

70051-19

9/20/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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 Jan 25, 2010: EPA Reg. No. 70051-19 (D425259)
and Fast Track Label Amendment Application of August 10, 2011 – Organic Labeling (D453789)

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, has been approved concurrently with this PRIA action.

SB:7511P:70071-19:091911

CONCURRENCES

SYMBOL	▶ 7511P	▶ 7511P					
SURNAME	▶ Bacchus	▶ Cult					
DATE	▶ 09/19/11	▶ 9/20/11					

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PFR-97TM 20% WDG

MICROBIAL INSECTICIDE

FOR ORGANIC PRODUCTION

For control of insect and mite pests on vegetables, fruits, ornamental plants, and other crops grown outdoors, in greenhouses or other cover, or in nurseries.

ACTIVE INGREDIENT:

Isaria fumosorosea Apopka Strain 97 (ATCC 20874) 20%*
(formerly *Paecilomyces fumosoroseus*)

OTHER INGREDIENTS: 80%

TOTAL: 100%

*Contains 1 x 10⁹ CFU/g (equivalent to 1.4% technical grade active ingredient)

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Net Contents: 1 pound / 5 pounds / 66 pounds

MANUFACTURED BY:

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



EPA Reg. No. 70051-19
EPA Est. No. 70051-CA-001

Lot Number:

Expiration date:

FIRST AID

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. 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.

ACCEPTED

SEP 20 2011

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 70051-19

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION

Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment:

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Mixers, loaders, applicators and other handlers must 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.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS:

User should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For outdoor, non-greenhouse use, do not apply when bees are actively foraging. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Do not allow contamination of or discharge into lakes, streams, ponds, or public waterways. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Apply this product only as specified in the label.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

For entry into treated areas that are permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, early-entry workers must wear:

- Coveralls, over long sleeve shirt, long pants.
- Waterproof gloves.
- Shoes plus socks.
- 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.

GENERAL

Mode of Action: *Isaria fumosorosea*, the active component in PFR-97™, is a naturally occurring fungus which infects many insect and mite pests that occur on foliage and other above-ground plant, as well as many soil-dwelling pests. Under proper environmental conditions, spores of the fungus attach to and penetrate the cuticle of the target pest. The fungus grows inside the insect causing its death. The fungus then emerges from the dead insect to release more spores to infect other insects.

Monitoring of pest pressure is critical to the effective use of PFR-97™. Efficacy results from germination and growth of the beneficial fungus over several days, so applications should start before pest numbers have reached crisis levels. PFR-97™ is most effective when application is initiated just before or at the first signs that target pests are present.

Optimal Environmental Conditions: PFR-97™ is most effective when relative humidity is 80% or higher for 8-10 hours. Watering walkways, operating sprinklers, misters or cooling pads will increase humidity levels. Application at times of low air movement and moderate temperature (70-90°F) will reduce drying conditions and maintain the effectiveness of the fungus.

Compatibility: PFR-97™ can be used in conjunction with most other pesticides and is compatible with beneficial arthropods. It can be mixed with copper-based fungicides without impacting performance. However, do not mix with other fungicides, or apply within 5 days of fungicide applications other than copper. PFR-97™ can be mixed with most insecticides for which such mixing is permitted by the label, in accordance with the most restrictive label limitations and precautions of all products used in the mixture. Do not exceed any label dosage rates. However, physical compatibility should be checked by mixing small quantities of each tank mix partner in correct proportions ("jar test") prior to the first time such a mixture is attempted.

DIRECTIONS FOR USE

GREENHOUSES (AND OTHER COVER), NURSERIES, AND LANDSCAPES:

For use on ornamental plants (foliage and flowering plants, cut flowers, greens, shrubs), vegetables, melons, strawberries, and other food crops (including transplants), herbs and spices, nursery stock (including bearing and nonbearing fruit trees and grapevines).

Mix PFR-97™ in clean water at a rate of **14 to 28 ounces of product per 100 gallons** of water. Agitate for 20-30 minutes before application to ensure a well-dispersed suspension.

Product may be premixed with 5 gallons of water per pound of PFR-97™ and agitated continuously for 20-30 minutes to completely suspend and hydrate the spores. Dilute this suspension to the final volume for application. This suspension can also be metered (injected) into a chemigation system without further dilution if desired.

Maintain agitation during application. Apply the suspension using one of the methods below, depending on target pest and application site (foliar or soil).

Foliar (spray) application	For control of whiteflies (<i>Bemisia</i> and <i>Trialeuroides</i> spp.), aphids, thrips, spider mites, leafminers (<i>Liriomyza</i> spp.), citrus leafminers, mealybugs, psyllids, and plant bugs (<i>Lygus</i> spp.)	<p>Apply to plants using pressurized spray equipment (such as backpack sprayer, tractor-mounted spray boom, hand-held spray gun or wand) mist-blower, cold fogger, electrostatic, or other applicator.</p> <p>Spray sufficient volume to achieve thorough coverage of leaves, flowers, fruit, and other above-ground plant parts with minimal run-off.</p> <p>Repeat applications at 3-10 day intervals over 2-3 weeks or as needed to maintain control. Frequent application may be required under dry conditions, during periods of increased pest build-up or reproduction, or rapid host plant growth. More frequent application at low rate (e.g. 14 - 16 oz/100 gal every 3 to 5 days) is more likely to improve results than using higher rates at low frequency (e.g. 28 oz/100 gal every 10 days).</p> <p>Use higher rates (24 - 28 oz/100 gal) when applying to large or dense plant canopies to ensure complete coverage.</p>
Soil application	To control black vine weevil and other root weevils, crown weevils, thrips pupae, grape phylloxera, rootworms, wireworms, Coleoptera grubs and larvae, Lepidoptera caterpillars and larvae, symphylans	<p><i>Drench application:</i> Apply as a drench of 4 fluid ounces per pot for pots up to 6" diameter, or 8 fl. oz. for pots up to 12" diameter. For pots larger than 12" in diameter, either apply 1 pint of drench per pot.</p> <p><i>Soil surface spray:</i> Spray the suspension on the soil surface. If targeting root-feeding insects, follow immediately by sufficient water from a watering can, hose, or overhead sprinkler irrigation to carry the spores into the root zone.</p> <p><i>Chemigation:</i> PFR-97™ may also be applied through drip or trickle chemigation. Mix in water as described above and apply using standard injection equipment to introduce into the irrigation lines. See the "Chemigation Bulletin" below for additional information.</p> <p><i>Soil injection against root-feeding insects:</i> The PFR-97™ suspension may be injected directly into the soil surrounding roots using pressurized shank or other injector. Inject in sufficient volume of water to wet the entire root zone.</p>

FOR ALL OUTDOOR-GROWN FOOD, NON-FOOD, AND SEED CROPS, including fruiting and leafy vegetables, melons and other cucurbits, potatoes, beans, citrus, pome fruits, stone fruits, tree nuts, grapes, herbs, spices, strawberries, sweet corn, cut flowers and other field-grown ornamental plants.

Apply **1 to 2 pounds of PFR-97™ per acre** in sufficient volume of water to attain thorough coverage of foliage, flowers, and fruit with minimal run-off.

Mix the required amount of product in clean water and agitate the spray mix for 20-30 minutes before application to ensure a well-dispersed suspension.

For low-volume application, premix with at least 2 gallons of water per pound of PFR-97™ and agitated continuously for 20-30 minutes to completely suspend and hydrate the spores. Dilute this suspension to the final volume for application. This suspension can also be metered (injected) into a chemigation system without further dilution if desired.

Maintain agitation during application. Apply the suspension using one of the methods below, depending on target pest and application site (foliar or soil).

Foliar (spray) application	For control of whiteflies (<i>Bemisia</i> and <i>Trialeuroides</i> spp.), aphids, thrips, spider mites, broad mites, rust mites, leafminers (<i>Liriomyza</i> spp.), citrus leafminers, mealybugs, psyllids, and plant bugs (<i>Lygus</i> spp.)	<p>Apply with pressurized spray equipment (such as backpack sprayer, tractor-mounted spray boom, hand-held spray gun or wand), air-assisted orchard sprayer, mist-blower, cold fogger, electrostatic, or other applicator.</p> <p>Repeat applications at 3-10 day intervals as needed to maintain control. Frequent application may be required under dry conditions, during periods of increased pest build-up or reproduction, or rapid host plant growth.</p> <p>More frequent application at low rate (1 lb/acre every 3 to 5 days, for example) is more likely to improve results than using higher rates at low frequency (such as 2 lb/acre every 10 days).</p> <p>Use higher rates (2 lb/acre) when applying to large or dense plant canopies to ensure complete coverage.</p>
Soil application	To control black vine and other root weevils, thrips pupae, rootworms, wireworms, Coleoptera grubs and larvae, Japanese beetle; Lepidoptera caterpillars and larvae, grape phylloxera, symphylans.	<p><i>Soil drench:</i> Apply the PFR-97™ suspension as a 4" to 8" banded drench or coarse spray onto the soil surface in the seed furrow, or as a broadcast spray or drench onto the planting bed or at the base of the tree or vine. To control insects beneath the soil surface, incorporate with overhead sprinkler irrigation or light cultivation.</p> <p><i>Chemigation:</i> PFR-97™ may also be applied through drip, trickle, and overhead or microjet sprinkler chemigation. Mix in water as described above and apply using standard injection equipment to introduce into the irrigation lines. See the "Chemigation Bulletin" below for additional information.</p> <p><i>Soil injection against root-feeding insects:</i> The PFR-97™ suspension may be injected directly into the soil surrounding roots using pressurized shank or other injector. Inject in sufficient volume of water to wet the entire root zone.</p>

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STORAGE AND DISPOSAL

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

Pesticide Storage: Keep unopened product refrigerated (40-50°F) and dry. Seal out moisture from unused material by closing the bag tightly after squeezing out excess air. Keep unused product refrigerated in the original package and use within 30 days after opening.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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.

CHEMIGATION BULLETIN

GENERAL INFORMATION:

Apply this product through pressurized irrigation systems such as drip (trickle) irrigation (including micro-irrigation through spaghetti tubes or individual tubes) or sprinkler irrigation (impact or microsprinklers, overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems); through gravity flow systems such as flood, furrow, or border irrigation; or with hand-held calibrated irrigation equipment (such as a hand-held wand with injector). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

DRIP (TRICKLE) AND MICRO-IRRIGATION CHEMIGATION:

1. The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

SPRINKLER CHEMIGATION:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

- 5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
- 8. Do not apply when wind speed favors drift beyond the area intended for treatment.

FLOOD, FURROW, OR BORDER CHEMIGATION:

- 1. Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential of water source contamination from the backflow if water flow stops.
- 2. Systems utilizing a pressurized water and pesticide injection system must meet the following requirements:
 - a. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
 - b. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
 - c. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
 - d. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
 - e. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
 - f. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 3. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.