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Re-evaluation Decision

RVD2019-12

# Triforine 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. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Triforine is a fungicide used to control fungal diseases in a range of berry crops, stone fruits, pome fruits, and ornamentals. Currently registered products containing triforine can be found in the Pesticide [Label Search](#) and in Appendix I. The regulatory approach for the re-evaluation of triforine was first presented in the Proposed Re-evaluation Decision PRVD2019-02, *Triforine and Its Associated End-use Products*,<sup>1</sup> which underwent a 90-day consultation period ending on 10 June 2019. PRVD2019-02 proposed that products containing triforine are acceptable for continued registration in Canada, provided that the proposed risk mitigation measures are in place: the addition of a minimum preharvest interval (PHI) for cherries, peaches, plums and prunes, updated statements for personal protective equipment (PPE), updated restricted-entry intervals (REIs), updated spray buffer zones, a statement to promote best management practices to protect bystanders from spray drift, and an updated hazard statement regarding the potential for triforine to leach into groundwater in order to protect human health and the environment.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2019-02, which lists all information used as the basis for the re-evaluation decision.

This document presents the final regulatory decision<sup>2</sup> for the re-evaluation of triforine, including the required risk mitigation measures to protect human health and the environment. All products containing triforine that are registered in Canada are subject to this re-evaluation decision.

### Outcome of Science Evaluation

With respect to human health, the health risks associated with the use of triforine and associated end-use products are acceptable when these products are used according to the revised label directions.

Triforine enters the environment when used as a fungicide on labelled crops. Based on the available scientific information, risks to the environment were found to be acceptable when triforine is used according to the revised label directions.

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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*.

Triforine is valued for its systemic properties, and as an alternative to manage resistance development in susceptible fungal pathogens. It is important to ornamental growers as there are few fungicides registered to control black spot on ornamentals.

## **Regulatory Decision for Triforine**

Health Canada has completed the re-evaluation of triforine. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing triforine is acceptable. An evaluation of available scientific information found that uses of triforine products meet current standards for protection of human health and the environment when used according to revised label directions, which include new mitigation measures. No additional data are required.

## **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 revised/updated label statements and/or mitigation measures required, as a result of the re-evaluation of triforine, are summarized below. Refer to Appendix II for details.

### **Human Health**

To protect human health, the following risk-reduction measures are required for continued registration of triforine in Canada:

- A minimum PHI of 60 days for cherries, peaches, plums and prunes to protect consumers.
- Updated statements for PPE to protect mixers, loaders and applicators.
- Updated REIs for certain agricultural crop activities to protect workers entering treated sites.
- A statement to promote best management practices in order to protect bystanders from spray drift.

### **Environment**

To protect the environment, the following risk-reduction measures are required for continued registration of triforine in Canada:

- Spray buffer zones to protect non-target terrestrial habitats (1–2 metres).
- An updated hazard statement on labels to warn users that triforine has the potential to leach into groundwater.

## **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 objection<sup>3</sup> regarding this decision on triforine 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.

The relevant test data on which the decision is based (as referenced in PRD2019-02) 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 by phone (1-800-267-6315) or by e-mail ([hc.pmra.info-arla.sc@canada.ca](mailto:hc.pmra.info-arla.sc@canada.ca)).

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

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**Appendix I Registered Triforine Products in Canada****Table 1 Products Requiring Label Amendments**

| <b>Registrant</b>                             | <b>Registration Number</b> | <b>Marketing Class</b> | <b>Product Name<sup>1</sup></b>                  | <b>Formulation Type</b>  | <b>Active Ingredient</b> |
|---|----------------------------|------------------------|--|--------------------------|--------------------------|
| Summit Agro North America Holding Corporation | 20333                      | Technical              | Technical Active Ingredient Funginex (Triforine) | Solid                    | 99.15%                   |
|   | 27686                      | Commercial             | Funginex DC Fungicide                            | Emulsifiable Concentrate | 190 g/L                  |

<sup>1</sup> As of 4 July 2019, excluding discontinued products or products with a submission for discontinuation.

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## Appendix II Label Amendments for Products Containing Triforine

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

### For Technical Grade Products:

Replace “guarantee” with “active ingredient” on the **PRIMARY PANEL**.

### For Commercial-Class Products:

Under **DIRECTIONS FOR USE**:

**Add** “Ground application only. **DO NOT** apply FUNGINEX DC Fungicide using aerial application equipment”

**Replace** use directions for blueberry (lowbush and highbush) on page 2 **with**:

#### “BLUEBERRY (LOWBUSH & Highbush)

- a) BRITISH COLUMBIA - for control of Mummy berry (*Monilinia vaccinii-corymbosi*), apply 3 L per hectare in 1,000 L of water. **Do not** make more than 4 applications per season. Apply in the spring at bud break and repeat 10 to 14 days later. Apply a third spray at early bloom and repeat 10 to 14 days later. Thoroughly wet all buds and shoots. **Do not** apply later than 60 days before harvest. Consult local extension service for proper application timing.
- b) EASTERN CANADA - for control of Mummy berry, apply 1.7 to 3 L per hectare in 1,000 L of water. **Do not** make more than 3 applications per season. Apply in the spring at bud break and repeat 10 to 14 days later. Apply a third spray at early bloom. **Do not** make more than three applications from leaf-bud break to pink-bud stage. Application of FUNGINEX DC Fungicide during or beyond early bloom may result in fruit russetting. Thoroughly wet all buds and shoots. **Do not** apply later than 60 days before harvest. Consult local extension service for proper application timing.”

**Replace** use directions for cranberry on page 2 **with**:

“**CRANBERRY (B.C. ONLY)**: For control of cottonball (*Monilinia oxycocci*), apply 3 L per hectare in 1,000 to 1,500 L of water in the spring at leaf bud-break. Repeat 10 to 14 days later. Apply third spray at early bloom and repeat 10 to 14 days later if disease persists. **Do not** make more than 4 applications per season. Thoroughly wet all buds and shoots. **Do not** apply later than 60 days before harvest. Consult local extension service for appropriate application timing.”

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**Replace** use directions for Saskatoon berry on page 2 **with**:

**“SASKATOON BERRIES:** For the control of Saskatoon-juniper rust (*Gymnosporangium* spp.) and Entomosporium leaf and berry spot (*Entomosporium mespili*), apply 3 L per hectare in a water volume (for example, 1,000 L/ha) sufficient to ensure thorough wetting - to the point where the solution drips from the plants. **Maximum one application per year.**

**TIMING:** A single application should be made between flower bud break and the white tip stage. **Do not** apply later than 60 days before harvest.”

**Replace** use directions for peaches, cherries, plums, prunes on page 2 **with**:

**“PEACHES, CHERRIES, PLUMS, PRUNES:** For control of the blossom blight stage of brown rot (*Monilinia fructicola*), mix 750 mL of FUNGINEX DC Fungicide per 1,000 L of water. **Do not** exceed 2.5 L of FUNGINEX DC per hectare. Make 2 to 3 applications from early to full bloom stage, depending on the length of the bloom period and conditions favouring brown rot. **Do not** reapply before 5 days. Follow provincial recommendations for appropriate timings. Maximum three applications per year. **Do not** apply later than 60 days before harvest.”

**Replace** use directions for Apple nursery stock and non-bearing apple trees on page 2 and page 3 **with**:

**“APPLE NURSERY STOCK AND NON-BEARING APPLE TREES:** For control of powdery mildew (*Podosphaera leucotricha*), apply 2.5 L FUNGINEX DC Fungicide per hectare by airblast sprayer at tight cluster, pink and petal fall stages. **Do not** reapply before 7 days. May be applied 2 weeks after petal fall (mid-summer) if necessary. Make a maximum of 5 applications per season.”

**Replace** use directions for ornamentals on page 3 **with**:

**“OUTDOOR ROSES AND ORNAMENTALS:** For control of powdery mildew (*Podosphaera pannosa*) and black spot (*Diplocarpon rosae*), mix 1 L per 1,000 L of water. Spray to thoroughly cover all plant surfaces. **Do not** apply more than 1 L of FUNGINEX DC Fungicide (190 g a.i.) per hectare. **Do not** apply more than 3 L of FUNGINEX DC Fungicide /ha (570 g a.i./ha) per season. **Do not** reapply before 5 days. Apply a maximum of 3 applications per year.”

Replace the current personal protection equipment safety statement under **PRECAUTIONS:**

“Wear chemical-resistant coveralls over long-sleeve shirt and long pants, chemical-resistant gloves and goggles during mixing, loading, application, clean up and repair.”

**with:**

“For ground applications, wear chemical-resistant coveralls over long-sleeve shirt and long pants, chemical-resistant gloves and goggles during mixing, loading, application, clean up and repair. Gloves are not required during application within a closed cab.

For airblast applications, wear chemical-resistant coveralls over long-sleeve shirt and long pants, chemical-resistant gloves and goggles during mixing, loading, application, clean up and repair. In addition, wear chemical-resistant headgear during open cab airblast application. Chemical-resistant headgear includes sou’wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection. Gloves are not required during application within a closed cab.”

Under **PRECAUTIONS**, add the following statements and table:

“Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”

“**DO NOT** enter or allow worker entry into treated areas during the restricted-entry intervals (REIs) specified in the following table”:

**Restricted-entry intervals required**

| <b>Crop</b>                                    | <b>Re-entry activities</b> | <b>Restricted-entry intervals</b> |
|--|----------------------------|-----------------------------------|
| Apple nursery stock and non-bearing apple tree | All activities             | 12 hours                          |
| Highbush blueberries                           | Irrigation (hand set)      | 6 days                            |
|  | All other activities       | 12 hours                          |
| Lowbush blueberries                            | Irrigation (hand set)      | 6 days                            |
|  | Scouting                   | 1 day                             |
|  | All other activities       | 12 hours                          |
| Cherries, peaches, plums/prunes                | All activities             | 12 hours                          |
| Cranberries                                    | Scouting                   | 2 days                            |
|  | All other activities       | 12 hours                          |
| Saskatoon berries                              | All activities             | 12 hours                          |
| Roses and ornamentals                          | All activities             | 12 hours                          |

Under **RESISTANCE-MANAGEMENT RECOMMENDATIONS**, update the contact information for reporting suspected resistance.

On page 5 under the “**RESISTANCE-MANAGEMENT RECOMMENDATIONS**”, under the 3<sup>rd</sup> bullet **Add** the following bullet: “Where possible, make use of predictive disease models to effectively time fungicide applications.”

On page 5 under the “**RESISTANCE-MANAGEMENT RECOMMENDATIONS**”, Add the following text to the 4<sup>th</sup> bullet “Notify the manufacturer if reduced sensitivity of the pathogen to FUNGINEX DC is suspected.”

Buffer zone statements and table are to be removed from **ENVIRONMENTAL HAZARDS** (page 4).

The following statements and buffer zone table are to be added to **DIRECTIONS FOR USE**:

**Buffer zones:**

“Spot treatments using hand-held equipment do not require a buffer zone.”

“The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).”

**Buffer Zones Required:**

| Method of application | Crop   |                            | Buffer Zones (metres) Required for the Protection of: |                  |                      |
|-----------------------|--|----------------------------|---|------------------|----------------------|
|                       |  |                            | Freshwater Habitat of Depths:                         |                  | Terrestrial Habitat: |
|                       |  |                            | Less than 1 m   | Greater than 1 m |                      |
| Field sprayer         | Cranberries, lowbush blueberries                 |                            | 0   | 0                | 1                    |
| Airblast              | Saskatoon berries                                | Early or late growth stage | 0   | 0                | 1                    |
|                       | Highbush blueberries                             | Early or late growth stage | 0   | 0                | 2                    |
|                       | Peaches, cherries, plums, prunes                 | Early growth stage         | 0   | 0                | 2                    |
|                       |  | Late growth stage          | 0   | 0                | 1                    |
|                       | Apple nursery stocks and non-bearing apple trees | Early growth stage         | 0   | 0                | 2                    |
|                       |  | Late growth stage          | 0   | 0                | 2                    |

“For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.”

“The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.”

Remove the heading **ENVIRONMENTAL HAZARDS** and replace with **ENVIRONMENTAL PRECAUTIONS**.

Under **ENVIRONMENTAL PRECAUTIONS**, remove:

“**TOXIC** to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.”

Under **ENVIRONMENTAL PRECAUTIONS**, add:

“**TOXIC** to non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.”

“This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.”