Proposed Registration Decision PRD2023-11

Cyclaniliprole 50SL Insecticide, Cyclaniliprole

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Overview

Proposed registration decision for Cyclaniliprole 50SL Insecticide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Cyclaniliprole 50SL Insecticide, containing the technical grade active ingredient cyclaniliprole, as a foliar insecticide for use on greenhouse tomato for control or suppression of western flower thrips, whiteflies, beet armyworm, bertha armyworm, cabbage looper and fall armyworm; greenhouse pepper for suppression of pepper weevil; greenhouse ornamentals for the suppression of western flower thrips and onion thrips and outdoor ornamentals for the suppression of redheaded flea beetle. This evaluation was completed under the User Requested Minor Use Label Expansion program, which is a cooperative program between Agriculture and Agri-Food Canada and Health Canada's Pest Management Regulatory Agency and includes participation by sponsor groups, manufacturers, and both provincial and federal governments.

The end use product, Cyclaniliprole 50SL Insecticide, and the active ingredient, cyclaniliprole, are currently registered for the control of various insect pests on a variety of field grown vegetable, tree nut and fruit crops. For details, see Proposed Registration Decision PRD2017-12, *Cyclaniliprole and Cyclaniliprole 50SL Insecticide*, and Registration Decision RD2017-17, *Cyclaniliprole and Cyclaniliprole 50SL Insecticide*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of Cyclaniliprole 50SL, containing cyclaniliprole, are acceptable.

This Overview describes the key points of the evaluation, while the Science evaluation provides detailed technical information on the human health, environmental and value assessments of Cyclaniliprole 50SL Insecticide, containing cyclaniliprole, when applied to outdoor and greenhouse ornamentals, greenhouse pepper and greenhouse tomato.

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[1] 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 proposed conditions of registration.

[1] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

The Act also requires that products have value[2] when used according to the 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 (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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca.

Before making a final registration decision on Cyclaniliprole 50SL Insecticide, containing cyclaniliprole, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on Cyclaniliprole 50SL Insecticide, containing cyclaniliprole, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science evaluation of this consultation document.

What is cyclaniliprole?

Cyclaniliprole is a member of the diamide group of insecticides that affects certain receptors in insect muscle, causing paralysis and death. Cyclaniliprole is the active ingredient in the end-use product Cyclaniliprole 50SL Insecticide. Cyclaniliprole 50SL Insecticide is applied via foliar applications to control or suppress a variety of pests on certain crops.

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2 "Value" as defined by subsection 2(1) of the *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."

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

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

Health considerations

Can approved uses of cyclaniliprole affect human health?

Cyclaniliprole 50SL Insecticide, containing cyclaniliprole, is unlikely to affect your health when used according to label directions.

Potential exposure to cyclaniliprole may occur through the diet (food and drinking water), when handling and applying the end-use product, or when entering an area that has been treated with the product. 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 selected to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose level at which no effects are observed. The health effects noted in animals occur at dose levels more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient cyclaniliprole was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It was non-irritating to the skin and eyes and did not cause an allergic skin reaction.

The end-use product, Cyclaniliprole 50SL Insecticide, was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin and did not cause an allergic skin reaction.

Registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of cyclaniliprole to cause neurotoxicity, immunotoxicity, genetic damage, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the liver. There was no evidence that the young were more sensitive to cyclaniliprole than the adult animal.

The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in water and food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1–2 years old, the subpopulation which would ingest the most cyclaniliprole relative to body weight, are expected to be exposed to less than 7% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from cyclaniliprole is not of health concern for all population subgroups.

Cyclaniliprole is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of cyclaniliprole is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using cyclaniliprole on greenhouse peppers and tomatoes are acceptable. The MRLs for this active ingredient can be found in the Science evaluation of this consultation document.

Occupational risks from handling Cyclaniliprole 50SL Insecticide

Occupational risks are not of concern when Cyclaniliprole 50SL is used according to the proposed label directions, which include protective measures.

Workers mixing, loading, or applying Cyclaniliprole 50SL, and workers entering recently treated areas, can be exposed to cyclaniliprole residues through direct skin contact or through inhalation. Therefore, the label specifies that anyone mixing, loading, and applying Cyclaniliprole 50SL must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. The label also requires that workers do not enter or be allowed into treated areas during the restricted-entry interval (REI) of 12 hours. Taking into consideration the label statements, the number of applications and the duration of exposure for handlers and postapplication workers, the risks to these individuals are not of health concern when Cyclaniliprole 50SL is used according to the proposed label directions.

Risks in residential and other non-occupational environments

Risks in residential and other non-occupational environments are not of health concern when Cyclaniliprole 50SL is used according to the proposed label directions and REIs are observed.

Residential risks from exposure to Cyclaniliprole 50SL when contacting treated ornamentals, such as trees and shrubs, following commercial application to outdoor ornamentals in residential areas are not of health concern.

Health risks to bystanders

Bystander risks are not of health concern when Cyclaniliprole 50SL is used according to the proposed label directions and spray drift restrictions are observed.

A standard label statement to protect against drift during application is on the label. Therefore, health risks to bystanders are not of concern when the end-use product is used according to the proposed label directions.

Environmental considerations

When used according to label directions, the environmental risks associated with the major new uses of cyclaniliprole and its associated end-use product, Cyclaniliprole 50SL Insecticide, on outdoor ornamentals, greenhouse ornamentals and greenhouse food crops are acceptable.

The environmental impact of the use of cyclaniliprole in field crops was evaluated in Proposed Registration Decision PRD2017-12, *Cyclaniliprole and Cyclaniliprole 50SL Insecticide*, and Registration Decision RD2017-17, *Cyclaniliprole and Cyclaniliprole 50SL Insecticide*. Cyclaniliprole is toxic to aquatic organisms, bees and other beneficial insects. Risk mitigation measures for these organisms are present on the registered label of Cyclaniliprole 50SL Insecticide.

The proposed major new uses of cyclaniliprole include application to outdoor ornamental plants, greenhouse ornamental plants and greenhouse food crops. It is possible that ornamental plants treated in greenhouses could be moved outside following application of cyclaniliprole. The proposed major new uses of cyclaniliprole are not expected to increase the environmental exposure of non-target organisms to cyclaniliprole compared to the registered use in field crops when label directions are followed. Restrictions on application timing for ornamental plants that are treated outside, or plants that are treated in greenhouses and then moved outside, are required to minimize exposure to bees.

The use of cyclaniliprole in greenhouses could result in adverse effects to bees and other beneficial insects used in greenhouse production. A label statement to inform users to avoid application of cyclaniliprole when bees and other beneficial insects are in the treatment area is required.

After a scientific review of the available information, the PMRA has concluded that the environmental risks associated with the major new uses of cyclaniliprole in outdoor ornamentals, greenhouse ornamentals and greenhouse food crops are acceptable when Cyclaniliprole 50SL Insecticide is used according to label directions.

Value considerations

What is the value of Cyclaniliprole 50SL Insecticide?

Cyclaniliprole 50SL Insecticide provides control or suppression of western flower thrips, whiteflies, beet armyworm, bertha armyworm, cabbage looper and fall armyworm on greenhouse tomatoes. The registration of Cyclaniliprole 50SL Insecticide for these uses will provide the first insecticide product to manage bertha armyworm and fall armyworm on greenhouse tomatoes, as well as an alternative product for use to manage the other listed pests.

Cyclaniliprole 50SL Insecticide provides suppression of pepper weevil on greenhouse peppers. The registration of Cyclaniliprole 50SL Insecticide for this use will provide greenhouse pepper growers with an alternative product for use to manage pepper weevil.

Cyclaniliprole 50SL Insecticide provides suppression of western flower thrips and onion thrips on greenhouse ornamentals. Cyclaniliprole is a new active ingredient for this use, which was identified as a priority for Canadian growers. Thrips are known for developing resistance to pesticides, so having many active ingredients available is important for resistance management.

Cyclaniliprole 50SL Insecticide provides suppression of redheaded flea beetle on outdoor ornamentals (excluding confiders). This will be the first insecticide product registered for this use in Canada.

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 key risk-reduction measures being proposed on the label of Cyclaniliprole 50SL Insecticide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

To reduce the potential exposure of workers to cyclaniliprole through direct skin contact or inhalation of sprays, workers mixing, loading and applying Cyclaniliprole 50SL and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

The label also requires that workers do not enter or be allowed entry into treated areas during the REI of 12 hours. Furthermore, standard label statements to protect against drift during application and to prevent the use of handheld airblast, mistblowers and foggers are present on the label.

Environment

The following new risk mitigation measures are required:

Greenhouse uses:

- Label statement to inform users to avoid application of cyclaniliprole when bees and other beneficial insects used in greenhouse production are in the treatment area.
- Label statement to prohibit the movement of bee-attractive plants outdoors if flowers that have been sprayed with cyclaniliprole remain on the plant.
- Label statement prohibiting the discharge of greenhouse releases, effluent or runoff to water.

Outdoor ornamentals:

- Label statement restricting application to the evening for bee attractive plants that are in bloom.
- Spray buffer zones of 1 metre to protect aquatic habitat.

Next steps

Before making a final registration decision on Cyclaniliprole 50SL Insecticide, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When the Health Canada makes its registration decision, it will publish a Registration Decision on Cyclaniliprole 50SL Insecticide, containing cyclaniliprole (based on the Science evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

1.0 The active ingredient, its properties and uses

There was no proposed change to the registered formulation of Cyclaniliprole 50SL Insecticide. For information about cyclaniliprole and its properties, refer to Proposed Registration Decision PRD2017-12.

1.1 Directions for use

Cyclaniliprole 50SL Insecticide is applied as a foliar application to:

- greenhouse tomatoes at 0.8–1.2 L product/ha. It may be applied up to 4 times per crop cycle at a minimum re-treatment interval of 5 days.
- greenhouse peppers at 1.2–2.0 L product/ha. It may be applied up to 3 times per crop cycle at a minimum re-treatment interval of 7 days.
- greenhouse ornamentals (including cut flowers, perennials and annuals) at 1.2–1.6 L product/ha. It may be applied up to 5 times per crop cycle (but no more than 6 L product/ha per crop cycle) with a minimum re-treatment interval of 7 days.
- outdoor ornamentals (excluding conifers) at a rate of 0.8 L product/ha. It may be applied up to 6 times per year with a minimum re-treatment interval of 5 days.

1.2 Mode of action

Cyclaniliprole is a ryanodine receptor modulator in the diamide class of chemistry (IRAC Mode of Action Group 28), which affects ryanodine receptors in insect muscle, causing paralysis and eventual death.

2.0 Methods of analysis

Please refer to PRD2017-12 for the detailed review of the methods of analysis.

3.0 Impact on human and animal health

3.1 Toxicology summary

Cyclaniliprole belongs to the anthranilic diamide class of pesticides. Pesticides of this class control insects through unregulated activation of ryanodine receptor channels, leading to internal calcium store depletion that impairs regulation of muscle contraction. Mammalian ryanodine receptors are substantially less sensitive to the effects of anthranilic diamides than the insect ryanodine receptors.

A detailed review of the toxicological database for cyclaniliprole was conducted previously and is summarized in PRD2017-12. Overall, the scientific quality of the toxicology database is acceptable, and the database is considered adequate to define the majority of the toxic effects that may result from exposure to cyclaniliprole.

The results of acute toxicity studies conducted with the end-use product Cyclaniliprole 50SL Insecticide are summarized in Appendix I, Table 3 in PRD2017-12. Cyclaniliprole 50SL Insecticide was of low acute toxicity by the oral, dermal, and inhalation routes of exposure in rats. It was minimally irritating to the eyes and non-irritating to the skin of rabbits and was negative for dermal sensitization when tested using the local lymph node assay in mice and the Buehler method in guinea pigs.

Toxicology reference values for use in the human health risk assessment were established previously and are reported in PRD2017-12. At that time, however, a reference value for use in assessing risk from long-term dermal exposure had not been established. For long-term dermal occupational risk assessment, the NOAEL of 1000 mg/kg bw/day from the 28-day dermal toxicity studies in rats was selected. The choice of this study was supported by the overall low level of toxicity in the cyclaniliprole toxicology database, including the absence of developmental, reproductive, or offspring toxicity as well as neurotoxicity at, or above, the limit dose of testing. In addition, there was no indication of increased toxicity with increased duration of dosing in the database. For this scenario, the target MOE is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers. The toxicology reference values for use in the human health risk assessment are summarized in Appendix I, Table 1.

Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for cyclaniliprole. Cyclaniliprole belongs to the anthranilic diamide class of pesticides. Although other pesticides of the same class that are known to target the insect ryanodine receptors are registered in Canada, there is insufficient evidence to link the apical endpoints observed in the toxicology databases for the anthranilic diamide class of pesticides with activation of mammalian ryanodine receptors. Furthermore, the observed effects with cyclaniliprole are indicative of more generalized toxicity, and a common mechanism of toxicity has not been identified. Therefore, no cumulative health risk assessment is required at this time.

3.2 Toxicology reference values

The toxicology reference values for use in the human health risk assessment are summarized in Appendix I, Table 1.

3.2.1 Route and duration of exposure

For mixers, loaders and applicators, occupational exposure to Cyclaniliprole 50SL is characterized as short-term in duration and is predominantly by the dermal and inhalation routes. For postapplication workers, occupational exposure to Cyclanililprole 50SL is characterized as intermediate-term in duration for outdoor uses and long-term in duration for indoor (greenhouse) uses and is predominantly by the dermal route.

3.3 Dermal absorption

A dermal absorption value was not used in the risk assessment since the dermal toxicological reference value for cyclaniliprole is based on a dermal toxicity study.

3.4 Occupational and residential risk assessment

3.4.1 Acute hazards of Cyclaniliprole 50SL insecticide product and mitigation measures

The acute hazard assessment indicated that Cyclaniliprole 50SL is of low acute toxicity via the oral, dermal, and inhalation routes, is minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction. Based on these acute hazards, no additional PPE is triggered for workers during mixing, loading, application, clean-up and repair. The PPE on the proposed label is considered acceptable to protect against the acute hazard of Cyclaniliprole 50SL.

3.4.2 Occupational exposure and risk

3.4.2.1 Mixer/Loader/Applicator exposure and risk assessment

Individuals have potential for exposure to cyclaniliprole during mixing, loading, application, clean-up and repair. Dermal and inhalation exposure estimates were generated from the Agricultural Handlers Exposure Task Force (AHETF) database, and the Pesticide Handlers Exposure Database (PHED, v1.1) for mixers, loaders and applicators applying Cyclaniliprole 50SL to outdoor ornamentals, greenhouse ornamentals, greenhouse peppers, and greenhouse tomatoes using groundboom, airblast, handheld, and automated application equipment. The applicant is a member of the AHETF and has full access to the data that were used to estimate worker exposure. The PPE in the risk assessment is based on handlers wearing a long-sleeved shirt, long pants, chemical resistant gloves, socks and shoes (Appendix I, Table 2).

The applicant is not a member of the Non-Dietary Exposure Task Force and therefore does not have access to the associated data to assess the risks from the use of handheld airblast/mistblower or handheld fogging application equipment. A label statement restricting the use of handheld airblast/mistblower or handheld fogging equipment will be added to the label.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the selected toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 100 for both dermal and inhalation exposure. Calculated MOEs are greater than the target MOE of 100 for all chemical handler scenarios for outdoor and greenhouse ornamentals, greenhouse peppers, and greenhouse tomatoes and are therefore not of health concern (Appendix I, Table 3).

Taking into account both the acute toxicity of the end-use product and the risk assessment of cyclaniliprole, workers are required to wear a long-sleeved shirt, long pants, chemical resistant gloves, socks and shoes. Gloves are not required during application within a closed cab.

3.4.2.2 Exposure and risk assessment for workers entering treated areas

There is potential for exposure of workers entering areas treated with Cyclaniliprole 50SL to complete tasks such as harvesting, disbudding, and pruning. Given the nature of activities performed, exposure should be primarily via the dermal route based on contact with treated foliage. Inhalation exposure is not expected as cyclaniliprole is considered non-volatile with a vapour pressure of 2.4×10^{-9} kPa at 25°C, which is less than the North American Free Trade Agreement (NAFTA) criterion for a non-volatile product for both outdoor scenarios [1×10^{-4} kPa (7.5×10^{-4} mm Hg) at 20–30 °C] and indoor scenarios [1×10^{-5} kPa (7.5×10^{-5} mm Hg)]. As such, a quantitative postapplication inhalation risk assessment is not required. Inhalation risk is not of health concern for postapplication workers as cyclaniliprole is considered to be non-volatile and the restricted-entry interval of 12 hours will allow residues to dry, suspended particles to settle, and vapours to dissipate.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue (DFR) values with activity-specific transfer coefficients (TCs). Activity TCs are based on data from the Agricultural Re-entry Task Force (ARTF). Chemical-specific DFR studies conducted on squash, apples, and grapes have previously been submitted and reviewed for cyclaniliprole; however, these studies are not applicable to greenhouse uses as all three studies were conducted outdoors. Therefore, a standard DFR value of 25% of the application rate coupled with 2% daily dissipation of residues were used in the exposure assessments for greenhouse ornamentals, greenhouse peppers, and greenhouse tomatoes. For the use on outdoor ornamentals, a standard DFR value of 25% of the application rate coupled with 3% daily dissipation from the apple DFR study on file were used in the exposure assessment.

Exposure estimates were compared to the toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 100. Only exposures and risks to the activities with the highest TCs are presented as MOEs for these activities exceed the target MOE of 100, and are thus, not of health concern (Appendix I, Table 4). The REI of 12 hours is adequate to protect workers entering treated areas to conduct post application activities.

3.4.3 Residential exposure and risk assessment

3.4.3.1 Handler exposure and risk

Cyclaniliprole 50SL is not a domestic class product and is not permitted for use in residential settings; therefore, a residential handler exposure assessment is not required.

3.4.3.2 Postapplication exposure and risk

Cyclaniliprole 50SL is proposed for use on outdoor ornamentals which includes residential areas. A such, a postapplication residential risk assessment is required.

3.4.3.2.2 Ornamentals in residential areas treated with Cyclaniliprole 50SL

When a commercial applicator is hired to treat outdoor ornamentals in a residential area, there is potential for residential postapplication dermal exposure to the public.

The residential postapplication dermal risk assessment was conducted for adults (16 years old and over) and children (6 to less than 11 years old), when contacting treated ornamentals, such as trees and shrubs.

Dermal exposure was estimated using the standard DFR value of 25% of the application rate and a dissipation rate of 3% dissipation/day, which is the most conservative dissipation rate determined from the chemical-specific DFR studies on file. These values were coupled with the transfer coefficients, durations of exposure and body weights from the 2012 United States Environmental Protection Agency Residential Standard Operating Procedures. Using the toxicological reference value, calculated MOEs were greater than the target MOE of 100 (Appendix I, Table 5) for all residential postapplication exposure scenarios on Day 0. As such, health risks are not of concern and the individuals can enter the treated area once the sprays have dried.

3.4.3.3 Bystander exposure and risk

Bystander exposure is considered negligible as application is limited to when there is low risk of drift beyond the area to be treated taking into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Therefore, bystander exposure and risk are not of health concern since the potential for drift is expected to be minimal.

3.5 Food residues exposure assessment

3.5.1 Residues in plant and animal foodstuffs

Please refer to PRD2017-12 for the complete review of residues of cyclaniliprole in plants and animal foodstuffs.

In the context of the current submissions, supervised residue trials conducted throughout Canada and the United States using an end-use product containing cyclaniliprole at approved rates in or on greenhouse tomatoes and greenhouse peppers are sufficient to support the proposed maximum residue limits in Table 3.5.1.

3.5.2 Dietary risk assessment

A chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™).

3.5.2.1 Chronic dietary exposure results and characterization

The following criteria were applied to the basic chronic analysis for cyclaniliprole: 100% crop treated, default processing factors (where available), maximum residue limits (MRLs) in/on crops and animal commodities. The basic chronic dietary exposure from all supported cyclaniliprole food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 6% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to cyclaniliprole from food and drinking water is 3.2% (0.009601 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for Children 1–2 years old at 6.5% (0.019438 mg/kg bw/day) of the ADI.

3.5.2.2 Acute dietary exposure results and characterization

No appropriate toxicological reference value attributable to a single dose for the general population (including children and infants) was identified, and acute dietary exposure assessment was not required.

3.5.3 Maximum residue limits

MRLs are proposed for each commodity included in the listed crop groupings in Table 3.5.1, in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides section of Canada.ca.

Table 3.5.1 Proposed maximum residue limit

Commodity	Proposed MRL (ppm)
Peppers/Eggplants (crop subgroup 8-09B)	1.5
Tomatoes (crop subgroup 8-09A)	0.7

For additional information on MRLs in terms of the international situation and trade implications, refer to Appendix II.

Please refer to PRD2017-12, Cyclaniliprole for a summary of the nature of the residues in plant matrices, analytical methodologies, and freezer storage stability data. Greenhouse trial data and chronic dietary risk estimates are summarized in Appendix I.

3.6 Aggregate exposure and risk

For ornamental uses of cyclaniliprole there is potential for individuals to be exposed via different routes and sources of exposure concurrently. As such, ornamentals in residential settings were considered.

Since both the chronic dietary (food and drinking water) and the dermal toxicology reference values are based on different toxicological endpoints/effects (and no effects were seen at the highest dose in the dermal study), no aggregation of dermal and dietary exposure is required.

For greenhouse tomato and greenhouse pepper uses of cyclaniliprole, the aggregate assessment consisted of combining food and drinking water exposure only, since residential exposure is not expected.

3.7 Health incident reports

As of 23 August 2023, no human or domestic animal incidents involving cyclaniliprole had been submitted to the PMRA.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Refer to PRD2017-12 and RD2017-17 for details on the environmental fate of cyclaniliprole.

4.2 Environmental risk characterization

An environmental risk assessment integrates environmental exposure and ecotoxicology information in order to estimate the potential for adverse effects to non-target organisms. This integration is achieved by comparing estimated environmental concentrations (EECs) to the concentrations at which adverse effects occur. EECs are estimated using standard models considering application rate(s), and chemical and environmental fate properties, including the dissipation of the pesticide between applications. Initially, a screening-level risk assessment was performed to identify the major new uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment used simple methods, conservative exposure scenarios, and sensitive effect metrics. Risk quotients (RQs) were calculated by dividing the exposure estimate by an appropriate effect metric (RQ = EEC/effect metric), and the risk quotient was then compared to the level of concern. If the screening level risk quotient was below the level of concern, the risk was considered to be negligible and no further risk characterization was necessary.

If the screening level risk quotient was equal to or greater than the level of concern, additional sources of information were considered and a refined risk assessment was conducted if necessary. The refined risk assessments took into consideration more realistic exposure scenarios and effects metrics, including results of higher tier semi-field and field pollinator studies.

Risks to non-target organisms other than bees (in other words, other terrestrial invertebrates, birds, mammals, non-target terrestrial plants and aquatic organisms)

With the exception of bees, risks to non-target organisms are evaluated using the maximum cumulative application rate. The maximum cumulative application rates for the proposed major new uses on outdoor ornamentals, greenhouse ornamentals and greenhouse food crops range from 240 to 300 g a.i./ha, with a maximum single rate of 100 g a.i./ha for greenhouse crops. The maximum cumulative registered rate of cyclaniliprole is 300 g a.i./ha, with a maximum single rate of 80 g a.i./ha. As such, the proposed major new uses are not expected to increase the environmental exposure of terrestrial invertebrates, birds, mammals, non-target terrestrial plants and aquatic organisms to cyclaniliprole.

Refer to PRD2017-12 and RD2017-17 for the environmental risk assessment for these organisms.

Risks to bees

Bees could be exposed to residues of cyclaniliprole when they collect pollen and nectar from flowers of bee attractive crops as a food source. Individual flowers generally only bloom for a short period of time. As such, it is unlikely that the same forager bee would be exposed to a flower that was sprayed with cyclaniliprole multiple times. Given this, risks to bees are evaluated using the maximum single application rate to estimate the highest potential exposure. Cyclaniliprole is not systemic but demonstrates translaminar movement, meaning that residues moving inside the plant remain mainly in the leaves. As such, bees are only likely to be exposed to cyclaniliprole in pollen and nectar when flowers are sprayed directly (in other words, pre-bloom applications are not expected to result in exposure through pollen and nectar).

The bee risk assessment conducted in PRD2017-12 determined that cyclaniliprole is toxic to bees. The results of semi-field and field studies demonstrated that application of cyclaniliprole at rates of 40 g a.i./ha and above require restrictions on application timing to reduce exposure of bees (application only at night) or at rates above 53 g a.i./ha (no application during bloom for highly attractive plants).

Major new use on outdoor ornamental plants: Bees can be exposed to residues of cyclaniliprole in pollen and/or nectar when applications are made to bee attractive crops during bloom. The use of cyclaniliprole on outdoor ornamentals (maximum single rate of 40 g a.i./ha) is not expected to increase the environmental exposure of bees when compared to the registered outdoor uses. Mitigation is required to limit applications on bee attractive blooming crops to the evening when most bees are not foraging. This is consistent with mitigation currently on registered label for outdoor uses at this rate.

Major new uses on greenhouse ornamentals and greenhouse food crops: The single application rate for greenhouse crops is 100 g a.i./ha, which is higher than the single registered rate of 80 g a.i./ha. Limited exposure of bees in the environment is expected from the use of cyclaniliprole in greenhouse-grown food crops (peppers and tomatoes) since they are not moved outdoors. However, pollinators in the environment could be exposed to residues of cyclaniliprole following application to bee attractive ornamental plants (perennials and annuals) in a greenhouse that are then placed outdoors. As it is possible that treated plants could be moved outside on the day of treatment, mitigation is required to prohibit the movement of bee-attractive plants outdoors if flowers that have been sprayed with cyclaniliprole remain on the plant. This is consistent with mitigation currently on registered labels for outdoor applications at rates above 53 g a.i./ha where highly attractive plants cannot be sprayed during bloom. Additionally, there is potential risk to bees and beneficial insects used for pollination and integrated pest management in greenhouses. A precautionary label statement to inform users to avoid application of cyclaniliprole when bees and other beneficial insects are in the treatment area due to potential toxicity is also required.

4.2.3 Incident reports

As of 23 August 2023, no environmental incidents involving cyclaniliprole had been submitted to the PMRA.

5.0 Value

Cyclaniliprole 50SL Insecticide will provide Canadian growers with an additional product for use to manage whiteflies, cabbage looper, beet armyworm and western flower thrips on greenhouse tomatoes. Cyclaniliprole 50SL Insecticide will also provide growers with a product to manage bertha armyworm and fall armyworm on greenhouse tomatoes, for which there are no alternatives. Support for these new uses was based on extrapolation from registered uses of the same product for the same pests on field tomatoes.

Cyclaniliprole 50SL Insecticide will provide Canadian growers with an additional product for use to manage pepper weevil on greenhouse peppers in an integrated pest management program. The report of a single efficacy trial provided evidence that Cyclaniliprole 50SL Insecticide will suppress pepper weevil on greenhouse peppers when applied according to the use directions on the label.

Cyclaniliprole 50SL Insecticide will provide a new mode of action for use to manage redheaded flea beetle on outdoor ornamentals (excluding conifers). The reports of two efficacy trials provided evidence that Cyclaniliprole 50SL Insecticide will suppress redheaded flea beetles on outdoor ornamentals (excluding conifers) when applied according to the use directions on the label.

Cyclaniliprole was already registered for suppression of western flower thrips and onion thrips on a variety of different food crops, including both herbaceous and woody plants and ranging from low growing plants to trees. That registered use pattern provided a basis to extrapolate to

ornamentals as a group, which also includes both herbaceous and woody plants with various growth forms. Data from a single efficacy trial on verbena confirmed that Cyclaniliprole 50SL Insecticide can provide suppression of western flower thrips and onion thrips when applied according to the use directions on the label.

Despite there being a number of alternative active ingredients registered for thrips on greenhouse ornamentals, this use was identified by Canadian growers as a priority for registration of new pest control products. Thrips are known for developing resistance to conventional insecticides, so having numerous active ingredients available is important for resistance management. Cyclaniliprole provides a new alternative active ingredient for thrips on greenhouse ornamentals.

6.0 Pest control product policy considerations

6.1 Toxic Substances Management Policy considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, cyclaniliprole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that cyclaniliprole and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to PRD2017-12 for further information on the TSMP assessment.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.[6]

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

The list is used as described in the PMRA Science Policy Note SPN2020-01[7] and is based on existing policies and regulations, including the Toxic Substance Management Policy and Formulants Policy,[8] and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999, (*substances designated under the *Montreal Protocol).*

The PMRA has reached the conclusion that cyclaniliprole and its end use product, Cyclaniliprole 50SL Insecticide, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Cyclaniliprole 50SL Insecticide, containing the technical grade active ingredient cyclaniliprole, as a foliar insecticide for use on greenhouse tomato for control or suppression of western flower thrips, whiteflies, beet armyworm, bertha armyworm, cabbage looper and fall armyworm; greenhouse pepper for suppression of pepper weevil; greenhouse ornamental suppression of western flower thrips and onion thrips and outdoor ornamentals for the suppression of redheaded flea beetle.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product is acceptable.

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7 PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the *Pest Control Products Act*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*

List of abbreviations

µg	micrograms
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
ALP	alkaline phosphatase
a.i.	active ingredient
ARTF	Agricultural Re-entry Task Force
ATPD	Area Treated Per Day
bw	body weight
CAF	composite assessment factor
cm	centimetres
DFR	Dislodgeable Foliar Residue
EEC	Estimated environmental concentration
g	gram
ha	hectare(s)
Hg	mercury
hr	Hour
kg	kilogram
kPa	Kilopascal
L	litre
LOQ	limit of quantitation
mg	milligram
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PHED	Pesticide Handler Exposure Database
PPE	Personal Protective Equipment
PRD	Proposed Registration Decision
ppm	parts per million
REI	Restricted-Entry Interval
RTI	Retreatment Interval
TC	Transfer Coefficient
TSMP	Toxic Substances Management Policy

Appendix I Tables and figures

Table 1 Toxicology endpoints for use in health risk assessment for Cyclaniliprole

Exposure scenario	Study	Point of departure and endpoint	CAF[1] or target MOE
Acute dietary	Not required as no endpoint of concern attributable to a single exposure was identified.		
Repeated dietary	90-day and 1-year dietary toxicity studies in the dog (combined results)	NOAEL = 27 mg/kg bw/day Increased liver weight and ALP, decreased albumin, centrilobular hepatocellular hypertrophy	100
	ADI = 0.3 mg/kg bw/day		
Short-, intermediate-, and long-term dermal	28-day dermal toxicity study in the rat	NOAEL = 1000 mg/kg bw/day No adverse effects noted at the highest dose tested	100
Short- and intermediate-term inhalation[2]	90-day dietary toxicity study in the dog	NOAEL = 27 mg/kg bw/day Increased liver weight and ALP, decreased albumin, centrilobular hepatocellular hypertrophy	100
Cancer	Not required since there was no evidence of tumourigenicity		

[1] CAF (composite assessment factor) refers to a total of uncertainty factor and *Pest Control Products Act* factor for dietary assessments; MOE refers to a target MOE for occupational and residential assessments.[2] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 2 AHETF and PHED unit exposure estimates for mixers, loaders and applicators handling Cyclaniliprole 50SL Insecticide (µg/kg a.i. handled)

Exposure scenario and PPE		Dermal[1]	Inhalation[2]
PPE: Single layer and chemical-resistant gloves			
Mixer/loader AHETF estimates			
A	Open mixing/loading of a liquid	58.5	0.63
Applicator AHETF estimates			
B	Open cab groundboom application	25.4	1.68
C	Open cab airblast application (without chemical-resistant hat)	3769.3	9.08
Mixer/loader + Applicator PHED estimates			
D	Open mix/load liquid, low pressure handwand (for manually-pressurized handwand)	943.4	45.2

Exposure scenario and PPE		Dermal[1]	Inhalation[2]
PPE: Single layer and chemical-resistant gloves			
E	Open mix/load liquid backpack	5445.9	62.1
F	Open mix/load liquid, high pressure handwand (for mechanically-pressurized handheld sprayers)	5585.5	151

1 No adjustment since the dermal reference value is based on a dermal study.
2 Light inhalation rate (except for backpack- moderate inhalation rate)

Table 3 Mixer/Loader/Applicator exposure and risk assessment – Outdoor and greenhouse ornamentals, greenhouse peppers and greenhouse tomatoes

Exposure scenario	Unit exposure (µg/kg a.i. handled)[1]		ATPD (ha/day)[2]	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day)[3]		MOE	
	Dermal	Inhalation			Dermal	Inhalation	Dermal[4]	Inhalation[5]
PPE: Single layer and chemical-resistant gloves								
A	58.5	0.63	3.6	0.10	2.63E-04	2.84E-06	3798670	9523810
A+B	83.9	2.31	26	0.04	1.09E-03	3.00E-05	916842	899101
A+C	3827.8	9.71	20	0.04	3.83E-02	9.71E-05	26125	278064
D	943.4	45.2	3.6	0.10	4.25E-03	2.03E-04	235562	132743
E	5445.9	62.1	3.6	0.10	2.45E-02	2.79E-04	40806	96618
F	5585.5	151	3.6	0.10	2.51E-02	6.80E-04	39786	39735

1 Unit exposures based on AHETF and PHED
2 ATPD of 3.6 ha/day from the 2015 StatsCan Census of Agriculture for the 95th percentile area of greenhouse vegetable production. ATPDs of 26 ha/day for groundboom and 20 ha/day for airblast application from the PMRA Default Area Treated per Day table (2023-01-18)
3 Daily exposure = (Unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)
4 Based on NOAEL = 1000 mg/kg bw/day, target MOE = 100 (see Table 1)
5 Based on NOAEL = 27 mg/kg bw/day, target MOE = 100 (see Table 1)

Table 4 Postapplication exposure and risk estimates for cyclaniliprole on day 0 after the last application

Crop/Use pattern	Postapplication activity	Peak DFR[1] (µg/cm^2)	Transfer coefficient[2] (cm^2/hr)	Dermal exposure[3] (mg/kg bw/day)	MOE[4]	REI[5] (hrs)
Outdoor ornamentals 6 applications at 40 g a.i./ha; 5 day RTI	Hand harvesting, disbudding, pruning	0.4240	4000	0.1696	5896	12
Greenhouse ornamentals 3 applications at 80 g a.i./ha and 1 application at 60 g a.i./ha (total 300 g a.i./ha/crop cycle); 7 day RTI	Hand harvesting, disbudding, pruning	0.6052	4000	0.242	4131	12
Greenhouse peppers 3 applications at 100 g a.i./ha; 7 day RTI	All activities	0.6554[6]	1400	0.0918	10898	12
Greenhouse tomatoes 4 applications at 60 g a.i./ha; 5 day RTI	All activities	0.5189[6]	1400	0.0727	13764	12

1 Peak DFR for outdoor ornamentals calculated using the standard 25% dislodgeable on the day of application and 3% dissipation per day from a chemical-specific dislodgeable foliar residue study on apples. Peak DFR for greenhouse ornamentals, peppers, and tomatoes calculated using the standard 25% dislodgeable on the day of application and 2% dissipation per day

2 Transfer coefficients obtained from PMRA Agricultural TCs Table (01.19.2023)

3 Exposure = (Peak DFR [µg/cm^2] × TC [cm^2/hr] × 8 hours × 100% dermal absorption) / (80 kg bw × 1000 µg/mg)

4 Based on a NOAEL of 1000 mg/kg bw/day, target MOE = 100 (see Table 1)

5 Minimum REI is 12 hours to allow residues to dry suspended particles to settle and vapours to dissipate.

Table 5 Residential post-application exposure to cyclaniliprole on outdoor ornamentals.

Scenario	Life stage	Peak DFR[1] (ug/cm^2)	Transfer coefficient[2] (cm^2/hr)	Exposure duration (hr/day)	Dermal exposure[3] (mg/kg bw/day)	Dermal MOE[4]	Re-entry interval
Trees and retail plants	Adult	0.4240	1700	1	9.01E-03	110983	Until sprays have dried
	Children (6 <11 years)	0.4240	930	0.5	6.16E-03	162298	

DFR = Dislodgeable foliar residue; MOE = Margin of Exposure

1 Calculated using the standard value of 25% of the application rate on Day 0 after the last application and 3% dissipation per day (from the apple DFR study). The DFR value was calculated based on 6 applications of the highest rate and an RTI of 5 days.

2 TCs were obtained from the PMRA memo entitled "Review of USEPA Residential SOPs (2012) Section 4: Gardens and Trees" (6 Sept 2019) and the 2012 USEPA SOP for Residential Pesticide Exposure Assessment.

3 Dermal Exposure = (Peak DFR [µg/cm^2] × TC [cm^2/hr] × Exposure duration [hours/day] / (Body weight [80 kg for adults; 32 kg for children] × 1000 µg/mg)

4 Based on a NOAEL of 1000 mg/kg bw/day, target MOE = 100 (see Table 1)

Table 6 Integrated food residue chemistry summary

Crop field trials and residue decline on greenhouse pepper								**PMRA # 3026867**
Greenhouse trials were conducted in 2017 in Canada. Trials were conducted in 4 separate greenhouses. A suspension formulation was applied three times as foliar directed sprays at a rate of 97–104 g a.i./ha/application for a total application rate of 298–307 g a.i./ha. The applications were made at 6 to 8-day intervals with the last application occurring 0 days before harvest. Residue decline data show that average residues of cyclaniliprole in/on bell pepper increased between the 0- and 3-day preharvest intervals (PHIs), then declined through the 14-day PHI to levels similar to those observed at the 0-day PHI.								
Commodity	**Total application rate (g a.i./ha)**	**PHI (days)**	**Residue levels (ppm)**					
			n	**LAFT**	**HAFT**	**Median**	**Mean**	**SD**
Cyclaniliprole								
Bell pepper	298–304	0–3	2	0.159	0.252	0.206	0.206	N/A
Non-bell pepper	306–307	0	2	0.158	0.588	0.373	0.373	N/A
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation, N/A = not applicable. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								

Crop field trials and residue decline on greenhouse tomato								PMRA # 3194253
Greenhouse trials were conducted in 2018 in the United States. Trials were conducted in 5 separate greenhouses. A suspension formulation was applied four times as foliar directed sprays at a rate of 58–65 g a.i./ha/application for a total application rate of 240–250 g a.i./ha. The applications were made at 4 to 5-day intervals with the last application occurring 0 days before harvest. Residue decline data show that average residues of cyclaniliprole in/on tomato were relatively consistent through the 7-day PHI but decreased by the 14-day PHI.								
Commodity	**Total application Rate (g a.i./ha)**	**PHI (days)**	**Residue levels (ppm)**					
			n	**LAFT**	**HAFT**	**Median**	**Mean**	**SD**
Cyclaniliprole								
Tomato	240–250	1–7	5	0.062	0.30	0.097	0.167	0.114
LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. Values based on per-trial averages. For computation, values < LOQ are assumed to be at the LOQ. n = number of independent field trials.								

Table 7 Food residue chemistry overview of risk assessment

Dietary risk from food and water			
	Population	**Estimated risk % of acceptable daily intake (ADI)**	
		Food alone	**Food and water**
Basic chronic dietary exposure analysis **ADI = 0.3 mg/kg bw/day** **Estimated chronic drinking water concentration = 79 µg a.i./L**	**All infants < 1 year**	2.1	4.1
	Children 1–2 years	5.7	6.5
	Children 3–5 years	4.7	5.3
	Children 6–12 years	2.8	3.3
	Youth 13–19 years	2.1	2.4
	Adults 20–49 years	2.5	3.0
	Adults 50+ years	2.6	3.1
	Females 13–49 years	2.6	3.1
	Total population	2.7	3.2

Table 8 List of supported uses

Supported use claims
Control of beet armyworm, bertha armyworm, cabbage looper and fall armyworm on greenhouse tomato at a rate of 0.8 L product/ha. Apply at the first sign of pest pressure, with a maximum of four applications per crop cycle and a minimum interval between treatments is 5 days.
Suppression of western flower thrips and whiteflies on greenhouse tomato at a rate of 1.2 L product/ha. Apply at the first sign of pest pressure, with a maximum of four applications per crop cycle and a minimum interval between treatments is 5 days.
Suppression of pepper weevil (*Anthonomus eugenii*) on greenhouse pepper, applied at 1.2–2.0 L product/ha. Apply at first sign of pest pressure, with a maximum of three applications per crop cycle with a minimum of seven days between treatments.
Suppression of western flower thrips and onion thrips on greenhouse ornamentals at a rate of 1.2–1.6 L product/ha. Apply when pests are first observed with a maximum of five applications (low rate only) with a maximum of 6 L/ha per crop cycle and a minimum of 7 days between applications. Spray volume should be sufficient to ensure good coverage up to 1000 L/ha. The maximum spray volume should be used when plant foliage is dense. Use the higher rate for high pest pressure. Avoid applying cyclaniliprole 50SL insecticide or other Group 28 insecticide consecutively more than 2 times within a 30 day period. Ornamental species and varieties may vary in their tolerance to pest control products. First use of cyclaniliprole 50SL insecticide should be limited to a small area of each variety to test for possible phytotoxicity before making large scale applications.
Suppression of Redheaded flea beetle (*Systena frontalis*) in outdoor ornamentals (excluding conifers) at a rate of 0.8 L product/ha. Spray volume should be sufficient for good coverage (935–1400 L/ha recommended). Apply at first sign of adults, with a maximum of 6 applications per crop cycle, and a minimum retreatment interval of 5 days.

Appendix II Supplemental maximum residue limit information—International situation and trade implications

New uses on greenhouse peppers and greenhouse tomatoes are concurrently being registered in Canada and the United States for cyclaniliprole. The MRLs proposed for cyclaniliprole in Canada are the same as corresponding tolerances established in the United States.

The established American tolerances for cyclaniliprole are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs listed for cyclaniliprole in or on any commodity on the Codex Alimentarius Pesticide Residues in Food website.

References

A. List of studies/information submitted by registrant

1.0 Human and animal health

PMRA Document Number	Reference
3026867	2019, Magnitude of the residue on Pepper, Greenhouse., DACO: 7.4.1,7.4.2
3194253	2020, Cyclaniliprole: Magnitude of the Residue on Greenhouse Tomato IR-4 PR No. 11894, DACO: 7.4.1,7.4.2

2.0 Environment

2398991	2012, Final Report (2nd Original) Effects of IKI-3106 TGAI (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory, DACO: 9.2.4.1,9.2.4.2,IIA 8.7.1,IIA 8.7.2
2399053	2012, Final Report (2nd Original) Effects of IKI-3106 50SL (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory, DACO: 9.2.8,IIIA 10.4.2.1,IIIA 10.4.2.2
2399054	2013, Final Report (2nd Original) Study on the Effect of IKI-3106 50SL on Honey Bees (*Apis mellifera* L.) under Field Conditions including Brood Assessments Field Test: Application after Bee Flight, DACO: 9.2.9,IIIA 10.4.5
2399059	2013, Final Report (2nd Original) Study on the Effect of IKI-3106 50SL on Honey Bees (*Apis mellifera* L.) under Field Conditions including Brood Assessments Field Test: Application After Bee Flight, DACO: 9.2.9,IIIA 10.4.5
2399062	2013, Final Report (2nd Original) Study on the Effect of IKI-3106 50SL on Honey Bees (*Apis mellifera* L.) under Field Conditions including Brood Assessments Field Test: Application during Bee Flight, DACO: 9.2.9,IIIA 10.4.5
2399068	2013, Final Report (2nd Original) Study on the Effect of IKI-3106 50SL on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions Tunnel Test: Application after Bee Flight, DACO: 9.2.8,IIIA 10.4.7
2399070	2013, Final Report (2nd Original) Study on the Effect of IKI-3106 50SL on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions Tunnel Test: Application After Bee Flight, DACO: 9.2.8,IIIA 10.4.7
2399073	2013, Final Report (2nd Original) Study on the Effect of IKI-3106 50SL on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions Tunnel Test: Application after Bee Flight, DACO: 9.2.8,IIIA 10.4.7

2524490	2015, IKI-3106 50 SL (80 g a.i. Cyclaniliprole / hectare): A semi-field study to evaluate potential effects on honeybee, *Apis mellifera* L. (Hymenoptera: Apidae), worker mortality and brood development following the application on *Phacelia tanacetifolia*, DACO: 9.2.8,IIIA 10.4.7
2612298	2014, Chronic Oral Toxicity Test of IKI-3106 50 SL on the Honey Bee (Apis mellifera L.) in the Laboratory, DACO: 9.2.4
2612300	2015, *Apis mellifera* larval toxicity test of IKI-3106, single oral exposure, DACO: 9.2.4
2614337	2016, Evaluation of Honeybee Colony Health and Productivity During and After Colony Exposure to Flowering Canola Fields Treated with IKI-3106 50 SL (Cyclaniliprole), DACO: 9.2.4
2663361	2016, AMENDED REPORT - IKI-3106 50SL: A Foliage Residue Toxicity Study with the Honeybee, DACO: 9.2.4
2718601	2016, IKI -3106 Technical Grade: Honey Bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure, DACO: 9.2.4

3.0 Value

2018-5560:

2929591	2018, Value Report - Cyclaniliprole 50SL Insecticide (cyclaniliprole) for redheaded flea beetle on outdoor ornamentals, DACO: 10.1
2929592	2018, Data Summary - Cyclaniliprole 50SL Insecticide (cyclaniliprole) for redheaded flea beetle on outdoor ornamentals, DACO: 10.2.3.1
2929593	2018, Field Trial Reports - Cyclaniliprole 50SL Insecticide (cyclaniliprole) for redheaded flea beetle on outdoor ornamentals, DACO: 10.2.3.3

2019-2117:

2994457	2019, Efficacy of Cyclaniliprole 50SL Insecticide (cyclaniliprole) for Suppression of Western Flower Thrips and Onion Thrips on Greenhouse Ornamentals, DACO: 10.1
2994458	2019, Value Data Summary Table - Cyclaniliprole 50 SL (cyclaniliprole) for the suppression of western flower thrips and onion thrips on GH ornamentals, DACO: 10.2.3.1
2994459	2017, Field Trial Reports - Cyclaniliprole 50 SL (cyclaniliprole) for the suppression of western flower thrips and onion thrips on GH ornamentals, DACO: 10.2.3.3

2019-4395:

3026868	2019, Value data report - Efficacy and Tolerence of Cyclaniliprole 50SL for the control of Pepper Weevil in GH Pepper, DACO: 10.1
3026870	2017, Field trial report - Tolerance to and efficacy of cyclaniliprole 50 SL for the control of pepper weevil in GH Pepper, DACO: 10.2.3.3

2021-0361:

3194254	2020, Value Report - Efficacy and Tolerance of Cyclaniliprole 50 SL (cyclaniliprole) for Suppression of Thrips and Whiteflies, and Control of Lepidoptera (Incl. Cabbage Looper, and Beet Armyworm) in Greenhouse Tomato, DACO: 10.1
3194256	2019, Efficacy of Cyclaniliprole 50 SL for the control thrips on greenhouse tomato, DACO: 10.2.3.3