

7173-242

10-03-2008

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



OFFICE
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

350 S-822950

October 3, 2008

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

Decision 388661

Attention: Ms. Rachel M. Callies

Subject **Chlorophacinone Vole Bait**
 EPA Reg. No. 7173-242
 Major Expansion of Non-Structural (Field) Uses
 Your amended application of January 11, 2008

Purpose This submission proposes to add major new non-structural (field) uses to this product and to the rodenticide, chlorophacinone, under sec 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Review We conducted a Risk Assessment of this expanded use, based on the data that we have in our files and that you submitted or cited in support of this amendment. We have concluded that we can approve your expanded use pattern for this product and the active ingredient, Chlorophacinone, provided you make certain labeling changes to mitigate risks to nontarget organisms. The approved label and comments in this letter reflect those labeling changes.

In your cover letter of January 11, 2008, you addressed several data requirement issues about which we have comments on two issues here.

1. Reproductive/Chronic Toxicity in Birds

The study that you submitted was actually one to address a) the acute dietary LC50 and subchronic toxicity to the Japanese Quail. It did not satisfy the requirement for either acute dietary LC50 or avian reproduction because the study did not follow the guideline requirements for such studies; did not address GLP requirements, and included no raw data.



Review-continued

2. Reproductive/Chronic Toxicity in Mammals (Waiver Request)

We have reviewed this waiver request and will send you a copy of our review as soon as it is available.

Labeling

The labeling submitted with the above letter is acceptable, provided that you submit one (1) copy of final printed labeling to us, with the following changes, before you ship the product.

- ✓ 1. Insert "only" after "For retail sale to and use ..." under the "Restricted Use Pesticide" heading.
- ✓ 2. Bold "If swallowed:", "If in eyes:", "If in eyes:", "If on skin or clothing:" and "Note to Physician or Veterinarian:" as it will make it much easier to find the proper information in case of an incident.
- ✓ 3. Under "ENVIRONMENTAL HAZARDS:", revise the 3rd Sentence to read: "Do not apply within 50 feet of any body of water (such as pond, lake, river or stream) or where raptors are actively feeding on voles."
- 4. Revise your "DIRECTIONS FOR USE" according to Enclosure 1.
- ✓ 5. Revise your "Container Disposal" text as follows:

Container Handling: Nonrefillable Container. Do not reuse or refill this container. Completely empty container into application equipment. Offer for recycling if available or dispose of empty bag 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.

Existing stocks Forms

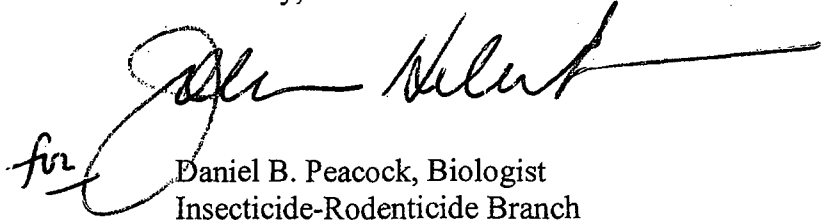
Stocks of product with existing labels may be used for eighteen (18) months.

Consequence for non-compliance

If this condition is 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 (phone); 703-305-6596 (fax); or peacock.dan@epa.gov (E-Mail).

Sincerely,



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

Attachments

1. Directions for Use for 7173-242
2. Stamped Label
2. Minimum Type Size Requirements for Final Printed Labels

File Location Dan Peacock, Flash Drive, J:\4G Dan\Documents\Word, WP, Excel, etc\Chlorophacinone\7173-242\7173-242, 1-11-2008
Amd\Approval\7173-242, exp use patterns, app ltr, 10-2-2008.long ver.doc

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. Causes moderate eye irritation. Do not get in eyes, on skin or on clothing. Wear gloves when handling bait or retrieving dead animals. 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: Contains chlorophacinone, an anticoagulant. For humans or dogs that have ingested this product, or have obvious poisoning symptoms (bleeding) or prolonged prothrombin times, give Vitamin K₁ by intramuscular or oral administration. Check prothrombin time every 3 days until values return to normal.

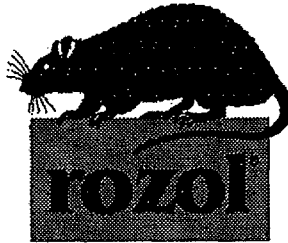
ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply within 50 feet of any body of water (such as pond, lake, river or stream). Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wastes.

ENDANGERED SPECIES CONSIDERATIONS:

NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Before applying this product, applicators must obtain information regarding the occurrence of endangered species and use limitations for this product. You may call EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

**RESTRICTED USE PESTICIDE
DUE TO HAZARD TO NONTARGET
ORGANISMS**

For retail sale to and use by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certificate.



VOLE BAIT

FOR CONTROL OF VOLES (*Microtus* spp.) IN ORCHARDS, NONCROP AREAS, NURSERIES, TREE & FORESTRY PLANTATIONS AND FOR CONTROL OF NORWAY RATS, ROOF RATS & HOUSE MICE IN OUTDOOR NONCROP AREAS

Active Ingredient: chlorophacinone 0.005%
Inert Ingredients 99.995%
Total 100.000%

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

LIPHA TECH Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

**Net Weight: 1 pound per 50 pounds
with COMMENTS
in EPA Letter Dated**

OCT 3 2008

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

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DIRECTIONS FOR USE:

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

VOLE CONTROL: FRUIT TREE ORCHARDS (BEARING AND NONBEARING) FOR PINE, MEADOW OR MOUNTAIN VOLE CONTROL:

USE RESTRICTIONS: For control of pine, meadow or mountain voles in pome fruit (apple, pear) and stone fruit (peach, cherry, apricot, plum, prune, nectarine) tree orchards. Apply after harvest (including drops), before new spring growth, and during which three days of rain-free and snow-free weather are expected. Do not apply within 50 feet of any body of surface water. Do not apply over bare ground or crops not specified above. Do not allow animals to graze or clean up drops in treated areas. Do not use hay cut after application for feed or bedding. Apply only by hand spot baiting and ground broadcasting (do not apply by broadcast in New York and Vermont).

APPLICATION DIRECTIONS: Before application, examine orchard floor to locate trails and runway systems to be treated. **Hand spot baiting:** Place about 1-1/2 ounces of bait in each active hole, trail or runway at each tree site (10 lbs per acre). Cover each placement (using grass, shingle or other material) to avoid exposing nontarget organisms.

Ground broadcast baiting: Using a commercial spreader, uniformly apply 20 lbs per acre for Pine voles (all states except Idaho, Oregon, Washington) and 10 lbs per acre for Meadow voles (all states except Oregon) and Mountain voles (Idaho, Oregon, Washington only). If populations are high, make a second application 1 - 2 months after the first. The maximum application rate is 40 lbs per acre per year for Pine voles, and 20 lbs per acre per year for Meadow and Mountain voles. To avoid exposing nontarget organisms, clean up any bait in piles for reuse or disposal according to the "Pesticide disposal" section of this label.

VOLE CONTROL IN NONCROP AREAS, NURSERIES, TREE AND FORESTRY PLANTATIONS:

USE RESTRICTIONS: For control of pine, meadow and mountain voles in terrestrial areas such as lawns, golf courses, parks and other ornamental turf areas, ornamental flower and shrub gardens, commercial nurseries, tree and forestry plantations, Christmas tree farms and other similar areas. This product must not be applied directly to food or feed crops, but may be applied along fence lines, border areas and buffer strips adjacent to crops. Where necessary, apply in tamper-resistant bait stations to prevent nontarget animals, domestic animals, children or pets from accessing the bait. Do not apply within 50 feet of any body of surface water. Do not allow animals to graze in treated areas. Do not use hay cut after application for feed or bedding.

APPLICATION DIRECTIONS:

Hand spot baiting: Place about 1-1/2 ounces of bait in active holes, trails or runways, or in tamper-resistant bait stations (10 lbs per acre) in areas where voles have been observed or are known to forage. Cover placements with grass or shingle to avoid exposing nontarget organisms.

Broadcast baiting: Using a commercial spreader, uniformly apply 10 lbs per acre. If populations are high, make a second application 1 - 2 months after the first. The maximum application rate is 20 lbs per acre per year. This product may also be applied under tarps placed over turf and garden areas for winter protection. Clean up any spilled bait or bait in piles for reuse or disposal according to label instructions. Do not apply by broadcast in New York and Vermont.

Continued on next page:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. This is a nonrefillable container.

Storage: Store in original container in a cool, dry, place inaccessible to children and pets. Store separately from fertilizer and away from products with strong odors. Collect and properly dispose of any spillage.

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: Do not reuse or refill this container. Completely empty container into application equipment. Offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY: To the extent consistent with applicable law, 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.

EPA Reg. No. 7173-242
EPA Est. No. 7173-WI-1

Alternate warranty statements:

Satisfaction guaranteed or your money back.

COGNISAL RODENT CONTROL:

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

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 hoofed 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 (IN AND AROUND BUILDINGS): This product may be used to control Norway rats, roof rats and house mice. Do not place near or inside ventilation duct openings. Do not contaminate food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment. May be used in and around homes, industrial, commercial, agricultural and public buildings (including loading docks and under granaries). It may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. This product is especially well suited for use in wet or damp areas. Do not apply bait directly to ground surface or in grass or other ground cover. Where necessary, apply in tamper-resistant bait stations to prevent non-target animals from accessing the bait. Do not broadcast bait.

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

USE RESTRICTIONS (IN OUTDOOR, NONCROP AREAS):

This weather-resistant product may be used to control Norway rats, roof rats and house mice in outdoor noncrop areas, such as river banks, gullies, irrigation ditches, railroad tracks, fences, garbage dumps, landfills and recycling facilities. This product must not be applied directly to food or feed crops, but may be applied along fence lines, border areas and buffer strips adjacent to crops. All placements must be in tamper-resistant bait stations or placed deeply into rat burrows. Do not broadcast bait. Do not apply product if heavy rain or flooding would result in contaminating aquatic environments.

APPLICATION DIRECTIONS:

Mice: Apply 1/4 to 1/2 ounce of bait (1-2 level tablespoons) per placement, usually spaced 8 to 12 feet apart. Larger amounts (up to 2 ounces) may be needed at points of very high mouse activity. Maintain a constant supply of fresh bait for 15 days or until signs of mouse activity cease.

Rats: Apply 4 to 16 ounces of bait per placement, usually spaced 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. Wearing gloves, collect and dispose of all visible dead animals and leftover bait, as well as any bait that has become accessible to non-target animals. To discourage reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. For a continuous infestation, set up permanent bait stations to intercept rodents that may migrate from surrounding areas and replenish bait as needed.

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