US Environmental Protection Agency
Office of Pesticide Programs

REREGISTRATION ELIGIBILITY DECISION
Phytophthora palmivora MWV PC Code 111301

February 15, 2006

REREGISTRATION ELIGIBILITY DECISION

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PC Code 111301

LIST D

CASE 4105

United States Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Ave., NW
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Phytophthora palmivora MWV
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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
cfu	colony forming unit(s)
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
HPLC	High Pressure Liquid Chromatography
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Microgram(s) Per Gram

GLOSSARY OF TERMS AND ABBREVIATIONS

mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPCA	Microbial Pest Control Agent
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NIOSH	National Institute of Occupational Safety and Health
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
OSP	Optical Spore Count
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
µg/L	Micrograms per liter
µg/mL	Micrograms per milliliter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its Reregistration Eligibility Decision (RED) on the active ingredient, live chlamydospores (lc) of *Phytophthora palmivora* MWV (referred to as *P. palmivora* MWV, PC code 111301). This decision includes a comprehensive reassessment of the required data and the use patterns of the registered active ingredient, which is specific for milkweed strangler vine (MWV) control.

Pesticidal products whose sole active ingredients qualify as biological agents may be exempt from certain generic data requirements necessary for conventional chemical pesticides. The data requirements relating to toxicology, residue chemistry, human exposure, ecological effects and environmental fate of the active ingredient are outlined in 40 CFR § 158.740 -- Guidelines for Microbial Control Agents. Devine Mycoherbicide with live chlamydospores of *Phytophthora palmivora* MWV (PC Code 111301) as the active ingredient was registered in 1981 by Abbott Laboratories (EPA Reg. No. 275-39), but was transferred on April 29, 2000 to Valent BioSciences Corporation (EPA Reg No. 73049-9). This active ingredient was used in products as a mycoherbicide for the control of *Morenia orderata*, strangler vine, or milkweed strangler vine, in citrus trees.

The generic active ingredient, *P. palmivora* (PC Code 111301) was registered prior to 1984 and is, therefore, subject to reregistration. All products containing the generic active ingredients were registered prior to the implementation of the aforesaid guidelines and the enactment of the Food Quality Protection Act of 1996 (FQPA) as further discussed in this document. FQPA amended the Federal Food, Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all Reregistration Eligibility Decisions (REDs) signed subsequent to August 3, 1996, are accordingly evaluated under the standards imposed by FQPA.

This RED document proposes to streamline the reregistration decision, and to implement both the microbial guidelines and the requirements of the FQPA, as they relate to this active ingredient. In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information. In addition, the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity is also assessed. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of the pesticide residues.

On March 26, 1981, an exemption from the requirement of a tolerance was established for *Phytophthora palmivora* "in or on the raw agricultural commodity citrus fruit" (40 CFR §180.1057, 46 FR 18695).

Data from Valent BioSciences Corporation demonstrate that there is a reasonable certainty that, if the pesticide is used as labeled, no adverse effects are expected to infants and children or to the general adult population. Acute oral, dermal, primary eye irritation, intratracheal instillation and hypersensitivity studies in test mammals demonstrate no potential adverse health effects under the conditions investigated. The active ingredient is not irritating to the eye or skin. No hypersensitive incidents to mammals have been reported in association with *Phytophthora palmivora*. A test study in support of the acute intraperitoneal guideline requirement was waived based on the results of the submitted acute mammalian and bird toxicity studies, and the inability of the microbe to survive at temperatures greater than 37°C. Test mammalian systems have also cleared the organism which was administered orally and intratracheally to rats. Thus, an immune response test was not required. No adverse effects been reported in association with *P. palmivora*, as required by section 6(a)2 of FIFRA, over the 2 decades in which this pesticide has been registered. However, should such incidents occur, the registrant is required to report them to the Agency in order to comply with Section 6(a)2 of FIFRA.

On January 19, 2006, the Agency reassessed the exemption from tolerances for residues of live chlamydospores of *Phytophthora palmivora* MWV under the standards of FQPA. The FQPA evaluation included exposure to the microbial pesticide residues from dietary (including drinking water), non-occupational residential, aggregate and cumulative exposure. EPA has no information to indicate that the toxic effects produced by the microbial pesticide would be cumulative with those of any other microbial pesticidal active ingredient. Exposure to the naturally occurring *P. palmivora* via drinking water is not likely to be greater than current/existing exposures. The pesticide is intended for terrestrial use only to citrus groves in certain counties in one state, Florida. It is to be applied once every two or three years as needed. Such limited application suggests a low potential for runoff. Thus, potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, municipal treatment of drinking water. Hence, risk via ingesting water exposed to the active ingredient is expected to be minimal to non-existent.

The potential for risk to workers and pesticide handlers via occupational exposure is expected to be minimal because of the low toxicity and low exposure potential of the pesticidal active ingredient. Besides, *P. palmivora* is a plant pathogen, which has not demonstrated any adverse effects against mammalian species as observed in the acute toxicology tests described in this RED. Pesticides containing this active ingredient are eligible for a 4 hour Restricted-entry Interval (REI) for early-entry workers. Other REIs may be recommended for End-use Products (EPs) depending on the formulation and the nature of the inerts. Appropriate Personal Protective Equipment (PPE) for handlers and early-entry workers, include long sleeved shirt, long pants, shoes, socks and a dust mist filtering respirator with the appropriate NIOSH prefix P-95, N-95, or R-95, as described in Section V of the RED.

Based on the use pattern and the low exposure potential, there are no indications that *P. palmivora* presents any toxic, infective, or pathogenic potential to terrestrial and aquatic non-target organisms. Avian oral and intraperitoneal injection tests demonstrate no adverse treatment-related toxicity effects in the mallard duck. Two studies in freshwater fish and *Daphnia* indicate no acute toxicity during the 96 hr test period to these non-target organisms at a dosage which is 1000 times the estimated environmental concentration (EEC). While these studies may not predict effects from chronic exposure, it must be kept in mind that the pesticide is to be applied about once every two years. Soil application only to citrus in certain counties in Florida, suggests low exposure potential and no adverse effects to freshwater and marine vertebrates and invertebrates.

This Microbial Pesticide Control Agent (MPCA), *Phytophthora palmivora* MWV, is very specific for *Morenia orderata*, milkweed strangler vine, or strangler vine, in citrus trees. It is a plant pathogen and is not known to have adverse effects on insects. It is a soil incorporated pesticide, with low exposure levels and potentially minimal to non-existent effects on non-target insects. Consequently, the data requirement was waived for honey bee and other beneficial non-target insects.

Phytophthora palmivora MWV has been shown to cause reduced emergence of seedlings or disease in the following ten (10) different crop groups: Cucurbitaceae (cucumbers, squash and gourd fruit families), Apocynaceae, Liliacae, Malvaceae, Solanaceae (potato family), Leguminosae (bean family), Compositae, Umbelliferae, Rutaceae and Ericaceae. The fungus has also been isolated from the roots of seven other additional plant families, which did not show any disease symptoms. These tests were conducted with doses which exceeded label rates. To mitigate against potential adverse effects of *Phytophthora palmivora* MWV on economically important non-target plants, the pesticide is not to be applied to areas in close proximity to agricultural sites where susceptible crop groups are grown.

This active ingredient has been shown to be non-viable above 32°C and the acute mammalian and avian tests exhibited low toxicity potential to mammals and birds (see **Sections IIIB** and **IIIC**). These justifications support the request to waive data for effects of *P. palmivora* on avian and wildlife mammalian species. On the basis of all the above considerations, the Agency has decided that this active ingredient is eligible for reregistration to Valent BioSciences Corporation. As other registrants register or reregister the product, appropriate Agency pesticide requirements will apply on a case-by-case basis.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review, the Reregistration Eligibility Decision (RED), by the U.S. Environmental Protection Agency (referred to as "the Agency" or US EPA) of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This RED document presents the Agency's decision regarding the reregistration eligibility of the registered uses of live chlamydospores of *Phytophthora palmivora* MWV (hereinafter sometimes referred to as *P. palmivora* MWV). The document consists of six sections. **Section I** is the introduction. **Section II** describes the microbial pesticide, its uses, data requirements and regulatory history. **Section III** discusses the product characterization, human health and environmental assessment based on the data available to the Agency. **Section IV** presents the reregistration decision for *P. palmivora* MWV. **Section V** discusses the reregistration requirements for the microbial pesticide. Finally, **Section VI** contains the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Active Ingredient Overview

The following active ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Live chlamydospores of *Phytophthora palmivora* MWV
- **Biological Names:** Live chlamydospores of *Phytophthora palmivora* MWV (initially mis-identified as *Phytophthora citrophthora*, a serious pathogen on orange)
- **OPP Chemical Codes:** 111301
- **Trade and Other Names:** ABG-5001, Devine; (initially mis-identified as *Phytophthora citrophthora*, a serious pathogen on orange)
- **Basic Manufacturer (Current as of February 15, 2006):**
  Valent BioSciences Corporation (sometimes referred to herein as VBC)
  1401 Sheridan Road
  North Chicago, IL 60064

Encore Technologies (ET; Plymouth, MN) was the exclusive licensee to manufacture, use, and sell Valent BioSciences Corporation (VBC) products containing *Phytophthora palmivora* MWV. ET was required to use VBC's manufacturing process, which is currently on file with the Agency. At this time there is no data compensation agreement with VBC who remains the registrant.

B. Use Profile

A sole microbial pesticide, containing the generic active ingredient, live chlamydospores of *Phytophthora palmivora* MWV (PC Code 111301) was registered in 1981 for the control of *Morenia orderata*, strangler vine or milkweed strangler vine, in citrus trees. The herbicide is sprayed to the soil near the root where the vine is growing. This fungus will initiate a root infection in milkweed strangler vine plants that starts to kill the vine in six to ten weeks following application, depending on the size and maturity of the vine. Populations of the vine generally continue to decrease over the period of a year after treatment. The registrant claims that Devine will not harm citrus trees. An exemption from tolerance was established on March 26, 1981, for its use in or on the raw

agricultural commodity citrus fruit (40 CFR §180.1057, 46 FR 18695). VBC's label for Devine Biological Herbicide (EPA Reg. No. 73049-9) indicated that the product is for use in Florida only and **"do not use in Clay, Gulf, Liberty, or Gadsden counties."**

Type of Pesticide: Microbial herbicide (mycoherbicide)

Use Sites: Citrus trees in Florida, but not in Clay, Gulf, Liberty, or Gadsden counties

Target Pests: *Morenia orderata* (strangler vine or milkweed strangler vine)

Formulation Types Registered: Liquid

Method and Rates of Application: Apply in any type of citrus grove, where permitted, from May through September after the weed has germinated or is actively growing. Only one treatment per season is necessary and 1 pint ($3.2x10^8$ per pint, $6.7x10^5$ live chlamydospores per mL) per treated acre. Mix with water in tank and apply with a herbicide boom sprayer to achieve uniform coverage of the soil under the tree canopy. Use at least 50 gallons of spray water per treated acre. The surface of the soil must be wet at the time of application. Adequate moisture can be achieved with either 2 inches of water, rainfall or irrigation, prior to treatment, or pretreatment by watering to a depth of 1 inch followed by an additional ½ inch on the third day after treatment.

C. Estimated Usage of Pesticide

Data are not available to the Agency to estimate the current usage of the pesticide.

D. Data Requirements

The following **confirmatory data**, as described in Section V of this RED, are to be submitted within 30 months of the manufacture of the pesticide:

A: Batch Analyses/Nominal Limits

1. Analysis of 5 batches are required at production, to include data relevant to detection, identification, enumeration and rejection limits of potential human pathogens (bacterial and fungal), using quality control and assurance methods to be used during large scale production. The 5 batch analysis must include storage stability and viability data. All batches containing metabolites or unintentional ingredients of toxicological concern, or human pathogens above regulatory levels must be destroyed.

B: Standard Data Requirements

The following is always required for all registered products:

1. Reports of incidents of adverse effects to humans or domestic animals are required under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16.

2. Before releasing products containing this active ingredient for shipment, the registrant is required to provide appropriate labels and satisfy other Agency requirements as discussed in this RED and as required for pesticide registration.

3. All batches containing metabolites or unintentional ingredients of toxicological concern, or human pathogens above regulatory levels must be destroyed.

E. Regulatory History

The active ingredient *P. palmivora* (PC Code 111301) was registered in 1981 by Abbott Laboratories (EPA Reg. No. 275-39), but was transferred on April 29, 2000 to Valent BioSciences Corporation (EPA Reg No. 73049-9). VBC's label for Devine Biological Herbicide (EPA Reg. No. 73049-9) indicated that the product is for use in Florida only and "do not use in Clay, Gulf, Liberty, or Gadsden counties."

Food Quality Protection Act

On March 26, 1981, prior to the enactment of the FQPA (1996), an exemption from the requirement of a tolerance for residues of the microbial insecticide *P. palmivora* was established "in or on the raw agricultural commodity citrus fruit" (40 CFR §180.1057, 46 FR 18695). Reassessment of the exemption from tolerance and compliance with the FQPA are discussed in this RED.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

1. Product Identity and Characterization

Devine Biological Herbicide, EPA Reg. No. 73049-9, is a mycoherbicide liquid for the control of *Morenia orderata*, strangler vine or milkweed strangler vine, in citrus trees. Phytophthora ABG-5001, milkweed vine isolate, has been deposited in the Florida Type Culture Collection (FTCC). It was isolated from citrus groves in Orange county and occurs naturally in only five Florida counties (Polk, Hillsborough, Pasco, Lake and Orange). The active ingredient (ai) was initially mis-identified as *Phytophthora citrophthora*, a serious pathogen of orange. Subsequent data submitted to the Agency have now positively identified the ai as *Phytophthora palmivora* MWV, have shown it to be specific for the strangler vine, and not infective or pathogenic to citrus. These data are acceptable.

One product is manufactured by an integrated manufacturing process using this active ingredient. It is present in the formulated product, DeVine® as 0.8% w/w live chlamydospores of *Phytophthora palmivora* MWV ($3.2x10^8$ per pint, $6.7x10^5$ live chlamydospores per mL). *Phytophthora palmivora* is a naturally occurring organism, which is applied to soil about once every two years. Hence, residues occurring at time of harvest of the treated citrus food commodities are not expected to be greater than those of naturally occurring levels in citrus groves.

Product characterization is summarized in Tables 1a and 1b. To identify this strain, *Phytophthora palmivora* MWV chlamydospores are tested in the greenhouse on 3-4 inch milkweed strangler vine (*Morrenia odorata*) seedlings grown in 2 x 2 inch pots. “Live” chlamydospores are identified by the integrity and smooth appearance of a thin-walled membrane surrounding the spores. Spores are counted in a standard hemacytometer. Disease is recognized in the target pest, milkweed strangler vine, by the appearance of wilted, down turned leaves compared with controls. Small purplish lesions may appear on the stem near the soil line. The plants become increasingly dehydrated after several days, and the symptoms become more pronounced. The fungus is re-isolated from plant stems when disease symptoms first appear.

The pesticide is manufactured as a liquid with a very short shelf life (approximately 1 month). It is to be stored refrigerated and used immediately. Spores can persist in the environment for more than six months, and effectively reinfect the pest, milkweed strangler vine. Inerts are considered as Generally Recognized As Safe (GRAS) ingredients and have been cleared for food use, when the pesticide is applied as soil treatment as labeled.

Table 1a: Product Characterization of *Phytophthora palmivora* MWV			
Guideline	**Study**	**Result**	**MRID #**
151-10 *885.1100	Product Identity	Live chlamydospores of *Phytophthora palmivora* MWV with trade names ABG-5001, Devine. The ai (initially mis-identified as *Phytophthora citrophthora*, a serious pathogen on orange), has now been positively identified as *P. palmivora* MWV, specific for milkweed strangler vine. **Acceptable.**	45734101 45734103
151-11 *885.1200	Manufacturing Process	The general description of the manufacturing process is adequate. It contains a complete description of chlamydospore production, maintenance (without genetic variation and contamination), and monitoring for quality assurance. However, the registrant must provide batch analysis data to show that human pathogens and other bacterial, fungal and other unintentional ingredients are within regulatory limits.	45734101
151-12 *885.1300	Discussion of Formation of Unintentional Ingredients	Throughout the testing of Devine®, there has not been any presence of any human or animal pathogens. If they are found, they are in quantities too small to pose any hazard. Two DeVine production lots were analyzed to demonstrate that the virulence was positive and human pathogen was negative. However, the registrant must provide batch analysis data to show that human pathogens and other bacterial, fungal and other unintentional ingredients are within regulatory limits.	45734101
151-23 *885.1400	Analysis of Samples	Analysis of treated food commodities for residues of *P. palmivora* is not required for an exemption from tolerance. Expected levels of the active ingredient are not expected to be greater than background.	
151-15 *885.1500	Certification of limits	Live chlamydospores of *Phytophthora palmivora* MWV at a concentration of 0.80% by weight (not less than 6.7×10^5 live chlamydospores/mL). "Other Ingredients" comprise 99.2% by weight	CSF
151-25 885.2300	Analytical Method	The general description of the analytical methods and pass-through techniques are adequate.	45734102

* OPPTS Harmonized Guidelines

Physical and chemical properties

Physical and chemical properties of *Phytophthora palimivora* MWV are described below in Table 1b.

Table 1b: Physical & Chemical Properties of *Phytophthora palmivora* MWV

Physical/Chemical Properties			
Guideline	**Study**	**Result**	MRID #
151-17	color	Light tan to dark brown	ERB Branch Review, 9-11-80
	pH	6-8	CSF, 2002
	Physical State	Mobile aqueous based suspension with a tendency toward particulate flocculation	ERB Branch Review, 9-11-80
	Storage Stability	Cultures stored during the growth phase, covered with sterile water on V-8 agar tubes are viable for 1-2 years stored at 25°C. Can also be stored in 10% glycerol at minus 80°C.	45734102
	Density/Relative Density/ Bulk Density	8.451 lbs/gal	CSF, 2002

*885.xxx = OPPTS Harmonized Guideline Nos.
**Guideline data requirements (40 CFR §158.740(a)) for melting point, boiling point, solubility, *vapor pressure, dissociation constant, octanol/water partition coefficient, oxidizing or reducing potential, flammability/flash point, explodability, miscibility, and dielectric breakdown voltage were not required because of the nature of the microbial pesticide.*

Unintentional Ingredients

Analysis of mycelia and supernatant broth of cultures of *Phytophthora palmivora* MWV is presented in Table 1c. *Phytophthora palmivora* MWV cultures were harvested, and the precipitate and supernate analyzed for mycotoxins (memorandum possibly 1981 from William Woodrow, HED/USEPA to Mr. Mountfort, RD/USEPA; Caswell file # 663AA, MRIDs 63089, 63090, 63091, 45734101). No aflatoxin (A, B, B_1, B_2, G_1, G_2,), Ochratoxin A and B, T-2 toxin, Zearalenone (F_2) was detected. If present, Diacetoxyscirpenol (DAS) is less than 200 ppb (LOD 100 ppb T-2) (Table 1c).

Table 1c: Mycotoxin screens - Mycelium and supernate of *Phytophthora palmivora*		
Mycotoxin	**Detected**	**Level of Detection (ppb)**
Aflatoxin A, B	None	50 ppb Ochratoxin A
Aflatoxin B_1, B_2, G_1, G_2	None	2
Ochratoxin A and B	None	50
Diacetoxyscirpenol	None	100
Zearalenone (F_2)	None	400

Other unintentional ingredients

Unintentional ingredients, such as coliform and fecal coliform bacteria or pathogens, such as *Salmonella*, *Shigella*, and *Vibrio* did not exceed acceptable standards. Similarly, total aerobic colony forming units or total aerobes and aerobic spore formers are at acceptable regulatory levels. Confirmatory data (analyses of 5 production batches) are required when the pesticide is manufactured.

B. Human Health and Risk Assessment

1. Food Clearances/Tolerances

In March 26, 1981, an exemption from the requirement of a tolerance was established for *Phytophthora palmivora* "in or on the raw agricultural commodity citrus fruit (40 CFR §180.1057, 46 FR 18695)."

This RED includes a reassessment of the exemption from tolerance for residues of *Phytophthora palimivora* in/on the food commodity citrus fruit. Below are the summaries of the data submitted to support the reassessment of the exemption from tolerance for *P. palmivora*. No adverse health or environmental effects are expected to infants, children and human adults in the US population when pesticides containing this active ingredient are used as labeled. No safety factor is required to reassess the exposure to infants and children. As summarized below, these considerations include dietary (including drinking water), aggregate and cumulative exposure to the pesticide.

2. Toxicology Assessment

A summary of the results of the Tier 1 Toxicology tests submitted in support of this reregistration

is presented in Table 2 and summarized below.

a. Acute Oral Toxicity (MRID 63097; OPPTS harmonized Guidelines 885.3050, 870.1100; previously OPP 152-30)

The MRIDs and guideline numbers are listed in Data Matrix dated 8/8/02. Based on the toxicity data summarized below, *P. palmivora* is not pathogenic to mammals and does not demonstrate any systemic toxicity.

An earlier sub-acute oral toxicity/pathogenicity five day study submitted for the Experimental Use Permit (EPA Reg. No. 275-EUP-21) and a temporary exemption from tolerance (Pesticide Petition 8G2056) was considered supplementary (memorandum dated July 17, 1978, from Toxicology Branch to Ms. Libby Zink, Special Registration Section/HED/USEPA). Five rats per sex were each dosed with $1x10^5$ cfu *Phytophthora citrophthora*. Weight gain and feed intake were not affected, and there were no deaths. Observation of the animals is not reported and autopsy was apparently not performed. This study did not investigate infectivity or pathogenicity of the organism. A subsequent acute oral test, described below, was conducted for 35 days. In the meanwhile, the identity of *P. citrophthora* was further investigated and the fungus was reclassified as *Phytophthora palmivora* by 1980.

Acute oral infectivity (MRID 63097)

The results of an acute oral infectivity test were reported under EPA Reg. No. 275-GO, and petition # OF2418 (memorandum possibly 1981 from William Woodrow, HED/USEPA to Mr. Mountfort, RD/USEPA; Caswell file # 663AA, MRID 63097). Three groups of 5 male and 5 female rats were treated separately with single doses of (a) saline, (b) *P. palmivora* spores (animals not bled) and (c) *P. palmivora* spores and observed for a 35 day period. The test material was administered by oral gavage at a dose of 2-3 mL/animal at 10^6 fungal units/mL. The following observations were made on days 0, 1, 2, 5,7, 14, 21, 28 and on day 35: body weights, feed consumption, rectal temperature, blood sample and gross necroscopy. The blood was analyzed for hematology and chemistry. Gross necroscopy on all animals included histopathology of tissues or organs that indicate infectivity or toxicity.

No mortality was observed. Oral treatment did not affect the rate of body weight gain, feed consumption, or rectal temperatures. Two rats were removed from the experiment. One rat which was sacrificed on day 16 had lung lesions, typical of chronic murine respiratory diseases. A second rat died on day 12, but was discovered too late to perform a meaningful necropsy. Symptomatology was similar to the sacrificed rat. It was believed that death and morbidity resulted from the chronic respiratory disease and was not caused by the fungus.

Blood hematology and chemistry were normal for young growing rats. Mean blood cell hemoglobin concentration and serum glutamic pyruvic transaminase were increased in rats treated with *P. palmivora*, when compared to controls. These changes, however, were small and not of statistical or toxicological significance. No abnormal changes related to the treatment were noted during necropsy. No abnormal behavioral effects were attributable to the fungus (MRID 63097). The data were considered Core-Minimum and the pesticide was assigned **Toxicity Category IV** for acute oral effects.

In the same memorandum, the reviewer summarized another test demonstrating the effect of simulated gastric and intestinal fluids on the survival of *P. palmivora* chlamydospores. These tests were conducted in triplicate for exposure periods up to 4 hours. Periodic tests for viability of the spores under these conditions showed that the fungus failed to survive a 15 minute exposure to gastric fluid, the shortest incubation period tested.

b. Primary Dermal Irritation (MRIDs 63097, 135063, 135064; OPPTS Harmonized Gdln 870.2500; previously OPP Gdln 152-34)

The memorandum cited immediately above (Woodrow to Mountfort, USEPA, 1981; MRIDs 63097, 135063, 135064) also summarizes the acute dermal study evaluated for the registration of the active ingredient. A five mL volume of *P. palmivora* was applied to the abraded epidermis of five male and five female rabbits. Control animals received an equal volume of sterile saline. Treated sites on all animals were protected by occlusive dressings, which were removed 24 hours after treatment. The animals were observed for 35 days for mortality, clinical symptoms of toxicity, infectivity or abnormal behavior. Blood hematology and blood chemistry parameters were measured. Gross pathology and histological examination of treated skin areas were performed. Effects on body weights and feed consumption, rectal temperature were noted. Dermal smears of treated areas were taken to assess viability of inoculum vs time. Treated areas were scored according to Draize for occurrence of erythema and edema.

There was no mortality, and chlamydospores remained viable on treated rabbit skin under wrapping for 24 hrs. Inoculum was not viable on treated skin at 48 hours post application. Very slight epidermal erythema was evident at 24 hours on 8 of 10 *P. palmivora* treated animals and on 5 of 10 controls. Edema was not noted on any animal. Blood hematology and serum chemistry parameters measured on days 7, 21, and 35 of the experiment were not affected by *P. palmivora.* Body weight gain, rectal temperature, and feed consumption were not influenced by *P. palmivora* at any time during the study. All animals appeared normal and showed no signs of abnormal behavior during the study. Gross necropsy and histological examination of the skin revealed no treatment related abnormal effects. The data were classified Core - Minimum and the pesticide was considered Toxicity Category IV for acute dermal effects.

c. Primary Eye Irritation (MRIDs 63097, 135065, 135066; OPPTS Harmonized Gdln 870.2400; OPP guideline 152-35)

Another summary evaluation (Woodrow to Mountfort memo, USEPA, 1981) describes a study investigating primary ocular irritation in six male and six female rabbits treated and observed over 35 days. The installation of 1.58×10^5 *P. palmivora* chlamydospores into the conjunctival sac of the rabbit caused no adverse effects such as increased irritation of inflammation of the conjunctiva or iris. Opacity of the cornea was not affected by *P. palmivora* Additionally, the conjunctival sac did not provide a suitable environment for sporulation of the fungus. It was possible to recover viable *P. palmivora* at time zero, but not at 24 hours after installation. There was no mortality and animal performance and behavior were normal throughout the study. All rabbits gained weight and maintained normal feed consumption and rectal temperatures during the study. The pesticide is not an eye irritant. The data were classified Core-Minimum and the pesticide was considered Toxicity Category IV for primary ocular effects.

d. Acute safety and infectivity - Intratracheal installation (MRIDs 63097, 68998; OPPTS Harmonized Gdln 885.3150)

An evaluation of the acute intratracheal instillation of *Phytophthora palmivora* in male Sprague Dawley rats was summarized in a 1981 memorandum (from William Woodrow, HED/USEPA to Mr. Mountfort, RD/USEPA; Caswell file # 663AA, MRIDs 63097, 68998). Ten male rats were given an intratracheal dose of 0.1 mL (1.58×10^5 spores) *P. palmivora* chlamydospores. Control rats received a volume of sterile saline equivalent to that of the fungus. Both groups were monitored at intervals up to 35 days for body weights, feed consumption, rectal temperatures, blood hematology and blood chemistry. No mortality, no viable fungus spores recovered from lung tissue, and no survival/penetration into alveolar tissue were noted, probably due to > 5µ size of spore (MRIDs 63097, 68998; taken from "Notes for meeting with Valent" dated 2/9/01).

Performance criteria, such as weight gain, feed consumption, gain/feed, and rectal temperature were comparable in controls and *P. palmivora*-treated animals. Similarly, no adverse effects on blood hematology parameters measured on days 7, 21, and 35, were noted in animals in either group. Blood serum concentrations of urea, alkaline phosphatase and cholesterol were lower in *P. palmivora*-treated animals compared to controls, but well within the range of normal values for the rat. It was not possible to recover *P. palmivora* from the lung at termination using either staining procedures or streaking freshly cut slices of the tissue onto agar. These data indicate that *P. palmivora* is unable to survive and sporulate when placed directly into the trachea of the rat.

e. Hypersensitivity study (MRID 63097; OPPTS Harmonized Gdln 870.2600; Guideline 152-36)

The closed patch or occlusive patch procedure was used to evaluate the potential of *P. palmivora* to hypersensitize the young guinea pig. *P. palmivora* was applied to the epidermis of 10 guinea pigs for a total of 10 successive days, followed by a 14-day rest period and challenge. Erythema, edema and other lesions were scored at 24 and 48 hours after each administration according to Draize. No erythema or edema was produced and body weight gains compared to control were normal. Under these test conditions, *P. palmivora* did not produce dermal hypersensitivity, as judged by Draize scores and comparison with controls treated with dichloronitrobenzene (DCNB). Thus, these data suggest that *P. palmivora* is not a primary skin irritant and most likely would not cause hypersensitization in humans experiencing repeated exposure to the fungus.

f. Hypersensitivity Incidents (Guideline 152-36; OPPTS Harmonized Gdln 885.3400)

To date, no hypersensitivity incidents have been reported in mammalian systems in association with the pesticidal use of this plant pathogen. However, in the future and in order to comply with FIFRA Section 6(a)(2) requirements under 40CFR159.152 and OPPTS 885.3400, any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

Table 2a: Tier I - Summary Acute Mammalian Toxicity of *Phytophthora palmivora* MWV

Guideline	Study	Toxicity Category	Results	MRID #
152-10 *885.3050	Acute oral toxicity/ pathogenicity	IV	Not infective/pathogenic as shown in acute oral toxicity tests in rats as described above.	63097
152-31 *885.3100	Acute Dermal	IV	Not infective/pathogenic via dermal route. See primary dermal irritation and hypersensitivity sections.	63097 135062 135063 135064
***885.3150**	Acute Intratracheal installation/ Pathogenicity		*P. palmivora* is unable to survive and sporulate when placed directly into the treachea or the rat treated with 1.58×10^5	63097 68998
***885.3200**	Acute Injection Toxicity/ Pathogenicity		Unlikely to cause adverse effects because *P. palmivora* will not grow at 37°C, product does not contain mycotoxins, and no reference to *P. palmivora* causing adverse health effects is found in literature.	63094 94924 94925
152-34 *870.2500	Primary Dermal Irritation	IV	Very slight erythema at 24 hours.	63097 135063 135064
152-35 *870.2400	Primary eye irritation	IV	No irritation noted.	63097 135065 135066
	Dermal Sensitization		No evidence of erythema or edema in guinea pigs.	63097 135063 135064
152-36	Hypersensitivity study	N/A	No hypersensitization effects observed in 10 *P. palmivora* treated guinea pigs in 10 days of 14 day study.	63097
152-37 *885.3400	Hypersensitivity Incidents	N/A	No reported incidents to date. Agency requires reports of adverse effects and hypersensitivity incidents to comply with 6(a)(2) 40CFR159.152.	None

*885.xxx = OPPTS Harmonized Guideline Nos.

g. Data Waiver Requests

(i) Acute Intravenous, Intracerebral, Intraperitoneal Injection toxicity/pathogenicity (MRIDs 94924, 94925; OPPTS Harmonized Gdln 885.3200; Guideline 152-33)

A request to waive test data for the acute intravenous, intracerebral, intraperitoneal injection toxicity/pathogenicity guideline requirements was based on studies submitted to support the acute oral toxicity and intravenous toxicity in avian species. The studies submitted were "Oral toxicity and pathogenicity in the young Mallard duck of a single oral dose of DeVine" (MRID 94924) and "Pathogenicity of DeVine injected intraperitoneally into the young Mallard duck" (MRID 94925).

Young Mallard ducks were given an oral gavage of either 10 mL of saline, autoclaved or viable DeVine (dose equivalent to a nature exposure of consumption of 17,000 L of water). Body weight and feed consumption data were collected weekly during the 28-day study period. The treatment did not affect body weight gain, feed consumption, and efficacy. No treatment-related gross lesions were observed at autopsy (MRID 94924).

Three mL of saline, autoclaved or viable DeVine were injected intraperitoneally into young Mallard ducks. Body weight and feed consumption data were collected weekly during the 28-day study period. Injection of DeVine into the peritoneal cavity was not toxic or pathogenic to the young mallard duck. Mean growth rate and feed consumption were less with ducks that received autoclaved or viable DeVine. These effects probably reflect the stress associated with the presence of a large amount of a foreign substance in the peritoneal cavity. No abnormal behavioral patterns were observed and no abnormal gross necropsy were noted (MRID 94925).

(ii) Immune response (Guideline 152-38; OPPTS Harmonized Gdln 885.3000)

Data from the toxicology tests reported above indicate no toxicity or pathogenicity when the active ingredient is administered orally or intratracheally. Results from these supporting toxicology tests indicate that test mammalian immune systems can clear the organism. In addition, no adverse effects were reported in the hypersensitivity study in guinea pigs. Moreover, the pesticide is applied once every two years and only to citrus groves in certain counties in Florida. The application rate is low, approximately 1 pint ($3.2x10^8$ per pint, $6.7x10^5$ live chlamydospores per mL) per treated acre during the growing season. Based on the low toxicity potential and limited use of the pesticide, the request to waive the immune response data was acceptable to the Agency.

h. Subchronic, Chronic Toxicity and Oncogenicity

Based on the data generated in accordance with the Tier I data requirements (40 CFR §158.740(c)), Tier II tests (Guidelines 152B-40 through 152B-49) involving acute oral, acute inhalation, subchronic oral, acute intraperitoneal/intracerebral, primary dermal, primary eye, immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity were not required. As a result, Tier III tests (Guidelines 152-50 through 53) involving chronic testing, oncogenicity testing, mutagenicity, and teratogenicity also were not required. Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed on this microbial pest control agent. The low acute toxicity in the Tier I studies, lack of survival, replication, infectivity, and lack of persistence of this organism does not warrant the additional Tier II or Tier III tests.

i. Effects on the Immune and Endocrine Systems

EPA is required under 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 was scientific basis for including, as part of the program, the androgen and thyroid 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 the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, *Phytophthora palmivora*, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this known plant pathogen. The submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) indicate that following acute oral, intratracheal, and primary dermal irritation, dermal sensitization and hypersensitization toxicity/pathogenicity studies, the immune and interacting endocrine system are still intact and able to process and clear the

active ingredient. In addition, based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to mammalian endocrine or immune systems.

3. Dietary Exposure and Risk Characterization (includes drinking water)

Dietary exposure: For the purpose of assessing the potential dietary exposure, Valent considered that *P. palmivora* would not be present in or on treated food commodities. The pesticide product is based on a fungus which occurs naturally in citrus groves in Florida which are the areas for which it is labeled. DeVine is applied as a single application to the soil and generally does not require reapplication for a number of years. *P. palmivora* MWV is applied to the ground around citrus trees and not directly applied to trees or the edible food commodity, citrus fruit. Translocation from the treated strangler vine to the edible fruit is highly unlikely since *P. palmivora* MWV is not pathogenic or systemic to citrus. It has been shown not to infect fruit under optimal experimental conditions. It is very host specific for the pest, milkweed strangler vine, and requires stringent environmental conditions for proliferation. It does not grow at temperatures higher than 37°C, and only survives in soil and plant host debris.

The acute oral toxicity tests indicate lack of toxicity/pathogenicity to mammals. Dietary exposure, if any, will be mitigated by peeling, washing and processing of citrus fruits harvested from treated areas. Therefore, consumer risk, to the US population of adult humans, infants and children, through dietary exposure in the environment or via residues in/on treated fruit is not a concern.

Dietary exposure via drinking water, as presented below (**see Section III.B.5** of this RED), does not pose an incremental risk over that which already exists to this naturally occurring microbe.

4. Occupational and Residential Exposure and Risk Characterization

a. Occupational Exposure

The microbe demonstrates low toxicity potential as observed in the acute toxicity studies. If the pesticide is used as labeled, low application rates to soil are not expected to pose adverse effects via occupational exposure to workers and pesticide handlers. Appropriate PPE and a 4 hour REI will mitigate occupational exposure and risk. PPE is required for mixer/loader, applicator and other pesticide handlers, and restricted-entry post-application workers. Such PPE includes long sleeve shirt, long pants, shoes, socks, waterproof gloves, goggles and a dust/mist filtering respirator with the NIOSH prefix N-95, R-95 or P-95 [**Section IV.D.d.]**

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

The potential for non-occupational, non-dietary exposure to the general population is expected to be minimal to non-existent. Non-occupational dermal and inhalation exposure is not likely to be greater than that which normally exists from naturally occurring *P. palmivora* strains, as discussed below. This determination is based on several rationales. The intratracheal study demonstrated that the pesticidal active ingredient is not infective to mammals when instilled into rats (see **Section III. B.2**. of this RED). Non-occupational or residential dermal and inhalation exposures are expected to be minimal. The pesticide is to be applied to citrus groves in Florida only and not to be applied in Clay, Gulf, Liberty, or Gadsden counties. Thus treated sites are not likely to be adjacent to school and daycare facilities. Moreover, the active ingredient is a plant pathogen which may not survive at mammalian body temperatures. The low application rates suggest that exposure is not likely to be greater than background *P. palmivora* levels. Finally, lack of reports of hypersensitivity incidents during historical use of this active ingredient (see Section III.B. of this RED), suggest that non-occupational dermal and inhalation hazards and risk will be minimal, if any occurs at all.

The Agency has concluded that, if the pesticide is used as labeled, non-occupational and residential exposure to human adults, children and infants, is not likely to be greater than that which exists to the naturally-occurring microbe.

5. Drinking Water Exposure and Risk Characterization

While *P. palmivora* MWV has an aquatic phase, it cannot persist in an aqueous environment. Exposure to *P. palmivora* in drinking water is not likely to be greater than current/existing exposures to *P. palmivora* strains. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, municipal treatment of water. The pesticide is to be applied to citrus groves in certain counties of Florida. The low application rate and application once every 2-3 years minimizes runoff. The pesticide is not for application to crops grown in water, and, if used as labeled, is not likely to accumulate in drinking water. Thus, exposure via drinking water from proposed use of this pesticide is not likely to pose any incremental risk to adult humans, infants or children.

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

Based on submitted studies, the pesticide demonstrates low acute oral toxicity potential, and was classified as Toxicity Category IV, the least toxic rating, for acute oral effects. The pesticide is not expected to survive mammalian body temperatures. This microbial pesticide is intended for use on the soil surrounding the roots of citrus trees only in Florida. Thus, exposure above naturally occurring background levels is expected to be insignificant. The negligible adverse results from Tier I studies did not trigger Tier II subchronic or Tier III chronic dietary exposure studies (see **Toxicology Assessment** and **Dietary Exposure and Risk** above). No toxicological endpoints were reported to indicate the need to consider a safety factor for acute or chronic dietary exposure to sensitive subpopulations particularly infants and children. Consequently, the low acute toxicity potential, and the low exposure scenario of this microbial herbicide, indicate that there is a reasonable certainty that no harm is likely to occur to infants and children from acute or chronic exposure to *P. palmivora* MWV residues.

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

In general, *P. palmivora* is a naturally occurring organism which has undergone no genetic modifications and is not likely to pose any undue adverse risk to the US adult human population, infants and children. This assessment is based on the low toxicity and exposure potential of the pesticide when it is used as labeled.

Dermal

Acute dermal non-occupational exposure is not likely to pose an undue adverse effect to adult humans, children, and infants (see Toxicology Assessment). This conclusion is made based on the following:

(i) the application rates are low once every two to three years suggesting a low exposure potential;
(ii) based on submitted studies (Section IIIB.2.b. of this RED) the acute dermal toxicity potential of this Toxicity Category IV pesticide is low;
(iii) the active ingredient, a plant pathogen does not survive above mammalian body temperatures;
(iv) no hypersensitivity incidents were reported in workers exposed to the pesticide during manufacture and use.

Oral

As discussed above, *P. palmivora* is considered as Toxicity Category IV for acute oral effects. Dietary exposure is not likely to pose an undue adverse effect to adult humans, children, and infants, based on this low toxicity potential observed in acute oral mammalian studies (see **Toxicology Assessment** and **Dietary Exposure and Risk Characterization** above).

Inhalation

Non-occupational inhalation exposure is likely to be minimal because the pesticide is applied to the soil at low rates once every two to three years only to citrus groves in certain counties in Florida. The inherent characterization of the microbe as plant pathogen with a very specific host range, the milkweed strangler vine, also suggests negligible adverse effects as a mammalian pathogen via inhalation. Inhalation exposure is not likely to pose an undue risk to exposed populations. This decision was based on the lack of reported adverse hypersensitivity effects during the time the pesticide has been in use. Also, the microbe is not likely to survive at human and mammalian body temperatures.

The greatest occupational inhalation exposure would occur to mixer/loaders, applicators, and early entry workers. Based on the low application rates and the method of application of the pesticide to the soil, inhalation exposure is not likely to pose a risk to workers. Nevertheless, the Agency has decided that all occupationally exposed workers must wear a dust/mist filtering respirator with the NIOSH prefix N-95, P-95 or R-95, because of the inerts in the End-use Product and the microbial nature of the active ingredient.

Summary - aggregate exposure

Aggregate exposure to *Phytophthora palmivora* MWV is not expected to be greater than that which currently exists. This includes exposure and risk from (a) the dietary route via potential transfer of secondary residues from treated food/feed commodities, and drinking water, and, from (b) dermal and inhalation non-occupational and occupational exposure. In summary, potential aggregate exposure is not expected or should be adequately mitigated, as long as the pesticide is used as labeled.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to live chlamydospores of *Phytophthora palmivora* MWV and other registered pesticides which have a common mechanism of toxicity. These considerations include the

possible cumulative effects of such residues on infants and children. Live chlamydospores of *Phytophthora palmivora* MWV do not appear to be toxic or pathogenic in test mammalian systems. There is no other registered product containing live chlamydospores of *Phytophthora palmivora* MWV. Thus, there is no indication that the fungal active ingredient shares any common mechanisms of toxicity with other registered pesticides. Therefore, no common mechanism of toxicity applies. Hence, cumulative exposure and risk to this active ingredient are not expected.

9. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(c) provides that EPA shall apply an additional ten-fold margin of exposure for infants and children in the case of threshold effects to account for prenatal and postnatal 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 uncertainty factors. In this instance, based on all the available information, the Agency concludes that the active ingredient, *Phytophthora palmivora*, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when the active ingredients are used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure approach to assess the safety of *Phytophthora palmivora.*

C. Environmental Assessment

1. Environmental Hazard Assessment

(i) Avian oral toxicity/pathogenicity (OPPTS 885.4050; Gdln 154-16)
(ii) Avian injection test (OPPTS 885.4050; Gdln 154 -17)
(iii) Wild mammal testing (OPPTS 885.4150; Gdln 154A-18)
(iv) Non-target Insect testing (OPPTS 885.4340; Gdln 154-23)
(v) Honeybee Testing (OPPTS 885.4380; Gdln 154-24)
(vi) Non-target Plant studies (OPPTS 885.4300; Gdln 154-22)
(vii) Freshwater Fish testing (OPPTS 885.4200; Gdln 154-19)
(viii) Freshwater Aquatic Invertebrate Testing (OPPTS 885.4240; Gdln 154-20)
(ix) Estuarine and Marine Animal testing (OPPTS 885.4280; Gdln 154-21)

[Provisions for granting waivers for data requirements are contained in 40 CFR Part 158.45.]

Based on the toxicity data developed by the registrant and the biology of the active ingredient, *P. palmivora* does not demonstrate any ecological hazard when used according to label directions. Agency review of all environmental and endangered species considerations are summarized in Table 3a and further discussed in the text below.

a. Hazard Characterization to Terrestrial Non-target Organisms

(i) Avian oral (MRID 94924; OPPTS 885.4050; Gdln 154 -16)
(ii) Avian injection test (MRID 94925; OPPTS 885.4050; Gdln 154 -17)

"Oral toxicity and pathogenicity in the young Mallard duck of a single oral dose of DeVine" (MRID 94924) and "pathogenicity of DeVine injected intraperitoneally into the young Mallard duck" (MRID 94925) by Valent were submitted to demonstrate the effects of the pesticide on avian species.

Three groups of young Mallard ducks were given an oral gavage of either (a) 10 mL of saline, (b) autoclaved or (c) viable *Phytophthora palmivora* MWV. The dose was equivalent to an environmental exposure of consumption of 17,000 L of water. Body weight and feed consumption data were collected weekly during the 28-day study period. The treatment did not affect body weight gain, feed consumption, and efficacy. No treatment-related gross lesions were observed at autopsy (MRID 94524).

Three mL of saline, autoclaved or viable DeVine were injected intraperitoneally into young Mallard ducks. Body weight and feed consumption data were collected weekly during the 28-day study period. Injection of DeVine into the peritoneal cavity was not toxic or pathogenic to the young mallard duck. Mean growth rate and feed consumption were less with ducks that received autoclaved or viable DeVine. These effects probably reflect the stress associated with the presence of a large amount of a foreign substance in the peritoneal cavity. No abnormal behavioral patterns were observed and no abnormal gross necropsy were noted (MRID 94925).

(iii) Wild mammal testing (OPPTS 885.4150; Gdln 154A-18)

These data are required only when the acute oral rodent toxicity/pathogenicity study (OPPTS 885.3050) is not sufficient for wild mammal hazard assessment. The acute oral 28 day infectivity rat study in support of reregistration of this active ingredient is sufficient to make a no apparent hazard finding to wild mammals (MRIDs 63097, 68998). The Agency concluded that *P. palmivora* demonstrated no toxicity or pathogenicity when administered to rats. According to this study, the acute oral LD_{50} is $>10^6$ fungal units/mL. Similarly, the intratracheal study in rodents demonstrated no infectivity or pathogenicity after an intratracheal dose of 1.58×10^5 *P. palmivora*

chlamydospores (MRID). Other toxicology studies also indicate that the pesticide is not likely to have an adverse affect on mammalian systems.

Based on the low observed mammalian toxicity/pathogenicity effects in the acute oral and the intratracheal toxicity/pathogenicity tests in rodents (**Section III. B.2.** of this RED) the Agency has concluded that use of this microbial pesticide is not likely to pose incremental hazards to wild mammals if used as labeled. No additional mammal testing at higher tiers is required.

(iv) Non-target Insect testing (OPPTS 885.4340; Gdln 154-23)

(v) Honeybee Testing (OPPTS 885.4380; Gdln 154-24)

The pesticide is a known plant pathogen and is not known to have any adverse effects on insects. The mycoherbicide is to be applied directly to soil from May to September when the pest, milkweed strangler vine, is actively growing. Initially only one treatment per season is necessary and in subsequent years it may only be applied once every two to three years. The soil treatment and the low exposure and phytopathogenicity indicate that *P. palmivora* MWV is not likely to have adverse effects on bees and other non-target beneficial insects. Therefore, development and submission of insect toxicity/pathogenicity data for this product is not required.

(vi) Non-target Plant Hazard Assessment (OPPTS 885.4300; Gdln 154-22)

Summaries of three plant infectivity/pathogenicity studies submitted to the agency (EBB Branch review, C. Natella 12/10/80) indicate that *P. palmivora* MWV does not appear to be a pathogen of citrus trees, at least not of the rootstock/scion combination in the field. The fungus has, however, been isolated from root samples of cucumber, squash, watermelon, begonia, bougainvillea, boxwood, hibiscus, oak areca palm, periwinkle, pittosporum, and snapdragon after inoculation of the soil. The only species which actually exhibited noticeable symptoms of disease were watermelon, periwinkle, and milkweed strangler vine.

There is also evidence that *P. palmivora* MWV in the soil can effect seed emergence of the following species: onion, cantaloupe, okra, watermelon,tomato, endive, cucumber, English (or garden) pea, and carrot. Root infection after soil inoculation has been detected in squash, watermelon, and English pea with infection resulting in death in the English pea. Root rot has also been observed in Carrizo orange seedlings grown in inoculated soil. Foliage inoculation has resulted in infection to English pea, Irish potato, tomato, and hybrid rhododendron (Purple Splendour).

Phytophthora palmivora MVW has been shown to cause disease or reduced emergence of seedlings in several economically important plant species representing ten different plant families (Cucurbitacaeae, Apocynacaeae, Liliacaeae, Malvacaeae, Solanacaeae, Leguminosae, Compositae, Umbeliferae, Rutacaeae and Ericacaeae). Most of these species were tested at the seedling stage. In addition, the fungus has been isolated from the root tissue of plants representative of seven additional plant families. These plants exhibited no disease symptoms. Therefore, in addition to species of the milkweed strangler vine family (Asclepiadaceae), plant species from a total of 17 plant families, herbaceous species as well as trees and shrubs, are capable of harboring *P. palmivora* MWV. It must be kept in mind that the doses for these tests were higher than the allowed label rate.

Nevertheless, as a result of consideration of these data, the Agency requires label language excluding use of DeVine in the vicinity of the susceptible crop plants.

b. Hazard Characterization for Aquatic Organisms

(vii) Freshwater Fish Hazard Assessment (MRID OPPTS 885.4200; Gdln 154-19)

A submited study shows that DeVine is not acutely toxic to rainbow trout at a dosage that is greater than 1000 times the estimated environmental concentration, based on the number of spores expected when the formulated product is applied at 1 pint/acre to 6 inches of water (MRID 94923. While this study may not predict effects from chronic exposure, it must be considered that the pesticide is to be applied about once every two years. Soil application only to citrus in certain counties in Florida suggests low to non-existent aquatic exposure and the likely potential of no adverse effects to freshwater fish species.

(viii) Freshwater Aquatic Invertebrate Hazard Assessment (MRID 94923; OPPTS 885.4240; Gdln 154-20)

A submitted study shows that DeVine is not acutely toxic to *Daphnia magna* at a dosage that is greater than 1000 times the estimated environmental concentration, based on the number of spores expected when the formulated product is applied at 1 pint/acre to 6 inches of water (MRID 94923). While this study may not predict effects from chronic exposure, it must be considered that the pesticide is to be applied about once every two years. Soil application only to citrus in certain counties in Florida suggests low to non-existent aquatic exposure and the likely potential of no adverse effects to freshwater invertebrate species.

(ix) Aquatic Animals - Freshwater and Estuarine (MRID 94923; OPPTS 885.4280; Gdlns 154-19, 154-20, 154-21)

While there is an aquatic phase in the life cycle of *P. palmivora* MWV, it does not persist in aquatic environments. The pesticide is to be applied to citrus groves in certain counties in Florida. Thus, there is a low potential for exposure to estuarine and marine animals. In addition, the specificity of the phytopathogen for milkweed strangler vine precludes its ability to have adverse effects on estuarine and marine animals.

c. Endangered species considerations

No incremental hazards of live chlamydospores of *Phytophthora palimivora* MWV are anticipated to endangered mammals on the basis of results from acute oral, acute dermal and other acute toxicity tests conducted in mammalian systems (see **Section III. B. Toxicology Assessment**). As indicated by the available data no adverse effects to Federally listed Endangered/Threatened avain species are expected when DeVine is used according to label specifications. The data and risk assessments in this review indicate that no toxic effects from DeVine are expected for fish, amphibians, reptiles, and other aquatic animal species, including invertebrate and arthropod Endangered Species. Infections of these species by *Phytophthora palimivora* are not known to occur. In addition, the registered use patterns preclude any direct exposure of aquatic animal or plant species to infectious doses of the mycoherbicide. There are two endangered plant species found in Florida: *Rhododendrum chamanni* and *Harperocallis flova* (*Liliaceae*). Rhododendron have been shown to be affected by this mycoherbicide; therefore, a statement on the label must exclude the product use in Florida's Clay, Gulf, Liberty or Gadsden counties where the species is found. [see **Section IIIB**, **IIIC.c.**]. Harper's beauty (*Harperocallis flova*) is only found in the Appalachian National Forest that borders both Liberty and Franklin Counties. There are no nearby agricultural areas, particularly no citrus is grown in the vicinity.

As a result of the above considerations there is a "not likely to adversely affect" (NLAA) endangered species determination when the labeling excludes applications in counties where endangered plants may be found.

2. Environmental Assessment and Risk Summary

Table 3: Eco-Toxicology Summary/Studies Evaluated

Guideline	Study	Status	MRID #
154-16 885.405	Avian toxicity/pathogenicity	Not an avian hazard shown by avian acute oral and intraperitoneal studies. Acceptable.	94924, 94925

Table 3: Eco-Toxicology Summary/Studies Evaluated

Guideline	Study	Status	MRID #
154-17 885.41	Avian pulmonary/inhalation toxicity/pathogenicity	Study required only on MPCAs related to known avian pathogens. Not an avian hazard because of low exposure levels and no hazard observed in avian oral and IP studies.	Not Applicable
154-19 885.42	Freshwater fish toxicity/pathogenicity	Not acutely toxic to rainbow trout at a dosage that is greater than 1000 times the estimated environmental concentration. Runoff not expected from low exposure levels. Acceptable.	94923
154-20 885.424	Freshwater Aquatic Invertebrate toxicity/pathogenicity	Not acutely toxic to Daphnia at a dosage that is greater than 1000 times the estimated environmental concentration. Acceptable.	94923
154-18 885.4150	Wild Mammal toxicity/pathogenicity	Mammalian tests demonstrate no undue adverse effects in the acute oral and intratracheal tests. Acceptable.	63097 135062, 135063, 135064
154-22 885.4300	Nontarget Plant toxicity/pathogenicity	In a greenhouse study of 30 different plant families and citrus trees only watermelon, periwinkle and milkweed strangler vine died or were diseased . There was no adverse effect on citrus trees. P. palmivore was detected on the roots of deveral other plant species without any overt symptomology. Acceptable	63096
154-23 885.434	Nontarget Insect toxicity/pathogenicity	*P. palmivora* MWV is a phytopathogen specific for milkweed strangler vine. There are no reports of any insect infections. Pesticide is to be applied once per season after two year periods to citrus groves in FL only. Limited exposure potential of this low toxicity pesticide is not expected to pose a risk to these non-target organisms.	None
154-24 885.4380	Honey Bee toxicity/pathogenicity		None
154-21 885.428	Estuarine and Marine Animals toxicity/pathogenicity		94923
Endangered Species Act (ESA)	Endangered Species Impact Assessment	See Section III.C.c. No "may effect" finding for birds, fish, reptiles, mammals and invertebrates. FL is the only state where the product may be used for control of milkweed strangler vine in citrus groves. A NLAA finding for plants. Not to be used in certain counties in FL where endangered plants are found.	Not Applicable

*885 series = OPPTS Microbial Pesticide Test Guideline Numbers.

IV. RISK MANAGEMENT AND REGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing the active ingredients live chlamydospores of *Phytophthora palmivora* MWV.

Although the Agency has found that all currently registered uses of *Phytophthora palmivora* MWV are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration or reregistration of products containing these active ingredients.

B. Regulatory Position

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients live chlamydospores of *Phytophthora palmivora* MWV, and pesticide products containing these active ingredients, the Agency has decided that the active ingredient is eligible for reregistration.

2. Eligible uses

Pesticides containing *Phytophthora palmivora* MWV are eligible for treatment control of milkweed strangler vine in citrus groves in certain counties in Florida as specified on the label.

3. Ineligible uses

This mycoherbicide is not to be used on other crops or pests except those specified on the registered label.

4. Food Quality Protection Act Considerations

a. Safety determinations

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act

(FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4.

In determining whether a tolerance or an exemption from tolerance meets the FQPA safety standard, section 408(b)(2)(c) directs EPA to consider information concerning the exposure of infants and children to pesticides in food, available information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met. These factors include the consideration of available information on the cumulative effects of the pesticide for which a tolerance is sought as well as other substances that have a common mechanism of toxicity and consideration of available information on the aggregate exposure levels of the population and of major subgroups of the population to the pesticide and related substances.

The Agency applies these standards to reassess the exemptions from tolerance for active ingredients during reregistration on a case by case basis. The assessment previously described in this RED demonstrates that the generic active ingredient, *Phytophthora palmivora* MWV, complies with the requirements of the Food Quality Protection Act of 1996. If EPA determines that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including, but not limited to, reconsideration of any portion of this RED.

b. Tolerance Reassessment

EPA has reassessed this exemption from tolerance as required by FIFRA § 4(g)(2)(E) and considers these reassessed exemptions from tolerances to be qualifying federal determinations under FFDCA § 408(n)(2). The exemption from tolerance was reassessed and found to comply with FQPA during reregistration.

c. CODEX Harmonization

There are no Codex harmonization considerations since there are no Codex Maximum Residue Limits set for food use of this active ingredient.

d. Non-food Reregistrations

The sole registered pesticide containing the active ingredient *Phytophthora palimivora* MWV is registered for food use on citrus only. There is no non-food use of this pesticide.

5. Endangered Species Statement

The pesticide is to be applied to control milkweed strangler vine in citrus groves in Florida only, but must not be applied in Clay, Gulf, Liberty or Gadsden counties [see **Section IIIB**, **IIIC.c.**].

C. Regulatory Rationale

Risk Mitigation
Health, Occupational, Non-occupational, Ecological and Environmental Effects

The following is a summary of the rationale for managing risks associated with the current use of live chlamydospores of *Phytophthora palmivora* MWV. Where labeling revisions are warranted, specific language is set forth in **Sections IV and V** of this document.

Risks, as a result of exposure to *Phytophthora palimivora* MWV and its chlamydospores via dietary route, and through potential inadvertent residues in drinking water, or by aggregate and cumulative effects, are expected to be minimal to non-existent. Pesticides containing these active ingredients are not likely to survive municipal treatment of drinking water. No other pesticide containing these active ingredients is registered, thus minimizing any potential for cumulative effects with other pesticides which share a common mechanism of action. Risks via aggregate exposure through oral, dermal, inhalation, and non-occupational routes are expected to be minimal to non-existent, based on the low toxicity potential of the microbe as discussed in this RED. Occupational risk is adequately mitigated by the use of appropriate PPE as discussed in the labeling part of **Section IV** of this RED.

D. Labeling

1. Manufacturing Use Product

It is the Agency's position that the labeling for manufacturing products containing live chlamydospores of *Phytophthora palmivora* MWV must comply with the pesticide labeling requirements in existence when such products are reregistered.

The label must include appropriate statements to indicate that the registered product is a manufacturing use product (MUP) if the intent is to use the product to formulate into end-use products (EP). Long sleeved shirt, long pants, shoes, socks, goggles, gloves and a dust/mist filtering respirator with the NIOSH prefix N-95, P-95 or R-95 are required when handling or formulating the MUP into the EP.

The following NPDES statement must be placed on the manufacturing use product for the active ingredient, live chlamydospores of *Phytophthora palmivora* MWV, at this time.

> "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."

2. End-use Product

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

a. End-use Product name: DeVine Herbicide

Ingredient Statement:w/w
Live chlamydospores of *Phytophthora palmivora* MWV 0.8%
Inert Ingredients 99.2%
Total 100.00%*

* viability of End-use Product is 6.7 x 10^5 CFU/gm

Based on the evaluation of the acute oral and acute pulmonary toxicity/infectivity studies submitted in support of the reregistration of the product, live chlamydospores of *Phytophthora palmivora* MWV, the signal word is "CAUTION". Signal words for other end-use products containing this active ingredient will vary depending on the toxicity/pathogenicity evaluations of those products.

b. Application Rate

The pesticide is to be applied at the rate of one pint in 50 gallons of water per acre (See label and **Section II.B.**)

c. NPDES statement

Because there is no separate manufacturing use product (MP) registered at this time, the NPDES statement shown above for MUP labeling is required for this End-use Product which is considered as produced by an integrated process. This is subject to review as other products are registered.

> "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."

d. Human Health Hazard
(i) Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with PR Notice 93-7, "Labeling Revisions required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7", which reflect the WPS (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170). Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices, such as, and including the WPS labeling.

Workers and handlers (including mixer/loader, applicators) and applying this product must wear long sleeved shirt, long pants, shoes, socks, goggles and gloves, as well as a dust/mist filtering respirator with NIOSH approval number prefix N-95, R-95 or P-95. Postapplication agricultural

workers and early-entry workers must wear PPE as described above for workers and handlers when entering treated areas during the restricted entry interval (REI) of 4 hours.

(ii) Non-Worker Protection Standard

There is no site registered that falls outside the scope of the Worker Protection Standard.

(iii) Other Precautionary Labeling

The Agency has examined the toxicological data base for live chlamydospores of *Phytophthora palmivora* MWV and concluded that the precautionary labeling required during this conditional registration process (i.e. Signal Word, First Aid Statements, WPS statements for pesticide handlers, and other label statements) adequately mitigates the risks associated with the proposed uses. Additional labeling may be required for other uses of products containing live chlamydospores of *Phytophthora palmivora* MWV on a case by case basis.

e. Environmental Hazards Labeling

Standard Environmental Hazards labeling statements are required for application of the currently registered End-use Product.

Provided (1) the pesticide is used as labeled; (2) that it is not used in certain counties where sensitive endangered plant species are found; and (3) that it is not used in the vicinity of certain sensitive crop plants, the risk of exposure to live chlamydospores of *Phytophthora palmivora* MWV is minimal to nonexistent to non-target organisms including endangered species.

The following statement is required in the environmental hazards section of the label:

> "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 wash waters."

f. Other Label statements

The label must comply with the Agency's current labeling requirements. Label statements to mitigate potential risks to endangered species are not required at this time based on ecological exposure scenarios discussed in **Section IIIC** of this RED. Spray drift is not expected from the permitted soil application of the sole registered product which contains live chlamydospores of

Phytophthora palmivora MWV. Should the formulation or methods of application change or should issues surface which change this assessment, the Agency will take appropriate regulatory action.

V. WHAT REGISTRANTS NEED TO DO

The Agency has evaluated the data submitted by Valent Biosciences Corporation and has not received any data from previous registrants associated with the manufacture and distribution of products containing live chlamydospores of *Phytophthora palmivora* MWV. Therefore, the comments below regarding data and labeling requirements only apply to Valent Biosciences Corporation. EPA has determined that live chlamydospores of *Phytophthora palmivora* MWV (PC Code 111301) are eligible for reregistration to that company provided that: (i) additional data that the Agency intends to require confirm this interim decision; and (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrant must amend the product labeling to incorporate the label statements set forth in **Section IV** above. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. For the Technical Grade Active Ingredient and the End-use product of *Phytophthora palmivora* MWV, the registrant must submit confirmatory data to establish nominal limits and analyses of five (5) production batches within 30 months of manufacture of the pesticide. These data are required to ascertain that human fungal and bacterial pathogens and unintentional ingredients are within regulatory limits and are not of toxicological concern.

B. For product reregistration the Agency requires:

(1) two copies of the confidential statement of formula (EPA Form 8570-4);

(2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

(3) five copies of the draft label incorporating all label amendments outlined in Table 25 of this document;

(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

(5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32).

Please contact Shanaz Bacchus at *bacchus.shanaz@epa.gov* with questions regarding generic and/or product reregistration. All materials submitted in response to the generic or product reregistration should be addressed to Shanaz Bacchus and sent to:

By US mail:
Document Processing Desk (DCI/BPPD)
US EPA/OPP (7511C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/BPPD)
Office of Pesticide Programs (7511C)
Room 910W38, Crystal Mall 2
1801 S. Bell St
Arlington, VA 22202

A. Manufacturing Use Products

Additional Generic Data Requirements

The generic data base, submitted by Valent Biosciences Corporation, supporting the reregistration of live chlamydospores of *Phytophthora palmivora* MWV for the above eligible uses has been reviewed and determined to be sufficient. The active ingredient, *Phytophthora palmivora* MWV is eligible for reregistration. However, the following data requirements, if applicable, are necessary to confirm the reregistration eligibility decision documented in this RED:

2. Labeling for Manufacturing Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear labeling to indicate that it is to be used for manufacturing purposes only.

B. For the End-use Product (EP)

Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and, if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The following are required when the pesticide is produced for commercial purposes.

a. Guidelines 151-10 through 151-16 (OPPTS Gdln 885.1300): Product Identity, Manufacturing Process and Quality Control

Analysis of five (5) production batches is required to include nominal limits and identification of the pesticide active ingredient and any unintentional ingredients, such as human bacterial and fungal pathogens of toxicological concern. Batches containing unintentional ingredients above regulatory levels must be destroyed.

b. Hypersensitivity Incidents

For registered and reregistered products, reports of incidents of adverse effects to humans or domestic animals are required at all times under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16.

c. Regulatory requirement - labels

Before releasing products for shipment, the registrant is required to provide appropriate final printed labels and other Agency requirements, as discussed in this RED, or as required.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell *Phytophthora palmivora* MWV products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

Table 4: Data required on production

Guideline	Title of Study	Data required	Date due
*885-1100 151-10	Product Identity	Identification of the active ingredient, viability and storage stability.	As batches are produced.
*885.1300 151-12	Discussion of Formation of Unintentional Ingredients	Human pathogen and metabolite (if any) identification and quantification.	During production of 5 batches (to be provided as batches are produced).
*885.1500 151-15	Certification of limits	Nominal Limits. Standard data requirement for production batches.	As batches are produced.

*OPPTS Harmonized Guidelines

VI. APPENDICES

This Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:
www.epa.gov/pesticides/reregistration

APPENDIX A. Use sites

Table 5 lists the use sites for the product. The registrant must comply with the appropriate labeling requirements before releasing products containing *Phytophthora palmivora* MWV as the active ingredient for shipment.

Table 5: Use Sites for Reregistration

Citrus groves in Florida. Not to be applied to Clay, Gulf, Liberty or Gadsden counties	**Official date reregistered:**

APPENDIX B. **Table of the Generic Data Requirements** and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case *Phytophthora palmivora* MWV covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to *Phytophthora palmivora* MWV and its spores in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for Reregistration of *Phytophthora palmivora* MWV

NEW GDLN	OLD GDLN	REQUIREMENT	USE PATTERN	CITATION(S)
	PRODUCT CHEMISTRY			
885.11	151-20	Product Identity	All	MRID 45734101, 45734103
885.12	151-21	Start. Mat. & Mfg. Process	All	MRIDs 45734101, 63089, 68997, 135061
885.13	151-22	Formation of Unintentional Ingredients	All	MRIDs 63089. 63090, 63091, 45734101
885-1400	151-23	Analysis of Samples (MUP, EP)	All	Not required for exemption from tolerance
885.15	151-25	Certification of limits	All	MRID 63090
885-2300	151-25	Analytical Method (EP)		MRIDs 45734102, 63091
	151-28	Physical and Chemical Properties	All	MRID 45734102, 63088, 63094, 68997, 97531
	TIER I TOXICOLOGY			
885.305	152-30	Acute Oral Toxicity/Pathogenicity	All	MRID 63097, 135062

Data Supporting Guideline Requirements for Reregistration of *Phytophthora palmivora* MWV

NEW GDLN	OLD GDLN	REQUIREMENT	USE PATTERN	CITATION(S)
	TIER I TOXICOLOGY(cont'd)			
885.31	152-31	Acute Dermal Toxicity - Rabbit/Rat	All	MRIDs 63097, 135063, 135064
885.315	152-32	Acute inhalation	All	MRIDs 63097 68998
885.32	152-33	Acute Intravenous, Intracerebral, Intraperitoneal injection	All	MRIDs 94924, 94925
870.25	152-34	Primary Dermal Irritation	All	MRID 135063, 135064
870.24	152-35	Primary Eye Irritation - Rabbit	All	MRID 135065, 135066
	152-36	Hypersensitivity study	All	MRID 63097
885.34	152-37	Hypersensitivity Incidents	All	None reported.
	TIER II TOXICOLOGY			
885.36	152-32	Subchronic toxicity/pathogenicity	AB	Not required, no Tier I triggers.

Data Supporting Guideline Requirements for Reregistration of *Phytophthora palmivora* MWV

NEW GDLN	OLD GDLN	REQUIREMENT	USE PATTERN	CITATION(S)
		NON-TARGET ORGANISMS - TIER I		
885.405	154-16	Avian oral pathogenicity/toxicity - bobwhite quail	AB	MRID 94924
885.41	154-17	Avian injection test	AB	MRID 94925
885.415	154-18	Wild mammal testing		MRID 63097, 135062, 135063, 135064
885.42	154-19	Freshwater fish toxicity/pathogenicity	AB	MRID 94923
885.424	154-20	Freshwater Aquatic Invertebrate toxicity/pathogenicity	AB	MRID 94923
885.43	154-22	Nontarget plant studies	AB	Must not be used on susceptible crops. For use in citrus groves in certain counties in Florida only.
885.434	154-23	Nontarget insect testing	AB	Known plant pathogen, specific for milkweed strangler vine. Low exposure, no adverse effects expected.

Data Supporting Guideline Requirements for Reregistration of *Phytophthora palmivora* MWV

NEW GDLN	OLD GDLN	REQUIREMENT	USE PATTERN	CITATION(S)
885.438	154-24	Honey bee testing	AB	Known plant pathogen specific for milkweed strangler vine. Low exposure, no adverse effects expected.
ESA		Endangered Species Impact Assessment	AB	No "may effect" finding for endangered species when the labeling excludes applications in counties where endangered plants may be found.

OCCUPATIONAL/RESIDENTIAL EXPOSURE

Occupational Exposure data requirements are not required for Toxicity Category IV pesticides.

RESIDUE CHEMISTRY

Residue chemistry data requirements are not required in this reregistration case, because of the use patterns and the potential lack of residues on treated crops, which are exempt from the requirements of a tolerance for this microbial pesticide with a low toxicity profile.

APPENDIX C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/biopesticides

These documents include:

Reregistration Eligibility Decision. *Phytophthora palmivora* MWV. Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, US EPA.

APPENDIX D. **Citations** Considered to be part of the Data Base Supporting the Reregistration of *Phytophthora palmivora* MWV

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an

identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

CITATIONS/BIBLIOGRAPHY

Studies submitted in support of this reregistration action for PC Code
MRID Citation Reference

MRID	Citation Reference
63088	Abbott Laboratories (1980) Efficacy of Disinfectants for Milkweed Vines. (Compilation; unpublished study received Sep 16, 1980 under 275-39; CDL:099648-A)
63089	Abbott Laboratories (19??) Manufacturing Directions. (Unpublished study received Sep 16, 1980 under 275-39; CDL:099648-B)
63090	Abbott Laboratories (19??) Specifications. (Unpublished study received Sep 16, 1980 under 275-39; CDL:099648-C)
63091	Abbott Laboratories (19??) Test Methods. (Unpublished study received Sep 16, 1980 under 275-39; CDL:099648-D)
63092	Woodhead, S.H.; Grove, W.E. (1980) Correlation of in vitro and in vivo Assay Methods Used for the Determination of *Phytophthora citrophthora* Chlamydospore Viability: Experiment # D911-2338-80. (Unpublished study received Sep 16, 1980 under 275-39; submitted by Abbott Laboratories, North Chicago, Ill.; CDL:099648-E)
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63098	Abbott Laboratories (1980) Efficacy of *Phytophthora palmivora* for Various Citrus Fruits. (Compilation; unpublished study received Sep 16, 1980 under 275-39; CDL:099648-K)
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45734102	Rehberger, L. (2002) *Phytophtora palmivora*: Analytical Methods: Lab Project Number: VBC 6387 METH. Unpublished study prepared by Valent Biosciences Corporation. 10 p.
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94270000	Abbott Laboratories (1990) Reregistration Phase 3 Response: *Phytophthora citrophthora*.
94270999	Abbott Laboratories (1990) Reregistration Phase 3 Response: *Phytophthora citrophthora*. Correspondence and Supporting Material.

APPENDIX E. Generic Data Call-In

A generic Data Call-in is not required.

APPENDIX F. EPA's Batching of *Phytophthora palmivora* MWV Products for Meeting Acute Toxicity Data Requirements for Reregistration.

Batching is not required for this active ingredient. The sole registered product is Devine, EPA Registration Number 74039-9. Registrant is Valent Biosciences Corporation, as discussed in this RED.

APPENDIX G. List of Registrants sent PDCI

Not required.

APPENDIX H. List of Available Relevant Documents

The following is a list of available documents for *Phytophtora palmivora* MWV and its spores that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Phil Hutton at (703)-308-8260.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for *Phytophtora palmivora* MWV.

The following documents are part of the Administrative Record for *Phytophtora palmivora* MWV and its spores and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Reregistration Eligibility Decision

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria