

7173-238

8/10/2005

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 10, 2005

LiphaTech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Attention: Mr. Thomas J. Schmit

Subject **Generation Meal**
 EPA Reg. No. 7173-238
 Your amended application of February 25, 2005

Purpose This submission, under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), submits 1) chemistry data on storage stability/corrosion characteristics to complete the initial registration requirements and 2) effectiveness data to add a sewer/burrow claim.

Chemistry Data We reviewed the storage stability/corrosion characteristics data and found them to be acceptable.

Effectiveness Data Rat Efficacy Test (MRID No. 464858-01)

This test with weathered bait was acceptable. We note that there was one extreme marginal feeder. In addition, several subjects survived for 10-17 days, suggesting that weathering the bait diminished its palatability and /or its potency slightly. The bait batch used in this bioassay seems to have retained its original level of active ingredient.

Mouse Efficacy Test (MRID No. 464858-02)

This test with weathered bait was acceptable. We note that the test batch seems to have lost some potency after weathering, but mice surviving after 5 days accepted it well relative to the challenge diet.

Label 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.

776357 R34
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775316 R34
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Label-continued

- 1. Revise the "USE RESTRICTIONS" as follows to insure that sites are clearly identified:

USE RESTRICTIONS: This product may be used to control Norway rats, roof rats, and house mice at the **Urban** and **Non-urban** sites identified below. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come into contact with food. Do not broadcast bait.

Urban Areas: This product may be used indoors only in transport vehicles (ships, trains, aircraft) and in related port or terminal buildings; in permitted areas of food processing facilities; and in homes, industrial, commercial, and public buildings, and similar man-made structures. Outdoors, this product may only be used within 15 feet of the types of buildings where indoor use is permitted. All outdoor bait placements must be made in tamper-resistant bait station, locked and secured as necessary, except for treatments of rat burrows performed and monitored as direct under "APPLICATION DIRECTIONS."

Non-urban Areas: This product may only be used inside of homes and agricultural buildings.

- 2. Revise the "For rat burrows:" section as follows:

For rat burrows: Only burrow openings within 15 feet of the specified types of buildings located in **Urban Areas** may be treated with this product. Using a long-handled spoon or scoop, insert 1 to 2 ounces of bait deep into each active burrow. Check treated burrows each morning and evening to make sure that bait has not been pushed out of burrows. Remove and properly dispose of any bait that has become accessible to children or nontarget animals.

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

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.

Existing stocks

You have 18 months to use stocks of product with existing labeling.

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,



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

Enclosure

Stamped label

Location

Dan Peacock, USB Flash Drive 1.1, F:\1-7-2005 Backup\Dan's Office Work\A Flash Drive 1\Difethialone\7173-238, revise label, 8-2-2005.wpd

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals

CAUTION: Keep away from children, domestic animals and pets. May be harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Do not get in eyes, on skin or on clothing. Wash arms, hands and face with soap and water after applying and before eating and smoking.

FIRST AID
Have this label with you when obtaining treatment advice. If swallowed: Call a poison control center or doctor 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. Do not give anything by mouth to an unconscious person. Note to Physician or Veterinarian: Contains difethialone, an anticoagulant. For humans or dogs that have ingested this product, or have obvious poisoning symptoms (bleeding) or lowered prothrombin times, give Vitamin K₁ by intramuscular or oral administration. Check prothrombin time every 3 days until values return to normal.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. 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 in original container in a cool, dry place inaccessible to children and pets. Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Dispose of empty container in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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.

Product No. Label No.



MEAL

**KILLS NORWAY RATS,
ROOF RATS, HOUSE MICE AND
WARFARIN-RESISTANT HOUSE MICE**

**NORWAY RATS AND HOUSE MICE CAN CONSUME A
LETHAL DOSE IN ONE NIGHT'S FEEDING
WITH FIRST DEAD RODENTS APPEARING
FOUR OR FIVE DAYS AFTER FEEDING BEGINS**

Active Ingredient: difethialone*	0.0025%
Inert Ingredients	99.9975%
Total	100.0000%

*Patented in the U.S.A.
EPA Reg. No. 7173-238 EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN
CAUTION: See side panel for additional precautionary statements.

LIPHA TECH 3600 W. Elm Street
Milwaukee, WI 53209
(800) 351-1476

NET WEIGHT: 1 pound up to 50 pounds
ACCEPTED with COMMENTS
EPA Letter Dated: **AUG 10 2005**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
7173-238**

Alternate "Storage and Disposal" statement for packaging intended solely for household use:

STORAGE AND DISPOSAL
Storage: Store in original container in a dry place inaccessible to children and pets.
Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Alternate warranty statements:
Satisfaction guaranteed or your money back.

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

READ THIS 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 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, unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used to control Norway rats, roof rats and house mice. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

Urban Areas: May be used indoors and in transport vehicles (ships, trains, aircraft). May be used outdoors within 15 feet of homes, food processing facilities, industrial, commercial, agricultural and public buildings, and similar manmade structures.

Non-urban Areas: This product may only be used inside of homes and agricultural buildings.

Selection of Treatment Areas: Determine areas where rats or mice will most likely find and consume bait. Generally, these are along walls, by gnawed openings, in corners and concealed places, between floors or walls, in burrows, or in locations where rodents or their signs have been seen. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:
Mice: Apply 1/4 to 1/2 ounce of bait per placement. Larger amounts (up to 2 ounces) may be placed at points of very high mouse activity. Space placements 8 to 12 feet apart. Maintain a constant supply of fresh bait for 15 days or until signs of mouse activity cease.
Rats: Apply 3 to 16 ounces of bait per placement. Space placements 15 to 30 feet apart. Maintain a constant supply of fresh bait for 10 days or until signs of rat activity cease.
For rat burrows: Insert 1 to 2 ounces of bait deep into each active burrow, using a long-handled spoon or scoop. Check treated burrows each morning and evening to make sure that bait has not been pushed out of burrows.
Follow-up: Replace contaminated or spoiled bait immediately. Collect and dispose of all visible dead animals and leftover bait properly. To discourage reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation occurs, repeat treatment. For a continuous infestation, set up permanent bait stations and replenish bait as needed.
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