Re-evaluation Decision RVD2020-04

Streptomyces strain K61 and Its Associated End-use Products

Final Decision

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Re-evaluation Decision

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 current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Streptomyces strain K61 is a bacterium that is used as a microbial pest control agent for the suppression of damping-off, root and crown rot, and wilt in various greenhouse ornamentals, vegetables, and herbs caused by common pathogenic fungi. The commercial end-use product is formulated as a wettable powder and is applied as a water suspension directly to the root zone/growing media of greenhouse plants. It can also be used as a seed treatment and is applied as a powder directly to seeds.

This document presents the final regulatory decision[1] for the re-evaluation of *Streptomyces* strain K61. All pest control products containing *Streptomyces* strain K61 that are registered in Canada (Appendix I) are subject to this re-evaluation decision. Prior to finalizing this decision, Health Canada published the Proposed Re-evaluation Decision PRVD2019-08, *Streptomyces strain K61and Its Associated End-use Products,*[2] for 90-day consultation.

One comment on the proposed restricted-entry interval (REI) label statement was received during the consultation process, and was taken into consideration for this final decision. The comment did not result in a change to the proposed decision for *Streptomyces* strain K61. Therefore, this final decision is consistent with the proposed re-evaluation decision stated in PRVD2019-08. Appendix II of this document summarizes the comment received during consultation process along with the response by Health Canada.

A reference list of all data used as the basis for the re-evaluation decision is included in PRVD2019-08.

Regulatory Decision for *Streptomyces* strain K61

Health Canada has completed the re-evaluation of *Streptomyces* strain K61. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing *Streptomyces* strain K61 is considered to be acceptable. Following a scientific review of the available information, Health Canada has determined that the health and environmental risks and the value of *Streptomyces* strain K61 are continued to be acceptable provided that label amendments, as summarized below and listed in Appendix III, are implemented. No additional data are required at this time.

- Clarification for use in greenhouses only;

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

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

- Updated personal protective equipment label statement;
- Updated warning label statements; and
- Restricted-entry interval label statement.

Next Steps

To comply with this decision, the required label amendments must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this document. Appendix I lists the products containing *Streptomyces* strain K61 that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[3] regarding this decision on *Streptomyces* strain K61 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 the PMRA's Pest Management Information Service.

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

Appendix I Registered *Streptomyces* strain K61 Products in Canada

Registered Products *Streptomyces* strain K61 as of 4 December 2019

Registration No.	Marketing Class	Registrant	Product Name	Formulation	Guarantee (cfu/g)
26264	Technical	Danstar Ferment AG	Mycostop biofungicide technical	live organism	1×10^8
26265	Commercial	Danstar Ferment AG	Mycostop biofungicide	live organism (wettable powder)	1×10^8

Appendix II Comments and Responses

The PMRA received the following comment relating to the Proposed Re-evaluation Decision PRVD2019-08, *Streptomyces strain K61 and Its Associated End-use Product*. The comment received is presented below, in conjunction with the Health Canada response.

1.0 Comment Related to the Health Risk Assessment

The comment pertains to the proposed restricted-entry interval (REI) labels statement:

> "Restricted-Entry Interval: DO NOT enter or allow worker entry into treated areas for 4 hours or until sprays have dried, unless wearing personal protective equipment, including waterproof gloves, a long-sleeved shirt, long pants, and socks with shoes."

The registrant requested that the PMRA consider allowing their product, Mycostop Biofungicide, to have the following statement approved by the United States Environmental Protection Agency (USEPA) for their identical product registered in the United States:

> "EXCEPTION: If the product is soil incorporated or soil injected, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Health Canada Response:

In Canada, Mycostop Biofungicide is registered for application as a water suspension by spraying or drenching the surface of growing media (such as, soil) or by using drip irrigation. It is not soil incorporated or soil injected; the spray must be allowed to dry before being handled by workers without the appropriate personal protective equipment (PPE). Therefore, the USEPA statement does not pertain to this approved use and the proposed REI statement must be included on the product label.

Appendix III Label Amendments for Commercial End-Use Products Containing *Streptomyces* strain K61

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

The following label statements are required:

I) Under **PRECAUTIONS**, the following statement must be included:

"**Restricted-Entry Interval**: DO NOT enter or allow worker entry into treated areas for 4 hours or until sprays have dried, unless wearing personal protective equipment, including waterproof gloves, a long-sleeved shirt, long pants, and socks with shoes."

II) Under **"PRECAUTIONS"**, complete the following:

Replace

"May cause sensitization by inhalation and skin contact. Avoid breathing dust or spray mist. Avoid contact with skin and eyes. Wear a long sleeved shirt, long pants, shoes plus socks, chemical resistant gloves, eye goggles and a dust mask (minimum standard MSHA/NIOSH TC-21C) when handling this product and during all clean up/repair activities. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

With

"May cause eye irritation. DO NOT get in eyes. May cause sensitization. Avoid contact with skin or clothing. Avoid inhaling/breathing dust or spray mist. Wear a long-sleeved shirt, long pants, eye goggles or face shield, water-proof gloves, shoes with socks, and a minimum of a NIOSH-approved particulate filtering face piece respirator with any N, R or P filter when handling, mixing/loading or applying the product, and during all clean-up/repair activities. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE:**

"For greenhouse use only."

V) On the **PRINCIPAL DISPLAY** panel, the following must be added:

"**CAUTION - EYE IRRITANT**"