Proposed Registration Decision PRD2019-07

Deltamethrin and Annihilator PolyZone

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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*, is proposing registration for the sale and use of Deltamethrin Technical Insecticide and Annihilator PolyZone, containing the technical grade active ingredient deltamethrin, to control crawling and flying insect pests by application on indoor and outdoor surfaces of agricultural buildings and structures.

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 and to control adult mosquitoes in residential and recreational areas. For details, see Proposed Registration Decision PRD2017-05, *Deltamethrin*; Registration Decision RD2017-08, *Deltamethrin*; PRVD2015-07, *Deltamethrin;* and RVD2018-27, *Deltamethrin and its associated End-use Products*. The use of deltamethrin on structures 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 the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of deltamethrin and Annihilator PolyZone.

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.

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

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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."

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 section of the Canada.ca website at Canada.ca/pesticides.

Before making a final registration decision on deltamethrin and Annihilator PolyZone, 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 active deltamethrin and Annihilator PolyZone, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

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

What Is Deltamethrin?

Deltamethrin is the active ingredient in the commercial class product Annihilator PolyZone Insecticide, which is used to kill various insect and tick pests in and on agricultural structures. Deltamethrin is a broad-spectrum synthetic pyrethroid insecticide which affects the insect nervous system causing paralysis and death.

Health Considerations

Can Approved Uses of Deltamethrin Affect Human Health?

Annihilator PolyZone, containing deltamethrin, is unlikely to affect your health when used according label directions.

Potential exposure to Annihilator PolyZone 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). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

[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; consequently, the signal words and hazard statement "DANGER POISON" are required on the label. 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, Annihilator PolyZone, is considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure, minimally irritating to the eyes, and is not expected to cause an allergic skin reaction. It is considered to be mildly irritating to the skin, and consequently, the signal word and hazard statement "CAUTION SKIN IRRITANT" are 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 Non-Occupational Environments

Estimated risks for non-occupational exposures are not of concern provided that directions specified on the label are observed.

Annihilator PolyZone is not proposed for use in residential areas. Non-occupational postapplication exposures to individuals in agricultural facilities treated with deltamethrin are not expected to result in unacceptable risk when Annihilator PolyZone is used according to label directions.

Occupational Risks from Handling Annihilator PolyZone

Occupational risks are not of concern when Annihilator PolyZone is used according to the proposed label directions, which includes protective measures.

A risk assessment was conducted for individuals handling and entering areas treated with Annihilator PolyZone.

People mixing, loading and applying Annihilator PolyZone in an occupational setting can come in direct contact with deltamethrin on the skin or through inhalation. Therefore the label will specify that a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes must be worn during mixing, loading, application, clean-up and repair activities. In addition, when treating overhead areas, it is recommended that applicators wear safety glasses, goggles or face shield and dust/mist respirator.

Occupational postapplication exposures to individuals entering agricultural facilities treated with deltamethrin are not expected to result in unacceptable risk when Annihilator PolyZone is used according to label directions.

Environmental Considerations

What Happens When Deltamethrin Is Introduced Into the Environment?

When deltamethrin is used according to label directions, the risks to the environment have been determined to be acceptable.

When used for control of crawling and flying insect pests, deltamethrin will be applied to the indoor and outdoor surfaces of buildings and structures, as a surface spray, spot treatment and as a crack and crevice spray. As a result, the amount of pesticide deposited on soil and water is expected to be minimal and will be localized to the interior and exterior surfaces of buildings and structures.

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 type of application method, exposure to the environment is expected to be minimal and the use of Annihilator PolyZone 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 Annihilator PolyZone

Annihilator PolyZone kills mosquitoes, stable flies, house flies, blue bottle flies, flesh flies, cluster flies, adult lesser mealworms and ticks in and on agricultural buildings and structures.

Mosquitoes, stable flies, house flies, blue bottle flies, flesh flies, cluster flies, adult lesser mealworms and ticks are nuisance pests for people, companion animals and livestock. Mosquitoes and ticks may transmit diseases to people and animals. Annihilator PolyZone kills these insects on contact, in and on agricultural buildings and structures such as dairy barns, poultry houses, swine barns, stables, dog kennels and storage sheds.

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 Deltamethrin Technical Insecticide and Annihilator PolyZone to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To avoid direct contact with deltamethrin on the skin or through inhalation, long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes must be worn during mixing, loading, application, clean-up and repair activities. In addition, when treating overhead areas, it is recommended that applicators wear safety glasses, goggles or face shield and dust/mist respirator.

Environment

Label statements are required to inform users that deltamethrin is toxic to 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 and Annihilator PolyZone, 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

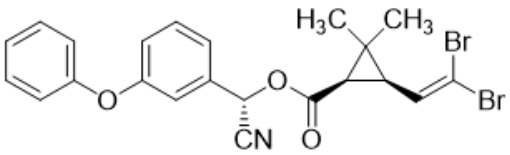
When Health Canada makes its registration decision, it will publish a Registration Decision on deltamethrin and Annihilator PolyZone (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection,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

Science Evaluation

Deltamethrin Technical Insecticide and Annihilator PolyZone

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
Density	0.55 g/cm^3
Vapour pressure at 20°C	1.24×10^{-5} mPa
Ultraviolet (UV)-visible spectrum	Not expected to absorb at $\lambda > 300$ nm

Property	Result
Solubility in water at 20°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—Annihilator PolyZone

Property	Result
Colour	tan
Odour	sweet malty odour
Physical state	liquid suspension
Formulation type	SU (suspension)
Guarantee	50 g/L
Container material and description	HDPE plastic jugs or totes
Density	1.05 g/mL
pH of 1% dispersion in water	4.6
Oxidizing or reducing action	Contains no strong oxidizing or reducing substances
Storage stability	Stable for 12 months in commercial packaging material
Corrosion characteristics	Not corrosive to commercial packaging material
Explodability	Contains no shock sensitive components

1.3 Directions for Use

Annihilator PolyZone is a commercial class insecticide used to kill mosquitoes, stable flies, house flies, blue bottle flies, flesh flies, cluster flies, adult lesser mealworms and ticks in and on agricultural buildings and structures such as dairy barns, poultry houses, swine barns, stables, dog kennels and storage sheds. It is applied at a concentration of 0.01 to 0.03% and at a rate of 0.8 to 2.5 mL of product/10 m^2 for spot applications or crack and crevice applications indoors and outdoors, and general surface applications on the outside of buildings. The product may be reapplied as necessary.

1.4 Mode of Action

Deltamethrin belongs to Insecticide Resistance Action Committee Mode of Action (IRAC MOA) 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

2.1 Methods for Analysis of the Active Ingredient

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

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.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Deltamethrin is a synthetic pyrethroid insecticide that operates via a neurotoxic mode of action in insects and mammals. Pyrethroids delay the closing of neuronal voltage-dependent sodium channels causing the depolarization of neurons. This affects action potentials and results in repetitive activity (Type I pyrethroids) or blockage of nerve conduction (Type II pyrethroids). Deltamethrin contains a cyano group and is classified as a Type II pyrethroid. Type II pyrethroids induce the “CS syndrome”, which is characterized by choreoathetosis (involuntary excessive movements progressing to sinuous writhing), sedation, salivation, dyspnoea, clonic seizures and body tremors.

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 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. Toxicological reference values for use in the human health risk assessment were established and are reported in PRVD2015-07. Several recently published literature studies, which investigated the toxicokinetics, neurotoxicity, and male reproductive effects following administration of deltamethrin, were identified and reviewed for their potential impact on the toxicological reference values previously established for use in the human health risk assessment. The findings from these literature studies, as well as the results of acute toxicity testing with the end-use product Annihilator PolyZone, are summarized below.

In acute toxicity testing, the end-use product Annihilator PolyZone was considered to be of low acute toxicity in rats via the oral, dermal, and inhalation routes of exposure, minimally irritating to the eyes and mildly irritating to the skin of rabbits, and not a dermal sensitizer in guinea pigs when tested via the Buehler method.

A toxicokinetics study investigated the effects of dose, vehicle, and age on toxicokinetics parameters in rats following oral gavage administration of deltamethrin. Results revealed that absorption was more rapid when the chemical was administered in glycerol compared to corn oil, and that a larger volume of corn oil delayed absorption. Additionally, it was found that plasma, brain, and liver levels of deltamethrin following oral administration were generally age- and dose-dependent, with higher levels observed in pups on postnatal day 15 compared to adults. Although the age-dependent differences in plasma levels were diminished at the lower dose levels, this was not true for brain or liver levels.

A supplemental study investigating the effects of deltamethrin on the brains of adult male rats revealed effects on oxidative stress markers in the serum and brain, as well as an increase in DNA damage and histopathological changes in the brain.

Studies with male mice investigated the effects of repeated oral gavage administration of deltamethrin on male reproductive organs, sperm and endocrine parameters, and fertility indices. Administration of deltamethrin for 45 days resulted in a reduction in testes, epididymides and seminal vesicle weights as well as decreases in sperm count, motility, and viability. Treatment-related histopathological alterations in the testes and alterations in male hormone levels were also observed. Similar results were noted in another study in which male mice received deltamethrin via oral gavage for 35 days and were then mated with untreated females to produce offspring. Administration of deltamethrin resulted in a reduction in male mating and fertility indices in addition to decreases in hormone levels and sperm quality, and histopathological alterations in the testes.

A similar study investigated the effect of deltamethrin on the testes, liver and kidneys of male rats following oral gavage administration for 28 days. Decreases in reproductive hormone levels and adverse effects on sperm parameters, such as decreased sperm count and motility and an increase in sperm abnormalities, were observed. These findings were similar to those observed in mice. Effects on testes, epididymides, and kidney weights, with corresponding dose-related histopathological alterations in these organs, were also noted.

The effects of deltamethrin on the fetal rat testes were investigated in a non-guideline developmental toxicity study in which pregnant female rats were administered deltamethrin via oral gavage during gestation. Maternal toxicity was evident as clinical signs of neurotoxicity, and decreases in body weight and body weight gain. There were no effects on cesarean section parameters. Examination of the testes of male fetuses indicated that deltamethrin induced no changes in the expression of several genes involved in cholesterol transport or in the steroid synthesis pathway in the testes. The results of the study indicated that in utero exposure to deltamethrin had no effect on the testosterone synthesis pathway in the male rat fetus at doses that were maternally toxic.

The effects noted in the literature studies were comparable to those summarized in PRVD2015-07, and there was no new evidence of increased sensitivity of the young to deltamethrin identified. Therefore, the previously established toxicological reference values for use in human health risk assessment remain unchanged, and the risk assessment is considered protective of the effects noted in the literature.

Results of the majority of the toxicology studies conducted on laboratory animals with deltamethrin are summarized in Appendix III of PRVD2015-07. Results of additional recently published literature studies, assessed subsequent to PRVD2015-07, are summarized in Appendix I, Table 2. Appendix I, Table 1 summarizes the results of the acute toxicity studies for the associated end-use product, Annihilator PolyZone. The toxicological reference values for use in the human health risk assessment are summarized in PRVD2015-07.

Incident Reports

As of 21 November 2018, the PMRA had received 25 human incident reports and 50 domestic animal incident reports involving deltamethrin products.

There were 11 human incidents considered to be at least possibly related to the exposure to the product. Exposures frequently occurred while applying or handling a deltamethrin product. Other less frequently reported exposures involved postapplication activities or spray drift from a nearby property. All of the incidents except for one were minor or moderate in severity, and associated with relatively minor symptoms such as non-serious skin or eye effects, throat irritation, malaise, and vomiting. There was one serious incident reported from the United States, which involved an individual who reported adverse effects and was hospitalized for approximately two months, following re-entry to a home treated with a deltamethrin product. The reported effects were muscular weakness and spasms, constipation, anorexia, upper abdominal pain and headache. However, there were uncertainties pertaining to the individual's health, the exposure details, and whether the pesticide product was misapplied. The incident is also of limited relevance to Annihilator PolyZone, which is not proposed for use in a residential site. Overall, due to the relatively minor nature of the majority of the reported symptoms, the lack of a consistent pattern in the various exposure scenarios, and the uncertainties and the limited relevance of the single serious incident, no additional risk mitigation measures are proposed on the basis of the human incident reports.

There were 25 domestic animal incidents considered to be at least possibly related to the deltamethrin products. The most frequently reported incidents involved dogs and cats, and incidents occurring in residential settings inside and outside the home. There were six incidents that were minor or moderate in severity and mainly involved minor gastrointestinal effects. Death was reported in 19 incidents and most frequently occurred in a residential setting. The most frequently reported scenarios involved exposure during application and postapplication, including re-entry to a treated site. There were also several unspecified exposure scenarios, which accounted for approximately half of the incidents; however, based on the provided information it is suspected these incidents involved possible postapplication exposure. Other less frequently reported exposures involved drift, accidental ingestion, or product bottle chewing.

Given that there is a potential for more serious effects to occur in domestic animals exposed to deltamethrin, appropriate label directions are proposed for Annihilator PolyZone to limit exposure of domestic animals to deltamethrin during and after product application.

3.2 Occupational and Residential Risk Assessment

3.2.1 Toxicological Endpoints

Occupational exposures to deltamethrin are expected to be mainly via the dermal and inhalation routes for workers engaged in mixing, loading and applying. The duration of exposure is expected to be short- (1–30 days) to intermediate-term (<180 days). Due to the use pattern of the end-use product and the non-volatility of the active ingredient, postapplication dermal and inhalation exposures are considered to be minimal.

3.2.1.1 Dermal Absorption

As the toxicological endpoint for the dermal risk assessment is based on a NOAEL from a dermal toxicity study, no dermal absorption factor is required.

3.2.2 Occupational Exposure and Risk

3.2.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Dermal and inhalation exposure estimates are based on mixers/loaders/applicators wearing baseline PPE consisting of a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. The end-use product can be applied with various types of handheld equipment such as manually pressurized handwand, backpack and mechanically pressurized handgun sprayers. The unit exposure values for the latter two equipment types were generated from PHED (version 1.1) and the former from a passive dosimetry study.

The amount of product handled per day varies by equipment type. The PMRA default values were used in the risk assessment.

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

Exposure estimates were compared to the toxicological reference value to obtain the margin of exposure (MOE). The calculated MOEs were above the target MOEs of 1000 for the dermal route and 300 for the inhalation route (Appendix I, Tables 3 and 4).

3.2.3 Postapplication Exposure and Risk

The applicant did not submit any information relating to tasks completed by workers or non-occupational people entering treated agricultural buildings and structures.

Guidance for completing postapplication exposure assessments in agricultural buildings is available in the USEPA 2012 Residential SOP. Section 5 (Outdoor Fogging/Misting Systems) provides guidance and algorithms for dermal and incidental oral non-occupational exposure assessments for animal barn misters once sprays have deposited on surfaces within barns. The dermal and incidental oral exposure assessments are based on default parameters for indoor environment scenarios in the SOP (Section 7). The transfer co-efficients (TC) in Section 7 (Indoor Environments) are based on studies of people completing jazzercise activities in residential areas to achieve maximum contact of the entire body on treated surfaces and would therefore greatly overestimate occupational/non-occupational exposures in animal barns. For exposure time, 4 and 2 hours are assumed for adults and children (aged 3–6 years), respectively. Four hours of daily exposure for adults is greater than that for hard surfaces in the home and is believed to be a conservative estimate of time spent inside an animal barn for non-occupational barn-related tasks. In addition, animal barn misters deposit residues indiscriminately and therefore residues may be present on items such as milking equipment and riding gear, which are frequently handled by people in both non- and occupational settings. However, in the case of Annihilator PolyZone, dermal contact with the inadvertently treated items is expected to be minimal as the approved use pattern is limited to spot and crack and crevice treatment of floors and walls.

The vapour pressure for deltamethrin is 1.24×10^{-8} kPa at 25°C (PRD2017-05) which meets the NAFTA waiver criteria for being non-volatile indoors.[5] As such, people entering a treatment area after residues have dried are not expected to be exposed to deltamethrin vapours.

Deltamethrin is currently registered for use on greenhouse ornamentals, greenhouse food crops, industrial oilseed crops, terrestrial feed and food crops, roadsides, shelterbelts, turf (including golf courses and in residential areas) and in human habitat and recreational areas. Postapplication risk assessments for adults (dermal occupational and non-occupational) and children (dermal and incidental oral) to treated turf areas have been completed under PRVD2015-07 and PRD2017-05. The potential for dermal exposure to treated turf is much higher than that proposed for Annihilator PolyZone. Therefore, dermal, inhalation and incidental oral risks are not expected to exceed those resulting from currently registered uses.

3.2.4 Aggregate Exposure and Risk

Aggregation of dermal exposure was not required as no adverse toxicological effects were noted following repeated dermal dosing. The only scenario which is expected to co-occur is incidental oral exposure (hand-to-mouth) and chronic dietary exposure, which is also not expected to exceed that resulting from currently registered uses of deltamethrin.

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5 Non-volatile products are defined as those having vapor pressures less than 1×10^{-5} kPa for indoor uses, and less than 1×10^{-4} kPa for outdoor uses at 20-30°C. NAFTA (1999). International Harmonisation Position Paper on Methodology Issues, Appendices. 18 January 1999.

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 and PRD2017-05.

For control of a wide variety of crawling and flying insect pests, deltamethrin is applied with hand pressurized or power operated sprayers both indoors and outdoors. Treatment applications are specified as spot treatments and crack & crevices sprays, and as general surface applications.

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); it is non-persistent to moderately persistent in both media. In water, deltamethrin is expected to bind to suspended matter and sediments, which is supported by aquatic field studies results where deltamethrin dissipated rapidly from the water column. Deposit into aquatic and terrestrial systems from the type of application proposed for indoor and outdoor surfaces of buildings and structures 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 (such as, 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 characterization 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*). Its use for control of adult mosquitoes at a maximum annual use of 15 g a.i./ha was assessed in PRD2017-05. Current application methods include conventional aerial and ground equipment such as rotary and fixed wing aircraft, boom sprayers, airblast sprayers, mist blowers and hand held sprayers. The proposed use of Annihilator PolyZone for control of crawling and flying insect applied with hand pressurized or power operated sprayers would result in a significantly lower use rate and more localized deposition of deltamethrin than currently registered for other uses. Therefore, exposure of non-target organisms, and environmental risk, are 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. Based on the assessment reported in PRVD2015-07, and the low potential for exposure from hand pressurized or power operated sprayers, 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 if they are present on the treatment area. However, based on the proposed used pattern, the potential impact on honeybees or other pollinators/beneficial insects is expected to be minimal. Precautionary label 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 is very highly toxic to fish and aquatic invertebrates. Impact on aquatic organisms is expected to be limited in view of the method and sites of spray application. Spray droplets may evaporate while they are suspended in the air and deposition in water bodies is expected to be limited.

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.

5.0 Value

The results from 12 trials supported the claim that Annihilator PolyZone will kill house flies, blue bottle flies, flesh flies, stable flies, mosquitoes, ticks and darkling beetle adults (lesser mealworm adults). Support for cluster flies was based on extrapolation from results for house flies. The trial results were sufficient to support use in and on agricultural buildings and structures such as dairy barns, poultry houses, swine barns, stables, dog kennels and storage sheds applied at rates of 0.8–2.5 mL product/10 m^2 with reapplication as necessary.

Alternative active ingredients from other mode of action (MOA) groups are registered for most of the supported uses of Annihilator PolyZone. Other group 3A active ingredients are registered for all supported uses of the proposed product; therefore, the product does not represent a new mode of action for the supported uses.

Of the pests on the Annihilator PolyZone label, resistance to deltamethrin has been reported in various mosquito species (Europe, Asia, Africa and the southern United States of America) and the house fly (Europe, Asia, United States of America and Canada). Therefore, appropriate resistance management strategies (as listed on the Annihilator PolyZone label) should be followed.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

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

- During the review process, Deltamethrin Technical Insecticide and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[6] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that Deltamethrin Technical Insecticide and its transformation products do not meet all of the TSMP Track-1 criteria.

Please refer to PRVD2015-07, *Deltamethrin*, for further information on the TSMP assessment.

[6] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

6.2 Formulants and Contaminants of Health Concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.[7] The list is used as described in the PMRA Notice of Intent NOI2005-01[8] and is based on existing policies and regulations, including the Toxic Substances Management Policy and Formulants Policy,[9] 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 conclusion that Deltamethrin Technical Insecticide and its end-use product Annihilator Polyzone do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database is adequate to characterize the potential health hazards associated with deltamethrin. There was no evidence of carcinogenicity in rats or mice after long-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.

Mixer, loader applicators handling Annihilator PolyZone and workers entering treated agricultural buildings and structures are not expected to be exposed to levels of deltamethrin that will result in an unacceptable risk when the end-use product is used according to label directions. The personal protective equipment of a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes is adequate to protect workers mixing, loading and applying. In addition, when treating overhead areas, it is recommended that applicators wear safety glasses, goggles or face shield and dust/mist respirator.

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7 SI/2005-114, last amended on 25 June 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Products Formulations and Contaminants of Health or Environmental Concern*.

8 PMRA's Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

Exposures to individuals entering treated buildings are not expected to result in unacceptable risks provided people do not enter until sprays have dried.

7.2 Environmental Risk

The use of Annihilator PolyZone, containing the active ingredient deltamethrin, is not expected to pose risks of concern to non-target terrestrial and aquatic organisms when used in accordance with the label directions. Precautionary label statements to advise users that deltamethrin is toxic to beneficial arthropods, bees and aquatic organisms are required.

7.3 Value

The submitted value information supported the use of Annihilator PolyZone to kill mosquitoes, stable flies, house flies, blue bottle flies, flesh flies, cluster flies, adult lesser mealworms and ticks in and on agricultural buildings and structures such as dairy barns, poultry houses, swine barns, stables, dog kennels and storage sheds when applied at 0.8–2 2.5 mL product/10 m^2 for spot or crack and crevice applications indoors and outdoors, and general surface applications on the outside of buildings.

8.0 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 Deltamethrin Technical Insecticide and Annihilator PolyZone, containing the technical grade active ingredient deltamethrin, to control crawling and flying insect pests by application on indoor and outdoor surfaces of agricultural buildings and structures.

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 products are acceptable.

List of Abbreviations

♂	male
♀	female
λ	wavelength
↑	increased
↓	decreased
µg	micrograms
a.i.	active ingredient
AMH	Anti-Müllerian hormone
AUC	area under the plasma concentration-time curve
Bax	Bcl-2-associated X protein
bw	body weight
C_{max}	maximum serum concentration
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
cm	centimetres
DACO	data code
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
EEC	estimated environmental exposure concentration
FSH	follicle-stimulating hormone
g	gram
GD	gestation day
GPx	glutathione peroxidase
GR	glutathione reductase
GSH	glutathione
GST	glutathione S transferase
ha	hectare(s)
HDPE	High Density Polyethylene
HMG-CoA	3-hydroxy-3-methylglutaryl-CoA
HPLC	high performance liquid chromatography
hr	hour(s)
IRAC	Insecticide Resistance Action Committee
IUPAC	International Union of Pure and Applied Chemistry
i.v.	intravenous
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LH	luteinizing hormone
LOC	level of concern
m^2	square meter(s)
MDA	malondialdehyde

mg	milligram
mL	millilitre
M/L/A	mixer/loader/applicator
MAS	maximum average score
MIS	maximum irritation score
MOA	Mode of Action
MOE	margin of exposure
mPa	megaPascal
mRNA	messenger ribonucleic acid
NAFTA	North American Free Trade Agreement
nm	nanometre
NOAEL	no observed adverse effect level
PChE	plasma cholinesterase
pH	measure of the acidity or basicity of an aqueous solution
PHED	Pesticide Handlers Exposure Database
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	postnatal day
PPE	personal protective equipment
PRD	Proposed Registration Decision
PRVD	Proposed Re-evaluation Decision
P450scc	cytochrome P450 side-chain cleavage
P450 17A1	cytochrome P450 17α-hydroxylase
RD	Registration Decision
RQ	risk quotient
SI	Statutory Instrument
SOD	superoxide dismutase
SOP	Standard Operating Procedure
SR-B1	scavenger receptor class B type 1
StAR	steroidogenic acute regulatory protein
SU	suspension
TAC	total antioxidant capacity
T_{max}	the time when the maximum serum concentration (Cmax) is reached
TC	transfer co-efficients
TSMP	Toxic Substances Management Policy
UE	Unit exposure
USEPA	United States Environmental Protection Agency
UV	ultraviolet
wt	weight
3β HSD	3 beta-hydroxysteroid dehydrogenase
17β HSD	17 beta-hydroxysteroid dehydrogenase
3-PBA	3-phenoxybenzoic acid

Appendix I Tables and Figures

Table 1 Toxicity Profile of Annihilator PolyZone 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 Up and Down Sprague Dawley rats PMRA #2738822	LD_{50} > 5000 mg/kg bw (♀) Low Toxicity
Acute Dermal Sprague Dawley rats PMRA #2738823	LD_{50} > 5000 mg/kg bw (♂/♀) Low Toxicity
Acute Inhalation Sprague Dawley rats PMRA #2738824	LC_{50} > 2.08 mg/L (♂/♀) Low Toxicity
Primary Eye Irritation New Zealand White rabbits PMRA #2738825	MAS[a] = 5.2/110 MIS[b] = 18.3/110 (at 1 hr) Minimally Irritating
Primary Skin Irritation New Zealand White rabbits PMRA #2738826	MAS = 2.0/8 MIS = 3.3/8 (at 1 hr) Mildly Irritating
Skin Sensitization Buehler Hartley albino guinea pigs PMRA #2738827	Negative

[a] MAS = Maximum Average Score for 24, 48 and 72 hrs

[b] MIS = Maximum Irritation Score

Table 2 Summary of Recently Published Literature Studies for 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. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted)

Study Type/ Animal/PMRA #	Study Results
Toxicokinetics	
Toxicokinetics: dose-, vehicle-, and age-dependent differences Sprague Dawley rats PMRA #2967884	Single i.v. dose (0.5 mg/kg bw in glycerol): Plasma concentrations ↓ rapidly during the first 6 hr post-injection, followed by a very slow decline for the remainder of the 96 hrs. Dose-dependence study (single oral gavage dose at 0.05, 0.1, 0.5, 1.0, or 5.0 mg/kg bw in corn oil): Absorption and elimination profiles were dose-dependent; linear kinetics were observed over the 100-fold dose range evaluated. Vehicle/volume study [single oral gavage dose in glycerol (1 mL/kg bw) or corn oil (1 or 5 mL/kg bw)]: Plasma levels rose more rapidly when deltamethrin was administered in glycerol compared to the same volume of corn oil (1 mL/kg bw); however, elimination rate and T_{max} values were not significantly different between vehicles. A larger volume of corn oil (5 mL/kg bw) delayed absorption. Overall AUC values were not significantly affected by vehicle or volume. Age-dependence study (single dose of 0.10, 0.25, or 0.50 mg/kg bw via oral gavage in corn oil to PND 15, 21 and 90 rats): Plasma, brain and liver levels of deltamethrin were generally age- and dose-dependent, with the highest levels observed in the PND 15 pups and lowest levels seen in the PND 90 rats. The age-dependent differences between the plasma C_{max} and AUC values diminished with decreasing dose; however, this was not the case for brain and liver C_{max} and AUC values.
Studies investigating reproductive effects (non-guideline)	
35 day ♂ reproductive toxicity (gavage) Effects on endocrine and reproductive parameters in ♂ mice mated with untreated ♀. Swiss albino mice PMRA #2967885	**Supplemental** **5 mg/kg bw/day:** ↓ mating and fertility indices in ♂ mice, ↓ in the number of pregnant ♀ and number of litters, ↓ semen ejaculate volume, ↓ sperm count, ↓ sperm motility, ↓ viability, ↑ abnormal sperm, ↓ testosterone and inhibin B levels, severe alterations of the seminiferous tubules, sloughing of germ cells into tubular lumen, ↑ vacuolization of germ cell cytoplasm, disruption of spermatogenic cells, atrophy of seminiferous tubules with a subsequent ↑ in the interstitial space.

Study Type/ Animal/PMRA #	Study Results
45 day ♂ reproductive toxicity (gavage) Swiss albino mice PMRA #2967886	**Supplemental** **≥3 mg/kg bw/day:** ↓ bw, ↓ testis, cauda epididymis and seminal vesicle wts, ↓ sperm count, ↓ sperm motility, ↓ sperm viability, ↓ serum testosterone, ↓ sialic acid of cauda epididymis, ↓ fructose in seminal vesicles, ↓ testicular 3β HSD and 17β HSD, ↑ severity of histopathological alterations in the testis (including ↓ spermatogenic cells, degeneration of spermatocytes and spermatids, severe deformity in seminiferous tubules, tubular atrophy, aspermatogenesis, vacuolization, cell necrosis and sloughing, Sertoli and Leydig cell degeneration)
28-day ♂ reproductive toxicity (gavage) Dose-dependent effect of deltamethrin on testis, liver and kidneys in ♂ rats Wistar rats PMRA #2967887	**Supplemental** **≥2 mg/kg bw/day:** ↓ sperm count, ↓ sperm motility, ↑ sperm abnormality, ↓ serum testosterone, LH and FSH, ↑ liver wt, ↑ lipid peroxidation in testis, liver and kidney, ↓ GSH in testis and kidney, ↑ SOD, ↓ CAT, ↓ GST, ↓ GPx, ↓ GR in testis, liver and kidney, ↑ severity of histopathological alterations in the testis (including degeneration of the seminiferous tubules, vacuole formation, tubules devoid of germ cells), liver (including degeneration and necrosis) and kidney (including degenerated renal tubules with intraluminal exfoliation and granular cast formation, leucocytic inflammatory cells, and enlarged renal veins congested with blood) **≥3 mg/kg bw/day**: ↓ testis and epididymis wt, ↑ kidney wt, ↓ GSH in liver, ↑ total protein in testis, liver and kidney
Developmental toxicity (gavage) Evaluation of the effects of deltamethrin on the fetal rat testis following dosing of dams GD 13-19 Sprague Dawley rats PMRA #2967888	**Supplemental** Maternal toxicity **10 mg/kg bw/day:** transient clinical signs of neurotoxicity (gait impairment, abnormal posture and mobility, hind limbs splayed/dragging), ↓ bw, ↓ adjusted bw (minus gravid uterine wt), ↓ bwg Developmental toxicity **10 mg/kg bw/day:** ↓fetal bw No effect on cesarean section parameters (# implantation sites, # live fetuses, post-implantation loss, % ♂ fetuses, ♂ anogenital distance). Fetal testis investigations No changes in fetal testicular mRNA levels of cholesterol synthesis-related genes (HMG-CoA synthase and HMG-CoA reductase) or genes involved in cholesterol transport and steroidogenesis (SR-B1, StAR, P450scc, 3βHSD, P450 17A1 and 17βHSD). No effect on protein expression of P450scc or P450 17A1, or in the ex vivo testicular production of androstenedione, 17-

Study Type/ Animal/PMRA #	Study Results
	hydroxyprogesterone or testosterone. No changes were observed after immunostaining for 3βHSD (identification of Leydig cells) and AMH (for identification of seminiferous cords and Sertoli cells). A dose-related ↑ in the deltamethrin metabolite 3-PBA was observed in the amniotic fluid collected from fetuses.
Other Studies	
12 week oral toxicity – effect on ♂ brain (gavage) Wistar rats PMRA #2967889	**Supplemental** **5 mg/kg bw/day:** ↓ bwg, ↑ brain and serum MDA, ↓ serum TAC and GSH, ↓ PChE, histopathological alterations in the brain (vacuolization, degeneration, hemorrhage, congested blood vessels), strong positive immune reaction to Bax antibody in the brain (may reflect ↑ apoptosis in neuronal cells), ↑ DNA damage in brain tissue

Table 3 Mixer/Loader/Applicator Dermal Risk Assessment

Exposure scenario	Dermal UE (µg/kg a.i. handled)	Amount Handled/ Day (L/day)	Application Rate (kg a.i./L)[1]	Dermal Exposure (mg/kg bw/day) [2]	Dermal MOE [3]
PPE: Single layer and chemical-resistant gloves					
PHED: Liquid, open pour, mechanically pressurized handgun (M/L/A)	5585.49	3800	0.0003	0.07959	12600
PHED: Liquid, open pour, backpack sprayer (M/L/A)	5445.85	150	0.0003	0.003063	326000
Liquid, open pour, manually pressurized handwand (M/L/A)	85843.55	150	0.0003	0.04829	20700

[1] Application Rate (kg a.i./L) = 6 mL/L × Conversion Factor (L/1000 mL) × Guarantee (50 g/L) × Conversion Factor (kg/1000 g)
[2] Dermal Exposure (mg/kg bw/day) = (Dermal Unit Exposure × Amount Handled × App. Rate)/(80 kg bw × 1000 µg/mg)
[3] Based on the dermal NOAEL of 1000 mg/kg bw/day, target MOE = 1000

Table 4 Mixer/Loader/Applicator Inhalation Risk Assessment

Exposure scenario	Inhalation UE (µg/kg a.i. handled)[1]	Amount Handled/Day (L/day)	Application Rate (kg a.i./L) [2]	Inhalation Exposure (mg/kg bw/day) [3]	Inhalation MOE [4]
PHED: Liquid, open pour, mechanically pressurized handgun (M/L/A)	151	3800	0.0003	0.002152	465
PHED: Liquid, open pour, backpack sprayer (M/L/A)	62.1	150	0.0003	0.000035	28600
Liquid, open pour, manually pressurized handwand (M/L/A)	328.52	150	0.0003	0.000185	5410

[1] Unit exposure values are light for manually pressurized handwand and mechanically pressurized handgun and moderate for backpack.
[2] Application Rate (kg a.i./L) = 6 mL/L × Conversion Factor (L/1000 mL) × Guarantee (50 g/L) × Conversion Factor (kg/1000 g)
[3] Inhalation exposure (mg/kg bw/day) = (Inhalation Unit Exposure × Amount Handled × App. Rate)/(80 kg bw × 1000 µg/mg)
[4] Based on the inhalation NOAEL of 1 mg/kg bw/day, target MOE = 300

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number | References

1.0 Chemistry

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2.0 Human and Animal Health

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3.0 Environment

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4.0 Value

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2738779 2016, Annihilator Polyzone Efficacy Summary Table, DACO: 10.2.3, 10.2.3.1, 10.2.3.4(D)
2807939 2017, 2017-1224-Annihilator PolyZone-Value Deficiency Response, DACO: 10.2, 10.3.2

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

2967884 Mortuza, T. , et al., 2017, Toxicokinetics of Deltamethrin: Dosage Dependency, Vehicle Effects, and Low-dose Age-Equivalent Dosimetry in Rats, Toxicological Sciences; 162(1),327-336 (2018), DACO: 4.5.9
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