

7173-215

06-04-2004

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 4, 2004

Mr. Thomas Schmit
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Dear Mr. Schmit:

**Subject: Application for amendment and revised labeling for Maki Mini Blocks
(Bromadiolone)
EPA Reg. No. 7173-215
Your Submission Dated October 13, 2003**

The Agency has reviewed your application for amendment dated October 13, 2003 and your revised label submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act.

- Your request to change the name of your product from "Maki Mini Blocks with Bitrex" to "Maki Mini Blocks" is acceptable.
- Your request to allow the sale of packages containing 4, 5, 6, 8, 10 or 12 individual mini blocks or "bulk" packages ranging in size from 1 pound up to 50 pounds is acceptable. Please note that all packages containing greater than 1 pound of product require additional precautionary statements labeling language noted in the Agency's comments below.
- The labeling referred to above, as amended, is acceptable provided you make the following changes before you release the product for shipment bearing the amended labeling:

DIRECTIONS FOR USE

1. Under **Directions for Use**, after the violation of Federal law statement, add the following two statements as per the RED for Rodenticides:
 - "Do not apply this product by any method not specified on this label."
2. Under **Directions for Use** in the "Use Restrictions" section:
 - In the second sentence, add "human or pet" before the last word "food."

- Add, "Do not place near or inside ventilation duct openings."
 - Modify the urban areas use restriction as follows: "This product may be used indoors. May only be used outdoors within 15 feet of homes, industrial, commercial, and public buildings." Change the phrase "in and around related port or terminal buildings" to "inside or within 15 feet of related port or terminal buildings."
3. Under **Directions for Use**, in the Application Directions section:
- In the second sentence in both the "Rats:" and "Mice:" sections, at the end of the sentences starting with "Space placements..." add "no further than 15 feet from the structures."
4. Under **Directions for Use** in the Application Directions section:
- In the second sentence of the "Follow-up" section, insert "Wear gloves to" prior to "collect and properly dispose of all dead animals..."

PRECAUTIONARY STATEMENTS

5. Under **Precautionary Statements**, after the signal word and statement "Keep away from humans, domestic animals and pets": replace the text starting with "May be harmful..." and ending with "...eating and smoking." with the following:
- ***For products less than or equal to one pound:***
 "Harmful if swallowed or absorbed through the skin because the material may reduce the clotting ability of blood and cause bleeding. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. If bait is handled, wear waterproof gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
 - ***For products greater than one pound:***
 "Harmful if swallowed or absorbed through the skin because the material may reduce the clotting ability of blood and cause bleeding. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear shirt and long pants, shoes and socks and chemical-resistant (such as waterproof) gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." (See No. 6 below for additional text required for products greater

than one pound.)

- 6. Under **Precautionary Statements**, for products greater than one pound, add a "User Safety Requirements" heading and section following the "Hazards to Humans and Domestic Animals" section with the following text: "Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."
- 7. Under **Precautionary Statements**, in the "First Aid" section, after the current "If Swallowed" statement, add the following: "Have person sip a glass of water if able to swallow" and "Do not induce vomiting unless told to do so by the poison control center or doctor." Or since the product is toxicity category IV for the acute oral route of exposure, you may delete the "If Swallowed" statement completely.
- 8. Under **Precautionary Statements**, in the "First Aid" section, it is recommended that separate "Note to Physician" and "Note to Veterinarian" text be placed on the labels.

- The "Note to Physician" section should read:

"This product may reduce the clotting ability of the blood and cause hemorrhaging. If poisoning symptoms occur, intramuscular and oral administration of Vitamin K1 may be needed. For human cases, Vitamin K1 is antidotal at 5-10 mg (not mg/kg) for children and 10-20 mg for adults. Repeated doses may be needed (based on monitoring of prothrombin times)."

- The "Note to Veterinarian" section must be revised as specified below and placed within a box:

"TREATMENT FOR PET POISONINGS

If pet or animal eats bait, call a veterinarian or Hotline Number (1-800-301-7976) at once.

NOTE TO VETERINARIAN

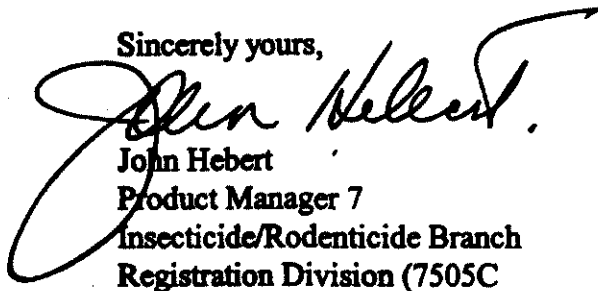
This product contains bromadiolone, an anticoagulant. For animals ingesting (or suspected of ingesting) bait, and/or having obvious poisoning symptoms, such as bleeding or lowered prothrombin times, give Vitamin K1 at 2-5 mg/kg. Repeated doses may be needed for up to 30 days (based on monitoring of prothrombin times). It may be necessary to check prothrombin times every 3 days until values return to normal. In severe cases, blood transfusions may be necessary.

- 9. Under **Precautionary Statements**, in the "Environmental Hazards" section:

- Add the sentence: "Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait."

Please note that product reregistration is currently pending and future labeling amendments may be required. Submit two copies of your final printed labeling before you release the product for shipment. A stamped copy is enclosed for your records. If you have any questions, please contact Ann Hanger at (703) 306-0395 or hanger.ann@epa.gov.

Sincerely yours,



John Hebert
Product Manager 7
Insecticide/Rodenticide Branch
Registration Division (7505C)

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Keep away from children, domestic animals and pets. May be harmful or fatal 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. If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. If on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Note to Physician or Veterinarian: If ingested, administer Vitamin K₁ intramuscularly or orally as indicated in bishydroxycoumarin overdose. Repeat as necessary based on monitoring of prothrombin time.

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 the material when such use and/or handling is contrary to label instructions.

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

STORAGE AND DISPOSAL:

Storage: Store in original container in a cool, 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.

MAKI

MINI BLOCKS

**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: bromadiolone	0.005%
Inert ingredients	99.995%
Total	100.000%
EPA Reg. No. 7173-215	EPA Est. No. 7173-WI-1

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See side panel for additional precautionary statements.

**LIPHA
TECH**

Manufactured by
LiphaTech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(800) 361-1476

Net Weight:

- 4 ounces (4 x 1 ounce blocks)
- 5 ounces (5 x 1 ounce blocks)
- 6 ounces (6 x 1 ounce blocks)
- 8 ounces (8 x 1 ounce blocks)
- 10 ounces (10 x 1 ounce blocks)
- 12 ounces (12 x 1 ounce blocks)
- or bulk package containing
1 pound up to 50 pounds

Optional marketing statements:

Contains bittering agent

Blox™ is a trademark of MacLellan Smith Ltd., Edinburgh, Scotland



**ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUN 4 2004**

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
7173-215

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 stolen from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooked 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. Do not broadcast bait.

Urban areas: This product may be used in and around homes, industrial, commercial and public buildings; 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.

Non-urban areas: This product may 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 ground openings, in or beside burrows, in corners and concealed places, between floors or walls, or in locations where rodents or their signs have been seen. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

(Qualifier statement only for package containing 4 blocks:)
This package contains enough bait (4 oz.) to bait 1 to 3 rats.

(Qualifier statement only for package containing 5 blocks:)
This package contains enough bait (5 oz.) to bait 1 to 4 rats.

(Qualifier statement only for package containing 6 blocks:)
This package contains enough bait (6 oz.) to bait 2 to 6 rats.

(Qualifier statement only for package containing 8 blocks:)
This package contains enough bait (8 oz.) to bait 2 to 7 rats.

(Qualifier statement only for package containing 10 blocks:)
This package contains enough bait (10 oz.) to bait 3 to 9 rats.

(Qualifier statement only for package containing 12 blocks:)
This package contains enough bait (12 oz.) to bait 3 to 12 rats.

Mice: Apply one block per placement. 2 blocks may be needed at points of high mouse activity. Space placements 8 to 12 feet apart. Two blocks may be needed at points of very high mouse activity. Maintain a constant supply of fresh bait for 10 days or until fresh signs of mouse activity cease.

Rats: Apply 3 to 10 blocks per placement. Space placements 15 to 30 feet apart. Maintain a constant supply of fresh bait for 10 days or until fresh signs of rat activity cease.

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. (2003)

