Proposed Registration Decision PRD2010-23

Typhula phacorrhiza Strain 94671

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Overview

Proposed Registration Decision for *Typhula phacorrhiza* strain 94671

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 Nivalis Technical and the end-use product Nivalis, containing the microbial pest control agent (MPCA) *Typhula phacorrhiza* strain 94671, to suppress both gray snow mould (*Typhula incarnata* and *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass on golf courses.

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 *Typhula phacorrhiza* strain 94671 and the end-use product Nivalis.

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.

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.

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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."

Before making a final registration decision on *Typhula phacorrhiza* strain 94671, 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 *Typhula phacorrhiza* strain 94671, 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 section of this consultation document.

What Is *Typhula phacorrhiza* strain 94671?

Typhula phacorrhiza strain 94671 is a fungus which belongs to the same genus as the gray snow mould pathogens (*Typhula ishikariensis* and *Typhula incarnata*) on turfgrass. As the active ingredient in Nivalis, *Typhula phacorrhiza* strain 94671 suppresses both gray snow mould (*Typhula incarnata & Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass. *Typhula phacorrhiza* strain 94671 competes directly with snow mould pathogens for nutrients and space under snow cover and suppresses disease development due to lack of food and space.

Health Considerations

Can Approved Uses of *Typhula phacorrhiza* strain 94671 Affect Human Health?

***Typhula phacorrhiza* strain 94671 is unlikely to affect your health when Nivalis is used according to the label directions.**

Exposure to *Typhula phacorrhiza* strain 94671 may occur during handling of Nivalis or when on a golf course with treated turf.

When assessing the health risks associated with microbial active ingredients, several key factors are considered: a microorganism's biological properties (e.g., production of toxic byproducts); reports of any adverse incidents; potential to cause disease or toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism. Toxicology studies in laboratory animals describe potential health effects from large doses for the purpose of identifying potential to cause disease or toxicity. There were no signs that *Typhula phacorrhiza* strain 94671 caused any significant toxicity or disease when tested on laboratory animals.

[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*.

Residues in Water and Food

Dietary risks from food and water are not of concern as there are no food uses and the likelihood of residues of *Typhula phacorrhiza* strain 94671 contaminating drinking water supplies is negligible.

Occupational Risks From Handling Nivalis

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

Users of Nivalis can come into direct contact with *Typhula phacorrhiza* strain 94671 primarily via the inhalation of dusts or exposure to the skin. As a standard requirement intended to minimize exposure, the label specifies that users of Nivalis must wear a long-sleeved shirt, long pants, closed footwear, waterproof gloves and a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products. A warning to avoid breathing dusts and to avoid contact with eyes is also on the end-use product label.

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Typhula phacorrhiza* strain 94671 Is Introduced Into the Environment?

Environmental risks are not of concern

Typhula species are commonly found on organic debris throughout temperate regions of the world and can cause diseases of cereals and grasses at low temperatures. Although some strains of *Typhula phacorrhiza* have been shown to be pathogenic to certain wheat cultivars, testing for pathogenicity on plants with the MPCA showed no adverse effects. The annual directed method of application of the end-use product prior to snowfall reduces exposure to non-target plants and organisms, therefore environmental risks are very low.

Value Considerations

What Is the Value of Nivalis?

Nivalis is a biofungicide that suppresses gray and pink snow mould on turfgrass

Nivalis contains dried mycelium and sclerotia of the fungus *Typhula phacorrhiza* in inoculated millet seeds. It has demonstrated effectiveness in suppressing both gray snow mould (*Typhula incarnata* & *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass. Nivalis is to be used on turf where continuous snow cover persists for 90 days or more. It provides a much wider window of opportunity for application compared to the conventional

fungicides since Nivalis can be applied well before the snow cover. Nivalis provides an additional mode of action to suppress snow mould on turf.

Measures to Minimize Risk

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

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

Key Risk-Reduction Measures

Human Health

To minimize exposure to *Typhula phacorrhiza* strain 94671, all handlers, loaders and applicators of Nivalis must wear long-sleeved shirts, long pants, waterproof gloves, closed footwear, and dust/mist filtering respirators/masks (NIOSH approval number prefix TC-21) or NIOSH approved respirators with any N-95, R-95, P-95 or HE filter for biological products. A label statement directing users to avoid inhaling dusts and to avoid contact with eyes is also included.

Environment

As a general precaution, statements will be added to the label to prohibit handlers from contaminating aquatic habitats including lakes, streams, ponds or other waters.

Next Steps

Before making a final registration decision on *Typhula phacorrhiza* strain 94671, 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 *Typhula phacorrhiza* strain 94671 (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

Typhula phacorrhiza strain 94671

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active microorganism	*Typhula phacorrhiza* strain 94671
Function	Control of snow mould caused by *T. ishikariensis*, *T. incarnate* and *Microdochium nivale* on golf course turf
Binomial name	*Typhula phacorrhiza* strain 94671
Taxonomic designation	
Domain	Eukaryota
Subdomain	Fungi/Metazoa group
Kingdom	Fungi
Subkingdom	Dikarya
Phylum	Basidiomycota
Subphylum	Agricomycotina (Hymenomycetes)
Class	Agaricomycetes incertae sedis
Order	Thelephorales
Family	Typhulaceae
Genus	*Typhula*
Species	*phacorrhiza*
Strain	94671
Patent Status information	No patents are held by the applicant in Canada.
Minimum purity of active	400,000 colony forming units (CFU)/kg
Identity of relevant impurities of toxicological, environmental and/or significance.	The TGAI does not contain any impurities or micro-contaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. The product must meet microbiological contaminants release standards. *Typhula phacorrhiza* strain 94671 does not produce any known toxins or any other known toxic metabolites.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product and End-Use Product —Nivalis Technical and Nivalis

Property	Nivalis
Colour	Beige
Physical state	Solid granule
Odour	Odourless to faintly anise-like
Stability	Stable when exposed to metals and metal ions. Not stable at temperatures >30°C.
Miscibility	n/a
Corrosion characteristics	Not expected to be corrosive. Results will be submitted with the one-year storage stability study.
pH	5.98 - 6.8 in aqueous solution (average. of 6.2 based on five submitted batches)
Viscosity	n/a
Density/Relative density/Bulk density	0.363 – 0.475 g/cm^3 (average of 0.439 g/cm^3 based on five submitted batches)
Water activity	0.311 – 0.423 aW (average of 0.377 aW based on five submitted batches)
Moisture	8.20 – 9.59% (average of 8.75% based on five submitted batches)

1.3 Directions for Use

Nivalis is to be used on turf where continuous snow cover persists for 90 days or more. Nivalis is for use on creeping bentgrass, Kentucky bluegrass, annual bluegrass, perennial ryegrass and other common species of turfgrass.

To suppress gray snow mould (*Typhula incarnata* and *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass, apply Nivalis by mechanical granular fertilizer spreader at the rate of 10 kg/100 m^2 of inoculated German millet seed for golf course fairways and 50 kg/100 m^2 for golf course greens and tees. Nivalis should be applied after the last mowing and before snowfall. Do not use water or equipment contaminated with fungicides likely to be harmful to the active ingredient fungus in this product. Do not apply within 2 weeks of fungicide applications.

1.4 Mode of Action

Typhula phacorrhiza strain 94671 competes directly with snow mould pathogens for nutrients and space under snow cover and suppresses disease development due to lack of food and space. It has not been found to produce antibiotics, and metabolites are not known to be important in the mode of action against targeted pests.

2.0 Methods of Analysis

2.1 Methods for Identification of the Microorganism

The active ingredient can be distinguished from other *Typhula* species by a number of methods including random amplification of polymorphic deoxyribonucleic acid (RAPD) analysis, restriction fragment length polymorphism (RFLP) analysis of the internal transcribed spacer (ITS) region, and DNA sequencing of the ITS region.

Restriction fragment length polymorphism analysis of the intergenic spacer region (IGS) of ribosomal DNA (rDNA) is used to distinguish between strain 94671 and other strains of *Typhula phacorrhiza*. The resulting amplification products are separately digested with the restriction enzymes *Alu*I, *Cfo*I, *Hae*II, *Hpa*II, *Mbo*I, and *Rsa*I and the digested DNA are separated on a gel. Similarity coefficients and genetic distances are calculated based on the presence or absence of bands and a dendrogram based on genetic distances places strain 94671 separately from the other strains of *Typhula phacorrhiza*.

2.2 Methods for Establishment of Purity of Seed Stock

Upon receipt by the manufacturing facility, *Typhula phacorrhiza* strain 94671 is plated and incubated to confirm that it is an actively growing culture with no visual contamination. Two plugs, taken from the edges of the culture plates, are transferred to sterilized vials containing a glycerol solution. For long-term storage, the vials are stored in liquid nitrogen. The viability of the stored culture is confirmed after 7 and 14 days of storage. To replenish this mother stock, the procedure is repeated using the contents of one of the remaining vials as starting material.

2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products

The label guarantee of both Nivalis Technical and Nivalis is 400,000 CFU/kg. The label indicates that one granule of the product is equivalent to one CFU as confirmed by the results of a plate count test. One gram of product contains 400 granules and, therefore, one kilogram of product contains 400,000 granules or 400,000 CFUs.

2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites

Nivalis is not intended for use on food or feed crops. Therefore, the establishment of a maximum residue limit (MRL) is not required for *Typhula phacorrhiza* strain 94671 and, as a result, no methods to determine and quantify the MPCA and relevant metabolites are required.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

The quality control procedures used to limit contaminating microorganisms during manufacture of Nivalis Technical and Nivalis are acceptable. Any product that does not meet the applicant's specifications for microbial contamination is destroyed.

2.6 Methods to Show Absence of Any Human and Mammalian Pathogens

As noted in section 2.5, quality control procedures are used to limit microbial contamination in Nivalis Technical and Nivalis. These procedures include contamination checks throughout the manufacturing process.

Acceptable microbial contaminant analysis data were submitted for five batches of Nivalis.

2.7 Methods to Determine Storage Stability, Shelf-life of the Microorganism

A one-year storage stability study is underway but results are not yet available. Methods for storage stability testing were not submitted. The label for the end-use product instructs users to store the product at 4°C but does not define a storage period. Until storage stability data are available, the label must indicate a maximum storage period of six months.

3.0 Impact on Human and Animal Health

3.1 Toxicity and Infectivity Summary

The PMRA conducted a detailed review of the toxicological database for *Typhula phacorrhiza* strain 94671. The database for Nivalis Technical is complete (see Appendix 1, Table 1), consisting of laboratory animal (*in vivo*) toxicity studies (acute oral toxicity, pilot acute intraperitoneal toxicity/pathogenicity) and acceptable waiver rationales in lieu of oral pathogenicity, pulmonary toxicity/infectivity, and inhalation toxicity/pathogenicity testing. In addition to the studies on the technical product, acute dermal toxicity, primary dermal irritation and eye irritation studies were conducted on the end-use product, Nivalis. The scientific quality of the data is high and the database is considered sufficient to characterize the toxicity and infectivity of this pest control agent and the end-use product.

Typhula phacorrhiza strain 94671 is of low acute toxicity via the oral route with an oral LD_{50} of >5000 mg/kg bw. Pathogenicity and infectivity testing via the oral route was waived as it was adequately demonstrated in the intraperitoneal (IP) pilot study (see below) that *Typhula phacorrhiza* strain 94671 is non-infective.

A pilot acute IP injection toxicity and pathogenicity study was conducted in order to develop a method to evaluate the IP toxicity, infectivity, and pathogenicity of *Typhula phacorrhiza* strain 94671 at a single high dose exposure with an adequate post-exposure observation period in preparation for a definitive study. There were no mortalities and all animals appeared normal during the study. With the exception of the animal that was scheduled for sacrifice one hour post-dosing, all other animals gained weight throughout the observation period. Thickened attachment points between the liver and the intestines were noted in all three animals sacrificed on day 21. *Typhula phacorrhiza* strain 94671 was not able to establish infection or persist in female rats at the dosed concentration (approximately 3.7×10^4 CFU/animal). No organisms were found in the blood, brain, lungs, liver, spleen, kidneys, lymph nodes, and cecum contents. The pilot study results indicated that *Typhula phacorrhiza* strain 94671 showed no evidence of toxicity or pathogenicity in rats following a single intraperitoneal injection administration of 3.7×10^4 CFU/rat.

Due to difficulties in producing adequate quantities of pure mycelium in liquid culture to perform full acute pulmonary toxicity/infectivity and acute injection toxicity/pathogenicity testing, the applicant submitted rationales to waive these studies based on the active ingredient's limited sporulation, low optimal growth temperature and lack of relationship to known or suspected human or animal pathogens. Results of acute oral toxicity testing and a pilot IP toxicity, infectivity and pathogenicity study were also used to support the waiver rationale.

In an acute dermal toxicity study, groups of five male and five female Sprague-Dawley rats were dermally exposed to 5050 mg/kg of Nivalis. All animals survived, appeared normal, and no dermal irritation was noted during the study. All males gained weight throughout the study. One female did not gain weight during the first week but gained slightly during the second week. Three females lost weight during the first week but gained weight during the second week. One female, however, did not regain its original weight. Dark red spots were noted on the lungs of all males and dark red lungs were noted in one female but, in the absence of any other adverse effects, these were not considered to be significant adverse effects. All other females had no observable abnormalities. Based on this study, the dermal $\mathbf{LD_{50}}$ is > 5050 mg/kg bw and Nivalis is of low acute toxicity via the dermal route.

In a primary dermal irritation study, one male and two female young adult New Zealand White rabbits were dermally exposed to 500 mg of Nivalis moistened with 0.5 mL of deionized water. Very slight erythema was noted in two rabbits one hour after patch removal with clearance by 24 hours. The test material was found to be non-irritating based on the maximum average score (MAS) over the 24, 48 and 72 hours observation points of 0.

In a primary eye irritation study, 0.1 mL of Nivalis was instilled into the conjunctival sac of the right eye of one male and two female young adult New Zealand White rabbits. No corneal opacity was noted in any rabbit although a slight dulling of the normal lustre was observed in

one quarter (or less) of the treated eye of one male and one female rabbit at the one hour observation point. No other signs of corneal involvement or iritis were observed at any observation point. Positive conjunctival irritation (redness with score 2) was noted in 2/3 rabbits one hour after test material instillation with resolution in one rabbit by 24 hours and in another rabbit by 48 hours. Hyperemic blood vessels were noted (score 1) in the eye of the last rabbit but was resolved by 24 hours. Minimal swelling (score 1) was observed in 2/3 rabbits at 1 hour but was resolved by 24 and 48 hours. Moderate discharge (score 2) and minimal discharge (score 1) was observed in 2/3 and 1/3 rabbits, respectively, at 1 hour but cleared by 24 hours. The maximum individual irritation score of 10 and the maximum mean irritation score (MIS) of 8 occurred at the one hour timepoint. The mean average score (MAS) over 24, 48 and 72 hours was 0.67. Based on the maximum MIS, Nivalis is considered to be minimally irritating to the eye.

Higher tier subchronic and chronic toxicity studies were not required because of the low acute toxicity of the MPCA, and no indications of infectivity, toxicity or pathogenicity in the test animals treated in the Tier I acute oral toxicity and pilot acute intraperitoneal injection toxicity/pathogenicity tests.

3.2 Occupational / Bystander Exposure and Risk Assessment

3.2.1 Occupational

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, loaders, and handlers exists, with the primary source of exposure to workers being inhalation of dusts or exposure to the skin.

To minimize inhalation exposure the dust mask requirement should be upgraded to a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products.

Although the applicant has included protective eyewear on its proposed label, eye protection is not required as Nivalis has been found to be only minimally irritating to the eye. The applicant has the option of retaining or removing the need for eye protection. A statement advising users to avoid contact with eyes is required.

With respect to dermal exposure, unbroken skin is a natural barrier to microbial invasion of the human body and so dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. *Typhula phacorrhiza* strain 94671 has not been identified as a wound pathogen and there is no indication that it could penetrate the intact skin of healthy individuals.

Risks from occupational exposure are not anticipated due to the low toxicity of the formulation and the adequate exposure mitigation measures recommended on the labels, including wearing of personal protective equipment (PPE) for commercial applications.

3.2.2 Bystander

The label allows commercial applications to golf turf only. Therefore, the potential for non-occupational exposure to bystanders including adults, infants and children is low. Risks from inadvertent exposure (e.g., golfers) are not anticipated due to the low toxicity of the formulation.

3.3 Dietary Exposure and Risk Assessment

3.3.1 Food

Nivalis is not proposed for use on food or feed crops and the label directs users to avoid spraying fruits and vegetables. Therefore, negligible to no risk is expected for the general population, including infants and children, or animals because there are no direct applications of Nivalis to food or feed crops. As a result, there is no concern for chronic risks posed by dietary exposure of the general population and sensitive subpopulations, such as infants and children.

3.3.2 Drinking Water

The likelihood that Nivalis could enter neighbouring aquatic environments as a result of run-off is negligible. No risks are expected from exposure via drinking water because exposure will be minimal and the formulation has a low toxicity profile. The Nivalis label will instruct users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. Furthermore, municipal treatment of drinking water is expected to remove the transfer of residues to drinking water. Therefore, potential exposure to *Typhula phacorrhiza* strain 94671, used in the manufacture of Nivalis, in surface and drinking water is negligible.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

As the end-use product, Nivalis, is not intended for direct applications to food crops, an acute reference dose (ARD) and an acceptable daily intake (ADI) for *Typhula phacorrhiza* strain 94671 are not required.

3.4 Maximum Residue Limits

As there are no direct applications to food, the establishment of a maximum residue limit is not required for *Typhula phacorrhiza* strain 94671 in the Nivalis end-use product.

3.5 Aggregate Exposure

As dietary (food and drinking water) exposures and non-occupational exposures (dermal and inhalation) are expected to be minimal, analysis of aggregate exposure is not required.

3.6 Cumulative Effects

The PMRA has considered available information on the cumulative effects of residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Besides naturally occurring strains of *Typhula phacorrhiza* in the environment, the PMRA is not aware of any other microorganisms, or other substances that share a common mechanism of toxicity with the active ingredient in the technical product. No cumulative effects are anticipated if the residues of *Typhula phacorrhiza* strain 94671 found in Nivalis interact with related strains of this microbial species.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

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. Environmental fate data (Tier II/III) are not normally required at Tier I, and are only triggered if significant toxicological effects in non-target organisms are noted in Tier I testing.

Several members of the genus *Typhula* are known to be the causative agent of diseases of cereals and grasses at low temperatures. *Typhula phacorrhiza* is a clavulate basidiomycete widely reported from Northern temperate zones. *Typhula phacorrhiza* is a psychrophilic saprotroph and sclerotia of *Typhula* spp. are often found on corn (*Zea mays* L.) residues and other organic debris after at least 80 days of snow cover. The sclerotia have been described as sessile and stalked and are not easily dislodged from the substrate to which they are attached. However, upon snowmelt the colonized dead plant tissues decompose allowing sclerotia to fall to the ground where they may remain dormant until temperatures required for optimal growth return in the fall. The optimal growth temperature for *Typhula phacorrhiza* strain 94671 is 4°C. *Typhula* species are able to grow at -5°C; however growth is not seen at 30°C.

The genus *Typhula* takes it name from the distinct club shaped spore producing structures called clavula. These sporophores arise from sclerotia and mature to produce basidiospores (sexual spores) at the fertile head. In *Typhula phacorrhiza* strains, the source of the primary inoculum is thought to be mycelium originating from sclerotia rather than basidiospores. Field testing confirmed that sporophores are typically found during rainy cold weather not unlike that found in the fall with peak levels reached just prior to the start of winter. The ability of *Typhula phacorrhiza* to produce sclerotia on a variety of organic substrates may allow for a competitive advantage over pathogenic species of snow moulds of golf turf for nutrients and space.

The occurrence of conidia (asexual spores) from the genus *Typhula* has been previously reported in the field; however their function is unknown and is not thought to play an important role in pathogenesis.

4.2 Effects on Non-Target Species

4.2.1 Effects on Terrestrial Organisms

The data and information submitted or available on the proposed microbial pest control agent (MPCA) and use pattern are sufficient to adequately characterize the risk to the terrestrial environment from the use of the end-use product, Nivalis.

The applicant provided a rationale to waive actual test data on *Typhula phacorrhiza* strain 94671 based on the optimal growth temperature of the MPCA being well below 15°C, competition for nutrient/space as the mode of action, the lack of a relationship between the MPCA and dermatophores or human pathogens, the MPCA's low toxicity to wild mammals from an estimated acute LD_{50} greater than 5000 mg/kg in rats, and that the use pattern of Nivalis reduces the possibility of unintentional exposure to non-target organisms.

Based on the application method and timing, birds and mammals foraging on treated turf may ingest the granular formulation. However, *Typhula phacorrhiza* strain 94671 does not grow at temperatures above 30°C which is lower than the average avian body temperature. Furthermore adverse effects to wild mammals is not expected based on the lack of treatment related adverse effects in acute toxicity testing (oral, dermal and ocular exposure) conducted on rats with the formulated product.

The rationale to waive data for effects to terrestrial invertebrates was based on the lack of effects toward these non-target organisms in the published scientific literature, given the common occurrence of *Typhula phacorrhiza* strains in the temperate environment.

No adverse effects were noted in a plant pathogenicity laboratory study conducted with *Typhula phacorrrhiza* strain 94671; however, the dose that test subjects received could not be confirmed and, as a result, this testing was considered to be supplemental information. Although certain isolates of *Typhula phacorrhiza* have been confirmed in the published scientific literature as being pathogenic to certain winter wheat cultivars, strain 94671 was not identified as one such pathogenic isolate. Based on the application method, Nivalis granules will be broadcast once per season on the golf greens and fairways in fall before snowfall. This directed method of application is expected to reduce the likelihood of unintentional exposure to non-target plants. In addition, based on acceptable research trials on golf course turf conducted to determine the efficacy and/or plant host spectrum of the proposed end-use product, Nivalis, the PMRA concluded no adverse effects on non-target plants were observed. The risk to terrestrial non-target plants from the proposed use of Nivalis is therefore expected to be minimal.

There is no evidence in the published literature that would indicate antibiotics or metabolites are produced by the MPCA as a mode of action against the snow moulds of turf caused by *Typhula incarnata* or *Typhula ishikariensis* and *Microdochium nivale*.

The proposed application to turf is not expected to result in a sustained increase in the background levels of *Typhula phacorrhiza* strain 94671 in the terrestrial environment. There is also no known relationship reported in the published scientific literature between *Typhula phacorrhiza* and known terrestrial animal pathogens and the risk posed by the golf turf use of Nivalis is not expected to present a concern for mammals, birds, terrestrial invertebrates and plants.

See Appendix I, Table 2, for a summary table of effects on terrestrial organisms.

4.2.2 Effects on Aquatic Organisms

The required studies which help characterize the risk *Typhula phacorrhiza* strain 94671 may pose to the aquatic environment specifically from the proposed use on golf turf were not submitted. Instead, an acceptable rationale was provided to waive the data requirements based on the limited exposure to the aquatic ecosystems from the proposed application method, the natural distribution of the MPCA, the lack of phytopathogenicity of *Typhula phacorrhiza* to terrestrial plants in laboratory and field studies, and that *Typhula phacorrhiza* strain 94671 is not known to be a pathogen of fish, aquatic invertebrates or plants.

The exposure to aquatic environments is expected to be minimal based on the directed application of the granular end-use product, Nivalis, by fertilizer spreader. *Typhula phacorrhiza* strain 94671 was isolated from corn fields and the sclerotia of *Typhula phacorrhiza* are commonly isolated from overwintered corn and other organic debris as it is reportedly abundant within the habitat range. The proposed application to turf is not expected to result in a sustained increase in the background levels of *Typhula phacorrhiza* strain 94671. Furthermore, as the MPCA is not considered to be an aquatic fungus, it is not expected to proliferate in aquatic ecosystems, which it may be exposed to in the event of post-application run off due to rain. A search conducted of the published scientific literature has not confirmed its isolation from more permanent bodies of water (ponds, streams, lakes, etc).

The data and information available on the proposed MPCA and proposed formulation are sufficient to adequately characterize the risk to the aquatic plants, from the proposed use of the end-use product, Nivalis containing *Typhula phacorrhiza* strain 96471, to control snow mould on golf course turf. There is also no known relationship reported in the published scientific literature between *Typhula phacorrhiza* and known aquatic animal pathogens and the MPCA is not expected to present a hazard to fishes or aquatic invertebrates from environmental exposure.

See Appendix I, Table 2, for a summary table of effects on aquatic organisms.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

Nine trials were reviewed for the control/suppression of gray snow mould (*Typhula incarnata and Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass, including creeping bentgrass greens and bluegrass fairways. Seven trials demonstrated the efficacy of Nivalis on *Typhula incarnata* in turfgrass greens (four trials) and fairways (three trials). Two trials had insufficient disease pressure where as five trials had moderate disease pressure with *Typhula incarnata* injury rates of 19 - 61% in the untreated-inoculated control. Nivalis treatments at a rate of 10 kg/100 m^2 provided *Typhula incarnata* control of 40 - 97% (average 52%) in five trials, while treatments at 5 kg/100 m^2 achieved 43 - 66% (average 53%) control in three trials.

Seven trials demonstrated the efficacy of Nivalis on *Typhula ishikariensis* in turfgrass greens (four trials) and fairways (three trials). Six trials had moderate to high disease pressure with *Typhula ishikariensis* injury rates of 23 - 95% in the untreated-inoculated control. Nivalis treatments at a rate of 10 kg/100 m^2 provided *Typhula ishikariensis* control of 19 - 80% (average 55%) in six trials, while treatments at 5 kg/100 m^2 had significantly less disease control than the 10 kg/100 m^2 treatments in two out of three trials. The 10 kg/100 m^2 rate provided numerically better disease suppression than the 5 kg/100 m^2 rate.

Seven trials demonstrated the efficacy of Nivalis on *Microdochium nivale* in turfgrass greens (three trials) and fairways (four trials). Six trials had moderate disease pressure with *Microdochium nivale* injury rates of 25 - 69% in the untreated-inoculated control. Nivalis treatments at a rate of 10 kg/100 m^2 provided *Microdochium nivale* control of 37 - 90% (average 68%) in six trials, while treatments at 5 kg/100 m^2 had significantly less disease control than the 10 kg/100 m^2 treatment in one trial and had comparable result to the 10 kg/100 m^2 treatment in another trial. The 10 kg/100 m^2 rate provided numerically better disease suppression than the 5 kg/100 m^2 rate.

A rate of 50 kg/100 m^2 was applied in two trials (one trial each on greens and fairways) for all three pathogens, and the efficacy was significantly increased only on the greens trial compared to the 10 kg/100 m^2 treatment. The efficacy of Nivalis at all rates was comparable to or lower than the commercial standards applied in the same experiment.

5.2 Phytotoxicity

No phytotoxicity or crop injury was reported from the efficacy trials. To further address concerns about the phytopathogenicity of *Typhula phacorrhiza* strain 96471, a literature review and a lab study were conducted. The infection study was done on a variety of plants, including tomato (*Solanum lycopersicum*), common geranium (*Pelargonium hortorum*), tobacco (*Nicotiana bentamiana*), wheat (*Triticum aestivum*), and rice (*Oryzae sativa*). Results indicated

that neither literature review nor lab study showed *Typhula phacorrhiza* to be a significant pathogen of plants. The lab experiments showed that *Typhula phacorrhiza* strain 94671 did not infect live plants at 4º C or 25º C. A second experiment at 25º C with more replicates gave the same results.

5.3 Economics

No market analysis was done for this application.

5.4 Sustainability

5.4.1 Survey of Alternatives

The alternative active ingredients registered for control or suppression of gray snow mould (*Typhula incarnata* and *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) on turfgrass are presented in Appendix I, Table 3.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Fungicide sensitivity of *Typhula phacorrhiza* strain 94671 was reported in two laboratory assays conducted in 1999 and 2000. Nine fungicides were tested in the trials, including Daconil, Rovral Green, Tersan, Eagle, PCNB, Fore, Arrest, Heritage and Banner. The concentrations of these fungicides were calculated based on actual use rates in the field. Results indicated that most fungicides against gray snow mould pathogens (*Typhula ishikariensis* and *Typhula incarnata*) also showed effects against *Typhula phacorrhiza*. However, variations in sensitivity were shown in some fungicides, such as Arrest, which could strongly inhibit *Typhula incarnata* growth and had much less effect on *Typhula phacorrhiza*. The 2000 report also demonstrated that sclerotia of *Typhula phacorrhiza* strain 94671 can withstand exposure to fungicide levels that would be lethal to mycelium.

In two field trials conducted in 2008, the compatibility of Nivalis with conventional fungicides was tested using PCNB 75WP or Daconil plus Rovral Green at 0, 2 and 4 weeks prior to Nivalis application. The application of these fungicides did not affect the efficacy of Nivalis. Therefore, *Typhula phacorrhiza* strain 94671 may be used in an integrated pest management program for snow mould in turf.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance management is not a concern for *Typhula phacorrhiza* because the mode of action is based on out competing snow mould disease for nutrients and space.

5.4.4 Contribution to Risk Reduction and Sustainability

Snow moulds are the most important winter diseases on perennial turfgrasses especially in the areas with long duration of snow cover. Management of snow mould diseases of turfgrass is currently conducted with the use of conventional fungicides. Nivalis is a biofungicide whose mode of action is based on competitive growth and exclusion of snow mould pathogens on turf. The use of Nivalis will contribute to an integrated pest management program for turf.

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 the 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 *Typhula phacorrhiza* strain 94671, 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 of were also considered, including microcontaminants in the technical product, Nivalis Technical, and formulants in the end-use product, Nivalis. The PMRA has reached the following conclusions:

- Nivalis Technical does not meet the Track 1 criteria because the active ingredient 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 product that would meet the TSMP Track-1 criteria.

Therefore, the use of Nivalis 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

Nivalis Technical 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* (Amended June 25, 2008 SI\2008-67). There are also no formulants or contaminants of health or environmental concern present in the associated end use-product, Nivalis.

7.0 Summary

7.1 Methods for Analysis of the Micro-organism as Manufactured

The product characterization data for Nivalis Technical and Nivalis were judged to be adequate to assess their potential human health and environmental risks. The TGAI was characterized and the specifications were supported by the analyses of a sufficient number of batches. Until storage stability data are available, the label must indicate a maximum storage period of six months at 4°C.

7.2 Human Health and Safety

The human health and safety information and data submitted in support of *Typhula phacorrhiza* strain 94671 were determined to be sufficiently complete to permit a registration decision on registration. *Typhula phacorrhiza* strain 94671 was of low toxicity via the oral and dermal routes and showed no evidence of toxicity or pathogenicity via the intraperitoneal route (pilot study). Based on the active ingredient's limited sporulation, low optimal growth temperature and lack of relationship to known or suspected human or animal pathogens, acceptable rationales were provided to waive acute pulmonary toxicity/infectivity and acute injection toxicity/pathogenicity testing.

Nivalis was found to be non-irritating to slightly irritating to the skin and minimally irritating to the eye. As is the case with all microbial pest control agents, *Typhula phacorrhiza* strain 94671 is a potential sensitizer.

Occupational exposure to *Typhula phacorrhiza* strain 94671 in Nivalis is expected to be minimal from the proposed use pattern if the recommended personal protective equipment on the product label is worn.

The label allows commercial applications to golf turf only. Therefore, the potential for non-occupational exposure to bystanders including adults, infants and children is low. Risks from inadvertent exposure are not anticipated due to the low toxicity of the formulation.

As there are no food uses proposed for Nivalis, dietary exposure to *Typhula phacorrhiza* strain 94671 is expected to be negligible to non-existent.

7.3 Environmental Risk

Environmental effects studies and waiver rationales were submitted to address the hazards of Nivalis Technical containing *Typhula phacorrhiza* strain 94671 to non-target organisms. These studies, rationales and other published information showed that the use of Nivalis containing *Typhula phacorrhiza* strain 94671 does not pose a significant risk to birds, mammals, arthropods (including honey bees), fish, non-arthropod invertebrates, plants, or algae.

No additional studies were required to address the environmental fate and behaviour of Nivalis Technical containing *Typhula phacorrhiza* strain 94671. Environmental fate data (Tier II/III) are not normally required in the absence of significant toxicological effects in non-target organisms in Tier I testing.

As a precaution, standard label statements will prohibit handlers from contaminating aquatic habitats including lakes, streams, ponds or other water bodies.

7.4 Value

Sufficient evidence of efficacy was provided to support the use of Nivalis to suppress disease symptoms of both gray snow mould (*Typhula incarnata* and *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) on turf at the proposed rates of 10 kg/100 m^2 for golf course fairways and 50 kg/100 m^2 for golf course greens and tees.

A summary of the proposed and accepted uses for Nivalis Biofungicide is presented in Appendix I, Table 4.

7.5 Unsupported Uses

All uses were supported.

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 Nivalis Technical and the end-use product Nivalis, containing the microbial pest control agent (MPCA) *Typhula phacorrhiza* strain 94671, to suppresses both gray snow mould (*Typhula incarnata* and *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass on golf courses.

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

ADI	acceptable daily intake
ARD	acute reference dose
aW	water activity
°C	degree(s) Celcius
bw	body weight
CFU	colony forming units
cm^3	centimetre(s) cubed
DNA	deoxyribonucleic acid
g	gram
HE	high efficiency
IGS	intergenic spacer
IP	intraperitoneal
ITS	internal transcribed spacer
kg	kilogram
LD_{50}	lethal dose 50%
m^2	metre(s) squared
mg	milligram
mL	millilitre
mm	millimetre(s)
MAS	maximum average score
MIS	maximum irritation score
MPCA	microbial pest control agent
MRL	maximum residue limit
n/a	not available
NIOSH	National Institute for Occupational Safety and Health
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
RAPD	random amplified polymorphic deoxyribonucleic acid
rDNA	ribosomal deoxyribonucleic acid
RFLP	restriction fragment length polymorphism
TGAI	technical grade of the active ingredient
TSMP	Toxic Substances Management Policy

Appendix I Tables and Figures

Table 1 Toxicity and Infectivity of *Typhula phacorrhiza* strain 94671 and its associated end-use product (Nivalis)

STUDY	SPECIES, STRAIN AND DOSES	RESULT	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES			
Oral toxicity	Rats, Sprague-Dawley (3♀) , 5000 mg/kg bw	LD_{50} > 5000 mg/kg bw	No mortalities and no clinical signs of toxicity. No gross necropsy findings. Pathogenicity and infectivity testing waived. **LOW TOXICITY**
Pilot injection (IP)	Rats, Sprague-Dawley (4♀), 3.7×10^4 CFU/animal	not toxic not pathogenic	No mortalities and no clinical signs of toxicity. Thickened attachment points between liver and intestines. The microbial pest control agent (MPCA) was not recovered from any tissue or fluid samples from animals sacrificed at study termination. **NOT TOXIC** **NOT PATHOGENIC**
Pulmonary toxicity/infectivity	A waiver rationale was submitted based on the active ingredient's limited sporulation, low optimal growth temperature, lack of relationship to human or animal pathogens and the results of the acute oral toxicity and pilot IP studies. **ACCEPTABLE**		
Injection (IP) toxicity/ pathogenicity	A waiver rationale was submitted based on the active ingredient's limited sporulation, low optimal growth temperature, lack of relationship to human or animal pathogens and the results of the acute oral toxicity and pilot IP studies. **ACCEPTABLE**		
Dermal toxicity	Rats, Sprague-Dawley (5♂, 5♀), 5050 mg/kg bw	LD_{50} > 5050 mg/kg bw	No mortalities. One animal failed to gain weight. Dark red spots on lungs of all males and dark red lungs in one female were not considered adverse effects. **LOW TOXICITY**
Dermal irritation	Rabbits, New Zealand White (1♂, 2♀), 500 mg/animal	MIS = 0.67 at 1 hour MAS = 0	On study day one, three males and four females exhibited very slight erythema and one female exhibited well-defined erythema. One male continued to have slight erythema from days two to six. Two females had slight erythema on day two. All animals returned to normal by day nine. There was no edema. **NON-TO SLIGHTLY IRRITATING**

STUDY	SPECIES, STRAIN AND DOSES	RESULT	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Eye irritation	Rabbits, New Zealand White ((1♂, 2♀)), 0.1 ml/animal	MIS = 8 at 1 hour MAS = 0.67	No corneal opacity. Slight dulling of normal lustre in eye of one ♂ and one ♀ at one hour. No iritis. Conjunctival irritation in 2/3 animals resolved by 24 and 48 hour timepoints. Hyperemic blood vessels in one animal resolved by 24 hour timepoint. Minimal swelling in 2/3 animals at hour resolved by 24 and 48 hour timepoints. Minimal to moderate discharge observed in all animals at one hour resolved by 24 hours. **MINIMALLY IRRITATING**

Table 2 Summary of Effects on Non-Target Organisms

Organism	Exposure	Protocol	Significant Effects and Comments	Reference
Terrestrial Organisms				
Vertebrates				
Birds	oral		A waiver request was submitted citing the inability of the MPCA to grow at temperatures above 30°C, lack of adverse effects reported in the published literature to birds and that the MPCA has no known relationship to animal pathogens. WAIVER ACCEPTED	1781432
	pulmonary		A waiver request was submitted citing the inability of the MPCA to grow at temperatures above 30°C, lack of adverse effects reported in the published literature to birds and that the MPCA has no known relationship to animal pathogens. WAIVER ACCEPTED	1781432
Wild 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. Laboratory animal studies showed that *Typhula phacorrhiza* strain 94671 is non-toxic by the oral route, and non-toxic and non-irritating by the ocular and dermal route in rats and rabbits respectively. WAIVER ACCEPTED			1781432
Invertebrates				
Arthropods				
Non-target Insect honey bees	A waiver request was submitted citing lack of adverse effects reported in the published literature to non-target insects and honey bees and that the MPCA has no known relationship to animal pathogens. WAIVER ACCEPTED			1781432

Organism	Exposure	Protocol	Significant Effects and Comments	Reference
Non-arthropods				
Invertebrates	A waiver request was submitted citing lack of adverse effects reported in the published literature to non-target insects and honey bees and that the MPCA has no known relationship to animal pathogens. WAIVER ACCEPTED			1781432
Vascular Plants				
Dicotyledonous plants	Inoculations of leaf surfaces of Tomato (*Solanum lycopersicum*), Geranium (*Pelargonium hortorum*) and Tobacco (*Nicotiana bentamiana*)	5 mm plug of MPCA from growing margins of the water agar culture placed on the leaf segment with mycelial side down and incubated at 25°C and another set at 4°C for 8 days.	No treatment related effects reported from the exposure of Dicotyledonous plants to the mycelial plug of the MPCA. Toxicity end points such as mortality, seedling emergence, growth inhibition, vegetative vigour were not reported. The concentration of the MPCA used in the study was not provided in the report. **Supplemental Study**	1852359
Monocotyledonus plants	Inoculum plug of MPCA on surface of cut wheat (*Tricum aestivum*) and rice (*Oryzae sativa*) leaves.	5 mm plug of MPCA grown on water agar was placed on a leaf segment mycelial side down and incubated at 25°C and another set at 4°C for 7days.	No treatment related effects reported from the exposure of Monocotyledonous plants to the mycelial plug of the MPCA. End points such as mortality, seedling emergence, growth inhibition, vegetative vigour were not reported. The concentration of the MPCA used in the study was not provided in the report. **Supplemental Study**	1852359
Aquatic Organisms				
Vertebrates				
Freshwater fish	A waiver request was submitted citing that the use pattern would result in negligible exposure to aquatic environments and an absence of adverse effects to freshwater fish reported in the published literature. WAIVER ACCEPTED			1781432
Estuarine and marine fishes	A waiver request was submitted citing that the use pattern would result in negligible exposure to aquatic environments and an absence of adverse effects to estuarine and marine fishes reported in the published literature. WAIVER ACCEPTED			1781432
Invertebrates				
Arthropod and non-arthropod invertebrates	A waiver request was submitted citing that the use pattern would result in negligible exposure to aquatic environments and an absence of adverse effects to aquatic invertebrates reported in the published literature. WAIVER ACCEPTED			1781432

Organism	Exposure	Protocol	Significant Effects and Comments	Reference
Aquatic Plants				
Vascular plants	A waiver request was submitted citing that the use pattern would result in negligible exposure to aquatic environments and the lack of adverse effects in pathogenicity testing of terrestrial plants. WAIVER ACCEPTED			1781432

Table 3 Alternative active ingredients registered for control/suppression of claimed diseases on the Nivalis accepted label.

Active ingredient	End-Use Product	Fungicide Classification	
		Group	Mode of Action
Azoxystrobin	Heritage, Heritage Maxx	11	Respiration
Azoxystrobin + propiconazole	Headway	11, 3	Respiration, C14-demethylation
Chlorothalonil	Daconil 2787 Flowable, Daconil Ultrex	M	Multisite
Chlorothalonil + propiconazole + fludioxonil	Instrata	M, 3, 12	Multisite, C14-demethylation, signal transduction
Iprodione	Rovral, Rovral Green GT, Proturf, Rovral G Granular, Quali-Pro Iprodione 240 SE	2	Signal transduction
Propiconazole	Banner Maxx, Qualipro Propiconazole 14.3ME	3	C14-demethylation
Thiram + carbathiin + oxycarboxin	Arrest-75W	M, 7	Multisite, respiration
Trifloxystrobin	Compass 50WG	11	Respiration
Thiophanate-methyl	Senator 75WP 1, Senator 70WP, Senator 70WP WSB	1	Mitosis and cell division
Triticonazole	Chipco Triton	3	C14-demethylation

Table 4 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed claim	Accepted claim
For control of gray and pink snow mould on turf **Method of Application:** Apply by mechanical granular fertilizer spreader at the rate of 10 kg/100 m^2 of inoculated German millet seed for golf course fairways and 50 kg/100 m^2 for golf course greens and tees. Do not use water or equipment contaminated with chemicals likely to be harmful to the active ingredient fungus in this product. **Application Timing:** NIVALIS should be applied after the last mowing and before snowfall. Do not apply within 2 weeks of fungicide applications.	As proposed with indication of suppression, rather than control on the label.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
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1770480	Hsiang, T., N. Matsumoto and S. Millet, 1999, Biology and Management of Typhula Snow Moulds of Turfgrass, Plant Disease 83(9):788-798. DACO: 11.1
1770503	Tier III - Overall Summary and Assessment (MPCA) - Document N for the MPCP & MPCA, DACO: 12.7, Document N
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1770546 Test and Study Reports (MPCA) - Snow mold disease control on creeping bentgrass using Typhula phacorrhiza at the Guelph Turfgrass Institute November 2008 – April 2009 (Bridging Data), DACO: 11.1

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1775223 2009, Product Chemistry for Nivalis Technical, DACO: 2.14.1, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.6, 3.5.1, 3.5.10, 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9 CBI

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