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Proposed Re-evaluation Decision

PRVD2025-01

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

*Consultation Document*

*(publié aussi en français)*

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Publications  
Pest Management Regulatory Agency  
Health Canada  
2 Constellation Drive  
8<sup>th</sup> floor, A.L. 2608 A  
Ottawa, Ontario K1A 0K9

Internet: [canada.ca/pesticides](http://canada.ca/pesticides)  
[pmra.publications-arla@hc-sc.gc.ca](mailto:pmra.publications-arla@hc-sc.gc.ca)

Information Service:  
1-800-267-6315  
[pmra.info-arla@hc-sc.gc.ca](mailto:pmra.info-arla@hc-sc.gc.ca)

Canada 

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## Table of Contents

Proposed re-evaluation decision for <i>Streptomyces lydicus</i> strain WYEC 108.....	1
Key risk-reduction measures.....	2
Next steps.....	2
Other information.....	2
Additional scientific information.....	2
1.0 Human health assessment.....	3
2.0 Environment assessment.....	5
3.0 Incident reports.....	5
4.0 Value assessment.....	5
Appendix I Registered Products Containing <i>Streptomyces lydicus</i> strain WYEC 108 in Canada as of October 10, 2024 <sup>1</sup> .....	6
Appendix II Proposed label updates for products containing <i>Streptomyces lydicus</i> strain WYEC 108.....	7
References.....	9

## **Proposed 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 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.

This document presents the proposed re-evaluation decision for *Streptomyces lydicus* strain WYEC 108, including the proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the Science evaluation on which the proposed decision is based.

*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. Currently registered products containing *Streptomyces lydicus* strain WYEC 108 can be found in the Pesticide Product Information Database and in Appendix I.

*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.

*Streptomyces lydicus* strain WYEC 108 has a multiple-site mode of action and has value in providing a pest management solution. Based on the current use pattern, the potential risks to human health (dietary, occupational and bystander) and the environment (aquatic and terrestrial organisms) are considered to be acceptable when products containing *Streptomyces lydicus* strain WYEC 108 are used according to the current label directions. As a result of re-evaluation, no additional mitigation measures are proposed, however, updates to standard label statements as per current labelling standards are proposed. Refer to Appendix II for details.

The registrant no longer supports uses of *Streptomyces lydicus* strain WYEC 108 on cannabis and industrial hemp. Therefore, these uses will not be re-evaluated, and will be removed from the labels.

### **Proposed re-evaluation decision for *Streptomyces lydicus* strain WYEC 108**

Under the authority of the *Pest Control Products Act*, and based on available scientific information in accordance with subsection 16(6) of the *Pest Control Products Act*, Health Canada is proposing for public consultation, pursuant to section 28 of the *Pest Control Products Act*, the continued registration of *Streptomyces lydicus* strain WYEC 108 and associated end-use products registered for sale and use in Canada under section 21 of the *Pest Control Products Act*.

This document is subject to a 90-day public consultation period.<sup>1</sup> Comments on the proposed decision can be submitted to the PMRA through PMRA Publications, or the Public Engagement Portal (Public Engagement Forms - Consultation Comment). All products containing *Streptomyces lydicus* strain WYEC 108 that are registered in Canada are subject to this proposed re-evaluation decision.

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

## **Key risk-reduction measures**

### **Human health**

Label improvements to meet current standards: update personal protective equipment for clarity and to add protective eyewear (goggles), and addition of standard spray drift.

### **Environment**

Label improvements to meet current standards: update environmental precautions and disposal.

## **Next steps**

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

Before making a re-evaluation decision on *Streptomyces lydicus* strain WYEC 108 under section 21 of the *Pest Control Products Act*, written comments received during the consultation period will be taken into consideration, and a science-based approach will be applied in making a final decision on *Streptomyces lydicus* strain WYEC 108. In accordance with subsection 28(5) of the *Pest Control Products Act*, Health Canada will then publish a final re-evaluation decision document, which will include the decision,<sup>2</sup> the reasons for it, a summary of the comments received on the proposed re-evaluation decision during the consultation period, and Health Canada's response to these comments.

## **Other information**

The relevant confidential test data on which the proposed decision is based are available for public inspection, upon application, in Health Canada's Reading Room. For more information or if you have questions, please contact the PMRA's Pest Management Information Service.

## **Additional scientific information**

No additional scientific data are being requested at this time.

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

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

## Science evaluation

*Streptomyces lydicus* strain WYEC 108 is registered as a fungicide for suppression of plant diseases caused by fungal pathogens and moulds in agricultural field- and/or greenhouse-grown food crops (African eggplant, blueberry, chayote, Chinese wax gourd, citron melon, cucumber, currant tomato, edible gourd, eggplant, garden huckleberry, gherkin, goji berry, grape, groundcherry, lettuce, martynia, *Momordica* spp., muskmelon, okra, pea eggplant, pepino, pumpkin, pepper (bell, non-bell) scarlet eggplant, squash, strawberry, sunberry, tomato, tomatillo, watermelon), and flowering ornamentals (cyclamen, geranium, Gerber daisy, petunia, verbena).

*Streptomyces lydicus* strain WYEC 108 is applied to foliage, soil, seed, and/or roots at transplant. It is applied using hand-held backpack or ground spray in fields/greenhouses, and in greenhouses, it is applied through hydroponic drip irrigation, as a soil drench, or by treating seeds. It is first applied during conducive-to-disease conditions, immediately after transplanting, or early in the plant's life as possible (in other words, whilst sticking cuttings, transferring starters, or sowing seeds), and application is repeated every 7 to 14 days or 4 to 12 weeks, depending on disease pressure.

### 1.0 Human health assessment

Health Canada has not established toxicological reference values and has used a qualitative approach for the human health assessment of *Streptomyces lydicus* strain WYEC 108 (Canada, 2007). The United States Environmental Protection Agency has used a similar qualitative approach to assess products containing *Streptomyces lydicus* strain WYEC 108 for similar uses (USEPA, 2019).

*Streptomyces* strain WYEC 108 is of low toxicity by the oral route, not pathogenic or infective via the pulmonary or intravenous routes, mildly irritating to the eye, and slightly irritating to the skin (Canada, 2007).

Applicators handling (in other words, mixing the product) or applying the suspension, and workers entering into treated sites, can be exposed to *Streptomyces lydicus* strain WYEC 108. Potential exposure is expected to be by the dermal and inhalation routes, and to an extent, in the eyes. As the PMRA considers all MPCAs to be potential sensitizers and as a result of acute testing, the current labels for *Streptomyces lydicus* strain WYEC 108 include the appropriate signal words "POTENTIAL SENSITIZER" and "CAUTION: EYE IRRITANT", as well as the precautionary statement "may cause sensitization". As such, the existing precautions require workers to wear personal protective equipment, including a long-sleeved shirt, long pants, waterproof gloves, socks and shoes, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95 during mixing/loading, application, clean-up, and repair and warn users to avoid direct contact (on the skin and in the eyes) and breathing in dust/mist. Further, as the product is mildly irritating to the eye, protective eyewear (goggles) for pesticide handlers is proposed (Appendix II).

To minimize potential post-application exposure to workers, the current labels restrict entry into treated sites for four hours after spraying or until the solution has dried unless wearing the appropriate personal protective equipment, including a long-sleeved shirt, long pants, waterproof gloves, socks and shoes.

An update to the label statement for personal protective equipment to add clarity for users and to add protective eyewear (goggles) for pesticide handlers is proposed to meet current labelling standards (Appendix II). Potential occupational risk to workers during all mixing/loading, application, and postapplication activities is considered acceptable with the proposed label updates. For workers, no additional mitigation measure is proposed.

As the end-use product labels do not permit the application of *Streptomyces lydicus* strain WYEC 108 to residential, recreational, and turf sites, residential and other non-occupational exposure is not expected. Therefore, residential and other non-occupational risk is considered acceptable. For bystanders, exposure is expected to be less than that of field workers and is considered negligible. For best practice, standard spray drift label statement is proposed (Appendix II).

*Streptomyces lydicus* strain WYEC 108 is registered for food use. *Streptomyces lydicus* is a common soil microorganism and application of end-use products to the registered food crops in agricultural fields and/or greenhouses is not expected to significantly increase the naturally occurring levels of *Streptomyces lydicus*. Additionally, no adverse effects have been attributed to dietary exposure of naturally occurring *Streptomyces lydicus* populations. *Streptomyces lydicus* strain WYEC 108 did not demonstrate oral toxicity at the maximum dose tested, and the MPCA is not known to produce mammalian toxins. The likelihood of residues of *Streptomyces lydicus* strain WYEC 108 contaminating drinking water is negligible. Therefore, dietary risk via food and drinking water from the use of *Streptomyces lydicus* strain WYEC 108 is considered acceptable.

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). Under the current conditions of use, exposure to *Streptomyces lydicus* strain WYEC 108 from residential, and other non-occupational sources is negligible, and based on the low toxicity profile, dietary risk is considered acceptable. Therefore, an aggregate assessment is not required.

The *Pest Control Products Act* requires that the PMRA consider the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. In its assessment of common mechanisms of toxicity, the PMRA considers both the taxonomy of microbial pest control agents as well as the production of any potentially toxic metabolites. For the current re-evaluation, the PMRA has determined that *Streptomyces lydicus* strain WYEC 108 shares a common mechanism of toxicity with other registered microbial pest control agents, namely *Streptomyces acidiscabies* strain RL-110T and *Streptomyces* strain K61.

The potential health risks from cumulative exposure of *Streptomyces lydicus* strain WYEC 108 and these other registered microbial pest control agents are acceptable when used as directed on the label, given their low toxicity and pathogenicity.

## 2.0 Environment assessment

*Streptomyces lydicus* strain WYEC 108 is a common soil microorganism. It can colonize the root system and act as a naturally occurring plant growth-promoting bacterium in the rhizosphere of various host plants.

As *Streptomyces lydicus* is ubiquitous in the environment, mammals, birds, and arthropod insects, including honeybees, are considered to have been exposed to naturally occurring populations of *Streptomyces lydicus*, and no adverse effects related to *Streptomyces lydicus* strain WYEC 108 have been noted (Canada, 2007a and 2010a). As well, the acute mammalian testing indicated low toxicity and no infectivity or pathogenicity in the test animals. Therefore, the potential risk to terrestrial non-target organisms is considered acceptable.

In fish, no adverse effects and no mortalities were reported in the acute toxicity testing. Also, no adverse effects in fish, algae, and aquatic plants related to *Streptomyces lydicus* strain WYEC 108 have been noted (Canada, 2007a). As *Streptomyces lydicus* strain WYEC 108 is not registered for aquatic use, potential for contamination is only possible as a result of spray drift and/or runoff in field applications. The existing label has the necessary mitigative measures (in other words, to reduce runoff, and for storage/disposal) to limit contamination of aquatic ecosystems. Therefore, the potential risk to aquatic organisms is considered acceptable. An update to the environmental precautions and disposal statements to meet current labelling standards is proposed (Appendix II).

*Streptomyces lydicus* strain WYEC 108 is not considered as a Track 1 substance as it does not meet all the Track 1 criteria as per the Toxic Substances Management Policy (Canada, 2007).

## 3.0 Incident reports

As of 25 July 2024, no human, domestic animal, or environmental incidents involving *Streptomyces lydicus* strain WYEC 108 or its related strains (in other words, *Streptomyces acidiscabies* strain RL-110T and *Streptomyces griseoviridis* strain K61) have been submitted to the PMRA.

## 4.0 Value assessment

*Streptomyces lydicus* strain WYEC 108 is a biopesticide to control fungal plant diseases and has acceptable value. *Streptomyces lydicus* strain WYEC 108 is a product that can be used in an integrated pest management system. Microbials and non-conventional fungicides such as *Streptomyces lydicus* strain WYEC 108 generally have a lower risk of resistance development as the active ingredient has a multiple-site mode of action.

**Appendix I Registered Products Containing *Streptomyces lydicus* strain WYEC 108 in Canada as of October 10, 2024<sup>1</sup>**

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

<sup>1</sup> excluding discontinued products or products with a submission for discontinuation

\* T = Technical Grade Active Ingredient; C = Commercial

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## Appendix II Proposed label updates 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 wash water.

Do NOT apply using aerial application equipment.”

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.”

## References

### Published Information

<b>PMRA Document Number</b>	<b>Reference</b>
1467333	Canada, 2007a. Proposed Registration Decision, PRD2007-10
1467336	Canada, 2007b. Registration Decision, RD2007-10
2010378	Canada, 2010. Evaluation Report for Category B, Subcategory 1.1, 3.11 and 3.12 Application Number 2010-4406
3619342	Canada, 2010a. Evaluation Report for Category B, Subcategory 4.6 Application Number 2010-5512
3621150	Canada, 2010b. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2010-3033 (D.3.2)
3621152	Canada, 2010c. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2010-3034 (D.3.2)
3621073	Canada, 2010d. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2010-4764 (D.3.2)
3621246	Canada, 2010e. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2010-4912 (D.3.2)
3621261	Canada, 2010f. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2010-4914 (D.3.2)
3621263	Canada, 2011. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2011-4917 (D.3.2)
2388568	Canada, 2013a. Evaluation Report for Category D, Subcategory 3.2 (URMULE) Application Number 2013-2070
3625675	Canada, 2013b. Evaluation Report for Category D, Subcategory 3.2 (URMULE) Application Number 2013-2071
3625713	Canada, 2013c. Evaluation Report for Category D, Subcategory 3.2 (URMULE) Application Number 2013-4055
2375400	Canada, 2014. Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application Number 2014-0519

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3011327	Canada, 2018a. Evaluation Report for Category B, Subcategory 2.3 Application Number 2018-5053
3011323	Canada, 2018b. Evaluation Report for Category B, Subcategories 1.1, 1.3 Application Number 2018-6668
3148889	Canada, 2020a. Evaluation Report for Category B, Subcategory 3.11, 3.12 Application Number 2020-0566
3139716	Canada, 2020b. Evaluation Report for Category B, Subcategory 1.1 Application Number 2020-0827
3207089	Canada, 2020c. Evaluation Report for Category B, Subcategory 1.1 Application Number 2020-3127
3211692	Canada, 2021. Evaluation Report for Category B, Subcategory 1.1 Application Number 2021-0359
3584009	US EPA, 2021. <i>Streptomyces lydicus</i> strain WYEC 108 Interim Registration Review Decision Case Number 6088. January 2021