

PM14

12455-15

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Ms. Cisse Spragins
Bell Laboratories, Inc.
3699 Kinsman Boulevard
Madison, WI 53704

Dear Ms. Spragins:

NOV 21 1991

Subject: Final Rat and Mouse Bait
EPA Registration No. 12455-15
Your Submissions Dated July 19 and July 23, 1991

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable, subject to the following:

1. With the information supplied by your company and by Crompton & Knowles Corporation on your behalf, the Confidential Statement of Formula dated July 18, 1991, is acceptable. The Agency has not yet made a decision on whether Malathion must be listed as an active ingredient, even though its presence is only to deter insects from eating the grain bait.
2. The information supplied with your letter of July 19, 1991, permitted us to complete the assessment of the efficacy studies submitted on November 29, 1990. These data are acceptable. The rat study has been assigned the MRID number 417136-01. Cite these numbers in your 8-month data submission for reregistration of this product.
3. 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.
4. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

The proposed revised labeling is basically consistent with that indicated in the Reregistration Eligibility Document (RED) for Warfarin. Because the "DIRECTIONS FOR

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

USE" section appears on the left and right side panels, it would be possible for individuals to focus on the subsections "SELECTION OF TREATMENT AREAS" and "APPLICATION DIRECTIONS" and to miss the paragraphs on safe use and "USE RESTRICTIONS" entirely. It would also be possible for some readers to "get lost" at the bottom of the left panel. To lessen the chances of such problems, add

"See right side panel for additional DIRECTIONS FOR USE."

at the bottom of the left side panel and insert the heading

"DIRECTIONS FOR USE (continued from left side panel)"

at the top of the right side panel.

The break in the "DIRECTIONS FOR USE" should not come in the middle of a paragraph. As the text block on the left side panel is nearly 1/2 inch narrower than that on the right side panel, it should be possible to complete the "USE RESTRICTIONS" paragraph on the left side panel.

Because this label is for a 25-lb. container, it should be possible to make the label large enough to allow you to "break-out" in a vertical listing the steps to be followed for safe storage and use of the product rather than to partially conceal this important information by running the text together in a closed paragraph. In the history of use of Warfarin products in the U.S., there have been many thousands of accidental nontarget exposure incidents involving this chemical, including some deaths. Nearly all of these incidents probably could have been prevented by proper protection of bait in use or storage. Users often poisoned their own or their client's children, pets, or livestock due to failure to heed language already on labels. The new label text is intended to increase awareness of the hazards associated with using rodenticide baits and simple steps that can be taken to mitigate potential problems. If these statements are buried on products' labels, compliance with the text might be no better than that with the "tamper-proof bait box" statement that the new statements are replacing.

5. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

10/11

JACKET COPY

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K, intramuscularly or orally, as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply this product to water, swamps, bogs, or potholes.

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 buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of

contaminating food or su with food. Do not broad

SELECTION OF TREAT where rats or mice will bait. Generally, these a ings, in or beside burr places, between floors rodents or their signs hav or snow. Remove as mu

APPLICAT

RATS: Apply 4 to 16 oz. uninterrupted supply of fre
MICE: Apply 1/4 to 1/2 oz. to 12-foot intervals. Large needed at points of very uninterrupted supply of fre
RATS/MICE: Replace co ately. Collect and dispose properly. To prevent reinfe water, and harborage as does occur, repeat treatm infestation is present, est replenish as needed.

STORAG

Do not contaminate water, **STORAGE:** Store only in inaccessible to children and **PESTICIDE DISPOSAL:** disposal of excess pestic violation of Federal Law. If by use according to label Pesticide or Environmental Waste representative at th guidance.

CONTAINER DISPOSAL pose of empty pail in a sar allowed by State and loca

lay out of smoke.

Final[®]

Rat and Mouse Bait

*Kills Norway Rats,
Roof Rats, and House Mice*

ACTIVE INGREDIENT:

Warfarin, [3-(alpha-Acetylbenzyl)-4-hydroxycoumarin].....	0.025%
INERT INGREDIENTS	99.975%
TOTAL 100.000%	

KEEP OUT OF REACH OF CHILDREN CAUTION

(See left panel for additional precautionary statements)

NET CONTENTS: 25 lbs. (11.4 Kg)

EPA EST. NO. 12455-WI-1

EPA REG. NO. 12455-15

Manufactured by



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

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 21 1991

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

12455-15