

7173-204

08/18/2005

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 18, 2005

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DP 317468

LiphaTech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209

Attention: Mr. Thomas J. Schmit

Subject **Difethialone Technical**
 EPA Reg. No. 7173-204
 Your amended application of February 25, 2005
 Your letter of August 15, 2005

Purpose This application, under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), submits data to support a change in the manufacturing establishment and an increase in the purity of active ingredient from 97.6% to 98.6%. In addition, you requested to modify the Personal Protective Equipment (PPE) text in your "PRECAUTIONARY STATEMENTS".

Data Review In support of this request, you submitted product chemistry data, a revised Confidential Statement of Formula (CSF) dated February 21, 2005, and a revised label.

Your revised CSF is acceptable. We have placed a copy in the files for this product. All other versions are obsolete.

However, you will need to submit the following additional information within one (1) year of receipt of this letter:

1. a replacement study for the Preliminary Analysis (830.1700), conducted under full GLP requirements, including quality assurance procedures and
2. a replacement page of Step 8 of the manufacturing process, adding the identity and amount of the 2nd of two reactants.

Label Your request to modify the PPE is acceptable. The labeling submitted with the above letter, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the following changes, before you ship your product.

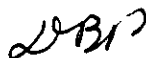
1. Place text involving medical emergencies ("For information ... 1-800-858-7378.") in your "First Aid" section, which contains similar information.
2. Under "Storage and Disposal", follow the "Pesticide Disposal" and "Container Disposal" texts in the previous version of your label (May 3, 1995) as products with "DANGER" as a signal word automatically require the more extensive text.

Existing stocks Stocks of existing labels may be used for eighteen (18) months.

Consequence for non-compliance 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.

Questions If you have questions about this letter or the review, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,



Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosures 1. Stamped Label

Location Dan Peacock, USB Flash Drive 1.1, F:\1-7-2005 Backup\Dan's Office Work\A Flash Drive 1\Difethialone\7173-204, new manufacturing process, 8-17-2005.wpd

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Fatal if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Do not breathe dust. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), eye goggles and rubber gloves when handling this product. Wash hands, arms and face before eating, drinking, chewing gum, using tobacco or using the toilet. Repeated exposure to small amounts of this product can produce cumulative toxicity. Persons at risk should have their prothrombin times checked periodically.

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.

EPA Reg. No. 7173-204
EPA Est. No. 37900-FR-01

LIPHA/TECH
3600 W. Elm Street
Milwaukee, WI 53209
(800) 351-1476

NET CONTENTS: 22 lb (10 kg)

DIFETHIALONE TECHNICAL

A RODENTICIDE FOR FORMULATING OTHER REGISTERED PRODUCTS

Active Ingredient: difethialone 98.6%
Other ingredients 1.4%
Total 100.0%

KEEP OUT OF REACH OF CHILDREN



**DANGER
POISON**



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 poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

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.

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. In severe cases, blood transfusions may be necessary. Check prothrombin time every 3 days until values return to normal.

See side panel for additional precautionary statements.

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 the following uses:

- Norway rats, roof rats and house mice.

This product may be used to formulate products for specific uses not listed on this label if the formulator, user group, or grower has complied with U.S. E.P.A. submission requirements regarding support of such uses.

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

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

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: 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: Seller makes no warranty, expressed or implied, concerning use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of product when such use and/or handling is contrary to label instructions.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 18 2005

Under the Federal Pesticide, and Rodenticide, and Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 7173-204
Page 1 of 1, Product label for EPA Reg. No. 7173-204
Submitted Feb 25, 2005

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