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



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 21, 2005

5-774 972 R-34 18 5-775 202 R-34

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

Attention: Mr. Thomas J. Schmit

Subject

Rozol Rodenticide Technical Powder

EPA Reg. No. 7173-75

Your amended application of February 17, 2005 Your letters of February 17 and March 14, 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 96.03% to 98.9%.

Data Review

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In support of this request, you submitted product chemistry data, a revised Confidential Statement of Formula (CSF) dated March 14, 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 a replacement study for the Preliminary Analysis (830.1700). The problems with this study are follows:

- The study must be conducted under full GLP requirements, including quality assurance procedures.
- The more sensitive and advanced HPLC/UV method, rather than the 2. Titration Method, should have been used.

A copy of the review is enclosed.

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Label

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. Under your "DIRECTIONS FOR USE", follow the text in the previous version of your label (February 7, 1996).
- 2. Place text involving medical emergencies ("For information ... 1-800-858-7378.") in your "First Aid" section, which contains similar information.
- 3. Under "Storage and Disposal", follow the "Pesticide Disposal" and "Container Disposal" texts in the previous version of your label (February 7, 1996) as products with "DANGER" as a signal word automatically require the more extensive text.

Existing stocks

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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 <u>peacock,dan@epa.gov</u> (by E-Mail).

Sincerely yours,

DBN

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

Enclosures

1. Chemistry Review

2. Stamped Label

Location

Dan Peacock, USB Flash Drive 1.1, E:\1-7-2005 Backup\Dan's Office Work\A Flash Drive 1\Chlorophacinone\7173-75, new manufacturing process, 7-19-2005.wpd

ROZOL RODENTICIDE TECHNICAL POWDER

A RODENTICIDE FOR FORMULATING **OTHER REGISTERED PRODUCTS**

Active Ingredient: chlorophacinone 98.9%

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Fatal if swallowed, absorbed through skin or inhaled. Corrosive, causes skin burns. Causes irreversible eye damage. 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. Exposure to this product during pregnancy should be avoided. 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. 7173-75 EPA Est. No. 54555-WG-01

Manufactured for



3600 W. Elm Street Milwaukee, WI 53209 1-800-351-1476

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 advice.

Note to Physician or Veterinarian: Contains chlorophacinone, an anticoagulant. For humans or dogs that have ingested this product, or have obvious poisoning symptoms (bleeding) or lowered 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 preduct in a manner inconsistent with its labeling.

Only for formulation into a redenticide for the following

- Norway rats, roof rats and house mice:
- around squirrels.

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

For information on this product (including health concerns, medical emergencies or pesticide incidents) call the National Pesticide Information Center at 1-800-858-7378. (07005)

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 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.

ACCEPTET CONTENTS: in EPA DECIPATE UP to 50 pounds

JUL 2 1 2005

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

7/73-75