

7173-184

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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 Rozol Pocket Gopher Bait
(Chlorophacinone)
EPA Reg. No. 7173-184
Your Submission Dated August 13, 2003

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

- Your request to allow the sale of 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 as 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 Treatment section:
 - After the statement "Bury dead animals and spilled bait found on soil surface immediately" add "using gloves."

PRECAUTIONARY STATEMENTS

- 3. 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. Avoid contact with skin, eyes or clothing. If bait is handled, wear 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. 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. 4 below for additional text required for products greater than one pound.)

- 4. 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.”

- 5. 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.”

- 6. 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

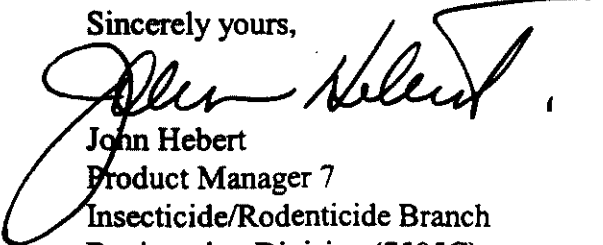
If pet or animal eats bait, call a veterinarian or Hotline Number (1-800-301-7976) at once.

NOTE TO VETERINARIAN

This product contains chlorophacinone, 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.

7. 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."
 - Add "Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas."

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
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals and pets. If swallowed or absorbed through the skin, this material may reduce the clotting ability of the blood and cause bleeding. If on skin, wash with soap and water.

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.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. 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 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. Do not contaminate water by cleaning of equipment or disposal of wastes.

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 use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of product when such use and/or handling is contrary to label instructions.

EPA Reg. No. 7173-184 EPA Est. No. 7173-WI-1

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.



rozol®
POCKET GOPHER
BAIT

FOR THE CONTROL
OF POCKET GOPHERS

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

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
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.
7173-184

DIRECTIONS FOR USE

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

Rozol Pocket Gopher Bait is recommended for use on lawns, golf courses, range land, and non-crop areas.

ENDANGERED SPECIES CONSIDERATIONS

Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists, U.S. Fish and Wildlife Service, Denver Regional Office.

This pesticide should not be used within one mile of active dens of the San Joaquin Kit Fox in the following California counties: Kern, Kings, Fresno, San Luis Obispo, Merced, Monterey, Santa Barbara, Ventura, Tulare, and San Benito. Prior to use, contact endangered species specialists at the California Department of Fish and Game or the U.S. Fish and Wildlife Service, Portland Regional Office for recommendations.

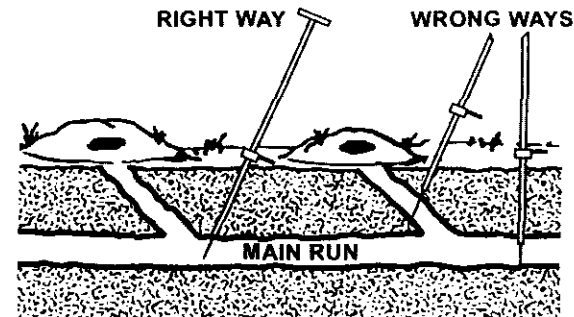
Directions for placing Rozol Pocket Gopher Bait for Pocket Gopher Control: Burrowing pocket gophers (*Thomomys* sp. and *Geomys* sp.) throw out low, fan-shaped mounds on either side of their underground tunnel. These lateral tunnels coming to the surface are on the flat side of the fan and these holes plugged with loose soil.

Treatment: Can be made in one or both of the following ways.

1. With a long-handled tablespoon, carefully remove the plug on the flat side of the fan. Carefully insert 1/2 cup of bait as far down into the hole as possible. Reclose opening, being careful not to cover the bait with soil.
2. Using a metal rod, probe 6-12 inches deep to locate the main tunnel. Consult diagram below for location to probe. Drop 1/2 cup of bait into the tunnel and cover the hole so light will not enter the tunnel system.

Consult Federal and State rodent control bulletins for a full discussion of pocket gopher burrowing habits.

Make 2-3 treatments per burrow system. Bury dead animals and spilled bait found on soil surface immediately. Maintain a constant supply of bait in the burrow system for as long as there is gopher activity. Do not apply bait on surface of soil.



The right and the wrong ways to use a probe for poisoning gophers are shown above. Be sure that bait is in the main runway - not in the laterals or imbedded in the bottom of the runway.

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