



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Registration Decision

PRD2023-09

Lecanicillium muscarium strain Ve6 and Mycotal Biological Insecticide

(publié aussi en français)

25 October 2023

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2 Constellation Drive
8th floor, A.L. 2608 A
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca

Information Service:
1-800-267-6315
pmra.info-arla@hc-sc.gc.ca

Canada 

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2023-9E (print version)
H113-9/2023-9E-PDF (PDF version)

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

Table of Contents

Overview	1
Proposed Registration Decision for <i>Lecanicillium muscarium</i> strain Ve6.....	1
What does Health Canada consider when making a registration decision?	1
What is <i>Lecanicillium muscarium</i> strain Ve6?.....	2
Health considerations	2
Environmental considerations	4
Value considerations.....	5
Measures to minimize risk.....	5
Next steps	6
Other information	6
Science evaluation	7
1.0 The active ingredient, its properties and uses.....	7
1.1 Directions for use.....	7
1.2 Mode of action.....	7
2.0 Methods of analysis	7
3.0 Impact on human and animal health.....	7
3.1 Toxicity and infectivity summary.....	7
3.1.1 Testing.....	7
3.1.2 Additional information.....	8
3.1.3 Incident reports related to human and animal health	8
3.1.4 Hazard analysis	8
3.2 Occupational, residential and bystander risk assessment.....	8
3.2.1 Occupational and postapplication exposure and risk.....	8
3.2.2 Residential and bystander exposure and risk	8
3.3 Dietary exposure and risk assessment	9
3.3.1 Food	9
3.3.2 Drinking water	9
3.3.3 Acute and chronic dietary risks for sensitive subpopulations.....	9
3.3.4 Aggregate exposure and risk.....	9
3.3.5 Maximum residue limits	10
3.4 Cumulative assessment.....	10
4.0 Impact on the environment.....	10
4.1 Fate and behaviour in the environment	10
4.2 Effects on non-target species.....	11
4.2.1 Effects on terrestrial organisms.....	11
4.2.2 Effects on aquatic organisms	12
4.3 Incident reports related to the environment.....	12
5.0 Value.....	12

6.0	Pest control product policy considerations	13
6.1	Toxic Substances Management Policy considerations	13
6.2	Formulants and contaminants of health or environmental concern.....	13
7.0	Proposed regulatory decision.....	14
	List of abbreviations	15
	References	16

Overview

Proposed Registration Decision for *Lecanicillium muscarium* strain Ve6

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#), is proposing registration for the sale and use of Mycotal Technical Biological Insecticide and Mycotal Biological Insecticide, containing the technical grade active ingredient *Lecanicillium muscarium* strain Ve6, for suppression of whiteflies on greenhouse ornamentals, cucumbers and peppers.

Lecanicillium muscarium strain Ve6 is currently registered for suppression of whiteflies on greenhouse tomatoes. For details, see Proposed Registration Decision PRD2020-14, *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, and Registration Decision RD2020-18, *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide. The preharvest interval and number of applications on greenhouse tomatoes is being revised in accordance with the proposed use on greenhouse ornamentals, cucumbers and peppers.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science evaluation provides detailed technical information on the human health, environmental and value assessments of *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide.

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 individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ 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 proposed conditions of registration. The Act also requires that products have value² when used according to the label directions. Conditions of registration may include 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 subpopulations in humans (for example, children). They also consider the unique characteristics of organisms in

¹ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

² "Value" as defined by subsection 2(1) of the *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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the [Pesticides section](#) of Canada.ca.

Before making a final registration decision on *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.³ Health Canada will then publish a Registration Decision⁴ on *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science evaluation of this consultation document.

What is *Lecanicillium muscarium* strain Ve6?

Lecanicillium muscarium strain Ve6 is a naturally occurring fungus that infects insects, growing into the insect's body and destroying tissues, thus causing death. It is the active ingredient in Mycotal Biological Insecticide, which is a pest control product for use on greenhouse crops.

Health considerations

Can approved uses of *Lecanicillium muscarium* strain Ve6 affect human health?

***Lecanicillium muscarium* strain Ve6 is unlikely to affect your health when Mycotal Biological Insecticide is used according to the label directions.**

Potential exposure to *Lecanicillium muscarium* strain Ve6 may occur when handling and applying Mycotal Biological Insecticide and when ingesting treated produce. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, 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.

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁴ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and age are taken into account in the risk assessment. Only uses that are determined as having no health risks of concern are considered acceptable for registration.

Studies in laboratory animals describe potential health effects from large doses of exposure to a microorganism and identify any pathogenicity, infectivity and toxicity concerns.

When *Lecanicillium muscarium* strain Ve6 was tested on laboratory animals, there was low toxicity following oral, inhalation and dermal exposures, and no infectivity when injected (intravenous). Furthermore, there was no sign that the microbial pest control agent (MPCA) *Lecanicillium muscarium* strain Ve6 caused any disease or genotoxic effects. In the absence of eye irritation testing, the technical grade active ingredient and end-use product are assumed to be eye irritants.

All microorganisms, including *Lecanicillium muscarium* strain Ve6, contain substances that are potential sensitizers and thus, sensitivity may possibly develop in individuals exposed to large quantities of *Lecanicillium muscarium* strain Ve6.

Residues in water and food

Dietary risks from food and water are acceptable.

Mycotal Biological Insecticide is already approved for use on greenhouse grown tomatoes, and residues of *Lecanicillium muscarium* strain Ve6 on treated produce are possible at the time of harvest. Metabolites of toxicological significance are not known to be produced by *Lecanicillium muscarium* strain Ve6. Furthermore, no signs of infectivity or toxicity were observed when *Lecanicillium muscarium* strain Ve6 was tested on laboratory animals. In addition, the likelihood of residues of *Lecanicillium muscarium* strain Ve6 contaminating drinking water supplies from the proposed applications of Mycotal Biological Insecticide to the new greenhouse grown crops (cucumbers, peppers and ornamentals) is expected to be low as the label has the necessary mitigation measures to limit contamination of drinking water. Consequently, health risks from dietary exposure are acceptable for all segments of the population, including infants, children, adults and seniors.

Occupational risks from handling Mycotal Biological Insecticide

Occupational risks are acceptable when Mycotal Biological Insecticide is used according to label directions, which include protective measures.

Workers handling Mycotal Biological Insecticide can be exposed to *Lecanicillium muscarium* strain Ve6 through direct skin or eye contact or through inhalation. To protect workers from exposure to Mycotal Biological Insecticide, the label states that workers must wear personal protective equipment, including a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes, and a NIOSH-approved particulate filtering facepiece

respirator with any N, R or P filter. The product label includes measures to restrict access to the treated area for four hours or until sprays have settled.

The occupational risks are acceptable when the precautionary statements on the label are observed.

Risks in residential and other non-occupational environments

Estimated risk for non-occupational exposure is acceptable.

Mycotal Biological Insecticide is proposed for commercial use as a diluted broadcast spray in greenhouses only. Residential and non-occupational exposure to Mycotal Biological Insecticide is therefore expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Environmental considerations

What happens when *Lecanicillium muscarium* strain Ve6 is introduced into the environment?

Environmental risks are acceptable.

Lecanicillium muscarium is a common microorganism that is widely distributed in the natural terrestrial environment. It has been isolated from numerous species of insects, mites and spiders in the tropics and in temperate regions. It has also been found on decaying food and organic material and is often isolated from soil and wood.

Mycotal Biological Insecticide is currently registered for use on greenhouse tomatoes and is not intended for outdoor uses. The proposed greenhouse uses of Mycotal Biological Insecticide are not expected to result in sustained increases in *Lecanicillium muscarium* in terrestrial and aquatic environments beyond natural background levels. *Lecanicillium muscarium* strain Ve6 may be introduced to the environment through disposal of treated plant waste and growth media. The spores of *Lecanicillium muscarium* strain Ve6 are not easily dispersed by air and are highly sensitive to UV light and desiccation.

Any spores that are transferred to soil by rainwater have limited long-term persistence in this environment and do not leach into ground water. While *Lecanicillium muscarium* strain Ve6 could enter aquatic environments through run-off from soil or treated plants, this microorganism should not become established in non-aerated or deep waters.

No overt adverse effects to birds, freshwater fish or honey bees were observed during testing. No evidence of significant adverse effects on birds, freshwater fish, non-target terrestrial arthropods, aquatic arthropods and terrestrial and aquatic plants were found in the published scientific literature. Also, *Lecanicillium muscarium* strain Ve6 was not toxic or pathogenic to laboratory mammals through a variety of exposure routes.

Based on a critical review of studies, scientific rationales and information from public sources, no significant effects to birds, wild mammals, fish, non-target terrestrial and aquatic arthropods, and plants are expected when Mycotal Biological Insecticide is applied according to directions on the label.

Value considerations

What is the value of Mycotal Biological Insecticide?

Mycotal Biological Insecticide provides a new active ingredient for suppression of whiteflies on greenhouse crops.

Whiteflies are important pests of greenhouse crops, both vegetables and ornamentals. Mycotal Biological Insecticide provides a new alternative, containing a new biological active ingredient, for the suppression of whiteflies on greenhouse cucumber, pepper and tomato, and greenhouse ornamental crops.

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 Mycotal Technical Biological Insecticide and Mycotal Biological Insecticide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The signal words “POTENTIAL SENSITIZER” and “CAUTION EYE IRRITANT” will appear on the primary display panel of the labels. The end-use product and technical grade active ingredient are considered potential sensitizers, and the end-use product contains the allergens milk and soy. In turn, “Contains the Allergens Milk and Soy” will appear on the primary display panel of the updated end-use product label, and workers handling or applying Mycotal Biological Insecticide must wear a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter. Furthermore, all unprotected workers are restricted from entering treated areas during application and for four hours following application or until sprays have dried.

Environment

The end-use product label will include environmental precaution statements that prevent the runoff and contamination of aquatic systems from the use of Mycotal Biological Insecticide. The label for the end-use product also includes an environmental precaution statement to minimize the risk to beneficial insects and pollinators used in greenhouse integrated pest management programs.

Next steps

Before making a final registration decision on *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When Health Canada makes its registration decision, it will publish a Registration Decision on *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

***Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide.**

1.0 The active ingredient, its properties and uses

Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide for details regarding the product characterization and analysis of Mycotal Technical Biological Insecticide and Mycotal Biological Insecticide.

1.1 Directions for use

Mycotal Biological Insecticide is applied as a foliar spray on greenhouse cucumber, pepper and tomato and greenhouse ornamentals. Application is made at a concentration of 1 g product per litre of water (0.1%), with a spray volume of 1000 L/ha for low crops and up to 2000 L/ha for high crops. The addition of a non-ionic surfactant at the rate of 0.02% is recommended but not required. The minimum reapplication interval is 7 days, the preharvest interval is 0 days and there is no maximum number of applications.

1.2 Mode of action

Spores of *Lecanicillium muscarium* strain Ve6 germinate on the host insect's cuticle and produce hyphae that penetrate the insect's body, proliferate and destroy internal tissues and thus cause mortality.

2.0 Methods of analysis

Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, for details.

3.0 Impact on human and animal health

3.1 Toxicity and infectivity summary

3.1.1 Testing

No new human health and safety studies were conducted for Mycotal Technical Biological Insecticide and Mycotal Biological Insecticide. Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, for details.

3.1.2 Additional information

An updated literature search of PubMed, MEDLINE and TOXFILE databases up to June 2023 was conducted. *Lecanicillium* and other phylogenetically close species/strains in the genus *Verticillium* were used as the search words. The results of the updated search uncovered no new reports of adverse effects for *Lecanicillium muscarium* strain Ve6.

Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and *Mycotal Biological Insecticide*, for additional details.

3.1.3 Incident reports related to human and animal health

Lecanicillium muscarium strain Ve6 is currently registered for use in Canada, and as of 14 June 2023, no incident reports have been submitted to the PMRA.

3.1.4 Hazard analysis

Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and *Mycotal Biological Insecticide* for details.

To update the label to current standards, the allergen statement “Contains the Allergens Milk and Soy” is required on the principal display panel of the end-use product.

3.2 Occupational, residential and bystander risk assessment

3.2.1 Occupational and postapplication exposure and risk

Mycotal Biological Insecticide is currently registered as a commercial insecticide for greenhouse tomatoes. The application equipment, methods and rates of application being proposed for greenhouse grown cucumbers, peppers and ornamentals are currently encompassed by the registered use pattern for *Mycotal Biological Insecticide*. Occupational exposure from the proposed new uses including unlimited applications is, therefore, not expected to be substantially different than that associated with the currently registered use. Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and *Mycotal Biological Insecticide*, for details.

3.2.2 Residential and bystander exposure and risk

Mycotal Biological Insecticide is currently registered as a commercial insecticide for greenhouse tomatoes only. Residential and bystander exposure and risk from the proposed new uses on greenhouse cucumbers, peppers and ornamentals is not expected to be substantially different than that associated with the currently registered use. Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and *Mycotal Biological Insecticide*, for details.

3.3 Dietary exposure and risk assessment

3.3.1 Food

The proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities. Furthermore, the preharvest interval (PHI) has been reduced from 1 day to 0 days with unlimited applications. The risks from consuming cucumbers, peppers and tomatoes treated with Mycotal Biological Insecticide treated up until the day of harvest are acceptable because *Lecanicillium muscarium* strain Ve6 demonstrated no toxicity, pathogenicity or infectivity in Tier I studies. No metabolites of toxicological significance have been shown to be produced by this MPCA. Consequently, there is no increased health risk for the general population, including infants and children, or domestic animals.

3.3.2 Drinking water

Mycotal Biological Insecticide is currently registered as a commercial insecticide for greenhouse tomatoes. Dietary exposure from drinking water due to the proposed new uses on greenhouse cucumbers, peppers and ornamentals is not expected to be substantially different than that associated with the currently registered use. Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium strain Ve6 and Mycotal Biological Insecticide*, for details.

3.3.3 Acute and chronic dietary risks for sensitive subpopulations

As noted above, when the end-use product is applied as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.3.4 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Mycotal Biological Insecticide is considered to be of low toxicity by the oral, dermal and inhalation routes, and will not be applied near or to drinking water. Furthermore, non-occupational exposure will be low when Mycotal Biological Insecticide is used as directed on the label. When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of *Lecanicillium muscarium* strain Ve6.

3.3.5 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Residues of *Lecanicillium muscarium* strain Ve6 on treated greenhouse grown cucumbers and peppers are possible at the time of harvest. Dietary risk to humans from the proposed use of Mycotal Biological Insecticide is acceptable due to the low toxicity profile of *Lecanicillium muscarium* strain Ve6, and since metabolites of toxicological significance are not known to be produced by this MPCA. In addition, the likelihood of residues contaminating drinking water supplies is low. Therefore, the PMRA has determined that specification of an MRL under the *Pest Control Products Act* is not required for *Lecanicillium muscarium* strain Ve6.

3.4 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. In its assessment of common mechanism of toxicity, PMRA considers both the taxonomy of MPCAs and the production of any potentially toxic metabolites. For the current evaluation, the PMRA has determined that *Lecanicillium muscarium* strain Ve6 is closely related to another species that is registered for use as an MPCA in Canada, *Metarhizium brunneum* strain F52. Although co-exposure to *Lecanicillium muscarium* strain Ve6 and *Metarhizium brunneum* strain F52 may occur through consumption of treated crops and handling of treated ornamentals, these MPCAs do not produce a common toxic metabolite, are of low toxicity and are not pathogenic. Thus, cumulative risks are acceptable.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium strain Ve6 and Mycotal Biological Insecticide*, for details.

Overall, it is not expected that the new greenhouse uses of Mycotal Biological Insecticide will result in a sustained increase of *Lecanicillium muscarium* strain Ve6 in outdoor terrestrial or aquatic environments beyond naturally occurring background levels.

4.2 Effects on non-target species

The PMRA has a four-tiered approach to environmental testing of microbial pesticides. Tier I studies consist of acute studies on up to seven broad taxonomic groups of non-target organisms exposed to a maximum hazard or Maximum Challenge Concentration (MCC) of the MPCA. The MCC is generally derived from the amount of the MPCA, or its toxin, expected to be available following application at the maximum recommended label rate multiplied by a safety factor. Tier II studies consist of environmental fate (persistence and dispersal) studies as well as additional acute toxicity testing of MPCAs. Tier III studies consist of chronic toxicity studies (life cycle studies), as well as definitive toxicity testing (for example, LC₅₀, LD₅₀). Tier IV studies consist of experimental field studies on toxicity and fate, and are required to determine whether adverse effects are realized under actual use conditions.

The type of environmental risk assessment conducted on MPCAs varies depending on the tier level that was triggered during testing. For many MPCAs, Tier I studies are sufficient to conduct environmental risk assessments. Tier I studies are designed to represent “worst-case” scenarios where the exposure conditions greatly exceed the expected environmental concentrations. The absence of adverse effects in Tier I studies are interpreted as minimal risk to the group of non-target organisms. However, higher tiered studies will be triggered if significant adverse effects on non-target organisms are identified in Tier I studies. These studies provide additional information that allows the PMRA to refine the environmental risk assessments. In the absence of adequate environmental fate and/or field studies, a screening level risk assessment can be performed to determine if the MPCA is likely to pose a risk to a group of non-target organisms.

The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value ($RQ = \text{exposure}/\text{toxicity}$), and the risk quotient is then compared to the level of concern (LOC).

If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (environmental fate and/or field-testing results). Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Effects on terrestrial organisms

No new studies were required to address the potential for effects on terrestrial organisms from exposure to *Lecanicillium muscarium* strain Ve6. Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and *Mycotal Biological Insecticide*, for details.

An updated literature search of the AGRICOLA, AGRIS, BIOSIS Previews, CAB ABSTRACTS, PubMed and TOXFILE databases up to June 2023 yielded no additional reports of adverse effects on non-target organisms. *Lecanicillium* and other phylogenetically close species/strains in the genus *Verticillium* were used as the search words.

Based on all the available information on the effects of *Lecanicillium muscarium*, the risks to birds, wild mammals and terrestrial plants from the proposed expanded uses in greenhouses of Mycotal Biological Insecticide are acceptable when the product is used according to the label directions.

Precautionary measures are required on the Mycotal Biological Insecticide label to alert operators of the potential hazard to beneficial arthropods that may be used in greenhouse Integrated Pest Management (IPM) programs.

4.2.2 Effects on aquatic organisms

No new studies were required to address the potential for effects on aquatic organisms from exposure to *Lecanicillium muscarium* strain Ve6. Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium* strain Ve6 and Mycotal Biological Insecticide, for details. An updated literature search of the AGRICOLA, AGRIS, BIOSIS Previews, CAB ABSTRACTS, EMBASE, MEDLINE, SCISEARCH and TOXFILE databases up to June 2023 yielded no new reports of adverse effects on non-target organisms. *Lecanicillium* and other phylogenetically close species/strains in the genus *Verticillium* were used as the search words.

Based on all the available information on the effects of *Lecanicillium muscarium* strain Ve6 to non-target aquatic organisms and the anticipated minimal environmental exposure resulting from the expanded greenhouse uses of Mycotal Biological Insecticide, the risks to aquatic organisms are acceptable when the product is used according to label directions.

4.3 Incident reports related to the environment

Lecanicillium muscarium strain Ve6 is currently registered for use in Canada. As of 14 June 2023, no incident reports related to the environment were submitted to the PMRA.

5.0 Value

Twelve greenhouse research trials were conducted on cucumbers, ornamentals and peppers, and included the two species of whiteflies that are most commonly greenhouse pests (*Trialeurodes vaporariorum* and *Bemisia tabaci*). The submitted trials were sufficient to support the new uses of Mycotal Biological Insecticide for suppression of whiteflies on greenhouse ornamentals, cucumbers and peppers using an application rate of 1 g/L in spray volumes of 1000–2000 L/ha with a 7-day reapplication interval. Mycotal Biological Insecticide provides a new active ingredient for whiteflies on the listed greenhouse crops.

6.0 Pest control product policy considerations

6.1 Toxic Substances Management Policy considerations

Refer to PRD2020-14/RD2020-18, *Lecanicillium muscarium strain Ve6 and Mycotol Biological Insecticide*, for details.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the technical as well as formulants and contaminants in the end-use product are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.⁵ The list is used as described in the PMRA Science Policy Note SPN2020-01⁶ and is based on existing policies and regulations including the *Toxic Substances Management Policy* and *Formulants Policy*⁷ and taking into consideration the Ozone-depleting Substance Regulations and Halocarbon Alternatives Regulations under the *Canadian Environmental Protection Act, 1999*, (substances designated under the Montreal Protocol).

The PMRA has reached the following conclusions:

- Technical grade Mycotol Technical Biological Insecticide does not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants of Health or Environmental Concern*.
- The end-use product, Mycotol Biological Insecticide, contains milk and soy that are allergens known to cause anaphylactic-type reactions, which are on the *List of Pest Control Product Formulants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006–02.

⁵ SI/2005-114

⁶ PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the Pest Control Products Act*

⁷ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

7.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Mycotal Technical Biological Insecticide and Mycotal Biological Insecticide, containing the technical grade active ingredient *Lecanicillium muscarium* strain Ve6, for suppression of whiteflies on greenhouse ornamentals, cucumbers and peppers.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

List of abbreviations

g	gram(s)
ha	hectare(s)
IPM	Integrated Pest Management
L	litre(s)
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LOC	level of concern
MCC	maximum challenge concentration
MPCA	microbial pest control agent
MRL	maximum residue limit
NIOSH	National Institute for Occupational Safety and Health
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
RQ	risk quotient
UV	ultraviolet

References

A. List of studies/Information submitted by registrant

1.0 Human and animal health

PMRA Document Number	Reference
3329532	2022, Use Description / Exposure Scenarios for Mycotal Biological Insecticide, DACO: 5.2

2.0 Value

PMRA Document Number	Reference
3329517	2022, Value Summary for Mycotal Biological Insecticide, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.4, 10.3, 10.3.1, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5
3329518	2011, Efficacy of Mycotal formulations (<i>Lecanicillium muscarium</i>) on the Greenhouse Whitefly (<i>Trialeurodes vaporariorum</i>), DACO: 10.2.3.3(D)
3329519	2012, Dose response of Mycotal (<i>Lecanicillium muscarium</i>) on the Greenhouse Whitefly (<i>Trialeurodes vaporariorum</i>), DACO: 10.2.3.3(D)
3329520	2013, Study comparing the efficacy of formulations of entomopathogenic fungi on whitefly (<i>Bemisia tabaci</i>), DACO: 10.2.3.3(D)
3329521	2014, Control of whiteflies (<i>Trialeurodes vaporariorum</i>) in greenhouse vegetables with <i>Lecanicillium muscarium</i> , DACO: 10.2.3.3(D)
3329522	2021, Control of White fly in Protected Cucumber in the Netherlands, 2020, DACO: 10.2.3.3(D)
3329523	2021, 2021 Canada Mycotal efficacy - cucumber, DACO: 10.2.3.3(D)
3329524	2021, Selectivity of <i>Verticillium lecanii</i> on Four Ornamental Crops, DACO: 10.2.3.3(D)
3329525	2021, 2021 Canada Mycotal efficacy_ornam, DACO: 10.2.3.3(D)
3329526	2014, Control of whiteflies (<i>Trialeurodes vaporariorum</i>) in ornamentals with <i>Lecanicillium muscarium</i> , DACO: 10.2.3.3(D)
3329527	2013, Control of whiteflies (<i>Trialeurodes vaporariorum</i>) in ornamentals with <i>Lecanicillium muscarium</i> , DACO: 10.2.3.3(D)
3329528	2002, Determination of Efficacy of Mycotal against White Fly in Sweet Pepper, 1 Greenhouse Site in Spain 2001, DACO: 10.2.3.3(D)
3329529	2002, Determination of Efficacy of Mycotal against Whitefly in Sweet Pepper, 1 Greenhouse Site in Spain 2002, DACO: 10.2.3.3(D)

- 3329530 2021, 2021 Canada Mycotol efficacy_pepper, DACO: 10.2.3.3(D)
3329531 2022, Summary of Trials for Mycotol Biological Insecticide - Applications for Pest Control and Crop Tolerance, DACO: 10.3.1