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Proposed Registration Decision

PRD2025-10

# ***Trichoderma asperellum strain T34 and Asperello T34 Biocontrol***

*(publié aussi en français)*

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# Overview

## Proposed registration decision for *Trichoderma asperellum* strain T34

Health Canada's Pest Management Regulatory Agency (PMRA), pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of T34 Biocontrol Technical and Asperello T34 Biocontrol, belonging to Biocontrol Technologies, S.L., containing the active ingredient *Trichoderma asperellum* strain T34, a biological fungicide to be used against certain fungal diseases on outdoor terrestrial food and feed crops (potato, and field grown lettuce, strawberry and raspberry).

*Trichoderma asperellum* strain T34 is currently registered for use on greenhouse ornamentals, greenhouse vegetables and cannabis produced commercially indoors. For details, see Proposed Registration Decision PRD2011-21, *Trichoderma asperellum* strain T34; Registration Decision RD2013-19, *Trichoderma asperellum* strain T34; PRD2020-03, *Trichoderma asperellum* strain T34, *Asperello T34 Biocontrol*; and RD2020-07, *Trichoderma asperellum* strain T34, *Asperello T34 Biocontrol*.

In addition to outdoor terrestrial food and feed crops, the proposed use pattern of Asperello T34 Biocontrol includes an additional greenhouse crop (tomato), new application methods, and a rate decrease in greenhouse cucurbit vegetables (Crop Group 9) against gummy stem blight.

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 *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol.

## What does Health Canada consider when making a registration decision?

The primary 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 acceptable<sup>1</sup> 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 value<sup>2</sup> when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

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

<sup>2</sup> "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."

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 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 and Pest Management portion of the Canada.ca website.

Before making a final registration decision on *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol, Health Canada's PMRA will consider any written comments received from the public directly related to the proposed decision in this consultation document.<sup>3</sup> Health Canada will then publish a Registration Decision<sup>4</sup> on *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol, 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 *Trichoderma asperellum* strain T34?

*Trichoderma asperellum* strain T34 is a microbial fungicide active ingredient with multiple modes of action against certain fungal diseases on greenhouse ornamentals, greenhouse vegetables, cannabis produced commercially indoors, potato, and field grown lettuce, strawberry, and raspberry.

## Health considerations

### Can approved uses of *Trichoderma asperellum* strain T34 affect human health?

***Trichoderma asperellum* strain T34 is unlikely to affect your health when Asperello T34 Biocontrol is used according to the label directions.**

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 gender 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.

Potential exposure to *Trichoderma asperellum* strain T34 may occur through the diet (food and drinking water) or when handling and applying Asperello T34 Biocontrol. 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;

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

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

- 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.

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 Asperello T34 Biocontrol was tested on laboratory animals, the end-use product was of low toxicity by the oral, dermal, inhalation and pulmonary routes of exposure, not irritating to the skin, and minimally irritating to the eye. There were no signs that it caused any disease in treated animals.

All microorganisms, including *Trichoderma asperellum* strain T34, contain substances that are potential sensitizers and thus, sensitivity may develop in individuals exposed to potentially large quantities of *Trichoderma asperellum* strain T34.

### **Residues in food and drinking water**

#### **Dietary risks from food and drinking water are acceptable.**

Similar to currently approved uses of Asperello T34 Biocontrol on greenhouse food crops, the proposed new uses on terrestrial food and feed crops may result in residues of *Trichoderma asperellum* strain T34 on treated agricultural crops at the time of harvest. However, populations of *Trichoderma* spp. on crops measured after application are low and decline over time. As well, no secondary metabolites of toxicological significance are detectable in the formulated product or in the edible parts of crops treated with the end-use product. While *Trichoderma asperellum* and other related *Trichoderma* species are abundant in nature, no cases involving foodborne illness have been reported. Moreover, there were no signs of infectivity, and low toxicity was observed when Asperello T34 Biocontrol was tested on laboratory animals. In addition, the likelihood of residues of *Trichoderma asperellum* strain T34 contaminating drinking water supplies is expected to be low as the label has the necessary mitigation measures to limit contamination of drinking water from the proposed uses of Asperello T34 Biocontrol. Consequently, health risks from dietary exposure are acceptable for all segments of the population, including infants, children, adults, and seniors.

### **Occupational risks from handling Asperello T34 Biocontrol**

#### **Occupational risks are acceptable when Asperello T34 Biocontrol is used according to label directions, which include protective measures.**

Asperello T34 Biocontrol is currently registered as a commercial fungicide for greenhouse food and non-food crops. The new uses include terrestrial food and feed crops. Workers handling Asperello T34 Biocontrol can be exposed to *Trichoderma asperellum* strain T34 through direct skin or eye contact or through inhalation. To protect workers from exposure to Asperello T34 Biocontrol, the label states that workers must wear personal protective equipment, including a long-sleeved shirt, long pants, 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 dried or dusts have settled. The proposed new uses do not pose any additional occupational exposure concerns.

The health risks to workers 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.**

Asperello T34 Biocontrol is currently registered as a commercial fungicide for greenhouse food and non-food crops. The product label includes measures to prevent bystander exposure such as reducing spray drift. For the general population involved in pick-your-own raspberry and strawberry activities, health risks are not of concern. Residential and non-occupational exposure to Asperello T34 Biocontrol is therefore expected to be low when the label directions are observed. Consequently, the health risk to residents and the general public is acceptable.

### **Environmental considerations**

#### **What happens when *Trichoderma asperellum* strain T34 is introduced into the environment?**

##### **Environmental risks are acceptable.**

The proposed use expansion of *Trichoderma asperellum* strain T34 to include terrestrial food and feed crops is expected to increase environmental exposure to this microorganism. Following application, *Trichoderma asperellum* strain T34 is likely able to survive in the environment under favourable environmental conditions (i.e., temperature, humidity) but, over time, populations of *Trichoderma asperellum* strain T34 are expected to return to natural background levels.

No overt adverse effects to birds, non-target terrestrial arthropods (including honey bees), or non-arthropod invertebrates were observed during testing. Toxicity and/or pathogenicity were observed in testing with fish, aquatic arthropods, and non-target aquatic plants; however, these effects occurred at levels that exceed estimated exposure levels when Asperello T34 Biocontrol is used according to the label directions for use. Aquatic exposure is expected to be negligible since the proposed new applications are soil-directed, and the label will include precautionary statements to limit drift, prohibit application to aquatic environments, and reduce runoff to aquatic habitats. Data previously submitted to support the initial registration of *Trichoderma asperellum* strain T34 were considered to determine that the risk of harm to wild mammals, soil microorganisms, and terrestrial plants is acceptable.

Based on a critical review of studies, scientific rationales and information from public sources, the risks to birds, wild mammals, fish, non-target terrestrial and aquatic arthropods, non-arthropod invertebrates, soil microorganisms, and plants are acceptable when Asperello T34 Biocontrol is applied according to directions on the label.

## **Value considerations**

### **What is the value of Asperello T34 Biocontrol?**

*Trichoderma asperellum* strain T34 suppresses or partially suppresses listed diseases on greenhouse vegetable crops and ornamentals, cannabis produced commercially indoors, potato, and field grown lettuce, strawberry, and raspberry.

Asperello T34 Biocontrol is a biological fungicide that will provide an alternative disease management product for use on these crops. This product may reduce the risk of resistance to conventional fungicides, as well as provide growers intending to avoid or minimize the use of synthetic pesticides with an additional tool for disease management.

### **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 T34 Biocontrol Technical and Asperello T34 Biocontrol to address the potential risks identified in this assessment are as follows.

### **Key risk-reduction measures**

#### **Human health**

The existing risk-reduction measures, including personal protective equipment for workers handling Asperello T34 Biocontrol and a 4-hour restricted-entry interval (REI) until sprays have dried or dusts have settled, are sufficient for the proposed expanded uses of Asperello T34 Biocontrol. A standard drift statement is required to mitigate exposure to residents and bystanders.

#### **Environment**

The end-use product label will include standard environmental precaution statements to prohibit aerial application, limit drift, and reduce runoff and contamination of aquatic systems from the use of Asperello T34 Biocontrol.

### **Next steps**

Before making a final registration decision on *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol, Health Canada's PMRA will consider any written comments received from the public that are directly related to this proposed decision, such as comments directed to the science evaluation, in response to this consultation document up to 30 days from the date of publication (26 September 2025) of this document.

If more time is required to provide comments, a request for an extension of up to 15 days can be made before the end of the original 30-day consultation period. Please forward all comments to PMRA Publications, through the Public Engagement Portal (Public Engagement Forms – Consultation Comment).

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 *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol (based on the Science Evaluation section 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 or if you have questions, please contact the Pest Management Information Service.

# Science evaluation

## *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol

### 1.0 The active ingredient, its properties and uses

#### 1.1 Physical and chemical properties of the technical grade active ingredient and the end-use product

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

#### 1.2 Directions for use

Asperello T34 Biocontrol is applied to indoor- or field-grown crops to manage certain diseases preventively by incorporation in the growing media, spray, or drench application to seed trays and seedling containers, in-furrow spray, chemigation after planting, or foliar applications.

#### 1.3 Mode of action

*Trichoderma asperellum* strain T34, classified as a Group BM02 fungicide by the Fungicide Resistance Action Committee (FRAC), has multiple putative modes of action against plant pathogens, including through colonization of growing media and plant roots, leading to competition, a protective physical barrier, direct parasitism of pathogens, and inducing systemic resistance in the host plant.

### 2.0 Methods of analysis

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, and to PRD2020-03, *Trichoderma asperellum* strain T34, Asperello T34 Biocontrol, for details.

### 3.0 Impact on human and animal health

#### 3.1 Toxicity and infectivity summary

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

#### 3.2 Occupational, residential and bystander risk assessment

##### 3.2.1 Occupational and postapplication exposure and risk

Asperello T34 Biocontrol is currently registered as a commercial fungicide for greenhouse food crops, greenhouse ornamentals, and cannabis produced commercially indoors. When handled according to label instructions, occupational exposure is expected to occur by the dermal and inhalation routes for handlers, mixer/loaders, and applicators. Ocular exposure is expected to be minimal.

The proposed expanded uses of Asperello T34 Biocontrol to include outdoor terrestrial food and feed crops, additional greenhouse food crops, and new application methods could result in workers handling the product more frequently or for longer periods. However, the maximum application rates are encompassed by registered rates, and the proposed new application methods of in-furrow spray and root dip are similar to the currently registered foliar spray applications and root bath application method, respectively. The label already includes appropriate personal protective equipment and precautionary statements for spray applications, and appropriate personal protective equipment (PPE) to mitigate the potential exposure from dip applications. Therefore, the proposed addition of terrestrial food and feed crops is not expected to increase the potential for occupational exposure if the product is applied according to label directions.

Risk mitigation measures such as PPE, including a long-sleeved shirt, long pants, waterproof gloves, socks and shoes, and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter are required to minimize exposure and protect applicators, mixer/loaders and handlers that are likely to be exposed. Unprotected workers are already prohibited from entering treated areas where Asperello T34 Biocontrol has been applied for 4 hours or until sprays have dried or dusts have settled.

Label warnings, restrictions and risk mitigation measures are adequate to protect users of Asperello T34 Biocontrol when applied to terrestrial food and feed crops. Overall, health risks to workers are acceptable when the precautionary statements on the label are followed which include PPE.

### **3.2.2 Residential and bystander exposure and risk**

Asperello T34 Biocontrol is a commercial class product. Given that strawberries and raspberries can be treated with Asperello T34 Biocontrol, there is potential for exposure during pick-your-own activities; however due to the low toxicity/pathogenicity profile of *Trichoderma asperellum* strain T34, risks to the general population are acceptable.

Although the addition of outdoor applications to the use pattern of Asperello T34 Biocontrol introduces the possibility of residential bystander exposure, the outdoor application methods are in-furrow spray, dip application prior to transplant, drench, and chemigation. Since the proposed outdoor application methods are directed towards the soil, and there are no broadcast spray applications proposed, the potential for drift from the proposed new application methods is expected to be minimal.

Residential bystander exposure from commercial use will be mitigated by the inclusion of the standard spray drift statement on the label. The statement advises against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Bystander exposure will be mitigated by the inclusion of a statement on the label, requiring all unprotected workers to remain out of treated areas until sprays have dried or dusts have settled.

Consequently, the health risk to bystanders and individuals in residential areas from the use of Asperello T34 Biocontrol is acceptable when label directions are observed.

### **3.3 Dietary exposure and risk assessment**

#### **3.3.1 Food**

Asperello T34 Biocontrol is already registered for use on greenhouse food crops. The dietary risk from the proposed use on terrestrial food and feed crops remains acceptable. For more details, refer to PRD2020-03, *Trichoderma asperellum strain T34, Asperello T34 Biocontrol*.

#### **3.3.2 Drinking water**

Although Asperello T34 Biocontrol will not be applied near, or directly to, water, some drinking water exposure may occur through run-off from treated outdoor areas following rainfall. Dietary exposure from drinking water is expected to be low as the label has the necessary mitigative measures to prevent contamination of drinking water sources from the proposed use of Asperello T34 Biocontrol. The label will instruct users not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes. Municipal treatment of drinking water is also expected to further reduce the transfer of residues to drinking water.

Health risks from residues of *Trichoderma asperellum* strain T34 in drinking water are acceptable due to the low toxicity/pathogenicity profile and limited exposure following application of Asperello T34 Biocontrol.

#### **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.

#### **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 (including pick-your-own) 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.

Asperello T34 Biocontrol is considered to be of low toxicity by the oral, dermal, and inhalation routes and the end-use product will not be applied near or to drinking water. The label includes statements to minimize non-occupational exposure in residential and commercial areas to the general Canadian population, including infants and children. When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of *Trichoderma asperellum* strain T34.

### 3.3.5 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

Residues of *T. asperellum* strain T34 on treated food crops are possible at the time of harvest. Dietary risk to humans from existing and new uses is acceptable due to the low toxicity profile of *T. asperellum* strain T34. Secondary metabolites of toxicological concern are not detectable on crops treated with the end-use product, and populations of *Trichoderma* spp. on crops after treatment are low and/or decrease following treatment. In addition, the likelihood of residues contaminating drinking water supplies is low.

Therefore, the specification of an MRL under the *Pest Control Products Act* is not required for *T. asperellum* strain T34.

### 3.4 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. In its assessment of common mechanism of toxicity, the PMRA considers both the taxonomy of the microbial pest control agents (MPCAs) and the production of any potentially toxic metabolites. For the current evaluation, the PMRA has determined that *Trichoderma asperellum* strain T34 shares a common mechanism of toxicity with the MPCAs *T. harzianum* Rifai strain T-22, *T. harzianum* Rifai strain KRL-AG2, *T. virens* strain G-41, *Gliocladium catenulatum* strain J1466, *T. asperellum* strain ICC 012, and *T. gamsii* strain ICC 080. The potential health risks from cumulative exposure of *Trichoderma asperellum* strain T34 and these other MPCAs are acceptable when used as labelled given the inherent low toxicity profile of *Trichoderma asperellum* strain T34 and the demonstrated absence of trichothecene toxins in the formulated product and on crops treated with Asperello T34 Biocontrol.

### 3.5 Health incident reports

As of 11 March 2025, no human or domestic animal incidents involving *Trichoderma asperellum* strain T34, or its related strains (i.e., *Trichoderma harzianum*, strain KRL-AG2; *Trichoderma virens*, strain G-41; *Trichoderma harzianum* Rifai, strain T-22; *Gliocladium catenulatum*, strain J1466; *Trichoderma asperellum*, strain ICC 012; and *Trichoderma gamsii*, strain ICC 080) were submitted to the PMRA.

## 4.0 Impact on the environment

### 4.1 Fate and behaviour in the environment

Data previously submitted to support the initial registration of *Trichoderma asperellum* strain T34 were considered to assess the potential for persistence in soils, plant growth media, and water. Refer to PRD2011-21, *Trichoderma asperellum strain T34*, for details.

Data previously submitted to address populations of *Trichoderma* spp. on treated crops and soil were also considered to assess the environmental fate of the MPCA as it relates to outdoor uses of Asperello T34 Biocontrol. Refer to PRD2020-03, *Trichoderma asperellum strain T34, Asperello T34 Biocontrol*, for details.

### 4.2 Effects on non-target species

The PMRA has a four-level 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, LC<sub>50</sub>, LD<sub>50</sub>). 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 is 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 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 LOC, 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

A detailed review of the terrestrial non-target studies and other supporting information was conducted in support of the use expansion for the technical grade active ingredient, T34 Biocontrol Technical, and the associated end-use product, Asperello T34 Biocontrol.

Four studies were submitted to address the hazards of Asperello T34 Biocontrol to birds, honey bees, parasitic wasps, and earthworms. These studies were performed with “*Trichoderma asperellum* strain T34” formulated product or “T34 Biocontrol” which are considered to be equivalent to the end-use product, Asperello T34 Biocontrol.

In a 30-day oral toxicity study, 30 northern bobwhite quail (*Colinus virginianus*; 21 days old) were exposed to Asperello T34 Biocontrol by oral gavage at a nominal dose of  $1 \times 10^8$  CFU/bird/day over 5 days for a total of  $5 \times 10^8$  CFU/bird, and observed for a total of 30 days. Attenuated test substance at the same concentration was tested concurrently. There were no treatment-related mortalities, behavioural abnormalities, or effects on body weight. No evidence of multiplication such as plaques or foci was noted in any bird at gross necropsy. Viability of the dosing suspension was not verified, and infectivity was not assessed.

A rationale was submitted to waive further avian oral testing for pathogenicity and infectivity. The rationale was based on the temperature of growth of *Trichoderma asperellum* strain T34 (no growth at temperatures  $>38^\circ\text{C}$ ), and the absence of adverse effects in other non-target species. No adverse effects to birds were found in the published scientific literature. The rationale is largely similar to that which was previously accepted for the initial registration of *Trichoderma asperellum* strain T34 in lieu of both avian oral and pulmonary testing (PRD2011-21, *Trichoderma asperellum* strain T34, for details).

In a 48-hour contact and dietary toxicity study, 50 honey bees (*Apis mellifera*) were exposed to *T. asperellum* strain T34 via contact at 100.0  $\mu\text{g}$  product/bee (equivalent to a nominal dose of  $1 \times 10^5$  CFU/bee) and 50 honey bees were exposed to *T. asperellum* strain T34 via the diet at 111.4  $\mu\text{g}$  product/bee (equivalent to a nominal dose of  $1.11 \times 10^5$  CFU/bee). There were no treatment related effects. Pathogenicity was not assessed.

In a 12-day dietary toxicity/pathogenicity study, 100 honey bees (*Apis mellifera*) were continuously exposed to *T. asperellum* strain T34 via the diet (in 50% sucrose solution) at a measured concentration of  $4.85 \times 10^7$  CFU/mL diet. There were no treatment-related differences in mortality, abnormal behaviour, or food consumption compared to the untreated control or inactivated test material groups. There were no toxic or pathogenic effects observed.

In a 48-hour contact toxicity study, parasitic wasps (*Aphidius rhopalosiphii*; 40/group) were exposed to the dried spray of *T. asperellum* strain T34 ( $1 \times 10^9$  CFU/g) in a glass plate test at nominal concentrations equivalent to application rates of 82.2, 189, 435, 1000, and 2300 g/ha in 200 L of water. A toxic reference item (dimethoate) and a negative control (water) were tested concurrently. There were no treatment-related mortalities.

In a 7-day contact toxicity study, predatory mites (*Typhlodromus pyri*; 60/group) were exposed to *T. asperellum* strain T34 ( $1 \times 10^9$  CFU/g) in a glass plate test at nominal concentrations equivalent to application rates of 82.2, 189, 435, 1000, and 2300 g/ha in 200 L of water. A toxic reference item (dimethoate) and a negative control (water) were tested concurrently. There were no treatment-related mortalities.

In an 8-week soil incorporation toxicity study, earthworms (*Eisenia fetida*; 40/group) were exposed to *T. asperellum* strain T34 at nominal concentrations of  $1.0 \times 10^6$ ,  $1.17 \times 10^6$ ,  $2.34 \times 10^6$ ,  $3.90 \times 10^6$ , and  $7.80 \times 10^6$  CFU/g soil dry weight (sdw). An untreated control was treated concurrently. There were no treatment-related effects on mortality, behavioural abnormalities, body weight gain or number of juveniles produced.

Test results are summarized in Appendix I, Tables 1 and 2.

Data previously submitted to support the initial registration of *T. asperellum* strain T34 were considered to assess the risk of harm to wild mammals, soil microorganisms, and terrestrial plants. Refer to PRD2011-21, *Trichoderma asperellum strain T34*, for details.

Based on all the available data and information on the effects of *T. asperellum* strain T34 to non-target terrestrial organisms, and the precautionary measures required on the Asperello T34 Biocontrol label, the risks to birds, wild mammals, arthropods (including honey bees), non-arthropod invertebrates, soil microorganisms and plants from the proposed use expansion of Asperello T34 Biocontrol to outdoor terrestrial crops are acceptable.

#### **4.2.2 Effects on aquatic organisms**

In a 96-hour toxicity study, 7 rainbow trout (*Oncorhynchus mykiss*) were aquatically exposed to Asperello T34 Biocontrol at a measured concentration of  $9.6 \times 10^5$  CFU/mL under static renewal conditions. There were no treatment-related mortalities or sub-lethal effects.

In a 30-day toxicity/pathogenicity study, 30 rainbow trout (*Oncorhynchus mykiss*) were aquatically exposed to Trichoderma T34 spores at a measured concentration of  $8.52 \times 10^5$  CFU/mL under static renewal conditions. An untreated control group and attenuated test item group were tested concurrently. There was no mortality observed in any group throughout the study duration. Body weight was statistically significantly reduced in the fish exposed to the test substance, relative to the untreated control. The same effect was not observed in the attenuated test item group, which could suggest pathogenicity; however, the necropsy findings in all animals were normal and there were no observable abnormalities in the fish. It is more likely that the adverse effects are due to the observed turbidity of the test suspensions. Infectivity was not assessed.

The no observed effect concentration (NOEC) for body weight gain in this study ( $<8.52 \times 10^5$  CFU/mL) is approximately four orders of magnitude greater than the estimated environmental concentration (EEC) in water (refer to Appendix II for EEC calculations).

In a 48-hour toxicity study, 20 daphnids (*Daphnia magna*) were aquatically exposed to *T. asperellum* strain T34 at a measured concentration of  $1.53 \times 10^6$  CFU/mL under static renewal conditions. An untreated control was tested concurrently. There was no mortality observed throughout the study.

In a 21-day toxicity/pathogenicity study, daphnids (20/group) were aquatically exposed to *T. asperellum* strain T34 at measured concentrations of  $1.01 \times 10^2$ ,  $6.84 \times 10^2$ ,  $7.75 \times 10^3$ ,  $8.10 \times 10^4$  and  $7.18 \times 10^5$  CFU/mL under static renewal conditions. Two attenuated test material groups (equivalent to  $10^5$  and  $10^6$  CFU/mL) and an untreated control were tested concurrently. Statistically significant mortality was observed in daphnids exposed to test material at  $7.18 \times 10^5$  CFU/mL, and reproductive output and biomass significantly decreased at  $7.18 \times 10^5$  CFU/mL and  $8.10 \times 10^4$  CFU/mL relative to the attenuated and untreated controls. Biomass was statistically significantly decreased in the  $10^6$  CFU/mL attenuated control group relative to the untreated control. Based on the results of the study, *Trichoderma asperellum* strain T34 is toxic to daphnids, and may also be pathogenic and infective. The NOEC for reproductive output and biomass effects in this study ( $7.75 \times 10^3$  CFU/mL) is approximately two orders of magnitude greater than the EEC in water (refer to Appendix II for EEC calculations).

The effect of *T. asperellum* strain T34 on the freshwater green alga (*Pseudokirchneriella subcapitata*) was studied at measured concentrations  $1.0 \times 10^5$ ,  $4.2 \times 10^4$ ,  $2 \times 10^4$ ,  $1.2 \times 10^4$ ,  $5.2 \times 10^3$ ,  $3.3 \times 10^3$ , and  $1.4 \times 10^3$  CFU/mL under static renewal conditions for 96 hours. There were dose-dependent and statistically significant reductions in growth rate and yield. The NOEC for yield reduction ( $1.4 \times 10^3$  CFU/mL) is approximately one order of magnitude greater than the EEC in water (refer to Appendix II for EEC calculations).

The effect of *T. asperellum* strain T34 on the freshwater floating vascular plant, duckweed (*Lemna gibba*), was studied at a measured concentration of  $1.51 \times 10^6$  CFU/mL under static renewal conditions for 7 days. There were no treatment-related effects on frond number, dry weight, growth rate, or yield relative to the untreated control.

Test results are summarized in Appendix I, Tables 1 and 2.

Adverse effects were observed for rainbow trout, daphnids, and algae; however, the NOEC values are greater than the EEC in all cases, so the screening-level RQs are less than the LOC. Therefore, no further risk characterization is necessary. Furthermore, the endpoint values do not trigger hazard labelling requirements for aquatic organisms. Although aquatic exposure is expected to be negligible because the proposed application methods for the outdoor use expansion are all soil-directed (soil spray or drench, drip chemigation, and in-furrow treatments), standard precautionary statements for outdoor applications will nevertheless advise users to reduce runoff to aquatic habitats.

The registrant also supplied a rationale to address the potential pathogenicity observed in the 30-day rainbow trout and 21-day daphnid studies. Based on the limited ability of *T. asperellum* strain T34 to proliferate in aquatic environments, and potentially confounding effects in the studies due to turbidity of the test suspensions, it is unlikely that the observed effects in the rainbow trout and daphnid studies are due to pathogenicity. From the weight of evidence, including the limited aquatic exposure expected, the proposed uses of Asperello T34 Biocontrol are unlikely to adversely affect fish or aquatic invertebrates.

Based on all the available data and information on the effects of *Trichoderma asperellum* strain T34 to non-target aquatic organisms and the precautionary measures required on the Asperello T34 Biocontrol label, the risks to fish, aquatic arthropods, aquatic plants, and algae from the proposed use of Asperello T34 Biocontrol are acceptable.

### **4.3 Incident reports related to the environment**

As of 11 March 2025, no environment incident reports involving *Trichoderma asperellum* strain T34 or related registered strains have been submitted to the PMRA or identified in the California Pesticide Illness Database or USEPA's Ecological Incident Information System.

## **5.0 Value**

Asperello T34 Biocontrol is a biological fungicide intended for use in an integrated pest management program to reduce infection levels of economically important diseases in greenhouse and field-grown crops. It also provides an alternative product for growers intending to avoid or minimize the use of synthetic pesticides.

Data from efficacy trials and scientific rationales supported the following disease claims: 1) suppression of crown rot on strawberry, crown and root rot on raspberry by preplant dip and drench or chemigation application; 2) lettuce drop on lettuce by pre-transplant and drench or chemigation; 3) suppression of black scurf on potatoes when applied as in-furrow spray; and 4) partial suppression of grey mold on greenhouse-grown tomato. Value information was also provided to support a rate decrease for a claim of suppression of gummy stem blight in greenhouse cucurbit vegetables (Crop Group 9).

Efficacy trial reports showed no evidence of crop injury from any of the Asperello T34 Biocontrol treatments.

The supported use claims are summarized in Appendix I, Table 3.

## **6.0 Pest control product policy considerations**

### **6.1 Toxic substances management policy considerations**

Refer to PRD2011-21, *Trichoderma asperellum strain T34*, for details.

## **6.2 Formulants and contaminants of health or environmental concern**

Refer to PRD2011-21, *Trichoderma asperellum strain T34*, for details.

## **7.0 Proposed regulatory decision**

Health Canada's PMRA, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of T34 Biocontrol Technical and Asperello T34 Biocontrol, containing the active ingredient *Trichoderma asperellum* strain T34, a biological fungicide to be used against certain fungal diseases on outdoor terrestrial food and feed crops (potato, field grown lettuce, strawberry and raspberry).

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**

°C	degrees centigrade
CFU	colony forming unit
cm	centimetre(s)
EC <sub>50</sub>	effective concentration on 50% of the population
EEC	estimated environmental concentration
FRAC	Fungicide Resistance Action Committee
g	gram(s)
ha	hectare(s)
L	litre(s)
LC <sub>50</sub>	lethal concentration 50%
LD <sub>50</sub>	lethal dose 50%
LOC	level of concern
LR <sub>50</sub>	lethal rate 50%
mL	millilitre(s)
MCC	maximum challenge concentration
MPCA	microbial pest control agent
MRL	maximum residue limit
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
NOEC	no observed effect concentration
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRD	Proposed Registration Decision
RD	Registration Decision
REI	restricted entry interval
RQ	risk quotient
sdw	soil dry weight
USEPA	United States Environmental Protection Agency

## Appendix I Tables and figures

**Table 1 Toxicity/Pathogenicity of Asperello T34 Biocontrol to Non-target Species**

Organism Group	Exposure	Significant Effect, Comments	Reference
<b>Terrestrial Organisms</b>			
<b>Vertebrates</b>			
Bobwhite quail ( <i>Colinus virginianus</i> ) <sup>1</sup>	30-day – oral exposure	There were no treatment-related effects on mortality, behaviour, or body weight.  The 30-day oral LD <sub>50</sub> was >5×10 <sup>8</sup> CFU/bird (maximum attainable dose)  <b>LOW TOXICITY</b>	3560135
<b>Invertebrates</b>			
<b>Arthropods</b>			
Honey bee ( <i>Apis mellifera</i> ), adult worker <sup>3</sup>	48-hour – Contact exposure  48-hour – Dietary exposure	There were no treatment-related effects on mortality or behaviour.  The 48-h contact LC <sub>50</sub> was >1×10 <sup>5</sup> CFU/bee  The 48-h dietary LC <sub>50</sub> was >1.11×10 <sup>5</sup> CFU/bee  <b>LOW TOXICITY</b>	3560141
Parasitic wasp ( <i>Aphidius rhopalosiphi</i> ) <sup>3</sup>	48-hour – contact exposure	There were no treatment-related mortalities.  The 48-hour LR <sub>50</sub> was >2300 g product/ha in 200 L water  <b>LOW TOXICITY</b>	3560142
Predatory mite ( <i>Typhlodromus pyri</i> ) <sup>3</sup>	7-day – contact	There were no treatment-related mortalities.  The 7-day LR <sub>50</sub> was >2300 g product/ha in 200 L water  <b>LOW TOXICITY</b>	3560143
<b>Non-arthropods</b>			
Earthworm ( <i>Eisenia fetida</i> ), adults <sup>2</sup>	8-week – Contact	No differences were observed between the control and treatment groups for mortality, body weight change, or number of juveniles produced.  The 8-week LC <sub>50</sub> was >7.8×10 <sup>6</sup> CFU/g sdw  <b>LOW TOXICITY</b> <b>NOT PATHOGENIC</b>	3560144

Organism Group	Exposure	Significant Effect, Comments	Reference
<b>Aquatic Organisms</b>			
<b>Vertebrates</b>			
Rainbow trout ( <i>Oncorhynchus mykiss</i> ) <sup>2</sup>	96-hour – aquatic exposure	No treatment-related mortalities or sub-lethal effects. The 96-hour LC <sub>50</sub> was >9.6×10 <sup>5</sup> CFU/mL  <b>LOW TOXICITY</b>	3560137
<b>Invertebrates</b>			
Daphnids ( <i>Daphnia magna</i> ) <sup>2</sup>	48-hour – aquatic exposure	No treatment-related mortalities. The 48-hour EC <sub>50</sub> was >1.53×10 <sup>6</sup> CFU/mL media  <b>LOW TOXICITY</b>	3560138
Daphnids ( <i>Daphnia magna</i> ) <sup>4</sup>	21-day – aquatic exposure	Mortality significantly increased in the 7.18×10 <sup>5</sup> CFU/mL test group compared to the untreated control. Reproductive output significantly decreased in the 7.18×10 <sup>5</sup> CFU/mL and 8.10×10 <sup>4</sup> CFU/mL test groups, relative to the attenuated test item and untreated controls. Biomass significantly decreased in the attenuated test item relative to the untreated control.  The 21-day LC <sub>50</sub> was 4.49×10 <sup>5</sup> CFU/mL The 21-day NOEC (total neonate production, neonates per surviving adult, and biomass effects) was 7.75×10 <sup>3</sup> CFU/mL  <b>TOXIC</b> <b>POSSIBLE PATHOGENICITY</b> <b>POSSIBLE INFECTIVITY</b>	3615081
<b>Plants</b>			
Green algae ( <i>Pseudokirchneriella subcapitata</i> ) <sup>2</sup>	96-hour – aquatic exposure	Growth rate was significantly reduced in the 5.2×10 <sup>3</sup> , 1.2×10 <sup>4</sup> , 2×10 <sup>4</sup> , 4.2×10 <sup>4</sup> and 9.8×10 <sup>4</sup> CFU/mL test groups compared to the control. Yield was significantly reduced in the 3.3×10 <sup>3</sup> , 5.2×10 <sup>3</sup> , 1.2×10 <sup>4</sup> , 2×10 <sup>4</sup> , 4.2×10 <sup>4</sup> and 9.8×10 <sup>4</sup> CFU/mL test groups compared to the control.  96-hour EC <sub>50</sub> (growth rate) was 4.3×10 <sup>4</sup> CFU/mL  The 96-hour NOEC (growth rate) was 3.3×10 <sup>3</sup> CFU/mL  The 96-hour EC <sub>50</sub> (yield) was 1.4×10 <sup>4</sup> CFU/mL  The 96-hour NOEC (yield) was 1.4×10 <sup>3</sup> CFU/mL	3560139

Organism Group	Exposure	Significant Effect, Comments	Reference
		<b>GROWTH INHIBITION YIELD REDUCTION</b>	
Duckweed ( <i>Lemna gibba</i> ) <sup>2</sup>	7-day – aquatic exposure	There were no significant differences in frond numbers, inhibition of biomass gain, or inhibition of growth rate observed.  The 7-day EC <sub>50</sub> was > 1.51×10 <sup>6</sup> CFU/mL  <b>LOW TOXICITY</b>	3560140

<sup>1</sup> The test material was T34 Biocontrol (1.19×10<sup>9</sup> CFU/g) which is considered equivalent to the end-use product.

<sup>2</sup> The test material was “*Trichoderma asperellum* strain T34 formulated product” (1.17×10<sup>9</sup> CFU/g) which is equivalent to the end-use product.

<sup>3</sup> The test material was *Trichoderma asperellum* strain T34 (1×10<sup>9</sup> CFU/g) which is considered equivalent to the end-use product.

<sup>4</sup> Both a limit test and definitive test were conducted in this study. The test material for the limit test was “*Trichoderma* T34 Spores 1E+10, lot no.T34-082-G sp1E+10 (0.99×10<sup>10</sup> CFU/g), and the test material for the definitive test was *Trichoderma asperellum* strain T34 (7.73×10<sup>9</sup> CFU/g).

**Table 2 Toxicity/Pathogenicity of T34 Biocontrol Technical to Non-target Species**

Organism Group	Exposure	Significant Effect, Comments	Reference
<b>Terrestrial Organisms</b>			
<b>Invertebrates</b>			
<b>Arthropods</b>			
Honey bee ( <i>Apis mellifera</i> ), adult worker <sup>1</sup>	12-day – Dietary exposure	There were no treatment-related effects on mortality, behaviour, or food consumption.  The 12-day dietary LC <sub>50</sub> was >4.85×10 <sup>7</sup> CFU/mL diet  <b>LOW TOXICITY NOT PATHOGENIC</b>	3615080
<b>Aquatic Organisms</b>			
<b>Vertebrates</b>			
Rainbow trout ( <i>Oncorhynchus mykiss</i> ) <sup>2</sup>	30-day – Aquatic	Body weight was significantly reduced in fish exposed to the test item, compared to both the untreated control and attenuated test item.  The 30-day NOEC (body weight gain) was <8.52×10 <sup>5</sup> CFU/mL of media  The 30-day LC <sub>50</sub> was >8.52×10 <sup>5</sup> CFU/mL of media  <b>LOW TOXICITY POSSIBLE PATHOGENICITY</b>	3615079

- <sup>1</sup> The test material was “*Trichoderma asperellum* strain T34; Sp1E+10”.
- <sup>2</sup> The test material was “Trichoderma T34 spores” ( $5.77 \times 10^9$  to  $0.99 \times 10^{10}$  CFU/g), which is considered equivalent to the technical grade active ingredient.

**Table 3 List of supported uses**

Supported use claim
<p><b>Crop:</b> Greenhouse cucurbit vegetables (Crop Group 9)</p> <p><b>Disease claim:</b> Suppression of gummy stem blight (<i>Didymella bryoniae</i>)</p> <p><b>Application Rate:</b> 250-500 g/ha</p> <p><b>Application Instruction:</b> Start the application at an early growth stage.</p> <p><b>Maximum no. of application per year:</b> Not specified</p> <p><b>Re-application interval:</b> 7-10 days</p> <p><b>Application Method:</b> Foliar spray</p> <p><b>Spray volume:</b> Apply in sufficient water volume to obtain thorough coverage.</p>
<p><b>Crop:</b> Greenhouse tomato</p> <p><b>Disease claim:</b> Partial suppression of grey mold (<i>Botrytis cinerea</i>)</p> <p><b>Application Rate:</b> 250-500 g/ha</p> <p><b>Application Instruction:</b> Begin applications prior to disease development or at the beginning of the symptoms. Use the higher rate and shorter spray interval in high susceptible crops or if a high disease pressure is predicted.</p> <p><b>Maximum no. of application per year:</b> N/A</p> <p><b>Re-application interval:</b> 7-10 days</p> <p><b>Application Method:</b> Foliar spray</p> <p><b>Spray volume:</b> Apply in sufficient water volume to obtain thorough</p>
<p><b>Crop:</b> Potato</p> <p><b>Disease claim:</b> Suppression of black scurf (<i>Rhizoctonia solani</i>)</p> <p><b>Application Rate:</b> 250 g/ha</p> <p><b>Application Instruction:</b> Apply preventively</p> <p><b>Re-application interval:</b> N/A</p> <p><b>Application Method:</b> In-furrow application</p>

Supported use claim
<p><b>Crop:</b> Field lettuce</p> <p><b>Disease claim:</b> Suppression of lettuce drop (<i>Sclerotinia sclerotiorum</i> and <i>Sclerotinia minor</i>)</p> <p><b>Application Rate:</b> 10 g/m<sup>3</sup> ( pre-transplant) and 250 -500 g/ha (in field)</p> <p><b>Application Instruction:</b> Apply preventively</p> <p><b>Maximum no. of application per year:</b> N/A</p> <p><b>Re-application interval:</b> 7-10 days</p> <p><b>Application Method:</b> Drench application or chemigation</p> <p><b>Spray volume:</b> Apply in sufficient water volume to obtain thorough coverage.</p>
<p><b>Crop:</b> Field or tunnel strawberries</p> <p><b>Disease claim:</b> Suppression of crown rot (<i>Phytophthora cactorum</i>)</p> <p><b>Application Rate:</b> 1 g/L (pre-transplant dip) and 500 g/ha (drench/chemigation)</p> <p><b>Application Instruction:</b> Prior to transplanting and after planting</p> <p><b>Maximum no. of application per year:</b> N/A</p> <p><b>Re-application interval:</b> Monthly during growing season</p> <p><b>Application Method:</b> Dip, drench application or chemigation</p> <p><b>Spray volume:</b> Apply in sufficient water volume that the product reaches the root zone</p>
<p><b>Crop:</b> Field or tunnel raspberries</p> <p><b>Disease claim:</b> Suppression of crown rot and root rot (<i>Phytophthora cinnamomi</i>)</p> <p><b>Application Rate:</b> 1 g/L (pre-transplant dip) and 500 g/ha (drench/chemigation)</p> <p><b>Application Instruction:</b> Prior to transplanting and after planting</p> <p><b>Maximum no. of application per year:</b> N/A</p> <p><b>Re-application interval:</b> Monthly during growing season</p> <p><b>Application Method:</b> Dip, drench application or chemigation</p> <p><b>Spray volume:</b> Apply in sufficient water volume that the product reaches the root zone</p>
<p><b>Application methods for field uses:</b></p> <p>Soil spray or drench, drip chemigation at 250-500 g/ha or 500 g/ha, and in-furrow at the rate of 250 g/ha, pre-plant seedling treatment as dip application at 1 g/1 L of water.</p>

## **Appendix II Estimated environmental concentration (EEC)**

### **Aquatic**

The maximum proposed outdoor application rate of Asperello T34 Biocontrol is 500 g/ha or  $5.0 \times 10^{11}$  CFU/ha. There are  $3.0 \times 10^6$  L of water in the top 30 cm of 1 ha. Therefore, assuming that the maximum application rate was applied to surface water, the agricultural EEC in water (top 30 cm layer) is  $1.67 \times 10^5$  CFU/L.

## References

### List of studies/Information submitted by registrant

#### 1.0 Environment

PMRA Document Number	Reference
3560139	2011, Toxicity of <i>Trichoderma asperellum</i> strain T34 to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition, DACO: M9.8.2
3560140	2011, Toxicity of <i>Trichoderma asperellum</i> strain T34 to the Aquatic Plant <i>Lemna gibba</i> in a Semi-Static Growth Inhibition Limit Test, DACO: M9.8.2
3560144	2010, Effects of <i>Trichoderma asperellum</i> strain T34 on Reproduction and Growth of Earthworms <i>Eisenia fetida</i> in Artificial Soil with 5% Peat, DACO: M9.6
3560138	2011, Acute Toxicity of <i>Trichoderma asperellum</i> strain T34 to <i>Daphnia magna</i> in a Static 48-hour Immobilisation Limit-Test, DACO: M9.5.2
3615081	2020, <i>Trichoderma asperellum</i> strain T34 Microbial Pest Control Agent (MPCA) Freshwater Aquatic Invertebrate Test with <i>Daphnia magna</i> , DACO: M9.5.2
3560141	2010, Effects of <i>Trichoderma asperellum</i> strain T34 (Acute Contact and Oral) on Honey Bees ( <i>Apis mellifera</i> L.) in the Laboratory, DACO: M9.5.1
3560142	2010, Effects of <i>Trichoderma asperellum</i> strain T34 on the Parasitoid <i>Aphidius rhopalosiphi</i> in the Laboratory - Dose Response Test -, DACO: M9.5.1
3560143	2010, Effects of <i>Trichoderma asperellum</i> strain T34 on the Predatory Mite <i>Typhlodromus pyri</i> in the Laboratory - Dose Response Test -, DACO: M9.5.1
3615080	2018, <i>Trichoderma asperellum</i> strain T34 Honey Bee, <i>Apis mellifera</i> , Non-target Insect Microbial Limit Test, DACO: M9.5.1
3560137	2011, Acute Toxicity of <i>Trichoderma asperellum</i> strain T34 to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) in a 96-hour Static Limit Test, DACO: M9.4.1
3615079	2020, <i>Trichoderma asperellum</i> strain T34 Microbial Pest Control Agent (MPCA) Freshwater Fish Test with <i>Oncorhynchus mykiss</i> (Rainbow Trout), DACO: M9.4.1
3560136	2015, Avian toxicity waiver for T34 Biocontrol, DACO: M9.2.2
3560135	2017, KIS-1103 Wettable Powder: An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite, DACO: M9.2.1
3693758	2025, Response to the Notice of Deficiencies for Asperello T34 Biocontrol, Sub. No. 2024-0138, DACO: M9.4,M9.5.2

## 2.0 Value

PMRA Document Number	Reference
3543875	2020, Efficacy and selectivity evaluation of T34 Biocontrol against <i>Phytophthora cactorum</i> on strawberry in open field conditions - Italy 2019, DACO: M10.2.2, M10.3.1
3543876	2020, Efficacy and selectivity evaluation of T34 Biocontrol against Gummy stem blight ( <i>Didymella bryoniae</i> ) on cucumber in protected conditions - Italy 2019, DACO: M10.2.2, M10.3.1
3543877	2020, Efficacy and selectivity evaluation of T34 Biocontrol against <i>Phytophthora cactorum</i> on strawberry in open field conditions - Italy 2019, DACO: M10.2.2, M10.3.1
3543878	2018, Efficacy and Selectivity Evaluation of T34 Against <i>Sclerotinia</i> on Lettuce in Open Field Conditions - Italy 2018, DACO: M10.2.2, M10.3.1
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3543892	2019, Determination of Efficacy of T34 Biocontrol against <i>Rhizoctonia solani</i> in Potato, Poland 2018, DACO: M10.2.2, M10.3.1
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