Re-evaluation Decision RVD2023-12

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

*Final Decision*

*(publié aussi en français)*

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# Re-evaluation decision for *Chondrostereum purpureum* strain PFC2139 and associated end use products

Under the authority of 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 health and environmental safety standards and continue to have value. The re-evaluation considers information from various sources such as data and information from pesticide manufacturers and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

*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 *Chondrostereum purpureum* strain PFC2139 can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2022-03, *Chondrostereum purpureum strain PFC2139 and Its Associated End-use Products*[1] containing the evaluation of *Chondrostereum purpureum* strain PFC2139 and proposed decision, underwent a 90-day consultation period ending on 20 June 2022. PRVD2022-03 proposed continued registration of *Chondrostereum purpureum* strain PFC2139 products in Canada, with the proposed updates to label directions and precautions to reflect the current labelling standards and improve clarity.

Health Canada received one comment relating to a product name. Commenter is listed in Appendix II. The comment is summarized in Appendix III along with the response by Health Canada. The comment did not result in revisions to the value assessment and did not result in changes to the proposed re-evaluation decision as described in PRVD2022-03. A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2022-03.

This document presents the final re-evaluation decision[2] for the re-evaluation of *Chondrostereum purpureum* strain PFC2139, including the required label updates required to bring labels to current standards and improve clarity. All products containing *Chondrostereum purpureum* strain PFC2139 that are registered in Canada are subject to this re-evaluation decision.

## Re-evaluation decision for *Chondrostereum purpureum* strain PFC2139

Health Canada has completed the re-evaluation of *Chondrostereum purpureum* strain PFC2139. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing *Chondrostereum purpureum* strain PFC2139 is

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

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

acceptable. An evaluation of available scientific information found that the use of *Chondrostereum purpureum* strain PFC2139 products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes label updates.

## Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required updated label statements as a result of the re-evaluation of *Chondrostereum purpureum* strain PFC2139, are summarized below. Refer to Appendix IV for details.

### Human Health

Label updates to meet current standards:

- Update to standard label statements (wording related to first aid and disposal).

### Environment

Label updates to meet current standards:

- Updates to standard label statements (use restrictions, environmental precautions and disposal).

## Next steps

To comply with this decision, the required amendments (label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

## Other information

Any person may file a notice of objection[3] regarding this decision on *Chondrostereum purpureum* strain PFC2139 and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact PMRA's Pest Management Information Service.

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

The relevant confidential test data on which the decision is based (as referenced in PRVD2022-03) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

# Appendix I Registered products containing *Chondrostereum purpureum* strain PFC2139 in Canada

**Table 1 Products Containing *Chondrostereum purpureum* strain PFC2139 Requiring (Label) Amendments[1]**

| Registration number | Class | Registrant | Product name | Formulation type | Active ingredient (%) |
|---|---|---|---|---|---|
| 27822 | T | Danstar Ferment AG. | CP-PFC2139 | Dust or powder | CPO $10^5$ to $10^7$ CFU/kg |
| 29292 | T | Danstar Ferment AG. | PT-PFC2139 | Wettable powder | CPO $1 \times 10^7$ to $5 \times 10^8$ CFU/kg |
| 27823 | C | Danstar Ferment AG. | Chontrol™ Paste | Paste | CPO $10^5$ to $10^7$ CFU/kg |
| 29293 | C | Danstar Ferment AG. | Lalcide Chondro | Paste | CPO $10^5$ to $10^7$ CFU/kg |

[1] As of 27 March 2023, excluding discontinued products or products with a submission for discontinuation.

T = Technical grade active ingredient, C = Commercial,
CPO = *Chondrostereum purpureum* strain PFC2139, CFU = colony-forming unit,

# Appendix II List of commenters to PRVD2022-03

List of commenters' affiliations for comments submitted in response to PRVD2022-03

| Category | Commenter |
|---|---|
| Registrant | Danstar Ferment AG/Lallemand Plant Care |

# Appendix III Comment and response

Health Canada received one written comment during the public consultation for the *Chondrostereum purpureum* strain PFC2139 proposed re-evaluation decision. Commenter affiliation is listed in Appendix II. The comment was considered during the final decision phase of this re-evaluation. The summarized comment and Health Canada's response is provided below.

## 1.0 Comment related to the product table

### 1.1 Comment

A comment was received from Danstar Ferment AG/Lallemand Plant Care regarding the product name for registration number 29293.

**Health Canada Response**

The product name for registration number 29293 has been updated. The name of the product is "Lalcide Chondro".

# Appendix IV Label amendments for products containing *Chondrostereum purpureum* strain PFC2139

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

**For all products:**

The **FIRST AID** section must be updated as per the PMRA Guidance Document, *First Aid Labelling Statements*, March 2022.

**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:

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."