



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

7173-258

Date of Issuance:

August 27, 2007

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Difethialone Paste Place Packs

Name and Address of Registrant (include ZIP Code):

LiphaTech  
3600 West Elm Street  
Milwaukee, WI 53209

Attention: Ms. Rachel M. Callies

*Handwritten:*  
R31  
5-815585  
5-811099  
5-805247  
5-815281  
5-815282  
1180

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

A. submit one (1) copy of final printed labeling, before you release the product for shipment, with the following changes:

1. On your "Optional Marketing Statements" modify Claims #25, 26, 27, and 28, as follows. Change: "No Mess" to "Reduced Mess" to reflect more accurately the actual outcome of the use of this product.
2. Historically, we have not allowed the terms "attractive" or "attracts" as label claims because they may mislead users to believe that the bait is attracting rodents from a distance, like a magnet or pheromone. You need to delete Claims #39, 40, and 41.

*Handwritten signature: DBP*

Daniel B. Peacock, Biologist  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

Date:

August 27, 2007

- 3. For the reason under #2 above, delete the word, "attractive" in Claims 37 and 38 and revise Claim #44 to read: "Demonstrated to Kill Mice".
- 4. Delete Claims 13 ("No Wax"); 14 ("No Wax Formula"); and 15 ("no Paraffins"), as claims such as these are not permitted under 40 CFR 156.10(1)(i); (ii); (iv); (vii); and (x). Users may be misled by these true statements into believing that the absence of such ingredients in this product make the product less risky or more effective than products with these ingredients, a determination that the Agency has not made.
- 5. Change the file symbol "7173-ELI" to the registration number, "EPA Reg. No. 7173-258".

B. Revise the Confidential Statement of Formula (CSF), dated May 24, 2007, to identify Ingredient 5 more exactly as the one used in the efficacy testing of this bait. See attached "Conclusions" in the efficacy review for the revision needed.

C. Within fifteen (15) months of registration, submit a storage stability and corrosion characteristics study and a dermal sensitization test for this product.

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.

A stamped copy of the label is enclosed. If you have any questions, please contact Dan Peacock by phone (703-305-5407), fax (703-305-6596), or E-Mail (peacock.dan@epa.gov).

- Enclosures:
- 1. Stamped Label
  - 2. Minimum Type Sizes for Final Printed Label
  - 3. Efficacy review

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Difethialone\7173-ELI\7173-253, Notice of Registration, 8-27-2007.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. Avoid contact with eyes, skin or clothing. Wear gloves when handling bait or 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. 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. Do not give anything by mouth to an unconscious person.

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 difethialone, an anticoagulant. For humans or dogs that have ingested this product, or have obvious poisoning symptoms (bleeding) or prolonged prothrombin times, give Vitamin K<sub>1</sub> 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. 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.

**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.

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. Offer for recycling if available or 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:** 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-XXX Product No. 258  
EPA Est. No. 7173-WI-1 Label

# Difethialone Paste Place Packs

**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%

**KEEP OUT OF REACH OF CHILDREN CAUTION**

See side panel for additional precautionary statements.

**LIPHATECH**

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

**Net Weight:**

- 4.2 ounces (12 x 0.35 oz. bait packs), or
- 6.3 ounces (18 x 0.35 oz. bait packs), or
- 8.4 ounces (24 x 0.35 oz. bait packs), or
- 10.5 ounces (30 x 0.35 oz. bait packs), or
- 12.6 ounces (36 x 0.35 oz. bait packs), or
- 14.7 ounces (42 x 0.35 oz. bait packs), or
- 1 pound up to 50 pounds

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

**STORAGE AND DISPOSAL**

This is a nonrefillable container.  
Storage: Store in original container in a dry place inaccessible to children and pets.  
Disposal: If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**ACCEPTED with COMMENTS to EPA Letter Dated:**

**AUG 27 2007**

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

**7173-258**

**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.

**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:** This product may only be used to control Norway rats, roof rats and house mice. 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.

**Urban areas:** This product may be used in and around homes, 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.

**Non-urban areas:** This product may only be used inside of homes and agricultural, industrial and commercial buildings.

**Selection of Treatment Areas:** Determine areas where rats and/or 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 rodents or their signs have been observed. Remove as much alternative food as possible.

**APPLICATION DIRECTIONS:**

- (Qualifier statement for 12 x 0.35 oz package:) This package contains enough bait (4.2 oz.) to kill 1 to 3 rats.
- (Qualifier statement for 18 x 0.35 oz package:) This package contains enough bait (6.3 oz.) to kill 2 to 6 rats.
- (Qualifier statement for 24 x 0.35 oz package:) This package contains enough bait (8.4 oz.) to kill 3 to 8 rats.
- (Qualifier statement for 30 x 0.35 oz package:) This package contains enough bait (10.5 oz.) to kill 3 to 10 rats.
- (Qualifier statement for 36 x 0.35 oz package:) This package contains enough bait (12.6 oz.) to kill 3 to 11 rats.
- (Qualifier statement for 42 x 0.35 oz package:) This package contains enough bait (14.7 oz.) to kill 4 to 12 rats.

**Mice:** Apply 1 pack per placement, usually spaced 8 to 12 feet apart. Up to four packs 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 12 to 48 packs 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 gloves, collect and dispose of all 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. (23607)

*Alternate warranty statements:*

Satisfaction guaranteed or your money back.

Page 1 of 3,  
Product label for EPA Reg. No. 7173-ELI  
Submitted 8/24/07 via email

4/7

"Mouse only" outer carton label:

**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.

**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.

**USE RESTRICTIONS:** This product may be used to control house mice. 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.

**Urban areas:** This product may only be used in and around homes, 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.

**Non-urban areas:** This product may only be used inside of homes and agricultural, industrial and commercial buildings.

**Selection of Treatment Areas:** Determine areas where 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 or in locations where rodents or their signs have been observed. Remove as much alternative food as possible.

**APPLICATION DIRECTIONS:**  
**Mice:** Apply 1 pack per placement, usually spaced 8 to 12 feet apart. Two packs 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. Replace contaminated or spoiled bait immediately. Wearing gloves, collect and dispose of all 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. (23607)

**Alternate warranty statements:**  
Satisfaction guaranteed or your money back.

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Satisfaction guaranteed or your money back.

Page 2 of 3  
Product label for EPA Reg. No. 7173-ELI  
Submitted 8/24/07 via email

# Difethialone Paste Place Packs

**KILLS HOUSE MICE AND  
WARFARIN-RESISTANT HOUSE MICE**

**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%

**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:**  
0.35 ounces up to 50 pounds

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

**STORAGE AND DISPOSAL**  
This is a nonrefillable container.  
Storage: Store in original container in a dry place inaccessible to children and pets.  
Disposal: If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**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. Avoid contact with eyes, skin or clothing. Wear gloves when handling bait or 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. 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. Do not give anything by mouth to an unconscious person.

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 difethialone, an anticoagulant. For humans or dogs that have ingested this product, or have obvious poisoning symptoms (bleeding) or prolonged prothrombin times, give Vitamin K<sub>1</sub> 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. 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.

**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.

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. Offer for recycling if available or 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:** 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-XXX      Product No.  
EPA Est. No. 7173-WI-1      Label

Place Pack Label:

Front:

**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 individually.  
Net Weight: 0.35 oz. (10 grams)

Back:

**Difethialone  
Paste Place  
Packs**

Active ingredient:  
difethialone . . . . . 0.025%

Inert ingredients: . . . . . 99.975%

Total: . . . . . 100.000%

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

Liphatech, Inc.  
Milwaukee, WI 53209  
414 351-1476

**Optional Marketing Statements:**

- |   |  |
|---|--|
| (1) Do not tear open the pack - rats and mice will chew through the wrapper to get at the bait. | (23) Mouse-Sized Portions                  |
| (2) Do not tear open the pack - mice will chew through the wrapper to get at the bait.          | (24) Mouse-Sized Portion Packs             |
| (3) Mice Eat Through the Package  | (25) No Mess Mini-Bait Packs               |
| (4) Mice will eat through film  | (26) No Mess Mini-Place Packs              |
| (5) Mice will eat through sachet  | (27) No Mess Paste                         |
| (6) Mice will eat through bait pack   | (28) No Mess Paste Formula                 |
| (7) Rats will eat through film  | (29) No Pellet Scatter                     |
| (8) Rats will eat through sachet  | (30) No Scattered Pellets                  |
| (9) Rats will eat through bait pack   | (31) No Loose Pellets                      |
| (10) Rodents will eat through film  | (32) No Pellet Spillage                    |
| (11) Rodents will eat through sachet  | (33) No Spill Formulation                  |
| (12) Rodents will eat through bait pack   | (34) No Spill Paste Formulation            |
| (13) No Wax   | (35) Demonstrated Palatability             |
| (14) No Wax Formula   | (36) Demonstrated Palatability for Mice    |
| (15) No Paraffins   | (37) Attractive Paste Formula              |
| (16) Solid Paste Formula  | (38) Attractive Paste Bait                 |
| (17) Soft Bait  | (39) Attracts Mice                         |
| (18) Soft Paste   | (40) Attracts Rats and Mice                |
| (19) Chewy Formula  | (41) Paste Formula Attracts Mice           |
| (20) Chewy Paste Formula  | (42) Demonstrated Rodent Control           |
| (21) Solid Bait Formula   | (43) Demonstrated Control                  |
| (22) Soft Bait Formula  | (44) Demonstrated to Attract and Kill Mice |
|   | (45) Package Allows Mice to Smell the Bait |

With other "paste" formulations that have been proposed for registration at various times, we have required field efficacy data to determine how well the baits perform under actual use conditions. Although a "paste" may be palatable and perform well in laboratory tests, how well it does under conditions of actual use could be affected by how palatable it remains over time. There also is a concern about contaminating the environment with something that might be difficult to clean up. With 7173-ELI being proposed to be in a placepack, however, the most serious concerns in these areas might be addressed by the product's packaging, at least until the rodents have at it. Consequently, I have not requested that field efficacy trials be run with the 7173-ELI product at this time. As noted previously, however, this bait's ability to control house mice seems questionable and could be explored further through field trials.

201.3 Labeling

See efficacy review of 7/3/07 for discussion of the labels and marketing statements proposed for this product.

202.0 CONCLUSIONS

See efficacy review of 7/3/07 for detailed comments on efficacy studies labels, and proposed marketing statements.

1. The batching information supplied on July 31, 2007, is sufficient to document the that the bait used ("lot 000008390") in the rat efficacy study (MRID No. 470521-11) was consistent in description to the bait described on the Confidential Statement of Formula dated "24 May 2007". However, the "**COMPOSITION SHEET**" of "August 2006" appended to the efficacy report lists "Sunflower fat" rather than "Hydrogenated Vegetable Fat" as a component of the product. If "lot 000008390" was made with sunflower fat, that specific ingredient must be claimed on the CSF for this product rather than the broader term "Hydrogenated Vegetable Fat". If some fat other than sunflower fat is used to make up 23% of this bait, that specific fat must be claimed.

The efficacy study assigned MRID No, 470521-01 is marginally acceptable but is applicable only to the specific bait formulation used as the test material in that study.

2. The rat placepack-penetration trial (MRID No. 471439-01) resulted in 100% mortality to Wistar strain Norway rats in the test group. That study remains acceptable for the limited purpose of suggesting that commensal rats will readily penetrate the placepack material used in the trial. The composition of the product actually used in this efficacy trial should be documented.
3. The batching information supplied on July 31, 2007, is sufficient to document the that the bait used ("lot 000008390") in the house mouse efficacy study (MRID No. 470521-12) was consistent in description to the bait described on the Confidential Statement of Formula dated "24 May 2007". However, the "**COMPOSITION SHEET**" of "August 2006" appended to the efficacy report lists "Sunflower fat" rather than "Hydrogenated Vegetable Fat" as a component of the product. If "lot 000008390" was made with sunflower fat, that specific ingredient must be claimed on the CSF for this product rather than the broader term "Hydrogenated Vegetable Fat". If some fat other than sunflower fat is used to make up 23% of this bait, that specific fat must be claimed.

This product barely met the performance criterion for testing according to Protocol 1.210. Acceptance of the test material was a very poor 16.3%, meaning that test-group mice took challenge diet in preference to bait by a ratio of more than 5:1. The two females that survived the study may have done so by avoiding the bait virtually entirely. Any reduction in bait

palatability that switching among ingredients that might be described as "Hydrogenated Animal Fat" could render this bait even less effective against house mice.

The efficacy study assigned MRID No. 470521-02 is marginally acceptable but is applicable only to the specific bait formulation used as the test material in that study.

4. The house mouse placepack-penetration trial (MRID No. 471439-02) resulted in 100% mortality to Swiss-Webster strain house mice in the test group. This test remains marginally acceptable. The formulation sheet for the test batch used in this efficacy trial should be provided.

William W. Jacobs  
Biologist  
Insecticide-Rodenticide Branch  
August 23, 2007