

## Consumer Product Safety

### Evaluation Report ERC2010-01, *Metarhizium anisopliae* strain F52

15 January 2010

HC Pub: 091102

ISBN: 978-1-100-13407-9 (print version)

ISBN: 978-1-100-13408-6 (PDF version)

Catalogue number: H113-26/2010-1E (print version)

Catalogue number: H113-26/2010-1E-PDF (PDF version)

This page is a summary of the Evaluation Report. If you would like more detail, please request the full Evaluation Report.

To obtain an electronic copy of the document, Evaluation Report ERC2010-01, *Metarhizium anisopliae strain F52*, please contact our [publications office](#).

Should you require further information please contact the [Pest Management Information Service](#).

### Table of Contents

- [Registration Decision for \*Metarhizium anisopliae\* Strain F52](#)
- [What Does Health Canada Consider When Making a Registration Decision?](#)
- [What Is \*Metarhizium anisopliae\* strain F52?](#)
- [Health Considerations](#)
- [Environmental Considerations](#)
- [Value Considerations](#)
- [Measures to Minimize Risk](#)
- [What Additional Scientific Information is Being Requested?](#)
- [Other Information](#)

### Summary

#### Registration Decision for *Metarhizium anisopliae* Strain F52

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of *Metarhizium anisopliae* strain F52 and the end-use product Met52 Granular Bioinsecticide, containing the technical grade active ingredient *Metarhizium anisopliae* strain F52, to control root weevils, specifically black vine weevil and strawberry root weevil, on container-grown ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

Evaluation Report ERC2010-01, *Metarhizium anisopliae strain F52*, describes the key points of the evaluation as well as provides detailed technical information on the human health, environmental and value assessments of *Metarhizium anisopliae* strain F52 and Met52 Granular Bioinsecticide.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of or exposure to the product under its proposed conditions of registration. The Act also requires that products have value when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive population groups in humans (such as children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information, please refer to the following:

- [Protecting Your Health and the Environment](#)
- [Pesticide Registration Process](#)
- [Pesticide Risk Reduction Program](#)

## What Is *Metarhizium anisopliae* strain F52?

*Metarhizium anisopliae* strain F52 is a soil-dwelling fungus that causes a fatal disease in certain insects. Formulated as Met52 Granular Bioinsecticide and incorporated into the growing medium, it can provide control of root weevils, specifically black vine weevil and strawberry root weevil, on container-grown ornamentals.

## Health Considerations

*Metarhizium anisopliae* strain F52 is unlikely to affect health when Met52 Granular Bioinsecticide is used according to the label directions.

People could be exposed to *Metarhizium anisopliae* strain F52 when handling and applying the product. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (such as production of toxic by-products);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *Metarhizium anisopliae* strain F52 were tested on laboratory animals, no signs of significant toxicity or disease were observed.

## Residues in Water and Food

### Dietary risks from food and water are not of concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRL are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

As there are no direct applications to food and as no adverse effects were reported in laboratory studies, the establishment of an MRL is not required for *Metarhizium anisopliae* strain F52 under paragraph 4(1)(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, section B.15.002 of the Food and

Drug Regulations. In addition, the likelihood of residues of *Metarhizium anisopliae* strain F52 contaminating drinking water supplies is negligible. Consequently, dietary exposure and risk are minimal to non-existent.

### Occupational Risks From Handling Met52 Granular Bioinsecticide

**Occupational risks are not of concern when Met52 Granular Bioinsecticide is used according to label directions, which include protective measures.**

Workers using Met52 Granular Bioinsecticide can come into direct contact with *Metarhizium anisopliae* strain F52 on the skin, in the eyes or by inhalation. For this reason, the label will specify that users exposed to Met52 Granular Bioinsecticide must wear waterproof gloves, eye goggles, a long-sleeved shirt, long pants, shoes plus socks and a dust/mist filtering respirator/mask (Mine Safety and Health [MSH] / National Institute of Occupational Safety and Health [NIOSH] approval number prefix TC-21C) or a National Institute of Occupational Safety and Health approved respirator with any N-95, R-95, P-95 or HE filter.

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

### Environmental Considerations

**Environmental risks are not of concern.**

*Metarhizium anisopliae* strain F52 is a non-indigenous soil microorganism that is pathogenic to specific host insects. Since the reproduction of conidiospores is reliant upon infection of a suitable host under conditions of high humidity, the proliferation of *Metarhizium anisopliae* strain F52 in the environment would be limited. It is likely that levels of *Metarhizium anisopliae* strain F52 would return to levels comparable to native populations of *Metarhizium anisopliae*.

Toxicity testing on non-target organisms shows that *Metarhizium anisopliae* strain F52 is capable of causing some adverse effects to certain aquatic organisms when exposed to high concentrations. However, the incorporation of Met52 Granular Bioinsecticide into the growing medium of potted plants is unlikely to result in significant contamination of aquatic environments. Therefore, the risk to aquatic organisms from the use of Met52 Granular Bioinsecticide is very low. Toxicity testing also shows that terrestrial non-target organisms, other than target insect species, were not adversely affected by *Metarhizium anisopliae* strain F52 when exposed to high concentrations.

### Value Considerations

**What Is the Value of Met52 Granular Bioinsecticide?**

**Incorporated into the growing medium, Met52 Granular Bioinsecticide can provide control of black vine weevil and strawberry root weevil on container-grown ornamentals.**

Met52 Granular Bioinsecticide provides a viable alternative for the control of certain serious pests on a variety of crops. Root weevils, particularly black vine weevil and strawberry root weevil, are major pests of many ornamentals and are considered very difficult to control. Few other pest control products are registered in Canada for use against these pests and most are older, conventional chemical insecticides. Met52 Granular Bioinsecticide must be incorporated into the growing medium to achieve acceptable efficacy, but also may remain viable for nine months after application.

### Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Met52 Granular Bioinsecticide to address the potential risks are as follows.

## Key Risk-Reduction Measures

### Human Health

Due to concerns about users developing allergic reactions through repeated high exposure to *Metarhizium anisopliae* strain F52, anyone handling or applying Met52 Granular Bioinsecticide must wear waterproof gloves, eye goggles, a long-sleeved shirt, long pants, shoes plus socks and a dust/mist filtering respirator/mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator/mask with any N-95, R-95, P-95 or HE filter.

### Environment

As a general precaution, statements will be added to the label to prohibit handlers from contaminating aquatic habitats or allowing effluent from greenhouses containing this product to enter lakes, streams, ponds or other water bodies.

## What Additional Scientific Information is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of Evaluation Report ERC2010-01, *Metarhizium anisopliae strain F52*, or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information by 30 September 2010.

### Human Health

- An acute oral toxicity study conducted with the end-use product, Met52 Granular Bioinsecticide
- Five microbial contamination tests of full-scale production batches of the end-use product
- A storage stability study conducted with the end-use product

### Other Information

As these conditional registrations relate to a decision on which the public must be consulted, the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in Evaluation Report ERC2010-01, *Metarhizium anisopliae strain F52*, (in other words the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's [Pest Management Information Service](#).

---

Date Modified: 2010-01-15