Reregistration Eligibility Decision for Phytophthora palmivora

January 2006

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

1/19/06

MEMORANDUM

SUBJECT: Tolerance Reassessment Decision Concerning the Tolerance Exemption for the Microbial Pesticide *Phytophthora palmivora* MWV

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TO: Debra Edwards, Director
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This document reassesses the tolerance exemption for the fungus *Phytophthora palmivora* MWV announced in the Federal Register on March 26, 1981 (46 FR 18695): 40 CFR 180.1057). This tolerance exemption covers citrus crops. In preparing the Reregistration Eligibility Document (RED) for this active ingredient (February 2006), no toxicological information of concern was found in the open literature or in-house files from 1981 onward. Therefore, the reassessment consisted of determining whether the 1981 tolerance exemption is consistent with the more stringent safety requirements that took effect on August 3, 1996 with passage of the FQPA. In coming to the required FQPA finding of a reasonable certainty of no harm, OPP has considered all of the factors described in FQPA regarding FFDCA section 408 (b)(2)(C) and section 408 (b)(2)(D)(i) to (ix).

Toxicity Studies. Studies submitted as part of the registrant's application for registration and recently reviewed for preparation of the RED showed no evidence of toxicity, pathogenicity or infectivity when *Phytophthora palmivora* MWV was tested in laboratory mammals. Therefore, no health risks to humans, including infants and children, are expected from exposure to *Phytophthora palmivora* MWV.

Conclusion. With the finding that this tolerance exemption is in compliance with FQPA, EPA concludes that the tolerance exemption for *Phytophthora palmivora* MWV has been reassessed and will be maintained.

Attachments:
1. *Phytophthora palmivora* MWV Tolerance Reassessment Risk Assessment Summary
2. 40 CFR section 180.1057 statement of tolerance exemption.
3. Summary of EPA's evaluation of the submitted toxicity studies (RED, February 2006)

Attachment 1.

***Phytophthora palmivora* MWV: Tolerance Reassessment Risk Assessment Summary**

A. Background.

Phytophthora palmivora MWV was isolated from citrus groves, where it attacks *Morenia orderata*, known as strangler vine or milkweed vine, a serious pathogen of citrus trees in Florida. The single registered product is applied only once every two years, and is approved only for use in Florida, so exposure of applicators and consumers is minimal.

B. Data Summary

The following toxicity and pathogenicity studies were among the studies reviewed for the RED (See attachment 3).

Acute Oral Toxicity/Pathogenicity
Acute Dermal Toxicity/Pathogenicity
Primary Eye Irritation
Primary Dermal Irritation

Pulmonary and injection studies were waived. All other data were also reviewed. No evidence of toxicity, infectivity, or pathogenicity in animals was found.

C. Search for Recent Information

A web search included Toxline, Google, and other sites. No indication of toxicity or pathogenicity to mammals was found.

D. FQPA Assessment:

1. Infants and Children. *Phytophthora palmivora* MWV is not likely to pose any hazards to infants and children consuming food treated with this organism.

2. Validity and Completeness of Data. The data on *Gliocladium virens* GL-21 remain valid to support the existing tolerance exemption, and no new information suggests any problem with maintaining the exemption.

3. Nature of Toxic Effects. No toxic effects have been identified.

4. Relationship of the Available Information to Human Risk. The available information is consistent with Agency requirements for new microbial pesticides of this nature for this use.

5. Information on Dietary Consumption. Because *Phytophthora palmivora* MWV is non-toxic and non-pathogenic, information on dietary consumption is not required, in conformity with the current Agency standard for this type of organism.

6. Cumulative Effects. Because *Phytophthora palmivora* MWV is non-toxic and non-pathogenic, no potential cumulative effects have been identified.

7. Aggregate Exposure. There are no other uses of *Phytophthora palmivora* MWV. Even if other uses existed, the non-toxic and non-pathogenic nature of the organism precludes concern for aggregate exposure.

8. Sensitive Subgroups. Because *Phytophthora palmivora* MWV is non-toxic and non-pathogenic, sensitive subgroups are not an issue.

9. Estrogen and Endocrine Effects. 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 hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require 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). When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, *Phytophthora palmivora* MWV may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on the weight of the evidence of available data, no endocrine system related effects have been identified for *Phytophthora palmivora* MWV.

10. Safety Factor. Because *Phytophthora palmivora* MWV is non-toxic and non-pathogenic, no safety factor is required.

E. Conclusion

The existing data and other information on the tolerance exemption of *Phytophthora palmivora* MWV have been re-examined and found to fulfill current Agency standards for this kind of microbial pesticide.

There is a reasonable certainty of no harm from the use of *Phytophthora palmivora* MWV under the existing tolerance exemption.

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Attach 2

§ 180.1057 Phytophthora palmivora; exemption from requirement of tolerance.

Phytophthora palmivora is exempted from the requirement of a tolerance in or on the raw agricultural commodity citrus fruit.

[46 FR 18695, Mar. 26, 1981]

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

In general, *P.p.* 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.

Attach 3. pg 2

Oral

As discussed above, *P.p.* 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 milk weed 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 palmovora* 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.

Attach 3, pg 3

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 ACC# 099648 099649
152-31 *885.3100	Acute Dermal	IV	Not infective/pathogenic via dermal route. See primary dermal irritation and hypersensitivity sections.	099648 099649
*885.3150	Acute Intratracheal installation/ Pathogenicity		*P.p.* unable to survive and sporulate when placed directly into the treachea or the rat treated with 1.58 x 10^5.	ACC# 099648 099649 check MRID
*885.3200	Acute Injection Toxicity/ Pathogenicity		Unlikely to cause adverse effects because *P.p.* will not grow at 37°C, product does not contain mycotoxins, and no reference to *P.p.* causing adverse health effects is found in literature.	
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	099648 099649
152-36	Hypersensitivity study	N/A	No hypersensitization effects observed in 10 *P.p.* 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.