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Proposed Re-evaluation Decision

PRVD2021-07

Straight Chain Lepidopteran Pheromones and their Associated End-use Products

Consultation Document

(publié aussi en français)

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Proposed re-evaluation decision

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 current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies to all re-evaluations.

Straight chain lepidopteran pheromones (SCLPs) are naturally occurring semiochemicals produced by moths and butterflies, and when used in pest control products, SCLPs are synthetic versions of these naturally occurring compounds. The SCLPs are registered to control several different moth populations in pome and stone fruit trees, tree nuts, grapes, outdoor woody ornamental trees (ties and canisters), and in forests and woodlands (pellets and microcapsules via aerial application). When released into the atmosphere, SCLP pesticides act as mating disruptors by interfering with the chemical communication between male and female insects to reduce the overall pest population in target crops.

This document presents the proposed regulatory decision for the re-evaluation of the following SCLPs which the PMRA has grouped on the basis of use pattern as well as their structural and toxicological similarity:

Straight Chain Lepidopteran Pheromone	CAS. No.
(Z)-11-tetradecenal	35237-64-0
(Z)-11-tetradecen-1-ol	34010-15-6
(Z)-9-tetradecen-1-yl acetate	16725-53-4
(Z)-11-tetradecenyl acetate	20711-10-8
1-Tetradecanol	112-72-1
1-Dodecanol	112-53-8
(E,E)-8,10-dodecadien-1-ol (Codlure)	33956-49-9
(Z)-9-dodecenyl acetate	16974-11-1
(E,Z)-9-dodecenyl acetate	Z isomer 16974-11-1 E isomer 35148-19-7
(E,Z)-11-tetradecenal	70893-80-0
(E,Z)-3,13-Octadecadien-1-yl acetate	53120-26-6

Under the authority of the *Pest Control Products Act*, and based on the evaluation of currently available scientific information, products containing a SCLP listed in Appendix I are proposed for continued registration in Canada. When the current label directions are followed, potential risks to human health and the environment are considered to be acceptable. SCLPs have value in providing a non-conventional solution for insect control. Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of the SCLPs, no further risk mitigation measures for product labels are proposed. To meet current standards, label updates for specific products are proposed in Appendix II. This document is

subject to a 90-day public consultation period, during which the public, including the pesticide manufacturers and stakeholders, may submit written comments and additional information to the PMRA.

Next steps

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional scientific information

No additional data are required.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

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

Science evaluation

1.0 Human health

1.1 Toxicological summary

SCLPs are naturally occurring long-chain fatty acids, and as such, they are metabolized by enzyme systems present in most living organisms, and/or they are excreted. In general, SCLPs have a non-toxic and species-specific mode of action. The available data indicates that SCLPs are considered to be of low acute toxicity by the oral, dermal, and inhalation exposure routes. They are mildly irritating when applied to skin, minimally irritating when exposed to eyes, and they are not expected to cause dermal sensitization. SCLPs are not mutagenic, and there is no evidence of developmental effects. Based on the chemical, physical, biological, and toxicological properties of SCLP compounds, adverse effects to human health are not expected following exposure. No toxicological endpoints for SCLPs have been established for quantitative risk assessment and as a result, a qualitative approach has been used to assess the potential risks of exposure to SCLPs.

1.2 Human exposure and risk

Workers can be exposed to the active ingredient during handling and attachment of end-use product dispensers on trees or during handling of the end-use products for aerial application. Exposure is expected to be primarily via the dermal route, but inhalation as a route of exposure is also possible. Occupational exposure from handling dispensers on trees and with the aerial application is considered to be acceptable with the current risk mitigation measures included on the end-use product labels:

- For dispensers on trees: current labels include the minimum personal protective equipment (PPE) requirements of chemical resistant gloves and eye protection, and precautionary statements on the labels of the automatic dispensers when setting up, repairing or removing the dispensers.
- For aerial application: current PPE requirements include a coveralls over short-sleeved shirt and pants, socks, shoes, gloves, goggles and respirator during mixing, loading, clean-up or repair of equipment.

No additional risk mitigation measures are proposed.

Postapplication workers can also be exposed when entering a treated site to perform tasks such as pruning, harvesting, scouting, and/or removing the dispensers. Minimal dermal exposure is expected from aerial application as the target application area is the upper canopy of forests and woodlots, and the product is not expected to reach ground level in significant quantities.

Postapplication exposure from the automatic dispensers is limited by releasing pheromone during evening hours when potential worker and bystander exposure is less likely because postapplication activities will occur during the day when the product is not being dispensed. Postapplication inhalation exposure is not expected to exceed ambient levels of pheromone that would be produced by natural moth populations during an infestation.

There are no domestic class products registered containing SCLPs. Therefore, direct residential exposure is not expected. Bystander exposure is expected to be minimal and is limited to exposure from entering treated residential, commercial, and/or woodland sites.

Based on the above considerations, current use patterns, and label directions, and low toxicity profile of SCLPs, postapplication and non-occupational (bystander) exposure to SCLPs is expected to be minimal, and the postapplication and non-occupational risk is considered to be acceptable. No additional mitigation measures are proposed.

The end-use products approved for aerial application are not registered for use on food or feed crops, and residues are not expected. 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 crops or drinking water sources. Based on the current use pattern and their rapid environmental dissipation, potential exposure to food and drinking water is expected to be minimal. When the current label directions are followed, potential dietary risk is considered to be acceptable. No additional mitigation measures are proposed.

1.3 Aggregate exposure assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Under the current conditions of use, risk from aggregate exposure to SCLPs is considered to be acceptable as dietary exposure and non-occupational exposure (limited to bystander) is minimal. No additional mitigation measures are proposed.

1.4 Cumulative exposure and risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA identified information indicating that SCLPs share a common mechanism of toxicity with other SCLP pest control products. However, given the inherent low toxicity of SCLPs to mammalian systems, the PMRA does not expect cumulative or incremental effects from exposure to residues of SCLPs when used as directed on the label. Therefore, there is no requirement for a cumulative assessment at this time.

2.0 Environment

Environmental persistence of SCLPs is expected to be limited as SCLPs rapidly break down in the environment. The SCLPs are not considered as Track 1 substances as they do not meet all the Track 1 criteria as per the Toxic Substances Management Policy, due to rapid dissipation in the environment.³

SCLPs are considered to have a species-specific mode of action. In general, they are well-characterized and considered to be of low toxicity to birds, mammals, and aquatic organisms. Effects on bees are not expected from SCLPs.

When used as directed, SCLPs are expected to remain as a vapour and not partition to water, soil, or accumulate in non-target organisms. Overall, given the currently registered use pattern, the low toxicity and species-specificity of SCLPs, the potential risk to non-target organisms and the environment is considered to be acceptable. No additional mitigation measures are proposed.

3.0 Value

SCLPs have value in providing a non-conventional solution for pest control as they can effectively be combined with other pest control practices and products to help control unwanted lepidopteran insects. Additionally, when used in integrated pest management programs, SCLPs can play a valuable part in resistance management and may help reduce the need for conventional insecticides.

4.0 Incident reports

As of 2 March 2021, no incident reports (human and environment) have been received by the PMRA for the SCLPs listed in Appendix I.

³ PMRA Regulatory Directive DIR99-03, Regulatory Directive: The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances under *Canadian Environmental Protection Act*.

Appendix I Straight chain lepidopteran pheromone pest control product information

Table 1 Registered technical class products containing straight chain lepidopteran pheromone active ingredients as of 2 March 2021

Registration number	Registrant	Product name	Formulation type	Guarantee
28815	Pacific Biocontrol Corporation	CM/LR TT Pheromone Technical	Liquid	(Z)-11-Tetradecenyl Acetate-39.34% (E,E)-8,10-Dodecadien-1-ol-39.95% 1-Dodecanol-6.21% 1-Tetradecanol-1.45% (Z)-9-Tetradecen-1-yl Acetate-4.49% (Z)-11-Tetradecen-1-ol-1.08% (Z)-11-Tetradecenal-1.03%
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

Table 2 Registered end-use products containing SCLP active ingredients as of 2 March 2021

Registration No.	Class	Registrant	Product name	Formulation type	Guarantee
28814	Commercial	Pacific Biocontrol Corporation	Isomate-CM/LR TT	Slow Release Generator	(Z)-11-Tetradecenyl Acetate-38.04% (E,E)-8,10-Dodecadien-1-ol-38.62% 1-Dodecanol-6.00% 1-Tetradecanol-1.40% (Z)-9-Tetradecen-1-yl Acetate-4.34% (Z)-11-Tetradecen-1-ol-1.05% (Z)-11-Tetradecenol-1.00%
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/R estricted	Sylvar Technologies Inc	Confound SBW	Microcapsule Suspension	(E,Z)-11-Tetradecenol-11%

* Associated Re-Evaluation: RVD2018-07

** Associated Re-Evaluation: RVD2018-28

Appendix II – Label Amendments

To meet current standards the following label amendments are proposed for the specified PCP Numbers.:

For PCP No. 32047, SEMIOS CM PLUS, Under “DIRECTIONS FOR USE” add the statement: “DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

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

The following label amendments are proposed to clarify the amount of active ingredient: *Under NET CONTENTS, replace the word “pheromone” with “product”*

References

Published Information

PMRA number	Reference
1536705	PRD2007-12, Proposed Registration Decision CM/LR TT Pheromone Technical
1565711	RD2008-05, Registration Decision CM/LR TT Pheromone Technical
	PRDD99-04, Proposed Regulatory Decision Document 3M Sprayable Pheromone for Mating Disruption of Blackheaded Fireworm Z-11-Tetradecenyl Acetate
666858	RDD2001-01, Regulatory Decision Document 3M Sprayable Pheromone for Mating Disruption of Blackheaded Fireworm (Z-11-tetradecenyl acetate)
	E92-03, Decision Document Grape Berry Moth Pheromone
	PRDD99-03, Proposed Regulatory Decision Document 3M MEC Eastern Pine Shoot Borer Pheromone 9-Dodecenyl Acetate
702718	RRD2004-03, Re-evaluation Decision Document Re-evaluation of 9-dodecenyl Acetate
2761938	E94-01, Decision Document Isomate-C (Codling Moth Pheromone)
697400	RRD2004-02, Re-evaluation Decision Document Re-evaluation of Codling Moth Pheromone
2805468	PRVD2017-05, Proposed Re-evaluation Decision E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate
2864456	RVD2018-07, Re-evaluation Decision E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate, and Their Associated End-use Products
1771411	Evaluation Report for Category B, Subcategory 2.6, 3.11 and 3.12 Application (Application Number: 2008-1295)
2472062	Evaluation Report for Category B, Subcategory 3.12 Application (Application Number: 2014-0899)
2554000	PRD2015-20, Proposed Registration Decision Codlure
2566177	RD2015-26, Registration Decision Codlure
1882297	PRD2010-10, Proposed Registration Decision (E,Z)-11-tetradecenal
1988449	RD2010-18, Registration Decision (E,Z)-11-tetradecenal
1452898	ERC2007-07, Evaluation Report (E,Z)-11-tetradecenal
2760962	Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1 Application (Application Number: 2016-3293)
2077287	Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application (Application Number: 2010-4670)
2855465	PRVD2018-07, Proposed Re-evaluation Decision (Z,Z)-3,13-Octadecadien1-yl acetate and Its Associated End-use Products
2920698	RVD2018-28, Re-evaluation Decision (Z,Z)-3,13-Octadecadien1-yl acetate and Its Associated End-use Products

PMRA number	Reference
831936	PRDD2004-03, Proposed Regulatory Decision Document Isomate-P Pheromone for use in Orchards for Mating Disruption of the Peach Tree Borer
911991	RDD2004-04, Regulatory Decision Document Isomate-P Pheromone for use in Orchards for Mating Disruption of the Peach Tree Borer
650082	REG2002-03, Regulatory Note Isomate-P Pheromone for use in Orchards for Mating Disruption of the Peach Tree Borer
2034725	Evaluation Report for Category A, Subcategory 1.1 Application (Application Number: 2010-2962)
2034726	Evaluation Report for Category A, Subcategory 1.1 Application (Application Number: 2010-2961)
1426999	Evaluation Report for Category B, Subcategory 3.11, 3.12 Application (Application Number: 2007-2481)
3138382	Evaluation Report for Category B, Subcategory 2.3, 2.4 Application (Application Number: 2020-0141)