Registration Decision RD2010-08

Sclerotinia minor strain IMI 344141

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Registration Decision for *Sclerotinia minor* strain IMI 344141

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 Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer (previously referred to as Sarritor Domestic Granular Biological Herbicide), containing *Sclerotinia minor* strain IMI 344141, to suppress top growth of dandelion, white clover and broadleaf plantain in turf.

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 proposed for conversion from conditional to full registration in the consultation document[1] Proposed Registration Decision PRD2010-04, *Sclerotinia minor* strain IMI 344141. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Sclerotinia minor* strain IMI 344141 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-04. This decision is consistent with the proposed registration decision stated in PRD2010-04.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-04, *Sclerotinia minor* strain IMI and the Evaluation Report ERC2007-02, *Sclerotinia minor* strain IMI 344141 that contain detailed evaluations of the information submitted in support of this registration. Please note that the product, Sarritor Selective Biological Lawn Weed Killer, was previously referred to as Sarritor Domestic Granular Biological Herbicide in ERC2007-02 and PRD2010-04. Furthermore, the information under Health Considerations and Measure to Minimize Risk has been updated in this document to reflect recent amendments to risk mitigation statements on the product labels.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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

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

4 "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 (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 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 *Sclerotinia minor* strain IMI 344141?

Sclerotinia minor strain IMI 344141 is a living fungus and is the active ingredient in Sarritor Technical Herbicide and its associated end-use products Sarritor Granular Biological Herbicide (Commercial) for commercial use and Sarritor Selective Biological Lawn Weed Killer for domestic use.

The fungus infects susceptible target plants and destroys target plant tissues above ground (top growth). The main component of the herbicide effect on target plants appears to be oxalic acid, which is secreted by *Sclerotinia minor*.

Health Considerations

Can Approved Uses of Sclerotinia minor strain IMI 344141 Affect Human Health?

Sclerotinia minor strain IMI 344141 is unlikely to affect your health when used according to the label directions of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer.

People could be exposed to *Sclerotinia minor* strain IMI 344141 when handling the end-use products or when these are being applied. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only the uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to *Sclerotinia minor* strain IMI 344141 and identify the dose where no effects are observed.

Sclerotinia minor strain IMI 344141 caused significant health effects in laboratory animals when a large dose was applied to the respiratory tract. As a result, the precautionary wording "Harmful if inhaled. DO NOT breath dust" is required on the product labels.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Sclerotinia minor is common in nature and is found around the world where the climate is temperate. Application of *Sclerotinia minor* strain IMI 344141 to turf is not expected to significantly increase the natural environmental background levels of *Sclerotinia minor*. No adverse effects from dietary exposure have been attributed to natural populations of *Sclerotinia minor* and none were observed during acute oral toxicity testing. Furthermore, no food uses are proposed for *Sclerotinia minor* strain IMI 344141. The establishment of a maximum residue limit is therefore not required for *Sclerotinia minor* strain IMI 344141 under Section 4(d) of the *Food and Drugs Act* as defined under Division 15, Section B.15.002 of the Food and Drug Regulations.

Occupational Risks from Handling Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer

Occupational risks are not of concern when Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer are used according to the label directions, which include protective measures.

Commercial and domestic applicators handling or applying Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer can come into direct contact with *Sclerotinia minor* strain IMI 344141 on the skin, in the eyes or by inhalation. Although Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer are not irritating to the skin or eyes, they contain substances that have the potential to cause hypersensitive reactions following repeated exposure. For this reason, the label requires that a long-sleeved shirt, long pants, shoes, socks and waterproof gloves be worn during handling and application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer.

As the inhalation of dust from Sarritor Granular Biological Herbicide (Commercial) has the potential to cause adverse effects in the lungs, respiratory protection suitable for preventing inhalation of biological products is required during loading, clean-up and repair activities. Recent changes to the application method for Sarritor Granular Biological Herbicide (Commercial) and changes to the container and use pattern of Sarritor Selective Biological Lawn Weed Killer resulted in a significant reduction in the estimated pulmonary exposure during application. Therefore, commercial and domestic applicators are no longer required to wear respiratory protection.

For the general population, skin exposure could occur during maintenance or recreational activities on treated turf, but is not expected to pose an undue risk on the basis of the low toxicity profile for *Sclerotinia minor* strain IMI 344141 by the oral and dermal routes of exposure. Once the product is applied to turf under the appropriate environmental conditions, airborne dust is not expected to be a concern, based on the granular formulation. Label directions indicate that

Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer should be applied when rainfall or irrigation will occur within 12 hours of application. This way, the potential that the bystanders inhale dust containing *Sclerotinia minor* strain IMI 344141 is expected to be reduced when the applied product is wetted. Health risk to bystanders is therefore not of concern.

Although no adverse effects were reported in workers using *Sclerotinia minor* strain IMI 344141, Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer during product development, like all microbes, *Sclerotinia minor* strain IMI 344141 contains substances that can cause hypersensitivity. As a result, commercial and domestic applicators are required to wear a long-sleeved shirt, long pants, shoes, socks and waterproof gloves during application to prevent repeated skin exposure. The label statement "POTENTIAL SENSITIZER" and the precautionary wording "May cause sensitization" are required on the product labels.

Environmental Considerations

What Happens When *Sclerotinia minor* strain IMI 344141 Is Introduced Into the Environment?

***Sclerotinia minor* strain IMI 344141 is pathogenic to terrestrial and aquatic plants, therefore the label will include warnings to avoid direct dosing of non-target plants, ornamental ponds, aquatic, estuarine or marine habitats.**

Sclerotinia minor is widespread in the environment, yet there are no published reports of disease associated with *Sclerotinia minor* in birds, wild mammals, earthworms, bees and other arthropods, aquatic invertebrates or fish.

A laboratory study showed that *Sclerotinia minor* strain IMI 344141 is not toxic or pathogenic to birds when ingested. A laboratory study designed to assess risk to honey bees from foraging around treated plants was classified as supplemental, but results suggested *Sclerotinia minor* was not toxic or pathogenic to bees. *Sclerotinia minor* is also a food source for many other ground-dwelling arthropods, indicating that it is of low toxicity to terrestrial arthropods. Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer did not affect earthworms at concentrations expected in the environment following a single application at the highest label rate. A second laboratory study conducted at significantly higher concentrations of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer indicated that earthworm survival was affected. However, study results also indicated that ammonium (produced as a result of the solid substrate decomposition) contributed to the toxicity of the end use product. Ammonium produced during use of the product is expected to be quickly metabolised by surrounding vegetation and not pose a hazard to earthworms.

Sclerotinia minor causes disease in many species of terrestrial plants. The product labels instruct users to avoid applying Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer to plants growing adjacent to treated turf.

Aquatic arthropods and fish were exposed to a range of test aquatic concentrations but were too low to determine potential effects. Laboratory studies indicate that aquatic plants are highly susceptible to *Sclerotinia minor* disease, and measures to minimize risk to aquatic plants will also protect fish and aquatic arthropods. Label statements instruct applicators not to apply Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer to ornamental ponds or aquatic, estuarine or marine habitats and not to allow mower clippings to enter such habitats for a few weeks following application.

Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer granules and *Sclerotinia minor* strain IMI 344141 do not persist in the environment and are not readily transferred from the site of application to aquatic habitats.

Value Considerations

What Is the Value of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer?

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer contain a living fungus that infects target plants and suppresses their top growth in turf.

Application of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer effectively suppresses top growth of dandelion in turf. Additional data were recently submitted to also support top growth suppression of white clover and broadleaf plantain in turf. Based on the mode of action of *Sclerotinia minor* strain IMI 344141, the development of herbicide resistance is unlikely. The availability of *Sclerotinia minor* strain IMI 344141 would enable further development of integrated and sustainable turf management practices, especially where the use of traditional chemical herbicides is not desirable.

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 Sarritor Granular Biological Herbicide (Commercial) and Sarritor Selective Biological Lawn Weed Killer to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To minimize the potential for the development of hypersensitivity to *Sclerotinia minor* strain IMI 344141 in commercial and domestic applicators, users are required to wear a long-sleeved shirt, long pants, shoes, socks and waterproof gloves to minimize skin exposure to *Sclerotinia minor* strain IMI 344141.

To minimize the potential to cause lung inflammation, respiratory protection suitable for preventing inhalation of biological products is required during loading, clean-up and repair activities for Sarritor Granular Biological Herbicide (Commercial).

Environment

Because Sclerotinia minor strain IMI 344141 is harmful to terrestrial and aquatic plants, a warning statement is included on the labels to avoid dosing of non-target plants, ornamental ponds or aquatic, estuarine or marine habitats. Users are instructed to direct mower clippings away from such habitats for the first few weeks after Sarritor Granular Biological Herbicide (Commercial) or Sarritor Selective Biological Lawn Weed Killer application.

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.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

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

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number: 1674618
Reference: 2008, Rationale for amendment of PPE label instructions, Data Numbering Code: 5.1, 5.14, 5.2

PMRA Document Number: 1674634
Reference: 2008, Occupation exposure - rationale for amendment of PPE label instructions, Data Numbering Code: 5.1, 5.14, 5.2

2.0 Environment

PMRA Document Number: 1595630
Reference: 2007, *Sclerotinia minor* (strain IMI 34414): Effects on adult worker honey bees, *Apis mellifera*, exposed to infected dandelion plants under laboratory conditions, Data Numbering Code: M9.5.1

PMRA Document Number: 1595631
Reference: 2008, Earthworm ecotoxicology testing of Sarritor Granular Biological Herbicide, Data Numbering Code: M9.6

3.0 Value

PMRA Document Number: 1674656
Reference: M. H. Abu-Dieyeh and Alan K. Watson, 2006, Effect of turfgrass mowing height on biocontrol of dandelion with *Sclerotinia minor*, Biocontrol Science And Technology, 16(5):509-524, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)

PMRA Document Number: 1674658
Reference: M. H. Abu-Dieyeh and Alan Watson, 2005, Impact of mowing and weed control on broadleaf weed population dynamics in turf, Journal Of Plant Interactions, 1(4) 239-252, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)

PMRA Document Number: 1674659
Reference: M. H. Abu-Dieyeh and Alan K. Watson, 2007, Population dynamics of broadleaf weeds in turfgrass as influenced by chemical and biological control methods, Weed Science, 55:371-380, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)

PMRA Document Number: 1674660
Reference: M. H. Abu-Dieyeh and Alan K. Watson, 2007, Efficacy of *Sclerotinia minor* for dandelion control: effect of dandelion accession, age and grass competition, Research Society Weed Research, 47:63-72, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)

PMRA Document Number: 1674661
Reference: M. H. Abu-Dieyeh, 2007, Grass overseeding and a fungus combine to control *Taraxacum officinale*, Journal Of Applied Ecology, 44:115-124, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)

PMRA Document Number: 1674662
Reference: 2008, Rationale for addition of broadleaf weeds to Sarritor labels, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)

PMRA Document Number: 1674663
Reference: 2008, Rationale for amendment to include dandelion control on the Sarritor labels, Data Numbering Code: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(b)