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Re-evaluation Decision

RVD2022-06

# Straight Chain Lepidopteran Pheromones and the Associated End-use Products

*Final Decision*

*(publié aussi en français)*

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## Re-evaluation Decision for straight chain lepidopteran pheromones and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental standards and continue to have value. The re-evaluation considers information from various sources such as data and information from pesticide manufacturers and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as risk management approaches and policies.

Straight chain lepidopteran pheromones (SCLPs) are naturally occurring semiochemicals registered to control several different moth populations in pome and stone fruit trees, tree nuts, grapes, outdoor woody ornamental trees, and in forests and woodlands. Currently registered products containing SCLPs can be found in Appendix I.

The Proposed Re-evaluation Decision PRVD2021-07, *Straight Chain Lepidopteran Pheromones and their Associated End-use Products*,<sup>1</sup> containing the evaluation of SCLPs and proposed decision, underwent a 90-day consultation period ending on 29 August 2021. PRVD2021-07 proposed continued registration of SCLPs and all associated registered end-use products for sale and use in Canada. No further risk mitigation measures for product labels were proposed; however, label updates are required to meet current labelling standards (Appendix III).

Health Canada received two comments from members of the public relating to concerns for increase in residues in food and its protection regarding health and the environment. The review of these comments did not change the outcome of the re-evaluation assessments as described in PRVD2021-07. These comments and Health Canada's responses are summarized in Appendix II of this document. A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2021-07.

This document presents the final regulatory decision<sup>2</sup> for the re-evaluation of SCLPs, including the label updates required to meet the current labelling standards. All products containing SCLPs that are registered in Canada are subject to this re-evaluation decision.

Health Canada has completed the re-evaluation of SCLPs. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing SCLPs is acceptable with the label updates (Appendix III). An evaluation of available scientific information found that uses of SCLPs products meet standards for protection of human health and the environment and have acceptable value under the current conditions of use. However, label updates are required to meet current labelling standards (Appendix III).

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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*.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required label updates, as a result of the re-evaluation of SCLPs, are summarized below. Refer to Appendix III for details (same as in PRVD2021-07).

#### **Label updates required to meet current labelling standards:**

- The net content of active ingredient should be described as “product” and not as “pheromone”.
- Add statement regarding cleaning of equipment and disposal of wastes.

#### **Next steps**

To comply with this decision, the required amendments (label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry. Refer to Appendix I for details on specific products impacted by this decision.

#### **Other information**

Any person may file a notice of objection<sup>3</sup> regarding this decision on SCLPs and its associated end-use products 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 section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA’s [Pest Management Information Service](#) by phone (1-800-267-6315) or by e-mail ([pmra-info-arla@hc-sc.gc.ca](mailto:pmra-info-arla@hc-sc.gc.ca)).

The relevant confidential test data on which the decision is based (as referenced in PRVD2021-07) 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.

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## Appendix I Straight chain lepidopteran pheromone pest control product information

**Table 1 Registered technical class products containing straight chain lepidopteran pheromone active ingredients<sup>4</sup>**

Registration number	Registrant	Product name	Formulation type	Guarantee
22898	Pacific Biocontrol Corporation	Codling Moth Pheromone Technical	Liquid	(E,E)-8,10-Dodecadien-1-ol-54.6% 1-Dodecanol-30.65% 1-Tetradecanol-6.23%
29353	Pacific Biocontrol Corporation	CM/OFM TT Pheromone Technical	Liquid	(Z)-8-Dodecen-1-ol Acetate-16.43%* (Z)-8-Dodecen-1-ol-0.23%* (E,E)-8,10-Dodecadien-1-ol-64.78% 1-Dodecanol-10.24% 1-Tetradecanol-2.07% (E)-8-Dodecen-1-ol Acetate-1.20%*
32046	Bedoukian Research, Inc.	Bedoukian CM Pheromone	Solid	(E,E)-8,10-Dodecadien-1-ol-94%
27524	Pacific Biocontrol Corporation	Grape Berry Moth Plus Pheromone Technical	Liquid	(Z)-9-Dodecenyl Acetate-94.87%
27140	Pacific Biocontrol Corporation	Peach Tree Borer Pheromone Technical	Liquid	(Z,Z)-3,13-Octadecadien-1-yl Acetate-89.29%** (E,Z)-3,13-Octadecadien-1-yl Acetate-3.63%
30041	Pacific Biocontrol Corporation	PTB Dual Pheromone Technical	Liquid	(Z,Z)-3,13-Octadecadien-1-yl Acetate-45.75%** (E,Z)-3,13-Octadecadien-1-yl Acetate-46.23%
25893	Bedoukian Research, Inc	Bedoukian 9-Dodecenyl Acetate Technical Pheromone	Liquid	(E,Z)-9-Dodecenyl Acetate-97%
28694	Bedoukian Research, Inc	Bedoukian Spruce Budworm Technical Pheromone	Liquid	(E,Z)-11-Tetradecenal-98%

\* Associated Re-Evaluation: RVD2018-07

\*\* Associated Re-Evaluation: RVD2018-28

<sup>4</sup> As of 7 March 2022, excluding discontinued products or products with a submission for discontinuation.

**Table 2 Registered End-Use Products Containing Straight Chain Lepidopteran Pheromone Active Ingredients<sup>5</sup>**

Registration No.	Class	Registrant	Product Name	Formulation Type	Guarantee
29352	Commercial	Pacific Biocontrol Corporation	Isomate-CM/OFM TT	Slow Release Generator	(Z)-8-Dodecen-1-ol Acetate-15.92%* (Z)-8-Dodecen-1-ol-0.22%* (E,E)-8,10-Dodecadien-1-ol-62.76% 1-Dodecanol-9.92% 1-Tetradecanol-1.40% (E)-8-Dodecen-1-ol Acetate-1.16%*
31589	Commercial	Pacific Biocontrol Corporation	Isomate CM Flex	Slow Release Generator	(E,E)-8,10-Dodecadien-1-ol-52.96% 1-Dodecanol-29.73% 1-Tetradecanol-6.04%
33842	Commercial	Pacific Biocontrol Corporation	Semios CM Eco	Pressurized Product	(E,E)-8,10-Dodecadien-1-ol-18.05%
32047	Commercial	SemiosBio Technologies Inc.	Semios CM Plus	Pressurized Product	(E,E)-8,10-Dodecadien-1-ol-18.05%
27525	Commercial	Pacific Biocontrol Corporation	Isomate-GBM Plus Grape Berry Moth Pheromone	Slow Release Generator	(Z)-9-Dodecenyl Acetate-91.07%
27141	Commercial	Pacific Biocontrol Corporation	Isomate-P Pheromone	Slow Release Generator	(Z,Z)-3,13-Octadecadien-1-yl Acetate-80.4%** (E,Z)-3,13-Octadecadien-1-yl Acetate-3.3%
30042	Commercial	Pacific Biocontrol Corporation	Isomate-PTB Dual	Slow Release Generator	(Z,Z)-3,13-Octadecadien-1-yl Acetate-43.74%** (E,Z)-3,13-Octadecadien-1-yl Acetate-44.2%
32730	Commercial / Restricted	Andermatt Canada Incorporated	Confound SBW	Microcapsule Suspension	(E,Z)-11-Tetradecenal-11%

\* Associated Re-Evaluation: RVD2018-07

\*\* Associated Re-Evaluation: RVD2018-28

<sup>5</sup> As of 7 March 2022, excluding discontinued products or products with a submission for discontinuation

## Appendix II Summary of Comments received during consultation of PRVD2021-07, and the Health Canada response

Commenter	Comment and response
<p>General Public:</p> <p>Two comments were received from the general public</p>	<p>Summary of comments:</p> <p>Two members of the public expressed opposition to any increase in lepidopteran pheromone residue levels in domestic and imported foods, and raised concerns regarding protection of human health and the environment.</p> <p>Health Canada response:</p> <p>Straight chain lepidopteran pheromones (SCLPs) are naturally occurring semiochemicals produced by moths and butterflies. SCLPs used in pest control products are synthetic versions of these naturally occurring compounds. The end-use products approved for use in food and feed crops are contained within ties and/or canisters and are slowly released into the atmosphere; they are not applied directly to food/feed crops or drinking water sources.</p> <p>For re-evaluations, including the re-evaluation of SCLPs, the dietary risk assessment is based on the currently registered use pattern. As such, the re-evaluation does not result in regulatory changes that would result in increased concentrations in foods produced in Canada or imported into Canada.</p> <p>As outlined in the Proposed Re-evaluation Decision PRVD2021-07, <i>Straight Chain Lepidopteran Pheromones and their Associated End-use Products</i>, the potential human health and environmental risks were determined to be acceptable based on the registered use pattern and inherently low toxicity profile of SCLPs.</p>

## **Appendix III Label amendments for products containing straight chain lepidopteran pheromone**

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

To meet current labelling standards, the following label amendments are required for the specified pest control product (PCP) registration numbers:

### **PCP Reg. No. 32047, SEMIOS CM PLUS**

Under “DIRECTIONS FOR USE”, add the following statement:

“DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

### **PCP Reg. No. 27141 and 30042, products containing (E,Z)-3,13 octadecadien-1-yl acetate**

Under NET CONTENTS, the following label amendment is required to clarify the amount of active ingredient:

Replace the word “pheromone” with “product”.