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## Consumer Product Safety

### Proposed Re-evaluation Decision PRVD2011-14, Chlorothalonil

**Notice to the reader:** The online consultation is now closed. Comments and suggestions received during the public consultation period are being considered in the finalization of this document. The final report will be made available as soon as possible.

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This page is a summary of the consultation document. If you would like to comment, please request the full consultation document.

To obtain a full copy of Proposed Re-evaluation Decision PRVD2011-14, Chlorothalonil, please contact our [publications office](#).

Should you require further information please contact the [Pest Management Information Service](#).

#### Summary

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#### What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the fungicide chlorothalonil, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and [Regulations](#), is proposing continued registration for the sale and use of products containing chlorothalonil in Canada.

An evaluation of available scientific information found that products containing chlorothalonil 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 chlorothalonil 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.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects all end-use products containing chlorothalonil registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document<sup>1</sup> that summarizes the science evaluation for chlorothalonil and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. This Summary describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of chlorothalonil.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to [Publications](#).

## 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](#), *Pest Management Regulatory Agency Re-evaluation Program*, presents the details of the re-evaluation activities and program structure. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please refer to the following:

- [Protecting Your Health and the Environment](#)
- [Pesticide Registration Process](#)
- [Pesticide Risk Reduction Program](#)

Given the outcome of foreign reviews, updated human health and environmental risk assessments and a review of the chemistry of Canadian products, the PMRA is proposing a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of chlorothalonil. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal [Toxic Substances Management Policy](#) [TSMP]).

For more details on the information presented in this summary, please refer to the Science Evaluation section of Proposed Re-evaluation Decision PRVD2011-14.

## What Is Chlorothalonil?

Chlorothalonil is a fungicide that is used to control fungal foliar disease of greenhouse (celery seedbed only) and field-grown crops [asparagus, blueberry, carrot, celery, chickpea, cole crops, cranberry, cucurbit, dry pea, evening primrose, ginseng, lentil, onion (dry bulb, green), parsnip, potato, strawberry, stone fruits, sweet corn, tomato, wheat], mushrooms, turf (specifically sod farms, and golf greens, tees and fairways), field-grown and greenhouse ornamentals and conifers, and is registered to control mildew in paints. Chlorothalonil is applied using either groundboom, airblast, backpack or aerial spray equipment, by farm workers. It can also be applied through the irrigation equipment in cranberry bogs and in mushroom houses using central or portable tanks for drench treatment. To control mildew in paints, chlorothalonil can be applied as a powder during the pigment grinding operation of the manufacturing process or applied as an aqueous dispersion during the pigment grinding operation, during or after letdown, or post-added to the finished product.

## Health Considerations

### Can Approved Uses of Chlorothalonil Affect Human Health?

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

People could be exposed to chlorothalonil by consuming food and water, through residential exposure (for example, golf courses and treated paint), while 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.

### 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.

Chlorothalonil is currently registered in Canada for use on asparagus, blueberry, cherry, chickpea, carrot, celery, cranberry, cole crops, cucurbits, evening primrose, ginseng, lentils, mushroom, nectarine, onions, parsnip, peach, peas (dry), potato, strawberry, sweet corn, tomato and wheat, and could be used in other countries on crops that are imported into Canada. MRLs established for chlorothalonil are listed in Appendix VI. 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 will be implemented in the future, as indicated in the December 2009 Information Note, [Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue](#).



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## Environmental Considerations

### What Happens When Chlorothalonil Is Introduced Into the Environment?

Chlorothalonil poses a potential risk to aquatic organisms, therefore additional risk reduction measures need to be observed.

When applied in the Canadian environment chlorothalonil is expected to be non-persistent in soil. Chlorothalonil is immobile in most soils and has a low potential to leach to groundwater. The major transformation product SDS-3701, however, is persistent in soil and has a potential to leach in some soils. Chlorothalonil may enter aquatic environments via spray drift and run-off. Once in the aquatic environment chlorothalonil is not persistent in surface waters and is expected to bind strongly to suspended particles and to partition into sediment. Residues of chlorothalonil have been detected in surface waters in sub-arctic and arctic lakes which show that it is subject to long range transport to remote regions.

The use of chlorothalonil is not expected to present a risk to terrestrial organisms including earthworms, bees, non-target plants, birds and small wild mammals. The major transformation product SDS-3701 is more toxic than chlorothalonil to birds and mammals, however, it is also not expected to present a risk to these organisms following applications of chlorothalonil in Canada.

In the aquatic environment chlorothalonil may pose a risk to some non-target aquatic organisms (particularly fish) as a result of spray-drift and run-off. In order to minimize the potential exposure to aquatic organisms, strips of land between the site of application and the aquatic areas (buffer zones) will be left unsprayed. The width of these buffer zones will be specified on the product label.

Several fish kill incidents associated with run-off of chlorothalonil residues have been reported in Canada and the U.S.A.

### 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 chlorothalonil, the PMRA is proposing further risk-reduction measures for product labels.

### Human Health

- Additional protective equipment to protect workers
- A restricted-entry interval to protect workers re-entering treated sites;
- A statement restricting entry into treated areas for use on turf (including golf greens, tees and fairways);
- A restriction of the number of applications per floral production cycle on greenhouse cut flowers; and
- A reduction of maximum application rates on golf courses.

### Environment

- Additional advisory label statements to reduce potential surface water contamination;
- Buffer zones to protect non-target aquatic organisms; and
- Changes to maximum application rate or number of yearly applications.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

### What Additional Scientific Information Is Required?

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.

### Next Steps

Before making a final re-evaluation decision on chlorothalonil, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision<sup>2</sup> document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

<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*.

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