepacks);
- C. Application for amended registration dated December 5, 1997, which included proposed revised labeling (third set of labels for this product) and requested that the efficacy claim "Kills Warfarin Resistant Norway Rats" be changed to "Kills Warfarin Resistant Norway Rats and House Mice";
- D. Application for amended registration dated January 8, 1998 and a followup to the same application dated February 4, 1998, which included more proposed revised labeling (fourth set of labels for this product) and requested that the single-feeding efficacy claim be changed to include house mice as well as Norway rats (a mouse placepack penetration study, MRID 444522-01, originally submitted for EPA Reg. No. 12455-91 was cited to support the addition of mice to the single-feeding claim for this product).

The conclusions of our review of these applications are discussed below.

- 1. Your CSF for this product, dated August 29, 1997 is conditionally acceptable from the standpoint of efficacy. Your proposed lower certified limit for Brodifacoum, 0.005%, is equal to the nominal concentration, please check the proposed lower certified limit. With respect to efficacy, it is acceptable for the lower certified limit to match the nominal (which was once our

general policy) or for the lower certified limit to be as low as 0.0045% (N - 10%N; 40 CFR 158.175).

2. With respect to the efficacy data you cited to support label claims for this product we have the following comments:
 - a. As with your similarly formulated 25-g placepack product (12455-91), we have concluded that the basic claims for controlling commensal rodents which you have proposed on the labeling for this product dated December 5, 1997 can be accepted conditionally based upon the efficacy data accepted for your similarly formulated loose-bait product (12455-90), your placepack-penetration study for rats (MRID# 442729-01), your prior representation that the placepack material used for 12455-91 is identical to that used for your registered Bromadiolone placepack products, and an assumption that the same placepack material used for those products would be used for 12455-OU. Please indicate if this assumption is correct.
 - b. With respect to your application for amended registration dated December 5, 1997, from the standpoint of efficacy we have no objection to the proposed expansion of the efficacy claim "Kills Warfarin Resistant Norway Rats" to "Kills Warfarin Resistant Norway Rats and House Mice". The proposed revised labels for the outer container and the individual 50-g placepacks submitted on December 5, 1997 are acceptable from the standpoint of efficacy.
 - c. We have examined the report of the mouse placepack-penetration study (MRID# 444522-01) submitted on December 19, 1997, to support claims proposed for your 25-g placepack product, 12455-91. You have referred to this study as being relevant to your 50-g Brodifacoum placepack product. However, we cannot complete evaluation of the study until we receive the following information:
 - i. documentation of the amount of bait in the placepack used in this test and the material from which the placepack is made;

- ii. documentation of the amount of challenge diet supplied in each cage on the day when the placepacks also were offered; and
 - iii. a full description of the procedures used to present challenge diet written by the individual who performed the procedures. Among other things, this account must describe (with dimensions) the containers used to dispense challenge diet, and indicate the number of such containers used and where they were deployed in the test and control enclosures. The account also must describe the procedures used to mix challenge diet, to store it, and to prepare it for use in rodent efficacy tests.
- d. Until this information is received and reviewed, we will withhold final decisions on the placepack-penetration study and the proposed expansion of the modified single-feeding claim, as it appears on the proposed labels submitted on January 8, 1998, and February 4, 1998. Please note that, when the above information is submitted, the "**APPLICATION DIRECTIONS**" for controlling "**HOUSE MICE:**" on the January 8 and February 4, 1998 labeling must be modified in the same manner as is indicated under item 3. below for the proposed labels submitted on December 5, 1997.
- e. The word "**FINAL**" may be used in the name of this product only if it is clearly indicated to be a brand name. Although the surest way to accomplish this qualification would be to add the word "**BRAND**" after "**FINAL**", you may use the registered trademark symbol "®" after "**FINAL**" provided
- i. that the symbol "®" appears after "**FINAL**" each time that it is used on the label; and
 - ii. that, in all instances of its use, the symbol "®" is clearly legible and at least one third as high as the text used for the word "**FINAL**".
- f. The labeling dated December 5, 1997, which we have stamped "ACCEPTED with COMMENTS" is only

acceptable for packaging arrangements of at least 8 placepacks. The 50-g placepacks may not be sold individually unless all claims and directions pertaining to the control of commensal rats are deleted from the label. Rat claims may appear on labeling for packaging arrangements of 2 to 8 placepacks, provided that an appropriate qualifying statement is added to the outer container's label to the effect that the amount of bait provided could not be expected to kill more than a specified limited number of rats. Qualifying statements for any packaging arrangements which need them must be proposed as amendments and accepted by EPA before such packaging arrangements may be used.

No packaging arrangements which pertain to individual or multiples of placepacks of any size other than 50-g may be used for this product at this time.

- g. Specific labeling changes that must be made are indicated under 3. below.
3. Before you release your product for shipment, the proposed labeling submitted on **December 5, 1997** for the 50-g size placepack must be modified as indicated below. **Unless otherwise specified, these changes must be made both to the label for the individual placepack and to the label for the outer container.**
- a. Revise the EPA Registration Number to read, "EPA Reg. No. 12455-94."
 - b. The "**HOUSE MICE:**" paragraph of the "**APPLICATION DIRECTIONS**" subsection of the "**DIRECTIONS FOR USE**" must be changed to read as indicated below.

HOUSE MICE: Open pack and apply 1/4 to 1/2 ounce of bait per placement. Space placements at 8- to 12-foot intervals. Larger placements, up to one unopened pack, may be needed at points of extremely high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days or until there no longer are fresh signs of mouse activity.

- c. With respect to the **"STORAGE AND DISPOSAL"** statement on your proposed labeling, the proposed statement is adequate for commercial use of this product. However, if you intend to sell this product for household use as well as commercial use, the **"STORAGE AND DISPOSAL"** statement on the **outer carton label only** must be modified to include directions for both household use and commercial use as follows:

"PESTICIDE DISPOSAL: Household use - Securely wrap original container and any unused bait in several layers of newspaper and discard in trash.
Commercial use - Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

CONTAINER DISPOSAL: Household use - Do not reuse empty container. Discard container in trash.
Commercial use - Completely empty container. Then dispose of empty container in sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

- III. Submit two copies of your revised final printed labeling before you release the product for shipment.

If the above specified 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.

Stamped copies of the labeling submitted with your application dated December 5, 1997 are enclosed for your records. Please note that, of the four sets of proposed labeling you submitted, the proposed revised labeling dated December 5, 1997 is the only labeling that is considered acceptable at this time. Further consideration will be given to your application dated January 8 and February 4, 1998 upon submission of the additional information requested above and additional proposed labeling, revised as indicated above. We remind you that, in order for us to review and process this information and labeling as efficiently as possible, you should resubmit only ONE application for amended registration that covers all of the points discussed above and five (5) copies each of your revised labeling for the

outer containers and the individual 50-g placepacks. If you have any questions about this letter, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,



Peg Perreault
Chemical Manager, Team 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

) Enclosures (2)

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 to 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, or 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 Norway rats, roof rats and house mice in and around homes, industrial, commercial, agricultural and public buildings, and similar manmade structures. FINAL® Place Pacs may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. This product may also be used in alleys. 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 their signs have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

See right side panel for additional DIRECTIONS FOR USE

Final®

RODENTICIDE

PLACE PAC

KILLS RATS AND MICE

*Kills Warfarin Resistant Norway Rats and House Mice
Norway rats may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.*

ACTIVE INGREDIENTS: 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%

*Contains Denatonium Benzoate TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

If on Skin: Wash with plenty of soap and water. Get medical attention if symptoms persist.

If in Eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

NOTE TO PHYSICIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K, intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

For specialized medical advice, call Bell Laboratories at 1-800-323-6628 or call the National Pesticide Telecommunications Network at 1-800-858-7378.

(SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.)

NET WEIGHT: 100 x 50 g

Mfg. by:



Bell Laboratories, Inc.
Madison, WI 53704 U.S.A.

EPA REG. NO. 12455-

EPA EST. NO. 12455-WI-1

DIRECTIONS FOR USE (Continued from left side panel.)

APPLICATION DIRECTIONS:

RATS: Apply 2 to 8 pacs (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until there no longer are signs of fresh rat activity.
HOUSE MICE: Apply 1 pac per placement. Space placements at 8- to 12-foot intervals. Maintain an uninterrupted supply of fresh bait for at least 15 days or until there no longer are signs of fresh mouse activity.

RATS/MICE: Replace contaminated or spoiled bait immediately. 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 as needed.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling bait.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds, and wildlife. This product can pose a secondary hazard to birds of prey and mammals. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

STORAGE AND DISPOSAL

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

STORAGE: Store only in original container, in a dry area inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty container. Then dispose of empty container in sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

with COMMENTS

In EPA Letter Dated:

© FINAL is a registered trademark of Bell Laboratories, Inc.

May 14, 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
12455-94

8069

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these are along walls, by framed openings, in or beside bunnies, raccoons and concealed places between floors and walls, or in locations where rodents or their signs have been seen. Place bait stations in areas of snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS: RATS: Apply 2 to 8 baits (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until there are no signs of fresh rat activity.

HOUSE MICE: Apply 1 bait per placement. Space placements at 8 to 12-foot intervals. Maintain an uninterrupted supply of fresh bait for at least 15 days or until there are no signs of fresh mouse activity.

PREVENT REINFESTATION: Repoint contaminated or spoiled bait immediately. Collect and dispose of all dead animals and leftover bait properly. To prevent reinfestation, find 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 as needed.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry area inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. Securely wrap original container in several layers of newspaper and discard in trash.



PLACE PAC KILLS RATS AND MICE

Kills Warfarin Resistant Norway Rats and House Mice

Norway rats may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.

ACTIVE INGREDIENT: Diphacoum 3-(p-(4'-bromo-1,1'-biphenyl)-4-yl)-1,2,3,4-tetrahydro-1-naphthol 0.005%
INERT INGREDIENTS 99.995%
TOTAL 100.000%
*Contains Dantrolene (Dantrolene)

KEEP OUT OF REACH OF CHILDREN CAUTION

NOTE TO PHYSICIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K, intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times. For specialized medical advice, call Bell Laboratories at 1-800-323-6628 or call the National Pesticide Telecommunications Network at 1-800-858-7378. FOR SPECIFIC STATEMENTS OF PRACTICAL TREATMENT, REFER TO THE OUTER CONTAINER LABEL FOR THIS PRODUCT.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May be harmful or fatal if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling bait.

ENVIRONMENTAL HAZARDS: This product is toxic to fish, birds, and wildlife. This product can pose a secondary hazard to birds of prey and mammals. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

Net Contents 1.76 oz. (50 grams)

Mfg. by:



Bell Laboratories, Inc.
Maddison, WI 53704 U.S.A.

EPA REG. NO. 12455-
EPA EST. NO. 12455-WI-1

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 to 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 household livestock, raccoons, bears, or other potentially destructive animals or 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 Norway rats, roof rats and house mice in and around homes, industrial, commercial, agricultural and public buildings, and similar structures. FINAL* Place Pac may also be used in transport vehicles (buses, trains, aircraft) and in and around related port or terminal buildings. This product may also be used in sewers. Do not use in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

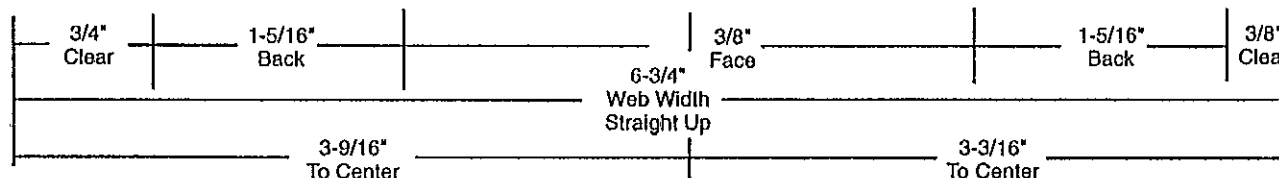
5.027"
Cut Off
3 Around
15.080"
Cylinder
Straight Up

ACCEPTED
with COMMENTS
In EPA Letter Dated:

May 14, 1998

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

12455-94



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