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Proposed Registration Decision PRD2010-04

Sclerotinia minor Strain IMI 344141

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Overview

Proposed 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 proposing full registration for the sale and use of Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide, containing *Sclerotinia minor* strain IMI 344141, to suppress dandelion top growth in turf.

Sarritor Technical Herbicide (Registration Number 28544), Sarritor Granular Biological Herbicide (Commercial) (Registration Number 28545) and Sarritor Domestic Granular Biological Herbicide (Registration Number 28546) are conditionally registered in Canada. The detailed review for Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide can be found in Evaluation Report ERC2007-02 *Sclerotinia minor* strain IMI 344141. The current applications were submitted to convert Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide from conditional registration to full registration.

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.

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 Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide.

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[1] 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[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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

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 PMRA's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on *Sclerotinia minor* strain IMI 344141, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on *Sclerotinia minor* strain IMI 344141, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA'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 *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 Domestic Biological Herbicide for domestic use. The fungus infects susceptible dandelion plants and destroys dandelion plant tissues above ground (top growth). The main component of the herbicide effect on the dandelion 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 Domestic Biological Granular Herbicide.**
>
> 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

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

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

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 "DO NOT breath dust" is required on the product labels. Furthermore, commercial as well as domestic applicators are required to wear respiratory protection suitable for preventing inhalation of biological products.

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 Domestic Granular Biological Herbicide

Occupational risks are not of concern when Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide. As the inhalation of dust from Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide has the potential to cause adverse effects in the lungs, respiratory protection is required during handling and application of these products to turf.

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 Domestic Granular Biological Herbicide 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 wet. 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide 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 Domestic Granular Biological Herbicide

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide contain a living fungus that infects dandelion plants and suppresses dandelion top growth in turf.

Application of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide effectively suppresses dandelion top growth 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

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 labels of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide 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.

Laboratory studies indicate the inhalation of large quantities of *Sclerotinia minor* strain IMI 344141 has the potential to cause inflammation of the lungs. As a result, users are required to wear a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any N-95, R-95, P-95 or HE filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. To ensure that domestic users have ready access to the appropriate protective equipment, the applicant is required to provide a suitable respirator with each package of Sarritor Domestic Granular Biological Herbicide.

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 Domestic Granular Biological Herbicide application.

Next Steps

Before making a final registration decision on *Sclerotinia minor* strain IMI 344141, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *Sclerotinia minor* strain IMI 344141 (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

1.0 The Active Ingredient, Its Properties and Uses

No chemistry data were required to convert *Sclerotinia minor* strain IMI1344141 to full registration. For a detailed assessment of the chemical properties, refer to Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI1344141*.

2.0 Methods of Analysis

Refer to Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI1344141* for a detailed assessment of the methods of analysis for *Sclerotinia minor* strain IMI1344141 and the manufactured products.

3.0 Impact on Human and Animal Health

No toxicology, food residues, or occupational and residential data were required in support of the conversion from conditional to full registration. For details of the toxicology, dietary and the occupational and residential risk assessments, refer to Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI1344141*.

4.0 Impact on the Environment

The impact on the environment has been previously evaluated and the outcome is presented in Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI 344141* and reiterated in this document. Information to address outstanding requirements was submitted to the PMRA and has been reviewed. They are found to adequately address outstanding environmental concerns related to the use of *Sclerotinia minor* strain IMI1344141.

4.1 Fate and Behaviour in the Environment

As presented in Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI 344141*, a request to waive the data requirement for environmental fate and behaviour testing of *Sclerotinia minor* strain IMI 344141 was previously submitted. Environmental fate data (Tier II/III) were required due to some toxicological effects in non-target organisms identified in Tier I testing. Environmental fate testing is intended to demonstrate whether a microbial pest control agent (MPCA) is capable of surviving or replicating in the environment to which it is applied, and could provide an indication of which non-target organisms may be exposed to the MPCA as well as provide an indication of the extent of exposure. The submitted waiver request provided information from the published literature and results from laboratory and field testing of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide and *Sclerotinia minor* strain IMI 344141.

Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules are not readily dislodged from the site of application. When applied, the granules settle through the turf and rest on the soil surface. Eruptive mycelial growth of *Sclerotinia minor* strain IMI 344141 from Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules does not persist in the absence of a host, and quickly decays. Previously submitted field experiments, using lettuce as a highly susceptible indicator species, showed no residual infectivity in the turf environment 4 months after the application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules to dandelion plants. Formation of sclerotia following application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to turf is rare and occurs mainly in the fall, more commonly associated with clumps of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules than with infected weed tissue. Although sclerotia represent the most resistant, resting stage of the fungus, they also have a limited survival in the field. In field soil box experiments submitted for the initial registration decision, the viability of sclerotia decreased rapidly in soil and after 11 months, no sclerotia could be recovered. In addition, previously submitted laboratory and field compost experiments showed that sclerotia were rapidly inactivated in active compost. The dissemination of *Sclerotinia minor* strain IMI 344141 from the site of application is minimal, with the exception that mowing may spread diseased dandelion clippings onto susceptible plants growing adjacent to treated turf, and these may develop lesions or disease. The possibility that vectors could disseminate *Sclerotinia minor* strain IMI 344141 from the site of application was also investigated. In studies submitted for the initial decision, the MPCA could not be recovered from the seeds of dandelion plants treated with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide. This suggested that seeds would not provide a vector for the off-target transfer of *Sclerotinia minor* strain IMI 344141. Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules could also be spread following ingestion by granivorous animals. Although some sclerotia could be recovered from the feces of cattle and mallard ducks, sclerotial viability was greatly reduced and fungal mycelia growing on Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules are expected to be even more susceptible to the environment of the digestive tract. Dispersal of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules by scatter-hoarding animals (e.g., chipmunks, squirrels) remains a possibility, but is expected to be of minimal risk to non-target plants.

Overall, the off-target spread of *Sclerotinia minor* strain IMI 344141 from sites treated with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is expected to be minimal, and *Sclerotinia minor* strain IMI 344141 is not expected to persist in the environment.

4.2 Effects on Non-Target Species (Appendix I, Table 1)

4.2.1 Effects on Terrestrial Organisms

Evaluation of the risk of *Sclerotinia minor* strain IMI 344141 to terrestrial organisms was based on toxicity data previously submitted for birds, and the replacement studies for honeybees and earthworms. Requests to waive the requirement for testing in wild mammals, other terrestrial arthropods and terrestrial plants were previously submitted and considered as part of the risk assessment.

Sclerotinia minor strain IMI 344141 did not cause mortality, clinical signs or findings at necropsy within 30 days in 14-day-old Northern Bobwhite (*Colinus virginianus*) dosed daily for five consecutive days by gavage with a mycelial suspension of *Sclerotinia minor* strain IMI 344141 (1.7×10^7 colony forming unit (CFU)/kg body weight/day). Infectivity was not assessed, as the viability of the MPCA in the test substance was not verified, and there was no attempt made to recover the MPCA from the tissues or organs. Based on the maximum growth temperature of *Sclerotinia minor* strain IMI 344141 (34°C), and on results of an intraperitoneal injection study in laboratory rats, infectivity is not expected in homeothermic animals. The requirement for wild mammal testing was waived based on the lack of infectivity reported in laboratory mammals tested as part of *Human Health and Safety Testing*, in which no toxic effects were noted in an acute oral toxicity study, and the formulated product was shown to be of low dermal toxicity and to be non- to minimally irritating to the skin and eyes. Effects including pneumonia and death were identified during pulmonary testing of laboratory mammals. These were thought to be due to an overwhelming immune response to the large quantities of microbial antigen introduced into the lungs by intratracheal instillation. Wild mammals are unlikely to be exposed to quantities sufficient to elicit such a response.

Sclerotinia minor is not known as a pathogen of terrestrial invertebrates. For the initial decision, it was concluded from the published literature that some organisms that feed on or parasitize fungal sclerotia include nematodes, earthworms, centipedes, snails, gall midge larvae (Diptera: Cecidomyidae), mites (Astigmata: Acaridae), bacteria and fungi. Larvae of the fungus gnat (*Bradysia* species) and larvae of spring tails (*Onychirus* species: Collembola) were observed feeding on sclerotia of *Sclerotinia sclerotiorum*. The low incidence of lettuce drop in Quebec muck soils is partially attributed to the feeding of *Bradysia* species larvae on sclerotia, in addition to the activities of mycoparasite moulds *Trichoderma*, *Sporidesmium*, *Gliocladium* and *Penicillium*. In a review of the published literature, no incidents of toxicity or pathogenicity were identified. Given that the distribution of *Sclerotinia minor* is widespread, reports in the literature would be expected if it was a pathogen of terrestrial invertebrates.

In a dietary toxicity study in honeybees (*Apis mellifera*) submitted for the initial registration decision, mortality was greater in groups fed a diet containing live or killed *Sclerotinia minor* strain IMI 344141 compared with negative controls. The study authors attributed this to reduced palatability of the adulterated diet, but because feed consumption was not measured, this could not be confirmed and a toxic effect could not be ruled out. The 8-day dietary Lethal Concentration 50% (LC50) and No Observed Effect Concentration (NOEC) were not calculated, but mortality in the test group fed a diet containing 100 CFU of *Sclerotinia minor* strain

IMI 344141 /mL in the diet was 48% and mortality in honeybees fed a diet containing 1 CFU/mL was greater than in the negative control group. As honeybees are likely to forage for nectar on treated flowering dandelion plants, a replacement study was required to convincingly demonstrate that these effects are not toxic or pathogenic in nature. In the replacement honey bee study designed to address Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide toxicity to bees from foraging activities around dandelion plants treated with the end-use product at rates up 100 times the maximum labelled rate, no treatment related effects were reported. The study is considered to be supplemental however, as the toxic effect the various granular formulation treatments may have had on the bees was confounded by the bees' tendency to fall into the feeders and drown.

Previously no clinical or behavioural effects were noted in earthworms exposed to environmental concentrations equivalent to those expected immediately following a single application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide at the highest label rate. However, the concentration range tested did not meet the requirement for maximum hazard testing and no range-finding study was done to justify the low concentrations tested. Due to the certain exposure of earthworms to Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide, a replacement study was required to expose earthworms to the maximum hazard concentration of 267 g of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide/kg dry soil. In the replacement contact toxicity study, earthworms were exposed to the maximum hazard concentration of 267 g of the granular formulation per kg dry soil. Effects on earthworm growth have occurred at soil concentrations ⩾ 21 g of the granular formulation per kg of soil and effects on earthworm reproduction have occurred at soil concentrations ⩾12 g of the granular formulation per kg of soil. However, at levels below 1g of the granular formulation per kg of soil, juvenile production was not affected. Effects observed may not have been attributed to the active ingredient but to the organic granular substrate used in the end-use formulation. The substrate used in the formulation of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide decomposes and one of the degradation products is ammonium. The toxicity of ammonium to earthworms has been well documented in the scientific literature. Further soil analysis for ammonium determined the LC50 to be 146 mg ammonium per kg of soil. Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide once applied to the environment is expected to produce ammonium as it degrades, however, it is expected to be quickly adsorbed and metabolized by the vegetation (leaves and roots) thus reducing potential exposure to earthworms. Based on the study results, the NOEC for reproduction was 1 g of the formulated product per kg soil or 800 CFU of *Sclerotinia minor* strain IMI 344141 per kg of soil. This is significantly higher than the expected environmental concentration following a single application at the highest labelled rate; reproductive effects are therefore not expected in earthworms exposed to Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide when it is applied following label directions. This study was classified as acceptable.

Previously for the initial registration decision, a waiver request of the requirement for toxicity/pathogenicity data for *Sclerotinia minor* strain IMI 344141 on non-target terrestrial plants was submitted. The waiver request is based on the rationale that the active ingredient is a known plant pathogen with a wide host range. Testing was therefore not considered necessary to assess the risks of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to terrestrial plant species. Experimental testing for phytotoxicity on broadleaf garden weeds, turf grasses and representative garden plants was conducted for the initial registration decision. Many broadleaf garden weeds were susceptible to infection with *Sclerotinia minor* strain IMI 344141 following spot treatment with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules. Turf grasses (Kentucky bluegrass, creeping red fescue, perennial ryegrass, annual ryegrass, creeping bentgrass, colonial bentgrass, chewing fescue, tall fescue and hard fescue) were resistant to infection by *Sclerotinia minor* strain IMI 344141 following both pre- and post-emergent applications of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide. The risk to non-target plants will be limited to those growing in or adjacent to treated turf as Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Biological Herbicide granules and *Sclerotinia minor* strain IMI 344141 do not persist in the environment and are not readily dispersed from the site of application. The Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide product labels advise users to avoid application to desirable broadleaf species.

4.2.2 Effects on Aquatic Organisms

As presented in Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI 344141,* the risk of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide to aquatic organisms was based on evaluation of toxicity data in one fish, one aquatic arthropod, and one aquatic plant species.

A 30-day toxicity study of 50 rainbow trout (*Oncorhynchus mykiss*) and a 21-day study in *Daphnia magna* were considered to be supplementary information because the range of aquatic concentrations tested (20, 39, 79, 158 and 315 CFU of *Sclerotinia minor* strain IMI 344141/mL) was insufficient to properly assess the risk of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to aquatic organisms. Maximum hazard testing is recommended where the toxicity of the test substance is expected to be low. This required a concentration of 1000 times the expected environmental concentration or 10^6 CFU/mL, whichever is greater and achievable. Although the formulation of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules makes it difficult to define the estimated environmental concentration in terms of a mycelial suspension, the dose used was clearly insufficient to meet the requirement for maximum hazard testing. An LC50 could not be calculated from the data and no range-finding test was submitted to justify the use of a lower dose. Although a single fish in the highest test group died, there was no evidence that this was a treatment-related mortality, as there were no associated clinical signs or findings on necropsy. No effects were observed in *Daphnia magna*. In spite of the insufficiency of the submitted studies, no replacement studies are required. In another study (see below), Sarritor Granular Biological Herbicide (Commercial) and Sarritor

Domestic Granular Biological Herbicide were shown to be pathogenic to an aquatic vascular plant, which was the most sensitive aquatic organism tested. Measures to mitigate the risk to aquatic vascular plants will therefore be sufficient to mitigate any potential risk to freshwater fish or invertebrates.

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules effects on the freshwater floating aquatic vascular plant *Lemna gibba* G3 was studied at concentrations of 4, 9, 20, 45 and 100 granules/100 mL under static conditions. A negative (no granules), blank (uninoculated granules) and heat-inactivated control treatments were also observed. The 7-day EC50 based on frond number was 44 granules/100 mL, with a 95% confidence interval of 0.0–88.0 granules/100 mL. The 7-day NOEC based on biomass was 9 granules/100 mL. As adverse effects in *Lemna* were not observed in the heat-inactivated control and because fungal mycelia were observed on the fronds in the 100 granules/100 mL treatment group, the effects observed in the treatment groups are thought to be due to infection of the plant tissues with *Sclerotinia minor* strain IMI 344141.

A waiver of the requirement for further aquatic plant toxicity/pathogenicity testing for *Sclerotinia minor* strain IMI 344141 was previously requested, based on the known host range of *Sclerotinia minor* which includes aquatic sedges, on results of the 7-day toxicity test with duckweed (*Lemna gibba* G3) and on the ability of *Sclerotinia minor* strain IMI 344141 mycelia to germinate from floating Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules and for mycelial threads to grow along the surface of the water. Adverse effects in emergent and floating aquatic plants are therefore expected if Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules are permitted to enter aquatic ecosystems. To mitigate against the risk of effects in aquatic plants, the end-use product labels specifically prohibit application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to aquatic, estuarine or marine ecosystems and applicators are instructed not to apply Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to self-contained ponds, such as garden ornamental ponds, to prevent nuisance damage to ornamental aquatic plants. In addition, the end-use labels indicate to direct mower clippings away from such habitats for the first few weeks after Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide application.

5.0 Value

Refer to Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI1344141* for a detailed value assessment.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

While reviewing *Sclerotinia minor* strain IMI 344141, the PMRA took into account the federal Toxic Substances Management Policy and followed its Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with its use were also considered, including microcontaminants in the technical product, Sarritor Technical Herbicide, and formulants in the end-use products, Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide. The PMRA has reached the following conclusions:

- Sarritor Technical Herbicide does not meet the Track 1 criteria because the active ingredient *Sclerotinia minor* strain IMI 344141 is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. There are also no formulants, contaminants or impurities present in the end-use products that would meet the TSMP Track-1 criteria.

Therefore, the use of Sarritor Technical Herbicide is not expected to result in the entry of Track 1 substances into the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

Sarritor Technical Herbicide does not contain any formulants of health or environmental concern identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. There are also no formulants or contaminants of health or environmental concern present in the associated end use-products, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide.

Therefore, the use of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is not expected to result in the entry of formulants or contaminants of health or environmental concern, into the environment.

7.0 Summary

7.1 Human Health and Safety

Refer to Evaluation Report ERC2007-02 *Sclerotinia minor strain IMI1344141* for a summary of the impacts of *Sclerotinia minor strain IMI1344141* on human health and safety.

7.2 Environmental Risk

Data and information submitted on the environmental fate and effects of *Sclerotinia minor* strain IMI 344141 were determined to be sufficiently complete to assess the environmental impact of this microbial pest control agent.

For the initial registration decision, information on the environmental fate and behaviour of *Sclerotinia minor* strain IMI 344141 was required because toxicological concerns were identified in certain non-target organism studies. Previously submitted laboratory and field testing of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide revealed that granules were not readily dislodged from the site of application on turf after settling through the turf and resting on the soil surface. Eruptive mycelia growth of *Sclerotinia minor* strain IMI 344141 from Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules were also shown to not persist in the absence of a plant host and as a result quickly disappear.

Previously submitted field experiments showed little residual herbicidal activity in turf four months after application to dandelion plants. Moreover, the potential for seasonal carryover of residues was also unlikely with this MPCA, as it rarely forms sclerotia, which are more resistant to harsh environmental conditions than mycelia, and when formed by strain IMI 341441, quickly lose their viability.

Sclerotinia minor is widespread in the environment, yet there are no published reports of disease associated with *Sclerotinia minor* in birds, wild mammals, earthworms, honeybees 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. Results of a previously submitted dietary study in honey bees were difficult to interpret, but *Sclerotinia minor* is also a food source for many other ground-dwelling arthropods, indicating that it is of low toxicity to terrestrial arthropods. In addition, a replacement laboratory study, designed to assess risk to honey bees from foraging around plants treated with Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide reported no treatment related effects. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide did not affect earthworms at concentrations expected in the environment following a single application at the highest label rate, but at higher concentrations tested in the laboratory, survival and reproduction were affected. However, the decomposition of the carrier which produces ammonium, a toxicant to earthworms, is believed to have contributed to these effects. Ammonium produced during use of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is expected to be adsorbed and 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 Domestic Granular Biological Herbicide to plants growing adjacent to treated turf.

Aquatic arthropods and fish were exposed to a range of test aquatic concentrations, however, the PMRA requirement for a maximal concentration of 1000 times the expected environmental concentration was not provided. As this maximum concentration was not tested, it is not possible to properly assess the risk of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to these organisms. However, laboratory studies indicate that aquatic plants are the most sensitive aquatic organism tested as they were susceptible to *Sclerotinia minor* disease at concentrations lower than the maximal concentration of 1000 times the expected environmental concentration. Therefore, the measures established to minimize risk to sensitive aquatic plants will be sufficient to protect fish and aquatic arthropods.

Label statements instruct applicators not to apply Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to ornamental ponds or aquatic, estuarine or marine habitats or to allow mower clippings to enter such habitats for a few weeks after application. Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Biological Herbicide 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, so these precautions are considered sufficient to minimize the risk to aquatic organisms.

At the time of initial registration, additional confirmatory scientific information was requested from the registrant to ensure that *Sclerotinia minor* strain IMI 344141 will not harm terrestrial arthropods (honeybees) or non-arthropod invertebrates (earthworms). The required studies were submitted and reviewed. No further data are required.

7.3 Value

Refer to Evaluation Report ERC2007-02 Sclerotinia minor strain IMI1344141 for a summary of the value of Sclerotinia minor strain IMI134414.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide, containing the technical grade active ingredient *Sclerotinia minor strain IMI1344141*, to suppress dandelion top growth 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.

List of Abbreviations

^{o}C	degree(s) Celcius
ADI	acceptable daily intake
ARD	acute reference dose
CFU	colony forming unit
CI	confidence interval
EC50	effective concentration on 50% of the population
EP	end-use Product
FDA	*Food and Drugs Act*
kg	kilograms
LC50	lethal concentration 50%
LD50	lethal dose 50%
NOEC	no observed effect concentration
NOEL	no observed effect level
mL	millilitre
MPCA	microbial pest control agent
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
TGAI	technical grade of the active ingredient
TSMP	Toxic Substances Management Policy

Appendix I Tables and Figures

Table 1 Toxicity to Non-Target Species

Organism	Exposure	Test Substance	Endpoint value	Significant Effects and Comments	Reference(s)
Terrestrial Organisms					
Vertebrates					
Birds (Bobwhite quail)	Oral	*Sclerotinia minor* strain IMI 344141 mycelial suspension 30 birds given a single dose of 1.7×10^7 CFU/kg bw daily for 5 consecutive days	LD50 > 1.7×10^7 CFU/kg bw/day × 5 days NOEC > 1.7×10^7 CFU/kg bw/day × 5 days	No mortalities, no clinical signs, no findings on necropsy NOT TOXIC	PMRA 1291623
Mammals	No study was submitted. In a waiver request, a literature search showed no reports of adverse effects in wild mammals despite the ubiquitous nature of the MPCA. The waiver request also cited laboratory animal studies reviewed as part of the Human Health and Safety database. Exposure of wild mammals is expected to be minimal, with ingestion of the end-use product granules by granivorous mammals the most probable route of exposure, accompanied by dermal exposure from handling the granular product. Laboratory animal studies showed that *Sclerotinia minor* strain IMI 344141 is not infective in rats, and is non-toxic by the oral route in rats, and non-toxic and non-irritating by the dermal route in rabbits. WAIVER ACCEPTED				PMRA 1291624

Invertebrates					
Bees *(Apis mellifera)*	Dietary	*Sclerotinia minor* strain IMI 344141 mycelial suspension 25 bees/group, dosed at 100, 10 or 1 CFU/mL diet	7 day cumulative mortalities in all test groups were ≥40%, and in the group fed a diet containing 100 CFU/mL, 7-day cumulative mortality was 48%. LC50 and NOEC not statistically defined	Study terminated on Day 8 when mortalities in controls exceeded 20%. Study authors proposed that mortalities were due to reduced palatability of diet, but rates of food consumption were not measured, so this could not be confirmed.	PMRA 1291626
	Contact	Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide ~57 bees group dosed at rates of: 0.4, 4.0 or 40.0 g end-use product per plant 40.0 g untreated carrier per plant. 40.0 g attenuated end-use product per plant.	End points such as LD50, LC50, NOEL and NOEC were not reported for the study	SUPPLEMENTARY The highest dose group had the greatest overall survival of bees (for bees found dead around plants and in feeders). No treatment related effects were reported. However the unexpected result of bees drowning in the feeders made interpretation of the results of the study difficult. SUPPLEMENTARY	PMRA 1595630

Other arthropods	No study was submitted. In a waiver request, a literature search showed no reports of adverse effects in arthropods, and that several arthropod species, representing multiple arthropod classes and orders are known to actively feed on *Sclerotinia minor* sclerotia, including centipedes (Class: Chilopoda), gall midge larvae (Order Diptera), mites (Order Astigmata), fungus gnat larvae (Order Diptera) and springtail larvae (Order Collembola). WAIVER ACCEPTED				PMRA 1291627
Earthworm *(Eisenia fetida)*	Acute	Sarritor (Commercial) Granular Biological Herbicide or Sarritor Domestic Granular Biological Herbicide granules 10 worms/ group dosed at 6.25, 125, 250, 500 or 1000 mg/kg dry soil	LC50 > 1000 mg/kg dry soil NOEC 1000 mg/kg soil No mortalities, no clinical signs, and no aversion to treated soil observed at the highest tested concentration. Test concentrations did not meet the maximum hazard concentration of 267 g/kg soil (1000 times the estimated environmental concentration).	All worms (including untreated controls) lost weight because worms were not fed during the test. Worms fed the heat-inactivated granular formulation lost significantly less weight than untreated control worms, possibly because the attenuated end-use product provided a food source	PMRA 1291629
	28-day Contact	Sarritor (Commercial) Granular Biological Herbicide or Sarritor Domestic Granular Biological Herbicide 10/worms/group exposed via soil to 1, 17, 27, 68, 136 and 267 g end-use product per kg soil. Controls included 10 g and 136 g untreated carrier per kg soil, a water control and a positive control (Carbaryl)	The following end points were determined graphically from the regression line: 28-day LC50 of 145 g/kg soil EC50 of 21 g/kg soil for earthworm growth EC50 of 12 g/kg soil for earthworm reproduction NOEC (juvenile production) of 1 g/kg soil.	SUPPLEMENTARY Earthworm mortality was also related to ammonium released from the decomposing granular substrate, an LC50 of 146 mg ammonium kg^{-1} was extrapolated from the regression line ACCEPTABLE	PMRA 1595631
Soil microbes	No study or waiver request submitted. Test data are not required for *Sclerotinia minor* strain IMI 344141, as there are no reports of adverse effects in the available scientific literature.				

Plants					
Vascular Plants	No formal study was submitted. A waiver was requested based on the known host range of *Sclerotinia minor* including over 100 plant species, mostly dicots. Based on the requirement for direct contact with fungal mycelia, plants with a prostrate or rosette growth habit are the most likely to be affected by off-target application of Sarritor (Commercial) Granular Biological Herbicide or Sarritor Domestic Granular Biological Herbicide. An informal experimental report was used to address the potential for pathogenicity in turf grasses, informal laboratory experimental reports were submitted. No adverse effects on any of the multiple turfgrass species tested were observed. WAIVER ACCEPTED				PMRA 1291630
Aquatic Organisms					
Vertebrates					
Freshwater fish Rainbow trout	Acute	*Sclerotinia minor* strain IMI 344141 10 fish per group exposed to 20, 39, 79, 158 and 315 CFU/mL in the aquatic environment and 2, 4, 8, 16 and 32 CFU/kg in the diet.	No clinical signs or pathological findings at necropsy.	There was one mortality in the group of fish exposed to 315 CFU/mL in the aquatic environment and 32 CFU/kg in the diet, but it was not evident that this death was treatment related. The test concentration was significantly below the maximum hazard concentration, and the viability of the mycelial suspension in the aquatic environment was not adequately confirmed. SUPPLEMENTARY	PMRA 1291630
Estuarine/ marine fish	No study or waiver request was submitted. Estuarine and marine fish are not expected to be exposed to the MPCA.				

Invertebrates					
Freshwater arthropods *Daphnia magna*	Acute	*Sclerotinia minor* strain IMI 344141 20 neonate daphnids per group exposed to 20, 39, 79, 158, or 315 CFU/mL in the aquatic environment.	21-day LC50 >315 CFU/mL 21-day NOEC 315 CFU/mL	No statistically significant differences in survival, reproduction or growth between treated daphnids and negative controls. The test concentration was significantly below the maximum hazard concentration, and the viability of the mycelial suspension in the aquatic environment was not adequately confirmed. SUPPLEMENTARY	PMRA 1291628
Estuarine/ marine arthropods	No study or waiver request was submitted. Estuarine and marine arthropods are not expected to be exposed to the MPCA.				
Non-arthropod invertebrates	No study or waiver request was submitted.				
Plants					
Algae	Acute	No study or waiver request submitted			

Freshwater Plants *Lemna gibba*	Acute	Sarritor (Commercial) Granular Biological Herbicide or Sarritor Domestic Granular Biological Herbicide granules 4, 9, 20, 45 granules/100 mL	7-day frond no. EC50 44 granules/100mL (95% CI: 0-88 granules/100mL) 7-day frond no. growth rate EC50 63 granules/100mL (95% CI: 44-77 granules/100 mL) 7-day biomass EC50 58 granules/100mL (95% CI: 0-88 granules/100 mL) 7-day biomass growth rate EC50 71 granules/100mL (95% CI: 61–81 granules/100 mL) NOEC = 9 granules/100 mL	ACCEPTABLE	PMRA 1291631
Freshwater Plants	A request was submitted to waive the requirement for additional testing of aquatic plant species. Based on the known host range of *Sclerotinia minor* and results of the 7-day toxicity test with *Lemna gibba*, we can predict that floating broadleaf aquatic vegetation and sedges (Cyperaceae) are susceptible to infection if Sarritor (Commercial) Granular Biological Herbicide or Sarritor Domestic Granular Biological Herbicide granules enter the aquatic environment. Floating granules are capable of myceliogenic germination at the surface of the water, but are viable for fewer than 4 days. WAIVER ACCEPTED				PMRA 1291632

References

A. List of Studies/Information Submitted by Registrant

Impact on theEnvironment

PMRA No.	Title
1595630	2007, Sclerotinia minor (strain IMI 34414): Effects on adult worker honey bees, Apis mellifera, exposed to infected dandelion plants under laboratory conditions, DACO: M9.5.1
1595631	2008, Earthworm Ecotoxicoloy Testing of Sarritor Granular Biological Herbicide, DACO: M9.6

B. Additional Information Considered

Published Information

PMRA No.	Title
1433082	2007, PMRA Evaluation Report, ERC2007-02 *Sclerotinia minor strain IMI 344141*. June 2.