RD2009-07

# Registration Decision

# Coniothyrium minitans strain CON/M/91-08

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# **Table of Contents**

Registration Decision for <i>Coniothyrium minitans</i> strain CON/M/91-08	]
What Does Health Canada Consider When Making a Registration Decision?	1
What is Coniothyrium minitans strain CON/M/91-08??	
Health Considerations	2
Environmental Considerations	3
Value Considerations	4
Measures to Minimize Risk	4
Other Information	4
References	7

# Registration Decision for Coniothyrium minitans strain CON/M/91-08

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u> and Regulations, is granting full registration for the sale and use of Contans WG Biological Fungicide and Contans WG, containing the technical grade active ingredient *Coniothyrium minitans* strain CON/M/91-08, to control fungal diseases in a variety of field and greenhouse vegetables.

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

These products were first proposed for registration in the consultation document<sup>1</sup> Proposed Registration Decision PRD2008-17, *Coniothyrium minitans strain CON/M/91-08*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for *Coniothyrium minitans* strain CON/M/91-08 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2008-17. This decision is consistent with the proposed registration decision stated in PRD2008-17.

For more details on the information presented in this Registration Decision, please refer to Proposed Registration Decision PRD2008-17, *Coniothyrium minitans strain CON/M/91-08*, that contains a detailed evaluation of the information submitted in support of this registration.

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

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>3</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 conditions of registration. The Act also requires that products have value<sup>4</sup> when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information

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

<sup>&</sup>lt;sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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

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

on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

# What is Coniothyrium minitans strain CON/M/91-08?

Coniothyrium minitans strain CON/M/91-08 is a microbial pest control agent used to control fungal plant disease on a variety of field and greenhouse vegetables. The end-use product Contans WG is a commercial fungicide product that contains *Coniothyrium minitans* strain CON/M/91-08 as the active ingredient.

Coniothyrium minitans strain CON/M/91-08 is a fungus that parasitizes *Sclerotinia* sclerotiorum. It specifically attacks long-lived, resting structures (sclerotia) of fungal plant pathogens belonging to the genus *Sclerotinia* in the soil.

#### **Health Considerations**

Can Approved Uses of *Coniothyrium minitans* strain CON/M/91-08 Affect Human Health?

Coniothyrium minitans strain CON/M/91-08 is unlikely to affect your health when Contans WG is used according to the label directions.

People could be exposed to *Coniothyrium minitans* strain CON/M/91-08 when handling and applying the product. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g. production of toxic byproducts), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses to identify any potential pathogenicity, infectivity and toxicity concerns. When *Coniothyrium minitans* strain CON/M/91-08 was tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

#### Residues in Water and Food

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

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

Strains of *Coniothyrium minitans* are common in nature and the use of Contans WG in agricultural fields and in greenhouses to control fungal disease on vegetables is not expected to significantly increase natural environmental background levels of this microorganism. Furthermore, when Coniothyrium minitans strain CON/M/91-08 was administered orally to rats, no signs that it caused toxicity or disease were observed. Although certain strains of *Coniothyrium minitans* produce secondary metabolites, Coniothyrium minitans strain CON/M/91-08 is not known to produce any secondary metabolites and has demonstrated low toxicity in animal studies. The establishment of a MRL is not, therefore, required for *Coniothyrium minitans* strain CON/M/91-08. As well, the likelihood of residues contaminating drinking water supplies is minimal to non-existent. Consequently, dietary exposure and risks are minimal to non-existent.

# Occupational Risks from Handling Contans WG

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

Workers using Contans WG can come into direct contact with Coniothyrium minitans strain CON/M/91-08 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that users exposed to Contans WG must wear gloves, a long-sleeved shirt, long pants, a National Institute of Occupational Safety and Health (NIOSH) approved respirator (with any N, P, R or HE filter) and shoes plus socks.

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

# **Environmental Considerations**

# What Happens When Contans WG Is Introduced into the Environment?

#### Environmental risks are not of concern.

Information on the environmental fate of *Coniothyrium minitans* strain CON/M/91-08 suggests that, as a soil microorganism, it is likely that Coniothyrium minitans strain CON/M/91-08 could survive in outdoor soil under suitable environmental conditions (i.e. the type of soil, moisture, acidity levels and temperature) but that over time the populations of *Coniothyrium minitans* strain CON/M/91-08 should return to naturally occurring levels.

There are no published reports of disease associated with Coniothyrium minitans in birds, wild mammals, fish, insects, earthworms, soil microorganisms and plants except for the intended pest and its close relatives, i.e. Sclerotinia species. Furthermore, studies designed to examine the effects of Coniothyrium minitans strain CON/M/91-08 on fish, aquatic insects and algae reported no adverse effects. Although studies on birds, wild mammals, terrestrial insects, earthworms, soil microorganisms and terrestrial plants were

not conducted, adequate information was available to determine that risks to these non-target organisms are not expected.

# **Value Considerations**

#### What Is the Value of Contans WG?

#### Contans WG reduces Sclerotinia inoculum in the soil.

When applied to soil or crop residues, hyphae (threadlike structures) of *Coniothyrium* minitans penetrate and subsequently degrade sclerotia. Infected sclerotia fail to germinate or produce apothecia, thereby preventing development of Sclerotinia disease.

# **Measures to Minimize Risk**

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Contans WG to address the potential risks identified in this assessment are as follows.

# **Key Risk-Reduction Measures**

# **Human Health**

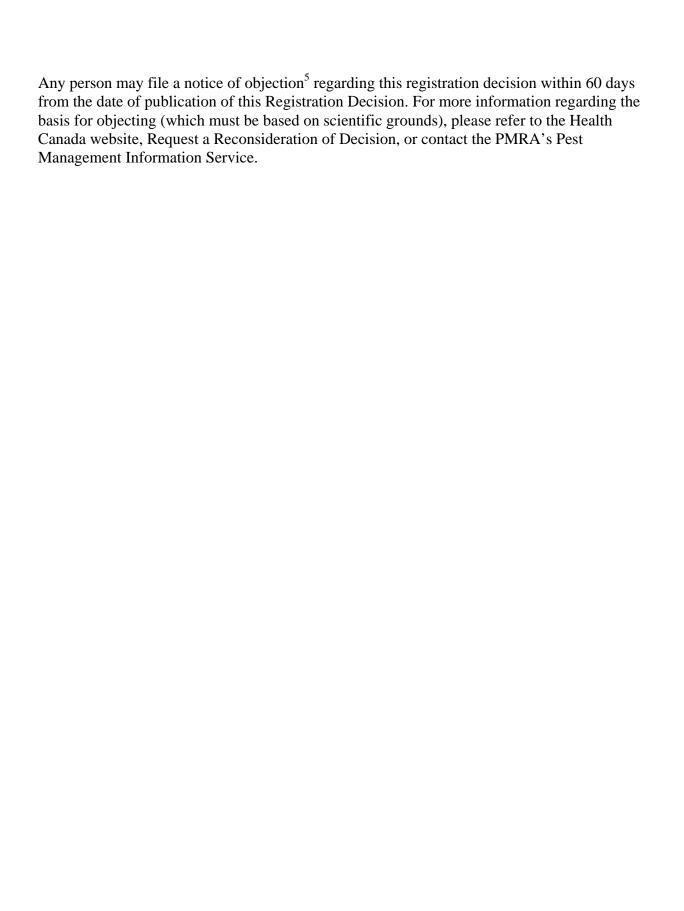
Because of concerns with users developing allergic reactions through repeated high exposure to Coniothyrium minitans strain CON/M/91-08, anyone handling or applying Contans WG must wear waterproof gloves, a long-sleeved shirt, long pants and shoes plus socks. In addition, mixers/loaders and applicators must wear a NIOSH approved respirator (with any N, P, R or HE filter).

#### **Environment**

As a general precaution, label statements will be added to the label requiring handlers to not contaminate irrigation or drinking water or aquatic habitats. In addition, instructions will be provided to limit runoff from treated fields and to keep effluent from greenhouses containing this product from entering lakes, streams, ponds or other water bodies.

# **Other Information**

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.



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

# References

# A. List of Studies/Information Submitted by Registrant

# 1.0 The Active Ingredient, Its Properties and Uses

# PMRA Document Number 1428857

**Reference** 2006, Contans WG Biological Fungicide Product Profile and Proposed Pattern of Use, DACO: M1.2

# 2.0 Methods of Analysis

# PMRA Document Number 1428824

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#### PMRA Document Number 1428825

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**Reference** 2006, Density and Tap Density of the Contans WG Formulation, 2006003, MRID: N/A, DACO: M2.12 CBI

#### PMRA Document Number 1428869

**Reference** Pfeffer, H., Lueth, P., 1990, Der Einfluss einer Rotkleemonokultur auf das antiphytopathogene Potential des Bodens in bezug auf Sclerotinia trifoliorum Erikss, N/A, MRID: N/A, DACO: M2.7

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#### PMRA Document Number 1428937

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# **PMRA Document Number** 1428943

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#### PMRA Document Number 1428839

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#### PMRA Document Number 1428864

**Reference** Pest Management Centre, 2005, Crop profile: Carrot, N/A, MRID: N/A, DACO: 10.4.2

# PMRA Document Number 1428865

**Reference** Pest Management Centre, 2005, Crop profile: Dry bean, N/A, MRID: N/A, DACO: M10.4.2

# PMRA Document Number 1428866

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# B. Additional Information Considered

# **Published Information**

# **Methods of Analysis**

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