



Re-evaluation Decision

RVD2025-05

# Streptomyces lydicus Strain WYEC 108 and Its Associated End-use Products

*Final decision*

*(publié aussi en français)*

**28 August 2025**

This document is published by the Health Canada Pest Management Regulatory Agency.  
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ISSN: 1925-1017 (print)  
1925-1025 (online)

Catalogue number: H113-28/2025-5E (print version)  
H113-28/2025-5E-PDF (PDF version)

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## Re-evaluation decision for *Streptomyces lydicus* strain WYEC 108 and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they meet current health and environmental standards and 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 directly related to the proposed re-evaluation decision, such as comments directed to the science evaluation, received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as risk management approaches and policies.

This document presents the final re-evaluation decision<sup>1</sup> for the re-evaluation of *Streptomyces lydicus* strain WYEC 108, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing *Streptomyces lydicus* strain WYEC 108 regulated under the *Pest Control Products Act* in Canada are subject to this re-evaluation decision.

*Streptomyces lydicus* strain WYEC 108 is a microbial pest control agent (MPCA) registered as a preventative fungicide to suppress fungal diseases in agricultural field- and/or greenhouse-grown food crops and flowering ornamentals, including use as a seed treatment in select greenhouse-grown food crops.

*Streptomyces lydicus* strain WYEC 108 is a naturally occurring bacteria. *Streptomyces lydicus* strain WYEC 108 works by invading and growing within the fungal pathogens, where it releases enzymes that break down the cell wall of fungi. It also readily grows on the tip of plant roots, which protects the plant's roots from plant pathogens by competing with and displacing fungi that may cause disease and by excreting metabolites that target disease fungi.

Currently registered products containing *Streptomyces lydicus* strain WYEC 108 can be found in the Pesticide Product Information Database and in Appendix I. The Proposed Re-evaluation Decision PRVD2025-01, *Streptomyces lydicus strain WYEC 108 and its Associated End-use Products*<sup>2</sup> containing the evaluation of *Streptomyces lydicus* strain WYEC 108 and proposed decision, underwent a 90 day consultation period ending on 30 April 2025. PRVD2025-01 proposed continued registration of *Streptomyces lydicus* strain WYEC 108 products in Canada, with updates to label directions and precautions to reflect the current labelling standards and to improve clarity (Appendix II).

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<sup>1</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

<sup>2</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

One comment was received from the public expressing concerns about animal testing and indicating that pesticides, in general, harm human health and or the environment. No comments specific to the assessments and proposed risk mitigation measures presented in PRVD2025-01 were received. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2025-01, which lists all information used as the basis for the re-evaluation decision.

## **Re-evaluation decision for *Streptomyces lydicus* strain WYEC 108**

Health Canada has completed the re-evaluation of *Streptomyces lydicus* strain WYEC 108. Under the authority of the *Pest Control Products Act*, Health Canada has completed all required evaluations and consultations and has determined that the registration of products containing *Streptomyces lydicus* strain WYEC 108 is required to be amended, in accordance with paragraph 21(2)(a) of the *Pest Control Products Act*. An evaluation of available scientific information found that all uses of *Streptomyces lydicus* strain WYEC 108 products meet current standards for protection of human health and the environment and have acceptable value when used with label updates.

Cannabis and industrial hemp uses were removed from the labels since they are no longer supported by the registrant.

### **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 amendments, including any revised/updated label statements, as a result of the re-evaluation of *Streptomyces lydicus* strain WYEC 108, are summarized below. Refer to Appendix II for details.

### **Label improvements to meet current standards**

#### **Human health**

- Update personal protective equipment to current standards, and include the standard spray drift statement.

#### **Environment**

- Update environmental precautions and disposal.

### **Implementation of the re-evaluation decision**

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides information and general timelines regarding the implementation of post-market decisions, (for example, up to 24-month timeline for label amendments). The post-market decision considers potential health and environmental risks regarding the use of the pest control product, and its value, when establishing the implementation timelines.

## Amendment timeframe

The implementation timeline of 24 months for the required amendments (label updates) for pest control products containing *Streptomyces lydicus* strain WYEC 108 is considered acceptable. These required amendments must be implemented within 24 months after the publication date of this decision document.

## Next steps

To comply with this decision, the required amendments (mitigation measures and 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.

## Other information

Any person may file a notice of objection<sup>3</sup>, which must be based on scientific grounds, regarding this decision on *Streptomyces lydicus* strain WYEC 108 and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision through the Public Engagement Portal (Public Engagement Portal (PEP) - Health Canada). The request for reconsideration must include the Notice of Objection form, the scientific explanation of the objection and the supporting scientific evidence in possession of the requestor that wouldn't already be in PMRA's possession or cite specific PMRA documentation they wish to rely on as supporting evidence (for example, scientific reports) in the form of electronic copies of cited references. Each of the references provided or cited must be clearly associated with the objection it supports. Failure to provide a complete package may result in the notice of objection being considered ineligible for further consideration by the PMRA.

The relevant confidential test data on which the decision is based (as referenced in PRVD2025-01) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the Pest Management Information Service.

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## Appendix I Registered products containing *Streptomyces lydicus* strain WYEC 108 in Canada

**Table 1** Products containing *Streptomyces lydicus* strain WYEC 108 requiring (label) amendments<sup>1</sup>

Registration number	Marketing class <sup>2</sup>	Registrant	Product name	Formulation type	Active ingredient
28673	T	Novozymes BioAg Limited	<i>Streptomyces lydicus</i> WYEC 108	Soluble Powder	$2.7 \times 10^8$ CFU/g (min.) (1.0%)
28672	C	Novozymes BioAg Limited	Actinovate SP	Soluble Powder	$1.0 \times 10^7$ CFU/g (min.) (0.0371%)
34041	C	Novozymes BioAg Limited	Actinovate AG Fungicide	Soluble Powder	$1.0 \times 10^7$ CFU/g (min.) (0.0371%)

<sup>1</sup> As of 2 May 2025, excluding discontinued products or products with a submission for discontinuation.

<sup>2</sup> T = Technical Grade Active Ingredient, C = Commercial

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## Appendix II Label amendments for products containing *Streptomyces lydicus* strain WYEC 108

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

### Technical Grade Active Ingredient:

1. Under STORAGE, DISPOSAL AND SPILLS, update the disposal with the following statement:

“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 and the provincial regulatory agency.”

### Commercial Class Products:

2. Remove all cannabis/hemp uses, including all statements specific to cannabis/hemp uses in the following sections:

DIRECTIONS FOR USE  
PRECAUTIONS

3. Replace the PRECAUTIONS section, with the following text:

“KEEP OUT OF REACH OF CHILDREN

May cause sensitization. May irritate eyes. Avoid contact with eyes, skin and clothing. Avoid breathing dust and spray mist. Wear a long-sleeved shirt, long pants, protective goggles, waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter when handling, mixing/loading or applying the product and during all clean-up/repair activities.

Restricted-Entry Interval (REI): DO NOT allow worker entry into treated areas for 4 hours or until sprays have dried unless wearing waterproof gloves, long-sleeved shirt, long pants, socks and shoes.

Apply only to agricultural crops when the potential for drift to areas of human habitation and human activity, such as houses, cottages, schools and recreational areas, is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”

4. Under the DIRECTIONS FOR USE, add the following statements:

“Preharvest Interval: [product name] can be used up to and including the day of harvest. PHI = 0 days.”

“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 wastes.

“DO NOT apply by air.”

5. Replace the text in the ENVIRONMENTAL PRECAUTIONS, with the following statements:

“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. Additional guidance can be found on the Runoff Mitigation portion of the [Canada.ca](http://Canada.ca) website”