

7173-258

5/30/2008

Page 1 of 6
Chat



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Rachel M. Callies
Product Registration
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

MAY 30 2008

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request General Label Change
EPA Reg.No. 7173-258
Application Dated April 29, 2009

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 04/29/08 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" received and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

276



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 7173-258	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Difethialone Paste Place Packs	PM# Insecticide/Rodenticide Branch	
5. Name and Address of Applicant (Include ZIP Code) Liphatech, Inc. 3600 W. Elm Street Milwaukee, WI 53209 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification (per PR Notice 98-10) of Minor Label Changes:

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations of 40 CFR 152.46, and no other changes have been made to the label or the confidential statement of formula for this product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 153.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
					<input checked="" type="checkbox"/> Paper
					Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4.2, 6.3, 8.4, 10.5, 12.6 or 14.7 oz, or 1 lb up to 50 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Rachel M. Callies	Title Regulatory Assistant	Telephone No. (Include Area Code) (414) 410-7235
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Assistant	
4. Typed Name Rachel M. Callies	5. Date 29 April 2008	



3 7 6
3600 WEST ELM STREET
MILWAUKEE, WI 53209
Tel: 414/351 1476 800/351 1476
Fax: 414/247 8166

Document Processing Desk
EPA Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
Attn: Mr. John Hebert

29 April 2008

Re: Notification of Minor Label Changes for
Difethialone paste Place Packs, EPA Reg. No. 7173-258

Dear Mr. Hebert,

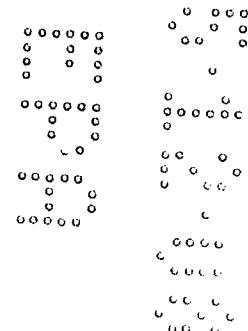
Enclosed is a notification of Minor Label Changes per PR Notice 98-10. As you can see by the enclosed label, the only changes are the addition of the word "individual" to two marketing statements. This change is being made to clarify that the place pack should not be opened but that the outer pouch containing the placepacks does have to be opened.

I have also corrected the EPA establishment number of the place pack of this product. This product is manufactured in France and shipped to us in the place packs. Therefore, the EPA establishment number has been changed to reflect the establishment in France. The outer packages that these placepacks are sold in still reflect our establishment number in Wisconsin because we do further package the place packs here.

Please contact me if you have any questions regarding this submission.

Sincerely,

Rachel M. Callies
Regulatory Assistant
Liphatech, Inc.
414-410-7235
calliesr@liphatech.com



4 7 6

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

Product No.
Label

Generation Paste Bait 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.

LIPHA TECH

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.

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. (12008)

Alternate warranty statements:

Satisfaction guaranteed or your money back.

Page 1 of 3,
Product label for EPA Reg. No. 7173-258

576

"Mouse only" outer carton label:

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 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. 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. 7173-258 Product No.
EPA Est. No. 7173-WI-1 Label

Generation Paste Bait 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.

LIPHATECH®
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.

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 only 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 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.

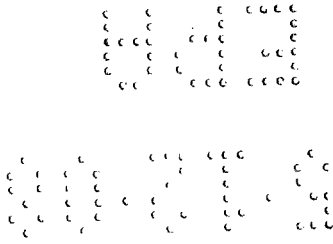
APPLICATION DIRECTIONS:

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.
(12008)

Alternate warranty statements:

Satisfaction guaranteed or your money back.

Page 2 of 3
Product label for EPA Reg. No. 7173-258



676

Place Pack Label:

Front:

**Generation
Paste Bait
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:

**Generation
Paste Bait
Packs**

Active Ingredient:
difethialone0025%

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

Optional Marketing Statements:

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

