UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

November 24, 2003

Bell Laboratories Inc. 3699 Kinsman Boulevard Madison, WI 53704

Attention: Mr. Craig A. Riekena

Subject: Quintox® Rat and Mouse Bait

EPA Reg. No. 12455-39

Your amended application of September 19, 2003

Purpose

The purpose of this submission is to revise your label under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to comply with PR Notices 2001-1 and 2001-6 and to make other labeling changes.

Label review

The labeling submitted with the above letter, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the following changes, before you ship your product.

1. Delete "For Organic Production".

To add this claim, your product must meet the criteria in the U.S. Department of Agriculture's (USDA's) National Organic Program (NOP) Rule and follow the procedures in EPA's PR Notice 2003-1. See Enclosure 1 to 3 for details. Note that the NOP Rule requires that the use of your active ingredient, Vitamin D₃, be for organic crop production, a site not on your label.

- 2. Change "Rats/Mice" to "Follow-up".
- 3. In the "STORAGE AND DISPOSAL" section, change "PESTICIDE STORAGE" to "STORAGE".

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

Page 2 of 2

Existing stocks

Stocks of existing labels may be used for eighteen (18) months.

Consequence for non-compliance

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 constitutes acceptance of these conditions.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock,dan@epa.gov (by E-Mail).

Sincerely yours,

DRP

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch Registration Division (7504C)

Enclosures

- 1. Criteria and Procedure to Add "For Organic Production" Claim
- 2. The National List in the Final Rule
- 3. PR Notice 2003-1
- 4. Stamped Label
- 5. Minimum Type Sizes for Final Printed Labels

Letter

Dan Peacock, Disk 130,A:\Vitamin D3\12455-39, revised label, PR 2001-1, 2001-6, 11-18-2003.wpd

QUINTOX®

RAT AND MOUSE BAIT FOR ORGANIC PRODUCTION KILLS RATS AND MICE

KILLS NORWAY RATS, ROOF RATS AND HOUSE MICE

ACTIVE INGREDIENT:

Cholecalciferol (CAS #67-97-0):...... 0.075%

INERT INGREDIENTS: 99.925% ACCEPTED with COMMENTS

TOTAL 100.000% with COMMENTS PA Letter Dated:

KEEP OUT OF REACH OF CHILDREN CAUTION

NOV 2 4 2003

Under the Federal Invecticide.
Fungicide, and Rudentaine Act
as amended, for the account.

FIRST AID

HAVE LABEL WITH YOU WHEN OBTAINING TREATMENT ADVICE IF SWALLOWED:

- •Call a poison control center, doctor, or 1-877-854-2494 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 the poison control center or doctor.
- Avoid use of all oils.

IF ON SKIN:

•Wash with plenty of soap and water.

NOTE TO PHYSICIAN OR VETERINARIAN

If serum calcium levels are elevated, treatment with Calcitonin is effective in reducing calcium to normal levels. Continue monitoring serum calcium and treat as necessary for hypercalcemia (Reference, AMA Drug Evaluations, Third Edition (1977), Chapter 16, pp. 248-251).

NET WEIGHT: 5.5 lbs. (2.5kg)

Manufactured by:

Bell Laboratories, Inc. Madison, WI 53704

EPA REG. NO. 12455-39 EPA EST. NO. 12455-WI-1

This Section For Product Label Identification Purposes Only: Quintox Rat and Mouse Bait, EPA Reg. No. 12455-39, Container Label, 091703 Page 1 of 3

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 nontarget animals to rodenticides. To help to prevent accidents:

- 1. Store unused product 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 bait stations when they are lifted, units must be secured or otherwise immobilized. 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, or unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of Norway rats, roof rats and house mice in and around homes, industrial and agricultural buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. When used in USDA-inspected facilities, this product must be applied in tamper-resistant bait stations. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats or mice will most likely find and consume the bait. Generally, these areas 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 and snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

RATS: Apply 2 to 8 oz. of bait (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days.

MICE: Apply 1/4 to 1/2 oz. (1 to 2 level tablespoons) of bait at 8 to 12 foet intervals. Larger placements (up to 1 oz.) may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days.

RATS AND MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all dead, exposed animals and leftover bait. 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 HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Do not apply this product 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.

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PESTICIDE STORAGE: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. **PESTICIDE DISPOSAL**: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

CONTAINER DISPOSAL: Do not reuse empty container. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Call your local waste agency for any questions on proper disposal.

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

091703