



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
7173-223

Date of Issuance:
MAR 13 1998

NOTICE OF PESTICIDE:
 Registration
 Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
DIFETHIALONE 0.125%
LIQUID CONCENTRATE

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

LiphaTech
3600 West Elm St.
Milwaukee, WI 53209
Attn: Kelly Rahn

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 sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. The proposed labeling submitted with your January 29, 1997 application for registration listed a nominal concentration of active ingredient that differed from the nominal concentration reported on your Confidential Statement of Formula. As we requested via telecon, you submitted proposed revised labeling by FAX on March 12, 1998 with the appropriate nominal concentration (% a.i.) reported in the Ingredients Statement. On your proposed revised labeling submitted March 12, 1998, make the labeling changes listed below before you release the product for shipment.

continued on p.2

Signature of Approving Official:

Date:

MAR 13 1998

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 7173-223.
- b. On the front panel, revise the instructions under "FIRST AID" to read exactly as follows:

"IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching the back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention."

- c. Delete the statement "MAY BE FATAL IF SWALLOWED OR ABSORBED THROUGH SKIN" from the front panel. This statement should appear under "PRECAUTIONARY STATEMENTS" on the left panel (see item d. below).
- d. The text under "PRECAUTIONARY STATEMENTS" must be revised to read as follows:

"WARNING: Keep away from humans, domestic animals, and pets. May be fatal if swallowed or absorbed through the skin. Causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Wear protective clothing and chemical-resistant gloves made of any waterproof material. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse."

- d. Below the "Note to physician" section, add the following sentence:

"For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Telecommunications Network at 1-800-858-7378."

- e. On the left panel, after the paragraph under "ENVIRONMENTAL HAZARDS," delete the statement "KEEP AWAY FROM FOODSTUFFS."
- f. On the right panel, change the second paragraph of the "DIRECTIONS FOR USE" to read as indicated below.

This product may be used only for the following purposes:

- 1. formulation of registered end-use rodenticide baits claimed to control Norway rats, roof rats, and/or house mice in and around homes; in and around industrial, commercial, and public buildings; inside agricultural buildings, in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings;
 - 2. uses for which the U.S. Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
 - 3. uses under experimental use permits which are in compliance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 40 CFR 172.
- g. Under "STORAGE AND DISPOSAL," the statement "Do not contaminate water, food, or feed by storage or disposal" should be left-justified and typed in lower case so it is clear that this statement is subordinate to the header "STORAGE AND DISPOSAL."
- 3. Submit two copies of your revised final printed labeling before you release the product for shipment.

Your application for registration included submissions of required product performance studies, acute toxicity studies, and product chemistry studies. The conclusions of our reviews of these studies are discussed below.

- 1. The laboratory efficacy studies submitted on January 29, 1997 suggest that the bait formulation tested was sufficiently palatable and lethal to the strains of Norway rats and house mice that were exposed to it. It is not fully established that the specific formulation proposed for registration under File Symbol 7173-EEG was a component of the bait lot that was bioassayed in the Fall of 1992.
- 2. The acute oral (81-1), acute dermal (81-2), eye irritation (81-4), dermal irritation (81-5), and dermal sensitization (81-6) studies you submitted are acceptable. Your request for waiver of the acute inhalation (81-3) data requirement is granted. The acute toxicity database for your product is considered complete. A copy of our acute toxicity data review is enclosed for your records.
- 3. The product chemistry studies you submitted satisfy the data requirements as specified in 40 CFR 158.160, 158.162, 158.165, 158.167, 158.170, 158.175, and 158.180 with respect to description of materials used to produce the product, description of production process, description of formulation process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical methods. In addition, since you have submitted a revised proposed draft label (March 12, 1998)

listing the same nominal concentration as that reported on the CSF dated January 29, 1997, your CSF is acceptable and fulfills the data requirement for product identity and composition.

Your product chemistry submission also satisfies the data requirements as specified in 40 CFR 158.190 with respect to physical and chemical properties. However, the physical and chemical data requirements for pH and viscosity remain outstanding. Within 30 days of receipt of this notice, you must indicate, in writing, how you intend to address these data gaps.

If the above specified 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 bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. If you have any questions regarding this notice, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,



Peg Perreault
Chemical Manager, Team 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosures (3)

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND
DOMESTIC ANIMALS**

WARNING

Keep away from humans, domestic animals and pets. May be fatal if swallowed or absorbed through the skin. Do not breathe the vapor, or spray mist because this material will reduce the clotting ability of the blood and cause bleeding.

Do not get in eyes, on skin or on clothing. Wear rubber gloves when handling as this product can be absorbed through the skin. Wash arms, hands, and face with soap and water after using and before eating or smoking. Contaminated clothing should be removed and washed before reuse.

In case of contact with skin, wash thoroughly with soap and plenty of water, for eyes, flush with plenty of water. If swallowed, call a physician immediately.

Note to physician: If ingested or absorbed by humans, domestic animals or pets, this material will reduce the clotting ability of the blood and cause bleeding. In such cases, treat as in bishydroxycoumarin overdoses, giving Vitamin K₁ orally or intramuscularly in mild cases and giving Vitamin K₁ intravenously and blood transfusions in severe cases. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

KEEP AWAY FROM FOODSTUFFS

WARRANTY: Seller makes no warranty, express 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.

**DIFETHIALONE 0.125%
LIQUID CONCENTRATE**

**A RODENTICIDE FOR FORMULATING INTO
REGISTERED END-USE RODENTICIDES**

Active Ingredient:

*3-(3-(4'-bromo(1,1'-biphenyl)-4-yl)-1,2,3,4-tetrahydro-1-naphthylonyl)-4-hydroxy-2H-1-benzothlopyran-2-one.....0.125%
Inert Ingredients.....99.875%
Total: 100.000%

*Difethialone - Patented in the U.S.A.

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

IF ON SKIN: Wash with plenty of soap and water.

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

MAY BE FATAL IF SWALLOWED OR ABSORBED THROUGH SKIN.

See left side panel for additional precautionary statements.

Manufactured By:

LiphaTech, Inc.
3101 West Custer Ave.
Milwaukee, WI 53209

NET CONTENTS: 5 Gallons (18.95 Liters)

ACCEPTED
with COMMENTS
In EPA Letter Dated:

March 13, 1998

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

7173-223

DIRECTIONS FOR USE

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

Only for formulation into a rodenticide for:

1. the following uses: Norway rats, roof rats, and house mice.
2. uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and
3. uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD OR FEED
BY STORAGE OR DISPOSAL.**

STORAGE: Avoid exposure to freezing temperatures. Store in original container in area not accessible to children and pets. Keep away from food and foodstuffs. In case of spillage, test area with absorbent material and dispose of according to pesticide disposal statement. Wash area with soap and water. Do not allow runoff to contaminate water.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Do not contaminate water by cleaning of equipment or disposal of wastes.

CONTAINER DISPOSAL:

PLASTIC CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

METAL CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities.

EPA Reg. No. 7173-XXX
EPA Est. No. 037900-FR-001