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Re-evaluation Decision

RVD2020-03

Uniconazole-P and Its Associated End-use Products

Final Decision

(publié aussi en français)

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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 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.

Uniconazole-P is a plant growth regulator registered for use on greenhouse ornamentals and greenhouse tomato seedlings for transplant only. Currently registered products containing uniconazole-P can be found in the Pesticide [Label Search](#) and in Appendix I. The regulatory approach for the re-evaluation of uniconazole-P was first presented in the Proposed Re-evaluation Decision PRVD2019-09, *Uniconazole-P and Its Associated End-use Products*,¹ which underwent a 90 day consultation period ending on 5 November 2019. PRVD2019-09 proposed that products containing uniconazole-P are acceptable for continued registration in Canada, provided that the additional proposed risk mitigation measures are in place. The proposed risk mitigation measures included the cancellation of the use on greenhouse ornamentals grown for cut flowers, and label updates to meet the current labelling standard and to improve clarity.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2019-09. All information used as the basis for the re-evaluation decision can be found in PRVD2019-09.

This document presents the final regulatory decision² for the re-evaluation of uniconazole-P, including the required risk mitigation measures to protect human health and the environment, as well as the label amendments required to bring labels to current standards. All products containing uniconazole-P that are registered in Canada are subject to this re-evaluation decision.

Outcome of Science Evaluation

Uniconazole-P is used in the greenhouse ornamental industry and tomato transplant seedling production in greenhouses. It is widely used on economically important ornamentals to enhance aesthetic appearance through producing more desirable, compact, and marketable crops.

With respect to human health, dietary risks and risks to workers from most uses were shown to be acceptable under the current conditions of use. However, risks were not shown to be acceptable for workers conducting postapplication activities for greenhouse ornamentals grown for cut flowers. Therefore, the use on greenhouse ornamentals grown for cut flowers will be cancelled. In addition, label updates will be made to meet the current labelling standard and to improve clarity.

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*.

When used according to the revised label directions of products containing uniconazole-P, risks to the environment are considered to be acceptable.

Regulatory Decision for Uniconazole-P

Health Canada has completed the re-evaluation of uniconazole-P. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing uniconazole-P is acceptable. An evaluation of available scientific information found that most uses of uniconazole-P products meet current standards for protection of human health and the environment when used according to revised label directions which include new mitigation measures.

The following uses of uniconazole-P will be cancelled since health risks were not shown to be acceptable:

- The use on greenhouse ornamentals grown for cut flowers.

Label amendments, as summarized below and listed in Appendix II, are required. No additional data are requested.

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. As a result of the re-evaluation of uniconazole-P, the following revised label statements and mitigation measures are required. Refer to Appendix II for details.

Human Health

To protect workers entering treated areas from occupational exposure, the following risk-reduction measures and label updates are required:

- Cancellation of uniconazole-P use on greenhouse ornamentals grown for cut flowers.
- Clarifications on the required personal protective equipment for workers mixing/loading and applying uniconazole-P.
- Specifying that the use of handheld mist blowers/airblast or handheld fogging equipment is not allowed.
- An update to the early re-entry interval statement on the Sumagic product label (Registration No. 25781).

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Refer to Appendix I for details on specific products impacted by this decision.

Other Information

Any person may file a notice of objection³ regarding this decision on uniconazole-P 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 by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

The relevant test data on which the decision is based (as referenced in PRVD2019-09) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

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

Appendix I Registered Uniconazole-P Products in Canada¹

Table 1 Products Requiring Label Amendments

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (% , g/L)
25780	T	Valent Canada, Inc.	Valent Uniconazole-P Technical	solution	76%
25781	C	Valent Canada, Inc.	Sumagic Plant Growth Regulator	emulsifiable concentrate	0.055%
32342	C	Fine Agrochemicals Limited	Concise	solution	0.055%

¹ as of 26 November 2019, excluding discontinued products or products with a submission for discontinuation

Table 2 Products Containing Uniconazole-P that Do Not Require label Amendments

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (% , g/L)
32171	T	Fine Agrochemicals Limited	Technical Uniconazole-P	solid	79.4%

¹ as of 26 November 2019, excluding discontinued products or products with a submission for discontinuation

Appendix II Label Amendments for Products Containing Uniconazole-P

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

I. LABEL AMENDMENTS FOR TECHNICAL GRADE ACTIVE INGREDIENTS CONTAINING UNICONAZOLE-P

For Valent Uniconazole-P Technical (Registration No. 25780):

PRINCIPAL DISPLAY PANEL

On the uniconazole-P technical product label, replace “Guarantee” with “Active Ingredient”

Update wording to specify the percent of active ingredient as 79%

II. LABEL AMENDMENTS FOR COMMERCIAL CLASS END-USE PRODUCT CONTAINING UNICONAZOLE-P

Cancelled Uses

Greenhouse ornamentals grown for cut flowers, any other reference to this use must be removed from all commercial class product labels

PRECAUTIONS

1. Personal Protective Equipment

Replace the following statement on commercial-class product labels (Registration Nos. 25781 and 32342):

“When mixing, loading, and applying the product, wear waterproof rain gear (for example, Tyvek coveralls) with a hood, respirator with an organic cartridge, chemical-resistant gloves, goggles, and rubber boots.”

With

“For mixing, loading, application, clean-up and repair wear waterproof rain gear (for example, Tyvek coveralls) with a hood, chemical-resistant gloves, goggles, socks, rubber boots and a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides.”

2. Restricted-Entry Interval (REI)

Replace the following statement on the commercial-class product label Registration No. 25781:

“DO NOT reenter treated area within 12 hours of application. If early reentry is required, then wear waterproof rain gear (for example, Tyvek coveralls), respirator with an organic chemical cartridge, chemical resistant gloves and rubber boots.”

With:

“DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. If required, applicators may enter treated areas within 12 hours for short-term tasks not involving hand labour if at least 4 hours has passed since application and waterproof rain gear (for example, Tyvek coveralls) with a hood, chemical-resistant gloves, goggles, socks, rubber boots and a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides is worn.”

3. Ornamental Restriction

Add the following statement to all end use product labels (Registration Nos. 25781 and 32342):

“DO NOT apply to ornamentals grown for cut flowers.”

DIRECTIONS FOR USE

Equipment Limitations

Add the following statement to the commercial-class product label (Registration No. 25781):

“DO NOT apply using handheld mist blowers/airblast or handheld fogging equipment.”

Replace the following statement on the commercial-class product label (Registration No. 32342):

“DO NOT apply this product using fogging equipment (handheld or automated), or using handheld mist blowers/airblast equipment.”

With

“DO NOT apply using handheld mist blowers/airblast or handheld fogging equipment.