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Registration Decision

Verticillium albo-atrum **strain WCS850**

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Registration Decision for *Verticillium albo-atrum* strain WCS850

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Verticillium* isolate WCS850 (Registration Number 29446) and Dutch Trig (Registration Number 29447), containing the microbial pest control agent *Verticillium albo-atrum* strain WCS850, to prevent Dutch elm disease in uninfected elm trees.

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 document¹ Proposed Registration Decision PRD2009-10, *Verticillium albo-atrum* strain WCS850. This Registration Decision² describes this stage of the PMRA's regulatory process for *Verticillium albo-atrum* strain WCS850 and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD 2009-10. This decision is consistent with the proposed registration decision stated in PRD2009-10.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-10, *Verticillium albo-atrum* strain WCS850 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 acceptable³ 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 value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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

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

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

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

What Is *Verticillium albo-atrum* strain WCS850?

Verticillium albo-atrum strain WCS850 is a microbial pest control agent (MPCA) used to prevent Dutch elm disease by inducing the treated tree's natural defense mechanisms, a process called induced systemic resistance. The end-use product, Dutch Trig, is a commercial fungicide product that contains *Verticillium albo-atrum* strain WCS850 as the active ingredient.

Health Considerations

Can Approved Uses of *Verticillium albo-atrum* strain WCS850 Affect Human Health?

***Verticillium albo-atrum* strain WCS850 is unlikely to affect your health when Dutch Trig is used according to the label directions.**

When assessing health risks, several key factors are considered:

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

Negligible exposure to *Verticillium albo-atrum* strain WCS850 is expected when handling and applying Dutch Trig. Dutch Trig is injected into trees using a completely closed application system and is packaged into thick polyethylene vials that are waterproof and virtually unbreakable.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *Verticillium albo-atrum* strain WCS850 were tested on laboratory animals, there were no signs that it caused any toxicity or disease. Furthermore, *Verticillium albo-atrum* strain WCS850 does not grow at temperatures above 30°C and few adverse effects to *Verticillium* spp. were reported in published scientific literature despite intensive research.

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

As there are no direct applications to food and no significant adverse effects were reported in Tier I acute toxicity/pathogenicity studies, the establishment of a maximum residue limit is not required for *Verticillium albo-atrum* strain WCS850 under paragraph 4(1)(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, section B.15.002 of the Food and Drug Regulations. In addition, the likelihood of residues of *Verticillium albo-atrum* strain WCS850 contaminating drinking water supplies is negligible. Consequently, dietary exposure and risk are minimal to non-existent

Occupational Risks From Handling Dutch Trig

Occupational risks are not of concern when Dutch Trig is used according to label directions, which include protective measures

Workers using Dutch Trig are not likely to come into direct contact with *Verticillium albo-atrum* strain WCS850 during application. Dutch trig is injected into trees using a specialized injection tool which was designed to prevent spillage. Furthermore, Dutch Trig is packaged in thick polyethylene vials that are waterproof and virtually unbreakable. However, minimal worker exposure to *Verticillium albo-atrum* strain WCS850 may occur via the dermal route during routine maintenance of the injection equipment. To prevent exposure during application and maintenance of the injection equipment, the label will specify that anyone applying or maintaining injection equipment must wear waterproof gloves, long-sleeved shirts, long pants, and shoes plus socks.

For bystanders, exposure is expected to be much less than that of handlers and applicators and is also considered negligible.

Environmental Considerations

What Happens When Dutch Trig is Introduced Into the Environment?

Environmental risks are not of concern

Verticillium albo-atrum strain WCS850 is a natural un-pigmented (white) variant of *Verticillium albo-atrum*. *Verticillium albo-atrum* is a plant pathogen that can infect many different tree species and vegetable crops causing *Verticillium* wilt disease. Strain WCS850 differs from the pigmented wild type in that it has lost its ability to produce resting structures and thus has lost its ability to persist in its natural environment. *Verticillium albo-atrum* strain WCS850 has also lost much of its ability to infect plants. After Dutch Trig is injected into elm trees, *Verticillium albo-atrum* strain WCS850 is contained within a growth ring of the treated elm tree. The WCS850 strain is just pathogenic enough to induce a natural resistance response in the injected elm, but has lost so much of its pathogenicity that it is no longer capable of successfully infecting an elm with *Verticillium* wilt disease. After injection, *Verticillium albo-atrum* strain WCS850 can only be recovered from the injection site, and only up to two weeks after injection.

The risk to terrestrial and aquatic organisms from the use of Dutch Trig is very low based on the negligible potential for environmental exposure.

Value Considerations

What Is the Value of Dutch Trig?

Dutch Trig induces resistance in elm trees to fend off beetle-inflicted Dutch elm disease infections with its own natural defence mechanisms.

Dutch Trig prevents Dutch elm disease in uninfected elms. The injection system is self contained consisting of virtually unbreakable plastic vials that can only be used in the Dutch Trig Tree Injection Tool. No mixing or diluting is required. Treatment with Dutch Trig causes no adverse effects on the tree and does not affect the beetle population or prevent beetles from feeding on elm trees. Dutch Trig can be used in the urban environment (streets, parks, backyards) on trees that provide aesthetic, environmental, economic and psychological benefits.

Measures to Minimize Risk

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

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

Key Risk-Reduction Measures

Human Health

To prevent exposure to *Verticillium albo-atrum* strain WCS850 during application and during routine maintenance of the injection equipment, anyone applying Dutch Trig or maintaining injection equipment must wear waterproof gloves, long-sleeved shirts, long pants, and shoes plus socks.

Environment

As a general precaution, statements were added to the label to prohibit handlers from contaminating aquatic habitats during routine maintenance of the injection system.

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 by phone (1-800-267-6315) or by e-mail (pmra_inforserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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

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