Re-evaluation Decision RVD2011-03

Triforine

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Re-evaluation Decision

After a re-evaluation of the fungicide triforine, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the use of triforine on roses and ornamentals in Canada.

An evaluation of available scientific information found that products containing triforine for use on outdoor roses and ornamentals do not present unacceptable risks to human health or the environment when used according to label directions. For the currently registered food uses, the evaluation of the available scientific information found that the use of triforine does not pose risks of concern to occupational handlers, or to the environment, when used according to label directions. As a condition of the continued registration of triforine uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

Risks from dietary and aggregate exposure to triforine will be assessed by the PMRA in the future and will be communicated in a separate document. It should be noted that the registration status of triforine and its end-use products registered in Canada might change as a result of the outcome of these risk assessments.

The regulatory approach for the re-evaluation of triforine was first presented in Proposed Re-evaluation Decision PRVD2010-13, *Triforine*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of triforine as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-13. To comply with this decision, registrants of products containing triforine will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

[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*.

Triforine, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of triforine. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated triforine and published its conclusions in a 2008 RED. The USEPA concluded that triforine was eligible for continued registration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the re-evaluation of ornamental uses of triforine in Canada, when applied using hand-held equipment. Additional human health risk assessments (occupational exposure) were conducted by the PMRA in order to evaluate the eligibility for continued registration of the uses not covered by the USEPA RED. As noted above, a dietary risk assessment, including a consideration of aggregate exposure to triforine will be conducted by the PMRA in the future. The USEPA RED was also an adequate basis for the evaluation of ecological exposure and risk for all the registered uses of triforine in Canada.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-13, *Triforine*.

What Is Triforine?

Triforine is a systemic fungicide that is used to control diseases such as black spot, rust, and powdery mildew in blueberries, cranberries, Saskatoon berries, stone fruits, apple nursery stocks and non-bearing apple trees, as well as on outdoor roses and ornamentals. Triforine is applied using airblast sprayer, groundboom and ground spray equipment by farm workers. In Eastern Canada only, it can be applied aerially on blueberries.

Health Considerations

Can Approved Uses of Triforine Affect Human Health?

Triforine is unlikely to affect your health when used according to the revised label directions.

People could be exposed to triforine by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that the use of triforine on roses and ornamentals was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Results from occupational risk assessments conducted by the PMRA indicated that the use of triforine on food crops was unlikely to affect the health of occupational handlers provided that risk-reduction measures were implemented.

Environmental Considerations

What Happens When Triforine Is Introduced Into the Environment?

Triforine is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms could be exposed to triforine in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of triforine, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Label statements to minimize bystander and domestic animal exposure
- Additional label statement prohibiting the use of triforine in greenhouses

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination
- Buffer zones to protect non-target, sensitive aquatic habitats
- Advisory label statements regarding potential toxicity to non-target organisms
- Changes to maximum number of yearly applications on roses and ornamentals

What Additional Scientific Information Is Required?

In order for the PMRA to complete terrestrial buffer zone calculations and to confirm aquatic buffer zone calculations, data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Other Information

Any person may file a notice of objection[3] 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 and Pest Management portion of Health Canada's 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 Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrant of triforine is required to provide these data or an acceptable scientific rationale to the PMRA for confirmation of aquatic buffer zones and calculation of terrestrial buffer zones within the timeline specified in the decision letter the PMRA will send.

- DACO 9.8.4: Terrestrial Vascular Plants - Seedling Emergence (USEPA OPPTS 850.4100 guideline) and Vegetative Vigour (USEPA OPPTS 850.4150 guideline).

- DACO 9.8.5: Aquatic Vascular Plants (USEPA OPPTS 850.4400 guideline)

These studies must be conducted according to the appropriate Office of Prevention, Pesticides and Toxic Substances (OPPTS) guidelines indicated