Consumer Product Safety

Re-evaluation Decision RVD2009-11, Carbathiin and Oxycarboxin

18 June 2009
HC Pub: 8288
ISBN: 978-1-100-12839-9 (print version)
ISBN: 978-1-100-12840-5 (PDF version)
Catalogue number: H113-28/2009-11E (print version)
Catalogue number: H113-28/2009-11E-PDF (PDF version)

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

(PDF Version - 69 K)

Table of Contents

After a re-evaluation of the fungicide carbathiin and oxycarboxin, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing carbathiin (as a seed treatment) and oxycarboxin (for control of rust on ornamentals grown in enclosed commercial structures) for the sale and use in Canada.

Carbathiin products registered for use as a tree seedling treatment, ornamentals outdoor and residential plantscapes treatment will no longer be supported by the registrant. Carbathiin and oxycarboxin products registered in Canada for use as a turf treatment will no longer be supported by the registrant.

An evaluation of available scientific information found that products containing carbathiin or oxycarboxin do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of carbathiin and oxycarboxin uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

Carbathiin end-use products that contain more than one active ingredient will be eligible for continued registration only when all those other active ingredients are determined to be eligible.

The regulatory approach for the re-evaluation of carbathiin and oxycarboxin was first presented in Proposed Re-evaluation Decision PRVD2008-25, *Carbathiin and Oxycarboxin*, a consultation document[1]. This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of carbathiin and oxycarboxin 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 PRVD2008-25. To comply with this

decision, registrants of products containing carbathiin and oxycarboxin will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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.

Carbathiin and oxycarboxin, two active ingredients in the current re-evaluation cycle, have 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 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 carbathiin and oxycarboxin. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The USEPA re-evaluated carbathiin and oxycarboxin and published its conclusions in a 2004 Reregistration Eligibility Decision.

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 PRVD2008-25, *Carbathiin and Oxycarboxin*.

What Are Carbathiin and Oxycarboxin?

Carbathiin is a systematic fungicide that is applied to seeds prior to planting to control various fungi that cause seed and seedling diseases such as smut, rot and blight. Carbathiin is applied both by commercial seed treaters and by on-farm applicators. Uses include seed treatment for barley, beans, canola, chickpeas, corn, flax, lentils, mustard, oats, onion, peas, rapeseed, rye, soybeans, triticale, wheat and bromegrass.

Oxycarboxin (carboxin sulfone), a metabolite of carbathiin, is a systematic fungicide applied as a watering solution to control rust on carnations in enclosed commercial greenhouses.

Health Considerations

Can Approved Uses of Carbathiin or Oxycarboxin Affect Human Health?

Carbathiin is unlikely to affect human health when used according to the revised label directions. Oxycarboxin is unlikely to affect your health when used according to the revised label directions.

Exposure to carbathiin may occur through diet (food and water), while conducting seed treatment activities or when loading and planting carbathiin-treated seed. Exposure to oxycarboxin is limited to a mixer/loader/applicator and to workers entering treated sites.

The PMRA considers two key factors when assessing health risk:

- 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 carbathiin and oxycarboxin were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and for carbathiin, equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Carbathiin is currently registered in Canada as a seed treatment for barley, beans, canola, chickpeas, corn, flax, lentils, mustard, oats, onion, peas, rapeseed, rye, soybeans, triticale, wheat and bromegrass, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for carbathiin in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Use of oxycarboxin is currently limited in Canada to non-food uses in enclosed commercial greenhouses. No MRLs have been established for oxycarboxin.

Environmental Considerations

What Happens When Carbathiin and Oxycarboxin Are Introduced Into the Environment?

Additional risk reduction measures are required on carbathiin labels. Carbathiin is unlikely to affect non-target organisms when used according to the revised label directions.

Environmental risk is assessed by the risk quotient method: the ratio of the estimated environmental concentration to the relevant effect's endpoint of concern. 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 degree of risk. The results of chronic risk assessments indicate there is a potential for chronic risk to seed-eating birds and mammals consuming carbathiin-treated seeds.

The USEPA concluded that the reregistration of carbathiin was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Given the oxycarboxin use is limited to enclosed commercial structures, environmental exposure is not expected.

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 carbathiin and oxycarboxin, the PMRA is requiring further risk-reduction measures for product labels.

Human Health Risks

Carbathiin

- Additional protective equipment to protect workers involved in seed treatment activities and in loading and planting treated seeds is required.

Oxycarboxin

- A restricted-entry interval to protect workers re-entering treated sites.

Environmental Risks

Carbathiin

- Additional advisory label statements to reduce potential surface and groundwater contamination are required.
- Additional advisory label statements to protect non-target sensitive terrestrial animals are required.

Oxycarboxin

No mitigation measures are required.

Other Information

Any person may file a notice of objection[3] regarding this decision on carbathiin and oxycarboxin 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.

Appendix I - Label Amendments for Products Containing Carbathiin and Oxycarboxin

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

A submission to request label revisions will be required within 90 days after the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

For Carbathiin End-Use Products:

I. The following statements must be included in a section entitled **Precautions:**

Dust/powder formulations:

All workers involved in treating seeds, clean-up, repair and maintenance of seed treatment equipment must wear a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks and a dust mask. Baggers, sowers and workers involved in handling treated seeds must wear a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks, and a dust mask to minimize exposure to dust from treated seeds.

Liquid formulations:

All workers involved in treating seeds, clean-up, repair and maintenance of seed treatment equipment must wear a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks. Baggers, sowers and workers involved in handling treated seeds must wear a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks, and a dust mask or appropriate respirator to minimize exposure to dust from treated seeds.

II. The following statements must be included in a section entitled **Environmental Hazards:**

In cleaning of equipment or disposing of wastes, do not contaminate water used for human or animal consumption or by wildlife and aquatic life or for irrigation purposes.

Treated seed may be hazardous to birds and mammals. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.

III. The following statement must be included in section entitled **Use Restrictions:**

DO NOT use treated seed for food, feed or oil processing.

DO NOT contaminate food, feed, domestic or irrigation water supplies, lakes, streams and ponds.

All bags containing treated seed for sale or use in Canada must be labelled or tagged as follows:

This seed has been treated with carbathiin. Wear a long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seeds. DO NOT use for food, feed or oil processing. Store away from food and feed.

IV. The following soil treatment uses must be removed from the carbathiin end-use product label (i.e. Registration Number 13051) **bedding plants, bench plants and tree seedling treatment.**

For Oxycarboxin End-Use Products:

I. The following statements must be included in a section entitled **Precautions:**

Do not re-enter or allow the re-entry into treated areas until 12 hours after application.

---

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*.

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

Date Modified: 2009-06-18