

***Paecilomyces fumosoroseus* Apopka Strain 97 (115002) Technical Document**

Issued: October 1998

Reason for Issuance: New Active Ingredient

I. Description of the Microbial

Generic Name(s) of the Active Ingredient(s): *Paecilomyces fumosoroseus* Apopka Strain 97

OPP Chemical Codes: 115002

Year of Initial Registration: 1998

Pesticide Type: Microbial Insecticide

U.S. and Foreign Producers:

Thermo Trilogy Corporation
7500 Grace Drive
Columbia, MD 21044

II. Use Sites, Application Timing & Target Pests

- **Target Pests:** Whiteflies, thrips, spider mites and aphids
- **Registered Uses:** A Manufacturing Use Product, PFR-97TM MUP, for formulation into an End-use Product, PFR-97TM 20% WDG for use in greenhouses and interiorscapes.
- **Application Timing:** Rates vary from 14 to 28 ounces of the beads in 100 gallons of water to reach a minimum concentration of 1×10^6 cfu/ml. Applications should be repeated at least once per week for four weeks. If insect pressure outside the greenhouse is high, the label recommends continued weekly applications.
- **Use Practice Limitations:** Do not apply at temperatures above 30C. High relative humidity (>90%) must be achieved and maintained for 12 hours to initiate product activity.

III. Food Clearances /Tolerances

A numeric tolerance or exemption from the requirement of a tolerance is not needed for this registration of the active ingredient on non-food crops in greenhouses and interiorscapes. The registrant has not repropoed the earlier request for the exemption from the requirement of a tolerance on all food commodities as required by the Food Quality

Protection Act of 1996. Additional data will be required to register more extensive uses of *Paecilomyces fumosoroseus* Apopka strain 97.

IV. Science Findings

A. Product Identity

The fungal active ingredient, *Paecilomyces fumosoroseus* Apopka strain 97, has been reported to be originally isolated in 1986 from a mealy bug in a greenhouse in Apopka, FL. The pure culture was identified in 1988 and deposited at the American Type Culture Collection (ATCC # 20874). *Paecilomyces* species occurs naturally in populations of infected and dead insects and randomly in soils around the world. The active ingredient can be cultured readily on various culture media and exists in several morphological stages, depending upon the culture medium. On solid medium, conidiophores, conidia and mycelia are predominant while submerged culture produces blastospores and mycelia.

B. Classification

The Agency has classified *Paecilomyces fumosoroseus* Apopka strain 97 as an active ingredient for use in microbial pesticides. This fungal strain is an entomopathogenic fungus of many orders of insects.

C. Toxicology

The following toxicity studies were submitted and reviewed for compliance with the requirements for registration:

a. Acute Toxicology

Guideline No. 152-30 Acute oral toxicity/pathogenicity: Toxicity Category IV.

Guideline No.152-31 Acute dermal toxicity: Toxicity Category III.

Guideline No.152-32 Acute pulmonary toxicity/pathogenicity: Toxicity Category IV.

Guideline No.152-33 Intraperitoneal injection toxicity/pathogenicity: Toxicity Category IV.

Guideline No.152-34 Primary dermal irritation: Toxicity Category IV.

Guideline Primary eye irritation: Toxicity Category IV.

No.152-35

Guideline
No.152-36 Dermal sensitization: Supplementary.

Guideline
No.152-37 Hyper-sensitivity incidents: Published literature pertaining to incidents involving strains of *Paecilomyces* have been evaluated and data submitted to demonstrate incident data do not involve PFR-97 Apopka strain. Incident data must be reported in a timely manner.

Guideline
No.152-49 Mutagenicity Testing (Ames Assay): Supplementary.

- b. Although the secondary metabolites called "beauveralides" were detected during the manufacturing process, they are not of human health concern, based on evaluation of the data submitted.

- c. **Subchronic, Chronic Toxicity and Oncogenicity**

Guidelines 152-40 through 152-53: Tier II tests and Tier III tests were not required since survival, replication, infectivity, toxicity, or persistence of the microbial agent was not observed in the test animals treated in the Tier I acute oral infectivity test.

D. Food Quality Protection Act Requirements

Safety factors from the Food Quality Protection Act (FQPA) were evaluated. These factors included available information concerning the aggregate exposure levels of consumers and users to the pesticide residue and to other related substances. On the basis of the data submitted, the ubiquitous nature of the organism in soils around the world, and the limited use patterns, the Agency has determined that there is a reasonable certainty of no harm to the general population, infants, children, and the environment from exposure to this microbial pesticide.

E. Human Health Effects

1. Dietary Exposure

**Acute and Chronic Dietary Risks for Sensitive Subpopulations,
Particularly Infants and Children**

This registration allows use only on non-food crops in greenhouses and interiorscapes. The registrant has not pursued the original request for an exemption from the requirements of a tolerance on all food/feed commodities. The proposed greenhouse, non-food use pattern is not likely to result in dietary exposure or residues on food/feed commodities. Therefore, potential risk from the consumption of treated commodities is not likely to occur for the general population, infants or children.

2. **Dose Response**

No toxicological endpoints are identified.

3. **Common Mode of Action**

There is no other registered product containing *Paecilomyces fumosoroseus* Apopka Strain 97 or any other strains of the microbial active ingredient. Data submitted indicate that fungal metabolites of concern such as aflatoxins and beauvericins are not produced by PFR-97™. While beauveralides may be a common secondary metabolite with other registered active ingredients, the Agency is not aware of a common mechanism of action among the metabolites from the various registered products producing this metabolite.

4. **Effects on the Immune and Endocrine Systems**

The Agency is not requiring information on the endocrine effects of this microbial pesticide at this time. There is no known metabolite that acts as an "endocrine disrupter" produced by this microorganism. As expected from non-pathogenic microorganism, the submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) indicate that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Therefore, no adverse effects to the endocrine or immune systems are known or expected.

5. **Occupational and Residential Exposure**

a. **Worker Exposure**

Based on the application methods listed on the product label, the potential for dermal, eye and inhalation exposures for pesticide handlers exists. Because of the lack of significant mammalian toxicity, worker exposure data (i.e., occupational exposure data) to

the active ingredient is not required at this time. It is the Agency's opinion that these occupational exposures and subsequent risks are negligible because this strain of the organism has been determined not to be pathogenic to humans and animals. The risks are expected to be minimal based on evaluations of submitted Tier I acute toxicity tests.

Risks from potential occupational exposure will be mitigated through the use of the following appropriate Personal Protective Equipment: long sleeved shirt, long pants, shoes, and socks as well as a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or equivalent NIOSH dust/mist filtering respirator bearing the prefix N-95, P-95 or R-95. Agricultural workers wearing the appropriate PPE can enter treated areas during the Restricted Entry Interval (REI) of 4 hours for PFR-97™ 20% WDG.

b. Residential, School and Day Care Exposure and Risk Characterization

The use sites are listed as either greenhouses or interiorscapes where the pesticide is intended to control whiteflies, aphids, thrips and spider mites on non-food crops. Nondietary exposure to these sites, where children are present, could occur, but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted studies.

6. Drinking Water Exposure and Risk Characterization

The microorganism *Paecilomyces fumosoroseus* is ubiquitous in many soils throughout the world. *P. fumosoroseus* is not known as an aquatic microorganism, and therefore is not expected to proliferate in aquatic habitats. Moreover, *Paecilomyces fumosoroseus* is not considered to be a risk to drinking water. Accordingly, drinking water is not being screened for *Paecilomyces fumosoroseus* as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *Paecilomyces fumosoroseus* through drinking water. Therefore, the potential of significant transfer of residues of this microbial pesticide to drinking water is minimal to nonexistent.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Dermal exposure via the skin would be the *primary* route of exposure for mixer/loader applicators. *Paecilomyces fumosoroseus* Apopka strain 97 is not known to be a human pathogen nor is it known to produce metabolites that are dermally absorbed. Based on the demonstrated lack of adverse effects in the intravenous study, it is the Agency's opinion that even cut skin should not pose a risk to health via entry of absorbed. *Paecilomyces fumosoroseus* Apopka strain 97 into the body. Inhalation exposure to workers and handlers is likely to be minimal.

he potential for aggregate exposure to this active ingredient is believed to be minimal to nonexistent for the intended uses. Dietary exposure to adult humans, infants and children is not likely to be of concern because the pesticide is to be applied to non-food crops in greenhouses and interiorscapes. The microorganism is ubiquitous in soils, is not known as an aquatic fungus and is not to be directly applied to water.

In summary, the potential aggregate exposure, derived from dermal and inhalation exposure via mixing, loading and applying *Paecilomyces fumosoroseus* Apopka strain 97 and the dietary exposure from drinking water containing this organism should fall well below the currently tested microbial safety levels.

8. Cumulative Effects

There is no other registered product containing *Paecilomyces fumosoroseus* Apopka Strain 97 or any other strains of the microbial active ingredient. Data submitted indicate that the fungal metabolites of concern such as aflatoxins and beauvericins are not produced by PFR-97™. While beauvaralides may be a common secondary metabolite with other registered active ingredients, the Agency is not aware of a common mechanism of action among the metabolites from the various registered products producing this metabolite. The data available show that the metabolite do not pose a hazard to human health and, therefore, there are no concerns about cumulative effects of this strain of the microbial active ingredient.

F. Ecological Effects

Guideline No.	Study	Status, Classification & Comments
154-16	Avian oral toxicity/ pathogenicity	SUPPLEMENTAL. MPCA was practically nontoxic to northern bobwhite. No reports of avian toxicity/ pathogenicity or incidents. The <i>in vitro</i>

		growth temperatures of the intended MPCA are too low to allow growth and development of PFR-97 Apopka strain in birds. No further avian testing required for this use, nor for outdoor terrestrial use patterns.
154-19	Fresh water fish toxicity/ pathogenicity	Data requirement waived for the limited use pattern.
154-20	Fresh water invertebrate toxicity/pathogenicity	Data requirement waived for the limited use pattern.
154-22	Nontarget plant toxicity/pathogenicity	Toxicity/infectivity endpoints unknown. Limited reports in the public literature of pathogenicity to outdoor terrestrial plants to date. Data are not required for this limited use pattern.
154-23	Nontarget insect toxicity/pathogenicity	The MPCA is a well-documented insect pathogen; however toxicity/pathogenicity endpoints are unknown for most insect species. Risk mitigation label language required for all labels.
154-24	Honeybee toxicity/pathogenicity	Toxicity/infectivity endpoints unknown. Studies are not required for this limited use in greenhouses.

G. Environmental Fate and Groundwater Data

The pesticide is not to be directly applied to water and the proposed uses limit exposure to the environment. Environmental fate data are required when toxicity/pathogenicity testing shows adverse effects. Such data will be required if adverse effects are observed from Tier I tests and if more extensive use patterns are sought.

V. Labeling Requirements

It is the Agency's position that the labeling for products containing *Paecilomyces fumosoroseus* Apopka Strain 97 must comply with the current pesticide labeling requirements.

0. Manufacturing Use Product Labeling:

Precautionary Statements must include the requirement for workers, when handling this product, to wear a dust-mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or equivalent dust-mist filtering respirator, meeting NIOSH standards, with prefix N-95, R-95 or P-95.

Directions for Use statements must include the following:

"This product is for manufacturing use only in the formulation of insecticides for greenhouses and interiorscapes".

Environmental Hazard Statement:

"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."

1. End-use Product Environmental Hazards Labeling

Provided the following statements are placed in the environmental hazards statement, the risk of exposure to *Paecilomyces fumosoroseus* Apopka Strain 97 is minimal to nonexistent to nontarget organisms including endangered species.

The following statements are required as Environmental Hazards labeling for the end-use product:

"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 rinsate or equipment washwaters."

"The potential effects of this product on non-target beneficial insects that may be used in greenhouse Integrated Pest Management Programs are not known."

VI. Summary of Data Gaps

0. The registrant must provide appropriate final printed labels to comply with Agency requirements prior to release and shipment of products containing this active ingredient.
1. If the registrant wishes to expand uses to food commodities, further ecological effects and environmental fate and effects data regarding aquatic and terrestrial non-target organisms, including honeybee and non-target insects, are required.

VII. Additional Contact Information

[Ombudsman, Biopesticides and Pollution Prevention Division](#) (7511P)
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