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RD2008-05

## Registration Decision

# CM/LR TT Pheromone Technical

*(publié aussi en français)*

**9 April 2008**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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**Canada** 

ISBN: 978-0-662-48446-2 (978-0-662-48447-9)  
Catalogue number: H113-25/2008-5E ( H113-25/2008-5E-PDF)

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# Overview

## Registration Decision for CM/LR TT Pheromone Technical

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and Regulations, is granting full registration for the sale and use of CM/LR TT Pheromone Technical and Isomate-CM/LR TT, which contain the following seven active compounds: (E,E)-8,10-dodecadien-1-ol, 1-dodecanol, 1-tetradecanol, Z-11-tetradecen-1-yl acetate, Z-9-tetradecen-1-yl acetate, Z-11-tetradecen-1-ol, and Z-11-tetradecenal. Isomate-CM/LR TT is proposed for mating disruption of the codling moth and leafroller moths on pome fruit, stone fruit, and tree nut crops.

An evaluation of available scientific information found that, under the 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, *CM/LR TT Pheromone Technical* ([PRD2007-12](#)). This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for CM/LR TT Pheromone Technical and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2007-12. This decision is consistent with the proposed registration decision stated in PRD2007-12.

For more details on the information presented in this Registration Decision, please refer to the related Proposed Registration Decision PRD2007-12, *CM/LR TT Pheromone Technical*, which 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 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.<sup>3</sup> The Act also requires that products have value<sup>4</sup> when used according

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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".

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 (e.g. children) as well as organisms in the environment (e.g. 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 visit the PMRA's website at [www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca).

## **What Is Isomate-CM/LR TT?**

Isomate-CM/LR TT is a slow-release dispenser containing CM/LR TT Pheromone Technical as the active ingredient. CM/LR TT Pheromone Technical contains seven chemical compounds that act as sex pheromones for the codling moth and four species of leafroller moths (obliquebanded, fruittree, threelined, and European leafrollers). Four of the seven chemical compounds in the active ingredient are currently registered in Canadian pest control products. Each of the three new chemical compounds is a part of the sex pheromone for one or more of the four leafroller species. These sex pheromones are produced by female moths and attract male moths for mating.

## **Health Considerations**

### **Can Approved Uses of Isomate-CM/LR TT Affect Human Health?**

**CM/LR TT Pheromone Technical is unlikely to affect your health when Isomate-CM/LR TT is used according to label directions.**

When assessing the health risks of the product Isomate-CM/LR TT, two key factors were considered: the toxicity of the product and the levels to which people may be exposed.

CM/LR TT Pheromone Technical contains the chemical compounds (E,E)-8,10-dodecadien-1-ol, 1-dodecanol, 1-tetradecanol, Z-11-tetradecen-1-yl acetate, Z-9-tetradecen-1-yl acetate, Z-11-tetradecen-1-ol, and Z-11-tetradecenal, which all belong to a group of compounds known as straight chain lepidopteran pheromones (SCLPs). These pheromones are naturally occurring compounds that are produced by many lepidopteran insect species (i.e. moths and butterflies) to communicate chemically with other members of the same species. In general, SCLPs are biodegraded to non-toxic compounds by enzyme systems that are present in most living organisms. Toxicity studies on SCLPs have generally indicated no mammalian toxicity. The PMRA, United States Environmental Protection Agency and European Union regulatory authorities have received no reports of adverse effects to human health from the use of SCLPs.

## **Residues in Water and Food**

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

Since CM/LR TT Pheromone Technical is unlikely to contact the crop or groundwater because it is contained in a discrete dispenser, the likelihood of residues contaminating food or water is negligible.

## **Occupational Risks From Handling Isomate-CM/LR TT**

### **Occupational risks are not of concern when Isomate-CM/LR TT is used according to label directions, which include protective measures.**

Pesticide applicators using Isomate-CM/LR TT may come in direct contact with the product during application. Therefore, the label specifies that applicators must wear suitable protective clothing, including chemical-resistant gloves and eye protection when handling the dispensers. Taking into consideration these label statements and the low toxicity of this product, the risks to applicators are not of concern.

The risk from bystander exposure or postapplication exposure is negligible because CM/LR TT Pheromone Technical is contained in slow-release dispensers that allow the active ingredient to volatilize gradually into the air at rates that are comparable to amounts of pheromone that would be expected during a moth infestation.

## **Environmental Considerations**

### **What Happens When Isomate-CM/LR TT Is Introduced Into the Environment?**

#### **The use of Isomate-CM/LR TT as a mating disruptant poses negligible risk to the environment.**

Isomate-CM/LR TT contains CM/LR TT Pheromone Technical, which is released into the environment through passive vapourization into air from fixed dispensers. The SCLP components of the active ingredient belong to a group of chemicals that are naturally based and known to break down rapidly in the environment.

The amount of active ingredient released through the use of Isomate-CM/LR TT is considered comparable to natural emissions and poses a low risk to non-target species. The active ingredient acts as a mating disruptant and does not have a toxic mode of action.

## Value Considerations

### What Is the Value of Isomate-CM/LR TT?

**Isomate-CM/LR TT has value in disrupting the mating of codling moths and obliquebanded, fruittree, threelined, and European leafroller moths, thus reducing the production of larvae that would otherwise damage pome fruit, stone fruit and tree nut crops.**

Application of Isomate-CM/LR TT dispensers in pome fruit, stone fruit or tree nut orchards produces numerous artificial sources of sex pheromone, which interferes with the ability of male moths to find females for mating. Females that fail to attract mates cannot lay fertile eggs; therefore, the next generation of larvae is reduced, limiting the damage the larvae would otherwise cause. Combining several pheromone components in a single dispenser creates a product that is effective for mating disruption of all five pest species with a single application.

### 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 risk-reduction measures on the label of Isomate-CM/LR TT are acceptable and no further additional risk-reduction measures are required.

### Other Information

1. The relevant test data on which the decision is based (as referenced in this document) 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\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca)).
2. 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 Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website ([www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html](http://www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html)) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail ([pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca)).

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

## References

### A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

#### 1.0 Chemistry

##### Technical Grade Active Ingredient

PMRA Identification Number	Reference
1378500	2006, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.0, 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.2, 2.13.3, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.

##### End-Use Product

PMRA Identification Number	Reference
1369602	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.0
1369605	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.1.1, 3.1.2
1369608	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.1.3, 3.1.4, 3.2.1
1369614	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.3.1, 3.3.2
1369620	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.4
1369624	2006, Part 3, Product Chemistry for Registration of an EP, DACO: 3.5



## 2.0 Impact on Human and Animal Health

PMRA Identification Number	Reference
1378548	2006, Part 4, Acute Toxicology Studies of a TGAI, DACO: 4.1, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.5.4, 4.5.5, 4.5.6
1383360	2006, MSDS-Product, DACO: 0.9
1383362	2006, Comprehensive Data Summary of a TGAI, DACO: 12.7
1369600	2006, Comprehensive Data Summary of an EP, DACO: 12.7
1369635	Part 4, Acute Toxicology Studies of an EP [SUMMARY], DACO: 4.6
1369636	2006, Part 4, Acute Toxicology Studies of a TGAI, DACO: 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.6
1369642	2006, Part 5, Exposure (Occupational and Bystander) of an EP, DACO: 5.1
1369643	2006, Part 5, Exposure (Occupational and Bystander) of an EP, DACO: 5.2
1369582	DACO: 0.9.1

## 3.0 Value

PMRA Identification Number	Reference
1369592	Isomate CM/LR Twin Tube (TT) 2005 Research: Evaluation of efficacy. 4 pp. DACO 10.2.3.3
1485594	2007. No Title. 19 pp. DACO 10.6

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**B. ADDITIONAL INFORMATION CONSIDERED****I) Published Information****1.0 Impact on Human and Animal Health**

PMRA Identification Number	Reference
1413251	2002, ENVIRONMENT DIRECTORATE, JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY. Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control. OECD