



Health Canada
Santé Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Registration Decision

PRD2010-22

Mineral Oil

(publié aussi en français)

9 September 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada 

HC Pub: 100470

ISBN: 978-1-100-15071-0 (978-1-100-15073-4)

Catalogue number: H113-9/2010-22E (H113-9/2010-22E-PDF)

© **Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2010**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Overview.....	1
Proposed Registration Decision for Mineral Oil.....	1
What Does Health Canada Consider When Making a Registration Decision?.....	1
What Is Compound Mineral Oil?	2
Health Considerations	2
Environmental Considerations	3
Value Considerations.....	4
Measures to Minimize Risk.....	4
Next Steps.....	5
Other Information	5
Science Evaluation.....	7
1.0 The Active Ingredient, Its Properties and Uses	7
1.1 Identity of the Active Ingredient.....	7
1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product.....	7
1.3 Directions for Use.....	9
1.4 Mode of Action.....	9
2.0 Methods of Analysis	10
2.1 Methods for Analysis of the Active Ingredient	10
2.2 Method for Formulation Analysis.....	10
2.3 Methods for Residue Analysis.....	10
3.0 Impact on Human and Animal Health	10
3.1 Toxicology Summary.....	10
3.2 Occupational/Bystander Exposure and Risk Assessment.....	10
3.3 Dietary and Drinking Water Assessment.....	11
4.0 Impact on the Environment.....	11
4.1 Fate and Behaviour in the Environment	11
4.2 Environmental Risk Characterization.....	11
4.2.1 Risks to Terrestrial Organisms	12
4.2.2 Risks to Aquatic Organisms	12
4.2.3 Incident Reports.....	13
5.0 Value.....	13
5.1 Effectiveness Against Pests	13
5.2 Economics.....	14
5.3 Sustainability	14
5.3.1 Survey of Alternatives	14
5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management.....	14
5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance	15
5.3.4 Contribution to Risk Reduction and Sustainability	15
6.0 Pest Control Product Policy Considerations.....	15
6.1 Toxic Substances Management Policy Considerations	15
6.2 Formulants and Contaminants of Health or Environmental Concern.....	16

7.0	Summary	16
7.1	Human Health and Safety	16
7.2	Environmental Risk	17
7.3	Value	17
8.0	Regulatory Decision	17
	List of Abbreviations	19
Appendix I	Tables and Figures	21
Table 1	Alternative Fungicides registered to control the Proposed Diseases on Golf Course Turf	21
Table 2	Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported	22
Appendix II	Inputs to Buffer Zones Models	23
References	25

Overview

Proposed Registration Decision for Mineral Oil

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 Spray Oil 10 Technical and Civitas Fungicide for Golf Course Turf, containing the technical grade active ingredient mineral oil, to control dollar spot and suppress spring leaf spot and pink and grey snow mould on golf courses, including fairways, greens, roughs and tees.

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.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

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 Spray Oil 10 Technical and Civitas Fungicide for Golf Course Turf.

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 acceptable¹ 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 value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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 (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on mineral oil, the PMRA will consider all comments received from the public in response to this consultation document.³ The PMRA will then publish a Registration Decision⁴ on mineral oil, 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 Compound Mineral Oil?

Mineral oil is a non-conventional pesticide product currently registered to control insect pests on various crops. The oil acts as a physical barrier to pathogens.

Health Considerations

Can Approved Uses of Mineral Oil Affect Human Health?

Mineral Oil is unlikely to affect your health when used according to label directions.

Exposure to mineral oil may occur when handling and applying the end-use product, Civitas Fungicide for Golf Course Turf. When assessing health risks, two key factors are considered: the levels where 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 (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, mineral oil, is of low acute toxicity by the oral, inhalation and dermal routes. Aliphatic solvents, such as mineral oil, are also considered to be mild eye and skin irritants, and non-sensitizing.

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.

The use for Civitas Fungicide for Golf Course Turf is as a fungicide to be applied to turf, which therefore should not result in additional exposure to sources of food or drinking water beyond currently registered food uses. Therefore, this use of mineral oil is not expected to result in dietary risk from consuming food or drinking water.

Occupational Risks From Handling Mineral Oil

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

There is potential for dermal and inhalation exposure to mineral oil when handling and applying Civitas Fungicide for Golf Course Turf. However, due to the low toxicity of mineral oil and the exposure mitigation measures on the label, there is no concern regarding occupational exposure to Civitas Fungicide for Golf Course Turf.

Environmental Considerations

What Happens When Mineral Oil Is Introduced Into the Environment?

Environmental risks to non-target organisms are not of concern when Mineral Oil and the end-use product, Civitas Fungicide for Golf Course Turf, are used on golf course turf according to label directions, which include precautionary label statements and buffer zones.

White Mineral Oil (CAS# 8042-47-5) is currently introduced into the environment when used as an agricultural insecticide (rutabaga, pome and stone fruits, prunes, Saskatoon berries, and Highbush blueberries) and on ornamentals. The use of Civitas Fungicide for Golf Course Turf will be a major new use as a fungicide on golf course turf (USC 30).

Mineral oil is eligible for review as a non-conventional product given the characteristics that it has low inherent toxicity to most non-target organisms; it is widely available to the public for other uses and has a long history of equivalent exposure to humans and the environment with minimal toxicity; it has a non-toxic mode of action; and it is unlikely to cause pest resistance. Therefore, only Tier 1 (acute toxicity) data are considered for the risk assessment initially.

Non-target species (for example, birds, mammals, plants, honeybees, fish, oysters, and daphnia) could be exposed to mineral oil in the environment from direct exposure of the pesticide during spraying, or from spray drift or runoff to surface water.

Mineral oil may pose a risk to some aquatic organisms. Precautionary label statements are being required on the label and buffer zones are required to mitigate exposure of sensitive aquatic habitats from spray drift.

Value Considerations

What Is the Value of Civitas Fungicide for Golf Course Turf?

Civitas Fungicide for Golf Course Turf is a reduced risk non-conventional fungicide that suppresses diseases on golf course turf.

There is an increasing demand for non-conventional pesticides for turf use due to pesticide bans implemented in Canada at the provincial and municipal levels. Civitas Fungicide for Golf Course Turf is a reduced risk product that is compatible with conventional pesticides and cultural methods employed to combat disease.

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 Civitas Fungicide for Golf Course Turf to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements “Keep out of reach of unauthorized personnel”, “May be harmful if swallowed or inhaled”, “Avoid contact with eyes, skin and clothing”, “Use with adequate ventilation”, and “Wash thoroughly after using” have been included in the Precautions section of the secondary display panel of the label for Civitas Fungicide for Golf Course Turf. Furthermore, the product label instructs applicators to wear chemical resistant gloves and long protective clothing during mixing, loading, application, clean-up and repair.

Additionally, the product label instructs applicators to apply only when the potential for drift to areas of human habitation or areas of human activity, such as houses, cottages, schools, and recreational areas, is minimal, and to take into consideration wind speed, wind direction, temperature, application equipment, and spray settings before applying.

Environment

Precautionary label statements are required on the label to mitigate potential runoff to aquatic systems.

To protect non-target aquatic organisms, precautionary label statements are required on the label, and Civitas Fungicide for Golf Course Turf cannot be sprayed within 1 to 5 metres of sensitive aquatic habitats. The distance required depends on the method of application and the depth of the water in the aquatic habitat.

Next Steps

Before making a final registration decision on mineral oil, 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 mineral oil (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

Mineral Oil

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Mineral Oil
Function	Insecticide, fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	White Mineral Oil
2. Chemical Abstracts Service (CAS)	White Mineral Oil
CAS number	8042-47-5, 8012-95-1, 72623-84-8
Molecular formula	C ₂₁ H ₄₄
Molecular weight	Average 296
Structural formula	Complex mixture of linear, branched and cycloparaffins with an average carbon number of C21
Purity of the active ingredient	100%

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

Technical Product—Mineral Oil Technical

Property	Result
Colour and physical state	Colourless (ASTM D 156-00, '+25') liquid
Odour	Neutral, no discernable odour
Melting range	N/A the product is a liquid
Boiling point or range	301°C–491.87°C

Property	Result						
Density	0.846 kg/L at 15°C						
Vapour pressure at 20°C	5.7×10^{-3} Pa						
Ultraviolet (UV)-visible spectrum	$\lambda_{\text{max}} = 210$ nm						
Solubility in water at 20°C	3 ± 1 mg/L						
Solubility in organic solvents at 20°C (g/100 mL)	<table border="0"> <tr> <td><u>Solvent</u></td> <td><u>Solubility</u></td> </tr> <tr> <td>coconut fat</td> <td>infinitely soluble</td> </tr> <tr> <td><i>n</i>-octanol</td> <td>infinitely soluble</td> </tr> </table>	<u>Solvent</u>	<u>Solubility</u>	coconut fat	infinitely soluble	<i>n</i> -octanol	infinitely soluble
<u>Solvent</u>	<u>Solubility</u>						
coconut fat	infinitely soluble						
<i>n</i> -octanol	infinitely soluble						
<i>n</i> -Octanol–water partition coefficient (K_{ow})	Could not be determined because of solubility issues.						
Dissociation constant ($\text{p}K_{\text{a}}$)	N/A						
Stability (temperature, metal)	No reaction when sample was tested against zinc powder. Formed distinct layers when mixed with monoammonium phosphate (MAP), commercial bleach and tap water.						

End-Use Product—Mineral Oil in Civitas Fungicide for Golf Course Turf

Property	Result
Colour	Colourless
Odour	Odourless
Physical state	Liquid at 20°C
Formulation type	Liquid
Guarantee	98 % Mineral Oil
Container material and description	HDPE jugs, bottles, totes 1 L to 1000 L.
Density	0.852 g/mL 0.83–0.88 kg/L
pH of 1% dispersion in water	4.95–5.04 for a 1 % solution in water
Oxidizing or reducing action	Not an oxidizing or reducing agent
Storage stability	Stable for 1 year at ambient temperature

Property	Result
Corrosion characteristics	<p>The following test materials were placed in contact with the proposed EP product for 28 days at 30°C. The results indicated that the test materials sorbed some of the end-use product during the test period. The mass change was most significant for high-density polyethylene.</p> <p>Aluminum: + 0.0196 mils/yr Carbon steel: + 0.1112 mils/yr Stainless steel: + 0.0166 mils/yr HDPE: + 4.0390 mils/yr</p> <p>A mil is 1/1000th of an inch.</p> <p>The sorption of the EP into HDPE would be about 0.1 mm per year.</p>
Explosibility	No explosive components

1.3 Directions for Use

Civitas Fungicide for Golf Course Turf should be applied as a preventative treatment or when conditions are favourable for disease development. The product must be used in conjunction with a dye as specified on the Civitas Fungicide label, to indicate the spray pattern on turf.

To control dollar spot on golf courses including fairways, greens, roughs and tees, apply Civitas Fungicide for Golf Course Turf to turf at a rate of 250–500 mL/100 m² on a 14 day interval.

Civitas Fungicide for Golf Course Turf may reduce symptoms of pink snow mould (*Microdochium nivale*) and grey snow mould (*Typhula ishikariensis*, *T. incarnata*) on golf courses including fairways, greens, roughs and tees. Apply a single application of Civitas Fungicide for Golf Course Turf to turf at a rate of 660–930 mL/100 m² OR apply two or more applications at a rate of 330–460 mL/100 m² on a 14-day interval prior to the development of permanent snow cover.

To suppress spring leaf spot (*Drechslera poae*) on golf courses including fairways, greens, roughs and tees, apply Civitas Fungicide for Golf Course Turf to turf at a rate of 250-500 mL/100 m² on a 14-day interval.

1.4 Mode of Action

Mineral oil appears to act as a physical barrier that can prevent spores from germinating or penetrating plant cells.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Spray Oil 10 Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Quantitative determination of the various hydrocarbons comprising mineral oil is performed with a high resolution mass spectrometer.

3.0 Impact on Human and Animal Health

Mineral oil, as a technical grade active ingredient, is currently registered as an insecticide, acaricide and fungicide for use on terrestrial food crops (USC 13 and 14) and outdoor ornamentals (USC 27). It is also approved as a formulant as paraffin oils (CAS No. 8012-95-1) and is on PMRA's Formulant List 3. The proposed use pattern of Civitas Fungicide for Golf Course Turf on turf (USC 30) is considered a major new use for Mineral oil.

3.1 Toxicology Summary

The PMRA recently completed a re-evaluation of the registered uses for mineral oil, as summarized in Proposed Re-evaluation Decision (PRVD2008-19), *Mineral Oil* and Re-evaluation Decision (RVD2008-32), *Mineral Oil*. The PMRA's re-evaluation of mineral oil relied mainly on test data summaries in the US Environmental Protection Agency's Interim Reregistration Eligibility Decision Document for Aliphatic Solvents and the Revised Reregistration Eligibility Decision for Aliphatic Solvents.

Mineral oil is of low acute toxicity by the oral, inhalation and dermal routes. Aliphatic solvents are also considered to be mild eye and skin irritants, and non-sensitizing. The end-use product, Civitas Fungicide for Golf Course Turf, contains no formulants of toxicological concern.

3.2 Occupational/Bystander Exposure and Risk Assessment

There is potential for dermal and inhalation exposure to the end-use product in occupational scenarios, including mixing, loading, and application. However, due to the low toxicity of mineral oil and the exposure mitigation measures on the label, there is no concern regarding occupational exposure to Civitas Fungicide for Golf Course Turf.

Precautions on the label include directions to avoid contact with eyes, skin and clothing, and to minimize breathing mists or vapour. Personal protective equipment (PPE) required on the label include long sleeved shirt, long pants, chemical-resistant gloves, and shoes plus socks. Directions on the label specify that this PPE is to be worn during mixing, loading, application and during clean-up and repair activities.

Contrary to RVD2008-32, which requires a restricted-entry interval (REI) of 12 hours for all commercial and domestic end-use products in Canada containing mineral oil, no REI is required on the label of Civitas Fungicide for Golf Course Turf, as the EP contains no formulants of toxicological concern.

3.3 Dietary and Drinking Water Assessment

The use of Civitas Fungicide for Golf Course Turf is not expected to result in additional exposure to mineral oil from sources of food or drinking water beyond currently registered food uses. Therefore, this use of mineral oil is not expected to result in dietary risk from consuming food or drinking water.

4.0 Impact on the Environment

A detailed assessment of the environmental impact of mineral oil is presented in the re-evaluation document PRVD2008-19, *Mineral Oil*.

4.1 Fate and Behaviour in the Environment

A detailed assessment of the fate and behaviour of mineral oil are presented in PRVD2008-19, *Mineral Oil*.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity, as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value ($RQ = \text{exposure}/\text{toxicity}$), and the risk quotient is then compared to the level of concern ($LOC = 1$). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

A tiered approach is used for non-conventional data requirements. Tier I data address the acute toxicity of a compound. The use of Civitas Fungicide for Golf Course Turf on golf course turf has greater application rates and frequency of application than the registered uses as an insecticide on agricultural crops. As a result, a risk assessment was performed to identify potential risks to terrestrial and aquatic organisms.

4.2.1 Risks to Terrestrial Organisms

Limited toxicity data on terrestrial organisms are available for mineral oils, as demonstrated in the re-evaluation document PRVD2008-19, *Mineral Oil*.

For birds and mammals, no acute oral toxicity was observed at the tested doses. Also, the non-toxic mode of action of mineral oils suggests that ingestion of mineral oil will not pose a risk to birds feeding on treated turf. Mineral oil can cause suffocation of viable embryos, if birds' eggs are exposed at an appropriate level. However, based on the proposed use pattern on golf course turf, the risk of exposure of bird eggs to a direct application of the oil is negligible.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms can be exposed to mineral oil as a result of spray drift and over-land runoff to surface water.

Data were insufficient to conduct a quantitative assessment for runoff. However, available information on the chemical behaviour of mineral oils suggests a low potential for mineral oil to be transported in water runoff. Thus, no further assessment was conducted. But mitigative label statements for runoff were required for the product label Civitas Fungicide for Golf Course Turf, as these standard label statements are required for all registered end-use products.

To evaluate the potential exposure of non-target organisms to spray drift, the EEC used for the screening level assumes exposure to the maximum application rate in a water body. A refined EEC was calculated for ground application using a value for maximum spray drift deposition as a percent of the cumulative rate at one metre downwind from the site of application. For ground application by boom sprayers on turf, the spray droplet size category ASAE medium is used; the maximum percent drift deposition for field boom sprayers with a medium droplet spray quality is 6% of the application rate. Potential risk from spray drift was still identified for these aquatic organisms after this refinement. Thus, mitigative label statements and buffer zones are needed to protect sensitive aquatic habitats from spray drift.

4.2.3 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website at www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

As of June 1, 2010, the PMRA is aware of a single Canadian incident report related to adverse effects on possible intoxication of a domestic cat with an insecticidal end-use product containing mineral oil. Intoxication signs were vomiting and diarrhea.

No incidents are reported in the USEPA Ecological Incident Information System for Mineral oils.

5.0 Value

5.1 Effectiveness Against Pests

Four trials were reviewed to support the claim of control of dollar spot; two were considered as supplementary data. Application of Civitas Fungicide for Golf Course Turf on a 14 day schedule indicated a level of control that ranges from high suppression to control regardless of the rate applied. Although efficacy was not ideal in all trials, the weight of evidence indicated that Civitas Fungicide for Golf Course Turf will control dollar spot under moderate to high disease pressure. Tank mixes with Daconil 2787 Flowable Fungicide and Banner MAXX Fungicide resulted in good efficacy with no phytotoxicity. Based on the reviewed data, the claim of control of dollar spot could be supported at the proposed rate on a 14 day interval.

One trial conducted in Canada during the winter of 2007 to 2008 was reviewed to support the claims of control of pink and grey snow moulds. Two additional trials were reviewed as supplementary data. Two applications of Civitas Fungicide for Golf Course Turf applied on a 14-day schedule resulted in partial suppression under high disease pressure when applied at a rate higher than proposed. A tank-mix with a half rate of Banner MAXX Fungicide resulted in good control and no phytotoxicity. Supplemental trials indicated that Civitas Fungicide for Golf Course Turf reduced snow mould symptoms ranging from partial suppression to full control. Based on the reviewed evidence, the claim that Civitas Fungicide for Golf Course Turf may reduce symptoms of pink and grey snow moulds with two or more applications at the proposed rate using a 14-day interval could be supported. Additional trials must be submitted to confirm the level of control.

Two trials conducted on spring leaf spot in the US were submitted and reviewed. The submitted trials resulted in partial suppression to suppression of spring leaf spot and melting out when Civitas Fungicide for Golf Course Turf was applied at rates much lower than those proposed on a 14 day schedule. The tank-mix with Daconil 2787 Flowable Fungicide did not improve efficacy; no phytotoxicity occurred as a result of the tank-mix. Based on the reviewed evidence, the claim of suppression of spring leaf spot is supported at the proposed rates and timings. Additional trial must be submitted to confirm efficacy on turfgrasses grown on golf courses.

Trials included tank mixes with Daconil 2787 and Banner MAXX Fungicide. Results showed improved or equivalent efficacy and no phytotoxicity occurred as a result of the tank mixes.

5.2 Economics

No market analysis was done for this submission.

5.3 Sustainability

5.3.1 Survey of Alternatives

The chemical fungicides listed in Table 1 are registered for control or suppression of diseases on turf recommended on the Civitas Fungicide for Golf Course Turf label.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Civitas Fungicide for Golf Course Turf represents a different mode of action that can be used to manage turf diseases, which will contribute to pest resistance management. This product has been shown to be compatible with conventional fungicides for alternation in a spray program. As a non-conventional pesticide, Civitas Fungicide for Golf Course Turf can be considered a component of an IPM strategy for the management of turf diseases.

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

Civitas Fungicide for Golf Course Turf is a reduced risk non-conventional fungicide. The possibility of the development of pest resistance to the active ingredient, mineral oil, is low.

5.3.4 Contribution to Risk Reduction and Sustainability

Pesticide bans implemented by provinces and municipalities often exclude golf courses, but Quebec, for example, has implemented a pesticide reduction plan for the industry and is promoting the use of non-conventional pest control products. In addition, several fungicide active ingredients registered for turf diseases are under re-evaluation. Civitas Fungicide for Golf Course Turf provides another mode of action that may be used to manage certain turf diseases.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, Technical grade Mineral Oil and the end-use product, Civitas Fungicide for Golf Course Turf, were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. Based on an assessment of the complete data package, the PMRA has reached the conclusion that these products do not meet TSMP Track 1 criteria. Refer to PRVD2008-19, *Mineral Oil* for more details.

⁵ DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use product are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.⁶ The list is used as described in the PMRA Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations including: DIR99-03; and DIR2006-02⁸, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the conclusion that Technical grade Mineral Oil and the end-use product, Civitas Fungicide for Golf Course Turf, do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.⁹

7.0 Summary

7.1 Human Health and Safety

The available toxicological information and reviews on mineral oil are sufficient to identify potential risks resulting from exposure to the active ingredient. Mineral oil is of low acute toxicity by the oral, inhalation and dermal routes. Aliphatic solvents, such as mineral oil, are also considered to be mild eye and skin irritants, and non-sensitizing. The end-use product, Civitas Fungicide for Golf Course Turf, contains no formulants of toxicological concern.

Occupational exposure via dermal or inhalation routes are not of concern due to the low toxicity of mineral oil, and when the product label precautionary statements are observed.

⁶ *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

⁷ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

⁸ DIR2006-02, PMRA Formulants Policy.

⁹ DIR2006-02, PMRA Formulants Policy.

7.2 Environmental Risk

Mineral oil could be introduced into the environment when used as a fungicide on golf course turf. Mineral oil will pose a negligible risk to terrestrial organisms. Risk was identified for aquatic organisms at the proposed rates of Civitas Fungicide for Golf Course Turf. Therefore, mitigative label statements and buffer zones are required on the label of the end-use product, Civitas Fungicide for Golf Course Turf, for the protection of non-target aquatic organisms.

7.3 Value

The data submitted to register Civitas Fungicide for Golf Course Turf are adequate to demonstrate efficacy for use on golf course turf in controlling, suppressing or reducing symptoms of the proposed diseases.

8.0 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 Spray Oil 10 Technical and Civitas Fungicide for Golf Course Turf, containing the technical grade active ingredient mineral oil, to control dollar spot and suppress spring leaf spot and pink and grey snow mould on golf courses, including fairways, greens, roughs and tees.

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

λ	wavelength
a.i.	active ingredient
ASAE	American Society of Agricultural Engineers
C	Celsius
CAS	Chemical Abstracts Service
EC ₅₀	effective concentration on 50% of the population
EEC	estimated environmental exposure concentration
EP	end-use product
FTIR	fourier transform infrared
g	gram
ha	hectare(s)
HDPE	high density polyethylene
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	<i>n</i> -octanol-water partition coefficient
L	litre
LOC	level of concern
m	metre(s)
MAP	monoammonium-phosphate
mg	milligram
mL	millilitre
mm	millimetre(s)
N/A	not applicable
nm	nanometre(s)
PAH	polynuclear aromatic hydrocarbons
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
REI	restricted-entry interval
RQ	risk quotient
TSMP	Toxic Substances Management Policy
US	United States
USC	use-site category
USEPA	United States Environmental Protection Agency
UV	ultraviolet
yr	year

Appendix I Tables and Figures

Table 1 Alternative Fungicides registered to control the Proposed Diseases on Golf Course Turf

Disease and Pest	Active Ingredient	Resistance Management Group
Dollar Spot (<i>Sclerotinia homeocarpa</i>)	Thiophanate-methyl	1
	Iprodione	2
	Propiconazole	3
	Triticonazole	3
	Myclobutanil	3
	Boscalid	7
	Pyraclostrobin	11
	Chlorothalonil	M
	<i>Bacillus subtilis</i> Q713	N/A
Leaf Spot (<i>Drechslera poae</i>)	Iprodione	2
	Propiconazole	3
	Azoxystrobin	11
	Pyraclostrobin	11
	Trifloxystrobin	11
	Captan	M
	Chlorothalonil	M
Pink Snow Mould (<i>Microdochium nivale</i>)	Thiophanate-methyl	1
	Iprodione	2
	Propiconazole	3
	Triticonazole	3
	Azoxystrobin	11
	Pyraclostrobin	11
	Fludioxonil	12
	Quintozene	14
	Chlorothalonil	M
Grey Snow Mould (<i>Typhula incarnata</i> , <i>T. ishikariensis</i>)	Iprodione	2
	Propiconazole	3
	Triticonazole	3
	Myclobutanil	3
	Pyraclostrobin	11
	Fludioxonil	12
	Quintozene	14
	Chlorothalonil	M

Table 2 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Use Claim	Supported/Not Supported
<p>Dollar Spot</p> <p>Use pattern: Apply Civitas Fungicide for Golf Course Turf to turf at a rate of 250–500 mL/100 m² to turf on a 14- to 21-day interval.</p>	<p>The claim is supported at the proposed rates applied on a 14-day interval.</p>
<p>Pink and Grey Snow Moulds</p> <p>Use pattern: Apply a single application Civitas Fungicide for Golf Course Turf to turf at a rate of 660–930 mL/100 m² prior to development of snow cover. Two or more applications may be applied at a rate of 330–460 mL/100 m² on a 14-day interval.</p>	<p>The claim is conditionally supported as “may reduce symptoms of pink and grey snow moulds” at the proposed rates. Additional data are required.</p>
<p>Spring leaf spot</p> <p>Use pattern: Apply Civitas Fungicide for Golf Course Turf to turf at a rate of 250–500 mL/100 m² on a 14- to 28-day interval.</p>	<p>The claim is conditionally supported as suppression at the proposed rates on a 14-day interval. Additional data are required.</p>

Appendix II Inputs to Buffer Zones Models

Ground Use Data (from proposed label)					
Crop	Formulation Type	Method of Application	Number of Applications	Maximum Application Rate (g a.i./ha)	Application Interval (days)
Golf course turf (fairways, greens, roughs, tees)	Solution (guarantee: 98%)	Ground	Max of 14	41 650	14 to 28

Model Input Data for Terrestrial and Aquatic Buffer Zones (from PRVD2008-19, Mineral Oil)		
Half life for aquatic buffer zones	stable	99999999 days
Most sensitive fish endpoint for amphibian risk assessment	n/a (no effects were observed in fish species)	
Most sensitive freshwater species	<i>Daphnia magna</i>	½ EC ₅₀ 0.45 mg a.i./L
Most sensitive estuarine/marine species	Oyster	½ EC ₅₀ 3.0 mg a.i./L

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1660933	2008, DACO 3 Chemistry Requirements for the Registration of a Manufacturing Concentrate and End-Use Product Formulated from A Registered Technical Grade of Active Ingredient or Integrated System Product-
1660934	2008, DACO 3.1.1-3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
1660935	2008, FORMULATION PROCESS, DACOS 3.2.1-3.2.3 ESTABLISHING CERTIFIED LIMITS, DACO 3.3.1, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
1730219	2001, Quantitative Determination of Hydrocarbon Types in Petroleum Distillates Product Chemistry for [CBI REMOVED], DACO: 3.4.1 CBI
1730220	2000, [CBI REMOVED] Chemical and Physical Properties, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
1730221	2009, [CBI REMOVED] APPLICATION FOR THE REGISTRATION OF A NEW PRODUCT, DACO: 3.5.13,3.5.15,3.5.4,3.5.5
1786967	2001, [CBI REMOVED]: Chemical and Physical Properties, DACO: 3.5.10
1786968	2009, Comparison of specs [CBI REMOVED], DACO: 3.5.10

2.0 Human and Animal Health

PMRAMRA Document Number	Reference
1758926	Statement of Product Specification Form, Spray Oil 10 Technical. DACO 0.1.6003.
1660914	Statement of Product Specification Form, Civitas Fungicide for Golf Course Turf and Ornamentals. DACO 0.1.6003.

3.0 Value

PMRA Document Number	Reference
1660922	2008, Summary, DACO: 10.1
1660924	2007, Chemical Trials For Dollar Spot Disease Control, Summer 2007c, DACO: 10.2.3.3(D),10.3.2(B)
1660925	2007, Chemical Trials For Dollar Spot Disease Control, Summer 2007b, DACO: 10.2.3.3(D),10.3.2(B)
1660926	2007, Snow Mold Disease Control on Creeping Bentgrass, DACO: 10.2.3.3(D),10.3.2(B)

1660927	2006, Chemical Trials for Dollar Spot Disease Control, DACO: 10.2.3.3(D),10.3.2(B)
1660928	2005, Snow Mold Disease Control on Creeping Bentgrass, DACO: 10.2.3.3(D),10.3.2(B)
1660929	2004, Chemical Trials for Dollar Spot Disease Control, DACO: 10.2.3.3(D),10.3.2(B)
1660930	2007, Evaluation of PC Turf Product 657 for turf safety of Tifdwarf Bermudagrass, 2007 and Evaluation of fungicides for control of Fairy Ring on Tifdwarf Bermudagrass, 2007., DACO: 10.2.3.3(D),10.3.2(B)
1660931	2008, Snow Mold Disease Control On Creeping Bentgrass: Petrocan Report November 2007 - May 2008, DACO: 10.2.3.3(D),10.3.2(B)
1660932	2008, Chemical Control of Spring leaf spot/Melting-out Disease of Kentucky Bluegrass, DACO: 10.2.3.3(D),10.3.2(B)
1788533	2008, Management of Spring Leaf Spot/Melting out in Kentucky Bluegrass with Civitas and its tank-mix with fungicide, DACO: 10.2.3.3(D)
1834689	E-mail Correspondence: M. Celetti to J. Chaput, OMAFRA, 2009-11-24

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

PMRA Document Number	Reference
1913005	Interim Reregistration Eligibility Decision (IRED) Document for Aliphatic Solvents (Mineral Oil and Aliphatic Petroleum Hydrocarbons). U.S. EPA, 12 July 2006.
1913010	Revised Reregistration Eligibility Decision for Aliphatic Solvents. U.S. EPA, 29 November 2007.
1923217	PRVD2008-19 Proposed Re-evaluation Decision: Mineral Oil, 29 May 2008.
1923276	RVD2008-32 Re-evaluation Decision: Mineral Oil, 20 August 2008.

2.0 Environment

PMRA Document Number	Reference
1602227	Re-evaluation Consultation Statement - PACR Publish English (PRVD2008-19), DACO: PACR_PDF_E
1634142	Re-evaluation Decision Statement - RRD Publish English (RVD2008-32), DACO: RRD_PDF_E

-
- 1621524 US EPA, 2006, Memorandum Describing the Environmental Fate and Effect Division's Ecological Risk Assessment on Aliphatic Oils (PC Codes 063502 and 063503) in Support of Reregistration Eligibility Decision, DACO: 12.5
- 1913005 US EPA, 2006, Reregistration Eligibility Decision Exposure and Risk Assessment on Lower Risk Pesticide Chemicals Interim Reregistration Eligibility Decision (IRED) Document for Aliphatic Solvents (Mineral Oil and Aliphatic Petroleum Hydrocarbons) CASE: Aliphatic Solvents (3004) Active Ingredients: Mineral Oils (063502) & Aliphatic Petroleum Hydrocarbons (063503), DACO: 12.5
- 1913010 US EPA, 2007, US Environmental Protection Agency Office of Pesticide Programs Revised Reregistration Eligibility Decision for Aliphatic Solvents Exposure and Risk Assessment on Lower Risk Pesticide Chemicals CASE: Aliphatic Solvents (3004) Active Ingredients: Mineral Oil (063502) & Aliphatic Petroleum Hydrocarbons (063503) , DACO: 12.5

ii) Unpublished Information

4.0 Environment

**PMRA
Document
Number Reference**

- 1836300 7003- INCIDENT REPORT, DACO: 0.1.7003