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Proposed Re-evaluation Decision

PRVD2022-03

***Chondrostereum purpureum* strain PFC2139 and Its Associated End-use Products**

Consultation Document

(publié aussi en français)

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Proposed re-evaluation decision

Under the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies to all re-evaluations.

Chondrostereum purpureum strain PFC2139 is a naturally-occurring biological herbicide registered for use in Canada for inhibiting resprouting and regrowth from cut stumps of certain deciduous trees in rights-of-way and for forest vegetation management. *Chondrostereum purpureum* strain PFC2139 is a native, fungus that is commonly distributed across Canada. The fungus is not host specific and has a wide host range with a preference for broad-leaved trees. Currently registered products containing *C. purpureum* strain PFC2139 can be found in Appendix I.

This document presents the proposed regulatory decision for the re-evaluation of *C. purpureum* strain PFC2139.

These products are shown to have value in providing a pest management solution. When the label directions are followed, potential risks to human health from occupational, dietary, and bystander exposure and to the environment are acceptable. Label directions, including risk mitigation measures to protect human health and the environment, must be followed by law. In order to meet current standards, label updates for products containing *C. purpureum* strain PFC2139 are proposed in Appendix II.

Under the authority of the *Pest Control Products Act*, and based on the evaluation of currently available scientific information, products containing *C. purpureum* strain PFC2139 listed in Appendix I are proposed for continued registration in Canada. All products containing *C. purpureum* strain PFC2139 registered in Canada are subject to this proposed re-evaluation decision.

This document is subject to a public consultation,¹ during which written comments and additional information may be submitted to [PMRA Publications](#). Before making a final re-evaluation decision on *C. purpureum* strain PFC2139, Health Canada will consider any written comments received in response to this consultation document.

Next steps

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

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

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

The relevant confidential test data on which the decision is based (as referenced in PRVD2022-03) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's [Pest Management Information Service](#) by phone (1-800-267-6315) or by e-mail (pmra-info-arla@hc-sc.gc.ca).

Additional scientific information

No additional data are required.

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

Science evaluation

1.0 Human health

1.1 Human exposure and risk

A toxicology review for *C. purpureum* strain PFC2139 (*C. purpureum* strain PFC2139) was previously conducted (PRD2007-03). Laboratory studies demonstrate that *C. purpureum* strain PFC2139 is of low acute toxicity and not pathogenic via the oral, pulmonary and dermal routes of exposure. It is slightly irritating to the skin and minimally irritating to the eye. No reports of adverse effects in mammals were noted in a recent literature search. No reproductive or developmental toxic effects are expected upon exposure to *C. purpureum* strain PFC2139. No adverse effects of *C. purpureum* strain PFC2139 to human health are expected.

Occupational workers can be exposed to the active ingredient during handling and application of the end-use products. The end-use products containing *C. purpureum* strain PFC2139 are formulated as a paste to be applied topically as a thin layer from a squeeze bottle or a backpack sprayer to freshly cut stumps during late summer to early fall at an average rate of 5 g/stump (approximately 5000 CFU/stump) depending on the stump diameter. Potential short-term dermal exposure to *C. purpureum* strain PFC2139 may occur when mixing and loading and applying the end-use products. For squeeze bottles, inhalation exposure is not anticipated as product is a paste. For backpack sprayers, large aperture spray nozzles (2-3 mm) are used, thus, inhalation exposure is not expected. Although toxicity is considered minimal from the current labelled use of the end-use products, the PMRA assumes that all microorganisms contain substances that can elicit positive hypersensitivity reactions, regardless of the outcome of sensitization testing. Current label warnings, restrictions and risk mitigation measures are adequate to protect occupational workers handling end-use products containing *C. purpureum* strain PFC2139. The occupational risks are acceptable when the precautionary statements on the labels are observed including the wearing of personal protective equipment consisting of a long-sleeved shirt, long pants, shoes plus socks and waterproof gloves when handling or applying the product and during all clean-up and repair activities.

Based on the formulation type and the use pattern, exposure to postapplication workers is not expected and re-entry restrictions are not required. The risk to postapplication is not considered of concern.

Potential bystander exposure is also expected to be low during application. However, the potential for bystander exposure may occur up to three years after application through the inhalation of spores that are released from fruiting bodies (mushrooms) on tree stumps treated with *C. purpureum* strain PFC2139. However, *C. purpureum* is abundant in the environment and the application of registered EPs containing *C. purpureum* strain PFC2139 is not expected to significantly increase environmental spore density beyond natural background levels produced by wild strains. Therefore, the risk to bystanders is considered acceptable.

There are no registered domestic class products containing *C. purpureum* strain PFC2139. Therefore, direct residential exposure is not expected.

The end-use products containing *C. purpureum* strain PFC2139 are not registered for use on food or feed crops and are not directly applied to water. Therefore, residues are not expected on food or in drinking water. Heavy rainfall might carry *C. purpureum* strain PFC2139 to water bodies but it is not expected to survive and multiply in aquatic environments. Municipal treatment of drinking water supplies would further reduce the possibility of *C. purpureum* strain PFC2139 occurring in drinking water. Therefore, the health risks from residues of *C. purpureum* strain PFC2139 on food and in drinking water are acceptable. No additional mitigation measures are proposed and the specification of a maximum residue limit (MRL) is not required for *C. purpureum* strain PFC2139.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). *Chondrostereum purpureum* strain PFC2139 is considered to be of low toxicity by the oral, pulmonary and dermal routes and the end-use products will not be applied to food crops or drinking water. Furthermore, non-occupational exposure will be low when the end-use products are used as directed on the label. Therefore, there is reasonable certainty that no harm will result from aggregate exposure of residues of *C. purpureum* strain PFC2139 from the uses of the end-use products.

1.2 Cumulative exposure and risk

The *Pest Control Products Act* requires that the PMRA considers the cumulative exposure to pesticides with a common mechanism of toxicity. In its assessment of common mechanism of toxicity, the PMRA considers both the taxonomy of microbial pest control agents (MPCAs) and the production of any potentially toxic metabolites. For the current re-evaluation, the PMRA has determined that *C. purpureum* strain PFC2139 does not share a common mechanism of toxicity with other registered MPCAs. Consequently, no cumulative effect from exposure with other related MPCAs is anticipated and a cumulative assessment is not required at this time.

2.0 Environmental assessment

Chondrostereum purpureum strain PFC2139 is a ubiquitous biological organism with a continuously distributed population across Canada. The extensive genetic diversity and out-crossing nature of *C. purpureum* isolates indicate that deployment of a single isolate across Canada will have a minimal impact on the resident population. Using the presence of fruiting bodies to estimate spore density, it was determined that the additional spore load, due to deployment of *C. purpureum* strain PFC2139, will be of the same order of magnitude, or less, than the natural spore load from resident populations of *C. purpureum*.

Chondrostereum purpureum presents a unique situation in which the target species in one situation (for example, rights-of-ways) are also the non-target plants of concern outside the treatment area. A critical review of environmental studies indicates that neither the spore load, nor the proximity to a spore source, determines whether non-target infection will occur. Instead,

the main determinant for infection is the presence of a recent wound. *Chondrostereum purpureum* is not considered a threat to hardwood trees in healthy forests but could contribute to the decline of severely stressed trees. However, the additional risk posed to susceptible injured trees, due to use of the end-use products, is acceptable as the additional spore load will not be significantly greater than the natural spore load.

Despite the natural prevalence of *C. purpureum* in the environment, a recent search of the literature has yielded no reports of adverse effects on birds, mammals, fish, arthropods, non-arthropod invertebrates and aquatic plants. The use of the end-use products will not expose non-target organisms to a significant increase of *C. purpureum* spores in aquatic or terrestrial environments. The risks to non-target organisms are acceptable and no additional mitigation measures are proposed.

Chondrostereum purpureum strain PFC2139 is a biological organism and is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. It is not considered Track 1 substances as per the Toxic Substances Management Policy.³

3.0 Value assessment

Chondrostereum purpureum strain PFC2139 is a biological herbicide. It has value in inhibiting the resprouting and regrowth from the cut stumps of multiple trees. Additionally, it provides a unique component in the integrated pest management system in forest.

4.0 Incident reports

As of 29 November 2021, no human, domestic animal, environment or packaging failure incidents involving *C. purpureum* strain PFC2139 have been reported to Health Canada.

³ Toxic Substances Management Policy.

Appendix I *Chondrostereum purpureum* strain PFC2139 pest control product information

Table 1 Registered products containing *Chondrostereum purpureum* strain PFC2139¹

Registration number	Class	Registrant	Product name	Formulation type	Guarantee
27822	Technical Grade Active Ingredient	Danstar Ferment AG	CP-PFC2139	Dust or powder	CPO 10^5 to 10^7 CFU/kg
29292	Technical Grade Active Ingredient	Danstar Ferment AG	PT-PFC2139	Wettable powder	CPO 1×10^7 to 5×10^8 CFU/kg
27823	Commercial	Danstar Ferment AG	Chontrol Paste	Paste	CPO 10^5 to 10^7 CFU/kg
29293	Commercial	Danstar Ferment AG	Lalcide Biofence	Paste	CPO 10^5 to 10^7 CFU/kg

CPO = *C. purpureum* strain PFC2139, CFU = colony-forming unit,

¹ As of 29 November 2021, excluding discontinued products or products with a submission for discontinuation.

Appendix II – Label amendments

To meet current standards, the following label amendments are proposed

For All products:

The **FIRST AID** section must be updated as per DIR2007-01.⁴

For all Technical Grade Active Ingredient products:

The following statement must appear on the principal panel:

“PREVENT ACCESS BY UNAUTHORIZED PERSONNEL”

The **DISPOSAL** statement must be updated to the following:

“DO NOT reuse this container for any purpose. For disposal, this empty container may be returned to the point of purchase (distributor/dealer).

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.”

For Commercial End-Use Products

1) Amend the **DIRECTIONS FOR USE** section to include a **USE RESTRICTIONS** subsection and the following:

“As this product is not registered for the control of pests in aquatic systems. DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wash water.”

2) Amend the **ENVIRONMENTAL PRECAUTIONS** section to include the following:

“To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil or clay. Avoid application when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body.”

3) Amend the **DISPOSAL** section to include the following:

“DO NOT reuse this container for any purpose. This is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

⁴ 2007, Regulatory Directive DIR2007-01, *First Aid Labelling Statements*.

1. Thoroughly empty the contents of the container. Follow provincial instruction for any required additional cleaning of the container prior to its disposal.
2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

References

Published Information

PMRA number	Reference
912023	2004, REG2004-09, Regulatory Note, <i>Chondrostereum purpureum</i> Strain PFC2139 Cp-PFC2139 (Technical Grade of Active Ingredient), Chontrol Paste (End-use Product)
1863941	2007, PRD2007-03, Proposed Registration Decision, <i>Chondrostereum Purpureum</i> strain PFC2139,
1469676	2007, RD2007-06, Registration Decision, <i>Chondrostereum purpureum</i> strain PFC2139,
2526676	2016, Evaluation Report for Category B, Subcategory 3.11, 3.4 Application
3145898	2020, Evaluation Report for Category B, Subcategory B.3.11 Application
	2004, EPA BIOPESTICIDES REGISTRATION ACTION DOCUMENT, <i>Chondrostereum purpureum</i> strain PFC 2139 (PC Code 081308),
	2019. EPA-HQ-OPP-2015-0051-0006. <i>Chondrostereum purpureum</i> isolate PFC 2139 Interim Registration Review Decision Case Number 6091