

Proposed Registration Decision

PRD2020-05

Fenpropathrin and Danitol EC Spray

(publié aussi en français)

8 June 2020

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

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

Catalogue number: H113-9/2020-5E (print version) H113-9/2020-5E-PDF (PDF version)

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Overview

Proposed Registration Decision for Fenpropathrin

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 Fenpropathrin Technical and Danitol EC Spray, containing the technical grade active ingredient fenpropathrin, to control several insect pests in various fruit and vegetable crops.

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 fenpropathrin and Danitol EC Spray.

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 acceptable¹ 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 value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the <u>Pesticides</u> section of the Canada.ca website.

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."

Before making a final registration decision on fenpropathrin and Danitol EC Spray, 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 Decision⁴ on fenpropathrin and Danitol EC Spray, 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 Fenpropathrin?

Fenpropathrin belongs to the pyrethroid class (IRAC mode of action Group 3) of insecticides. It is a broad-spectrum insecticide/miticide, which controls pests from many different orders and families of insects in the listed crops. Fenpropathrin works by contact and ingestion and modulates the sodium channels in nerves resulting in paralysis and death of the pest. It is the active ingredient in the commercial class product, Danitol EC Spray.

Health Considerations

Can Approved Uses of Fenpropathrin Affect Human Health?

Danitol EC Spray, containing fenpropathrin, is unlikely to affect your health when used according to label directions.

Potential exposure to fenpropathrin may occur through the diet (food and water), when handling and applying the product, or when coming into contact with treated areas. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are 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.

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.

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*.

In laboratory animals, the active ingredient fenpropathrin was of high acute toxicity by the oral route; consequently, the signal word and hazard statement "DANGER – POISON" are required on the label. It was of moderate acute toxicity dermally and of slight acute toxicity through inhalation exposure. Fenpropathrin was non-irritating to the eyes and slightly irritating to the skin, and did not cause an allergic skin reaction.

The acute toxicity of the end-use product, Danitol EC Spray containing fenpropathrin, was high via the oral route; consequently, the signal word and hazard statement "DANGER – POISON" are required on the label. It was of low acute toxicity through the dermal and inhalation routes of exposure. It was severely irritating to the eyes and moderately irritating to the skin; consequently, the hazard statement "EYE AND SKIN IRRITANT" is required on the label. Danitol EC Spray has the potential to cause an allergic skin reaction; consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the 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 fenpropathrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints used for risk assessment were mortality and effects on the nervous system. There is some concern for increased sensitivity of the young exposed to pyrethroids, such as fenpropathrin. 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 chronic dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation which would ingest the most fenpropathrin relative to body weight, are expected to be exposed to less than 3% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from fenpropathrin is not of health concern for all population subgroups.

Aggregate acute dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most fenpropathrin relative to body weight, are expected to be exposed to less than 58% of the acceptable reference dose. Based on these estimates, the acute dietary risk from fenpropathrin is not of health concern for all population subgroups.

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

Residue trials conducted throughout the United States using fenpropathrin on succulent shelled peas, Crop Group (CG) 8-09, CG 9, CG 11-09, CG 12-09, Crop Subgroup (CSG)13-07 A and B, and CG 14-11 are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Occupational Risks from Handling Danitol EC Spray

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

Farmers and custom applicators who mix, load or apply Danitol EC Spray as well as field workers entering freshly treated fields can come in direct contact with fenpropathrin residues on the skin. Therefore, the label specifies that anyone mixing/loading Danitol EC spray must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, chemical-resistant footwear and socks and protective eyewear (goggles or faceshield). Additionally, workers applying Danitol EC Spray with open-cab airblast equipment must wear coveralls, chemicalresistant footwear and chemical-resistant gloves over long-sleeved shirt, long pants, plus chemical-resistant headgear. When applying more than 39 L of Danitol EC Spray per day, opencab airblast workers must wear chemical-resistant coveralls instead of coveralls.

The label also requires that workers do not enter treated fields up to a maximum of 23 days (depending on the crop and associated postapplication activity) after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and postapplication workers, the risk to these individuals are not of health concern.

Risks in Residential and Other Non-Occupational Environments

Risks in residential and other non-occupational environments are not of health concern when Danitol EC Spray is used according to the proposed label directions and restrictedentry intervals (REIs) are observed.

Residential exposure during pick-your-own fruit activities in treated orchards and farms are not of health concern.

Risks to Bystanders

Bystander risks are not of health concern when Danitol EC Spray is used according to the label directions and spray drift restrictions are observed.

Potential for bystander exposure is considered minimal and is expected to be significantly less than exposure estimated for workers. Based on the worker assessment, bystander exposure is not of concern.

Environmental Considerations

What Happens When Fenpropathrin is Introduced into the Environment?

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

Fenpropathrin enters the environment when applied as a foliar spray to control mites on berry and orchard crops and vegetables. When fenpropathrin is released into the environment, it can enter soil and surface water where it can persist under certain conditions. In the presence of sunlight, fenpropathrin can break down quickly in shallow water. It can also break down through the action of microbes in soil. Fenpropathrin binds to soil and is not expected to move downward and enter groundwater. In surface water, fenpropathrin will move into sediments where it can persist. Fenpropathrin is not likely to accumulate in tissues of organisms. Fenpropathrin is not expected to travel long distances from where it was applied.

Fenpropathrin does not present a risk of concern to earthworms and aquatic vascular plants. When used according to labelled application rates, fenpropathrin may pose risks to pollinators, beneficial insects, birds, mammals, plants and aquatic organisms. Mitigation measures including spray buffer zones, course spray, mandatory vegetative filter strips, restriction of application during bloom for bee-attractive crops and precautionary label statements are required to reduce exposure to these organisms. When fenpropathrin is used according to the label and the required risk reduction measures are applied, the environmental risks are considered acceptable.

Value Considerations

What is the Value of Danitol EC Spray?

Danitol EC Spray controls or suppresses various key insects and mites affecting various vegetable, berry, tree fruit and tree nut crops.

Danitol EC Spray is a new management tool for control or suppression of important insect and mite pests in vegetable, berry, tree fruit and tree nut crops. Danitol EC Spray will aid in resistance management for several pest/crop combinations, for example, blueberry maggot on bushberries, peach twig borer on tree nuts, and spotted wing drosophila on fruiting vegetables and pome fruits.

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 Fenpropathrin Technical and Danitol EC Spray to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To reduce the potential of workers coming into direct contact with fenpropathrin on the skin or through inhalation of spray mists, anyone mixing and loading Danitol EC Spray and performing cleaning and repair activities must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, chemical-resistant footwear and socks and protective eyewear (goggles or faceshield). Additionally, workers applying Danitol EC Spray with open-cab airblast equipment must wear coveralls, chemical-resistant footwear and chemical-resistant gloves over long-sleeved shirt, long pants, plus chemical-resistant headgear. When applying more than 39 L of Danitol EC Spray per day, open-cab airblast workers must wear chemical-resistant coveralls instead of coveralls. Risks to workers are not of health concern when Danitol EC Spray is used according to the label directions and restricted-entry intervals (REIs) are observed. In addition, standard label statements to protect against drift during application are found on the label.

Сгор	Postapplication activity	Restricted-entry interval (REI) and/or Pre-harvest interval (PHI)
Bushberry and	Hand set irrigation	17 days
Caneberry Crop Subgroups	Tying/training (raspberry), hand harvesting, mechanically-assisted harvesting	15 days
	Hand harvesting, scouting (lowbush blueberry)	13 days
	Scouting, hand weeding, hand pruning, bird control (Saskatoon berry), frost control (Saskatoon berry)	7 days
	Mechanical harvesting	3 days
	All other activities	24 hours
Succulent Peas	Succulent Peas Hand set irrigation	
	Harvesting	7 days
	All other activities	24 hours
Cucumbers	Hand set irrigation	15 days
	Harvesting, training	7 days
	All other activities	24 hours
Cucurbit	Hand set irrigation	20 days
Vegetables Crop Group (except	Hand harvesting, mechanically-assisted harvesting, training	9 days
cucumbers)	Mechanical harvesting	7 days
	All other activities	24 hours
Tomatoes	Hand set irrigation	17 days
	Hand harvesting, mechanically assisted harvesting, tying/training	6 days

Table of Restricted-entry interval and/or Pre-harvest interval (PHI) by crop and postapplication activity

Сгор	Postapplication activity	Restricted-entry interval (REI) and/or Pre-harvest interval (PHI)
	Mechanical harvesting	3 days
	All other activities	24 hours
Fruiting	Hand set irrigation	11 days
Vegetables Crop	Hand harvesting, mechanically assisted	7 days
Group (except	harvesting, tying/training	
tomatoes)	Mechanical harvesting	3 days
	All other activities	24 hours
Pome and Stone	Thinning	23 days
Fruit Crop	Hand harvesting, mechanically assisted	16 days
Groups	harvesting	
	Mechanical harvesting of pome fruit	14 days
	Scouting, hand pruning	7 days
	Mechanical harvesting of stone fruit	3 days
	All other activities	24 hours
Tree Nuts Crop	Scouting, hand pruning	7 days
Group	Mechanical harvesting	3 days
	All other activities	24 hours

Environment

With the following risk reduction measures on the label, the risks are considered acceptable:

- Environmental hazard statements for bees, beneficial insects, birds, mammals, plants and aquatic organisms;
- Spray buffer zones to protect non-target aquatic and terrestrial habitats;
- Application restriction during bloom for bee-attractive crops;
- A mandatory vegetative filter strip between the treatment area and the edge of a water body to reduce run-off.

Next Steps

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

Other Information

When the Health Canada makes its registration decision, it will publish a Registration Decision on fenpropathrin and Danitol EC Spray (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

Fenpropathrin and Danitol EC Spray

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Ac	tive substance	Fenpropathrin			
Fu	nction	Insecticide			
Ch	emical name				
1.		(<i>RS</i>)-α-cyano-3-phenoxybenzyl 2,2,3,3- tetramethylcyclopropanecarboxylate			
2.	Chemical Abstracts Service (CAS)	cyano(3-phenoxyphenyl)methyl 2,2,3,3- tetramethylcyclopropanecarboxylate			
CA	AS number	39515-41-8			
Mo	olecular formula	C ₂₂ H ₂₃ NO ₃			
Me	olecular weight	349.42			
Sti	ructural formula				

Purity of the active 92.0% ingredient

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

Property Result				
Colour and physical state	Yellow to solid			
Odour	Faint characteristic odour			
Melting range	45–50 °C			
Boiling point or range	377 °C			
Density (at 20 °C)	1.103 g/mL			
Vapour pressure at 20 °C	0.730 mPa			
Ultraviolet (UV)-visible spectrum	<u>pH</u> $\lambda_{\max}(nm)$			
	neutral 277.6 acidic 277.6 basic 307.6			
Solubility in water at 25 °C	10.3 µg/L			
Solubility in organic solvents at 20 °C	SolventSolubility (g/L)cyclohexanone950Xylene860Methanol267			
<i>n</i> -Octanol-water partition coefficient (K_o)	$\log K_{\rm ow} = 6.0$			
Dissociation constant (p <i>K</i> _a)	Does not dissociate in environmental pH range			
Stability (temperature, metal)	Stable to light at $\lambda > 350$ nm. Stable to heat (40 °C and 60 °C) for at least one year.			

End-Use Product—Danitol EC Spray

Property	Result
Colour	Clear amber
Odour	Hydrocarbon odour
Physical state	Liquid
Formulation type	Emulsifiable concentrate
Guarantee	30.9%
Container material and description	fluorinated high density polyethylene (HDPE),
	plastic bottles or totes, 1 L to bulk
Density	0.962 g/mL at 20 °C
pH of 1% dispersion in water	5.2
Oxidizing or reducing action	Product does not contain oxidizing or reducing agents.

Property	Result
Storage stability	The product's active content is stable when stored in commercial containers (fluorinated HDPE bottles) for 1 year at ambient temperature.
Corrosion characteristics	Not corrosive to commercial packaging material over 1 year at ambient temperature.
Explodability	This product is not potentially explosive.

1.3 Directions for Use

Danitol EC Spray can be applied by ground as a foliar application to various vegetable, berry, tree fruit and tree nut crops. Application rates are 224–448 g a.i./ha and varies for pest/crop group combination. Listed crops are caneberries (Crop Subgroup 13-07A), bushberries (Crop Subgroup 13-07B), fruiting vegetables (Crop Group 8-09), cucurbit vegetables (Crop Group 9), succulent shelled pea (includes English pea, garden pea, green pea), pome fruit (Crop Group 11-09), stone fruit (Crop Group 12-09) and tree nuts (Crop Group 14-11). One application per year is allowed for the majority of crops with a maximum seasonal application rate of 224 or 448 g a.i./ha per year. Repeat applications may be made to a few specific crops if monitoring indicates it is necessary with intervals varying from 7 to 14 days depending on crop group.

1.4 Mode of Action

Fenpropathrin belongs to the pyrethroid class (IRAC mode of action Group 3) of insecticides. It is a broad-spectrum insecticide/miticide, which controls pests from many different orders and families of insects in the listed crops. Fenpropathrin works by contact and ingestion and modulates the sodium channels in nerves resulting in paralysis and death of the pest.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided 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.

2.3 Methods for Residue Analysis

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) and Gas chromatography method with mass spectroscopy and (GC/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media.

The gas chromatography method RM 22-4 for plant matrices using either electron capture detection (GC-ECD), nitrogen phosphorous detection (GC-NPD) or mass spectrometric detection with selected ion monitoring (GC-MS/SIM) was developed for data generation and enforcement purposes. The method fulfilled the requirements with regards to specificity, accuracy and precision at the method limits of quantitation (0.01 to 0.05 ppm). Acceptable recoveries (70–120%) were obtained in plant matrices when fortified at 0.01 ppm to 10 ppm. The method was tested through FDA (*Food and Drugs Act*) multi-residue methods, and fenpropathrin was completely recovered. Hence the method were similar to those used in the metabolism studies; thus, further demonstration of extraction efficiency with radiolabelled crops was not required for the enforcement method. Methods for residue analysis are summarized in Appendix I, Tables 1a and b.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Fenpropathrin, as with other synthetic pyrethroid insecticides, 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 the neuron; this interferes with the ability of the nervous system to relay nerve transmissions and results in downstream clinical effects. Affected neuronal action potentials result in repetitive activity (Type I pyrethroids) or blockage of nerve conduction (Type II pyrethroids). Type II pyrethroids are chemically classified as those with a cyano group on the alpha carbon, while Type I pyrethroids lack this functional group. Pyrethroids induce one of three different neurotoxicity syndromes. The "T syndrome" is generally induced by Type I pyrethroids and is characterized by aggressive sparring, increased sensitivity and fine whole body tremor. The "CS syndrome," generally produced by Type II pyrethroids, is characterized by initial pawing and burrowing, salivation and choreoathetosis (involuntary excessive movements progressing to sinuous writhing). Finally, a mixed Type I/Type II neurotoxic syndrome may be observed. Fenpropathrin, a pyrethroid with an alpha-carbon cyano group, is a Type II pyrethroid which produces a mixed neurotoxic syndrome.

A detailed review of the toxicological database for fenpropathrin was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The human health risk assessment also considered information found in the published literature. The scientific quality of the data is high and the database is considered adequate to characterize the potential health hazards associated with fenpropathrin.

The results from the majority of the toxicological studies conducted with fenpropathrin are summarized in the <u>Evaluation Report for application number 2008-1306</u>, prepared for the establishment of import maximum residue limits (MRLs). The previous evaluation for the establishment of import MRLs focused on toxicity studies conducted via the oral route.

Additional information available for the current evaluation that was not considered in the previous evaluation included additional acute toxicity studies, a 90-day dietary toxicity study in dogs, 28-day dietary immunotoxicity studies in rats (one dose range-finding study and one main study), repeat-dose dermal toxicity studies in rats and rabbits, and a request to waive the requirement for a repeated exposure inhalation toxicity study.

A summary of the principal findings noted in oral toxicity studies conducted with fenpropathrin follows, as well as more detailed information relating to studies conducted via other routes of exposure (for example, dermal and inhalation) that were not discussed in the previous Evaluation Report. Findings in certain studies were also reassessed as part of this evaluation, and toxicological reference values have been updated from those outlined in the previous Evaluation Report.

In acute toxicity testing in rats, fenpropathrin was demonstrated to be of high toxicity via the oral route, of moderate toxicity via the dermal route, and of slight toxicity via the inhalation route. It was also of high acute toxicity to mice via the oral route. Fenpropathrin was non-irritating to the eyes and slightly irritating to the skin of rabbits, and was not a potential skin sensitizer when tested in guinea pigs using the Buehler method.

In acute toxicity testing, the end-use product, Danitol EC Spray, was of high toxicity in rats via the oral route of exposure. It was of low acute toxicity via the dermal route to rabbits and via the inhalation route to mice and rats. Danitol EC Spray was severely irritating to the eyes and moderately irritating to the skin of rabbits and was a potential dermal sensitizer when tested in guinea pigs using the Landsteiner method.

Following repeated dermal exposure to fenpropathrin, there were no systemic effects noted in either sex of rats or rabbits. The requirement for a repeat-dose inhalation toxicity study was waived since it was shown that: 1) on the basis of acute toxicity studies, toxicity to fenpropathrin via the inhalation route does not result in higher toxicity than via the oral route, 2) systemic effects for pyrethroids in general (particularly with respect to respiratory pathology) typically occur at higher dose levels than those inducing neurotoxicity, and 3) margins of exposure exceeded 1000 for all inhalation exposure scenarios when using a toxicological reference value from an oral study.

In repeat-dose dietary toxicity studies with adult mice, rats, and dogs, signs of neurotoxicity were noted in all species. In the newly available 90-day dietary toxicity study in dogs, in addition to signs of neurotoxicity, increased incidences of soft/mucoid stools, diarrhea and emesis were noted at the lowest dose tested. At high dose levels of fenpropathrin, increased mortality was also noted in all species, but there was no evidence of neuropathology. There was no evidence of dysregulation of the immune system in the newly available 28-day dietary immunotoxicity studies in rats, either in a dose range-finding study or in the main study.

Overall, it was concluded that there was no evidence of genotoxicity for fenpropathrin. There was no evidence of oncogenicity in mice exposed to fenpropathrin via the diet for 18 months or in rats exposed via the diet for two years.

In oral gavage developmental toxicity testing, there was no evidence of increased sensitivity of the young in rats or rabbits. In the previous evaluation, the maternal NOAEL in the developmental toxicity study in the rat was based on decreases in body weight gain and food consumption in maternal animals. However, upon re-examination of this study, it was noted that there was no impact of these findings on the overall body weight of the animals; therefore, the decreased body weight gain and food consumption were not considered adverse in the current evaluation. In addition, the effects on fetal ossification in the rat, which previously formed the basis of the developmental NOAEL, were similarly elevated across all dose levels with no dose-response trend and were, therefore, not considered to be related to treatment. Consequently, the NOAELs and LOAELs in the rat developmental toxicity study have been modified from the previous evaluation, as summarized in Appendix I, Table 2 of this document. In the dietary 2-generation reproductive toxicity study in rats, body tremors, mortality, and decreased testes weight were observed in the offspring in the presence of maternal toxicity (reduced body weight, tremors, and mortality). There was no evidence of teratogenicity or reproductive toxicity.

In acute oral gavage neurotoxicity studies in rats, neurotoxic effects were observed on the day of dosing. In an acute neurotoxicity study published in the peer-reviewed literature and conducted in male rats (PMRA# 2007554), motor activity (the only behavioural parameter assessed) was decreased at dose levels comparable to those producing neurotoxicity in the guideline acute neurotoxicity study. An updated analysis was conducted on the results of the published study to obtain a benchmark dose level, the results of which are summarized in Appendix I, Table 3 of this document.

A dietary developmental neurotoxicity (DNT) study assessed potential effects on the developing nervous system following in utero and early postnatal exposure. A dietary range-finding DNT study was also conducted to evaluate the lactational and placental transfer potential of fenpropathrin. It was determined that fenpropathrin can be transferred to offspring via the placenta and maternal milk, but the DNT studies did not identify any sensitivity of the young. Studies from the published literature indicate that pharmacodynamic and pharmacokinetic factors, notably age-dependent maturation of key metabolic processes, may lead to increased sensitivity of the young to pyrethroid toxicity. Young animals have incomplete maturation of the enzyme systems that detoxify pyrethroids, particularly the carboxylesterases and cytochrome P450 enzyme families. Consequently, pyrethroid concentrations in target tissues may be higher in young animals than in adults given the same dose level. In general, pyrethroid neurotoxicity is correlated with peak plasma concentrations of the compound, and gavage dosing results in greater internal doses compared to dietary administration. The pyrethroids are regarded as having a narrow window of time-to-peak-effect. The design of a developmental neurotoxicity study does not consider time-to-peak-effect and may therefore miss the window of peak toxicity for the pyrethroids resulting in residual uncertainty regarding sensitivity of the young.

Recently, the results of work undertaken by the Council for Advancement of Pyrethroid Human Risk Assessment (CAPHRA) to address potential sensitivity of the young were submitted to the PMRA. The CAPHRA data may have implications on the entire class of pyrethroids, and consequently these data are being addressed separately from assessments for individual pyrethroids. Until these data are evaluated, residual uncertainty regarding sensitivity of the young is reflected in the form of a database uncertainty factor. Results of the previously evaluated toxicology studies conducted on laboratory animals with fenpropathrin are summarized in Appendix I, Table 1 of the Evaluation Report for application number 2008-1306. Results of additional toxicology studies, submitted or re-assessed subsequent to the 2008 evaluation, are summarized in Appendix I, Table 3 of this document. Appendix I, Table 2 of this document summarizes the results of the acute toxicity studies for the associated end-use product, Danitol EC Spray. The toxicological reference values for use in the human health risk assessment are summarized in Appendix I, Table 4.

Health Incident Reports

As of 29 January 2019, no human or domestic animal incident reports involving fenpropathrin have been submitted to the PMRA.

3.1.1 Pest Control Products Act Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for fenpropathrin. The database contains the full complement of required studies including oral gavage developmental toxicity studies in rats and rabbits, and a dietary 2-generation reproductive toxicity study in rats. In addition, a dietary DNT study in rats and a pilot dietary DNT study that examined the placental and lactational transfer of fenpropathrin to rat pups were also available.

With respect to concerns relevant to the assessment of risk to infants and children, there was no evidence of increased sensitivity of the young from in utero exposure to fenpropathrin in oral developmental toxicity studies in rats or rabbits. There was no indication of increased sensitivity in the offspring compared to parental animals in the reproduction study or the guideline DNT study.

Young animals have incomplete maturation of enzyme systems which detoxify pyrethroids and thus may be more susceptible to their effects due to higher and prolonged brain concentrations, compared to adults (PMRA# 2007551). The database lacks additional information to fully characterize the potential for juvenile sensitivity to the neurotoxic effects of fenpropathrin. Thus, an adequate assessment of sensitivity of the young is currently not available, and residual uncertainty remains concerning sensitivity of the young to potential neurotoxic effects of fenpropathrin. Recently, the results of work undertaken by the CAPHRA to address potential sensitivity of the young were submitted to the PMRA. Until these data are evaluated, this residual uncertainty is reflected in the form of a database uncertainty factor of threefold in the risk assessment. Since these concerns were addressed with a database uncertainty factor, the *Pest Control Products Act* factor (PCPA factor) was reduced to onefold.

3.2 Acute Reference Dose

To estimate acute dietary risk, the BMDL₂₀ of 5.3 mg/kg bw from a published non-guideline acute neurotoxicity study was selected, based on decreased motor activity data in adult rats. Reduced motor activity was considered the critical endpoint since it is a sensitive neurobehavioral endpoint relevant to pyrethroid toxicity and was the result of a single exposure conducted by a relevant route and is, therefore, relevant to an acute risk assessment. The BMDL₂₀ was specifically selected based on the reported variability of motor activity in control rats in the literature (PMRA# 2351167). Since there is concern that the critical endpoint in adults may not be adequate for assessment of the young, a threefold database uncertainty factor was applied for risk assessment purposes. As discussed in the *Pest Control Products Act* Hazard Characterization (Section 3.1.1), the PCPA factor was reduced to onefold. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were also applied. The composite assessment factor (CAF) is thus 300.

The acute reference dose (ARfD) is calculated according to the following formula:

$$ARfD = \frac{BMDL_{20}}{CAF} = \frac{5.3 \text{ mg/kg bw}}{300} = 0.02 \text{ mg/kg bw of fenpropathrin}$$

3.3 Acceptable Daily Intake

To estimate risk following repeated dietary exposure, the acceptable daily intake (ADI) was determined on the basis of findings from two co-critical studies: the NOAEL of 3.1 mg/kg bw/day in female parental rats and offspring from the dietary 2-generation reproductive toxicity study and the NOAEL of 3.1 mg/kg bw/day in the 12-month dietary toxicity study in dogs. Neurotoxic effects were noted at the LOAEL in each study, and these studies represented the lowest NOAELs in the database following extended exposure. In female parental rats and offspring, body tremors and mortality were noted at the LOAEL of 9.1 mg/kg bw/day. In dogs, tremors were noted in both sexes, and decreased body weight gain, as well as increased glucose and serum creatinine were noted in females at the LOAEL of 8.1/7.7 mg/kg bw/day. Residual uncertainty regarding potential sensitivity of the young was addressed via the application of a 3-fold database uncertainty factor. As discussed in the *Pest Control Products Act* Hazard Characterization (Section 3.1.1), the PCPA factor was reduced to onefold. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were also applied. The CAF is thus 300.

The ADI is calculated according to the following formula:

 $ADI = \frac{NOAEL}{CAF} = \frac{3.1 \text{ mg/kg bw/day}}{300} = 0.01 \text{ mg/kg bw/day of fenpropathrin}$

Cancer Assessment

There was no evidence of oncogenicity and, therefore, no cancer risk assessment is necessary.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Reference Values

Exposure to fenpropathrin is expected to be mainly via the dermal and inhalation routes for chemical handlers and through the dermal route for postapplication workers. Exposure is expected to be short- to intermediate-term in duration since the product can be applied up to four times during the growing season by farmers and over 30 days per season by custom applicators.

Short-, Intermediate- and Long-Term Dermal

For short-, intermediate-, and long-term occupational exposures via the dermal route, the NOAEL of 3.1 mg/kg bw/day in offspring from the dietary 2-generation reproductive toxicity study was selected for risk assessment. Neurotoxic effects were noted at the LOAEL and this study represented the lowest NOAEL in the database following extended exposure. In offspring, body tremors and mortality were noted at the LOAEL of 9.1 mg/kg bw/day in the presence of similar maternal toxicity findings consisting of tremors and mortality. In the reproductive toxicity study, effects were observed in offspring from the second generation that were not observed in the first generation. The available short-term dermal toxicity study for risk assessment.

The target margin of exposure (MOE) for these scenarios is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability as well as a threefold database uncertainty factor to address the residual uncertainty regarding potential sensitivity of the young. The selection of this study and target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Short-, Intermediate- and Long-Term Inhalation

For short-, intermediate-, and long-term occupational exposures via the inhalation route, the points of departure from two co-critical studies were selected for risk assessment: the NOAEL of 3.1 mg/kg bw/day in female parental rats and offspring from the dietary 2-generation reproductive toxicity study in rats and the NOAEL of 3.1 mg/kg bw/day in the 12-month dietary toxicity study in dogs. Neurotoxic effects were noted at the LOAEL in each study, and these studies represented the lowest NOAELs in the database following extended exposure. In female parental rats and offspring, body tremors and mortality were noted at the LOAEL of 9.1 mg/kg bw/day. In dogs, tremors were noted in both sexes, and decreased body weight gain, as well as increased glucose and serum creatinine, were noted in females at the LOAEL of 8.1/7.7 mg/kg bw/day. A repeat-exposure inhalation toxicity study was not available, thus necessitating the use of an oral study for risk assessment. These studies were determined to be appropriate for all durations of exposure since effects on the most sensitive endpoint (neurotoxicity) were evident at the LOAELs and there was no pronounced evidence of increased toxicity following increased duration of dosing.

The target MOE for these scenarios is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability as well as a threefold database uncertainty factor to address the residual uncertainty regarding potential sensitivity of the young. The selection of these studies and target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation). For fenpropathrin, the aggregate assessment consisted of combining food and water exposure only, since residential exposure is not expected. The most relevant toxicological endpoints and assessment factors for acute and chronic oral aggregate exposure are the same as those selected for the ARfD (see Section 3.2) and ADI (See section 3.3), respectively.

Cumulative Assessment

The *Pest Control Products Act* requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Fenpropathrin belongs to a group of chemicals classified as pyrethroids. Pyrethroids and pyrethrins have a common mechanism of toxicity wherein they possess the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. Upon completion of the re-evaluation of the individual chemicals in the pyrethroid group, cumulative risk will be assessed as a separate exercise, incorporating all relevant members of the common mechanism group(s).

3.4.1.1 Dermal Absorption

A rat in vivo dermal absorption study was reviewed and considered to be acceptable. Based on the data presented in the study, a dermal absorption value of 33% was selected for the risk assessment of fenpropathrin.

The extent of absorption of radioactivity following dermal application of ¹⁴C-fenpropathrin at three different dose levels to rats in an emulsifiable concentrate (EC) formulation were investigated in an in vivo dermal absorption study in rats. A single dose of ¹⁴C-fenpropathrin (\geq 99% radiochemical purity) was applied to male Sprague-Dawley rats at three dose levels. The high dose (300 mg/L) was equivalent to the Danitol EC Spray formulation, and the lower doses (15 mg/L and 0.3 mg/L) were equivalent to the application rate of the product. The animals were exposed to the test material between 0.5 and 24 hours after which time the animals were terminated and samples collected. As sacrifice time coincided with exposure duration (skin wash occurred at termination), the fate of the skin-bound residues could not be monitored. The exposed skin was not tape-stripped; therefore, chemical deposition within the skin was not determined.

The radioactivity in all matrices was analyzed by liquid scintillation counting. Dermal absorption values included the percent dose absorbed and the amount found in the skin bound residues. The dermal absorption value from the 10 hour-sacrifice was considered to be the most appropriate as this is the exposure duration that is expected in the field. In addition, given the variability in actual deposition under field conditions, it is considered appropriate to derive an estimate of dermal absorption based on the results from the low dose, as a percent dermal absorption was highest at this dose level. Therefore, the dermal absorption value of 33% was chosen as the most appropriate from the low dose group sacrificed at 10 hours. This value includes the skin-bound residues of fenpropathrin at the skin test site and is therefore considered not to underestimate dermal absorption.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mitigation to the Acute Toxicity of the End-use Product Danitol EC Spray

The acute hazard assessment indicated that Danitol EC Spray is severely irritating to the eyes and moderately irritating to the skin of rabbits. Based on these acute hazards, coveralls over a long-sleeved shirt, long pants, socks, chemical-resistant footwear, chemical-resistant gloves and goggles/face shield are required for workers during mixing, loading, application, clean-up and repair. In addition, chemical-resistant headgear is required during open-cab airblast application.

3.4.2.2 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to fenpropathrin during mixing, loading, application, clean-up and repair. Dermal and inhalation exposure estimates for workers completing these tasks were generated from the Agricultural Handlers Exposure Task Force (AHETF) database, Pesticide Handlers Exposure Database (PHED, v1.1) and Non-Dietary Exposure Task Force (Appendix I, Table 5).

Exposure to workers mixing, loading and applying Danitol EC Spray is expected to be of shortto intermediate-term duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixer/loaders/applicators applying Danitol EC Spray to bushberries, caneberries, cucurbit vegetables, fruiting vegetables, succulent shelled peas, pome fruits, stone fruits and tree nuts using groundboom, airblast and handheld equipment. The PPE in the risk assessment is based on handlers wearing a long-sleeved shirt, long pants, chemicalresistant gloves, and socks. Additionally, workers applying Danitol EC Spray with open-cab airblast equipment must wear coveralls, chemical-resistant footwear and chemical-resistant gloves over long-sleeved shirt, long pants, plus chemical-resistant headgear. When applying more than 39 L of Danitol EC Spray per day, open-cab airblast workers must wear chemicalresistant coveralls.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value. 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.

The combined dermal and inhalation exposure estimates were compared to the toxicological reference value to obtain the margin of exposure (MOE); all MOEs are equal or greater than 300 (target MOE of 300). Therefore there is no health risks of concern for workers handling fenpropathrin (Appendix I, Table 6).

3.4.2.3 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers entering areas treated with fenpropathrin to complete tasks such as setting irrigation lines, hand harvesting, scouting, transplanting, hand weeding and thinning. Given the nature of activities performed, dermal contact with treated surfaces should be primarily via the dermal route based on dermal contact with treated foliage. Inhalation exposure is expected to be negligible as fenpropathrin is considered non-volatile with a vapour pressure of 2.15×10^{-9} kPa (at 25 °C), which is less than the North American Free Trade Agreement (NAFTA) criteria for a non-volatile product for outdoor scenarios $[1 \times 10^{-4}$ kPa (7.5 × 10-4 mmHg) at 20–30° C]. The duration of exposure is considered to be short- to intermediate-term.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. Activity transfer coefficients are based on data from the Agricultural Reentry Task Force (ARTF). Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue value of 25% of the application rate coupled with 10% daily dissipation of residues were used in the exposure assessment was used in the exposure assessment.

For the postapplication risk assessment, exposure estimates were compared to the toxicological reference value to obtain the MOE; all MOEs are equal or greater than the target MOE of 300. Therefore, there is no health risks of concern for workers entering treated fields. (Appendix I, Table 7).

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Danitol EC Spray is not a domestic class product; therefore, a residential assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

3.4.3.2.1 Pick-Your-Own (PYO) Activities

Given that fruits and berries can be treated with fenpropathrin, there is potential for exposure to fenpropathrin from pick-your-own activities. The postapplication occupational risk assessment is protective of the risk associated with dermal exposure to this scenario.

3.4.3.2.2 Trees Treated with Danitol EC Spray in Residential Areas

Commercial applicators may not apply Danitol EC Spray to orchard trees in residential areas since Danitol EC Spray is not permitted for use in residential areas. Therefore, a postapplication exposure assessment for residential orchard trees was not required.

3.4.4 Bystander Exposure and Risk

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

3.5 Aggregate Exposure and Risk

There is potential for individuals to be exposed to fenpropathrin via different routes and sources of exposure concurrently. As such, the following scenario was considered.

3.5.1 Pick-Your-Own (PYO) Scenario

Given that fruit and nut trees and berries can be treated with fenpropathrin, there is potential for aggregate exposure during pick-your-own activities. Since the acute dietary (food and drinking water) and short-term toxicological reference values are based on different toxicological endpoints/effects, no aggregation of dermal and dietary exposure is required.

3.6 Exposure From Drinking Water

3.6.1 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) in potential drinking water sources were calculated for both groundwater and surface water.

For drinking water, fenpropathrin (FDK) was modelled as a combined residue with the transformation products decarboxy-fenpropathrin (dFDK) and tetramethylcyclopropane carboxamide (TMPe) (Table 3.6.1.1).

Estimated environmental concentrations in water for the combined residues were calculated for use in human health risk assessments using the Pesticide Water Calculator (PWC, version 1.52).

For surface water, PWC calculates the amount of pesticide entering the water body by run-off and drift, and the subsequent degradation of the pesticide in the water system. EECs are calculated by modelling a total land application area of 173 ha draining into a 5.3 ha reservoir with a depth of 2.7 m. Groundwater EECs are calculated by simulating leaching through a layered soil profile and reporting the average concentration in the top 1 m of a water table that is 2 to 5 m deep. Level 1 EECs for surface water were calculated based on a single standard scenario. Level 1 EECs in groundwater were calculated for several scenarios representing different regions of Canada; only the highest EECs from across these scenarios are reported. All drinking water scenarios were run for 50 years. Level 1 EECs are reported in Tables 3.6.1-2, below.

Fate Parameter	Drinking Water	Ecological Water
$K_{\rm oc}$ (L/kg)	Combined FDK ¹ and dFDK ² : 132 000 TMPe ³ : 48	FDK: 132 000
Water half-life (days at 20 °C) (or whole system aerobic aquatic half-life)	Combined FDK and dFDK: 197 TMPe: stable	FDK:197
Sediment half-life (days at 20 °C) (or anaerobic half-life)	Combined FDK and dFDK: 252 and TMPe: stable	FDK: 252
Photolysis half-life (days at 40° latitude)	Combined FDK and dFDK: 1.11 TMPe: stable	FDK: 1.1
Hydrolysis (days)	Combined FDK and dFDK: stable TMPe: stable	FDK: stable
Soil half-life (days at 20 °C)	Combined FDK and dFDK: 701 TMPe: stable	FDK: 701

 Table 3.6.1.1 Major fate inputs for drinking water modelling

¹FDK - fenpropathrin; ²dFDK - decarboxy-fenpropathrin; ³TMPe - tetramethylcyclopropane carboxamide.

Table 3.6.1.2 Level 1 Estimated environmental concentrations of fenpropathrin and its
transformation products decarboxy-fenpropathrin and
tetramethylcyclopropane carboxamide in potential sources of drinking water
as the parent equivalent.

Use Pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily ¹	Yearly ²	Daily ³	Yearly ⁴
2 applications of 448 g a.i./ha at a 7-day interval	< 0.01	< 0.01	7.0	0.65

¹ 90th percentile of daily average concentrations

² 90th percentile of 365-day moving average concentrations

³ 90th percentile of the peak concentrations from each year

⁴ 90th percentile of yearly average concentration

3.7 Food Residues Exposure Assessment

3.7.1 Residues in Plant and Animal Foodstuffs

Animal studies were not considered, as the petitioned crops are not fed to animals. The residue definition for risk assessment and enforcement in plant products is parent fenpropathrin. The enforcement analytical method is valid for the quantitation of fenpropathrin residues in crop matrices. The residues of fenpropathrin are stable in diverse crops for 12 months when stored in a freezer at <-20 °C. Therefore, fenpropathrin residues are considered stable in the petitioned frozen crop matrices and processed crop fractions for this duration. The raw agricultural

commodities of apples, plums and tomatoes were processed, and fenpropathrin residues concentrated in dried plums $(2.6\times)$. Crop field trials conducted throughout the United States using an end-use product containing fenpropathrin at either approved or exaggerated rates in or on succulent shelled peas and various crop groups (CG 8-09, CG 9, CG 11-09, CG 12-09, CSG 13-07 A and B, and CG 14-11) are sufficient to support the maximum residue limits.

3.7.2 Dietary Risk Assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCIDTM).

3.7.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the intermediate chronic analysis for fenpropathrin: Default and experimental processing factors were used when available; Canadian CFIA and American PDP monitoring data were used for almost all commodities; American residue data on file were used for the determination of supervised trial median residues (STMdR) residues for currants, almonds, pecans, peanuts and undelinted cottonseed; residue data from trials in India were used for the determination of the STMdR for tea (green and black); the mean residues from monitoring or STMdR values were extended from representative commodities within a crop group to other commodities within the same crop group.

The intermediate chronic dietary exposure from all supported fenpropathrin food uses for the representative population subgroups ranged from 0.5-2.9% of the ADI. The refined aggregate exposure from food and drinking water (EEC value = $0.65 \mu g a.i./L$, Level 2, surface water) is not of health concern. Specifically a range from 0.7-3.0% of the ADI was obtained for all population subgroups.

3.7.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the refined acute analysis for fenpropathrin: Default and experimental processing factors were used when available; Canadian CFIA and American PDP monitoring data were used for almost all commodities; American residue data on file were used for the determination of highest average field trial (HAFT) residues for currants, almonds, pecans, peanuts and undelinted cottonseed; residue data from trials in India were used for the determination of HAFT residues for tea (green and black); the maximum residues from monitoring or HAFT residues were extended from representative commodities within a crop group to other commodities within the same crop group.

The refined acute dietary exposure for all supported fenpropathrin registered and imported commodities was estimated to be 12–57% of the ARfD for the general population (95th percentile, deterministic) and all population subgroups. The refined aggregate exposure from food and drinking water (EEC value = $7.0 \ \mu g a.i./L$, Level 2, surface water) is not of health concern. Specifically 13–58% of the ARfD was obtained for the general population and all population subgroups.

3.7.3 Aggregate Exposure and Risk

The aggregate risk for fenpropathrin consists of exposure from food and drinking water sources only; there are no residential uses.

3.7.4 Maximum Residue Limits

Maximum residue limits (MRLs) for the petitioned crops have already been established in accordance with the <u>Residue Chemistry Crop Groups</u> webpage in the Pesticides section of the Canada.ca website. The following revised MRL is proposed for tree nuts:

Commodity	Proposed MRL (ppm)
Tree Nuts (CG 14-11)	0.15

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

The nature of the residues in plant matrices, analytical methodologies, field trial data, and acute and chronic dietary risk estimates are summarized in Appendix I, Tables 1b, 8 and 9.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Based on its physicochemical properties, fenpropathrin is insoluble in water (0.0141 mg/L at 20– 25 °C). It has a low vapour pressure (0.730 mPa at 20 °C), but a Henry's law constant of 1.785×10^{-4} atm m³/mol indicates that fenpropathrin may volatilize from wet soil or aqueous solution. Hydrolysis is not an important route of dissipation of fenpropathrin under acidic and neutral conditions. However, under alkaline conditions (for example, a marine environment), fenpropathrin is expected to undergo rapid hydrolysis to form four major transformation products including the amide analog of fenpropathrin (CONH₂-fenpropathrin), tetramethyl-1cyclopropane carboxylic acid (TMPA), tetramethylcyclopropane carboxamide (TMPe), and 3phenoxybenzoic acid (3-PBA). Fenpropathrin will also undergo rapid phototransformation in clear shallow water to form three major transformation products TMPA, 3-PBA and decarboxyfenpropathrin (dFDK) (Single First Order DT₅₀ = 16 h). Minor phototransformation products included 4'-OH-fenpropathrin, CONH₂-fenpropathrin, 3-phenoxybenzaldehyde (3-PBAld), desphenyl-fenpropathrin, COOH-fenpropathrin and CO₂.

In the terrestrial environment, fenpropathrin is expected to be slightly persistent to persistent in aerobic soil. Under laboratory conditions, aerobic soil DT_{50} values range from 37 to 274 days. The majority of fenpropathrin mineralizes to CO_2 (up to 59.9%) and non-extractable residues. Only one major transformation product, 3-PBA was identified from laboratory aerobic soil biotransformation studies. Minor transformation products included CONH₂-fenpropathrin, desphenyl-fenpropathrin, 4'-OH-fenpropathrin and COOH-fenpropathrin. Under field conditions, fenpropathrin is non-persistent to moderately persistent in soil conditions; DT_{50} values from terrestrial field dissipation studies conducted in the United States (Michigan, Mississippi, New

York, Washington, and California) range from 7 to 76 days. Under anaerobic soil conditions, fenpropathrin is expected to be moderately persistent to persistent ($DT_{50} = 66-192$ days). Compared to aerobic soil conditions, the mineralization in soil is 10.6% and the accumulation of non-extractable residues is minor. Tetramethyl-1-cyclopropane carboxylic acid, 3-PBA and CO₂ were identified as major transformation products from laboratory anaerobic biotransformation studies; minor transformation products included TMPe, 4'-OH-fenpropathrin, CONH₂-fenpropathrin, COOH-fenpropathrin, desphenyl-fenpropathrin and non-extractable residues. Phototransformation on soil is not expected to be a route of transformation.

Fenpropathrin is practically immobile in soil due to its strong adsorption onto soil particles (K_{FOC} = 33 006–247 388 (L/kg-OC)^{-l/n}) and its insolubility in water (0.0141 mg/L at 20–25 °C). When taking into consideration the criteria for determining leaching properties and the groundwater ubiquity score (GUS), it was determined that fenpropathrin is unlikely to leach through soil into groundwater. There was no evidence of residue mobility under field conditions. Fenpropathrin residues including desphenyl-fenpropathrin and CONH₂-fenpropathrin are found within the upper 5–15 cm of soil. Therefore, fenpropathrin residues are not expected to leach into groundwater.

Fenpropathrin can enter aquatic environments through spray drift and run-off from the application site. In aquatic environments, fenpropathrin is expected to be moderately persistent under aerobic aquatic conditions (DT_{50} ranging from 66–76 days) and moderately persistent to persistent under anaerobic aquatic conditions (DT_{50} range = 62–742 days). Major transformation products 3-PBA; TMPA, 4'-OH-fenpropathrin, CO₂ and non-extractable residues were identified from laboratory aerobic and anaerobic aquatic biotransformation studies. Minor transformation products included desphenyl-fenpropathrin, CONH₂-fenpropathrin, COOH-fenpropathrin, dFDK, TMPe and 3-PBAld. Mineralization to CO₂ occured to a similar amount under both aerobic aquatic conditions (up to 12.65%) and under anaerobic aquatic conditions (11.7%). Partitioning of fenpropathrin to sediment was shown to occur prior to transformation.

The log octanol/water partitioning coefficient for fenpropathrin (log $K_{ow} = 6.0$) suggests a potential for bioaccumulation in aquatic organisms. Laboratory derived bioconcentration factors (BCFs) in fish ranged from 200 in muscle tissue to 1400 in viscera of fish. The whole body steady state BCF reached 830 and depuration occurred rapidly (within 3 days), indicating that fenpropathrin is not expected to bioaccumulate.

Fenpropathrin is not expected to undergo long-range transport in the atmosphere. Fenpropathrin is characterized by low volatility, a high octanol/water partition coefficient, and low water solubility. While the calculated Henry's Law Constant suggests fenpropathrin has the potential to volatilize from water or moist soil surfaces, fenpropathrin has a strong sorption capacity and a tendency to bind to organic matter in water, sediment and soil. The EpiSuite v4.11 model indicates volatilization half-lives from a Model River and a Model Lake of 6 and 72 days, respectively, for fenpropathrin, and free fenpropathrin in water may undergo phototransformation with an environmental half-life of ca. 3 days at pH 5. Fenpropathrin is therefore not expected to be readily released into the atmosphere. Once in air, fenpropathrin is expected to undergo atmospheric oxidation with an estimated AOPWIN half-life of 7.2 hours.

Environmental fate data for fenpropathrin and its transformation products, in the terrestrial and aquatic environment, are summarized in Appendix I, Tables 10 and 11.

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 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 (in other words, 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 = 1 for most species, 0.4 for acute risk to pollinators, and 2 for glass plate studies using the standard beneficial arthropod test species, *Typhlodromus pyri* and *Aphidius rhopalosiphi*; LOC = 1 is used for higher tier tests of the standard arthropod test species and for other arthropod test species). If the screening level RQ is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ 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.

4.2.1 Risks to Terrestrial Organisms

A risk assessment for fenpropathrin and its transformation products was conducted for terrestrial organisms. For acute toxicity studies, uncertainty factors of 1/2 of the EC₅₀ (LC₅₀) are typically used in modifying the toxicity values for terrestrial invertebrates and of 1/10 the EC₅₀ (LC₅₀) for birds and mammals when calculating risk quotients. No uncertainty factors are applied to chronic NOEC endpoints. A summary of terrestrial toxicity data is presented in Appendix I, Table 12. Results of the accompanying risk assessment are presented in Appendix I, Tables 13 to 28.

Earthworms

Earthworms can be exposed to fenpropathrin when this compound reaches the soil following spray applications. The expected environmental concentration is therefore calculated based on a direct application of fenpropathrin to bare soil at the maximum cumulative application rate, which takes into account the maximum labelled application rate, the application interval and the dissipation of the compound in soil.

Fenpropathrin was not toxic to earthworms on an acute basis (28-day LC_{50} >400 mg a.i./kg soil), while chronic exposure resulted in a reduction of the reproduction rate at 50 mg a.i./kg soil. At the highest cumulative application rate of 890.6 g a.i./ha (224 + 336 + 336 g a.i./ha with a 7-day interval and 701 days soil half-life), the calculated EEC in soil is 0.396 mg a.i./kg soil. The associated risk quotients for acute (RQ <0.002) and chronic (RQ =0.016) exposures indicate the use of fenpropathrin is expected to pose a negligible acute and chronic risk to earthworms.

Overall conclusion about potential risks to earthworms

The use of fenpropathrin poses acceptable acute and chronic risk to earthworms.

Bees (pollinators)

Tier I risk assessment

Foraging bees could be exposed directly to fenpropathrin spray droplets during application or to fenpropathrin residues found on the surface of leaves (contact exposure). Foraging bees could also be exposed to fenpropathrin through the ingestion of pollen and nectar contaminated from direct spray (oral exposure). In addition, brood may be exposed to fenpropathrin as foraging bees bring contaminated pollen and nectar back to the hive.

In laboratory tests, fenpropathrin was highly toxic to adult honey bees when applied directly on bees, or through diet consumption with oral and contact LD_{50} values of 0.051 and 0.055 µg a.i./bee, respectively. Following chronic oral exposure, adult bee mortality was affected at doses ≥ 0.037 µg a.i./bee/day.

Based on a foliage residue toxicity test which exposed adult honeybees to leaves that were sprayed with the end-use product formulation registered in the United States (Danitol 2.4 EC) at 448 g a.i./ha, the time needed to reduce lethality in bees to 25% was 35 hours (RT_{25} : 35 hours). It is noted that the Danitol 2.4 formulation (guarantees: 31.0% w/w) is similar to the end-use product Danitol EC Spray (guarantee: 30.9 % w/w) being proposed for registration in Canada.

Acute exposure to larvae resulted in an LD_{50s} of 0.16 µg a.i./larvae. When honey bee larvae were exposed to a diet treated with fenpropathrin for 4 days and observed for 22 days, mortality was observed at the three highest doses tested (NOED = 0.28 µg a.i./larvae). From the larval study, the 22-day adult percent emergence NOED and LOED values for fenpropathrin to honey bees were determined to be 0.78 and 1.6 µg a.i./larva, respectively. All risk quotients calculated for fenpropathrin exceeded the LOC of 1.0 (RQ = 3–866).

In a Tier I refined assessment, floral residues obtained from published data were compared to Tier I endpoints for adult and larval bees. Flowering rape fields were sprayed with 60 g a.i./ha fenpropathrin end-use product (which is below the seasonal maximum application rate proposed in Canada). Residue levels of fenpropathrin in flower samples were determined to be 6409, 1646, 412 and 58.7 ppb after 0, 3, 7 and 14 days of treatment, respectively. Based on acute oral and chronic exposures for adult bees, the acute risk is exceeded between day 0 and 7 (RQs declining from 37 to 2.4) and the chronic risk is exceeded during the entire 14-day bloom period (RQs declining from 125 to 1.1). There is also a potential acute and chronic risk identified for larva; however, owing to lower toxicity (in other words, endpoint), the RQ values are only exceeded for the day 0 and/or day 3 residues.

Overall conclusion about potential risks to pollinators

Overall, there is a potential risk to pollinators from foraging on crops treated with fenpropathrin. In order to mitigate this risk, application to be attractive crops will be restricted during the bloom period. With the proposed mitigation, the risks are considered acceptable.

Beneficial arthropods

The risk assessment for beneficial arthropods considers that the main route of exposure for these non-target organisms is from contact with treated plant material both on the treated area (from direct spray on the crop) and at the margins of the treated field (from spray drift). The expected concentration of fenpropathrin residues on foliage within the treated field is calculated as the cumulative application rate, which takes into account the maximum labelled application rate, the application interval, and the dissipation of the compound on the surface of the leaves.

In laboratory tests carried out with freshly dried residues on a glass plate, fenpropathrin caused adverse acute effects on the parasitoid wasp and predatory mite. The 48-h LR₅₀ of Danitol 2.4 EC Spray was 7.57 g a.i./ha in 200 L water/ha for the parasitoid wasp A. *rhopalosiphi*. The 7-day LR₅₀ of Danitol 2.4 EC Spray (similar to the proposed end-use product Danitol EC Spray) was 0.0052 and 7.57 g a.i./ha for the predatory mite *T. pyri*, and parasitic wasp, *A. rhopalosiphi*, respectively. The screeening level risk quotients calculated for both the parasitoid wasp and the predatory mite exceeded the screening level of LOC of 2 from both in-field and off-field exposure (RQs = 5.0 to 83 and RQs >7.1 × 10^3 to >1.1 × 10^5 , respectively).

The refined risk assessment was conducted using results from extended laboratory studies whereby arthropods were exposed to residues sprayed onto leaves. The calculated refined risk quotients exceeded the LOC of 1 from both in-field and off-field exposure (RQ >1.1 × 10³ to >1.9 × 10⁴ for the predatory mite *T. pyri*; and 0.15 to 2.6 for the parasitoid wasp *A. rhopalosiphi*).

The risk to predatory and parasitic arthropods was further characterized by adjusting the amount of exposure off-field by considering a vegetation distribution factor of 0.1 for drift (see Appendix I, Table 15). The refined risk quotients using results from extended laboratory studies did not exceed the LOC of 1 for the parasitoid wasp *A. rhopalosiphi* (RQ = 0.01-0.37).

However, they did exceed for the predatory mite *T. pyri*, following both ground and airblast applications ($RQ = 315-10\ 474$). The mode of toxic action of fenpropathrin as a miticide explains the high sensitivity of the predatory mite *T. pyri* to this compound.

Overall conclusion about potential risks to beneficial arthropods

Overall, there is a potential risk to beneficial arthropods, particularly mites, from exposure to fenpropathrin. A label statement to reduce spray drift to non-target habitats where beneficial arthropods reside is required. With the proposed mitigation, the risks are considered acceptable.

Birds and mammals

For the bird and mammal risk assessment, the ingestion of food items contaminated by spray droplets is considered to be the main route of exposure. The risk assessment is thus based on the estimated daily exposure which takes into account the expected concentration of fenpropathrin on various food items immediately after the last application and the food ingestion rate of different sizes of birds and mammals.

In general, fenpropathrin exhibited low toxicity to zebra finch and the mallard duck on an acute basis (LD_{50} >70 mg a.i./kg bw and 1089 mg a.i./kg bw, respectively). When fenpropathrin was administered in the diet, mortality was observed at the two highest doses tested (2150 and 10 000 mg a.i. /kg diet) in mallard duck and no mortality was observed in the bobwhite quail (LD_{50} >1000 mg a.i./kg bw/day). In reproductive tests, cracked eggs were observed in bobwhite quail at 112.5 and 450 mg a.i./kg dw diet levels. A slight effect upon embryo viability was observed in mallard ducks at 500 mg a.i./kg dw diet level.

Fenpropathrin was moderately toxic to rats on an acute oral basis ($LD_{50} = 67 \text{ mg a.i./kg bw}$). In a two-generation reproductive test, mortality occurred in females. Treatment related reproductive effects at 2.6 mg a.i./kg/bw/day included increased pup loss at birth and decreased pup testes weights.

The risk quotients calculated at the screening level for fenpropathrin exceeded the LOC of 1 on a chronic basis for birds (RQs from 13 to 26), and both acute and chronic basis for mammals (RQs ranged from 4 to 22, with higher potential risk on a chronic basis).

The risk to birds and mammals was further characterized considering feeding guilds, maximum and mean residue levels, and in-field and off-field exposures (Appendix I, Tables 17 and 20), using the mean residue values, the feeding preference item consumption and food items contaminated from spray drift off the treated field. Considering in-field exposure and maximum residues, risk quotients exceeded the level of concern for reproductive effects. When considering mean residues of fenpropathrin in food items, risk quotients exceeded the level of concern for small and medium sized insectivorous birds and mammals (maximum RQs less than 13) and also for large herbivorous birds and mammals (RQs of 2 (acute effects) and 6 (reproductive effects), respectively).

Risks from off-field exposure were investigated assuming 74 and 6% drift from airblast and ground boom sprayer (medium droplet) applications, respectively (Appendix I, Tables 17 and 20). Considering 74% off-field drift, mean residues and no effect endpoints, risk quotients exceeded the level of concern for birds from reproductive effects (RQs ranging from 1 to 9) and mammals (RQs ranging from 1 to 4). No risk was identified to birds or mammals from 6% off-field drift.

Toxicity tests with birds and mammals often have a large range between doses. As such, when considering the no effect level of a study in the risk assessment (No Observed Effect Level or NOEL), the next highest dose causing effects, the Lowest Observable Effects Level (LOEL) may be quite a bit higher. In order to consider the dose at which effects actually occurred, the LOEL was also compared to the EEC. The on-field risk considering mean residue levels was low for birds and mammals (RQs of ≤ 2 for insectivorous birds and for mammals) (Appendix I, Tables 18 and 21). In addition, it is conservative to assume that the diet of birds and mammals will be comprised primarily of contaminated food. Birds and mammals would need to consume a large proportion of their diet, as a single food item (for example, 28–99%), from a field treated at the highest seasonal application rate, to reach the lowest effect endpoint (Appendix I, Tables 19a, 19b, 22a, and 22b). The off-field risk considering the LOEL with 74% drift for birds and mammals was low (RQs ranging from ≤ 2), and no off-field risk was identified for 6% drift (Appendix I, Tables 18 and 21).

Overall conclusion about potential risks to birds and mammals

The overall potential risk to birds and mammals is low given that the risk assessment is conservative (assumes 100% diet is comprised of insects or plants from the treated field) and the RQs are low. As it is unlikely that diet would be composed entirely of insect or plant food items from the treated field, the risk is considered acceptable. Although the risk to birds and mammals is considered acceptable, a label statement is required to inform the user of the potential hazard.

Terrestrial plants

Non-target plants may be exposed to fenpropathrin by direct overspray and spray drift. Based on an EEC equal to the maximum cumulative application rate for the proposed uses (adjusted for dissipation between applications), and the most sensitive ER_{25} for seedling emergence and vegetative vigour (448 and >392 g a.i./ha, respectively, the highest rates tested), the calculated risk quotient exceeded the LOC at the screening level (RQs of <1.6 to 2), indicating that terrestrial plants may be at risk from direct overspray of fenpropathrin.

The risk to terrestrial vascular plants was further characterized by looking at off-field exposure from drift. For an ASAE (American Society of Agricultural Engineers) "medium" droplet size, the maximum spray drift deposition at one meter downwind from the point of application is 6% (ground application), 74% (early season airblast application) and 59% (late season airblast application). Based on the risk quotients using the off-field EECs from drift, the LOC for terrestrial vascular plants was not exceeded for ground or airblast application (RQ = <0.10 to <0.84).

Overall conclusion about potential risks to terrestrial vascular plants

Any potential risks to terrestrial plants are considered acceptable with proposed mitigation measures, including terrestrial buffer zones.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms can be exposed to fenpropathrin and its transformation products through spray drift or run-off into aquatic habitats. A risk assessment for fenpropathrin and its transformation products 4'-OH-fenpropathrin, TMPA, 3-PBA and CONH₂-fenpropathrin was undertaken for freshwater and marine organisms. As invertebrates and fish demonstrate the greatest sensitivity to fenpropathrin compared to its transformation products, the refined risk assessment was based solely on toxicity and exposure to fenpropathrin. A summary of aquatic toxicity data is presented in Appendix I, Table 24. For acute toxicity studies, uncertainty factors of 1/2 of the EC₅₀ (LC₅₀) are typically used for aquatic plants and invertebrates and of 1/10 the EC₅₀ (LC₅₀) fish species when calculating risk quotients (RQs). No uncertainty factors are applied to chronic NOEC endpoints. For groups where the level of concern (LOC) is exceeded (thus, if RQ \geq 1), a refined Tier 1 assessment is conducted to determine risk resulting from spray drift and run-off separately. Screening risk quotients for fenpropathrin and its transformation products were calculated based on the highest maximum seasonal application rate for all uses (ground application of 224 + 336 + 336 g a.i./ha). The accompanying risk assessment is presented in Appendix I, Tables 22 to 28.

Screening Level Assessment

Aquatic invertebrates

Fenpropathrin, the end-use product Danitol EC Spray (as represented in the study by S-3206 2.4LB/G EC, which is a similar formulation), and transformation product 4'-OH-fenpropathrin were very highly toxic to Daphnia. Transformation product 3-PBA was slightly toxic to Daphnia, while TMPA and CONH2-fenpropathrin had no adverse effect to Daphnia at the highest concentrations tested (up to 72 000 µg/L for TMPA). Fenpropathrin and/or the end-use product Danitol 2.4 EC (purity: 31.5% w/w) were very highly toxic on an acute basis to freshwater midge (Chironomus dilutus), freshwater amphipod (Hyalella azteca), marine mysid shrimp (Mysidopsis bahia), and marine amphipod (Leptocheirus plumulosus). The LC₅₀ ranged from 0.00781 to 4.82 µg a.i./L in pore water (amphipods). No adverse effect of fenpropathrin to eastern oyster (Crassostrea virginica) was observed at the highest concentrations tested (up to 1600 µg a.i./L). Based on chronic exposure to freshwater invertebrates, there were effects on survival and reproduction to daphnia at a concentration of 0.35 µg a.i./L. Amphipod survival and chironomid emergence were affected at concentrations of 0.4 and 0.071 µg a.i./L, respectively, when fenpropathrin was applied to sediment (where it is expected to partition in the environment). A 28-day chronic exposure to the marine mysid shrimp resulted in reproductive effects at 0.024 µg a.i./L.

The screening level risk quotients for freshwater invertebrates resulting from acute and chronic exposures to fenpropathrin exceeded the LOC ($RQ = 411-27\ 948$). The risk quotient for marine invertebrates resulting from acute and chronic exposures to fenpropathrin also exceeded the LOC at the screening level ($RQ = 3.5-11\ 473$). The risk quotient for freshwater invertebrates from acute exposure to the transformation product, 4'-OH-fenpropathrin exceeded the LOC at screening level (RQ = 8.4). The acute and chronic risks to aquatic invertebrates were thus further assessed. The risk quotients for freshwater invertebrates from acute exposure to the transformation products, TMPA, CONH₂-fenpropathrin and 3-PBA did not exceed the LOC at the screening level (RQ < 1).

Fish

Fenpropathrin and/or its end-use product were demonstrated to be very highly toxic to rainbow trout (*Oncorhynchus mykiss*), bluegill sunfish (*Lepomis macrochirus*), channel catfish (*Ictalurus punctatus*) and sheepshead minnow (*Cyprinodon variegatus*) on an acute basis. The LC₅₀ ranged from 2.2 μ g a.i/L (rainbow trout and bluegill sunfish) to 21 μ g a.i/L (sheepshead minnows). Following chronic exposure of fathead minnow for 260 days, effects on growth were observed at a concentration of 0.23 μ g a.i/L. The transformation product 3-PBA was slightly toxic to rainbow trout with a LC₅₀ of 14 300 μ g/L.

The risk quotients for freshwater fish resulting from acute and chronic full life cycle exposures to fenpropathrin exceeded the LOC at the screening level (RQ = 494-1197). The risk quotients for marine fish resulting from acute and early-life stage exposures to fenpropathrin also exceeded the LOC at the screening level (RQ = 70-134). The risk quotients for freshwater fish from acute exposure to the transformation product 3-PBA did not exceed the level of concern at the screening level. The acute and chronic risks from exposure of fish to fenpropathrin were thus further assessed.

Amphibians

To assess the risk to amphibians, fish toxicity endpoints are used as surrogate data, when amphibian data are not available, to represent aquatic life-stages of amphibians. The difference between fish and amphibian risk assessments is related to the water depth used for the estimated environmental concentrations (water depth of 15 cm for amphibians).

Using surrogate endpoints from acute study with the bluegill sunfish, and chronic study with fathead minnow, along with EECs for fenpropathrin in a 15 cm deep body of water, the risk quotients for amphibians resulting from acute and chronic exposures to fenpropathrin exceeded the LOC at the screening level (RQ = 2659-6428). The acute and chronic risks to amphibians were thus further assessed.

Freshwater algae and vascular plants

The effects of fenpropathrin were assessed with freshwater green alga (*Pseudokirchneriella subcapitata*), freshwater blue-green alga (*Anabaena flos-aquae*), freshwater diatom (*Navicula pelliculosa*), duckweed (*Lemna gibba*) and marine diatom (*Skeletonema costatum*). The marine

diatom was the most sensitive species with a 96-h IC₅₀ of 62.64 μ g a.i./L (inhibition: area under the curve). The transformation product 3-PBA affected the biomass of freshwater green alga; the 72-hour E_bC₅₀ was calculated to be 33 790 μ g a.i./L.

The screening level risk quotient for freshwater algae resulting from acute exposure to fenpropathrin and its transformation product 3-PBA did not exceed the LOC. The risk quotient for marine algae resulting from acute exposure to fenpropathrin exceeded the LOC at the screening level (RQ = 3.5). The acute risk to marine algae was thus further assessed. The risk quotients for aquatic vascular plants resulting from exposure to fenpropathrin did not exceed the LOC at the SCR at the screening level for the floating monocot, *Lemna gibba* (RQ<1). The use of fenpropathrin poses acceptable risk to aquatic vascular plants.

Spray drift refinement

Similar to the terrestrial risk assessment, the risk to aquatic organisms from spray drift from the treated sites was also assessed by taking into consideration drift deposition of spray quality of ASAE medium droplet size for ground boom (6%) (based on 224 + 336 + 336 g a.i./ha), airblast early season (74%) and airblast late season (59%) (based on 1×448 g a.i./ha) at 1 m downwind from the site of application. Appendix I, Table 27 summarizes the refined drift risk assessment of fenpropathrin to aquatic organisms.

The refined risk quotients considering drift, for freshwater and marine aquatic invertebrates, fish, and amphibians indicate that the LOC from fenpropathrin exposure due to spray drift is exceeded for ground and airblast applications (RQ = 4.2-4358). The refined risk quotients for marine algae indicate that the LOC from exposure to fenpropathrin due to spray drift is not exceeded for ground application, but it is still exceeded for airblast (early and late seasons) application (RQ = 1.1-1.3). To mitigate aquatic life risks associated with spray drift of fenpropathrin from field spray applications, restrictions of wind speed (8 km/hr) along with medium spray quality will be required resulting in spray buffer zones ranging between 1 and 75 m.

Overall conclusion about potential risks from drift to freshwater and marine organisms

Spray buffer zones will be required on the fenpropathrin product label to protect freshwater and marine aquatic organisms from the potential effects of spray drift from the use of fenpropathrin. In addition, restrictions will be placed on wind speed (8 km/h), and medium sprayer quality will be required in order to further reduce potential spray drift. With implementation of these proposed mitigation measures, the risks are considered acceptable.

Runoff Refinement

The screening level risk quotients for amphibian, fish, aquatic invertebrates and algae exposed to fenpropathrin exceeded the LOC. The EEC used for the screening level assumes a direct application to a water body. In order to better characterize the risk, the risk from exposure to run-off into a body of water directly adjacent to the application field was determined using the run-off 90th percentile of the EECs predicted by PRZM-EXAMS. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a

pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body (0.15 m depth) was also used to assess the risk to amphibians, as a potential risk was identified at the screening level.

The risk quotients for exposure to fenpropathrin through run-off are provided in Appendix I, Table 28. The risk quotients were calculated using toxicity endpoints and EECs representing the 90th percentile of 96-hour concentration (acute assessment) and 21-day concentration (chronic assessment). The risk quotients exceeded the LOC for, *Daphnia magna*, *Chironomus dilutus*, *Hyalella azteca*, bluegill sunfish (*Lepomis macrochirus*), fathead minnow (*Pimephales promelas*), amphibian, and marine mysid shrimp (*Mysidopsis bahia*), (freshwater, RQ = 2–67; marine, RQ = 27–67). Aquatic organisms, therefore, may be at risk from fenpropathrin residues in run-off following applications for the different use-patterns across the country. Standard label statements to mitigate runoff into aquatic habitats, as well as mandatory vegetative filter strips, are therefore required on the label for all fenpropathrin end-use products for agricultural uses.

Overall conclusion about potential risks from run-off to freshwater and marine invertebrates and fish, and amphibians

Standard label statements to mitigate run-off will be required on the fenpropathrin label. In addition, based on the fate, persistence and toxicity of fenpropathrin, a mandatory 10 m vegetative filter strip will also be required to protect aquatic organisms from the potential effects of run-off. With implementation of these proposed mitigation measures, the risks are considered acceptable.

Water Monitoring

As fenpropathrin has a long registration history in the United States, a water monitoring assessment was conducted. Danitol 2.4 EC Insecticide is registered in the United States for a variety of agricultural and non-agricultural uses (at the same rate as the proposed Canadian rate, although for more crops).

Available American surface water monitoring data reveals few detections of fenpropathrin in the samples analyzed between 2004 and 2017 (49 out of 7057 samples; <1% detection). Water monitoring data from the United States indicates fenpropathrin is seldom detected in ambient surface water (0.46% of 6298 samples). The highest concentration detected (2.98 μ g/L) was from a sewer waste water influent sample taken in California (2016). As this sample is waste water influent, it is not considered to be relevant to the ecological risk assessment. The second highest concentration (0.0351 μ g/L) is nearly two orders of magnitude lower than the maximum concentrations and was from a sample taken in a ditch in California (2016). The method limit of detection (LOD) for samples varied from 0.00003 μ g/L to 0.4 μ g/L. Many data sources reported a range of LOD values for their dataset, but LOD values for individual samples were not specified. Up to 2072 of the total samples (33%) could have had a LOD higher than the most sensitive aquatic endpoint (>0.019 μ g/L). In the United States, labels require a 10-foot (3 m) wide vegetative filter strip.

Although monitoring data from the United States is a useful indicator of potential concentrations of fenpropathrin in the Canadian environment, the quantitative ecological risk assessment is reliant on values from water modeling.

4.2.3 Environmental 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). Information on the reporting of incidents can be found on the <u>Report a Pesticide Incident</u> page of the Canada.ca website.

As of 29 January 2019, four incidents were reported in the USEPA's Ecological Incident Information System (EIIS). One incident involved fish mortality resulting from run-off after application. The fish kills (200 fish) occurred in a canal adjacent to cotton sites receiving insecticidal applications of Danitol 2.4 EC. Given the concentrations found in soil samples (130– 1300 ppm) and in gill tissues of fish (0.036 ppm and 0.068 ppm), fenpropathrin was considered to be the probable cause of the fish kill. One incident reported the death of an unknown number of honeybees following application of Danitol to an orange orchard. In the two remaining incidents, melons were damaged after they were directly treated with fenpropathrin.

The PMRA concluded that the information from the incident reports is consistent with the known toxicity hazard of fenpropathrin to fish and bees. The proposed label statements including spray buffer zones, mandatory vegetative filter strips, and restriction of application during bloom, are expected to reduce potential exposures to non-target organisms.

5.0 Value

Pest claims were supported by efficacy data plus scientific rationales and use history information. Weight of evidence (including crop and pest grouping principles) supported control of listed pests on listed crops. Extrapolation among pests was possible in many cases because of similarities in pest biology and feeding damage; extrapolation among crops was possible because of similarities in plant architecture and canopy structure.

Fenpropathrin represents a new mode of action for several pests in several crops including:

- caneberries: cherry fruitworm, Japanese beetle, plum curculio;
- bushberries: blueberry maggot, cherry fruitworm, Japanese beetle, plum curculio;
- fruiting vegetables: spotted winged drosophila;
- pome fruits: spotted wing drosophila; and
- tree nuts: European red mite, twospotted spider mite, peach twig borer, obliquebanded leafroller.

Consequently, fenpropathrin may aid in resistance management for these crop/pest combinations. Danitol EC Spray also provides growers with a new active ingredient to use against listed pests, including spotted winged drosophila on fruit crops.

6.0 Pest Control Product Policy Considerations

6.1 Assessment of the Active Ingredient under the Toxic Substances Management Policy

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, that is, 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, fenpropathrin and its transformation products were assessed in accordance with DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that fenpropathrin and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to Appendix I, Table 29 for further information on the TSMP assessment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.⁶ The list is used as described in NOI2005-01⁷ and is based on existing policies and regulations, including the Toxic Substances Management Policy¹ and DIR2006-02⁸, 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 technical grade fenpropathrin and the end-use product Danitol EC Spray do not contain any formulants or contaminants identified in the *List of Pest Control product Formulants and Contaminants of Health or Environmental Concern.*

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

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

⁶ SI/2005-114, last amended on June 25, 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

⁷ 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.*

⁸ PMRA's Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for fenpropathrin is adequate to characterize the potential health hazards associated with fenpropathrin. In short- and long-term oral toxicity studies with adult animals, the target of toxicity was the nervous system. The most sensitive endpoints used for risk assessment were mortality and effects on the nervous system. No systemic toxicity was observed following repeated exposure via the dermal route. There was no evidence of dysregulation of the immune system. Fenpropathrin was not considered to be genotoxic. There was no evidence of oncogenicity in rats or mice after longer-term dosing. Fenpropathrin did not cause birth defects in rats or rabbits, and did not cause any adverse effects on reproduction in rats. There was no evidence of increased sensitivity of the young in reproduction or developmental toxicity studies; however, residual uncertainty remains regarding sensitivity of the young to the effects of pyrethroids. 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 fenpropathrin and workers entering treated fields are not expected to be exposed to levels of fenpropathrin that will result in an unacceptable risk when Danitol EC Spray is used according to label directions. The personal protective equipment on the product label is coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, chemical-resistant footwear and socks and protective eyewear (goggles or faceshield). Additionally, workers applying Danitol EC Spray with open-cab airblast equipment must wear coveralls, socks chemical-resistant footwear and chemical-resistant gloves over long-sleeved shirt, long pants, plus chemical-resistant headgear. When applying more than 39 L of Danitol EC Spray per day using open-cab airblast equipment, chemical-resistant coveralls are required.

The nature of the residues in plants is adequately understood. The residue definition for enforcement is fenpropathrin in plant products. The proposed uses of fenpropathrin on succulent shelled peas and several crop groups (CG 8-09, CG 9, CG 11-09, CG 12-09, CSG 13-07 A and B, and CG 14-11) do 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. Sufficient crop residue data have been reviewed, and accompanying MRLs have already been established on all petitioned crops - with the exception of tree nuts (CG14-11), which will be revised to 0.15 ppm.

Commodity	Established MRL (ppm)
Succulent shelled peas	0.02
Fruiting vegetables (CG 8-09)	1.0
Cucurbit vegetables (CG 9)	0.5
Pome Fruits (CG 11-09)	5.0
Stone Fruits (CG 12-09), except cherries	1.4
Cherries	5.0

Established MRL (ppm)
12
3.0

Commodity	Proposed MRL (ppm)	
Tree Nuts (CG 14-11)	0.15	

7.2 Environmental Risk

To mitigate risks to non-target terrestrial and aquatic organisms from spray drift, buffer zones (1–75 metres) (including reduced wind-speed and coarse spray), and label statements to inform users of potential risks to the environment are required. A 10 m vegetative filter strip is required to reduce potential exposures to non-target aquatic organisms from run-off. To reduce pollinator exposure, application during bloom is restricted for bee attractive crops. When fenpropathrin is used in accordance with the label and the required risk reduction measures are applied, the reduced environmental exposure is deemed adequate and risks are considered acceptable.

7.3 Value

Value information demonstrated that Danitol EC Spray, which contains the active ingredient fenpropathrin, controls or suppresses various insects and mites on a variety of agricultural crops. This product is a new management tool for control of many important insect pests of fruit and vegetable crops, including spotted winged drosophila.

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 Fenpropathrin Technical and Danitol EC Spray containing the technical grade active ingredient fenpropathrin, to control several insect pests in various fruit and vegetable crops.

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

*	incurrent
	increased
+	decreased
$\downarrow_{\overset{\frown}{\circ}} \\ \begin{array}{c} \downarrow \\ \uparrow \\ \lambda \end{array}$	male
¥	female
	wavelength
μg	micrograms
1/n	exponent for the Freundlich isotherm
3-PBA	3-phenoxybenzoic acid
3-PBAld	3-phenoxybenzaldehyde
°C	degree centigrade
a.i.	active ingredient
ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
AOPWIN	Atmospheric Oxidation Program for Microsoft Windows
Appl	application
AR	applied radioactivity
ARfD	acute reference dose
ARTF	Agricultural Reentry Task Force
ASAE	American Society of Agricultural Engineers
atm	atmosphere
ATPD	Area Treated per Day
BAF	bioaccumulation factor
BCF	bioconcentration factor
BMDL	benchmark dose lower confidence limit
bw	body weight bodyweight gain
bwg CA	California
CAF	
CAPHRA	composite assessment factor Council for Advancement of Pyrethroid Human Risk Assessment
CAS	Chemical Abstracts Service
CBI	confidential business information
CEPA	Canadian Environmental Protection Act
CFIA	Canadian Food Inspection Agency
CG	crop group
CSG	crop subgroup
cm	centimetres
CO ₂	carbon dioxide
CONH ₂	amide analog of fenpropathrin
d	day(s)
DACO	data code
DEEM-FCID	Dietary Exposure Evaluation Model
DFOP	double first-order in parallel
DIR	Regulatory Directive
dFDK	decarboxy-fenpropathrin
DFR	dislodgeable entry interval

DNT	developmental neurotoxicity
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in
~ ~	concentration)
DT ₉₀	dissipation time 90% (the dose required to observe a 90% decline in
	concentration)
dw	dry weight
EC	emulsifiable concentrate
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
EIIS	USEPA Ecological Incident Information System
ELS	early life stage
EPA	United States Environmental Protection Agency
ER_{25}	effective rate for 25% of the population
ER_{50}	effective rate on 50% of the population
F_1	first generation
fc	food consumption
FDA	Food and Drugs Act
FDK	fenpropathrin
FIR	food ingestion rate
g	gram
GAP	Good Agricultural Practice
GC-ECD	gas chromatography with electron capture detection
GC-MS	gas chromatography with electron cupture detection gas chromatography mass spectroscopy
GC-MS/SIM	gas chromatography mass spectroscopy with selected ion monitoring
GC-NPD	gas chromatography mass spectroscopy with selected for monitoring gas chromatography with nitrogen-specific thermionic detection
GD	
GUS	gestation day
	groundwater ubiquity score
h	hour
ha	hectare(s)
HAFT	highest average field trial
HDT	highest dose tested
HDPE	high density polyethylene
Hg	mercury
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC	high performance liquid chromatography
hr(s)	hour(s)
IC ₅₀	inhibition concentration on 50% of the population
IORE	indeterminate order rate equation
IRAC	Insecticide Resistance Action Committee
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
$K_{ m F}$	Freundlich adsorption coefficient
KFOC	Freundlich adsorption coefficient normalized to organic carbon
km	kilometre
$K_{ m oc}$	organic-carbon partition coefficient
$K_{ m ow}$	<i>n</i> -octanol-water partition coefficient

kPa	kiloPascal
Kra L	litre
L LAFT	
	lowest average field trial
LC_{50}	concentration estimated to be lethal to 50% of the test population
LD_{50}	dose estimated to be lethal to 50% of the test population
LLMV	lowest limit of method validation
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEL	Lowest Observable Effects Level
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre(s)
m^3	cubic metre
mg	milligram
mg/kg	milligram(s)/kilogram(s)
mL	millilitre
MAS	maximum average score
Max	maximum
Min	minimum
MIS	maximum irritation score
mmHg	millimeter(s) of mercury
MOE	margin of exposure
mol	mole
mPa	milliPascals
MRL	maximum residue limit
MS	mass spectrometry
	molecular weight
mw	number of field trials
n n/a	
	not applicable
NAFTA	North American Free Trade Agreement
NDETF	Non-Dietary Exposure Task Force
nm	nanometre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
NZW	New Zealand white
OC	organic carbon
PBI	plantback interval
PCPA	Pest Control Product Act
PDP	Pesticide Data Program
PHI	preharvest interval
p <i>K</i> a	dissociation constant
pН	measure of the acidity or basicity of an aqueous solution
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency

ppb	parts per billion
ppm	parts per million
ppt	parts per trillion
PWC	Pesticide Water Calculator
РҮО	pick your own
RT ₂₅	residual time needed to reduce the activity of the test substance and bring
	the test organism mortality down to 25%
RAC	raw agricultural commodity
REI	restricted entry interval
RTI	retreatment interval
RQ	risk quotient
SD	Standard Deviation
SFO	single first-order
STMdR	supervised trial median residue
t _{1/2}	half-life
T_R	representative half-life
TMPA	tetramethyl-1-cyclopropane carboxylic acid
TMPe	tetramethylcyclopropane carboxamide
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UR	unextracted residues
USEPA	United States Environmental Protection Agency
UV	ultraviolet
W	week(s)
yr	year(s)

Appendix I Tables and Figures

Table 1aResidue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Soil	GPL-MTH- 084	CONH2- fenpropathrin TMPA	HPLC/MS/MS	0.01 ppm	PMRA# 2730268
Sediment		fenpropathrin	GC/MS	0.05 ppb	PMRA# 2730270
Fresh water		fenpropathrin	GC/MS	0.1 ppt	PMRA# 2730272
Drinking water	GPL-MTH- 085	CONH2- fenpropathrin	HPLC/MS/MS	1 ppb	PMRA# 2730274
		4'-OH- Fenpropathrin			
		TMPA			

Table 1bResidue Analysis

Matrix	Method ID	Analyte	Method Type		LOQ	Reference
Plant (primary and secondary crops)	RM 22-4	Fenpropathrin	Data gathering/enforce ment method for plant matrices/GC- ECD, GC-NPD, GC-MS/SIM	0.1 0.02 0.01- 0.05	Cottonseed, cottonseed oil Pecan nutmeat, plums Various crops	PMRA#1782580

Table 2Toxicity Profile of Danitol EC Spray Containing Fenpropathrin

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	High Toxicity
Rat (CD)	$LD_{50} = 66 \text{ mg/kg bw}$
PMRA# 2730028	
Acute dermal toxicity	Low Toxicity
Rabbit (NZW)	$LD_{50} > 2000 \text{ mg/kg bw}$
PMRA# 2730029	

Study Type/Animal/PMRA#	Study Results
Acute inhalation toxicity (whole-	•
body)	
	$LC_{50}(c^{2}) = 4.3 \text{ mg/L}$
Mouse (Swiss-Webster)	$LC_{50}(\bigcirc) = 4.5 \text{ mg/L}$
PMRA# 2730031	
Acute inhalation toxicity (whole-	Low Toxicity
body)	
Rat (Sprague-Dawley)	$LC_{50} > 5.4 \text{ mg/L}$
PMRA# 2730030	
r MIKA# 2750050	
Acute inhalation toxicity (whole-	Low Toyicity
body)	Low Toxicity
	$LC_{50}(c) = 3.7 \text{ mg/L} (1-\text{hr exposure})$
Rat (Sprague-Dawley)	$LC_{50}(\bigcirc) = 2.8 \text{ mg/L (1-hr exposure)}$
DMD A # 2720022	
PMRA# 2730032	Supplemental: Based on 1 hr exposure.
Eye irritation	Moderately Irritating
Rabbit (NZW)	MAS = 33
	MIS = 37.7 (72 hrs)
PMRA# 1580165	
Eye irritation	Severely Irritating
Rabbit (NZW)	MAS = 27.4
	MAS = 27.4 MIS = 32 (72 hrs)
PMRA# 1580166	
	Persistence to Day 21.
Dermal irritation	Moderately Irritating
Rabbit (NZW)	MAS = 3.8
	MAS = 3.8 MIS = 4.7 (24 hrs)
PMRA# 1580224	
Dermal sensitization	Potential Dermal Sensitizer
(Landsteiner)	
Guinea pig (Hartley)	Supplemental: Limited reporting, not enough animals tested; however, study results indicated a positive response.
PMRA# 2730033	

Table 3Summary of Selected Toxicity Studies for Technical Fenpropathrin⁶

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. Effects seen above the LOAEL(s) have not been reported in this table for most studies for reasons of brevity

Study Type/Animal/PMRA#	Study Results
Acute oral toxicity	High Toxicity
Mouse (DD)	$LD_{50} (\stackrel{\frown}{\bigcirc}) = 67 \text{ mg/kg bw}$ $LD_{50} (\stackrel{\bigcirc}{\bigcirc}) = 58 \text{ mg/kg bw}$
PMRA# 2940207	Supplemental: Limited reporting.
Acute dermal toxicity	Moderate Toxicity
Rat (Sprague-Dawley)	LD_{50} (\checkmark) = 1600 mg/kg bw LD_{50} (\updownarrow) = 870 mg/kg bw
PMRA# 2794453	Supplemental: Limited reporting.
Acute dermal toxicity	Low Toxicity
Rat (Sprague-Dawley)	$LD_{50} > 5000 \text{ mg/kg bw}$
PMRA# 2794455	
Acute dermal toxicity	Low Toxicity
Rat (Sprague-Dawley)	$LD_{50} > 2000 \text{ mg/kg bw}$
PMRA# 2794456	
Acute dermal toxicity	Low Toxicity
Rabbit (NZW)	$LD_{50} > 2000 \text{ mg/kg bw}$
PMRA#2794454	Supplemental: Limited reporting.
Acute inhalation toxicity (vapour)	LC_{50} (mouse and rat) > 0.009 μ g/L
Mouse (Swiss-Webster) Rat (Sprague-Dawley)	Supplemental: Only one dose tested at an extremely low concentration. Low dose based on low vapour pressure of active ingredient.
PMRA# 2794457	
Acute inhalation toxicity	Slight Toxicity
Rat (Sprague-Dawley)	LC_{50} is between 0.5 and 1.0 mg/L
PMRA# 2794458	
Eye irritation	Unwashed eyes: Effects were only observed in conjunctiva (24 and 48 hrs).
Rabbit (Japanese albino)	Washed eyes: Effects were only observed in conjunctiva (24 hrs).
PMRA# 2730251	Supplemental: Limited reporting.

Study	Study Results
Type/Animal/PMRA#	
Eye irritation	Non-Irritating
Rabbit (NZW)	MAS = 0
PMRA# 2794460	MIS = 6 (1 hr)
Dermal irritation	No signs of irritation noted in any animal.
Rabbit (Japanese albino)	Supplemental: Limited reporting.
PMRA# 2730251	
Dermal irritation	Slightly Irritating
Rabbit (NZW)	MAS = 0.8 MIS = 1 (48 and 72 hrs)
PMRA# 2794459	
Dermal sensitization	Negative.
(Draize)	Supplemental: Limited reporting.
Guinea pig (Hartley)	Supplemental: Limited reporting.
PMRA# 2730252	
Dermal sensitization	Negative.
(Buehler)	
Guinea pig (Hartley)	
PMRA# 2794461	
Dermal sensitization	Negative.
(Buehler)	
Guinea pig (Hartley)	Supplemental: Limited reporting.
PMRA# 2794462	
Acute subcutaneous and	Subcutaneous:
intraperitoneal toxicity	
	LD_{50} ($^{\circ}$) = 1350 mg/kg bw (mouse); 1410 mg/kg bw (rat)
Mouse (DD)	$LD_{50} (\bigcirc) = 900 \text{ mg/kg bw (mouse)}; 900 \text{ mg/kg bw (rat)}$
Rat (Sprague-Dawley)	
DMD 1 # 2010208	Intraperitoneal:
PMRA# 2940208	LD_{50} ($^{\circ}$) = 230 mg/kg bw (mouse); 225 mg/kg bw (rat)
	$LD_{50}(\bigcirc) = 210 \text{ mg/kg bw (mouse)}; 225 \text{ mg/kg bw (rat)}$ $LD_{50}(\bigcirc) = 210 \text{ mg/kg bw (mouse)}; 180 \text{ mg/kg bw (rat)}$
	Supplemental: Non-guideline study with limited reporting.
90-day oral toxicity (dietary)	NOAEL not established
Dog Paggla	LOAEL = 7.4/9.4 mg/kg bw/day (MP)
Dog, Beagle	Effects at LOAEL: \uparrow incidence/frequency of soft/mucoid stools and diarrhea, emesis,
PMRA# 2730253, 2730254	tremors (lout of 6 per sex, week 2-3) $(3/2)$.

Study Type/Animal/PMRA#	Study Results
7-day dermal toxicity	NOAEL and LOAEL not established (range-finding study)
	(ango mang stady)
Rat (Sprague-Dawley)	Effects at 1000 mg/kg bw/day: bw loss days 1–4, \downarrow bwg, \downarrow reticulocytes (\circlearrowleft)
PMRA# 1580164	Histological examination of skin not performed.
21-day dermal toxicity	NOAEL (systemic) = 1000 mg/kg bw/day (\Im/\Im)
Rat (Sprague-Dawley)	No treatment-related systemic effects.
PMRA# 1580169	
21-day dermal toxicity	NOAEL (systemic) = 3000 mg/kg bw/day ($\sqrt[3]{+}$)
Rabbit (NZW)	3000 mg/kg bw/day: ↑erythema (barely perceptible to slight) and edema (barely perceptible to very slight) at both abraded and intact test sites.
PMRA# 2730256	
	No treatment-related systemic effects.
90-day inhalation toxicity	Waiver request based on:
Waiver request	1. Acute toxicity via inhalation route does not result in higher toxicity than via oral route.
PMRA# 2794463	 2. For pyrethroids in general, systemic effects (particularly with respect to respiratory pathology) typically occur at higher doses than those inducing neurotoxicity. 3. Margins of exposure exceeded 1000 for all inhalation exposure scenarios when using a toxicological reference value from an oral study.
	Waiver granted
Developmental toxicity (gavage)	Maternal NOAEL = 6.5 mg/kg bw/day LOAEL = 11 mg/kg bw/day
Rat (Fischer 344) PMRA # 1782570	Effects at LOAEL: \uparrow mortality (6 out of 30 animals died and one sacrificed moribund, all between GD 7-13; 2/6 died GD 7), clinical signs of toxicity (ataxia, sensitivity to external stimuli, tremors, chromodacryorrhea, spastic jumping, prostration, convulsions, hunched appearance, and squinted eyes), bw loss, \downarrow bwg, \downarrow fc (GD 6-8, 8-11).
	Developmental
	NOAEL = 11 mg/kg bw/day
	LOAEL not established. No treatment-related effects noted at the highest dose level.
	No oridonos of consitivity of the young
28-day Immunotoxicity	No evidence of sensitivity of the young. NOAEL and LOAEL not established (range-finding study)
(dietary)	
Rat (Sprague-Dawley)	Effects at 42 mg/kg bw/day: twitching, \downarrow bw, \downarrow bwg (\bigcirc).
PMRA# 2730261	
28-day Immunotoxicity	NOAEL = 26 mg/kg bw/day (\bigcirc)
(dietary) Rat (Sprague-Dawley)	Effects at the LOAEL: hyperactivity, hyper-reactivity to touch, \uparrow activity, twitching, \downarrow bw, \downarrow bwg.
PMRA# 2730260	No treatment-related effect on RBC plaque forming assay.

Study Type/Animal/PMRA#	Study Results
Acute Neurotoxicity	BMDL ₂₀ = 5.3 mg/kg bw (3)
(gavage)	
	Based on \downarrow motor activity.
Rat (Long-Evans)	
PMRA# 2007554	
Acute Neurotoxicity	Comparative functional observational battery of twelve commercial pyrethroid
(gavage)	insecticides in $\stackrel{?}{\circ}$ rats following acute oral exposure.
Rat (Sprague-Dawley)	Effects at 15 mg/kg bw and above: \uparrow rearing, slight tremors, clonic convulsions, biting of self (at 15 mg/kg bw only), salivation, hunched body, \uparrow startle response (at 15
PMRA# 2007556	mg/kg bw only), no hindlimb extension (at 15 mg/kg bw only).
	Effects at 30 mg/kg bw: exaggerated hindlimb flexing, ataxia, gait impairment
	(slight), coarse tremors.
	There were no statistically significant changes in forelimb or hindlimb grip strength,
	rotarod performance, or hindlimb footsplay at either dose level when compared to controls.

⁶ As noted in Section 3.1, the results from the majority of the toxicology studies conducted with fenpropathrin are summarized in the Evaluation Report for <u>application number 2008-1306</u>, prepared for the establishment of import maximum residue limits (MRLs).

Table 4Toxicological Reference Values for Use in Health Risk Assessment for
Fenpropathrin

Exposure Scenario	Study	Point of Departure and Endpoint	CAF ¹ or Target MOE
Acute dietary	Acute oral neurotoxicity in the rat	BMDL ₂₀ = 5.3 mg/kg bw Reduced motor activity	300
Repeated dietary	ARfD = 0.02 mg/kg bw Co-critical studies: 2-generation dietary reproductive toxicity in the rat 12-month dietary toxicity in the dog	Parental and Offspring NOAEL = 3.1 mg/kg bw/day Body tremors and mortality in female parents and offspring NOAEL = 3.1 mg/kg bw/day Decreased body weight gain, increased glucose and creatinine in females, and tremors in both sexes	300
Short-term, intermediate-term, and long-term dermal ²	ADI = 0.01 mg/kg bw/day 2-generation dietary reproductive toxicity in the rat	Offspring NOAEL = 3.1 mg/kg bw/day Body tremors and mortality in females	300

Exposure Scenario	Study	Point of Departure and Endpoint	CAF ¹ or Target MOE
Short-term, intermediate-term, and long-term inhalation ³	Co-critical studies: 2-generation dietary reproductive toxicity in the rat 12-month dietary toxicity in the dog	Parental and Offspring NOAEL = 3.1 mg/kg bw/day Body tremors and mortality in female parents and offspring NOAEL = 3.1 mg/kg bw/day Decreased body weight gain, increased glucose and creatinine in females, and tremors in both sexes	300
Cancer	A cancer risk assessment was	not required.	

¹CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational assessments.

² Since an oral NOAEL was selected, a dermal absorption factor of 33% was used in a route-to-route extrapolation. ³ Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 5AHETF/PHED/NDETF Unit Exposure Estimates for Mixer/Loaders and
Applicators Handling Danitol EC Spray (µg/kg a.i. handled)

	Scenario	Dermal ¹	Dermal absorbed ²	Inhalation ³	Total unit exposure ⁴
Mixer	/loader AHETF estimates				
А	Open Mix/Load Liquids, SL, CR Gloves (AHETF)	58.5	19.3	0.63	19.9
В	Open Mix/Load Liquids, Cotton Coveralls, CR Gloves (AHETF)	31.3	10.3	0.63	11.0
Appli	cator AHETF estimates				
С	Open Cab Airblast Liquids, SL, CR Hat (AHETF)	414.9	136.9	9.08	146.0
D	Open Cab Airblast Liquids, Cotton Coveralls, CR Hat (AHETF)	158.0	52.1	9.08	61.2
E	Open Cab Airblast Liquids, CR Coveralls, CR Hat (AHETF)	106.8	35.2	9.08	44.3
F	Closed Cab Airblast Liquids, SL, CR Hat (AHETF)	21.0	8.38	0.32	8.70
G	Open Cab Groundboom, SL, CR Gloves (AHETF)	25.4	8.4	1.68	10.1
Mixer	/loader + applicator AHETF & P	HED estin	nates		
Airbla					
A+C	Open Mix/Load Liquids, SL, CR Gloves + Open Cab Airblast Liquids, SL, CR Hat	473.4	156.2	9.71	165.9
A+D	Open Mix/Load Liquids, SL, CR Gloves + Open Cab Airblast Liquids, Cotton	216.5	71.4	9.71	81.2

	Scenario	Dermal ¹	Dermal absorbed ²	Inhalation ³	Total unit exposure ⁴
	Coveralls, CR Hat				
A+E	Open Mix/Load Liquids, SL, CR Gloves + Open Cab Airblast, CR Coveralls, CR Gloves	165.3	54.5	9.71	64.2
B+D	Open Mix/Load Liquids, Cotton Coveralls, CR Gloves + Open Cab Airblast Liquids, Cotton Coveralls, CR Hat	189.3	62.4	9.71	72.2
B+E	Open Mix/Load Liquids, Cotton Coveralls, CR Gloves + Open Cab Airblast Liquids, CR Coveralls, CR Hat	138.1	45.5	9.71	55.3
A+F	Open Mix/Load Liquids, SL, CR Gloves + Closed Cab Airblast Liquids, SL, CR Hat	83.9	27.6	0.32	28.6
Grour	ıdboom				
A+G	Open Mix/Load Liquids, SL, CR Gloves + Open Cab Groundboom, Cotton Coveralls, CR Gloves	73.0	24.0	2.31	26.3
Hand	held				
Н	Open M/L (SL, gloves), Low Pressure Handwand (for manually-pressurized handwand) (PHED)	943.4	311.3	45.2	356.5
Ι	Open M/L (SL, gloves), Backpack (PHED)	5445.9	1797.1	62.1	1859.2
J	M/L/A using handheld airblast (CR coveralls, CR hood over SL, CR gloves and respirator) (NDETF)	32562	10745	3940	14685

¹ No MEA adjustments for AHETF unit exposure estimates. ² Adjusted with dermal absorption factor 33%

³ Light inhalation rate with the exception of backpack and handheld airblast where moderate inhalation rate was used

⁴ Total unit exposure: Dermal exposure + inhalation exposure

Mixer/Loader/Applicator Risk Assessment for Chemical Handlers Table 6

Exposure scenario AHETF/PHED unit exposure (µg/kg a.i. handled) ¹		ATPD (ha/day) ²	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day) ³	MOE ⁴
Mixer/Loader & Ap	plicator				
Open Mix/Load	81.2	20	0.448	0.00910	341
Liquids, SL, CR					
Gloves + Open Cab					

Exposure scenario	AHETF/PHED unit exposure (µg/kg a.i. handled) ¹	ATPD (ha/day) ²	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day) ³	MOE ⁴
Airblast Liquids, Cotton Coveralls, CR Hat					
Open Mix/Load Liquids, Cotton Coveralls, CR Gloves + Open Cab Airblast Liquids, Cotton Coveralls, CR Hat	72.2	34	0.336	0.0103	300
Open Mix/Load Liquids, Cotton Coveralls, CR Gloves + Open Cab Airblast Liquids, CR Coveralls, CR Hat	55.3	40	0.336	0.00929	334
Open Mix/Load Liquids, SL, CR	28.6	20	0.448	0.00321	967
Gloves + Closed Cab Airblast Liquids, SL, CR Hat		40	0.336	0.00481	644
Open Mix/Load Liquids, SL, CR	30.0	26	0.336	0.00328	946
Gloves + Open Cab Groundboom, SL, CR Gloves		60		0.00756	410
Liquid, Open Pour, Low Pressure Hand Wand, SL, CR Gloves	356.5	0.75	0.336	0.00112	2760
Liquid, Open Pour, Backpack, SL, CR Gloves	1859.2	0.75	0.336	0.00586	529

¹ AHETF/PHED/NDETF unit exposure (see Table 2)

² Default Area Treated Per Day tables (2009). ATPD for hand-held sprayer equipment was calculated using the values from these tables (in other words, 150 L/day), maximum application rate of 0.336 kg a.i./ha and a minimum spray volume of 200 L/ha for caneberries and bushberries.

³ Daily exposure = (AHETF unit exposure \times ATPD \times Rate) / (80 kg bw \times 1000 µg/mg)

⁴ Based on NOAEL = 3.1 mg/kg bw/day, target MOE = 300

Сгор	Postapplication activity	Transfer coefficient (cm²/hr) ¹	Max. Appl. Rate kg a.i./ha × Appl/yr	Min. RTI (days)	Peak DFR (µg/cm²)² after last application	Dermal exposure (mg/kg bw/day) ³	MOE ⁴	REI ⁵
Bushberry and	Hand set irrigation	1750	0.336 × 2	14	0.172	0.0099	312	17 days
caneberry subgroups	Hand harvesting, tying/training (raspberry)	1400			0.213	0.0098	316	15 days
	Hand harvesting, scouting (lowbush blueberry)	1100			0.262	0.0095	326	13 days
	Scouting, hand weeding, hand pruning, bird control (Saskatoon berry), frost control (Saskatoon berry)	640			0.0494	0.0104	300	7 days
	Transplanting	230			1.03	0.0078	396	12 hrs
Succulent Peas	Hand set irrigation	1750	0.224 × 1	-	0.1757	0.0101	305	11 days
	Hand harvesting	1100			0.2678	0.0097	319	7 days
	Scouting	210	-		0.5600	0.0039	799	12 hrs
	Hand weeding	70	-		0.5600	0.0013	2396	12 hrs
Cucumber s	Hand set irrigation	1750	0.336 × 1	-	0.1729	0.0100	310	15 days
	Hand harvesting, mechanically- assisted harvesting, training	550			0.5511	0.0100	310	4 days (moved up to 7 days to account for the PHI)
	Transplanting	230			0.8400	0.0064	486	12 hrs
	Scouting, hand weeding, hand pruning, thinning fruit, turning (pumpkin)	90			0.8400	0.0025	1243	12 hrs
Cucurbit vegetables	Hand set irrigation	1750	0.224×1 and $0.336 \times$	7	0.1665	0.0096	322	20 days
(except cucumber s)	Hand harvesting, mechanically- assisted harvesting, training (gourd, summer squash, watermelon)	550	2 (for a maximum of 0.896 season)		0.531	0.0096	322	9 days
	Transplanting	230			1.370	0.0104	300	12 hrs
	Scouting, hand weeding, hand pruning, thinning	90			1.370	0.0041	762	12 hrs

Table 7Postapplication Dermal Exposure and Risk for Fenpropathrin

Сгор	Postapplication activity	Transfer coefficient (cm²/hr) ¹	Max. Appl. Rate kg a.i./ha × Appl/yr	Min. RTI (days)	Peak DFR (µg/cm²) ² after last application	Dermal exposure (mg/kg bw/day) ³	MOE ⁴	REI ⁵
	fruit, turning (pumpkin)							
Fruiting	Hand set	1750	0.224 × 1	-	0.1757	0.0101	305	11 days
vegetable	irrigation		-					
s (except tomatoes	Hand harvesting, tying/training	1100			0.2678	0.0097	319	7 days
)	Hand harvesting, tying/training	550			0.5600	0.0102	305	12 hrs
	Transplanting	230			0.5600	0.0043	729	12 hrs
	Scouting (okra,	210			0.5600	0.0039	799	12 hrs
	bell pepper) Hand pruning, scouting (eggplant), thinning fruit, hand weading	90	-		0.5600	0.0017	1864	12 hrs
	hand weeding Hand weeding (okra, bell pepper)	70	-		0.5600	0.0013	2396	12 hrs
Fruiting	Hand set	1750	0.224×4	7	0.170	0.0098	316	17 days
Vegetable (Tomatoes)	irrigation Hand harvesting, tying/training	550	-		0.541	0.0098	316	6 days
	Transplanting	230	-		1.02	0.0077	402	12 hrs
	Scouting (okra, bell pepper)	210			1.02	0.0070	440	12 hrs
	Hand pruning, scouting (eggplant), thinning fruit, hand weeding	90			1.02	0.0030	1026	12 hrs
	Hand weeding (okra, bell pepper)	70			1.02	0.0023	1319	12 hrs
Pome and	Thinning	3000	0.448×1	-	0.0993	0.0098	315	23 days
Stone Fruit	Hand harvesting	1400			0.2075	0.0096	323	16 days
riun	Scouting, hand pruning, training (apples)	580			0.5357	0.0103	302	7 days
	Transplanting	230	-		1.1200	0.0085	365	12 hrs
	Hand weeding, orchard maintenance, bird control (stone fruit), propping (stone fruit)	100			1.1200	0.0037	839	12 hrs
Tree Nuts	Scouting, hand pruning	580	0.448 × 1	-	0.5357	0.5357 0.0103 302	302	7 days
	Transplanting	230	1		1.120	0.0085	365	12 hrs
	Mechanical harvesting (shaking)	190	1		1.120	0.0070	441	12 hrs
	Orchard maintenance, poling, hand	100			1.120	0.0037	839	12 hrs

Сгор	Postapplication activity	Transfer coefficient (cm²/hr) ¹	Max. Appl. Rate kg a.i./ha × Appl/yr	Min. RTI (days)	Peak DFR (μg/cm ²) ² after last application	Dermal exposure (mg/kg bw/day) ³	MOE ⁴	REI ⁵
	weeding							

¹ Transfer coefficients obtained from PMRA Agricultural TCs table .

² Calculated using the default DFR calculator with 25% dislodgeable residue on the day of last application and 10%

dissipation per day except for cucurbit vegetables (except cucumbers) which was calculated manually.

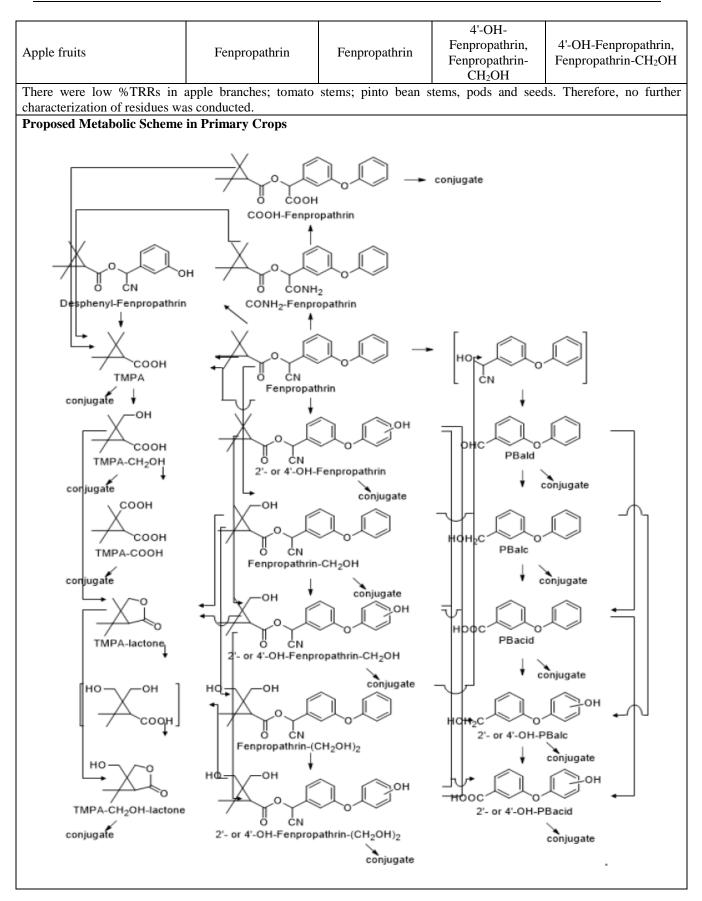
³ Exposure = (Peak DFR $[\mu g/cm^2] \times TC [cm^2/hr] \times 8$ hours \times 33% dermal absorption) / (80 kg bw \times 1000 $\mu g/mg$).

⁴ Based on a NOAEL of 3.1 mg/kg bw/day, target dermal MOE = 300.

⁵ Minimum REI is 12 hours to allow residues to dry.

Table 8 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIL	DUE IN BEAN, APPI	LE, T	OMATO	P	MRA# 158023	33, 1580234, 1580235	
Radiolabel Position	Cyclopropyl- ¹⁴ C			Ben	zyl- ¹⁴ C		
Test Site	Pinto Bean: Foliar Tomato: Foliar spi Apple: Foliar spra	oray to		5			
Total Rate	Tomato: 4 applica	ations a	ns at 0.224 kg a.i./ha/ at 0.224 kg a.i./ha/apj 0.448 kg a.i./ha/app;	p; total	rate of 0.88-0.	.90 kg a.i./ha	
Matrices	PHI		Cyclopropyl- ¹⁴ C			Benzyl- ¹⁴ C	
Watrices	(days)		TRRs (ppm)		,	TRRs (ppm)	
Pinto bean – leaves	15		5.10			8.8	
Pinto bean – stem	15		0.63			1.3	
Pinto bean – bean pod	15		0.10			0.10	
Pinto bean – bean	15		0.073			0.027	
Tomato – leaves	19		4.0			5.8	
Tomato – stem	19		0.53			0.49	
Tomato – fruit	19		0.037			0.10	
Apples – leaves	14		15.9			12.2	
Apples – branches	14		2.5			4.0	
Apples – fruit	14		1.4			2.11	
Metabolites Identified	Major Metaboli	ites (>1	0% of the TRRs)	Μ	linor Metabolit	es (<10% of the TRRs)	
Radiolabel Position	Cyclopropyl- ¹⁴	⁴ C	Benzyl- ¹⁴ C	Cycl	opropyl- ¹⁴ C	Benzyl- ¹⁴ C	
Pinto bean leaves	Fenpropathrin	n	Fenpropathrin, PB aldehyde conjugate		None	None	
Tomato leaves	Fenpropathrin	n	Fenpropathrin		propathrin- CH ₂ OH) ²	Fenpropathrin- (CH ₂ OH) ²	
Tomato fruits	Fenpropathrin	1	Fenpropathrin		None None		
Apple leaves	Fenpropathrin	ı	Fenpropathrin	Fen	4'-OH- propathrin, propathrin- CH ₂ OH	4'-OH-Fenpropathrin, Fenpropathrin-CH ₂ OH	



CONFINI Leaf lettuc				OTATIONAL CROP	S – 1	PMRA# 2730041			
Radiolabe	l Positio	n		[cyclopropyl-1- ¹⁴ C]fenpropathrin or [phenoxyphenyl- ¹⁴ C]fenpropathrin					
Test site	'est site			Bare soil contained in wooden, plastic lined boxes, which were placed in ventilated screened enclosures.					
Applicatio	on rate ai	nd timing		1.6–1.8 kg a.i./ha, and	l aged for 31, 122	and 365 days.			
Metabolit	etabolites Identified			Major Metabolit TRI		Minor Metabolit TRI			
		%TRR	s (ppm)						
Matrices	PBI (days)	[cyclopr opyl]	[phenox yphenyl]	[cyclopropyl- ¹⁴ C]fenpropathrin	[phenoxypheny ¹⁴ C]fenpropath		[phenoxyphenyl- ¹⁴ C]fenpropathrin		
Immature	30	0.621	0.121	TMPA derivatives	None	None	4'-OH-PBA		
wheat	120	0.496	0.098	None	None	None	None		
forage	365	0.696	0.092	TMPA derivatives	3-PBA, 4'-OH-P	BA None	None		
	30	1.904	0.378	TMPA derivatives	None	None	3-PBA, 4'-OH- PBA		
Wheat straw	120	3.592	0.615	TMPA derivatives	None	None	3-PBA, 4'-OH- PBA		
	365	0.664	0.161	TMPA derivatives	4'-OH-PBA	None	3-PBA		
	30	1.802	0.184	TMPA derivatives	None	None	None		
Wheat	120	3.125	0.204	TMPA derivatives	None	None	4'-OH-PBA		
chaff	365	1.289	0.117	TMPA derivatives (including cis- and trans-TMPA-COOH)	None	None	None		
	30	0.712	0.122	TMPA derivatives	None	Fenpropathrin	None		
Wheat	120	1.369	0.079	TMPA derivatives	None	None	3-PBA		
grain	365	0.568	0.077	TMPA derivatives (including cis- and trans-TMPA-COOH)	None	None	None		
Leaf Lettuce	30	0.599	0.411	TMPA derivatives	None	TMPA	Fenpropathrin, Fenpropathrin- amide, 3-PBA, 4'- OH PBA		
Lenuce	120	0.355	0.246	TMPA derivatives	None	None	None		
	365	0.141	0.063	TMPA derivatives	None	None	3-PBA		
	30	0.431	0.173	TMPA derivatives	None	None	None		
Carrot	120	0.265	0.121	TMPA derivatives	None	Fenpropathrin amide	Fenpropathrin- amide		
	365	0.058	0.053	TMPA derivatives	None	Fenpropathrin amide	Fenpropathrin- amide		

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Proposed Metabo	A			CoH-Fengropathrin TMPA-derivative CogH H Hogo Trans-TMPA COOH	A	н со _л н А соон			
FREEZER STOR							PMRA# 178	2581	
Tested Matrices			Test (mor	ed Intervals	;	Tempe	erature (°C)	Category	,
Apple fruit				12.0				High wate	r
Pear fruit				12.0				High water	
Cottonseed	Fenprop	athrin		12.0			<-20	High oil	
Grapes	Tenprop	aumm		12.7			<-20	High acid	
Oranges				12.0				High acid	
Concurrent storage was demonstrated i months), tomato pa demonstrated in 5 o petition.	in strawberry (6 aste, juice, wet	5 months), + dry pom	, raspberry (7 nace (5 month	months), cuc (18) and non-be	umbe ell per	r (8 month opers (10 r	ns), melon (6 m nonths). While	nonths), toma e storage stab	to RAC (6 ility was not
CROP FIELD TR	RIALS & RESI	DUE DE	CLINE ON	SUCCULE	NT		PMRA# Vai	rious	
SHELLED PEAS						ND B.			
AND CG 14-11	, ,	,	,	,					
Crop field trials we concentrate (2.4 EC									
trials. Foliar applic									
enforcement metho									
diverse crop types									
were generally in a conducted pre-DIR								sed, as the stu	idies were
i	Total		. 0			Residue Lev	-		
Commodity	Application Rate	PHI (days)	n	LAFT		IAFT	Median	Mean	SD
Succulant shallor a	(g a.i./ha)						PMRA# 17825	506	
Succulent shelled pe		201 : /	ho /on rlingt	n v 1 or-Back	on f.	no total ce			dor DII
GAP: Foliar ground		-							-
Succulent shelled peas	896	6-7	8	<0.02	<	<0.02	< 0.02	<0.02	None

Fruiting Vegetable	s (CG8-09)					PMRA# 1782 (tomatoes)	2597 (peppers),	1782595
GAP: Tomatoes: Foliar g days and a 3-day P All other crops: Fo PHI.	HI.	-				_		
Bell peppers	896	2–4	6	0.14	0.67	0.37	0.40	0.17
Non-bell peppers	-	2–4	4	0.24	0.40	0.33	0.33	0.08
Tomatoes		3	9	0.05	0.55	0.19	0.21	0.15
Cucurbit Vegetable	es (CG9)) 252 (cantaloup ash), 1782588 (
GAP: Cucumber: Foliar PHI. All other crops: Fo an RTI of 7 days an	liar ground app nd a 7-day PHI.	lications o	of 224-336 g a.	i./ha/applicatio	n × 2–3 applica	tions for a total	of 896 g a.i./ha	a/season with
Cantaloupe	896	7	10	0.07	0.27	0.16	0.17	0.08
Summer squash		6–8	7	< 0.01	0.03	0.01	0.02	0.01
Cucumber	672–1120	6–8	8	< 0.01	0.05	0.01	0.02	0.02
Pome Fruits (CG1)	1-09)						2582 (apple), 15 (); 1782584 (pe (um)	
GAP: Foliar groun	d applications o	f 224-448	g a.i./ha/appli	cation × 1 appl	ication, for a to			a 14-day
PHI.	896	14	4	0.48	1.13	0.61	0.77	0.40
Apples		14	14*	0.14	1.30	0.61	0.68	0.36
		14	18 (total)	0.14	1.30	0.61	0.70	0.34
		14	4	0.27	1.80	0.71	0.88	0.69
Pears		14	11**	0.19	1.23	0.43	0.50	0.30
		14	15 (total)	0.19	1.80	0.43	0.60	0.46
*Data was scaled fro						1		
**Data was scaled f Stone Fruits (CG12		a to 896 g	a.1/ha using the	proportionality	principle.) 243 (cherries), 80257 (plums)	, 1580244
GAP: Foliar groun PHI.	d applications o	f 224-448	g a.i./ha/appli	cation × 1 appl	ication, for a to			a 3-day
Cherries	861–933	3	6	1.44	3.38	1.90	2.22	0.84
Peaches	894	3-4	10	0.44	1.03	0.71	0.74	0.19
Plums (fresh)	910	3-4	6	0.18	0.55	0.24	0.29	0.13
Caneberries (CSG	13-07A)					PMRA# 1782	.598	
GAP: Foliar groun 14 days and a 3-day		f 224-336	g a.i./ha/appli	cation × 2 appl	ications, for a to			h an RTI of
Caneberries (blackberries and raspberries)	890–963	2-3	7	1.10	5.80	2.05	3.14	2.00
Bushberries (CSG						PMRA# 1782		
GAP: Foliar groun 14 days and a 3-day		f 224-336	g a.i./ha/appli	$cation \times 2$ appl	ications, for a to	otal of 672 g a.i.	/ha/season wit	h an RTI of
Blueberries (highbush)	650–690	3	8	0.79	2.75	1.73	1.76	0.73
Lowbush blueberries	680	3	1	Min = 1.31	Max = 2.52	-	1.92	-

Free Nuts (CG 14-	11)					PMRA# 1580 (pecans))245 (almonds)	, 1580249
GAP: Foliar groun	d applications	of 224-448 g	g a.i./ha/applica	ation × 1 appli	cation, for a to	· · · · · · · · · · · · · · · · · · ·	ha/season with	a 3-day
PHI. Almonds (nutmeat)	896	3	5	< 0.02	0.03	0.02	0.02	< 0.01
Pecans	896	3	5	< 0.02	0.05	0.02	0.03	0.01
LAFT = Lowest Avera Values based on per-tr n = number of indeper	rial averages. For condent field trials.	computation, v	values < LLMV (I					
RESIDUE DAT A	A IN ROTATI	ONAL CH	ROPS			PMRA# 27	30042 and 27	30043
Two trials (two ea Regions 4 and 10.		ettuce and	wheat) were c	conducted dur	ing the 1989 g	rowing season	in NAFTA G	rowing
0	Total				Residue Lo	evels (ppm)		
Commodity	Application Rate (kg a.i./ha)	PBI (days)	n		LAFT		HAF	Г
Fenpropathrin		I		I		I		
Wheat forage		29-30	2		< 0.02		< 0.02	
(Immature, Stage		127-131	2		< 0.02		< 0.02	
II)		361-365	2		< 0.02		< 0.02	
	-	29-30	2		< 0.02		< 0.02	
Wheat forage (Immature, Milk		127-131	2		< 0.02		< 0.02	!
stage)		361— 365	2		< 0.02		< 0.02	
		29-30	2		< 0.02		< 0.02	
Wheat grain		127-131	2		< 0.02		< 0.02	
		361-365	2		< 0.02		< 0.02	
		29-30	2		< 0.02		< 0.02	
Wheat straw	1.68	127-131	2		< 0.02		< 0.02	
		361-365	2		< 0.02		< 0.02	
		29–30	2		< 0.02		< 0.02	
Carrot roots		127-131	2		< 0.02		< 0.02	
		361-365	2		< 0.02		<0.02	
		29–30	2		< 0.02		< 0.02	
Carrot tops		127–131	2		< 0.02		< 0.02	
		361-365	2		< 0.02		< 0.02	
		29–30	2		< 0.02		< 0.02	
Lettuce leaves		127–131	2		< 0.02		< 0.02	
		361-365	2	İ	< 0.02		< 0.02	

LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation.Values based on per-trial averages. For computation, values < LLMV (Lowest Limit of method validation, 0.02 ppm) are assumed to be at the LLMV. n = number of independent field trials.

Based on the results of the field accumulation study, a plant-back interval of 365 days is required for all crops not listed on the label.

PROCESSED FOOD A	AND FEED – Apples, To	matoes, Plums	P	MRA# 1580	0240, 1580257, 1782595		
Processing studies were	Processing studies were conducted in various NAFTA regions using Danitol 2.4 EC at 0.896 kg a.i./ha (plums, 2-fold						
	ate), 3.58 kg a.i./ha (apple						
maximum seasonal use r	ate). Adequate storage sta	bility data are available o	n diverse croj	p types to su	pport the storage		
intervals of the processe	d food and feed. Samples	were analyzed using a val	lidated analyt	ical method			
RAC	Processed Fractions	RAC HAFT (ppm)	Average P Fac	Processing Anticipated Residues			
Apple	Juice	1.13	0.0)5	0.06		
Tomato	Juice	0.55	0.0)5	0.03		
Tomato	Paste	0.55	0.	3	0.17		
Plums	Dried	0.55	2.	6	1.43		

Table 9Food Residue Chemistry Overview of Metabolism Studies and Risk
Assessment

	PLANT STUI	DIES		
RESIDUE DEFINITION FOR ENFO Plant matrices	DRCEMENT	Fenpropathrin		
RESIDUE DEFINITION FOR RISK Plant matrices	ASSESSMENT	Fenp	ropathrin	
METABOLIC PROFILE IN DIVER	SE CROPS	Similar in apple, to	omato and pinto bean.	
FAT SOLUBLE RE	SIDUE		No	
DIETARY RISK FROM FOOD ANI) WATER			
			ATED RISK DAILY INTAKE (ADI)	
	POPULATION		Food and Water	
		Food Alone	Level 2 EEC	
Defined characteristications component	All infants < 1 year	1.2	1.7	
Refined chronic dietary exposure analysis	Children 1–2 years	2.9	3.0	
ADI = 0.01 mg/kg bw/day	Children 3 to 5 years	2.2	2.4	
	Children 6–12 years	1.1	1.2	
Level 2 Estimated chronic drinking water concentration = 0.65 µg a.i./L	Youth 13–19 years	0.6	0.7	
	Adults 20–49 years	0.6	0.7	
	Adults 50+ years	0.5	0.7	
	Females 13-49 years	0.6	0.7	
	Total population	0.8	0.9	
Refined acute dietary exposure analysis, 95 th percentile	POPULATION		ATED RISK RENCE DOSE (ARfD)	
		Food Alone	Food and Water	

	PLANT STU	DIES	
ARfD = 0.02 mg/kg bw			Level 2 EEC
Level 2 Estimated acute drinking	All infants < 1 year	19.5	21.9
water concentration = 7.0 μg a.i./L	Children 1–2 years	56.6	58.0
	Children 3–5 years	44.6	45.8
	Children 6–12 years	26.1	26.7
	Youth 13–19 years	12.1	13.0
	Adults 20–49 years	14.9	15.8
	Adults 50+ years	16.2	16.9
	Females 13–49 years	15.8	16.5
	Total population	19.1	20.1

Table 10Fate and Behaviour in the Environment

Property	Test substance	Value ¹	Transformation products	Comments	PMRA#
Abiotic transformat	ion				
Hydrolysis at 25 \pm	¹⁴ C-1-cyclopropyl	pH 5: DT ₅₀ : 295–3336 d; DT ₉₀ :	Major (pH 9):	May be a route of	2730275
1 °C	fenpropathrin (acid);	981–11080 d (SFO)	TMPA, TMPe, 3- PBA, CONH ₂ -	dissipation under alkaline	
	¹⁴ C-phenoxyphenyl	pH 7: DT ₅₀ : 488–618 d; DT ₉₀ :	fenpropathrin	conditions, only.	
	(alcohol)	1621–2053 d (SFO)	Minor (pH 9): Unidentified		
		pH 9: DT ₅₀ :11.4 d; DT ₉₀ : 62.2 d			
		(IORE); $T_{R \text{ IORE}} = 18.7 \text{ d}$			
		pH 9: DT ₅₀ :14.5 d; DT ₉₀ :48.3 d			
	Combined labels	(SFO)			2720276
Phototransformatio n on sandy loam	¹⁴ C-1-cyclopropyl (acid);		Minor: CONH2-	Not a route of transformation in	2730276
soil (Fresno, CA) at	(acid);	DT ₅₀ : 14939 d; DT ₉₀ : 49625 d	fenpropathrin	the environment.	
22.5 ± 3.8 °C, pH		D150. 14757 d, D190. 47025 d	UR, CO ₂	the environment.	
7.9.	¹⁴ C-phenoxyphenyl		010, 002		
	(alcohol)				
	Combined labels				
Phototransformatio	¹⁴ C-1-cyclopropyl		Major (pH 5):	May be a route of	2730277
n in water	(acid);		TMPA, Decarboxy-	dissipation in	
			Fenpropathrin, 3-	clear shallow	
	¹⁴ C-phenoxyphenyl (alcohol)		PBA	water.	
			Minor (pH 5):		
	Combined labels:	DT ₅₀ : 16 h; DT ₉₀ > 24 h	CONH2-		
		(irradiated) ; Calculated t ¹ / ₂ =	fenpropathrin,		
		18.5 h; Environmental	Desphenyl-		
		phototransformation t_{2} = 3h.	fenpropathrin, 4'-		
			OH-fenpropathrin,		

Property	Test substance	Value ¹	Transformation products	Comments	PMRA#
			COOH- fenpropathrin, 3-		
Phototransformatio	Fenpropathrin	Fenpropathrin is not expected to b			low vapour
n in air		pressure and its high adsorptive c	apacity to suspended or	ganic matters.	
Biotransformation Biotransformation	[Benzyl-	California, Fresno Silt loam	Major:	Forneronathrin is	2730278
in aerobic soil	¹⁴ C]fenpropathrin	DT ₅₀ : 155; DT ₉₀ : 515 d (SFO)	Major. CO ₂ , UR Minor: 3-PBA, CONH ₂ - fenpropathrin, desphenyl- fenpropathrin, 4'- OH-fenpropathrin, COOH- fenpropathrin	Fenpropathrin is moderately persistent	2130278
	[phenoxyphenyl- ¹⁴ C]fenpropathrin	Sharkey, Mississippi Silt loam soil DT ₅₀ : 37.4 d; DT ₉₀ : 916 d (DFOP) Slow $t_{1/2} = 387$ d Davidson, Georgia Sandy loam soil DT ₅₀ : 274 d; DT ₉₀ : 2192 d (DFOP) Slow $t_{1/2} = 826$ d Atwater, California Loamy sand soil DT ₅₀ : 51.4 d; DT ₉₀ : 1567 d	Major: 3-PBA, CO ₂ , UR Minor: Desphenyl- fenpropathrin , CONH ₂ - fenpropathrin, 4'- OH-fenpropathrin	Fenpropathrin is slightly persistent to persistent	2730279
Biotransformation in aerobic water:sediment systems	[cyclopropyl-1- ¹⁴ C] fenpropathrin [phenoxyphenyl- ¹⁴ C]fenpropathrin Combined labels:	(DFOP) Slow $t_{1/2} = 718 \text{ d}$ Taunton River: Water: silt loam (pH 6.1, 20 \pm 2 °C) DT ₅₀ : 66.1 d; DT ₉₀ : 2348 d (IORE); T _{R IORE} = 707 d	Major: 3-PBA; TMPA, 4'- OH-fenpropathrin, CO ₂ , UR Minor: Desphenyl- fenpropathrin, CONH ₂ - fenpropathrin, Decarboxy- fenpropathrin, TMPe, 3- phenoxybenzaldehy de	Fenpropathrin is moderately persistent	2730281
	[cyclopropyl-1- ¹⁴ C] fenpropathrin [phenoxyphenyl- ¹⁴ C]fenpropathrin Combined labels:	We weantic River: Water: sand (pH 5.2, 20 \pm 2 °C) DT ₅₀ : 75.6 d; DT ₉₀ : 320 d (DFOP) Slow t _{1/2} = 105 d	Major: 3-PBA, TMPA, 4'- OH-fenpropathrin, UR Minor: Desphenyl-		

Property	Test substance	Value ¹	Transformation products	Comments	PMRA#
			fenpropathrin , CONH2- fenpropathrin, COOH- fenpropathrin, Decarboxy- fenpropathrin, TMPe, 3- phenoxybenzaldehy de, CO2		
Biotransformation in anaerobic soil	[cyclopropyl-1- ¹⁴ C]fenpropathrin	Penn Water:silt loam (20 ± 2 °C, pH 6.9)	Major: TMPA, 3-PBA, CO2	Fenpropathrin is moderately persistent	2730280
		DT ₅₀ : 70.5 d; DT ₉₀ : 291 d (DFOP) Slow $t_{1/2} = 95.2$ d	Minor: TMPe, 4'-OH-	persistent	
	[phenoxyphenyl- ¹⁴ C]fenpropathrin Combined labels	DT ₅₀ : 67.2 d; DT ₉₀ : 443 d (IORE); T _{R IORE} = 133 d DT ₅₀ : 66.2 d; DT ₉₀ : 314 d	fenpropathrin, CONH ₂ - fenpropathrin, COOH-		
	[cyclopropy]-1- ¹⁴ C]fenpropathrin	 (DFOP) Slow t_{1/2} = 109 d Atwater Water: loamy sand (20 ± 2 °C, pH 6.9) DT₅₀: 165 d; DT₉₀: 598 d (DFOP) Slow t_{1/2} = 187 d 	fenpropathrin, desphenyl- fenpropathrin, UR	Fenpropathrin is moderately persistent to persistent	
		(DFOF) Slow $t_{1/2} = 187$ d Davidson Water: sandy loam $(20 \pm 2 \ ^{\circ}C, pH 6.8)$ DT ₅₀ : 192 d; DT ₉₀ : 817 d (DFOP) Slow $t_{1/2} = 269$ d	Major: TMPA Minor: TMPe, 4'-OH- fenpropathrin,		
		Sharkey Water: silt loam (20 ± 2 °C, pH 5.7) DT ₅₀ : 128; DT ₉₀ : 424 d (SFO)	fenpropatnrin, CONH ₂ - fenpropathrin, COOH- fenpropathrin, desphenyl- fenpropathrin, UR, CO ₂		
Biotransformation in anaerobic water:sediment systems	[cyclopropyl-1- ¹⁴ C]fenpropathrin [phenoxyphenyl- ¹⁴ C]fenpropathrin Combined labels:	Taunton River (silt loam, pH 6.0, at 20 ± 2 °C) DT ₅₀ : 742 d; DT ₉₀ : 3633 d (DFOP) Slow t _{1/2} = 1240 d	Major: TMPA, 3-PBA, CO ₂ , UR Minor: TMPe, 4'-OH- fenpropathrin, CONH ₂ - fenpropathrin,	Fenpropathrin is persistent	2730285

Property	Test substance	Value ¹	Transformation products	Comments	PMRA#
	[phenoxyphenyl-	Fresno, California (loam, pH 7.2, 25±1 °C)	COOH- fenpropathrin, Decarboxy- fenpropathrin	Fenpropathrin is moderately	2730283
	¹⁴ C]fenpropathrin	DT ₅₀ : 74.8 d; DT ₉₀ : 293 d (IORE); T _{R IORE} = 88.2 d	Major: 3-PBA Minor: 4'-OH-	persistent	
	[cyclopropyl-1- ¹⁴ C]fenpropathrin	California (loam soil systems (water, pH 6.5; soil, pH 7.5,t $25 \pm 1^{\circ}$ C) DT ₅₀ : 61.8 d; DT ₉₀ : 263 d (IORE); T _{R IORE} = 79.1 d (acceptable with restriction)	fenpropathrin, CONH2- fenpropathrin, COOH- fenpropathrin, UR, CO2	Fenpropathrin is moderately persistent	2730284
			Major: TMPA Minor: CONH ₂ - fenpropathrin, COOH- fenpropathrin, UR, CO ₂		
Mobility					
Adsorption/desorpti on in soil (5 soils)	[phenoxyphenyl- ¹⁴ C]fenpropathrin	$K_F = 960-4508 (L/kg-soil)^{-l/n}$ $K_{FOC} = 33\ 006-247\ 388 (L/kg-OO)$ 1/n = 0.886-0.998	C) ^{-1/n}	Immobile	2730288
6 soils	[phenoxyphenyl- ¹⁴ C]fenpropathrin	$K_{F} = 13-247 \text{ (L/kg-soil)}^{-1/n}$ $K_{FOC} = 577-40 \text{ 261 (L/kg-OC)}^{-1/n}$ $1/n = 0.607-0.992$		Immobile	2730286 2730287
Volatilization		thrin is not expected to be volatile u capacity to suspended organic matter		sed on its low vapour	pressure
Field dissipation stu	dies ²				
Michigan; Mississippi New York Tree cropped soils	Danitol 2.4 EC (End- use Product)	Michigan, Metamora Sandy Loam pH 6.2: DT ₅₀ :34.2 d; DT ₉₀ : 114 d (SFO) Mississippi, Dundee fine sandy loam, pH 6.8: DT ₅₀ :18.8 d; DT ₉₀ : 62.4 d (SFO) New York, sandy loam, pH 5.7: DT ₅₀ :17.7 d; DT ₉₀ : 58.9 d (SFO) acceptable with	Minor (Mississippi and New York soils, only): desphenyl- fenpropathrin	No residues beyond 5 cm soil depth Other transformations were not measured Slightly persistent	2730291
Washington Apple cropped soils	Danitol 2.4 EC (End- use Product)	restriction) Tieton, Loam, Sandy loam, Silt loam, pH 7.8–8.4: DT ₅₀ : 76.4 d; DT ₉₀ : 511 d (DFOP) Slow $t_{1/2} = 188$ d	Minor: desphenyl- fenpropathrin	No residues beyond 7.5 cm soil depth Moderately persistent	2730293
New York Apple cropped soils	Danitol 2.4 EC (End- use Product)	New York, Loam, Sandy loam, Silt loam loam, pH 5.0–6.7:	Minor: desphenyl-	No residues beyond 7.5 cm	2730292

Property	Test substance	Value ¹	Transformation	Comments	PMRA#
			products		
		DT ₅₀ :8.75 d; DT ₉₀ : 29.1 d	fenpropathrin	soil depth	
		(SFO)		Non-persistent	
California	Danitol 2.4 EC (End-	California Fresno, Sandy Loam,	Minor:	No residues	2730299
Bare soil	use Product)	Sandy Clay Loam, Loamy	CONH ₂ -	beyond 15 cm soil	2730300
		Sand, Silt Loam, Loam pH 6.5–	fenpropathrin	depth	
		8.5:			
		DT50: 6.86 d; DT90: 52.6		Non-persistent	
		d (IORE); $T_{R \text{ IORE}} = 15.8 \text{ d}$		_	
Bioaccumulation / H	Bioconcentration		•		
Bioconcentration	[cyclopropyl-l-14C]	Whole body steady state BCF =		depuration half-	2730348
and Metabolism	fenpropathrin and	830	Transformation	life for the total	2730350
with Bluegill	[Benzyl- ¹⁴ C]		products formed by	radioactive	
sunfish (Lepomis	fenpropathrin		hydroxylation then	residues ~3 days	
macrochirus)			conjugated with		
Accumulation and	[Benzyl-1- ¹⁴ C]-	Whole body steady state BCF =	sulfate and	depuration half-	2730349
metabolism with	fenpropathrin	516-620	glucuronic acid	life for the total	
Carp (Cyprinus				radioactive	
carpio)				residues 1.8 days	
¹ Kinetics models: SI	FO = single first-order; IO	RE = indeterminate order rate equation	tion; DFOP = double fin	rst order in parallel; T ₁	R =
representative half-li	fe (IORE); Slow t ¹ / ₂ = repre	esentative half-life (DFOP);			
² TFD studies did no	t measure a large number	of transformation products. Legends	s: UR, unextracted resid	lues.	

Table 11 Transformation Products Formed in the Environment

Designation	Chemical name	Chemical structure	Study	max %AR (day)	%AR at Study End (study length, day)	References (PMRA#)
	•	Р	ARENT	•	•	
Fenpropathrin	IUPAC: (RS)-α- cyano-3- phenoxybenzyl 2,2,3,3- tetramethylcyclop ropanecarboxylat e CAS: Cyano(3- phenoxyphenyl)m ethyl 2,2,3,3- tetramethylcyclop ropanecarboxylat e CAS No.: 39515- 41-8 Formula: C ₂₂ H ₂₃ NO ₃ MW: 349.4 g/mol SMILES: CC3(C)C(C(=O)O C(C#N)c2cccc(Oc Iccccc1)c2)C3(C) C	$ \begin{array}{c} \begin{array}{c} \begin{array}{c} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \\ \\ \end{array} $				
TRANSFORMATION PRODUCTS						
ТМРА	IUPAC: 2,2,3.3- Tetramethylcyclo propanecarboxylic		Aerobic soil Anaerobic soil	- 66.5 (210)	- 66.5 (210)	- 2730280
	acid Formula: C ₈ H ₁₄ O ₂		Soil phototransformation Aqueous	- 10.9 (0.66)	- 6.6 (1)	- 2730277

Designation	Chemical name	Chemical structure	Study	max %AR (day)	%AR at Study End (study length, day)	References (PMRA#)
	MW: 142.2 g/mol	H ₃ C CH ₃	phototransformation			
	SMILES: CC1(C([C@H]1C	\times	Hydrolysis (pH 9)	41.9 (21)	14.1 (30)	2730275
	(=0)0)(C)C)C	ОН	Aerobic aquatic	39.5 (61)	2.54 (152)	2730281
		н₃с́ Сн₃ ∭	Anaerobic aquatic	15.4 (244)	15.4 (244)	2730285 2730284
		0		83.7 (240)	83.6 (360)	2750204
~~~~			Field studies	-	-	-
CONH ₂ -	<b>IUPAC:</b> (RS)-α-		Aerobic soil	0.3 (181)	0.3 (181)	2730279
fenpropathrin	carbamoyl-3- phenoxybenzyl		Anaerobic soil	-	-	-
	2,2,3.3-		Soil phototransformation	5.6 (30)	5.6 (30)	2730276
	tetramethylcyclop ropanecarboxylate		Aqueous	6.5 (1)	6.5 (1)	2730277
	Formula:		Hydrolysis (pH 9)	<b>10.9</b> (21)	10 (30)	2730275
	C ₂₂ H ₂₅ NO ₄ MW: 367.4 g/mol		Aerobic aquatic	1.33 (91)	1.18 (152)	2730281
	SMILES:		Anaerobic aquatic	2.3 (244)	2.3 (244)	2730285
	[H][C@](OC(=O) [C@H]1C(C1(C)			1.27 (120)	0 (360)	2730284
	C(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)		Field studies	0.06 (1, 7)	0.01 (61–299)	2730299/
	c2cc(ccc2)Oc3cc ccc3					2730300
TMPe	2,2,3,3- Tetramethylcyclo propanecarboxami de	H ₃ C CH ₃ H ₃ C CH ₃ H ₃ C CH ₃ NH ₂	Aerobic soil	-	-	-
			Anaerobic soil	-	-	-
			Soil phototransformation	-	-	Ξ
	Formula:		Aqueous	-	-	-
	C ₈ H ₁₅ NO		phototransformation Hydrolysis (pH 9)	12.2 (30)	<b>12.2</b> (30)	2730275
	<b>MW:</b> 141.2 g/mol		Aerobic aquatic	4.89 (30)	0.57 (152)	2730281
	SMILES:		Anaerobic aquatic	-	-	-
	CC1(C([C@H]1C (=O)N)(C)C)C		Field studies	-	-	-
3-PBAld	IUPAC: 3-		Aerobic soil	-		-
	Phenoxybenzalde hyde CAS No.: 39515- 51-0 Formula: C ₁₃ H ₁₀ O ₂ MW: 198.2 g/mol SMILES: O=Cc(cc(Oc(cccc	H O O	Anaerobic soil	-	-	-
			Soil phototransformation	-	-	_
			Aqueous	4.0 (0.66)	0.8 (1)	2730277
			phototransformation Hydrolysis	_		
			Aerobic aquatic	0.99 (91)	0.16 (152)	2730281
			Anaerobic aquatic	0.99 (91)	0.10 (132)	2730281
	1)c1)cc2)c2		Field studies	-	-	-
2 DD 4	IUPAC: 3-		Aerobic soil	<b>31.8</b> (181)	<b>31.8</b> (181)	2730279
3-PBA	Phenoxybenzoic acid CAS No.: 3739-	но	Anaerobic soil	<b>50.1</b> (210)	<b>50.1</b> (210)	2730280
			Soil	(=10)	-	
	CAS No.: 3739- 38-6		phototransformation			
	Formula:		Aqueous phototransformation	<b>19.3</b> (1)	<b>19.3</b> (1)	2730277
			Hydrolysis (pH 9)	<b>62.4</b> (30)	<b>62.4</b> (30)	2730275
			Aerobic aquatic	<b>20.59</b> (91)	1.99 (152)	2730281
	OC(=0)c2cccc(0		Anaerobic aquatic	<b>16.1</b> (121)	ND (244)	2730285
	c1ccccc1)c2			<b>66.9</b> (270)	<b>66.9</b> (270)	2730283
			Field studies	-	-	-
4'-OH-	<b>IUPAC</b> : (RS)-α-		Aerobic soil	1 (30)	0 (181)	2730279
fenpropathrin	cyano-3-(4-		Anaerobic soil	4.7 (21)	0 (210)	2730280

Designation	Chemical name	Chemical structure	Study	max %AR (day)	%AR at Study End (study length, day)	References (PMRA#)
	hydroxyphenoxy) benzyl 2,2,3.3-	He cHa	Soil phototransformation	-	-	-
	tetramethylcyclop ropanecarboxylate		Aqueous phototransformation	0.6 (1)	0.6 (1)	2730277
	Formula: C ₂₂ H ₂₃ NO ₄		Hydrolysis	-	-	-
	MW: 365.42		Aerobic aquatic	<b>10.71</b> (30)	6.36 (152)	2730281
	g/mol SMILES:		Anaerobic aquatic	4.0 (244)	4.0 (244)	2730285
	[H][C@@](OC(= O)[C@H]1C(C1( C)C)(C)C)(c2cc(c cc2)Oc3ccc(cc3) O)C#N		Field studies	-	-	-
			Aerobic soil	-	-	-
Decarboxy	<b>IUPAC:</b> (2R)-2-		Anaerobic soil	-	-	-
fenpropathrin	(3- phenoxyphenyl)-		Soil phototransformation	-	-	Ξ
	2-(2,2,3,3- tetramethylcyclop ropyl)acetonitrile		Aqueous phototransformation Hydrolysis	<b>10.9</b> (1)	<b>10.9</b> (1)	2730277
	Formula:	$X \cap \cap$	Aerobic aquatic	4.47 (30)	3.12 (152)	2730281
	C ₂₁ H ₂₃ NO MW: 305.4 g/mol	H ₃ C CH ₃ H ^V CN	Anaerobic aquatic	5.0 (30)	3.94 (244)	2730285
<b>SMILES:</b> [H][C@](C#N)(c1 cccc(c1)Oc2cccc c2)C3C(C3(C)C)(	<b>SMILES:</b> [H][C@](C#N)(c1		Field studies	-	-	-
desphenyl-	<b>IUPAC:</b> (RS)-α-		Aerobic soil	0.7 (181)	0.7 (181)	2730279
fenpropathrin	cyano-3-		Anaerobic soil	-	-	_
	hydroxybenzyl 2,2,3.3- tetramethylcyclop		Soil phototransformation	-	-	-
	ropanecarboxylate Formula:	CH3 CH3	Aqueous phototransformation	0.1 (1)	0.1 (1)	2730277
	C ₁₆ H ₉ NO ₃	сн. Сосн. ОН	Hydrolysis	-	-	-
	MW: 273.3 g/mol SMILES:	CH3 O CN	Aerobic aquatic	4.76 (152)	4.76 (152)	2730281
	[H][C@@](OC(=	~	Anaerobic aquatic	-	-	-
	O)[C@H]1C(C1( C)C)(C)C)(c2cc(c cc2)O)C#N		Field studies	-	-	-
соон-	<b>IUPAC:</b> (RS)-α-		Aerobic soil	0.3 (14, 62)	0 (181)	2730279
fenpropathrin	carboxy-3- phenoxybenzyl	izyl	Anaerobic soil	-	-	-
	2,2,3.3- tetramethylcyclop		Soil phototransformation	-	-	-
	ropanecarboxylate Formula:		Aqueous phototransformation	3.5 (1)	3.5 (1)	2730277
	$C_{22}H_{24}O_5$	сна сна	Hydrolysis	-	-	-
	MW: 368.4 g/mol SMILES:	CH3-COCH- A A	Aerobic aquatic	0.63 (152)	0.63 (152)	2730281
	[H][C@](OC(=O) [C@H]1C(C1(C)	(C) ))O)	Anaerobic aquatic	0.4 (121) 0.6 (360)	ND (244) 0.6 (360)	2730285 2730284
	C)(C)C)(C(=O)O) c2cc(ccc2)Oc3cc ccc3		Field studies	-	-	-

Designation	Chemical name	Chemical structure	Study	max %AR (day)	%AR at Study End (study length, day)	References (PMRA#)
Carbon	IUPAC: Carbon		Aerobic soil	59.9 (365)	59.9 (365)	2730278
dioxide	dioxide Formula: CO ₂	o <u> </u>	Anaerobic soil	10.6 (210)	10.6 (210)	2730280
	MW: 44 g/mol SMILES:		Soil phototransformation	0.1 (30)	0.1 (30)	2730276
	C(=O)=O		Aqueous phototransformation	0.9 (1)	0.9 (1)	2730277
			Hydrolysis	-	-	-
			Aerobic aquatic	12.65 (152)	12.65 (152)	2730281
			Anaerobic aquatic	11.7 (244)	11.7 (244)	2730285
			Field studies	-	-	-

*Bold numbers indicate major transformation products (>10%); Ref: PMRA# 2730211.

#### Table 12Toxicity to Non-Target Terrestrial Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
Invertebrates	·		·	·	
Earthworm Eisenia fetida	28-day Acute, 56- ayd Chronic, artificial soil	fenpropathrin T.G (91.7% w/w)	28-d LC ₅₀ >400 mg, 56- d NOEC (reproduction) = 25 mg Technical Grade Active Ingredient/kg soil dw (nominal)	n/a	2730303
Predatory mite, <i>Typhlodromus</i> <i>pyri</i>	7-day Acute and Chronic, glass plates	Danitol 2.4 EC Spray (31.0% a.i.w/w)	7-day $LR_{50} = 5.24 \text{ mg}$ a.i./ha, 14-day NOER (reproduction) = 1.56 mg a.i./ha (nominal)	n/a	2730308
	7-day Acute and Chronic, extended spray residues on plant surfaces		7-day $LR_{50} = 31.6 \text{ mg}$ a.i./ha, 14-day $ER_{50}$ (reproduction) > 40.8 mg a.i./ha (nominal)	n/a	2730309
Parasitoid, Aphidius rhopalosiphi	48-h Acute and Chronic, glass plates	Danitol 2.4 EC Spray (31.0% a.i.w/w)	48-h LR ₅₀ = 7.57 g a.i./ha, 14-day NOER = 6.32 g a.i./ha (nominal)	n/a	2730311
	48-h Acute and Chronic, extended spray residues on plant surfaces		$\begin{array}{l} \mbox{48-h LR}_{50} = 242 \ g \\ a.i./ha, \\ 14\mbox{-day ER}_{50} \\ (reproduction) > 179.2 \\ g \ a.i./ha \ (nominal) \end{array}$	n/a	2730310
Honeybee (Apis	48-h Acute Oral	Fenpropathrin (purity: 91.7%	48-h LD ₅₀ = $0.055 \ \mu g$ a.i./bee (nominal)	Highly toxic	2730305
mellifera)	48-h Acute Contact	a.i.w/w)	48-h $LD_{50} = 0.051 \ \mu g$ a.i./bee (nominal)	Highly toxic	2730305

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
	96-h Acute larva	Fenpropathrin (purity: 91.7% a.i.w/w)	96-h LD ₅₀ = 0.16 μg a.i./larva, 96-h NOEL = 0.037 μg a.i./larva (nominal)	Highly toxic	2730306
	Acute, Foliar residue	Danitol 2.4 EC (purity: 31% a.i. w/w)	$RT_{25}^{b} = 35 h$ (Appl. rate of 448 g a.i./ha)	n/a	2730304
	Acute, Foliar residue	Fenpropathrin (Appl. rate of 60 g a.i./ha)	The Daily flower hazard of was determined to 128.18 23.19, 8.24, 3.58 and 1.17 7, 10 and 14 days of treat	3, 96.48, 32.91, 7 after 0, 1, 3, 5,	3064229
	Chronic larva	Fenpropathrin (purity: 91.7% a.i.w/w)	8-day NOED = 0.28 μg a.i./larva (larval survival) 22-day NOED = 1.6 μg a.i./larva (pupal survival) 22-day NOED = 0.78 μg a.i./larva (adult emergence) (measured)	n/a	2730307
	Chronic adult 10- day oral	Fenpropathrin (purity: 91.7% a.i.w/w)	10-day NOED = 0.015 μg a.i./bee/day (measured)	n/a	2730312
Birds Zebra finch, <i>Taeniopygia</i> guttata	Acute oral	Fenpropathrin (purity: 91.7% a.i.w/w)	14-d LD ₅₀ > 70 mg a.i./kg-bw (nominal) Note: Birds regurgitated food in all dose groups	Non-toxic at highest tested dose	2730352
Bobwhite 5-day Dietary quail, <i>Colinus</i> <i>virginianus</i>	5-day Dietary	SD 41706 (purity: 89% a.i.w/w)	5-d LD ₅₀ > 1000 mg a.i./kg bw/day (> 10 000 mg a.i./kg diet) (not corrected for purity)	Practically non-toxic	2730353
	21-w Reproduction	SD 41706 or S- 3206 (purity: 89% a.i.w/w) Danitol T.G (purity: 91.9% a.i.w/w) Fenpropathrin Technical (purity: 90% a.i.w/w)	21-d NOEC = 2.0 mg a.i./kg dw diet (highest tested dose) 21-w NOEC = 109.0 mg a.i./kg dw diet (measured) 21-w NOEL = 1.94 mg a.i./kg bw/day (cracked eggs)	n/a	2730355 2730356 2730357
		90% a.i.w/w)	(22.5 mg a.i./kg dw diet)		

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
			21-w LOEL = 9.7 mg a.i./kg bw/day		
			(112.5 mg a.i./kg dw diet) (not corrected for purity)		
Mallard duck, <i>Anas</i>	Acute oral	SD 41706 (purity: 89%	$14-d LD_{50} = 1089 mg$ a.i./kg bw	Slightly toxic	2730351
platyrhynchos	5-day Dietary	a.i.w/w)	LD ₅₀ : 979 mg a.i./kg bw/day	Moderately toxic	2730354
	21-w Reproduction	SD 41706 (purity: 89%	(4640 mg a.i./kg diet) 21-w NOEC = 2.0 mg a.i./kg dw diet (highest	n/a	2730358
		a.i.w/w) Fenpropathrin	tested dose: no effects) (0.24 mg a.i./kg bw/day) 21-w NOEC = 12.08		2730359
		Technical (purity: 90% a.i.w/w)	mg a.i./kg bw/day (embryo viability) (125 mg a.i./kg dw diet)		
			21-w LOEL = 48.32 mg a.i./kg bw/day (500 mg a.i./kg dw diet) (not corrected for purity)		
Mammals			punty)		
Rat, Sprague- Dawley	Acute	S-3206 (purity: 91.8% a.i.w/w)	14-d $LD_{50} = 67 \text{ mg}$ a.i./kg-bw (female)	Moderately toxic	1782547
Rat	2-generation reproductive toxicity study	S-3206 (purity: 91.8% a.i.w/w)	NOAEL ( $F_{1, /o}$ offspring) = 2.6/3.1 mg a.i./kg bw/day (measured) (based on body tremors and mortality in females an decreased body weights in males and females and pup viability) LOAEL = 7.79 mg a.i./kg bw/ day (mortality)	n/a	1782565
Rat	Developmental toxicity study	S-3206 (purity: 91.9% a.i.w/w)	NOAEL = 3.3 mg a.i./kg bw/day (nominal) (incomplete	n/a	1782570

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
			ossification in fetuses)		
Vascular plants			·	·	•
Vascular plant,	14-day Seedling	Danitol 2.4 EC	ER ₂₅ = 448 g a.i./ha	n/a	2730364
10 species	emergence/ryegrass	Spray (purity:			
	14-day Vegetative	31.4% a.i.w/w)	ER ₂₅ > 392 g a.i./ha	n/a	2730365
	vigour/tomato				
			s, where applicable; $n/a = not a$ ance and bring the test organis		to 25%

#### Table 13 Screening Level Risk Assessment on Non-Target Species

Organism	Exposure	Endpoint Value	EEC ^a	RQ	Level of Concern exeeded?
Invertebrates					
Earthworm	28-d acute	LC ₅₀ /2 > 200 mg a.i./kg soil	0.396 mg a.i./kg soil	<0.002	No
	56-d chronic	NOEC = 25 mg a.i./kg soil	0.396 mg a.i./kg soil	0.016	No
Bee adult	48-h contact	$LD_{50} = 0.051$ µg a.i./bee	$0.448 \text{ kg a.i/ha} \times 2.4 \mu\text{g}$ a.i./bee per kg/ha = 1.075 $\mu\text{g}$ a.i./bee	21	Yes
	48-h oral	LD ₅₀ =0.055 µg a.i./bee	0.448 kg a.i./ha $\times$ 29 µg a.i./bee per kg/ha = 12.992 µg a.i./bee	236	Yes
	10-d chronic	NOEL = 0.015 µg a.i./bee/day	0.448 kg a.i./ha $\times$ 29 µg a.i./bee per kg/ha = 12.992 µg a.i./bee	866	Yes
Bee larva	96-h acute	LD ₅₀ =0.16 µg a.i./bee	$0.448 \text{ kg a.i./ha} \times 12 \mu \text{g}$ a.i./bee per kg/ha = $3.376 \mu \text{g}$ a.i./bee	33	Yes
	8-d chronic (survival)	NOED = 0.28 µg a.i./bee/day	$0.448 \text{ kg a.i./ha} \times 12 \mu \text{g}$ a.i./bee per kg/ha = 5.376 $\mu$ g a.i./bee	19	Yes
	22-d chronic (pupal survival)	NOED = 1.6 µg a.i./bee/day	0.448 kg a.i./ha $\times$ 12 µg a.i./bee per kg/ha = 5.376 µg a.i./bee	3.4	Yes
	22-d chronic (adult emergence)	NOED = 0.78 µg a.i./bee/day	0.448 kg a.i./ha $\times$ 12 µg a.i./bee per kg/ha = 5.376 µg a.i./bee	6.9	Yes
Predatory arthropod, <i>Typhlodromus</i> <i>pyri</i>	7-d acute contact, glass plate	LR ₅₀ = 0.00524 g a.i./ha	In-field: ground application, cumulative rate: 627.75 g a.i./ha	In-field > $1.1 \times 10^5$ Off-field	Yes
руп			Off-field : ground application,medium droplets, 6% of rate: 37.6 g a.i./ha	$> 7.1 \times 10^{3}$ > 6.3 × 10 ⁴ > 5 × 10 ⁴	

Organism	Exposure	Endpoint Value	EEC ^a	RQ	Level of Concern exeeded?
	7-d acute, extended spray residues	LR ₅₀ = 0.0316 g a.i./ha	Off-field : airblast application (single application ^d ), fine droplets, early season 74% of rate: 331.5 g a.i./ha Off-field : airblast application		Yes
arthropod, c Aphidius p rhopalosiphi 4 e	48-h acute contact, glass plate	LR ₅₀ =7.57 g a.i./ha	(single application), fine droplets, late season	In-field 83 Off-field 5.0 43.8 35	Yes
	48-h acute, extended spray residues	LR ₅₀ =242 g a.i./ha		In-field 2.6 Off-field 0.15 1.3 1.09	Yes (except for off-field ground application)
Vascular plant		1	1	1	
Vascular plants 10 species	21-d seedling emergence	$ER_{25} = 448 g$ a.i./ha	In-field: 224 + 336 + 336 g a.i./ha Cumulative rate of 890.6 g a.i./ha	1.99	Yes ^b
			Off-field (ground appl., 6% drift): 53.4 g a.i./ha	0.12	No
			Airblast application (single application), early season	0.74	
			(74%): 331.5 g a.i./ha Airblast application (single application), late season (59%):264.3 g a.i./ha	0.59	
	21-d vegetative vigour	$ER_{25} > 392 g$ a.i./ha	In-field: 224 + 336 + 336 g a.i./ha Cumulative rate of 627.75 g a.i./ha	< 1.6	Yes ^c
			Off-field (ground appl., 6% drift): 37.6 g a.i./ha	< 0.10	No
			Airblast application (single application), early season	< 0.84	
			(74%): 331.5 g a.i./ha Airblast application (single application), late season (59%):264.3 g a.i./ha	< 0.67	

The cumulative rate of 890.6 g a.1./ha (224 + 336 + 336 g a.1./ha with a 7-day interval and 701 days soil half-life). "The cumulative rate of 627.75 g a.i./ha (224 + 336 + 336 g a.i./ha with a 7-day interval and 10 days foliar dissipation). LOC of 0.4 and 1.0 for acute and chronic pollinator risk assessment, respectively. ^dSingle airblast application at 448 g a.i./ha. Terrestrial plants off-field assessment for airblast considers  $1 \times 448$  g a.i./ha application rate, and for ground considers 224 + 336 + 336 g

Terrestrial plants off-field assessment for airblast considers  $1 \times 448$  g a.i./ha application rate, and for ground considers 224 + 336 + 33 a.i./ha application rate.

### Table 14Tier I Refined Risk Assessment of Fenpropathrin for Adult and Larval Bees,<br/>Foliar Application at a Rate of 60 g a.i./ha

Floral residue	Acute RQ+			Chronic RQ++				
(ppb)	Adult bee		Larval bee	Adult bee		Larval bee		
	Nurse bee	Nectar	Nurse bee	Nurse bee	Nectar	Nurse bee		
		forager			forager			
Day 0: 6409	18.8	36.7	4.95	63.9	125	1.02		
Day 3: 1646	4.83	9.43	1.27	16.4	32.1	0.26		
Day 7: 412	1.21	2.36	0.32	4.11	8.02	0.07		
Day 14: 58.7	0.17	0.34	0.05	0.59	1.14	0.01		
Note: Adult bee endpoints: acute oral: 0.051 µg a.i./bee; chronic oral: 0.015 µg a.i./bee; Larval bee endpoints: acute oral: 0.160 µg								
a.i./larvae; chronic ora	a.i./larvae; chronic oral: 0.780 µg a.i./bee							
+ acute LOC is 0.4								

++ chronic LOC is 1.0

Shaded cells indicate RQ exceeds the LOC (level of concern)

### Table 15Refined Risk Assessment of Fenpropathrin for Beneficial Arthropods from<br/>Drift Using a Vegetation Distribution Factor

Сгор	Application rate (g a.i./ha), method of application and maximum number of application per season and drift percentage	Refined off-field EEC with drift (g a.i./ha) (considering a 10 d half-life) and vegetation distribution factor of 0.10	LC ₅₀ and NOER values	RQ (Level of concern)
		2.8 Lowest rate	48 hr glass: Predatory mite LR ₅₀ : 0.0052 g a.i./ha (dead + escapees)	538 ( <b>Yes</b> )
Bushberry (Crop Subgroup 13- 07B) and Caneberry (Crop Subgroup 13- 07A)	224-336 Ground equipment 2 (14 d interval) Medium (6%)		48 hr glass: Predatory mite LR ₅₀ : 0.0089 g a.i./ha (dead + escapees) Extended spray residue: Predator reproduction: $> 0.041$ g a.i./ha ( Extended spray residue: Predatory mite LR ₅₀ : 0.00316 g a.i./ha 48 hr glass: Parasitoid wasp LR ₅₀ : 7.57 g a.i./ha Extended spray residue: parasitoid wasp LR ₅₀ : 242 g a.i./ha Extended spray residue: Parasito	0.37 (No) 0.01 (No)
Pome fruit (Crop Group 11-09)	448 Ground with airblast equipment	Late season airblast: 26.4	reproduction: > 179.2 g a.i./ha ( 48 hr glass: Predatory mite $LR_{50}$ : 0.0052 g a.i./ha (dead + escapees)	
Stone Fruit (Crop Group 12-09)	Late airblast 59% Early airblast	Early season airblast: 33.1	48 hr glass: Predatory mite LR ₅₀ : 0.0089 g a.i./ha (dead + escapees)	Late airblast: 2966 ( <b>Yes</b> ) Early airblast: 3719 ( <b>Yes</b> )

Сгор	Application rate (g a.i./ha), method of application and maximum number of application per season and drift percentage	Refined off-field EEC with drift (g a.i./ha) (considering a 10 d half-life) and vegetation distribution factor of 0.10	LC ₅₀ and NOER values	RQ (Level of concern)
Tree nuts (Crop Group	74%		Extended spray residue: Predator reproduction: > 0.041g a.i./ha (r	
14-11)			Extended spray residue: Predatory mite LR ₅₀ : 0.00316 g a.i./ha	Late airblast: 8354 ( <b>Yes</b> ) Early airblast: 10474 ( <b>Yes</b> )
			48 hr glass: Parasitoid wasp LR ₅₀ : 7.57 g a.i./ha	Late airblast: 3.5 ( <b>Yes</b> ) Early airblast: 4.4 ( <b>Yes</b> )
			Extended spray residue: Parasitoid wasp LR ₅₀ : 242 g a.i./ha	Late airblast: 0.10 (No) Early airblast: 0.14 (No)
			Extended spray residue: Parasite reproduction: > 179.2 g a.i./ha (	
vegetation distribu habitat structure. N be appropriate base	tion factor of 0.10 is applied since the fost of the drift would be intercepted ed on data presented at the ESCORT	e drift values overestimate by the top or side portions workshop. Refined EEC =	default of 10 half-life. For the off-field $e_{XJ}$ drift to the lower or interior portions of a s of the habitat structure. This default value Off-field EEC (with drift) $\times$ 0.1. , and for ground considers 224 + 336 + 33	three-dimensional e was estimated to

# Table 16Screening Level Risk Assessment of Fenpropathrin for Birds and Mammals,<br/>Foliar Application at Multiple Rates of 224 + 336 + 336 g a.i./ha and 7-day<br/>Interval

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE* (mg a.i./kg bw)	RQ			
Small Bird (0.02 kg)		-	-	_			
Acute	108.90	Insectivore	51.10	0.47			
Reproduction	1.94	Insectivore	51.10	26.3			
Medium Sized Bird (0.1 k	xg)		•				
Acute	108.90	Insectivore	39.88	0.37			
Reproduction	1.94	Insectivore	39.88	20.6			
Large Sized Bird (1 kg)							
Acute	108.90	Herbivore (short grass)	25.76	0.24			
Reproduction	1.94	Herbivore (short grass)	25.76	13.3			
Small Mammal (0.015 kg)							
Acute	6.70	Insectivore	29.39	4.39			
Reproduction	2.60	Insectivore	29.39	11.3			

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE* (mg a.i./kg bw)	RQ		
Medium Sized Mammal (	0.035 kg)	Insectivore				
Acute	6.70	Herbivore (short grass)	57.00	8.51		
Reproduction	2.60	Herbivore (short grass)	57.00	21.9		
Large Sized Mammal (1 l	ĸg		-	-		
Acute	6.70	Herbivore (short grass)	30.46	4.55		
Reproduction	2.60	Herbivore (short grass)	30.46	11.7		
Reproduction2.60Herbivore (short grass)30.4611.7*EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/bw) × EEC, where: FIR: Food Ingestion Rate. For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight grater than 200 g, the "all birds" equation was used: Passerine Equation (body weight < or = 200 g): FIR (g dry weight/day) = 0.398(bw in g)^{0.850} All birds Equation (body weight >200 g): FIR (g dry weight/day) = 0.648 (bw in g) 0.651 For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235(bw in g)^{0.822} bw: Generic Body Weight EEC: Concentration of pesticide on food item. At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used. Shaded cells indicate RQ exceeds the LOC (level of concern)30.4611.7						

# Table 17Refined Avian Risk Assessment Using Maximum and Mean Fenpropathrin<br/>Residue Values on the Highest Crop Application Rate (considering 74% drift<br/>at application rate of 1 × 448 g a.i./ha and 6% drift at application rate of 224<br/>+ 336 + 336 g a.i./ha and 7-day interval)

			Ma	ximum no	mogram residu	ies	ľ	Mean nom	ogram residu	ies
			On-f	ïeld	Off-fi	eld	On-f	field	Off	-field
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ for 74% drift (RQ for 6% drift)
Small Bird (	0.02 kg)						-			
	108.90	Insectivore	36.5	0.3	26.9	0.2	25.2	0.23	18.6	0.17
Acute	108.90	Granivore (grain and seeds)	5.64	0.1	4.18	0.0	2.69	0.02	1.99	0.02
	108.90	Frugivore (fruit)	11.3	0.1	8.35	0.1	5.38	0.05	3.98	0.04
	97.90	Insectivore	36.5	0.4	26.9	0.3	25.2	0.26	18.6	0.19
Dietary	97.90	Granivore (grain and seeds)	5.64	0.1	4.18	0.0	2.69	0.03	1.99	0.02
	97.90	Frugivore (fruit)	11.3	0.1	8.35	0.1	5.38	0.05	3.98	0.04
	1.94	Insectivore	36.5	18.8	26.9	13.9	25.2	12.9	18.6	9.60 (1.0)
Reproducti on	1.94	Granivore (grain and seeds)	5.64	2.9	4.18	2.2	2.69	1.39	1.99	1.0
	1.94	Frugivore (fruit)	11.3	5.8	8.35	4.3	5.38	2.77	3.98	2.05 (0.23)

			Ma	ximum no	mogram residu	ies	]	Mean nom	ogram residu	ies
			On-f	ïeld	Off-fi	eld	On-	field	Off	field
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ for 74% drift (RQ for 6% drift)
Medium Siz	ed Bird (0.1 l	kg)	-	-	-	-	-	-	-	-
	108.90	Insectivore	28.5	0.3	21.1	0.2	19.6	0.18	14.5	0.13
Acute	108.90	Granivore (grain and seeds)	4.40	0.0	3.26	0.0	2.10	0.02	1.55	0.01
	108.90	Frugivore (fruit)	8.81	0.1	6.52	0.1	4.20	0.04	3.11	0.03
	97.90	Insectivore	28.5	0.3	21.1	0.2	19.65	0.20	14.5	0.15
Dietary	97.90	Granivore (grain and seeds)	4.40	0.0	3.26	0.0	2.10	0.02	1.55	0.02
	97.90	Frugivore (fruit)	8.81	0.1	6.52	0.1	4.20	0.04	3.11	0.03
	1.94	Insectivore	28.5	14.7	21.1	10.9	19.65	10.13	14.54	7.50 (0.85)
Reproducti on	1.94	Granivore (grain and seeds)	4.40	2.3	3.26	1.7	2.10	1.08	1.55	0.80
	1.94	Frugivore (fruit)	8.81	4.5	6.52	3.4	4.20	2.17	3.11	1.60 (0.18)
Large Sized	Bird (1 kg)	(inuit)								(0.10)
	108.90	Insectivore	8.31	0.1	6.15	0.1	5.74	0.05	4.25	0.04
	108.90	Granivore (grain and seeds)	1.29	0.0	0.95	0.0	5.74	0.05	0.45	0.00
Acute	108.90	Frugivore (fruit)	2.57	0.0	1.90	0.0	1.23	0.01	0.91	0.01
	108.90	Herbivore (short grass)	18.4	0.2	13.6	0.1	6.53	0.06	4.83	0.04
	108.90	Herbivore (long grass)	11.2	0.1	8.31	0.1	3.66	0.03	2.71	0.02
	108.90	Herbivore (Broadleaf	17.0	0.2	12.6	0.1	5.62	0.05	4.16	0.04
	97.90	plants) Insectivore	8.31	0.1	6.15	0.1	5.74	0.06	4.25	0.04
D	97.90	Granivore (grain and seeds)	1.29	0.0	0.95	0.0	5.74	0.06	0.45	0.00
Dietary	97.90	Frugivore (fruit)	2.57	0.0	1.90	0.0	1.23	0.01	0.91	0.01
	97.90	Herbivore (short grass)	18.4	0.2	13.6	0.1	6.53	0.07	4.83	0.05
	97.90	Herbivore (long grass)	11.2	0.1	8.31	0.1	3.66	0.04	2.71	0.03
	97.90	Herbivore (Broadleaf plants)	17.0	0.2	12.6	0.1	5.62	0.06	4.16	0.04
Reproducti	1.94	Insectivore	8.31	4.3	6.15	3.2	5.74	2.96	4.25	2.19 (0.25)
on	1.94	Granivore (grain and seeds)	1.29	0.7	0.95	0.5	5.74	2.96	0.45	0.23
	1.94	Frugivore (fruit)	2.57	1.3	1.90	1.0	1.23	0.63	0.91	0.47
	1.94	Herbivore (short grass)	18.4	9.5	13.6	7.0	6.53	3.37	4.83	2.49 (0.28)

		Ma	ximum noı	nogram residu	es	Mean nomogram residues				
		On-f	ield	Off-fie	eld	On-fi	ield	Off-field		
Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ for 74% drift (RQ for 6% drift)	
1.94	Herbivore (long grass)	11.2	5.8	8.31	4.3	3.66	1.89	2.71	1.40 (0.16)	
1.94	Herbivore (Broadleaf plants)	17.0	8.8	12.6	6.5	5.62	2.90	4.16	2.14 (0.24)	

Note: shaded cells indicate RQ exceeds the LOC (level of concern)

### Table 18Avian Risk Based On LOEL Values for Reproduction (considering 74 and<br/>6% drift)

			Maximu	m nomogi	am residue:	5	Mean no	mogram re	esidues		
			On-field		Off-field		On-field		Off-field	l	
	Toxici ty (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ 74% drift	RQ 6% drift
Small Bird (	0.02 kg)					•		•	·		·
Reproducti on	9.70	Insectivor e	36.5	3.76	26.9	2.78	25.2	2.60	18.6	1.92	0.22
	9.70	Granivore (grain and seeds)	5.64	0.58	4.18	0.43	2.69	0.28	1.99	0.21	0.02
	9.70	Frugivore (fruit)	11.29	1.16	8.35	0.86	5.38	0.55	3.98	0.41	0.05
Medium Size	ed Bird (0	.1 kg)									
Reproducti on	9.70	Insectivor e	28.46	2.93	21.06	2.17	19.65	2.03	14.54	1.50	0.17
	9.70	Granivore (grain and seeds)	4.40	0.45	3.26	0.34	2.10	0.22	1.55	0.16	0.02
	9.70	Frugivore (fruit)	8.81	0.91	6.52	0.67	4.20	0.43	3.11	0.32	0.04
Large Sized	Bird (1 kg	g)	•	•			•		•		
Reproducti on	9.70	Insectivor e	8.31	0.86	6.15	0.63	5.74	0.59	4.25	0.44	0.05
	9.70	Granivore (grain and seeds)	1.29	0.13	0.95	0.10	5.74	0.59	0.45	0.05	0.01
	9.70	Frugivore (fruit)	2.57	0.27	1.90	0.20	1.23	0.13	0.91	0.09	0.01
	9.70	Herbivore (short grass)	18.38	1.90	13.60	1.40	6.53	0.67	4.83	0.50	0.06
	9.70	Herbivore (long grass)	11.22	1.16	8.31	0.86	3.66	0.38	2.71	0.28	0.03

		Maximu	m nomogr	am residues		Mean nor	nogram re	esidues	sidues			
		On-field		Off-field		On-field		Off-field				
Toxici ty (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ 74% drift	RQ 6% drift		
9.70	Herbivore (forage crops)	17.01	1.75	12.59	1.30	5.62	0.58	4.16	0.43	0.05		

### Table 19aRefined Avian Risk Assessment Using Mean Residue and LOEL Values<br/>(74% drift)

			On-fiel	d		Off-field	
Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC
		Smal	ll birds (20	g)			
Reproduction	Insectivore (small insects)	25.18	2.60	38	18.63	1.92	52
9.7 mg a.i./kg bw/d	Granivore (grain and seeds)	2.69	0.28	-	1.99	0.21	-
	Frugivore (fruit)	5.38	0.55	-	3.98	0.41	-
		Medium s	sized birds	(100 g)			
Reproduction	Insectivore	19.65	2.03	49	14.54	1.50	67
9.7 mg a.i./kg bw/d	Granivore (grain and seeds)	2.10	0.22	-	1.55	0.16	-
bw/d	Frugivore (fruit)	4.20	0.43	-	3.11	0.32	-
		Large	birds (1000	) g)			-
Reproduction	Insectivore	5.74	0.59	-	4.25	0.44	-
9.7 mg a.i./kg bw/d	Granivore (grain and seeds)	5.74	0.59	-	0.45	0.05	-
	Frugivore (fruit)	1.23	0.13	-	0.91	0.09	-
	Herbivore (short grass)	6.53	0.67	-	4.83	0.50	-
	Herbivore (long grass)	3.66	0.38	-	2.71	0.28	-
	Herbivore (forage crops)	5.62	0.58	-	4.16	0.43	-

### Table 19bRefined Avian Risk Assessment Using Mean Residue and LOEL Values (6%<br/>drift)

			On-fiel	1	Off-field			
Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC	
		Smal	ll birds (20	g)				
Reproduction	Insectivore (small insects)	35.28	3.64	28	2.12	0.22	-	
9.7 mg a.i./kg	Granivore (grain and seeds)	3.77	0.39	-	0.23	0.02	-	

			On-fiel	d		Off-field	
Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC
bw/d	Frugivore (fruit)	7.54	0.78	-	0.45	0.05	-
		Medium s	sized birds	(100 g)			
Reproduction	Insectivore	27.53	2.84	35	1.65	0.17	-
9.7 mg a.i./kg bw/d	Granivore (grain and seeds)	2.94	0.30	-	0.18	0.02	-
bw/d	Frugivore (fruit)	5.89	0.61	-	0.35	0.04	-
		Large	birds (100	) g)	-	-	
Reproduction	Insectivore	8.04	0.83	-	0.48	0.05	-
9.7 mg a.i./kg bw/d	Granivore (grain and seeds)	8.04	0.83	-	0.05	0.01	-
	Frugivore (fruit)	1.72	0.18	-	0.10	0.01	-
	Herbivore (short grass)	9.15	0.94	-	0.55	0.06	-
	Herbivore (long grass)	5.14	0.53	-	0.31	0.03	-
	Herbivore (forage crops)	7.88	0.81	-	0.47	0.05	-

Table 20Refined Mammalian Risk Assessment Using Maximum and Mean<br/>Fenpropathrin Residue Values on the Highest Crop Application Rate<br/>(considering 74% drift at application rate of 1 × 448 g a.i./ha and 6% drift at<br/>application rate of 224 + 336 + 336 g a.i./ha and 7-day interval)

			Maximum	nomogra	m residues		Mean no	omogram re	sidues	
			On-field		Off-field		On-field		Off-field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ for 74% drift (RQ for 6% drift)
Small Mamma	nl (0.015 kg)		-	-	-	-	-	-	-	-
	6.70	Insectivore	20.97	3.13	15.5	2.32	14.48	2.16	10.7	1.60 (0.18)
Acute	6.70	Granivore (grain and seeds)	3.25	0.48	2.40	0.359	1.55	0.231	1.15	0.171
	6.70	Frugivore (fruit)	6.49	0.969	4.80	0.717	3.10	0.462	2.29	0.342
	2.60	Insectivore	20.97	8.07	15.5	5.97	14.48	5.57	10.7	4.12 (0.46)
Reproduction	2.60	Granivore (grain and seeds)	3.25	1.25	2.40	0.923	1.55	0.59	1.15	0.440
	2.60	Frugivore (fruit)	6.49	2.49	4.80	1.85	3.10	1.19	2.29	0.881 (0.10)
Medium Sized	Mammal (0.03	35 kg)								
Acute	6.70	Insectivore	18.39	2.74	13.6	2.03	12.70	1.89	9.39	1.40 (0.15)
	6.70	Granivore (grain and	2.85	0.425	2.11	0.31	1.36	0.203	1.00	0.150

			Maximum	1 nomogra	m residues		Mean nomogram residues				
			On-field		Off-field		On-field	l	Off-field		
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ for 74% drift (RQ for 6% drift)	
		seeds)									
	6.70	Frugivore (fruit)	5.69	0.849	4.21	0.628	2.71	0.405	2.01	0.299	
	6.70	Herbivore (short grass)	40.68	6.07	30.1	4.49	14.45	2.16	10.7	1.60 (0.18)	
	6.70	Herbivore (long grass)	24.84	3.70	18.4	2.74	8.11	1.21	6.00	0.896 (0.10)	
	6.70	Herbivore (forage crops)	37.64	5.62	27.9	4.16	12.44	1.86	9.21	1.3741 (0.15)	
	2.60	Insectivore	18.39	7.07	13.6	5.23	12.70	4.89	9.39	3.61 (0.41)	
	2.60	Granivore (grain and seeds)	2.85	1.09	2.11	0.810	1.36	0.521	1.00	0.386	
Reproduction	2.60	Frugivore (fruit)	5.69	2.19	4.21	1.62	2.71	1.04	2.01	0.773 (0.08)	
	2.60	Herbivore (short grass)	40.68	15.6	30.1	11.6	14.45	5.56	10.7	4.11 (0.46)	
	2.60	Herbivore (long grass)	24.84	9.55	18.38	7.07	8.11	3.12	6.00	2.31 (0.26)	
	2.60	Herbivore (Broadleaf plants)	37.64	14.5	27.9	10.7	12.44	4.79	9.21	3.54 (0.40)	
Large Sized M	lammal (1 kg)	plants)									
	6.70	Insectivore	9.82	1.46	7.27	1.09	6.78	1.01	5.02	0.749	
	6.70	Granivore (grain and seeds)	1.52	0.227	1.13	0.168	0.73	0.108	0.54	(0.08) 0.080	
Acute	6.70	Frugivore (fruit)	3.04	0.453	2.25	0.336	1.45	0.216	1.07	0.160	
	6.70	Herbivore (short grass)	21.74	3.24	16.1	2.40	7.72	1.15	5.71	0.8523 (0.09)	
	6.70	Herbivore (long grass)	13.27	1.98	9.82	1.47	4.33	0.647	3.21	0.479	
	6.70	Herbivore (Broadleaf plants)	20.11	3.00	14.9	2.22	6.65	0.992	4.92	0.734 (0.08)	

			Maximum	nomogran	n residues		Mean no	mogram res	idues	
			On-field		Off-field		On-field		Off-field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ for 74% drift (RQ for 6% drift)
	2.60	Insectivore	9.82	3.78	7.27	2.80	6.78	2.61	5.02	1.93 (0.21)
	2.60	Granivore (grain and seeds)	1.52	0.58	1.13	0.432	0.73	0.279	0.54	0.2064
Reproduction	2.60	Frugivore (fruit)	3.04	1.17	2.25	0.865	1.45	0.558	1.07	0.413
	2.60	Herbivore (short grass)	21.74	8.36	16.1	6.19	7.72	2.97	5.71	2.197 (0.24)
	2.60	Herbivore (long grass)	13.27	5.10	9.82	3.77	4.33	1.67	3.21	1.23 (0.14)
	2.60	Herbivore (Broadleaf plants)	20.11	7.73	14.9	5.72	6.65	2.56	4.92	1.89 (0.21)

Note: shaded cells indicate RQ exceeds the LOC (level of concern)

### Table 21Mammalian Risk Based on LOEL Values for Reproduction (74 and 6%<br/>drift)

			Maximun	n nomograr	n residues		Mean no	mogram re	esidues		
			On-field		Off-field		On-field		Off-field	1	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ 74% drift	RQ 6% drift
Small Mam	mal (0.015 k	g)									
Acute	6.70	Insectivore	20.9	3.13	15.5	2.32	14.5	2.16	10.7	1.60	0.18
	6.70	Granivore (grain and seeds)	3.25	0.48	2.40	0.36	1.55	0.23	1.15	0.17	0.02
	6.70	Frugivore (fruit)	6.49	0.97	4.80	0.72	3.10	0.46	2.29	0.34	0.04
Reproducti	7.80	Insectivore	20.9	2.69	15.5	1.99	14.5	1.86	10.7	1.37	0.16
on	7.80	Granivore (grain and seeds)	3.25	0.42	2.40	0.31	1.55	0.20	1.15	0.15	0.02
	7.80	Frugivore (fruit)	6.49	0.83	4.80	0.62	3.10	0.40	2.29	0.29	0.03
Medium Siz	ed Mammal	(0.035 kg)	•	•		•	•	•	•		
Acute	6.70	Insectivore	18.4	2.74	13.6	2.03	12.7	1.89	9.39	1.40	0.16
	6.70	Granivore (grain and seeds)	2.85	0.42	2.11	0.31	1.36	0.20	1.00	0.15	0.02
	6.70	Frugivore (fruit)	5.69	0.85	4.21	0.63	2.71	0.41	2.01	0.30	0.03
	6.70	Herbivore (short grass)	40.7	6.07	30.1	4.49	14.5	2.16	10.7	1.60	0.18

			Maximur	n nomograr	n residues		Mean no	mogram re	esidues				
			On-field		Off-field		On-field		Off-field	1			
	Toxicity (mg a.i./kg bw/d)	(mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ 74% drift	RQ 6% drift	
	6.70	Herbivore (long grass)	24.8	3.71	18.4	2.74	8.11	1.21	6.00	0.90	0.10		
	6.70	Herbivore (forage crops)	37.6	5.62	27.9	4.16	12.4	1.86	9.21	1.37	0.16		
Reproducti	7.80	Insectivore	18.4	2.36	13.6	1.74	12.7	1.63	9.39	1.20	0.14		
on	7.80	Granivore (grain and seeds)	2.85	0.36	2.11	0.27	1.36	0.17	1.00	0.13	0.01		
	7.80	Frugivore (fruit)	5.69	0.73	4.21	0.54	2.71	0.35	2.01	0.26	0.03		
7.80	7.80	Herbivore (short grass)	40.7	5.22	30.1	3.86	14.5	1.85	10.69	1.37	0.16		
	7.80	Herbivore (long grass)	24.84	3.18	18.4	2.36	8.11	1.04	6.00	0.77	0.09		
7.	7.80	Herbivore (forage crops)	37.64	4.83	27.9	3.57	12.4	1.60	9.21	1.18	0.13		
Large Sized	Mammal (1												
Acute	6.70	Insectivore	9.82	1.47	7.27	1.09	6.78	1.01	5.02	0.75	0.09		
	6.70	Granivore (grain and seeds)	1.52	0.23	1.13	0.17	0.73	0.11	0.54	0.08	0.01		
	6.70	Frugivore (fruit)	3.04	0.45	2.25	0.34	1.45	0.22	1.07	0.16	0.02		
	6.70	Herbivore (short grass)	21.7	3.24	1618	2.40	7.72	1.15	5.71	0.85	0.10		
	6.70	Herbivore (long grass)	13.3	1.98	9.82	1.47	4.33	0.65	3.21	0.48	0.05		
	6.70	Herbivore (forage crops)	20.1	3.00	14.9	2.22	6.65	0.99	4.92	0.73	0.08		
Reproducti	7.80	Insectivore	9.82	1.26	7.27	0.93	6.78	0.87	5.02	0.64	0.07		
on	7.80	Granivore (grain and seeds)	1.52	0.19	1.13	0.14	0.73	0.09	0.54	0.07	0.01		
	7.80	Frugivore (fruit)	3.04	0.39	2.25	0.29	1.45	0.19	1.07	0.14	0.02		
7	7.80	Herbivore (short grass)	21.7	2.79	16.1	2.06	7.72	0.99	5.71	0.73	0.08		
	7.80	Herbivore (long grass)	13.3	1.70	9.82	1.26	4.33	0.56	3.21	0.41	0.05		
	7.80	Herbivore (forage crops)	20.1	2.58	14.9	1.91	6.65	0.85	4.92	0.63	0.07		

### Table 22aRefined Mammalian Risk Assessment Using Mean Residue and LOEL<br/>Values (74% drift)

			On-fiel	d	Off-field				
Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC		
		Small	Mammal (1	5 g)					
Acute	Insectivore	14.48	2.16	46	10.72	1.60	63		
6.7 mg a.i./kg bw/d	Granivore (grain and seeds)	1.55	0.23	-	1.15	0.17	-		
ow/a	Frugivore (fruit)	3.10	0.46	-	2.29	0.34	-		
Reproduction	Insectivore	14.48	1.86	53	10.72	1.37	73		
7.8 mg a.i./kg bw/d	Granivore (grain and seeds)	1.55	0.20	-	1.15	0.15	-		
	Frugivore (fruit)	3.10	0.40	-	2.29	0.29	-		
		Medium-si	zed Mamm	al (35 g)					
	Insectivore	12.70	1.89	53	9.39	1.40	71		
	Granivore (grain and seeds)	1.36	0.20	-	1.00	0.15	-		
Acute 6.7 mg a.i./kg bw/d	Frugivore (fruit)	2.71	0.41	-	2.01	0.30	-		
	Herbivore (short grass)	14.45	2.16	46	10.69	1.60	62		
	Herbivore (long grass)	8.11	1.21	82	6.00	0.90	-		
	Herbivore (forage crops)	12.44	1.86	53	9.21	1.37	73		
	Insectivore	12.70	1.63	61	9.39	1.20	83		
	Granivore (grain and seeds)	1.36	0.17	-	1.00	0.13	-		
Reproduction 7.8 mg a.i./kg	Frugivore (fruit)	2.71	0.35	-	2.01	0.26	-		
bw/d	Herbivore (short grass)	14.45	1.85	54	10.69	1.37	73		
	Herbivore (long grass)	8.11	1.04	96	6.00	0.77	-		
	Herbivore (forage crops)	12.44	1.60	62	9.21	1.18	85		
	1	Large-size	d Mammal	(1000 g)					
	Insectivore	6.78	1.01	99	5.02	0.75	-		
	Granivore (grain and seeds)	0.73	0.11	-	0.54	0.08	-		
Acute 6.7 mg a.i./kg	Frugivore (fruit)	1.45	0.22	-	1.07	0.16	-		
bw/d	Herbivore (short grass)	7.72	1.15	87	5.71	0.85	-		
	Herbivore (long grass)	4.33	0.65	-	3.21	0.48	-		
	Herbivore (forage crops)	6.65	0.99	-	4.92	0.73	-		
Reproduction	Insectivore	6.78	0.87	-	5.02	0.64	-		
7.8 mg a.i./kg	Granivore (grain and seeds)	0.73	0.09	-	0.54	0.07	-		
bw/d	Frugivore (fruit)	1.45	0.19	-	1.07	0.14	-		
	Herbivore (short grass)	7.72	0.99	-	5.71	0.73	-		
	Herbivore (long grass)	4.33	0.56	-	3.21	0.41	-		
	Herbivore (forage crops)	6.78	1.01	99	4.92	0.63	-		

Note: shaded cells indicate RQ exceeds the LOC (level of concern)

### Table 22bRefined Mammalian Risk Assessment Using Mean Residue and LOEL<br/>Values (6% drift)

			On-fiel	d	Off-field		
Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC	EDE (mg a.i./kg bw)	RQ	Diet percentage to reach LOC
		Small 1	Mammal (1	5 g)			
Acute	Insectivore	20.29	3.03	33	1.22	0.18	-
6.7 mg a.i./kg bw/d	Granivore (grain and seeds)	2.17	0.32	-	0.13	0.02	-
o w/u	Frugivore (fruit)	4.34	0.65	-	0.26	0.04	-
Reproduction	Insectivore	20.29	2.60	38	1.22	0.16	-
7.8 mg a.i./kg bw/d	Granivore (grain and seeds)	2.17	0.28	-	0.13	0.02	-
	Frugivore (fruit)	4.34	0.56	-	0.26	0.03	-
		Medium si	zed Mamm	al (35 g)			
	Insectivore	17.79	2.66	38	1.07	0.16	-
	Granivore (grain and seeds)	1.90	0.28	-	0.11	0.02	-
Acute 6.7 mg a.i./kg	Frugivore (fruit)	3.80	0.57	-	0.23	0.03	-
bw/d	Herbivore (short grass)	20.24	3.02	33	1.21	0.18	-
	Herbivore (long grass)	11.36	1.70	58	0.68	0.10	-
	Herbivore (forage crops)	17.43	2.60	38	1.05	0.16	-
	Insectivore	17.79	2.28	44	1.07	0.14	-
	Granivore (grain and seeds)	1.90	0.24	-	0.11	0.01	-
Reproduction 7.8 mg a.i./kg	Frugivore (fruit)	3.80	0.49	-	0.23	0.03	-
bw/d	Herbivore (short grass)	20.24	2.60	38	1.21	0.16	-
	Herbivore (long grass)	11.36	1.46	68	0.68	0.09	-
	Herbivore (forage crops)	17.43	2.24	45	1.05	0.13	-
	1	Large size	l Mammal	(1000 g)			
	Insectivore	9.51	1.42	70	0.57	0.09	-
	Granivore (grain and seeds)	1.02	0.15	-	0.06	0.01	-
Acute 6.7 mg a.i./kg	Frugivore (fruit)	2.03	0.30	-	0.12	0.02	-
bw/d	Herbivore (short grass)	10.82	1.61	62	0.65	0.10	-
	Herbivore (long grass)	6.07	0.91	-	0.36	0.05	-
	Herbivore (forage crops)	9.32	1.39	72	0.56	0.08	-
Reproduction	Insectivore	9.51	1.22	82	0.57	0.07	-
7.8 mg a.i./kg	Granivore (grain and seeds)	1.02	0.13	-	0.06	0.01	-
bw/d	Frugivore (fruit)	2.03	0.26	-	0.12	0.02	-
	Herbivore (short grass)	10.82	1.39	72	0.65	0.08	-
	Herbivore (long grass)	6.07	0.78	-	0.36	0.05	-
	Herbivore (forage crops)	9.32	1.19	84	0.56	0.07	-

Note: shaded cells indicate RQ exceeds the LOC (level of concern)

### Table 23Maximum Run-off EECs (in µg a.i./L) for the Ecological Risk Assessment of<br/>Fenpropathrin

Lico	Water	Water column				Pore water		
Use	depth	Peak	24-hour	96-hour	21-day	Peak	21-day	
$1 \times 224$ g a.i./ha + 2 ×	15 cm	54	1.8	0.65	0.32	0.26	0.25	
336, 7-day interval	80 cm	10	1.8	0.64	0.32	0.26	0.25	

### Table 24Toxicity of Fenpropathrin and Transformation Products to Non-Target<br/>Aquatic Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
		Freshwater i	nvertebrates	·	
Cladocera Daphnia magna	48h-Acute Static	S-3206 TG (91.4%)	LC ₅₀ : 0.53 µg a.i./L (nominal)	Very highly toxic	2730313
		S-3206 2.4 lb/G EC (30% a.i.)	LC ₅₀ : 0.87 µg a.i./L (nominal)	-	2730314
	48h-Acute Static- renewal	4'-OH-fenpropathrin	LC ₅₀ : 27.3 µg /L (measured)		2730315
		ТМРА	LC ₅₀ > 72 000 μg /L (measured)	No adverse effet at highest concentration	2730316
		CONH ₂ - fenpropathrin	$EC_{50} > 970 \ \mu g \ /L$ (measured)	tested	2730317
	48h-Acute Static	3-PBA	EC ₅₀ = 35 400 µg /L (lethargy and immobilization) (nominal)	Slightly toxic	2940216
Amphipod Hyalella azteca	10 d-Acute Static- renewal	Fenpropathrin TG (91.7%) Applied to sediment	LC ₅₀ : 58.4 $\mu$ g a.i./kg sediment The 10-day LC ₅₀ is 0.00781 $\mu$ g a.i./L in pore	Very highly toxic	2730322
			water; (NOEC acceptable with restriction) (measured)		
	10 d-Acute Static	Fenpropathrin TG (100%)	LC ₅₀ : 10 μg a.i./kg sediment EC ₅₀ (growth): 8.5 μg	Very highly toxic	2730324
		Applied to sediment	a.i./kg sediment (measured) (Pore water data not		

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
			available)		
Diptera Chironomus dilutus	10 d-Acute Static- renewal	Fenpropathrin TG (100%)	LC ₅₀ : 450 µg a.i./kg sediment EC ₅₀ (growth): 230 µg	Very highly toxic	2730323
		Applied to sediment	a.i./kg sediment (measured) Pore water data not available		
Cladocera Daphnia magna	21 d- Chronic Flow- through	[cyclopropyl-1- ¹⁴ C] Fenpropathrin	NOEC (survival and young/adult reproduction days): 0.22 µg a.i./L (measured) (acceptable with restriction)	n/a	2730318
Amphipod Hyalella azteca	42 d- Chronic Static- renewal	Fenpropathrin TG (91.7%) Applied to sediment	NOEC (day-28 survival): 0.09 µg a.i./L pore water (Time Weighted Average measured)	n/a	2730320
Diptera Chironomus dilutus	59 d-life- cycle S tatic- renewal	Fenpropathrin TG (91.7%)	NOEC (day-59 emergence): 0.027 µg a.i./L pore water (measured)	n/a	2730321
		Applied to sediment			
		-	r aquatic-phase amphibian		1
Rainbow trout Salmo gairdneri	96h-Acute Static	S-3206 TG (91.4%)	LC ₅₀ : 2.2 µg a.i./L (nominal)	Very highly toxic	2730335
		S-3206 2.4LB/G EC (30% a.i.)	LC ₅₀ : 3 µg a.i./L (nominal)		2730336
		3-PBA	LC ₅₀ : 14 300 µg /L (measured)	Slightly toxic	2940217
Bluegill sunfish Lepomis macrochirus	96h-Acute Static	S-3206 TG (91.4%)	LC ₅₀ : 2.2 μg a.i./L (nominal)	Very highly toxic	2730337
		S-3206 2.4LB/G EC (30% a.i.)	LC ₅₀ : 2.31 µg a.i./L (nominal)		2730338
Channel catfish Ictalurus punctatus	96h-Acute Static	S-3206 TG (91.4%)	LC ₅₀ : 5.5 µg a.i./L (nominal) (acceptable with restriction)		2730339

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
		S-3206 2.4LB/G EC (30% a.i.)	LC ₅₀ : 6.6 µg a.i./L (nominal)		2730340
Fathead minnow Pimephales promelas	260-d Full life-cycle Flow- through	Fenpropathrin TG (93.7%)	NOEC (F ₀ growth): 0.091 µg a.i./L (measured)	n/a	2730345, 2730344, 2730347
		Freshwater pla	•		-
Green alga Pseudokirchneriella subcapitata	96 h-Acute Static	Fenpropathrin TG (91.7%)	EC ₅₀ (growth) >590 μg a.i./L (measured TWA)	n/a	2730360
	96 h-Acute Static	3-PBA	$EC_{50}$ (biomass) = 33 790 $\mu$ g/L (measured)	n/a	2940218
Blue-green algae Anabaena flos- aquae	96 h-Acute Static	Fenpropathrin TG (91.7%)	IC ₅₀ (growth) >1000 μg a.i./L (initial measured) (>630 μg a.i./L final measured)	n/a	2730361
Diatom Navicula pelliculosa	96 h-Acute Static	Fenpropathrin TG (91.7%)	IC ₅₀ (cell density) >1000 μg a.i./L (initial measured) (>0.22 mg a.i/L, final measured)	n/a	2730362
Vascular plant Duckweed <i>Lemna gibba</i>	7d- Dissolved Static renewal	Fenpropathrin TG (91.7%)	IC ₅₀ (growth) >1 000 μg a.i./L (initial measured) (>0.61 mg a.i./L, final measured)	n/a	2730366
		Estuarine/marin	ne invertebrates		
Mysid shrimp Mysidopsis bahia	96h-Acute Static	¹⁴ C-Danitol Technical	LC ₅₀ : 0.019 μg a.i./L (nominal)	Very highly toxic	2730325
		Danitol 2.4 EC (31.5% a.i.)	LC ₅₀ : 0.104 µg a.i./L (measured)		2730326
Eastern Oysters (Crassostrea virginica)	96h-Acute Flow through	¹⁴ C-Danitol Technical	LC ₅₀ > 125.0 μg a.i./L (measured)	No adverse effect at the highest test concentration	2730330
	96h-Acute Flow	Danitol 2.4 EC (31.5% a.i.)	EC ₅₀ : >1 600 μg a.i./L (nominal)		2730328

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	PMRA#
	through				
Amphipods	10d-Acute	Fenpropathrin TG	LC ₅₀ : 4.82 µg a.i./L pore	Very highly	2730334
Leptocheirus	Static	(91.7%)	water	toxic	
plumulosus		Applied to sediment	(measured)		
Mysid shrimp	28d-Chronic	¹⁴ C-Danitol	NOEC (day-28	n/a	2730332
Mysidopsis bahia	Flow	Technical	reproduction): 0.012 µg		
	through		a.i./L		
			(measured)		
		Estuarine/r	narine fish		
Sheepshead	96h-Acute	S-3206 T.G.	LC ₅₀ : 3.1 µg a.i./L	Very highly	2730341
minnows	Static	(91.4%)	(nominal) (acceptable	toxic	
Cyprinodon variegatus			with restriction)		
		Danitol 2.4 EC	LC ₅₀ : 21 µg a.i./L	-	2730342
		(31.5% a.i.)	(based on nominal, and good recovery in study)		
	33d- early	Fenpropathrin TG	NOEC (larval survival):	n/a	2730343
	life stage	(91.7%)	0.81 µg a.i./L		
	Flow				
	through		(measured)		
		Estuarine/n	narine alga	•	
Marine Diatom	96h-Acute	Fenpropathrin TG	IC ₅₀ (area under the	n/a	2730363
Skeletonema	Static	(91.7%)	curve): 62.64 µg a.i./L		
costatum					
			(measured)		

^a USEPA classification, where applicable; n/a, not applicable.

#### Table 25 Screening Level Risk Assessment of Fenpropathrin to Aquatic Organisms

Organism	Exposure	Endpoint value (µg a.i./L)	EEC (μg a.i./L)* 80 cm (unless otherwise stated)	RQ	Level of concern exceeded?
	Fr	eshwater species			
Cladocera	Acute	EC ₅₀ /2 - 0.265	109	411	Yes
Daphnia magna	Chronic	NOEC - 0.22 (survival and young/adult reproduction)	109	495	Yes

Organism	Exposure	Endpoint value (µg a.i./L)	EEC (μg a.i./L)* 80 cm (unless otherwise stated)	RQ	Level of concern exceeded?
Diptera Chironomus dilutus	Chronic	NOEC = 0.027 (day 59 emergence)	109	037	Yes
Amphipod Hyalella azteca	Acute	$LC_{50}/2 = 0.0039$ pore water	109	27 948	Yes
	Chronic	NOEC - 0.09 (day 28 survival)	109	1211	Yes
Bluegill sunfish Lepomis macrochirus	Acute	LC ₅₀ /10 - 0.22	109	494	Yes
Fathead minnow Pimephales promelas	Chronic	NOEC - 0.091 (growth)	109	1197	Yes
Amphibians	Acute ( <i>L.</i> <i>macrochirus</i> as surrogate)	LC ₅₀ /10 - 0.22	585 (15 cm)	2659	Yes
	Chronic (P. promelas as surrogate)	NOEC - 0.091 (growth)	585 (15 cm)	6428	Yes
Green alga Pseudokirchneriella subcapitata	Acute	EC ₅₀ /2 > 295	109	< 0.37	No
Duckweed Lemna gibba	Dissolved	$EC_{50}/2 > 500$	109	<0.21	No
	_	Marine species	-	-	
Crustacean	Acute	LC ₅₀ /2: 0.0095	109	11 473	Yes
Mysid shrimp <i>Mysidopsis</i> bahia	Chronic	NOEC: 0.012 (reproduction)	109	9 083	Yes
Sheepshead minnows	Acute	$LC_{50}/2 = 1.55$	109	70.3	Yes
Cyprinodon variegatus	Chronic - ELS	NOEC = $0.81$	109	134	Yes
		(larval survival)			
Marine Diatom Skeletonema costatum	Acute	$EC_{50}/2 = 31.32$	109	3.5	Yes
*EECs exceed the solubility lin still exceeded in most cases. Screening level EEC based on a.i./L; 15 cm EEC = 585 μg a.i	direct application to wa		-		-

### Table 26Screening Level Risk Assessment of Fenpropathrin Transformation Products<br/>to Aquatic Organisms

Organism	Compound	Acute Endpoint value (µg /L)	EEC (µg /L)	RQ	Level of concern exceeded?
Freshwater species					
Cladocera Daphnia magna	4'-OH- fenpropathrin	$LC_{50}/2 = 13.65$	114	8.4	Yes
	TMPA	$LC_{50}/2 > 36000$	44.4	0.0	
	CONH ₂ - fenpropathrin	$LC_{50}/2 > 485$	115	0.2	
	3-PBA	$EC_{50}/2 = 17700$	57.1	0.0	
Rainbow trout, Salmo gairdneri	3-PBA	LC ₅₀ /10 =1430	57.1	0.0	No
Green alga Pseudokirchneriella subcapitata	3-PBA	EC ₅₀ /2 = 16895 (biomass)	57.1	0.0	

### Table 27Refined Risk Assessment of Fenpropathrin for Aquatic Organisms from<br/>Drift

Organism	Exposure	Endpoint value	Ref	ined EEC*	RQ	Level of	
		(µg a.i./L)	(	µg a.i./L)		Concern	
	·	Freshw	ater speci	es	·		
Cladocera			Ground a	ppl.: 6.5	24.7		
Daphnia magna	Acute	$EC_{50}/2 = 0.265$	Airblast	E. season: 41.4	156		
	Acute	LC ₅₀ /2- 0.205	appl.	L. season: 33	124	Yes	
	Chronic	NOEC= 0.22	Ground a		30	-	
			Airblast	E. season: 41.4	188		
			appl.	L. season: 33	150		
Bluegill sunfish	Acute	$LC_{50}/10 = 0.22$	Ground a	ppl.: 6.5	30		
Lepomis			Airblast E. season: 41.4		188	Yes	
macrochirus			appl.	L. season: 33	150		
Fathead minnow	Chronic	NOEC= 0.091	Ground appl.: 6.5		72		
Pimephales			Airblast	E. season: 41.4	455	Yes	
promelas			appl.	L. season: 33	363		
Amphibians	Acute (L.	$LC_{50}/10 = 0.22$	Ground a	ppl.: 35.1	159		
(fish end-points)	macrochirus		Airblast	E. season:221	1004	Yes	
	as surrogate)		appl.	L. season: 176.2	801	- Yes	
	Chronic (P.	NOEC = 0.091	Ground a	ppl.: 35.1	386		
	<i>promelas</i> as		Airblast	E. season: 221	2429	N/	
	surrogate)		appl.	L. season:	1936	Yes	
				176.2			
		Mari	ne species	•		•	
Crustacean	Acute	$LC_{50}/2 = 0.0095$	Ground a	ppl.: 6.5	688		
Mysid shrimp			Airblast	E. season: 41.4	4358	Yes	
Mysidopsis			appl	L. season: 33	3474	1	

Organism	Exposure	<b>Endpoint value</b> (µg a.i./L)	-	<b>ined EEC*</b> ug a.i./L)	RQ	Level of Concern
bahia	Chronic	NOEC = 0.012	Ground a	ppl.: 6.5	545	
			Airblast	E. season: 41.4	3450	Yes
			appl	L. season: 33	2750	
Fish	Acute	$LC_{50}/2 = 1.55$	Ground a	ppl.: 6.5	4.2	
Sheepshead			Airblast	E. season: 41.4	26.7	Yes
minnows			appl	L. season: 33	21.3	
Cyprinodon	Chronic	NOEC = 0.81	Ground a	ppl.: 6.5	8.1	
variegatus			Airblast	E. season: 41.4	51.1	Yes
			appl	L. season: 33	40.7	
Marine Diatom	Acute	$EC_{50}/2 = 31.32$	Ground a	ppl.: 6.5	0.2	No
Skeletonema			Airblast	E. season: 41.4	1.3	Vac
costatum			appl	L. season: 33	1.1	Yes

*Drift depositions: 6% (ground application, 224 + 336 + 336 g a.i./ha) based on EEC of 109 and 585 mg/L for 80 and 15 cm depth, respectively; 74% (air blast application early season) and 59% (air blast application late season) based on EEC of 56 and 299 mg/L for 80 and 15 cm depth, respectively. Airblast application based on  $1 \times 448$  g a.i./ha application rate. **Note:** EECs exceed the solubility limit of 14.1µg a.i./L for fenpropathrin; however, even considering the limit of solubility the risk is still exceeded in most cases.

### Table 28Refined Risk Assessment of Fenpropathrin for Aquatic Organisms from<br/>Predicted Run-off

Organism	Exposure	Endpoint value (µg a.i./L)	Refined EEC (µg a.i./L)* 80 cm (unless otherwise stated)	RQ	Level of concern exceeded?
	Fr	eshwater species			
Cladocera	48 hr Acute	$EC_{50}/2 = 0.265$	0.64	2.4	Yes
Daphnia magna	Chronic	NOEC = 0.22	0.32	1.45	Yes
Amphipod Hyalella azteca	10 d Acute	$LC_{50}/2 = 0.0039$ (pore water)	0.26	67	Yes
Diptera Chironomus dilutus	59 d Chronic	NOEC = 0.027	0.32	12	Yes
Amphipod Hyalella azteca	42 d Chronic	NOEC = 0.09 (pore water)	0.26	2.9	Yes
Bluegill sunfish Lepomis macrochirus	96 hr Acute	$LC_{50}/10 = 0.22$	0.64	2.9	Yes
Fathead minnow Pimephales promelas	260 d Chronic	NOEC = 0.091	0.32	3.5	Yes
Amphibians	Acute ( <i>L</i> . <i>macrochirus</i> as surrogate)	$LC_{50}/10 = 0.22$	0.65 (15 cm)	2.9	Yes
	Chronic (P. promelas as surrogate)	NOEC = 0.091	0.32 (15 cm)	3.5	Yes
		Marine species	I		1
Crustacean	96 hr Acute	$LC_{50}/2 = 0.0095$	0.64	67	Yes

Organism	Exposure	Endpoint value (µg a.i./L)	Refined EEC (µg a.i./L)* 80 cm (unless otherwise stated)	RQ	Level of concern exceeded?
Mysid shrimp Mysidopsis bahia	28 d Chronic	NOEC = 0.012	0.32	27	Yes
Amphipods Leptocheirus plumulosus	10 d Acute	$LC_{50}/2 = 2.41$ (pore water)	0.26	0.11	No
Sheepshead minnows	96 hr Acute	LC ₅₀ /2=1.55	0.64	0.41	No
Cyprinodon variegatus	33 d Chronic - ELS	NOEC= 0.81	0.32	0.40	No
Marine Diatom Skeletonema costatum	96 hr Acute	EC ₅₀ /2= 31.32	0.64	0.02	No
*EECs representing the 90 ^t (chronic assessment) as pre-			assessment) ar	nd 21-day co	ncentration

## Table 29Toxic Substances Management Policy Considerations-Comparison to TSMP<br/>Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track	1 Criterion value	Fenpropathrin Are criteria met?
Toxic or toxic equivalent as defined by the <i>Canadian Environmental</i> <i>Protection Act</i>	Yes		Yes
Predominantly anthropogenic ²		Yes	Yes
	Soil	Half-life ≥ 182 days	Laboratory studies: DT ₅₀ of 37.4 to 274 days in aerobic soil and 66.2 to 192 days in anaerobic soil Field studies: DT ₅₀ of 6.8–76.4 days
	Water	Half-life ≥ 182 days	Not applicable, fenpropathrin is insoluble
	Whole system (Water + Sediment)	Half-life ≥ 365 days	Total system DT ₅₀ values range from 61.8 to 742 days in aerobic and anaerobic water-sediment systems.
Persistence ³ :	Air	Half-life ≥ 2 days or evidence of long range transport	Fenpropathrin is not expected to undergo long range transport in the atmosphere. Fenpropathrin is characterized by low volatility, a high octanol/water partition coefficient, and low water solubility. While the calculated Henry's law constant suggests fenpropathrin has the potential to volatilize from water or moist soil surfaces, fenpropathrin has a strong sorption capacity and a tendency to bind to organic matter in water, sediment, and soil. The volatilization half-lives for fenpropathrin from rivers and lakes are estimated as 6 and 72 days,

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Fenpropathrin Are criteria met?
		respectively, and free fenpropathrin in water may undergo phototransformation with an environmental half-life of about 3 days at pH 5. Fenpropathrin is therefore not expected to be readily released into the atmosphere, but, once in air, fenpropathrin is expected to undergo atmospheric oxidation with an estimated half- life of 7.2 hours.
	$\log K_{\rm OW} \ge 5$	Yes: 6
Bioaccumulation ⁴	$BCF \ge 5000$	No: 830
	$BAF \ge 5000$	Not available
the chemical a TSMP Track 1 sub	stance (all four criteria must be met)?	No, does not meet all TSMP Track 1 criteria.
teria. Assessment of the toxicity crit he policy considers a substance "pre	c or toxic equivalent for the purpose of initially erion may be refined if required (in other word dominantly anthropogenic" if, based on expert human activity, rather than to natural sources of	ls, all other TSMP criteria are met). judgment, its concentration in the

environment medium is largely due to human activity, rather than to natural sources or releases. ³ If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

⁴Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example,  $\log K_{ow}$ ).

#### Appendix II Supplemental Maximum Residue Limit Information— International Situation and Trade Implications

Fenpropathrin is an active ingredient now being registered for domestic use in Canada. The maximum residue limits (MRLs) established for fenpropathrin in Canada are the same as corresponding tolerances already promulgated in the United States

Table 1 compares the MRLs established for fenpropathrin in Canada with corresponding American tolerances and Codex MRLs⁹. American tolerances are listed in the <u>Electronic Code of</u> <u>Federal Regulations</u>, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity.

### Table 1Comparison of Canadian MRLs, American Tolerances and Codex MRLs<br/>(where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
CG8-09	1.0	1 (CG 8-10)	1 (peppers) 10 (dried chili peppers) 1 (tomato)
CG9	0.5	0.5 (CG 9A) 0.5 (CG 9B)	None
CG11-09	5.0	5 (CG 11-10)	None
CG12-09	1.4 (stone fruits, except cherry) 5.0 (cherries)	1.4 (CG 12, except cherry) 5.0 (sweet+ tart cherry)	1 (plum subgroup) 3 (dried prunes)
Succulent Shelled Peas	0.02	0.02 (succulent pea)	None
CSG13-07A	12	12	None
CSG13-07B	3	3	None
CG14-11	0.15	0.10 (CG 14)	0.15 (tree nuts)

⁹ The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

#### References

PMRA References Document Number

#### A. List of Studies/Information Submitted by Registrant

PMRA	References
Document	
Number	

#### 1.0 Chemistry

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1580132	1983, Description of Manufacturing Process of S-3206, DACO: 2.11.3 CBI
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2730025	2016, Enforcement Analytical Method for Determination of Fenpropathrin in
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#### 2.0 Human and Animal Health

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#### **B.** Additional Information Considered

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