



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 12, 2018

Kylli Paavola
Compliance Specialist
Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Subject: PRIA Label Amendment –To review efficacy data submitted to support *Peromyscus* mice for the Basic confidential statement of formula (dated 01/07/11), add a study to data matrix, and to add new brand name
Product Name: Difethialone Soft Bait
EPA Registration Number: 7173-258
Application Date: 1/26/18
Decision Number: 537945

Dear Ms. Paavola:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then 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.

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EPA Reg. No. 7173-258
Decision No. 537945

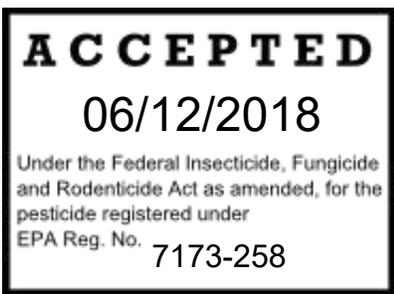
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Marianne Lewis by phone at (703 308-8043) or via email at lewis.marianne@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gene Benbow".

Gene Benbow, Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

PCO Use Label, Center/Front Panel:



Difethialone Soft Bait

FOR INDOOR AND OUTDOOR USE

**KILLS NORWAY RATS, ROOF RATS, HOUSE MICE,
WARFARIN-RESISTANT HOUSE MICE**

(Optional when other species are listed as target species on label directions:

KILLS OTHER RODENT SPECIES AS LISTED ON THIS LABEL)

(Optional when other species are listed as target species on label directions:

KILLS RATS, MICE, DEER MICE, AND MEADOW VOLES*)

**NORWAY RATS AND HOUSE MICE MAY 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
800-351-1476

Net Weight:
16 lbs up to 50 lbs

This bait is packaged in 0.35 ounce (10 grams) individual pouches

Alternate pouch sizes:

This bait is packaged in 1.4 ounce (40 grams) individual pouches

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.

*Use not permitted in California

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

Product No.:
Label No:

PCO Use Label, side/back/inner panel:

| FIRST AID | |
|--|---|
| If swallowed: | <ul style="list-style-type: none">• 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: | <ul style="list-style-type: none">• 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: | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin with plenty of water for 15-20 minutes.• Call a poison control center or doctor immediately for treatment advice. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| 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 K ₁ intramuscularly or orally. Repeat as necessary based on monitoring of prothrombin times. | |

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Harmful if 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 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 exist, 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.

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 may be disposed of in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **[Plastic:]** Completely empty container, then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill. **[Paper:]** Completely empty container, then dispose of empty container 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.

Optional Statements:

Satisfaction guaranteed or your money back

This package includes (X number of units) (Brand name of wire cage feeder).

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 can only be used to control Norway rats, roof rats and house mice

(Optional species that may be listed on label as target pests along with California restriction)

| | |
|--|--|
| Deer mouse (<i>Peromyscus maniculatus</i>) | White-footed mouse (<i>Peromyscus leucopus</i>) |
| Cotton mouse (<i>Peromyscus gossypinus</i>) | |
| Cotton rat* (<i>Sigmodon hispidus</i>) | Meadow vole* (<i>Microtus pennsylvanicus</i>) |
| Eastern harvest mouse* (<i>Reithrodontomys humuli</i>) | White-throated woodrat* (<i>Neotoma albigula</i>) |
| Golden mouse* (<i>Ochrotomys nuttalli</i>) | Southern plains woodrat* (<i>Neotoma micropus</i>) |
| Polynesian rat* (<i>Rattus exulans</i>) | Mexican woodrat* (<i>Neotoma mexicana</i>) |

*Not permitted for use against the following species in California: Cotton rat, Eastern harvest mouse, Golden mouse, Polynesian rat, Meadow vole, White-throated woodrat, Southern plains woodrat, and Mexican woodrat.

in and within 100 feet of man-made structures constructed in a manner so as to be vulnerable to commensal rodent invasions and/or to harboring or attracting rodent infestations. Examples of such structures include homes and other permanent or temporary residences, food processing facilities, industrial and commercial buildings, trash receptacles, agricultural and public buildings, transport vehicles (ships, trains, aircraft), docks and port or terminal buildings, and related structures around and associated with these sites. Fence and perimeter baiting beyond 100 feet from a structure, as defined above, is prohibited. 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, feed, food or feed handling equipment, or milk or meat handling equipment. Do not apply directly to food or feed crops. Do not broadcast bait. Burrow baiting with this product is prohibited.

Selection of Treatment Areas: Determine areas where rats and/or house mice [*when optional species are claimed: rats, mice, and/or meadow voles**] will most likely find and consume bait. Generally, these are along walls, by gnawed openings, in corners and concealed places, between floors or walls, beside burrows, or in locations where signs of rats and/or house mice [*when optional species are claimed: rats, mice, and/or meadow voles**] have been observed. Remove as much alternative food as possible.

APPLICATION DIRECTIONS: *(Note: Only one of the two sets of application directions will appear on actual label)*

Application Directions for 0.35 oz. (10 g) size:

Each pouch contains 0.35 oz. (10 g)

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

Rats: Apply 9 to 43 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.

PCO Use Label, side/back/inner panel:

Application Directions for 1.4 oz. (40 g) size:

Each pouch contains 1.4 oz. (40 g)

House Mice [Mice and Meadow Voles*]: Apply 1 pouch per placement, usually spaced 8 to 12 feet apart. Maintain a constant supply of fresh bait for 15 days or until signs of activity cease.

Rats: Apply 2 to 11 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.

Optional statement(s) for all sizes:

Bait may be removed from the pouch and placed in a feeding device that secures the unwrapped bait in a bait station. Discard empty wrapper in the trash.

Pouches can be secured in a bait station, skewered on a wire and placed between or below floor slats, or on a nail (in locations out of reach of children, pets and nontarget animals).

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.

Difethialone Soft Bait

FOR INDOOR AND OUTDOOR USE

**KILLS NORWAY RATS, ROOF RATS, HOUSE MICE,
WARFARIN-RESISTANT HOUSE MICE**

*(Optional when other species are listed as target species on label directions:
KILLS OTHER RODENT SPECIES AS LISTED ON THIS LABEL)*

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FOUR OR FIVE DAYS AFTER FEEDING BEGINS**

| | |
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| 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
800-351-1476

Net Weight:
8 lbs up to 50 lbs

This bait is packaged in 0.35 ounce (10 grams) individual pouches

Alternate pouch sizes:

This bait is packaged in 1.4 ounce (40 grams) individual pouches

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.

*Use not permitted in California

Agricultural Label, side/back/inner panel:

| FIRST AID: Have this label with you when obtaining treatment advice. | |
|--|---|
| If swallowed: | <ul style="list-style-type: none">• 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: | <ul style="list-style-type: none">• 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. |
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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 may be disposed of in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. **[Plastic:]** Completely empty container, then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill. **[Paper:]** Completely empty container, then dispose of empty container 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.

Optional Statements:

Satisfaction guaranteed or your money back

This package includes (X number of units) (Brand name of wire cage feeder).

Agricultural Label, side/back/inner panel:

DIRECTIONS FOR USE

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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.
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(Optional species that may be listed on label as target pests along with California restriction)

| | |
|---|--|
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| Cotton rat* (<i>Sigmodon hispidus</i>) | Meadow vole* (<i>Microtus pennsylvanicus</i>) |
| Eastern harvest mouse* (<i>Reithrodontomys humul</i>) | White-throated woodrat* (<i>Neotoma albigula</i>) |
| Golden mouse* (<i>Ochrotomys nuttall</i>) | Southern plains woodrat* (<i>Neotoma micropus</i>) |
| Polynesian rat* (<i>Rattus exulans</i>) | Mexican woodrat* (<i>Neotoma mexicana</i>) |

*Not permitted for use against the following species in California: Cotton rat, Eastern harvest mouse, Golden mouse, Polynesian rat, Meadow vole, White-throated woodrat, Southern plains woodrat, and Mexican woodrat.

in and within 100 feet of agricultural buildings and man-made agricultural structures constructed in a manner so as to be vulnerable to commensal rodent invasions and/or to harboring or attracting rodent infestations. Fence and perimeter baiting, beyond 100 feet from an agricultural structure as defined above, is prohibited. 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, feed, food or feed handling equipment, or milk or meat handling equipment. Do not apply directly to food or feed crops. Do not broadcast bait.

Burrow baiting with this product is prohibited.

Selection of Treatment Areas: Determine areas where rats and/or house mice [*when optional species are claimed: rats, mice, and/or meadow voles**] will most likely find and consume bait. Generally, these are along walls, by gnawed openings, in corners and concealed places, between floors or walls, beside burrows, or in locations where signs of rats and/or house mice [*when optional species are claimed: rats, mice, and/or meadow voles**] have been observed. Remove as much alternative food as possible.

APPLICATION DIRECTIONS: *(Note: Only one of the two sets of application directions will appear on actual label)*

Application Directions for 0.35oz. (10 g) size:

Each pouch contains 0.35 oz. (10 g)

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

Rats: Apply 9 to 43 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.

Agricultural Label, side/back/inner panel:

Application Directions for 1.4 oz. (40 g) size:

Each pouch contains 1.4 oz. (40 g)

House Mice [Mice and Meadow Voles*]: Apply 1 pouch per placement, usually spaced 8 to 12 feet apart. Maintain a constant supply of fresh bait for 15 days or until signs of activity cease.

Rats: Apply 2 to 11 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.

Optional statement(s) for all sizes:

Bait may be removed from the pouch and placed in a feeding device that secures the unwrapped bait in a bait station. Discard empty wrapper in the trash.

Pouches can be secured in a bait station, skewered on a wire and placed between or below floor slats, or on a nail (in locations out of reach of children, pets and nontarget animals).

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.

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

Front Panel:

| |
|--|
| Difethialone Soft Bait |
| 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 pouches individually. |
| Net Weight: 0.35 oz (10 grams) |

Back Panel:

| |
|---------------------------------------|
| Difethialone Soft Bait |
| Active Ingredient: |
| difethialone 0.0025% |
| Inert Ingredients: 99.9975% |
| Total: 100.0000% |
| EPA Reg. No. 7173-258 |
| EPA Est. No. |
| Liphatech, Inc., Milwaukee, WI 53209 |
| 800-351-1476 |

Alternate pouch sizes:
Net Weight: 1.4 oz. (40 grams)

{ALTERNATE LANGUAGE FOR BOTH PCO AND AGRICULTURAL USE PRODUCTS:

See outer package[pail][carton][label] for complete directions for use and precautionary statements. It is illegal to sell these bait pouches individually.}

Optional Marketing Statements for both PCO and Agricultural Use Products:

Made in France
Convenient & easy-to-use
Controls rodents