Registration Decision RD2015-26

Codlelure

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Registration Decision for Codlelure

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 Bedoukian CM Pheromone and Semios CM, containing the technical grade active ingredient codlelure, which is intended to disrupt codling moth (*Cydia pomonella*) mating and is to be used on apples, pears, and other pome fruits; as well as peaches, prunes, and other stone fruits.

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[1] Proposed Registration Decision PRD2015-20,*Codlelure*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for codlelure and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-20. This decision is consistent with the proposed registration decision stated in PRD2015-20.

For more details on the information presented in this Registration Decision, please refer PRD2015-20, *Codlelure*, 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[3] 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[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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.*

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

4 "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 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. These methods and policies also consider the nature of the effects observed and the uncertainties 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 Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Codlelure?

Codlelure is a major component of the sex pheromone of the codling moth and is the active ingredient in the end-use product Semios CM. This product is formulated for release from automated aerosol dispensers for mating disruption of codling moth in pome and stone fruit orchards. In nature, the sex pheromone is produced by female moths and attracts male moths for mating.

Health Considerations

Can Approved Uses of Codlelure Affect Human Health?

Codlelure is unlikely to affect human health when used according to label directions.

The straight-chain lepidopteran pheromone (SCLP), codlelure, which is used to formulate Semios CM, is unlikely to have a negative effect on human health when the product is used according to label directions. SCLPs are naturally occurring compounds that are produced by many lepidopteran insect species (moths and butterflies) to communicate with other members of the same species.

Exposure to codlelure may occur when handling or applying Semios CM or by entering orchards that are treated with Semios CM. 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.

In general, SCLPs are non-toxic compounds that are readily metabolized by most living organisms. Toxicity studies on SCLPs have generally indicated no mammalian toxicity. Exposure to people from the use of Semios CM is, therefore, not expected to be of concern.

Occupational Risks from Handling Semios CM

Occupational risks are not of concern when Semios CM is used according to the proposed label directions, which include protective measures.

Semios CM is to be applied by commercial applicators who will affix dispensers in the upper third of the tree canopy in orchards.

Occupational exposure to individuals handling Semios CM is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary statements (for example, wearing of personal protective equipment) and hygiene statements on the label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Residential and Bystander Exposure and Risk

As the application of Semios CM involves only authorized personnel, bystander exposure is expected to be minimal and not of concern when the end-use product is used according to the label directions. Residential exposure is also likely to be minimal when the label directions are followed for Semios CM.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Semios CM is formulated as an aerosol that is automatically dispensed in the upper canopy of orchards with the nozzle pointed away from foliage and fruit. The maximum application rate of Semios CM is 277 g of active ingredient per hectare per year. The PMRA has determined that because codlelure is classified as an SCLP and has a maximum application rate that is below the allowable safe limit of 375 g of active ingredient per hectare per year established for SCLPs, a maximum residue limit does not need to be specified for it under the *Pest Control Products Act*. Refer to Regulatory Proposal PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals* for specific details regarding the safe limit of active ingredient per hectare per year established for SCLPs.

No risk due to exposure from drinking water is anticipated as codlelure is unlikely to enter drinking water sources.

Environmental Considerations

What Happens When Codlelure Is Introduced Into the Environment?

Bedoukian CM Pheromone contains the technical grade active ingredient codlelure. Codlelure, when used in Semios CM aerosol canisters, enters the environment through vaporization into air by release from automated aerosol "puff-emitting" dispensers in orchards (apples, pears, and other pome fruits; peaches, prunes, and other stone fruits).

The active ingredient is an SCLP, which is a well-defined group of chemicals that are naturally-produced and are known to dissipate rapidly in the environment and, thus, pose minimal risk. Through this use pattern, and because of the inherent nature of SCLPs, limited environmental exposure is expected.

Value Considerations

What Is the Value of Semios CM?

Semios CM controls codling moth by mating disruption in pome and stone fruit orchards.

Semios CM dispensers are placed in pome or stone fruit orchards and release the pheromone, codlelure, into the atmosphere. This release of pheromone interferes with the ability of male codling moths to find mates, thus reducing the number of larvae that damage pome and stone fruit. Semios CM can be used as part of an integrated pest management program for codling moth by both conventional and organic producers and is compatible with other management strategies. In conventional orchards, the use of pheromone-based mating disruption can reduce the need for application of conventional pest control products. Resistance to pheromone-based mating disruption is unlikely to develop.

Semios CM is dispensed by a new technology for releasing codling moth pheromone for mating disruption. It is a liquid formulation which is released by automatic dispensers as an aerosol spray. Other registered products for mating disruption of codling moth are solid dispensers. In comparison to the solid dispensers, far fewer Semios CM dispensers are required per unit area, which may result in time and labour savings during installation. Semios CM dispensers also release pheromone only during the period of time when the moths are active, in contrast to the solid dispensers which release pheromone continuously. They also release the same amount of pheromone throughout the season for season-long consistency in application rate, even at the end of the growing season when rates from solid dispensers tend to decline as their supply of pheromone becomes depleted.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the label of Semios CM to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The key risk-reduction measures being proposed on the label of the technical product (Bedoukian CM Pheromone) and end-use product (Semios CM) to address the potential risks identified in this assessment are as follows.

The signal words "DANGER – SKIN IRRITANT" are required on the principal display panels of the labels for both Bedoukian CM Pheromone and Semios CM. The signal words "WARNING – EYE IRRITANT" are required on the principal display panel of the Semios CM label and the signal words "CAUTION – EYE IRRITANT" are required on the principal display panel of the Bedoukian CM Pheromone label.

Standard hazard and precautionary statements are also required on the end-use product labels to inform workers of the irritation potential of the active ingredient to the skin and eyes. Workers handling containers of Semios CM will be required to wear standard personal protective equipment including chemical resistant gloves, coveralls, goggles or face shield, long-sleeved shirt, shoes, and socks.

A restricted-entry interval is not required for Semios CM.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-20) 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).

Any person may file a notice of objection[5] 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.

[5] As per subsection 35(1) of the *Pest Control Products Act.*