

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) 1200 Pennslvania Ave., N.W. Washington, D.C. 20460

EPA Reg.

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71512-8

Term of Issuance: Conditional

Name of Pesticide Product:

Technical Fluazinam Fungicide

NOTICE OF PESTICIDE:

 $\underline{\mathbf{x}}$ Registration Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

ISK Biosciences Corporation 7470 Auburn Road, Suite A Concord, OH 44077-9703

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 (FIFRA).

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 Section 3(c)(7)(A) provided that you:

- Submit and/or cite all data required for registration 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:

Revise the EPA Registration Number to read, "EPA Reg. No. 71512-8."

- Submit the following health effects:
 - Guideline 870.3465 28-day inhalation toxicity study in rats. a. Due December 2003 (waiver requested).
 - b. Guideline 870.6300 - Developmental neurotoxicity study in rats (TGAI test material). Submit protocol for Agency approval by March 15, 2003 and submit the study two (2) years after approval of the protocol.

Signature of Approving Official:

Date:

Dennis M. McNeilly

Acting Product Manager (22)

Fungicide Branch, Registration Division (7505C)

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- c. Guideline 870.6200 Subchronic neurotoxicity screening battery in rats, conditionally required based on the results of the developmental neurotoxicity study. This study must be submitted, if required by the Agency, two (2) years after notification by the Agency.
- d. Guideline 860.1850 Processed commodity study on potatoes at a higher treatment level, 5X. Study was due July 2002, however the Agency is evaluating a 1/17/02 waiver request rebutting the need for this study. Due December 2003 (waiver requested).
- 4. Submit the following environmental fate and effects data:
 - a. Guideline 835.2410 (161-3) Photodegradation in soil. Due December 2003 (waiver requested).
 - b. Guideline 835.6100 (164-1) Terrestrial Field Dissipation. A concurrent storage stability study must be submitted Due December 2004 (waiver requested).
 - c. Guideline 850.1300 or 850.1400 (122-1 or 123-1) Tier I or Tier II Terrestrial Plant Growth, seedling emergence and vegetative vigor. Due December 2003.

Submit one copy of the revised final printed label for the record.

If the conditions enumerated above are not complied with, the egistration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Enclosure



TECHNICAL FLUAZINAM FUNGICIDE

ACCEPTED
with COMMENTS
In EPA Letter Dated

MAR - 5 2003

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

ACTIVE INGREDIENT: Fluazinam*

*3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-trifluoromethyl-2-pyridinamine (CA)

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alquien 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 additional precautionary and first aid statements.

Read entire label carefully and use only as directed.

For 24-Hour Emergency Medical Assistance call 1-888-484-7546. For Chemical Emergency: Spill, leak, fire, or accident, call CHEMTREC 1-800-424-9300.

ISK Biosciences Corporation 7470 Auburn Road, Suite A Concord, Ohio 44077 EPA Reg. No. 71512-EPA Est. No. 36990-FR-001

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Causes skin irritation. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Do not breathe dust. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Avoid contact with skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Do not take internally.

FIRST AID

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

IF INHALED: 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.

IF ON SKIN: 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 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-hour emergency medical assistance, call 1-888-484-7546.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

USER SAFETY RECOMMENDATIONS:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, aquatic invertebrates, and marine/estuarine organisms. 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.

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 crops, peanuts and potatoes.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

STORAGE: Store in original container, in a secured, dry place separate from other pesticides, fertilizer, food, and 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 the 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) and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants to those persons lawfully acquiring title to this product that at the time of first sale of this product by Seller that this product conformed to its chemical description and was 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. EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITTION OF DAMAGES, SELLER MAKES NO OTHER EXPESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MECHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO. In no event shall Seller's liability for any breach of warranty or guaranty exceed the purchase price of the product as to which a claim is made.

Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, including, but not limited to, incompatibility with other products unless otherwise expressly provided in Directions for Use of this product, weather conditions, cultural practices, moisture conditions or other environmental conditions outside of the ranges that are generally recognized as being conducive to good agricultural and/or horticultural practices.