

7173-258

11/29/10

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

*Decisions # 424563, 428434
360
155 5-886 221, 5-886 220*

NOV 24 2010

Attention: Mr. Thomas Schmit

Subject Difethialone Paste Place Packs
EPA Reg. No. 7173-258
Your resubmissions of July 28 and November 23, 2010

Purpose This submission includes revised labels to comply with the Risk Mitigation Decision of May 28, 2008, under sec 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and current requirements.

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

Note Should you wish to add a reference to the company's website on your label, please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, **regardless of whether a website is referenced on your product's label**, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Terms and Conditions

Terms/Conditions of Sale/Distribution (for Agricultural Building Only Use)

The registrant must not sell or distribute the product in a manner that results in sale in stores oriented towards residential consumers (e.g., grocery, drug, hardware, home improvement stores). The registrant may sell or distribute the product in a manner that results in sale in stores oriented towards agricultural consumers (i.e., farm, agricultural, tractor stores).

This product may not be sold in packaging that holds less than 8 pounds of bait.

Terms/Conditions of Sale/Distributions (for PCO Use)

The registrant must not sell or distribute the product in a manner that results in sale in stores oriented towards residential consumers (e.g., grocery, drug, hardware, home improvement stores). The registrant may sell or distribute the product in a manner that results in sale in stores oriented towards agricultural consumers (i.e., farm, agricultural, tractor stores) and pest control operators.

This product may not be sold in packaging that holds less than 16 pounds of bait.

Compliance with Risk Mitigation

With the above changes, this product will be in full compliance with the Agency's revised May 28, 2008 "*Risk Mitigation Decision for Ten Rodenticides*" and current requirements .

Existing stocks

- The registrant may not distribute or sell existing stocks of this product after June 4, 2011 unless they conform to the terms and conditions of registration as amended today.
- Any person other than the registrant may sell and distribute existing stocks of this product with the previously approved label until such stocks are exhausted.
- Any person may use existing stocks of this product with the previously approved label until such stocks are exhausted.

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.

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,



John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosures

- 1. Stamped Label
- 2. Minimum Type Sizes for Final Printed Labels

File Location

Dan Peacock, Flash Drive, 16gb, E:\4G
Dan\Doc\Word\Difethialone\Registration Actions\7173-258\7173-258, rev
label, RMD Com. 11-23-2010 approval ltr.doc

410

PCO Use Label, Center/Front Panel:

Difethialone Paste Place Packs

FOR INDOOR AND OUTDOOR USE

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%

ACCEPTED

KEEP OUT OF REACH OF CHILDREN

NOV 24 2010

CAUTION

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

See [side][back][inner][outer] [panel][carton][label] for additional precautionary statements.

EPA Reg. No: 7173-258

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

Net Weight:

- 16 lbs (4 pails X 4 lbs each), or
 - 16 lbs (2 pails X 8 lbs each), or
 - 18 lbs (2 pails X 9 lbs each), or
 - 32 lbs (4 pails x 8 lbs each), or
 - 40 lbs (4 pails X 10 lbs each)
- or
- 16 lbs up to 50 lbs

Statement required on label of inner packages holding less than 16 pounds of bait:
It is illegal to sell this product in individual containers holding less than 16 pounds of bait.

007173-00258.11232010

PCO Use Label, side/back/inner panel:

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Keep away from children, domestic animals and pets. All handlers (including applicators) must wear long-sleeved shirt, long pants, shoes, socks, and waterproof gloves. Any person who retrieves carcasses or unused bait following application of this product must wear waterproof gloves.

User Safety Requirements: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet, and change into clean clothing.

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.

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 immediately 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 immediately for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Contains the anticoagulant difethialone. If swallowed, this material may reduce the clotting ability of blood and cause bleeding. For humans or animals ingesting bait and/or showing obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K₁ intramuscularly or orally. Also for pets, if needed, check prothrombin time every 3 days until values return to normal (up to 30 days). In severe cases, blood transfusions may be needed.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to mammals and birds. Dogs, cats and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this 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 when disposing of equipment wash water or rinsate.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

Pesticide 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 in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **[Plastic:]** Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill. **[Paper:]** Dispose of empty container by placing in trash or at an approved waste disposal facility.

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.

PCO Use Label, side/back/inner panel:

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. Use only for the sites, pests, and application methods described 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 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.

Note: Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait.

USE RESTRICTIONS: This product may only be used to control Norway rats, roof rats and house mice in and around homes and residential buildings, food processing facilities, industrial, commercial, agricultural and public buildings, and similar man-made structures. It may also be used 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 apply further than 50 feet from buildings. Do not sell this product in individual containers holding less than 16 pounds of bait. Do not place near or inside ventilation duct openings. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment. Do not broadcast bait.

Selection of Treatment Areas: Determine areas where rats and/or house 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 or beside burrows, or in locations where rats and/or house mice or their signs have been observed. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

House Mice: Apply 1 [pack][pouch] per placement, usually spaced 8 to 12 feet apart. Up to 4 [packs][pouches] may be needed at points of very high house mouse activity. Maintain a constant supply of fresh bait for 15 days or until signs of house mouse activity cease.

Rats: Apply 6 to 25 [packs][pouches] per placement, usually spaced 15 to 30 feet apart. Maintain a constant supply of fresh bait for 10 days or until signs of rat activity cease.

Follow-up: Replace contaminated or spoiled bait immediately. Wearing waterproof 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 and replenish bait as needed.

EPA Reg. No. 7173-258

EPA Est. No. 7173-WI-1

Product No.:

Label No:

Optional Statements:

Satisfaction guaranteed or your money back.

Do not tear open the [pack][pouch] - rats and mice will chew through the wrapper to get at the bait.

Agricultural Buildings Only Label, Center/Front Panel:

Difethialone Paste Place Packs

For Use In and Around Agricultural Buildings Only

FOR INDOOR AND OUTDOOR USE

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	<u>99.9975%</u>
Total	100.0000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [side][back][inner][outer] [panel][carton][label] for additional precautionary statements.

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

Net Weight:

8 lbs (4 pails X 2 lbs each)

8 lbs (2 pails X 4 lbs each)

or

8 pounds up to 50 pounds

Statement required on label of inner packages holding less than 8 pounds of bait:
It is illegal to sell this product in individual containers holding less than 8 pounds of bait.

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Agricultural Buildings Only Label, side/back/inner panel:

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Keep away from children, domestic animals and pets. All handlers (including applicators) must wear long-sleeved shirt, long pants, shoes, socks, and waterproof gloves. Any person who retrieves carcasses or unused bait following application of this product must wear waterproof gloves.

User Safety Requirements: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet, and change into clean clothing.

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.

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 immediately 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 immediately for treatment advice.

TREATMENT FOR PET POISONING: If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN: Contains the anticoagulant difethialone. If swallowed, this material may reduce the clotting ability of blood and cause bleeding. For humans or animals ingesting bait and/or showing obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K₁ intramuscularly or orally. Also for pets, if needed, check prothrombin time every 3 days until values return to normal (up to 30 days). In severe cases, blood transfusions may be needed.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to mammals and birds. Dogs, cats and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this 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 when disposing of equipment wash water or rinsate.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

Pesticide 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 in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **[Plastic:]** Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill. **[Paper:]** Dispose of empty container by placing in trash or at an approved waste disposal facility.

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.

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Agricultural Buildings Only Label, side/back/inner panel:

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. Use only for the sites, pests, and application methods described 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.

Note: Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait.

USE RESTRICTIONS: This product may only be used to control Norway rats, roof rats and house mice in and around agricultural buildings. Do not use in homes or other human residences. Do not apply further than 50 feet from agricultural buildings. Do not sell this product in individual containers holding less than 8 pounds of bait. Do not place near or inside ventilation duct openings. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment. Do not broadcast bait.

Selection of Treatment Areas: Determine areas where rats and/or house 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 or beside burrows, or in locations where rats and/or house mice or their signs have been observed. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

House Mice: Apply 1 [pack][pouch] per placement, usually spaced 8 to 12 feet apart. Up to four [packs][pouches] may be needed at points of very high house mouse activity. Maintain a constant supply of fresh bait for 15 days or until signs of house mouse activity cease.

Rats: Apply 6 to 25 [packs][pouches] per placement, usually spaced 15 to 30 feet apart. Maintain a constant supply of fresh bait for 10 days or until signs of rat activity cease.

Follow-up: Replace contaminated or spoiled bait immediately. Wearing waterproof 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 and replenish bait as needed.

EPA Reg. No. 7173-258
EPA Est. No. 7173-WI-1

Product No.:
Label No:

Optional Statements:

Satisfaction guaranteed or your money back.

Do not tear open the [pack][pouch] - rats and mice will chew through the wrapper to get at the bait.

**PLACE PACK LABEL
FOR BOTH PCO AND
AGRICULTURAL USE PRODUCTS:**

Front Panel:

Difethialone Paste Place Packs
KEEP OUT OF REACH OF CHILDREN, PETS AND NONTARGET ANIMALS
CAUTION: See carton for complete directions and precautions. It is illegal to sell these bait [packs][pouches] individually.
Net Weight: 0.35 oz (10 grams)

Back Panel:

Difethialone Paste Place Packs
Active Ingredient: difethialone..... 0.0025%
Inert Ingredients: 99.9975%
Total: 100.0000%
EPA Reg. No. 7173-258
EPA Est. No. 81629-FRA-1
Liphatech, Inc., Milwaukee, WI 53209
414-351-1476
MADE IN FRANCE

ALTERNATE CAUTION LANGUAGE:

See outer [package][pail][carton][label] for complete directions and precautions. It is illegal to sell these bait [packs][pouches] individually.