Tetramethrin and Its Associated End-use Products

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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 safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Tetramethrin is a synthetic pyrethroid insecticide registered for use on a broad spectrum of insect pests on a variety of sites including: structural sites (indoors and outdoors), indoor house plants, outdoor wasp and hornet nests, outdoor ornamentals and outdoor residential sites. Registered products containing tetramethrin in Canada can be accessed through the PMRA’s label transcription service.1

This document presents the regulatory decision2 for the re-evaluation of tetramethrin, including the required risk mitigation measures to protect human health and the environment. All products containing tetramethrin that are registered in Canada are subject to this re-evaluation decision. This re-evaluation decision has undergone consultation on the Proposed Re-evaluation Decision PRVD2016-10, Tetramethrin,3 which ended on 10 May 2016.

The PMRA received two comments relating to the health risk assessment and the implementation of label amendments. These comments are summarized in Appendix I along with the responses by the PMRA. The comments did not result in a change to risk assessments. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2016-10. A reference list of data used as the basis for the proposed re-evaluation decision is included in PRVD2016-10, and further data used in the re-evaluation decision is listed in Appendix III.

Regulatory Decision for Tetramethrin

The PMRA has completed the re-evaluation of tetramethrin. Under the authority of the Pest Control Products Act, the PMRA is granting continued registration of products containing tetramethrin for sale and use in Canada. An evaluation of available scientific information found that most uses of tetramethrin products do not present unacceptable risks to human health or the environment when used according to the conditions of registration, including amended label directions. Certain uses of tetramethrin are cancelled to address potential risks of concern to human health. Label amendments, as summarized below and listed in Appendix II, are required for all technical and end-use products. No additional data are requested at this time.

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2 “Decision statement” as required by subsection 28(5) of the Pest Control Products Act.

3 “Consultation statement” as required by subsection 28(2) of the Pest Control Products Act.
Risk Mitigation Measures

Registered pesticide product labels include specific direction for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law.

Human Health

- Cancellation of garden broadcast treatments, indoor broadcast treatments and indoor perimeter treatments is required to protect homeowners and those entering treated residential areas.

- Updated label statements are required to meet current label standards and minimize unnecessary exposure.

Environment

- Advisory label statements are required to protect bees and aquatic organisms.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all products labels sold by registrants no later than 24 months after the publication date of this decision document.

Other Information

Any person may file a notice of objection\(^4\) regarding this decision on tetramethrin 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 the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA Pest Management Information Service.

\(^4\) As per subsection 35(1) of the *Pest Control Products Act.*
Appendix I  Comments and Responses

1.0  Comments Relating to Occupational and Residential Exposure

Comments relating to occupational and residential exposure were received from the Canadian Consumer Specialty Products Association.

Comment 1.1

The dermal absorption factor of 50% determined by the PMRA is overly conservative and is not in keeping with the findings of the United States Environmental Protection Agency (USEPA). Tetramethrin has an acute LD$_{50}$ of > 5000 mg/kg in rats, and rat skin is anatomically different than human skin in that it is typically more permeable to chemicals; and therefore represents a worst-case scenario for human skin. The Non-Dietary Exposure Task Force’s study “Pyrethroid Exposure: Contact Transfer and Dermal Absorption Exposure of Surface Residues” indicates that the dermal absorption of pyrethrins is 0.74%.

PMRA Response

The PMRA acknowledges that rat skin is typically more permeable to chemicals than human skin. As such, dermal absorption values derived from rat in vivo studies are considered to be health protective estimates when used in health risk assessments for pest control products. As no dermal absorption study was submitted for tetramethrin, a weight-of-evidence approach was used and the PMRA was able to refine the dermal absorption factor from 100% to 50%.

The study “Pyrethroid Exposure: Contact Transfer and Dermal Absorption Exposure of Surface Residues” was designed to estimate the transfer of pyrethrins, piperonyl butoxide and $N$-Octyl bicycloheptene dicarboximide from treated carpet to human volunteers. Volunteers performed a set of floor exercises while wearing body dosimeters on carpeting which had been treated with a total release fogger containing these chemicals. Urine samples were collected from volunteers and the amount of the excreted metabolite was compared to the parent compound that was transferred to the body suit, gloves and socks. Although the study provides data regarding indoor exposure, the study was not specific to tetramethrin, which is a requirement for the determination of a dermal absorption factor.

Since the comments provided did not include information that could be used to further revise the current dermal absorption factor of 50% for tetramethrin, this component of the risk assessment remains unchanged from that used in PRVD2016-10.

Comment 1.2

Tetramethrin degrades quickly, and given the use pattern, exposure for the general population is expected to be low.

PMRA Response

The exposure and risk assessment estimated the potential exposure of Canadians to tetramethrin based on the registered uses and application rates. The models and assumptions, such as the USEPA Residential Standard Operating Procedures, were informed by registrant studies and
confirmed that both applicator and postapplication exposure to tetramethrin will occur when used in accordance with label instructions.

For outdoor uses of tetramethrin, in the absence of chemical-specific data, a daily default 10% dissipation rate was applied in the risk assessment to account for dissipation following multiple treatments that may occur through the season. For the indoor assessment, it was assumed that only single applications are made during a single year. The methodologies applied in the indoor inhalation postapplication risk assessment of tetramethrin accounted for degradation by applying a rate of decay for airborne particles.

Environmental data indicate that tetramethrin has a half-life of 12.5-14 days in soil and 13-25 days in water. Since the postapplication assessment assumes that zero days have elapsed following an application of tetramethrin, degradation is not expected to have a significant impact on available residues in the risk assessment. Data are not available to characterize the persistence of tetramethrin residues in indoor environments. It is assumed that residues will be more persistent indoors relative to those out of doors. The tetramethrin risk assessment accounts for degradation appropriately.

2.0 Comments Relating to Label Changes

Comments relating to the implementation of label amendments were received from the registrant Premier Tech.

Comment 2.1

Several aerosol products contain both d-phenothrin and tetramethrin. Re-evaluation decisions for d-phenothrin (Re-evaluation Decision RVD2016-05, *d-Phenothrin*) and tetramethrin will impact the same marketplace labels, but not within a timeframe that will make it practical or possible to incorporate all required label changes resulting from both re-evaluations within the same production revision schedule. The PMRA should align implementation timeframes and use consistent wording for label changes across pyrethroids under re-evaluation. This will allow registrants to combine all label changes related to these active ingredients in a single update.

PMRA Response

The PMRA recognizes that the implementation of label changes for end-use products co-formulated with two or more pyrethroid active ingredients may be complicated by the timing of their respective re-evaluation decisions. The PMRA is considering aligning the final re-evaluation decision dates for several pyrethroids that are currently in the review phase. However, given that risks of concern have already been identified for tetramethrin in PRVD2016-10, the final decision for this active ingredient, as well as the related label amendments, will not be further delayed. The PMRA is making efforts to standardize the label language, namely by clarifying the different application types for structural uses and developing baseline precautionary statements.
Appendix II  Label Amendments for Products Containing Tetramethrin

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

I. FOR TECHNICAL GRADE PRODUCTS AND MANUFACTURING CONCENTRATES

Under ENVIRONMENTAL HAZARDS:

Add the following: “Toxic to aquatic organisms.”

II. FOR END-USE PRODUCTS

The following residential uses are to be cancelled: outdoor broadcast treatments in gardens, indoor broadcast treatments and indoor perimeter treatments. All label directions related to these uses must be removed from end-use product labels.

Under USE PRECAUTIONS:

Add the following: “Keep out of reach of children and pets.”

Remove any statement concerning re-entry from domestic-class product labels.

Where applicable, add the following to product labels with indoor uses:

“Remove animals for a minimum of 1 hour when spraying room. Following treatment, ventilate all rooms, do not access for a minimum of 15 minutes and do not re-enter before ventilation is complete. Avoid contact with treated surfaces until dry.”

Under ENVIRONMENTAL HAZARDS:

Add: “Toxic to aquatic organisms.”

Add the following to product labels with outdoor uses: “Toxic to bees. Do not spray bees.”

Under DIRECTIONS FOR USE:

Remove any statement such as “Repeat as necessary” or “Repeat at frequent intervals” from product labels with indoor uses.

Remove any statement targeting stray insects in the home from product labels with indoor uses.

Add the following to appropriate domestic-class product labels with indoor uses:

“Do not use tetramethrin in food handling, storage or preparation areas while food is present.”
“Use only for spot or crack and crevice applications.”

Add the following to appropriate domestic-class product labels with outdoor uses:

“Use only for spot, perimeter or crack and crevice applications.”

Make the following changes to products registered for use on wasp and hornet nests:

Remove any statements concerning removal of the treated nest.

Add: “After 48 hours, wear gloves to remove the treated nest.”

As appropriate, add definitions for spot treatment, perimeter application, crack and crevice application and residential areas:

“A spot treatment is made to a localized surface area not greater than 0.2 m². Spots are not to be adjoining and the total area of spots is not to exceed 10% of the surface area being treated (for example, floors, walls, ceilings).”

“A crack and crevice application is made into narrow openings on the surfaces of the structure. Such openings commonly occur at expansion joints, utility entry points and between different elements of construction (for example, baseboards, moulding).”

“An exterior perimeter/band application of a pest control product is made as a band or strip less than 1 m wide.”

“Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public including children may potentially be exposed. Non-residential areas include, but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock housing and poultry, pet kennels).”
## Appendix III  Additional References

### A. List of Studies/Information Submitted by Registrant

<table>
<thead>
<tr>
<th>PMRA Document Number</th>
<th>Reference</th>
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<tbody>
<tr>
<td>1826572</td>
<td>2004, Pyrethroid Exposure: Contact Transfer and Dermal Absorption Exposure of Surface Residues, DACO 5.8.</td>
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### B. Published Information

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