

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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

SEP 20 2011

Ms. Chris Dively, Regulatory Manager Certis USA LLC 9145 Guilford Road, Suite 175 Columbia, MD 21046

Re: First Food use - Isaria fumosorosea (formerly Paecilomyces fumosoroseus) Apopka Strain 97
PRIA Code B630 due September 20, 2011: Pesticide Petition 9F7665 Application Dated 12/17/09 (D425261)
Amendment Application of July 26, 2011: EPA Reg. No. 70051-17 (D452621) - Taxonomy

Dear Ms. Dively:

The amendments referred to above, submitted in connection with registration under FIFRA section 3(c)(5), are acceptable provided that you:

- 1. Submit and/or cite all data required for registration/registration review of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Provide analysis of five (5) batches when the pesticide is produced.
- 3. Submit final printed labels prior to shipment of the pesticide product. Refer to the A-79 enclosure for further description of final printed labeling.

During processing of these applications for registration amendment and for the first food use of this microbial active ingredient, the taxonomical classification has changed in accordance with the Agricultural Research Service Collection of Entomopathogenic Fungal (ARSEF) Cultures, January 24, 2011. The Agency has, therefore, processed these applications with the new name *Isaria fumosorosea* Apopka strain 97 per your request of July 26, 2011. The final rule for the Pesticide Petition 9F7665 approving the first food use will be published in the Federal Register shortly (see 40 CFR.180.1306).

The Confidential Statement of Formula dated 08/25/11 supersedes all previously approved basic formulations for the End-use Product EPA Reg. No. 70051-19.

The Fast Track Label amendment application, submitted August 10, 2011 for organic labeling of the End-use Product, EPA Reg. No. 70051-19, has been approved concurrently with this PRIA action.

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SB:7511P:70071-19:091711

CONCURRENCES								
SYMBOL	7511P	75118						
	Bacchus	aug						
	9/19/11	9/20/m						

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PFR-97[™] MUP

For Manufacturing Use Only in the Formulation of Insecticides for use on Crops and in Greenhouses and Nurseries,

ACTIVE INGREDIENT:

Isaria fumosorosea Apopka strain 97	7.0%*
(ATCC #20874) (formerly Paecilomyces fumosoroseus Apopka strain 97)	
OTHER INGREDIENTS:	93.0%
TOTAL:	100.0%

*Contains> 108 CFU/ml

KEEP OUT OF REACH OF CHILDREN CAUTION

Manufactured by: Certis USA, L.L.C. 9145 Guilford Road, Suite 175 Columbia, MD 21046

ACCEPTED

the pesticide registered under

EPA Reg. No.

SEP 20 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for

70051-17

EPA Reg. No. 70051-17 EPA Est. No. 70051-CA-001

NET CONTENTS: 30 kg.

LOT NO .:

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing vapor. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. For handling activities, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with prefix N-95, R-95, or P-95.

SEE SIDE/BACK PANEL FOR FIRST AID

FIRST AID

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 a poison control center or doctor. Do not give anything 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 product diluted in accordance with the directions for use gets on skin, medical attention is not required.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

ENVIRONMENTAL HAZARDS

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 in the formulation of insecticides for use in greenhouses and nurseries. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **Pesticide Storage:** Store in a cool, dry place away from direct sunlight. **Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

<u>Container Handling:</u> After each fermentation wash the inside of the fermenter, then sterilize it. Dispose of rinsate and sterilant on site, if allowed by state and local regulations, or at an approved waste disposal facility.

WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. To the extent required by law, Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

EXPIRATION DATE: USE WITHIN 30 DAYS AFTER OPENING

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