Proposed Registration Decision PRD2023-05

DeltaGard SC Insecticide, containing deltamethrin

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Overview

Proposed Registration Decision for DeltaGard SC 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 DeltaGard SC Insecticide, containing the technical grade active ingredient deltamethrin, to control box tree moth on outdoor-grown boxwood. 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.

Deltamethrin Technical Insecticide (Registration Number 18092) is currently registered in Canada for use on greenhouse ornamentals, greenhouse food crops, industrial oilseed crops, terrestrial feed and food crops, roadsides, shelterbelts, indoor and outdoor surfaces of agricultural buildings and structures, and turf for the control of numerous insect pests and to control adult mosquitoes in residential and recreational areas. For details, see PRD2019-07 and RD2019-15, *Deltamethrin and Annihilator PolyZone;* PRVD2015-07, *Deltamethrin;* and RVD2018-27, *Deltamethrin and its associated End-use Products*. The use of deltamethrin on outdoor ornamentals is a new use for this active ingredient.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of DeltaGard SC Insecticide, containing deltamethrin, are acceptable.

This Overview describes the key points of the evaluation, while the Science evaluation Section provides detailed technical information on the human health, environmental and value assessments of DeltaGard SC Insecticide, containing deltamethrin, when applied to outdoor ornamentals.

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides portion of Canada.ca.

Before making a final registration decision on deltamethrin, DeltaGard SC, 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 deltamethrin, DeltaGard SC, 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 Section of this consultation document.

What is deltamethrin?

Deltamethrin is the active ingredient in the commercial class product DeltaGard SC Insecticide, which is used to kill various insect pests on turf, greenhouse floriculture crops, and outdoor-grown boxwood. Deltamethrin is a broad-spectrum synthetic pyrethroid insecticide which affects the insect nervous system causing paralysis and death.

Health considerations

Can approved uses of deltagard SC insecticide affect human health?

DeltaGard SC Insecticide, containing deltamethrin, is unlikely to affect your health when used according to label directions.

Potential exposure to DeltaGard SC Insecticide may occur when handling and applying the product, or through worker or bystander exposure following application. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to

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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*.

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). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below dose 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 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.

The end-use product DeltaGard SC Insecticide is considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure and minimally irritating to the eyes and skin. An allergic skin reaction may occur following repeated dermal exposure, and consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the product label.

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 deltamethrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoint used for risk assessment was neurotoxicity, characterized by a reduced reflex response in young animals. There is some indication that the young may be more sensitive than the adult animal; this sensitivity may reflect age-dependent differences such as the maturation of key metabolic processes.

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.

Risks in residential and other non-occupational environments

Non-occupational risks are not of concern when DeltaGard SC is used according to label directions.

As there is no potential exposure to homeowners mixing, loading, and applying deltamethrin, only a residential postapplication risk assessment was required. Residential postapplication exposure may occur from the commercial application of DeltaGard SC to boxwood.

Potential exposure to the public is expected to occur primarily by the dermal route when coming into contact with treated foliage. Residential postapplication activities met the target dermal margin of exposure (MOE) for all populations and are not of concern.

Occupational risks from handling DeltaGard SC

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

Workers who mix, load or apply DeltaGard SC as well as postapplication workers entering treated areas can be exposed to deltamethrin residues through direct skin contact and through inhalation. Therefore, the label specifies that anyone mixing/loading and applying DeltaGard SC must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. In addition, the label permits the use of handheld mist blowers/airblast equipment. Workers applying DeltaGard SC using handheld mist blower/airblast equipment must wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides. The label also requires that workers not enter treated fields for twelve (12) hours after application. Taking into consideration these label statements, the number of applications, and the expectation of the exposure period for handlers and workers, the health risk to these individuals from exposure to DeltaGard SC is not a concern.

As application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity, bystander exposure is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental considerations

What happens when deltamethrin is introduced into the environment?

Environmental risks associated with the uses of deltamethrin, and its associated end-use product DeltaGard SC Insecticide, are acceptable when used according to label directions.

Deltamethrin was found to be toxic to bees, beneficial insects, mammals and aquatic organisms. The current product label for DeltaGard SC Insecticide has statements to reduce harmful effects on bees, beneficial insects, mammals and aquatic organisms, including spray buffer zones to protect non-target terrestrial and aquatic habitats.

The new use to control the box tree moth on outdoor-grown boxwood is within the currently registered application rate for the active ingredient deltamethrin, however, the use of airblast equipment is new to the DeltaGard SC Insecticide label. As such, spray buffer zones specific to the use of airblast application methods are required on the DeltaGard SC Insecticide.

Value considerations

What is the value of DeltaGard SC?

DeltaGard SC Insecticide controls the invasive species box tree moth (*Cydalia perspectalis*) on outdoor-grown boxwood.

Box tree moth is an invasive species, which only feeds on boxwood, causing significant damage which can result in unmarketability and lead to plant mortality. Boxwood is a slow-growing and high-value ornamental crop. Box tree moth is a major threat to the Canadian boxwood nursery industry and the export market for Canadian-grown boxwood.

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 DeltaGard SC to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

Because there is potential for users' skin to come into direct contact with deltamethrin residues, anyone mixing/loading and applying DeltaGard SC (except for applicators using handheld mist blower/airblast equipment) must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Workers applying DeltaGard SC using handheld mist blower/airblast equipment must wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.

In addition, standard label statements to protect against drift during application are on the label. For postapplication re-entry activities, workers must not enter into treated areas during the restricted-entry interval (REI) of 12 hours.

Environment

- An update to the existing label language to mitigate risks to pollinators is required to bring it in line with current risk mitigating measures.
- Spray buffer zones for non-target aquatic and terrestrial habitats are required for the airblast application method.

Next steps

Before making a final registration decision on DeltaGard SC Insecticide, containing deltamethrin, 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 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 DeltaGard SC Insecticide, containing deltamethrin (based on the Science evaluation Section 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

The was no proposed change to the registered formulation of DeltaGard SC Insecticide. For information about deltamethrin and its properties, refer to *Proposed Registration Decision PRD2019-07*, (referred to as PRD2019-07 in the rest of this consultation document).

1.1 Directions for use

DeltaGard SC Insecticide is applied to outdoor-grown boxwood to control box tree moth (*Cydalima perspectalis*) in a foliar spray at a rate of 250 to 300 mL/ha when egg masses begin to hatch or when first signs of insect feeding are evident. A maximum of three applications may be made per year at 5–7 day intervals in an application volume of 200–500 L/ha.

1.2 Mode of action

Deltamethrin belongs to Insecticide Resistance Action Committee Mode of Action Group 3A (pyrethroids/pyrethrin) sodium channel modulator insecticides. Deltamethrin causes excessive firing of nerves which leads to paralysis and death of the target pest.

2.0 Methods of analysis

There was no proposed change to the active ingredient or the end use product formulation. For more information about the methods of analysis, refer to PRD2019-07.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of the toxicology database for deltamethrin was conducted previously and is summarized in the Proposed Re-evaluation Decision, PRVD2015-07 as well as updated in PRD2019-07. An extensive toxicology database is available for the assessment of human health risks of deltamethrin and the data quality is considered adequate to define the majority of the toxic effects that may result from exposure to deltamethrin. Toxicology reference values for use in the human health risk assessment were established and are reported in PRVD2015-07.

In acute toxicity testing, the end-use product DeltaGard SC Insecticide was of low acute toxicity in rats via the oral and inhalation routes of exposure and was of low acute toxicity via the dermal route in rabbits. It was minimally irritating to the eyes and skin of rabbits and is considered to be a potential skin sensitizer based on the results of testing in guinea pigs using the Buehler method.

3.2 Occupational and residential risk assessment

3.2.1 Toxicological reference values

Occupational exposure to DeltaGard SC is characterized as short-term in duration for mixer/loader/applicators and intermediate-term in duration for postapplication workers and is primarily by the dermal and inhalation routes.

Please refer to PRVD2015-07, Deltamethrin for the detailed toxicological reference values table.

3.2.2 Occupational exposure and risk

3.2.2.1 Mixer/Loader/Applicator exposure and risk assessment

Individuals have the potential for exposure to DeltaGard SC Insecticide during mixing, loading, application, clean-up and repair activities.

Exposure estimates were derived for workers mixing and loading a liquid with an open-transfer system. Dermal and inhalation exposure estimates were from the Agricultural Handlers Exposure Task Force (AHETF) database and/or the Pesticide Handlers Exposure Database (PHED, v1.1) for mixers, loaders and applicators applying DeltaGard SC Insecticide to boxwood using open cab groundboom, open cab airblast, and conventional handheld application equipment. For handheld mist blower/airblast application equipment, exposure estimates were from data generated by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Non-Dietary Exposure Task Force (NDETF). The unit exposure values in the risk assessment are based on handlers wearing various levels of PPE.

Dermal exposure was estimated using the unit exposure values, the amount of product handled per day (derived from the maximum application rate and the default area treated per day), and the dermal absorption value of 100%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Dermal and inhalation exposures were 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 MOEs are 1000 for dermal exposure and 300 for inhalation exposure. Calculated MOEs were greater than the target MOEs for mixer/loader/applicators.

Table 3.2.2.1 Mixer/loader/applicator risk assessment for workers exposed to deltamethrin when using DeltaGard SC on boxwood

Scenario	Dermal unit exposure (µg/kg a.i. handled)	Inhalation unit exposure (µg/kg a.i. handled)	Area treated per day (ha/day)	Rate (kg a.i/ha)	Dermal exposure estimate (mg/kg bw/day)[1]	Inhalation exposure estimate (mg/kg bw/day)[1]	Dermal MOE[2] (Target = 1000)	Inhalation MOE[3] (Target = 300)
Open cab groundboom	83.9	2.31	26	0.015	4.09E-04	1.13E-05	2444913	88800
Open cab airblast	3827.8	9.71	20	0.015	1.44E-02	3.64E-05	69666	27463
Manually pressurized handwand	943.37	45.20	0.75 (150 L)	0.015	1.33E-04	6.36E-06	7537987	157325
Backpack sprayer	5445.85	62.10	0.75 (150 L)	0.015	7.66E-04	8.73E-06	1305785	114511
Mechanically pressurized handwand	5585.49	151.11	19 (3800 L)	0.015	1.99E-02	5.38E-04	50256	1859
Handheld mist blower/airblast	32619.5	3940.63	2 ha	0.015	1.22E-02	1.48E-03	81751	677

[1] Daily Exposure Estimate = (Unit Exposure × Area Treated per Day (ATPD) × Rate)/(80 kg bw × 1000 µg/mg)
[2] Based on NOAEL = 1000 mg/kg bw/day, target MOE = 1000
[3] Based on NOAEL = 1 mg/kg bw/day, target MOE = 300

Taking into account both the acute toxicity of the end-use product and the risk assessment of deltamethrin, anyone mixing/loading and applying DeltaGard SC (except for applicators using handheld mist blower/airblast equipment) must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. For workers applying DeltaGard SC using handheld mist blower/airblast equipment, there is only a single PPE scenario for which unit exposure estimates are available to estimate exposure. Therefore, workers applying DeltaGard SC using this equipment must wear the PPE associated with this scenario, which includes chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.

3.2.2.2 Exposure and risk assessment for workers entering treated areas

There is potential for exposure of workers entering areas treated with DeltaGard SC. The duration of exposure is considered to be of intermediate-term. Given the nature of activities performed, exposure should be primarily via the dermal route based on dermal contact with treated foliage. Postapplication inhalation exposure is not considered to be a significant route of exposure as deltamethrin is relatively non-volatile with a low vapour pressure of 1.2×10^{-11} kPa at 25°C, which is less than the North American Free Trade Agreement (NAFTA) criterion for a non-volatile product for outdoor scenarios (1×10^{-4} kPa at 20-30 °C) and the specified restricted-entry interval (REI) will allow residues to dry and suspended particles to settle.

Quantitative postapplication worker risk assessments were conducted for the re-evaluation of deltamethrin (PRVD2015-07) and included field peppers. Field peppers have the same use pattern as boxwood and the input parameters used in the field pepper risk assessment were identical to those that would be used for the boxwood use pattern. For postapplication workers, the calculated MOE for the activity with the highest transfer coefficient was ~79 000 which exceeded the target MOE of 1000. Therefore, the risk assessment conducted for field peppers is adequate to cover potential exposure from the use of deltamethrin on boxwood, and postapplication exposure to workers is not expected to result in health risks of concern.

3.2.3 Residential exposure and risk assessment

3.2.3.1 Handler exposure and risk

There is no potential for residential handler exposure to deltamethrin from the use of DeltaGard SC on boxwood because this use pattern does not involve domestic class use.

3.2.3.2 Postapplication exposure and risk

There is potential for postapplication exposure to the public in a residential setting following commercial application of DeltaGard SC to boxwood. Potential exposure to the public is expected to occur primarily by the dermal route when coming into contact with treated foliage. The residential postapplication dermal risk assessment was conducted for adults (16 years old and over) and children (6 to less than 11 years old), which are considered the index life stages for the exposure scenario, when contacting treated boxwood.

Since no chemical-specific dislodgeable foliar residue (DFR) data for deltamethrin were submitted, the risk assessment used the current default DFR values. Dermal exposure to individuals entering treated areas was estimated by coupling the DFR values with activity-specific transfer coefficients from the USEPA Residential 2012 SOPs. Exposure was normalized to mg/kg bw/day by using the default body weight of 80 kg and a 1 to 2.2-hour exposure period for adults, as well as the default body weight of 32 kg and a 0.5 to 1.1-hour exposure period for children. Exposure estimates were then compared to the dermal toxicology reference value of 1000 mg/kg bw/day to obtain the MOEs. The target MOE is 1000 for dermal exposure.

The calculated MOEs for residential postapplication exposure exceeded the target MOE for all life stages and scenarios. Therefore, residential dermal exposure is not expected to result in any health risks of concern.

Table 3.2.3.2 Residential postapplication exposure for DeltaGard SC on boxwood

Scenario	Life stage	DFR[1] (µg/cm^2)	Weight unit conversion factor (mg/ug)	Transfer coefficient[2] (cm^2/hr)	Exposure time (hr)	Dermal exposure[3] (mg/kg bw/day)	Dermal MOE[4]
Gardens	Adult	0.0727	0.001	8400	2.2	1.68E-02	59531
	Children (6 <11 yrs)	0.0727	0.001	4600	1.1	1.15E-02	86967
Trees and retail plants	Adult	0.0727	0.001	1,700	1	1.55E-03	647134
	Children (6 <11 yrs)	0.0727	0.001	930	0.5	1.06E-03	946347

DFR = Dislodgeable foliar residue; MOE = Margin of Exposure

[1] Calculated using the values of 25% of the application rate on Day 0 after the last application (PMRA default deposition) and 10% dissipation per day (default dissipation). The DFR value was calculated based on 3 applications at a rate of 15 g deltamethrin/ha and a re-treatment interval (RTI) of 5 days.

[2] TCs were obtained from the PMRA memo entitled "Review of U.S. EPA Residential SOPs (2012) Section 4: Gardens and Trees" and the 2012 U.S. EPA SOP for Residential Pesticide Exposure Assessment.

[3] Dermal Exposure = (Peak DFR [µg/cm^2] × TC [cm^2/hr] × Exposure duration [hours/day] × [100% dermal absorption]) / (Body weight [80 kg for adults; 32 kg for children] × 1000 µg/mg)

[4] Based on a dermal NOAEL of 1000 mg/kg bw/day; Target MOE of 1000.

3.2.3.3 Bystander exposure and risk

Bystander exposure is expected to be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature, application equipment and sprayer settings.

3.3 Health incident reports

From April 2007 to 24 February 2022, 33 human and 55 domestic animal incidents involving deltamethrin had been submitted to the PMRA.

Sixteen human incidents (46%) were considered to be possibly related to the reported deltamethrin product. Exposure scenarios reported in people include contact with treated plant material, exposure when mixing/loading or applying a deltamethrin product, equipment failure and drift from an application site. The symptoms reported in people were mainly minor in nature and include effects such as nausea, skin or eye irritation, shortness of breath, throat irritation or headache. The remaining incident reports, including 13 serious incidents (11 United States and 2

Canada – classified as death and major) were considered to either have insufficient information on the reported circumstances of deltamethrin exposure or the reported effects (for example, stroke, slurred speech, jaundice) were not typical of the reported deltamethrin pesticide.

Twenty three domestic animal incidents (42%) were considered to be possibly related to the reported deltamethrin product. Most of these incidents (18 reports) were serious incidents (classified as death) that occurred in the United States. The incidents commonly involved pets and reported exposure scenarios include contact with product residues, ingesting or licking treated plant material, drift/run-off from an application site. The symptoms reported in animals include lethargy, anorexia, excessive salivation, shortness of breath, ataxia, seizures as well as death.

The product label of the DeltaGard SC Insecticide for the proposed use to control box tree moth on boxwood in Canada has been updated with appropriate signal words, personal protective equipment requirements as well as precautionary statements to minimize any potential dermal, ocular or inhalation exposure in users (applicators) when mixing, loading or applying the product. In order to minimize the chance of postapplication exposure in people (including children) and pets, the DeltaGard SC Insecticide label includes a statement to prevent access of people and pets to treated areas until after the pesticide residues have dried.

3.4 Cumulative assessment

Deltamethrin is a member of the pyrethroid class of chemicals, which have a common mechanism of toxicity wherein they all possess the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. As part of the process in determining the need to conduct a cumulative risk assessment, other important considerations must be explored, such as defining and comparing the use patterns of the different chemicals belonging to a class of pesticides with a common mechanism of toxicity to determine if the same uses are registered, whether the uses are wide-ranging, if there are residential uses, and the potential for co-occurrence of exposure to the different chemicals.

As the major new use for deltamethrin is only for the control of box tree moth on boxwood, the dietary contribution of deltamethrin will not be impacted. The contribution to the residential exposure of deltamethrin, through this new use, will be limited. Thus, the dietary and residential exposure to deltamethrin resulting from this new use will be minimal and as such can be supported.

Upon completion of the re-evaluation of the individual chemicals in the pyrethroid group, a cumulative risk assessment will be conducted as a stand-alone evaluation, which is consistent with the process described in PMRA’s framework on cumulative health risk assessment (SPN2018-02).

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Deltamethrin can enter soil and surface water where it can persist under certain conditions. In soil, deltamethrin binds strongly to soil particles, making it unlikely to move downward in the soil and reach groundwater. In aquatic environments, deltamethrin will rapidly move out of water and into the sediments where it can persist. Deltamethrin is known to move into the atmosphere, but is unlikely to persist in air or move in air to remote locations such as the Arctic. Deltamethrin is not likely to accumulate in the tissues of organisms such as fish.

Please refer to PVRD2015-07 for details on the fate and behaviour of deltamethrin in the environment.

4.2 Environmental risk characterization

Please refer to PVRD2015-07 for details on the risks to terrestrial and aquatic organisms.

The previous risk characterization showed that deltamethrin poses a potential risk to bees, beneficial insects, mammals and aquatic organisms. The current product label for DeltaGard SC Insecticide has statements to reduce harmful effects on bees, beneficial insects, mammals and aquatic organisms, including spray buffer zones to protect non-target terrestrial and aquatic habitats.

The application rate for the control of box tree moth is within the currently registered application rate for deltamethrin. Airblast application, however, is not currently on the registered label for DeltaGard SC Insecticide. As such, spray buffer zones for airblast were calculated. Based on the risk identified to off-target sensitive habitats, spray buffer zones of up to 3 m are required to protect terrestrial habitats, up to 45 m are required to protect amphibian and freshwater habitats, and up to 85 m are required to protect marine/estuarine habitats.

In addition, an update to the label language to mitigate risks to pollinators is required to bring it in line with current risk mitigating measures.

When all label guidance is followed, the risk to non-target organisms from the use of DeltaGard SC Insecticide was found to be acceptable.

4.3 Environmental incident reports

One Canadian environmental incident was reported in PRVD2015-07. The role of deltamethrin was considered unlikely. Please refer to PVRD2015-07 for details. No new incident has been reported up to February 24, 2022.

5.0 Value

Value information reviewed was a scientific rationale to extrapolate control of box tree moth on outdoor-grown boxwood from registered control claims for related pests on similar deltamethrin products. This rationale was acceptable to support a claim that DeltaGard SC Insecticide will control box tree moth on outdoor-grown boxwood at an application rate of 250 to 300 mL/ha.

This use has value as box tree moth is an invasive species, which can cause severe damage to boxwood. Box tree moth larvae feed on foliage and stems. Box tree moth damage decreases marketability of boxwood, and can lead to plant mortality. In addition, as box tree moth is an invasive species, control of this pest is required for export of Canadian-grown boxwood to certain export markets.

Registered alternatives for control of box tree moth contain strains of the active ingredient *Bacillus thuringiensis. Bacillus thuringiensis* requires ingestion of treated plant material to cause mortality, resulting in damage to the plant, and is slower-acting than deltamethrin. DeltaGard SC Insecticide will provide boxwood growers with an alternative product, which kills box tree moth on contact. Deltamethrin provides a new mode of action for the supported use.

6.0 Pest control product policy considerations

6.1 Assessment of the active ingredient under the Toxic Substances Management Policy

The PMRA has reached the conclusion that technical grade deltamethrin does not meet the Toxic Substances Management Policy (TSMP) Track 1 criteria, and is not expected to form any transformation products which would meet the TSMP Track 1 criteria. Please refer to PVRD2015-07 for further details on the TSMP assessment.

6.2 Formulants and contaminants of health or environmental concern

The PMRA has reached the conclusion that technical grade deltamethrin and its end-use product DeltaGard SC Insecticide do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. Please refer to PVRD2015-07 for further details on the TSMP assessment.

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 DeltaGard SC Insecticide, containing the technical grade active ingredient deltamethrin, to control box tree moth on outdoor-grown boxwood.

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.

List of abbreviations

µg	microgram(s)
AHETF	Agricultural Handlers Exposure Task Force
a.i.	active ingredient
ATPD	area treated per day
bw	body weight
cm	centimetre(s)
DFR	dislodgeable foliar residue
ha	hectare(s)
kg	kilogram(s)
L	litre(s)
mg	milligram(s)
mL	millilitre(s)
MOE	margin of exposure
NAFTA	North American Free Trade Agreement
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
REI	restricted-entry interval
RTI	re-treatment interval
SOP	standard operating procedure
TC	transfer coefficient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

References

A. List of studies/Information submitted by the applicant

1.0 Value

2964399 2019, Value Rationale, DACO: 10.1
2964400 2019, Species Bridging Table, DACO: 10.1