

71512-6

03/30/2004

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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:
71512-6

Date of Issuance:
MAR 30 2004
Date of Expiration:
MAR 30 2009

NOTICE OF PESTICIDE:
x Registration
____ Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:
Technical Fosthiazate

Name and Address of Registrant (include ZIP Code):

ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, Ohio 44077

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 section 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. Make the following label changes before you release the product for shipment:

- a. Add the phrase "EPA Registration Number 71512-6".
- b. Add the following text as first sentence in the Environmental Hazards paragraph:
"This pesticide is toxic to birds, mammals, and aquatic invertebrates."

(continued on page 2)

Signature of Approving Official:

Rita Kumar

Date:

MAR 30 2004

3. Submit the following data. These data requirements must be fulfilled in accordance with applicable provisions of the Good Laboratory Practice, as laid out in the Code of Federal Regulation (CFR) Volume 40, Part 160, and submitted in the format described in Pesticide Registration (PR) Notice 86-5:

Residue Chemistry

- a. The final report of the 3 year storage stability data for tomato.
- b. Data are required depicting the frozen storage stability of fosthiazate and ASC-67131 in a representative foliage commodity. A tobacco storage stability study will suffice.
- c. Analytical grade reference standards for the fosthiazate metabolite ASC-67131 must be submitted to the EPA standards repository.
- d. Additional data are required to characterize insoluble residues in 30 days after treatment (DAT) rotated wheat commodities.
- e. Storage stability data are required to support the additional analyses required on the 30-DAT wheat forage, straw, and grain.

Toxicology

- a. 28-day inhalation study in rats with fosthiazate is required, as there is concern for toxicity by the inhalation route following exposure on multiple days in a commercial setting. You may follow the protocol provided in OPPTS Guideline 870.3465 (90-day inhalation study) but cease exposure at 28 days.
- b. A developmental neurotoxicity (DNT) study in rats with comparative ChE measurements in adults and pups.

Occupational

A worker exposure study for activities involving contact with treated soil conducted concurrently with a soil residue dissipation study is needed to assess postapplication risk.

These data requirements are 875.2200 and 875.2400 in Group B-Postapplication Exposure Monitoring Test Guidelines in the Series 875-Occupational and Residential Exposure Test Guidelines.

4. Submit production information (gallons produced) for this product for the fiscal year in which this use is conditionally registered, in accordance with FIFRA section 29. The fiscal year begins October 1, and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year. This information should be submitted to:

Registration Support Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street SW
Washington D.C. 20460

5. This registration is time-limited and will terminate on March 30, 2009 unless renewed by EPA. Please note that, regardless of whether you satisfy all applicable conditions, this conditional registration will expire automatically on March 30, 2009. Sale and distribution of the subject product after March 30, 2009 will be illegal.

6. Prior to the end of a five year period after the initial registration, EPA will make a determination whether to renew or deny the registrations based on the available information. All information EPA is to consider in support of renewal of this registration must be submitted by December 30, 2008. Data submitted in support of this registration after that date will not be considered "available information" for purposes of a decision on renewal of this registration. If EPA does not make a determination by March 30, 2009, either to extend or deny this registration, EPA's inaction will constitute a denial of application for registration.

7. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(a). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,

Rita Kumar

Rita Kumar
Senior Regulatory Specialist
Insecticide Rodenticide Branch
Registration Division (7505C)

Enclosure



TECHNICAL FOSTHIAZATE

For Manufacturing Use Only

Active Ingredient:	Fosthiazate [(RS)-O-ethyl S-(1-methylpropyl) (2-oxo-3-thiazolidinyl) phosphonothioate].....	96.0%
Other Ingredients:	4.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING - AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See side panel for first aid and additional precautionary statements.

Read entire label carefully and use only as directed.

ISK Biosciences Corporation

7470 Auburn Road, Suite A
Concord, Ohio 44077

EPA Reg. No. 71512-_____

EPA Est. No. _____

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAR 30 2004
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
71512-6

Net Contents:

FIRST AID Technical Fosthiazate is an organophosphate nematicide.	
If swallowed	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor 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 for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Contains an organophosphate (fosthiazate) that inhibits cholinesterase. Probable mucosal damage may contraindicate the use of gastric lavage.</p> <p>Symptoms of cholinesterase inhibition may include salivation, sweating, headache, nausea, muscle twitching, tremors, poor coordination, blurred vision, tears, abdominal cramps, diarrhea, chest discomfort, and pinpoint pupils.</p> <p>Treat patient's symptoms immediately. Immediately administer oxygen, assist in respiration, suction secretions, and maintain airway. Immediately decontaminate skin and hair with soap and water. Persons attending to the victim should avoid direct contact with heavily contaminated clothing and vomitus, and wear rubber gloves while washing exposed or contaminated areas</p> <p>Consider taking venous blood for determination of blood cholinesterase activity (use heparin tube). Intravenously administer 2 to 4 mg Atropine at 5 to 10 minute intervals until signs of atropine toxicity appear (dry flushing of skin: tachycardia as high as 140 beats per minute). Some atropinization should be maintained for 48 hours. If severe poisoning, include: pralidoxime (2-PAM) in therapy. Administer 2-PAM intravenously at 1 mg over a 30 minute period via infusion of 100 cc to 250 cc. Avoid the use of opiates and phenothiazine. Carefully monitor patient because continued absorption of the poison may occur resulting in fatal relapse after initial improvement.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24-Hour Medical Emergency Assistance call 1-888-484-7546.</p> <p align="center">For Chemical Emergency Assistance, Spill, Leak, Fire or Accident, call CHEMTREC 1-800-424-9300.</p>	

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals**WARNING / AVISO**

May be fatal if swallowed or absorbed through the skin. Causes substantial but temporary eye damage. Harmful if inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing vapor. Wear goggles or face shield. Wear protective clothing and rubber gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. **Do not** discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Directions for Use

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

THIS PRODUCT IS FOR MANUFACTURING USE ONLY. It is only to be used in the formulation of US EPA registered end-use products, registered for use on the approved labeled crop, tomatoes.

Storage and Disposal

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

Pesticide Storage: Store in original container, in a secure, dry, cool, locked area where children, unauthorized persons, and animals cannot enter. **Do not** store in the same area with food or feed.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: **Do not** reuse empty container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Warranty and Limitation of Damages

Seller warrants to those persons lawfully acquiring title to this product that at the time of the first sale of this product by seller that this product conformed to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with Seller's directions under normal conditions of use, and Buyers and users of this product assume the risk of any use contrary to such directions. **SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.** In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.