United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7511C)

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R.E.D. FACTS

***Phytophthora palmivora* MWV ***

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers that describe the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet current human health and safety standards and can be used without posing unreasonable risks to human health and the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for the pesticide *Phytophthora palmivora* MWV, case number 4105.

Use Profile

Phytophthora palmivora MWV is a fungal active ingredient used on

citrus crops to control the weed *Morenia orderata*, commonly known as strangler vine or milkweed vine. As of the date of this document (March 2006), there was one registered product containing this active ingredient. The liquid product is mixed with water and sprayed approximately every other season onto soil under citrus crops, after the weed has germinated or is actively growing. The active ingredient occurs naturally in five Florida counties (Polk, Hillsborough, Pasco, Lake, and Orange), and use is limited to those counties.

Regulatory History

The first and only product containing the active ingredient *P. palmivora* MWV was registered in 1981 for use against milkweed vine on citrus. A final rule exempting *P. palmivora* MWV from the requirement of a tolerance on citrus fruit was issued in March 1981. In January 2006, EPA reassessed the tolerance exemption and concluded it should remain in effect. The pesticide product containing *P. palmivora* MWV as the active ingredient is "DeVine Herbicide" (Valent BioSciences Corporation: EPA Reg No. 73049-9).

Human Health Assessment

Toxicity

Toxicity/pathogenicity studies on *P. palmivora* MWV show that this organism is not expected to adversely affect humans or other mammals. Its only targets are plants. Following is a brief summary of the major studies carried out on rodents.

1. Acute Oral Toxicity

Male and female rats were dosed by oral gavage. No abnormal changes or mortality were noted during 35 days of observation and sampling. The fungal active ingredient is not infective or pathogenic to test mammals via the oral route.

2. Primary Dermal Irritation

No abnormal observations of skin changes or behavior occurred among rabbits dosed for 24 hours and observed for the following 35 days. The active ingredient is not considered a dermal irritant when tested under acute exposure conditions.

3. Primary Eye Irritation

Rabbits treated and observed daily for 35 days showed no adverse eye effects, such as increased irritation or inflammation of the conjunctiva or iris. Therefore, *P. palmivora* MWV is not considered a primary eye irritant.

4. Intratracheal Installation

No adverse effects were seen in the test group of rats compared with the control group. The study shows that *P. palmivora* MWV is unable to survive and sporulate when placed directly into the trachea of the rat.

5. Hypersensitivity Study

Under standard test conditions, guinea pigs showed no dermal hypersensitivity when they received a daily epidermal exposure for 10 days and were challenged 14 days later. The data indicate that *P. palmivora* MWV is unlikely to cause hypersensitivity in humans repeatedly exposed to the fungus.

No reports of hypersensitivity incidents have been received to date. Any hypersensitivity incidents that occur in the future must be reported to the Agency.

6. Studies Waived

Additional health studies, including effects on the immune and endocrine systems, were waived based on the results described above, literature reports, and minimum expected exposure.

Environmental Assessment

Environmental Assessment

Based on the Agency's assessment of toxicity data and the biology of the active ingredient, *P. palmivora* MWV is not expected to present an ecological hazard when products containing it are used according to label directions. The active ingredient has been demonstrated to be pathogenic and toxic only to plants. Studies and reports show no adverse effects to any organisms except plants. Environmental and endangered species data are summarized below.

a. Hazard Characterization to Terrestrial and Aquatic Non-target Organisms

i) Avian oral test

ii) Avian injection test

These tests were performed using viable or autoclaved (non-viable) DeVine Herbicide Product. No toxic or pathogenic effects were seen in young Mallard ducks 28 days after a single oral or IP dose, indicating that the product is not toxic or pathogenic to young Mallard ducks.

(iii) Freshwater Fish Hazard Assessment

(iv) Freshwater Aquatic Invertebrate Hazard Assessment

Submitted data show that the registered product, DeVine Herbicide, containing *P. palmivora* MWV, is not acutely toxic to rainbow trout or to *Daphnia magna* at an exposure greater than 1000 times the estimated environmental concentration when label directions are followed.

(v) Non-target Plants

Three studies show that *P. palmivora* MWV is not a pathogen of citrus crops in Florida. However, after soil inoculation, *P. palmivora* MWV has been detected in squash, watermelon, and English pea, with infection causing death of the English pea. Foliage inoculation has led to infection in English pea, Irish potato, tomato, and hybrid rhododendron (Purple Splendour).

Phytophthora palimivora MVW causes disease in seeds or causes reduced emergence of seedlings in several economically important plant species representing ten different plant families. In addition, the fungus has been isolated from the root tissue of plants representative of seven additional plant families, although no disease symptoms were seen. In total, *Phytophthora palmivora* MWV has been detected in 17 plant families, excluding the milkweed family *Asclepiadaceae*.

STUDIES WAIVED

The active ingredient is a known plant pathogen and is not known to have any adverse effects on vertebrates, insects, or other invertebrates. The rationale for not requiring the following studies is provided below.

(vi) Wild mammal testing

Gavage and intratracheal studies on rodents show that no risks to wild mammals are expected from approved uses of *P. palmivora* MWV as a pesticide active ingredient.

(vii) Non-target Beneficial Insect Testing

(viii) Honeybee Testing

Because the pesticide product is applied directly to soil once every two or three years, exposure to bees and other beneficial insects will be minimal, with no harm expected. Therefore, submission of insect toxicity/pathogenicity data for this product is not required.

(ix) Aquatic Animals -Freshwater and Estuarine

Phytophthora. palmivora MWV does not persist in aquatic environments. Data for freshwater and estuarine animals have been waived, based on lack of adverse effects in freshwater fish and invertebrates, and evidence that *P. palmivora* MWV infects only plants.

b. Endangered Species Considerations

The data and risk assessments in this RED indicate that *P. palmivora* MWV will have no toxic or infectious effects except to certain plants. Two endangered plant species found in Florida are of concern: *Rhododendrum chamanni* and *Harperocallis flova* (*Liliaceae*). Mitigation is described below.

RISK ASSESSMENT AND MITIGATION MEASURES

Non-plants

No risks are expected to humans or other vertebrate or invertebrate species because *P. palmivora* MWV is neither toxic nor pathogenic to organisms other than plants. The active ingredient is applied to soil around citrus plants approximately every two years in five specified counties in Florida, so exposures to humans and other non-target organisms will be extremely low. As with most microbial pesticide products, the Agency requires that workers use appropriate Personal Protective Equipment (PPE) to minimize risk, including the risk of allergic reactions.

Plants–endangered species

The Agency finds that mitigation measures are adequate to protect the two endangered plant species in Florida that might be at risk.
To prevent exposure to the endangered rhododendron *Rhododendrum chamanni*, products containing *P. palmivora* MWV cannot be applied in the four counties where *R. chamanni* grows: Clay, Gulf, Liberty and Gadsden. The other endangered plant species, Harper's beauty (*Harperocallis flova*), is not found in areas with citrus crops, so *H. flova* will not be exposed to *P. palmivora* MWV from pesticidal use.

Regulatory Conclusion

Products containing the active ingredient *P. palmivora* MWV are eligible for reregistration providing the registrant implements risk mitigation measures and fulfills other requirements described in the RED.

For More Information

For information about the *P. palmivora* MWV RED, or registration of individual products containing *P. palmivora* MWV, please contact the

Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, US EPA, Washington, DC 20460, telephone 703-308-8712.

For more information about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508C), Office

of Pesticide Programs, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 am Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is http://npic.orst.edu.