

71512-8

1/31/2011

1044



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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

JAN 31 2011

Subject: Technical Fluazinam Fungicide; 71512-8
Decision 412724 (new use on apple)
Decision 411457 (new use on carrot)

Omega 500F; 71512-1
Decision 411455 - new use on carrot
Decision 412726 - new use on apple

Decision 411458 - Petition 9E7570 - carrot
Decision 412727 - Petition 9F7571 - apple

Dear Mr. Peplowski:

The labels referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to add apple and carrot, are acceptable provided the following conditions are satisfied:

Submit to the Agency the following conditional data or items by the stated due date:

1. As per the prior EPA acceptance letters dated 3/27/08 and 5/28/10 for these products, submit the conditional data listed in those letters (eg. immunotoxicity study by December 31, 2011, etc.). Also with the immunotoxicity or next conditional data to be submitted below, provide a status summary of what was required in prior EPA letters vs what was submitted with copies of the EPA letters.
2. By 1/31/2012, submit multiresidue method testing data for the regulated animal metabolites, AMPA and DAPA
3. By 1/31/2012 a study that analyzes samples from the lettuce field trial for residues of AMGT. The residue data must be supported by data depicting the frozen

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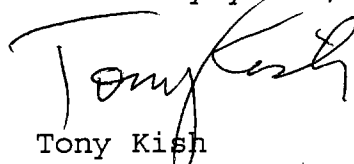
storage stability of AMGT in the lettuce samples. This requirement was in the EPA letter dated 5/28/2010 but no due date was listed.

EFED BASED REQUIRED CONDITIONAL DATA (see EFED review dated 1/28/2011 for details). Submit all by 1/31/2012

4. 835.6100, 835.6200 Environmental Chemistry Methods and ILVs for soil, water, and sediment.
5. 850.2100 - Avian acute oral toxicity using a passerine sp.
6. 850.1400 - Fish Early Life Stage for Estuarine/Marine Fish
7. 850.1350 - Aquatic invertebrate Life-Cycle Marine Study
8. 850.4150 - Tier I terrestrial plant growth- Veg. Vigor
9. 850.4400 - Tier I Aquatic Plant Growth- duckweed
10. 850.5400 - Tier I Aquatic Plant Growth - green algae, freshwater and marine diatom
11. 850.1790 - Whole Sediment Chronic Toxicity Invert.
12. LABEL CHANGES- Within 45 days submit two copies of the final printed labeling for each product and for the carrot restrictions on Omega 500F change '6 pints' to '4 pints' to match the HED review basis of 2.08 lb ai./season, and delete the duplicate lettuce section on page 9.

If you have any questions about this letter, please contact me at (703)308-9443 or kish.tony@epa.gov.

Sincerely yours,



Tony Kish
Product Manager (22)
Fungicide Branch
Registration Division (7504P)

Attachments: Label stamped "ACCEPTED WITH COMMENTS"



TECHNICAL FLUAZINAM FUNGICIDE

ACTIVE INGREDIENT: Fluazinam* 96.8%
 OTHER INGREDIENTS: 3.2%
 Total 100.0%

*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 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 additional precautionary statements.

Read entire label carefully and use only ~~AS DIRECTED~~ with COMMENTS

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

EPA Reg. No. 71512-8
 EPA Est. No. 83736-KOR-001

Made in Korea

Net Contents: 100 KG

AGREED.
 with COMMENTS
 JAN 3 4 2011
 JAN 3 1 2011
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 as amended, for the pesticide
 registered under EPA Reg. No.
 71512-8

| FIRST AID | |
|--|--|
| 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 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. |
| If on skin | <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 swallowed | <ul style="list-style-type: none"> • 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. | |
| NOTE TO PHYSICIAN | |
| Probable mucosal damage may contraindicate the use of gastric lavage. | |
| HOT LINE NUMBER | |
| For 24-Hour Medical Emergency Assistance Call 1-888-484-7546. | |
| For Chemical Emergency, Spill, Leak, Fire or Accident, Call CHEMTREC 1-800-424-9300. | |

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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.

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.

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 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: Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill, or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

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 following approved labeled crops: apples; edible-podded legume vegetables (Crop Subgroup 6A, except peas), succulent beans (Crop Subgroup 6B, except peas), dry beans (Crop Subgroup 6C, except peas and soybeans); brassica (cole) leafy vegetables (Crop Group 5), including turnip greens; bushberry (Crop Subgroup 13-07B); carrots; ginseng; lettuce; onion, bulb (Crop Subgroup 3-07A); peanuts; potatoes.

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. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.** To the extent consistent with applicable law, 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.

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