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Consumer Product Safety

Proposed Re-evaluation Decision PRVD2011-07, Thiophanate-methyl

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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 PRVD2011-07, *Thiophanate-methyl*, please contact our [publications office](#).

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

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What Is the Proposed Re-evaluation Decision?

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

Preliminary risk and value assessments for thiophanate-methyl were published in [Re-evaluation Note REV2007-12, Preliminary Risk and Value Assessments of Thiophanate-Methyl](#) (27 September 2007). The PMRA identified potential risks to the environment, to workers both during application and during re-entry activities and to the general population through drinking water exposure. By means of REV2007-12, the PMRA invited the public and all interested parties to submit information that could be used to refine the assessments and/or mitigate exposure risks.

Comments, data and information received in response to REV2007-12 were reviewed and used to revise the risk and value assessments, as necessary, and to propose regulatory action. Appendix I of Proposed Re-evaluation Decision PRVD2011-07, *Thiophanate-methyl*, summarizes the comments received during the consultation process and provides the PMRA's response to these comments.

An evaluation of available scientific information found that products containing thiophanate-methyl do not present unacceptable risks to human health or the environment when used according to revised label directions. The PMRA is proposing a requirement for additional data and risk-reduction measures on labels to further protect human health and the environment, as a condition for continued registration

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

Proposed Re-evaluation Decision PRVD2011-07, *Thiophanate-methyl* is a consultation document that summarizes the science evaluation for thiophanate-methyl and presents the reasons for the proposed re-evaluation decision. The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of thiophanate-methyl.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of Proposed Re-evaluation Decision PRVD2011-07, *Thiophanate-methyl*. 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, PMRA Re-evaluation Program](#), presents the details of the re-evaluation activities and program structure.

Thiophanate-methyl was re-evaluated under Program 2 which includes all products for which a Canadian regulatory decision requires a detailed in-house re-evaluation covering the full range of assessments of the risks to human health and the environment, as well as consideration of value. In particular, an assessment of efficacy may be performed where there is the need to reduce identified risks to human health and the environment through the reduction of use rates or frequency of use.

What is Thiophanate-methyl?

Thiophanate-methyl (TPM) is a broad spectrum, Resistance Management Group 1 (methyl benzimidazole carbamate) fungicide. Thiophanate-methyl is a systemic fungicide with protective and curative action. The systemic action of this fungicide results in disruption of fungal mitosis, and the mode of action is by inhibition of tubulin formation. The registered uses (not including emergency registrations) of thiophanate-methyl belong to the following use site categories: greenhouse non-food crops, terrestrial food crops, outdoor ornamentals (Commercial and Domestic Class products), turf and seed treatment for food and feed. It is applied by means of watering equipment, ground and aerial hydraulic sprayers, dry seed treatment container or seeder box, slurry machines or hand mixing with paddle or shovel, granular spreader and squeeze duster by farmers, farm and nursery workers, professional applicators, and residential gardeners. Carbendazim is the primary metabolite of thiophanate-methyl.

Health Considerations

Can Approved Uses of Thiophanate-Methyl Affect Human Health?

Thiophanate-methyl is unlikely to affect human health when used according to the revised label directions, which include additional risk-reduction measures. Potential exposure to thiophanate-methyl may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing 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 the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The cancer risk estimates include a number of conservative (health protective) assumptions that may overestimate exposure, and therefore risk. The application of the proposed mitigation measures reduces the risk for postapplication activities. Proposed protective measures to reduce worker exposure require consultation with user groups to determine their feasibility and acceptability to the agricultural community. Additional data such as information on typical use pattern (typical rates, number of applications, survey information on critical worker activities that may take place during the application window, etc.) may also help to refine the current risk assessment and could reduce the proposed restricted-entry intervals.

To address most occupational concerns, additional risk-reduction measures are required on thiophanate-methyl labels. Thiophanate-methyl is unlikely to affect human health for workers when used according to the revised label directions. Most of these risk reduction measures are feasible but some are not. The PMRA is soliciting feedback on these proposed measures.

Non-cancer risks from drinking water exposure are not of concern. Potential cancer risk from drinking water exposure is uncertain, as estimates are based on conservative upper bound assumptions from water modelling. Once further information on the use pattern is considered, exposure from drinking water will be reassessed.

Residues in Food and Water

Dietary acute and chronic risks from food are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

The acute and chronic dietary (food only) exposures to thiophanate-methyl are less than the reference doses for all population subgroups. Therefore, acute and chronic dietary exposures to thiophanate-methyl are not of concern.

The acute and chronic dietary (food only) exposure to carbendazim, the primary metabolite of thiophanate-methyl, are less than the reference doses for all population subgroups. Therefore, acute and chronic dietary exposures to carbendazim are not of concern.

The lifetime cancer risk from food-only exposure to both thiophanate-methyl and carbendazim is not of concern.

Dietary risks from the acute and chronic aggregate exposures to food and drinking water to thiophanate-methyl and carbendazim are not of concern.

Potential concentrations of thiophanate-methyl and carbendazim in drinking water sources were estimated using modelling results only, as no reliable monitoring data were available. These modelled estimates are developed with a number of conservative assumptions and are generally considered to be upper-bound estimates. These drinking water estimates were combined with the food-only exposure to estimate the potential aggregate exposure from both food and drinking water.

The acute and chronic exposures to thiophanate-methyl from food and drinking water sources are less than the reference doses for all population subgroups. Therefore, acute and chronic dietary exposure to thiophanate-methyl are not of concern.

The acute and chronic exposures to carbendazim, the primary metabolite of thiophanate-methyl, from food and drinking water sources are less than the reference doses for all population subgroups. Therefore, acute and chronic dietary exposure to carbendazim are not of concern.

Lifetime cancer risk estimates exceed 1×10^{-6} when dietary (food-only) and drinking water exposures are aggregated.

The lifetime cancer risk from food and drinking water exposure to both thiophanate-methyl and carbendazim is estimated to be greater than 1×10^{-6} . However, the water modelling estimates used a number of conservative assumptions and are considered upper-bound estimates. Upon receipt of confirmatory data requested in this PRVD, updated use pattern information including drift considerations, application rates, timing of application and regional scenarios will be used to revise the drinking water estimates.

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 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. Generally, food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Maximum residue limits (MRLs) of thiophanate-methyl in or on food are currently established under the *Pest Control Products Act*. Canadian food crop uses include apples, cherries, dry common beans, lowbush blueberries, nectarines, peaches, pears, plums, potatoes (cut seed), prunes, raspberries, strawberries, sugar beets, sweet corn and white beans. The residue definition is methyl 1-(butylcarbamoyl)benzimidazol-2-ylcarbamate (benomyl), methyl benzimidazol-2-ylcarbamate (carbendazim) and 1,2-di-(3-methoxy-carbonyl-2-thioureido)benzene (thiophanate-methyl), expressed as carbendazim. These MRLs and the residue definition are common for the pesticides benomyl, carbendazim and thiophanate-methyl. 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.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern when used according to revised label directions.

Thiophanate-methyl is registered for use on residential roses, flowers, ornamentals and junipers. Cancer and non-cancer risk estimates associated with applying dusts to residential ornamentals are not of concern, if a new label statement is implemented limiting the use to 3 applications per year.

Non-occupational postapplication exposure may occur through gardening in treated areas or golfing on treated golf turf. Non-occupational postapplication risk is not of concern for gardeners and golfers, provided the maximum application rate for golf course turf is reduced, as proposed by the registrant.

Aggregate risk from exposure incurred as a patron of a "Pick Your Own" Orchard or Berry facility was not assessed.

"Pick Your Own (PYO)" facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled thiophanate-methyl products. Estimates of exposure that aggregate the dermal exposure incurred during harvest and the dietary exposure from consuming fresh fruit were not assessed for thiophanate-methyl.

Occupational Risks From Handling Thiophanate-methyl

The majority of occupational risks are not of concern provided additional mitigation measures are followed.

Occupational risk assessments consider exposure to workers who mix, load, and apply the pesticide. Most occupational risks are of concern for agricultural scenarios based on the current use pattern. However, if engineering controls and/or personal protective equipment are used, the majority of uses have no health concerns. These measures are needed to minimize potential exposure and protect worker's health. Regarding commercial seed treatment, additional data are required for continued registration, as risks to workers continue to be of concern after consideration of all feasible mitigation measures. For those uses that continue to have health risk concerns, further mitigation or consideration of removal of the use is needed.

Postapplication risks are not of concern provided additional mitigation measures are followed.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Based on the current use pattern for agricultural scenarios reviewed for this re-evaluation, non-cancer and cancer postapplication risks to workers performing activities, such as thinning, pruning and harvesting of most crops, did not meet current standards and are of concern. However, when the proposed mitigation measures such as lengthened restricted-entry intervals, restricting the number of applications and lowering application rates are considered, the risks to postapplication workers are acceptable. Some of the proposed restricted-entry intervals are not considered agronomically feasible. The PMRA is requesting comments on the feasibility of the restricted-entry intervals. The generation of additional data may refine the current risk assessment and would be required to reduce the proposed restricted-entry intervals.

Environmental Considerations

What Happens When Thiophanate-Methyl Is Introduced Into the Environment?

The risk from thiophanate-methyl to birds and mammals is not a concern, given their mobile nature, and hence, reduced exposure. Thiophanate-methyl has negligible risk to aquatic organisms, except for risk to amphibians. The transformation product, methyl 2-benzimidazolylcarbamate (carbendazim) poses chronic risk to aquatic invertebrates. Additional risk reduction measures need to be observed.

As a result of the use of thiophanate-methyl outdoors, it can be found in soil and water. However, it is not persistent as it is rapidly broken down into the transformation product carbendazim. The latter persists in soil and water. Carbendazim adsorbs to soil and so is only slightly mobile in soil.

Foliar applications of thiophanate-methyl do not present an acute risk to birds at the maximum application rates used in agriculture (2 applications at 1.575 kg a.i./ha). However, at the higher application rates used on turf (12.25 kg a.i./ha), there is a risk to small birds when consumed in the diet. This conclusion was based on the conservative assumption that 100% of the diet is contaminated, when the birds are present in-field. However, given the mobile nature of birds the exposure would be less. When birds are present off-field, the risk from spray applications is negligible. With respect to reproductive effects in birds present in-field, the level of concern was not exceeded except at the application rates used on turf. Off-field, the reproductive risk was negligible. Granular applications of thiophanate-methyl which are used on turf, did not exceed the level of concern for acute risk, except for small birds the size of a sparrow.

Thiophanate-methyl when used in turf, poses an acute risk to small mammals present in-field but not when present off-field. Use in turf also poses a dietary risk to small mammals present in-field and at a reduced level off-field. The reproductive level of concern is exceeded particularly when used in turf to small mammals present in-field, but is negligible off-field. The assessment of risk to small mammals was also based on the conservative assumption that 100% of the diet is contaminated. Foliar applications of thiophanate-methyl do not pose a risk to bees present in-field, except at the application rates used on turf. The risk to bees is negligible off-field. It poses a risk to earthworms present in-field at nearly all application rates, while off-field the risk is negligible at all application rates, except mainly at the application rates used in turf.

A refined assessment of the risks to aquatic life indicates that thiophanate-methyl in runoff and spray drift is not a concern (acute or chronic) to fish at the application rates used in agriculture and on turf. Runoff and spray drift do not present an acute risk to aquatic invertebrates. However, the chronic risk level of concern for aquatic invertebrates is exceeded following exposure to the moderately persistent transformation product methyl 2-benzimidazolylcarbamate that is formed in the water from both runoff and spray drift of thiophanate-methyl. Thiophanate-methyl spray drift into aquatic habitat poses some risk to amphibians but risk is negligible from exposure through runoff. The risk to aquatic plants and algae from thiophanate-methyl from spray drift or from runoff is negligible.

Value Considerations

What is the Value of Thiophanate-methyl?

Thiophanate-methyl has a number of important uses when applied as a seed treatment or when applied by drench and foliar means.

Important fully registered uses of thiophanate-methyl include seed treatment use on dry common beans for the control of seed-borne anthracnose, potato seed treatment for the control of several seed-borne and soil-borne diseases, and turf treatments for the control of several fungal diseases. Drench and foliar treatments are also important to the potted ornamentals industry for the control of several soil-borne and foliar plant diseases of ornamentals that need to be produced to very high quality standards, especially for export. The latter industry typically lacks effective alternatives. The floriculture industry produces high value crops and is a significant player in the horticultural segment of the economy of several Canadian provinces.

Thiophanate-methyl has been used extensively in agriculture and horticulture for over thirty years and is important in resistance management due to its systemic activity.

This active ingredient is still a component in the management of several diseases, allowing fungicide rotation to prevent or delay the development of fungicide resistance. Because of its systemic properties, its wide pest control spectrum and ease of use, thiophanate-methyl is of economic value to the seed potato, dry bean seed, greenhouse ornamental and turf industries, where it is an efficient and economical method of controlling several important diseases with a single application. Since thiophanate-methyl is a systemic active ingredient, unlike many alternative products, it allows for flexible methods of application and timing on many crops as the active ingredient is transported to the site of infection.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to [protect human and environmental health](#). These directions must be followed by law.

Risk-reduction measures are being proposed to address potential risks identified in this assessment. These measures, in addition to those already identified on existing thiophanate-methyl product labels, are designed to further protect human health and the environment. The following additional key risk-reduction measures are being proposed.

Human Health

To protect mixer/loader/applicators:

- Additional protective equipment when mixing/loading and applying to all crops.
- * Packaging of all thiophanate-methyl products currently listed as wettable powders in water soluble packaging, except for those intended for seed treatment use.
- Limited amount of thiophanate-methyl used per day for several crops (white beans, outdoor ornamentals, greenhouse potted ornamentals, dry common beans on-farm seed treatment, potatoes on-farm cut seed treatment).
- * Restrictions on number of applications allowed per season.

To protect workers entering treated sites:

- Restricted-entry Intervals are required for all crops.
- * Turf use limited to golf course greens and tees only.
- * Restrictions on number of applications allowed per season.
- * Maximum turf rate reduced to 12.25 kg a.i./ha.

* These risk reduction measures were proposed by the Registrant and/or growers.

Environment

- Additional advisory statements to protect non-target species.
- Buffer zones for aquatic habitats.

What Additional Scientific Information Is Required?

Confirmatory data will be required under section 12 of the *Pest Control Products Act*. The registrants of thiophanate-methyl must provide data or an acceptable scientific rationale to the PMRA for the following requirements as listed in Appendix II.

Human Health

Worker exposure studies for the specific uses indicated:

- mixer/loader/applicator - passive dosimetry data or biological monitoring data for on-farm potato seed treatment and planting
- mixer/loader/applicator - passive dosimetry data or biological monitoring data for dry common beans and sweet corn on-farm planting
- mixer/loader/applicator - passive dosimetry data or biological monitoring data for commercial seed treatment (dry common beans and sweet corn)

Residue chemistry studies:

- Enforcement analytical methodology
- Inter-laboratory analytical methodology validation
- Multi-residue analytical methodology evaluation

Toxicology data are required:

- Developmental neurotoxicity in rats (DACO 4.5.14) for thiophanate-methyl
- Developmental neurotoxicity in rats (DACO 4.5.14) for carbendazim

PMRA also requires any other studies conducted in response to the EPA 2001 RED.

Next Steps

Before making a re-evaluation decision on thiophanate-methyl, 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, which 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.

The PMRA is requesting comments from registrants and grower groups on the feasibility of lower application rates, product packaging, additional protective equipment, limits to amount of product used per day, and restricted-entry intervals. Specifically, the PMRA is requesting comments on the proposed restricted-entry intervals as listed in Table 8.1.1.1 of Proposed Re-evaluation Decision PRVD2011-07, *Thiophanate-methyl* and the proposed turf restriction for use on golf course greens and tees only. The PMRA is also soliciting other possible risk mitigation proposals.

Other Information

At the time that the re-evaluation decision is made, the PMRA will publish an Evaluation Report on thiophanate-methyl in the context of this re-evaluation decision (based on the Science Evaluation of Proposed

Re-evaluation Decision PRVD2011-07, *Thiophanate-methyl*). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

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