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Registration Decision

RD2016-16

# Thymol

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## Registration Decision for Thymol

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted full registration for the sale and use of Thymol E\_9509758 and Thymovar containing the technical grade active ingredient thymol to control Varroa mites (*Varroa destructor*) on honey bees (*Apis mellifera*).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document<sup>1</sup> Proposed Registration Decision PRD2010-18, *Thymol*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for thymol, summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-18. This decision is consistent with the proposed registration decision stated in PRD2010-18.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-18, *Thymol* that contains a detailed evaluation of the information submitted in support of this registration.

### What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>3</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value<sup>4</sup> when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as 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 when predicting the impact of pesticides. For

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<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*.

<sup>3</sup> "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

<sup>4</sup> "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

## **What Is Thymol?**

Thymol is a volatile oil which is found in oil of thyme. While the mode of action of thymol is not known, it is believed that the site of action is the nervous system in insects. Thymol vapourizes at varying rates, depending on temperature. Thymovar is a product containing thymol for control of varroa mite (*Varroa destructor*) in honeybee hives. Through volatilization from the Thymovar wafers, thymol vapours build up in the hive. Varroa mites are more sensitive to thymol than bees; therefore, the thymol vapours are at a high enough concentration to be toxic to varroa mites but are not high enough to harm bees. Thymol is not effective on mites within brood cells; therefore, the treatment period must be long enough to ensure that the brood in cells which are capped at the onset of treatment have time to emerge.

## **Health Considerations**

### **Can Approved Uses of Thymol Affect Human Health?**

**Thymol is unlikely to affect your health when used according to label directions.**

Exposure to thymol may occur when handling and applying the end-use product, Thymovar. When assessing health risks, two key factors are considered: the levels where 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 the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Thymol E\_9509758, is of moderate acute toxicity by the oral route, slight acute toxicity by the dermal route, and low acute toxicity by inhalation. Thymol is corrosive to the eyes and extremely irritating to the skin. Additionally, it is a known respiratory irritant and a dermal sensitizer. Based on available information and a long history of safe use as a food additive, cosmetics ingredient, and its presence in foods and beverages, exposure to thymol is unlikely to result in any short-term toxicity, prenatal developmental toxicity or genotoxicity.

### **Residues in Water and Food**

**Dietary risks from food and water are not of concern.**

The amount of thymol present as residue in honey following the application of Thymovar in beehives is not expected to exceed natural or artificial amounts typically used to flavour foods and beverages. Therefore, the direct application to beehives with wafers impregnated with thymol is not expected to result in any dietary risk due to exposure from food or water.

## **Occupational Risks From Handling Thymovar**

**Occupational risks are not of concern, when Thymovar is used according to label directions, which include protective measures.**

Pesticide applicators can come into direct contact with thymol when handling and applying Thymovar to beehives. Potential exposure routes include direct contact with the skin and indirect contact of thymol vapour with the eyes and lungs. Although thymol is known for its corrosive and irritating properties, the product label contains a number of mitigative measures to limit potential exposure to the applicators.

As Thymovar is a Commercial class product that requires direct application inside beehives, bystander exposure is expected to be negligible and therefore not of concern.

## **Environmental Considerations**

### **What Happens When Thymol Is Introduced Into the Environment?**

Thymol is a naturally occurring essential oil that transforms rapidly under environmental conditions. During the use of Thymovar for control of varroa mite in beehives, exposure of the chemical to the environment is expected to be limited. The product is applied as textile wafers containing the active ingredient thymol, which evaporates into the closed beehives.

Environmental exposure would occur primarily through leakage during application or from improper disposal of used wafers. Based on limited environmental exposure, the chemical's natural occurrence and the likelihood for relatively rapid transformation under environmental conditions, the proposed use of thymol is not expected to pose a significant risk to the environment. Therefore, further review of the environmental chemistry, fate, and toxicology of thymol was not considered necessary.

## **Value Considerations**

### **What Is the Value of Thymovar?**

**Thymovar controls varroa mite (*Varroa destructor*) in honeybee hives.**

Efficacy studies from various locations, including Quebec, Switzerland, Portugal, Turkey, Italy, Germany, Greece, and the Netherlands, were reviewed in support of Thymovar. These studies found that Thymovar generally provided control of varroa mites in excess of 90% when applied according to label directions, with no significant adverse effects. Thymovar is used for control of varroa mite in honeybee hives by applying 2 consecutive applications of ½ a wafer in nucleus hives, 1 wafer in 1 storey hives, or 2 wafers in 2 storey hives. Applications are left in the hive for 3-4 weeks. Applications must only be made when temperatures are above 12°C and below 30°. No significant adverse effects are expected provided that the Thymovar wafers are not placed directly over brood and temperatures do not exceed 30°C.

## 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.

The key risk-reduction measures being proposed on the label of Thymovar to address the potential risks identified in this assessment are as follows.

### Human Health

The statements, “WARNING – POISON”, “DANGER – CORROSIVE TO EYES”, and “DANGER – SKIN IRRITANT” have been included on the principal display panel of the general label and “Harmful or Fatal if swallowed”, “CORROSIVE to the eyes”, “CORROSIVE to the skin”, “DO NOT get on skin, eyes or clothing”, “Avoid inhaling the vapour” and “Handle Thymovar in a well-ventilated area” have been included in the Precautions section of the secondary display panel of the product label. Furthermore, the product label instructs applicators to wear chemical resistant gloves, long-sleeved shirt and pants, shoes and socks, and eye goggles or a face shield when handling Thymovar.

The Thymovar product label requires that all of the honey supers are removed prior to treatment and that the product be applied before the honey flow or after all surplus honey has been removed. Additionally, the label also instructs beekeepers not to extract honey from treated combs of the brood chambers in the following spring.

### Other Information

The relevant test data on which the decision is based (as referenced in PRD2010-18, *Thymol*) are available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa). For more information, please contact the PMRA’s Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.info@hc-sc.gc.ca).

Any person may file a notice of objection<sup>5</sup> regarding this registration decision within 60 days from the date of publication of this Registration 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 Health Canada’s website (Request a Reconsideration of Decision) or contact the PMRA’s Pest Management Information Service.

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<sup>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.