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Registration Decision

RD2014-25

Cydia pomonella **Granulovirus Strain M**

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Registration Decision for *Cydia pomonella* Granulovirus Strain M

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 CYD-X Technical and CYD-X Insecticidal Virus, containing the biological active ingredient *Cydia pomonella* Granulovirus Strain M, for the control of codling moth in apples.

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 document¹ Proposed Registration Decision PRD2014-09, *Cydia pomonella* Granulovirus strain M. This Registration Decision² describes this stage of the PMRA's regulatory process for *Cydia pomonella* Granulovirus strain M and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-09. This decision is consistent with the proposed registration decision stated in PRD2014-09.

For more details on the information presented in this Registration Decision, please refer to PRD2014-09, 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 acceptable³ 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 value⁴ 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 (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 more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Cydia pomonella* Granulovirus Strain M?

Cydia pomonella Granulovirus strain M is a naturally occurring baculovirus that is used as a microbial pest control agent for the control of codling moth (*Cydia pomonella*) larvae on apple trees. *Cydia pomonella* Granulovirus strain M must be ingested by codling moth larvae to become infected with the virus. Upon ingestion, the viral occlusion bodies dissolve in the larvae midgut and release infectious virions. The virions then enter the cell that line the digestive tract and replicate in the nuclei of these cells. The resulting replicated virions rapidly spread the infection to the other organs within the larva. Within a few days after ingestion of CYD-X Insecticidal Virus, the infected larva stops feeding, becomes sluggish and discoloured and eventually dies from a massive viral infection. After death, the larvae disintegrate, releasing new occlusion bodies that may infect other codling moth larvae upon ingestion. Exposed codling moth larvae die within three to seven days after ingestion of CYD-X Insecticidal Virus, depending on dosage and ambient temperature. Codling moth death may occur more quickly at higher temperatures and higher dosages. Some damage to the fruit may occur before the larvae die.

Health Considerations

Can Approved Uses of *Cydia pomonella* Granulovirus Strain M Affect Human Health?

***Cydia pomonella* Granulovirus strain M is unlikely to affect your health when used according to label directions.**

People can be exposed to *Cydia pomonella* Granulovirus strain M when handling and applying CYD-X Insecticidal Virus and when consuming treated produce.

When assessing health risks, several key factors are considered such as:

- the microorganism's biological properties (for example, production of toxic by-products);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the levels to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. Because of the close relationships within the family Baculoviridae, results and findings from studies with various other baculoviruses are considered applicable to *Cydia pomonella* Granulovirus strain M and may be used for risk assessment purposes.

Studies in the published literature examining the effects of the exposure of various baculoviruses to laboratory animals yielded no signs of toxicity, disease or irritation. No member of this family of viruses is known to infect vertebrate animals. Furthermore, baculoviruses are highly host specific and have only been found in arthropods. The presence of insect debris in CYD-X Insecticidal Virus, however, may cause irritation if inhaled or exposed to the skin or eye. Finally, baculoviruses are commonly found in nature at relatively high levels.

The use of CYD-X Insecticidal Virus is not expected to significantly increase the baculovirus level in the environment. Baculoviruses have also been used for biological insect control for over 100 years. There have been no adverse effects noted as a result of either natural populations of baculoviruses or to applications of baculovirus-based pesticides.

As is the case with all microbial pest control agents, *Cydia pomonella* Granulovirus strain M contains substances that can cause allergic reactions in people who are repeatedly exposed to it at high concentrations. However, these reactions can be avoided if farm workers and applicators follow label recommendations to minimize or limit exposure to CYD-X Insecticidal Virus.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based maximum residue limits to ensure the food Canadians eat is safe.

Although isolates of *Cydia pomonella* Granulovirus are common in nature, the residues of *C. pomonella* Granulovirus strain M remaining on produce from the use of CYD-X Insecticidal Virus are expected to be higher than levels naturally occurring on fruit; however, studies in the published literature on other baculoviruses have demonstrated a lack of toxicity when laboratory animals were exposed via the oral route. Similarly, no signs of infectivity were observed in tissue culture testing.

Furthermore, the mode of action associated with baculoviruses is not dependent on toxin production. Therefore, dietary risks are minimal to non-existent and the establishment of a maximum residue limit is not required for *Cydia pomonella* Granulovirus strain M.

The likelihood of residues contaminating drinking water supplies is minimal. Consequently, dietary risks are also minimal.

Occupational Risks From Handling *Cydia pomonella* Granulovirus Strain M

Occupational risks are not of concern when CYD-X Insecticidal Virus is used according to the proposed label directions, which include protective measures.

Workers using CYD-X Insecticidal Virus can come into direct contact with *Cydia pomonella* Granulovirus strain M (that is, through contact with skin or eyes, or by inhalation). Although the potential for toxicity is low in individuals exposed to *Cydia pomonella* Granulovirus strain M, the presence of insect debris in the end-use product may cause irritation if inhaled or exposed to the skin or eyes. Sensitization may also occur upon repeated exposure to high concentrations of the product. For this reason, users must wear a long-sleeved shirt, long pants, shoes plus socks, water-proof gloves, eye goggles and a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products while handling, mixing/loading or applying the product and during all clean-up/repair activities.

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Cydia pomonella* Granulovirus Strain M is Introduced Into the Environment?

Environmental risks are not of concern.

Cydia pomonella Granulovirus strain M is a natural baculovirus isolate that infects and kills the larval life stage of codling moth insects. Baculoviruses are generally specific to certain insect species. No member of the Baculoviridae family is known to infect vertebrates or plants. Granuloviruses have only been reported from members of the order Lepidoptera (moths and butterflies). Infectivity of Granuloviruses is limited to insect species within the same family as the host from which it was originally isolated (codling moth; *C. pomonella*). In the case of *Cydia pomonella* Granulovirus strain M, infectivity is limited to the family Tortricidae. Effects on even more distantly-related non-target organisms are, therefore, not expected.

Furthermore, baculoviruses are ubiquitous in the environment. The use of CYD-X Insecticidal Virus to control codling moth in apple orchards is not expected to significantly increase the baculovirus load in the environment beyond naturally-occurring levels. Baculoviruses, including other strains of *Cydia pomonella* Granulovirus, have been extensively used as biological control agents. No reports of adverse effects have been noted on non-target organisms due to either natural population of baculoviruses or to applications of baculovirus-based pesticide products.

Value Considerations

What Is the Value of *Cydia pomonella* Granulovirus Strain M?

CYD-X Insecticidal Virus has value in controlling codling moth, which is a major pest of apples; it can be used by organic growers and in integrated pest management programs.

The crop and pest combination of apples and codling moth has been identified in the Grower Priority Database as a high priority. *Cydia pomonella* Granulovirus strain M can be used by organic growers and is another tool that can be utilized in codling moth integrated pest management programs.

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 CYD-X Insecticidal Virus to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Statements warning users that the product is a dermal and eye irritant, as well as a potential sensitizer, are required on the label.

To minimize exposure to mists generated while handling, mixing/loading or applying the product and during all clean-up/repair activities, users must wear a long-sleeved shirt, long pants, shoes plus socks, water-proof gloves, eye goggles and a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products.

Environment

As a general precaution, to reduce runoff, users must not apply the product to aquatic systems and contamination of irrigation or drinking water supplies and aquatic habitats is prohibited. Furthermore, users are directed to not apply the product by air and to follow application instructions to minimize spray drift. Standard disposal statements for unused or unwanted product and the product container also apply.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-09, *Cydia pomonella Granulovirus strain M*) 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 objection⁵ 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 Pesticide and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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