Registration Decision RD2015-12

Paecilomyces fumosoroseus strain FE 9901

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Registration Decision for *Paecilomyces fumosoroseus* strain FE 9901

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of NoFly Technical and NoFly WP, containing the microbial pest control agent *Paecilomyces fumosoroseus* strain FE 9901, for the control of whiteflies and thrips in greenhouse 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.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-18, *Paecilomyces fumosoroseus strain FE 9901*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Paecilomyces fumosoroseus* strain FE 9901, summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2014-18. This decision is consistent with the proposed registration decision stated in PRD2014-18.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-18, *Paecilomyces fumosoroseus strain FE 9901*that contains a detailed evaluation of the information submitted in support of this registration.

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[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Paecilomyces fumosoroseus* strain FE 9901?

Paecilomyces fumosoroseus strain FE 9901 is a microbial pest control agent used to control whiteflies and thrips in greenhouse ornamentals. *Paecilomyces fumosoroseus* strain FE 9901 is an entomopathogen that infects and kills insects. The end-use product, NoFly WP, is a commercial insecticide that contains *P. fumosoroseus* strain FE 9901 as the active ingredient.

Health Considerations

Can Approved Uses of *Paecilomyces fumosoroseus* strain FE 9901 Affect Human Health?

***Paecilomyces fumosoroseus* strain FE 9901 is unlikely to affect your health when NoFly WP is used according to the label directions.**

People could be exposed to *P. fumosoroseus* strain FE 9901 when handling and applying NoFly WP. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- 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 *P. fumosoroseus* strain FE 9901 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease. Furthermore, *P. fumosoroseus* strain FE 9901 does not grow at temperatures above 35°C and no adverse effects to *P. fumosoroseus* were reported in published scientific literature.

Residues in Water and Food

Dietary risks from water and food 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 MRLs are established for the *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 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, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals. Consequently, the establishment of an MRL is not required for *P. fumosoroseus* strain FE 9901. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling NoFly WP

Occupational risks are not of concern when NoFly WP is used according to label directions, which include protective measures.

Growers handling NoFly WP can come into direct contact with *P. fumosoroseus* strain FE 9901 on the skin, in the eyes or by inhalation. For this reason, the product label specifies that growers exposed to this end-use product must wear waterproof gloves, long-sleeved shirts, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), long pants and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

For the bystander, 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

What Happens When NoFly WP Is Introduced Into the Environment?

Environmental risks are not of concern.

Following application, *P. fumosoroseus* strain FE 9901 is likely able to survive in the environment under favourable environmental conditions (i.e. temperature, humidity) but over time, populations of *P. fumosoroseus* strain FE 9901 are expected to return to natural background levels.

The effects of *P. fumosoroseus* strain FE 9901 on beneficial and/or environmentally-important insects were examined. Studies showed that *P. fumosoroseus* strain FE 9901 was toxic or infectious to some beneficial insects, however, no adverse effects to wasps were found. The end-use product label advises users that NoFly WP may be harmful to pollinators, including bees, and to some beneficial insects, and will alert users to avoid applying NoFly WP directly to bees while they are foraging. This is a precautionary measure aimed at minimizing exposure of bees even though there are no reports indicating that *P. fumosoroseus* is pathogenic or toxic to bee species.

Although avian pulmonary/inhalation/injection, wild mammal, fish, aquatic insect, earthworms, microorganisms, and plant testing were not conducted, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected. There are no published reports of disease associated with *P. fumosoroseus* strain FE 9901 in birds, wild mammals, fish, aquatic insects, earthworms, microorganisms, and plants. Also, minimal exposure to non-target organisms is anticipated from the use of NoFly WP to control whiteflies and thrips in greenhouses.

Value Considerations

What Is the Value of NoFly WP?

Applied as a foliar spray, NoFly WP controls whiteflies and thrips on greenhouse crops and is compatible with the use of *Encarsia* species as biological control agents.

The value of NoFly WP is that it provides an effective alternative for control of whiteflies and thrips in the greenhouse environment. Whiteflies and thrips are serious pests of a wide variety of greenhouse crops in Canada and certain species have been known to develop resistance to chemical insecticides. NoFly WP provides a non-chemical mode of action and has been shown to be compatible with the use of *Encarsia* species, parasitoids that are commonly used as biological control agents for whiteflies in greenhouses.

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 being proposed on the label of NoFly WP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As with all microbial pest control products, there are concerns with users developing allergic reactions through repeated high exposures to *P. fumosoroseus* strain FE 9901. Therefore, anyone handling NoFly WP must wear waterproof gloves, long-sleeved shirts, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), long pants and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential. An additional risk reduction measure is a 4-hour restricted entry interval immediately following product application. All early-entry workers to treated sites will be required to wear personal protective equipment, including a NIOSH-approved respirator until spray mists have settled.

Environment

As a general precaution, the label prohibits the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The label also directs growers to not allow effluent or run-off from greenhouses containing this product to enter lakes, streams, ponds or other waters and to avoid contaminating surface water by disposal of equipment wash waters. The product label further advises users that NoFly WP may be harmful to pollinators (including bees) and to some beneficial insects that may be used in greenhouse integrated pest management programs. A statement will also instruct users to avoid direct applications to bees while they are foraging.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-18, *Paecilomyces fumosoroseus strain FE 9901*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*