Proposed Registration Decision PRD2017-05

Deltamethrin

(publié aussi en français)

28 February 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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

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

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2017-5E (print version)
H113-9/2017-5E-PDF (PDF version)

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Overview

Proposed Registration Decision for Deltamethrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Deltamethrin Technical Insecticide and DeltaGard 20EW, containing the technical grade active ingredient deltamethrin, to control adult mosquitoes in residential and recreational areas.

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 and turf for the control of numerous insect pests. The use of deltamethrin on human habitat and recreational areas to control adult mosquitoes is a new use for this active ingredient.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

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 Deltamethrin Technical Insecticide and DeltaGard 20EW.

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. 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.

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

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."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides.

For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on deltamethrin, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on deltamethrin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA'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 Deltamethrin?

Deltamethrin is the active ingredient found in the commercial class product, Deltagard 20EW, which controls adult mosquitoes in residential and recreational areas.

Health Considerations

Can Approved Uses of Deltamethrin Affect Human Health?

DeltaGard 20EW, containing deltamethrin, is unlikely to affect your health when used according to the proposed label directions, which include additional risk reduction measures.

Potential exposure to DeltaGard 20EW may occur when handling and applying the product, or through bystander exposure following application. When assessing health risks, two key factors are considered: the levels where no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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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*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses 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, acute oral toxicity of deltamethrin ranged from low to high. Deltamethrin is of low to moderate acute inhalation toxicity, and is of low acute dermal toxicity. Deltamethrin is not an eye or skin irritant; however, itching, tingling or burning sensations of the skin may occur as a result of its effect on nerves in the skin. Exposure to deltamethrin is not expected to cause an allergic skin reaction.

The end-use product, DeltaGard 20EW, is of low toxicity via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eyes and non-irritating to the skin; however, it could potentially cause an allergic skin reaction. Based on these findings, the hazard statement "Potential Skin Sensitizer" appears on the label.

Registrant-supplied short, and long term (lifetime) animal toxicity tests, as well as information from published scientific literature were collectively 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 these and any 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 to 2 years old, the subpopulation which would ingest the most deltamethrin relative to body weight, are expected to be exposed to less than 29% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from deltamethrin is not of health concern for any population subgroups.

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 66% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was children 1 to 2 years old.

Occupational Risks From Handling DeltaGard 20EW

Occupational risks are not of concern when DeltaGard 20EW is used according to the proposed label directions, which include protective measures.

Commercial applicators who mix, load and/or apply DeltaGard 20EW, as well as workers re-entering recently treated residential areas, can come in direct contact with DeltaGard 20EW residues on the skin or through inhalation of spray mists. Therefore, the label specifies that anyone mixing/loading and applying DeltaGard 20EW must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, and a respirator with a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister for pesticides. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and re-entry workers, the risks to these individuals are not a concern.

Risks in Residential and Other Non-Occupational Environments

Residential and non-occupational risks are not of health concern when DeltaGard 20EW is used according to the label directions.

Deltamethrin is applied to residential areas by commercial applicators only; and therefore, there is no potential exposure to homeowners mixing, loading, or applying the pesticide. Non-occupational postapplication risks are not of concern for any population, including children. There is no risk of concern for bystanders entering treated sites.

Environmental Considerations

What Happens When Deltamethrin Is Introduced Into the Environment?

When used according to label directions, deltamethrin is not expected to pose risks of concern to the environment.

Deltamethrin, when used for control of adult mosquitoes, will be applied by non-thermal fogging using ultra-low volume (ULV) sprayers. The droplets of pesticide are very small and do not drift or deposit on soil or water like larger droplets and may evaporate while they are suspended in the air. As a result, the amount of pesticide deposited on land and water is expected to be minimal. Additionally, treatment typically occurs at night or in early morning when adult mosquitoes are most active, and other non-target organisms may be less active.

In laboratory studies, deltamethrin was found to be toxic to bees, beneficial insects, and aquatic organisms when exposed to high enough concentrations. Due to the reduced potential for exposure of non-target organisms because of the small droplet sizes produced during application, and as mosquito spray programs are conducted at night or early morning, when honeybees and other beneficial insects are less likely to be foraging, the proposed use of DeltaGard 20EW is not expected to pose risks of concern to non-target terrestrial and aquatic organisms when used in accordance with the label directions.

Value Considerations

What Is the Value of DeltaGard 20EW?

Mosquitoes can be a nuisance and may transmit diseases to people. DeltaGard 20EW controls adult mosquitoes in residential and recreational areas.

DeltaGard 20EW is a new product to control adult mosquitoes in residential and recreational areas. It can be used with other management practices in mosquito control programs.

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 20EW to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Since handlers can come in direct contact with DeltaGard 20EW on the skin or through inhalation of spray mists, anyone mixing, loading and applying DeltaGard 20EW must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, and a respirator with a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister for pesticides. In addition, a statement to protect against application in a manner that will directly contact workers or other persons is on the label.

Environment

Label statements are required to inform users that deltamethrin may affect bees, beneficial insects and aquatic organisms, and to prevent contamination of irrigation, drinking water supplies and aquatic habitats.

Next Steps

Before making a final registration decision on deltamethrin, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA 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). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency’s response to these comments.

Other Information

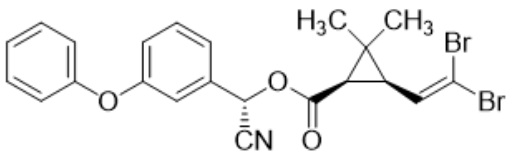
When the PMRA makes its registration decision, it will publish a Registration Decision on deltamethrin (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Deltamethrin

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Deltamethrin
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(*S*)-*α*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate
2. Chemical Abstracts Service (CAS)	(*S*)-cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate
CAS number	52918-63-5
Molecular formula	$C_{22}H_{19}Br_2NO_3$
Molecular weight	505.2
Structural formula	
Purity of the active ingredient	99.5%

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Deltamethrin Technical Insecticide

Property	Result
Colour and physical state	Colourless crystals
Odour	Odourless
Melting range	100-102°C
Boiling point or range	Not applicable
Bulk density	0.55 g/cm^3
Vapour pressure at 25°C	1.24×10^{-5} mPa

Property	Result
Ultraviolet (UV)-visible spectrum	Not expected to absorb at $\lambda > 300$ nm
Solubility in water at 20-25°C	< 0.2 µg/L
Solubility in organic solvents at 20°C	Solvent — Solubility (g/L) Dioxane — 900 Cyclohexanone — 750 Dichloromethane — 700 Acetone — 500 Benzene — 450 Dimethylsulfoxide — 450 Xylene — 250 Ethanol — 15 Isopropanol — 6
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} = 4.6
Dissociation constant (pK_a)	Not applicable
Stability (temperature, metal)	Stable at ≤ 190°C; under UV irradiation and in sunlight, a *cis-trans* isomerization, splitting of the ester bond, and loss of bromine occur; more stable in acidic than alkaline media.

End-Use Product—DeltaGard 20EW

Property	Result
Colour	White
Odour	Odourless
Physical state	Liquid
Formulation type	Suspension
Guarantee	20 g/L
Container material and description	Plastic (high density polyethylene)
Density	1.005-1.025 g/mL
pH of 1% dispersion in water	7.9
Oxidizing or reducing action	Some components of the product are incompatible with strong oxidizing agents.
Storage stability	Stable for 14 days at 54°C in the commercial packaging
Corrosion characteristics	Non-corrosive to the packaging material
Explodability	Not explosive

1.3 Directions for Use

DeltaGard 20EW is a commercial class insecticide used for adult mosquito control in residential and recreational areas. It is to be applied using vehicle-mounted ULV ground sprayers at a rate of 25-75 mL product per hectare (0.5-1.5 g deltamethrin per hectare). The highest rate is recommended for dense vegetation and when targeting difficult to control species of mosquitoes. If mosquitoes continue to be a problem, DeltaGard 20EW may be reapplied at 3-day intervals. No more than 10 applications are permitted in a year.

1.4 Mode of Action

Deltamethrin is a pyrethroid insecticide which belongs to Insecticide Resistance Action Committee Mode of Action (MOA) Group 3A insecticides that causes excessive firing of nerves. This leads to paralysis and death of an insect.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods previously provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

High performance liquid chromatography method with tandem mass spectrometric detection (HPLC-MS/MS; Method 00855/M004 in plant matrices) was developed for data gathering purposes (Appendix I, Table 1). This method fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70-120%) were obtained in plant matrices.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for deltamethrin was conducted previously and is summarized in the Proposed Re-evaluation Decision, PRVD2015-07, *Deltamethrin*. An extensive toxicology database is available for 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.

Results of the toxicology studies conducted on laboratory animals with deltamethrin are summarized in PRVD2015-07, *Deltamethrin*. Toxicology endpoints for use in human health risk assessment were established and are reported in PRVD2015-07, *Deltamethrin*.

In acute toxicity testing, the end-use product DeltaGard 20EW was of low toxicity via 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 positive for skin sensitization when tested in the local lymph node assay in mice. Results of the toxicology studies conducted on laboratory animals with DeltaGard 20EW can be found in Appendix I, Table 2.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 4 October 2016, incidents submitted to the PMRA that involved deltamethrin included 17 human, 42 domestic animal, 2 environmental incidents, and 3 incidents involving a combination of humans, domestic animals or the environment.

When reviewed, many of the effects reported in the human incidents were not considered to be associated with the reported exposure scenarios. Generally, minor effects were reported in the human incidents. Exposure mostly occurred following accidental contact during the use of the product.

Domestic animal incidents most frequently occurred following exposure around the home. The proposed product may be used in areas in which pets could be exposed (for example, residential areas, playgrounds). The product label was modified in order to help reduce the potential of pets being accidentally exposed during, and following the use of the product.

Overall, the assessment of incident reports involving deltamethrin did not identify any significant health or environmental effects.

3.1.1 *Pest Control Products Act* Hazard Characterization

Please refer to PRVD2015-07, *Deltamethrin,* for a summary of the previously reviewed data.

3.2 Determination of Acute Reference Dose

Please refer to PRVD2015-07, *Deltamethrin,* for a summary of the previously reviewed data.

3.3 Determination of Acceptable Daily Intake

Please refer to PRVD2015-07, *Deltamethrin,* for a summary of the previously reviewed data.

3.4 Occupational and Residential Risk Assessment

Occupational exposures to DeltaGard 20EW are characterized as short- to intermediate-term for commercial mixers, loaders, and applicators and short-term for postapplication exposures in residential areas. Worker exposures are predominantly by the dermal and inhalation routes, and dermal, inhalation, and incidental oral (children 1<2 years old only) routes for homeowners, including children.

3.4.1 Toxicological Endpoints

Please refer to PRVD2015-07, *Deltamethrin,* for a summary of the previously reviewed data.

3.4.1.1 Dermal Absorption

As the toxicological endpoint for the short- and intermediate-term dermal risk assessments are based on a no observed adverse effect level (NOAEL) from a dermal toxicity study, no dermal absorption factor was required for the risk assessment.

3.4.2 Occupational Exposure and Risk

Workers can be exposed to deltamethrin through mixing, loading or applying the pesticide, and/or when entering a treated site to conduct postapplication activities following a mosquito abatement program.

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Individuals have potential for exposure to DeltaGard 20EW during mixing, loading and application. Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted. Dermal and inhalation exposure estimates for workers (mixing and loading) were generated from the Pesticide Handlers Exposure Database (PHED, version 1.1). Unit exposures for airblast applicators were taken from the Agricultural Handlers Exposure Task Force (AHETF) database.

Commercial applicators may handle DeltaGard 20EW for short to intermediate periods of time. Therefore, most applicators have the potential for short-term (1-30 days) exposure, with the exception of some commercial applicators who may spray throughout the mosquito season; these scenarios were considered to have intermediate-term exposure (30 days to <6 months). Exposure estimates were derived for mixer/loaders and applicators applying DeltaGard 20EW to residential areas using only truck-mounted ULV fogging equipment, as this is the method currently employed. The exposure estimates are based on mixers/loaders and applicators wearing a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, and a respirator with a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister for pesticides.

Dermal exposure was estimated (Table 3.4.2.1-1) 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 toxicological endpoints (no, or lowest observed adverse effects levels) to obtain the margin of exposure (MOE); the target MOE is 1000 for dermal exposures and 300 for inhalation exposures.

Table 3.4.2.1-1 Mixer/loader/applicator (M/L/A) dermal exposure and risk estimates.

Exposure scenario	Dermal unit exposure (µg/kg a.i. handled)*	Inhalation unit exposure (µg/kg a.i. handled)*	Max. ATPD† (ha/d)	Amount a.i. handled per day (kg a.i./day)	Daily dermal exposure (mg/kg bw/day)‡	Daily inhalation exposure (mg/kg bw/day)‡	Dermal MOE¶	Inhalation MOE¶
PPE: Long-sleeved shirt, long pants, chemical-resistant gloves, respirator, and shoes plus socks								
Airblast M/L/A (for ground-based, truck-mounted ULV equipment)	3820.44	1.07	1200	1.8	0.08596	0.0000241	11633	41537

* Mixer/loader unit exposures from PHED database; applicator unit exposures from AHETF database.
† ATPD for the application equipment is taken from PMRA default ATPD Tables (airblast, 1200 ha/d), assumed to be undiluted spray volume, as a conservatism.
Amount a.i. handled per day (kg a.i./d) = Maximum area treated per day (ha/d) × 0.001 kg/g × Application rate (1.5 g deltamethrin/ha)
‡ Daily exposure = (Unit exposure × Amount a.i. handled/day) / (80 kg bw × 1000 µg/mg); the inhalation exposure includes adjustment for the use of a NIOSH respirator by mixer/loader and applicator
¶ Margin of Exposure (MOE) = Toxicological endpoint / Exposure; dermal endpoint is a $NOAEL_{dermal}$ = 1000 mg/kg bw/day, target MOE = 1000; Inhalation endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

Calculated MOEs for dermal and inhalation risks were greater than the target MOEs. Therefore, risk estimates associated with mixing, loading, and applying are not of concern using truck-mounted ULV equipment, provided the required personal protective equipment (PPE) is worn.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure of workers re-entering areas treated with DeltaGard 20EW. Based on the use pattern, there is potential for short- to intermediate-term postapplication worker exposure to deltamethrin residues, and the primary route of exposure for workers re-entering treated areas would be through the dermal route. Postapplication exposure activities include, but are not limited to turf, sod, and golf course maintenance.

Dermal exposure of workers entering treated areas is estimated by coupling turf transferable residue values with activity-specific transfer coefficients (Table 3.4.2.2-1). No product-specific transferable turf studies were submitted to support transferable residues from settled fog particles of DeltaGard 20EW. Therefore, dermal exposures were estimated using a peak TTR value (1% of the maximum application rate) and 10% daily dissipation, maximum application rate, 10

applications, and a re-treatment interval (RTI) of 3 days. The use of peak turf residues is expected to overestimate the deposition of residues from fogging.

Exposure estimates were compared to the dermal toxicological endpoint to obtain the margin of exposure (MOE); the target MOE is 300.

Table 3.4.2.2-1 Occupational postapplication dermal exposure from settled residues of DeltaGard 20EW in a mosquito abatement program.

Site	Activity	TC (cm^2/h)	TTR ($\mu g/cm^2$)	Dermal Exposure[a] (mg/kg bw/day)	MOE[b]	REI (days)
Golf course/ turf/ sod	Planting/ transplanting	6700	0.00053	0.000355	2800000	0

REI = restricted-entry interval; MOE = margin of exposure

[a] Dermal exposure (mg/kg bw/day) = (TC × TTR_t × ET × DA × CF) / BW

Where, TC (cm^2/h) = transfer coefficient;

TTR_t ($\mu g/cm^2$) = turf transferable residue at time (t) = day 0 after the 10^{th} application of 1.5g a.i./ha (0.015 $\mu g/cm^2$) with a 3-day interval:

A peak default TTR value of 1% of the application rate with 10% daily dissipation (golf course and turf maintenance, and sod)

ET (h) = Exposure Time of 8 hours/day

DA (%) = dermal absorption factor (=1, as the dermal toxicology endpoint is from a dermal study)

CF = conversion factor (0.001 mg/µg)

BW (kg) = adult body weight of 80 kg

[b] Margin of Exposure (MOE) = Toxicological endpoint / Exposure; dermal endpoint is a $NOAEL_{dermal}$ = 1000 mg/kg bw/day, target MOE = 1000

The target MOE is met, and airborne residues will have deposited onto the ground or have dissipated into the air. Therefore, risks to workers entering areas that have been recently treated for mosquito abatement are not of concern.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Only commercial handlers are permitted to use DeltaGard 20EW; therefore, no domestic handler exposure assessment is required.

3.4.3.2 Postapplication Dermal Exposure and Risk

Residential areas are defined as any use sites where bystanders,including children, may be potentially exposed during or after application. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.

As applications can be made in residential areas, postapplication dermal exposure estimates (Table 3.4.3.2-1) were generated following the USEPA Standard Operating Procedures (SOPs) for Residential Exposure Assessments (October, 2012). Four exposure scenarios were

considered: Gardening; mowing turf; high contact activities on residential turf on the day of application; and golfing. Dermal exposures were assessed on the day (Day 0) of the 10th application.

Table 3.4.3.2-1 Residential postapplication dermal exposure to deposited residues from applications of DeltaGard 20EW in a mosquito abatement program.

Subpopulation	Scenario	DFR/TTR Value[1] (µg/cm^2)	Transfer Coefficient[2] (cm^2/h)	Dermal Exposure[3] (mg/kg bw/day)	Dermal MOE[4]
Adult (16<80 years old)	Gardens	0.0133	8400	0.00306	330000
Youth (11<16 years old)			4600	0.00176	570000
Youth (6<11 years old)			4600	0.00210	480000
Adult (16<80 years old)	Turf – Mowing	0.00053	5500	0.0000364	27000000
Youth (11<16 years old)			4500	0.0000418	24000000
Adult (16<80 years old)	Turf – Residential high contact activities		180000	0.00179	560000
Youth (11<16 years old)			148000	0.00179	560000
Child (1<2 years old)			49000	0.00354	280000
Adult (16<80 years old)	Golfing		5300	0.000140	7100000
Youth (11<16 years old)			4400	0.000164	6100000
Youth (6<11 years old)			2900	0.000108	9300000

[1] DFR/TTR values are based on an application rate of 0.015 µg a.i./cm^2, after 10 applications with a 3 day re-treatment interval. Default DFR value of 25% and TTR value of 1% of the application rate were used for gardens and turf, respectively, with a daily default dissipation rate of 10%.

[2] Transfer coefficients (cm^2/h) and exposure duration (h) obtained from the USEPA Residential SOP (October, 2012; section 3, Lawns and Turf and section 4, Gardens and Trees). Adult transfer coefficient is scaled to age range-specific body surface areas.

[3] Dermal Exposure = DFR_t or $TTR_t \times TC \times ET \times CF / BW$

Where, TC (cm^2/h) = transfer coefficient;

DFR_t or TTR_t (µg/cm^2) = dislodgeable foliar or turf transferable residue at time (t) = day 0

ET (hours/day) = Exposure Time =

Gardens: Adults, 2.2; Youth (11<16 years old), 1.1; Child (1<2 years old), 1.1

Turf – Mowing: Adults, 1; Youth (11<16 years old), 1;

Turf - High Contact: Adults, 1.5; Youth (11<16 years old), 1.3; Child (1<2 years old), 1.5

Golfing: Adults, 4; Youth (11<16 years old), 4; Child (6<11 years old), 4

DA (%) = dermal absorption factor (=1, as the dermal toxicology endpoint is from a dermal study)

CF = conversion factor (0.001 mg/µg)

BW (kg) = body weight; adult, 80 kg; youth (11<16 years old), 57 kg; youth (6<11 years old), 32 kg; child (1<2 years old, 11 kg)

[4] Margin of Exposure (MOE) = Toxicological endpoint / Exposure; dermal endpoint is a $NOAEL_{dermal}$ = 1000 mg/kg bw/day, target MOE = 1000

Risks from dermal contact with residues that have settled in residential areas are not considered to be of concern to homeowners, including children.

3.4.3.3 Postapplication Inhalation Exposure and Risk

Considering that re-entry into treated areas may occur directly after a single fogging/misting application, postapplication inhalation exposure is likely. In the absence of air concentration data, a risk assessment is based on the well-mixed box (WMB) approach which assumes that the application rate is evenly distributed over the area to be treated (for example, 1 hectare) and scaled to the volume available in the breathing zone (1 m × 1 m area multiplied by a height of 0.5 m) of the homeowner, including children. By converting an application rate expressed in g a.i./ha into a concentration expressed on a per cubic metre (m^3) basis, the breathing zone concentration can be calculated. This value is combined with the inhalation rate and exposure time to estimate the amount of active inhaled.

These estimates are based on upper-percentile assumptions and are believed to be a reasonable high-end estimate of inhalation exposure following ground ULV application of a mosquitocide (Table 3.4.3.3-1).

Table 3.4.3.3-1 Potential postapplication inhalation exposure risks from mosquito abatement treatments in residential areas.

Subpopulation	Inhalation Exposure[1,2] (mg/kg bw/day)	Inhalation MOE[3]
Adult (16<80 years old)	0.0000360	28000
Youth (11<16 years old)	0.0000431	23000
Children (1<2 years old)	0.0001350	7400

[1] Application rate (mg/m^3) = [(1.5 g a.i./ha × 1000 mg/g × 0.0001 ha/m^2/0.5 m)] = 0.3 mg/m^3

[2] Inhalation Exposure (mg/kg bw/day) = (AR × F × IR × ET) / BW

Where:

AR = Applied Rate, amount applied to a 1 m × 1 m × 0.5 m high area (0.3 mg/m^3) using ground ULV equipment

F = Fraction of chemical available in outdoor air for exposure to a ground ULV application adjusted for the "infinite dilution" attributable to being outdoors (1%) (PRVD2010-18);

IR = Inhalation rate (m^3/h) during light activity (0.64 for adults (16<80 years old); 0.63 for youth (11<16 years old); and 0.33 for children (1<2 years old), SPN2014-01);

ET = Exposure time (hours) using Turf - High Contact exposure time: Adults, 1.5; Youth (11<16 years old), 1.3; and Child (1<2 years old), 1.5 (Residential SOP (2012); Lawns and Turf;

BW = Body weight; adult, 80 kg; youth (11<16 years old), 57 kg; child (1<2 years old, 11 kg)

[3] Margin of Exposure (MOE) = Toxicological endpoint / Exposure; inhalation endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

Risks from inhalation exposure from an ULV treatment directly after treatment are not considered to be of concern for homeowners, including children.

3.4.3.4 Incidental Oral Exposure

There is potential for short-term exposure of children (1<2 years old) through contact with transferable residues following commercial application of DeltaGard 20EW treatments in residential areas that drift and deposit onto residential lawns and soil. Incidental non-dietary oral exposure was assessed for children (1<2 years old) playing on turf (Tables 3.4.3.4-1, -2 and -3). Incidental oral exposures can be estimated from hand-to-mouth, object-to-mouth, and soil ingestion pathways (Section 3, Lawns and Turf; Residential SOPs, 2012).

Table 3.4.3.4-1 Residential postapplication incidental oral exposure: Hand-to-Mouth

Subpopulation	TTR Value[1] (µg/cm^2)	Oral Exposure[2] (mg/kg bw/day)	MOE[3]
Child (1< 2 years old)	0.0053	0.000073	14000

[1] TTR value is based on application rate of 0.015 µg a.i./cm^2 × 1% retained on turf, 10 applications, daily default dissipation rate of 10%, and a 3 day re-treatment interval were used to estimate residues settled on turf.

[2] H-to-M Oral Dose (mg/kg bw/day) = [Hand Residue (mg/cm^2) × (Fraction of hand mouthed/event (0.13) × Surface Area of one hand (150 cm^2)) × (Exposure Time (h) × Replenishment Intervals (4/h)) × (1 – (1 – Saliva Extraction Factor (0.48)) $^{\text{Number events per hour (20)/Replenishment Intervals (4/h)}}$)] / Body Weight (11 kg). Exposure time is 1.5 hours, as stated in the USEPA Residential SOP, Section 3, Turf (2012);

Where, Hand Residue (mg/cm^2) = (DE × Fai_{hands}) / (SA_H × 2)

DE = dermal exposure (mg)

Fai_{hands} is the residue available for transfer (based on 10 applications; 3 day interval)

SA_H = typical surface area of one hand (cm^2)

[3] Margin of Exposure (MOE) = Toxicological endpoint / Exposure; oral endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

Table 3.4.3.4-2 Residential postapplication incidental oral exposure: Soil ingestion

Subpopulation	SRt[1] (µg/g)	Ingestion Rate (IgR) (mg/day)	Oral Exposure[2] (mg/kg bw/day)	MOE[3]
Child (1< 2 years old)	0.01005	50	4.6×10^{-8}	22000000

[1] SRt = Soil residue (µg/g) on day t=0 = SRt = AR × FS × $(1\text{-}FD)_t$ × CF1 × CF2 × CF3

AR = application rate (kg a.i./m^2) = 1.5g a.i./ha × 0.001 kg/g × 0.0001 m^2/ha

FS = fraction of a.i. available in uppermost cm of soil (fraction/cm) = 100% = 1;

FD = fraction of residue that dissipates daily = 10% = 0.1 (unitless);

t = postapplication day on which exposure is being assessed = 0;

CF1 = weight unit conversion factor (10^9 µg/kg);

CF2 = area unit conversion factor (0.0001 m^2/cm^2);

CF3 = soil volume to weight unit conversion factor (0.67 cm^3/g soil).

[2] Where Oral exposure (mg/kg bw/day) = SRt × SIgR × CF4/BW;

SRt = soil residue on day "t" (µg/g);

SIgR = ingestion rate of soil (mg/day);

CF4 = weight unit conversion factor (1×10^{-6} g/µg)

BW = Body Weight (11 kg)

[3] Margin of Exposure (MOE) = Toxicological endpoint / Exposure; oral endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

Table 3.4.3.4-3 Residential postapplication incidental oral exposure: Object-to-Mouth

Subpopulation	Object Residue[1] (µg/cm^2)	Exposure Time (hours/day)	OtM events per hour	Oral Exposure[2] (mg/kg/day)	MOE[3]
Child (1<2 years old)	0.0015	1.5	8.8	6.2×10^{-7}	1602000

OtM = object-to-mouth

[1] Where Object Residue (µg/cm^2) = Residue Available for Transfer (µg/cm^2) × Fraction of Residue Transferred; based on 10 applications; 3 day interval.

[2] Where Absorbed Dose (mg/kg bw/day) = [Object Residue (µg/cm^2) × 0.001 mg/µg × Surface Area Object Mouthed (10 cm^2/event) × (Exposure Time (h/day) × Replenishment Intervals (4/h)) × (1 – (1 – Saliva Extraction (0.48)) $^{\text{Number of object-to-mouthevents (8.8/h)}}$ /Replenishment Intervals (4/h))]/ Body weight (11 kg).

[3] Margin of Exposure (MOE) = Toxicological endpoint / Exposure; oral endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

There are no risks of concern for children (1<2 years old) from incidental oral exposure to deltamethrin following hand-to-mouth, soil ingestion, and/or object-to-mouth residue transfer in treated residential areas where residues from mosquito abatement fog have settled onto the ground.

3.4.3.5 Residential Aggregate Assessment

The PMRA conducts a residential aggregate assessment combining dermal, dietary, and non-dietary exposures, as appropriate, pending the determination of appropriate aggregate endpoints. Since no adverse toxicological effects were noted following repeated dermal dosing, exposures via the dermal route were not aggregated during re-evaluation of deltamethrin (PRVD2015-07, *Deltamethrin*); therefore, no dermal exposure aggregation is required for a mosquito abatement use.

Postapplication exposure scenarios that can be combined for short-term exposure durations are the inhalation and hand-to-mouth scenarios, as there is a common toxic effect for short-term aggregation. The potential combinations of co-occurrence of the hand-to-mouth/object-to-mouth/soil ingestion scenarios throughout a particular period of time are numerous. Combining all three scenarios would be overly conservative because of the conservative nature of each individual assessment. Therefore, only the hand-to-mouth oral exposure is aggregated with the inhalation exposure. The PMRA also includes the chronic dietary exposure in this aggregate assessment (Table 3.4.3.5-1).

Table 3.4.3.5-1 Aggregation of postapplication oral (non-dietary and dietary) ingestion and inhalation of deltamethrin residues by children 1<2 years old.

Route of ingestion	Oral Exposure (mg/kg bw/day)	Aggregate MOE[4] (target = 300)
Non-dietary, Hand-to-mouth[1]	0.000073	931
Chronic dietary exposure[2]	0.000867	
Inhalation exposure[3]	0.0001350	

[1] From the residential postapplication child hand-to-mouth assessment
[2] From Dietary Exposure Assessment (food and water, PRVD2015-07, *Deltamethrin*)
[3] From the residential postapplication inhalation assessment
[4] Aggregate Margin of Exposure (MOE) = Toxicological endpoint / Exposure (H-t-M + chronic dietary + inhalation); using SPN2003-04; inhalation and oral endpoint is a $LOAEL_{oral}$ = 1 mg/kg bw/day, target MOE = 300

Aggregate risks are not a concern for children (1<2 years old).

3.4.3.6 'Pick-Your-Own' Exposure Assessment

Exposures to the public entering areas previously treated as part of a mosquito abatement program near a pick-your-own fruit farm facility are not expected to be greater than those resulting from the registered use of deltamethrin on pick-your-own fruits, and not considered to be of concern.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

Please refer to PRVD2015-07, *Deltamethrin*, for a summary of the previously reviewed data. The residue definition for risk assessment and enforcement in plant products and animal commodities (except milk) is the sum of cis-, trans- and αR-isomers of deltamethrin. For milk, the residue definition is the sum of cis-, trans- and αR-isomers of deltamethrin, calculated on the fat content.

The data gathering analytical method 00855/M004 is valid for the quantitation of cis-, trans- and α-R-deltamethrin residues in various plant matrices. The residues of deltamethrin are stable under freezer storage in five diverse crops: oily commodity (cotton) for 19 months, leafy vegetable (lettuce) for 16.5 months, *Brassica* (cabbage) for 24 months, fruit (apple) for 12 months, fruiting vegetable (tomato) for 24 months, and a cereal grain (wheat) for 12 months. Adequate feeding studies were previously carried out to assess the anticipated residues in livestock matrices, which encompass the current uses. Confirmatory crop field trials conducted in NAFTA Region 5 using end-use products containing deltamethrin at approved rates in or on alfalfa, grass, and lettuce are sufficient to confirm that the mosquitocide use will not result in residues exceeding the established maximum residue limits (MRLs).

3.5.2 Dietary Risk Assessment

Acute and chronic (non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™). Please refer to PRVD2015-07, *Deltamethrin*.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The dietary exposure estimates from food and water ranged from 7 to 29% of the ADI and are not of concern. Please refer to PRVD2015-07, *Deltamethrin*, for a summary of the previously reviewed data.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The refined acute dietary exposure estimate of deltamethrin from food and water accounted for less than 66% of the ARfD for all population subgroups and is below the level of concern. Please refer to PRVD2015-07, *Deltamethrin*, for a summary of the previously reviewed data.

3.5.3 Maximum Residue Limits

Confirmatory crop field trials conducted in NAFTA Region 5 using end-use products containing deltamethrin at approved rates in or on alfalfa, grass, and lettuce are sufficient to confirm that the mosquitocide use will not result in residues exceeding the established MRLs. Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management portion of Health Canada's website for the established MRLs for deltamethrin.

The analytical methodology and field trial data are summarized in Appendix I, Tables 1 and 3. Please refer to PRVD2015-07, *Deltamethrin*, for a summary of the previously reviewed data.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The properties and environmental fate characterization of deltamethrin have been previously reviewed and reported in PRVD2015-07, *Deltamethrin*.

For control of adult mosquitoes, deltamethrin will be applied by non-thermal fogging using truck-mounted ULV sprayers. Treatment typically occurs at night or early morning when adult mosquitoes are most active. ULV application (or fogging) is characterized by the production of fine droplets (5–20 µm). The droplets of pesticide are very small and do not drift or deposit like larger droplets. Spray droplets may evaporate during this period of suspension in the air, and as such, do not deposit on surfaces (for example, soil, water, plants).

Deltamethrin is expected to degrade rapidly in the air, as it is susceptible to photochemical oxidative reactions (half-life is estimated to be 16 hours). Biotransformation is a route of transformation of deltamethrin in aerobic soil (DT_{50} = 6.1–72 days) and water (DT_{50} = 4–141 days), where it is non-persistent to moderately persistent in both media. Aquatic field studies indicate that deltamethrin dissipates rapidly through volatilization from water surfaces (1 hour to 35.7 hours). When applied as fine droplets/fogging, deltamethrin is expected to dissipate through volatilization and atmospheric reactions. Thus, deposit into aquatic and terrestrial systems from this type of application is greatly reduced and exposure to the environment is expected to be minimal.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific 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 uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

An environmental risk characterisation of deltamethrin had been previously completed for its use as an insecticide on food and non-food crop sites with single season application rates up to 135 g a.i./ha (for further details, please see PRVD2015-07, *Deltamethrin*). DeltaGard 20EW for control of adult mosquitoes will be used at a maximum single application rate of 1.5 g a.i./ha with an annual maximum of 10 applications, resulting in a total maximum annual use of 15 g a.i./ha. Consequently, the proposed use of DeltaGard 20EW for adult mosquito control would result in a lower use rate of deltamethrin than currently registered for other uses, and a significantly lower seasonal maximum use rate than the current maximum. Therefore, based on a reduced application rate, and minimal deposition to soil, water and plants expected from ULV application, exposure of non-target organisms is expected to be minimal.

4.2.1 Risks to Terrestrial Organisms

The effects of deltamethrin on terrestrial organisms (at higher rates of application) have been previously reported in PRVD2015-07, *Deltamethrin*. Based on the assessment reported in PRVD2015-07, *Deltamethrin*, and the low potential for exposure from ULV application (see Section 4.1), deltamethrin is not expected to pose risks of concern to earthworms, birds, mammals or terrestrial vascular plants.

Deltamethrin is highly toxic to beneficial insects such as the honeybee, and could pose a risk to terrestrial arthropods that are active at the time of treatment. The potential impact on honeybees or other pollinators/beneficial insects that may be present in treated areas is expected to be minimal as mosquito spray programs are conducted at night or early mornings when honeybees and other beneficial insects are less likely to be actively foraging. However, statements are required on the label to advise users that exposure of beneficial arthropods and bees may be harmful.

4.2.2 Risks to Aquatic Organisms

The effects of deltamethrin on aquatic organisms (at higher rates of application) have been previously reported in PRVD2015-07, *Deltamethrin*. Deltamethrin is very highly toxic to fish and aquatic invertebrates. Impact on aquatic organisms is expected to be limited in view of the ULV method of spray application. These droplets are very small and do not drift or deposit like larger droplets. The ULV method is used with the intention of keeping spray droplets suspended in the air. Spray droplets may evaporate while they are suspended in the air and may not be deposited at all.

The application rates of DeltaGard 20EW to control mosquitoes are nine times less than the maximum annual rate allowed for use on currently registered crops. Precautionary label statements will instruct users to avoid contamination of sensitive aquatic environments, such as sloughs, ponds, prairie potholes, lakes, rivers, streams and wetlands, when cleaning and rinsing spraying equipment and containers.

4.2.3 Incident reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

As of 4 October 2016, two incidents of environmental relevance had been submitted to the PMRA that involved deltamethrin. Both incidents involved multiple active ingredients or circumstances that were not attributed to the labelled use of the product. Overall, the assessment of incident reports involving deltamethrin did not identify any significant environmental effects and would not affect the environmental risk assessment.

5.0 Value

Mosquitoes can be a nuisance and also pose a risk to human health because they may transmit diseases such as West Nile Virus disease. DeltaGard 20EW is a new commercial class product for use in residential and recreational areas to control mosquitoes. Other active ingredients registered to control adult mosquitoes include malathion and dichlorvos (organophosphates, MOA group 1A), carbaryl (carbamates, MOA group 1B) and other pyrethroids (MOA group 3A), such as d-trans allethrin and pyrethrins. DeltaGard 20EW can be used with other mosquito control practices, such as using a registered larvicide and non-chemical control methods (for example, draining standing bodies of water), in a mosquito control program.

The performance of DeltaGard 20EW to control species of *Aedes*, *Anopheles* and *Culex* mosquitoes was investigated in seven field trials conducted in Manitoba and in six states in the US (Michigan, Texas, Florida, California, Louisiana and North Carolina). These studies demonstrated that DeltaGard 20EW provided 94-100% control of adult mosquitoes when applied at 0.5-1.5 g a.i./ha using ULV equipment. Most trials did not show a difference in product performance between 0.5, 1.0 and 1.5 g a.i./ha. However, a rate effect was observed in two studies with the lower rates (i.e. 0.5 g a.i. and 1.0 g a.i./ha) being less effective compared to the higher rate (i.e. 1.5 g a.i./ha). These data supported the label statement to use a higher rate for certain mosquito populations or dense vegetation.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Deltamethrin does not meet all Track 1 criteria, and is not considered a Track 1 substance. Deltamethrin does not form any transformation products that meet all Track 1 criteria. Please refer to PRVD2015-07, *Deltamethrin*, for information on the Pest Control Product Policy considerations of deltamethrin.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[5] The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies

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[5] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[6] NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New *Pest Control Products Act.*

and regulations including: DIR99-03; and DIR2006-02,[7] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade deltamethrin does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

- DeltaGard 20EW does not contain any formulants or contaminants of environmental concern identified in the *Canada Gazette*.

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 Summary

7.1 Human Health and Safety

The toxicology database reviewed for deltamethrin is adequate to define the majority of toxic effects that may result from exposure. There was no evidence of carcinogenicity in rats or mice after longer-term dosing. 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 toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Mixers, loaders, and applicators handling DeltaGard 20EW, and workers re-entering treated residential, urban, and recreational areas are not expected to be exposed to levels of deltamethrin that will result in an unacceptable risk when DeltaGard 20EW is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Residential exposures of individuals entering treated areas are not expected to result in unacceptable risks when DeltaGard 20EW is used according to label directions.

The nature of deltamethrin residues in plant and animal is understood based on previously reviewed plant and animal metabolism studies. The residue definition is the sum of cis-, trans- and αR-isomers of deltamethrin in all commodities, except milk. For milk, the residue definition is the sum of cis-, trans- and αR-isomers of deltamethrin, calculated on the fat content.

The proposed use of deltamethrin as a mosquitocide does not constitute a risk of concern for chronic or acute dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Residue trials conducted in NAFTA Region 5

[7] DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

using deltamethrin on alfalfa, grass, and leaf lettuce are acceptable to support the mosquitocide use. For the MRLs for this active ingredient, please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management portion of Health Canada's website.

7.2 Environmental Risk

The use of DeltaGard 20EW containing the active ingredient deltamethrin, applied by ULV, is not expected to pose risks of concern to the environment. Precautionary label statements to advise users that deltamethrin may cause harm to beneficial arthropods, bees and aquatic organisms will be required.

7.3 Value

The submitted value information supports the use of DeltaGard 20EW to control adult mosquitoes in residential and recreational areas when applied at 0.5-1.5 g a.i. deltamethrin/ha using ULV equipment. DeltaGard 20EW is a new commercial class product to control mosquitoes and can be used in mosquito control programs.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Deltamethrin Technical Insecticide and DeltaGard 20EW, containing the technical grade active ingredient deltamethrin, to control adult mosquitoes in residential and recreational areas.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	microgram(s)
a.i.	active ingredient
AD	administered dose
ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
AR	application rate
ARfD	acute reference dose
ARTF	Agricultural Reentry Task Force
ATPD	area treated per day
BBCH	Biologishe Bundesanstalt, Bundessortenamt and Chemical industry
bw	body weight
CAS	Chemical Abstracts Service
CF	conversion factor
cm	centimetre(s)
DA	dermal absorption factor
DALA	days after last application
DE	dermal exposure
DFR	dislodgeable foliar residues
DT_{50}	dissipation time 50% (dose required to observe a 50% decline in concentration)
EEC	estimated environmental exposure concentration
EIIS	Ecological Incident Information System
EW	emulsion
ET	exposure time
Fai_{hands}	residue available for transfer
FD	fraction of residue that dissipates daily
FS	fraction of a.i. available in uppermost cm of soil
g	gram(s)
GAP	good agricultural practice
ha	hectare(s)
HAFT	highest average field trial
HPLC	high performance liquid chromatography
h	hour(s)
ILV	independent laboratory validation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol-water partition coefficient
L	litre(s)
LAFT	lowest average field trial
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOQ	limit of quantitation
m	meter(s)
mg	milligram(s)

mL	millilitre(s)
MAS	maximum average score for 24, 48 and 72 hours
MIS	maximum irritation score
M/L/A	mixer/loader/applicator
MOA	mode of action
MOE	margin of exposure
mPa	milliPascal(s)
MS/MS	tandem mass spectrometry
m/z	mass-to-charge ratio of an ion
MRL	maximum residue limit
MRM	multiresidue method
NAFTA	North American Free Trade Agreement
NIOSH	National Institute for Occupational Safety and Health
NR	not reported
NOAEL	no observed adverse effect level
NZW	New Zealand white
PBI	plantback interval
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RD	residue definition
REI	restricted-entry interval
RTI	re-treatment interval
RQ	risk quotient
SA_H	typical surface area of one hand
SD	standard deviation
SIgR	ingestion rate of soil
SOP	standard operating procedure
SRt	soil residue on day t (postapplication day on which exposure is being assessed)
TC	transfer coefficient
TSMP	Toxic Substances Management Policy
TTR	transferable turf residues
ULV	ultra-low volume
US	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
WMB	well-mixed box

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference
Plant	00855/M004	Cis-, trans-, and α-R deltamethrin	LC-MS/MS	**0.01 ppm for each analyte**	**Edible crops**	PMRA #2672316
				0.05 ppm for each analyte	**Wheat (straw), barley (whole plant)**	

Table 2 Toxicity Profile of DeltaGard 20EW containing Deltamethrin

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Sprague Dawley rats PMRA #2672308	LD_{50} = 3129 mg/kg bw (♀) Low toxicity
Acute dermal toxicity Sprague Dawley rats PMRA #2672309	LD_{50} > 5000 mg/kg bw Low toxicity
Acute inhalation toxicity (nose-only) Wistar rats PMRA #2672310	LC_{50} > 5.07 mg/L Low toxicity

Study Type/Animal/PMRA #	Study Results
Dermal irritation NZW rabbits PMRA #2672312	MAS = 0, MIS = 0 Non-irritating
Eye irritation NZW rabbits PMRA #2672311	MAS = 4.2, MIS = 10.7 at 1h Minimally irritating
Dermal sensitization (local lymph node assay) CBA/J mouse PMRA #2672313	Dermal sensitizer

Table 3 Integrated Food Residue Chemistry Summary

Please refer to PRVD2015-07, *Deltamethrin*, for more information on residue chemistry.

CROP FIELD TRIALS ON ALFALFA, GRASS, AND LETTUCE	PMRA #2672317
Field trials were conducted in 2012 on alfalfa, grass, and leaf lettuce in the United States in NAFTA Growing Region 5 (6 trials). Deltamethrin EW Adulticide was applied ten times at a 3-day RTI using broadcast foliar ULV spray application (ground-based fogging equipment) at seasonal rates of 7.5 g a.i./ha (0.5-fold GAP), or 15 g a.i./ha (1.0-fold GAP). The last application was made 0 days before harvest. Storage stability data are available to support the frozen storage intervals of all samples from the current confirmatory residue trials (13 months). The data gathering method 00855/M004 was concurrently validated during the field trials.	

Summary of Total Residues from Field Trials with Deltamethrin

Crop Matrix	No. of Appl.	Applic. Rate (g a.i./ha)	PHI (days)	n	*Cis* and *Trans*-Deltamethrin Residues (ppm), expressed as parent equivalents			
					LAFT	HAFT	Mean	SD
Alfalfa Forage	1	7.4-7.6	0	4	0.0055	0.0089	0.0073	0.0030
	2	7.5-7.8	0	4	0.0108	0.0131	0.0120	0.0020
	3	7.6	0	4	0.0131	0.0139	0.0135	0.0042
	4	7.4-7.6	0	4	0.0173	0.0200	0.0187	0.0014
	5	7.5-7.6	0	4	0.0202	0.0206	0.0204	0.0036
	6	7.5-7.7	0	4	0.0136	0.0209	0.0172	0.0047
	7	7.4	0	4	0.0249	0.0388	0.0313	0.0075
	8	7.4-7.6	0	4	0.0115	0.0281	0.0198	0.0114
	9	7.5-7.7	0	4	0.0170	0.0434	0.0302	0.0178
	10	7.5-7.6	0	4	0.0162	0.0380	0.0271	0.0136
Alfalfa Forage	1	15	0	4	<0.004	0.0069	0.0055	0.0018
	2	15-16	0	4	0.0075	0.0363	0.0219	0.0168
	3	15-16	0	4	0.0093	0.0294	0.0194	0.0122
	4	15	0	4	0.0147	0.0360	0.0254	0.0124
	5	15	0	4	0.0164	0.0455	0.0310	0.0174

	6	15	0	4	0.0124	0.0463	0.0293	0.0202
	7	15	0	4	0.0143	0.0324	0.0228	0.0101
	8	15	0	4	0.0290	0.0409	0.0349	0.0102
	9	15	0	4	0.0397	0.0620	0.0508	0.0158
	10	15	0	4	0.0301	0.0671	0.0343	0.0332
Alfalfa Hay	1	7.4-7.6	0	4	0.0150	0.0480	0.0316	0.0193
	2	7.5-7.8	0	4	0.0399	0.0707	0.0555	0.0233
	3	7.6	0	4	0.0365	0.0456	0.0413	0.0065
	4	7.4-7.6	0	4	0.0548	0.1530	0.0564	0.0069
	5	7.5-7.6	0	4	0.0589	0.0805	0.0603	0.0029
	6	7.5-7.7	0	4	0.0278	0.0522	0.0400	0.0176
	7	7.4	0	4	0.0380	0.0716	0.0613	0.0125
	8	7.4-7.6	0	4	0.0357	0.0624	0.0480	0.0205
	9	7.5-7.7	0	4	0.015	0.0679	0.0565	0.0140
	10	7.5-7.6	0	4	0.0618	0.0848	0.0681	0.0195
Alfalfa Hay	1	15	0	4	0.0150	0.0213	0.0182	0.0049
	2	15-16	0	4	0.0193	0.0592	0.0393	0.0305
	3	15-16	0	4	0.0205	0.0643	0.0424	0.0255
	4	15	0	4	0.0326	0.0935	0.0631	0.0352
	5	15	0	4	0.0348	0.0736	0.0515	0.0193
	6	15	0	4	0.0217	0.1410	0.0792	0.0680
	7	15	0	4	0.0391	0.0680	0.0537	0.0263
	8	15	0	4	0.0352	0.0805	0.0579	0.0314
	9	15	0	4	0.0428	0.1101	0.0765	0.0404
	10	15	0	4	0.0363	0.1110	0.0272	0.0108
Lettuce Leaves	1	7.4-7.5	0	4	0.0035	0.0234	0.0139	0.0114
	2	7.5-7.6	0	4	0.0208	0.0236	0.0225	0.0069
	3	7.5-7.6	0	4	0.0128	0.0384	0.0259	0.0150
	4	7.5-7.6	0	4	0.0165	0.0372	0.0271	0.0120
	5	7.3-7.4	0	4	0.0210	0.0225	0.0169	0.0087
	6	7.5-7.6	0	4	0.0080	0.0284	0.0185	0.0119
	7	7.5	0	4	0.0065	0.0290	0.0180	0.0133
	8	7.4-7.5	0	4	0.0062	0.0278	0.0172	0.0127
	9	7.5-7.6	0	4	0.0045	0.0349	0.0200	0.0175
	10	7.5-7.6	0	4	0.0080	0.0425	0.0255	0.0201
Lettuce Leaves	1	15	0	4	0.0051	0.0140	0.0098	0.0052
	2	15	0	4	0.0101	0.0192	0.0150	0.0063
	3	15	0	4	0.0102	0.0106	0.0107	0.0009
	4	15	0	4	0.0120	0.0168	0.0147	0.0032
	5	15	0	4	0.0122	0.0153	0.0140	0.0034
	6	15	0	4	0.0065	0.0087	0.0079	0.0014
	7	15	0	4	0.0085	0.0342	0.0213	0.0150
	8	15	0	4	0.0061	0.0202	0.0134	0.0083
	9	15	0	4	0.0057	0.0365	0.0214	0.0183
	10	15	0	4	0.0063	0.0331	0.0200	0.0158
Grass Forage	1	7.4-7.6	0	4	0.0053	0.0149	0.0103	0.0064
	2	7.5-7.8	0	4	0.0117	0.0197	0.0159	0.0058
	3	7.5-7.6	0	4	0.0216	0.0292	0.0255	0.0055
	4	7.5-7.6	0	4	0.0174	0.0188	0.0183	0.0014

	5	7.4-7.5	0	4	0.0169	0.0189	0.0181	0.0012
	6	7.5-7.8	0	4	0.0153	0.0297	0.0226	0.0089
	7	7.4	0	4	0.0223	0.0316	0.0271	0.0062
	8	7.3-7.5	0	4	0.0295	0.0324	0.0310	0.0023
	9	7.4-7.6	0	4	0.0261	0.0285	0.0274	0.0043
	10	7.5	0	4	0.0303	0.0339	0.0321	0.0086
Grass Forage	1	15	0	4	0.0076	0.0135	0.0108	0.0043
	2	15-16	0	4	0.0114	0.0157	0.0137	0.0029
	3	15	0	4	0.0202	0.0259	0.0232	0.0037
	4	15	0	4	0.0190	0.0245	0.0220	0.0037
	5	14-15	0	4	0.0192	0.0257	0.0227	0.0046
	6	15	0	4	0.0146	0.0248	0.0199	0.0086
	7	15	0	4	0.0274	0.0342	0.0309	0.0063
	8	15	0	4	0.0305	0.0317	0.0302	0.0038
	9	15	0	4	0.0222	0.0748	0.0486	0.0308
	10	15	0	4	0.0252	0.0698	0.0470	0.0295
Grass Hay	1	7.4-7.6	0	4	<0.02	0.0867	0.0535	0.0389
	2	7.5-7.8	0	4	0.0319	0.0772	0.0549	0.0262
	3	7.5-7.6	0	4	0.0411	0.0809	0.0613	0.0235
	4	7.5-7.6	0	4	0.0521	0.0795	0.0661	0.0171
	5	7.4-7.5	0	4	0.0461	0.122	0.0842	0.0438
	6	7.5-7.8	0	4	0.0573	0.0955	0.0767	0.0224
	7	7.4	0	4	0.0574	0.137	0.0974	0.0491
	8	7.3-7.5	0	4	0.0501	0.133	0.0914	0.0474
	9	7.4-7.6	0	4	0.0550	0.162	0.1087	0.0618
	10	7.5	0	4	0.0491	0.188	0.1188	0.0805
Grass Hay	1	15	0	4	0.0298	0.0421	0.0362	0.0108
	2	15-16	0	4	0.0324	0.0555	0.0443	0.0137
	3	15	0	4	0.0712	0.0823	0.0771	0.0065
	4	15	0	4	0.0987	0.121	0.1095	0.0153
	5	14-15	0	4	0.0791	0.123	0.1011	0.0265
	6	15	0	4	0.0729	0.152	0.1124	0.0460
	7	15	0	4	0.1036	0.154	0.0640	0.0459
	8	15	0	4	0.1277	0.139	0.0753	0.0612
	9	15	0	4	0.1179	0.354	0.0851	0.0388
	10	15	0	4	0.1495	0.347	0.1116	0.0438

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 samples.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2672304	2016, DeltaGard 20EW Information to Address PMRA DACO Elements 3.1.1, 3.1.2, 3.1.3 and 3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2672305	2013, Product Chemistry of BES 0668 Insecticide, DACO: 3.2.1, 3.2.2, 3.3.1, 3.4.1, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 8.2.1 CBI
2672306	2015, Deltagard PHI: Accelerated Storage Stability, DACO: 3.5.10,3.5.14,3.5.5 CBI
2678783	2016, DeltaGard 20EW – Updated Description of the Formulation Process, DACO: 3.2.2 CBI
244663	2000, Analytical Method Deltamethrin (AE F032640), [CBI Removed] in Technical Grade and Pure Active Ingredient by HPLC, DACO: 2.13.1 CBI
244665	2000, Analytical Method Deltamethrin (AE F032640), [CBI Removed] in Technical Grade and Pure Active Ingredient by HPLC, DACO: 2.13.1 CBI
244669	2000, Analytical Method Deltamethrin (AE F032640), [CBI Removed] in Technical Grade and Pure Active Ingredient by HPLC, DACO: 2.13.1 CBI
244711	2001, Analytical Profile of Five Production Batches of Deltamethrin (AE F032640) TGAI, DACO: 2.13,2.13.3 CBI
244730	Chemistry Screen (Template), DACO: 2.15 CBI
244956	2002, Deltamethrin Technical Insecticide. PART 2 Product Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGAI) or an Integrated System Product (ISP), DACO: 2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.12.2,2.13.1,2.13.2,2.13.3,2.2, 2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
245023	2001, Deltamethrin (AE F032640), Description of the Manufacturing Process of the Technical AI, DACO: 2.11 CBI
245024	1999, Analytical Method Determination of Deltamethrin (AE F032640) in water dispersible granules (WDG), water dispersible tablets (TB), emulsifiable granules (EG), emulsifiable concentrates (EC) and suspension concentrates (SC) by liquid chromatography (HPLC), DACO: 2.13,2.13.1 CBI
1545789	2007, Deltamethrin Technical Insecticice Part 2 Chemistry Requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product (ISP), DACO: 2.1,2.11,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.12.2,2.13,2.13.1,2.13.2,2.13.3,2.2,2.3,2.3.1,2.4, 2.5,2.6,2.7,2.8,2.9 CBI
1545790	2001, Deltamethrin: Description of the Manufacturing Process of the Technical AI, DACO: 2.11,2.11.3 CBI
1545791	2005, Material Accountability of AE F032640 (Deltamethrin) Analytical Profile of Five Production Batches from [CBI Removed], DACO: 2.12,2.13,2.13.1,2.13.2,2.13.3 CBI
1545793	2007, Validation of Analytical Method AL027/00-0 Determination of [CBI Removed] in Technical Grade and Pure Deltamethrin (AE F032640) by HPLC, DACO: 2.13.1 CBI
1545794	2000, Validation of the Analytical Method AL025/00-0 for the Determination of [CBI Removed] in AE F032640, DACO: 2.13.1 CBI

PMRA Document Number	Reference
1545795	2000, Validaton of Analytical Method AL026-00-0 for the Determination of [CBI Removed] in AE F032640, DACO: 2.13.1 CBI
1549295	2002, Deltamethrin technical insecticide, DACO: 2.1,2.11.1,2.11.2,2.11.3, 2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1549297	2007, Deltamethrin - Manufacturing process [CBI Removed] of the technical active substance, DACO: 2.11.1,2.11.2,2.11.3 CBI
1549298	2001, Description of the manufactoring process of the technical AI Code: AE F032640, DACO: 2.11.1,2.11.3 CBI
1549299	2008, Impurities of deltamethrin technical material - Description, formation & justification, DACO: 2.11.4 CBI
1549300	2006, Composition statement - Technical material - Deltamethrin - TC, DACO: 2.12.1 CBI
1549301	2001, Analytical profile of five production batches Deltamethrin technical grade active ingredient Code: AE F032640, DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CBI
1549302	1999, The determination of deltamethrin (AE F032640) in water dispersible granules (WDG), water dispersible tablets (TB), emulsifiable granules (EG), emulsifiable concentrates (EC) and suspension concentrates (SC) by liquid chromatography (HPLC), DACO: 2.13.1
1549303	2000, Analytical method deltamethrin Determination of [CBI Removed] in technical grade and pure active ingredient by HPLC Deltamethrin technical grade active ingredient Code: AE F032640, DACO: 2.13.1 CBI
1549304	2000, Validation of the analytical method AL025/00-0 for the determination of [CBI Removed] in AE F032640 Deltamethrin technical grade active ingredient Code: AE F032640, DACO: 2.13.1 CBI
1549305	2000, Analytical method deltamethrin Determination of [CBI Removed] in technical grade and pure active ingredient by HPLC Deltamethrin technical grade active ingredient Code: AE F032640, DACO: 2.13.1 CBI
1549306	2000, Analytical method deltamethrin Determination of [CBI Removed] in technical grade and pure active ingredient by HPLC Deltamethrin technical grade active ingredient Code: AE F032640, DACO: 2.13.1 CBI
1549307	2000, Validation of the analytical method AL026/00-0 for the determination of [CBI Removed] in AE F032640 Deltamethrin technical grade active ingredient Code: AE F032640, DACO: 2.13.1 CBI
1549308	2003, Validation of the analytical method AL003/99-2 for the determination of AE F032640 (active ingredient) in technical AE F032640, DACO: 2.13.1 CBI
1549309	2007, Validation of analytical method AL027/00-0 - determination of [CBI Removed] in technical grade and pure deltamethrin (AE F032640) by HPLC Code: AE F032640 (deltamethrin, TGAI), DACO: 2.13.1 CBI
1549310	2005, Material accountability of AE F032640 (Deltamethrin) Analytical profile of production batches from [CBI Removed], DACO: 2.13.3 CBI
1549311	1990, Deltamethrin active ingredient: Determination of color, physical state, odor, density and pH., DACO: 2.14.1,2.14.2,2.14.3,2.14.6
1549312	1991, Deltamethrin A.I. - Determination of Octanol/Water partition coefficient., DACO: 2.14.10,2.14.11
1549313	1993, Deltamethrin: Structural analysis., DACO: 2.14.12
1549314	1991, Deltamethrin A.I.: Determination of stability., DACO: 2.14.13

PMRA Document Number	Reference
1549315	2008, Storage Stability of deltamethrin technical substance - AE F032640 (Deltamethrin), DACO: 2.14.14
1549316	2002, Melting point/melting range deltamethrin substance technical Codes: AE F032640 00 1D99 0014, AE F032640 00 1D99 0015, AE F032640 00 1D99 0016, DACO: 2.14.4,2.14.5
1549317	2000, Determination of the density Deltamethrin substance, technical Code: AE F032640 00 1D99 0006, DACO: 2.14.6
1549318	2000, Solubility in water at 20 °C - Deltamethrin, substance: pure - Code: AE F032640 00 1B99 0012, DACO: 2.14.7
1549319	2000, Solubility in organic solvents at 20 °C Deltamethrin substance technical Code: AE F032640 00 1D99 0002, DACO: 2.14.8
1549320	1991, Deltamethrin A.I. - Determination of vapour pressure., DACO: 2.14.9
1549321	1995, Deltamethrin: Henry's law constant., DACO: 2.16
1549322	1991, Deltamethrin a.i.: Determination of corrosion characteristics., DACO: 2.16
1549323	1996, Deltamethrin substance, technical: Flammability (solids)., DACO: 2.16
1549324	1996, Deltamethrin substance, technical: Auto-flammability (solids - determination of relative self-ignition temperature)., DACO: 2.16
1549325	2000, Explosive properties Deltamethrin substance, technical Code: AE F032640 00 1D98 0002, DACO: 2.16
1549326	2005, Oxidizing properties Deltamethrin (AE F032640); substance, technical Code: AE F032640 00 1D98 0002, DACO: 2.16
1730687	2009, Deltamethrin Manufacturing Process [CBI Removed] of the Technical Active Substance, DACO: 2.11.2 CBI
1730688	Specifications, DACO: 2.12 CBI
1794222	[CBI Removed] Product Chemistry for Deltamethrin, DACO: 2.1,2.2,2.3,2.4,2.5, 2.6,2.7,2.8,2.9
1794225	[CBI Removed] Product Chemistry for Deltamethrin, DACO: 2.1,2.2,2.4,2.5,2.6, 2.7,2.8,2.9
1794228	1988, [CBI Removed] Technical and Analytical Information required for the registration on an active principle. Product Chemistry, Method of Manufacture, Specifications, Quality Control, Analytical Data and Methodology, Physical and Chemical Properties, DACO: 2.1,2.10,2.11,2.12,2.13,2.13.1,2.13.4,2.14.13, 2.14.8,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
1794241	[CBI Removed] Active Ingredient Specifications, Quality Control Procedures Description, Decamethrine/Stability, Partition Coefficient, Evidence of Chemical Structure, Registration Information/EPA., DACO: 2.1, 2.10, 2.11, 2.12, 2.13, 2.14.1, 2.14.11, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9

2.0 Human and Animal Health

PMRA Document Number	Reference
2672308	2013, BES 0668 Insecticide: Acute Oral Toxicity Up And Down Procedure In Rats, DACO: 4.6.1
2672309	2016, BES 0668 Insecticide: Acute Dermal Toxicity Study In Rats - Limit Test, DACO: 4.6.2

PMRA Document Number	Reference
2672310	2016, BES 0668 Insecticide: Acute Inhalation Toxicity Study In Rats - Limit Test, DACO: 4.6.3
2672311	2016, BES 0668 Insecticide: Primary Eye Irritation Study In Rabbits, DACO: 4.6.4
2672312	2016, BES 0668 Insecticide: Primary Skin Irritation Study In Rabbits, DACO: 4.6.5
2672313	2016, BES 0668 Insecticide: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2672314	2016, Occupational exposure and risk assessment for deltamethrin DeltaGard 20EW formulation for commercial control of mosquitoes in Canada, DACO: 5.1,5.2,5.3,5.6
2672315	2016, DeltaGard 20EW Information to Address PMRA DACO Element 5.2 Use Description / Scenario, DACO: 5.2
2672325	2015, Deltamethrin. Human Health Risk Assessment for the Proposed Use of Deltamethrin as a Mosquito Adulticide over Agricultural Crops, DACO: M12.5.4,M12.5.5,M12.5.7
2672316	2009, Validation of BCS Method 00855/M004 for the Determination of cis-Deltamethrin, trans-Deltamethrin and alpha-R-Deltamethrin in Foodstuff of Plant Origin, DACO: 7.2.1.
2672317	2013, Deltamethrin - Magnitude of the Residue in/on Alfalfa, Leaf Lettuce, and Grass following Ultra Low Volume (ULV) Spray for Mosquito Control, DACO: 7.4.1,7.4.2.

3.0 Value

PMRA Document Number	Reference
2672294	2016, DeltaGard 20EW a 20 g/L water-based formulation of the active ingredient deltamethrin for the control of adult mosquitoes in Canada, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3(C),10.4,10.5.1,10.5.2,10.5.3,10.5.4,10.5.5
2672295	2013, A summary of laboratory and field efficacy trials for BES0668 Insecticide against important public health pests, DACO: 10.1,10.2.3.1
2672296	2016, DeltaGard 20EW a 20 g/L water-based formulation of the active ingredient deltamethrin for the control of adult mosquitoes in Canada, DACO: 10.2.3.1
2672297	2013, Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of Patriot adulticide using ground ULV sprayer against *Aedes aegypti* mosquitoes in Florida, DACO: 10.2.3.3(C)
2672299	2013, Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of Patriot adulticide using ground ULV sprayer against *Aedes* sp. and *Culex* sp. mosquitoes in California, DACO: 10.2.3.3(C)
2672300	2013, Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of Patriot adulticide using ground ULV sprayer against *Anopheles* sp. and *Culex* sp. mosquitoes in North Carolina, DACO: 10.2.3.3(C)
2672302	2015, Evaluation of DeltaGard for ULV application for adult mosquito control in Winnipeg, Manitoba, DACO: 10.2.3.4(C)
2680868	2013, Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of Patriot adulticide using ground ULV sprayer against *Aedes sollicitans* mosquitoes in Texas, DACO: 10.2.3.3(C)
2680869	2012, Field demonstration study to determine efficacy of Patriot adulticide using ground ULV sprayer against field-collected *Culex quinquefasciatus* mosquitoes in Louisiana, DACO: 10.2.3.3(C)
2680871	2003, Canadians Brace for West Nile Virus, DACO: 10.5
2680872	Gubler D., 2007, The Continuing Spread of West Nile Virus in the Western

PMRA Document Number	Reference
	Hemisphere, DACO: 10.5
2680873	2013, Guide for Public Health Units: Considerations for Adult Mosquito Control, DACO: 10.5

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

PMRA Document Number	Reference
2409268	U.S. EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment. EPA: Washington, DC. October 2012.

ii) Unpublished Information

1.0 Human and Animal Health

PMRA Document Number	Reference
2115788	Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer coefficients. Submission #2006-0257. CBI