

7173-242

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



OFFICE
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 21, 2007

R-35 5-801366
1165

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

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 April 11, 2006

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).

Background The Agency registered this product on November 9, 2005. The uses approved were identical to the 15 SLNs that individual states had registered to Liphatech for vole use. Following registration, Liphatech cancelled those duplicative SLNs. In compliance with the 1992 Rodenticide Cluster Reregistration Eligibility Decision (RED) Document, this product was classified as a "Restricted Use Pesticide", "Due to Hazard to Nontarget Organisms".

Current Use Pattern The current use pattern for this product is as follows:

1. Pome Fruits, Stone Fruits (dorm application) (hand spot, ground broadcast): 15 states, Voles
2. X'Mas Trees, Com Nurseries, Tree Plantations, (hand spot, ground broadcast) 2 states, Voles
3. Forestry Plantations, (hand spot), 1 state, Voles

Expanded Use Patterns

This request represents a major expansion of the non-structural (field) uses for this product or for the rodenticide, chlorophacinone, as follows:

<p>Expanded Use Pattern #1 (Geographical Expansion):</p> <p>“Current Use” + use in 50 states for all sites</p>
<p>Expanded Use Pattern #2 (Application Method):</p> <p>“Current Use” + Aerial Application in 50 states, Pome & Stone Fruits</p>
<p>Expanded Use Pattern #3 (Expansion for Product, but not for Active):</p> <p>Structural Uses: Buildings/Transport Vehicles Norway/Roof Rat, House Mouse</p>
<p>Expanded Use Pattern #4 (Expansion for Product, but not for Most Sites for Active)</p> <p>Non-Structural (Field) NON-CROP AREAS: River Banks, Gullies, Irrigation Ditches Railroad Tracks, Fence Lines Buffer Strips and Border Areas adjacent to crops Garbage Dumps, Landfills, Recycling Facilities Along Sidewalks & Pavement, Walls {Tamper-resistant bait stations or deep placement in burrows mandatory) Norway/Roof Rat, House Mouse</p>
<p>Expanded Use pattern #5 (Expansion for Active, New Sites):</p> <p>“Current Use” + Additional NON-CROP AREAS: Lawns, Golf Courses, Parks Other Ornamental Areas, Ornamental Flower and Shrub Gardens, Fence lines, Border Areas and Buffer Strips next to crops,</p>

Risk Assessment

For expanded use patterns of chlorophacinone for vole control [new sites, expanded geographical areas and expanded application method (aerial)], we have conducted an Environmental Fate and Effects Risk Assessment and have concluded that additional fate and effects data would be required before we could properly assess the risks of such expanded use for vole control.

For existing commensal field uses of chlorophacinone for commensal rodent control (such as “river banks, gullies, irrigation ditches, buffer strips and border areas adjacent to crops), we have concluded that we would also need the same data to assess risks, even if placements were in tamper-resistant bait stations (TRBS) or deeply in burrows, because of the potential to contaminate aquatic environments during periods of heavy rain or flooding.

Risk Mitigation

For existing uses, we would not impose those data requirements until we required them for all actives with similar uses (chlorophacinone, diphacinone, and zinc phosphide) under a data call-in. In the interim, we would require mandatory placement in TRBSs or deeply in burrows and this label precaution: "Do not apply product if heavy rains or flooding would result in contaminating aquatic environments."

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. Revise the "READ THIS LABEL" as follows: **"READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.**
2. Divide the "DIRECTIONS FOR USE" into two major sections: **"VOLE CONTROL" AND COMMENSAL RODENT CONTROL**". For "VOLE CONTROL", use the text approved November 9, 2005. Follow Enclosure 4 for proper use directions.
3. Begin your "WARRANTY" with, "To the extent consistent with applicable law, seller ..."
4. Increase the type size and spacing of characters so that text is clearly readable. Refer to Enclosure 5. Minimum Type Size Requirements for Final Printed Labels".
5. Revise the text under your product name to read, **"FOR CONTROL OF VOLES (*Microtus* spp.) IN ORCHARDS AND FOR CONTROL OF NORWAY RATS, ROOF RATS & HOUSE MICE IN OUTDOOR, NONCROP AREAS"**

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.

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 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.

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. 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: Completely empty bag into application equipment. 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: 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.

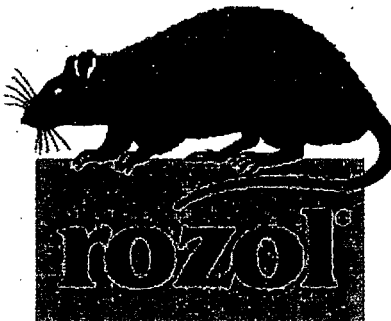
EPA Reg. No. 7173-242
EPA Est. No. 7173-WI-1

Alternate warranty statements:

Satisfaction guaranteed or your money back.

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 VOLE (*Microtus* spp.) IN ORCHARDS, VINEYARDS & NONCROP AREAS 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

ACCEPTED
Net Weight: 50 pounds
to EPA Letter Dated:

JUN 21 2007

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

7173-242

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 precautions.

VOLE CONTROL IN ORCHARDS (BEARING & NONBEARING):
USE RESTRICTIONS: For control of pine, meadow or mountain voles in orchards of pome fruit (apple, pear) and stone fruit (peach, nectarine, etc.). Apply after fall harvest (including drops), before new spring growth, and during which three days of rain-free and snow-free weather are expected. Allow bait to fall through grass or vegetation to the ground surface but 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 broadcast baiting (broadcast baiting not allowed in New York or Vermont). Aerial application is allowed in Washington and Oregon, and may be allowed in other states. Consult with your state pesticide agency to determine if aerial application is allowed in your state.
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), or near vegetation, rock outcrops and fence lines that provide harborage to voles. 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. Clean up any spilled bait or bait in piles for reuse or disposal according to label instructions.

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 non-target animals, domestic animals, children or pets from accessing the bait. 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.

RAT AND MOUSE CONTROL:
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.

RAT AND MOUSE CONTROL IN OUTDOOR NONCROP AREAS:

USE RESTRICTIONS: 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, loading areas, under granaries, along sidewalks and pavement, walls, fences, garbage dumps, landfills recycling facilities and 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. All placements must be in tamper-resistant bait stations or placed deep into rat burrows. Do not broadcast bait.

RAT AND MOUSE CONTROL IN AND AROUND STRUCTURES: USE RESTRICTIONS:

This product may be used to control Norway rats, roof rats and house mice in and around homes, industrial, commercial, agricultural and public buildings, transport vehicles (ships, trains, aircraft) and related port or terminal buildings, and similar man-made structures. Do not place bait where it may contaminate food or surfaces that come in direct contact with food.

APPLICATION DIRECTIONS:

Selection of Treatment Areas: Inspect infested areas and surrounding areas to locate nesting sites, travel routes and feeding sites. Place rodenticide as close as possible to nesting sites and travel routes. Remove as much alternative food as practical.

Mice: Apply sufficient bait in each placement to assure an uninterrupted supply between service visits (at least 1/2 ounce) per placement. Space placements 8 to 12 feet apart. Maintain an uninterrupted supply of fresh bait for 15 days or until signs of mouse activity cease.

Rats: Apply sufficient bait in each placement to assure an uninterrupted supply between service visits (at least 4 ounces), 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.

For rat burrows, insert 1/2 to 1 ounce 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.

Follow-up: Replace contaminated or spoiled bait during each service visit. Coordinate collection and proper disposal of dead animals as they are discovered around treatment area. 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. (03707)