



007173-00224-060799

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Systems Integration Group, Inc.

PM 25

7173-224

6/7/99

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

EPA Reg. Number:
7173-224

Date of issuance:

JUN -7 1999

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Term of issuance: Conditional

Name of Pesticide Product:

DIFETHIALONE 0.5% DRY
CONCENTRATE

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 the 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. Modify your proposed labeling as indicated below before you release the product for shipment.

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Signature of Approving Official:

Date:

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- a. Revise the EPA Registration Number to read: "EPA Reg. No. 7173-224.
- b. On the front panel below the signal word "WARNING", add the heading "FIRST AID", centered on the panel above the block of instructions beginning with "If Swallowed:".
- c. On the left panel, 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. Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse. Exposure to this product during pregnancy should be avoided."

- d. In the "Note to Physician:" section, revise the second sentence to read "In such cases, treat as in bishydroxycoumarin overdoses, giving Vitamin K₁ orally or intramuscularly", i.e. delete the entire second half of the sentence beginning with "in mild cases and giving Vitamin K₁ intravenously...."
- e. 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."

- f. On the right panel, modify the "DIRECTIONS FOR USE" to read as indicated below.

"DIRECTIONS FOR USE"

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Formulators using this product are responsible for obtaining registrations or experimental use permits for their formulated products.

This product may only be used to formulate rodenticide end-use products which are:

- 1. registered for use to control Norway rats, roof rats, and/or house mice in:

- a. **URBAN AREAS** [for use only in and around homes; in and around industrial, commercial, and public buildings and similar man-made structures; in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings] and/or
- b. **NON-URBAN AREAS** (for use only inside of homes and/or agricultural buildings);

- 2. registered for 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; or
- 3. authorized for use for experimental purposes that 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 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.

4. Your application for registration included the submission of acute toxicity, product chemistry, and efficacy studies. The conclusions of our reviews of these studies are discussed below.

a. 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. However, your request for waiver of the acute inhalation (81-3) data requirement cannot be granted at this time. We have not received sufficient information to reach a conclusion on your request. You indicated that several attempts were made to conduct an inhalation study on this material, but you submitted no further information. Within 30 days of receipt of this Notice, you must submit additional information regarding the attempts to mill this product or to otherwise reduce the particle size. Your waiver request will be given further consideration upon receipt of the additional information. A copy of the acute toxicity review is enclosed for your records.

b. 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, 158.180, and 158.190 with respect to description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, enforcement analytical methods, and physical and chemical

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properties. Your CSF dated May 29, 1998 is acceptable provided you change the total weight in block 17 on the CSF to 1,000 lbs. Instead of 100 lbs. Please submit a revised CSF reflecting this change. A copy of the product chemistry review is enclosed for your records.

- c. Of the efficacy studies cited to support the registration of this product, two were not accepted by EPA. The MRID Nos. For the accepted studies are: 420640-02 [Norway rats (wild)]; 420640-08 [Wistar rats]; 433609-02 [Wistar rats]; and 433716-02 [Swiss-Webster mice]. Additional efficacy data are not required for this product at this time.

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 contact me at (703) 305-5417 or via E-mail at Perreault.Peg@epa.gov.

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. Avoid contact with skin, eyes, or clothing. Do not breathe dust. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse. Exposure to this product during pregnancy should be avoided.

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.

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 such use and/or handling of this material when such use and/or handling is contrary to label instructions.

DIFETHIALONE 0.5% DRY CONCENTRATE

A RODENTICIDE FOR FORMULATION INTO REGISTERED END-USE RODENTICIDES

ACTIVE INGREDIENT:

*3-(3-(4'-bromo(1,1'-biphenyl)-4-yl)-1,2,3,4-tetrahydro-1-naphthylenyl)-4-hydroxy-2H-1-benzothioopyran
-2-one 0.5%
INERT INGREDIENTS..... 99.5%
TOTAL..... 100.00%

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

KEEP OUT OF REACH OF CHILDREN

WARNING

If Swallowed: Call 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 Inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

If in Eyes: Flush with plenty of water. Call physician if irritation persists.

IN ALL CASES OF HUMAN INGESTION IMMEDIATELY NOTIFY A PHYSICIAN.

See left panel for additional
Precautionary statements.

MANUFACTURED BY:
LiphaTech, Inc.
3101 West Custer Ave.
Milwaukee, WI 53209

NET WEIGHT: _____

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 US 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 US EPA requirements.

STORAGE AND DISPOSAL

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

STORAGE: Avoid exposure to freezing temperatures. Store only in original container in an area inaccessible to children and pets. Do not store near food or feed.

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.

EPA Reg. No. 7173-
EPA Est. No. 7173-WI-01

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

June 7, 1999

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

7173-224

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