BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Paecilomyces lilacinus strain 251
(PC Code 028826)
6/7/05

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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I. EXECUTIVE SUMMARY

Paecilomyces lilacinus is a naturally occurring fungus commonly found in soils. It produces distinctive lilac-colored colonies. Unlike many other *Paecilomyces lilacinus* strains, *P. lilacinus* strain 251 does not produce mycotoxins or paecilotoxins, as shown by chromatographic analyses and lack of toxicity to mammals and other organisms. In laboratory studies, it grows optimally at 21-27 degrees C, and does not grow or survive above 36 degrees C. *This strain was isolated from infected nematode eggs in the Philippines, and correctly described taxonomically in 1974. As a pesticide active ingredient, P. lilacinus* strain 251 *will be used to control plant root nematodes on many food and non-food crops. It acts by infecting eggs, juveniles, and adult females of various plant pathogenic nematodes including Meloidogyne* spp. (root knot nematodes); *Radopholus similis* (burrowing nematode); *Heterodera* spp. and *Globodera* spp. (cyst nematodes); *Pratylenchus* spp. (root lesion nematodes).

Toxicology, Human Exposure, and Risks

Evaluations of mammalian toxicology data comply with the Food Quality Protection Act (FQPA) of 1996, and are sufficient to support the conditional registration of this microbe as a nematicide. Based on the absence of toxic effects at the maximum doses tested, the active ingredient is categorized as Toxicity Category III for acute oral and acute dermal toxicity. It is classified as Toxicity Category IV for acute dermal irritation and acute eye irritation. No adverse effects were seen in a toxicity/pathogenicity pulmonary study, and a comparable intraperitoneal study is categorized as supplemental. The active ingredient is not a dermal sensitizer. A waiver was granted for an immune study. [Section III.B.1]

Food Tolerances

This is the first proposed U.S. registration for *Paecilomyces lilacinus* strain 251. For this Section 3(c)(7)(C) conditional registration, a permanent exemption from the requirement of a tolerance *on all food commodities is being established.*

FQPA Considerations

The Agency has considered Paecilomyces lilacinus strain 251 *in light of the safety factors of the Food Quality Protection Act (FQPA) of 1996, and has made a determination of reasonable certainty of no harm to the U.S. population in general, and to infants and children in particular. The fungus is normally found in the environment, and its use as a pesticide active ingredient is not expected to increase exposure above background levels.*

In this assessment, no acute, subchronic, chronic, immune, endocrine, or nondietary exposure issues have been identified that may have any incremental adverse effects on infants, children, or the general U.S. population. Based on the toxicology studies, a safety factor is not required for residues of *Paecilomyces lilacinus* strain 251.

Dietary exposure and risk are not likely to increase as a result of use of *Paecilomyces lilacinus* strain 251 *in pesticide products.* Potential risks via exposure to drinking water or runoff will be minimal because the fungus moves through soil slowly and attaches to plant root nematodes. Inhalation exposure is unlikely because the product is applied directly to soil as a liquid preparation. *Furthermore, there is no indication that the fungus shares any common mechanisms of toxicity with other active ingredients to affect cumulative exposure and risk to this pesticide [Section III.B.8]. Thus, the proposed uses of P. lilacinus* strain 251 *as a pesticide are not likely to cause any incremental risk to infants, children, or adults.*

Occupational and Residential Exposure and Risk

Potential exposure of workers and pesticide handlers to Paecilomyces lilacinus strain 251 *is not expected to pose any undue risk. Worker exposure and risk are minimized by the requirement that workers use appropriate Personal Protective Equipment (PPE) and by a Restricted-Entry Interval (REI) of 4 hours.* Residential exposure and risk are not expected because the active ingredient is not toxic or pathogenic to mammals, and is not approved for residential use. *[Section III.B.4].*

Ecological and Environmental Exposure and Risks

No adverse effects are expected at field concentrations of the active ingredient, based on studies on non-target organisms including insects, beneficial nematodes, rainbow trout, *Daphnia magna*, predatory mites, and single cell green algae.

Waivers were granted for toxicity studies on birds, honeybees, wild mammals, and estuarine vertebrates and invertebrates, for the following reasons. Bird and honeybee exposures will be very low; the microbe does not grow at bird or mammalian body temperatures; several hymenopteran species were not harmed when tested with *Paecilomyces lilacinus* strain 251; no adverse effects were seen in laboratory mammalian studies; data from freshwater organisms are sufficient to cover estuarine organisms.

Based on the expected field concentrations and the general lack of toxicity seen in non-target organisms, no increased risks are expected from pesticidal use of *Paecilomyces lilacinus* strain 251 according to label directions.

D. Data Requirements

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed these submissions to ensure they comply with Agency data requirements for granting this conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). For *Paecilomyces lilacinus* strain 251*, the product identity and analysis data, as well as the information submitted for acute mammalian toxicology and ecological effects are sufficient to allow the proposed use patterns. Based on evaluations of the submitted data and information, as discussed in this document, the Agency foresees no unreasonable adverse effects to human health or the environment from the use of* *Paecilomyces lilacinus* strain 251 as labeled. Under the terms of the conditional registration, granted on March 30, 2005, the registrant is required to submit the following information.

The registrant must submit an acceptable Intraperitoneal Toxicity/Pathogenicity Study, (OPPTS guideline # 885.3200) to complete the pathogenicity requirements for an unconditional registration. In the submitted intraperitoneal injection study, MRID # 460042-01, uncertainty in the test dose caused the study to be considered supplemental rather than acceptable. The Agency generally requires two pathogenicity studies to grant a full registration to a live microbial active ingredient. The registrant has submitted one acceptable pathogenicity study; therefore, a second one is needed.

II. OVERVIEW

A. Product Overview

- **Microbial Pesticide Name:** *Paecilomyces lilacinus* strain 251
- **Depository Number**: AGAL 89/030550. (Australia)
- **Trade Name(s):** MeloCon WG; Paecil; BioACT WG; Nemachek
- **OPP Chemical Code**: PC Code 028826
- **Basic Manufacturer:** Prophyta Biologischer Pflanzenschutz GmbH (Germany)
- **US Agent:** WF Stoneman Co. LLC, PO Box 465, McFarland, WI 53558-0465

B. Use Profile

Type of Pesticide: Microbial nematicide

Mechanism of action: *P. lilacinus* strain 251 parasitizes and subsequently kills eggs, juveniles, and adult females of various plant parasitic nematodes.

Use Sites:

Terrestrial Food: Vegetables, bananas, pineapples, grapevines, strawberries, and citrus, peach, and nut trees.

Terrestrial Non-Food: Ornamentals, tobacco, turf

Target Pests for Active Ingredient: Plant parasitic nematodes in soil. Examples include *Meloidogyne* spp. (Root knot nematodes); *Radopholus similis* (Burrowing nematode); *Heterodera* spp. and *Globodera* spp. (Cyst nematodes); *Pratylenchus* spp. (Root lesion nematodes); *Rotylenchulus reniformis* (Reniform Nematode); *Nacobbus* spp. (False Root-knot Nematodes).

Formulation Type: End product is formulated as a water dispersible granule containing 6.0% by weight of active ingredient.

Method and Rates of Application:

Timing: Varies with crop. In general, 14 days pre-plant; just before planting, 6 weeks after planting, repeat every 6 weeks to 4 months
Rates of Application: Maximum application: 0.24 pounds ai per acre; 4 pounds of product per acre.

Method of Application: Apply fungal suspension to agricultural soil through drip irrigation, or water in the suspension around base of each plant. If neither of these methods is possible, spray the soil surface around the base of each plant, and drench in afterwards using the irrigation system.

C. Estimated Usage

Because this is a new active ingredient, it is not possible to estimate usage.

D. Data Requirements

Submitted data satisfy the requirements for a conditional registration. To qualify for an unconditional registration, the registrant must submit a confirmatory Intraperitoneal Injection Study, OPPTS guideline # 885.3200.

E. Regulatory History

Prophyta Biologischer Pflanzenschutz GmbH, Germany (US Agent: WF Stoneman Co. LLC, Box 465, McFarland, WI 53558-0465) submitted an application for registration of MeloCon WG, a product containing the new active ingredient, *Paecilomyces lilacinus* strain 251. This application was announced in the Federal Register on November 14, 2003 (68 FR 64623-5) (FRL-7331-8). The company also filed a petition to establish a tolerance

exemption for *Paecilomyces lilacinus* strain 251 when used on crops; on November 7, 2003 (68 FR 63088-92) (FRL 7331-7), the Federal Register announced receipt of the petition. The microbe is approved for pesticide use in South Africa, New Caledonia, and Bulgaria, and is under consideration for approval by the European Union.

This document contains data supporting a conditional registration for MeloCon WG as a microbial nematicide product. A permanent exemption from the requirement of a tolerance for *Paecilomyces lilacinus* strain 251 was published in the Federal Register on April 13, 2005 (70 FR 19278-83) (FRL-7708-4)

On March 30, 2005, MeloCon WG (EPA Reg # 72444-2) was granted a conditional registration. The registration was announced in the Federal Register on June 3, 2005 (70 FR 32612-14) (FRL-7715-9).

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

1. Microbe Characteristics:

The agency has approved the fungus *Paecilomyces lilacinus* strain 251 as a microbial pesticide active ingredient. MeloCon WG contains living conidia of *P. lilacinus* strain 251 as the active ingredient. This strain grows optimally at 21-27 degrees C, and does not grow or survive above 36 degrees C. Unlike many other *Paecilomyces lilacinus* strains, *P. lilacinus* strain 251 does not produce mycotoxins or paecilotoxins, as shown by laboratory analyses and lack of toxicity to mammals and other organisms.

2. Product Chemistry

Product chemistry data that support the registration of *P. lilacinus* strain 251 are summarized in Table 1.

Table 1. Physical and Chemical Properties for *P. lilacinus* strain 251

OPPTS GUIDELINE Number	STUDY	RESULT	MRID#
885.1100	Product Identity and Disclosure of Ingredients	Acceptable	463056-01
885.1200	Manufacturing Process	Acceptable	463056-01
885.1300	Formation of Unintentional Ingredients	Acceptable	463056-01
885.1400	Analysis of Samples	Acceptable	463056-01
885.1500	Certification of Limits	Acceptable	463056-01
830.6302, 830.6303, 830.6304, 830.7000, 885.7300	Product Chemistry	Acceptable	463056-01
Non- guideline study	Influence of Temperature on Germination of Spores	Spores survive 5 days at 36^0 C, and die at 37^0 C. Optimum growth occurs 21^0 to 27^0 C.	460292-01
Non-guideline study	Presence of Paecilotoxins	No evidence of known toxins was seen in chromatographic studies.	462832-03

B. Human Risk Assessment

There is a reasonable certainty that no harm will result from exposure to *P. lilacinus* strain 251. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

1. Human Toxicity Assessment

a. Acute Toxicity

All required mammalian toxicology/pathogenicity study results have been submitted or waived, and adequately satisfy data requirements to support registration. Details are provided below.

Table 2. Toxicity Data Requirements

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
870.1100	Acute Oral Toxicity	LD_{50} oral toxicity of *P. lilacinus* strain 251 in rats is > 2000 mg/kg. **Toxicity Category III**, ACCEPTABLE;	462832-01
870.1200	Acute Dermal Toxicity	LD_{50} acute dermal toxicity of *P. lilacinus* strain 251 in rats is > 2000 mg/kg mg/kg. **Toxicity Category III** ACCEPTABLE	462832-02
885.3150	Acute Pulmonary Toxicity/ Pathogenicity (one intratracheal dose)	No signs of toxicity or pathogenicity were detected. ACCEPTABLE.	459418-04
885.3200	Acute Intraperitoneal Toxicity/Pathogenicity	SUPPLEMENTARY (Dose of test material not directly determined)	460042-01
870.2400	Primary Eye Irritation	No signs of irritation in rabbits. **Toxicity Category IV.** ACCEPTABLE.	460042-07
870.2500	Primary Dermal Irritation	No signs of irritation in rabbits. **Toxicity Category IV.** ACCEPTABLE	459418-06

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
870.2600	Delayed Contact Hypersensitivity in Guinea Pigs	Not a dermal sensitizer. ACCEPTABLE.	459418-07
885.3400	Reporting Hypersensitivity Incidents	To be reported if any incidents occur	No incidents reported
880.3800	Immune Response	No evidence of adverse effects on immune response in various rodent studies.	WAIVED

Acute Oral Toxicity - Rat (870.1100; MRID 462832-01)

Methods: Five male and five female rats were dosed with the test material (2000 mg/kg body weight), administered as a 10% w/w suspension in water by gavage. The test animals were observed for clinical signs of toxicity post-dosing and once daily for 14 days. All animals were necropsied and organ weights were recorded.
Results: All animals survived the study. All animals gained weight during the study. No abnormal clinical signs and no gross abnormalities were noted. The oral LD_{50} for males, females, and combined was greater than 2000 mg/kg. This places Bioact *(Paecilomyces lilacinus*) batch No. 90228 in TOXICITY CATEGORY III. for oral toxicity.
Classification: ACCEPTABLE.

Acute Dermal Toxicity-Rat, (870.1200; MRID 462832-02)

Methods: The test material (2000 mg/kg body weight/animal) was applied to five male and five female rats on the clipped dorsal trunk in an area of 36 cm^2. The application site was covered with a 7.5 x 7.5 cm gauze patch held in place with hypoallergenic tape. The coverings were removed after 24 hours and the excess test material was removed with moistened gauze. The test animals were observed for clinical signs of toxicity frequently after treatment and once daily thereafter for 14 days. The rats were euthanized on day 15, but no necropsies were performed.

Results: All rats survived the study. No animals showed any clinical signs during the study. One female had very slight erythema on day 2 with clearance by day 3. All animals had normal body weight gain and there were no gross abnormalities at necropsy.
The dermal LD_{50} for males, females, and combined was greater than 2000 mg/kg. This places Bioact *(Paecilomyces lilacinus*), batch No. 90228 in TOXICITY CATEGORY III.. **Classification: ACCEPTABLE**.

Acute Intraperitoneal Injection Toxicity/Pathogenicity - Rat (885-3200; MRID 460042-01)

Methods: The analytical certificate of the test material states that the nominal content of the active ingredient was 2×10^9 cfu/g, and that the analytical content was 4.48×10^9 cfu/g. The testing laboratory did not confirm the analytic content before administering the test material to 5 male and 5 female rats by a single intraperitoneal dose of 2000mg/kg body weight.
Results:: No deaths were observed in the treated or control groups during the study.

- **Gross Necropsy:** Both control and test animals showed evidence of mycoplasmosis at necropsy. Findings included: hemorrhagic consolidation, pneumonic foci, hepatization of lungs, congested liver or liver with whitish foci, congested kidneys, cystic pancreas, enlarged spleen.
- **Infectivity Results:** The digestive tract of one test male and one test female had 270 and 290 cfu/organ, respectively, which was attributed to environmental contamination. No test organisms were detected in any of the test animals or in two control animals in the following organs: liver, kidney, spleen, lungs, brain, urinary bladder, lymphatic ganglia, or thymus.

Classification: **SUPPLEMENTARY (because of uncertainty of test dose)**

Acute Pulmonary Toxicity/Pathogenicity - Rat (885.3150; MRID 459418-04)

Methods: Test material was found to contain 6.5×10^9 viable spores/g. The test material was administered in a single intratracheal dose to 35 male and 35 female rats. The rats in Groups 2 through 7 received 0.05 mL (2.5×10^8 conidia) of Bioact®WG in 0.8% sodium chloride buffer solution.
Results: The presented data show no clinical signs in rats. *Paecilomyces lilacinus* was detected in lungs with clearance by day 15 after dosing, in lung lymph nodes with clearance by day 15 after dosing, and in tracheal lymph nodes with clearance by day 4 after dosing. The test organism was

also detected in cecal content probably due to swallowing of the test organism at dosing. *Paecilomyces lilacinus* was not detected in kidneys, liver, spleen, blood, brain, or lymph nodes (cervical and mesenteric). Necropsy studies showed no observable abnormalities due to the test organism. Therefore, based on the presented/submitted data, the test organisms were not toxic, infective, or pathogenic to rats.
Classification: ACCEPTABLE

Primary Eye Irritation - Rabbit (870.2400; MRID 460042-07)

Methods: For three male rabbits, the test material (100 mg/eye/animal) was applied in the conjunctival sac of one eye, and the other eye was instilled with 0.1 mL of distilled water as a control. The eyes were examined and scored 1, 24, 48 and 72 hours after test material instillation.
Results: All animals survived the study. No corneal opacity or iritis or any other signs of irritation were noted on any rabbit. TOXICITY CATEGORY IV.
Classification: ACCEPTABLE

Skin Sensitization - Guinea Pig (870.2600; MRID 459418-07)

Methods: Twenty guinea pigs were induced and challenged according to the method of Buehler, while 25 other animals served as positive and negative controls. The flank of all guinea pigs was clipped prior to each treatment. For the induction, approximately 0.5 g of test material moistened with water was applied epicutaneously and occluded for 6 hours. The procedure was repeated once each week for three consecutive weeks. Twelve days after the last induction, the test animals were challenged with 0.25 g of test material.
Results: No reaction was noted on any test animal after the first and the second inductions. A few animals showed confluent or non-confluent erythema 24 hours after the third induction. No positive reaction was noted on any test or naive control animals after challenge. The results of the DNCB positive control were appropriate. The product was not a dermal sensitizer. No deaths were observed in any group.
Classification: ACCEPTABLE.

Primary Dermal Irritation - Rabbit (870.2500; MRID 459418-06)

Methods: The fur on the dorsal trunk of three female rabbits was clipped on the day prior to treatment. For treatment, 0.5 g of test material was placed on a patch which was taped to the skin

for four hours. Dermal examination was recorded at 1, 24, 48, and 72 hours after removal of the patch.

Results: All rabbits survived the study. One rabbit had barely perceptible erythema one hour after patch removal with clearance by 24 hours. No dermal irritation was noted on any other rabbit. The primary irritation index was 0.33. *Paecilomyces lilacinus* strain 251 was essentially non-irritating and is in TOXICITY CATEGORY IV.

Classification: ACCEPTABLE.

Immune Response (880.3800) (WAIVED)

A waiver for an immune response study was granted, based on results of various rodent studies that showed no evidence of adverse effects to the immune system, as explained below (MRID # 462832-01; 459418-04).

Animal behavior and weight gain remained normal, and there was no excess morbidity or mortality in the studies. No organ abnormalities attributed to the test material were seen on necropsy. In a pulmonary pathogenicity study, the fungal titre in various organs decreased during the first 8 days after dosing, and clearance was complete by 14 days. This clearance provides evidence that the immune system was functioning, although a concomitant explanation is that the conidia became non-viable over time because they do not survive more than a few days at temperatures above 36°C. Taken together, these data indicate that *Paecilomyces lilacinus* strain 251 does not interfere with immune system function.

b. Subchronic Toxicity and Chronic Toxicity

Subchronic and chronic toxicity studies were not required because survival, replication, infectivity, toxicity, or persistence of the microbial agent was not observed in the treated animals in the acute studies.

c. Effects on the Endocrine and Immune Systems

Endocrine Systems. EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include

evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations.

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, *P. lilacinus* strain 251 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for *P. lilacinus* strain 251.

Immune System. There is no evidence to suggest that *P. lilacinus* strain 251 has adverse effects on the immune systems of mammals or other non-target organisms tested. As expected from a non-toxic, non-pathogenic microorganism, the submitted studies in rodents using several routes of exposure indicate that the immune system remains intact. For example, all test animals remained healthy and maintained normal weight and behaviors during these studies. Although the pathogenicity data are consistent with clearance by an active immune system, an alternate explanation is that the test organisms died because they were exposed to temperatures beyond their survival range.

2. Dose Response Assessment

No toxicological responses have been identified. Therefore, a dose response assessment was not performed.

3. Dietary Exposure and Risk Characterization

Humans and animals are commonly exposed to *P. lilacinus* strain 251, an organism found in soil. No toxicological or pathological endpoints were identified for *P. lilacinus* strain 251, as demonstrated in Table 2, Toxicity Data Requirements of this document. These data are sufficient to support a tolerance exemption for this active ingredient.

4. Occupational, Residential, School, and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Occupational exposure to *P. lilacinus* strain 251 is minimized by the use of personal protective equipment and a restricted reentry interval of 4 hours for treated areas.

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

No indoor residential, school, or day care uses currently appear on the proposed label. Non-dietary human exposure to *P. lilacinus* strain 251 is not expected at these sites. In the absence of any toxicological/pathogenic endpoints, risk from the consumption of residues of *P. lilacinus* strain 251 from its pesticidal use on food is not expected for populations, including infants and children, in residential, school, and day care environments.

5. Drinking Water Exposure and Risk Characterization

No risks are expected from exposure to *P. lilacinus* strain 251 via drinking water because exposure will be minimum and the organism shows no harmful effects on animals that were exposed orally. The potential for transfer of *P. lilacinus* strain 251 to surface or ground water during run-off is considered minimal to non-existent, due to its slow movement in soil and its attachment to plant root nematodes. The organism is normally found in soil. Labels instruct users not to allow *P. lilacinus* strain 251 to enter bodies of water during use or disposal. Therefore, potential exposure to *P. lilacinus* strain 251 in surface and drinking water is negligible.

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children, in the case of threshold effects, to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure are often referred to as margins of safety or as uncertainty factors. EPA concludes that the toxicity and exposure data are sufficient to show that there is a reasonable certainty that no harm will result to infants and children from dietary exposure to *P. lilacinus* strain 251 residues. Because no threshold effects were detected, an additional safety factor is not required.

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

a. Aggregate Exposure

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational

exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

b. Aggregate Risks from Multiple Routes of Exposure

There is reasonable certainty that no harm will result from aggregate exposure to residues of MeloCon WG to the U.S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the lack of toxicity/pathogenicity in oral, dermal, and pulmonary studies in rodents, and lack of adverse effects in other non-target organisms tested. Exposure to infants and children should be minimal indoors because there are no approved indoor uses. Inhalation exposure is unlikely because the end product is a water soluble granule that is mixed directly into soil. No risk from dietary exposure is anticipated, given the lack of oral toxicity and the Agency's decision to grant the active ingredient an exemption from tolerance. Dermal exposure is unlikely except in occupational settings, and workers are required to protect their skin with PPE. Because the risk from each exposure route is minimal to non-existent, the aggregate risks from oral, dermal, and pulmonary exposure routes are also minimal to non-existent. With no threshold effects of concern, EPA has not used a margin of exposure approach to assess the safety of MeloCon WG.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to ***P. lilacinus*** strain 251 and to any other substances that may share a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *P. lilacinus* strain 251 is not toxic or pathogenic, based on mammalian laboratory tests that showed no adverse effects. Thus, there is no indication that *P. lilacinus* strain 251 shares any common mechanisms of toxicity with other substances. At present, there are no other registered products containing *P. lilacinus* strain 251.

9. Risk Characterization

The Agency has considered human exposure to the nematicide, *P. lilacinus* strain 251 in light of the relevant safety factors in FQPA and FIFRA. It has also considered the lack of toxicity and pathogenicity in laboratory studies by various routes of exposure. Based on these considerations, no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, are expected from approved uses of products containing *P. lilacinus* strain 251.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

MRID NO: 45941805, Effects on Non-Target Invertebrates
MRID NO: 45941808, Effects on beneficial Nematode Species
MRID NO: 46004202, Acute Toxicity Testing in Rainbow Trout
MRID NO: 46004203, Freshwater Aquatic Invertebrate Testing, *Daphnia magna*
MRID NO: 46004204, Non-Target Plant Studies: Single Cell Green Algae
MRID NO: 46004205, Non-Target Insect Testing: Aphid Parasitoid
MRID NO: 46004206, Non-Target Insect Testing: Predatory Mite
MRID NO: 46029201, Effect of Temperature on Germination and Mycelium Growth

Table 3. Toxicity Data on Non-target Organisms

Guide-line No *	Study	Results	MRID NO
885.4050 885.4100	*Avian Oral Test;* *Avian Inhalation Test*	These studies were waived because no oral or inhalation avian exposure is expected from approved uses of MeloCon WG. The product is applied directly to soil as a solution, and then mixed into the soil. Furthermore, no evidence of toxicity or pathogenicity to non-target organisms was seen in a large variety of studies. *P. lilacinus* strain 251 doesn't grow at 36^0 C or higher.	WAIVER GRANTED
885.4150	Wild Mammal Toxicity/ Pathogenicity	Extensive studies with laboratory rodents show that no toxicity or pathogenicity risks are expected for wild mammals if users follow label directions for MeloCon WG. See Table 2 of this document for details.*P. lilacinus* strain 251 doesn't grow at 36^0 C or higher.	WAIVER GRANTED

Guide-line No *	Study	Results	MRID NO
885-4340; Non-guideline studies	Insects and other Non-target Invertebrates	Tested species included earthworms, slaters, brine shrimp, collembola, termites, German cockroaches, mealworms, paper nest wasps, ants, and beneficial nematodes. Of these, only ants, termites, and entomopathogenic nematodes were susceptible to the high doses used in these experiments (5 to 10 X field application rates); adverse effects were not detected at the lower concentrations expected in field use.	459418-05
885.4340	Non-target Insect Testing: aphid parasitoid	*P. lilacinus* strain 251 was tested with the aphid parasitoid *Aphidius rhopalosiphi* (a hymenopteran) at the field concentration of 30kg/2000L water per hectare. After 48 hours, mortality of test organism was 38%, and survivors had reduced fecundity. Need additional testing to determine LC 50 in this wasp. UNACCEPTABLE	460042-05
885.4340	Non-target Insect Testing: predatory mite	No adverse effects were seen in the predatory mite (*Typhlodromus pyri*) exposed for 14 days to *P. lilacinus* strain 251 at the field application rate of 30kg/2000L water per hectare.	460042-06
Non-guideline study	Beneficial Nematodes	One free-living nematode species and two entomopathogenic nematode species were exposed to large numbers of conidia of *P. lilacinus* strain 251 placed directly on their cuticle. No adverse impact was seen .	459418-08
885.4380	Honeybee Testing	Because the product will be applied to and then incorporated into soil, exposure to honeybees is expected to be minimal. *P. lilacinus* is already ubiquitous in soil, and use of the registered product is not expected to increase environmental concentrations. Studies with several other hymenopteran species found no adverse effects at expected field concentrations.	WAIVER GRANTED

Guide-line No *	Study	Results	MRID NO
885.4200	Freshwater Fish Testing	Toxicity of *P. lilacinus* strain 251 to rainbow trout was tested under static conditions. The 96-hour LC50 was estimated to be above 100 mg/L (>2 x 10^8 conidia per L)	460042-02
885.4240	Freshwater Aquatic Invertebrate Testing, Tier I	Acute toxicity of *P. lilacinus* strain 251 to young *Daphnia magna* was determined in a 48-hour static bioassay. The 48-hour EC_{50} was estimated to be > 100 mg/L (>2 x 10^8 conidia per /L). The NOEC was 100 mg/L (>2 x 10^8 conidia per /L).	460042-03
885.4280	Estuarine/Marine Organisms Toxicity/Pathogenicity	The data submitted for freshwater fish and *Daphnia* (MRID Nos. 4600042-02 and -03), as well as for other invertebrates, are sufficient to demonstrate that MeloCon WG is not likely to pose a hazard to estuarine or marine organisms.	WAIVER GRANTED
885.4300	*Non-target Plant Studies: Single cell green algae*	The ability of *P. lilacinus* strain 251 to inhibit growth of the green alga *Desmodesmus subspicatus* was tested at six concentrations (10-142 mg/L of *P. lilacinus*) for 72 hours. Growth inhibition was seen. LOEC was 1.0 x 10^8 conidia/L, and NOEC was 5.8 x 10^7 conidia/L. Field concentrations are expected to be very low because MeloCon WG is approved only for soil use, and little movement through soil is expected.	460042-04
None	Endangered Species Impact Assessment	The Agency performed an ESA assessment and determined that no adverse effects are expected on endangered/threatened species. With no toxicity or pathogenicity expected at field concentrations, there is no "may affect" finding for endangered species.	None assigned

* OPPTS Harmonized Guideline Numbers

Hazard Assessment

All but one of the submitted studies are scientifically sound and are adequate for hazard assessment from the proposed uses of MeloCon WG, containing *Paecilomyces lilacinus* strain 251 for biological control of parasitic nematodes in agricultural soils. Some of the

studies deviate from the EPA testing guidelines. These deviations, however, do not affect the usefulness of the data for hazard assessment from the proposed uses.

The submitted studies show that a wide variety of non-target species has been exposed to the active ingredient and end product at doses exceeding the maximum field application rate of 4 lbs. formulated product per acre. The toxicity and (in most cases) pathogenicity of *Paecilomyces lilacinus* strain 251 was evaluated on freshwater fish, aquatic invertebrates, single celled algae, entomopathogenic nematodes (two species), earthworms, slaters, brine shrimp, collembola, termites, cockroaches, beetle larvae, fly pupae, paper-nest wasps, ants, and sheep parasitic nematodes (two species). The majority of the invertebrates tested were not affected by artificially high levels of *P. lilacinus* strain 251. Ants, termites and entomopathogenic nematodes were the only species susceptible to the high doses used in these experiments (5- to 10-X field application rates). Only one of the species tested was adversely affected when exposed to *P. lilacinus* at a dose considered close to that likely to be encountered in the field. A dose-response study would be necessary to determine the effects of *P. lilacinus* strain 251 on the hymenopteran *Aphidius rhopalosiphi*, but several other hymenopteran species showed no adverse effects at field concentrations. A count of free-living nematodes from soil samples obtained from sugar cane, tomato, carrot, onion and banana efficacy trials showed no indication that *P. lilacinus* strain 251 is a threat to free living nematode populations.

2. Environmental Fate

Paecilomyces lilacinus strain 251 does not persist in soil. Immediately after application, elevated levels of *P. lilacinus* were detected in soil, but eight weeks later, levels had returned to background. Because of this non-persistence, the label on the single registered end product tells the user to apply the product every six weeks. Dispersal from the site of application is not likely to occur at detectable levels because the fungus moves in soil slowly and attaches to plant parasitic nematodes.

3. Ecological Risk Characterization

The submitted data show that MeloCon WG, containing *Paecilomyces lilacinus* strain 251, applied at the rate of 4 lbs./acre, will not have detrimental effects on vertebrate or invertebrate populations and no epizootics are expected among the non-target species affected by high dose laboratory tests. The adverse effects noted in several cases at high test doses are likely due to the artificial conditions created in the laboratory. Ideal

laboratory conditions often permit infection and multiplication in a variety of non-target hosts. This is a result of a deliberate exposure to a large amount of inoculum and artificial laboratory conditions conducive to infection and pathogenicity (e.g. ideal humidity and temperature) seldom encountered in the field. Therefore, field application rates resulting in lower pathogen concentration than the lowest effective laboratory dose do not pose a risk to target species populations that are affected by large laboratory test doses. This need for a critical infectious dose and favorable conditions holds true for both the target and non-target species.

D. EFFICACY DATA

No efficacy data are required to be submitted for review by the Agency because no public health uses are involved.

IV. PUBLIC INTEREST FINDING

The Agency finds that the use of P. lilacinus strain 251 under this conditional registration would be in the public interest. The criteria for Agency evaluation of public interest findings are outlined in 51 FR No. 43, Wednesday March 5, 1986. Under part IV.A, the proposed product may qualify for an automatic presumptive finding that the proposed conditional registration is in the public interest if

1) it is for a minor crop use,
2) it is a unique replacement for pesticides of concern, or
3) it is for use against a public health pest.

P. lilacinus strain 251 satisfies criteria 1) and 2) above. It is being approved for use on all agricultural commodities, including minor crops, thus satisfying the first criterion for a public interest finding. P. lilacinus strain 251 also satisfies the second criterion for a public interest finding because it is a unique replacement for several toxic chemicals, such as chlorpyrifos, aldicarb, and carbofuran, now used for controlling plant root nematodes. P. lilacinus strain 251 is the first live microbial pesticide approved as a nematicide. It presents minimum to no risk to humans and the environment because it is not harmful to mammals or other terrestrial and aquatic organisms tested, and does not survive or grow at human body temperature. It also does not persist in soil, needing re-application every six to 16 weeks. Human exposure is minimized by application directly to soil and by required PPE for workers. Label directions tell users to avoid

contaminating water bodies through application, runoff,or disposal. Based on these considerations, the Agency concludes that the public interest will be served with this conditional registration.

V. RISK MANAGEMENT AND REGISTRATION DECISION

A. Determination of Eligibility (for conditional registration)

Section 3(c)(7)(C) of FIFRA provides for the conditional registration of a pesticide containing a new active ingredient (i.e, not contained in any currently registered pesticide) "for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe." Such a conditional registration will be granted "only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest."

P. lilacinus strain 251 is eligible for a conditional registration under Section 3(c)(7)(C) of FIFRA because its proposed use is in the public interest, and its use is not likely to pose any unreasonable risk to health or the environment. Certain conditions apply to this eligibility and the applicant must take certain actions (i.e., generate and provide certain data) described under **B. Regulatory Position** of this document.

B. Regulatory Position

1. Conditional Registration

Based on the data and analysis provided above, and additional factors addressed below, the Agency finds P. lilacinus strain 251 eligible for a conditional registration. Under the conditional registration, the registrant is required to provide the information specified below, which the Agency will review and assess.

Within 18 months of the date of the conditional registration, the registrant must submit a confirmatory Intraperitoneal Toxicity/Pathogenicity Study, (OPPTS guideline # 885.3200) to complete the pathogenicity requirements for an unconditional registration. For microbial pesticides, the Agency generally requires two acceptable studies showing

that the organism is not pathogenic in laboratory mammals. The registrant submitted one acceptable study showing no pathogenic effects in rats after pulmonary exposure, and an intraperitoneal study that was considered supplementary because of uncertainty in the test dose.

The supplementary IP study did not fully characterize the administered dosage. However, the results of the study indicate that the administered dosage contained some viable spores, and that there was no pathogenicity or other adverse effects from the administered dosage.

Based upon dosing statements in EPA Guideline 885-3200, quoted below, it may not have been clear to the registrant that the Agency possibly might need a detailed dose characterization for this study.

Dosing (EPA Guideline # 885-3200)

> "(iv) Dose quantification. Techniques used to quantify the units of MPCA in any dose will depend on the group of microorganisms to which the MPCA belongs. *Where possible* [Italics added], determinations of viable, or potentially viable, or infective units in each dose should be made. A measurement of metabolism associated with a defined biomass may be the preferred technique for quantification of mycelial forms of MPCAs. Quantification should be done concurrently with testing."

In addition, the potential registrant is a German company that followed OECD harmonized guidelines in preparing their submission. When the testing laboratory, located in India, could not locate an OECD or harmonized guideline for the EPA-required microbial IP study, the laboratory modified an existing harmonized guideline, which, unfortunately, did not include the need for determining the microbial concentration in the material to be administered. Based on these factors, it would have been difficult for the applicant to know that the submission would not be acceptable in this particular respect until the Agency made that finding.

While a confirmatory IP pathology study is in preparation, no unreasonable adverse effects are anticipated from use of this product according to label directions. The label requires users to comply with the following actions to mitigate risk: use of a NIOSH-approved respirator with an N, P, R, or HE filter; wearing of long-sleeved shirt and pants, waterproof gloves, and shoes and socks; waiting 4-hours to re-enter a treated area, and not allowing

by-standers in the area suring application. These label restrictions must remain on the label until a confirmatory IP study has been submitted and found acceptable.

Other mammalian and non-mammalian studies show that no adverse effects are expected under field conditions. In addition, a temperature growth curve indicates that the organism cannot survive or grow at or above 36 degrees C, and is therefore highly unlikely to be pathogenic to birds or mammals. Based on the weight of evidence, the Agency finds it is in the public interest to allow use of this pesticide active ingredient until the required study is submitted and reviewed.

2. Exemption from the Requirement of a Tolerance

EPA announced in the Federal Register on November 7, 2003 (68 FR 63088-92) (FRL 7331-7) that it had received a pesticide petition (PP 3F6737) from Prophyta Biologischer Pflanzenschutz GmbH, Germany (US Agent: WF Stoneman Co. LLC, 6307 Mourning Dove Drive, McFarland, WI 53558-9019), proposing [pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d)], to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of the microbial pesticide, *P. lilacinus* strain 251, on growing crops.

EPA is issuing a notice establishing an exemption from the requirement of a tolerance for residues of *P. lilacinus* strain 251 in or on all food commodities. FR CITATION TO BE COMPLETED

3. CODEX Harmonization

There are no CODEX values for *P. lilacinus* strain 251 .

4. Risk Mitigation

There are no significant human risk issues relating to dietary risk including drinking water, residential risk, or ground and surface water contamination. Therefore, mitigation measures for these risks are not required. Although high concentrations of *P. lilacinus* strain 251 were slightly toxic to ants and termites, no adverse effects are expected at field concentrations, and these results do not trigger the need for non-target mitigation measures on the label. Occupational risk will be mitigated by required use of appropriate personal protective equipment (PPE) and a 4-hour REI.

5. Endangered Species Statement

The Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the Crop Life America. Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

The Agency performed an Endangered Species Act assessment and determined that no adverse effects are expected on endangered/threatened species. With no toxicity or pathogenicity expected at field concentrations, there is no "may affect" finding for endangered species. Therefore, labels for these products do not need to include language designed to protect endangered or threatened species.

C. Labeling Rationale

Precautionary labeling is required to minimize risks to humans and the environment.

1. Human Health Hazard (WPS and non-WPS)

P. lilacinus strain 251 products with commercial use sites are subject to the Worker Protection Standard. Because of the low toxicity of *P. lilacinus* strain 251, the Re-Entry Interval for uses within the scope of WPS is 4 hours. Precautionary statements and personal protective equipment as specified in Part VI of this document are required based on the acute toxicity categories of this organism.

VI. LABELING ACTIONS REQUIRED BY REGISTRANTS

A. Precautionary Labeling

P. lilacinus strain 251 products must state the following under the heading "Precautionary Statements":

Personal Protective Equipment: Applicators and other handlers must wear:

Long sleeved shirt and long pants.
Waterproof gloves.
Shoes plus socks.
NIOSH-approved respirator with any N, P, R, or HE filter.

WPS labels must state the following under the heading “User Safety Recommendations”

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

B. Environmental Hazards Labeling

1. End Product Environmental Hazards Labeling

The risk from *P. lilacinus* strain 251 to non-target organisms, including endangered or threatened species, is minimal to nonexistent so long as the following required statement is on the label and followed:

> "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 by cleaning of equipment or disposal of equipment washwaters. "

2. Application Rate

It is the Agency's position that the labeling for the pesticide product containing *P. lilacinus* strain 251 as the active ingredient complies with the current pesticide labeling requirements. The Agency has not limited the number of applications per season of this active ingredient.

C. Labeling Requirements

1. The label will include all information required in the OPP Label Review Manual, including the items listed below.

- Signal word is "Caution," based on toxicity category III.
- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Directions for Use

2. Ingredient statement for End Product

End Product Name: *MeloCon WG*

Ingredient Statement:

*Paecilomyces lilacinus strain 251**	6.0 %
Other Ingredients	94.0 %
Total	*100.0 %*

** Contains a minimum of 1 x 10^{10} cfu/g* product

Table 3. Product Use Sites.

MeloCon WG	**Date Registered**
Terrestrial Food: Vegetables; strawberries; grape vines; pineapples; and nut, citrus, peach and banana trees Terrestrial Non-Food: Ornamentals, tobacco, turf	March 30, 2005

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