Special Review Decision

Santé

Canada

SRD2021-05

Special Review Decision: Pymetrozine

Final Decision Document

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Special review decision

Pursuant to subsection 17(2) of the Pest Control Products Act, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of pymetrozine based on the decision taken by Norway to prohibit all uses of pymetrozine. The aspect of concern for the special review under subsection 17(2) is relevant to human health (potential carcinogenicity of pymetrozine).

In addition, pursuant to subsection 17(1) of the *Pest Control Products Act*, Health Canada initiated a special review of pymetrozine based on information related to pymetrozine and its transformation products in drinking water. The aspect of concern for the special review under subsection 17(1) of the *Pest Control Products Act* is relevant to human health (potential cancer risk from pymetrozine and its metabolites through drinking water exposure).

Health Canada evaluated the aspects of concern that prompted the above two special reviews in accordance with subsection 18(4) of the Pest Control Products Act. The proposed special review decisions were published for consultation¹ in the Proposed Special Review Decision PSRD2020-04, Special Reviews of Pymetrozine and Its Associated End-use Products Consultation Document. One comment was received during the consultation period (Appendix II), and it did not change the outcome of the proposed special review decisions.

Pymetrozine is an insecticide used for the control of aphids in leafy vegetables (Crop Group 4), potatoes, highbush blueberries, tobacco, *Rhodiola rosea*, outdoor ornamentals, greenhouse vegetables (pepper, tomato, cucumber and eggplant) and to control Balsam twig aphid on Christmas trees. It is also registered for the control of aphids and the reduction of whiteflies on ornamental plants in greenhouses. Currently registered products containing pymetrozine are listed in Appendix I.

Special review under subsection 17(1) of the Pest Control Products Act

Following evaluation of available scientific information related to the aspect of concern (potential cancer risk from pymetrozine and its metabolites through drinking water exposure) Health Canada has determined that continued registration of products containing pymetrozine is considered to be acceptable with the following risk mitigation measures:

- Cancel all outdoor uses of pymetrozine:
 - leafy vegetables (Crop Group 4)
 - potatoes

- highbush blueberries
- tobacco
- Rhodiola rosea
- outdoor ornamentals
- Christmas trees

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

• A revised label statement prohibiting effluent or runoff from greenhouses containing pymetrozine to enter into aquatic systems as per the current label standards.

Special review under subsection 17(2) of the Pest Control Products Act

Following evaluation of available scientific information related to the aspect of concern (potential carcinogenicity of pymetrozine) Health Canada found that:

- The potential cancer risk (dietary) is considered to be acceptable with the following risk mitigation measures:
 - o Cancel all outdoor uses of pymetrozine:
 - leafy vegetables (Crop Group 4)
 - potatoes
 - highbush blueberries
 - tobacco
 - Rhodiola rosea
 - outdoor ornamentals
 - Christmas trees
 - A revised label statement prohibiting effluent or runoff from greenhouses containing pymetrozine to enter into aquatic systems as per the current label standards.
- Greenhouse uses: The potential cancer risk of pymetrozine (occupational) is considered to be acceptable with the following risk mitigation measures:
 - o PPE requirement of a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.
 - For greenhouse ornamentals grown for cut flowers to minimize exposure to postapplication workers: A limit of 1000 L spray solution per hectare; and a reduction of the maximum application rate from 10 g a.i./100 L to 8.5 g a.i./100 L.
 - $\circ~$ For greenhouse vegetables: To improve clarity, a maximum spray volume of 2000 L/ha is required.

Based on the assessment of the aspects of concern under subsection 17(1) and subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act*, is confirming the current registration of pymetrozine products for sale and use in Canada with risk mitigation measures (Appendix III). All pest control products containing pymetrozine that are registered in Canada are subject to the special review decision.

This document presents the final regulatory decision² for the special reviews of pymetrozine.

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

Next steps

To comply with this decision, the required label amendments (Appendix III) must be implemented 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.

The cancelled product (Reg. No. 27274) will be phased out according to the implementation timeline outlined below:

- One (1) year of sale by registrant from the date of special review decision, followed by:
- One (1) year of sale by retailer from the last date of sale by registrant, followed by;
- One (1) year of permitted use from the last date of sale by retailer.

Other information

Any person may file a notice of objection³ regarding this decision on pymetrozine within 60 days from the date of publication of this Special Review 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.

As per subsection 35(1) of the Pest Control Products Act.

Appendix I Registered products containing pymetrozine in Canada

Table 1 Registered Products Containing Pymetrozine as of 8 February 2021

Registration Number	Marketing Class	Registrant	Product Name	Guarantee
27272	Technical	Syngenta Canada Inc.	Pymetrozine Technical	98.3%
27273ª	Commercial	Syngenta Canada Inc.	Endeavor 50WG Insecticide	50%
27274 ^b	Commercial	Syngenta Canada Inc.	Fulfill 50WG Insecticide	50%

^a Only greenhouse uses will remain as a result of the special review decision (Appendix III)

^b This product will be cancelled as a result of the special review decision as all outdoor uses must be removed (Appendix III)

Appendix II Comment and response

Commenter	Comment	Health Canada Response
Canadian Nursery Landscape Association	Allow sufficient time for phase out of cancelled uses on outdoor ornamentals	Phase out timelines for cancelled uses are outlined in the Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review. Details of the implementation timeline for label amendments (24 months), and cancellation of the product (three years) are outlined under the section on Next Steps in the Special review decision.

Appendix III Label amendments

The label amendments presented below do not include all label requirements for individual enduse products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

The labels of all end-use products containing pymetrozine in Canada must be amended as follows to further protect human health.

- 1) All label directions concerning outdoor uses must be removed. This includes use on:
 - leafy vegetables (Crop Group 4)
 - potatoes
 - highbush blueberries
 - tobacco
 - Rhodiola rosea
 - outdoor ornamentals
 - Christmas trees.

As a result, the following product will be cancelled: Reg. No. 27274.

- 2) For Greenhouse uses: The following label statement must be added to the PRECAUTIONS section:
 - "Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair."
- 3) The following label statements must be added to end-use products with greenhouse uses:

Add to "DIRECTIONS FOR USE IN GREENHOUSE ORNAMENTALS":

Under the Application Rates column add the following:

"For greenhouse ornamentals grown for cut flowers apply 10 - 17 g product/100L of water and DO NOT exceed a spray volume of 1000 L water/ha"

Add to "APPLICATION DIRECTIONS IN GREENHOUSE CUCUMBER, PEPPERS, TOMATOES AND EGGPLANT":

"DO NOT exceed a spray volume of 2000 L water/ha"

Under "ENVIRONMENTAL PRECAUTIONS":

Remove the following wording:

"Do not discharge effluent, waste and drainage water containing this product into water bodies, such as lakes, streams, ponds, rivers, and estuaries."

And replace with:

"DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters."